

CORE-MD

(Coordinating Research and Evidence for Medical Devices)

Appendix

**Quality and transparency of clinical evidence for high-risk
cardiovascular medical devices:
A systematic evaluation by the CORE-MD Consortium.**

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Appendix 1

Summary of high-risk cardiovascular medical devices accompanied with the landmark date of CE-mark approval considered in the current analysis.

Class of device	Devices	CE-mark date (month/year)
Coronary bioresorbable scaffolds	Absorb & Absorb GT1 Bioresorbable Vascular Scaffold System [Abbott]	January 2011 & April 2015
	ART-Stent [Arterial Remodeling Technologies S.A.]	May 2015
	DESolve (DESolve Scaffold System) [Elixir Medical]	May 2013
	DESolve 100 (DESolve Scaffold System) [Elixir Medical]	May 2014
	Magmaris Coronary Resorbable Magnesium Scaffold [Biotronik]	June 2016
	Meres (MeRes100 Bioresorbable Scaffold) [Meril Life Sciences]	August 2019
Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug [St Jude/Abbott]	December 2008
	Amplatzer Amulet [St Jude/Abbott]	January 2013
	Ultraseal [Cardia]	2016
	LAMBRE [Lifetech Scientific]	June 2016
	LARIAT Suture Delivery Device [SentreHEART]	October 2015
	Watchman [Boston Scientific]	October 2005
	Watchman FLX (1 st generation) [Boston Scientific]	November 2015
	Watchman FLX (2 nd generation) [Boston Scientific]	March 2019
Transcatheter aortic valve implantation systems	Centera [Edwards Lifesciences]	February 2018
	CoreValve [Medtronic]	May 2007
	CoreValve Evolut R [Medtronic]	September 2014
	CoreValve Evolut Pro [Medtronic]	July 2017
	CoreValve Evolut Pro+ [Medtronic]	April 2021
	Direct Flow [Medical]	January 2013
	Engager [Medtronic]	February 2013
	Jena Valve [JenaValve]	September 2011

	Lotus [Boston Scientific]	October 2013
	Lotus Edge [Boston Scientific]	September 2016
	Myval [Meril Life Sciences]	June 2019
	NVT Allegra [Biosensors]	April 2017
	Portico [Abbott]	November 2012
	Sapien [Edwards Lifesciences]	September 2007
	Sapien XT [Edwards Lifesciences]	March 2010
	Sapien S3 [Edwards Lifesciences]	January 2014
	Sapien 3 Ultra [Edwards Lifesciences]	November 2018
	Symetis Acurate TA [Boston Scientific]	October 2011
	Symetis Acurate Neo [Boston Scientific]	September 2014
	Symetis Acurate Neo 2 [Boston Scientific]	April 2020
Transcatheter mitral valve repair/replacement systems	Edge-to-Edge Repair:	
	MitraClip [Abbott]	March 2008
	MitraClip NT [Abbott]	January 2016
	MitraClip NTR [Abbott]	February 2018
	MitraClip XTR [Abbott]	February 2018
	MitraClip G4 [Abbott]	September 2020
	PASCAL [Edwards Lifesciences]	February 2019
	PASCAL Ace [Edwards Lifesciences]	May 2020
	Annuloplasty:	
	Cardioband Mitral [Valtech Cardio / Edwards Lifesciences]	September 2015
	Carillon Mitral Contour System [Cardiac dimensions]	February 2009 Enhanced device in September 2011
	Mitralign [Mitralign Inc / Edwards Lifesciences]	February 2016
	Mitral Valve Replacement:	
	Tendyne [Abbott]	January 2020
	Other approaches:	
	Harpoon TDS-5 [Edwards Lifesciences]	May 2020
	NeoChord DS1000 [NeoChord, Inc.]	December 2012

Surgical valves	<u>Aortic bioprosthesis:</u>	
	Avalus [Medtronic]	August 2017
	Biocor Aortic [Abbott]	June 2007
	Crown PRT [Sorin/Livanova/Corcym]	July 2014
	Epic Aortic [Abbott]	June 2007
	Inspiris Resilia [Edwards Lifesciences]	September 2016
	Intuity [Edwards Lifesciences]	February 2012
	Intuity Elite [Edwards Lifesciences]	April 2014
	Mitroflow [Sorin/Livanova/Corcym]	July 2011
	Perceval [Sorin/Livanova/Corcym]	January 2011
	Perceval Plus [Sorin/Livanova/Corcym]	July 2020
	Perimount Magna, model 3000/3000TFX [Edwards Lifesciences]	2004
	Perimount Magna Ease, model 3300 TFX [Edwards Lifesciences]	December 2006
	Solo Smart [Sorin/Livanova/Corcym]	November 2013
	Trifecta [Abbott]	March 2010
	3F Enable [Medtronic]	December 2009
	<u>Aortic mechanical:</u>	
	Aortic ON-X with Conform-X sewing ring [Cryolife]	2002
	Aortic ON-X with anatomic sewing ring [Cryolife]	2012
	<u>Mitral bioprosthesis:</u>	
	Biocor Mitral [Abbott]	June 2007
	Epic Mitral [Abbott]	June 2007
	Magna Mitral Ease, model 7300 and 7300TFX [Edwards Lifesciences]	July 2010
	Perimount Plus, model 6900 PTFX [Edwards Lifesciences]	April 2004
Leadless pacemaker	Micra VR TPS [Medtronic]	April 2015
	Micra AV TPS [Medtronic]	June 2020
Subcutaneous implantable cardioverter defibrillator	EMBLEM MRI S-ICD [Boston Scientific]	April 2016

CE, Conformance Européenne.

Each device is shortlisted by name and the corresponding manufacturer is mentioned in brackets.

Appendix 2

Databases, number of results, and details of literature search strategies for each class of high-risk cardiovascular medical device of interest in separate.

Coronary bioresorbable scaffolds: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	2426
Embase	2000-2021	2996
Cochrane Library*	2000-2021	358
Total number of records retrieved: 5780		
Total number of records after de-duplication: 3385		

*CENTRAL with trial register records removed

Coronary bioresorbable scaffolds: Details of individual search strategies.

Ovid MEDLINE(R) ALL

- 1 *tissue scaffold/ 15822
- 2 *absorbable implants/ 5940
- 3 1 or 2 21055
- 4 coronary.tw. 410532
- 5 3 and 4 1090
- 6 ((bioresorbable or resorbable) adj2 scaffold*).mp. 1798
- 7 (coronary adj2 scaffold*).mp. 148
- 8 (bvs and (coronary or scaffold*).tw. 618
- 9 (absorb GT1 or magmaris or desolve or desolve100 or meres100).mp. 86
- 10 ((abbott or biotronic or meril or elixer) adj2 (scaffold* or stent*)).mp. 138
- 11 arterial remodeling technologies.mp. 2
- 12 ((ART or meres) adj2 (scaffold* or stent*)).mp. 29
- 13 or/5-12 2443
- 14 limit 13 to yr="2000 -Current" 2426

Embase

- 1 bioresorbable scaffold/ 2362
- 2 ((bioresorbable or resorbable) adj2 scaffold*).mp. 3823
- 3 (coronary adj2 scaffold*).mp. 274
- 4 (bvs and (coronary or scaffold*).tw. 1395
- 5 (absorb GT1 or magmaris or desolve or desolve100 or meres100).mp. 380
- 6 ((abbott or biotronic or meril or elixer) adj2 (scaffold* or stent*)).mp. 681
- 7 arterial remodeling technologies.mp. 23
- 8 ((ART or meres) adj2 (scaffold* or stent*)).mp. 34
- 9 or/1-8 4548
- 10 limit 9 to conference abstract status 1526
- 11 9 not 10 3022
- 12 limit 11 to yr="2000 -Current" 2996

Cochrane Library (CENTRAL)

- #1 MeSH descriptor: [Tissue Scaffolds] explode all trees 82
- #2 MeSH descriptor: [Absorbable Implants] explode all trees 712
- #3 #1 or #2 754

#4 coronary:ti,ab,kw 59489
#5 #3 and #4 231
#6 (bioresorbable or resorbable):ti,ab,kw NEAR/2 scaffold*:ti,ab,kw 355
#7 (coronary NEAR/2 scaffold*):ti,ab,kw 25
#8 (absorb GT1 or magmaris or desolve or desolve100 or meres100):ti,ab,kw 23
#9 (abbott or biotronic or meril or elixer):ti,ab,kw NEAR/2 (scaffold* or stent*):ti,ab,kw 69
#10 arterial remodeling technologies:ti,ab,kw 3
#11 (ART or meres):ti,ab,kw NEAR/2 (scaffold* or stent*):ti,ab,kw 3
#12 #5 or #6 or #7 or #8 or #9 or #10 or #11 with Publication Year from 2000 to 2021, in Trials 566
#13 conference:pt 184574
#14 #12 not #13 419
NB: 61 records from trials registers removed total no. remaining = 358

Devices for left atrial appendage occlusion: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	1414
Embase	2000-2021	1895
Cochrane Library*	2000-2021	192
Total number of records retrieved: 3501		
Total number of records after de-duplication: 2392		

*CENTRAL with trial register records removed

Devices for left atrial appendage occlusion: Details of individual search strategies.

Ovid MEDLINE(R) 1 exp *"Prostheses and Implants"/ 380182 2 (left atrial adj4 (occlusion* or occlud* or closure)).tw. 1518 3 (LAAC or LAAO).tw.507 4 2 or 3 1737 5 1 and 4 445 6 (amplatzer adj4 (percutaneous or left atrial or atrial appendage or LAAC or LAAO)).mp. 204 7 (watchman adj4 (percutaneous or left atrial or atrial appendage or LAAC or LAAO or device)).mp. 280 8 (amplatzer left atrial appendage adj4 (closure or occluder or occlusion or device)).mp. 4 9 (amplatzer ACP or Amplatzer Amulet or amplatzer plug).mp. 83 10 (watchman left atrial appendage adj4 (closure or occluder or occlusion or device)).mp. 42 11 (watchman flx or "watchman 1st gen*" or "watchman 2nd gen*").mp. 7 12 (watchman or amplatzer or lariat or lambre or ultraseal).kf. 381 13 ((lariat or lambre or ultraseal) adj4 (percutaneous or left atrial or atrial appendage or LAAC or LAAO)).mp. 60 14 ((lariat or lambre or ultraseal) adj4 (closure or occluder or occlusion or device or LAAC or LAAO)).mp. 97 15 or/5-14 1108 16 limit 15 to yr="2000 -Current" 1105
Ovid MEDLINE(R) Epub Ahead of Print and In-Process, In-Data-Review & Other Non-Indexed Citations 1 (left atrial adj4 (occlusion* or occlud*)).tw. 247 2 (LAAC or LAAO).tw.191 3 1 or 2 356 4 (percutaneous or device*).tw. 156480 5 3 and 4 238 6 (amplatzer adj4 (percutaneous or left atrial or atrial appendage)).tw. 27 7 (watchman adj4 (percutaneous or left atrial or atrial appendage)).tw. 53 8 (amplatzer left atrial appendage adj4 (closure or occluder or occlusion or device)).tw. 3 9 (amplatzer ACP or Amplatzer Amulet or amplatzer plug).tw. 22 10 (watchman left atrial appendage adj4 (closure or occluder or occlusion or device)).tw. 8 11 (watchman flx or "watchman 1st gen*" or "watchman 2nd gen*").tw. 12 12 ((lariat or lambre or ultraseal) adj4 (percutaneous or left atrial or atrial appendage)).tw. 14 13 ((lariat or lambre or ultraseal) adj4 (closure or occluder or occlusion or device)).tw. 31 14 or/5-13 309
Embase 1 *"left atrial appendage closure device"/ 1421

2 (percutaneous adj4 (occlusion* or occlud* or device* or closure)).mp. 10890
 3 (left atrial appendage or LAAC or LAAO).mp. 9546
 4 2 and 3 1184
 5 1 or 4 2235
 6 (amplatzer adj4 (percutaneous or left atrial or atrial appendage or LAAC or LAAO)).mp. 425
 7 (watchman adj4 (percutaneous or left atrial or atrial appendage or LAAC or LAAO or device)).mp. 987
 8 (amplatzer left atrial appendage adj4 (closure or occluder or occlusion or device)).mp. 9
 9 (amplatzer ACP or Amplatzer Amulet or amplatzer plug).mp. 428
 10 (watchman left atrial appendage adj4 (closure or occluder or occlusion or device)).mp. 106
 11 (watchman flx or "watchman 1st gen*" or "watchman 2nd gen*").mp. 58
 12 ((lariat or lambre or ultraseal) adj4 (percutaneous or left atrial or atrial appendage or LAAC or LAAO)).mp. 133
 13 ((lariat or lambre or ultraseal) adj4 (closure or occluder or occlusion or device or LAAC or LAAO)).mp. 242
 14 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 3141
 15 limit 14 to conference abstract status 1241
 16 14 not 15 1900
 17 limit 16 to yr="2000 -Current" 1895

Cochrane Library (CENTRAL)

#1 MeSH descriptor: [Prostheses and Implants] explode all trees 17754
 #2 "left atrial":ti,ab,kw 2113
 #3 (LAAO or LAAC):ti,kw,ab 106
 #4 #2 or #3 2126
 #5 #1 and #4 46
 #6 (amplatzer or watchman or lariat or lambre or ultraseal):ti,ab,kw 205
 #7 #5 or #6 with Publication Year from 2000 to 2021, in Trials 233
 NB: results from trial registers screened out = 41

Transcatheter aortic valve implantation systems: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	15376
Embase	2000-2021	21484
Cochrane Library*	2000-2021	884
Total number of records retrieved: 37700		
Total number of records after de-duplication: 22250		

*CENTRAL with trial register records removed

Transcatheter aortic valve implantation systems: Details of individual search strategies.

Ovid MEDLINE(R) ALL 1 Heart Valve Prosthesis/ 37722 2 Heart Valve Prosthesis Implantation/ 24597 3 (valve adj2 prothes*).mp. 42 4 or/1-3 53268 5 aortic Valve/ 35105 6 exp aortic valve disease/ 58214 7 (aortic adj2 (valve* or annuloplasty or insuffic* or repair)).mp. 87296 8 or/5-7 104285 9 4 and 8 28491 10 (transcatheter or trans-catheter or percutaneous).mp. 189551 11 9 and 10 7700 12 transcatheter aortic valve implantation/ 7858 13 ((transcatheter or trans-catheter or percutaneous) adj2 aortic valve repair*).mp. 21 14 ((transcatheter or trans-catheter or percutaneous) adj2 aortic valve implant*).mp. 6526 15 ((transcatheter or trans-catheter or percutaneous) adj2 aortic valve replac*).mp. 10539 16 (TAVR or TAVI or TAHV or PAVR or PAVI).mp. 9410 17 ((sapien* or centera) adj5 (aortic or valve* or edwards)).mp. 1594 18 ((corevalue or engager) adj5 (aortic or valve* or medtronic)).mp. 18 19 ((lotus or symetis) adj5 (aortic or valve* or Boston)).mp. 185 20 (portico adj5 (aortic or valve* or abbott)).mp. 63 21 NVT allegro.mp. 4 22 (direct flow adj5 (aortic or valve*)).mp. 51 23 (jena valve or myval).mp. 57 24 or/11-23 15651 25 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dt. 20211489 26 24 and 25 15376	Embase 1 exp aortic valve prosthesis/ 6642 2 aortic Valve/ 5300 3 exp aortic valve disease/ 19755 4 (aortic adj2 (valve* or annuloplasty or insuffic* or repair)).mp. 93809 5 or/1-4 96396 6 (transcatheter or trans-catheter or percutaneous).mp. 309444 7 5 and 6 32929 8 exp transcatheter aortic valve implantation/ 25561 9 ((transcatheter or trans-catheter or percutaneous) adj2 aortic valve repair*).mp. 29 10 ((transcatheter or trans-catheter or percutaneous) adj2 aortic valve implant*).mp. 26733
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11 ((transcatheter or trans-catheter or percutaneous) adj2 aortic valve replac*).mp. 10757
 12 (TAVR or TAVI or TAHV or PAVR or PAVI).mp. 19916
 13 ((sapien* or centera) adj5 (aortic or valve* or edwards)).mp. 6484
 14 ((corevalue or engager) adj5 (aortic or valve* or medtronic)).mp. 147
 15 ((lotus or symetis) adj5 (aortic or valve* or Boston)).mp. 799
 16 (portico adj5 (aortic or valve* or abbott)).mp. 213
 17 NVT allegra.mp. 11
 18 (direct flow adj5 (aortic or valve*)).mp. 173
 19 (jena valve or myval or j-valve).mp. 136
 20 or/7-19 34603
 21 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dc. 25151205
 22 20 and 21 33876
 23 limit 22 to conference abstract status 12392
 24 22 not 23 21484

Cochrane Library (CENTRAL)

#1 MeSH descriptor: [Heart Valve Prosthesis] explode all trees 545
 #2 MeSH descriptor: [Heart Valve Prosthesis Implantation] explode all trees 822
 #3 (valve NEAR/2 prothes*):ti,ab,kw 3
 #4 #1 or #2 or #3 1168
 #5 MeSH descriptor: [Aortic Valve] explode all trees 487
 #6 MeSH descriptor: [Aortic Valve Disease] explode all trees 690
 #7 (aortic NEAR/2 (valve* or annuloplasty or insuffic* or repair*)):ti,ab,kw 3154
 #8 {OR #5-#7} 3303
 #9 #4 and #8 651
 #10 (transcatheter or trans-catheter or percutaneous):ti,ab,kw 22880
 #11 #9 and #10 250
 #12 MeSH descriptor: [Transcatheter Aortic Valve Replacement] explode all trees 174
 #13 ((transcatheter or trans-catheter or percutaneous) NEAR/2 aortic valve repair*):ti,ab,kw 35
 #14 ((transcatheter or trans-catheter or percutaneous) NEAR/2 aortic valve replac*):ti,ab,kw 699
 #15 ((transcatheter or trans-catheter or percutaneous) NEAR/2 aortic valve implant*):ti,ab,kw 823
 #16 (TAVR or TAVI or TAHV or PAVR or PAVI):ti,ab,kw 896
 #17 (sapien* or centera):ti,ab,kw NEAR/5 (aortic or valve* or edwards):ti,ab,kw 154
 #18 (corevalue or engager):ti,ab,kw NEAR/5 (aortic or valve* or medtronic):ti,ab,kw 0
 #19 (lotus or symetis):ti,ab,kw NEAR/5 (aortic or valve* or Boston):ti,ab,kw 37
 #20 portico:ti,ab,kw NEAR/5 (aortic or valve* or abbott):ti,ab,kw 10
 #21 "NVT allegra":ti,ab,kw 0
 #22 "direct flow":ti,ab,kw NEAR/5 (aortic or valve*):ti,ab,kw 3
 #23 (jena valve or myval or j-valve):ti,ab,kw 9
 #24 #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 with Cochrane Library publication date Between Jan 2000 and Aug 2021 1069

Transcatheter mitral valve repair/replacement systems: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	4006
Embase	2000-2021	4766
Cochrane Library*	2000-2021	305
Total number of records retrieved: 9032		
Total number of records after de-duplication: 5858		

*CENTRAL with trial register records removed

Transcatheter mitral valve repair/replacement systems: Details of individual search strategies.

Ovid MEDLINE(R) ALL 1 Heart Valve Prosthesis/ 37611 2 Heart Valve Prosthesis Implantation/ 24472 3 (valve adj2 prothes*).mp. 42 4 or/1-3 53079 5 Mitral Valve/ 31430 6 Mitral Valve Insufficiency/ 24217 7 mitral valve annuloplasty/ 1722 8 (mitral adj2 (valve* or annuloplasty or insuffic* or repair or replace*)).mp. 73310 9 or/5-8 73310 10 4 and 9 18744 11 (transcatheter or trans-catheter or percutaneous).mp. 188927 12 10 and 11 2368 13 ((transcatheter or trans-catheter or percutaneous) adj2 mitral valve repair*).mp. 1029 14 ((transcatheter or trans-catheter or percutaneous) adj2 mitral valve replace*).mp. 444 15 ((transcatheter or trans-catheter or percutaneous) adj2 mitral valve implant*).mp. 147 16 ((transcatheter or trans-catheter or percutaneous) adj2 annuloplasty).mp. 136 17 (TMVR or TMVI).mp. 443 18 mitraclip.mp. 1588 19 ((Pascal or harpoon or neochord) adj3 (mitral or edwards or transcatheter or trans-catheter or valve or repair or implant or device)).mp. 108 20 ((cardioband or carillon or mitralign) adj3 (mitral or transcatheter or trans-catheter or valve or repair or implant or device)).mp. 81 21 tendyne.mp. 34 22 ("neochord DS1000" or harpoon TDS5 or harpoon TDS-5).mp. 13 23 (Mitra* adj5 (abbott or edwards or valtech or neochord or cardiac dimensions)).mp. 600 24 edge to edge repair*.mp. 487 25 (transcatheter or trans-catheter or percutaneous or TMVR or TMVI).mp. 188957 26 24 and 25 351 27 or/12-22,26 4117 28 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dt. 20210800 29 27 and 28 4006	
Embase 1 exp mitral valve replacement/ 13076 2 (mitral adj3 (annuloplasty or insuffic* or implant* or replace*)).mp. 21707 3 1 or 2 21707 4 (transcatheter or trans-catheter or percutaneous).mp. 308360	

5 3 and 4 4107
 6 ((transcatheter or trans-catheter or percutaneous) adj2 mitral valve repair*).mp. 1840
 7 ((transcatheter or trans-catheter or percutaneous) adj2 mitral valve replace*).mp. 651
 8 ((transcatheter or trans-catheter or percutaneous) adj2 mitral valve implant*).mp. 258
 9 ((transcatheter or trans-catheter or percutaneous) adj2 annuloplasty).mp. 250
 10 (TMVR or TMVI).mp. 746
 11 ((Pascal or harpoon or neochord) adj3 (mitral or edwards or transcatheter or trans-catheter or valve or repair or implant or device)).mp. 241
 12 ((cardioband or carillon or mitralign) adj3 (mitral or transcatheter or trans-catheter or valve or repair or implant or device)).mp. 222
 13 tendyne.mp. 136
 14 ("neochord DS1000" or harpoon TDS5 or harpoon TDS-5).mp. 59
 15 (Mitra* adj5 (abbott or edwards or valtech or neochord or cardiac dimensions)).mp. 1545
 16 edge to edge repair*.mp. 701
 17 (transcatheter or trans-catheter or percutaneous or TMVR or TMVI).mp. 308396
 18 16 and 17 518
 19 or/5-15,18 6829
 20 limit 19 to conference abstract status 1887
 21 19 not 20 4942
 22 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dc. 25236570
 23 21 and 22 4766

Cochrane Library (CENTRAL)

#1 MeSH descriptor: [Heart Valve Prosthesis] explode all trees 544
 #2 MeSH descriptor: [Heart Valve Prosthesis Implantation] explode all trees 816
 #3 (valve NEAR/2 prothes*):ti,ab,kw 3
 #4 #1 or #2 or #3 1162
 #5 MeSH descriptor: [Mitral Valve] explode all trees 433
 #6 MeSH descriptor: [Mitral Valve Annuloplasty] explode all trees 33
 #7 MeSH descriptor: [Mitral Valve Insufficiency] explode all trees 382
 #8 (mitral NEAR/2 (valve* or annuloplasty or insuffic* or repair or replace*)):ti,ab,kw 2151
 #9 {OR #5-#8} 2151
 #10 #4 and #9 292
 #11 (transcatheter or trans-catheter or percutaneous):ti,ab,kw 22755
 #12 #10 and #11 44
 #13 ((transcatheter or trans-catheter or percutaneous) NEAR/2 mitral valve repair*):ti,ab,kw 119
 #14 ((transcatheter or trans-catheter or percutaneous) NEAR/2 mitral valve replac*):ti,ab,kw 29
 #15 ((transcatheter or trans-catheter or percutaneous) NEAR/2 mitral valve implant*):ti,ab,kw 65
 #16 ((transcatheter or trans-catheter or percutaneous) NEAR/2 annuloplasty):ti,ab,kw 7
 #17 (TMVR or TMVI):ti,ab,kw 34
 #18 mitraclip:ti,ab,kw 150
 #19 ((Pascal or harpoon or neochord) NEAR/3 (mitral or edwards or transcatheter or trans-catheter or valve or repair or implant or device)):ti,ab,kw 6
 #20 ((cardioband or carillon or mitralign) NEAR/3 (mitral or transcatheter or trans-catheter or valve or repair or implant or device)):ti,ab,kw 16
 #21 tendyne:ti,ab,kw 3
 #22 ("neochord DS1000" or harpoon TDS5 or harpoon TDS-5):ti,ab,kw 3
 #23 (Mitra* NEAR/5 (abbott or edwards or valtech or neochord or cardiac dimensions)):ti,ab,kw 153
 #24 "edge to edge repair*":ti,ab,kw 24

#25 (transcatheter or trans-catheter or percutaneous or TMVR or TMVI):ti,ab,kw 22755

#26 #24 and #25 18

#27 {OR #12-#23} 365

#28 #26 or #27 365

NB: 60 records from trial registers removed result = 305

Aortic surgical valves: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	4495
Embase	2000-2021	1530
Cochrane Library*	2000-2021	562
Total number of records retrieved: 6436		
Total number of records after de-duplication: 4901		

*CENTRAL with trial register records removed

Aortic surgical valves: Details of individual search strategies.

Ovid MEDLINE(R) ALL 1 exp Heart Valve Prosthesis Implantation/is, mt [Instrumentation, Methods] 14313 2 exp Heart Valve Prosthesis/is, mt, su [Instrumentation, Methods, Surgery] 703 3 1 or 2 15016 4 aortic.tw,kf. 236082 5 3 and 4 9729 6 exp *Cardiovascular Surgical Procedures/ 324578 7 aortic valve/su, is 19114 8 ((surgery or surgical) adj2 (repair or implant* or replac*)).tw,kf. 47631 9 6 or 7 or 8 374412 10 5 and 9 9295 11 (aortic adj2 (bioprosthetic or mechanical)).tw,kf. 1698 12 10 or 11 10632 13 (transcatheter or trans-catheter or percutaneous).mp. 193391 14 12 not 13 4799 15 (perimount adj3 (magna or ease or "3000" or 3000TFX or 3300TFX)).tw,kf. 106 16 (edwards adj3 (inspiris resilia or intuity)).tw,kf. 91 17 ((sorin or livanova or corcym) adj3 (mitroflow or crown PRT or solo smart or perceval)).tw,kf. 151 18 (medtronic adj3 (avalus or 3F enable)).tw,kf. 27 19 ((St Jude or Abbott) adj3 (epic aortic or trifecta or biocor aortic)).tw,kf. 20 (cryolife adj3 aortic).tw,kf. 10 21 (aortic ONX or aortic ON-X).tw,kf. 5 22 or/15-21 417 23 14 or 22 5048 24 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dt. 20207117 25 23 and 24 4495	
Embase 1 exp *aortic valve replacement/ 22154 2 (aortic valve* adj2 (implant* or prosthetic*)).tw,kf. 14410 3 1 or 2 26690 4 *heart surgery/ 35011 5 ((surgery or surgical) adj2 (repair or implant*)).tw,kf. 45365 6 4 or 5 79591 7 3 and 6 648 8 (aortic adj2 (bioprosthetic or mechanical)).tw,kf. 2469 9 7 or 8 3093 10 (transcatheter or trans-catheter or percutaneous).mp. 317162	

11 9 not 10 1942
 12 (perimount adj3 (magna or ease or "3000" or 3000TFX or 3300TFX)).tw,kf. 172
 13 (edwards adj3 (inspiris resilia or intuition)).tw,kf. 160
 14 ((sorin or livanova or corcym) adj3 (mitroflow or crown PRT or solo smart or perceval)).tw,kf. 249
 15 (medtronic adj3 (avalus or 3F enable)).tw,kf. 36
 16 ((St Jude or Abbott) adj3 (epic aortic or trifecta or biocor aortic)).tw,kf. 126
 17 (cryolife adj3 aortic).tw,kf. 13
 18 (aortic ONX or aortic ON-X).tw,kf. 5
 19 or/11-18 2582
 20 limit 19 to conference abstract status 884
 21 19 not 20 1698
 22 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dc. 24864070
 23 21 and 22 1530

Cochrane Library (CENTRAL)

#1 MeSH descriptor: [Heart Valve Prosthesis] explode all trees 554
 #2 MeSH descriptor: [Heart Valve Prosthesis Implantation] explode all trees 849
 #3 #1 or #2 1194
 #4 aortic:ti,ab,kw 10379
 #5 #3 and #4 737
 #6 MeSH descriptor: [Cardiovascular Surgical Procedures] explode all trees 20767
 #7 MeSH descriptor: [Aortic Valve] explode all trees 505
 #8 (surgery or surgical):ti,ab,kw NEAR/3 (repair or implant*):ti,ab,kw 4403
 #9 #6 or #7 or #8 25170
 #10 #5 and #9 704
 #11 (aortic):ti,ab,kw NEAR/2 (bioprosthetic or mechanical):ti,ab,kw 95
 #12 #10 or #11 760
 #13 (transcatheter or trans-catheter or percutaneous):ti,ab,kw 23306
 #14 #12 not #13 484
 #15 (perimount):ti,ab,kw NEAR/3 (magna or ease or "3000" or 3000TFX or 3300TFX):ti,ab,kw 11
 #16 (edwards):ti,ab,kw NEAR/3 (inspiris resilia or intuition):ti,ab,kw 5
 #17 (sorin or livanova or corcym):ti,ab,kw NEAR/3 (mitroflow or crown PRT or solo smart or perceval):ti,ab,kw 10
 #18 (medtronic):ti,ab,kw NEAR/3 (avalus or 3F enable):ti,ab,kw 2
 #19 (St Jude or Abbott):ti,ab,kw NEAR/3 (epic aortic or trifecta or biocor aortic):ti,ab,kw 34
 #20 (cryolife):ti,ab,kw NEAR/3 (aortic):ti,ab,kw 0
 #21 (aortic ONX or aortic ON-X):ti,ab,kw 116
 #22 #15 or #16 or #17 or #18 or #19 or #20 or #21 172
 #23 #14 or #22 615
 NB: 53 records from trial registers removed result = 562

Mitral surgical valves: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	2828
Embase	2000-2021	1659
Cochrane Library*	2000-2021	202
Total number of records retrieved: 4672		
Total number of records after de-duplication: 3696		

*CENTRAL with trial register records removed

Mitral surgical valves: Details of individual search strategies.

Ovid MEDLINE(R) ALL

- 1 exp Heart Valve Prosthesis Implantation/is, mt [Instrumentation, Methods]
- 2 exp Heart Valve Prosthesis/is, mt, su [Instrumentation, Methods, Surgery]
- 3 1 or 2
- 4 mitral.tw,kf.
- 5 3 and 4
- 6 exp *Cardiovascular Surgical Procedures/
- 7 mitral valve/su, is
- 8 ((surgery or surgical) adj2 (repair or implant*)).tw,kf.
- 9 6 or 7 or 8
- 10 5 and 9
- 11 (Mitral adj2 (bioprosthetic or mechanical)).tw,kf.
- 12 10 or 11
- 13 (transcatheter or trans-catheter or percutaneous).mp.
- 14 12 not 13
- 15 (perimount or "6900 PTFX" or "magna mitral ease").mp.
- 16 (edwards adj3 ("7300" or "7300TFX")).mp.
- 17 ((st jude or abbot or epic or biocor) adj3 mitral).mp.
- 18 or/14-17
- 19 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dt.
- 20 18 and 19 2828

Embase

- 1 *mitral valve replacement/ 3892
- 2 (mitral valve* adj2 (implant* or prosthetic*)).tw,kf. 1266
- 3 1 or 2 4927
- 4 *heart surgery/ 34945
- 5 ((surgery or surgical) adj2 (repair or implant*)).tw,kf. 45256
- 6 4 or 5 79418
- 7 3 and 6 235
- 8 (Mitral adj2 (bioprosthetic or mechanical)).tw,kf. 1414
- 9 7 or 8 1635
- 10 (transcatheter or trans-catheter or percutaneous).mp. 316392
- 11 9 not 10 1258
- 12 (perimount or "6900 PTFX" or "magna mitral ease").mp. 1063
- 13 (edwards adj3 ("7300" or "7300TFX")).mp. 1
- 14 ((st jude or abbot or epic or biocor) adj3 mitral).mp. 123
- 15 or/11-14 2392

16 (200* or 201* or 2020* or 202101* or 202102* or 202103* or 202104* or 202105* or 202106* or 202107* or 202108*).dc. 24881869
17 15 and 16 2200
18 limit 17 to conference abstract status 541
19 17 not 18 1659

Cochrane Library (CENTRAL)

#1 MeSH descriptor: [Heart Valve Prosthesis] explode all trees
#2 MeSH descriptor: [Heart Valve Prosthesis Implantation] explode all trees
#3 #1 or #2
#4 mitral:ti,ab,kw
#5 #3 and #4
#6 MeSH descriptor: [Cardiovascular Surgical Procedures] explode all trees
#7 MeSH descriptor: [Mitral Valve] explode all trees and with qualifier(s): [surgery - SU]
#8 (surgery or surgical):ti,ab,kw NEAR/3 (repair or implant*):ti,ab,kw
#9 #6 or #7 or #8
#10 #5 and #9
#11 Mitral:ti,ab,kw NEAR/2 (bioprosthetic or mechanical):ti,ab,kw
#12 #10 or #11
#13 (transcatheter or trans-catheter or percutaneous):ti,ab,kw
#14 #12 not #13
#15 (perimount or "6900 PTFX" or "magna mitral ease"):ti,ab,kw
#16 edwards:ti,ab,kw NEAR/3 ("7300" or "7300TFX"):ti,ab,kw
#17 (st jude or abbot or epic or biocor):ti,ab,kw NEAR/3 mitral:ti,ab,kw
#18 #15 or #16 or #17
#19 #14 or #18 216
NB: 14 records from trial registers removed result = 202

Leadless pacemaker: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	670
Embase	2000-2021	804
Cochrane Library*	2000-2021	31
Total number of records retrieved: 1505		
Total number of records after de-duplication: 862		

*CENTRAL with trial register records removed

Leadless pacemaker: Details of individual search strategies.

Ovid MEDLINE(R) ALL

- 1 exp Pacemaker, Artificial/ 28188
- 2 exp Cardiac Pacing, Artificial/ 25715
- 3 (pacemaker or pace maker or pace-maker).mp. 47854
- 4 or/1-3 66461
- 5 leadless.mp. 683
- 6 ((transcatheter or trans-catheter) adj2 pacing).mp. 138
- 7 TPS.tw. 5878
- 8 5 or 6 or 7 6561
- 9 4 and 8 642
- 10 (leadless adj3 (pacemaker or pace maker or pace-maker or transcatheter or trans-catheter or pacing)).mp. 526
- 11 ("transcatheter pacing system" or "trans-catheter pacing system").mp. 102
- 12 (micra adj5 (pacemaker or pace maker or pace-maker)).mp. 126
- 13 (micra TPS or micra AV or AV TPS or nanostim).mp. 89
- 14 (medtronic adj3 (micra or AV or TPS)).mp. 37
- 15 9 or 10 or 11 or 12 or 13 or 14 676
- 16 limit 15 to yr="2000 -Current" 670

Embase

- 1 exp leadless pacemaker/ 609
- 2 (pacemaker or pace maker or pace-maker).mp. 58261
- 3 leadless.mp. 1256
- 4 ((transcatheter or trans-catheter) adj2 pacing).mp. 276
- 5 TPS.tw. 10584
- 6 3 or 4 or 5 11815
- 7 2 and 6 1176
- 8 (leadless adj3 (pacemaker or pace maker or pace-maker or transcatheter or trans-catheter or pacing)).mp. 1056
- 9 ("transcatheter pacing system" or "trans-catheter pacing system").mp. 199
- 10 (micra adj5 (pacemaker or pace maker or pace-maker)).mp. 349
- 11 (micra TPS or micra AV or AV TPS).mp. 110
- 12 (medtronic adj3 (micra or AV or TPS)).mp. 289
- 13 1 or 7 or 8 or 9 or 10 or 11 or 12 1269
- 14 limit 13 to conference abstract status 460
- 15 13 not 14 809
- 16 limit 15 to yr="2000 -Current" 804

Cochrane Library (CENTRAL)

- #1 MeSH descriptor: [Pacemaker, Artificial] explode all trees 736

#2 MeSH descriptor: [Cardiac Pacing, Artificial] explode all trees 1462
#3 (pacemaker or pace maker or pace-maker):ti,ab,kw 2821
#4 #1 or #2 or #3 3761
#5 leadless:ti,ab,kw 27
#6 (transcatheter or trans-catheter):ti,ab,kw NEAR/2 pacing:ti,ab,kw 4
#7 TPS:ti,ab,kw 449
#8 #5 or #6 or #7 475
#9 #4 and #8 18
#10 leadless:ti,ab,kw NEAR/3 (pacemaker or pace maker or pace-maker or transcatheter or trans-catheter or pacing):ti,ab,kw 19
#11 transcatheter pacing system*:ti,ab,kw 18
#12 trans-catheter pacing system*:ti,ab,kw 1
#13 micra:ti,ab,kw NEAR/5 (pacemaker or pace maker or pace-maker):ti,ab,kw 5
#14 (micra TPS or micra AV or AV TPS or nanostim):ti,ab,kw 9
#15 medtronic:ti,ab,kw NEAR/3 (micra or AV or TPS):ti,ab,kw 5
#16 {OR #9-#15} 39
NB : 8 results from trials registers removed = 31

Subcutaneous implantable cardioverter defibrillator: Databases and number of results.

Database/Interface	Dates covered	Number of records
Ovid MEDLINE ALL	2000-2021	969
Embase	2000-2021	1281
Cochrane Library*	2000-2021	33
Total number of records retrieved: 2283		
Total number of records after de-duplication: 1430		

*CENTRAL with trial register records removed

Subcutaneous implantable cardioverter defibrillator: Details of individual search strategies.

Ovid MEDLINE(R) ALL

1 Defibrillators, Implantable/ 17606
 2 subcutaneous.mp. 161440
 3 1 and 2 831
 4 subcutaneous implantable cardioverter defibrillator.mp. 515
 5 subcutaneous ICD.mp. 285
 6 (SICD or S-ICD).mp. 535
 7 ((EMBLEM or Boston) adj5 (subcutaneous or SICD or S-ICD)).mp. 24
 8 3 or 4 or 5 or 6 or 7 1137
 9 limit 8 to yr="2000 -Current" 969

Embase

1 exp implantable cardioverter defibrillator/ 41770
 2 subcutaneous.mp. 319250
 3 1 and 2 1549
 4 subcutaneous implantable cardioverter defibrillator.mp. 837
 5 subcutaneous ICD.mp. 582
 6 (SICD or S-ICD).mp. 1777
 7 ((EMBLEM or Boston) adj5 (subcutaneous or SICD or S-ICD)).mp. 111
 8 3 or 4 or 5 or 6 or 7 2641
 9 limit 8 to conference abstract status 1342
 10 8 not 9 1299
 11 limit 10 to yr="2000 -Current" 1281

Cochrane Library (CENTRAL)

#1 MeSH descriptor: [Defibrillators, Implantable] explode all trees 1000
 #2 subcutaneous:ti,ab,kw 28062
 #3 #1 and #2 38
 #4 "subcutaneous implantable cardioverter defibrillator":ti,ab,kw 19
 #5 "subcutaneous ICD":ti,ab,kw 19
 #6 (SICD or S-ICD)ti,ab,kw 1
 #7 (EMBLEM or Boston):ti,ab,kw NEAR/5 (subcutaneous or SICD or S-ICD):ti,ab,kw 0
 #8 #3 or #4 or #5 or #6 or #7 with Publication Year from 2000 to 2021, in Trials 39
 NB: 6 records from trials registers removed = 33

Appendix 3

Detailed summary of items extracted from reports of eligible studies.

The following items related to population/study, intervention, comparator, and outcomes were extracted from each study:

-- Population/study characteristics: journal, sample size, number and geographic areas (Europe, North America, South America, Asia-Pacific) of participating sites, year of publication in the issued journal and the time point of publicly available report, recruitment period, funding sources (industry-related / non-industry-related / both / none declared), previously registered study-protocol in dedicated platform or protocol previously available in peer-reviewed publication, study design (non-randomized, randomized (superiority, non-inferiority, equivalence)), different time-points of follow-up duration, patients lost to follow-up, drop-outs and cross-over patients, whether the authors report any power calculations (if yes, details will be also extracted (power, alpha-level, planned sample size, expected effect size), whether interim analysis was performed (in which framework), whether the final statistical analysis was done in frequentist or Bayesian framework or both, whether the authors cite and suggest a previously published report regarding further details of the study design or the study protocol was available in a clinical trials registry. We also mentioned whether the study was prematurely terminated and we also recorded the reasons reported. We summarized patient- and procedural-characteristics related to each device. Finally, we scrutinized the main document and any accompanied supplementary material for information related to patients' involvement in any stage of study design, conduct of the study or results interpretation.

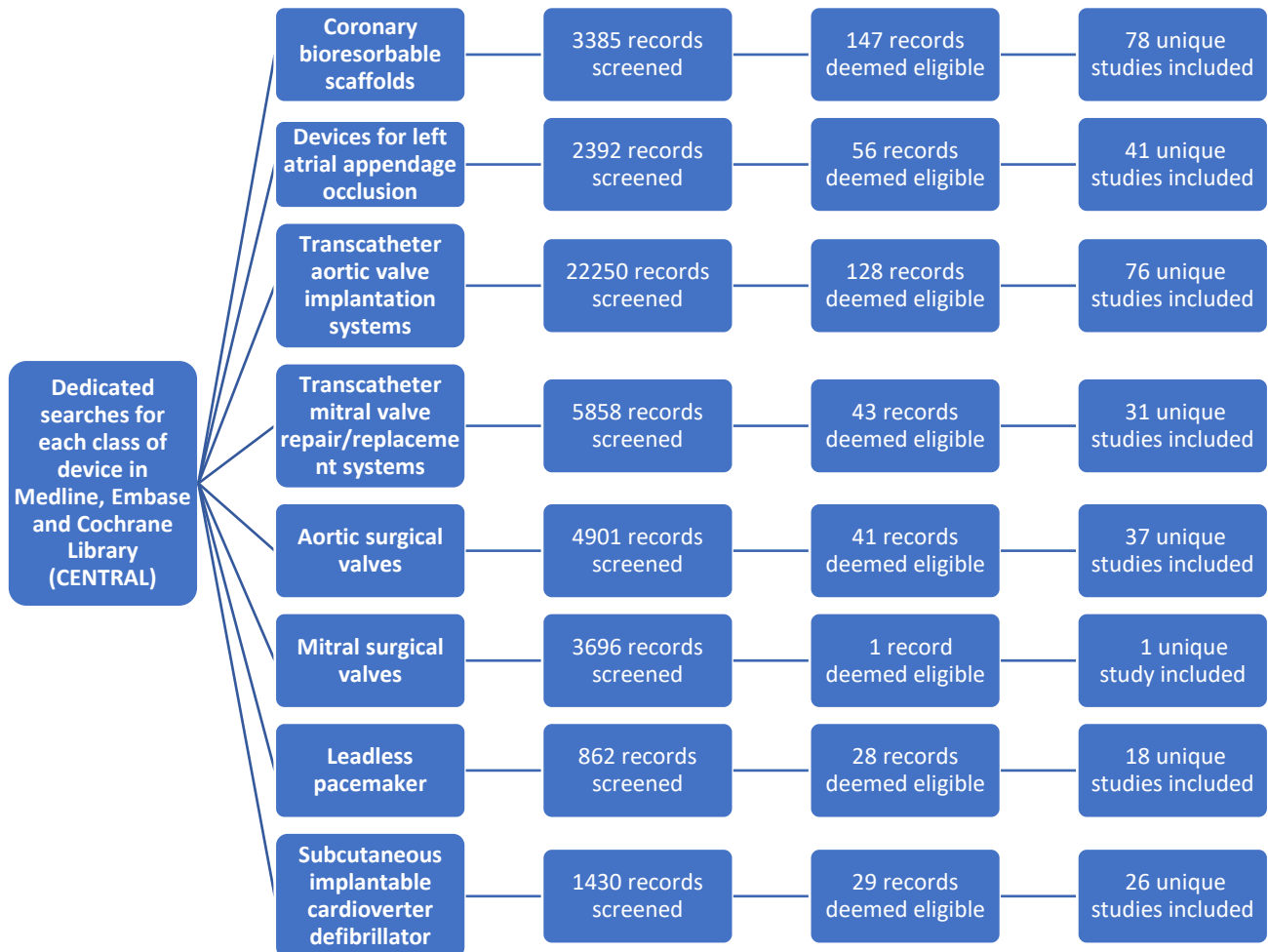
-- Intervention(s)/Comparator(s): the index device of interest, comparator devices and the "control" intervention(s) (if any) were specified in each study (medical therapy, devices, drug-delivery devices, non-drug treatments including sham interventions or surgery, or no-comparison (single arm studies)).

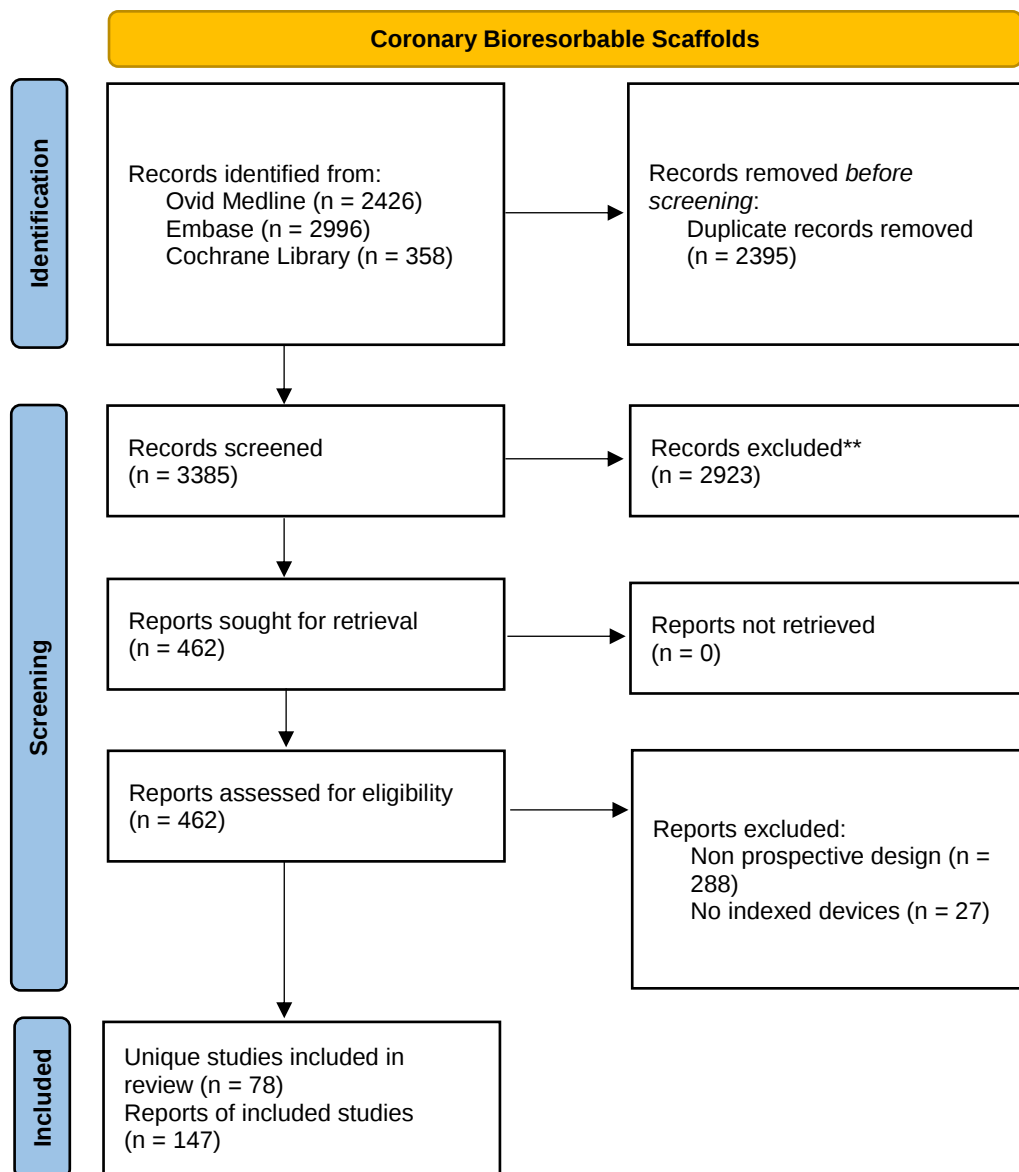
-- Outcome(s): We specified the primary outcome or co-primary outcomes of interest in each study. For each primary outcome we specified whether it is single/composite (the components will be recorded), binary/continuous/discrete (for each outcome), clinical/non-clinical (i.e. laboratory information, imaging)/both, surrogate endpoint(s), risk prediction score(s) (as component of a composite endpoint or single primary endpoint). We mentioned whether device-related complications were specifically described. The metric used for the primary outcome was recorded. We also recorded whether the investigators provide information related to the primary outcome and sex/age-specific subgroups and whether they claim a subgroup-specific difference for the primary outcome. We recorded whether the results are in favor of the index device for the primary

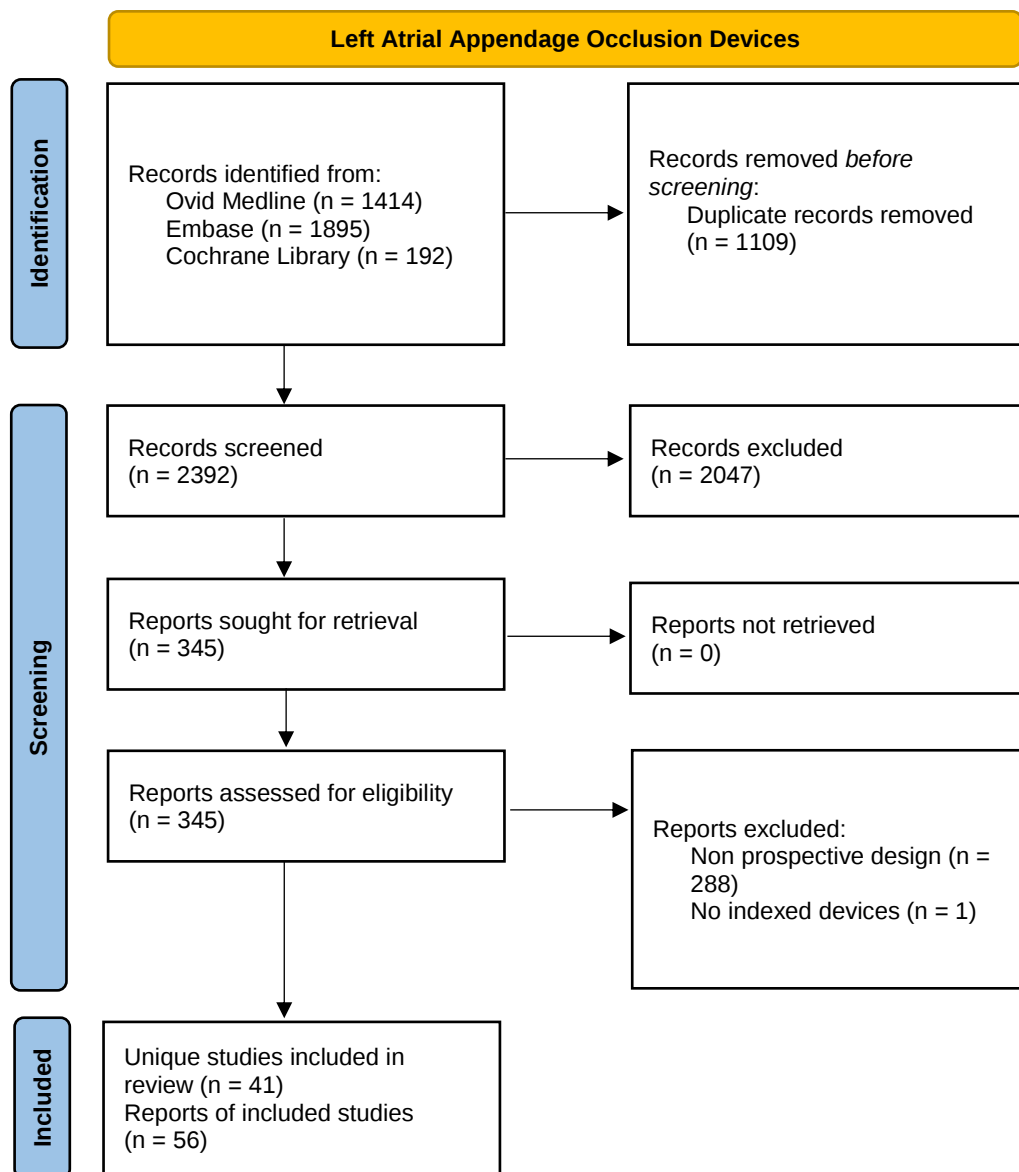
outcome, and whether the authors claim sex- or age-specific differences for the primary outcome. Finally, we mentioned the method of outcomes adjudication, if reported. Of note, some outcome definitions are subject to change over time and we used those reported for the primary endpoint and at time of longest follow-up.

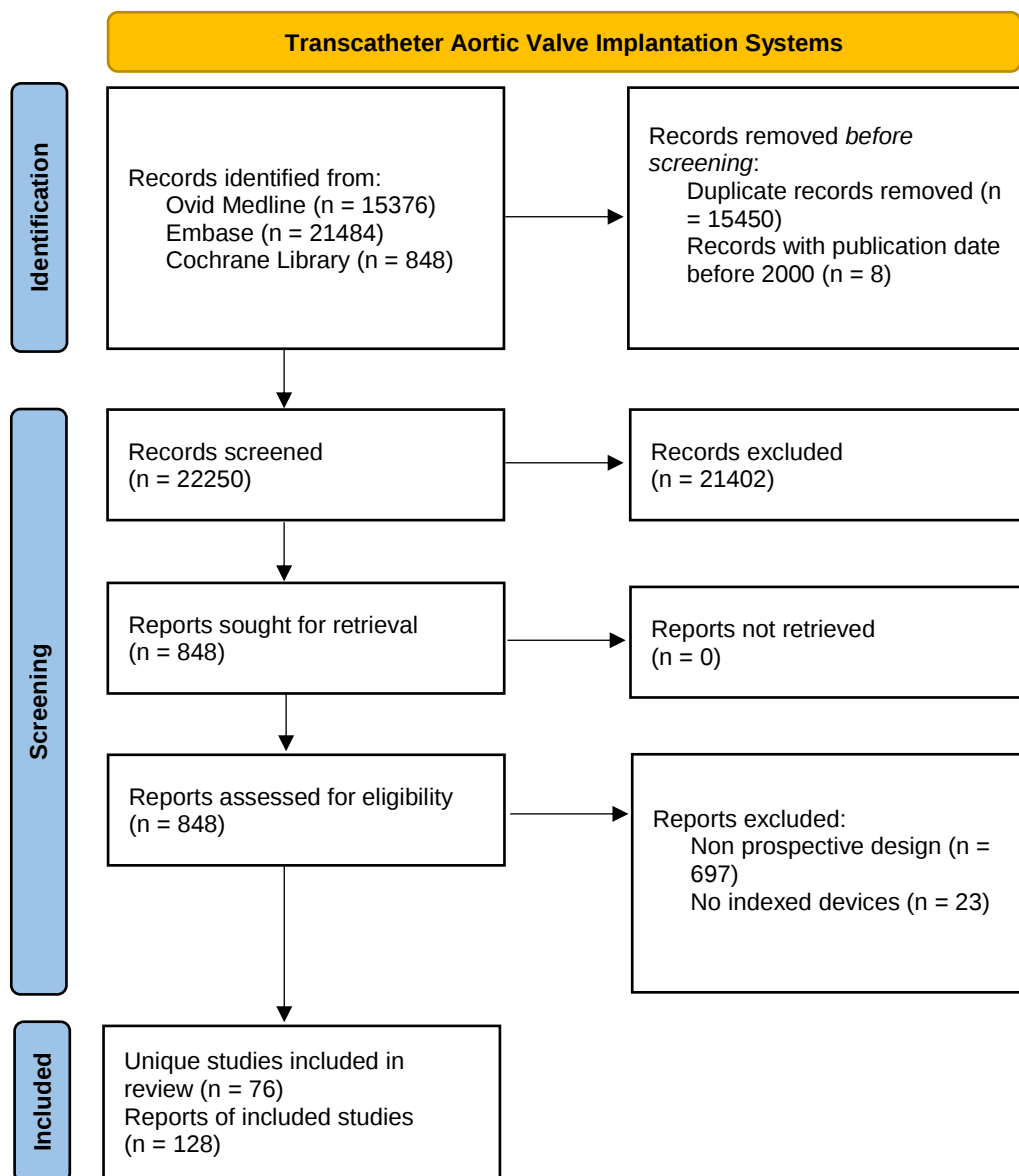
Appendix 4

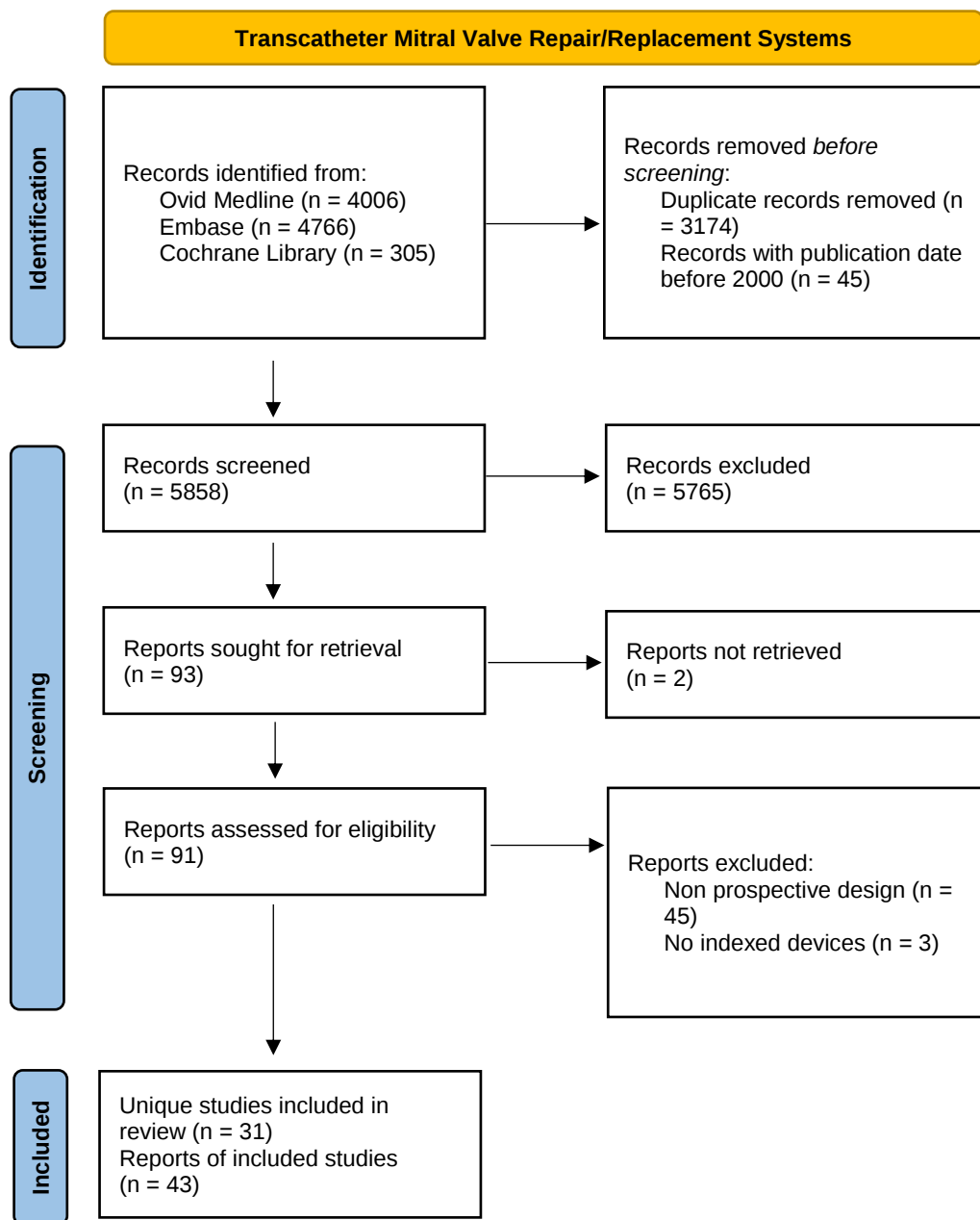
Study selection flow-chart for all classes of high-risk cardiovascular medical devices.

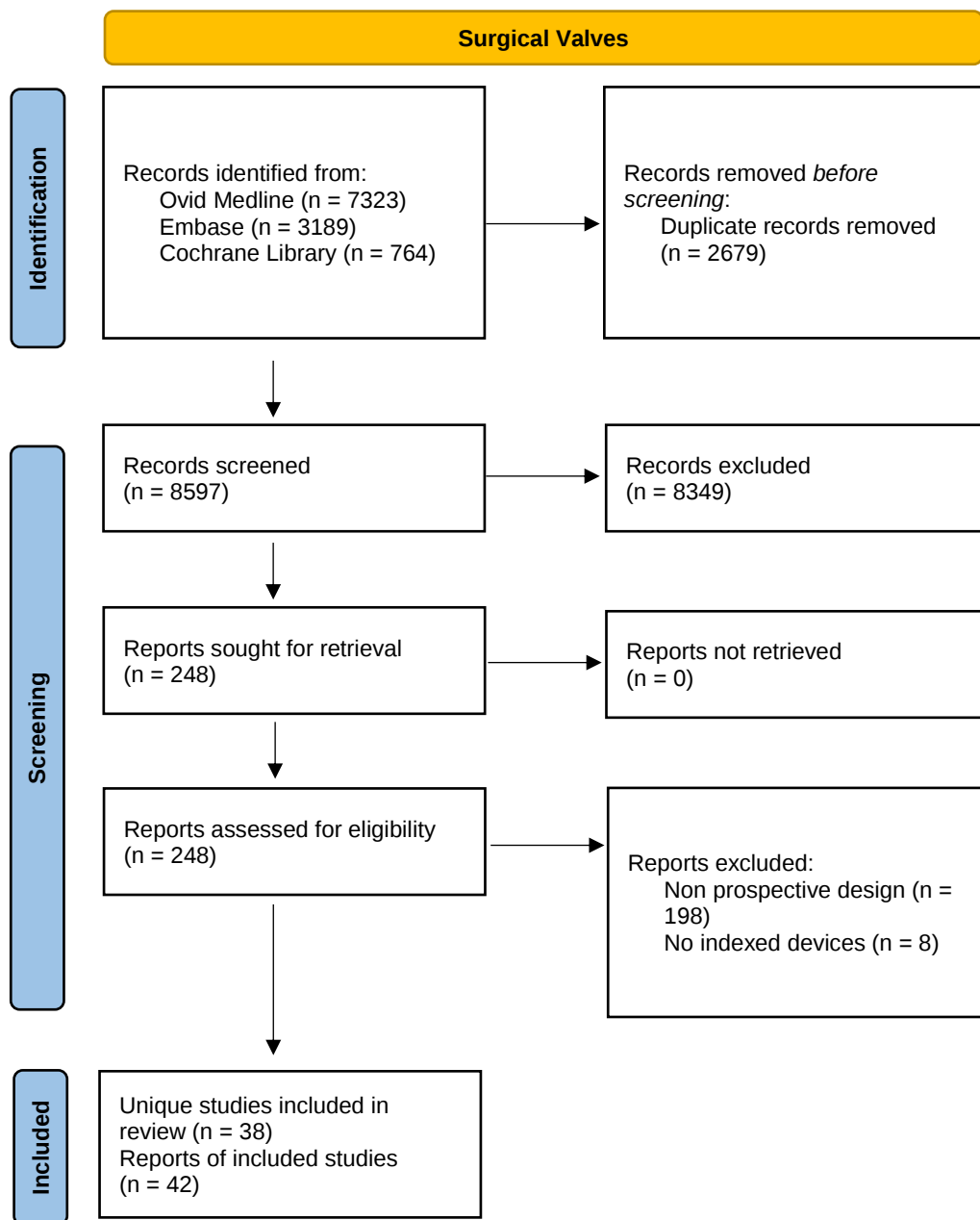


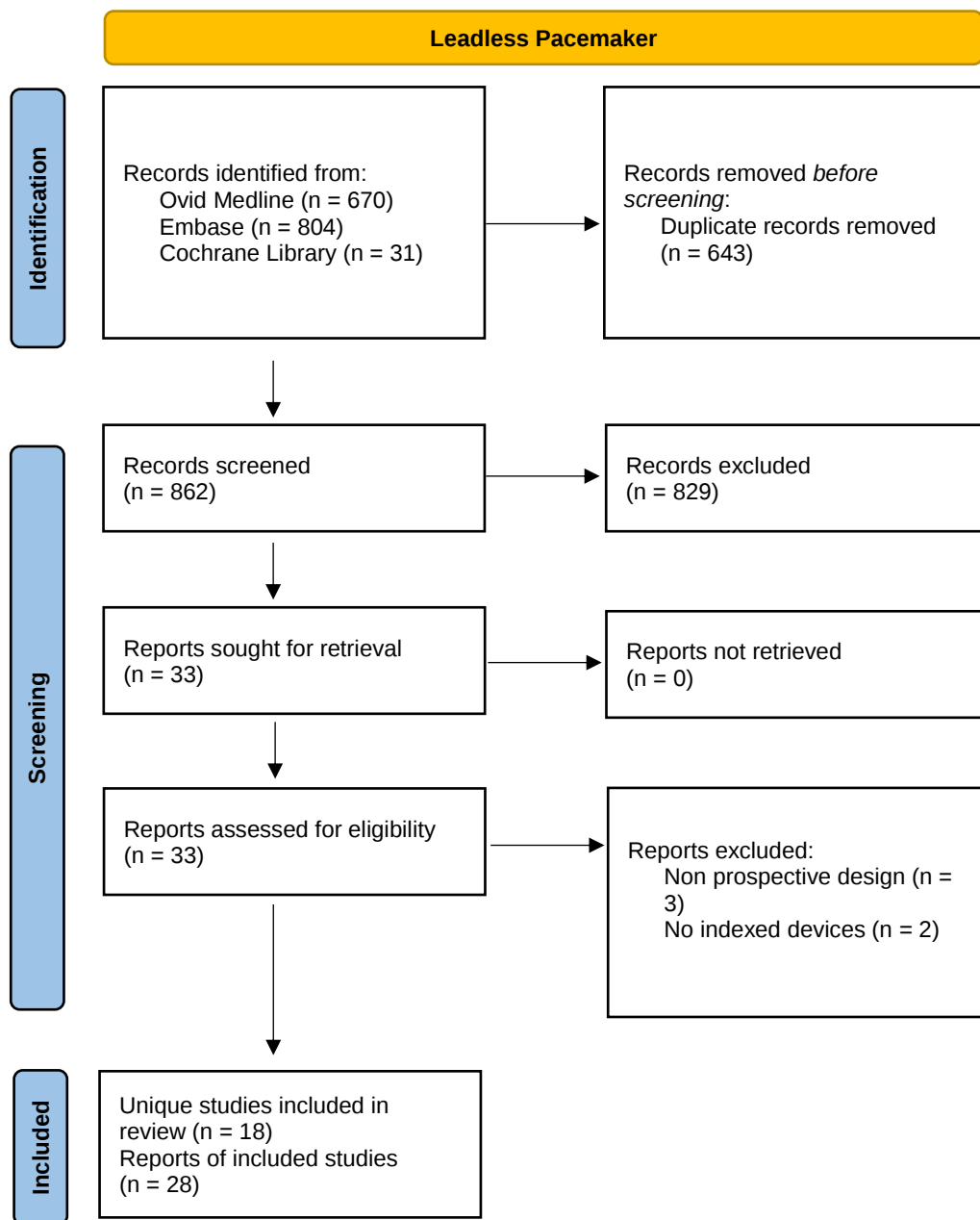


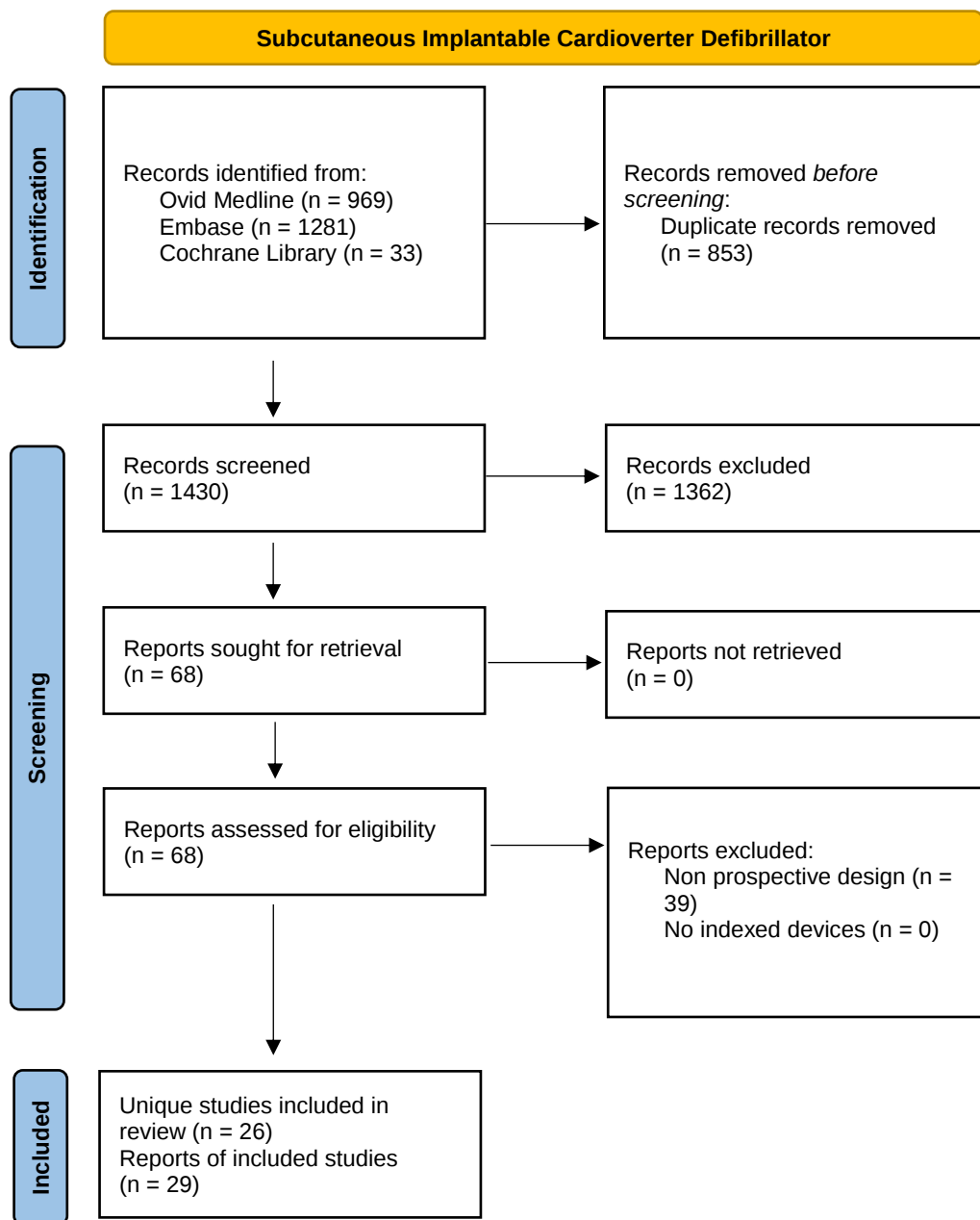












Appendix 5

Number of studies for each high-risk cardiovascular device with CE-mark approval and median (interquartile range) of studies per device by class for which eligible reports of prospective studies were identified.

Devices	Number of eligible studies for each device	Median (IQR) number of eligible studies per device by class
Coronary bioresorbable scaffolds	78	3 (2 - 9)
Absorb & Absorb GT1 Bioresorbable Vascular Scaffold System [Abbott]	63	
DESolve / DESolve 100 (DESolve Scaffold System) [Elixir Medical]	3	
Magmaris Coronary Resorbable Magnesium Scaffold [Biotronik]	9	
Meres (MeRes100 Bioresorbable Scaffold) [Meril Life Sciences]	2	
>1 eligible devices in the same study	1	
Devices for left atrial appendage occlusion	41	4 (2 - 8)
Amplatzer Cardiac Plug [St Jude/Abbott]	2	
Amplatzer Amulet [St Jude/Abbott]	2	
LAMBRE [Lifetech Scientific]	4	
LARIAT Suture Delivery Device [SentreHEART]	7	
Watchman [Boston Scientific]	10	
Watchman FLX (1 st generation) [Boston Scientific]	1	
Watchman FLX (2 nd generation) [Boston Scientific]	4	
>1 eligible devices in the same study	11	
Transcatheter aortic valve implantation systems	76	3 (1 – 7)
Centera [Edwards Lifesciences]	1	
CoreValve [Medtronic]	12	
CoreValve Evolut R [Medtronic]	5	
CoreValve Evolut Pro [Medtronic]	2	
Direct Flow [Medical]	3	
Engager [Medtronic]	2	
Jena Valve [JenaValve]	1	
Lotus / Lotus Edge [Boston Scientific]	7	
Myval [Meril Life Sciences]	1	
NVT Allegra [Biosensors]	1	
Portico [Abbott]	7	
Sapien [Edwards Lifesciences]	7	
Sapien XT [Edwards Lifesciences]	6	
Sapien S3 [Edwards Lifesciences]	7	
Symetis Acurate Neo [Boston Scientific]	4	
Symetis Acurate Neo 2 [Boston Scientific]	1	
>1 eligible devices in the same study	9	
Transcatheter mitral valve repair/replacement systems	31	3 (3 – 5)
Edge-to-Edge Repair:		

MitraClip [Abbott]	13	
PASCAL [Edwards Lifesciences]	2	
Annuloplasty:		
Cardioband Mitral [Valtech Cardio / Edwards Lifesciences]	3	
Carillon Mitral Contour System [Cardiac dimensions]	4	
Mitralign [Mitralign Inc / Edwards Lifesciences]	1	
Mitral Valve Replacement:		
Tendyne [Abbott]	2	
Other approaches:		
Harpoon TDS-5 [Edwards Lifesciences]	3	
NeoChord DS1000 [NeoChord, Inc.]	3	
Surgical valves	38	2 (1 - 4)
Aortic bioprosthesis:		
Avalus [Medtronic]	3	
Crown PRT [Sorin/Livanova/Corcym]	1	
Epic Aortic [Abbott]	1	
Inspiris Resilia [Edwards Lifesciences]	1	
Intuity [Edwards Lifesciences]	11	
Mitroflow [Sorin/Livanova/Corcym]	2	
Perceval [Sorin/Livanova/Corcym]	10	
Perimount Magna/Magna Ease, model 3000/3000TFX/3300 TFX [Edwards Lifesciences]	1	
Trifecta [Abbott]	5	
3F Enable [Medtronic]	2	
Mitral bioprosthetic:		
Perimount Plus, model 6900 PTFX [Edwards Lifesciences]	1	
Leadless pacemaker	18	-- *
Micra VR TPS [Medtronic]	18	
Subcutaneous implantable cardioverter defibrillator	26	-- *
EMBLEM MRI S-ICD [Boston Scientific]	26	

IQR, interquartile range.

*One single high-risk device in the class.

Each device is shortlisted by name and the corresponding manufacturer is mentioned in brackets.

Appendix 6

Reference lists of the eligible studies considered, grouped by class of device and ordered by Pubmed identifier.

Coronary bioresorbable scaffolds:

PMID	Citation
34290573	J Interv Cardiol. 2021 Jul 1;2021:5590093. doi: 10.1155/2021/5590093. eCollection 2021.
34173699	Catheter Cardiovasc Interv. 2022 Feb;99(3):523-532. doi: 10.1002/ccd.29837. Epub 2021 Jun 26.
34125947	Kardiol Pol. 2021;79(7-8):827-832. doi: 10.33963/KP.a2021.0035. Epub 2021 Jun 14.
33723086	J Invasive Cardiol. 2021 Apr;33(4):E281-E293. Epub 2021 Mar 4.
33600069	Catheter Cardiovasc Interv. 2021 Jul 1;98(1):E69-E77. doi: 10.1002/ccd.29557. Epub 2021 Feb 18.
33363447	J Interv Cardiol. 2020 Dec 3;2020:8821525. doi: 10.1155/2020/8821525. eCollection 2020.
33269506	Catheter Cardiovasc Interv. 2021 Nov 15;98(6):1102-1110. doi: 10.1002/ccd.29396. Epub 2020 Dec 2.
33118696	Catheter Cardiovasc Interv. 2021 Oct;98(4):713-720. doi: 10.1002/ccd.29329. Epub 2020 Oct 29.
33069847	J Am Coll Cardiol. 2020 Nov 17;76(20):2289-2301. doi: 10.1016/j.jacc.2020.09.547. Epub 2020 Oct 15.
32944608	Int J Cardiol Heart Vasc. 2020 Sep 4;31:100623. doi: 10.1016/j.ijcha.2020.100623. eCollection 2020 Dec.
32881396	Catheter Cardiovasc Interv. 2021 Jul 1;98(1):E1-E8. doi: 10.1002/ccd.29260. Epub 2020 Sep 3.
32763098	Rev Port Cardiol (Engl Ed). 2020 Aug;39(8):421-425. doi: 10.1016/j.repc.2019.09.018. Epub 2020 Aug 3.
32525410	Circ Cardiovasc Interv. 2020 Jan;13(1):e008383. doi: 10.1161/CIRCINTERVENTIONS.119.008383. Epub 2020 Jan 9.
32515738	EuroIntervention. 2020 Dec 4;16(11):e938-e941. doi: 10.4244/EIJ-D-20-00024.
32451321	EuroIntervention. 2020 Oct 23;16(8):645-653. doi: 10.4244/EIJ-D-19-01079.
32315682	Int J Cardiol. 2020 Aug 1;312:27-32. doi: 10.1016/j.ijcard.2020.04.051. Epub 2020 Apr 18.
32310130	EuroIntervention. 2020 Dec 4;16(11):e913-e921. doi: 10.4244/EIJ-D-20-00198.
32279841	Am J Cardiol. 2020 Jun 1;125(11):1624-1630. doi: 10.1016/j.amjcard.2020.02.031. Epub 2020 Mar 15.
32213737	Circ J. 2020 Apr 24;84(5):733-741. doi: 10.1253/circj.CJ-19-1184. Epub 2020 Mar 26.
32205067	Cardiovasc Revasc Med. 2020 Oct;21(10):1244-1250. doi: 10.1016/j.carrev.2020.03.023. Epub 2020 Mar 19.
32000796	J Transl Med. 2020 Jan 30;18(1):33. doi: 10.1186/s12967-020-02230-1.
31918929	JACC Cardiovasc Interv. 2020 Jan 13;13(1):116-127. doi: 10.1016/j.jcin.2019.09.047.
31912983	Catheter Cardiovasc Interv. 2021 Jan 1;97(1):48-55. doi: 10.1002/ccd.28699. Epub 2020 Jan 8.
31708522	Circ J. 2019 Nov 25;83(12):2460-2465. doi: 10.1253/circj.CJ-19-0636. Epub 2019 Nov 8.
31587103	Heart Vessels. 2020 Apr;35(4):463-473. doi: 10.1007/s00380-019-01516-9. Epub 2019 Oct 5.
31553222	Circulation. 2019 Dec 3;140(23):1895-1903. doi: 10.1161/CIRCULATIONAHA.119.042584. Epub 2019 Sep 25.
31553204	Circulation. 2019 Dec 3;140(23):1904-1916. doi: 10.1161/CIRCULATIONAHA.119.043467. Epub 2019 Sep 25.
31511193	Int J Cardiol. 2020 Feb 1;300:93-98. doi: 10.1016/j.ijcard.2019.08.045. Epub 2019 Aug 30.
31217148	EuroIntervention. 2020 Jun 12;16(2):e155-e163. doi: 10.4244/EIJ-D-18-01203.
31197750	Neth Heart J. 2019 Nov;27(11):541-549. doi: 10.1007/s12471-019-1293-7.
31147304	EuroIntervention. 2019 Sep 20;15(7):603-606. doi: 10.4244/EIJ-D-19-00325.
31104821	Int J Cardiol. 2019 Sep 1;290:21-26. doi: 10.1016/j.ijcard.2019.04.095. Epub 2019 May 3.
31085503	EuroIntervention. 2020 Jun 12;16(2):e147-e154. doi: 10.4244/EIJ-D-18-01138.
31062692	EuroIntervention. 2020 Dec 4;16(11):e904-e912. doi: 10.4244/EIJ-D-18-00884.
31053981	Int J Cardiovasc Imaging. 2019 Jul;35(7):1199-1210. doi: 10.1007/s10554-019-01537-5. Epub 2019 May 4.
31029616	JACC Cardiovasc Interv. 2019 May 27;12(10):967-979. doi: 10.1016/j.jcin.2019.03.004. Epub 2019 Apr 24.
30975219	Trials. 2019 Apr 11;20(1):210. doi: 10.1186/s13063-019-3293-8.
30968559	Catheter Cardiovasc Interv. 2020 Jan;95(1):89-96. doi: 10.1002/ccd.28193. Epub 2019 Apr 9.
30905344	Rev Esp Cardiol (Engl Ed). 2019 Apr;72(4):357-359. doi: 10.1016/j.rec.2018.04.026. Epub 2018 Jul 7.
30803936	EuroIntervention. 2020 Feb 7;15(15):e1375-e1382. doi: 10.4244/EIJ-D-18-01000.
30676384	Coron Artery Dis. 2019 May;30(3):183-187. doi: 10.1097/MCA.0000000000000699.
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Appendix 7

Detailed study-level characteristics of interest.

PubMed identifier primary report	Class of device	Specific device	Sample size	Sample size specify	Study sites	Geographic area	Publication year-Epub	Recruitment period (start)	Recruitment period (end)	Funding source	Pre-registered	Published protocol	Study design	Non-RCT study design	RCT study design
33723086	Coronary bioresorbable scaffolds	Absorb BVS	15	Intention-to-treat	1	Europe	March-21	February-16	February-17	Industry-related	Yes	Yes	RCT	Not applicable	Unclear
31912983	Coronary bioresorbable scaffolds	Absorb BVS	100	As-treated	1	South America	January-20	November-14	October-16	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31217148	Coronary bioresorbable scaffolds	Absorb BVS	70	As-treated	1	Europe	June-20	Not reported	Not reported	Non-industry related	Yes	No	RCT	Not applicable	Unclear
33600069	Coronary bioresorbable scaffolds	Magmaris	90	As-treated	6	Europe	July-21	December-16	December-18	Non-industry related	No	No	non-RCT	Cohort	Not applicable
34290573	Coronary bioresorbable scaffolds	Absorb BVS	13	Intention-to-treat	1	Europe	July-21	January-15	December-17	Industry-related	No	No	RCT	Not applicable	Unclear
32881396	Coronary bioresorbable scaffolds	Magmaris	1075	As-treated	86	Multiple	September-20	September-16	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
34125947	Coronary bioresorbable scaffolds	Magmaris	191	As-treated	1	Europe	June-21	January-16	December-20	Non-industry related	No	No	non-RCT	Cohort	Not applicable
32763098	Coronary bioresorbable scaffolds	Magmaris	42	As-treated	1	Europe	August-20	June-16	April-17	Non-industry related	No	No	non-RCT	Cohort	Not applicable
33269506	Coronary bioresorbable scaffolds	Meres	64	As-treated	5	Multiple	December-20	February-16	June-17	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
32525410	Coronary bioresorbable scaffolds	Absorb BVS	176	As-treated	1	Asia-Pacific	January-20	September-16	January-18	Non-industry related	Yes	No	RCT	Not applicable	Superiority
33363447	Coronary bioresorbable scaffolds	Absorb BVS	34	As-treated	2	Europe	December-20	March-16	March-17	Industry-related	Yes	No	RCT	Not applicable	Superiority
31085503	Coronary bioresorbable scaffolds	Absorb BVS	66	Intention-to-treat	1	Europe	June-20	December-13	March-17	Industry-related	No	No	RCT	Not applicable	Superiority

32279841	Coronary bioresorbable scaffolds	Absorb BVS	341	Intention-to-treat	9	Asia-Pacific	March-20	June-16	January-18	Non-industry related	Yes	No	RCT	Not applicable	Non-inferiority
32451321	Coronary bioresorbable scaffolds	Absorb BVS	1670	Intention-to-treat	45	Europe	October-20	September-15	August-17	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
33069847	Coronary bioresorbable scaffolds	Absorb BVS	182	Intention-to-treat	15	Multiple	October-20	June-14	December-17	Industry-related	Yes	No	RCT	Not applicable	Superiority
32205067	Coronary bioresorbable scaffolds	Absorb BVS	38	Intention-to-treat	4	Europe	March-20	June-16	May-17	Industry-related	Yes	No	RCT	Not applicable	Superiority
31587103	Coronary bioresorbable scaffolds	Absorb BVS	13	Intention-to-treat	1	Asia-Pacific	October-19	September-15	December-16	Industry-related	No	No	non-RCT	Case-control	Not applicable
30235969	Coronary bioresorbable scaffolds	Absorb BVS	217	As-treated	1	Asia-Pacific	September-18	March-12	April-14	Non-industry related	No	No	non-RCT	Cohort	Not applicable
30520980	Coronary bioresorbable scaffolds	Absorb BVS	262	Intention-to-treat	5	Europe	January-19	September-13	March-17	Both	Yes	No	RCT	Not applicable	Non-inferiority
30286520	Coronary bioresorbable scaffolds	Absorb BVS	812	As-treated	26	Multiple	October-18	January-10	October-13	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
30277460	Coronary bioresorbable scaffolds	Absorb BVS	33	As-treated	1	Europe	May-19	February-13	March-14	Industry-related	No	Yes	non-RCT	Cohort	Not applicable
30905344	Coronary bioresorbable scaffolds	Absorb BVS	9	As-treated	1	Europe	July-18	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
31053981	Coronary bioresorbable scaffolds	DESolve	10	As-treated	1	Europe	May-19	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31197750	Coronary bioresorbable scaffolds	Absorb BVS	150	Intention-to-treat	18	Europe	November-19	April-15	March-17	Industry-related	No	No	non-RCT	Cohort	Not applicable
30975219	Coronary bioresorbable scaffolds	Absorb BVS	20	As-treated	1	Europe	April-19	Not reported	Not reported	Industry-related	No	No	RCT	Not applicable	Non-inferiority
30170828	Coronary bioresorbable scaffolds	Absorb BVS	37	Intention-to-treat	1	Europe	August-18	February-16	March-17	Both	No	No	RCT	Not applicable	Equivalence
30561875	Coronary bioresorbable scaffolds	Absorb BVS	38	As-treated	1	Europe	January-19	February-16	June-17	Industry-related	No	No	non-RCT	Cohort	Not applicable
30676384	Coronary bioresorbable scaffolds	Absorb BVS	30	As-treated	1	Europe	May-19	February-15	July-16	Both	No	No	non-RCT	Cohort	Not applicable

31553204	Coronary bioresorbable scaffolds	Magmaris	150	Intention-to-treat	11	Europe	September-19	June-17	June-18	Non-industry related	Yes	Yes	RCT	Not applicable	Superiority
31029616	Coronary bioresorbable scaffolds	Absorb BVS	60	Intention-to-treat	1	Europe	April-19	August-13	December-14	Both	Yes	No	RCT	Not applicable	Unclear
31708522	Coronary bioresorbable scaffolds	Absorb BVS	135	Intention-to-treat	9	Asia-Pacific	November-19	December-16	December-17	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29131802	Coronary bioresorbable scaffolds	Absorb BVS	1005	As-treated	24	Europe	January-18	January-14	October-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29656279	Coronary bioresorbable scaffolds	Magmaris	18	As-treated	1	Europe	April-18	December-16	October-17	Non-industry related	Yes	No	non-RCT	Cohort	Not applicable
29901443	Coronary bioresorbable scaffolds	Absorb BVS	120	Intention-to-treat	15	Europe	December-18	Not reported	Not reported	Industry-related	No	No	RCT	Not applicable	Unclear
29774520	Coronary bioresorbable scaffolds	Absorb BVS; DESolve; DESolve 100; Magmaris	29	Intention-to-treat	1	Europe	May-18	January-16	July-16	None declared	No	No	non-RCT	Cohort	Not applicable
29512092	Coronary bioresorbable scaffolds	Absorb BVS	29	As-treated	1	Europe	March-18	January-14	September-15	None declared	No	No	non-RCT	Case-control	Not applicable
29168541	Coronary bioresorbable scaffolds	Absorb BVS	165	As-treated	2	Europe	November-17	December-12	October-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
29983253	Coronary bioresorbable scaffolds	Absorb BVS	573	As-treated	3	Multiple	June-18	May-12	December-14	Industry-related	No	No	non-RCT	Cohort	Not applicable
30266412	Coronary bioresorbable scaffolds	Absorb BVS	2604	Intention-to-treat	147	Multiple	September-18	August-14	March-17	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
28432385	Coronary bioresorbable scaffolds	Absorb BVS	9	As-treated	1	Europe	April-17	January-15	November-15	None declared	No	No	non-RCT	Cohort	Not applicable
28866036	Coronary bioresorbable scaffolds	Absorb BVS	141	Intention-to-treat	19	Europe	August-17	April-14	December-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28853189	Coronary bioresorbable scaffolds	Absorb BVS	122	As-treated	1	Europe	August-17	December-12	December-14	None declared	No	No	non-RCT	Cohort	Not applicable
28438304	Coronary bioresorbable scaffolds	Absorb BVS	1505	As-treated	23	Europe	March-17	October-12	December-15	Non-industry related	Yes	Yes	non-RCT	Cohort	Not applicable

27807948	Coronary bioresorbable scaffolds	Absorb BVS	200	Intention-to-treat	1	Europe	November-16	Not reported	Not reported	Industry-related	No	No	RCT	Not applicable	Equivalence
28935077	Coronary bioresorbable scaffolds	Absorb BVS	505	Intention-to-treat	22	Europe	September-17	September-15	January-17	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
28568564	Coronary bioresorbable scaffolds	Absorb BVS	319	As-treated	1	Europe	June-17	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28829745	Coronary bioresorbable scaffolds	Absorb BVS	3231	As-treated	92	Europe	December-17	November-13	January-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28504218	Coronary bioresorbable scaffolds	Meres	108	As-treated	13	Asia-Pacific	July-17	May-15	April-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28527768	Coronary bioresorbable scaffolds	Absorb BVS	60	Intention-to-treat	2	Asia-Pacific	May-17	August-14	October-14	None declared	No	No	RCT	Not applicable	Unclear
28504219	Coronary bioresorbable scaffolds	Absorb BVS	1002	As-treated	38	Europe	July-17	November-14	January-16	Both	Yes	Yes	non-RCT	Cohort	Not applicable
28402237	Coronary bioresorbable scaffolds	Absorb BVS	1845	Intention-to-treat	5	Europe	March-17	August-13	December-15	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
27013155	Coronary bioresorbable scaffolds	DESolve	126	As-treated	13	Multiple	March-16	November-11	June-12	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
27476094	Coronary bioresorbable scaffolds	Absorb BVS	249	As-treated	1	Europe	July-16	September-12	January-15	Industry-related	No	No	non-RCT	Cohort	Not applicable
27998840	Coronary bioresorbable scaffolds	Absorb BVS	17	Intention-to-treat	1	Europe	December-16	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
27290673	Coronary bioresorbable scaffolds	Absorb BVS	40	As-treated	1	Europe	June-16	March-13	October-14	Non-industry related	No	No	non-RCT	Cohort	Not applicable
27245123	Coronary bioresorbable scaffolds	Absorb BVS	23	Intention-to-treat	1	Europe	June-16	August-14	August-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
26567454	Coronary bioresorbable scaffolds	Absorb BVS	100	Intention-to-treat	2	Asia-Pacific	November-15	December-10	October-13	None declared	No	No	non-RCT	Cohort	Not applicable
26405232	Coronary bioresorbable scaffolds	Absorb BVS	191	As-treated	8	Europe	September-15	January-14	September-14	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
27806897	Coronary bioresorbable scaffolds	Absorb BVS	501	Intention-to-treat	46	Multiple	October-16	November-11	June-13	Industry-related	Yes	Yes	RCT	Not applicable	Superiority

27173858	Coronary bioresorbable scaffolds	Absorb BVS	114	As-treated	2	Europe	May-16	December-12	March-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
26457558	Coronary bioresorbable scaffolds	Absorb BVS	2008	Intention-to-treat	193	Multiple	November-15	August-87	April-14	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
26471805	Coronary bioresorbable scaffolds	Absorb BVS	480	Intention-to-treat	24	Asia-Pacific	December-15	July-13	March-14	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
26330419	Coronary bioresorbable scaffolds	Absorb BVS	400	Intention-to-treat	38	Asia-Pacific	December-15	April-13	December-13	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
26015294	Coronary bioresorbable scaffolds	Absorb BVS	23	As-treated	1	Europe	October-15	March-13	August-13	Non-industry related	No	No	non-RCT	Cohort	Not applicable
25136885	Coronary bioresorbable scaffolds	Absorb BVS	135	Intention-to-treat	1	Europe	February-15	August-12	August-13	None declared	No	No	non-RCT	Cohort	Not applicable
26342404	Coronary bioresorbable scaffolds	Absorb BVS	27	As-treated	2	Europe	October-15	January-13	June-13	Non-industry related	No	No	non-RCT	Cohort	Not applicable
25720622	Coronary bioresorbable scaffolds	Absorb BVS	240	As-treated	1	Europe	March-15	November-12	November-13	Industry-related	Yes	No	RCT	Not applicable	Superiority
26654975	Coronary bioresorbable scaffolds	Absorb BVS	24	As-treated	1	Europe	December-15	July-13	January-14	Non-industry related	No	No	non-RCT	Cohort	Not applicable
26269391	Coronary bioresorbable scaffolds	Absorb BVS	120	As-treated	1	Europe	November-15	October-12	September-14	None declared	No	No	non-RCT	Cohort	Not applicable
25499836	Coronary bioresorbable scaffolds	Absorb BVS	183	Intention-to-treat	6	Europe	June-15	April-12	March-13	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
24394380	Coronary bioresorbable scaffolds	Absorb BVS	49	Intention-to-treat	1	Europe	March-14	November-12	April-13	None declared	No	No	non-RCT	Cohort	Not applicable
25563622	Coronary bioresorbable scaffolds	Absorb BVS	100	As-treated	1	Europe	September-14	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
24139932	Coronary bioresorbable scaffolds	DESolve	16	As-treated	2	Multiple	January-14	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
23332165	Coronary bioresorbable scaffolds	Magmaris	46	As-treated	5	Multiple	March-13	July-10	December-10	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
21958884	Coronary bioresorbable scaffolds	Absorb BVS	101	Intention-to-treat	9	Multiple	October-11	March-09	November-09	Industry-related	Yes	No	non-RCT	Cohort	Not applicable

19286089	Coronary bioresorbable scaffolds	Absorb BVS	30	Intention-to-treat	4	Multiple	March-09	March-06	July-06	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
17544767	Coronary bioresorbable scaffolds	Magmaris	63	Intention-to-treat	8	Multiple	June-07	Not reported	Not reported	Industry-related	No	No	non-RCT	Cohort	Not applicable
26470647	Coronary bioresorbable scaffolds	Magmaris	123	As-treated	13	Multiple	January-16	October-13	May-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
17397680	Devices for left atrial appendage occlusion	Watchman	66	As-treated	7	Multiple	April-07	Not reported	Not reported	Industry-related	No	No	non-RCT	Cohort	Not applicable
19683639	Devices for left atrial appendage occlusion	Watchman	707	Intention-to-treat	59	Multiple	August-09	February-05	June-08	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiorty
23062528	Devices for left atrial appendage occlusion	LARIAT	89	Intention-to-treat	1	Europe	July-13	December-09	December-10	None declared	No	No	non-RCT	Cohort	Not applicable
23583249	Devices for left atrial appendage occlusion	Watchman	150	Intention-to-treat	4	Multiple	June-13	January-09	November-11	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
23973952	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug	80	Intention-to-treat	1	Europe	December-13	June-10	June-12	None declared	No	No	non-RCT	Cohort	Not applicable
24319042	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug	20	As-treated	1	Europe	January-14	November-10	November-12	None declared	No	No	non-RCT	Cohort	Not applicable
24820753	Devices for left atrial appendage occlusion	Amplatzer Amulet	25	As-treated	1	North America	July-14	July-12	June-13	Non-industry related	No	No	non-RCT	Cohort	Not applicable
24998121	Devices for left atrial appendage occlusion	Watchman	407	Intention-to-treat	50	North America	July-14	January-10	January-12	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiorty
25281005	Devices for left atrial appendage occlusion	LARIAT	50	As-treated	8	Multiple	January-15	July-10	April-13	None declared	No	No	non-RCT	Cohort	Not applicable
26354821	Devices for left atrial	Watchman FLX	36	As-treated	1	Europe	September-15	February-10	June-11	None declared	No	No	non-RCT	Cohort	Not applicable

	appendage occlusion														
26738659	Devices for left atrial appendage occlusion	Watchman	102	Intention-to-treat	1	Europe	December-15	June-06	August-10	None declared	No	No	non-RCT	Cohort	Not applicable
26822918	Devices for left atrial appendage occlusion	Watchman	1025	As-treated	47	Multiple	January-16	October-13	May-15	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
27128539	Devices for left atrial appendage occlusion	LARIAT	72	As-treated	1	Europe	July-16	January-14	August-14	None declared	No	No	non-RCT	Cohort	Not applicable
27973336	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug; Amplatzer Amulet	107	As-treated	1	Europe	April-17	March-10	March-15	None declared	No	No	non-RCT	Cohort	Not applicable
28041899	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug; Amplatzer Amulet; Watchman	46	As-treated	1	Europe	December-16	July-11	December-15	None declared	No	No	non-RCT	Cohort	Not applicable
28409845	Devices for left atrial appendage occlusion	Amplatzer Amulet; Watchman	67	As-treated	1	Europe	April-17	January-14	January-16	None declared	No	No	non-RCT	Cohort	Not applicable
28649053	Devices for left atrial appendage occlusion	Amplatzer Amulet	1088	As-treated	61	Multiple	September-17	June-15	September-16	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
29122133	Devices for left atrial appendage occlusion	LAMBRE	153	As-treated	12	Asia-Pacific	November-17	March-14	January-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
29149516	Devices for left atrial appendage occlusion	LAMBRE	30	As-treated	1	Europe	December-17	October-16	August-17	Industry-related	No	No	non-RCT	Cohort	Not applicable
29477973	Devices for left atrial appendage occlusion	LARIAT	66	As-treated	1	North America	July-18	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
29525913	Devices for left atrial	Watchman	151	As-treated	4	Europe	March-18	May-12	October-15	None declared	No	Yes	non-RCT	Cohort	Not applicable

	appendage occlusion														
29540492	Devices for left atrial appendage occlusion	Amplatzer Amulet; Watchman	436	As-treated	33	Europe	March-18	April-13	September-15	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
29706393	Devices for left atrial appendage occlusion	Amplatzer Amulet; Watchman	50	As-treated	8	Europe	July-18	May-14	September-17	None declared	No	No	non-RCT	Cohort	Not applicable
29759399	Devices for left atrial appendage occlusion	LARIAT	139	As-treated	5	Multiple	December-15	March-09	November-12	None declared	No	No	non-RCT	Cohort	Not applicable
30305484	Devices for left atrial appendage occlusion	Watchman	54	As-treated	10	Asia-Pacific	October-18	February-17	July-17	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
30583991	Devices for left atrial appendage occlusion	Amplatzer Amulet; LAMBRE; Watchman	140	As-treated	1	Europe	December-18	April-16	September-17	None declared	No	No	non-RCT	Cohort	Not applicable
30586229	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug; Amplatzer Amulet	19	As-treated	1	Europe	January-19	January-15	July-18	None declared	No	No	non-RCT	Cohort	Not applicable
30884101	Devices for left atrial appendage occlusion	LARIAT	89	As-treated	1	Europe	March-19	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31008181	Devices for left atrial appendage occlusion	Watchman	201	As-treated	9	Asia-Pacific	April-19	January-14	October-15	Both	Yes	Yes	non-RCT	Cohort	Not applicable
31092201	Devices for left atrial appendage occlusion	Watchman	189	Intention-to-treat	1	Europe	May-19	Not reported	Not reported	None declared	Yes	Yes	non-RCT	Cohort	Not applicable
31596044	Devices for left atrial appendage occlusion	LARIAT	153	Intention-to-treat	4	Multiple	October-19	December-09	June-12	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31707534	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug; Amplatzer	641	As-treated	38	Europe	November-19	July-14	January-16	None declared	Yes	Yes	non-RCT	Cohort	Not applicable

		Amulet; Watchman													
32586585	Devices for left atrial appendage occlusion	Amplatzer Amulet; Watchman; Watchman FLX	415	Intention-to-treat	10	Europe	June-20	October-15	January-19	Non-industry related	Yes	Yes	RCT	Not applicable	Non-inferiority
33189641	Devices for left atrial appendage occlusion	Watchman FLX 2nd gen	165	As-treated	12	Europe	November-20	March-19	June-19	None declared	Yes	No	non-RCT	Cohort	Not applicable
33251673	Devices for left atrial appendage occlusion	LAMBRE	153	As-treated	12	Asia-Pacific	December-20	March-14	January-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
33334441	Devices for left atrial appendage occlusion	Watchman FLX 2nd gen	91	As-treated	1	Europe	August-20	March-19	January-20	Both	No	No	non-RCT	Cohort	Not applicable
33533089	Devices for left atrial appendage occlusion	Watchman FLX 2nd gen	30	As-treated	1	North America	February-21	April-19	December-19	None declared	No	No	non-RCT	Cohort	Not applicable
33820423	Devices for left atrial appendage occlusion	Watchman FLX 2nd gen	400	As-treated	29	North America	April-21	May-18	November-18	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
33915971	Devices for left atrial appendage occlusion	LAMBRE	55	As-treated	1	Asia-Pacific	April-21	March-17	November-19	None declared	No	No	non-RCT	Cohort	Not applicable
34097038	Devices for left atrial appendage occlusion	Amplatzer Cardiac Plug; Amplatzer Amulet; Watchman	525	As-treated	13	Europe	September-21	October-14	April-18	Non-industry related	No	No	non-RCT	Cohort	Not applicable
34459659	Devices for left atrial appendage occlusion	Amplatzer Amulet; Watchman	1878	Intention-to-treat	108	Multiple	August-21	September-16	March-19	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
25787196	Transcatheter aortic valve implantation systems	CoreValve	280	Intention-to-treat	3	Europe	March-15	December-09	May-13	Non-industry related	Yes	No	RCT	Not applicable	Superiority
30761515	Transcatheter aortic valve	NVT Allegra	27	As-treated	1	Europe	February-19	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable

	implantation systems														
21075775	Transcatheter aortic valve implantation systems	Sapien	130	Intention-to-treat	9	Europe	November-10	April-07	January-08	Industry-related	No	No	non-RCT	Cohort	Not applicable
26718510	Transcatheter aortic valve implantation systems	Sapien XT	560	Intention-to-treat	28	North America	December-15	April-11	February-12	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
21639811	Transcatheter aortic valve implantation systems	Sapien	699	Intention-to-treat	25	Multiple	June-11	May-07	August-09	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
27400898	Transcatheter aortic valve implantation systems	Sapien S3	583	Intention-to-treat	29	North America	July-16	October-13	September-14	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
20961243	Transcatheter aortic valve implantation systems	Sapien	358	Intention-to-treat	21	Multiple	September-10	May-07	March-09	Industry-related	Yes	Yes	RCT	Not applicable	Superiority
28973091	Transcatheter aortic valve implantation systems	Sapien S3	1592	As-treated	51	North America	August-17	October-13	September-14	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
27040324	Transcatheter aortic valve implantation systems	Sapien XT	2032	Intention-to-treat	57	North America	February-20	December-11	November-13	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
30883058	Transcatheter aortic valve implantation systems	Sapien S3	1000	Intention-to-treat	71	Multiple	May-19	March-16	October-17	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
22657270	Transcatheter aortic valve implantation systems	Portico	10	Intention-to-treat	Not reported	North America	July-12	Not reported	Not reported	None declared	No	No	non-RCT	Case-control	Not applicable
32771997	Transcatheter aortic valve implantation systems	Portico	45	Intention-to-treat	6	Europe	August-20	April-17	June-18	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
32593323	Transcatheter aortic valve implantation systems	Portico	750	Intention-to-treat	52	Multiple	September-20	May-14	October-17	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority

28797431	Transcatheter aortic valve implantation systems	Portico	222	Intention-to-treat	12	Multiple	August-17	December-11	September-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
30111522	Transcatheter aortic valve implantation systems	Portico	941	Intention-to-treat	61	Multiple	August-18	April-13	June-17	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
24595532	Transcatheter aortic valve implantation systems	Sapien XT	69	As-treated	3	Asia-Pacific	August-17	April-10	April-11	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
22520622	Transcatheter aortic valve implantation systems	CoreValve; Sapien	106	As-treated	1	Europe	February-12	November-07	December-09	None declared	No	No	non-RCT	Cohort	Not applicable
27542790	Transcatheter aortic valve implantation systems	Portico	102	Intention-to-treat	6	Europe	December-16	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
30808296	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	100	As-treated	1	Europe	February-19	September-13	November-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
26345138	Transcatheter aortic valve implantation systems	CoreValve	160	Intention-to-treat	3	Europe	July-15	December-07	April-12	None declared	No	No	non-RCT	Cohort	Not applicable
33031491	Transcatheter aortic valve implantation systems	CoreValve Evolut R; CoreValve Evolut Pro	150	As-treated	25	North America	October-20	December-18	October-19	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
34348863	Transcatheter aortic valve implantation systems	Sapien S3	28	As-treated	2	Asia-Pacific	August-21	September-16	January-18	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
25455463	Transcatheter aortic valve implantation systems	Sapien XT	47	As-treated	1	Asia-Pacific	February-15	Not reported	Not reported	Industry-related	No	No	non-RCT	Cohort	Not applicable
20826252	Transcatheter aortic valve implantation systems	CoreValve; Sapien	99	As-treated	1	Europe	November-10	November-07	December-08	Non-industry related	No	No	non-RCT	Cohort	Not applicable
24169077	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	11	As-treated	3	Asia-Pacific	October-13	April-12	April-12	Industry-related	Yes	No	non-RCT	Cohort	Not applicable

25257635	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	120	Intention-to-treat	14	Multiple	September-14	October-13	April-13	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28555592	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	250	Intention-to-treat	20	Multiple	May-17	October-12	April-14	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29297076	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	912	Intention-to-treat	912	Multiple	January-18	September-14	December-15	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
33191317	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	60	Intention-to-treat	5	Asia-Pacific	July-21	June-15	August-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
30621976	Transcatheter aortic valve implantation systems	Lotus, Lotus Edge	1014	Intention-to-treat	41	Multiple	January-19	June-16	October-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
31570258	Transcatheter aortic valve implantation systems	Symetis Acurate neo	739	Intention-to-treat	20	Europe	September-19	February-17	February-19	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
33054367	Transcatheter aortic valve implantation systems	Symetis Acurate neo	796	Intention-to-treat	23	Europe	December-20	April-17	April-19	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
32049283	Transcatheter aortic valve implantation systems	CoreValve Evolut R	447	Intention-to-treat	7	Europe	February-20	April-16	April-18	Non-industry related	Yes	No	RCT	Not applicable	Equivalence
25946437	Transcatheter aortic valve implantation systems	Sapien XT	2688	Intention-to-treat	99	Europe	April-15	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
22581299	Transcatheter aortic valve implantation systems	Sapien	70	Intention-to-treat	2	Europe	August-12	November-08	May-11	Non-industry related	No	No	RCT	Not applicable	Superiority
28304219	Transcatheter aortic valve implantation systems	CoreValve; CoreValve Evolut R	1746	Intention-to-treat	87	Multiple	April-17	June-12	June-16	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
30715097	Transcatheter aortic valve implantation systems	TAVI	246	As-treated	1	North America	February-19	February-14	June-17	Non-industry related	No	No	non-RCT	Cohort	Not applicable

18573397	Transcatheter aortic valve implantation systems	Sapien	40	As-treated	2	North America	April-08	December-06	February-08	None declared	No	No	non-RCT	Cohort	Not applicable
20637648	Transcatheter aortic valve implantation systems	Sapien	168	As-treated	3	Europe	July-10	February-06	April-08	Industry-related	No	No	non-RCT	Cohort	Not applicable
34148125	Transcatheter aortic valve implantation systems	Symetis Acurate neo 2	120	Intention-to-treat	9	Europe	June-20	January-00	November-17	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29554265	Transcatheter aortic valve implantation systems	Symetis Acurate neo	60	Intention-to-treat	7	Europe	October-18	January-00	October-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28804056	Transcatheter aortic valve implantation systems	Symetis Acurate neo	89	Intention-to-treat	6	Multiple	October-17	January-12	October-13	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
24682842	Transcatheter aortic valve implantation systems	CoreValve	1015	Intention-to-treat	44	Multiple	March-14	May-10	July-11	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29268926	Transcatheter aortic valve implantation systems	CoreValve	203	As-treated	23	Multiple	December-17	March-15	July-16	Both	Yes	No	non-RCT	Cohort	Not applicable
23517843	Transcatheter aortic valve implantation systems	Centera	15	As-treated	2	Multiple	March-13	January-10	January-12	Industry-related	No	No	non-RCT	Cohort	Not applicable
24682026	Transcatheter aortic valve implantation systems	Sapien XT	241	Intention-to-treat	5	Europe	April-14	March-12	December-13	Non-industry related	Yes	No	RCT	Not applicable	Superiority
27793402	Transcatheter aortic valve implantation systems	CoreValve	100	Intention-to-treat	9	Europe	May-17	September-12	February-14	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
25999108	Transcatheter aortic valve implantation systems	CoreValve	200	Intention-to-treat	9	Europe	May-15	February-11	April-13	Industry-related	No	No	non-RCT	Cohort	Not applicable
24678937	Transcatheter aortic valve implantation systems	CoreValve	795	Intention-to-treat	45	North America	March-14	February-11	September-12	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority

21492762	Transcatheter aortic valve implantation systems	CoreValve	126	Intention-to-treat	9	Multiple	April-11	January-06	January-08	None declared	No	No	non-RCT	Case-control	Not applicable
17015786	Transcatheter aortic valve implantation systems	CoreValve	25	Intention-to-treat	1	Europe	October-06	February-05	November-05	Industry-related	No	No	non-RCT	Cohort	Not applicable
24662399	Transcatheter aortic valve implantation systems	CoreValve	55	As-treated	4	Asia-Pacific	July-17	October-11	August-13	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28183466	Transcatheter aortic valve implantation systems	CoreValve Evolut R	241	Intention-to-treat	23	North America	February-17	September-14	July-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
24657695	Transcatheter aortic valve implantation systems	CoreValve	489	Intention-to-treat	41	North America	May-14	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
22440213	Transcatheter aortic valve implantation systems	CoreValve	146	Intention-to-treat	1	Europe	March-12	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
20031667	Transcatheter aortic valve implantation systems	Direct Flow	15	Intention-to-treat	1	Europe	October-08	September-07	March-08	Industry-related	No	No	non-RCT	Cohort	Not applicable
22995116	Transcatheter aortic valve implantation systems	Direct Flow	31	Intention-to-treat	3	Multiple	September-12	October-07	August-08	Industry-related	No	No	non-RCT	Cohort	Not applicable
26762913	Transcatheter aortic valve implantation systems	Direct Flow	100	Intention-to-treat	9	Europe	March-14	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
16545654	Transcatheter aortic valve implantation systems	Sapien	36	Intention-to-treat	1	Europe	March-06	Not reported	Not reported	Industry-related	No	No	non-RCT	Cohort	Not applicable
25456759	Transcatheter aortic valve implantation systems	Sapien S3	150	As-treated	16	Multiple	December-14	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
32246266	Transcatheter aortic valve implantation systems	Sapien S3	56	Intention-to-treat	1	Europe	May-20	January-14	May-16	Both	Yes	Yes	RCT	Not applicable	Superiority

22743081	Transcatheter aortic valve implantation systems	Engager	11	Intention-to-treat	1	Europe	October-12	March-10	July-11	None declared	No	No	non-RCT	Cohort	Not applicable
21148541	Transcatheter aortic valve implantation systems	Engager	30	Intention-to-treat	3	Europe	April-11	August-08	October-09	None declared	Yes	No	non-RCT	Cohort	Not applicable
30883053	Transcatheter aortic valve implantation systems	CoreValve; CoreValve Evolut R; CoreValve Evolut Pro	1468	Intention-to-treat	86	Multiple	March-19	March-16	November-18	Industry-related	Yes	No	RCT	Not applicable	Non-inferiority
32418883	Transcatheter aortic valve implantation systems	Sapien S3	293	Intention-to-treat	5	Europe	May-20	May-17	January-18	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
32748789	Transcatheter aortic valve implantation systems	CoreValve Evolut Pro	629	Intention-to-treat	39	Multiple	November-20	February-18	January-19	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28797353	Transcatheter aortic valve implantation systems	CoreValve Evolut R	1038	Intention-to-treat	53	Multiple	August-17	January-16	December-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
22551129	Transcatheter aortic valve implantation systems	CoreValve; Sapien; Sapien XT	3195	As-treated	34	Europe	March-12	January-10	October-11	Industry-related	No	No	non-RCT	Cohort	Not applicable
29444998	Transcatheter aortic valve implantation systems	Portico	222	Intention-to-treat	12	Multiple	February-18	December-11	September-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
22508111	Transcatheter aortic valve implantation systems	Jena Valve	67	As-treated	7	Europe	April-12	October-10	July-11	Industry-related	No	No	non-RCT	Cohort	Not applicable
30860059	Transcatheter aortic valve implantation systems	CoreValve Evolut R; Sapien S3	200	Intention-to-treat	11	North America	May-19	Not reported	Not reported	Non-industry related	Yes	Yes	non-RCT	Cohort	Not applicable
32381181	Transcatheter aortic valve implantation systems	CoreValve Evolut R; Sapien S3	61	Intention-to-treat	6	North America	May-20	August-16	September-19	Non-industry related	Yes	Yes	non-RCT	Cohort	Not applicable
29348010	Transcatheter aortic valve	CoreValve Evolut Pro	60	Intention-to-treat	8	North America	January-18	July-16	November-16	Industry-related	No	No	non-RCT	Cohort	Not applicable

	implantation systems														
31566572	Transcatheter aortic valve implantation systems	Myval	30	Intention-to-treat	14	Asia-Pacific	August-20	July-17	February-18	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
26315740	Transcatheter aortic valve implantation systems	CoreValve Evolut R	60	As-treated	6	Multiple	August-15	October-13	July-14	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29131801	Transcatheter aortic valve implantation systems	Symetis Acurate Neo	1000	As-treated	24	Europe	November-17	October-14	April-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
34004077	Transcatheter mitral valve repair/replacement systems	PASCAL	45	As-treated	24	Multiple	May-21	January-19	January-19	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
31255562	Transcatheter mitral valve repair/replacement systems	PASCAL	124	As-treated	14	Multiple	July-19	January-17	January-20	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
34141859	Transcatheter mitral valve repair/replacement systems	MitraClip	29	As-treated	1	Multiple	June-21	January-14	January-18	None declared	No	No	non-RCT	Cohort	Not applicable
33979403	Transcatheter mitral valve repair/replacement systems	MitraClip	187	As-treated	4	Europe	May-21	January-14	January-18	Non-industry related	No	No	non-RCT	Cohort	Not applicable
32065722	Transcatheter mitral valve repair/replacement systems	MitraClip	50	As-treated	1	Europe	February-20	January-14	January-15	None declared	No	No	non-RCT	Cohort	Not applicable
30077993	Transcatheter mitral valve repair/replacement systems	MitraClip	78	As-treated	Not reported	North America	August-18	January-07	January-08	Industry-related	No	No	non-RCT	Cohort	Not applicable
25011722	Transcatheter mitral valve repair/replacement systems	MitraClip	351	As-treated	Not reported	Multiple	July-14	January-07	January-14	None declared	Yes	No	non-RCT	Cohort	Not applicable
30898200	Transcatheter mitral valve repair/replacement systems	Tendyne	100	As-treated	24	Multiple	March-19	January-14	January-17	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28040318	Transcatheter mitral valve	Tendyne	30	As-treated	8	Multiple	December-16	January-14	January-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable

	repair/replace ment systems														
26655529	Transcatheter mitral valve repair/replace ment systems	NeoChord DS1000	49	As- treated	1	Europe	Novembe r-15	January-13	January-14	None declared	No	No	non-RCT	Cohort	Not applicable
27436878	Transcatheter mitral valve repair/replace ment systems	Harpoon TDS-5	11	As- treated	2	Europe	July-16	January-15	January-15	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
30124798	Transcatheter mitral valve repair/replace ment systems	Cardioband Mitral	60	As- treated	11	Europe	February- 19	January-13	January-16	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
26586779	Transcatheter mitral valve repair/replace ment systems	Cardioband Mitral	31	As- treated	5	Europe	Novembe r-15	Not reported	Not reported	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
33047896	Transcatheter mitral valve repair/replace ment systems	Carillon Mitral Countour System	15	As- treated	1	Europe	October- 20	January-11	January-13	Industry- related	No	No	non-RCT	Cohort	Not applicable
22613584	Transcatheter mitral valve repair/replace ment systems	Carillon Mitral Countour System	53	Intentio n-to- treat	7	Europe	May-12	Not reported	Not reported	Industry- related	No	No	non-RCT	Cohort	Not applicable
27493761	Transcatheter mitral valve repair/replace ment systems	Carillon Mitral Countour System	36	Intentio n-to- treat	5	Europe	July-16	Not reported	Not reported	Industry- related	No	No	non-RCT	Cohort	Not applicable
27712741	Transcatheter mitral valve repair/replace ment systems	Cardioband Mitral	31	As- treated	5	Europe	October- 16	January-13	January-14	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
25944047	Transcatheter mitral valve repair/replace ment systems	MitraClip	20	As- treated	1	Europe	May-15	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
24100100	Transcatheter mitral valve repair/replace ment systems	NeoChord DS1000	13	As- treated	1	Europe	October- 13	January-11	January-12	None declared	No	No	non-RCT	Cohort	Not applicable
24895448	Transcatheter mitral valve repair/replace ment systems	MitraClip	107	As- treated	1	Europe	June-14	January-10	January-13	None declared	No	No	non-RCT	Cohort	Not applicable
24076529	Transcatheter mitral valve	NeoChord DS1000	30	As- treated	7	Europe	Septemb er-13	January-09	January-12	Industry- related	Yes	No	non-RCT	Cohort	Not applicable

	repair/replace ment systems														
23747789	Transcatheter mitral valve repair/replace ment systems	MitraClip	567	As- treated	14	Europe	June-13	January-09	January-11	None declared	No	No	non-RCT	Cohort	Not applicable
22188385	Transcatheter mitral valve repair/replace ment systems	MitraClip	33	As- treated	1	Europe	Decembe r-11	January-10	January-11	None declared	No	No	non-RCT	Cohort	Not applicable
21463154	Transcatheter mitral valve repair/replace ment systems	MitraClip	279	Intentio n-to- treat	37	North America	April-11	January-05	January-08	Industry- related	Yes	Yes	RCT	Not applicab le	Non- inferiorty
31521683	Transcatheter mitral valve repair/replace ment systems	Carillon Mitral Countour System	120	Intentio n-to- treat	24	Multiple	Septemb er-19	January-15	January-17	Industry- related	Yes	Yes	RCT	Not applicab le	Superiority
30145927	Transcatheter mitral valve repair/replace ment systems	MitraClip	304	Intentio n-to- treat	37	Europe	August- 18	January-13	January-17	Both	Yes	No	RCT	Not applicab le	Superiority
30280640	Transcatheter mitral valve repair/replace ment systems	MitraClip	614	Intentio n-to- treat	78	North America	Septemb er-18	January-12	January-17	Industry- related	Yes	Yes	RCT	Not applicab le	Superiority
16325053	Transcatheter mitral valve repair/replace ment systems	MitraClip	27	As- treated	6	Multiple	October- 05	Not reported	Not reported	None declared	Yes	No	non-RCT	Cohort	Not applicable
19597051	Transcatheter mitral valve repair/replace ment systems	Carillon Mitral Contour System	48	Intentio n-to- treat	Not reporte d	Europe	July-09	Not reported	Not reported	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
27339489	Transcatheter mitral valve repair/replace ment systems	Mitralign percutaneo us annuloplast y system	71	As- treated	10	Multiple	June-16	Not reported	Not reported	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
29102688	Transcatheter mitral valve repair/replace ment systems	Harpoon TDS-5	30	As- treated	6	Multiple	Novembe r-17	December -15	November -16	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
34053453	Surgical valves	Perceval	78	As- treated	13	Multiple	May-21	March-11	March-19	Industry- related	Yes	No	non-RCT	Cohort	Not applicable
33478837	Surgical valves	Perceval	819	As- treated	47	Multiple	Decembe r-20	March-16	Septembe r-18	Industry- related	Yes	Yes	RCT	Not applicab le	Superiority

33597099	Surgical valves	Perceval	658	As-treated	25	Europe	January-21	February-10	September-13	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
28605428	Surgical valves	Inspiris Resilia	689	As-treated	27	Multiple	September-17	January-13	March-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
34830622	Surgical valves	Crown PRT; Trifecta; Perimount Magna Ease (3300 TFX)	154	As-treated	1	Europe	November-21	June-14	June-17	Non-industry related	Yes	No	RCT	Not applicable	Superiority
33776017	Surgical valves	Avalus	11	As-treated	Not reported	Asia-Pacific	March-21	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
34036633	Surgical valves	Intuity	170	As-treated	1	Europe	May-21	June-12	July-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
32674180	Surgical valves	Intuity	510	As-treated	1	Europe	July-20	March-12	September-17	Non-industry related	No	No	non-RCT	Cohort	Not applicable
30137264	Surgical valves	Intuity	700	As-treated	1	Europe	March-19	May-10	May-19	Industry-related	No	No	non-RCT	Cohort	Not applicable
28475690	Surgical valves	Avalus	1110	As-treated	38	Multiple	September-17	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
31875777	Surgical valves	Perceval	480	As-treated	29	Multiple	December-19	March-11	September-18	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
30553598	Surgical valves	Perceval	289	As-treated	18	North America	October-18	June-13	January-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29778342	Surgical valves	Avalus	864	As-treated	36	Multiple	April-18	May-14	June-16	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
29415382	Surgical valves	Intuity	493	As-treated	26	Europe	October-17	July-12	July-14	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28453629	Surgical valves	Intuity	287	As-treated	6	Europe	Aug 17	January-10	October-12	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
28369288	Surgical valves	Intuity	150	As-treated	1	Europe	July-17	July-12	April-15	Industry-related	No	No	non-RCT	Cohort	Not applicable
27817951	Surgical valves	Intuity	839	As-treated	29	North America	October-16	September-12	December-15	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
25441065	Surgical valves	Intuity	100	As-treated	5	Europe	November-14	May-12	February-13	Industry-related	Yes	No	RCT	Not applicable	Unclear
26656235	Surgical valves	Trifecta	837	As-treated	1	Europe	December-15	January-09	March-13	None declared	No	No	non-RCT	Cohort	Not applicable
27964975	Surgical valves	Trifecta	710	As-treated	11	North America	November-16	January-07	January-09	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
26245628	Surgical valves	Perceval	658	As-treated	25	Europe	August-15	February-10	September-13	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
26984983	Surgical valves	Mitroflow	440	As-treated	1	Europe	March-16	January-99	January-14	None declared	No	No	non-RCT	Cohort	Not applicable
25750010	Surgical valves	Perceval	731	As-treated	25	Europe	March-15	April-07	August-12	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable

26892076	Surgical valves	Intuity	158	As-treated	6	Europe	January-16	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
26589286	Surgical valves	Trifecta	178	As-treated	9	Europe	November-15	January-11	June-12	None declared	No	No	non-RCT	Cohort	Not applicable
25451486	Surgical valves	Intuity	60	As-treated	1	Europe	October-14	March-12	August-13	None declared	No	No	non-RCT	Cohort	Not applicable
25439772	Surgical valves	Perimount Magna (3000/3000 TFX); Epic Aortic; Mitroflow	300	Intention-to-treat	1	North America	September-14	August-09	November-11	Industry-related	No	No	RCT	Not applicable	Superiority
23477687	Surgical valves	Trifecta	1014	As-treated	31	Multiple	March-13	January-07	January-09	None declared	No	No	non-RCT	Cohort	Not applicable
24787699	Surgical valves	3F Enable	141	As-treated	10	Europe	April-14	March-07	December-09	Industry-related	No	No	non-RCT	Cohort	Not applicable
25106682	Surgical valves	Perceval	243	As-treated	23	Europe	August-14	April-07	February-13	Industry-related	No	No	non-RCT	Cohort	Not applicable
23058665	Surgical valves	Intuity	146	As-treated	6	Europe	October-12	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
23825161	Surgical valves	Trifecta	200	As-treated	1	Europe	July-13	July-10	September-12	None declared	No	No	non-RCT	Cohort	Not applicable
23673064	Surgical valves	Perceval	100	As-treated	1	Europe	August-13	March-10	December-11	None declared	No	No	non-RCT	Cohort	Not applicable
22818964	Surgical valves	Mitroflow	276	As-treated	6	North America	July-12	November-03	September-11	Industry-related	No	No	non-RCT	Cohort	Not applicable
22541180	Surgical valves	Perceval	208	As-treated	2	Europe	May-12	January-07	September-11	None declared	No	No	non-RCT	Cohort	Not applicable
21277603	Surgical valves	Epic Aortic	557	As-treated	22	North America	February-11	January-02	March-06	None declared	No	No	non-RCT	Cohort	Not applicable
21342776	Surgical valves	3F Enable	140	As-treated	10	Europe	February-11	March-07	December-09	Industry-related	No	No	non-RCT	Cohort	Not applicable
29029949	Surgical valves	Perimount Plus (6900 PTFX)	132	As-treated	1	Asia-Pacific	August-17	January-00	December-16	None declared	No	No	non-RCT	Cohort	Not applicable
33682228	Leadless pacemaker	Micra TPS	21	As-treated	Not reported	Multiple	March-21	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
33217535	Leadless pacemaker	Micra TPS	28	As-treated	1	Asia-Pacific	November-20	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
33418071	Leadless pacemaker	Micra TPS	443	As-treated	1	Europe	January-21	June-15	December-19	Non-industry related	No	No	non-RCT	Cohort	Not applicable
34141021	Leadless pacemaker	Micra TPS	31	Intention-to-treat	Not reported	Asia-Pacific	May-21	October-18	April-20	Non-industry related	No	No	non-RCT	Cohort	Not applicable

32860605	Leadless pacemaker	Micra TPS	21	As-treated	Not reported	Europe	August-20	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31395499	Leadless pacemaker	Micra TPS	129	As-treated	1	Europe	August-19	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
29986008	Leadless pacemaker	Micra TPS	15	As-treated	1	Europe	January-19	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
30392985	Leadless pacemaker	Micra TPS	79	Intention-to-treat	1	Asia-Pacific	October-18	November-15	April-18	Non-industry related	No	No	non-RCT	Cohort	Not applicable
30550834	Leadless pacemaker	Micra TPS	51	As-treated	1	Asia-Pacific	December-18	September-15	April-18	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31180481	Leadless pacemaker	Micra TPS	83	As-treated	1	Europe	August-19	May-14	November-18	Non-industry related	No	No	non-RCT	Case-control	Not applicable
30176097	Leadless pacemaker	Micra TPS	51	As-treated	1	Europe	September-18	February-14	September-16	Non-industry related	No	No	non-RCT	Cohort	Not applicable
29758405	Leadless pacemaker	Micra TPS	64	As-treated	12	Multiple	May-18	Not reported	Not reported	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
26551877	Leadless pacemaker	Micra TPS	725	Intention-to-treat	56	Multiple	November-15	Not reported	Not reported	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
30221378	Leadless pacemaker	Micra TPS	137	As-treated	5	Europe	September-18	June-15	June-17	Non-industry related	No	No	non-RCT	Cohort	Not applicable
28666317	Leadless pacemaker	Micra TPS	23	As-treated	1	Europe	May-18	October-14	December-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
27855290	Leadless pacemaker	Micra TPS	14	As-treated	1	Europe	November-16	May-15	July-16	Non-industry related	No	No	non-RCT	Cohort	Not applicable
28040461	Leadless pacemaker	Micra TPS	30	As-treated	1	Europe	December-16	June-15	May-16	Non-industry related	No	No	non-RCT	Cohort	Not applicable
28502871	Leadless pacemaker	Micra TPS	795	As-treated	96	Multiple	May-17	July-15	January-17	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
33516714	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	301	As-treated	28	Europe	January-21	July-18	September-19	Non-industry related	No	No	non-RCT	Cohort	Not applicable
32860605	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	52	As-treated	Not reported	Europe	August-20	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable

33073614	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	1116	Intention-to-treat	110	Multiple	October-20	June-15	February-18	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
33969569	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	1099	As-treated	7	Europe	May-21	May-14	December-19	Non-industry related	Yes	No	non-RCT	Cohort	Not applicable
34307829	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	30	As-treated	1	Europe	July-21	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
34140203	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	22	As-treated	1	North America	April-21	March-18	March-19	Non-industry related	No	No	RCT	Not applicable	Superiority
32613315	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	75	As-treated	1	Europe	July-20	September-16	February-17	Non-industry related	No	No	non-RCT	Cohort	Not applicable
33538124	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	100	As-treated	1	Europe	February-21	November-18	June-20	Non-industry related	No	No	non-RCT	Cohort	Not applicable
32757521	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	849	As-treated	39	Multiple	August-20	March-11	January-17	Industry-related	Yes	Yes	RCT	Not applicable	Non-inferiority
31813098	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	49	As-treated	1	North America	December-19	January-18	April-19	Industry-related	No	No	non-RCT	Cohort	Not applicable
32596027	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	24	As-treated	1	North America	June-20	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable
31778266	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	91	As-treated	10	Europe	December-19	March-17	August-17	Non-industry related	Yes	No	non-RCT	Case-control	Not applicable
30661851	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	44	As-treated	12	Europe	January-19	April-13	March-18	None declared	No	No	non-RCT	Cohort	Not applicable
30609077	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	69	As-treated	1	Europe	January-19	September-15	January-17	Non-industry related	No	No	non-RCT	Cohort	Not applicable

31512339	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	15	As-treated	1	Europe	September-19	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
31048064	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	41	As-treated	1	Europe	June-19	January-14	January-18	Non-industry related	No	No	non-RCT	Cohort	Not applicable
29758404	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	1984	As-treated	Not reported	Europe	June-18	January-15	December-16	Industry-related	No	No	non-RCT	Cohort	Not applicable
28502872	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	1637	As-treated	86	North America	May-17	August-13	May-16	Industry-related	Yes	Yes	non-RCT	Cohort	Not applicable
27943358	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	36	As-treated	Not reported	Europe	February-17	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
28536837	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	16	As-treated	1	Europe	May-17	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
28007749	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	82	As-treated	1	Europe	December-17	Not reported	Not reported	Non-industry related	No	No	non-RCT	Cohort	Not applicable
27068637	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	102	As-treated	1	Europe	March-16	July-10	June-15	Non-industry related	No	No	non-RCT	Cohort	Not applicable
25687749	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	15	As-treated	1	Europe	February-15	June-12	December-13	Non-industry related	No	No	non-RCT	Cohort	Not applicable
23707489	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	39	As-treated	1	Europe	May-13	October-10	December-11	Non-industry related	No	No	non-RCT	Cohort	Not applicable
23979626	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	330	Intention-to-treat	33	Multiple	August-13	Not reported	Not reported	Industry-related	Yes	No	non-RCT	Cohort	Not applicable
22035049	Subcutaneous implantable cardioverter defibrillator	EMBLEM S-ICD	64	As-treated	Not reported	North America	October-11	Not reported	Not reported	None declared	No	No	non-RCT	Cohort	Not applicable

PubMed identifier primary report	Follow-up in the primary publication (months)	Max follow-up available (months)	Power calculations	Interim analysis	Type of interim analysis	Final statistical analysis	Early termination of the study	Reason of termination	Patient's involvement
33723086	30	36	No	No	Not applicable	Frequentist framework	Yes	Comparator device retracted from market	No involvement/Unclear
31912983	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31217148	13	13	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33600069	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34290573	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32881396	12	12	Yes	Yes	after 400 patients	Frequentist framework	No	Not applicable	No involvement/Unclear
34125947	12	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32763098	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33269506	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32525410	0	0	Yes	No	Not applicable	Frequentist framework	Yes	BVS retracted from market	No involvement/Unclear
33363447	12	24	Yes	No	Not applicable	Frequentist framework	Yes	BVS retracted from market	No involvement/Unclear
31085503	0	1	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32279841	12	12	Yes	No	Not applicable	Frequentist framework	Yes	BVS retracted from market	No involvement/Unclear
32451321	12	12	Yes	Yes	safety review	Frequentist framework	Yes	safety concerns at interim analysis	No involvement/Unclear
33069847	25	25	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32205067	6	12	Yes	No	Not applicable	Frequentist framework	Yes	BVS retracted from market	No involvement/Unclear
31587103	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30235969	36	36	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30520980	8	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

30286520	36	36	Yes	Yes	after 512 patients	Frequentist framework	No	Not applicable	No involvement/Unclear
30277460	36	36	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30905344	60	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31053981	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31197750	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30975219	3	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30170828	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30561875	9	9	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30676384	9	9	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31553204	12	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31029616	36	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31708522	3	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29131802	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29656279	1	5	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29901443	6	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29774520	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29512092	6	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29168541	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29983253	48	48	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30266412	1	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28432385	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28866036	9	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

28853189	12	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28438304	3	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27807948	0	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28935077	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28568564	12	36	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28829745	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28504218	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28527768	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28504219	12	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28402237	24	36	Yes	Yes	safety review	Frequentist framework	Yes	safety concerns	No involvement/Unclear
27013155	24	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27476094	18	18	No	Yes	after 180 patients	Frequentist framework	No	Not applicable	No involvement/Unclear
27998840	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27290673	9	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27245123	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26567454	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26405232	6	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27806897	36	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27173858	12	36	No	Yes	not prespecified	Frequentist framework	No	Not applicable	No involvement/Unclear
26457558	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26471805	12	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26330419	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

26015294	12	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25136885	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26342404	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25720622	9	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26654975	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26269391	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25499836	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24394380	3	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25563622	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24139932	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23332165	12	36	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21958884	12	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
19286089	6	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
17544767	4	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26470647	6	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
17397680	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
19683639	18	47.6	Yes	Yes	After 600 patient-years of follow-up	Bayesian framework	No	Not applicable	No involvement/Unclear
23062528	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23583249	14.4	14.4	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23973952	11.7	11.7	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24319042	13.6	13.6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24820753	1.46	1.46	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

24998121	12	47.9	No	Yes	Adaptive interim analysis in which the predictive probabilities of success were calculated; enrollment was to be stopped early if the predictive probability of success at an interim analysis exceeded 0.95	Bayesian framework	No	Not applicable	No involvement/Unclear
25281005	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26354821	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26738659	36	36	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26822918	1	21	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27128539	3	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27973336	27.6	27.6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28041899	12.6	12.6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28409845	0.2	0.2	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28649053	2.4	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29122133	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29149516	0.2	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29477973	Not reported	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29525913	16	16	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29540492	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29706393	24	24	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29759399	34.8	34.8	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30305484	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30583991	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30586229	17.4	17.4	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30884101	59	59	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

31008181	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31092201	19.2	19.2	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31596044	78.8	78.8	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31707534	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32586585	20	20	Yes	Yes	Comparison of actual to expected event rates in order to potentially stop the study if the recruitment was insufficient or if the endpoints occurred with significantly less frequency than expected	Frequentist framework	No	Not applicable	No involvement/Unclear
33189641	55	55	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33251673	3	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33334441	0	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33533089	0	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33820423	0.25	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33915971	0.12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34097038	0.12	24.3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34459659	18	18	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25787196	12	72	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30761515	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21075775	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26718510	24	40	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21639811	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27400898	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
20961243	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28973091	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

27040324	24	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30883058	12	24	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22657270	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32771997	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32593323	24	24	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28797431	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30111522	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24595532	6	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22520622	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27542790	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30808296	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26345138	24	72	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33031491	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34348863	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25455463	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
20826252	3	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24169077	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25257635	1	12	Yes	Yes	Frequentist analysis	Frequentist framework	No	Not applicable	No involvement/Unclear
28555592	12	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29297076	12	24	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33191317	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30621976	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

31570258	1	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33054367	12	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32049283	1	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25946437	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22581299	3	3	Yes	No	Not applicable	Frequentist framework	Yes	excess of events	No involvement/Unclear
28304219	24	24	Yes	Yes	Bayesian analysis	Bayesian framework	No	Not applicable	No involvement/Unclear
30715097	12	12	No	No	Not applicable	Bayesian framework	No	Not applicable	No involvement/Unclear
18573397	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
20637648	12	12	No	Yes	Frequentist analysis	Frequentist framework	No	Not applicable	No involvement/Unclear
34148125	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29554265	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28804056	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24682842	12	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29268926	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23517843	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24682026	1	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27793402	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25999108	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24678937	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21492762	24	48	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
17015786	1	0.5	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24662399	6	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

28183466	1	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24657695	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22440213	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
20031667	1	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22995116	36	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26762913	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
16545654	24	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25456759	1	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32246266	12	12	Yes	No	Not applicable	Frequentist framework	Yes	Study enrolment was preliminary halted, due to the EU release of a new-generation SEV (Medtronic Evolut) and slow enrolment.	No involvement/Unclear
22743081	1	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21148541	12	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30883053	24	24	Yes	Yes	the analysis of the primary objective	Bayesian framework	No	Not applicable	No involvement/Unclear
32418883	1	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32748789	1	Not reported	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28797353	1	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22551129	12	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29444998	12	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22508111	1	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30860059	12	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32381181	12	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

29348010	1	36	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31566572	12	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26315740	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29131801	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34004077	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31255562	1	24	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34141859	18	25	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33979403	12	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32065722	6	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30077993	60	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25011722	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30898200	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28040318	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26655529	3	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27436878	1	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30124798	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26586779	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33047896	72	72	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22613584	1	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27493761	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27712741	1	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25944047	0.23	0.23	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

24100100	1	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24895448	6	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24076529	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23747789	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22188385	0.23	0.23	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21463154	12	60	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31521683	12	12	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30145927	12	24	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30280640	24	36	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
16325053	1	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
19597051	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27339489	1	6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29102688	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34053453	55.5	55.5	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33478837	12	12	Yes	Yes	Bayesian adaptive Goldilocks approach	Bayesian framework	No	Not applicable	No involvement/Unclear
33597099	12	45.6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28605428	14.4	48	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34830622	12	12	Yes	No	Not applicable	Frequentist framework	Yes	Study valve discontinued	No involvement/Unclear
33776017	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34036633	60	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32674180	33.6	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30137264	28	108	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

28475690	23.3	23.3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31875777	28.8	84	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30553598	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29778342	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29415382	21.6	21.6	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28453629	44.4	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28369288	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27817951	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25441065	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26656235	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27964975	72	72	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26245628	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26984983	72.5	180	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25750010	11.5	61.2	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26892076	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26589286	20.5	30	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25451486	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25439772	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23477687	24	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
24787699	33.1	61.2	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25106682	14.6	24	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23058665	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

23825161	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23673064	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22818964	48	60	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22541180	10	48	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21277603	26.4	48	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
21342776	12	14	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29029949	204	204	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33682228	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33217535	Not reported	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33418071	22	22	No	No	Not applicable	Frequentist and Bayesian framework	No	Not applicable	No involvement/Unclear
34141021	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32860605	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31395499	8	8	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29986008	3	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30392985	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30550834	7	7	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31180481	18	18	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30176097	18	18	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29758405	Not reported	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
26551877	4	16.4	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30221378	4	4	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

28666317	2	2	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27855290	3	3	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28040461	5	5	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28502871	2	7	No	Yes	presepecified analysis	Frequentist framework	No	Not applicable	No involvement/Unclear
33516714	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32860605	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33073614	18	18	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33969569	28.9	28.9	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34307829	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
34140203	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32613315	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
33538124	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32757521	49	49	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31813098	1	1	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
32596027	0.03	0.03	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31778266	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30661851	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
30609077	14	14	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31512339	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
31048064	12	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
29758404	16	16	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28502872	1	12	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

27943358	10	10	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28536837	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
28007749	43	43	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
27068637	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
25687749	Not reported	Not reported	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23707489	18	18	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
23979626	6	6	Yes	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear
22035049	0	0	No	No	Not applicable	Frequentist framework	No	Not applicable	No involvement/Unclear

Appendix 8

Interventions and outcomes in study-level.

PubMed identifier primary report	Comparator or device	Primary outcome	Single / Composite outcome	Binary / Continuous / Categorical outcome	Clinical / Non-clinical outcome	Surrogate endpoint	QoL	Risk prediction score	Device-related complication(s)	Sex-subgroup	Sex-subgroup difference	Age-subgroup	Age-subgroup difference	Outcome adjudication
33723086	Axxess bifurcation device (Biosensors)	change in minimal luminal area (MLA) from baseline to 30 months (OCT)	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
31912983	Not applicable	composite of all-cause death, any stroke, any myocardial infarction, or any revascularization in-hospital	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
31217148	EES (Xience)	difference in Doppler ultrasound average peak velocity	Single	Continuous	Non-clinical	Yes	Yes	No	Yes	No	Not applicable	No	Not applicable	No
33600069	Not applicable	composite of cardiac death, target vessel myocardial infarction, and target lesion revascularization	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
34290573	Not applicable	change in maxLCBI4mm	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
32881396	Not applicable	target lesion failure	Composite	Binary	Clinical	No	Yes	No	No	No	Not applicable	No	Not applicable	Yes
34125947	Not applicable	target lesion failure	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
32763098	Not applicable	target lesion failure	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No

33269506	Not applicable	composite of cardiac death, myocardial infarction, and target lesion revascularization	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
32525410	Absorb BVS	composite of minimal scaffold area < 5 mm ² , residual area stenosis > 20%, percent ISA struts > 5%, major edge dissection, or scaffold disruption	Composite	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
33363447	Not applicable	composite of all-cause mortality, non-fatal myocardial infarction, and unplanned revascularization	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
31085503	EES (Xience)	difference between groups in changes of pressure-derived corrected index of microvascular resistance (cIMR) after PCI	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
32279841	EES (Xience)	composite of cardiac death, myocardial infarction, device thrombosis, or ischemia-driven target-lesion revascularization at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
32451321	EES (Xience)	composite of cardiac death, target vessel myocardial infarction or clinically indicated target lesion revascularization at 12 months	Composite	Binary	Clinical	No	Yes	No	No	Yes	No	No	Not applicable	Yes
33069847	Not applicable	IVUS-derived minimum lumen area at 25 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes

32205067	Absorb BVS	difference between groups in in-scaffold minimal lumen area at 6 months assessed by OCT	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	Yes
31587103	EES (Synergy)	mean neointimal thickness at 12 months	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	Yes
30235969	Not applicable	composite of cardiac death, target-vessel myocardial infarction, target lesion revascularization	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30520980	EES (Xience)	percent diameter stenosis at 6-8 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	Yes	No	No	No	Yes
30286520	Not applicable	composite of cardiac death, non-fatal myocardial infarction, ischemia-driven target lesion revascularization	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes
30277460	Not applicable	composite of cardiac death, target-vessel myocardial infarction, target lesion revascularization (in-scaffold re-occlusion not included)	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30905344	Not applicable	device resorption at 5 years	Single	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
31053981	Not applicable	change in difference between actual scaffold diameter and nominal size at baseline versus in the proximal main vessel at 1 month assessed by OCT	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
31197750	Not applicable	composite of all-cause death, any myocardial	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	Yes	No	Yes

		infarction, ischemia-driven target vessel revascularization at 12 months												
30975219	EES (Synergy)	percentage of uncovered struts at 3 months	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	Yes
30170828	Absorb BVS	procedural success (<50% residual stenosis and TIMI III flow in main- and side-branch)	Single	Binary	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30561875	Not applicable	change in index of microcirculatory resistance (IMR) from baseline to 9 month post-PCI	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
30676384	Not applicable	correlation between levels of (multiple) inflammatory markers and neointimal burden	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
31553204	SES (Orsiro)	in-scaffold/in-stent vasodilatory response $\geq 3\%$ after intracoronary nitroglycerin injection at 12-months angiographic follow-up	Single	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
31029616	EES (Xience)	interaction between device type and time of hyperemic myocardial blood flow from 1 month to 1 year to 3 years	Single	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
31708522	Not applicable	definite or probable scaffold thrombosis at 3 months	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29131802	Not applicable	composite of cardiac death, target vessel myocardial infarction, and ischemia-driven	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes

		target lesion revascularization												
29656279	Not applicable	composite of cardiac death, target vessel myocardial infarction, and target lesion revascularization at 30 days	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29901443	multiple DES	percent uncovered struts at 6 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29774520	Not applicable	feasibility of OCT-based implantation protocol	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
29512092	Absorb BVS	rate of uncovered struts at 6 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29168541	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29983253	Not applicable	composite of cardiac death, target-vessel myocardial infarction, target-lesion revascularization	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes
30266412	EES (Xience)	composite of cardiac death, target-vessel myocardial infarction, ischemia-driven target-lesion revascularization at 30 days	Composite	Binary	Clinical	No	Yes	No	Yes	Yes	No	Yes	No	Yes
28432385	Not applicable	percentage of uncovered struts at 6 months	Single	Continuous	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28866036	Not applicable	in-segment lumen diameter at 6-9 months	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	Yes
28853189	Not applicable	late lumen loss at 12 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes

28438304	Not applicable	target vessel revascularization at 3 months	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes
27807948	EES (Synergy)	mean difference in fluoroscopy time	Single	Continuous	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28935077	Not applicable	composite endpoint of cardiac death, target vessel myocardial infarction, ischemia-driven target lesion revascularization at 30 days	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28568564	Not applicable	composite of cardiac death, myocardial infarction not clearly related to a non-target vessel, ischemia-driven target lesion revascularization	Composite	Binary	Clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
28829745	Not applicable	composite of death, target-vessel revascularization, myocardial infarction	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes
28504218	Not applicable	composite of cardiac death, myocardial infarction, and ischaemia-driven target lesion revascularization at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28527768	Mirage BVS	mean difference in in-scaffold late-lumen-loss at 12 months	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	Yes
28504219	Not applicable	composite of cardiac death, target-vessel myocardial infarction, ischemia-driven target-vessel revascularization at 1 year	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes

28402237	EES (Xience)	composite of cardiac death, target-vessel myocardial infarction, target-vessel revascularization (= target-vessel failure) at 2 years	Composite	Binary	Clinical	No	No	No	Yes	Yes	Yes	No	Not applicable	Yes
27013155	Not applicable	late lumen loss at 6 months by QCA	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
27476094	Not applicable	composite of cardiac death, myocardial infarction, target lesion revascularization	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
27998840	Not applicable	released plaque material	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
27290673	Not applicable	composite of cardiac death, target vessel myocardial infarction, or clinically driven target vessel revascularization at 9 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
27245123	Not applicable	stent thrombosis	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
26567454	Not applicable	composite of death, myocardial infarction, target lesion revascularization at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26405232	EES (Xience)	difference in healing score (OCT) at 6 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
27806897	EES (Xience)	difference in vasomotion after 3 years	Single	Continuous	Non-clinical	Yes	Yes	No	No	No	Not applicable	No	Not applicable	Yes
27173858	Not applicable	composite of death, reinfarction or target vessel	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

		revascularization at undetermined timepoint												
26457558	EES (Xience)	composite of cardiac death, target-vessel myocardial infarction, ischemia-driven target-lesion revascularization (= target lesion failure) at 12 months	Composite	Binary	Clinical	No	Yes	No	No	Yes	No	Yes	No	Yes
26471805	EES (Xience)	late lumen loss at 12 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26330419	EES (Xience)	composite of cardiac death, target-vessel myocardial infarction, ischemia-driven target-lesion revascularization (= target lesion failure) at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26015294	Not applicable	mean neointimal thickness (um) at 12 months in OCT	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
25136885	Not applicable	composite of all-cause death, any myocardial infarction, and target vessel revascularization at 6 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26342404	Not applicable	target vessel revascularization	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
25720622	EES; BES	late lumen loss at 9 months	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
26654975	Not applicable	change in minimal scaffold diameter to reference stent diameter ratio (MR-Ratio) from post-implantation to post-dilation	Single	Continuous	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

26269391	Not applicable	composite of cardiac death, myocardial infarction with re-occlusion of target vessel, revascularization of target vessel at 6 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
25499836	Not applicable	composite of cardiac death, myocardial infarction, and ischaemia-driven target lesion revascularization at 12 months	Composite	Binary	Clinical	No	Yes	No	Yes	No	Not applicable	No	Not applicable	No
24394380	Not applicable	rate of TIMI III flow post-procedure	Single	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
25563622	Not applicable	composite of death, myocardial infarction, and clinically driven target lesion revascularization at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
24139932	Not applicable	composite of cardiac death, myocardial infarction, and ischaemia-driven target lesion revascularization at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
23332165	Not applicable	target lesion failure at 12 months	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
21958884	Not applicable	late lumen loss at multiple timepoints	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
19286089	Not applicable	composite of cardiac death, myocardial infarction, and ischaemia-driven target lesion revascularization at	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes

		unclearly defined timepoint												
17544767	Not applicable	composite of cardiac death, myocardial infarction, and ischaemia-driven target lesion revascularization at 4 months	Composit e	Binary	Clinical	No	Yes	No	Yes	No	Not applica ble	No	Not applica ble	No
26470647	Not applicable	late lumen loss at 6 months by QCA	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applica ble	No	Not applica ble	Yes
17397680	Not applicable	successful device implantation and successful sealing of the LAA as measured by TEE at 45 days after implant without major adverse events	Composit e	Binary	Both	No	No	No	Yes	No	Not applica ble	No	Not applica ble	No
19683639	NA	primary composite endpoint of stroke, cardiovascular death and systemic embolism	Composit e	Binary	Clinical	No	No	No	Yes	Yes	Yes	Yes	No	Yes
23062528	Not applicable	complete LAA closure at 1 year TEE	Single	Binary	Non-clinical	No	No	No	Yes	No	Not applica ble	No	Not applica ble	No
23583249	Not applicable	composite of ischemic stroke, hemorrhagic stroke, systemic embolism, and cardiovascular/unex plained death	Composit e	Binary	Clinical	No	No	No	Yes	No	Not applica ble	No	Not applica ble	No
23973952	Watchma n [Boston Scientific]	successful device implantation	Single	Binary	Non-clinical	No	No	No	Yes	No	No	No	No	No
24319042	Not applicable	procedural complications	Composit e	Binary	Clinical	No	No	No	Yes	No	Not applica ble	No	Not applica ble	No
24820753	Not applicable	procedural complications	Composit e	Binary	Clinical	No	No	No	Yes	No	Not applica ble	No	Not applica ble	No

24998121	NA	composite of stroke, systemic embolism, CV/unexplained death	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
25281005	Not applicable	atrial fibrillation burden	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
26354821	Not applicable	technical success: successful delivery and release of the occluder into the LAA	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
26738659	Not applicable	transient ischemic attack, stroke, intracranial hemorrhage, and death	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
26822918	Not applicable	procedural complications	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
27128539	Not applicable	stroke, embolic events and death of any cause at one year	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
27973336	Not applicable	device-related thrombosis	Single	Binary	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28041899	Not applicable	ischemic stroke	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28409845	Not applicable	major complications included bleedings BARC 3-5, device embolization, circulatory failure, cardiopulmonary resuscitation, and death.	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28649053	Not applicable	major complications included death, stroke, embolism, bleeding BARC 3-5, all device embolisations and	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

		major vascular complications.												
29122133	Not applicable	major complications including death, stroke, systemic embolism, device embolization, pericardial bleeding requiring an intervention (cardiac tamponade), or other major bleeding requiring invasive treatment or blood transfusion	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29149516	Not applicable	implant success	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29477973	Not applicable	reservoir function	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
29525913	Not applicable	death, stroke, TIA, major bleeding	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29540492	Not applicable	procedural success rate	Single	Binary	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
29706393	Not applicable	procedural complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29759399	Not applicable	procedural complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30305484	Not applicable	procedural complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30583991	Amplatzer Amulet, LAMBRE, Watchman	procedural complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30586229	Not applicable	procedural complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

30884101	NA	clinical outcomes at 17 months	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
31008181	Not applicable	composite of ischaemic stroke/TIA/SE at 2 years	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
31092201	Not applicable	stroke and bleedings at follow-up	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
31596044	Not applicable	composite of cerebrovascular events and systemic embolisms	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
31707534	Not applicable	composite of cerebrovascular events and systemic embolisms	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
32586585	NA	composite of stroke, TIA; systemic embolism; clinically significant bleeding; cardiovascular death; or significant peri-procedural or device-related complications	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
33189641	Not applicable	procedural complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
33251673	Not applicable	leak at 3 months after LAAC	Single	Binary	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
33334441	Not applicable	technical and procedural success	Composite	Binary	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
33533089	Not applicable	composite of procedural related complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
33820423	Not applicable	procedural related complications at 7 days	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
33915971	Not applicable	procedural related complications at 3 days	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

34097038	Not applicable	procedural related complication intrahospital	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
34459659	Watchman [Boston Scientific]	composite of procedure related complications, all-cause death, or major bleeding at 12 months	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
25787196	NA	composite of all-cause mortality, stroke, or myocardial infarction	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
30761515	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
21075775	Not applicable	all-cause mortality	Single	Binary	Clinical	No	Yes	No	Yes	No	Not applicable	No	Not applicable	Yes
26718510	Sapient (Edwards Lifesciences)	composite of all-cause mortality, major stroke, and rehospitalization	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
21639811	NA	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
27400898	Not applicable	all-cause mortality	Single	Binary	Clinical	No	Yes	No	Yes	No	Not applicable	No	Not applicable	Yes
20961243	NA	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	No
28973091	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
27040324	NA	composite of all-cause mortality or disabling stroke	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	No
30883058	NA	composite of all-cause mortality, stroke, or rehospitalization	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
22657270	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
32771997	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

32593323	Corevalve (Medtronic), Corevalve Evolut R (Medtronic), Corevalve Evolut Pro (Medtronic), Sapien (Edwards Lifesciences), Sapien XT (Edwards Lifesciences), Sapien S3 (Edwards Lifesciences)	composite of all-cause mortality or disabling stroke	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28797431	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30111522	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
24595532	Not applicable	improvements in AVA (≥ 1.0 cm ²) and NYHA functional classification	Composite	Discrete	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
22520622	Not applicable	QQL changes after TAVI	Single	Continuous	Clinical	Yes	Yes	No	No	Yes	Yes	No	Not applicable	No
27542790	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30808296	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
26345138	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

33031491	Not applicable	composite of all-cause mortality or disabling stroke	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
34348863	Not applicable	composite of all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
25455463	Not applicable	myocardial function and aortic valve hemodynamics in CMR	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	Yes
20826252	Not applicable	QoL with Short Form 36 Health Survey Questionnaire	Single	Continuous	Clinical	Yes	Yes	No	No	No	Not applicable	No	Not applicable	No
24169077	Not applicable	successful implantation without MACCE	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
25257635	Not applicable	all-cause mortality	Single	Binary	Both	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28555592	Not applicable	all-cause mortality	Single	Binary	Both	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29297076	Corevalve (Medtronic)	composite of all-cause mortality, stroke, life-threatening or major bleeding, stage 2/3 acute kidney injury, or major vascular complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
33191317	Not applicable	composite of all-cause mortality, stroke, life-threatening or major bleeding events, acute kidney injury [Stage 2/3], and major vascular complications	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30621976	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	No
31570258	Sapien S3 (Edwards Lifesciences)	composite of all-cause mortality, any stroke, life threatening or	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

		disabling bleeding, major vascular complications, coronary artery obstruction requiring intervention, acute kidney injury (stage 2 or 3), rehospitalisation for valve-related symptoms or congestive heart failure, valve related dysfunction requiring repeat procedure, moderate or severe prosthetic valve regurgitation, or prosthetic valve stenosis												
33054367	Corevalve (Medtronic)	composite of all-cause mortality or stroke	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
32049283	Sapien S3 (Edwards Lifesciences)	all-cause mortality, stroke, moderate/severe prosthetic valve regurgitation, and permanent pacemaker implantation	Composite	Binary	Clinical	Yes	No	No	Yes	Yes	No	Yes	No	No
25946437	Not applicable	all-cause mortality	Single	Binary	Clinical	No	Yes	No	Yes	No	Not applicable	No	Not applicable	No
22581299	NA	composite of all-cause mortality, cerebral stroke and/or renal failure requiring haemodialysis	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28304219	NA	composite of all-cause mortality or disabling stroke	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes

30715097	Not applicable	functional status changes	Single	Discrete	Clinical	No	Yes	No	No	No	Not applicable	No	Not applicable	No
18573397	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
20637648	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
34148125	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29554265	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28804056	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
24682842	Not applicable	composite of all-cause mortality, myocardial infarction, stroke, or reintervention	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29268926	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
23517843	Not applicable	procedural success	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
24682026	Corevalve (Medtronic)	procedural success	Composite	Binary	Both	No	No	No	Yes	Yes	No	Yes	No	Yes
27793402	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
25999108	Not applicable	new-onset Class I or Class II indications for permanent pacemaker implantation	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
24678937	any SAVR	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
21492762	Not applicable	major adverse cardiovascular and	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes

		cerebrovascular events												
17015786	Not applicable	procedural success	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
24662399	Not applicable	composite of improvement of at least 1 NYHA class and an EOA >1.2cm2	Composite	Binary	Both	Yes	Yes	No	Yes	No	Not applicable	No	Not applicable	No
28183466	Not applicable	composite of all-cause mortality and disabling stroke	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
24657695	Not applicable	all-cause mortality or major stroke	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
22440213	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
20031667	Not applicable	procedural success	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
22995116	Not applicable	procedural success	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
26762913	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
16545654	Not applicable	procedural success	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
25456759	Not applicable	all-cause mortality	Single	Binary	Both	Yes	Yes	No	Yes	No	Not applicable	No	Not applicable	No
32246266	Corevalve (Medtronic)	severity of post-procedural AR, quantitatively assessed by MRI	Single	Discrete	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
22743081	Not applicable	procedural success	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
21148541	Not applicable	procedural success	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

30883053	any SAVR	composite of all-cause mortality or disabling stroke	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
32418883	Not applicable	length of hospital stays and reasons for prolonged hospitalisation beyond 3 days	Single	Continuous	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
32748789	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28797353	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
22551129	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29444998	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
22508111	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
30860059	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
32381181	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29348010	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
31566572	Not applicable	survival	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26315740	Not applicable	the rate of all-cause mortality and the rate of any stroke at 30 days	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes
29131801	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
34004077	Not applicable	cardiovascular mortality, stroke, myocardial infarction	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes

		(MI), new need for renal replacement therapy, severe bleeding (defined as major bleeding or above per Mitral Valve Academic Research Consortium, MVARC), 16 and non-elective mitral valve re-intervention												
31255562	Not applicable	Procedural success was defined as at least 1 device deployed and delivery system successfully retrieved, as intended, at the time of the patient's exit from the procedure room; evidence of MR reduction to grade $\leq 2+$ at discharge; and no need for a surgical or percutaneous intervention prior to hospital discharge. Clinical success was defined as procedural success with evidence of MR reduction to grade $\leq 2+$ and without major adverse events (MAEs) at 30 days	Composite	Binary	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
34141859	Not applicable	left ventricular reverse remodeling	Single	Binary	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
33979403	Not applicable	All-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

32065722	Not applicable	improvement of LA function	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
30077993	Not applicable	Survival	Single	Binary	Clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
25011722	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30898200	Not applicable	Survival	Single	Binary	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28040318	Not applicable	freedom from cardiovascular mortality, stroke, and device dysfunction	Composite	Binary	Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26655529	Not applicable	Survival	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
27436878	Not applicable	successful implantation of ≥1 ePTFE artificial cords on the mitral valve, and demonstration of MR reduction from severe to moderate or less at the conclusion of the procedure and at 30 days	Composite	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
30124798	Not applicable	Survival	Single	Binary	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26586779	Not applicable	technical success rate of Cardioband implantation, defined as the ability to advance the implant, load anchors, anchor the implant to the tissue, and retract the implant delivery system;	Composite	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes

33047896	Not applicable	All-cause mortality	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
22613584	Not applicable	composite of death, myocardial infarction, cardiac perforation, device embolization, or surgery for device failure	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
27493761	Not applicable	all-cause mortality, myocardial infarction, cardiac perforation necessitating intervention, device embolisation or the occurrence of surgery or percutaneous intervention related to the device.	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes
27712741	Not applicable	technical success rate of Cardioband implantation	Composite	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
25944047	Not applicable	MRI parameters at 1week after mitral clip	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
24100100	Not applicable	major adverse cardiovascular events	Composite	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
24895448	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
24076529	Not applicable	major adverse event	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
23747789	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
22188385	Not applicable	Primary Efficacy: diminishing MR to mild (1+) or less	Single	Binary	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
21463154	mitral valve	freedom from death, from surgery for	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	Yes	Yes

	surgery (replacement or repair)-type of device not specified	mitral-valve dysfunction, and from grade 3+ or 4+ mitral regurgitation												
31521683	sham procedure	change in mitral regurgitant volume at 12 months, measured by quantitative echocardiography according to an intention-to-treat analysis	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
30145927	Not applicable	a composite of death from any cause or unplanned hospitalization for heart failure	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
30280640	Not applicable	all hospitalization for heart failure	Single	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	Yes
16325053	Not applicable	freedom from death, myocardial infarction, cardiac tamponade, cardiac surgery for failed clip, clip detachment, stroke, or septicemia	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
19597051	Not applicable	composite of death, myocardial infarction, coronary sinus dissection/perforation, device embolization, or PCI related to device	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
27339489	Not applicable	composite of death, stroke, myocardial infarction, or emergent surgery or intervention	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

29102688	Not applicable	successful implantation of 1 or more ePTFE artificial cords on the MV, with subsequent reduction of MR from severe to moderate or less at the conclusion of and 30 days after the procedure	Single	Binary	Clinical/Non-clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
34053453	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
33478837	stented biological valve	MACCE	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
33597099	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28605428	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
34830622	Magna Ease vs. Crown PRT vs. Trifecta	haemodynamic changes	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
33776017	Not applicable	composite change in NYHA-FC and EOAI	Composite	Binary	Non-clinical	Yes	Yes	No	Yes	No	Not applicable	No	Not applicable	No
34036633	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
32674180	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30137264	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
28475690	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes

31875777	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
30553598	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
29778342	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29415382	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28453629	Not applicable	study valve related Mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
28369288	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
27817951	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	Yes
25441065	Full Sternotomy AVR with bioprosthetic valve	aortic cross clamp time	Single	Continuous	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26656235	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
27964975	Not applicable	hemodynamic performance	Single	Continuous	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26245628	Not applicable	30-day overall and valve-related mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26984983	CE Perimount	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
25750010	Not applicable	all-cause and cardiac mortality	Single	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes

26892076	Not applicable	mortality by surgical approach	Single	Binary	Clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
26589286	Not applicable	all-cause mortality	Single	Binary	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
25451486	Not applicable	all-cause mortality and valve related mortality	Single	Binary	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
25439772	Epic, Magna, Mitroflow	hemodynamic performance	Single	Continuous	Non-clinical	Yes	No	No	No	No	Not applicable	No	Not applicable	No
23477687	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
24787699	Not applicable	all-cause mortality and valve related death	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
25106682	Not applicable	all-cause mortality	Single	Binary	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
23058665	Not applicable	all-cause mortality and valve related death	Single	Binary	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	Yes
23825161	Not applicable	all-cause mortality	Single	Binary	Both	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
23673064	Soprano, Mitroflow, Freedom Solo, Bicarbon Fitline, Bicarbon Overline	in-hospital and 30 day mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
22818964	Not applicable	haemodynamic changes	Single	Continuous	Non-clinical	Yes	No	No	Yes	No	Not applicable	No	Not applicable	No
22541180	Not applicable	all-cause mortality	Single	Binary	Both	No	No	No	Yes	No	Not applicable	No	Not applicable	No
21277603	Not applicable	all-cause mortality	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

21342776	Not applicable	all-cause mortality	Single	Binary	Both	No	No	No	Yes	No	Not applicable	No	Not applicable	No
29029949	Not applicable	QOL	Composite	Continuous	Non-clinical	Yes	Yes	No	No	No	Not applicable	No	Not applicable	No
33682228	Not applicable	artifact volume in MRI	Single	Continuous	Non-clinical	No	No	No	Yes	No	No	No	No	No
33217535	Not applicable	electrical parameters after implantation	Single	Continuous	Non-clinical	No	No	No	Yes	No	No	No	No	No
33418071	Transvenous pacemaker	device-related complications	Composite	Binary	Both	No	No	No	Yes	No	No	No	No	No
34141021	Not applicable	angle of RV septum	Single	Continuous	Non-clinical	No	No	No	Yes	No	No	No	No	No
32860605	Not applicable	number of patients showing oversensing during body scanning	Single	Binary	Non-clinical	No	No	No	No	Yes	No	Yes	No	No
31395499	Not applicable	safety of Micra implantation	Composite	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
29986008	Not applicable	adverse events caused by MRI	Single	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
30392985	Not applicable	implantation success rate	Single	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
30550834	Not applicable	safety of midseptal implantation	Composite	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
31180481	Not applicable	complications after Micra in TLE patients	Composite	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
30176097	Not applicable	best vector for rate response	Single	Discrete	Non-clinical	No	No	No	No	No	No	No	No	No
29758405	Not applicable	AV synchrony during AV sequential pacing	Single	Continuous	Non-clinical	No	No	No	No	No	No	No	No	No
26551877	Not applicable	freedom from complications after Micra implantation	Composite	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
30221378	With and without AVN ablation	complications after AVN ablation in Micra patients	Single	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
28666317	Not applicable	changes in tricuspid valve regurgitation after implantation of a leadless PM	Single	Discrete	Non-clinical	No	No	No	Yes	No	No	No	No	No

27855290	Not applicable	clinical outcomes and clinicians experience	Single	Discrete	Clinical	No	No	No	Yes	No	No	No	No	No
28040461	Not applicable	clinical outcomes and clinicians experience	Single	Discrete	Clinical	No	No	No	Yes	No	No	No	No	No
28502871	Not applicable	acute and long-term safety performance of the Micra system	Composite	Binary	Clinical	No	No	No	Yes	No	No	No	No	No
33516714	Not applicable	conversion success after S-ICD shock delivery	Single	Binary	Clinical	No	No	No	Yes	Yes	Yes	Yes	No	No
32860605	Not applicable	number of patients showing oversensing during body scanning	Single	Binary	Non-clinical	No	No	No	No	Yes	No	Yes	No	No
33073614	Not applicable	inadequate shock free rate in S-ICD patients	Single	Binary	Both	No	No	No	No	No	Not applicable	No	Not applicable	No
33969569	NA	device-related complications	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
34307829	Not applicable	pain perception reduction	Single	Continuous	Clinical	No	Yes	No	No	No	Not applicable	No	Not applicable	No
34140203	Not applicable	pain score VAS	Single	Continuous	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
32613315	Not applicable	eligibility of S-ICD implantation in LVAD patients	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
33538124	Not applicable	eligibility of S-ICD implantation in ACHD patients	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
32757521	NA	Composite of device-related complications and inappropriate shocks	Composite	Binary	Clinical	No	No	No	Yes	Yes	No	Yes	No	No
31813098	Not applicable	successful same-day discharge after S-ICD implantation	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No
32596027	Not applicable	successful same-day discharge after S-ICD implantation	Single	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	No

31778266	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
30661851	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
30609077	Not applicable	slert burden during S-ICD remote monitoring	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
31512339	Not applicable	DFT in S-ICD patients	Single	Continuous	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
31048064	Not applicable	incidence of myopotential oversensing	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
29758404	Two software versions were compared	risk of inappropriate shocks depending on the activation of the SMARTpass filter	Single	Binary	Clinical	No	No	No	No	No	Not applicable	No	Not applicable	No
28502872	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
27943358	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
28536837	Not applicable	effectiveness of midazolam sedation	Single	Continuous	Clinical	No	Yes	No	No	No	Not applicable	No	Not applicable	No
28007749	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
27068637	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	No	No	Not applicable	No	Not applicable	No
25687749	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No

23707489	Not applicable	Not specified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Yes	No	Not applicable	No	Not applicable	No
23979626	Not applicable	180-day S-ICD System complication-free rate	Composite	Binary	Clinical	No	No	No	Yes	No	Not applicable	No	Not applicable	Yes
22035049	Arrhythmia detection algorithms	appropriate detection of ventricular tachyarrhythmias	Single	Binary	Non-clinical	No	No	No	No	No	Not applicable	No	Not applicable	Yes

Appendix 9

Risk-of-Bias assessment in study-level.

Risk-of-Bias assessment with the ROBINS-I (“Risk Of Bias In Non-randomised Studies - of Interventions”) tool of non-randomized studies comparing health effects of two or more interventions.

PubMed identifier primary report	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	ROBINS-I RoB judgement
31587103	Low	Moderate	Low	Low	Low	Moderate	Critical	Critical
29512092	Critical	Critical	Low	Low	Critical	Low	Moderate	Critical
23973952	Critical	Low	Low	Low	Low	Serious	Low	Critical
30583991	Serious	Critical	Low	Low	Low	Serious	Low	Critical
30884101	Serious	Critical	Low	Low	Low	Serious	Low	Critical
26984983	Serious	Moderate	Low	Low	Low	Serious	Serious	Serious
23673064	Serious	Moderate	Low	Low	Low	Serious	Serious	Serious
33418071	Serious	Moderate	Moderate	Low	Low	Serious	Moderate	Serious
30221378	Critical	Critical	Moderate	Low	Low	Moderate	Moderate	Critical
33969569	Serious	Moderate	Low	Low	Low	Low	Low	Moderate
34307829	Critical	Critical	Critical	Critical	Moderate	Critical	Moderate	Critical
31778266	Critical	Moderate	Moderate	Critical	Moderate	Moderate	Moderate	Critical
29758404	Critical	Critical	Serious	Low	Low	Low	Low	Critical
27943358	Critical	Critical	Serious	Low	Low	Moderate	Moderate	Critical
22035049	Critical	Moderate	Critical	Low	Low	Low	Serious	Critical

Ordered by the class of devices as shown in previous Tables.

Risk-of-Bias assessment with the ROB 2 (“Risk of Bias 2”) tool of randomized studies of interventions.

PubMed identifier primary report	Bias arising from the randomisation process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	RoB-2 RoB judgement
33723086	Some concerns	Some concerns	Low	Low	High	High
31217148	Low	Some concerns	Low	Low	Low	Some concerns
34290573	Low	Some concerns	Low	Low	Low	Some concerns
32525410	Low	Low	Low	Low	Low	Low
33363447	Low	Low	Low	Some concerns	High	High
31085503	Low	Low	Low	Low	Low	Low
32279841	Low	Low	Low	Low	Low	Low
32451321	Low	Low	Low	Low	Low	Low
33069847	Low	Low	Some concerns	Some concerns	Low	Some concerns
32205067	Some concerns	Low	Some concerns	Low	Low	Some concerns
30520980	Low	Low	Low	Low	Low	Low
30975219	Some concerns	High	High	Some concerns	High	High
30170828	Low	Low	Low	Low	Low	Low
31553204	Low	Low	Low	Some concerns	Low	Some concerns
31029616	Low	Low	Low	Low	High	High

29901443	Low	Low	Some concerns	Some concerns	Low	Some concerns
30266412	Low	Low	Low	Low	Low	Low
27807948	Low	Low	Low	Low	Low	Low
28527768	High	Low	Low	Low	High	High
28402237	Low	Low	Low	Low	Low	Low
26405232	Low	Low	Low	Some concerns	Low	Some concerns
27806897	Low	Low	Low	Low	Low	Low
26457558	Low	Low	Low	Low	Low	Low
26471805	Low	Low	Low	Low	Low	Low
26330419	Low	Low	Low	Low	Low	Low
25720622	Low	Some concerns	Low	Some concerns	Low	Some concerns
19683639	Low	Low	Low	Low	Low	Low
24998121	Low	Low	Low	Low	Low	Low
32586585	Low	Low	Low	Low	Low	Low
34459659	Low	Low	Low	Low	Low	Low
25787196	Low	Low	Low	Moderate	Low	Low
26718510	Low	Low	Low	Low	Low	Low
21639811	Low	Some concerns	Low	Low	Low	Low
20961243	Low	Some concerns	Low	Low	Low	Some concerns
27040324	Low	Some concerns	Low	Low	Low	Low
30883058	Low	Some concerns	Low	Low	Low	Low
32593323	Low	Low	Low	Low	Low	Low

29297076	Low	Low	Low	Low	Low	Low
31570258	Low	Low	Low	Low	Low	Low
33054367	Low	Low	Low	Low	Some Concerns	Some Concerns
32049283	Low	Low	Low	Low	Low	Low
22581299	Low	Low	Low	Some concerns	Low	Some concerns
28304219	Low	Low	Low	Some concerns	Low	Some Concerns
24682026	Low	Low	Low	Low	Low	Low
24678937	Low	Low	Low	Low	Low	Low
32246266	Low	Some concerns	High	Low	Low	High
30883053	Low	Low	Low	Low	Low	Low
21463154	Low	Low	Low	Low	Low	Low
31521683	Low	Low	Low	Low	Low	Low
30145927	Low	Low	Low	Low	Low	Low
30280640	Low	Low	Low	Low	Low	Low
33478837	Low	Some concerns	Low	Some concerns	Low	Some concerns
34830622	Low	Low	Low	Some concerns	Low	Some concerns
25441065	Some concerns	Some concerns	Low	High	Low	High
25439772	Low	Some concerns	High	High	Low	High
34140203	Some concerns	Some concerns	Low	High	Some concerns	High
32757521	Low	Low	Low	Low	Low	Low

Ordered by the class of devices as shown in previous Tables.

Appendix 10

Reported reasons for earlier study termination among prospective clinical trials evaluating high-risk cardiovascular devices.

Class of high-risk cardiovascular device	Medical condition / intervention	Time-point of publicly available report (Epub)	Industry-versus investigator-initiated trial	Verbatim text as reported in the manuscript of the main study publication
Coronary bioresorbable scaffolds	Complex coronary bifurcation lesions	March 2021	Investigator	"... Active enrollment of patients was prematurely halted in early 2017 because of apprehension regarding the increased risk of scaffold thrombosis with the BVS ...", "... Due to the withdrawal of the Absorb BVS from the market in 2017, the planned number of patients could not be attained ..." [33723086]
Coronary bioresorbable scaffolds	OCT-guided PCI with BVS	January 2020	Investigator	"... The recruitment was prematurely terminated in March 2018 because the manufacturer stopped supplying BVS...", "...The recruitment was prematurely terminated in March 2018 because the manufacturer stopped supplying BVS..." [32525410]
Coronary bioresorbable scaffolds	OCT-guided PCI of vulnerable intermediate lesions	December 2020	Investigator	"...The trial was stopped prematurely after retraction from the market of the Absorb BVS...", "...The trial was stopped prematurely after the reporting of increased stent-thrombosis and the subsequent retraction from the market of the Absorb stent ..." [33363447]
Coronary bioresorbable scaffolds	PCI in diffuse long coronary lesions	March 2020	Investigator	"... The trial was terminated early because the manufacturer stopped supplying BVS ...", "... However, the recruitment was prematurely terminated in March 2018 after enrollment of 341 patients because the manufacturer stopped supplying BVS ..." [32279841]
Coronary bioresorbable scaffolds	PCI in patients at high risk of restenosis	October 2020	Investigator	"... The enrolment was discontinued prematurely because of a high thrombosis and TVMI rate in the BVS arm ...", "... The trial was prematurely stopped on the recommendation of the

				Data and Safety Monitoring Board based on safety concerns seen in interim analyses ...”, “... Although non-inferiority of the primary endpoint was met, definite or probable device thrombosis and TVMI rates were significantly higher in the BVS group compared with the EES group, which resulted in premature cessation of recruitment to the study ...” [32451321]
Coronary bioresorbable scaffolds	OCT-guided PCI with BVS	March 2020	Investigator	“... The trial was prematurely stopped on May 31, 2017 after enrollment of 38 of 270 planned patients (14%) following the retraction of the device in Europe ...”, “...The trial was stopped prematurely in May 2017 after enrollment of 38 of 270 planned patients due to the anticipated retraction of the device in Europe on May 31, 2017 ...” [32205067]
Coronary bioresorbable scaffolds	PCI in routine clinical practice	March 2017	Investigator	“... The data and safety monitoring board recommended early reporting of the study results because of safety concerns ...”, “... This article is an early report of the data, which the data and safety monitoring board recommended to be released owing to safety concerns ...”, “...After a safety review on November 11, 2016, the data and safety monitoring board recommended early reporting of the results because of safety concerns ...”, “... In this preliminary analysis from the trial, we found that the rate of definite or probable device thrombosis in the scaffold group was approximately 3.5 times as high as that in the stent group over the course of 2 years ...” [28402237]
Transcatheter aortic valve implantation	Transapical TAVI in operable elderly patients with severe aortic stenosis	August 2012	Investigator	“... After advice from the Data Safety Monitoring Board, the study was prematurely terminated after the inclusion of 70 patients because of an excess of events in the a-TAVI group...”, “... After inclusion of 11 patients, we experienced three potentially severe adverse events in the a-TAVI group (one case of left main occlusion, one case of aortic rupture and one case of up-stream valve embolisation). The study was put on hold, and the Data Safety Monitoring Board

				(DSBM) contacted. It was decided to increase the age limit for inclusion to ≥ 75 years and to exclude patients with prior heart surgery. This was done to increase the general risk of the study cohort and to enable a swift conversion to SAVR, if needed. After inclusion of 70 patients, the study was terminated prematurely after advice from the DSBM. This decision was based on a general impression of too many adverse events and procedure-related complications following the a-TAVI treatment ...”, “... The STACCATO trial was prematurely terminated because of an overall excess of adverse events in transcatheter treated patients in comparison with patients receiving SAVR ...” [22581299]
Transcatheter aortic valve implantation	TAVI in patients with patients with severe symptomatic aortic stenosis	May 2020	Investigator	“... Study enrolment was preliminary halted, due to the EU release of a new-generation SEV (Medtronic Evolut) and slow enrolment ...” [32246266]
Surgical valves	Patients required surgical aortic valve replacement	November 2021	Investigator	“... Due to the commercialization of the new Trifecta with glide technology and a new anti-calcification treatment (AC) Linx™ in 2016, the commercialization of the initial model of the prosthesis was discontinued. Consequently, the study was interrupted in 2017, when the prosthesis was no longer available at our center ...” [34830622]

Studies are ordered by the year of publication in the corresponding class of devices as have been also listed in the main text and tables.

BVS, bioresorbable vascular scaffolds; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; TVMI, target vessel myocardial infarction; EES, everolimus-eluting stent; TAVI, transcatheter aortic valve implantation; SAVR, surgical aortic valve replacement; EU, European Union; SEV, self-expandable valve.