CORE-MD

Coordinating Research and Evidence for Medical Devices

Database of studies of high-risk medical devices

Deliverable 1.1

Deliverable factsheet

Source Activity:	Work package n. 1, Task 1.1
Title:	Database of studies of high-risk medical devices
Lead Beneficiary:	RCSI
Nature:	Report
Dissemination level:	Public
Editor:	Windecker Stephan (Insel Gruppe AG)
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Status:	Final
Date:	18.02.2023
Contractual Delivery Date:	31.12.2022

Version Log

Issue Date	Version	Involved	Comments
30/01/2023	0.1	Insel Gruppe AG, RCSI, UOXF	First draft for format and quality check
03/02/2023	1.0	ESC	Final version format and quality check for submission
18/02/2023	2.0	Insel Gruppe AG	Corrections on the list of cardiac studies. Some missing studies added, some studies removed (nof fulfilling inclusion criteria, device or study type, and one device with no CE-mark).

Acronyms and abbreviations

AV	Atrioventricular
CGM	Continuous Glucose Monitoring
MVR	Mitral Valve Replacement
OCT	Optical Coherence Tomography
PCI	Percutaneous Coronary Intervention
PMID	Pubmed Identifier
SPECT/CT	Single-Photon Emission Computed Tomography
S-ICD	Subcutaneous Implantable Cardioverter-Defibrillator
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty
TPS	Transcatheter Pacing System
T1D	Type 1 Diabetes

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Executive Summary

Work package 1 of the CORE-MD project aims to evaluate methods used to generate evidence for high-risk medical devices. This work package has been divided into four tasks (Tasks 1.1 to 1.4).

Task 1.1 is dedicated to the methodologies used in published clinical studies of high-risk medical devices. We aim to map the existing evidence on high-risk medical devices through broad systematic reviews of the medical literature and to evaluate characteristics of the available evidence through meta-epidemiological assessments. Specifically, we review the clinical evidence of class III, permanently implanted devices in the fields of cardiology and orthopaedics and review the evidence of high-risk devices in the field of diabetes.

The protocols of the methodology used for the literature search in the three fields of cardiac, diabetes and orthopedic devices have been published [1-3].

The aim of this deliverable is to setup and provide a database of the selected studies resulting from the different literature searches.

Next steps will be the data extraction and analysis (D1.2) and the preparation of the masucripts for publication (D1.3).

1 Cardiac devices

Prospective studies (2000-2020) fulfilling the pre-specified inclusion criteria for the systematic review are listed according to the following class of cardiac devices:

1) **Coronary bioresorbable scaffolds** for percutaneous treatment of coronary artery disease
2) **Left atrial appendage occlusion devices** for percutaneous treatment of thromboembolic stroke prevention
3) **Transcatheter aortic valve implantation devices** for treatment of symptomatic, severe stenosis of native aortic valves
4) **Transcatheter mitral valve repair and replacement devices** for treatment of symptomatic moderate-severe native mitral valve disease
5) **Surgical heart valve replacement devices** for native aortic and mitral valve disease
6) **Leadless pacemakers**
7) **Subcutaneous implantable cardioverter-defibrillators**.

For each class of devices, the first table indicates the name of the devices used for the literature search.

The studies are listed according to their PMID number (in descending order), which is automatically assigned by PubMed after a manuscript is published in an indexed journal. However, the publication date in the print journal also tabulated in the listings may be deferred.

Detailed information about the information sources, search strategies and study eligibility criteria are available in the published protocol [1].

1.1 Coronary bioresorbable scaffolds

Table 1. Coronary bioresorbable scaffolds: list of devices

Class of device	Devices
Coronary bioresorbable scaffolds	**Absorb GT1** Bioresorbable Vascular Scaffold System [Abbott] **ART-Stent** [Arterial Remodeling Technologies S.A.] **DESolve** (DESolve Scaffold System) [Elixir Medical] **DESolve 100** (DESolve Scaffold System) [Elixir Medical] **Magmaris** Coronary Resorbable Magnesium Scaffold [Biotronik] **Meres** (MeRes100 Bioresorbable Scaffold) [Meril Life Sciences]

Table 2. List of prospective studies fulfilling the pre-specified inclusion criteria on coronary bioresorbable scaffolds

PMID	Title	First author	Journal	Publication Year
34290573	Reduction of Lipid-Core Burden Index in Nonculprit Lesions at Follow-Up after ST-Elevation Myocardial Infarction: A Randomized Study of Bioresorbable Vascular Scaffold versus Optimal Medical Therapy	Kefer J	J Interv Cardiol	2021
34173699	Five-year angiographic, OCT and clinical outcomes of a randomized comparison of everolimus and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds	Schukraft S	Catheter Cardiovasc Interv	2022
34125947	Long-term clinical follow-up of the resorbable magnesium scaffolds in acute coronary syndrome patients	Włodarczak A	Kardiol Pol	2021
33723086	COmplex Bifurcation Lesions: RAndomized Comparison of Modified-T Stenting vs Reconstruction With Self-Expanding Stent and Bioresorbable Scaffold: COBRA II	Bennett J	J Invasive Cardiol	2021
33600069	Long-term clinical, angiographic, and optical coherence tomography findings of Mg-based bioresorbable scaffold in patients with acute coronary syndrome	Gutiérrez-Barrios A	Catheter Cardiovasc Interv	2021

33363447	Pre-Emptive OCT-Guided Angioplasty of Vulnerable Intermediate Coronary Lesions: Results from the Prematurely Halted PECTUS-Trial	Mol JQ	J Interv Cardiol	2020
33269506	Imaging and 2-year clinical outcomes of thin strut sirolimus-eluting bioresorbable vascular scaffold: The MeRes-1 extend trial	Abizaid A	Catheter Cardiovasc Interv	2021
33118696	Three-year clinical outcomes of the absorb bioresorbable vascular scaffold compared to Xience everolimus-eluting stent in routine PCI in patients with diabetes mellitus-AIDA sub-study	Kerkmeijer LSM	Catheter Cardiovasc Interv	2021
33069847	Percutaneous Coronary Intervention for Vulnerable Coronary Atherosclerotic Plaque	Stone GW	J Am Coll Cardiol	2020
32944608	Scaffold underexpansion and late lumen loss after bioresorbable scaffold implantation: Insights from ABSORB JAPAN trial	Okada K	Int J Cardiol Heart Vasc	2020
32881396	BIOSOLVE-IV-registry: Safety and performance of the Magmaris scaffold: 12-month outcomes of the first cohort of 1,075 patients	Verheye S	Catheter Cardiovasc Interv	2021
32763098	12-month clinical outcomes after Magmaris percutaneous coronary intervention in a real-world cohort of patients: Results from the CardioHULA registry	Abellas-Sequeiros RA	Rev Port Cardiol (Engl Ed)	2020
32525410	Optical Coherence Tomography for Coronary Bioresorbable Vascular Scaffold Implantation: A Randomized Controlled Trial	Lee SY	Circ Cardiovasc Interv	2020
32515738	Bioresorbable scaffolds versus everolimus-eluting metallic stents: five-year clinical outcomes of the randomised ABSORB II trial	Onuma Y	EuroIntervention	2020

32451321	Bioresorbable vascular scaffold versus metallic drug-eluting stent in patients at high risk of restenosis: the COMPARE-ABSORB randomised clinical trial	Smits PC	EuroIntervention	2020
32315682	Peri-strut low intensity areas and in-scaffold neointima growth after bioresorbable scaffold implantation in STEMI. A serial optical coherence tomography study	Ochijewicz D	Int J Cardiol	2020
32310130	Bioresorbable scaffolds versus permanent sirolimus-eluting stents in patients with ST-segment elevation myocardial infarction: vascular healing outcomes from the MAGSTEMI trial	Gomez-Lara J	EuroIntervention	2020
32279841	Bioresorbable Vascular Scaffolds Versus Drug-Eluting Stents for Diffuse Long Coronary Narrowings	Seo J	Am J Cardiol	2020
32213737	Long-Term Outcomes of Absorb Bioresorbable Vascular Scaffold vs. Everolimus-Eluting Metallic Stent - A Randomized Comparison Through 5 Years in Japan	Kozuma K	Circ J	2020
32205067	Randomized Comparison of Optical Coherence Tomography Versus Angiography to Guide Bioresorbable Vascular Scaffold Implantation: The OPTICO BVS Study	Ueki Y	Cardiovasc Revasc Med	2020
32000796	Bioresorbable scaffold implantation in STEMI patients: 5 years imaging subanalysis of PRAGUE-19 study	Kočka V	J Transl Med	2020
31918929	Randomized Comparison Between Everolimus-Eluting Bioresorbable Scaffold and Metallic Stent: Multimodality Imaging Through 3 Years	Onuma Y	JACC Cardiovasc Interv	2020
31912983	Absorb bioresorbable vascular scaffold outcomes following implantation with routine intravascular imaging guidance	Costantini CR	Catheter Cardiovasc Interv	2021

31708522	Absorb GT1 Bioresorbable Vascular Scaffold System - 1-Year Post-Marketing Surveillance in Japan	Suzuki N	Circ J	2019
31587103	Different vascular healing process between bioabsorbable polymer-coated everolimus-eluting stents versus bioresorbable vascular scaffolds via optical coherence tomography and coronary angioscopy (the ENHANCE study: ENdothelial Healing Assessment with Novel Coronary tEchnology)	Wan Ahmad WA	Heart Vessels	2020
31553222	Clinical Outcomes Before and After Complete Everolimus-Eluting Bioresorbable Scaffold Resorption: Five-Year Follow-Up From the ABSORB III Trial	Kereiakes DJ	Circulation	2019
31553204	Magnesium-Based Resorbable Scaffold Versus Permanent Metallic Sirolimus-Eluting Stent in Patients With ST-Segment Elevation Myocardial Infarction: The MAGSTEMI Randomized Clinical Trial	Sabaté M	Circulation	2019
31511193	A paradox in sex-specific clinical outcomes after bioresorbable scaffold implantation: 2-year results from the AIDA trial	Kerkmeijer LSM	Int J Cardiol	2020
31217148	Coronary vasomotor function and myocardial flow with bioresorbable vascular scaffolds or everolimus-eluting metallic stents: a randomised trial	Gomez-Lara J	EuroIntervention	2020
31197750	The 1-year safety and efficacy outcomes of Absorb bioresorbable vascular scaffolds for coronary artery disease treatment in diabetes mellitus patients: the ABSORB DM Benelux study	Hommels TM	Neth Heart J	2019
31147304	Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent in routine PCI: three-year clinical outcomes from the AIDA trial	Kerkmeijer LSM	EuroIntervention	2019

31104821	Two-year clinical outcomes of the "Italian diffuse/multivessel disease absorb prospective registry" (IT-DISAPPEARS)	De Carlo M	Int J Cardiol	2019
31085503	Procedural microvascular activation in long lesions treated with bioresorbable vascular scaffolds or everolimus-eluting stents: the PROACTIVE trial	Pellicano M	EuroIntervention	2020
31062692	Outcomes of bioresorbable vascular scaffolds versus everolimus-eluting stents by coronary complexity: a sub-analysis of the AIDA trial	Kraak RP	EuroIntervention	2020
31053981	Procedural findings and early healing response after implantation of a self-apposing bioresorbable scaffold in coronary bifurcation lesions	Holck EN	Int J Cardiovasc Imaging	2019
31029616	Myocardial Blood Flow and Coronary Flow Reserve During 3 Years Following Bioresorbable Vascular Scaffold Versus Metallic Drug-Eluting Stent Implantation: The VANISH Trial	Stuijfzand WJ	JACC Cardiovasc Interv	2019
30975219	Re-endothelialisation after Synergy stent and Absorb bioresorbable vascular scaffold implantation in acute myocardial infarction: COVER-AMI study	Lhermusier T	Trials	2019
30968559	Clinical outcomes at 2 years of the Absorb bioresorbable vascular scaffold versus the Xience drug-eluting metallic stent in patients presenting with acute coronary syndrome versus stable coronary disease-AIDA trial substudy	Tijssen RYG	Catheter Cardiovasc Interv	2020
30905344	Functional and Structural Coronary Recovery at the 5-year Follow-up After Bioresorbable Vascular Scaffold Implantation. An Optical Coherence Tomography Analysis	Goncalves-Ramírez LR	Rev Esp Cardiol (Engl Ed)	2019
30803936	Safety and performance of the second-generation drug-eluting absorbable metal scaffold (DREAMS 2G) in patients with de novo coronary lesions: three-year clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial	Haude M	EuroIntervention	2020

30676384	Association between inflammatory biomarkers and neointimal response following elective implantation of the ABSORB bioresorbable vascular scaffold	Rampat R	Coron Artery Dis	2019
30666963	Twelve-month outcomes of 400 patients treated with a resorbable metal scaffold: insights from the BIOSOLVE-IV registry	Verheye S	EuroIntervention	2020
30627287	Pharmacokinetic Study of Sirolimus-Eluting BioResorbable Vascular Scaffold System for Treatment of De Novo Native Coronary Lesions: A Sub-Study of MeRes-1 Trial	Chandra P	Cardiol Res	2018
30561875	The effect of elective implantation of the ABSORB bioresorbable vascular scaffold on coronary microcirculation: Serial assessment using the index of microcirculatory resistance	Rampat R	Microcirculation	2019
30537203	Early outcome of magnesium bioresorbable scaffold implantation in acute coronary syndrome-the initial report from the Magmaris-ACS registry	Wlodarczak A	Catheter Cardiovasc Interv	2019
30530403	Five-year safety and performance data of a novel third-generation novolimus-eluting bioresorbable scaffold in single de novo lesions	Verheye S	EuroIntervention	2019
30520980	Prospective, randomized trial of bioresorbable scaffolds vs. everolimus-eluting stents in patients undergoing coronary stenting for myocardial infarction: the Intracoronary Scaffold Assessment a Randomized evaluation of Absorb in Myocardial Infarction (ISAR-Absorb MI) trial	Byrne RA	Eur Heart J	2019
30398967	Three-year follow-up of the randomised comparison between an everolimus-eluting bioresorbable scaffold and a durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction (TROFI II trial)	Katagiri Y	EuroIntervention	2018

30314835	One-Year Results Following a Pre-Specified ABSORB Implantation Strategy in ST-Elevation Myocardial Infarction (BVS STEMI STRATEGY-IT Study)	Ielasi A	Cardiovasc Revasc Med	2019
30286520	Three-year clinical outcomes of patients treated with everolimus-eluting bioresorbable vascular scaffolds: Final results of the ABSORB EXTEND trial	Costa JR Jr	Catheter Cardiovasc Interv	2019
30277460	Bioresorbable vascular scaffolds in coronary chronic total occlusions: clinical, vasomotor and optical coherence tomography findings at three-year follow-up (ABSORB-CTO study)	Gheorghe L	EuroIntervention	2019
30266412	Blinded outcomes and angina assessment of coronary bioresorbable scaffolds: 30-day and 1-year results from the ABSORB IV randomised trial	Stone GW	Lancet	2018
30235969	Long-term outcome of first 300 implanted Absorb bioresorbable vascular scaffolds in an all-comers Middle East population	Al Nooryani A	J Int Med Res	2019
30170828	A randomized trial comparing two stent sizing strategies in coronary bifurcation treatment with bioresorbable vascular scaffolds - The Absorb Bifurcation Coronary (ABC) trial	Rampat R	Cardiovasc Revasc Med	2019
30082268	Comparison of everolimus-eluting bioresorbable vascular scaffolds and metallic stents: three-year clinical outcomes from the ABSORB China randomised trial	Xu B	EuroIntervention	2018
29983253	Long-term follow-up of BVS from a prospective multicenter registry: Impact of a dedicated implantation technique on clinical outcomes	Regazzoli D	Int J Cardiol	2018
29901443	Device specificity of vascular healing following implantation of bioresorbable vascular scaffolds and bioabsorbable polymer metallic drug-eluting stents in human coronary arteries: the ESTROFA OCT BVS vs. BP-DES study	de la Torre Hernandez JM	EuroIntervention	2018

29786537	Complete two-year follow-up with formal non-inferiority testing on primary outcomes of the AIDA trial comparing the Absorb bioresorbable scaffold with the XIENCE drug-eluting metallic stent in routine PCI	Tijssen RYG	EuroIntervention	2018
29774520	Implantation of bioresorbable scaffolds under guidance of optical coherence tomography: Feasibility and pilot clinical results of a systematic protocol	Gutiérrez-Chico JL	Cardiol J	2018
29656279	Drug-Eluting Resorbable Magnesium Scaffold Implantation in ST-Segment Elevation Myocardial Infarction: A Pilot Study	de Hemptinne Q	J Invasive Cardiol	2018
29622143	Bioresorbable Scaffold for Treatment of Coronary Artery Lesions: Intravascular Ultrasound Results From the ABSORB Japan Trial	Okada K	JACC Cardiovasc Interv	2018
29521477	Serial intravascular ultrasound evaluation of the DESolve™ novolimus-eluting bioresorbable coronary scaffold system	Barreira G	Catheter Cardiovasc Interv	2018
29512092	Optical coherence tomography-guided versus angiography-guided implantation of everolimus-eluting bioresorbable vascular scaffolds: Comparison of coverage, apposition and clinical outcome. The ALSTER-OCT ABSORB registry	Heeger CH	Cardiol J	2018
29292064	In vivo serial invasive imaging of the second-generation drug-eluting absorbable metal scaffold (Magmaris - DREAMS 2G) in de novo coronary lesions: Insights from the BIOSOLVE-II First-In-Man Trial	Garcia-Garcia HM	Int J Cardiol	2018
29168541	Evaluation of bioresorbable vascular scaffolds in acute coronary syndrome: A two-center, one-year follow-up analysis	Iwańczyk S	Cardiol J	2018
29155384	First serial optical coherence tomography assessment at baseline, 12 and 24 months in STEMI patients treated with the second-generation Absorb bioresorbable vascular scaffold	Kochman J	EuroIntervention	2018

29131802	Acute and one-year clinical outcomes following implantation of bioresorbable vascular scaffolds: the ABSORB UK Registry	Baumbach A	EuroIntervention	2018
29131799	Multislice computed tomography assessment of everolimus-eluting Absorb bioresorbable scaffolds in comparison with metallic drug-eluting stents from the ABSORB Japan randomised trial	Tanabe K	EuroIntervention	2018
29100702	3-Year Clinical Outcomes With Everolimus-Eluting Bioresorbable Coronary Scaffolds: The ABSORB III Trial	Kereiakes DJ	J Am Coll Cardiol	2017
29094677	Four-year follow-up of the randomised comparison between an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II Trial)	Chevalier B	EuroIntervention	2018
28935077	A Prospective Evaluation of a Pre-Specified Absorb BVS Implantation Strategy in ST-Segment Elevation Myocardial Infarction: The BVS STEMI STRATEGY-IT Study	Ielasi A	JACC Cardiovasc Interv	2017
28866036	Bioresorbable Vascular Scaffolds for Patients With In-Stent Restenosis: The RIBS VI Study	Alfonso F	JACC Cardiovasc Interv	2017
28853189	Clinical and angiographic outcome of a single center, real world population treated with a dedicated technique of implantation for bioresorbable vascular scaffolds. The FAtebenefratelli Bioresorbable Vascular Scaffold (FABS) registry	Cortese B	J Interv Cardiol	2017
28829745	Everolimus-eluting bioresorbable scaffolds in patients with coronary artery disease: results from the German-Austrian ABSORB RegIstRy (GABI-R)	Nef HM	EuroIntervention	2017
28734923	Diagnostic Accuracy of Coronary CT Angiography for the Evaluation of Bioresorbable Vascular Scaffolds	Collet C	JACC Cardiovasc Imaging	2018

28662808	Arterial Remodeling After Bioresorbable Scaffolds and Metallic Stents	Serruys PW	J Am Coll Cardiol	2017
28576627	Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds: Two-year clinical outcomes of the EVERBIO II trial	Arroyo D	Int J Cardiol	2017
28568564	Long-term clinical results of bioresorbable absorb scaffolds using the PSP-technique in patients with and without diabetes	Markovic S	J Interv Cardiol	2017
28527768	Randomized Comparison of Absorb Bioresorbable Vascular Scaffold and Mirage Microfiber Sirolimus-Eluting Scaffold Using Multimodality Imaging	Tenekecioglu E	JACC Cardiovasc Interv	2017
28504219	One-year clinical results of the Italian diffuse/multivessel disease ABSORB prospective registry (IT-DISAPPEARS)	Testa L	EuroIntervention	2017
28504218	First-in-human evaluation of a novel poly-L-lactide based sirolimus-eluting bioresorbable vascular scaffold for the treatment of de novo native coronary artery lesions: MeRes-1 trial	Seth A	EuroIntervention	2017
28438304	Thirty-Day Outcomes After Unrestricted Implantation of Bioresorbable Vascular Scaffold (from the Prospective RAI Registry)	Cortese B	Am J Cardiol	2017
28432385	Bioresorbable vascular scaffolds in coronary chronic total occlusions revascularization: safety assessment related to struts coverage and apposition in 6-month OCT follow-up	Abellas-Sequeiros RA	Heart Vessels	2017
28427593	Economic Outcomes of Bioresorbable Vascular Scaffolds Versus Everolimus-Eluting Stents in Patients Undergoing Percutaneous Coronary Intervention: 1-Year Results From the ABSORB III Trial	Baron SJ	JACC Cardiovasc Interv	2017

28402237	Bioresorbable Scaffolds versus Metallic Stents in Routine PCI	Wykrzykowska JJ	N Engl J Med	2017
28262625	Is quantitative coronary angiography reliable in assessing the late lumen loss of the everolimus-eluting bioresorbable polylactide scaffold in comparison with the cobalt-chromium metallic stent?	Sotomi Y	EuroIntervention	2017
28012050	Comparative assessment of "plaque/media" change on three modalities of IVUS immediately after implantation of either everolimus-eluting bioresorbable vascular scaffold or everolimus-eluting metallic stent in Absorb II study	Zeng Y	Int J Cardiovasc Imaging	2017
27998840	Quantification and characterisation of released plaque material during bioresorbable vascular scaffold implantation into right coronary artery lesions by multimodality intracoronary imaging	Hildebrandt HA	EuroIntervention	2016
27993756	Change in lumen eccentricity and asymmetry after treatment with Absorb bioresorbable vascular scaffolds in the ABSORB cohort B trial: a five-year serial optical coherence tomography imaging study	Suwannasom P	EuroIntervention	2017
27896897	Expanded clinical use of everolimus eluting bioresorbable vascular scaffolds for treatment of coronary artery disease	Diletti R	Catheter Cardiovasc Interv	2017
27807948	Procedural resources utilization and clinical outcomes with bioresorbable everolimus-eluting scaffolds and Pt-Cr everolimus-eluting stent with resorbable abluminal polymer in clinical practice. A randomized trial	de la Torre Hernandez JM	Catheter Cardiovasc Interv	2017
27806897	Comparison of an everolimus-eluting bioresorbable scaffold with an everolimus-eluting metallic stent for the treatment of coronary artery stenosis (ABSORB II): a 3 year, randomised, controlled, single-blind, multicentre clinical trial	Serruys PW	Lancet	2016

27597270	Two-year clinical, angiographic, and serial optical coherence tomographic follow-up after implantation of an everolimus-eluting bioresorbable scaffold and an everolimus-eluting metallic stent: insights from the randomised ABSORB Japan trial	Onuma Y	EuroIntervention	2016
27564310	Randomised comparison of a bioresorbable everolimus-eluting scaffold with a metallic everolimus-eluting stent for ischaemic heart disease caused by de novo native coronary artery lesions: the 2-year clinical outcomes of the ABSORB II trial	Chevalier B	EuroIntervention	2016
27721215	Is quantitative coronary angiography reliable in assessing the lumen gain after treatment with the everolimus-eluting bioresorbable polylactide scaffold?	Sotomi Y	EuroIntervention	2016
27497358	Evaluation of myocardial blood flow and coronary flow reserve after implantation of a bioresorbable vascular scaffold versus metal drug-eluting stent: an interim one-month analysis of the VANISH trial	Stuijfzand WJ	EuroIntervention	2016
27476094	Mid- to Long-Term Clinical Outcomes of Patients Treated With the Everolimus-Eluting Bioresorbable Vascular Scaffold: The BVS Expand Registry	Felix CM	JACC Cardiovasc Interv	2016
27339838	Acute Gain in Minimal Lumen Area Following Implantation of Everolimus-Eluting ABSORB Biodegradable Vascular Scaffolds or Xience Metallic Stents: Intravascular Ultrasound Assessment From the ABSORB II Trial	Sotomi Y	JACC Cardiovasc Interv	2016
27290675	Safety and performance of the DRug-Eluting Absorbable Metal Scaffold (DREAMS) in patients with de novo coronary lesions: 3-year results of the prospective, multicentre, first-in-man BIOSOLVE-I trial	Haude M	EuroIntervention	2016
27290673	Percutaneous coronary intervention for chronic total occlusion of the coronary artery with the implantation of bioresorbable everolimus-eluting scaffolds. Poznan CTO-Absorb Pilot Registry	Lesiak M	EuroIntervention	2016

27245123	Edge-to-Edge Technique to Minimize Ovelapping of Multiple Bioresorbable Scaffolds Plus Drug Eluting Stents in Revascularization of Long Diffuse Left Anterior Descending Coronary Artery Disease	Rigatelli G	J Interv Cardiol	2016
27173858	Long-term follow-up after bioresorbable vascular scaffold implantation in STEMI patients: PRAGUE-19 study update	Toušek P	EuroIntervention	2016
27013155	Serial Multimodality Imaging and 2-Year Clinical Outcomes of the Novel DESolve Novolimus-Eluting Bioresorbable Coronary Scaffold System for the Treatment of Single De Novo Coronary Lesions	Abizaid A	JACC Cardiovasc Interv	2016
26936236	Edge Vascular Response After Resorption of the Everolimus-Eluting Bioresorbable Vascular Scaffold - A 5-Year Serial Optical Coherence Tomography Study	Tateishi H	Circ J	2016
26892411	A Polylactide Bioresorbable Scaffold Eluting Everolimus for Treatment of Coronary Stenosis: 5-Year Follow-Up	Serruys PW	J Am Coll Cardiol	2016
26878467	Two-year follow-up after bioresorbable vascular scaffold implantation in STEMI patients - Results from PRAGUE-19 study	Toušek P	Int J Cardiol	2016
26874547	One-Year Results of Bioresorbable Vascular Scaffolds for Coronary Chronic Total Occlusions	Vaquerizo B	Am J Cardiol	2016
26766027	Vascular response to everolimus- and biolimus-eluting coronary stents versus everolimus-eluting bioresorbable scaffolds--an optical coherence tomography substudy of the EVERBIO II trial	Kallinikou Z	Swiss Med Wkly	2016
26739828	Impact of the Everolimus-eluting Bioresorbable Scaffold in Coronary Atherosclerosis	Campos CM	Rev Esp Cardiol (Engl Ed)	2016

26654975	The duration of balloon inflation affects the luminal diameter of coronary segments after bioresorbable vascular scaffolds deployment	Sorrentino S	BMC Cardiovasc Disord	2015
26628591	One-Year Clinical and Computed Tomography Angiographic Outcomes After Bioresorbable Vascular Scaffold Implantation During Primary Percutaneous Coronary Intervention for ST-Segment-Elevation Myocardial Infarction: The PRAGUE-19 Study	Widimsky P	Circ Cardiovasc Interv	2015
26567454	Twelve-Month Outcomes With a Bioresorbable Everolimus-Eluting Scaffold: Results of the ESHC-BVS Registry at Two Australian Centers	Robaei D	J Invasive Cardiol	2016
26472338	Systemic Pharmacokinetics of Everolimus Eluted From the Absorb Bioresorbable Vascular Scaffold: An ABSORB III Substudy	Rizik DG	J Am Coll Cardiol	2015
26471805	Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease: ABSORB China Trial	Gao R	J Am Coll Cardiol	2015
26470647	Safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de-novo coronary artery lesions (BIOSOLVE-II): 6 month results of a prospective, multicentre, non-randomised, first-in-man trial	Haude M	Lancet	2016
26457558	Everolimus-Eluting Bioresorbable Scaffolds for Coronary Artery Disease	Ellis SG	N Engl J Med	2015
26405232	Everolimus-eluting bioresorbable stent vs. durable polymer everolimus-eluting metallic stent in patients with ST-segment elevation myocardial infarction: results of the randomized ABSORB ST-segment elevation myocardial infarction-TROFI II trial	Sabaté M	Eur Heart J	2016

26342404	Bioabsorbable drug-eluting vascular scaffold for the treatment of coronary in-stent restenosis: A two center registry	Moscarella E	Cardiovasc Revasc Med	2015
26330419	A randomized trial evaluating everolimus-eluting Absorb bioresorbable scaffolds vs. everolimus-eluting metallic stents in patients with coronary artery disease: ABSORB Japan	Kimura T	Eur Heart J	2015
26269391	Implantation of everolimus-eluting bioresorbable scaffolds in a diabetic all-comers population	Wiebe J	Catheter Cardiovasc Interv	2015
26015294	A 12-month angiographic and optical coherence tomography follow-up after bioresorbable vascular scaffold implantation in patients with ST-segment elevation myocardial infarction	Kochman J	Catheter Cardiovasc Interv	2015
25720622	Comparison of everolimus- and biolimus-eluting coronary stents with everolimus-eluting bioresorbable vascular scaffolds	Puricel S	J Am Coll Cardiol	2015
25563622	Bioresorbable vascular scaffolds in patients with acute coronary syndromes: the POLAR ACS study	Dudek D	Pol Arch Med Wewn	2014
25499836	Beyond the early stages: insights from the ASSURE registry on bioresorbable vascular scaffolds	Wöhrle J	EuroIntervention	2015
25499833	Bioresorbable everolimus-eluting vascular scaffold for the treatment of chronic total occlusions: CTO-ABSORB pilot study	Vaquerizo B	EuroIntervention	2015
25428734	Bioresorbable everolimus-eluting vascular scaffold in patients with ST-segment elevation myocardial infarction: Optical coherence tomography evaluation and clinical outcomes	Kochman J	Cardiol J	2015

25230593	A bioresorbable everolimus-eluting scaffold versus a metallic everolimus-eluting stent for ischaemic heart disease caused by de-novo native coronary artery lesions (ABSORB II): an interim 1-year analysis of clinical and procedural secondary outcomes from a randomised controlled trial	Serruys PW	Lancet	2015
25136885	Initial experience and clinical evaluation of the Absorb bioresorbable vascular scaffold (BVS) in real-world practice: the AMC Single Centre Real World PCI Registry	Kraak RP	EuroIntervention	2015
24769555	The ABSORB EXTEND study: preliminary report of the twelve-month clinical outcomes in the first 512 patients enrolled	Abizaid A	EuroIntervention	2015
24419808	Bioresorbable vascular scaffolds in acute ST-segment elevation myocardial infarction: a prospective multicentre study 'Prague 19'	Kočka V	Eur Heart J	2014
24394380	Everolimus-eluting bioresorbable vascular scaffolds for treatment of patients presenting with ST-segment elevation myocardial infarction: BVS STEMI first study	Diletti R	Eur Heart J	2014
24291783	Dynamics of vessel wall changes following the implantation of the absorb everolimus-eluting bioresorbable vascular scaffold: a multi-imaging modality study at 6, 12, 24 and 36 months	Serruys PW	EuroIntervention	2014
24156961	Five-year clinical and functional multislice computed tomography angiographic results after coronary implantation of the fully resorbable polymeric everolimus-eluting scaffold in patients with de novo coronary artery disease: the ABSORB cohort A trial	Onuma Y	JACC Cardiovasc Interv	2013
24139932	A next-generation bioresorbable coronary scaffold system: from bench to first clinical evaluation: 6- and 12-month clinical and multimodality imaging results	Verheye S	JACC Cardiovasc Interv	2014

23332165	Safety and performance of the drug-eluting absorbable metal scaffold (DREAMS) in patients with de-novo coronary lesions: 12 month results of the prospective, multicentre, first-in-man BIOSOLVE-I trial	Haude M	Lancet	2013
23048057	First serial assessment at 6 months and 2 years of the second generation of absorb everolimus-eluting bioresorbable vascular scaffold: a multi-imaging modality study	Ormiston JA	Circ Cardiovasc Interv	2012
22721662	Vascular response of the segments adjacent to the proximal and distal edges of the ABSORB everolimus-eluting bioresorbable vascular scaffold: 6-month and 1-year follow-up assessment: a virtual histology intravascular ultrasound study from the first-in-man ABSORB cohort B trial	Gogas BD	JACC Cardiovasc Interv	2012
22516401	Differences in neointimal thickness between the adluminal and the abluminal sides of malapposed and side-branch struts in a polylactide bioresorbable scaffold: evidence in vivo about the abluminal healing process	Gutiérrez-Chico JL	JACC Cardiovasc Interv	2012
21959320	Four-year clinical follow-up of the ABSORB everolimus-eluting bioresorbable vascular scaffold in patients with de novo coronary artery disease: the ABSORB trial	Dudek D	EuroIntervention	2012
21958884	Evaluation of the second generation of a bioresorbable everolimus-eluting vascular scaffold for the treatment of de novo coronary artery stenosis: 12-month clinical and imaging outcomes	Serruys PW	J Am Coll Cardiol	2011
21098436	Evaluation of the second generation of a bioresorbable everolimus drug-eluting vascular scaffold for treatment of de novo coronary artery stenosis: six-month clinical and imaging outcomes	Serruys PW	Circulation	2010
20884431	Three-year results of clinical follow-up after a bioresorbable everolimus-eluting scaffold in patients with de novo coronary artery disease: the ABSORB trial	Onuma Y	EuroIntervention	2010

20398874	Monitoring in vivo absorption of a drug-eluting bioabsorbable stent with intravascular ultrasound-derived parameters a feasibility study	Bruining N	JACC Cardiovasc Interv	2010
19286089	A bioabsorbable everolimus-eluting coronary stent system (ABSORB): 2-year outcomes and results from multiple imaging methods	Serruys PW	Lancet	2009
18992650	Late stent recoil of the bioabsorbable everolimus-eluting coronary stent and its relationship with plaque morphology	Tanimoto S	J Am Coll Cardiol	2008
18342684	A bioabsorbable everolimus-eluting coronary stent system for patients with single de-novo coronary artery lesions (ABSORB): a prospective open-label trial	Ormiston JA	Lancet	2008
17544767	Temporary scaffolding of coronary arteries with bioabsorbable magnesium stents: a prospective, non-randomised multicentre trial	Erbel R	Lancet	2007
17503509	Comparison of in vivo acute stent recoil between the bioabsorbable everolimus-eluting coronary stent and the everolimus-eluting cobalt chromium coronary stent: insights from the ABSORB and SPIRIT trials	Tanimoto S	Catheter Cardiovasc Interv	2007

1.2 Left atrial appendage occlusion devices

Table 3. List of left atrial appendage occlusion devices

Class of device	Devices
Left atrial appendage occlusion systems/devices	**Amplatzer Cardiac Plug** [St Jude/Abbott] **Amplatzer Amulet** [St Jude/Abbott] **Watchman** [Boston Scientific] **Watchman FLX** (1st generation) [Boston Scientific] **Watchman FLX** (2nd generation) [Boston Scientific] **LARIAT** Suture Delivery Device [SentreHEART] **LAMBRE** [Lifetech Scientific] **Cardia Ultraseal** [Cardia]

Table 4. List of prospective studies fulfilling the pre-specified inclusion criteria on leaft atrial appendage occlusion devices

PMID	Title	First author	Journal	Publication Year
34459659	Amplatzer Amulet Left Atrial Appendage Occluder Versus Watchman Device for Stroke Prophylaxis (Amulet IDE): A Randomized, Controlled Trial	Lakkireddy D	Circulation	2021
34097038	Left atrial appendage occlusion in the UK: prospective registry and data linkage to Hospital Episode Statistics	Willits I	Eur Heart J Qual Care Clin Outcomes	2021
33957090	Left atrial appendage closure in patients with prohibitive anatomy: Insights from PINNACLE FLX	Ellis C	Heart Rhythm.	2021
33915971	Left Atrial Appendage Closure with a New Occluder Device: Efficacy, Safety and Mid-Term Performance	Llagostera-Martín M	J Clin Med	2021

33820423	Primary Outcome Evaluation of a Next-Generation Left Atrial Appendage Closure Device: Results From the PINNACLE FLX Trial	Kar S	Circulation	2021
33533089	Intracardiac echocardiography-guided implantation of the Watchman FLX left atrial appendage closure device	Turagam MK	J Cardiovasc Electrophysiol	2021
33334441	The Watchman FLX Device: First European Experience and Feasibility of Intracardiac Echocardiography to Guide Implantation	Korsholm K	JACC Clin Electrophysiol	2020
33251673	Incidence, risk factors, and clinical impact of peridevice leak following left atrial appendage closure with the LAmbre device-Data from a prospective multicenter clinical study	Wang G	J Cardiovasc Electrophysiol	2021
33189641	Procedural and Short-Term Results With the New Watchman FLX Left Atrial Appendage Occlusion Device	Cruz-González I	JACC Cardiovasc Interv	2020
32946860	Comparison in Patients < 75 Years of Age - Versus - Those > 75 Years on One-year-Events With Atrial Fibrillation and Left Atrial Appendage Occluder (From the Prospective Multicenter German LAARGE Registry)	Nasasra A	Am J Cardiol	2020
32595176	Efficacy and Safety of Left Atrial Appendage Closure With WATCHMAN in Japanese Nonvalvular Atrial Fibrillation Patients - Final 2-Year Follow-up Outcome Data From the SALUTE Trial	Aonuma K	Circ J	2020
32586585	Left Atrial Appendage Closure Versus Direct Oral Anticoagulants in High-Risk Patients With Atrial Fibrillation	Osmancik P	J Am Coll Cardiol	2020

32464648	Initial and long-term antithrombotic therapy after left atrial appendage closure with the WATCHMAN	Ledwoch J	Europace	2020
32451320	WATCHMAN versus ACP or Amulet devices for left atrial appendage occlusion: a sub-analysis of the multicentre LAARGE registry	Ledwoch J	EuroIntervention	2020
32236717	Left atrial appendage closure in patients with a reduced left ventricular ejection fraction: results from the multicenter German LAARGE registry	Fastner C	Clin Res Cardiol	2020
31707534	Interventional occlusion of left atrial appendage in patients with atrial fibrillation. Acute and long-term outcome of occluder implantation in the LAARGE Registry	Brachmann J	J Interv Card Electrophysiol	2020
31596044	Long-term clinical outcomes from real-world experience of left atrial appendage exclusion with LARIAT device	Parikh V	J Cardiovasc Electrophysiol	2019
31103540	Incidence, Characterization, and Clinical Impact of Device-Related Thrombus Following Left Atrial Appendage Occlusion in the Prospective Global AMPLATZER Amulet Observational Study	Aminian A	JACC Cardiovasc Interv	2019
31092201	Cerebrovascular events, bleeding complications and device related thrombi in atrial fibrillation patients with chronic kidney disease and left atrial appendage closure with the WATCHMAN™ device	Luani B	BMC Cardiovasc Disord	2019
31008181	Left atrial appendage closure with WATCHMAN in Asian patients: 2 year outcomes from the WASP registry	Phillips KP	Int J Cardiol Heart Vasc	2019

30939908	Evaluating Real-World Clinical Outcomes in Atrial Fibrillation Patients Receiving the WATCHMAN Left Atrial Appendage Closure Technology: Final 2-Year Outcome Data of the EWOLUTION Trial Focusing on History of Stroke and Hemorrhage	Boersma L	Circ Arrhythm Electrophysiol	2019
30884101	Reduction in risk of stroke and bleeding after left atrial appendage closure with LARIAT device in patients with increased risk of stroke and bleeding: Long term results	Litwinowicz R	Catheter Cardiovasc Interv	2019
30586229	Oral anticoagulation and left atrial appendage closure: a new strategy for recurrent cardioembolic stroke	Masjuan J	Eur J Neurol	2019
30583991	Left atrial appendage occlusion using LAmbre Amulet and Watchman in atrial fibrillation	Chen S	J Cardiol	2019
30305484	Percutaneous WATCHMAN Left Atrial Appendage Closure for Japanese Patients With Nonvalvular Atrial Fibrillation at Increased Risk of Thromboembolism - First Results From the SALUTE Trial	Aonuma K	Circ J	2018
29806820	Left atrial appendage occlusion with the AMPLATZER Amulet device: one-year follow-up from the prospective global Amulet observational registry	Landmesser U	EuroIntervention	2018
29759399	Left Atrial Appendage Ligation in Nonvalvular Atrial Fibrillation Patients at High Risk for Embolic Events With Ineligibility for Oral Anticoagulation: Initial Report of Clinical Outcomes	Sievert H	JACC Clin Electrophysiol	2015

29706393	Implant success and safety of left atrial appendage occlusion in end stage renal disease patients: Peri-procedural outcomes from an Italian dialysis population	Genovesi S	Int J Cardiol	2018
29540492	Percutaneous Left Atrial Appendage Closure Is a Reasonable Option for Patients With Atrial Fibrillation at High Risk for Cerebrovascular Events	Teiger E	Circ Cardiovasc Interv	2018
29525913	Percutaneous Left Atrial Appendage Closure with WATCHMAN™ device: peri-procedural and mid-term outcomes from the TRAPS Registry	Mazzone P	J Interv Card Electrophysiol	2018
29477973	Mechanical function of the left atrium is improved with epicardial ligation of the left atrial appendage: Insights from the LAFIT-LARIAT Registry	Dar T	Heart Rhythm	2018
29313819	Real-world safety and efficacy of WATCHMAN LAA closure at one year in patients on dual antiplatelet therapy: results of the DAPT subgroup from the EWOLUTION all-comers study	Bergmann M	EuroIntervention	2018
29149516	Feasibility of percutaneous left atrial appendage closure using a novel LAmbre occluder in patients with atrial fibrillation: Initial results from a prospective cohort registry study	Chen S	J Cardiovasc Electrophysiol	2018
29122133	Percutaneous Left Atrial Appendage Closure With the LAmbre Device for Stroke Prevention in Atrial Fibrillation: A Prospective, Multicenter Clinical Study	Huang H	JACC Cardiovasc Interv	2017
28649053	Left atrial appendage occlusion with the AMPLATZER Amulet device: periprocedural and early clinical/echocardiographic data from a global prospective observational study	Landmesser U	EuroIntervention	2017

28606886	Safety and efficacy of early anticoagulation drug regimens after WATCHMAN left atrial appendage closure: three-month data from the EWOLUTION prospective, multicentre, monitored international WATCHMAN LAA closure registry	Bergmann M	EuroIntervention	2017
28577840	Efficacy and safety of left atrial appendage closure with WATCHMAN in patients with or without contraindication to oral anticoagulation: 1-Year follow-up outcome data of the EWOLUTION trial	Boersma L	Heart Rhythm	2017
28409845	Procedural success and intra-hospital outcome related to left atrial appendage morphology in patients that receive an interventional left atrial appendage closure	Fastner C	Clin Cardiol	2017
28041899	Left Atrial Appendage Closure in Patients with Atrial Fibrillation and Previous Intracerebral Hemorrhage	Renou P	J Stroke Cerebrovasc Dis	2017
27973336	Transcatheter left atrial appendage occlusion in patients with atrial fibrillation and a high bleeding risk using aspirin alone for post-implant antithrombotic therapy	Korsholm K	EuroIntervention	2017
27128539	Left atrial appendage ligation with the next generation LARIAT(+) suture delivery device: Early clinical experience	Bartus K	Int J Cardiol	2016
26822918	Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry	Boersma LV	Eur Heart J	2016
26738659	Percutaneous Left Atrial Appendage Closure With the Watchman Device: Long-Term Results Up to 5 Years	Wiebe J	JACC Cardiovasc Interv	2015

26354821	Left atrial appendage closure: First in man with the 4th generation WATCHMAN device	Ledwoch J	Catheter Cardiovasc Interv	2016
25399274	Percutaneous left atrial appendage closure vs warfarin for atrial fibrillation: a randomized clinical trial	Reddy VY	JAMA	2014
25281005	Impact of left atrial appendage exclusion using an epicardial ligation system (LARIAT) on atrial fibrillation burden in patients with cardiac implantable electronic devices	Afzal MR	Heart Rhythm	2015
24998121	Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial	Holmes DR Jr	J Am Coll Cardiol	2014
24820753	Left atrial appendage occlusion: initial experience with the Amplatzer™ Amulet™	Freixa X	Int J Cardiol	2014
24319042	Left atrial appendage occlusion in atrial fibrillation after intracranial hemorrhage	Horstmann S	Neurology	2014
23973952	Left atrial appendage closure followed by 6 weeks of antithrombotic therapy: a prospective single-center experience	Chun KR	Heart Rhythm	2013
23583249	Left atrial appendage closure with the Watchman device in patients with a contraindication for oral anticoagulation: the ASAP study (ASA Plavix Feasibility Study With Watchman Left Atrial Appendage Closure Technology)	Reddy VY	J Am Coll Cardiol	2013

23325525	Percutaneous left atrial appendage closure for stroke prophylaxis in patients with atrial fibrillation: 2.3-Year Follow-up of the PROTECT AF (Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation) Trial	Reddy VY	Circulation	2013
23062528	Percutaneous left atrial appendage suture ligation using the LARIAT device in patients with atrial fibrillation: initial clinical experience	Bartus K	J Am Coll Cardiol	2013
22381428	The clinical impact of incomplete left atrial appendage closure with the Watchman Device in patients with atrial fibrillation: a PROTECT AF (Percutaneous Closure of the Left Atrial Appendage Versus Warfarin Therapy for Prevention of Stroke in Patients With Atrial Fibrillation) substudy	Viles-Gonzalez JF	J Am Coll Cardiol	2012
19683639	Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial	Holmes DR	Lancet	2009
17397680	Initial worldwide experience with the WATCHMAN left atrial appendage system for stroke prevention in atrial fibrillation	Sick PB	J Am Coll Cardiol	2007

1.3 Transcatheter aortic valve implantation devices

Table 5. List of transcatheter aortic valve implantation systems/devices

Class of device	Devices
Transcatheter aortic valve implantation systems/devices	**Centera** [Edwards Lifesciences] **CoreValve** [Medtronic] **CoreValve Evolut R** [Medtronic] **CoreValve Evolut Pro** [Medtronic] **CoreValve Evolut Pro+** [Medtronic] **Direct Flow** [Medical] **Engager** [Medtronic] **Jena Valve** [JenaValve] **Lotus** [Boston Scientific] **Lotus Edge** [Boston Scientific] **Myval** [Myval] **NVT Allegra** [Biosensors] **Portico** [Abbott] **Sapien** [Edwards Lifesciences] **Sapien XT** [Edwards Lifesciences] **Sapien S3** [Edwards Lifesciences] **Sapien 3 Ultra** [Edwards Lifesciences] **Symetis Acurate TA** [Boston Scientific] **Symetis Acurate Neo** [Boston Scientific] **Symetis Acurate Neo 2** [Boston Scientific]

Table 6. List of prospective studies fulfilling the pre-specified inclusion criteria on transcatheter aortic valve implantation systems/devices

PMID	Title	First author	Journal	Publication Year
34348863	One-year outcomes of the pivotal clinical trial of a balloon-expandable transcatheter aortic valve implantation in Japanese dialysis patients	Maeda K	J Cardiol	2021

34331844	Final 3-year clinical outcomes following transcatheter aortic valve implantation with a supra-annular self-expanding repositionable valve in a real-world setting: Results from the multicenter FORWARD study	Van Mieghem NM	Catheter Cardiovasc Interv	2022
34179981	Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement	Jørgensen TH	Eur Heart J	2021
34148125	The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes	Möllmann H	Clin Res Cardiol	2021
34092091	Five-Year Clinical and Quality of Life Outcomes From the CoreValve US Pivotal Extreme Risk Trial	Arnold SV	Circ Cardiovasc Interv	2021
33926657	Impact of Anesthesia Strategy and Valve Type on Clinical Outcomes After Transcatheter Aortic Valve Replacement	Feistritzer HJ	J Am Coll Cardiol	2021
33750210	One-Year Outcomes of a Randomized Trial Comparing a Self-Expanding With a Balloon-Expandable Transcatheter Aortic Valve	Kim WK	Circulation	2021
33713618	Transcatheter aortic valve replacement in low-risk patients: 2-year results from the LRT trial	Waksman R	Am Heart J	2021
33663731	Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk	Leon MB	J Am Coll Cardiol	2021
33199247	Three-Year Outcomes With a Contemporary Self-Expanding Transcatheter Valve From the Evolut PRO US Clinical Study	Wyler von Ballmoos MC	Cardiovasc Revasc Med	2021

33191317	Clinical Outcomes in Patients Treated With a Repositionable and Fully Retrievable Aortic Valve - REPRISE Japan Study	Saito S	Circ J	2021
33054367	Comparison of Self-Expanding Bioprostheses for Transcatheter Aortic Valve Replacement in Patients With Symptomatic Severe Aortic Stenosis: SCOPE 2 Randomized Clinical Trial	Tamburino C	Circulation	2020
33031491	Transcatheter Aortic Valve Replacement in Low-risk Patients With Bicuspid Aortic Valve Stenosis	Forrest JK	JAMA Cardiol	2021
32997095	Five-Year Health Status After Self-expanding Transcatheter or Surgical Aortic Valve Replacement in High-risk Patients With Severe Aortic Stenosis	Arnold SV	JAMA Cardiol	2021
32771997	Clinical Outcomes of the Portico Transcatheter Aortic Valve Delivered via Alternative Access: 30-Day and 1-Year Results of the Portico ALT Study	van Wely M	J Invasive Cardiol	2020
32748789	Thirty-day clinical outcomes of the Evolut PRO self-expanding transcatheter aortic valve: the international FORWARD PRO study	Manoharan G	EuroIntervention	2020
32593323	Self-expanding intra-annular versus commercially available transcatheter heart valves in high and extreme risk patients with severe aortic stenosis (PORTICO IDE): a randomised, controlled, non-inferiority trial	Makkar RR	Lancet	2020
32418883	Evaluation of length of stay after transfemoral transcatheter aortic valve implantation with SAPIEN 3 prosthesis: A French multicentre prospective observational trial	Durand E	Arch Cardiovasc Dis	2020

32381181	Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic Severe Bicuspid Aortic Valve Stenosis	Waksman R	JACC Cardiovasc Interv	2020
32305398	5-Year Outcomes After TAVR With Balloon-Expandable Versus Self-Expanding Valves: Results From the CHOICE Randomized Clinical Trial	Abdel-Wahab M	JACC Cardiovasc Interv	2020
32272848	Echocardiographic Results of Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients: The PARTNER 3 Trial	Pibarot P	Circulation	2020
32246266	Randomised comparison of a balloon-expandable and self-expandable valve with quantitative assessment of aortic regurgitation using magnetic resonance imaging	Kooistra NHM	Neth Heart J	2020
32049283	Comparison of newer generation self-expandable vs. balloon-expandable valves in transcatheter aortic valve implantation: the randomized SOLVE-TAVI trial	Thiele H	Eur Heart J	2020
32029248	Complete 2-Year Results Confirm Bayesian Analysis of the SURTAVI Trial	Van Mieghem NM	JACC Cardiovasc Interv	2020
31995682	Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement	Makkar RR	N Engl J Med	2020
31826675	Hemodynamics and Subclinical Leaflet Thrombosis in Low-Risk Patients Undergoing Transcatheter Aortic Valve Replacement	Khan JM	Circ Cardiovasc Imaging	2019
31640455	Pacemaker Implantation and Dependency After Transcatheter Aortic Valve Replacement in the REPRISE III Trial	Meduri CU	J Am Heart Assoc	2019

31577923	Health Status After Transcatheter Versus Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis	Baron SJ	J Am Coll Cardiol	2019
31570258	Safety and efficacy of a self-expanding versus a balloon-expandable bioprosthesis for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: a randomised non-inferiority trial	Lanz J	Lancet	2019
31566572	First-in-human evaluation of a novel balloon-expandable transcatheter heart valve in patients with severe symptomatic native aortic stenosis: the MyVal-1 study	Sharma SK	EuroIntervention	2020
30947942	1-Year Outcomes of the CENTERA-EU Trial Assessing a Novel Self-Expanding Transcatheter Heart Valve	Tchétché D	JACC Cardiovasc Interv	2019
30929507	Computed Tomography-Based Indexed Aortic Annulus Size to Predict Prosthesis-Patient Mismatch	Head SJ	Circ Cardiovasc Interv	2019
30883058	Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients	Mack MJ	N Engl J Med	2019
30883053	Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients	Popma JJ	N Engl J Med	2019
30860059	TAVR in Low-Risk Patients: 1-Year Results From the LRT Trial	Waksman R	JACC Cardiovasc Interv	2019
30810703	Two-Year Outcomes After Transcatheter Aortic Valve Replacement With Mechanical vs Self-expanding Valves: The REPRISE III Randomized Clinical Trial	Reardon MJ	JAMA Cardiol	2019

30808296	Single-center evaluation of a next generation fully repositionable and retrievable transcatheter aortic valve replacement	Berntorp K	BMC Cardiovasc Disord	2019
30773838	Clinical outcomes of the Lotus Valve in patients with bicuspid aortic valve stenosis: An analysis from the RESPOND study	Blackman DJ	Catheter Cardiovasc Interv	2019
30761515	Transfermoral aortic valve implantation using self-expanding New Valve Technology (NVT) Allegra bioprosthesis: A pilot prospective study	Jagielak D	Cardiol J	2021
30732707	Durability of Transcatheter and Surgical Bioprosthetic Aortic Valves in Patients at Lower Surgical Risk	Søndergaard L	J Am Coll Cardiol	2019
30715097	Evaluation of Changes in Functional Status in the Year After Aortic Valve Replacement	Kim DH	JAMA Intern Med	2019
30704298	Five-Year Clinical and Echocardiographic Outcomes from the Nordic Aortic Valve Intervention (NOTION) Randomized Clinical Trial in Lower Surgical Risk Patients	Thyregod HGH	Circulation	2019
30621976	Use of a Repositionable and Fully Retrievable Aortic Valve in Routine Clinical Practice: The RESPOND Study and RESPOND Extension Cohort	Van Mieghem NM	JACC Cardiovasc Interv	2019
30466832	1-Year Outcomes With the Evolut R Self-Expanding Transcatheter Aortic Valve: From the International FORWARD Study	Manoharan G	JACC Cardiovasc Interv	2018
30261238	Transcatheter Aortic Valve Replacement With a Repositionable Self-Expanding Prosthesis: The PORTICO-I Trial 1-Year Outcomes	Søndergaard L	J Am Coll Cardiol	2018

30249462	5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients	Gleason TG	J Am Coll Cardiol	2018
30111522	Early commercial experience from transcatheter aortic valve implantation using the Portico™ bioprosthetic valve: 30-day outcomes in the multicentre PORTICO-1 study	Maisano F	EuroIntervention	2018
29554265	Prospective multicentre evaluation of a novel, low-profile transapical delivery system for self-expandable transcatheter aortic valve implantation: 6-month outcomes	Conradi L	Eur J Cardiothorac Surg	2018
29530883	Hemodynamic and Echocardiographic Comparison of the Lotus and CoreValve Transcatheter Aortic Valves in Patients With High and Extreme Surgical Risk: An Analysis From the REPRISE III Randomized Controlled Trial	Asch FM	Circulation	2018
29444998	Treatment of Aortic Stenosis With a Self-Expanding, Resheathable Transcatheter Valve: One-Year Results of the International Multicenter Portico Transcatheter Aortic Valve Implantation System Study	Linke A	Circ Cardiovasc Interv	2018
29348010	Early Outcomes With the Evolut PRO Repositionable Self-Expanding Transcatheter Aortic Valve With Pericardial Wrap	Forrest JK	JACC Cardiovasc Interv	2018
29297076	Effect of Mechanically Expanded vs Self-Expanding Transcatheter Aortic Valve Replacement on Mortality and Major Adverse Clinical Events in High-Risk Patients With Aortic Stenosis: The REPRISE III Randomized Clinical Trial	Feldman TE	JAMA	2018
29268926	Self-Expanding Transcatheter Aortic Valve System for Symptomatic High-Risk Patients With Severe Aortic Stenosis	Reichenspurner H	J Am Coll Cardiol	2017

28973091	Association of Paravalvular Regurgitation With 1-Year Outcomes After Transcatheter Aortic Valve Replacement With the SAPIEN 3 Valve	Pibarot P	JAMA Cardiol	2017
28804056	Transfemoral TAVI using the self-expanding ACURATE neo prosthesis: one-year outcomes of the multicentre "CE-approval cohort"	Möllmann H	EuroIntervention	2017
28797431	Implantation and 30-Day Follow-Up on All 4 Valve Sizes Within the Portico Transcatheter Aortic Bioprosthetic Family	Möllmann H	JACC Cardiovasc Interv	2017
28797353	Clinical Outcomes With a Repositionable Self-Expanding Transcatheter Aortic Valve Prosthesis: The International FORWARD Study	Grube E	J Am Coll Cardiol	2017
28658491	Health Status Benefits of Transcatheter vs Surgical Aortic Valve Replacement in Patients With Severe Aortic Stenosis at Intermediate Surgical Risk: Results From the PARTNER 2 Randomized Clinical Trial	Baron SJ	JAMA Cardiol	2017
28633375	Final 5-year clinical and echocardiographic results for treatment of severe aortic stenosis with a self-expanding bioprosthesis from the ADVANCE Study	Gerckens U	Eur Heart J	2017
28555592	Repositionable percutaneous aortic valve implantation with the LOTUS valve: 30-day and 1-year outcomes in 250 high-risk surgical patients	Meredith IT	EuroIntervention	2017
28484830	Insights on mid-term TAVR performance: 3-year clinical and echocardiographic results from the CoreValve ADVANCE study	Bleiziffer S	Clin Res Cardiol	2017
28321003	Midterm Outcomes With a Self-Expandable Transcatheter Heart Valve in Japanese Patients With Symptomatic Severe Aortic Stenosis	Sawa Y	Circ J	2017

28321002	Five-Year Outcomes of the First Pivotal Clinical Trial of Balloon-Expandable Transcatheter Aortic Valve Replacement in Japan (PREVAIL JAPAN)	Sawa Y	Circ J	2017
28304219	Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients	Reardon MJ	N Engl J Med	2017
28183466	Early Clinical Outcomes After Transcatheter Aortic Valve Replacement Using a Novel Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis Who Are Suboptimal for Surgery: Results of the Evolut R U.S. Study	Popma JJ	JACC Cardiovasc Interv	2017
27793402	One-Year Outcomes of Transcatheter Aortic Valve Implantation Using the Direct Aortic Approach	Bruschi G	Ann Thorac Surg	2017
27542790	Multicentre clinical study evaluating a novel resheathable annular functioning self-expanding transcatheter aortic valve system: safety and performance results at 30 days with the Portico system	Manoharan G	EuroIntervention	2016
27400898	One-Year Clinical Outcomes With SAPIEN 3 Transcatheter Aortic Valve Replacement in High-Risk and Inoperable Patients With Severe Aortic Stenosis	Herrmann HC	Circulation	2016
27313280	Self-Expanding Transcatheter Aortic Valve Replacement Versus Surgical Valve Replacement in Patients at High Risk for Surgery: A Study of Echocardiographic Change and Risk Prediction	Little SH	Circ Cardiovasc Interv	2016
27296202	Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement: The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial	Søndergaard L	Circ Cardiovasc Interv	2016

27159659	Four-year experience with the CoreValve transcatheter heart valve	Kovac J	EuroIntervention	2016
27050187	3-Year Outcomes in High-Risk Patients Who Underwent Surgical or Transcatheter Aortic Valve Replacement	Deeb GM	J Am Coll Cardiol	2016
27040324	Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients	Leon MB	N Engl J Med	2016
26892084	1-Year Outcomes With the Fully Repositionable and Retrievable Lotus Transcatheter Aortic Replacement Valve in 120 High-Risk Surgical Patients With Severe Aortic Stenosis: Results of the REPRISE II Study	Meredith IT	JACC Cardiovasc Interv	2016
26762913	Prospective Multicenter Evaluation of the Direct Flow Medical Transcatheter Aortic Valve System: 12-Month Outcomes of the Evaluation of the Direct Flow Medical Percutaneous Aortic Valve 18F System for the Treatment of Patients With Severe Aortic Stenosis (DISCOVER) Study	Lefèvre T	JACC Cardiovasc Interv	2016
26718510	A Randomized Evaluation of the SAPIEN XT Transcatheter Heart Valve System in Patients With Aortic Stenosis Who Are Not Candidates for Surgery	Webb JG	JACC Cardiovasc Interv	2015
26508386	Regression of Paravalvular Aortic Regurgitation and Remodeling of Self-Expanding Transcatheter Aortic Valve: An Observation From the CoreValve U.S. Pivotal Trial	Oh JK	JACC Cardiovasc Imaging	2015
26383718	2-Year Outcomes After Iliofemoral Self-Expanding Transcatheter Aortic Valve Replacement in Patients With Severe Aortic Stenosis Deemed Extreme Risk for Surgery	Yakubov SJ	J Am Coll Cardiol	2015

26345138	Transcatheter aortic valve implantation in very elderly patients: immediate results and medium term follow-up	Pascual I	J Geriatr Cardiol	2015
26292584	Health Status After Transcatheter or Surgical Aortic Valve Replacement in Patients With Severe Aortic Stenosis at Increased Surgical Risk: Results From the CoreValve US Pivotal Trial	Arnold SV	JACC Cardiovasc Interv	2015
26271061	1-Year Outcomes After Transcatheter Aortic Valve Replacement With Balloon-Expandable Versus Self-Expandable Valves: Results From the CHOICE Randomized Clinical Trial	Abdel-Wahab M	J Am Coll Cardiol	2015
26055947	2-Year Outcomes in Patients Undergoing Surgical or Self-Expanding Transcatheter Aortic Valve Replacement	Reardon MJ	J Am Coll Cardiol	2015
25999108	Optimal Implantation Depth and Adherence to Guidelines on Permanent Pacing to Improve the Results of Transcatheter Aortic Valve Replacement With the Medtronic CoreValve System: The CoreValve Prospective, International, Post-Market ADVANCE-II Study	Petronio AS	JACC Cardiovasc Interv	2015
25946437	European experience with the second-generation Edwards SAPIEN XT transcatheter heart valve in patients with severe aortic stenosis: 1-year outcomes from the SOURCE XT Registry	Schymik G	JACC Cardiovasc Interv	2015
25788234	5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial	Mack MJ	Lancet	2015
25788231	5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial	Kapadia SR	Lancet	2015

25787196	Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial	Thyregod HG	J Am Coll Cardiol	2015
25700755	Health status after transcatheter aortic valve replacement in patients at extreme surgical risk: results from the CoreValve U.S. trial	Osnabrugge RL	JACC Cardiovasc Interv	2015
25456759	Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve	Webb J	J Am Coll Cardiol	2014
25455544	Hemodynamic outcomes of transcatheter aortic valve replacement and medical management in severe, inoperable aortic stenosis: a longitudinal echocardiographic study of cohort B of the PARTNER trial	Douglas PS	J Am Soc Echocardiogr	2015
25455463	Early effects of transcatheter aortic valve implantation and aortic valve replacement on myocardial function and aortic valve hemodynamics: insights from cardiovascular magnetic resonance imaging	Crouch G	J Thorac Cardiovasc Surg	2015
25257635	Transcatheter aortic valve replacement for severe symptomatic aortic stenosis using a repositionable valve system: 30-day primary endpoint results from the REPRISE II study	Meredith Am IT	J Am Coll Cardiol	2014
25205802	Long-term outcomes of inoperable patients with aortic stenosis randomly assigned to transcatheter aortic valve replacement or standard therapy	Kapadia SR	Circulation	2014
24682842	Treatment of aortic stenosis with a self-expanding transcatheter valve: the International Multi-centre ADVANCE Study	Linke A	Eur Heart J	2014

24682026	Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial	Abdel-Wahab M	JAMA	2014
24678937	Transcatheter aortic-valve replacement with a self-expanding prosthesis	Adams DH	N Engl J Med	2014
24662399	First clinical trial of a self-expandable transcatheter heart valve in Japan in patients with symptomatic severe aortic stenosis	Sawa Y	Circ J	2014
24657695	Transcatheter aortic valve replacement using a self-expanding bioprosthesis in patients with severe aortic stenosis at extreme risk for surgery	Popma JJ	J Am Coll Cardiol	2014
24595532	Clinical efficacy of transcatheter aortic valve replacement for severe aortic stenosis in high-risk patients: the PREVAIL JAPAN trial	Sawa Y	Surg Today	2015
24211506	Prospective multicenter evaluation of the direct flow medical transcatheter aortic valve	Schofer J	J Am Coll Cardiol	2014
24169077	Transfemoral aortic valve replacement with the repositionable Lotus Valve System in high surgical risk patients: the REPRISE I study	Meredith IT	EuroIntervention	2014
22995116	Direct Flow Medical valve	Bijuklic K	EuroIntervention	2012
23517843	Transcatheter aortic valve replacement with a new self-expanding transcatheter heart valve and motorized delivery system	Binder RK	JACC Cardiovasc Interv	2013

22818074	Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A)	Reynolds MR	J Am Coll Cardiol	2012
22743081	Feasibility of the Engager™ aortic transcatheter valve system using a flexible over-the-wire design	Sündermann SH	Eur J Cardiothorac Surg	2012
22657270	Transcatheter aortic valve replacement with the St. Jude Medical Portico valve: first-in-human experience	Willson AB	J Am Coll Cardiol	2012
22581299	A prospective, randomised trial of transapical transcatheter aortic valve implantation vs. surgical aortic valve replacement in operable elderly patients with aortic stenosis: the STACCATO trial	Nielsen HH	EuroIntervention	2012
22551129	Registry of transcatheter aortic-valve implantation in high-risk patients	Gilard M	N Engl J Med	2012
22520622	One-year results of health-related quality of life among patients undergoing transcatheter aortic valve implantation	Krane M	Am J Cardiol	2012
22508111	Transapical transcatheter aortic valve implantation using the JenaValve™ system: acute and 30-day results of the multicentre CE-mark study	Treede H	Eur J Cardiothorac Surg	2012
22443479	Two-year outcomes after transcatheter or surgical aortic-valve replacement	Kodali SK	N Engl J Med	2012
22443478	Transcatheter aortic-valve replacement for inoperable severe aortic stenosis	Makkar RR	N Engl J Med	2012

22440213	Aortic regurgitation index defines severity of peri-prosthetic regurgitation and predicts outcome in patients after transcatheter aortic valve implantation	Sinning JM	J Am Coll Cardiol	2012
21969017	Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis	Reynolds MR	Circulation	2011
21639811	Transcatheter versus surgical aortic-valve replacement in high-risk patients	Smith CR	N Engl J Med	2011
21492762	2-year follow-up of patients undergoing transcatheter aortic valve implantation using a self-expanding valve prosthesis	Buellesfeld L	J Am Coll Cardiol	2011
21148541	Transapical aortic valve implantation with a self-expanding anatomically oriented valve	Falk V	Eur Heart J	2011
21075775	One year follow-up of the multi-centre European PARTNER transcatheter heart valve study	Lefèvre T	Eur Heart J	2011
20961243	Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery	Leon MB	N Engl J Med	2010
20826252	Quality of life among patients undergoing transcatheter aortic valve implantation	Krane M	Am Heart J	2010
20637648	One-year interim follow-up results of the TRAVERCE trial: the initial feasibility study for trans-apical aortic-valve implantation	Walther T	Eur J Cardiothorac Surg	2011

20031667	Retrograde transarterial implantation of a nonmetallic aortic valve prosthesis in high-surgical-risk patients with severe aortic stenosis: a first-in-man feasibility and safety study	Schofer J	Circ Cardiovasc Interv	2008
18573397	United States feasibility study of transcatheter insertion of a stented aortic valve by the left ventricular apex	Svensson LG	Ann Thorac Surg	2008
17015786	Percutaneous implantation of the CoreValve self-expanding valve prosthesis in high-risk patients with aortic valve disease: the Siegburg first-in-man study	Grube E	Circulation	2006
16545654	Treatment of calcific aortic stenosis with the percutaneous heart valve: mid-term follow-up from the initial feasibility studies: the French experience	Cribier A	J Am Coll Cardiol	2006

1.4 Transcatheter mitral valve repair and replacement devices

Table 7. List of transcatheter mitral valve repair and replacement devices

Class of device	Devices
Transcatheter mital valve repair and replacement systems	Edge-to-Edge Repair: **MitraClip** [Abbott] **MitraClip NT** [Abbott] **MitraClip NTR** [Abbott] **MitraClip XTR** [Abbott] **MitraClip G4** [Abbott] **PASCAL** [Edwards Lifesciences] **PASCAL Ace** [Edwards Lifesciences] Annuloplasty: **Cardioband** Mitral [Valtech Cardio / Edwards Lifesciences] **Carillon Mitral Countour System** [Cardiac dimensions] **Mitralign** [Mitralign Inc / Edwards Lifesciences] Mitral Valve Replacement: **Tendyne** [Abbott] Other approaches: **Harpoon TDS-5** [Edwards Lifesciences] **NeoChord DS1000** [NeoChord, Inc.]

Table 8. List of prospective studies fulfilling the pre-specified inclusion criteria on transcatheter mitral valve repair and replacement systems

PMID	Title	First Author	Journal	Publication Year
33038223	Safety and performance of a novel transventricular beating heart mitral valve repair system: 1-year outcomes	Gammie JS	Eur J Cardiothorac Surg	2021
34039025	Relationship Between Residual Mitral Regurgitation and Clinical and Quality-of-Life Outcomes After Transcatheter and Medical Treatments in Heart Failure: COAPT Trial	Kar S	Circulation	2021

33619896	Functional outcomes with Carillon device over 1 year in patients with functional mitral regurgitation of Grades 2+ to 4+: results from the REDUCE-FMR trial	Khan MS	ESC Heart Fail	2021
34391744	Sex-Specific Outcomes of Transcatheter Mitral-Valve Repair and Medical Therapy for Mitral Regurgitation in Heart Failure	Kosmidou I	JACC Heart Fail	2021
34004077	Early outcomes from the CLASP IID trial roll-in cohort for prohibitive risk patients with degenerative mitral regurgitation	Lim DS	Catheter Cardiovasc Interv	2021
33632476	3-Year Outcomes of Transcatheter Mitral Valve Repair in Patients With Heart Failure	Mack MJ	J Am Coll Cardiol	2021
34141859	Extent and determinants of left ventricular reverse remodeling in patients with secondary mitral regurgitation undergoing MitraClip implantation	Spieker M	Int J Cardiol Heart Vasc	2021
34020928	2-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study	Szerlip M	JACC Cardiovasc Interv	2021
33979403	Safety, effectiveness and costs of percutaneous mitral valve repair: A real-world prospective study	Willits I	PLoS One	2021
32194195	Health Status Changes and Outcomes in Patients With Heart Failure and Mitral Regurgitation: COAPT Trial	Arnold SV	J Am Coll Cardiol	2020
33092705	NYHA Functional Classification and Outcomes After Transcatheter Mitral Valve Repair in Heart Failure: The COAPT Trial	Giustino G	JACC Cardiovasc Interv	2020
33047896	Long-term prognosis of patients treated by coronary sinus-based percutaneous annuloplasty: single centre experience	Lipiecki J	ESC Heart Fail	2020

32065722	Left atrial global function in chronic heart failure patients with functional mitral regurgitation after MitraClip	Öztürk C	Catheter Cardiovasc Interv	2020
33092709	1-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study	Webb JG	JACC Cardiovasc Interv	2020
30894288	Health Status After Transcatheter Mitral-Valve Repair in Heart Failure and Secondary Mitral Regurgitation: COAPT Trial	Arnold SV	J Am Coll Cardiol	2019
31476260	Percutaneous repair or medical treatment for secondary mitral regurgitation: outcomes at 2 years	Iung B	Eur J Heart Fail	2019
30077993	Five-year outcomes of transcatheter reduction of significant mitral regurgitation in high-surgical-risk patients	Kar S	Heart	2019
31255562	Transcatheter Valve Repair for Patients With Mitral Regurgitation: 30-Day Results of the CLASP Study	Lim DS	JACC Cardiovasc Interv	2019
30124798	Transcatheter mitral valve repair for functional mitral regurgitation using the Cardioband system: 1 year outcomes	Messika-Zeitoun D	Eur Heart J	2019
30898200	Initial Feasibility Study of a New Transcatheter Mitral Prosthesis: The First 100 Patients	Sorajja P	J Am Coll Cardiol	2019
31521683	The REDUCE FMR Trial: A Randomized Sham-Controlled Study of Percutaneous Mitral Annuloplasty in Functional Mitral Regurgitation	Witte KK	JACC Heart Fail	2019
30145927	Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation	Obadia JF	N Engl J Med	2018

30280640	Transcatheter Mitral-Valve Repair in Patients with Heart Failure	Stone GW	N Engl J Med	2018
28831993	Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study	Praz F	Lancet	2017
26655529	Transapical off-pump mitral valve repair with Neochord implantation: Early clinical results	Colli A	Int J Cardiol	2016
27436878	Transapical Beating-Heart Mitral Valve Repair With an Expanded Polytetrafluoroethylene Cordal Implantation Device: Initial Clinical Experience	Gammie JS	Circulation	2016
27493761	Coronary sinus-based percutaneous annuloplasty as treatment for functional mitral regurgitation: the TITAN II trial	Lipiecki J	Open Heart	2016
26586779	Cardioband, a transcatheter surgical-like direct mitral valve annuloplasty system: early results of the feasibility trial	Maisano F	Eur Heart J	2016
28040318	Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation: A Global Feasibility Trial	Muller DWM	J Am Coll Cardiol	2017
27712741	Transcatheter Mitral Annuloplasty in Chronic Functional Mitral Regurgitation: 6-Month Results With the Cardioband Percutaneous Mitral Repair System	Nickenig G	JACC Cardiovasc Interv	2016
26718672	Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation: 5-Year Results of EVEREST II	Feldman T	J Am Coll Cardiol	2015
25944047	Assessment of acute changes in ventricular volumes, function, and strain after interventional edge-to-edge repair of mitral regurgitation using cardiac magnetic resonance imaging	Lurz P	Eur Heart J Cardiovasc Imaging	2015

25011722	Percutaneous mitral valve repair for mitral regurgitation in high-risk patients: results of the EVEREST II study	Glower DD	J Am Coll Cardiol	2014
24100100	Off-pump transapical implantation of artificial chordae to correct mitral regurgitation: early results of a single-center experience	Rucinskas K	J Thorac Cardiovasc Surg	2014
24895448	Acute changes of mitral valve geometry during interventional edge-to-edge repair with the MitraClip system are associated with midterm outcomes in patients with functional valve disease: preliminary results from a prospective single-center study	Schueler R	Circ Cardiovasc Interv	2014
24076529	Off-pump transapical implantation of artificial neo-chordae to correct mitral regurgitation: the TACT Trial (Transapical Artificial Chordae Tendinae) proof of concept	Seeburger J	J Am Coll Cardiol	2014
23747789	Percutaneous mitral valve interventions in the real world: early and 1-year results from the ACCESS-EU, a prospective, multicenter, nonrandomized post-approval study of the MitraClip therapy in Europe	Maisano F	J Am Coll Cardiol	2013
23665364	4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation	Mauri L	J Am Coll Cardiol	2013
22188385	In-hospital outcome of patients with severe mitral valve regurgitation classified as inoperable and treated with the MitraClip® device	Divchev D	J Interv Cardiol	2012
22613584	Treatment of functional mitral regurgitation by percutaneous annuloplasty: results of the TITAN Trial	Siminiak T	Eur J Heart Fail	2012
21463154	Percutaneous repair or surgery for mitral regurgitation	Feldman T	N Engl J Med	2011

1.5 Surgical heart valve replacement devices

Table 9. List of surgical heart valve replacement devices

Class of device	Devices
Surgical heart valves	Aortic bioprosthetic: **Avalus** [Medtronic] **Biocor Aortic** [Abbott] **Crown PRT** [Sorin/Livanova/Corcym] **Epic Aortic** [Abbott] **Inspiris Resilia** [Edwards Lifesciences] **Intuity** [Edwards Lifesciences] **Intuity Elite** [Edwards Lifesciences] **Mitroflow** [Sorin/Livanova/Corcym] **Perceval** [Sorin/Livanova/Corcym] **Perceval Plus** [Sorin/Livanova/Corcym] **Perimount Magna, model 3000/3000TFX** [Edwards Lifesciences] **Perimount Magna Ease, model 3300 TFX** [Edwards Lifesciences] **Solo Smart** [Sorin/Livanova/Corcym] **Trifecta** [Abbott] **3F Enable** [Medtronic] Aortic mechanical: **Aortic ON-X with Conform-X sewing ring** [Cryolife] **Aortic ON-X with anatomic sewing ring** [Cryolife] Mitral bioprosthetic: **Biocor Mitral** [Abbott] **Epic Mitral** [Abbott] **Magna Mitral Ease, model 7300 and 7300TFX** [Edwards Lifesciences] **Perimount Plus, model 6900 PTFX** [Edwards Lifesciences]

1.5.1 Aortic surgical valves

Table 10. List of prospective studies fulfilling the pre-specified inclusion criteria on surgical heart (aortic) valves

PMID	Title	Author	Journal	Publication Year
34053453	Clinical outcomes after implantation of a sutureless aortic bioprosthesis with concomitant mitral valve surgery: the SURE-AVR registry	Baghai	J Cardiothorac Surg	2021
33478837	Sutureless versus conventional bioprostheses for aortic valve replacement in severe symptomatic aortic valve stenosis	Fischlein	J Thorac Cardiovasc Surg	2021
33597099	Midterm outcomes with a sutureless aortic bioprosthesis in a prospective multicenter cohort study	Fischlein	J Thorac Cardiovasc Surg	2021
32340804	Intermediate-term outcomes of aortic valve replacement using a bioprosthesis with a novel tissue	Johnston	J Thorac Cardiovasc Surg	2021
33776017	Two-Year Results of the 17-mm Avalus Aortic Valve in the PERIGON Japan Trial	Okita	Circ J	2021
34036633	Five-year outcomes of rapid-deployment aortic valve replacement with the Edwards Intuity valve	Pelce	J Card Surg	2021
32674180	Single-Center Outcomes with Rapid Deployment Aortic Valve Replacement	Schlömicher	Thorac Cardiovasc Surg	2021
34830622	One-Year Hemodynamic Performance of Three Cardiac Aortic Bioprostheses: A Randomized Comparative Clinical Trial	Montero-Cruces	J Clin Med	2021

32832413	Outcome of rapid deployment aortic valves: long-term experience after 700 implants	Coti	Ann Cardiothorac Surg	2020
31590957	Safety, efficacy, and hemodynamic performance of a stented bovine pericardial aortic valve bioprosthesis: Two-year analysis	Dagenais	J Thorac Cardiovasc Surg	2020
31875777	Minimally Invasive Aortic Valve Replacement with Sutureless Valves: Results From an International Prospective Registry	Glauber	Innovations (Phila)	2020
30553598	Prospective US investigational device exemption trial of a sutureless aortic bioprosthesis: One-year outcomes	Suri	J Thorac Cardiovasc Surg	2019
30137264	Intermediate-term outcome of 500 consecutive rapid-deployment surgical aortic valve procedures	Andreas M	Eur J Cardiothorac Surg	2019
29778342	One-year outcomes associated with a novel stented bovine pericardial aortic bioprosthesis	Sabik	J Thorac Cardiovasc Surg	2018
29415382	One-year outcomes after rapid-deployment aortic valve replacement	Young	J Thorac Cardiovasc Surg	2018
28475690	Safety, effectiveness and haemodynamic performance of a new stented aortic valve bioprosthesis	Klautz R	Eur J Cardiothorac Surg	2017
28453629	Long-term outcomes of a rapid deployment aortic valve: data up to 5 years	Laufer	Eur J Cardiothorac Surg	2017

28605428	The COMMENCE trial: 2-year outcomes with an aortic bioprosthesis with RESILIA tissue	Puskas	Eur J Cardiothorac Surg	2017
28369288	Rapid-deployment aortic valve replacement for severe aortic stenosis: 1-year outcomes in 150 patients	Theron	Interact Cardiovasc Thorac Surg	2017
27817951	TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve	Barnhart	J Thorac Cardiovasc Surg	2016
26656235	Early haemodynamic performance of a latest generation supra-annular aortic bioprosthesis: experience from a large single-centre series	Deutsch	Eur J Cardiothorac Surg	2016
27964975	Midterm, multicenter clinical and hemodynamic results for the Trifecta aortic pericardial valve	Goldman	J Thorac Cardiovasc Surg	2016
26245628	Clinical and haemodynamic outcomes in 658 patients receiving the Perceval sutureless aortic valve: early results from a prospective European multicentre study (the Cavalier Trial)	Laborde	Eur J Cardiothorac Surg	2016
26984983	Durability after aortic valve replacement with the Mitroflow versus the Perimount pericardial bioprosthesis: a single-centre experience in 2393 patients	Nielsen	Eur J Cardiothorac Surg .	2016
26935407	Haemodynamic benefits of rapid deployment aortic valve replacement via a minimally invasive approach: 1-year results of a prospective multicentre randomized controlled trial	Borger M	Eur J Cardiothorac Surg	2016

25750010	European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients	Shrestha	Eur J Cardiothorac Surg	2016
26892076	Early outcomes after isolated aortic valve replacement with rapid deployment aortic valve	Wahlers	J Thorac Cardiovasc Surg	2016
26589286	St. Jude Medical Trifecta aortic valve: results from a prospective regional multicentre registry	Mariscalco	J Cardiothorac Surg	2015
25451486	Minimal access rapid deployment aortic valve replacement: initial single-center experience and 12-month outcomes	Schlömicher	J Thorac Cardiovasc Surg	2015
25441065	A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement	Borger M	Ann Thorac Surg	2015
25439772	Do differences in early hemodynamic performance of current generation biologic aortic valves predict outcomes 1 year following surgery?	Thalji	J Thorac Cardiovasc Surg	2015
24787699	Clinical performance of a sutureless aortic bioprosthesis: five-year results of the 3f Enable long-term follow-up study	Englberger	J Thorac Cardiovasc Surg	2014
25106682	Aortic valve replacement and concomitant procedures with the Perceval valve: results of European trials	Shrestha	Ann Thorac Surg	2014
23477687	The St Jude Medical Trifecta aortic pericardial valve: results from a global, multicenter, prospective clinical study	Bavarai J	J Thorac Cardiovasc Surg	2014

23058665	One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System	Kocher	J Thorac Cardiovasc Surg	2013
23825161	St. Jude Medical Trifecta™ aortic valve perioperative performance in 200 patients	Permanyer	Interact Cardiovasc Thorac Surg	2013
23673064	The Perceval S aortic valve has the potential of shortening surgical time: does it also result in improved outcome?	Santarpino	Ann Thorac Surg	2013
22818964	Mitroflow aortic bioprosthesis 5-year follow-up: north american prospective multicenter study	Asch	Ann Thorac Surg	2012
22541180	Sutureless perceval aortic valve replacement: results of two European centers	Folliguet	Ann Thorac Surg	2012
21277603	St Jude Medical Epic porcine bioprosthesis: results of the regulatory evaluation	Jamieson	J Thorac Cardiovasc Surg	2011
21342776	Clinical experience with the ATS 3f Enable® Sutureless Bioprosthesis	Martens	Eur J Cardiothorac Surg	2011

1.5.2 Mitral surgical valves

Table 11. List of prospective studies fulfilling the pre-specified inclusion criteria on surgical heart (mitral) valves

PMID	Title	Author	Journal	Publication Year
29029949	Mitral Valve Replacement Using Carpentier-Edwards Pericardial Bioprosthesis in Patients With Rheumatic Heart Disease Aged Below 40 Years: 17-Year Results	Chowdhury	Heart Lung Circ	2018

1.6 Leadless pacemakers

Table 12. List of leadless pacemakers

Class of device	Devices
Leadless pacemakers	**Micra VR TPS** [Medtronic] **Micra AV TPS** [Medtronic]

Table 13. List of prospective studies fulfilling the pre-specified inclusion criteria on leadless pacemaker

PMID	Title	First author	Journal	Publication Year
34141021	Individualized left anterior oblique projection based on pigtail catheter visualization facilitates leadless pacemaker implantation	Yamao K	J Arrhythm	2021
33928713	Behavior of AV synchrony pacing mode in a leadless pacemaker during variable AV conduction and arrhythmias	Garweg C	J Cardiovasc Electrophysiol	2021
33682228	Quantification of artifacts during cardiac magnetic resonance in patients with leadless Micra pacemakers	Hála P	J Cardiovasc Electrophysiol	2021
33418071	Conventional single-chamber pacemakers versus transcatheter pacing systems in a "real world" cohort of patients: A comparative prospective single-center study	Martinez-Sande JL	Indian Pacing Electrophysiol J	2021
33217535	Implantation of the Micra transcatheter pacing system: A single center North India experience	Kumar V	Indian Pacing Electrophysiol J	2021

32860605	Security millimetre wave body scanner safe for patients with leadless pacemakers or subcutaneous implantable cardioverter-defibrillators	Blažek P	J Interv Card Electrophysiol	2021
32717315	Predictors of atrial mechanical sensing and atrioventricular synchrony with a leadless ventricular pacemaker: Results from the MARVEL 2 Study	Garweg C	Heart Rhythm	2020
31709982	Atrioventricular Synchronous Pacing Using a Leadless Ventricular Pacemaker: Results From the MARVEL 2 Study	Steinwender C	JACC Clin Electrophysiol	2020
31395499	Performance of the Micra cardiac pacemaker in nonagenarians	El Amrani A	Rev Esp Cardiol (Engl Ed)	2020
31180481	Micra pacemaker implant after cardiac implantable electronic device extraction: feasibility and long-term outcomes	Zucchelli G	Europace	2019
30687931	Behavior of leadless AV synchronous pacing during atrial arrhythmias and stability of the atrial signals over time-Results of the MARVEL Evolve subanalysis	Garweg C	Pacing Clin Electrophysiol	2019
30550834	Safety and feasibility of a midseptal implantation technique of a leadless pacemaker	Hai JJ	Heart Rhythm	2019
30392985	Leadless Permanent Pacing: A Single Centre Australian Experience	Denman RA	Heart Lung Circ	2019
30221378	Acute and long-term outcomes of simultaneous atrioventricular node ablation and leadless pacemaker implantation	Martínez-Sande JL	Pacing Clin Electrophysiol	2018

30176097	Physical activity detection in patients with intracardiac leadless pacemaker	Bari Z	J Cardiovasc Electrophysiol	2018
30168233	Health-related quality of life impact of a transcatheter pacing system	Tjong FVY	J Cardiovasc Electrophysiol	2018
30103071	Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control	El-Chami MF	Heart Rhythm	2018
29986008	Monocenter Investigation Micra® MRI study (MIMICRY): feasibility study of the magnetic resonance imaging compatibility of a leadless pacemaker system	Blessberger H	Europace	2019
29973228	Artefacts in 1.5 Tesla and 3 Tesla cardiovascular magnetic resonance imaging in patients with leadless cardiac pacemakers	Kiblboeck D	J Cardiovasc Magn Reson	2018
29758405	Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: Results from the Micra atrioventricular feasibility studies	Chinitz L	Heart Rhythm	2018
28666317	Right ventricular and tricuspid valve function in patients chronically implanted with leadless pacemakers	Salaun E	Europace	2018
28502871	A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry	Roberts PR	Heart Rhythm	2017
28192207	Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study	Duray GZ	Heart Rhythm	2017

28040461	The Micra Leadless Transcatheter Pacemaker. Implantation and Mid-term Follow-up Results in a Single Center	Martínez-Sande JL	Rev Esp Cardiol (Engl Ed)	2017
27871854	Rate adaptive pacing in an intracardiac pacemaker	Lloyd M	Heart Rhythm	2017
27855290	Transcatheter leadless cardiac pacing: The new alternative solution	Da Costa A	Int J Cardiol	2017
26551877	A Leadless Intracardiac Transcatheter Pacing System	Reynolds D	N Engl J Med	2016
26045305	Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study	Ritter P	Eur Heart J	2015

1.7 Subcutaneous implantable cardioverter-defibrillators

Table 14. List of subcutaneous implantable cardioverter-defibrillators

Class of device	Devices
Subcutaneous implantable cardioverter defibrillator	**EMBLEM MRI S-ICD** [Boston Scientific]

Table 15. List of prospective studies fulfilling the pre-specified inclusion criteria on subcutaneous implantable cardioverter defibrillator

PMID	Title	First author	Journal	Publication Year
34307829	Adjunctive hypnotic communication for analgosedation in subcutaneous implantable cardioverter defibrillator implantation. A prospective single center pilot study	Scaglione M	Int J Cardiol Heart Vasc	2021
34140203	Use of Serratus Anterior Plane and Transversus Thoracis Plane Blocks for Subcutaneous Implantable Cardioverter-Defibrillator (S-ICD) Implantation Decreases Intraoperative Opioid Requirements	Shariat A	J Cardiothorac Vasc Anesth	2021
33969569	Rate and impact on patient outcome and healthcare utilization of complications requiring surgical revision: Subcutaneous versus transvenous implantable defibrillator therapy	Palmisano P	J Cardiovasc Electrophysiol	2021
33538124	Eligibility for subcutaneous implantable cardioverter-defibrillator in adults with congenital heart disease	Zormpas C	ESC Heart Fail	2021
33516714	Is 40 Joules Enough to Successfully Defibrillate With Subcutaneous Implantable Cardioverter-Defibrillators?	Biffi M	JACC Clin Electrophysiol	2021
33213814	1-Year Prospective Evaluation of Clinical Outcomes and Shocks: The Subcutaneous ICD Post Approval Study	Burke MC	JACC Clin Electrophysiol	2020

33073614	Primary Results From the Understanding Outcomes With the S-ICD in Primary Prevention Patients With Low Ejection Fraction (UNTOUCHED) Trial	Gold MR	Circulation	2021
32860605	Security millimetre wave body scanner safe for patients with leadless pacemakers or subcutaneous implantable cardioverter-defibrillators	Blažek P	J Interv Card Electrophysiol	2021
32757521	Subcutaneous or Transvenous Defibrillator Therapy	Knops RE	N Engl J Med	2020
32613315	Eligibility for subcutaneous implantable cardioverter-defibrillator in patients with left ventricular assist device	Zormpas C	J Interv Card Electrophysiol	2021
32596027	Same-day Discharge after Subcutaneous Implantable Cardioverter-defibrillator Implantation is Safe and Cost-effective	Swinning J	J Innov Card Rhythm Manag	2020
32376304	Outcomes of subcutaneous implantable cardioverter-defibrillator in dialysis patients: Results from the S-ICD post-approval study	El-Chami MF	Heart Rhythm	2020
31813098	Feasibility and safety of same day subcutaneous defibrillator implantation and send home (DASH) strategy	Okabe T	J Interv Card Electrophysiol	2020
31778266	Serratus anterior plane block in subcutaneous implantable cardioverter defibrillator implantation: A case-control analysis	Ziacchi M	J Cardiovasc Electrophysiol	2020
31512339	Minimal defibrillation thresholds and the correlation with implant position in subcutaneous implantable-defibrillator patients	Quast ABE	J Cardiovasc Electrophysiol	2019
31048064	Incidence of myopotential induction in subcutaneous implantable cardioverter-defibrillator patients: Is the oversensing issue really solved?	van den Bruck JH	Heart Rhythm	2019

30661851	Subcutaneous implantable cardioverter defibrillator in patients with arrhythmogenic right ventricular cardiomyopathy: Results from an Italian multicenter registry	Migliore F	Int J Cardiol	2019
30609077	A report on the impact of remote monitoring in patients with S-ICD: Insights from a prospective registry	Ninni S	Pacing Clin Electrophysiol	2019
29798794	Impact of Body Mass Index on Safety and Efficacy of the Subcutaneous Implantable Cardioverter-Defibrillator	Frankel DS	JACC Clin Electrophysiol	2018
29758404	Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter-defibrillator	Theuns DAMJ	Heart Rhythm	2018
28536837	Controlled sedation with midazolam and analgesia with nalbuphine to alleviate pain in patients undergoing subcutaneous implantable cardioverter defibrillator implantation	Peyrol M	J Interv Card Electrophysiol	2017
28502872	Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results	Gold MR	Heart Rhythm	2017
28007749	Intermuscular technique for implantation of the subcutaneous implantable cardioverter defibrillator: long-term performance and complications	Winter J	Europace	2017
27943358	Intermuscular Two-Incision Technique for Subcutaneous Implantable Cardioverter Defibrillator Implantation: Results from a Multicenter Registry	Migliore F	Pacing Clin Electrophysiol	2017
27068637	Intraoperative Defibrillation Testing of Subcutaneous Implantable Cardioverter-Defibrillator Systems-A Simple Issue?	Frommeyer G	J Am Heart Assoc	2016
25687749	Magnetic resonance imaging in patients with a subcutaneous implantable cardioverter-defibrillator	Keller J	Europace	2015

23979626	Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator	Weiss R	Circulation	2013
23707489	Two-incision technique for implantation of the subcutaneous implantable cardioverter-defibrillator	Knops RE	Heart Rhythm	2013
22035049	Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START study	Gold MR	J Cardiovasc Electrophysiol	2012

2 Diabetes devices

Detailed information about the information sources, search strategies and study eligibility criteria are available in the published protocol[1].

Table 16. List of selected papers featuring eligible studies on diabetes devices

PMID	Device	First author	Title	Journal	Publication Year
35136338	Medtronic 670G	Amole, M.	Real-World Experience With Automated Insulin Pump Technology in Veterans With Type 1 Diabetes	Federal Practitioner	2021
35116007	Control IQ & Medtronic 780G	Bassi, M.	A Comparison of Two Hybrid Closed-Loop Systems in Italian Children and Adults With Type 1 Diabetes	Frontiers in Endocrinology	2022
35099298	Medtronic 670G	Jacobsen, S. S.	Glycemic effects and predictors of increased time-in-range after initiating MiniMed 670G: a 12-month observational study	Diabetes technology & therapeutics	2022
35099294	Control-IQ	Levy, C.	Insulin Delivery and Glucose Variability throughout the Menstrual Cycle on Closed Loop Control for Women with Type 1 Diabetes	Diabetes Technology & Therapeutics	2022
35099278	Loop	Suttiratana, S.	Qualitative Study of User Experiences with Loop, an Open-Source Automated Insulin Delivery (AID) System	Diabetes Technology & Therapeutics	2022

35072781	Medtronic 780G	Petrovski, G.	Successful transitioning children and adolescents with type 1 diabetes from multiple daily injections to advanced hybrid closed-loop system in 10 days: a prospective intervention study on MiniMed 780G system	Acta Diabetologica	2022
35045227	CamAPS FX	Ware, J.	Randomized Trial of Closed-Loop Control in Very Young Children with Type 1 Diabetes	New England Journal of Medicine	2022
35020488	Control-IQ	Ekhlaspour, L.	Glycemic Outcomes in Baseline Hemoglobin A1C Subgroups in the International Diabetes Closed-Loop (iDCL) Trial	Diabetes Technology & Therapeutics	2022
35020476	Control-IQ	Scully, K. J.	The effect of Control IQ TM hybrid closed loop technology on glycemic control in adolescents and adults with cystic fibrosis related diabetes	Diabetes Technology & Therapeutics	2022
35001477	Medtronic 670G	Forlenza, G. P.	Glycemic outcomes of children 2–6 years of age with type 1 diabetes during the pediatric MiniMed™ 670G system trial	Pediatric Diabetes	2022
34984786	Eversense	Renard, E.	Reduction of clinically important low glucose excursions with a long-term implantable continuous glucose monitoring system in adults with type 1 diabetes prone to hypoglycaemia: the France Adoption Randomized Clinical Trial	Diabetes, Obesity & Metabolism	2022
34962164	Control-IQ	Schoelwer, M.	Assessment for Predictors of Rise in HbA1c During Extended Use of a Closed-Loop Control System	Diabetes Technology & Therapeutics	2021

34858339	Medtronic 780G	Tornese, G.	Six-Month Effectiveness of Advanced vs. Standard Hybrid Closed-Loop System in Children and Adolescents With Type 1 Diabetes Mellitus	Frontiers in Endocrinology	2021
34844995	Medtronic 670G	McAuley, S. A.	Closed-Loop Insulin Delivery Versus Sensor-Augmented Pump Therapy in Older Adults With Type 1 Diabetes (ORACL): A Randomized, Crossover Trial	Diabetes Care	2022
34816597	Control-IQ	Renard, E.	Outcomes of hybrid closed-loop insulin delivery activated 24/7 versus evening and night in free-living prepubertal children with type 1 diabetes: A multicentre, randomized clinical trial	Diabetes, Obesity & Metabolism	2022
34789504	Medtronic 670G	Paldus, B.	A Randomized Crossover Trial Comparing Glucose Control During Moderate-Intensity, High-Intensity, and Resistance Exercise With Hybrid Closed-Loop Insulin Delivery While Profiling Potential Additional Signals in Adults With Type 1 Diabetes	Diabetes Care	2022
34780283	Loop	Wong, J.	Discontinued Use of the Loop Insulin Dosing System: A Mixed-Methods Investigation	Diabetes Technology & Therapeutics	2021
34725723	Medtronic 780G	Thivolet, C.	Hybrid closed Loop improved glucose control compared to sensor-augmented pumps in outpatients with type 1 diabetes in real-life conditions with telehealth monitoring	Acta Diabetologica	2021
34694909	Medtronic 780G	Carlson, A. L.	Safety and Glycemic Outcomes During the MiniMed TM Advanced Hybrid Closed-Loop System Pivotal Trial in Adolescents and Adults with Type 1 Diabetes	Diabetes Technology & Therapeutics	2021

34668782	Medtronic 670G	Proietti, A.	Six-Month Glycemic Control with a Hybrid Closed-Loop System in Type 1 Diabetes Patients in a Latin American Country	Diabetes Technology & Therapeutics	2022
34633418	Medtronic 670G	Abraham, M. B.	Effect of a Hybrid Closed-Loop System on Glycemic and Psychosocial Outcomes in Children and Adolescents With Type 1 Diabetes: A Randomized Clinical Trial	JAMA Pediatrics	2021
34632815	Medtronic 670G	Bozzetto, L.	Clinical Outcomes of Remote Training for Advanced Diabetes Technologies During the COVID-19 Pandemic	Journal of Diabetes Science and Technology	2021
34609917	Control-IQ	Toschi, E.	Closed-Loop Insulin Therapy in Older Adults with Type 1 Diabetes: Real-World Data	Diabetes Technology & Therapeutics	2022
34569850	Medtronic 670G	Ju, Z.	Advanced Diabetes Technology Remains Underutilized in Underserved Populations: Early Hybrid Closed-Loop System Experience at an Academic Safety Net Hospital	Diabetes Technology & Therapeutics	2022
34524023	Medtronic 670G	Dubose, S. N.	Real-World, Patient-Reported and Clinic Data from Individuals with Type 1 Diabetes Using the MiniMed 670G Hybrid Closed-Loop System	Diabetes Technology and Therapeutics	2021
34524022	Medtronic 780G	Morrison, D.	Comparable Glucose Control with Fast-Acting Insulin Aspart Versus Insulin Aspart Using a Second-Generation Hybrid Closed-Loop System During Exercise	Diabetes Technology & Therapeutics	2022
34524003	Medtronic 780G	Silva, J. D.	Real-World Performance of the MiniMed TM 780G System: First Report of Outcomes from 4120 Users	Diabetes Technology & Therapeutics	2022

34515521	Eversense	Garg, S. K.	Evaluation of Accuracy and Safety of the Next-Generation Up to 180-Day Long-Term Implantable Eversense Continuous Glucose Monitoring System: The PROMISE Study	Diabetes Technology & Therapeutics	2022
34453208	Medtronic 780G	Wheeler, B. J.	Improved technology satisfaction and sleep quality with Medtronic MiniMed® Advanced Hybrid Closed-Loop delivery compared to predictive low glucose suspend in people with Type 1 Diabetes in a randomized crossover trial	Acta Diabetologica	2021
34362816	Medtronic 780G	Lee, M. H.	Fast-Acting Insulin Aspart Versus Insulin Aspart Using a Second-Generation Hybrid Closed-Loop System in Adults With Type 1 Diabetes: A Randomized, Open-Label, Crossover Trial	Diabetes Care	2021
34349267	CamAPS HX	Boughton, C. K.	Fully automated closed-loop glucose control compared with standard insulin therapy in adults with type 2 diabetes requiring dialysis: an open-label, randomized crossover trial	Nature Medicine	2021
34329691	Medtronic 780G	Beato-Vibora, P. I.	Amelioration of user experiences and glycaemic outcomes with an Advanced Hybrid Closed Loop System in a real-world clinical setting	Diabetes Research & Clinical Practice	2021
34315271	Medtronic 670G	Paldus, B.	First Randomized Controlled Trial of Hybrid Closed Loop Versus Multiple Daily Injections or Insulin Pump Using Self-Monitoring of Blood Glucose in Free-Living Adults with Type 1 Diabetes Undertaking Exercise	Journal of Diabetes Science & Technology	2021
34270335	Medtronic 670G	Bode, B.	Ultrarapid Lispro Demonstrates Similar Time in Target Range to Lispro with a Hybrid Closed-Loop System	Diabetes Technology & Therapeutics	2021

34270328	Medtronic 780G	Hood, K. K.	Lived Experience of Advanced Hybrid Closed-Loop Versus Hybrid Closed-Loop: Patient-Reported Outcomes and Perspectives	Diabetes Technology & Therapeutics	2021
34227214	Control-IQ	Cherubini, V.	Effectiveness of a closed-loop control system and a virtual educational camp for children and adolescents with type 1 diabetes: A prospective, multicentre, real-life study	Diabetes, Obesity & Metabolism	2021
34196924	Eversense	Boscari, F.	Implantable and transcutaneous continuous glucose monitoring system: a randomized cross over trial comparing accuracy, efficacy and acceptance	Journal of Endocrinological Investigation	2022
34120699	Medtronic 670G	Nally, L. M.	A Pilot Study of Youth With Type 1 Diabetes Initiating Use of a Hybrid Closed-Loop System While Receiving a Behavioral Economics Intervention	Endocrine Practice	2021
34115959	Control-IQ	Kudva, Y. C.	Patient-Reported Outcomes in a Randomized Trial of Closed-Loop Control: The Pivotal International Diabetes Closed-Loop Trial	Diabetes Technology & Therapeutics	2021
34099518	Omnipod 5	Brown, S. A.	Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customizable Glycemic Targets in Pediatric and Adult Participants With Type 1 Diabetes	Diabetes Care	2021
34096789	Control-IQ	Messer, L. H.	Real-World Use of a New Hybrid Closed Loop Improves Glycemic Control in Youth with Type 1 Diabetes	Diabetes Technology & Therapeutics	2021
34095484	Medtronic 670G	Atif, Z.	Efficacy of Hybrid Closed-Loop Insulin Delivery System in a Hospital Setting: A Case Series	Aace Clinical Case Reports	2021

34058303	Medtronic 670G	Horowitz, M. E.	An analysis of Medtronic MiniMed 670G insulin pump use in clinical practice and the impact on glycemic control, quality of life, and compliance	Diabetes Research & Clinical Practice	2021
34021021	CamAPS FX	Chen, N. S.	User Engagement With the CamAPS FX Hybrid Closed-Loop App According to Age and User Characteristics	Diabetes Care	2021
34015178	Medtronic 670G	Varimo, T.	First year on commercial hybrid closed-loop system-experience on 111 children and adolescents with type 1 diabetes	Pediatric Diabetes	2021
34010499	Medtronic 670G	Berget, C.	Real-world performance of hybrid closed loop in youth, young adults, adults and older adults with type 1 diabetes: Identifying a clinical target for hybrid closed-loop use	Diabetes, Obesity & Metabolism	2021
33999488	Medtronic 670G & Loop	Jeyaventhan, R.	A real-world study of user characteristics, safety and efficacy of open-source closed-loop systems and Medtronic 670G	Diabetes, Obesity & Metabolism	2021
33961340	Medtronic 670G	Da Silva, J.	Real-world performance of the MiniMed TM 670G system in Europe	Diabetes, Obesity & Metabolism	2021
33958309	Medtronic 670G	Wang, L. R.	Real-World Patient Experience of Long-Term Hybrid Closed-Loop Insulin Pump Use	Canadian Journal of Diabetes	2021
33906916	iLet	Castellanos, L. E.	Performance of the Insulin-Only iLet Bionic Pancreas and the Bihormonal iLet Using Dasiglucagon in Adults With Type 1 Diabetes in a Home-Use Setting	Diabetes Care	2021

33838993	Medtronic 670G	Beato-Vibora, P. I.	Real-world outcomes with different technology modalities in type 1 diabetes	Nutrition Metabolism & Cardiovascular Diseases	2021
33784196	Control-IQ	Breton, M. D.	One Year Real-World Use of the Control-IQ Advanced Hybrid Closed-Loop Technology	Diabetes Technology & Therapeutics	2021
33784187	Medtronic 780G	Beato-Vibora, P. I.	Rapid Improvement in Time in Range After the Implementation of an Advanced Hybrid Closed-Loop System in Adolescents and Adults with Type 1 Diabetes	Diabetes Technology & Therapeutics	2021
33689454	Control-IQ	Schoelwer, M. J.	Predictors of Time-in-Range (70-180 mg/dL) Achieved Using a Closed-Loop Control System	Diabetes Technology & Therapeutics	2021
33628834	Medtronic 670G	Malone, S. K.	Characterizing Glycemic Control and Sleep in Adults with Long-Standing Type 1 Diabetes and Hypoglycemia Unawareness Initiating Hybrid Closed Loop Insulin Delivery	Journal of Diabetes Research	2021
33606901	CamAPS FX	Boughton, C. K.	Hybrid closed-loop glucose control with faster insulin aspart compared with standard insulin aspart in adults with type 1 diabetes: A double-blind, multicentre, multinational, randomized, crossover study	Diabetes, Obesity & Metabolism	2021
33594987	Eversense	Boscari, F.	Comparing the accuracy of transcutaneous sensor and 90-day implantable glucose sensor	Nutrition, Metabolism and Cardiovascular Diseases	2021

33579715	Medtronic 780G	Collyns, O. J.	Improved Glycemic Outcomes With Medtronic MiniMed Advanced Hybrid Closed-Loop Delivery: Results From a Randomized Crossover Trial Comparing Automated Insulin Delivery With Predictive Low Glucose Suspend in People With Type 1 Diabetes	Diabetes Care	2021
33555982	Medtronic 670G	Burckhardt, M. A.	Impact of Hybrid Closed Loop Therapy on Hypoglycemia Awareness in Individuals with Type 1 Diabetes and Impaired Hypoglycemia Awareness	Diabetes Technology & Therapeutics	2021
33502062	Control-IQ	Messer, L. H.	Initiating hybrid closed loop: A program evaluation of an educator-led Control-IQ follow-up at a large pediatric clinic	Pediatric Diabetes	2021
33453783	Medtronic 670G & 780G	Bergenstal, R. M.	A comparison of two hybrid closed-loop systems in adolescents and young adults with type 1 diabetes (FLAIR): a multicentre, randomised, crossover trial	Lancet	2021
33451264	Control-IQ	Bisio, A.	The Impact of a Recently Approved Automated Insulin Delivery System on Glycemic, Sleep, and Psychosocial Outcomes in Older Adults With Type 1 Diabetes: A Pilot Study	Journal of Diabetes Science & Technology	2021
33450533	Medtronic 670G	Gomez, A. M.	Virtual training on the hybrid close loop system in people with type 1 diabetes (T1D) during the COVID-19 pandemic	Diabetes & Metabolic Syndrome	2021
33431420	Diabeloop DBLG1	Amadou, C.	Diabeloop DBLG1 Closed-Loop System Enables Patients With Type 1 Diabetes to Significantly Improve Their Glycemic Control in Real-Life Situations Without Serious Adverse Events: 6-Month Follow-up	Diabetes Care	2021

33430621	Medtronic 670G	Usoh, C. O.	Real-World Efficacy of the Hybrid Closed-Loop System	Journal of Diabetes Science and Technology	2021
33404325	Control-IQ	Cobry, E. C.	Health-Related Quality of Life and Treatment Satisfaction in Parents and Children with Type 1 Diabetes Using Closed-Loop Control	Diabetes Technology & Therapeutics	2021
33397767	Inreda AP	Blauw, H.	Fully Closed Loop Glucose Control With a Bihormonal Artificial Pancreas in Adults With Type 1 Diabetes: An Outpatient, Randomized, Crossover Trial	Diabetes Care	2021
33355258	Control-IQ	Kanapka, L. G.	Extended Use of the Control-IQ Closed-Loop Control System in Children With Type 1 Diabetes	Diabetes Care	2021
33325779	Omnipod 5	Forlenza, G. P.	First Outpatient Evaluation of a Tubeless Automated Insulin Delivery System with Customizable Glucose Targets in Children and Adults with Type 1 Diabetes	Diabetes Technology & Therapeutics	2021
33289242	Control-IQ	Bisio, A.	Sleep and diabetes-specific psycho-behavioral outcomes of a new automated insulin delivery system in young children with type 1 diabetes and their parents	Pediatric Diabetes	2021
33226840	Loop	Lum, J. W.	A Real-World Prospective Study of the Safety and Effectiveness of the Loop Open Source Automated Insulin Delivery System	Diabetes Technology & Therapeutics	2021
33216667	Control-IQ	Isganaitis, E.	Closed-Loop Insulin Therapy Improves Glycemic Control in Adolescents and Young Adults: Outcomes from the International Diabetes Closed-Loop Trial	Diabetes Technology & Therapeutics	2021

33185480	Medtronic 780G	Nimri, R.	Feasibility Study of a Hybrid Closed-Loop System with Automated Insulin Correction Boluses	Diabetes Technology & Therapeutics	2021
33155824	Control-IQ	O'Malley, G.	Clinical Management and Pump Parameter Adjustment of the Control-IQ Closed-Loop Control System: Results from a 6-Month, Multicenter, Randomized Clinical Trial	Diabetes Technology & Therapeutics	2021
33090016	Medtronic 670G	Ozer, K.	Fast Acting Insulin Aspart Compared with Insulin Aspart in the Medtronic 670G Hybrid Closed Loop System in Type 1 Diabetes: An Open Label Crossover Study	Diabetes Technology & Therapeutics	2021
33055139	Medtronic 670G	McAuley, S. A.	Six Months of Hybrid Closed-Loop Versus Manual Insulin Delivery With Fingerprick Blood Glucose Monitoring in Adults With Type 1 Diabetes: A Randomized, Controlled Trial	Diabetes Care	2020
33044604	Medtronic 670G	Petrovski, G.	One-year experience of hybrid closed-loop system in children and adolescents with type 1 diabetes previously treated with multiple daily injections: drivers to successful outcomes	Acta Diabetologica	2021
32998989	Medtronic 670G	Lehmann, V.	Lower Daily Carbohydrate Intake Is Associated With Improved Glycemic Control in Adults With Type 1 Diabetes Using a Hybrid Closed-Loop System	Diabetes Care	2020
32926958	Medtronic 670G	Longo, M.	Glycemic control in people with type 1 diabetes using a hybrid closed loop system and followed by telemedicine during the COVID-19 pandemic in Italy	Diabetes Research & Clinical Practice	2020
32885596	CamAPS HX	Banholzer, N.	Effect of nutrition on postprandial glucose control in hospitalized patients with type 2 diabetes receiving fully automated closed-loop insulin therapy	Diabetes, Obesity & Metabolism	2021

32846114	Control-IQ	Pinsker, J. E.	Real-World Patient-Reported Outcomes and Glycemic Results with Initiation of Control-IQ Technology	Diabetes Technology & Therapeutics	2021
32846062	Control-IQ	Breton, M. D.	A Randomized Trial of Closed-Loop Control in Children with Type 1 Diabetes	New England Journal of Medicine	2020
32784247	Eversense	Fokkert, M.	Performance of the Eversense versus the Free Style Libre Flash glucose monitor during exercise and normal daily activities in subjects with type 1 diabetes mellitus	BMJ Open Diabetes Research & Care	2020
32678672	Medtronic 670G	Vigersky, R. A.	The Effectiveness of Virtual Training on the MiniMed TM 670G System in People with Type 1 Diabetes During the COVID-19 Pandemic	Diabetes Technology & Therapeutics	2021
32520594	Medtronic 670G	Hsu, L.	Fast-Acting Insulin Aspart Use with the MiniMedTM670G System	Diabetes Technology and Therapeutics	2021
32471910	Control-IQ	Brown, S. A.	Glycemic Outcomes of Use of CLC Versus PLGS in Type 1 Diabetes: A Randomized Controlled Trial	Diabetes Care	2020
32421355	Medtronic 670G	Tornese, G.	Glycemic Control in Type 1 Diabetes Mellitus During COVID-19 Quarantine and the Role of In-Home Physical Activity	Diabetes Technology & Therapeutics	2020
32212971	Medtronic 670G	Cobry, E. C.	Impact of the Hybrid Closed-Loop System on Sleep and Quality of Life in Youth with Type 1 Diabetes and Their Parents	Diabetes Technology & Therapeutics	2020

32119790	Control-IQ	Schoelwer, M. J.	Safety and Efficacy of Initializing the Control-IQ Artificial Pancreas System Based on Total Daily Insulin in Adolescents with Type 1 Diabetes	Diabetes Technology & Therapeutics	2020
32037699	Eversense	Irace, C.	Clinical use of a 180-day implantable glucose sensor improves glycated haemoglobin and time in range in patients with type 1 diabetes	Diabetes, Obesity & Metabolism	2020
31953687	Medtronic 670G	Petrovski, G.	10-Day structured initiation protocol from multiple daily injection to hybrid closed-loop system in children and adolescents with type 1 diabetes	Acta Diabetologica	2020
31885123	Medtronic 670G	Messer, L. H.	Real world hybrid closed-loop discontinuation: Predictors and perceptions of youth discontinuing the 670G system in the first 6 months	Pediatric Diabetes	2020
31876178	Medtronic 670G	Petrovski, G.	From Multiple Daily Injections to Hybrid Closed-Loop System in Ten Days, Utilizing a Structured Initiation Protocol	Journal of Diabetes Science & Technology	2020
31855446	Medtronic 670G	Beato-Vibora, P. I.	Prospective Analysis of the Impact of Commercialized Hybrid Closed-Loop System on Glycemic Control, Glycemic Variability, and Patient-Related Outcomes in Children and Adults: A Focus on Superiority Over Predictive Low-Glucose Suspend Technology	Diabetes Technology & Therapeutics	2020
31837064	Medtronic 670G	Berget, C.	Six months of hybrid closed loop in the real-world: An evaluation of children and young adults using the 670G system	Pediatric Diabetes	2020
31796571	Medtronic 670G	Lee, M. H.	Glucose and Counterregulatory Responses to Exercise in Adults With Type 1 Diabetes and Impaired Awareness of Hypoglycemia Using Closed-Loop Insulin Delivery: A Randomized Crossover Study	Diabetes Care	2020

31789447	Medtronic 670G	Akturk, H. K.	Long-term real-life glycaemic outcomes with a hybrid closed-loop system compared with sensor-augmented pump therapy in patients with type 1 diabetes	Diabetes, Obesity & Metabolism	2020
31758630	Medtronic 670G	Polsky, S.	Case series of a hybrid closed-loop system used in pregnancies in clinical practice	Diabetes/Metabolism Research Reviews	2020
31709736	Medtronic 670G	Duffus, S. H.	Increased proportion of time in hybrid closed-loop "Auto Mode" is associated with improved glycaemic control for adolescent and young patients with adult type 1 diabetes using the MiniMed 670G insulin pump	Diabetes, Obesity & Metabolism	2020
31697182	Eversense	Tweden, K. S.	Longitudinal Analysis of Real-World Performance of an Implantable Continuous Glucose Sensor over Multiple Sensor Insertion and Removal Cycles	Diabetes Technology & Therapeutics	2020
31618560	Control-IQ	Brown, S. A.	Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes	New England Journal of Medicine	2019
31617752	Medtronic 670G	Lepore, G.	Switching from Suspend-Before-Low Insulin Pump Technology to a Hybrid Closed-Loop System Improves Glucose Control and Reduces Glucose Variability: A Retrospective Observational Case-Control Study	Diabetes Technology & Therapeutics	2020
31592137	MiniMed MIP 2007C	van Dijk, P. R.	Different routes of insulin administration do not influence serum free thiols in type 1 diabetes mellitus	Endocrinology, Diabetes and Metabolism	2019
31548247	Medtronic 670G	Lal, R. A.	One Year Clinical Experience of the First Commercial Hybrid Closed-Loop System	Diabetes Care	2019

31418587	Eversense	Deiss, D.	Real-World Safety of an Implantable Continuous Glucose Sensor Over Multiple Cycles of Use: A Post-Market Registry Study	Diabetes Technology & Therapeutics	2020
31385732	Eversense	Sanchez, P.	Real-World Data from the First U.S. Commercial Users of an Implantable Continuous Glucose Sensor	Diabetes Technology and Therapeutics	2019
31384716	MiniMed MIP 2007C	Van Dijk, P. R.	Route of Insulin Does Not Influence 25-Hydroxyvitamin D Concentrations in Type 1 Diabetes: A Brief Report	Journal of the Endocrine Society	2019
31347928	Medtronic 670G	Kaur, H.	Efficacy of Hybrid Closed-Loop System in Adults with Type 1 Diabetes and Gastroparesis	Diabetes Technology & Therapeutics	2019
31264889	Medtronic 770G	Lee, M. H.	Glucose Control in Adults with Type 1 Diabetes Using a Medtronic Prototype Enhanced-Hybrid Closed-Loop System: A Feasibility Study	Diabetes Technology & Therapeutics	2019
31166801	Medtronic 670G	Salehi, P.	Efficacy and Safety of Real-Life Usage of MiniMed 670G Automode in Children with Type 1 Diabetes Less than 7 Years Old	Diabetes Technology & Therapeutics	2019
31099946	Control-IQ	Ekhlaspour, L.	Closed loop control in adolescents and children during winter sports: Use of the Tandem Control-IQ AP system	Pediatric Diabetes	2019
31055947	Medtronic 670G	Grando, M. A.	Patient Perception and Satisfaction With Insulin Pump System: Pilot User Experience Survey	Journal of Diabetes Science & Technology	2019

30938036	Eversense	Aronson, R.	First assessment of the performance of an implantable continuous glucose monitoring system through 180 days in a primarily adolescent population with type 1 diabetes	Diabetes, Obesity & Metabolism	2019
30925083	Eversense	Christiansen, M. P.	A Prospective Multicenter Evaluation of the Accuracy and Safety of an Implanted Continuous Glucose Sensor: The PRECISION Study	Diabetes Technology & Therapeutics	2019
30888835	Control-IQ	Forlenza, G. P.	Successful At-Home Use of the Tandem Control-IQ Artificial Pancreas System in Young Children During a Randomized Controlled Trial	Diabetes Technology & Therapeutics	2019
30865545	Medtronic 670G	Faulds, E. R.	Real-World Implications of Hybrid Close Loop (Hcl) Insulin Delivery System	Endocrine Practice	2019
30862242	Medtronic 670G	Berget, C.	A Clinical Training Program for Hybrid Closed Loop Therapy in a Pediatric Diabetes Clinic	Journal of Diabetes Science & Technology	2020
30620641	Medtronic 770G	Paldus, B.	Glucose Control Using a Standard Versus an Enhanced Hybrid Closed Loop System: A Randomized Crossover Study	Diabetes Technology & Therapeutics	2019
30585770	Medtronic 670G	Forlenza, G. P.	Safety Evaluation of the MiniMed 670G System in Children 7-13 Years of Age with Type 1 Diabetes	Diabetes Technology & Therapeutics	2019
30305346	Control-IQ	Brown, S.	First Look at Control-IQ: A New-Generation Automated Insulin Delivery System	Diabetes Care	2018

30239219	Medtronic 670G	Adams, R. N.	Psychosocial and Human Factors During a Trial of a Hybrid Closed Loop System for Type 1 Diabetes Management	Diabetes Technology & Therapeutics	2018
30160523	Medtronic 670G	Stone, M. P.	Retrospective Analysis of 3-Month Real-World Glucose Data After the MiniMed 670G System Commercial Launch	Diabetes Technology & Therapeutics	2018
29444895	Medtronic 670G	Messer, L. H.	Optimizing Hybrid Closed-Loop Therapy in Adolescents and Emerging Adults Using the MiniMed 670G System	Diabetes Care	2018
29381090	Eversense	Christiansen, M. P.	A Prospective Multicenter Evaluation of the Accuracy of a Novel Implanted Continuous Glucose Sensor: PRECISE II	Diabetes Technology & Therapeutics	2018
29148821	Medtronic 670G	Cordero, T. L.	The Effect of Prior Continuous Glucose Monitoring Use on Glycemic Outcomes in the Pivotal Trial of the MiniMed TM 670G Hybrid Closed-Loop System	Diabetes Technology & Therapeutics	2017
28990436	Eversense	Barnard, K. D.	Acceptability of Implantable Continuous Glucose Monitoring Sensor	Journal of Diabetes Science & Technology	2018
28574723	Medtronic 670G	Jayawardene, D. C.	Closed-Loop Insulin Delivery for Adults with Type 1 Diabetes Undertaking High-Intensity Interval Exercise Versus Moderate-Intensity Exercise: A Randomized, Crossover Study	Diabetes Technology & Therapeutics	2017

28474383	DiaPort	Dassau, E.	Intraperitoneal insulin delivery provides superior glycaemic regulation to subcutaneous insulin delivery in model predictive control-based fully-automated artificial pancreas in patients with type 1 diabetes: a pilot study	Diabetes, Obesity & Metabolism	2017
28340542	Medtronic 670G	Iturralde, E.	Expectations and Attitudes of Individuals With Type 1 Diabetes After Using a Hybrid Closed Loop System	Diabetes Educator	2017
28134564	Medtronic 670G	Garg, S. K.	Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes	Diabetes Technology & Therapeutics	2017
27629148	Medtronic 670G	Bergenstal, R. M.	Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients With Type 1 Diabetes	JAMA	2016
27621143	Medtronic 670G	de Bock, M.	Exploration of the Performance of a Hybrid Closed Loop Insulin Delivery Algorithm That Includes Insulin Delivery Limits Designed to Protect Against Hypoglycemia	Journal of Diabetes Science & Technology	2017
27287189	MiniMed MIP 2007C	Boering, M.	Effects of intraperitoneal insulin versus subcutaneous insulin administration on sex hormone-binding globulin concentrations in patients with type 1 diabetes mellitus	Endocrine Connections	2016
27191182	Medtronic 670G	Ly, T. T.	Automated hybrid closed-loop control with a proportional-integral-derivative based system in adolescents and adults with type 1 diabetes: individualizing settings for optimal performance	Pediatric Diabetes	2017
26582805	MiniMed MIP 2007C	van Dijk, P. R.	Intraperitoneal versus subcutaneous insulin therapy in the treatment of type 1 diabetes mellitus	Netherlands Journal of Medicine	2015

26177299	Eversense	Wang, X.	Long-Term Home Study on Nocturnal Hypoglycemic Alarms Using a New Fully Implantable Continuous Glucose Monitoring System in Type 1 Diabetes	Diabetes Technology & Therapeutics	2015
26049550	Medtronic 670G	Ly, T. T.	Day and Night Closed-Loop Control Using the Integrated Medtronic Hybrid Closed-Loop System in Type 1 Diabetes at Diabetes Camp	Diabetes Care	2015
25856045	MiniMed MIP 2007C	van Dijk, P. R.	Continuous intraperitoneal insulin infusion versus subcutaneous insulin therapy in the treatment of type 1 diabetes: effects on glycemic variability	Diabetes Technology & Therapeutics	2015
24735100	MiniMed MIP 2007C	Schaepelynck, P.	Assessment of a new insulin preparation for implanted pumps used in the treatment of type 1 diabetes	Diabetes Technology & Therapeutics	2014
23865977	MiniMed MIP 2007C	Hedman, C. A.	Intraperitoneal insulin delivery to patients with type 1 diabetes results in higher serum IGF-I bioactivity than continuous subcutaneous insulin infusion	Clinical Endocrinology	2014
22912916	MiniMed MIP 2007C	van Dijk, P. R.	Complications of continuous intraperitoneal insulin infusion with an implantable pump	World Journal of Diabetes	2012
19740082	DiaPort	Liebl, A.	A reduction in severe hypoglycaemia in type 1 diabetes in a randomized crossover study of continuous intraperitoneal compared with subcutaneous insulin infusion	Diabetes, Obesity & Metabolism	2009
19429874	MiniMed MIP 2007C	Logtenberg, S. J.	Improved glycemic control with intraperitoneal versus subcutaneous insulin in type 1 diabetes: a randomized controlled trial	Diabetes Care	2009

19048281	MiniMed MIP 2007C	Haveman, J. W.	Surgical aspects and complications of continuous intraperitoneal insulin infusion with an implantable pump	Langenbecks Archives of Surgery	2010

3 Orthopedic devices

Detailed information about the information sources, search strategies and study eligibility criteria are available in the published protocol [3].

3.1 Hip stems

Table 17. List of selected papers featuring eligible studies on hip stems

PMID	First author	Year	Device	Publication title	Journal
31558044	Buttaro	2021	Minihip	4- to 8-year complication analysis of 2 'partial collum' femoral stems in primary THA	Hip International
32904196	Gabor	2020	Accolade	Outcomes with Two Tapered Wedge Femoral Stems in Total Hip Arthroplasty Using an Anterior Approach	J Orthopaedics
32662662	Macheras	2020	Quadra	Early failure of an uncemented femoral stem, as compared to two other stems with similar design, following primary total hip arthroplasty performed with direct anterior approach	Hip International
27793497	Grant	2017	Accolade	Cementless Tapered Wedge Femoral Stems Decrease Subsidence in Obese Patients Compared to Traditional Fit-and-Fill Stems	J Arthroplasty
28224576	Vervest	2005	Alloclassic	The Zweymüller cementless total hip prosthesis in patients aged 50 years and younger	Hip International
15568521	Wick	2004	Alloclassic	Radiological changes in second- and third-generation Zweymüller stems	JBJS Br

11486619	Flamme	2001	Biconta ct	Characteristics of the learning curve in total hip endoprosthesis exemplified by the BiContact prosthesis	Z Orthop
9417263	Eckardt	1997	Alloclas sic	Radiologische Veränderungen nach Implantation zweier unterschiedlicher zementfreier Hüftschaftsysteme	Fortschr Röntgenstr
27476179	Badhe	2002	Biconta ct	The uncemented Bicontact total hip arthroplasty in octogenarians. Medium-term results	Eur J Orthop Surg Traumatol
11845084	Bonnomet	2001	Alloclas sic	Comportement d'une tige fémorale droite en arthroplastie totale primaire non cimentée de la hanche chez les patients de moins de 65 ans	Revue de chirurgie orthopédiq ue
30795936	Rahm	2019	Quadra	Uncemented Total Hip Arthroplasty Through the Direct Anterior Approach: Analysis of a Consecutive Series of 275 Hips With a Minimum Follow-Up of 10 Years	The Journal of Arthroplasty
17027538	Pieringer	2006	Alloclas sic	Long-term Results of the Cementless ALLOCLASSIC Hip Arthroplasty System Using a 28-mm Ceramic Head	Journal of Arthroplasty
11886913	Grübl	2002	Alloclas sic	Cementless Total Hip Arthroplasty with a Tapered, Rectangular Titanium Stem and a Threaded Cup. A MINIMUM TEN-YEAR FOLLOW-UP	JBJS Am
30415580	Erivan	2019	Avenir	7-year results of primary total hip arthroplasty with the uncemented Avenir stem	HIP Internationa l
24891001	Berstock	2014	C-stem	A5-8 Year Retrospective Follow-Up of the C-Stem AMT FemoralComponent: Patient Reported Outcomes and Survivorship Analysis	J Arthroplasty

9549574	Delaunay	1998	Alloclassic	Cementless primary total hip replacement Four to eight year results with the Zweymüller-Alloclassic prosthesis	International Orthopaedics
12892182	Pieringer	2003	Alloclassic	Cementless total hip arthroplasty in patients older than 80 years of age	JBJS Br
34287700	Dammerer	2021	Accolade	Subsidence of a metaphyseal-anchored press-fit stem after 4-year follow-up: an EBRA-FCA analysis	Arch Orthop Trauma Surg
32243564	Kolisek	2020	Accolade	Mid-Term Follow Up of Newer-Generation Morphometric Wedge Stems for Total Hip Arthroplasty (THA)	Surg Technol Int
32490772	Vanryckeghem	2020	Avenir	Direct anterior total hip arthroplasty in supine position using regular OR table : case series and review of complication and reoperation rate	Acta Orthop. Belg
32044777	Melnic	2020	Minihip	Catastrophic Failure of a MiniHip Femoral Stem: A Case Report	JBJS Case Connect
30448326	Tian	2019	Accolade	Direct Anterior Approach Total Hip Arthroplasty Using a Morphometrically Optimized Femoral Stem, a Conventional Operating Table, Without Fluoroscopy	J Arthroplasty
30755122	Rinaldi	2018	Collomis	Mid-term results with a neck-preserving femoral stem for total hip arthroplasty.	Hip International
30058529	Slullitel	2018	Minihip	Periprosthetic stress fracture around a well-fixed type 2B short uncemented stem	SICOT-J

25472754	Scemama	2015	Quadra	Minimum five-year wear rate of metal-on-highly cross-linked polyethylene in primary total hip arthroplasty	International Orthop
17939094	Takata	2007	Biocontact	Experiences with Bicontact Ceramic-Ceramic Total Hip Arthroplasty	Z Orthop Unfall
17015598	Grübl	2006	Alloclassic	Cementless total hip arthroplasty with the rectangular titanium Zweymuller stem. A concise follow-up, at a minimum of fifteen years, of a previous report	JBJS Am
16129743	Pospischill	2005	Alloclassic	Cementless total hip arthroplasty using a threaded cup and a rectangular tapered stem. Follow-up for ten to 17 years	JBJS Br
15741618	Yoo	2005	Biocontact	Alumina-on-Alumina Total Hip Arthroplasty A FIVE-YEAR MINIMUM FOLLOW-UP STUDY	JBJS Am
15118821	Jessen	2004	Alloclassic	Metal/metal--a new (old) hip bearing system in clinical evaluation. Prospective 7-year follow-up study	Der Orthopäde
12728424	Pieringer	2003	Alloclassic	Long-term results with the cementless Alloclassic brand hip arthroplasty system	Journal of Arthroplasty
12571308	Garcia-Cimbrelo	2003	Alloclassic	Total Hip Arthroplasty with Use of the Cementless Zweymüller Alloclassic System	JBJS Am
11753773	Dohle	2001	Alloclassic	Radiological analysis of osseointegration after implantation of the Zweymüller-Alloclassic total hip system	Z Orthop Ihre Grenzgeb

11486621	Weissinger	2001	Alloclassic	Long-term results with Zweymuller cement-free Alloclassic stem	Z Orthop Ihre Grenzgeb
11172270	Delaunay	2001	Alloclassic	Grit-Blasted Titanium Femoral Stem in Cementless Primary Total Hip Arthroplasty A 5- to 10-Year Multicenter Study	Journal of Arthroplasty
11148419	Delaunay	2000	Alloclassic	Second-generation metal bearings in cementless primary total hip arthroplasty: rationale, French homologation and preliminary results	Revue de chirurgie orthopédique
8749763	Huo	1995	Alloclassic	Total Hip Arthroplasty Using the Zweymuller Stem Implanted Without Cement A Prospective Study of Consecutive Patients With Minimum 3-Year Follow-up Period	J Arthroplasty
33508723	Nazari-Farsani	2021	Accolade	Contributing factors to the initial femoral stem migration in cementless total hip arthroplasty of postmenopausal women	J Biomech
33521204	Garbarino	2021	Accolade	Does Structured Postgraduate Training Affect the Learning Curve in Direct Anterior Total Hip Arthroplasty? A Single Surgeon's First 200 Cases	Arthroplasty today
30989339	Samy	2019	Minihip	Stem length in primary cementless total hip arthroplasty: Does it make a difference in bone remodeling?	Eur J Orthop Surg Traumatol .
30168759	Ferguson	2018	Minihip	Primary stability of a short bone-conserving femoral stem: a two-year randomized controlled trial using radiostereometric analysis	BJJ
26375526	Pierce	2015	Accolade	Second-Generation Versus First-Generation Cementless Tapered Wedge Femoral Stems	Orthopedics

26033054	Flatoy	2015	C-stem	Triple taper stem design shows promising fixation and bone remodelling characteristics radiostereometric analysis in a randomised controlled trial	BJJ
17187333	Steimer	2006	Biconta ct	Primary stability of cementless implanted hip stems made of titanium alloy with metaphyseal fixation. A prospective clinical Roentgen-Stereometry-Analysis (RSA) study	Z Orthop Ihre Grenzgeb
30364820	Engelhardt	2018	Minihip	Long-term results of an anatomically implanted hip arthroplasty with a short stem prosthesis (Minihip)	World J Orthopedics
17939096	Ochs	2007	Biconta ct	Prospective Long-Term Follow-Up of the Cementless Bicontact Hip Stem with Plasmapore	Z Orthop Unfall
12375250	Badhe	2002	Biconta ct	The Uncemented Bi-Contact Total Hip Arthroplasty	J Arthroplasty
32662662	Macheras	2020	Avenir	Early failure of an uncemented femoral stem, as compared to two other stems with similar design, following primary total hip arthroplasty performed with direct anterior approach	Hip Internationa l
32147340	Warth	2020	Accolad e	Inadequate Metadiaphyseal Fill of a Modern Taper-Wedge Stem Increases Subsidence and Risk of Aseptic Loosening: Technique and Distal Canal Fill Matter!	J Arthroplasty
28676374	Fleischman	2017	Accolad e	Reduced Incidence of Intraoperative Femur Fracture With a Second-Generation Tapered Wedge Stem	J Arthroplasty
28648706	Colacchio	2017	Accolad e	Total Hip Intraoperative Femur Fracture: Do the Design Enhancements of a Second-Generation Tapered-Wedge Stem Reduce the Incidence?	J Arthroplasty

28993084	Dietrich	2018	Quadra	Perioperative Fractures in Cementless Total Hip Arthroplasty Using the Direct Anterior Minimally Invasive Approach: Reduced Risk With Short Stems	The Journal of Arthroplasty
24500832	Muller	2014	Quadra	Anterior minimally invasive approach for total hip replacement: five-year survivorship and learning curve	Hip International
32435953	Knoth	2020	Avenir	A retrospective analysis of surgical outcomes following direct anterior hip arthroplasty with or without a surgical extension table	International Orthopaedics
N/A	Krieger	2013	Collomis	COLLO-MIS Chapter 12 published in book with title: Kurzschaftendoprothesen Editor Jerosch, J	Book chapter
12822078	Grübl	2003	Alloclassic	Six to ten year results of use of the alloclassic hip prosthesis--a multicentre survival analysis	Z Orthop
18057355	Hallan	2007	Filler	Medium- and long-term performance of 11 516 uncemented primary femoral stems from the Norwegian arthroplasty register	JBJS Br
18057355	Hallan	2007	Biocontact	Medium- and long-term performance of 11 516 uncemented primary femoral stems from the Norwegian arthroplasty register	JBJS Br
30063590	De Steiger	2018	Quadra	Cross-Linked Polyethylene for Total HipArthroplasty Markedly Reduces Revision Surgery at 16 Years	JBJS Am
33479835	Nugent	2021	Quadra	Acetabular screws do not improve early revision rates in primary total hip arthroplasty. An instrumented registry analysis	International Orthop

33479835	Nugent	2021	Accolade	Acetabular screws do not improve early revision rates in primary total hip arthroplasty. An instrumented registry analysis	International Orthop
26101669	Dettmer	2015	Minihip	Comparison of Patient-Reported Outcome from Neck-Preserving, Short-Stem Arthroplasty and Resurfacing Arthroplasty in Younger Osteoarthritis Patients	Adv Orthop
29576639	Khemka	2018	Minihip	Total Hip Arthroplasty by the Direct Anterior Approach Using a Neck-preserving Stem: Safety, efficacy and learning curve	Indian J Orthop

3.2 Hip cups

Table 18. List of selected papers featuring eligible studies on hip cups

PMID	First author	Year	Device	Publication title	Journal
22161085	Massin	2012	Polarcup	Fixation failures of dual-mobility cups: a mid-term study of 2601 hip replacements	Clin Orthop Relat Res
22826015	Yoon	2012	Plasmacup	Alumina-on-alumina THA performed in patients younger than 30 years: A 10-year minimum followup study.	Clin Orthop Relat Res
30453838	Nahas	2018	Exceed	Independent assessment and outcomes of 196 short-tapered stems short-term follow-up and review of the literature	J Orthop Surg (Hong Kong)
30795936	Rahm	2019	Versafit	Uncemented Total Hip Arthroplasty Through the Direct Anterior Approach: Analysis of a Consecutive Series of 275 Hips With a Minimum Follow-Up of 10 Years	J of Arthroplasty
24500832	Müller	2014	Versafit	Anterior minimally invasive approach for total hip replacement: five-year survivorship and learning curve	Hip Int
34101664	Beel	2021	Versafit	The Effect of a Distal Centralizer on Cemented Femoral Stems in Arthroplasty Shown on Radiographs and SPECT/CT	JBJS
31752951	Cypres	2019	Polarcup	Long-term outcomes of a dual-mobility cup and cementless triple-taper femoral stem combination in total hip replacement: a multicenter retrospective analysis	J Orthop Surg Res

29186943	Faldini	2017	Versafit	Modified minimally invasive direct anterior approach through a bikini incision for total hip arthroplasty: technique and results in young female patients	J Biol Regul Homeost Agents
28002919	Faldini	2016	Versafit	Is a minimally invasive anterior approach effective in old patients? A pilot study	J Biol Regul Homeost Agents
25739650	Kaipel	2015	AnaNova	Migration characteristics and early clinical results of the NANOS® short-stem hip arthroplasty	Wien Klin Wochenschr
25081512	Shin	2014	Plasmacup	Comparison between preassembled and modular cups in primary cementless total hip arthroplasty: A two-year minimum follow-up study.	J Arthroplasty
25472754	Scemama	2015	Versafit	Minimum five-year wear rate of metal-on-highly cross-linked polyethylene in primary total hip arthroplasty	International Orthopaedics
19298026	Bauchu	2008	Polarcup	The dual-mobility POLARCUP: first results from a multicenter study	Orthopedics
18245593	Koo	2008	Plasmacup	Isolated Fracture of the Ceramic Head After Third-Generation Alumina-on-Alumina Total Hip Arthroplasty	JBJS Am
17974894	Nam	2007	Plasmacup	Alumina-debris-induced osteolysis in contemporary alumina-on-alumina total hip arthroplasty	JBJS Am
33263447	Rochcongar	2021	RMpressfit	Reduced wear in vitamin E-infused highly cross-linked polyethylene cups: 5-year results of a randomized controlled trial	Acta Othopaedica

31698977	Jorgensen	2020	Exceed	Higher early proximal migration of hemispherical cups with electrochemically applied hydroxyapatite (BoneMaster) on a porous surface compared with porous surface alone: a randomized RSA study with 53 patients	Acta Orthop
17939093	Ochs	2007	Plasmacup	EBRA migration patterns of the Plasmacup with ceramic or polyethylene inserts: a randomised study	Z Orthop Unfall
32529389	Lee	2021	Exceed	Preventing ceramic liner fracture after Delta ceramic-on-ceramic total hip arthroplasty	Arch Orthop Trauma Surg
25449586	Kang	2015	Plasmacup	Third-Generation Alumina-on-Alumina Total Hip Arthroplasty: 14 to 16-Year Follow-Up Study	J Arthroplasty
20660234	Lee	2010	Plasmacup	Alumina-on alumina total hip arthroplasty. A concise follow-up , at a minimum of ten years, of a previous report	JBJS Am
33427897	Garavaglia	2021	Versafit	Short stem total hip arthroplasty with the direct anterior approach demonstrates suboptimal fixation	International Orthopaedics
33023553	Anderl	2020	RMpressfit	Peri-acetabular bone remodelling after uncemented total hip arthroplasty with monoblock press-fit cups: An observational study.	BMC Musculoskelet Disord .
33516632	Mahmood	2021	RMpressfit	Survivorship and Patient-Reported Outcomes of an Uncemented Vitamin E eInfused Monoblock Acetabular Cup: A Multicenter Prospective Cohort Study	The Journal of Arthroplasty

33384276	Comtesse	2021	RMpressfit	Wear and migration are not influenced by head size in a vitamin E-infused highly cross-linked polyethylene acetabular cup	Orthopaedics & Traumatology: Surgery & Research
28106229	Wyatt	2017	RMpressfit	The RM Pressfit vitamys: 5-year Swiss experience of the first 100 cups	Hip Int (accepted date)
24442859	Kaipel	2014	AnaNova	Migration characteristics and early clinical results of a novel-finned press-fit acetabular cup	Wien Klin Wochenschr
22777589	Ha	2012	Plasmacup	Acetabular Component Positioning Using Anatomic Landmarks of the Acetabulum	Clin Orthop Relat Res
33617161	Brodt	2021	RMpressfit	An Isoelastic Monoblock Cup Retains More Acetabular and Femoral Bone Than a Modular Press-Fit Cup	JBJS Am
31694404	Kenanidis	2021	RMpressfit	Survival of monoblock RM vitamys compared with modular PINNACLE cups: mid-term outcomes of 200 hips performed by a single surgeon	HIP International
31609753	Aepli	2019	RMpressfit	Electrosurgery Induced Femoral Stem Fracture in Total Hip Arthroplasty	JBJS Am
22541583	Moretti	2012	Plasmacup	Peripheral neuropathy after hip replacement failure: is vanadium the culprit?	the lancet
30303878	Inacio	2018	Exceed	What Is the Risk of Revision Surgery in Hydroxyapatite-coated Femoral Hip Stems? Findings From a Large National Registry.	Clin Orthop Relat Res

33479835	Nugent	2021	Versafit	Acetabular screws do not improve early revision rates in primary total hip arthroplasty. An instrumented registry analysis	International Orthopaedics

3.3 Knee systems

Table 19. List of selected papers featuring eligible studies on kmee systems

PMID	First author	Year	Device	Publication title	Journal
29691173	Serna-Berna	2018	Trekking	Cruciate-Retaining vs Posterior-Stabilized Primary Total Arthroplasty. Clinical Outcome Comparison With a Minimum Follow-Up of 10 Years	J Arthroplasty
21159598	Koskinen	2020	NexGen	Mid-term results for three contemporary total knee replacement designs - a comparative study of 104 patients with primary osteoarthritis	Scand J Surg
15995438	Bertin	2005	NexGen	Cruciate-retaining total knee arthroplasty at 5 to 7 years followup	Clin Orthop Relat Res
20440662	Schwartz	2010	NexGen	Cruciate-retaining TKA using a third-generation system with a four-pegged tibial component: a minimum 10-year followup note	Clin Orthop Relat Res
34095405	Keogh	2021	LCS	Nontraumatic Tibial Polyethylene Insert Cone Fracture in Rotating-Platform Total Knee Arthroplasty	Arthroplasty Today
32873449	Meding	2021	Vanguard	Progressive Tibial Bearing Sagittal Plane Conformity in Cruciate-Retaining Total Knee Arthroplasty	J Arthroplasty
31883762	Kaipel	2020	Vanguard	Convincing long-term results independent from the postoperative leg alignment following cementless total knee arthroplasty	Knee

30467023	Rassir	2019	LCS	The value of postoperative prosthesis alignment and patellar height measurements on standard X-rays after Total Knee Arthroplasty: Does it relate to knee function after 5 years?	The Knee
26704792	van Houten	2016	Balansys	Patella position is not a determinant for anterior knee pain 10 years after balanced gap total knee arthroplasty.	Knee Surg Sports Traumatol Arthrosc
25993350	Hack	2015	NexGen	10-Year Follow-Up of the NexGen CR Total Knee Prosthesis	Z Orthop Unfall
19268598	Minoda	2009	NexGen	Comparison between highly cross-linked and conventional polyethylene in total knee arthroplasty	The Knee
18672343	Helm	2009	NexGen	Preliminary results of an uncemented trabecular metal tibial component in total knee arthroplasty	J Arthroplasty
18075748	Wyss	2008	Balansys	Tension controlled ligament balanced total knee arthroplasty: 5-year results of a soft tissue orientated surgical technique.	Arch Orthop Trauma Surg
17437082	van Hal	2007	Balansys	The anterior-posterior laxity after total knee arthroplasty inserted with a ligament tensor.	Knee Surg Sports Traumatol Arthrosc
15662312	Bozic	2005	NexGen	Implant survivorship and complication rates after total knee arthroplasty with a third-generation cemented system: 5 to 8 years followup	Clin Orthop Relat Res
31293193	Koppens	2019	SigmaHigh Performance	Equal tibial component fixation of a mobile-bearing and fixed-bearing medial unicompartmental knee arthroplasty: a randomized controlled RSA study with 2-year follow-up	Acta Orthop

31005431	Jang	2019	Vanguard	Comparison of Anterior-Stabilized and Posterior-Stabilized Total Knee Arthroplasty in the Same Patients: A Prospective Randomized Study	J Arthroplasty
26993570	Sanz-Ruiz	2016	LCS	Does a new implant design with more physiological kinematics provide better results after knee arthroplasty?	Knee
24793892	Jo	2014	NexGen	A comparison of stability and clinical outcomes in single-radius versus multi-radius femoral design for total knee arthroplasty	J Arthroplasty
24986944	Dossett	2014	Vanguard	A randomised controlled trial of kinematically and mechanically aligned total knee replacements: two-year clinical results	JBJS Br
23992142	Henricson	2013	NexGen	Trabecular metal tibia still stable at 5 years An RSA study of 36 patients aged less than 60 years.	Acta Orthop
23054522	Seon	2012	NexGen	No Better Flexion or Function of High-flexion Designs in Asian Patients With TKA	Clin Orthop Relat Res
21752586	Lizaur-Utrilla	2012	Trekking	Greater satisfaction in older patients with a mobile-bearing compared with fixed-bearing total knee arthroplasty	J Arthroplasty
21946980	Jacobs	2012	Balansys	Functional performance of mobile versus fixed bearing total knee prostheses: a randomised controlled trial	Knee Surg Sports Traumatol Arthrosc
16826105	Henricson	2006	NexGen	Mobile bearings do not improve fixation in cemented total knee arthroplasty.	Clin Orthop Relat Res

12375237	Tanzer	2002	NexGen	Posterior-stabilized versus cruciate-retaining total knee arthroplasty - Balancing the gap.	J Arthroplasty
29945574	Napier	2018	LCS	A prospective evaluation of a largely cementless total knee arthroplasty cohort without patellar resurfacing: 10-year outcomes and survivorship	BMC Musculoskelet Disord
29739264	Ohrn	2018	Vanguard	A 2-year RSA study of the Vanguard CR total knee system: A randomized controlled trial comparing patient-specific positioning guides with conventional technique	Acta Orthop
29147743	Koppens	2018	SigmaHigh Performance	Low implant migration of the SIGMA® medial unicompartmental knee arthroplasty	Knee Surgery, Sports Traumatology, Arthroscopy
16819692	Chiu	2006	NexGen	The native femoral sulcus as the guide for the medial/lateral position of the femoral component in knee arthroplasty: Normal patellar tracking in 690/700 knees--a prospective evaluation	Acta Orthopaedica
33380967	Dubin	2020	Logic	Design Modifications of the Posterior-Stabilized Knee System May Reduce Anterior Knee Pain and Complications Following Total Knee Replacement	HSSJ
23632673	Gothesen	2013	NexGen	Survival rates and causes of revision in cemented primary total knee replacement: a report from the Norwegian Arthroplasty Register 1994-2009	JBJS Br
33268208	Law	2021	Vanguard	Midterm Outcomes and Survivorship of Anterior Stabilized Versus Cruciate Retaining Bearing in Primary Total Knee Arthroplasty	J Arthroplasty

31686181	Hauer	2020	SigmaHigh Performance	Greater activity, better range of motion and higher quality of life following unicompartmental knee arthroplasty: a comparative case-control study	Archives of Orthopaedic and Trauma Surgery
24502700	Piepers	2014	LCS	Do refinements to original designs improve outcome of total knee replacement? A retrospective cohort study	J Orthop Surg Res
19225852	Lombardi	2009	Vanguard	Is recovery faster for mobile-bearing unicompartmental than total knee arthroplasty?	Clin Orthop Relat Res
26451389	Nassif	2015	Vanguard	Clinical Outcomes in Men and Women following Total Knee Arthroplasty with a High-Flex Knee: No Clinical Effect of Gender	Scientific World Journal
26481407	Emerson	2016	Vanguard	A Comparison of 2 Tibial Inserts of Different Constraint for Cruciate-Retaining Primary Total Knee Arthroplasty: An Additional Tool for Balancing the Posterior Cruciate Ligament	J Arthroplasty
24534535	Jacobs	2014	Vanguard	Factors influencing patient satisfaction two to five years after primary total knee arthroplasty	J Arthroplasty
23702268	Schroer	2014	Vanguard	Seven-year survivorship and functional outcomes of the high-flexion Vanguard complete knee system	J Arthroplasty
29406454	Montonen	2018	Vanguard	What Is the Long-term Survivorship of Cruciate-retaining TKA in the Finnish Registry?	Clin Orthop Relat Res
24306696	Peltola	2013	NexGen	Learning curve for new technology?: a nationwide register-based study of 46,363 total knee arthroplasties	J Bone Joint Surg Am

26179889	Petursson	2015	LCS	Better survival of hybrid total knee arthroplasty compared to cemented arthroplasty	Acta Orthop
21619502	Lygre	2011	LCS	Failure of total knee arthroplasty with or without patella resurfacing	Acta Orthop
21619502	Lygre	2011	NexGen	Failure of total knee arthroplasty with or without patella resurfacing	Acta Orthop
23632673	Gothesen	2013	LCS	Survival rates and causes of revision in cemented primary total knee replacement: a report from the Norwegian Arthroplasty Register 1994-2009	JBJS Br
24306696	Peltola	2013	Vanguard	Learning curve for new technology?: a nationwide register-based study of 46,363 total knee arthroplasties	JBJS Am
26119884	DeSteiger	2015	NexGen	Lower prosthesis-specific 10-year revision rate with crosslinked than with non-crosslinked polyethylene in primary total knee arthroplasty	Acta Orthop
??	Cely	2021	Logic	Pain and patellofemoral functionality in total knee arthroplasty: a comparative cohort study of two prosthesis designs	Current Orthopaedic Practice
31256639	Kahlenberg	2019	Logic	Comparison of patient-reported outcomes based on implant brand in total knee arthroplasty: a prospective cohort study	Bone Joint J
21504309	Gothesen	2011	LCS	Short-term outcome of 1,465 computer-navigated primary total knee replacements 2005-2008	Acta Orthop

20158405	Lygre	2010	NexGen	Does patella resurfacing really matter? Pain and function in 972 patients after primary total knee arthroplasty An observational study from the Norwegian Arthroplasty Register	Acta Orthop
31883758	Ascione	2020	Logic	Experience-optimised fast track improves outcomes and decreases complications in total knee arthroplasty	The Knee
23142442	Komistek	2013	LCS	Clinical and kinematic outcomes of a rotating platform posterior stabilized total knee system	J Arthroplasty

4 Summary and conclusions

This deliverable provides a comprehensive list of the slected studies following the literature searches.

Table 20. Distribution of selected studies among classes of cardiac devices

Class of devices	Number of devices	Search output	Selected studies
Bioresorbable scaffolds	6	3385	148
Left atrial appendage occlusion	8	2392	56
Transcatheter aortic valve replacement	20	22250	125
Transcatheter mitral valve repair/replacement	13	5858	41
Surgical aortic valves	17	4901	41
Surgical mitral valves	4	3696	1
Leadless pacemaker	2	862	28
Subcutaneous implantable cardioverter-defibrillator	1	1430	29

Table 21. Selected studies for diabetes medical devices

Class of devices	Number of devices	Search output	Selected studies
Implantable CGM devices; implantable insulin pumps; automated insulin delivery devices	14	4165	144

Table 22. Orthopedic devices (random selection of 30 hip and knee devices)

Class of devices	Number of devices	Search output	Selected studies
Hip stems	N/A	760	63
Hip cups	N/A	302	34
Knee systems	N/A	1078	54

Next steps will be the data extraction and analysis and the preparation of the masucripts for publication (deliverables 1.2 and 1.3).

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CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 965246.