Supplementary data

Supplemental Table 1. Safety signals published in the 4 data sources – hip stems

Hip stem	Safety signal published in literature	Safety signal published (CORE-MD tool)	Safety signal published by manufacturer	Identified as outlier in registry
Accolade II (uncemented, Stryker)	Surgical related issue (Failure to optimise canal fill with appropriate broaching and surgical technique may predispose femoral components to failure from aseptic loosening)(25)	-	-	Yes - SOFCOT (2019) - AOANJRR (2019 – 2022), but only as a construct with Trident Tritanium cup
Alloclassic Zweymuller SL (uncemented, Zimmer)	-	2 the USA (A210106: wrong label) (first publication: 2012)	-	Yes - SK-SAR (2011), but only as a construct with Zweymuller Alloclassic CSF cup - NJR website, but only as a construct with Pinnacle metal liner cup

	Avenir (uncemented, Zimmer)		-		10: 1 Australia, 1 France, 4 Germany and 4 USA (A210106: wrong label) (first publication: 2011)		-		Yes - AOANJRR (2019-2023), but only as a construct with Fitmore cup
	BiContact (uncemented, B Braun)		-		-		-		-
	COLLO-MIS (uncemented, LimaCorporate)		-		-		-		-
	C-Stem AMT Total Hip System (cemented, DePuy)		-		-		-		Yes - NJR website, but only as a hip construct with Bi-mentum DM cup - SK-SAR 2011, but only as a construct with Ultima MK2 cup
	Filler 3ND (cemented, Biotechni)		-		-		-		-
	MiniHip (uncemented, Corin)		Implant breakage(24) and poor patient-reported clinical outcomes(24)		-		-		-
	QUADRA (uncemented, Medacta)		Intra-operative fracture(26), aseptic loosening and radiolucent lines(26),		-		-		Yes -NZJR registry (2021): rate/100 observed component-years higher than 2

			significantly higher revision rate when compared with comparable stems(27) (But Quadra S stem used(26) as well as Quadra H(27))						
	Stelia stem (uncemented, Stemcup)		-		-		-		Yes - SIRIS (2019), but as a hip construct with ANA.NOVA hybrid cup

AOANJRR = Australian Orthopaedic Association National Joint Replacement Registry; NJR = National Joint Registry; NZJR = New ZEALAND Joint Registry; SK-SAR = Slovak Arthroplasty Register; SOFCOT = hip arthroplasty registry of the French Orthopaedic Society; SIRIS = Swiss national registry for hip and knee replacement

Supplemental Table 2. Safety signals published in the 4 data sources – hip cups

Hip cup	Safety signal published in literature	Safety signal published (CORE-MD tool)	Safety signal published by manufacturer	Identified as outlier in registry
ANA.NOVA cup (uncemented, ImplanTec)	Increased total migration of the implant(28)	-	-	Yes - SIRIS (2019), but only as a construct with Stelia stem
AneXys (uncemented, Mathys)	-	-	-	-
Cenator (cemented, Corin)	-	-	-	-
EcoFit (uncemented, Implantcast)	-	5: 1 Czechia, 1 Germany, 1 Italy, 1 Spain and 1 USA (A0501 (1x): detachment of device or device component; A2103 (4x): Inadequate instructions for healthcare professional) (first publication: 2020)	-	-
Exceed ABT Cup (uncemented, Zimmer)	-	-	-	Yes - SIRIS (2019), but only as a construct with Exception stem
IP X-LINKed (cemented, Waldemar LINK)	-	-	-	Yes - SHAR (2015)
Plasmacup SC (uncemented, B Braun)	Poor patient-reported clinical	-	-	Yes - SK-SAR (2011), but

			outcomes(29,30), osteolysis(30), ceramic head fracture(30,32)						only with a cemented Centrament stem - AOANJRR (2011-2023)	
	POLARCUP (cemented, Smith & Nephew)		-		-		-		Yes - SHAR (2013 and 2018)	
	RM pressfit Vitamys (uncemented, Mathys)		-		1 Germany (A020501: difficult to open or remove packaging material) (first publication: 2012)		-		Yes - SIRIS (2019), but only with a cemented CCA stem	
	Versafit CC Trio (uncemented, Medacta)		-		-		-		Yes - AOANJRR (2017-2023) but only in a construct with Taperloc stem	

AOANJRR = Australian Orthopaedic Association National Joint Replacement Registry; SK-SAR = Slovak Arthroplasty Register; SHAR = Swedish Hip Arthroplasty Register; SIRIS = Swiss national registry for hip and knee replacement.

Supplemental Table 3. Safety signals published in the 4 data sources – knee implants

Knee implant	Safety signal published in literature	Safety signal published (CORE-MD tool)	Safety signal published by manufacturer	Identified as outlier in registry
ACS Unicondylar (uncemented, Implantcast)	-	-	-	-
BalanSys CR (Mathys)	-	-	-	-
Innex Gender (Zimmer)	-	-	-	-
LCS complete (DePuy)	Fracture through the polyethylene insert cone (33), poor patient-reported clinical outcome (34), higher risk of aseptic tibial loosening (35)	1: Ireland (A2303: improper or incorrect procedure or method) (first publication: 2015)	-	Yes - AOANJRR (2012–2023) - NJR website
Optetrak Logic RBK (Exactech)	Early aseptic loosening and increased presence and severity of backside burnishing with early cement-implant interface debonding(7), poor patient-reported clinical outcome(8)	-	-	-
NexGen CR (Zimmer)	-	24: 2 Germany and 22 the USA (A1803 (2x): device reprocessing problem; A170102 (22x): component	-	Maybe - SKAR (2002) “NexGen”

					incompatible) (first publication: 2012)					
	Optetrak CR (Exactech)		-		-		-		Yes - AOANJRR (2010-2023)	
	Sigma High Performance Partial Knee (DePuy)		-		-		-		-	
	TREKKING CR (SAMO)		-		-		-		Maybe - AOANJRR (2013-2023) “Trekking”	
	Vanguard CR (Zimmer)		Higher risk of early revision(36)		5: 1 Australia, 1 the Netherlands, and 3 the USA (A2102 (1x): lack of maintenance documentation or guidelines; A210106 (4x) wrong label) (first publication: 2008)		-		Maybe - SKAR (2009-2011 and 2014-2017) “Vanguard”	

AOANJRR = Australian Orthopaedic Association National Joint Replacement Registry; NJR = National Joint Registry; SKAR = Swedish Knee Arthroplasty Register.

Supplemental Table 4. Categorisation of the unique safety signals using IMDRF codes

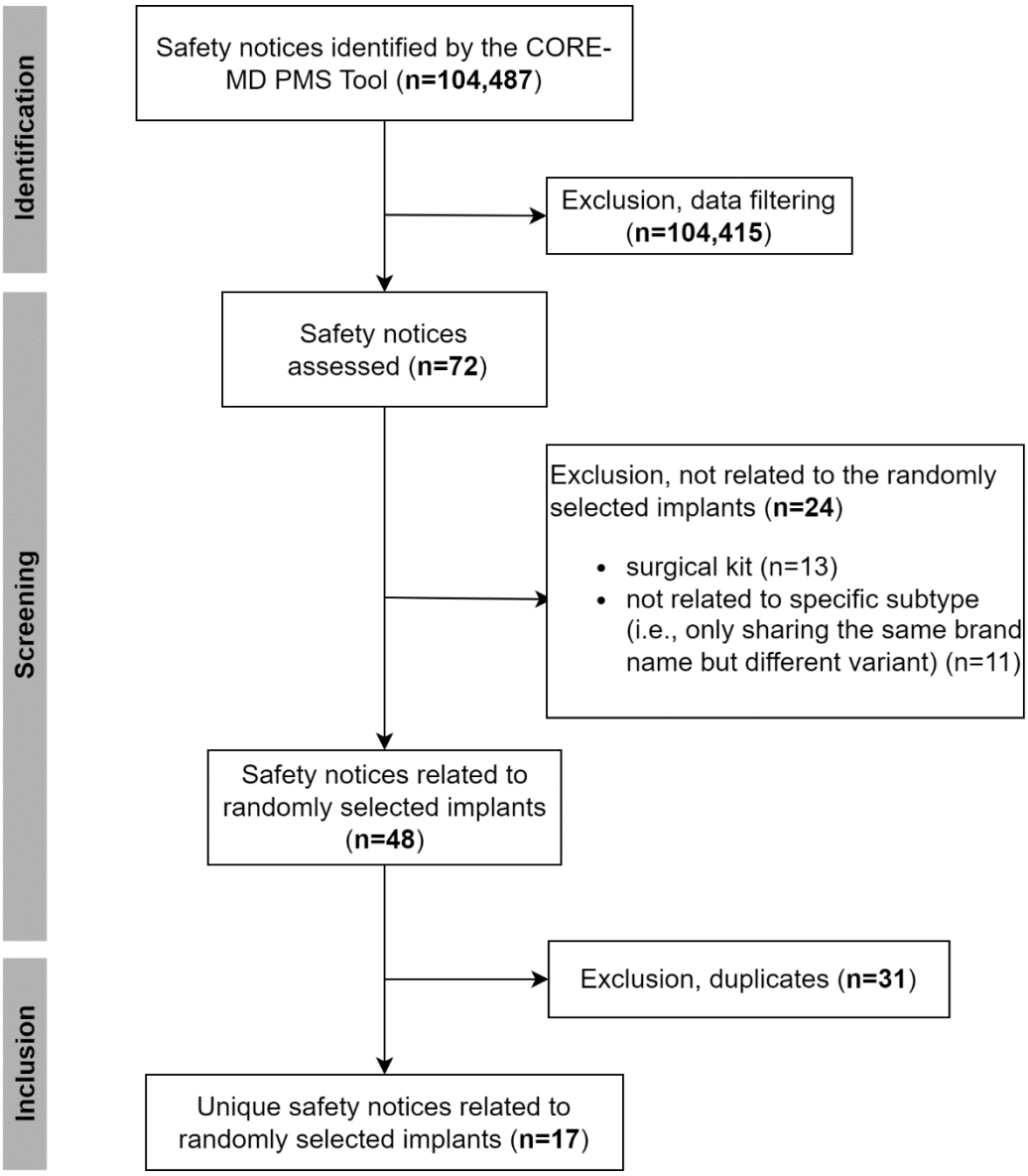
Implant	**A0202** (Defective Component)	**A020501** (Difficult to Open or Remove Packaging Material)	**A0501** (Detachment of Device or Device Component)	**A170102** (Component Incompatible)	**A1803** (Device Reprocessing Problem)	**A2103** (Inadquate instructions for healthcare professional)	**A210106** (Wrong Label)	**A2303** (Improper or Incorrect Procedure or Method)
Alloclassic (hip stem)	-	-	-	-	-	-	1	-
Avenir (hip stem)	-	-	-	-	-	-	4	-
EcoFit (hip cup)	-	-	1	-	-	1	-	-
RM pressfit Vitamys (hip cup)	-	1	-	-	-	-	-	-
LCS complete (knee implant)	-	-	-	-	-	-	-	1
Nexgen CR (knee implant)	-	-	-	2	2	-	-	-
Vanguard CR (knee implant)	1	-	-	-	-	-	3	-

Supplemental Table 5. Timing of publishing publicly released safety signals for implants with safety signals from more than 1 data source

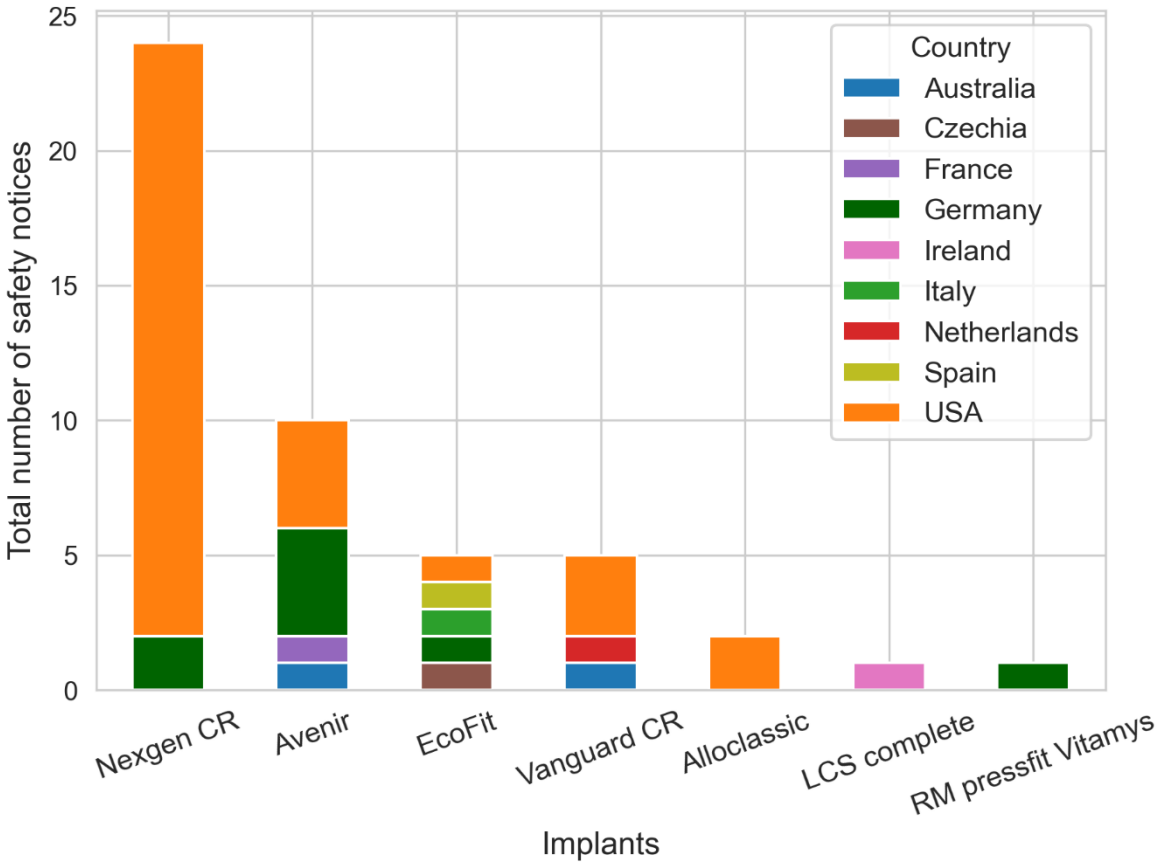
Implant	Literature	CORE-MD PMS tool [a]	Manufacturer	Outlier identification
Accolade II (hip stem)				
Alloclassic (hip stem)				
Avenir (hip stem)				
QUADRA (hip stem)				
ANA.NOVA (hip cup)				
Plasmacup (hip cup)				
RM pressfit Vitamys (hip cup)				
LCS complete (knee implant)				
Nexgen CR (knee implant)				
Vanguard CR (knee implant)				

[a] The timing of publication refers to the time the safety notice was originally published on the individual websites of national competent authorities/regulatory agencies.

Green cells indicate that the safety signal for this implant was published at first in this data source; Red cells indicate that the safety signal for this implant was published later than another data source for this implant; Blank cells indicate that no safety signals or related reports were available from these data sources



Supplemental Figure 1. Flowchart showing the selection process of the randomly selected implants with safety notices



Supplemental Figure 2. Number of relevant safety notices retrieved from different national competent authorities/regulatory agencies for the randomly selected implants