



Zusatzdokument „Erläuterung Leitprodukte“ zur XML-Spezifikation V4.0.0-RFC

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1. Einführung

Die aktuellen Erfahrungen bei der Meldung von Endoprothesen zeigen, dass im Rahmen der Meldung die Unterscheidung zwischen Artikel und Zubehör in den Gesundheitseinrichtungen zu größeren Problemen führt. Um hier Abhilfe zu schaffen, soll das Meldeverfahren verschlankt werden.

Die Meldung von Brustimplantaten und Aortenklappen ist hiervon nicht betroffen!

2. Änderungen im Vorgehen

- **Anhand von EMDN-Kodes werden so genannte „Leitprodukte“ definiert (Quelle der EMDN-Kodes: <https://webgate.ec.europa.eu/dyna2/emdn/Z1206>)**
 - „Leitprodukte“ bei Hüftprothesen (P0908) sind alle Produkte mit folgenden „Wurzel-EMDN-Kodes“ (weitere Details siehe Anlage 1):
 - P090803: HIP PROSTHESES ACETABULAR COMPONENTS
 - P090804: HIP PROSTHESES FEMORAL COMPONENTS
 - „Leitprodukte“ bei Knieprothesen (P0909) sind alle Produkte mit folgenden „Wurzel-EMDN-Kodes“ (weitere Details siehe Anlage 2):
 - P090903: BICOMPARTMENTAL PRIMARY IMPLANT KNEE PROSTHESES
 - P090904: UNICOMPARTMENTAL KNEE PROSTHESES (UNICONDYLAR)
 - P090905: REVISION KNEE PROSTHESES
 - P090906: KNEE PROSTHESES FOR LARGE RESECTIONS
 - P090907: PATELLO-FEMORAL KNEE PROSTHESES
- **Festlegung für „Leitprodukte“**
 - Nur Leitprodukte sind relevant für die Ausstellung einer Meldebestätigung.
 - Nur diese sind in der Produktdatenbank registrierungspflichtig.
 - Die Unterscheidung wird im Melde-Datensatz und im Artikelsystem durch zusätzliche Informationen für Hüft- und Kniekomponenten abgebildet.
- **Umgang mit „Nicht-Leitprodukten“ bei Endoprothesen**
 - Produkte, die gem. obenstehender Definition nicht zu den Leitprodukten Endoprothesen zählen, aber in diesem Zusammenhang implantiert werden (z.B. Schrauben, Muttern, Knochenzement, Cerclage-Material), können (weiterhin) freiwillig von den Produktherstellern in der Produktdatenbank des IRD registriert werden.
 - Die verantwortlichen Gesundheitseinrichtungen übermitteln bei ihrer Meldung an die Registerstelle die Daten gem. Anlage 2 IRegBV aller implantierten Medizinprodukte. Für die Gesundheitseinrichtungen entfällt die Unterscheidung zwischen Artikel und Zubehör; es werden alle implantierten Produkte gescannt.
 - Damit können sowohl in Bezug auf Kombinationen von Leitprodukten mit den anderen implantierten Produkten als auch für die anderen Produkte selbst bei ihrer Verwendung bei implantatbezogenen Maßnahmen aussagekräftige statistische Auswertungen durchgeführt werden.



Anlage 1: Liste aller EMDN-Kodes unterhalb des Levels 3 P0908 HIP PROSTHESES

Grün markiert: EMDN-Kodes von Leitprodukten Endoprothesen; rot markiert: EMDN-Kodes von Nicht- Leitprodukten Endoprothesen

KODE Level 4	Level 5	Level 6	Level 7	TERM	Katalogwert IRD
P090803				HIP PROSTHESES ACETABULAR COMPONENTS	
	P09080301			PRIMARY IMPLANT ACETABULAR CUPS	0292001
		P0908030101		PRIMARY IMPLANT CEMENTED ACETABULAR CUPS	0292001
			P090803010101	PRIMARY IMPLANT CEMENTED METAL ACETABULAR CUPS	0292001
			P090803010102	PRIMARY IMPLANT CEMENTED POLYETHYLENE ACETABULAR CUPS, ONE-PIECE	0292001
			P090803010199	PRIMARY IMPLANT CEMENTED ACETABULAR CUPS - OTHER	0292001
		P0908030102		PRIMARY IMPLANT UNCEMENTED ACETABULAR CUPS	0292001
			P090803010201	PRIMARY IMPLANT UNCEMENTED METAL ACETABULAR CUPS	0292001
			P090803010202	PRIMARY IMPLANT UNCEMENTED ONE-PIECE POLYETHYLENE ACETABULAR CUPS	0292001
			P090803010203	PRIMARY IMPLANT UNCEMENTED ONE-PIECE METAL ACETABULAR CUPS	0292001
			P090803010299	PRIMARY IMPLANT UNCEMENTED ACETABULAR CUPS - OTHER	0292001
	P09080302			HIP RESURFACING ACETABULAR COMPONENTS	0292001
	P09080303			REVISION SURGERY ACETABULAR CUPS	0292001
		P0908030301		REVISION SURGERY CEMENTED ACETABULAR CUPS	0292001
		P0908030302		REVISION SURGERY UNCEMENTED ACETABULAR CUPS	0292001
	P09080304			HIP PROSTHESES ACETABULAR INSERTS	0292002
		P0908030401		HIP PROSTHESES POLYETHYLENE ACETABULAR INSERTS	0292002
			P090803040101	STANDARD POLYETHYLENE HIP PROSTHESES INSERTS	0292002
			P090803040102	ECCENTRIC POLYETHYLENE HIP PROSTHESES INSERTS	0292002
			P090803040103	RETENTIVE POLYETHYLENE HIP PROSTHESES INSERTS, ANTI-DISLOCATION	0292002
		P0908030402		HIP PROSTHESES CERAMIC ACETABULAR INSERTS	0292002
		P0908030403		HIP PROSTHESES METAL ACETABULAR INSERTS	0292002

		P0908030499		HIP PROSTHESES ACETABULAR INSERTS – OTHER	0292002
	P09080305			DUAL-MOBILITY ACETABULAR COMPONENTS	
		P0908030501		DOUBLE-MOBILITY ACETABULAR CUPS	0292001
			P090803050101	CEMENTED DOUBLE-MOBILITY ACETABULAR CUPS	0292001
			P090803050102	UNCEMENTED DOUBLE-MOBILITY ACETABULAR CUPS	0292001
		P0908030502		DOUBLE-MOBILITY ACETABULAR COMPONENTS INSERTS	0292002
	P09080306			PRE-ASSEMBLED ACETABULAR COMPONENTS (ACETABULAR CUP + INSERT)	0292005
		P0908030601		PRE-ASSEMBLED ACETABULAR COMPONENTS WITH CERAMIC INSERT	0292005
		P0908030602		PRE-ASSEMBLED ACETABULAR COMPONENTS WITH POLYETHYLENE INSERTS	0292005
		P0908030699		PRE-ASSEMBLED ACETABULAR COMPONENTS - OTHER	0292005
P090804				HIP PROSTHESES FEMORAL COMPONENTS	
	P09080401			PRIMARY IMPLANT FEMORAL STEMS	0292004
		P0908040101		PRIMARY IMPLANT CEMENTED FEMORAL STEMS	0292004
			P090804010101	CEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT	0292004
			P090804010102	CEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL	0292004
			P090804010105	CEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, FOR PRESERVATION	0292004
			P090804010106	CEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT	0292004
			P090804010107	CEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL	0292004
		P0908040102		PRIMARY IMPLANT UNCEMENTED FEMORAL STEMS	0292004
			P090804010201	UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, STRAIGHT	0292004
			P090804010202	UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, ANATOMICAL	0292004
			P090804010205	UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH FIXED NECK, FOR PRESERVATION	0292004
			P090804010206	UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, STRAIGHT	0292004
			P090804010207	UNCEMENTED FEMORAL STEMS FOR PRIMARY IMPLANT, WITH MODULAR NECK, ANATOMICAL	0292004

	P09080402			HIP RESURFACING FEMORAL COMPONENTS	0292004
	P09080403			REVISION SURGERY FEMORAL STEMS	0292004
		P0908040301		REVISION SURGERY CEMENTED FEMORAL STEMS	0292004
			P090804030101	REVISION CEMENTED FEMORAL STEMS, WITH FIXED NECK	0292004
			P090804030102	REVISION CEMENTED FEMORAL STEMS, WITH MODULAR NECK	0292004
		P0908040302		REVISION UNCEMENTED FEMORAL STEMS	0292004
			P090804030201	REVISION UNCEMENTED FEMORAL STEMS, WITH FIXED NECK	0292004
			P090804030202	REVISION UNCEMENTED FEMORAL STEMS, WITH MODULAR NECK	0292004
	P09080404			LARGE RESECTIONS FEMORAL STEMS	0292004
	P09080405			FEMORAL HEADS	0292003
		P0908040501		FEMORAL HEADS FOR PRIMARY IMPLANT OF PARTIAL PROSTHESES	0292003
			P090804050101	CERAMIC FEMORAL HEADS, PARTIAL HIP REPLACEMENT	0292003
			P090804050102	METAL FEMORAL HEADS, PARTIAL HIP REPLACEMENT	0292003
			P090804050199	FEMORAL HEADS FOR PRIMARY IMPLANT OF PARTIAL PROSTHESES - OTHER	0292003
		P0908040502		FEMORAL HEADS FOR PRIMARY IMPLANT OF TOTAL PROSTHESES	0292003
			P090804050201	CERAMIC FEMORAL HEADS, TOTAL HIP REPLACEMENT	0292003
			P090804050202	METAL FEMORAL HEADS, TOTAL HIP REPLACEMENT	0292003
			P090804050299	FEMORAL HEADS FOR PRIMARY IMPLANT OF TOTAL PROSTHESES - OTHER	0292003
		P0908040503		HIP PROSTHESES, BI-ARTICULAR CUPS	0292003
		P0908040504		REVISION FEMORAL HEADS	0292003
	P09080406			ONE-PIECE FEMORAL PROSTHESES (STEM+HEAD)	0292006
	P09080407			MODULAR NECKS	0292004
P090805				HIP PROSTHESES SPACERS	0292042
P090880				HIP PROSTHESES – ACCESSORIES	0292042
	P09088001			ACETABULAR RINGS	0292042
	P09088002			ACETABULAR MESHES	0292042
	P09088003			HIP PROSTHESES AUGMENTS	0292042
	P09088004			HIP PROSTHESES ADAPTERS (INCLUDING CONES AND SLEEVES)	0292042
	P09088005			HIP PROSTHESES CENTRALIZERS	0292042
	P09088006			FEMORAL INTRAMEDULLARY CAPS	0292042

	P09088007			HIP PROSTHESES FIXING SCREWS	0292042
	P09088099			HIP PROSTHESES - OTHER ACCESSORIES	0292042
P090899				HIP PROSTHESES – OTHER	0292042

Anlage 2: Liste aller EMDN-Kodes unterhalb des Levels 3 P0909 KNEE PROSTHESES

Grün markiert: EMDN-Kodes von Leitprodukten Endoprothesen; rot markiert: EMDN-Kodes von Nicht- Leitprodukten Endoprothesen

KODE Level 4	Level 5	Level 6	Level 7	TERM	Katalogwert IRD
P090903				BICOMPARTMENTAL PRIMARY IMPLANT KNEE PROSTHESES	
	P09090301			BICOMPARTMENTAL PRIMARY IMPLANT FEMORAL COMPONENTS	0293002
		P0909030101		BICOMPARTMENTAL PRIMARY IMPLANT CEMENTED FEMORAL COMPONENTS	0293002
		P0909030102		BICOMPARTMENTAL PRIMARY IMPLANT UNCEMENTED FEMORAL COMPONENTS	0293002
		P0909030103		BICOMPARTMENTAL PRIMARY IMPLANT CEMENTABLE FEMORAL COMPONENTS	0293002
	P09090302			BICOMPARTMENTAL PRIMARY IMPLANT TIBIAL COMPONENTS	0293001
		P0909030201		BICOMPARTMENTAL PRIMARY IMPLANT TIBIAL PLATES	0293001
			P090903020101	BICOMPARTMENTAL PRIMARY IMPLANT CEMENTED MOBILE BEARING TIBIAL PLATES	0293001
			P090903020102	BICOMPARTMENTAL PRIMARY IMPLANT UNCEMENTED MOBILE BEARING TIBIAL PLATES	0293001
			P090903020103	BICOMPARTMENTAL PRIMARY IMPLANT CEMENTABLE MOBILE BEARING TIBIAL PLATES	0293001
			P090903020104	BICOMPARTMENTAL PRIMARY IMPLANT CEMENTED FIXED BEARING TIBIAL PLATES	0293001
			P090903020105	BICOMPARTMENTAL PRIMARY IMPLANT UNCEMENTED FIXED BEARING TIBIAL PLATES	0293001
			P090903020106	BICOMPARTMENTAL PRIMARY IMPLANT CEMENTABLE FIXED BEARING TIBIAL PLATES	0293001
		P0909030202		BICOMPARTMENTAL PRIMARY IMPLANT TIBIAL INSERTS	0293001
			P090903020201	BICOMPARTMENTAL PRIMARY IMPLANT MOBILE BEARING TIBIAL INSERTS	0293001
			P090903020202	BICOMPARTMENTAL PRIMARY IMPLANT FIXED BEARING TIBIAL INSERTS	0293001
		P0909030203		BICOMPARTMENTAL PRIMARY IMPLANT TIBIAL COMPONENTS, MONOBLOCK	0293001
			P090903020301	BICOMPARTMENTAL PRIMARY IMPLANT TIBIAL COMPONENTS, MONOBLOCK MADE OF POLYETHYLENE	0293001
			P090903020399	BICOMPARTMENTAL PRIMARY IMPLANT TIBIAL COMPONENTS, MONOBLOCK - OTHER	0293001
P090904				UNICOMPARTMENTAL KNEE PROSTHESES (UNICONDYLAR)	

	P09090401			UNICOMPARTMENTAL KNEE PROSTHESES FEMORAL COMPONENTS (UNICONDYLAR)	0293002
		P0909040101		UNICOMPARTMENTAL KNEE PROSTHESES FEMORAL COMPONENTS (UNICONDYLAR), CEMENTED	0293002
		P0909040102		UNICOMPARTMENTAL KNEE PROSTHESES FEMORAL COMPONENTS (UNICONDYLAR), UNCEMENTED	0293002
	P09090402			UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS	0293001
		P0909040201		UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL PLATES	0293001
			P090904020101	MOBILE CEMENTED UNICOMPARTMENTAL PRIMARY IMPLANT TIBIAL PLATES	0293001
			P090904020102	MOBILE UNCEMENTED UNICOMPARTMENTAL PRIMARY IMPLANT TIBIAL PLATES	0293001
			P090904020103	FIXED CEMENTED UNICOMPARTMENTAL PRIMARY IMPLANT TIBIAL PLATES	0293001
			P090904020104	FIXED UNCEMENTED UNICOMPARTMENTAL PRIMARY IMPLANT TIBIAL PLATES	0293001
		P0909040202		UNICOMPARTMENTAL KNEE REPLACEMENT TIBIAL INSERTS	0293001
			P090904020201	MOBILE UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL INSERTS	0293001
			P090904020202	UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL INSERTS, FIXED	0293001
		P0909040203		PRE-ASSEMBLED UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS (INSERT + TIBIAL PLATE)	0293001
			P090904020301	KNEE PROSTHESES TIBIAL COMPONENTS, PREASSEMBLED, CEMENTED	0293001
			P090904020302	UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS, PREASSEMBLED, UNCEMENTED	0293001
		P0909040204		UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS, MONOBLOCK	0293001
			P090904020401	UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS, MONOBLOCK, MADE OF POLYETHYLENE	0293001
			P090904020499	UNICOMPARTMENTAL KNEE PROSTHESES TIBIAL COMPONENTS, MONOBLOCK - OTHER	0293001
P090905				REVISION KNEE PROSTHESES	
	P09090501			REVISION KNEE PROSTHESES FEMORAL COMPONENTS	0293002
	P09090502			REVISION KNEE PROSTHESES TIBIAL COMPONENTS	0293001
		P0909050201		REVISION KNEE PROSTHESES TIBIAL PLATES	0293001
			P090905020101	REVISION KNEE PROSTHESES MOBILE BEARING TIBIAL PLATES	0293001
			P090905020102	REVISION KNEE PROSTHESES FIXED BEARING TIBIAL PLATES	0293001
		P0909050202		REVISION KNEE PROSTHESES TIBIAL INSERTS	0293001

			P090905020201	REVISION KNEE PROSTHESES MOBILE BEARING TIBIAL INSERTS	0293001
			P090905020202	REVISION KNEE PROSTHESES FIXED BEARING TIBIAL INSERTS	0293001
P090906				KNEE PROSTHESES FOR LARGE RESECTIONS	
P090907				PATELLO-FEMORAL KNEE PROSTHESES	0293002
	P09090701			FEMORAL TROCHLEA RESURFACING COMPONENTS	0293002
	P09090702			PATELLAR COMPONENTS	0293003
		P0909070201		PATELLAR COMPONENTS, MONOBLOCK	0293003
		P0909070202		PATELLAR COMPONENTS, MODULAR	0293003
P090908				KNEE PROSTHESES SPACERS	0293042
P090980				KNEE PROSTHESES – ACCESSORIES	0293042
	P09098001			KNEE PROSTHESES AUGMENTS	0293042
	P09098002			KNEE PROSTHESES ADAPTERS (INCLUDING CONES AND SLEEVES)	0293042
	P09098003			KNEE PROSTHESES OBTURATORS AND PLUGS	0293042
	P09098004			KNEE PROSTHESES CENTRALISERS	0293042
	P09098006			KNEE PROSTHESES STEMS	0293042
		P0909800601		KNEE PROSTHESES FEMORAL STEMS	0293042
		P0909800602		KNEE PROSTHESES TIBIAL STEMS	0293042
	P09098099			KNEE PROSTHESES - ACCESSORIES – OTHER	0293042
P090999				KNEE PROSTHESES – OTHER	0293042