

Manufacturer:

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Germany

Medical Device(s):

ic-Heads

Intended Use:

The ic-Heads are femoral heads intended for articulation with acetabular cup inserts as part of a total hip arthroplasty or with bipolar components as part of a hemi hip arthroplasty. They are connected modularly with hip stems.

The ic-Bipolar Head and ic-Unipolar Head are femoral heads for the hemi hip arthroplasty.

The ic-Bipolar Head is intended to articulate freely with the natural acetabulum on its outer surface, and interface with an ic-head on its inner surface where it allows free rotation of the ic-head.

The ic-Unipolar Head is connected to a hip stem and intended to articulate freely with the natural acetabulum.

REF Number(s):

REF-Numbers see Attachment I - IV

Classification:

Class III

(Council Directive 93/42/EEC, Annex IX, rule 8, in conjunction with commission directive 2005/50/EC)

Standard(s) applied:

EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11135-1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Requirements for materials, sterile barrier systems and packaging systems
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN ISO 14630	Non-active surgical implants - General requirements
EN ISO 21534	Non-active surgical implants - Joint replacement implants - Particular requirements

GMDN code(s) and term(s):

P 33175	Metallic femoral head prosthesis
P 33695	Femoral head bipolar component
P 61786	Hip hemiarthroplasty femur prosthesis (en)

We declare under our sole responsibility that the medical devices listed in the attachment(s) are in conformity with the essential requirements of Annex I of Council Directive 93/42/EEC and have undergone the conformity assessment procedure according to Annex II of Council Directive 93/42/EEC.

Notified Body:

MEDCERT GmbH
Pilatuspool 2
20355 Hamburg
Germany

EC Certificate of Conformity

Council Directive 93/42/EEC Annex II excluding section 4
Certificate No.: 7092GB410201201A
Validity: 01/12/2020 - 27/05/2024

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II, section 4
Certificate No.: 13190GB411210112A
Validity: 12/01/2021 – 27/05/2024

Identification:

CE 0482


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Buxtehude, 14.01.2021
Place, date

i.V. Juliane Höppner
Abteilungsleitung / Head of Regulatory Affairs

EU Declaration of Conformity

Attachment I

Reference number	item description	size	GMDN	GTIN
23122200	ic-head CoCrMo taper 12/14mm	Ø 22mm S	P 33175	4048844016616
23122205	ic-head CoCrMo taper 12/14mm	Ø 22mm M	P 33175	4048844016623
23122210	ic-head CoCrMo taper 12/14mm	Ø 22mm L	P 33175	4048844016630
23872800	ic-head CoCrMo taper 12/14mm	Ø 28mm S	P 33175	4048844017040
23872805	ic-head CoCrMo taper 12/14mm	Ø 28mm M	P 33175	4048844017057
23872810	ic-head CoCrMo taper 12/14mm	Ø 28mm L	P 33175	4048844017064
23872815	ic-head CoCrMo taper 12/14mm	Ø 28mm XL	P 33175	4048844017071
23872820	ic-head CoCrMo taper 12/14mm	Ø 28mm, XXL	P 33175	4048844017088
23872825	ic-head CoCrMo taper 12/14mm	Ø 28mm, XXXL	P 33175	4048844017095
23873200	ic-head CoCrMo taper 12/14mm	Ø 32mm S	P 33175	4048844017101
23873205	ic-head CoCrMo taper 12/14mm	Ø 32mm M	P 33175	4048844017118
23873210	ic-head CoCrMo taper 12/14mm	Ø 32mm L	P 33175	4048844017125
23873215	ic-head CoCrMo taper 12/14mm	Ø 32mm XL	P 33175	4048844017132
23873220	ic-head CoCrMo taper 12/14mm	Ø 32mm, XXL	P 33175	4048844017149
23873225	ic-head CoCrMo taper 12/14mm	Ø 32mm, XXXL	P 33175	4048844017156
23873600	ic-head CoCrMo taper 12/14mm	Ø 36mm S	P 33175	4048844255589
23873605	ic-head CoCrMo taper 12/14mm	Ø 36mm M	P 33175	4048844245276
23873610	ic-head CoCrMo taper 12/14mm	Ø 36mm L	P 33175	4048844255596
23873615	ic-head CoCrMo taper 12/14mm	Ø 36mm XL	P 33175	4048844245290
23873620	ic-head CoCrMo taper 12/14mm	Ø 36mm, XXL	P 33175	4048844255602
23873625	ic-head CoCrMo taper 12/14mm	Ø 36mm, XXXL	P 33175	4048844245313
23222200	ic-head CoCrMo TiN taper 12/14mm	Ø 22mm, S	P 33175	4048844278182
23222205	ic-head CoCrMo TiN taper 12/14mm	Ø 22mm, M	P 33175	4048844282585
23222210	ic-head CoCrMo TiN taper 12/14mm	Ø 22mm, L	P 33175	4048844278366
27872800	ic-head titanium taper 12/14mm	Ø 28mm S	P 33175	4048844018092
27872805	ic-head titanium taper 12/14mm	Ø 28mm M	P 33175	4048844018108

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Attachment II

Reference number	item description	size	GMDN	GTIN
27872810	ic-head titanium taper 12/14mm	Ø 28mm L	P 33175	4048844018115
27872815	ic-head titanium taper 12/14mm	Ø 28mm XL	P 33175	4048844018122
27872820	ic-head titanium taper 12/14mm	Ø 28mm, XXL	P 33175	4048844018139
27872825	ic-head titanium taper 12/14mm	Ø 28mm, XXXL	P 33175	4048844018146
27873200	ic-head titanium taper 12/14mm	Ø 32mm S	P 33175	4048844018153
27873205	ic-head titanium taper 12/14mm	Ø 32mm M	P 33175	4048844018160
27873210	ic-head titanium taper 12/14mm	Ø 32mm L	P 33175	4048844018177
27873215	ic-head titanium taper 12/14mm	Ø 32mm XL	P 33175	4048844018184
27873220	ic-head titanium taper 12/14mm	Ø 32mm, XXL	P 33175	4048844018191
27873225	ic-head titanium taper 12/14mm	Ø 32mm, XXXL	P 33175	4048844018207
27873600	ic-head titanium taper 12/14mm	Ø 36mm S	P 33175	4048844018214
27873605	ic-head titanium taper 12/14mm	Ø 36mm M	P 33175	4048844018221
27873610	ic-head titanium taper 12/14mm	Ø 36mm L	P 33175	4048844018238
27873615	ic-head titanium taper 12/14mm	Ø 36mm XL	P 33175	4048844018245
27873620	ic-head titanium taper 12/14mm	Ø 36mm, XXL	P 33175	4048844018252
27873625	ic-head titanium taper 12/14mm	Ø 36mm, XXXL	P 33175	4048844018269
27122800*	ic-head titanium taper 14/16mm	Ø 28mm, S	P 33175	4048844017934
27122805*	ic-head titanium taper 14/16mm	Ø 28mm, M	P 33175	4048844017941
27122810*	ic-head titanium taper 14/16mm	Ø 28mm, L	P 33175	4048844017958
27122815*	ic-head titanium taper 14/16mm	Ø 28mm, XL	P 33175	4048844017965
27122820*	ic-head titanium taper 14/16mm	Ø 28mm, XXL	P 33175	4048844017972
27122825*	ic-head titanium taper 14/16mm	Ø 28mm, XXXL	P 33175	4048844017989
27123200*	ic-head titanium taper 14/16mm	Ø 32mm, S	P 33175	4048844017996
27123205*	ic-head titanium taper 14/16mm	Ø 32mm, M	P 33175	4048844018009
27123210*	ic-head titanium taper 14/16mm	Ø 32mm, L	P 33175	4048844018016
27123215*	ic-head titanium taper 14/16mm	Ø 32mm, XL	P 33175	4048844018023
27123220*	ic-head titanium taper 14/16mm	Ø 32mm, XXL	P 33175	4048844018030
27123225*	ic-head titanium taper 14/16mm	Ø 32mm, XXXL	P 33175	4048844018047

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Attachment III

Reference number	item description	size	GMDN	GTIN
27123600*	ic-head titanium taper 14/16mm	Ø 36mm, S	P 33175	4048844018054
27123605*	ic-head titanium taper 14/16mm	Ø 36mm, M	P 33175	4048844108137
27123610*	ic-head titanium taper 14/16mm	Ø 36mm, L	P 33175	4048844018078
27123615*	ic-head titanium taper 14/16mm	Ø 36mm, XL	P 33175	4048844018085
26874000	ic-Unipolar head taper 12/14mm	Ø 40mm	P 61786	4048844107796
26874200	ic-Unipolar head taper 12/14mm	Ø 42mm	P 61786	4048844017811
26874400	ic-Unipolar head taper 12/14mm	Ø 44mm	P 61786	4048844017828
26874600	ic-Unipolar head taper 12/14mm	Ø 46mm	P 61786	4048844017835
26874700	ic-Unipolar head taper 12/14mm	Ø 47mm	P 61786	4048844017842
26874800	ic-Unipolar head taper 12/14mm	Ø 48mm	P 61786	4048844017859
26874900	ic-Unipolar head taper 12/14mm	Ø 49mm	P 61786	4048844017866
26875000	ic-Unipolar head taper 12/14mm	Ø 50mm	P 61786	4048844017873
26875100	ic-Unipolar head taper 12/14mm	Ø 51mm	P 61786	4048844017880
26875200	ic-Unipolar head taper 12/14mm	Ø 52mm	P 61786	4048844017897
26875400	ic-Unipolar head taper 12/14mm	Ø 54mm	P 61786	4048844017903
26875600	ic-Unipolar head taper 12/14mm	Ø 56mm	P 61786	4048844017910
26875800	ic-Unipolar head taper 12/14mm	Ø 58mm	P 61786	4048844017927
21512238	ic-bipolar head CoCrMo	Ø 22/38mm	P 33695	4048844015855
21512239	ic-bipolar head CoCrMo	Ø 22/39mm	P 33695	4048844112127
21512240	ic-bipolar head CoCrMo	Ø 22/40mm	P 33695	4048844015879
21512241	ic-bipolar head CoCrMo	Ø 22/41mm	P 33695	4048844112134
21510042	ic-bipolar head CoCrMo	Ø 28/42mm	P 33695	4048844015657
21510043	ic-bipolar head CoCrMo	Ø 28/43mm	P 33695	4048844015664
21510044	ic-bipolar head CoCrMo	Ø 28/44mm	P 33695	4048844015671
21510045	ic-bipolar head CoCrMo	Ø 28/45mm	P 33695	4048844015688
21510046	ic-bipolar head CoCrMo	Ø 28/46mm	P 33695	4048844015695
21510047	ic-bipolar head CoCrMo	Ø 28/47mm	P 33695	4048844015701

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Attachment IV

Reference number	item description	size	GMDN	GTIN
21510048	ic-bipolar head CoCrMo	Ø 28/48mm	P 33695	4048844105211
21510049	ic-bipolar head CoCrMo	Ø 28/49mm	P 33695	4048844015725
21510050	ic-bipolar head CoCrMo	Ø 28/50mm	P 33695	4048844015732
21510051	ic-bipolar head CoCrMo	Ø 28/51mm	P 33695	4048844015749
21510052	ic-bipolar head CoCrMo	Ø 28/52mm	P 33695	4048844015756
21510053	ic-bipolar head CoCrMo	Ø 28/53mm	P 33695	4048844015763
21510054	ic-bipolar head CoCrMo	Ø 28/54mm	P 33695	4048844015770
21510055	ic-bipolar head CoCrMo	Ø 28/55mm	P 33695	4048844015787
21510056	ic-bipolar head CoCrMo	Ø 28/56mm	P 33695	4048844015794
21510057	ic-bipolar head CoCrMo	Ø 28/57mm	P 33695	4048844105204
21510058	ic-bipolar head CoCrMo	Ø 28/58mm	P 33695	4048844015817
21510059	ic-bipolar head CoCrMo	Ø 28/59mm	P 33695	4048844015824
21510060	ic-bipolar head CoCrMo	Ø 28/60mm	P 33695	4048844015831
21510062	ic-bipolar head CoCrMo	Ø 28/62mm	P 33695	4048844015848

End of schedule. No additional information past this point.