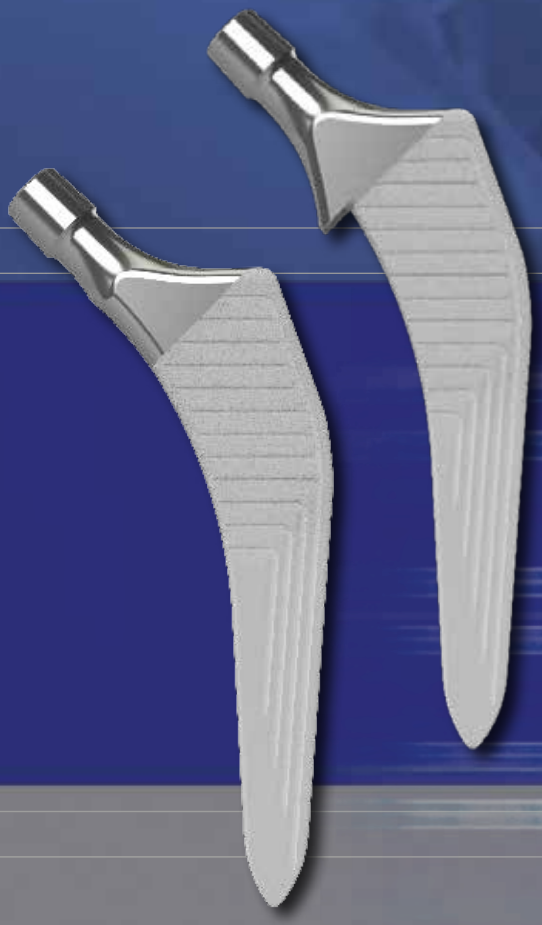
AMIStem SYSTEM

THE LOGICAL EVOLUTION OF HIP STEM DESIGN

FIRST STEM SPECIFICALLY DESIGNED FOR AMIS



Surgical Technique

Joint | Spine | Sports Med

Medacta International

INTRODUCTION

This document describes the Surgical Technique for the AMIStem System. The AMIStem product range is composed of:

- AMIStem-P: cementless stem in Titanuim-Niobium alloy with Titanium plasma spray coating on the proximal area and HA coating on the shaft
- AMIStem-P Collared: cementless collared stem in Titanuim-Niobium alloy with Titanium plasma spray coating on the proximal area and HA coating on the shaft

For more information regarding implantation using the AMIS approach, please see the dedicated AMIS Surgical Technique.

Please read the instructions for use thoroughly and, should you have any questions concerning product compatibility, contact your Medacta representative.

AMIStem-P

AMIStem-P Collared

CAUTION

Federal law (USA) restricts this device to sale distribution and use by or on the order of a physician.

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1 INDICATIONS OF USE

The hip prosthesis AMIStem-P and AMIStem-P Collared are designed for cementless use in total hip arthroplasty, for primary or revision surgery. Hip replacement is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid polyarthritis, or congenital hip dysplasia
- Avascular necrosis of the femoral head
- Acute traumatic fracture of the femoral head or neck
- Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement

2 CONTRAINDICATIONS

Total or partial hip replacement is contraindicated in the following cases:

- Acute, systemic or chronic infection
- Skeletal immaturity
- Muscular, neurological or vascular deficiency of the affected limb
- Bone destruction, or loss of bone characteristics that may compromise the stability of the implant
- Pathologies that may compromise the functionality of the implant in any way

Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications.
It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

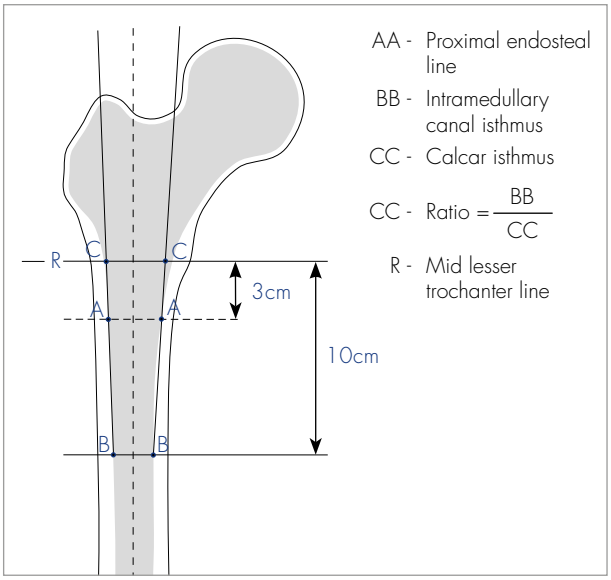
3 PRE-OPERATIVE PLANNING

Careful preoperative planning is essential. It will help the surgeon to pre-select the femoral implant size in order to recreate as closely as possible the patient's anatomy. In addition, using the set of X-ray templates to the scale of 1.15:1 (with an X-ray of the same magnification), it will be possible to determine:

- The implant size
- The level of the neck cut
- The prosthetic rotation centre

An important parameter to be analysed is the shape of the femoral canal. Dorr classified different anatomies in 3 types of bone, based on roentgenographic evaluation and bone biopsy and histomorphometry.

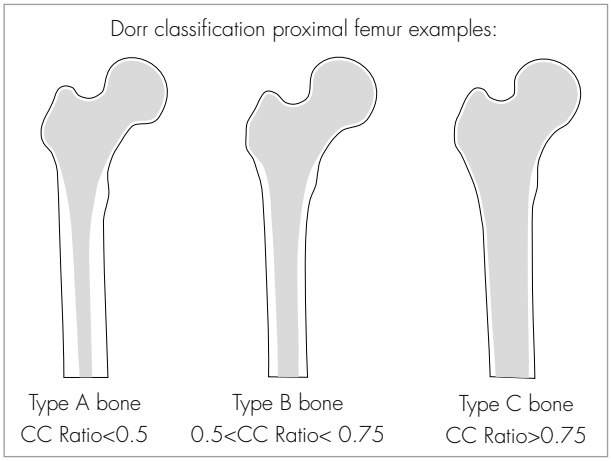
Considering radiographic evaluation, the shape of the proximal femur can be assessed through the canal to calcar isthmus ratio (CC Ratio), calculated as the ratio between the intramedullary canal isthmus (BB*) and the calcar isthmus (CC**).



* *The intramedullary canal isthmus (BB) is given by the distal endosteal contact points located 10 cm below the reference line through the mid lesser trochanter.*

** *The calcar isthmus (CC) is measured on R and is given by the line conecting the proximal endosteal points (AA, 3 cm below R), and distal endosteal points (BB, 10 cm below R). Dorr et al considered the proximal distance of 3 cm and distal distance of 10 cm optimal to the endosteal measurements.*

According to Dorr classification 3 different types of bone can be identified:
Type A bone (CC Ratio<0.5): shows thick cortices with a narrow funnel shape of the proximal femoral canal.
Type B bone (0.5<CC Ratio< 0.75): presents thin medial and posterior cortices, frequently with irregular endosteal surfaces.
Type C bone (CC Ratio>0.75): has seriously thin medial and posterior cortices with a wide cylindrical shape femoral canal[1,2].



The CC Ratio is an indicator of the shape of the proximal femur and aids the implant selection for the AMIStem system.

NOTE: the final implant will be selected intra-operatively because of possible discrepancies between actual conditions and templating.

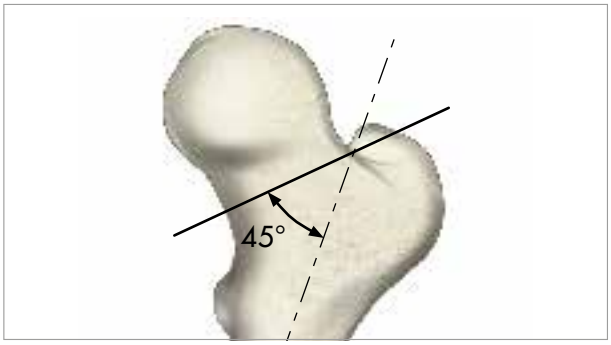
[1] Dorr LD, Faugere MC, Mackel AM, Gruen TA, Bognar B, Malluche HH. Structural and cellular assessment of bone quality of proximal femur. Bone, 1993 May-Jun;14(3):231-42.
[2] Sah AP, Thornhill TS, LeBoff MS, Glowacki J. Correlation of Plain Radiographic Indices of the Hip with Quantitative Bone Mineral Density. Osteoporos Int, 2007 Aug;18(8):1119-26.

4 SURGICAL APPROACH

These stems have been developed especially for use during the AMIS surgical approach (AMIS=Anterior Minimally Invasive Surgery). The choice of surgical approach is up to the surgeon and specific instrumentation for posterior and lateral approaches is also available. Please see the dedicated AMIS Surgical Technique to experience the synergy between AMIStem and AMIS approach.

5 FEMORAL NECK OSTEOTOMY

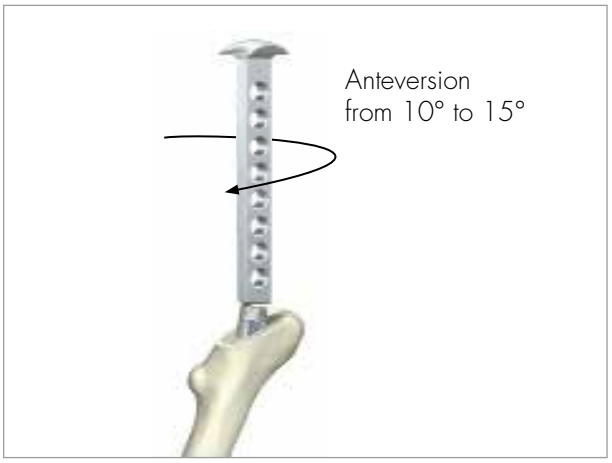
The level of the neck cut is determined during preoperative planning using the X-ray templates.
The femoral neck osteotomy is at an angle of 45° to the diaphyseal axis of the femur.
The resection is performed with an oscillating saw, taking care to maintain the 45° angle.
The femoral head is removed using an extractor.



6 FEMORAL PREPARATION

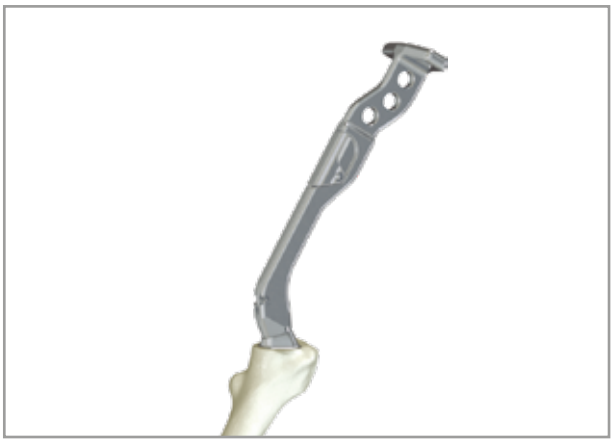
For access to the medullary canal, the thigh is held in the position providing the best exposure of the diaphyseal axis, depending on the selected approach.

To avoid undersizing and varus positions of the stem, a box chisel is applied opposite the digital fossa of the femoral neck.
Guide the chisel with a slight anteversion: this step is essential for correct application of the broach and implant. This removes a block of cancellous bone.

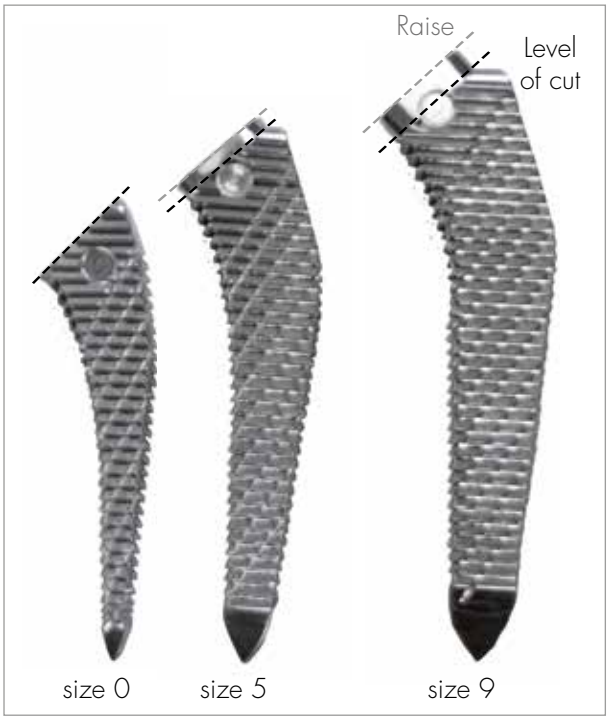


It is recommended to make a slight recess in the neck base or in the trochanteric overhang.

The femoral diaphysis is prepared using sequential broaches.
Assemble the broach on the manual broach handle.



The AMIStem implant has a neck length that increases with the size. In order to always use the same trial necks, **THE BROACHES HAVE A RAISE without teeth. The raise is different for each size and leads the level of the cut.** The broaches must be inserted to the optimum level determined by the 45° cut, until the level of the last tooth.



WARNING

Never force impaction when the broach is blocked in the diaphysis.

NOTE: the size 0 and size 00 broaches do not have the raise.

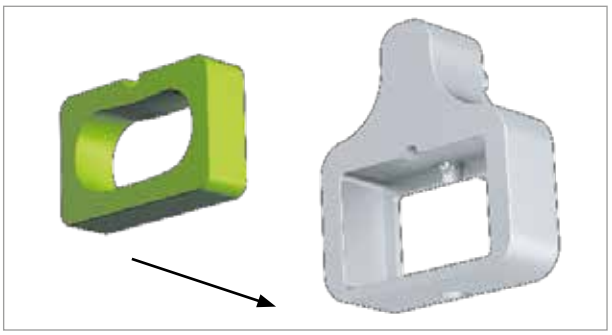
Broaches of increasing sizes are introduced until complete locking; the first broach determines the positions of the following broaches.

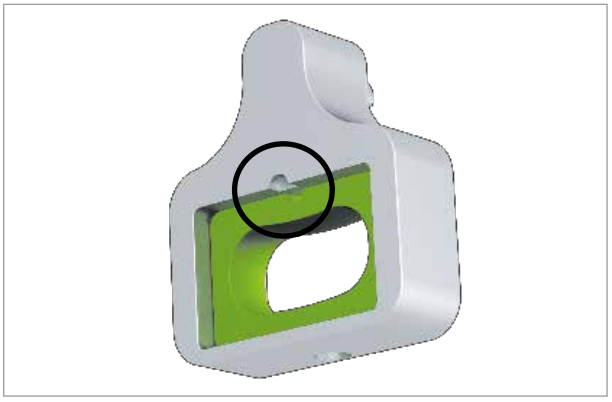
Check the broach anteversion.

The final broach should be rotationally stable to assure stability of the implant.

7 CALCAR PREPARATION

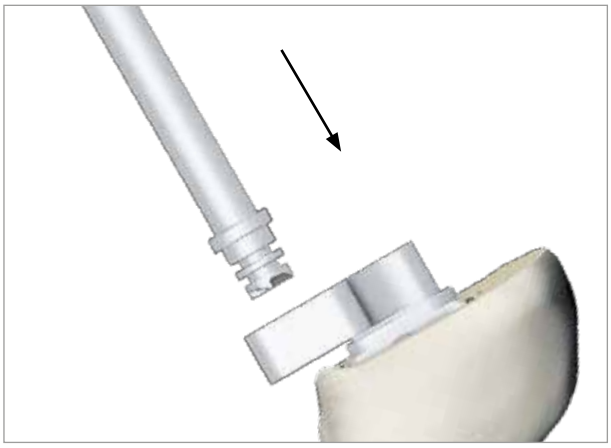
After completely locking the broach in the diaphysis, the broach handle can be removed.
In case of a collared stem, to ensure an adequate calcar preparation, check that the bone cut level corresponds to the last broach tooth. If the broach is under the correct level a recut can be done or the calcar reamer can be used to achieve a flat resection surface.
A support guide to connect with the broach is available together with 10 different calcar adaptors (one for each femoral broach size). The color of the adaptor represents a specific broach size relating to the color of the package label of the final stem, as reported in the paragraph "Implants nomenclature".
Position the correct calcar adaptor in the support guide, aligning both landmarks.

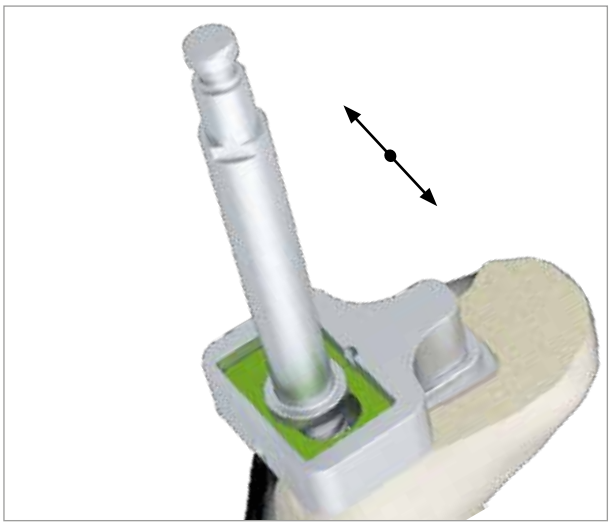




Lock the assembly (support guide and correct calcar adaptor) by pressing it onto the socket.

Mill the excess bone with the calcar reamer.





The calcar reamer automatically blocks at the cut level.

8 TRIALING

After completely locking the broach in the diaphysis, the broach handle or the calcar reamer (with guide) can be removed.

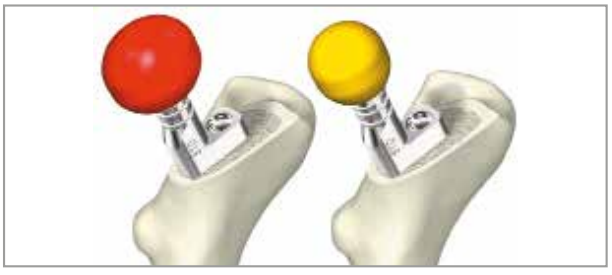
A trial neck, standard or lateralized, is fitted to the broach.

To lock the trial necks to the broach press onto the socket; to unlock pull the neck.

Trial heads of different diameters and sizes are available to perform the trial reductions.
A trial head is fitted to the trial neck by pushing it onto the taper.

TRICK

To make head insertion easier wet the head before insertion.



After placement of the trial or final acetabular component, the trial reduction is performed with the help of the head impactor.

NOTE: the head impactor must be used only for head impaction and not for the correction of the acetabular shell position.

To remove a trial head, simply pull it.

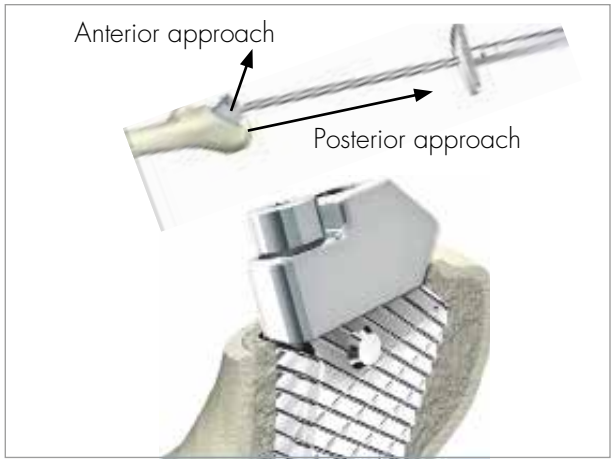
TRICK

If the trial head is difficult to remove from the trial neck, wet the trial head - trial neck assembly. Turn and pull a little on the trial head in order to facilitate its extraction.

After checking and testing mobility, joint stability and lower limb length, remove the broach.

TRICK

An extraction system can be used if the broach is difficult to remove. First screw the broach extractor into the broach. Depending on the selected approach, screw the screwed stem extractor M8 onto the broach extractor. Pull out the broach.



9 FINAL IMPLANT

9.1 Cementless implant

Insert the final prosthesis into place. The final prosthesis size corresponds to the size of the last trial stem or manual broach.

WARNING

Take care not to damage the taper's micro-thread when positioning the final implant.

The stem is inserted to the limit corresponding to the test. Carefully perform the final impaction using a dedicated impactor.

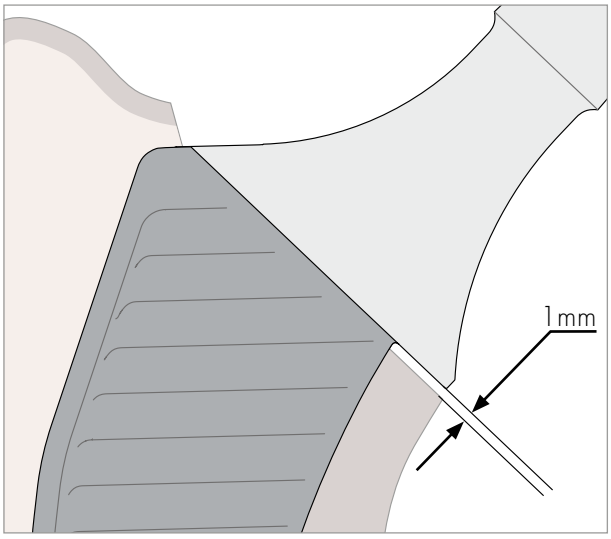
The anteversion of the stem is guided by the quadrangular recess left in the femur by the broaches.

CAUTION

Under no circumstances should the implant anteversion be changed at this stage.

WARNING

Never force impaction when the stem is blocked in the diaphysis.



NOTE: the AMIStem-H Collared, together with the calcar preparation technique, was designed to leave a distance of 1 mm between the collar and the medial calcar. Please bear this in mind during final impaction.

A further trial reduction can then be performed to determine the final head size.

CAUTION

The metal head sizes XL (for ∅ 28 mm and ∅ 32 mm) and XXL (for ∅ 28 mm, ∅ 32 mm and ∅ 36 mm) have a collar. This may decrease the Range of Motion in comparison to shorter head sizes. Always perform trial reduction with the chosen head.

The stem taper must be thoroughly cleaned before impacting the prosthetic head.
Place in position the final head of the chosen size.

WARNING

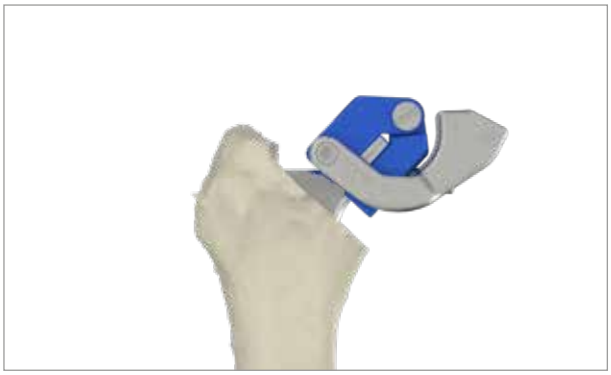
Never use a metal hammer to fix the ceramic head. Use only the plastic head impactor provided for this purpose.

NOTE: For further details about ceramic femoral heads, please refer to the instructions for use for ceramic femoral heads.

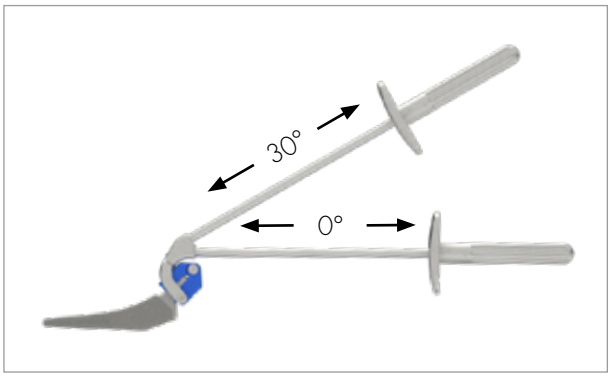
10 REMOVAL PROCEDURE

After impaction, if the final stem needs to be removed or repositioned, a stem repositioner is available. This repositioner can be used with any hip approach, including the AMIS technique.

Assemble the stem repositioner by unscrewing the screw with the 3.5mm screwdriver to open the plastic clamps. Then, assemble it to the implanted stem until this is firmly seated between the plastic clamps and re-tighten the screw. The metal body should be positioned on the medial side of the stem.



Depending on the selected approach, screw the threaded stem extractor M8 onto the stem repositioner (30° hole is suggested for the AMIS approach). Pull out the stem.



11 IMPLANTS NOMENCLATURE

AMIStem-P

Standard	Size	Lateralised
01.18.399	00[1]	-
01.18.400	0	01.18.410
01.18.401	1	01.18.411
01.18.402	2	01.18.412
01.18.403	3	01.18.413
01.18.404	4	01.18.414
01.18.405	5	01.18.415
01.18.406	6	01.18.416
01.18.407	7	01.18.417
01.18.408	8	01.18.418
01.18.409	9	-

AMIStem-P Collared

Standard	Size	Lateralised
01.18.429	00[1]	-
01.18.430	0	01.18.440
01.18.431	1	01.18.441
01.18.432	2	01.18.442
01.18.433	3	01.18.443
01.18.434	4	01.18.444
01.18.435	5	01.18.445
01.18.436	6	01.18.446
01.18.437	7	01.18.447
01.18.438	8	01.18.448
01.18.439	9	-

Calcar Adaptor - Colour Reference

Size	00[1]	0	1	2	3	4	5	6	7	8	9
Colour	Magenta	Dark Green	Red	Yellow	Light Brown	Light Green	Dark Blue	Silver	Pink	Light Blue	Orange

[1] On request

HEADS


Diameter (mm)	Size	CoCr	MectaCer BIOLOX *delta*
∅ 22	S	01.25.124	-
∅ 22	M	01.25.123	-
∅ 28	S	01.25.011	01.29.201
∅ 28	M	01.25.012	01.29.202
∅ 28	L	01.25.013	01.29.203
∅ 28	XL	01.25.014	-
∅ 28	XXL	01.25.015	-
∅ 32	S	01.25.021	01.29.204
∅ 32	M	01.25.022	01.29.205
∅ 32	L	01.25.023	01.29.206
∅ 32	XL	01.25.024	01.29.207
∅ 32	XXL	01.25.025	-
∅ 36	S	01.25.030	01.29.208
∅ 36	M	01.25.031	01.29.209
∅ 36	L	01.25.032	01.29.210
∅ 36	XL	01.25.033	01.29.211
∅ 36	XXL	01.25.034	-
∅ 40	S	-	01.29.212
∅ 40	M	-	01.29.213
∅ 40	L	-	01.29.214
∅ 40	XL	-	01.29.215

MectaCer BIOLOX Option system[1]

Head Diameter (mm)	Reference
∅ 28	01.29.230H
∅ 32	01.29.231H
∅ 36	01.29.232H
∅ 40	01.29.233H
∅ 44	01.29.234H

Sleeve Size	Reference
S	01.29.240A
M	01.29.241A
L	01.29.242A
XL	01.29.243A

[1] Specific for revision cases

NOTES

NOTE FOR STERILIZATION

The instruments are not sterile upon delivery. Instruments must be cleaned before use and sterilized in an autoclave respecting the US regulations, directives where applicable, and following the manufacturers instructions for use of the autoclave. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilization of Medacta® International reusable orthopaedic devices" available at www.medacta.com.

REDEFINING BETTER
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MEDACTA.COM

Medacta
International

Medacta International SA
Strada Regina - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
info@medacta.ch

Find your local dealer at: medacta.com/locations

AMIStem
Surgical Technique

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