AMIStem SYSTEM

FIRST STEM SPECIFICALLY DESIGNED FOR AMIS

Surgical Technique

Hip | Knee | Spine | Navigation

Medacta International

INTRODUCTION

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

- *AMIStem - H: cementless stem in Titanium- Niobium alloy with HA coating*
- *AMIStem - H Collared: cementless collared stem in Titanium- Niobium alloy with HA coating. May assist in the prevention of subsidence in patients that present Dorr Type C bone.*
- *AMIStem - C: cemented stem in high nitrogen stainless steel*

For more details about implantation with 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 - H

AMIStem - H Collared

AMIStem - C

INDEX

1 INDICATIONS OF USE

The AMIStem hip prostheses are designed to be used in total or partial hip arthroplasty, for primary or revision surgery. Total hip arthroplasty is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthrosis, 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, partial hip arthroplasty, hip resurfacing replacement or total hip arthroplasty

Partial hip arthroplasty is indicated in the following cases:

- Acute traumatic fracture of the femoral head or neck
- Non-union of femoral neck fracture
- Avascular necrosis of the femoral head
- Primary pathology involving the femoral head but with a non deformed acetabulum

2 CONTRAINDICATIONS

The AMIStem contraindications are the standard contraindications for total or partial hip arthroplasty:

- Acute, systemic or chronic infection
- Skeletal immaturity
- Severe muscular, neurological, vascular deficiency or other pathologies of the affected limb that may compromise the functionality of the implant
- Bone condition that may compromise the stability of the implant

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.

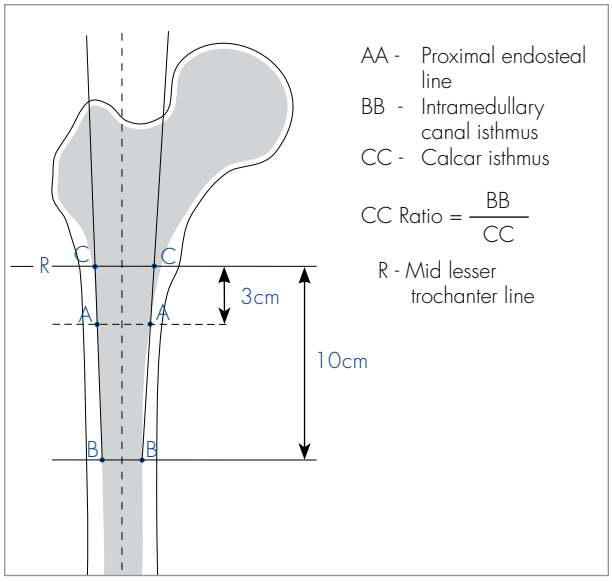
3 PREOPERATIVE PLANNING

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.*

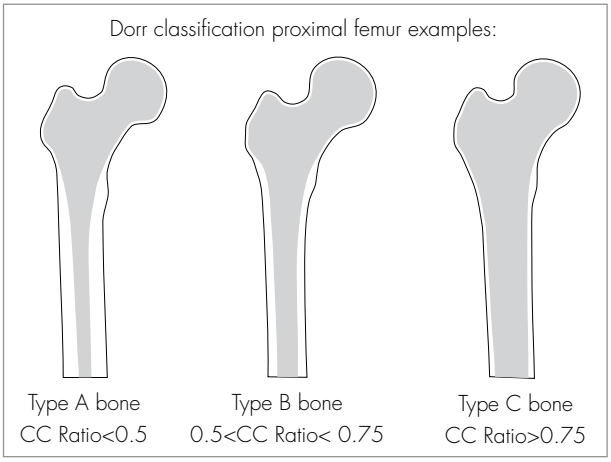
** *The calcar isthmus (CC) is measured on R and is given by the line connecting the proximal endosteal points (AA, 3 cm below R) and distal endosteal points (10 cm below R). Dorr et al considered the proximal distance of 3 cm and distal distance of 10 cm optimal to the endosteal measurements.*

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 size will be selected intra-operatively due to 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.

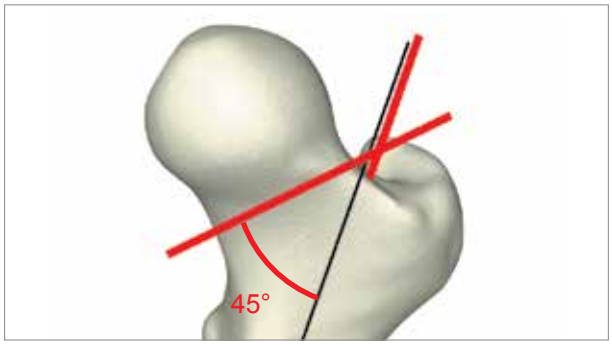
[2] Sah AP, Thornhill TS, LeBoff MS, Glowacki J. Correlation of Plain Radiographic Indices of the Hip with Quantitative Bone Mineral Density. Osteoporos Int, 2007 Aug;18(8):1119-26.

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

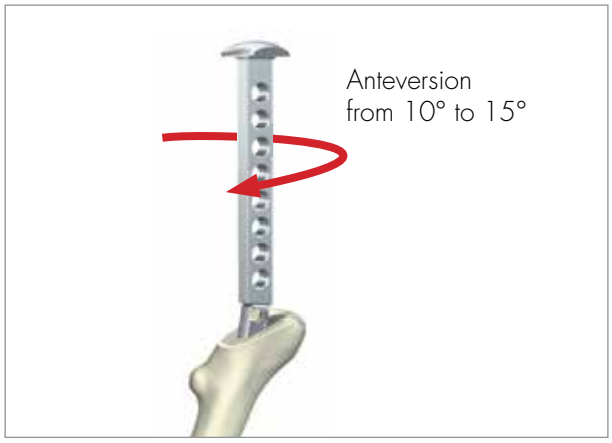
The level of the neck cut is determined during preoperative planning using the X-ray templates.
The femoral neck osteotomy is at an angle of 45° to the diaphyseal axis of the femur.
The resection is performed with an oscillating saw, taking care to maintain the 45° angle.
The femoral head is removed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



6 FEMORAL PREPARATION

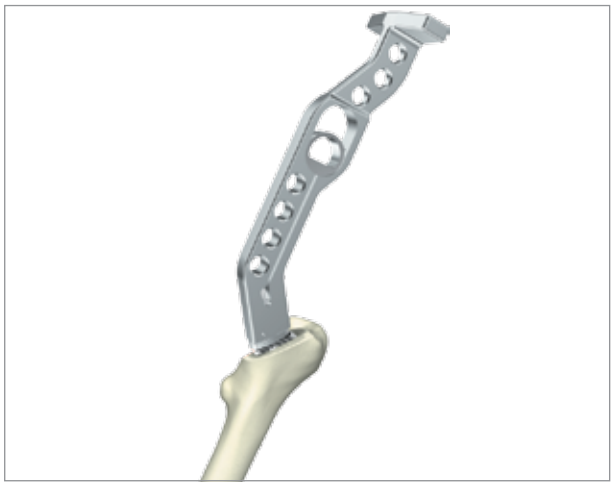
For access to the medullary canal, the thigh is held in the position providing the best exposure of the diaphyseal axis, depending on the selected approach.

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.

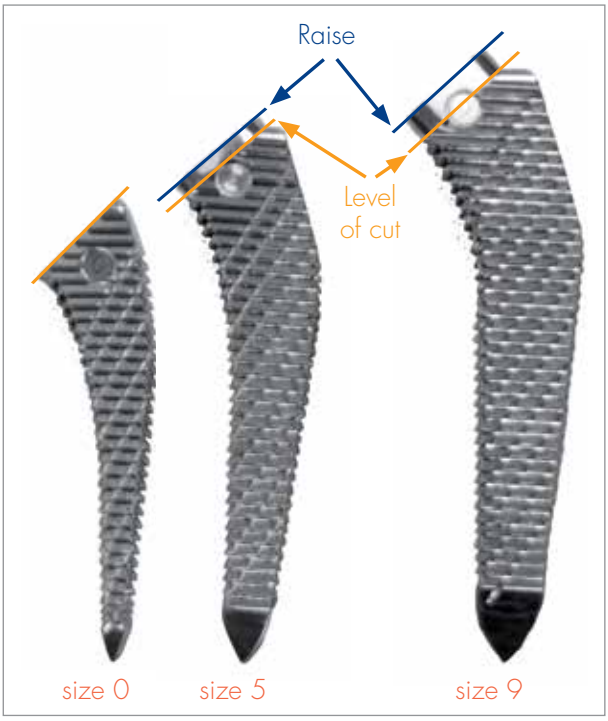


It is recommended to make a slight recess in the neck base or in the trochanteric overhang.

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 has to be above the femoral 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 00 broaches do not have the raise.

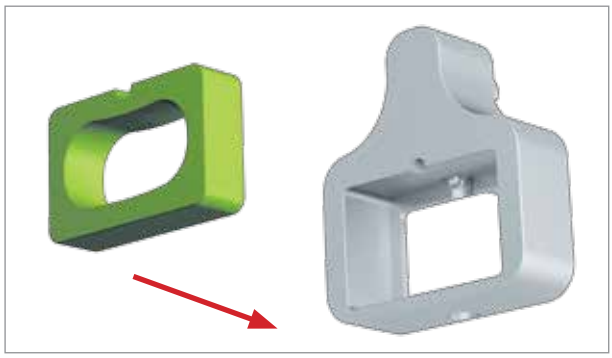
Broaches of increasing sizes are introduced until complete locking; the first broach determines the positions of the following broaches.

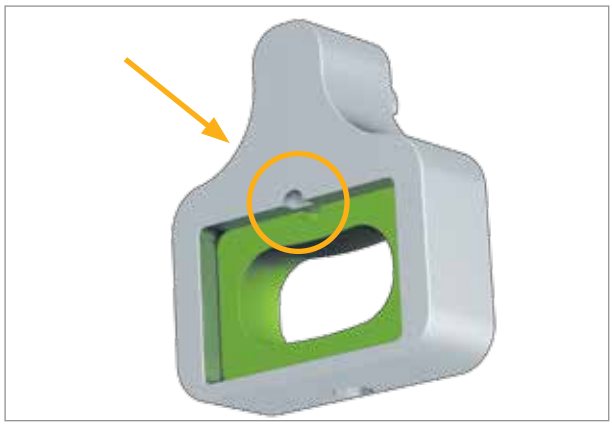
Check the broach anteversion.

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

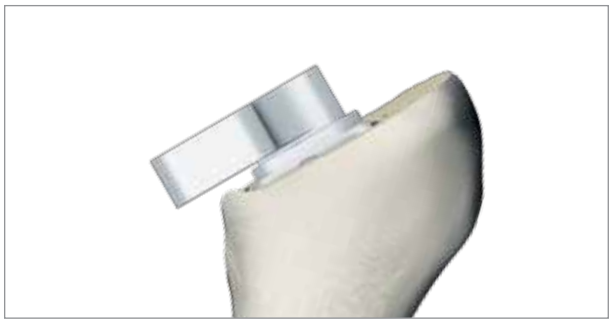
7 CALCAR PREPARATION

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.

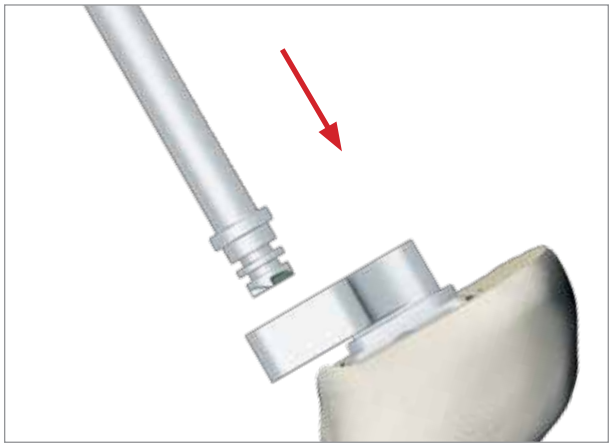


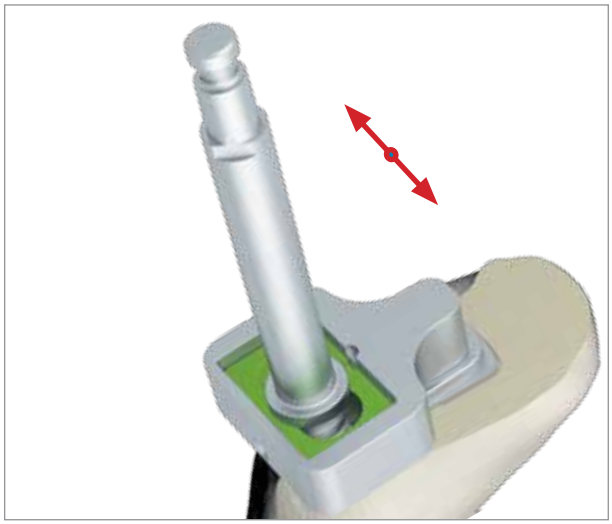


Lock the assembly (support guide and correct calcar adaptor) by pressing it onto the socket.



Mill the excess bone with the calcar reamer.





The calcar reamer automatically blocks at the cut level.

8 TRIALING

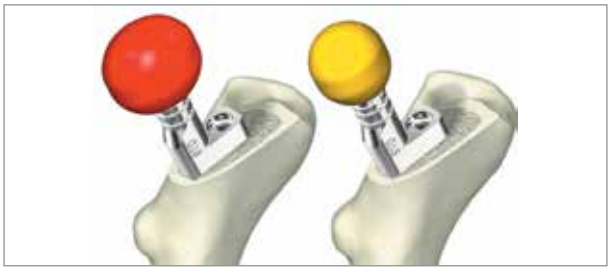
After completely locking the broach in the diaphysis, the broach handle or the calcar reamer (with guide) can be removed.
A trial neck, standard or lateralised, is fitted to the broach.

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

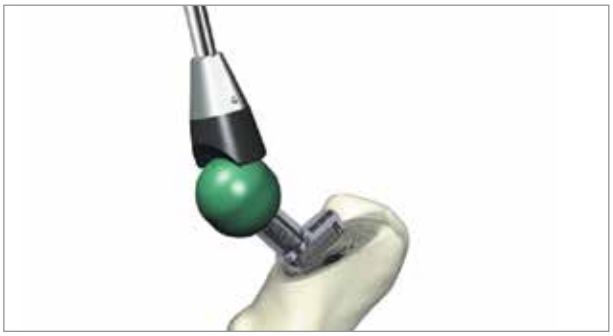
Trial heads of different diameters and sizes are available to perform the trial reductions.
A trial head is fitted to the trial neck by pushing it onto the taper.

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.

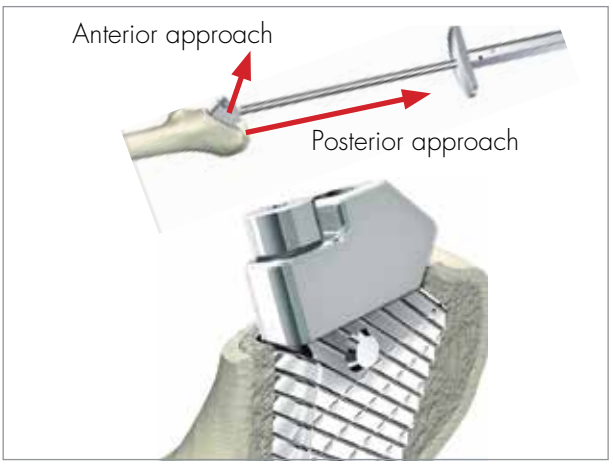
TRICK

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 IMPLANTS

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

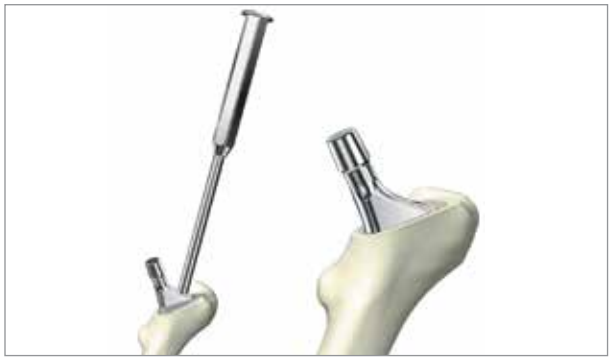
Take care not to damage the taper's micro-thread when positioning the final implant.

The stem is inserted to the limit corresponding to the test and matching the end of the macrostructures. 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.

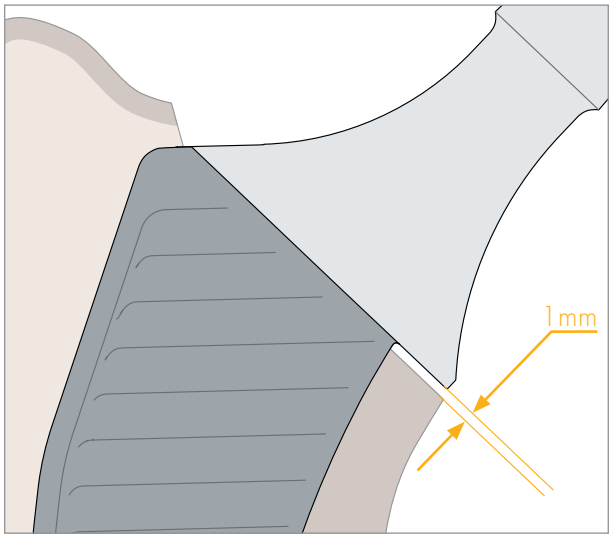
CAUTION

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.

9.2 Cemented implant

Two different techniques can be used for the final implant positioning.
Technique 1 produces a thick and complete cement mantle around the stem: the reamed femoral cavity is 1.4 mm larger than the implanted prosthesis.
Technique 2 (line-to-line reaming) has a thinner cement mantle and it produces a cavity which is the same size as the inserted prosthesis: after the cement insertion the prosthesis is implanted as a press-fit.[3]
Broach and stem selection must be done according to the following table.

TABLE FOR BROACH AND STEM SELECTION

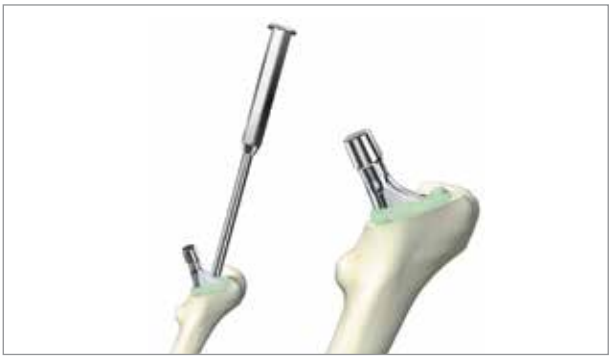
Broach size	Stem size Tech 1	Stem size Tech 2
0	-	0
1	0	1
2	1	2
3	2	3
4	3	4
5	4	5
6	5	6
7	6	7
8	7	8
9	8	-

CAUTION

If the pre-operative planning shows that the size 9 broach is required, be sure to use the first reaming surgical technique (Tech 1) and implant the size 8 as the final stem.

Remove any loose, unsupportive cancellous bone from the canal with a spoon or canal brush.
Close the distal canal with a medullary plug at least 1 cm distal to the tip of the stem.

Clean the intramedullary canal with pulse lavage and dry it. Keep the canal packed until cement is ready to be injected.
Using retrograde cementation, introduce the cement into the canal by means of a cement gun.
Pressurise the cement column to allow the cement to interdigitate into the cancellous bone.



Introduce the femoral stem into the medullary canal until the optimal position, established during the trial step, is reached.
Hold the stem securely in the correct position with the stem impactor until the cement has hardened in order to avoid the stem moving from its optimal position.

WARNING

Take care not to damage the neck's micro-thread whilst placing the final implant.

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 smaller sizes. Always perform trial reduction with the chosen head.

The stem taper must be thoroughly cleaned before placing 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.

[3] Skinner JA, Todo S, Taylor M, Wang JS, Pinskerova V, Scott G. Should the cement mantle around the femoral component be thick or thin? J Bone Joint Surg Br. 2003 Jan;85(1):45-51.

10 IMPLANTS NOMENCLATURE

AMIStem-H

Standard	Size	Lateralised
01.18.098	00[1]	-
01.18.130	0	01.18.140
01.18.131	1	01.18.141
01.18.132	2	01.18.142
01.18.133	3	01.18.143
01.18.134	4	01.18.144
01.18.135	5	01.18.145
01.18.136	6	01.18.146
01.18.137	7	01.18.147
01.18.138	8	01.18.148
01.18.139	9	-

AMIStem-H Collared

Standard	Size	Lateralised
01.18.229	00[1]	-
01.18.230	0	01.18.240
01.18.231	1	01.18.241
01.18.232	2	01.18.242
01.18.233	3	01.18.243
01.18.234	4	01.18.244
01.18.235	5	01.18.245
01.18.236	6	01.18.246
01.18.237	7	01.18.247
01.18.238	8	01.18.248
01.18.239	9	-

AMIStem-C

Standard	Size	Lateralised
-	-	-
01.18.150	0	01.18.100
01.18.151	1	01.18.101
01.18.152	2	01.18.102
01.18.153	3	01.18.103
01.18.154	4	01.18.104
01.18.155	5	01.18.105
01.18.156	6	01.18.106
01.18.157	7	01.18.107
01.18.158	8	01.18.108
-	-	-

Calcar Adaptor - Colour Reference

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

[1] On request

HEADS



Diameter	Size	Stainless steel	CoCr	CeramTec BIOLOX *delta*	CeramTec BIOLOX Option[II]
Ø 22 mm	S	01.25.130[I]	01.25.124[I]	-	-
Ø 22 mm	M	25055.2203[I]	01.25.123[I]	-	-
Ø 28 mm	S	25055.2801	01.25.011	38.49.7175.445.00	38.49.7176.935.81
Ø 28 mm	M	25055.2803	01.25.012	38.49.7175.455.00	38.49.7176.935.82
Ø 28 mm	L	25055.2805	01.25.013	38.49.7175.465.00	38.49.7176.935.85
Ø 28 mm	XL	25055.2807	01.25.014	-	38.49.7176.935.84
Ø 28 mm	XXL	25055.2810[I]	01.25.015[I]	-	-
Ø 32 mm	S	25055.3201	01.25.021	38.49.7175.665.00	38.49.7176.945.81
Ø 32 mm	M	25055.3203	01.25.022	38.49.7175.675.00	38.49.7176.945.82
Ø 32 mm	L	25055.3205	01.25.023	38.49.7175.685.00	38.49.7176.945.85
Ø 32 mm	XL	25055.3207	01.25.024	38.49.7181.345.00	38.49.7176.945.84
Ø 32 mm	XXL	25055.3210[I]	01.25.025[I]	-	-
Ø 36 mm	S	-	01.25.030	38.49.7179.275.00	38.49.7176.965.81
Ø 36 mm	M	-	01.25.031	38.49.7179.285.00	38.49.7176.965.82
Ø 36 mm	L	-	01.25.032	38.49.7179.295.00	38.49.7176.965.85
Ø 36 mm	XL	-	01.25.033	38.49.7175.925.00	38.49.7176.965.84
Ø 36 mm	XXL	-	01.25.034[I]	-	-
Ø 40 mm	S	-	-	38.49.7179.885.00	38.49.7179.815.81
Ø 40 mm	M	-	-	38.49.7179.895.00	38.49.7179.815.82
Ø 40 mm	L	-	-	38.49.7179.905.00	38.49.7179.815.85
Ø 40 mm	XL	-	-	38.49.7179.915.00	38.49.7179.815.84
Ø 40 mm	XXL	-	-	-	-

[I] On request
[II] Specific for ceramic head revision

11 POSSIBLE IMPLANT COMBINATIONS

All Medacta possible implant combinations are represented in the table "Medacta Hip product compatibility" (ref. 99.99.COM), available at www.medacta.com.

NOTE: in case of a ceramic-on-ceramic bearing it is compulsory to use compatible ceramic femoral heads and liners.

NOTES

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave noting the regulations of the country, EU directives where applicable and following the instructions for use of the autoclave manufacturer. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.

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AMIStem
Surgical Technique

ref: 99.14ASTEM.12
rev. 09

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CE 0476