AMIStem-P

HIP SYSTEM

HERITAGE MEETS PROGRESS

Surgical Technique

Joint | Spine | Sports Med

Medacta International

CAUTION

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

INDEX

1. INTRODUCTION

This document describes the Surgical Technique for the AMIStem System.

The AMIStem product range is composed of:

- AMIStem-P: cementless stem manufactured from Titanuim-Niobium alloy with Titanium plasma spray coating on the proximal area and HA coating on the shaft
- AMIStem-P Collared: cementless collared stem manufactured from Titanuim-Niobium alloy with Titanium plasma spray coating on the proximal area and HA coating on the shaft
- AMIStem-C: cemented stem manufactured from high nitrogen stainless steel

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

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

AMIStem-P

AMIStem-P Collared

AMIStem-C

1.

1.1 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

1.2 CONTRAINDICATIONS

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

- Acute, systemic or chronic infection
- Skeletal immaturity
- Severe muscular, neurological, or 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.

1.3 PRE-OPERATIVE PLANNING ACCORDING TO DORR CLASSIFICATION

Straight femoral stems have produced good, reliable results with clinical follow-ups of more than 20 years[1,2,3].
However, the suggestion that shorter femoral stems preserve bone[4] and facilitate the stem introduction (especially for minimally invasive surgeries)[5], promotes intensive efforts to develop more conservative short stems.

The AMIStem system is the first stem specifically designed for AMIS (Anterior Minimally Invasive Surgery).

Depending on the patient anatomy and bone conditions the AMIStem system offers different solutions.

Cementless options:

- AMIStem-P
- AMIStem-P Collared

Cemented option:

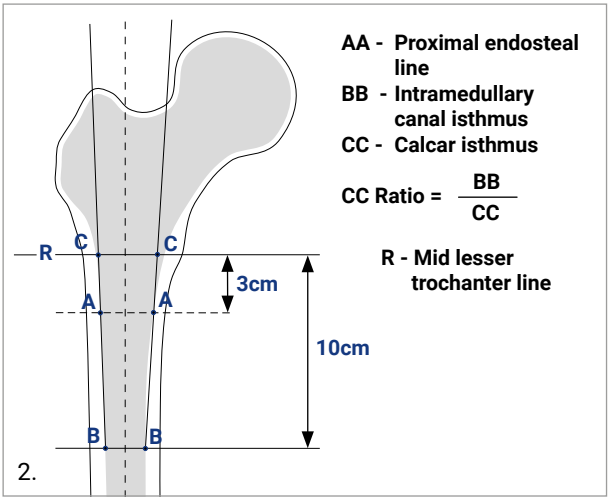
- AMIStem-C

Careful pre-operative planning is essential. Using X-ray templates (with the same magnification of the patient's X-ray), will help determine the following:

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

With the goal of planning the appropriate joint biomechanics. An important parameter to be analysed is the shape of the femoral canal. Dorr classified different bone anatomies in 3 types of bone anatomies, based on roentgenographic evaluation, bone biopsy and histomorphometryl[6].

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**).



2.

* 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.

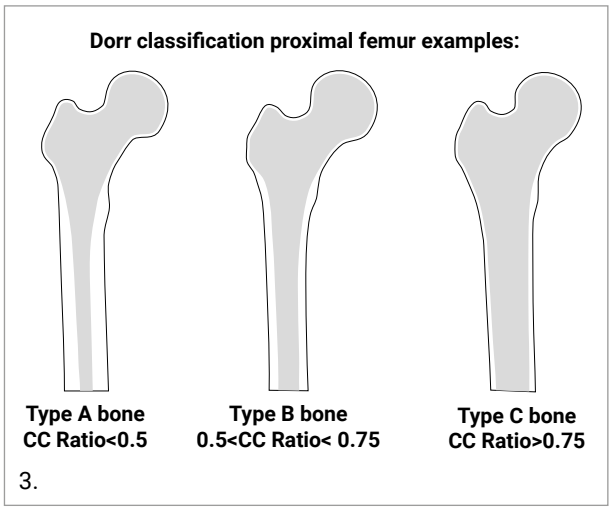
** The calcar isthmus (CC) is measured on R and is given by the line connecting the proximal endosteal points (AA,3 cm below R) and distal endosteal points (10 cm below R). Dorr et al considered the proximal distance of 3 cm and distal distance of 10 cm optimal to the endosteal measurements.

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 moderates medial and posterior cortices, frequently with irregular endosteal surfaces.

Type C bone (CC Ratio>0.75): has extremely thin medial and posterior cortices with a wide cylindrical shape femoral canal[6,7].



3.

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

With these 3 types of bone anatomy, different solutions can be considered:

Type A bone: is challenging and needs careful stem selection, as the narrow femoral shape could increase the risk of distal fixation.

Distal canal preparation will the help or monobloc reamers might be advisable to create more space distally.

Then, where there is good bone quality, a cementless stem can be chosen (AMIStem-P, AMIStem-P Collared).

Another option could be to reduce the stem press-fit in combination with proximal bone grafting and use AMIStem-P or AMIStem-P Collared.
Finally, it is possible to opt for the cemented version AMIStem-C.

Type B bone: this type needs careful bone quality consideration, where the use of AMIStem-P is advisable for good bone quality, and AMIStem-C for less good quality.

Type C bone: since this type of bone presents extremely thin cortices, one option is advisable, again depending on bone quality assesment:

- AMIStem-P Collared to reduce the risk of secondary subsidence
- AMIStem-C when cementation is preferred

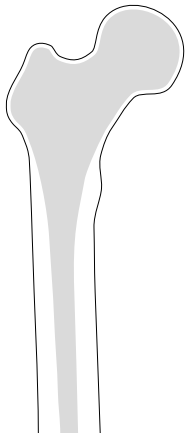
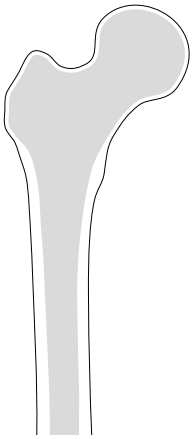
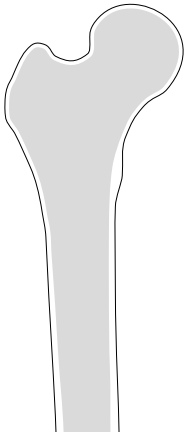
AMIStem decision-making according to Dorr classification		
Dorr A Narrow canal with thick cortical walls (champagne flute canal)	**Dorr B** Moderate cortical walls	**Dorr C** Wide canal with thin cortical walls (stove-pipe canal)
		
Suitable AMIStem options		
• **Cementless options** AMIStem-P (with good bone quality) AMIStem-P Collared **Optional:** reduce press-fit by proximal bone grafting • **Cemented option** AMIStem-C (Quadra-H, MiniMAX, Quadra-C, MasterLoc)	• **Cementless options** AMIStem-P (with good bone quality) AMIStem-P Collared (with poor bone quality) • **Cemented options** AMIStem-C (with poor bone quality) (Quadra-H, MiniMAX, Quadra-C, MasterLoc)	• **Cemented option** AMIStem-C • **Collared option** AMIStem-P Collared (Quadra-H, Quadra-C)

Table 1: AMIStem decision making according to Dorr classification.

This decision tree should be considered as a general suggestion. It must not be regarded as a definition of indications or contraindications. It is the surgeon's responsibility to assess the patient and make the appropriate choice based on clinical indications, experience and education.

NOTE: the final implant size will be selected intra-operatively due to possible discrepancies between actual conditions and templating.

1.4 SURGICAL APPROACH

These stems have been developed especially to be used with the AMIS surgical approach (AMIS=Anterior Minimally Invasive Surgery). The choice of surgical approach is up to the surgeon and specific instrumentation for standard and lateral approaches are also available.

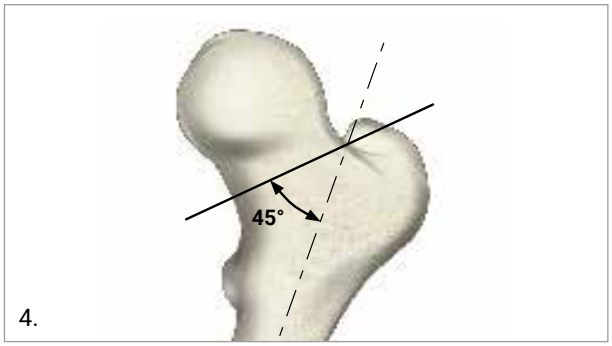
Please see the dedicated AMIS Surgical Technique to note the synergy between AMIStem and AMIS approach.

2. FEMORAL NECK OSTEOTOMY

The level of the neck cut is determined during preoperative planning using the X-ray templates.

The femoral neck osteotomy should be planned in accordance with the anatomy of the patient. The suggested resection angle for this implant is 45° to the diaphyseal axis of the femur.
The resection is performed with an oscillating saw, taking care to maintain the planned neck resection.

The femoral head is removed using an extractor.



4.

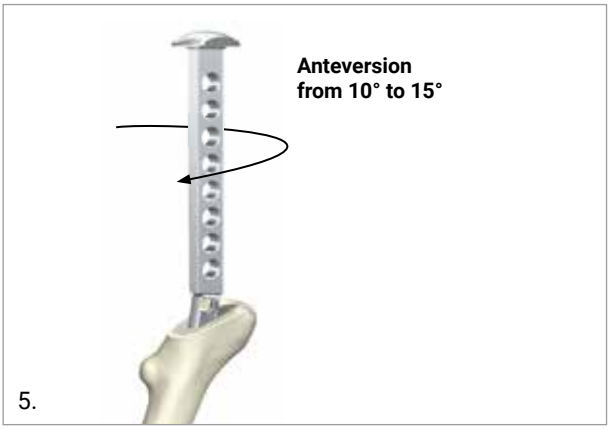
3. FEMORAL PREPARATION

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 positioning the stem in a varus position, 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.

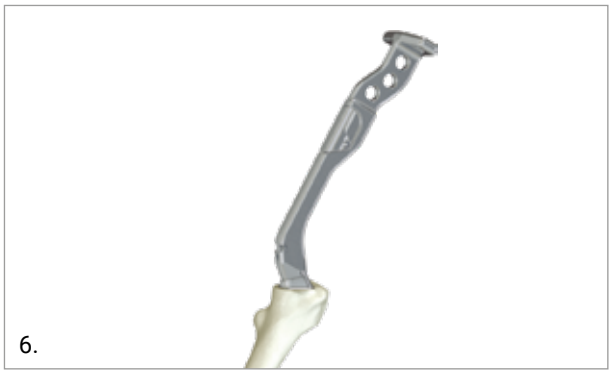


5.

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.


6.

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

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

Check the broach anteversion.

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

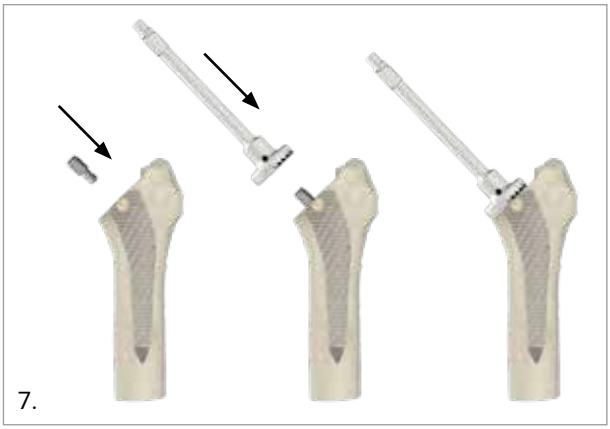
4. CALCAR PREPARATION

Once the final broach has been seated to the desired level, the broach handle is removed, and the calcar reamer can be used, if desired.

Place the adaptor in the broach.

Insert the calcar reamer on the adapter and ream the femoral neck, keeping the reamer parallel and in contact with the calcar.

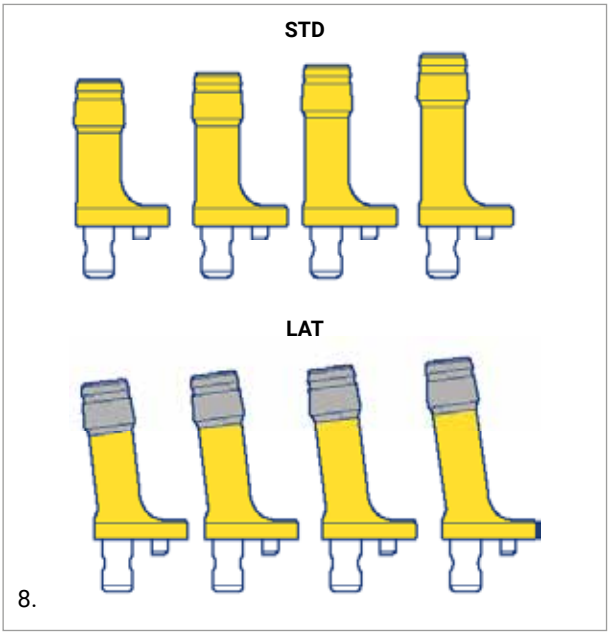
NOTE: if implanting a collared stem, the use of calcar reamer is highly recommended.



7.

5. TRIALING

A trial neck, standard (4 sizes) or lateralized (4 sizes), is fitted into the broach.



8.

All AMIStem-P standard trial necks are completely golden, AMIStem-P lateralized trial necks are golden with a grey taper. They both reproduce an accurate head center only if assembled with the correct broach.

For a correct coupling refer to the table below showing compatibility between trial neck and broach size.

The compatibility of the trial neck and the broach size is also marked on the side of each trial neck.

STANDARD TRIAL NECKS

TRIAL NECK REF.	BROACH SIZE	BROACH REF.
01.18.10.061	00	01.18.10.409
	0	01.18.10.410
	1	01.18.10.411
01.18.10.062	2	01.18.10.412
	3	01.18.10.413
	4	01.18.10.414
01.18.10.063	5	01.18.10.415
	6	01.18.10.416
	7	01.18.10.417
01.18.10.064	8	01.18.10.418
	9	01.18.10.419

LATERALIZED TRIAL NECKS

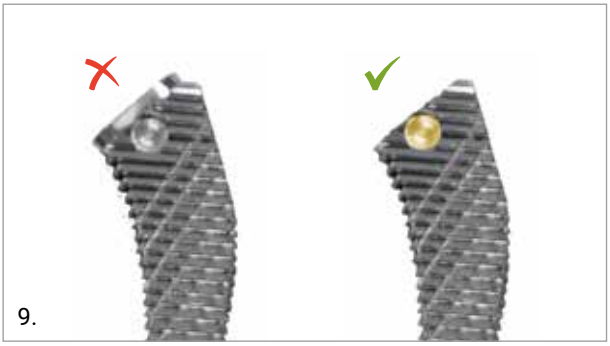
TRIAL NECK REF.	BROACH SIZE	BROACH REF.
01.18.10.065	0	01.18.10.410
	1	01.18.10.411
01.18.10.066	2	01.18.10.412
	3	01.18.10.413
01.18.10.067	4	01.18.10.414
	5	01.18.10.415
01.18.10.068	6	01.18.10.416
	7	01.18.10.417
	8	01.18.10.418

WARNING
Check the compatibility table before selecting the trial neck to ensure the correct coupling.

Make sure that the reference numbers of broach and trial neck are compatible as per the compatibility table.

WARNING
Broaches with a "raise" must not to be coupled with AMIStem-P trial necks.

NOTE: The AMIStem-P broaches can also be distinguished by a golden mark on the side.


9.

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

Trial heads of different diameters and heights are available to perform the trial reduction.

A trial head is fitted to the trial neck by pushing it onto the taper.


10.


11.

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


12.

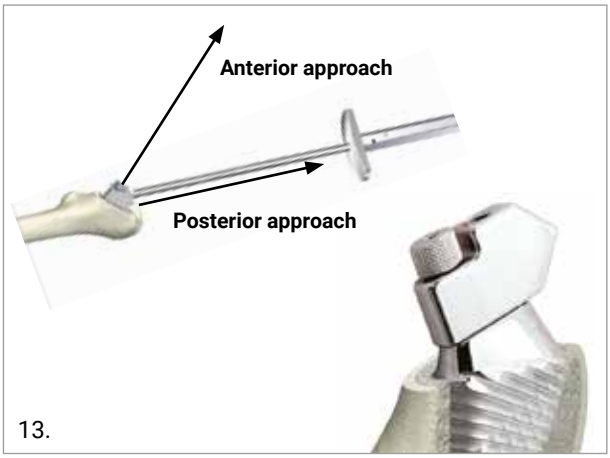
NOTE: The head impactor must be used only for head impaction and not for the correction of the acetabular shell position.

To remove a trial head, simply pull it.

TRICK
Moisten the Head-Trial Neck assembly. Twist and gently pull the trial head in order to remove it.

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.



13.

6. FINAL IMPLANT

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

WARNING
Visually inspect the stem to make sure that no small scratches, indentations or surface damage have occurred, as this may be detrimental to the mechanical performance of the stem and may result in long term fracture of the device.

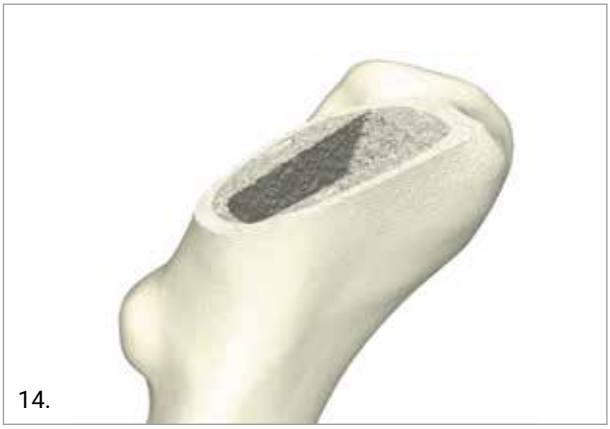
WARNING
Always impact the final head with the plastic head impactor provided for this purpose.

CAUTION
The metal head sizes XL (for Ø 28 mm and Ø 32 mm) and XXL (for Ø 28 mm, Ø 32 mm and Ø 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.

6.1 CEMENTLESS IMPLANT

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

The stem is inserted to the limit corresponding to the test and matching the end of the macrostructures. Carefully perform final impaction using the dedicated impactor.


14.

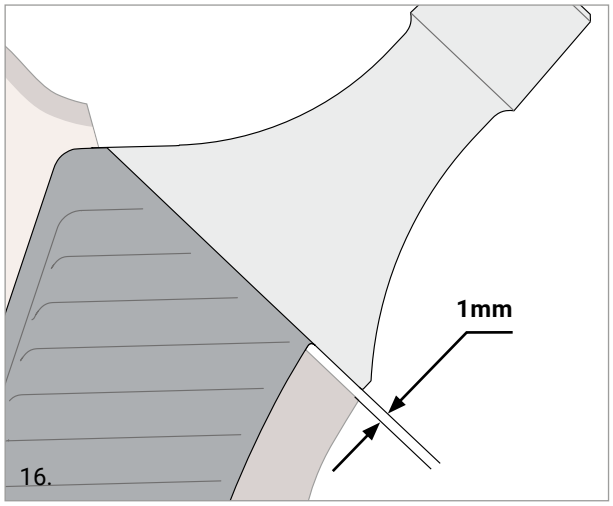
The anteversion of the stem is guided by the quadrangular recess left in the femur by the broaches.

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


15.

WARNING

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



16.

NOTE: the collared version, together with the calcar preparation technique, was designed to leave a distance of 1mm 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.

The stem taper must be thoroughly cleaned before impacting the prosthetic head.

Place the final head of the chosen size in position.


17.

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

6.2 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 that is the same size as the inserted prosthesis: after cement insertion the prosthesis is implanted as a press-fit.[8]

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

Size 9 is not available, therefore follow Tech.1 when a size 9 broach has been used.

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.

18.

Introduce the femoral stem into the medullary canal until the optimal position, keeping in mind that the laser-mark corresponds to the end of the broach.

Avoid moving the stem until the cement has hardened.

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

The stem taper must be thoroughly cleaned before placing the prosthetic head.

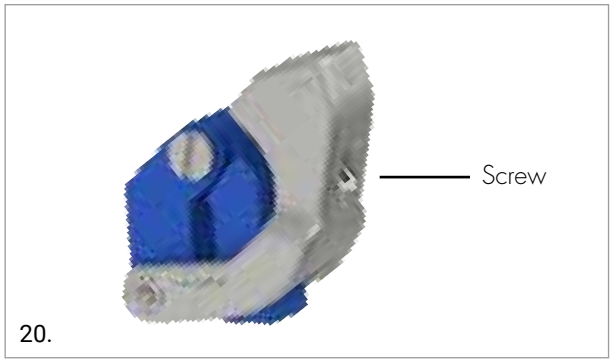
Place the final head of the chosen size in position.

19.

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

7. 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.

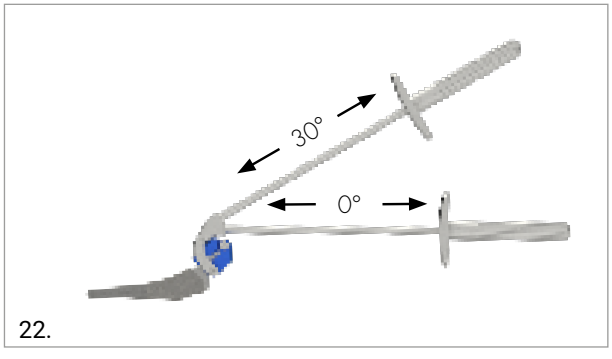


20.

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.

21.

screw. The metal body should be positioned on the medial side of the stem.



22.

8. IMPLANTS NOMENCLATURE

AMISTEM-P

STANDARD	SIZE	LATERALIZED
01.18.399	00 I	-
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	LATERALIZED
01.18.429	00 II	-
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	-

AMISTEM-C

STANDARD	SIZE	LATERALIZED
-	-	-
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

FEMORAL HEADS

DIAMETER	SIZE	CoCr	Mectacer BIOLOX delta
Ø 22 mm	S	01.25.124[I]	-
Ø 22 mm	M	01.25.123[I]	-
Ø 28 mm	S	01.25.011	01.29.201
Ø 28 mm	M	01.25.012	01.29.202
Ø 28 mm	L	01.25.013	01.29.203
Ø 28 mm	XL	01.25.014	-
Ø 28 mm	XXL	01.25.015[I]	-
Ø 32 mm	S	01.25.021	01.29.204
Ø 32 mm	M	01.25.022	01.29.205
Ø 32 mm	L	01.25.023	01.29.206
Ø 32 mm	XL	01.25.024	01.29.207
Ø 32 mm	XXL	01.25.025[I]	-
Ø 36 mm	S	01.25.030	01.29.208
Ø 36 mm	M	01.25.031	01.29.209
Ø 36 mm	L	01.25.032	01.29.210
Ø 36 mm	XL	01.25.033	01.29.211
Ø 36 mm	XXL	01.25.034[I]	-
Ø 40 mm	S	-	01.29.212
Ø 40 mm	M	-	01.29.213
Ø 40 mm	L	-	01.29.214
Ø 40 mm	XL	-	01.29.215

[I] On demand

MECTACER BIOLOX OPTION SYSTEM[II]

HEAD DIAMETER (mm)	REFERENCE
Ø 28	01.29.230H
Ø 32	01.29.231H
Ø 36	01.29.232H
Ø 40	01.29.233H

SLEEVE SIZE	REFERENCE
S	01.29.240A
M	01.29.241A
L	01.29.242A
XL	01.29.243A

[II] Specific for revision cases

9. POSSIBLE IMPLANT COMBINATIONS

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

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

REFERENCES

[1] 20 years of Zweimüller cement free hip endoprosthesis, Jatros Orthopäedie, Jahrgang 5 Dez. 1999 – ISSN 0941-4770

[2] Zweymüller K, 20 years of Zweymüller hip endoprosthesis, Hans Huber Verlog 2002, ISSN 3-456-83431-4, 29-39

[3] Bonnomet et al. Comportement d'une tige femorale droite on arthroplastie totale primaire non cimentée de la hanche chez les patients de moins de 65ans. Rev. de Chir Orthop 2001, 87, 802-814

[4] Chen H, et al. Bone remodeling characteristics of a short-stemmed total hip replacement, The Journal of Artrhoplasty 2008, Vol. 00, No. 0

[5] Lombardi A V, et al. A short stem solution: Through small portals, BFA Orthopedics 2009, 32:663

[6] 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

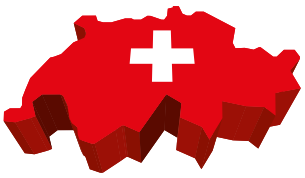
[7] Sah AP, Thornhill TS, LeBoff MS, Glowacki J. Correlation of Plain Radiographic Indices of the Hip with Quantitative Bone Mineral Density. Osteoporos Int, 2007 Aug;18(8):1119-26

[8] 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

Part numbers subject to change.

NOTE FOR STERILIZATION

The instrumentation is 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 manufactures instructions for use of the autoclave. For detailed instructions please refer to the document "Recommendations for cleaning decontamination and sterilisation of Medacta International orthopaedic devices" available at www.medacta.com.



REDEFINING BETTER
IN ORTHOPAEDICS
AND SPINE SURGERY

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-P
Surgical Technique

ref: 99.14ASTEMPS.12US
rev. 01

Last update: June 2019