

X-acta



Surgical Technique

Joint

Spine

Sports Med

INDEX

1. INTRODUCTION	4
1.1 Indication for use	4
1.2 Contraindications	4
2. PREOPERATIVE PLANNING	4
3. SURGICAL APPROACH	5
4. FEMORAL NECK OSTEOTOMY	5
5. FEMORAL STEP	5
5.1 Femoral Preparation	5
5.2 Trials	6
6. FINAL STEM POSITIONING	7
7. IMPLANTS NOMENCLATURE	8
8. POSSIBLE IMPLANT COMBINATIONS	10

1. INTRODUCTION

This document describes the Surgical Technique for the X-acta femoral stem.



The X-acta is a highly polished, double tapered stem. This is a collarless cemented stem manufactured in wrought high nitrogen stainless steel with a PMMA distal centralizer to facilitate correct stem positioning and uniform cement distribution.

For details 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.

1.1 INDICATION FOR USE

The X-acta stem is designed for use in total or partial hip arthroplasty to provide increased patient mobility and reduced pain by replacing the damaged hip joint, in 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

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

- Acute, systemic or chronic infection
- Skeletal immaturity
- Severe muscular, neurological, vascular deficiency or other pathologies of the affected limb that may compromise the function 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.

2. PREOPERATIVE PLANNING

Precise X-rays overlays are available as part of the pre-operative evaluation process.

Careful preoperative planning is essential. It will help the surgeon to pre-select the implant sizes in order to restore an architecture corresponding to the operated patient's anatomy.

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 prosthetic rotation centre
- The level of the neck cut

- The neck length
- The overall dimension of the distal centralizer (the distal centralizer is shown both in completely open and completely closed configuration)

It is essential to obtain the appropriate cement mantle. The X-ray templates indicate a cement mantle which is 2 mm thick.

WARNING

The final implant will be selected intra-operatively, because of possible discrepancies between actual conditions and templating.

3. SURGICAL APPROACH

The choice of surgical approach is up to the surgeon. The instrumentation has been developed for a posterior approach. Specific instrumentation for the anterior

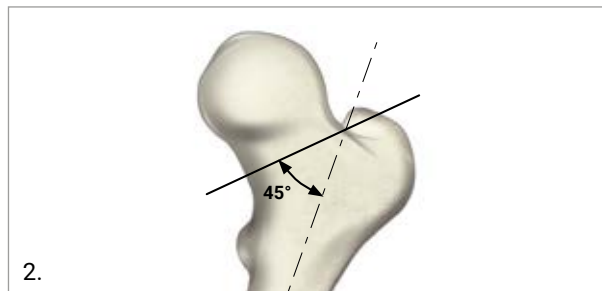
approach is available upon request (for further information see the AMIS dedicated surgical technique).

4. FEMORAL NECK OSTEOTOMY

The level of the neck cut is determined during preoperative planning using 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 femoral head is removed using an extractor.



5. FEMORAL STEP

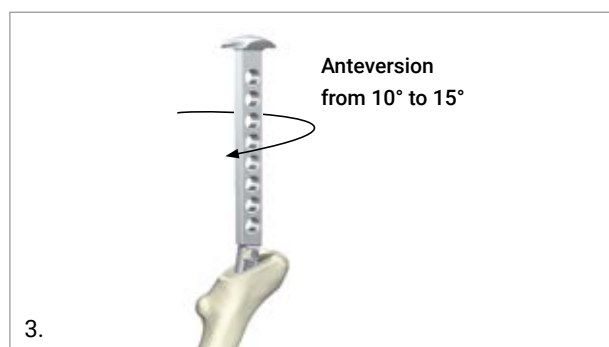
5.1 FEMORAL PREPARATION

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.



Rasps are oversized by 2 mm on each side in comparison with the corresponding implant.

The rasps have depth indicator holes that correspond to the depth indicator markings on the final implant. These indicators are 4 mm apart. The surgeon should ensure that these three holes are not all left proud of the femur because this would risk leaving a stem with inadequate proximal support.



Sequential femoral rasps are used to prepare the proximal femur up to the planned stem size, taking care to preserve a sufficient cancellous bone mantle for cement interdigitation.

Assemble the rasp on the broach handle.

5.2 TRIALS

After having achieved a satisfactory fit of the broach in the diaphysis, the broach handle is removed.

A trial neck is fitted to the broach. Pull the trial neck to remove it.

Trial necks have a pin. The trial neck is correctly coupled to the broach when the pin is inserted into the dedicated broach housing.



NOTE: Two trial necks were designed with different orientation of the pins to prevent assembly on the wrong rasps. Furthermore, trial necks compatible with the rasps 35.5 mm, 37.5 mm and 44 mm are sandblasted and the trial neck compatible with the broach 50 mm is mirror polished and bears a "50" figure etched on the base (Figure 4). The rasps have a different buttonhole orientation, as shown in the images, in order to ensure correct trial neck combination.

See the table below for trial neck-rasp size combinations

TRIAL NECK	REFERENCES
X-Acta Trial Neck for Rasps 35.5, 37.5 & 44 mm	01.21.10.1020
X-Acta Trial Neck for Rasp 50 mm	01.21.10.1030

The X-acta is a collarless stem, which allows for correction of leg length by adjusting the depth of stem insertion. If trial reduction shows that the leg length has been excessively lengthened, the rasp can be carefully seated further down the femur. If the leg has been shortened, the stem may be left a little prouder in the femur.

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

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

After placement of the trial on the final acetabular component, the trial reduction is performed using the head impactor.

NOTICE: The head impactor must only be used for head impaction and not for correcting the acetabular shell position.

Simply pull the trial head to remove it.

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

When the correct leg length and offset have been achieved, the stem will be placed in line with the corresponding hole on the rasp.



6. FINAL STEM POSITIONING

Remove any loose, unsupportive, cancellous bone from the canal with a curette or canal brush.

Close the distal canal with a medullary plug at least at 1 cm distal to the tip of the stem. Pay close attention to the choice of the distal plug to ensure it can resist the cement pressure. Clean the intramedullary canal with pulse lavage and dry it with sponges. Keep the canal packed until the cement is ready to be injected.

Using retrograde cementation, introduce the cement into the canal using a cement gun. Pressurize the cement column to allow the cement to interdigitate into the cancellous bone. Introduce the femoral stem with the stem impactor (the size corresponds to the last rasp used) into the medullary canal with the distal centralizer in place.

NOTICE: to fit the distal centralizer onto the stem, carefully push the centralizer on the distal tip of the stem applying pressure softly with the thumb.



WARNING

If the femoral canal diameter is smaller than the overall dimension of the distal centralizer in the completely closed configuration (\varnothing 10 mm), do not use the distal centralizer.

Place a thumb over the antero-medial femoral neck while inserting the stem to maintain cement pressure. This will help to ensure that the stem remains aligned axially avoiding the risk of the stem shifting. It is recommended to slowly insert the stem until it has reached the chosen depth marker as judged by the corresponding hole on the rasp.

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 taper's micro-thread while placing the final implant.

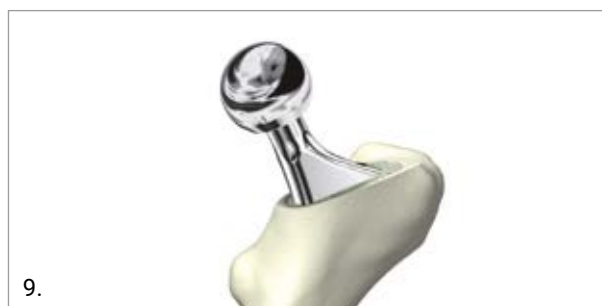
A further trial reduction can be performed with the trial heads to determine the final neck length.



CAUTION: Some final heads do not completely cover the femoral stem taper. The sizes involved are: 22 M, 28 L for the metal heads; 28 L and XL, 32 XL, 36 XL for ceramic heads. In case of frequent excursion to the maximum Range of Motion, this may cause an increased wear of the polyethylene liner caused by taper/liner impingement. The metal head sizes XL (for \varnothing 28 mm and \varnothing 32 mm) and XXL (for \varnothing 28 mm, \varnothing 32 mm and \varnothing 36 mm) have a collar. This may decrease the Range of Motion in comparison to smaller sizes. Always perform a trial reduction with the chosen head.

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

Place the final head of the chosen size in position and fix it with the aid of the head impactor.

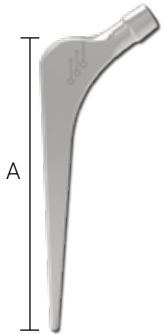


WARNING

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

NOTICE: for further details about ceramic femoral heads, please refer to the instruction for use for ceramic femoral heads.

7. IMPLANTS NOMENCLATURE



X-ACTA DOUBLE TAPERED CEMENTED STEM

		STEM BODY SIZE					A - Shoulder length (mm)
		0	1	2	3	4	
OFFSET	35.5 mm	01.21.001	-	-	-	-	127
	37.5 mm	01.21.002	01.21.003	01.21.004	01.21.005	01.21.006	149
	44 mm	01.21.007	01.21.008	01.21.009	01.21.010	01.21.011	148
	50 mm	-	01.21.012	01.21.013	01.21.014	01.21.015	148



X-ACTA DOUBLE TAPERED CEMENTED STEM - SHORT

		STEM BODY SIZE					A - Shoulder length (mm)
		0	1	2	3	4	
OFFSET	35.5 mm	-	-	-	-	-	-
	37.5 mm	01.21.102	01.21.103	01.21.104	01.21.105	01.21.106	124
	44 mm	01.21.107	01.21.108	01.21.109	01.21.110	01.21.111	123
	50 mm	-	01.21.112	01.21.113	01.21.114	01.21.115	123



DISTAL CENTRALISER

	REFERENCES
DISTAL CENTRALIZER	01.21.100



FEMORAL HEADS

DIAMETER	SIZE	STAINLESS STEEL	CoCr	CeramTec BIOLOX delta	CeramTec BIOLOX Option ^{II}	Mectacer BIOLOX delta
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	01.29.201
Ø 28 mm	M	25055.2803	01.25.012	38.49.7175.455.00	38.49.7176.935.82	01.29.202
Ø 28 mm	L	25055.2805	01.25.013	38.49.7175.465.00	38.49.7176.935.85	01.29.203
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	01.29.204
Ø 32 mm	M	25055.3203	01.25.022	38.49.7175.675.00	38.49.7176.945.82	01.29.205
Ø 32 mm	L	25055.3205	01.25.023	38.49.7175.685.00	38.49.7176.945.85	01.29.206
Ø 32 mm	XL	25055.3207	01.25.024	38.49.7181.345.00	38.49.7176.945.84	01.29.207
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	01.29.208
Ø 36 mm	M	-	01.25.031	38.49.7179.285.00	38.49.7176.965.82	01.29.209
Ø 36 mm	L	-	01.25.032	38.49.7179.295.00	38.49.7176.965.85	01.29.210
Ø 36 mm	XL	-	01.25.033	38.49.7175.925.00	38.49.7176.965.84	01.29.211
Ø 36 mm	XXL	-	01.25.034 ^I	-	-	-
Ø 40 mm	S	-	-	38.49.7179.885.00 ^I	38.49.7179.815.81 ^I	01.29.212
Ø 40 mm	M	-	-	38.49.7179.895.00 ^I	38.49.7179.815.82 ^I	01.29.213
Ø 40 mm	L	-	-	38.49.7179.905.00 ^I	38.49.7179.815.85 ^I	01.29.214
Ø 40 mm	XL	-	-	38.49.7179.915.00 ^I	38.49.7179.815.84 ^I	01.29.215
Ø 40 mm	XXL	-	-	-	-	-

^I On demand

^{II} Specific for revision cases

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

8. POSSIBLE IMPLANT COMBINATIONS

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

NOTICE: In the case of a ceramic on ceramic bearing it is compulsory to use compatible ceramic femoral heads and liners.

Part numbers subject to change.

NOTE FOR STERILISATION

The instrumentation is not sterile upon delivery. It must be cleaned before use and sterilised in an autoclave in accordance with 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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