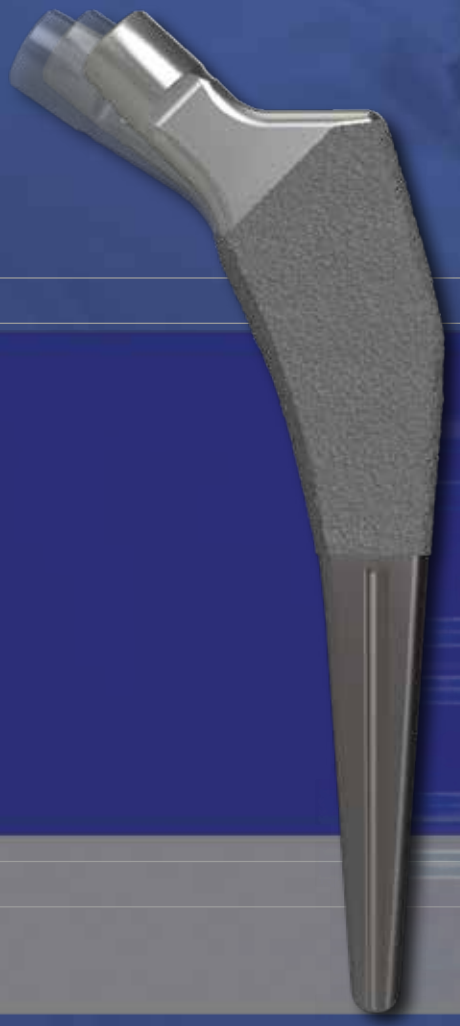
MasterLoc®

HIP SYSTEM

UNDERSTANDING TRADITION, MASTERING INNOVATION



Surgical Technique

Joint | Spine | Sports Med

Medacta International

INDEX

1. INTRODUCTION

This document describes the Surgical Technique for the MasterLoc Hip System femoral stem.

1. **MasterLoc Hip System - Mectagrip coated**

The MasterLoc femoral stem is cementless, flat and double tapered, designed to accurately restore the patient's biomechanics with minimal bone removal. 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.

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

1.1 INDICATIONS OF USE

The MasterLoc stem is designed for use in total or partial hip arthroplasty to provide increased patient mobility and reduce 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, 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 PREOPERATIVE PLANNING

Careful preoperative planning is essential. It will help the surgeon to plan for the appropriate implant size in order to recreate as closely as possible the patient's joint biomechanics.

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
- Appropriate femoral head centre
- The level of the neck resection

The MasterLoc Hip System was designed with the goal of maximizing implant fit in the proximal femur. Additionally, the distal geometry of the implant has been reduced compared to traditional flat, tapered wedge implants, enhancing the fit of the implant in the metaphysis while also accommodating those patients who present with Dorr Type A femoral canals.

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

1.4 SURGICAL APPROACH

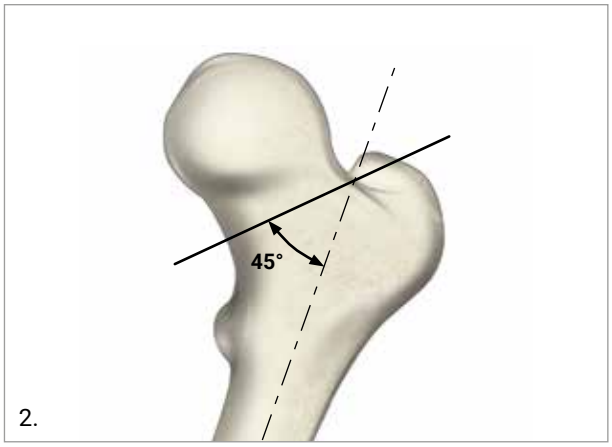
The choice of surgical approach is up to the surgeon. The instrumentation has been developed for a conventional approach. Specific instrumentation for the anterior approach is available upon request (for further information see the AMIS dedicated surgical technique).

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.



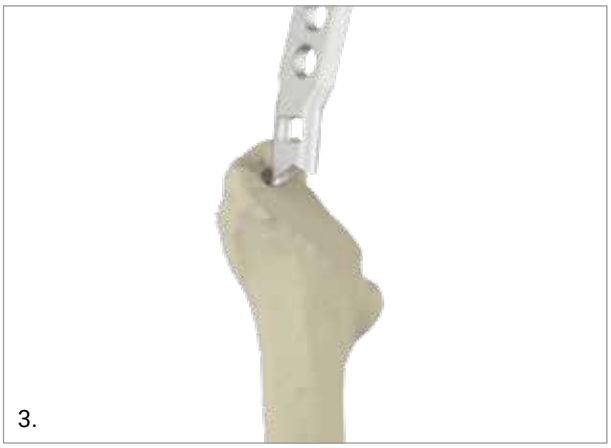
2.

3. FEMORAL PREPARATION

To gain access to the medullary canal, the thigh is held in the position that provides the best exposure of the diaphyseal axis, depending on the selected approach.

To avoid undersizing and varus positions of the stem, a box chisel should be applied to the opposite side of the digital fossa of the femoral neck.

Guide the chisel with the appropriate anteversion: this step is essential for the correct application of the broach and implant.



3.

This removes a block of cancellous bone.

TIP

The following surgical tips may minimize the risk of putting the stem into varus position:
- To ensure the stem is placed fully lateral within the femur, make sure that the axis of the stem is aligned with the femoral axis. If necessary, remove some bone from the proximal-lateral part before fully inserting the broach to allow it to find a proper alignment.
- In case a lateral ridge of cortical-like bone is present on the lateral edge of the resected femoral neck, remove it. A curette or a rongeur may be of assistance.

To prepare the femur, the canal can be opened by utilizing the canal finder. For the AMIS approach, a curved starter rasp is available (the AMIS slim starter), for the other approaches there is a straight canal finder.

4.

The femur is prepared using sequential broaches.

Assemble the first broach on the broach handle.

For detailed instructions on how to use the broach handle, please see chapter 9 – INSTRUMENT DETAILS.

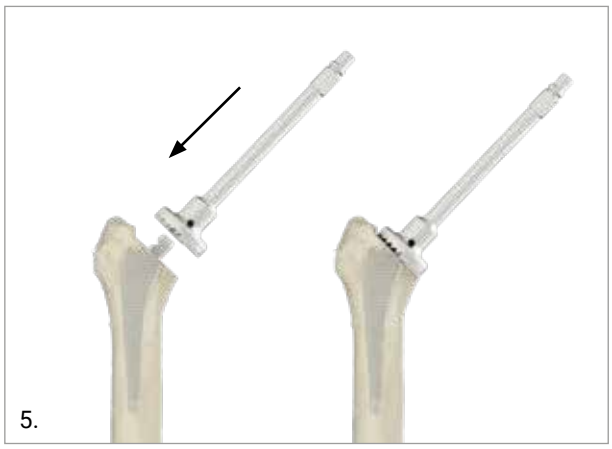
NOTICE: Incorrect assembly of the broach handle with the broach may damage the connection.

Begin broaching with the smallest broach and increase sequentially until the desired fit is achieved. Please note that the orientation of the smallest broach will dictate the medial/lateral and anterior/posterior position for further femoral canal preparation.

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

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 calcar reamer guide over the broach's peg. Push it into the broach and ream the femoral neck, ensuring alignment to avoid fracturing the femur.



5.

NOTICE: Use the small calcar reamer for broach sizes 1 to 6. Use the large calcar reamer for broach sizes 7 to 14.

4. TRIALING

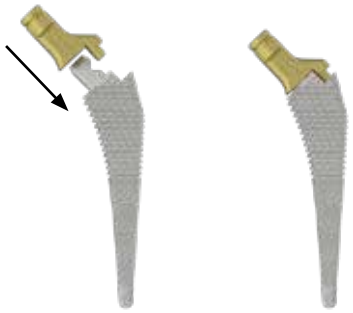
Fit the trial neck to the broach. To lock the trial neck to the broach, press onto the peg; to unlock, pull the neck.

Trial necks have a pin.

Pin

6.

The trial neck is correctly coupled to the broach only when the pin is inserted into the dedicated broach housing. A clicking sound indicates that the trial neck has been correctly assembled on the broach.



An audible "CLICK" can be heard once the trial is properly assembled

7.

NOTICE: If the trial neck is not sitting well on the broach, it might be due to some lateral bone that has not been removed. Once this bone is removed, the trial neck should seat properly.

Different trial necks are available for different broach sizes.

NOTICE: For easier identification the STD trial necks are yellow, the LAT trial necks are blue and the LAT Plus trial necks are green:

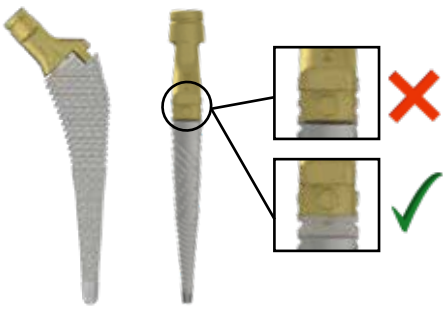
TRIAL NECKS

SIZE	STD	LAT	LAT Plus
1	01.39.10.0020 	01.39.10.0022 	01.39.10.0018 (only for sizes 4 to 6) 
2			
3			
4			
5			
6			
7	01.39.10.0021 	01.39.10.0023 	01.39.10.0019 
8			
9			
10			
11			
12			
13	-		
14	-		

Before trialing the component, ensure the correct trial neck for the selected broach is used.

CAUTION

Depending on the size of the broach, the trial neck may not be in line with the proximal surface of the broach. The height of the trial neck is defined when the distal surface of the trial neck's pin is in contact with the dedicated broach housing.



Pin IN LINE with dedicated broach housing

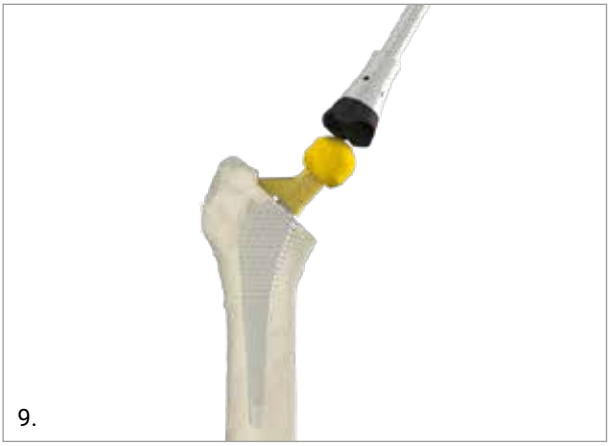
8.

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.

TIP
To make head insertion easier, moisten it before insertion.

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



9.

NOTICE: 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.

TIP
Moisten the trial head/trial neck assembly. Twist and gently pull the trial head to extract it.

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

10.

5. FINAL IMPLANTS

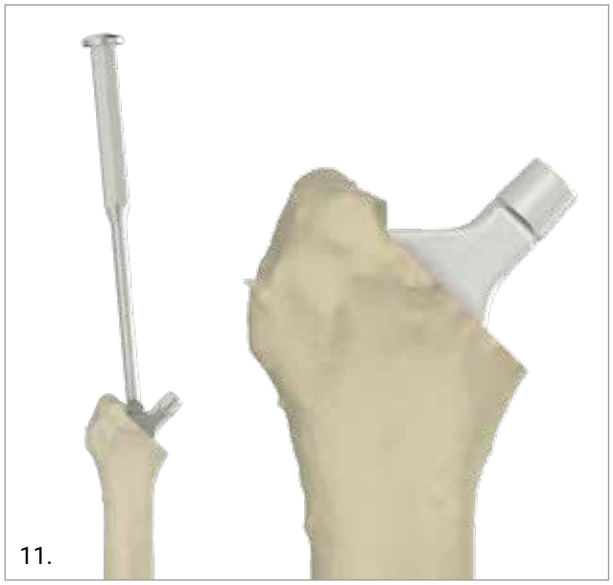
Insert the final prosthesis into place. The final prosthesis size corresponds to the size of the last broach.

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 trialing and matching the beginning of the coating.

Carefully perform the final impaction using a dedicated impactor.

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


11.

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

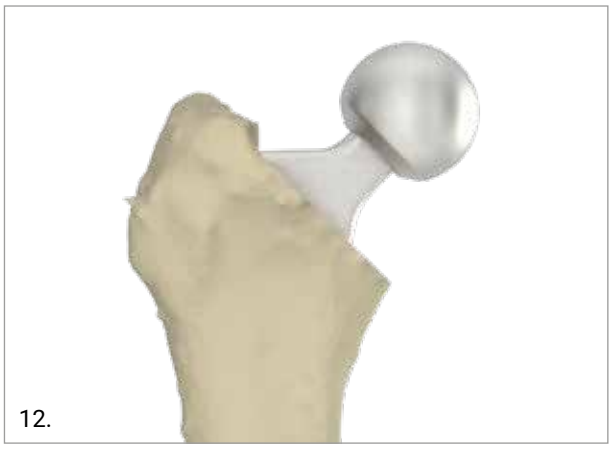
A further trial reduction can be performed with the trial heads to determine the final head size.

WARNING
MasterLoc LAT Plus is not compatible with XXL femoral heads.

CAUTION
Metal head sizes XL (for Ø28 mm and Ø32 mm) and XXL (for Ø28 mm, Ø32 mm and Ø36 mm) have a collar which may decrease the Range of Motion compared to smaller sizes. Always perform trial reduction with the chosen head.

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

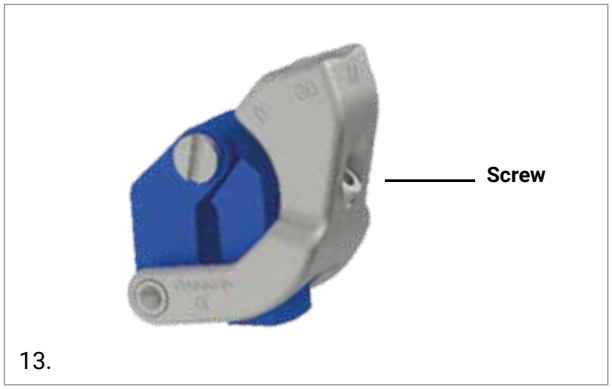
Place the final head of the chosen size in position and secure it using the head impactor.


12.

WARNING
Never strike the final femoral head directly with a metal mallet or hammer. Use only the plastic head impactor provided for this purpose.

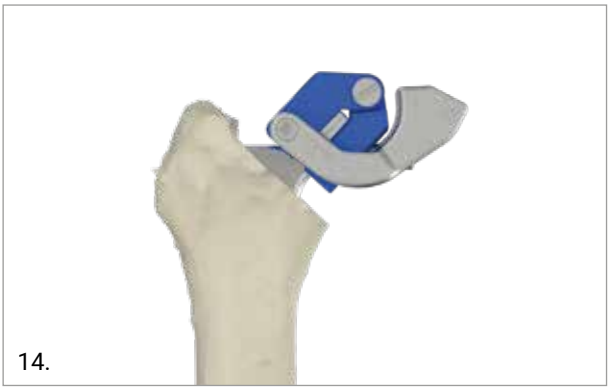
NOTICE: For further details about ceramic femoral heads, please refer to the instructions for use for ceramic femoral heads.

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



13.

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.



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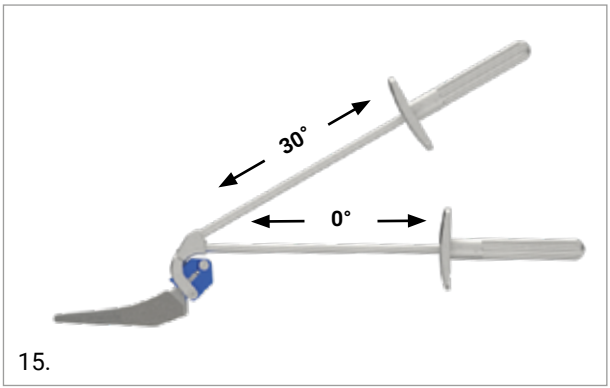


15.

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.

6. INSTRUMENT DETAILS

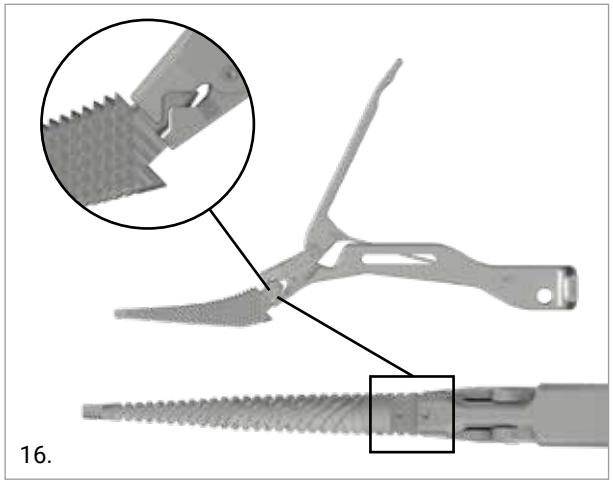
To assemble the MasterLoc broach onto its broach handle follow the instructions given below.

These instructions are valid for the following broach handles:

REFERENCE	DESCRIPTION	
01.36.10.0070	AMIS Pincer broach handle	
01.36.10.0073	Pincer broach handle	
01.39.10.0024	Straight pincer broach handle	
01.10.10.198	Offset 30° pincer broach handle RIGHT	
01.10.10.199	Offset 30° pincer broach handle LEFT	

6.1 BROACH ASSEMBLY

Assemble the broach by lifting up the lever as shown. The broach is correctly positioned into the triangular locking system when the circular mark on the broach matches the one on the broach handle.



16.

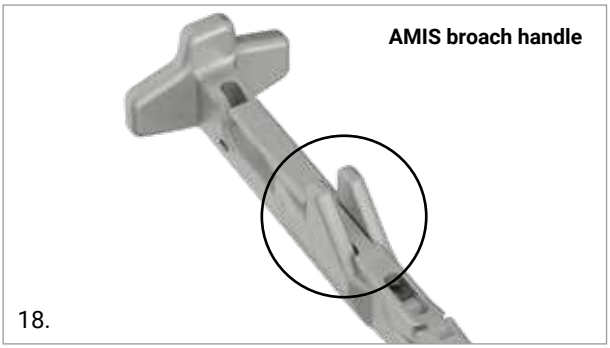
Once assembled, lower the lever and check that it is fully seated down.

17.

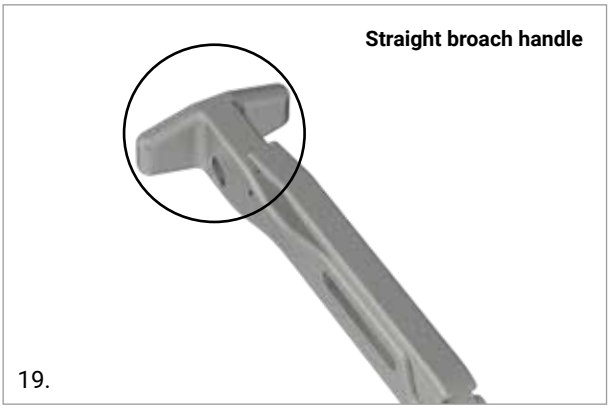
The broach is now assembled on the broach handle.

TIP

To extract the broach easily from the femoral canal, the surgeon should grip the handle in a way that allows the user to strike the corresponding anvil:



18.

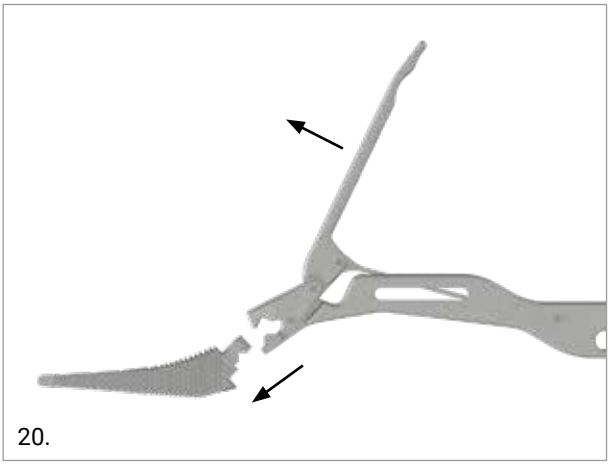


19.

Never strike on other parts of the handle, especially near the lever.

6.2 BROACH DISASSEMBLY

Remove the broach from the handle by lifting up the lever and pulling the broach.


20.

WARNING
Do not disassemble the broach handles. Their design allows washing without the need for disassembly.

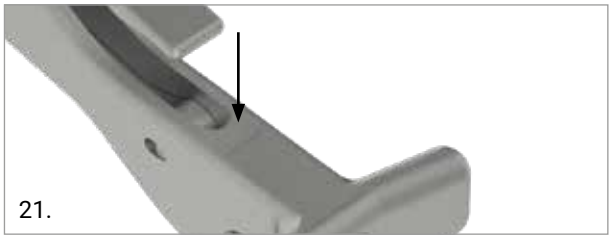
6.3 BROACH HANDLE ADJUSTMENT (ONLY WHEN STRICTLY NECESSARY)

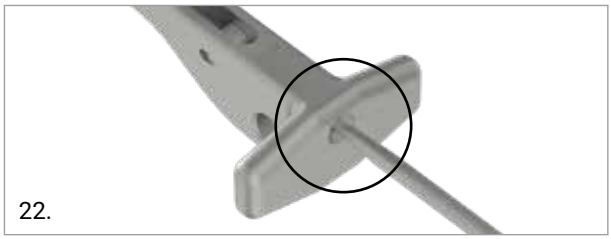
The MasterLoc broach handle grip can be adjusted.

In order to do so, use the 3.5 mm screwdriver (reference 1.113) present in the MasterLoc ancillary set, and follow the instructions below:

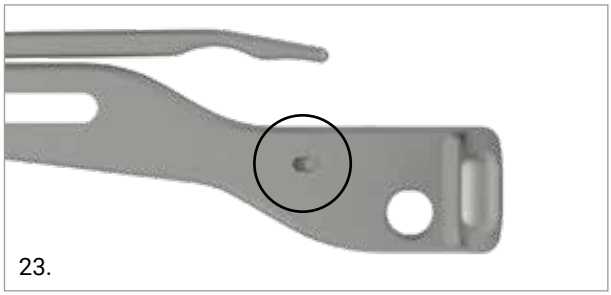
- Hold down the button (Fig.20)
- While holding the button down, insert the screwdriver in the set screw (Fig.21):
  To increase the handle grip: turn clockwise and the sliding pin will move in the broach's direction.
  To decrease the handle's grip: turn counterclockwise and the sliding pin will move in the anvil's direction.

NOTICE: The set screw is quite sensitive, therefore do not turn more then 45° at a time.


21.


22.

WARNING
The sliding pin is initially set in a position with a good compromise between functionality and grip. The closer the pin is to the broach the more grip it will have. An excessive grip may damage the broach handle.


23.

After setting the MasterLoc broach handle, assemble it with a broach and check its stability in all directions. The broach should be stable inside the broach handle.

6.4 POSTERIOR PINCER BROACH HANDLE

Another broach handle option was developed specifically for posterior approach. The reference for this posterior pincer broach handle is 01.10.10.189.

24.

7. IMPLANT NOMENCLATURE

MASTERLOC HIP SYSTEM

SIZE	STANDARD (STD)	LATERALIZED (LAT)	LATERALIZED PLUS (LAT PLUS) not compatible with XXL heads
1	01.39.001	01.39.201	-
2	01.39.002	01.39.202	-
3	01.39.003	01.39.203	-
4	01.39.004	01.39.204	01.39.404
5	01.39.005	01.39.205	01.39.405
6	01.39.006	01.39.206	01.39.406
7	01.39.007	01.39.207	01.39.407
8	01.39.008	01.39.208	01.39.408
9	01.39.009	01.39.209	01.39.409
10	01.39.010	01.39.210	01.39.410
11	01.39.011	01.39.211	01.39.411
12	01.39.012	01.39.212	01.39.412
13	-	01.39.213 [I]	01.39.413 [I]
14	-	01.39.214 [I]	01.39.414 [I]

[I] On demand

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
***NOTE:** Not compatible with MasterLoc LAT Plus

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

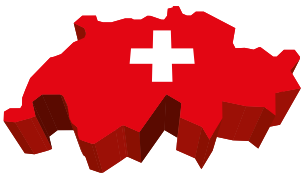
[II] Specific for revision cases

.

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
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MasterLoc®
Surgical Technique

ref: 99.73.12US
rev. 06

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