

# **INTRODUCTION**

This document describes the surgical technique for the AMIS-K, a cemented stem based on the Charnley-Kerboull concept.

Read the instructions carefully and if you have any questions concerning product compatibility please contact your local Medacta representative.



AMIS-K



# INDEX

1.	INDICATIONS OF USE	4
2.	CONTRAINDICATIONS	4
3.	PREOPERATIVE PLANNING	4
4.	SURGICAL APPROACH	5
_	FEMORAL NEOK COTFOTOMY	-
5.	FEMORAL NECK OSTEOTOMY	5
6.	FEMORAL PREPARATION	6
	6.1 Broaching	7
7.	TRIALING	8
0	FINIAL IMPLANTS	
8.	FINAL IMPLANTS	9
9.	INSTRUMENT DETAILS	10
	9.1 Broach assembly	11
	9.2 Broach disassembly	11
	9.3 Broach handle regulation (ONLY WHEN STRICTLY NECESSARY)	12
10.	IMPLANTS NOMENCLATURE	13
11	POSSIBLE IMPLANT COMBINATIONS	15
1 I.	FUSSIBLE INFLANT CUNDINATIONS	l C

#### 1. INDICATIONS OF USE

The AMIS-K stem is designed for cemented 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

#### 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.

#### 3. PREOPERATIVE PLANNING

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.

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 prosthetic rotation centre
- The level of The neck cut
- The neck length

#### **WARNING**

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

#### **CAUTION**

When AMIS-K stem size 0S1 is coupled with heads  $\emptyset$ 22mm size S or  $\emptyset$ 28mm size S and Native Cup the ROM in flexion-extension is less than 100°. Always perform trial reduction with the chosen head.



# 4. 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).

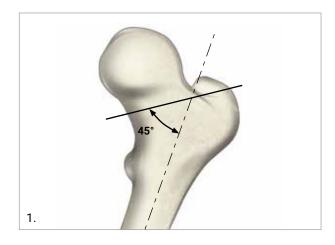
# 5. FEMORAL NECK OSTEOTOMY

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  $45^{\circ}$  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.



#### **OPTION**

The femoral diaphysis can be prepared using the sequential broaches or standard intramedullary reamers.



Assemble the broach on the broach handle.

The broaches must be inserted to the optimum level determined by the neck cut, until the level of the chosen depth marker.

Sequential femoral broaches are used to prepare the proximal femur up to the planned stem size.



#### 6.1 **BROACHING**

To assist with the initial cases, please refer to the table below for the 'broach sequence' for the preparation of the femoral canal.

with the	miliar cases,	Broach sequence												
	0S1	0S1	<u></u>											
	1S2	0S1	<u></u>	1S2	$\rightarrow$									
	2S1	0S1	$\rightarrow$	1S2	$\overline{}$	2SL1	$\rightarrow$							
	2L1	0S1	$\rightarrow$	1S2	$\rightarrow$	2SL1	$\leq$							
	2S2	0S1	$\rightarrow$	1S2	$\rightarrow$	2SL1	$\overline{}$	2SL2	$\rightarrow$					
	2L2	0S1	$\rightarrow$	1S2	$\rightarrow$	2SL1	$\overline{}$	2SL2	$\rightarrow$					
	2S3	0S1	$\rightarrow$	1S2	$\rightarrow$	2SL1	$\overline{}$	2SL2	$\overline{}$	2SL3	$\rightarrow$			
	2L3	0S1	>	1S2	>	2SL1	>	2SL2	$\rangle$	2SL3	>			
	3S1	0S1	$\rightarrow$	1S2	$\rightarrow$	2SL1	$\rightarrow$	3SL1	$\rangle$					
	3L1	0S1	$\rightarrow$	1S2		2SL1	$\rightarrow$	3SL1	>					
	3S2	0S1		1S2	$\rightarrow$	2SL1	$\rightarrow$	3SL1	$\rangle$	3SL2	$\supset$			
	3S3	0S1	$\rightarrow$	1S2		2SL1	$\rangle$	3SL1	$\rangle$	3SL2	$\rightarrow$	3SL3	$\rangle$	
mplant	3L2	0S1	$\rangle$	1S2		2SL1	$\rangle$	3SL1	$\rangle$	3SL2	$\supset$			
Imp	3L3	0S1	$\rangle$	1S2		2SL1	$\rangle$	3SL1	$\rangle$	3SL2	$\rangle$	3SL3	$\rangle$	
	<b>4</b> S1	0S1	$\rangle$	1S2		2SL1	$\rangle$	3SL1	$\rangle$	4SL1				
	4L1	0S1		1S2		2SL1	$\rangle$	3SL1	$\rangle$	4SL1	$\supset$			
	4S2	0S1	$\rangle$	1S2		2SL1	$\rangle$	3SL1	$\rangle$	4SL1	$\rangle$	4SL2	$\rangle$	
	4S3	0S1		1S2		2SL1	$\rangle$	3SL1	$\rangle$	4SL1	$\rangle$	4SL2	$\geq$	4SL3
	4L2	0S1		1S2		2SL1	$\rangle$	3SL1	$\rangle$	4SL1	$\rangle$	4SL2	$\rangle$	
	4L3	0S1		1S2		2SL1	$\rangle$	3SL1	$\rangle$	4SL1	$\geq$	4SL2		4SL3
	5R1	0S1		1S2		2SL1	$\geq$	3SL1	$\geq$	4SL1	$\geq$	5R1	$\rangle$	
	5R2	0S1		1S2		2SL1	$\geq$	3SL1	$\rangle$	4SL1	$\geq$	5R1	$\geq$	5R2
	2D1	0S1		1S2		2D1			_					
	3D1	0S1		1S2	$\rightarrow$	2D1	$\geq$	3D1	$\geq$		_			
	4D1	0S1		1S2		2D1	$\rightarrow$	3D1	$\geq$	4D1				
	5D1	0S1		1S2		2D1	$\rangle$	3D1	$\rangle$	4D1	$\rangle$	5D1	$\rangle$	

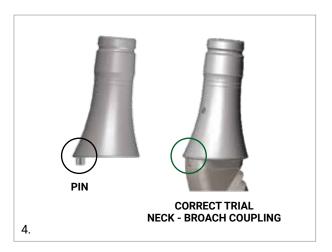
This table shows the implant sizes, pre-operative planning with the templates, and the broach sizes. Please find in the first gray column the planned implant size and follow the broaching sequence from left to right. For example, to implant a stem size 4S1 we recommend the following broach sequence:

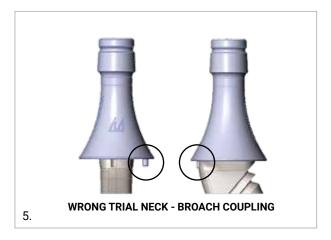
#### 7. TRIALING

After complete locking 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

Trial necks have a pin. The trial neck is correctly coupled to the broach only when the pin is inserted into the dedicated broach housing without protruding.





**NOTICE:** to verify correct coupling, check that the pin does not protrude from the housing. The trial neck is not correctly positioned or the wrong trial neck size has been selected, if the pin protrudes. See paragraph "10 - Implants Nomenclature" for correct trial neck-broach size combinations.

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

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

#### **TRICK**

A mechanical engraving on the trial neck taper indicates the trial neck size.

Different surface treatments help to identify standard and lateralized necks: standard necks are sandblasted while the lateralized are mirror polished.



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

**NOTICE:** the Head Impactor must only be used for head impaction and not for the correction of the acetabular shell position.

#### **CAUTION**

When AMIS-K stem size 0S1 is coupled with heads Ø22mm size S or Ø28mm size S and Native Cup the ROM in flexion-extension is less than 100°. Always perform trial reduction with the chosen head.

Simply pull the trial head to remove.

As an alternative trial stems are available on request. After checking and testing mobility, joint stability and lower limb length, remove the broach or the trial stem.



#### 8. FINAL IMPLANTS

The final implant size is the same as the final broach size. This allows cementation with the "line-to-line" technique. 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 stem size corresponds with size of last rasp used).

Push the stem down into the cement until the optimal position, established during the trial step, has been 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 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**

The head sizes XL (for  $\emptyset$  28 mm and  $\emptyset$  32 mm) and XXL (for  $\emptyset$  28 mm,  $\emptyset$  32 mm and  $\emptyset$  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 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 instructions for use for ceramic femoral heads.

Reduce the hip.

# 9. INSTRUMENT DETAILS

To assemble the AMIS-K rasp onto its broach handle follow the instructions here below.

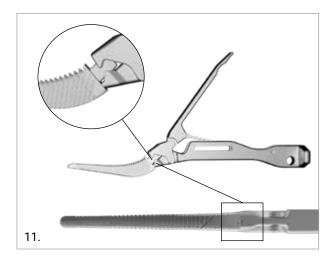
These instructions are valid for the following broach handles:

REFERENCE	DESCRIPTION			
01.36.10.0070	AMIS Pincer broach handle			
01.36.10.0073	Pincer broach handle	.0		
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			

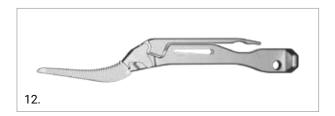


#### 9.1 BROACH ASSEMBLY

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.



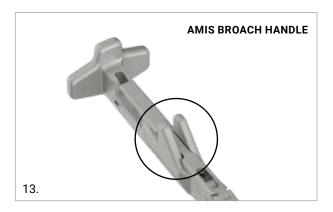
Once assembled, lower the lever and check that it is fully seated down.



The rasp is now assembled on the broach handle.

#### **TRICK**

To extract the broach easily from the femoral canal, the surgeon should grip the handle in a way that allows for the user to strike on the suitable anvil.

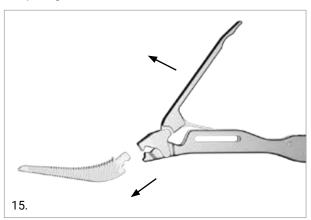




Never strike on other parts of the handle, especially near the lever.

#### 9.2 BROACH DISASSEMBLY

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



#### **WARNING**

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

# 9.3 BROACH HANDLE REGULATION (ONLY WHEN STRICTLY NECESSARY)

The AMIS-K broach handle grip can be adjusted. In order to do so, use the 3.5 mm screwdriver (reference 1.113) present in the AMIS-K ancillary set, and follow the instructions here below:

- Hold down the button (Fig.16)
- While holding the button down, insert the screwdriver in the set screw (Fig.17):
   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 sensible, therefore do not turn more then 45° at a time.

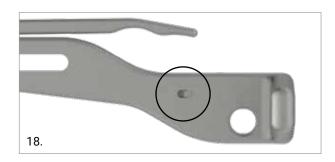




#### **WARNING**

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.



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



# 10. IMPLANTS NOMENCLATURE

## **AMIS-K CEMENTED STEM**

## STANDARD

REF.	DESCRIPTION	TRIAL NECK SIZE	BROACH SIZE
01.20.001	AMIS-K 0S1 *	0S	0S1
01.20.002	AMIS-K 1S2	1S	1S2
01.20.003	AMIS-K 2S1	2S	2SL1
01.20.005	AMIS-K 2S2	2S	2SL2
01.20.007	AMIS-K 2S3	2S	2SL3
01.20.009	AMIS-K 3S1	3S	3SL1
01.20.011	AMIS-K 3S2	3S	3SL2
01.20.024	AMIS-K 3S3	3S	3SL3
01.20.013	AMIS-K 4S1	4S	4SL1
01.20.015	AMIS-K 4S2	4S	4SL2
01.20.026	AMIS-K 4S3	4S	4SL3

## LATERALIZED

REF.	DESCRIPTION	TRIAL NECK SIZE	BROACH SIZE	
01.20.004	AMIS-K 2L1	2L	2SL1	
01.20.006	AMIS-K 2L2	2L	2SL2	
01.20.008	AMIS-K 2L3	2L	2SL3	
01.20.010	AMIS-K 3L1	3L	3SL1	
01.20.012	AMIS-K 3L2	3L	3SL2	
01.20.025	AMIS-K 3L3	3L	3SL3	
01.20.014	AMIS-K 4L1	4L	4SL1	
01.20.016	AMIS-K 4L2	4L	4SL2	
01.20.027	AMIS-K 4L3	4L	4SL3	

#### **REVISION**

REF.	DESCRIPTION	TRIAL NECK SIZE	BROACH SIZE
01.20.017	AMIS-K 5R1	5S	5R1
01.20.018	AMIS-K 5R2	5S	5R2

#### **DYSPLASTIC**

	REF.	DESCRIPTION	TRIAL NECK SIZE	BROACH SIZE
	01.20.020	AMIS-K 2D1	2S	2D1
	01.20.021	AMIS-K 3D1	3S	3D1
	01.20.022	AMIS-K 4D1	4S	4D1
ĺ	01.20.023	AMIS-K 5D1	5S	5D1

<sup>&</sup>lt;sup>1</sup>To be coupled only with S, M, L heads

<sup>\*</sup> See CAUTION on page 4











## **FEMORAL HEADS**

LINIONAL IILADS						
DIAMETER	SIZE	STAINLESS STEEL	CoCr	CeramTec BIOLOX delta	CeramTec BIOLOX Option "	Mectacer BIOLOX delta
Ø 22 mm *	S *	01.25.1301	01.25.124	-	-	-
Ø 22 mm	М	25055.22031	01.25.123	-	-	-
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	М	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	25055.28101	01.25.015	-	-	-
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	М	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	25055.32101	01.25.025	-	-	-
Ø 36 mm	S	-	01.25.030	38.49.7179.275.00	38.49.7176.965.81	01.29.208
Ø 36 mm	М	-	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	-	-	-
Ø 40 mm	S	-	-	38.49.7179.885.001	38.49.7179.815.81	01.29.212
Ø 40 mm	М	-	-	38.49.7179.895.001	38.49.7179.815.821	01.29.213
Ø 40 mm	L	-	-	38.49.7179.905.001	38.49.7179.815.851	01.29.214
Ø 40 mm	XL	-	-	38.49.7179.915.001	38.49.7179.815.841	01.29.215
Ø 40 mm	XXL	-	-	-	-	-

On demand

# MECTACER BIOLOX OPTION SYSTEM"

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

<sup>&</sup>quot; Specific for revision cases \* See CAUTION on page 4

<sup>&</sup>quot; Specific for revision cases
\* See CAUTION on page 4



# 11. POSSIBLE IMPLANT COMBINATIONS

All Medacta implant combinations are represented in the table "Medacta Hip product compatibility" (réf. 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 respecting the regulations of the country, EU directives where applicable and following the instruction for use of the autoclave manufacturer. 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.





#### 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

All trademarks and registered trademarks are the property of their respective owners. This document is not intended for the US market. Please verify approval of the devices described in this document with your local Medacta representative.

AMIS-K Surgical Technique

ref: 99.15K.12 rev. 06

Last update: January 2019 **C€ 0476**