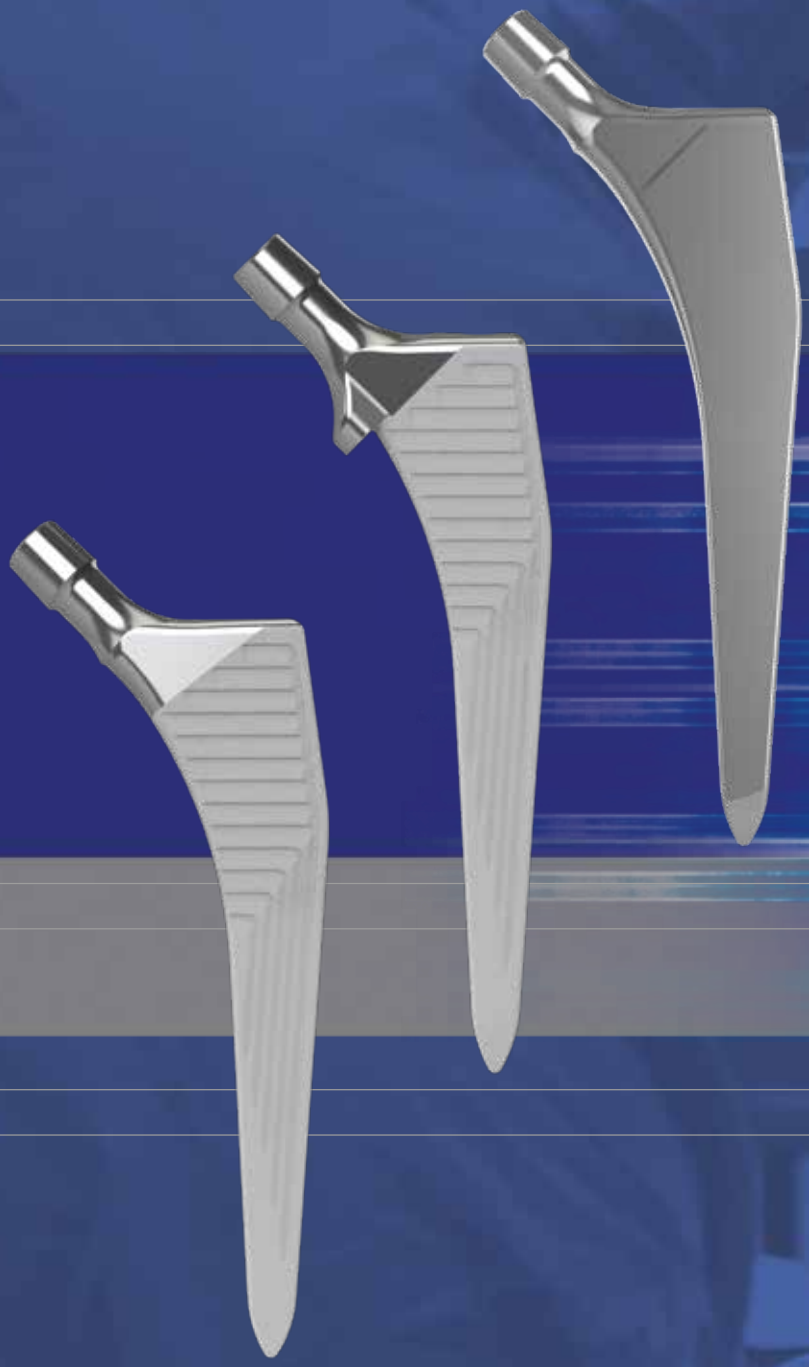
QUADRA-P

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

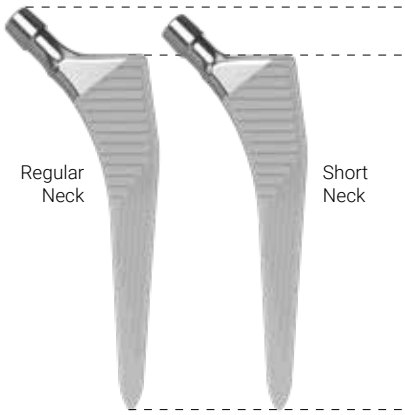
This document describes the Surgical Technique for the QUADRA-P System:

- QUADRA-P is a cementless stem in Titanium-Niobium alloy with Titanium plasma spray coating (MectaGrip) on the proximal area and HA coating on the shaft. It is available in "regular neck (STD and LAT)" and "short neck (STD and LAT)".
- QUADRA-P Collared is a cementless collared stem in Titanium-Niobium alloy with Titanium plasma spray coating (MectaGrip) on the proximal area and HA coating on the shaft.
- QUADRA-P Cemented is a cemented stem manufactured from high nitrogen stainless steel

This document describes the Surgical Technique of manual broach handle procedures to implant the QUADRA-P stems.

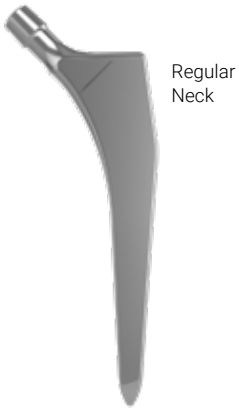
For details regarding implantation using the AMIS Approach, please see the dedicated AMIS Surgical Technique.

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



QUADRA-P

QUADRA-P
Collared



QUADRA-P
Cemented

1.

1.1 INDICATIONS OF USE

The hip prosthesies QUADRA-P and QUADRA-P collared are designed for cementless use in total or partial hip arthroplasty, for primary or revision surgery. The hip prosthesis QUADRA-P cemented is designed for cemented use in total or partial hip arthroplasty in primary or revision surgery.

Hip replacement 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.

1.2 CONTRAINDICATIONS

Contraindications for use of the QUADRA-P stems 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 in any way.

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

Careful pre-operative planning is essential. It will help the surgeon to pre-select the femoral implant size 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 level of the neck cut
- The neck length
- The prosthetic rotation centre

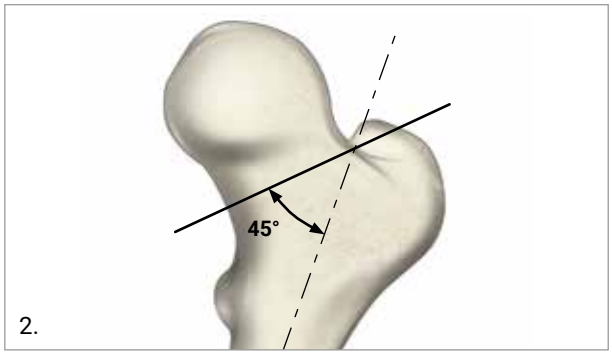
NOTE: The final implant will be selected intra-operatively, because of possible discrepancies between actual conditions and templating.

1.4 SURGICAL APPROACH

The choice of surgical approach is up to the surgeon. The instrumentation has been developed for a standard 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 pre-operative 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.



2.

3. FEMORAL PREPARATION

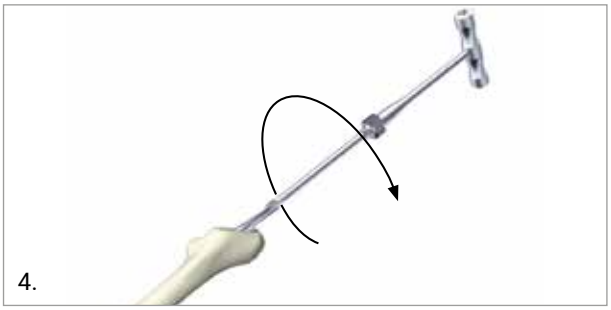
To gain access to the medullary canal, the thigh is held in the position providing the best exposure of the diaphyseal axis, depending on the selected approach.

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.


3.

This removes a block of cancellous bone.

If needed, the endomedullary cancellous bone can be reamed using the metaphyseal reamer assembled with the T shaped Handle for reamer. Check the axis and ensure cortical continuity. It is recommended to make a slight recess in the neck base or in the trochanteric overhang, if necessary to clear for the shoulder of the broach, then of the stem.


4.

The femoral diaphysis is prepared using sequential broaches. Assemble the broach with the broach handle.


5.

OPTION

Broaches of increasing sizes, starting from size 0, are introduced until complete locking; the first broach determines the position of the following broaches.

The broaches must be inserted to optimum level determined by the 45° cut.

WARNING

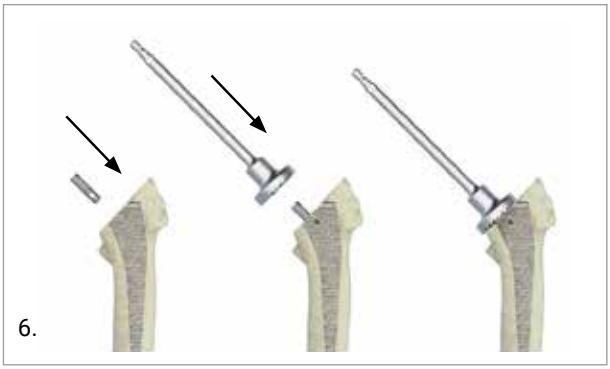
Never force impaction when the broach is blocked in the diaphysis.

The final broach should be rotationally stable to ensure 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 adapter 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 the calcar reamer is highly recommended



6.

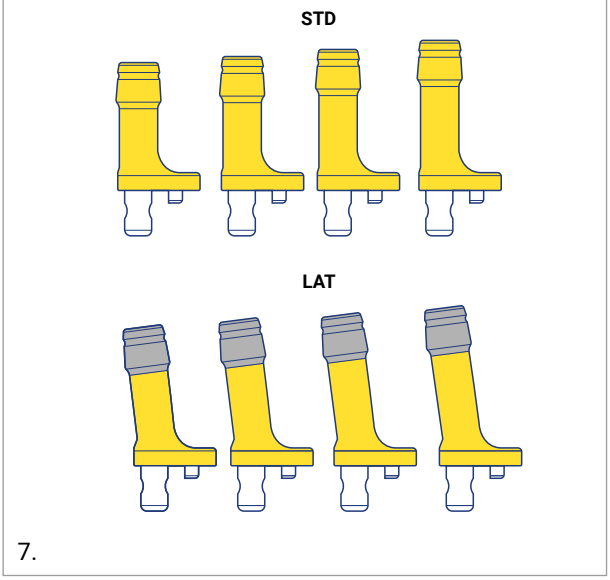
5. TRIALING

After complete locking of the broach in the diaphysis, the broach handle is removed. A trial neck is fitted into the broach.

Different trial necks are available for different stem versions and broach sizes. For easier identification COLOR CODE has been implemented.

For QUADRA-P regular neck stems (cementless, collared, cemented) 8 trial necks are available: 4 sizes STD (completely gold) and 4 sizes LAT (gold with a grey taper).

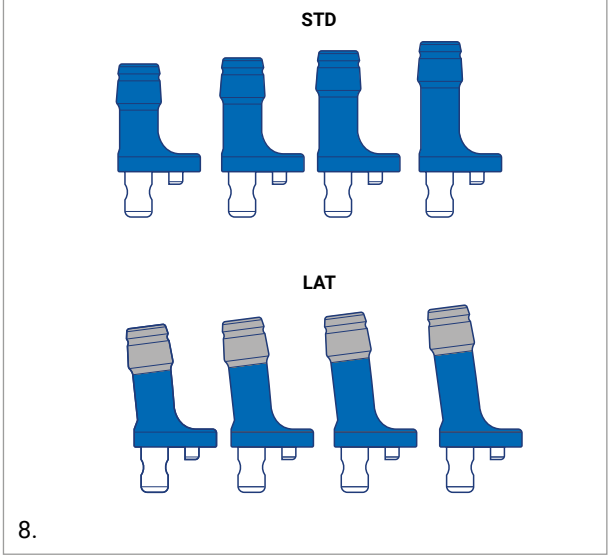
QUADRA-P REGULAR NECK



7.

For Quadra-P short neck stems 8 dedicated short trial necks are available: 4 sizes STD (completely blue) and 4 sizes LAT (blue with a grey taper).

QUADRA-P SHORT NECK



8.

Each trial neck reproduce an accurate head center only if assembled with the correct broach. For a correct coupling refer to the tables 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 (STD) TRIAL NECKS

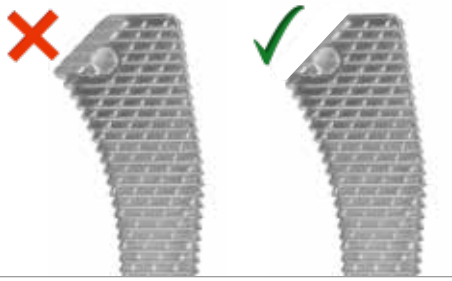
REGULAR REF. (gold)	SHORT REF. (blue)	BROACH SIZE	BROACH REF.
01.18.10.061	01.18.10.069	00	01.10.10.0350
		0	01.10.10.045
		1	01.10.10.018
01.18.10.062	01.18.10.070	2	01.10.10.019
		3	01.10.10.020
		4	01.10.10.021
01.18.10.063	01.18.10.071	5	01.10.10.022
		6	01.10.10.023
		7	01.10.10.024
01.18.10.064	01.18.10.072	8	01.10.10.0638
		9	01.10.10.0639
		10	01.10.10.0640

LATERALIZED (LAT) TRIAL NECKS

REGULAR REF. (gold with grey taper)	SHORT REF. (blue with grey taper)	BROACH SIZE	BROACH REF.
01.18.10.065	01.18.10.073	0	01.10.10.045
		1	01.10.10.018
01.18.10.066	01.18.10.074	2	01.10.10.019
		3	01.10.10.020
01.18.10.067	01.18.10.075	4	01.10.10.021
		5	01.10.10.022
01.18.10.068	01.18.10.076	6	01.10.10.023
		7	01.10.10.024
		8	01.10.10.0638
		9	01.10.10.0639
		10	01.10.10.0640

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 QUADRA-P trial neck.



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.

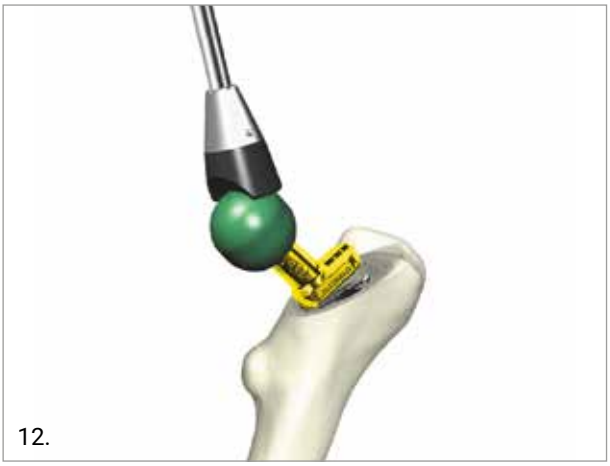
A trial head is fitted to the trial neck by pushing it onto the taper.

10.

11.

TRICK
To make head insertion easier moisten it before insertion.

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



12.

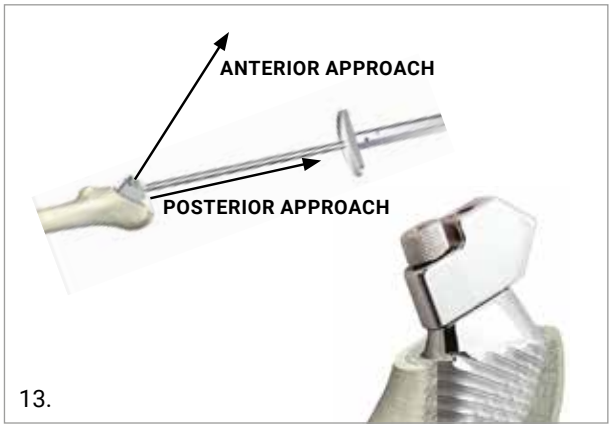
NOTE: The head impactor must be used only for head impaction and not for the correction of the acetabular shell position.

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

CAUTION
Femoral stems are subject to severe cycle stress. Always carry out a final visual inspection, before inserting the implant, to verify that no scratches or surface damages have occurred, particularly in the neck area. Small surface damages may significantly reduce service life and lead to complications, including stem fracture.

WARNING
Take care not to damage the taper's micro-thread while placing the final implant. Insert the implant into the femoral cavity, using the stem impactor to push it down.

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

CAUTION
The head sizes XL (for Ø28 mm and Ø32 mm) and XXL (for Ø28 mm, Ø32 mm and Ø36 mm) have a collar. This may decrease the Range of Motion in comparison to shorter sizes. Always perform trial reduction with the chosen head. The head size S (for Ø22 mm) may decrease the Range of Motion when used with a Native acetabular cup.

6.1 CEMENTLESS IMPLANTS

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.

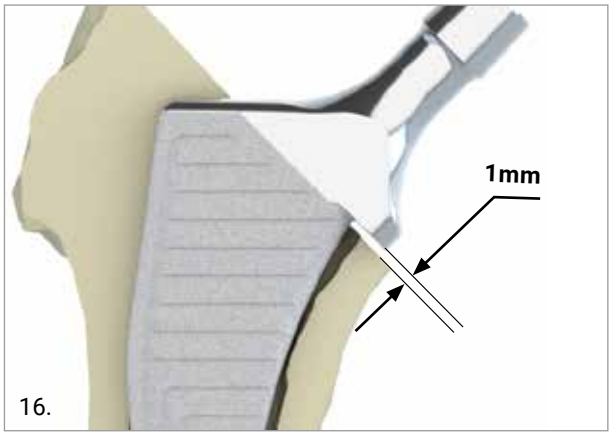
14.

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.

The protective cap is removed from the taper. Another trial reduction can be performed to determine the final neck length.

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 femoral cavity is 1.4 mm larger than the implanted prosthesis.

Technique 2 (line-to-line broaching) 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.

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
00	-	-
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.
Size 00 is not available, therefore follow Tech.2 when a size 0 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 it has reached the desired 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

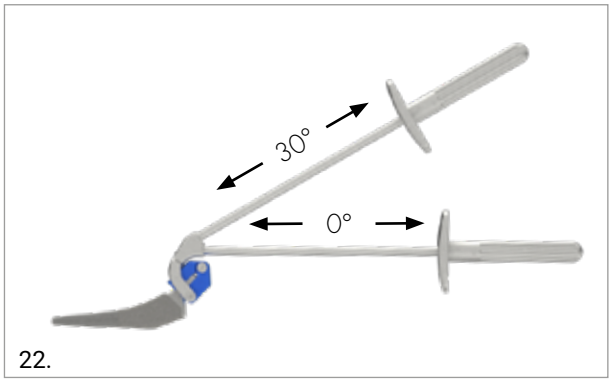
After impaction, if the final stem needs to be removed or repositioned, a stem repositioner is available. This repositioner can be used with any hip approach, including the AMIS technique.

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


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
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

NOTE: The MectaCer BIOLOX Option femoral heads cannot be combined with the Quadra-P Cemented stem.

QUADRA-P

REGULAR NECK			SHORT NECK		
STANDARD	SIZE	LATERALIZED	STANDARD	SIZE	LATERALIZED
01.12.119	00 [II]	-	-	-	-
01.12.120	0	01.12.140	01.12.250	0SN	01.12.270
01.12.121	1	01.12.141	01.12.251	1SN	01.12.271
01.12.122	2	01.12.142	01.12.252	2SN	01.12.272
01.12.123	3	01.12.143	01.12.253	3SN	01.12.273
01.12.124	4	01.12.144	01.12.254	4SN	01.12.274
01.12.125	5	01.12.145	01.12.255	5SN	01.12.275
01.12.126	6	01.12.146	01.12.256	6SN [I]	01.12.276
01.12.127	7	01.12.147	01.12.257	7SN [I]	01.12.277
01.12.128	8	01.12.148	01.12.258	8SN [I]	01.12.278
01.12.129	9	01.12.149	01.12.259	9SN [I]	01.12.279
01.12.130	10	01.12.150	01.12.260	10SN [I]	01.12.280

SN = Short Neck

[I] Availability upon approved special request only.
[II] On Demand

QUADRA-P COLLARED

REGULAR NECK		
STANDARD	SIZE	LATERALIZED
01.12.159	00 [II]	-
01.12.160	0	01.12.180
01.12.161	1	01.12.181
01.12.162	2	01.12.182
01.12.163	3	01.12.183
01.12.164	4	01.12.184
01.12.165	5	01.12.185
01.12.166	6	01.12.186
01.12.167	7	01.12.187
01.12.168	8	01.12.188
01.12.169	9	01.12.189
01.12.170	10	01.12.190

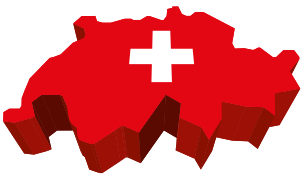
QUADRA-P CEMENTED

REGULAR NECK		
STANDARD	SIZE	LATERALIZED
01.12.210	0	01.12.230
01.12.211	1	01.12.231
01.12.212	2	01.12.232
01.12.213	3	01.12.233
01.12.214	4	01.12.234
01.12.215	5	01.12.235
01.12.216	6	01.12.236
01.12.217	7	01.12.237
01.12.218	8	01.12.238

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

QUADRA-P System
Surgical Technique

ref: 99.14PS.12US
rev. 01

Last update: July 2019