permedica
ORTHOPAEDICS

EXACTA
Femoral Stem

SURGICAL TECHNIQUE

CE
0426

Both our Sales Representatives and Product Specialists are at Your complete disposal for any further information and/or explanation about the contents of this Surgical Technique

EXACTA
FEMORAL STEMS SYSTEM

The EXACTA femoral system by permedica provides two straight femoral stems available in double version:

EXACTA cementless: providing a press-fit stem with bone contact surface finishing in different versions (X-Pore, Ha and HaX-Pore coated);

EXACTA PLUS cemented: mirror polished surface stem with smoothed shape.

Both versions available in Standard 135° and LATERALIZED 127° option.

The stem's design is based upon the principle of a self-locking stem, thus ensuring optimal anchoring guaranteed by a double cortical bone contact in the meta-diaphyseal region on the medial-lateral plane.

Longitudinal and transversal grooves on the anterior and posterior surface guarantees adequate axial and rotational stability.

The stem has a thin rectangular cross-section thus favouring the stem's wedging into the femoral medullary canal. The tapered diaphyseal portion allows for good centering of the implant in the femoral canal avoiding high stresses on the distal cortical walls.

The neck section has a reduced diameter enhancing the range of motion of the joint, avoiding impingement with the inner rim of the acetabular cup.

A special hole on the top allows the insertion of the stem introducer, for the correct alignment and positioning of the stem as well as the coupling with a sliding hammer extraction device.

A niche on the medial region of the prosthetic neck allows the housing of a punch for stem removal if necessary.

NOTE:
For further information please refer to the Instructions For Use supplied in the package of each single device.

ATTENTION:
Other than the implementation of a correct Surgical Technique, a good clinical outcome of a THA also depends upon several factors such as bone stock quality, wear values and correct implant sizing.

INDICATION FOR USE

Use of the EXACTA stems is indicated in the following conditions:

- ✓ avascular necrosis of the femoral head;
- ✓ Fractures of the femoral neck/head;
- ✓ rheumatoid arthritis;
- ✓ primary/secondary arthrosis;
- ✓ post-traumatic arthrosis;
- ✓ collagen diseases;
- ✓ displasies and congenital dislocation of the hip joint;
- ✓ epiphyisiolisis.

SURGICAL PROCEDURE

ATTENTION:
This Surgical Technique should be considered a guide or example to assist orthopaedic Surgeons already trained in Total Hip Arthroplasty. It's objective is to demonstrate the various instruments used for the implantation of the EXACTA stem by permedica. *The knowledge and experience of the Surgeon will guide him throughout the steps of the implantation.*

PRE-OPERATIVE PLANNING 1

The aim of preoperative planning is to choose the most suitable prosthesis to implant, determine the ideal anchorage position, establish the correct positioning for good biomechanical reconstruction, correct eventual dysmetria and verify the size.

With these objectives in mind it is necessary to carry out a radiographical exam of the coxo-femoral joint (pelvis and proximal third of the femur) with projected Anterior-Posterior and Latero-Lateral images, with enough focal distance to obtain an enlargement of at least 15%.

In summary, a correct preoperative planning is advisable in order to carry out the following general characteristic evaluation:

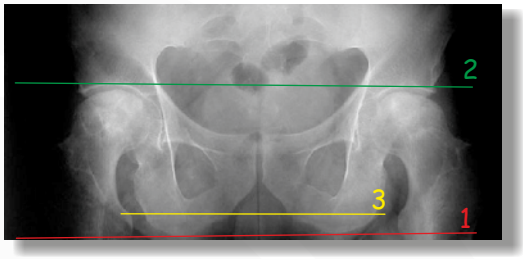


Fig. 1: Pre-operative planning

CENTER OF ROTATION REPRODUCTION

From the A/P pelvis radiograph the controlateral femoral head center of rotation can be determined, when it is healthy, and the distance from the radiographic U is quantified.

EVALUATION OF EVENTUAL DYSMETRIA

Three horizontal lines are traced (**Fig. 1**): a Bi-ischiatic line (1), between the inferior margins of the ischium; an above acetabular line (2), between the upper margins of the acetabular cavity, and a bi-tronchanteric line (3), between the two lesser tronchanters.

If these three lines are parallel amongst themselves, there is no dysmetria.

If lines (1) and (2) are parallel but line (3) is divergent, there is dysmetria due to a deformation of the femur.

If lines (2) and (3) are parallel but (1) is divergent, there is a dysmetria due to a cotyloid deformation.

In the case that all three lines are divergent amongst themselves, there is a combined dysmetria, determined by a cotyloid deformation as well as a femur deformation.

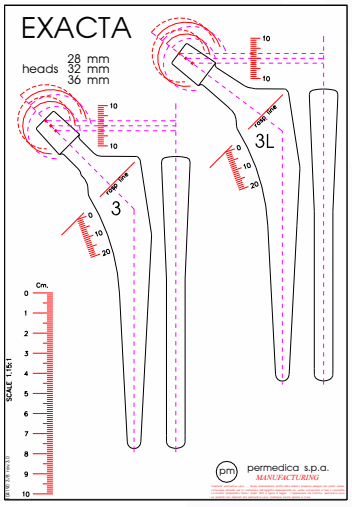
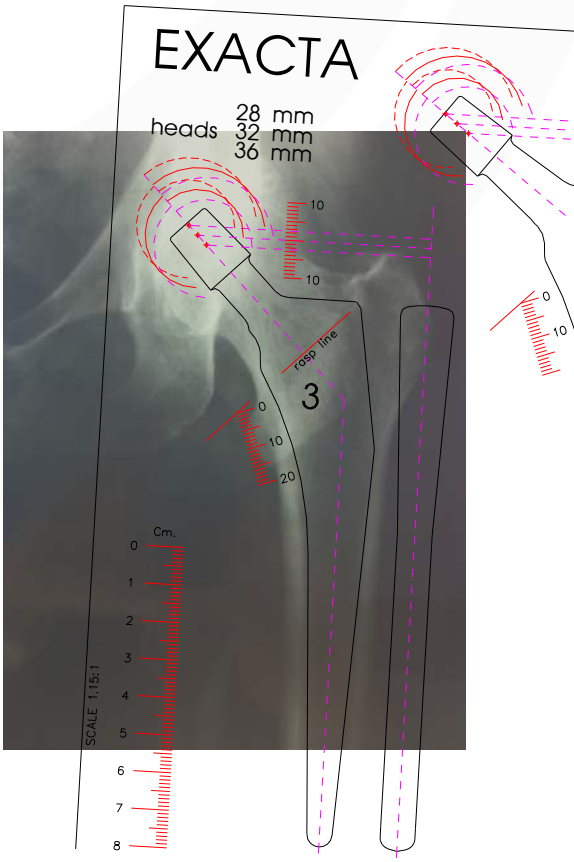


Fig. 1b: size evaluation

EVALUATION OF THE IMPLANT SIZE

After having studied and evaluated the above mentioned information via radiographic templates (with 15% magnification), choose the optimal size combination for the femoral component as well as the acetabular component (**Fig. 1b**).

It is possible to prepare a traced radiographic lucent of the hip by placing the template over the prosthesis to be implanted.



IMPORTANT!

Determine the correct level of the femoral neck osteotomy by placing the template of the better fitting size over the involved hip x-ray, aligning the line referring to the center of rotation to the top of the *Greater Trochanter.* The Rasp Line marked on the broach will indicate the correct level of the femoral neck resection.

This mark is engraved on each rasp and indicates the precise sinking level.

Please note that the length of the neck (Rasp Line-Center of Rotation) is 41 to 46.5mm depending on the size (refer to table at page 7).

ATTENTION

It would be advisable to evaluate, already in the pre-operative planning phase, the opportunity to use an EXACTA LATERAL stem.

Failing to execute accurate pre-operative planning could lead to poor results. The intervention should be carefully planned based upon X-Ray screening.

Before the operation it is furthermore necessary to investigate the possibility of any possible allergic reactions of the patient towards implantable device materials.

2 SURGICAL APPROACH

The initial exposure of the joint for the EXACTA stems implantation can be achieved by following any standard surgical approach, according to Surgeon's preferences and/or habits.

The following illustrated technique refers to an implant realized via a Postero-Lateral Approach.

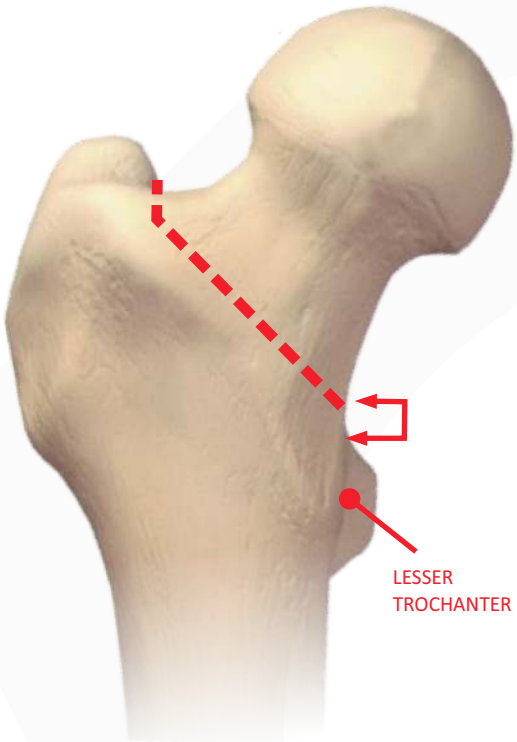


Fig. 2:

3 JOINT EXPOSURE

The incision is centered on the posterior half of the *Greater Trochanter* and extended distally along the femoral diaphysis for 10 cm. and proximally following the direction of the gluteus maximus fibers.

The *Fascia Lata* is divided in line with the cutaneous incision. The *Gluteus Maximus* is divided longitudinally via a blunt dissection. Cauterize the bleeding points.

Expose the *Short External Rotators muscles* positioning a blunt retractor between the *Capsule* and the *Gluteus Medius*, putting them in tension via internal rotation of the joint. Pass a suturing thread into the *Piriformis Tendon* in order to evidence the position for successive re-insertion. Detach entirely or separately the *External Rotators muscles* by carrying out an incision as close as possible to the bone.

Cut the *Joint Capsule* starting from the Acetabular Cavity margin and going till the base of the *Femoral Neck*.

Dislocate the *Femoral Head* turning the joint internally with the knee flexed. In some cases it is necessary to section the Round ligament first.

Utilize a doube pointed retractor in order to lift the femoral head thus providing optimal exposure.

Fig. 3:

4 FEMORAL NECK OSTEOTOMY

Before proceeding to the osteotomy of the femoral head, it is important to remove any osteophytes and periosteal tissues to allow clear vision of the head/neck limits.

The neck osteotomy is carried out using an oscillating saw, referring to the lesser trochanter and at the distance measured in the pre-operative planning (**Fig. 2**).

The femoral head is removed and preserved for eventual future bone grafts.

5 STARTING THE FEMORAL CANAL

The medullary canal is initiated utilizing the indicated Starting Chisel (S12010). Striking the chisel, a rectangular cleft is made allowing for the insertion of the first rasp. The chisel must be held as laterally as possible. (**Fig. 3**)

Identify the axis of the femoral canal using a long curette or a rigid reamer.

*To lock/unlock the broach onto the Handle (**Fig. 4**):*

① *open the locking system by pulling the lever* A

② *engage the broach in the connection* B

③ *lock the broach by pushing back the lever* A

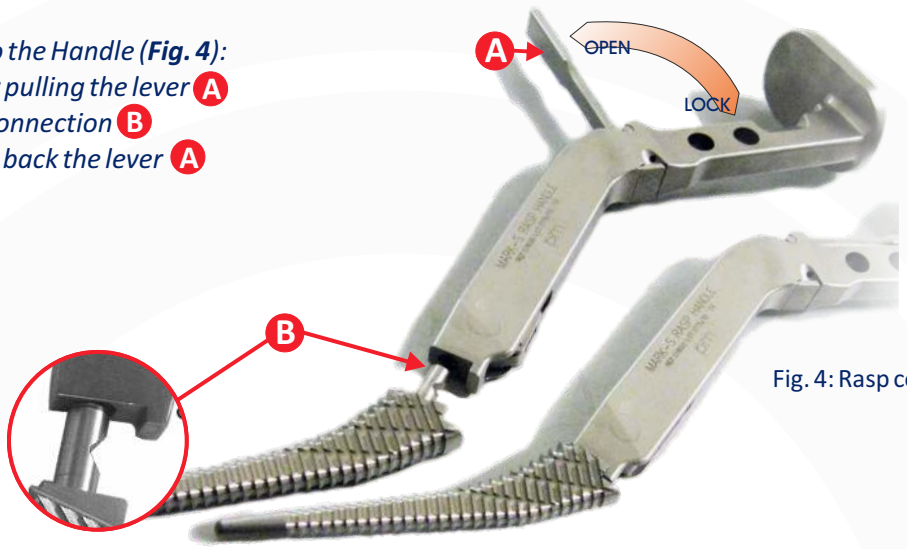


Fig. 4: Rasp connection

NOTE:

In addition to the CURVED Impacting Handle (S11600) supplied as standard, it is also available a STRAIGHT Handle and Double Off-set Handles (in LEFT and RIGHT version) to be used with anterior approach.

A special Adapter (S11607) is also available to allow broaches impaction by using the Sliding Hammer Impactor (S10012) as well as a pneumatic hammer (Woodpecker).

The smallest size broach is assembled onto the Impacting Handle and inserted into the prepared site. The special design of both the broach and the handle make it possible to preserve the *Greater Trochanter*, allowing to insert the broach slightly medially (**Fig. 5a**) and then change the direction to follow the diaphyseal axis by pushing the handle laterally (towards the *Greater Trochanter*) while hammering the broach.

The broach must be pushed until totally embedded. It may be necessary to repeat the extraction and reinsertion a few times to help removal of bony debrise.

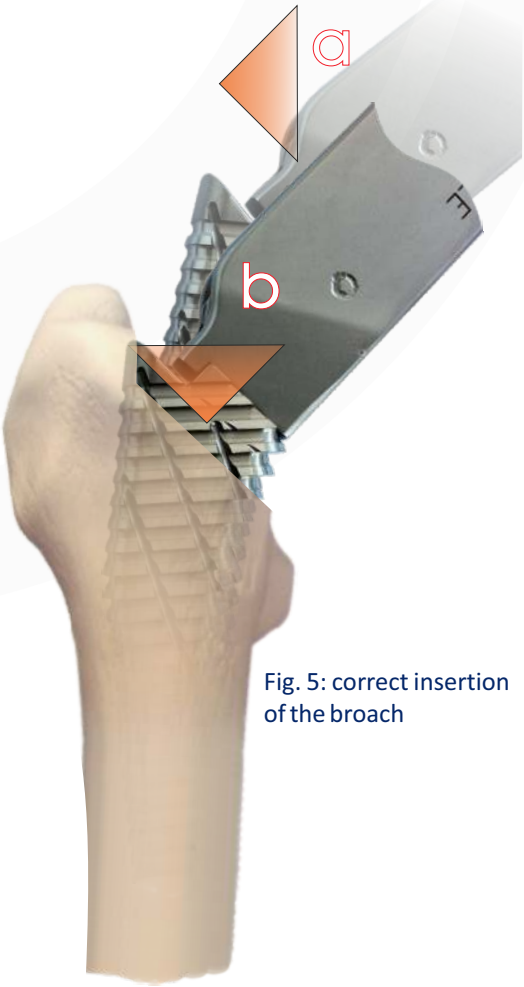


Fig. 5: correct insertion of the broach

Fig. 6: correct sinking of the final broach

Proceed inserting the next broaches, increasing the size until reaching the correct size determined in the pre-op planning (anyway the surgeon should feel the broach locking onto the cortical walls and not sinking any further, stable to torsion and opposing resistance to extraction). If the osteotomy has been made in compliance to the pre-op planning, the Rasp Line mark should be leveled to the osteotomy (**Fig. 6**). If the broach sinks further, the next size is normally required.

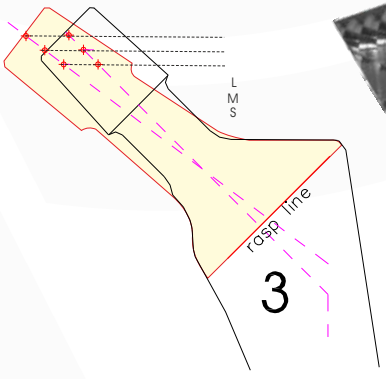
Whenever the final broach should be considerably smaller (two or more sizes) than that evaluated during the pre-operative planning it would be necessary to verify the correct insertion of the rasp within the femoral canal and, if necessary, carry out any corrections before inserting the final implant.

7 TRIAL EVALUATION

Having reached the desired fit, the last broach utilized is left in place. Inserting onto it the apposite Trial Neck for the EXACTA Mark S broach and a Trial Head, it will be possible to carry out a trial reduction. (**Fig. 7**).

ATTENTION:

The MARK S rasps have STANDARD (S11610) and a LATERAL (S11620) trial neck, both fitting all sizes of rasps.



The Lateralized option allows to change the angle of the neck (127°), increasing the offset and improving muscles tension without changing the limb length.

After inserting a Medium Neck Trial Head compatible with the inner diameter of the implanted acetabular cup's liner, reduce the hip to evaluate mobility and stability through a full range of motion (high flexion, external/internal rotation, abduction/adduction) and check for any impingement.

The appropriate neck length of the ball head to be used is determined as well. This is considered optimal if, by extending the limb and applying traction, an excursion of about 10mm is allowed. If the excursion should be different, evaluate the opportunity of using a Short or Long neck ball head.

The neck length of the Trial Heads is identifiable by a colour coding:

GREEN = *SHORT Neck / XL-Neck (old type)*

BLUE = *MEDIUM Neck*

GREY = *LONG Neck*

YELLOW = *XL (Extra-Long) Neck*

WARNINGS regarding use of ExtraLong ball-heads:

Although the system foresees the use of Extralong ball heads, this could lead to an alteration of the correct biomechanics, with huge lever arms and high stresses on the implanted components. Therefore, use of this type of ball heads should be carefully evaluated, also considering the patient's weight and morphology.

Fig. 7

IMPLANTATION OF THE DEFINITIVE STEM 8

PRESSFIT STEM

EXACTA cementless stems: *the definitive Stem to be implanted will be the same size of the last broach utilized.*

Once drawn from the sterile packaging, the Stem is manually engaged into the previously prepaired femoral site.

Screw the apposite Stem Impacting End (S11622) onto the Universal Impactor Handle (S12011).

Lodge the tip into the niche onto extreme top of the stem(**Fig. 8**) and impact with a hammer until complete seating (**Fig. 9**).

Fig. 8

Fig. 9

Fig. 10

CEMENTED STEM

EXACTA PLUS (cemented): the definitive Stem to be implanted will be the same size of the last rasp utilized. Please note that the cemented stem is undersized compared to the rasp to allow 1mm cement mantle around the prosthesis: if a thicker cement mantle should be desired, a smaller size can be selected having care to adjust its insertion accordingly with the sinking lines.

Once drawn from the sterile packaging, the Stem is engaged onto the Stem Holder/Driver (S11623). Insert the threaded end into the stem and use the integrated knurled knob to screw it into the niche on the top of the stem (**Fig. 10**) then tighten using the Knob Key.

Fig. 11a: sinking level referring to the Greater Trochanter

The prepared femoral cavity is filled with bone cement, following the most favourite cementing technique. It is anyway advisable to plug the diaphysis distally to the stem in order to avoid cement leakage towards the distal femur.

The stem is driven into the femoral canal and sank till it's final seating. For a correct sinking refer to the sinking lines marked on the proximal part of the stem.

ATTENTION:

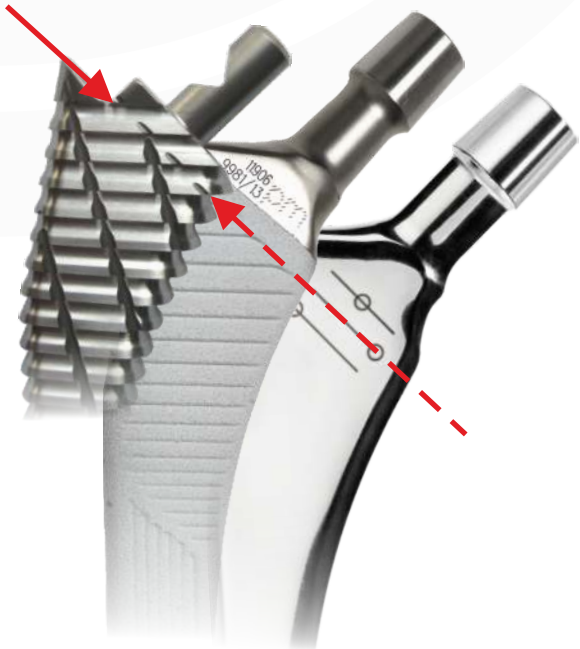
The central sinking line refers to the resection line marked on the rasp (**Fig.11b**). Please remind anyway that a reliable landmark to refer to is the center of the morse taper (center of rotation) aligned to the *Greater Trochanter* (**Fig. 11a**).

Apply a continuous pressure till complete hardening of the bone cement, removing the bone cement in excess overflowing from the femoral canal.

WARNING:

DO NOT USE EXTRALONG BALL HEADS with EXACTA PLUS LATERAL stem

Fig. 11b: sinking lines.



IMPLANTATION OF THE BALL HEAD 9

Once the stem is definitively seated it will be possible to repeat a trial, in case of any doubt,by using the Trial Heads. Once the correct ball head has been established, proceed to implante the definitive one.

Remove the plastic cap protecting the taper and manually insert the selected Ball Head onto the stem taper, applying axial pressure and torsion to achieve perfect locking.

After positioning, the Ball Head is impacted using the proper Impacting End S10014 assembled with the Universal Impacting Handle S12011 (**Fig. 12**).

Fig. 12

WARNINGS:

☑ *Ceramic Ball Heads should be gently impacted. NEVER hit them directly with metal instruments.*

☑ *Whenever replacment of a ceramic ball head should be necessary, an accurate investigation of the cone surface should be effected. Any visible damage (i.e. grooves/scratches) would compromise the geometrical/dimensional precision of the cone and use of a new ceramic ball head must be AVOIDED.*

10 STEM REMOVAL

Whenever it should be necessary to remove the stem, an apposite Extraction Punch (S10023) is provided. Screw it onto the Universal Impactor Handle (S12011) and insert it into the niche at the base of the stem neck. Impact heavily with an hammer to remove the stem.

An Extraction Threaded Adapter to be used with the Sliding Hammer is also available upon request.

In this case, connect the quick coupling Extraction Adapter (S11012) to the Sliding Hammer Impactor/Extractor (S10012) and screw it into the threaded hole in the top of the stem.

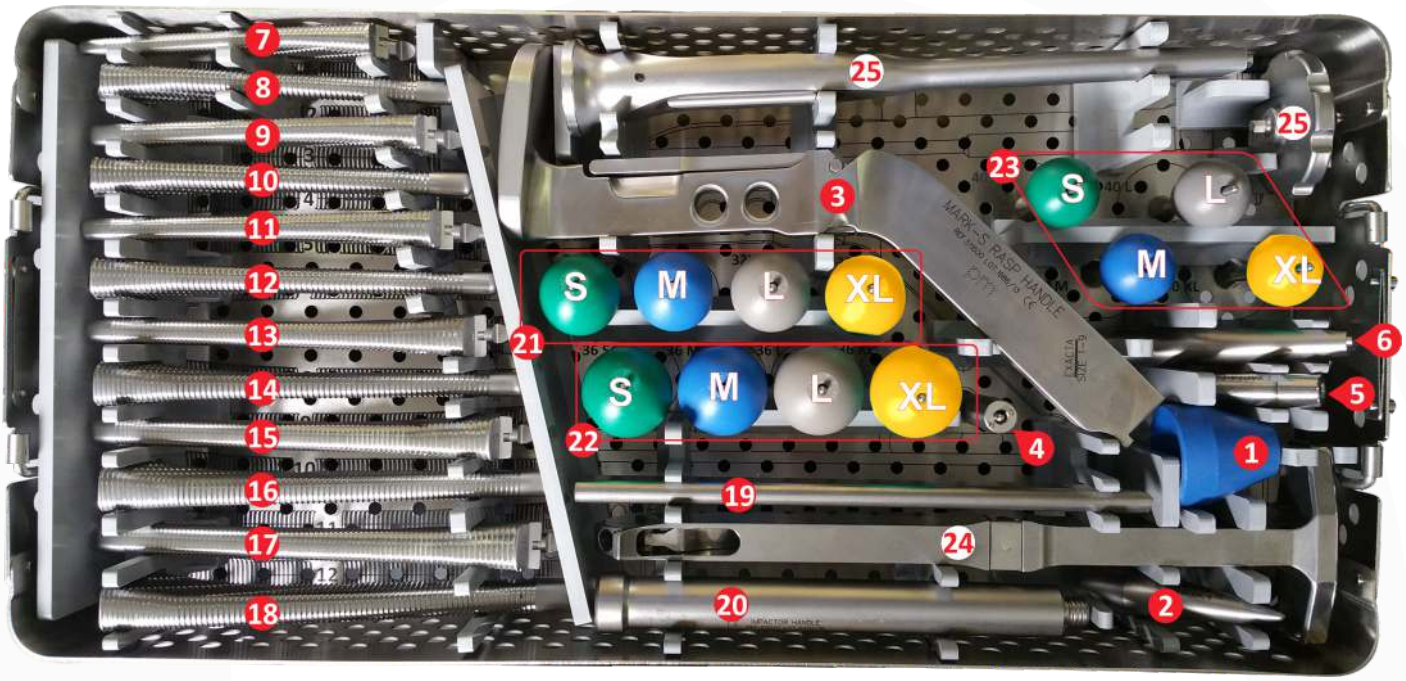
11 POST - OPERATIVE CARE

Post-op care strategy is very important to allow the patient a correct recovery. The guidelines are established by the Surgeon and should consider several factors such as age, weight and bony structure of the patient.

In any case, it is necessary to avoid excessive load of the lower limb for a certain amount of time.

ATTENTION: the Surgeon is required to schedule regular check ups to veryfy the implant status.

EXACTA INSTRUMENTS SET S11650



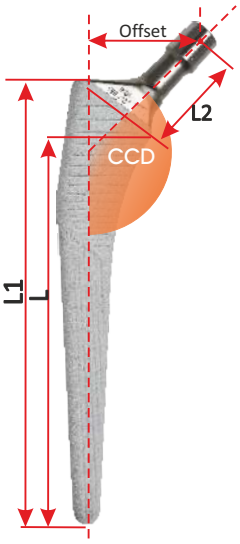
S11652 EXACTA STEM: Instruments Sterilization Case 12 sizes

1 S10014 HEAD IMPACTING END
2 S10023 CONICAL IMPACTING TIP
3 S11600 RASP HANDLE Mark S - CURVED
4 S11610 EXACTA: TRIAL CONE for Mark S Rasps - STD
5 S11620 EXACTA: TRIAL CONE for Mark S Rasps - LAT
6 S11622 STEM IMPACTING END - Buttonholed
7 S11711 EXACTA: Mark S Rasp - Fine Pitch- size 1
8 S11712 EXACTA: Mark S Rasp - Fine Pitch- size 2
9 S11713 EXACTA: Mark S Rasp - Fine Pitch- size 3
10 S11714 EXACTA: Mark S Rasp - Fine Pitch- size 4
11 S11715 EXACTA: Mark S Rasp - Fine Pitch- size 5
12 S11716 EXACTA: Mark S Rasp - Fine Pitch- size 6
13 S11717 EXACTA: Mark S Rasp - Fine Pitch- size 7
14 S11718 EXACTA: Mark S Rasp - Fine Pitch- size 8
15 S11719 EXACTA: Mark S Rasp - Fine Pitch- size 9
16 S11720 EXACTA: Mark S Rasp - Fine Pitch- size 10
17 S11721 EXACTA: Mark S Rasp - Fine Pitch- size 11
18 S11722 EXACTA: Mark S Rasp - Fine Pitch- size 12
19 S12010 STARTING BOX CHISEL
20 S12011 UNIVERSAL IMPACTING HANDLE
21 S20131 TRIAL HEAD Ø 32mm - SHORT NECK
S20132 TRIAL HEAD Ø 32mm - MEDIUM NECK
S20133 TRIAL HEAD Ø 32mm - LONG NECK
S20134 TRIAL HEAD Ø 32mm - XL NECK
22 S20137 TRIAL HEAD Ø 36mm - SHORT NECK
S20138 TRIAL HEAD Ø 36mm - MEDIUM NECK
S20139 TRIAL HEAD Ø 36mm - LONG NECK
S20140 TRIAL HEAD Ø 36mm - XL NECK
23 S20181 TRIAL HEAD Ø 28mm - SHORT NECK
S20182 TRIAL HEAD Ø 28mm - MEDIUM NECK
S20183 TRIAL HEAD Ø 28mm - LONG NECK
S20184 TRIAL HEAD Ø 28mm - XL NECK

OPTIONAL/ALTERNATIVE INSTRUMENTS

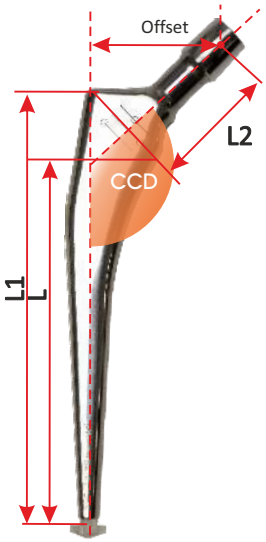
24 S11601 RASP HANDLE Mark S - STRAIGHT
25 S11623 Stem Holder with threaded Rod - Integrated Knob
7 S11731 EXACTA: Mark S Rasp - LONG Pitch- size 1
8 S11732 EXACTA: Mark S Rasp - LONG Pitch- size 2
9 S11733 EXACTA: Mark S Rasp - LONG Pitch- size 3
10 S11734 EXACTA: Mark S Rasp - LONG Pitch- size 4
11 S11735 EXACTA: Mark S Rasp - LONG Pitch- size 5
12 S11736 EXACTA: Mark S Rasp - LONG Pitch- size 6
13 S11737 EXACTA: Mark S Rasp - LONG Pitch- size 7
14 S11738 EXACTA: Mark S Rasp - LONG Pitch- size 8
15 S11739 EXACTA: Mark S Rasp - LONG Pitch- size 9
16 S11740 EXACTA: Mark S Rasp - LONG Pitch- size 10
17 S11741 EXACTA: Mark S Rasp - LONG Pitch- size 11
18 S11742 EXACTA: Mark S Rasp - LONG Pitch- size 12

EXACTA Femoral Stem - Cementless



Size	L1 mm	L mm	Standard - CCD 135° Offset mm	Standard - CCD 135° L2 mm	HaX-Pore Reference	X-Pore Reference	HA Reference	Lateral - CCD 127° Offset mm	Lateral - CCD 127° L2 mm	HaX-Pore Reference	X-Pore Reference	HA Reference
1	130,5	108,3	38,7	39,0	11901	11501	11601*	44,7	43,7	11911	11511	11621*
2	140,5	118,3	39,3	39,0	11902	11502	11602*	45,5	43,8	11912	11512	11622*
3	145,5	122,1	40,1	40,0	11903	11503	11603*	46,5	45,2	11913	11513	11623*
4	150,5	126,4	40,9	41,0	11904	11504	11604*	47,5	46,4	11914	11514	11624*
5	155,5	130,8	41,6	41,9	11905	11505	11605*	48,4	47,3	11915	11515	11625*
6	160,5	135,1	42,3	42,6	11906	11506	11606*	49,3	48,2	11916	11516	11626*
7	165,5	139,6	43,0	43,1	11907	11507	11607*	50,2	48,9	11917	11517	11627*
8	170,5	144,5	43,7	43,1	11908	11508	11608*	51,1	49,0	11918	11518	11628*
9	175,4	149,2	43,7	43,1	11929	11529	11609*	51,7	49,3	11937	11539	11629*
10	180,4	153,9	44,2	43,1	11930	11530	11610*	52,7	50,0	11938	11540	11630*
11	185,4	158,6	45,7	44,5	11931*	11531*	11611*	52,7	50,0	11939*	11541*	11631*
12	190,4	163,2	45,7	44,5	11932*	11532*	11612*	52,7	50,0	11940*	11542*	11632*

EXACTA PLUS Femoral Stem - Cemented



Size	L1 mm	L mm	Standard - CCD 135° Offset mm	Standard - CCD 135° L2 mm	Polished Reference	Matt Reference	Lateral - CCD 127° Offset mm	Lateral - CCD 127° L2 mm	Polished Reference	Matt Reference
1	117,4	96,3	38,7	39,0	11701	11771*	43,7	42,7	11711	11786*
2	120,0	97,9	38,7	39,0	11702	11772*	43,7	42,9	11712	11787*
3	130,0	107,8	39,3	39,0	11703	11773*	45,3	43,5	11713	11788*
4	135,0	111,7	40,0	40,0	11704	11774*	46,6	45,2	11714	11789*
5	140,0	115,8	40,9	41,2	11705	11775*	47,4	46,1	11715	11790*
6	145,0	120,3	41,6	41,9	11706	11776*	48,1	46,9	11716	11791*
7	150,0	124,7	42,3	42,6	11707	11777*	48,8	47,7	11717	11792*
8	155,0	129,1	42,9	43,1	11708	11778*	49,0	47,4	11718	11793*
9	160,0	134,1	43,7	43,1	11729	11779*	51,1	49,0	11739	11794*
10	165,0	138,8	43,7	43,1	11730	11780*	51,7	49,3	11740	11795*
11	170,0	143,5	44,2	43,1	11731*	11781*	52,7	50,0	11741*	11796*
12	175,0	148,2	45,7	44,5	11732*	11782*	52,7	50,0	11742*	11797*

Information

INTENDED PURPOSE:

EXACTA stems are intended for use in total or partial Hip Replacement procedures, combined with a femoral ball head (or a bi-articular head) and an acetabular cup. Indicated for primary hip arthroplasties in cases of serious joint degeneration, mainly due to arthrosis and post-traumatic degenerative factors. Device fixation is obtained by means of primary cementless press-fit stabilization or by using bone cement, depending on the version utilized.

MATERIALS:

Cementless stems: Titanium Aluminium Niobium forged alloy (Ti6Al7Nb) ISO5832/11
Cemented stem: PM734 higly nitrogenized Stainless Steel forged alloy ISO5832/9

SURFACE FINISHING:

EXACTA HaX-Pore: double coating 300µm pure Titanium+50µm Hydroxyapatite $Ca_{10}(OH)_2(PO_4)_6$ plasma sprayed
EXACTA X-Pore: coating 300µm pure Titanium plasma sprayed
EXACTA HA: coating 80µm Hydroxyapatite $Ca_{10}(OH)_2(PO_4)_6$ plasma sprayed
EXACTA Plus: mirror polished or matt (sandblasted, on request) finishing surface

STERILIZATION:

Method: Irradiation (*Beta or Gamma rays - minimum dose 25 kGy*) or vaporized Hydrogen Peroxide (*VH2O2*).
Validity: 5 years (*Beta*) - 10 years (*Gamma-VH2O2*).

CLASSIFICATION:

Class III as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendements.

NOTES

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Ref. TC045EN Rev. 02.3 - 2021/09