permedica
ORTHOPAEDICS

ProMotion RM

Modular Revision Stem

SURGICAL TECHNIQUE

CE
0426

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

ProMotion

MODULAR REVISION STEM

Until few years ago the only devices available for hip revision cases, resections in femoral neoplasies and femoral reconstructions were special or custom made devices or anyway prostheses with straight monobloc long stems .

Custom made devices are generally very expensive while the monobloc prostheses are often not offering a satisfactory anchoring to the bone, dismetry of the lower limbs and a non physiological movement. Moreover, these devices does not allow any intra-operative correction of the dismetries nor of the anteversion degree.

The development of this titanium made revision stem was based on the unsatisfactory experiences with the above mentioned devices. The targets to pursuit were: the improvement of the surgical technique, optimization of the bone-implant contact, reduction of the inventory and reasonable price.

The PM ProMotion modular revision prosthesis allows multiple solutions to fit the single situations, while maintaining a reduced inventory.

The star shaped ribs and the conical design of the diaphyseal stem allow a secure interlocking in the femur with optimal rotational stability, reducing risks of stem sinking. The parabolic displacement of the ribs guarantees a high stability degree and spare of the cancellous trabecular structures thus enhancing the remodelling process of the femoral dyaphisis .

The material chosen was the Ti6Al7Nb Titanium Niobium forged alloy due to its relevant characteristics of resistance and high biocompatibility. The anti-torsion conical connection, standard for all the modules, together with a carefully designed set of instruments allows for a secure and safe implantation.

The Diaphyseal Stem is also available in cemented version, in 3 diameters (12mm, 14mm and 16mm) and two lengths (140mm and 200mm, only in straight version).

The implantation technique is the same with the only difference that the definitive components, once defined with the trials, must be assembled on the nurse's trolley in the definitive configuration (see APPENDIX 1 at page 18).

ATTENTION:

- ✓*For further information please refer to the Instructions For Use supplied in the package of each single device.*
- ✓*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

Main indication for use of the PM ProMotion stem are:
✓arthroplasty revision;
✓periprosthetic/sub-prosthetic fractures;
✓neoplams;
✓reconstructions.

SURGICAL PROCEDURE

WARNINGS:
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 explain how to use the various instruments for the implantation of the PM ProMotion System. The knowledge and experience of the Surgeon will guide him throughout the steps of the implantation.

GENERAL CONSIDERATIONS

Before to face any arthroplasty revision surgery, the Surgeon should carefully study the case. More than the X-Ray investigation it would be necessary to acquire all the information about the prosthetic components used in the previous arthroplasty, asking the patient the clinical file or, if the case, requesting the necessary information to the hospital/clinic where the first operation was done.

It should be considered that a stable anchoring of the diaphyseal stem must be sought at the level of the femoral istmus, for at least 7/8 cm. Whenever this area should be compromised, or anyway not suitable to guarantee a stable anchoring of the PM ProMotion stem, it would be advisable to evaluate alternative solutions.

PRE-OPERATIVE PLANNING 1

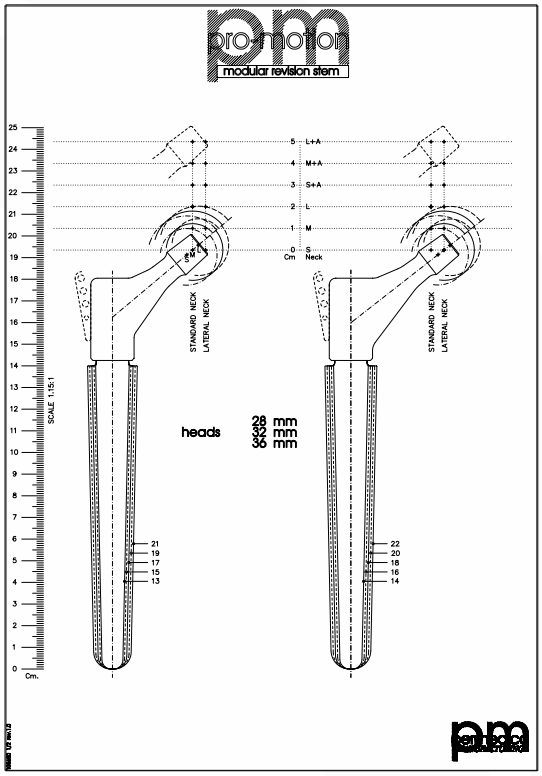
It is advisable to make a pre-operative plan in order to:

- ✓select the most suitable prosthesis to implant;
- ✓determine the ideal anchoring site;
- ✓establish the correct positioning for good biomechanical reconstruction;
- ✓correct eventual dysmetria;
- ✓roughly determine the correct size of implant to be used.

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%.

X-Ray templates with 15% magnification are available to help the surgeon in determining the implant size better fitting the patient anatomy.

The surgeon could always reconsider, during surgery, the choice made with the pre-operative planning.



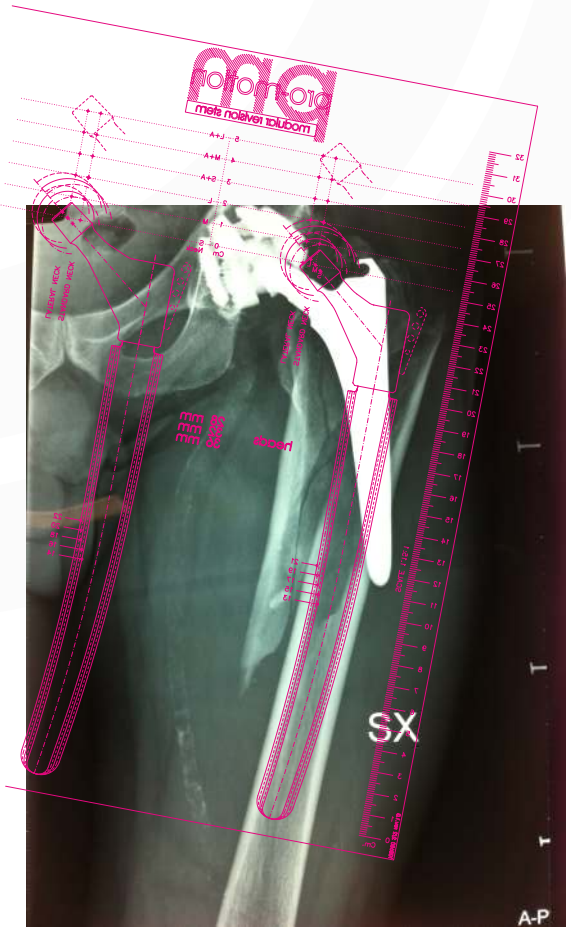
WARNINGS

It should be considered that a stable anchoring of the diaphyseal stem should be pursuit at the level of the femoral Istmus for at least 7/8cm. Whenever this region should be compromised or anyway not suitable to guarantee a stable anchoring og the PM ProMotion stem, it would be appropriate to evaluate alternative solutions.

It is advisable to evaluate, already in the pre-operative planning phase, the opportunity to use a metaphyseal body with OFFSET.

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 IMPLANT SELECTION

The ideal implant should be evaluated to guarantee a stable anchoring of at least 7/8cm distally to the site of the old implant. This can be achieved thanks to the modular construction of the device.

A B

The *Diaphyseal Stems* are proposed in two lengths and different diameters, in STRAIGHT and CURVED version.

C

The cemented *Diaphyseal Stems*are proposed two lengths and 3 diameters, only in STRAIGHT version.

D E

The Metaphyseal Bodies are available in two versions: STANDARD with CCD angle of 130° and LATERALIZED with CCD of 127° and 5mm offset.

F

Extension Bodies are available to be interposed between the *Diaphyseal Stem* and the *Metaphyseal Body*, thus allowing to increase the total length of the implant.

G H

All the modules composing the prosthesis are tightened by means of an axial force controlled by a *Torque Limiter* and secured by *a Locking Screw*, SHORT or LONG depending whenever an *Extension Body* is used or not.

I

A *Screw Cap*, included into the packaging of the *Metaphyseal Body,* provides sealing of the access hole.

J

A *Trochanteric Module* to be assembled onto the *Metaphyseal Body* is also available, allowing for use of suture wires for tendons re-fixation.

The *Metaphyseal Body* can be freely oriented over 360° indipendently by the stem positioning.

Thanks to the modular construction it is possible to achieve a total stem length between 190 and 300 mm by utilizing Metaphyseal Bodies from 50 mm to 100 mm (see Table 1).

Tab.1 Achievable lengths	Metaphyseal Body					
Stem	Short - S	Medium - M	Long - L	Short - S	Medium - M	Long - L
				+ Extension Body 30mm		
140mm	190mm	200mm	210mm	220mm	230mm	240mm
200mm	250mm	260mm	270mm	280mm	290mm	300mm

Considering that when facing a revision the quality of the bone could be already quite compromised, it would be advisable to evaluate carefully the opportunity to use intramedullary reamers to prepare the diphyseal canal, with the purpose to avoid any further weakening.

Although, use of reamers could be necessary to remove eventual bony obstructions, that could occur distally to the old prosthesis, impeding the positioning of the new diaphyseal stem.

Whenever reaming should be necessary, it could be carried out by using standard flexible intramedullary reamers, following the rule below .

GENERAL RULE
Ø FLEX. REAMER = STEM 4mm larger

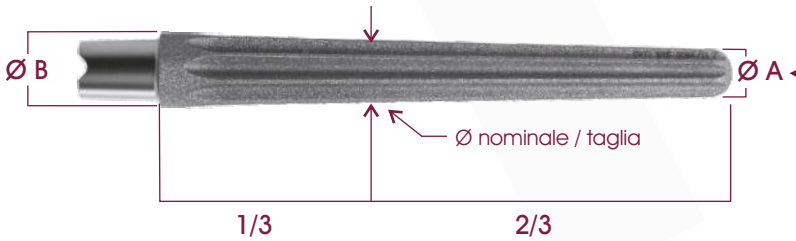
Cementless stem

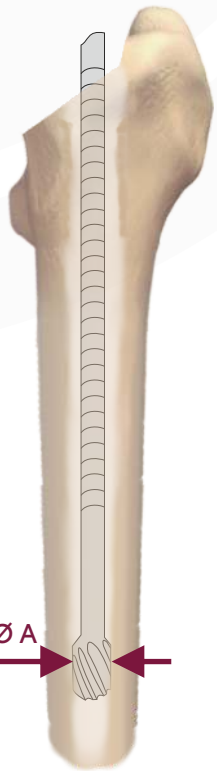
Ø reamer	Stem size	Ø distal (A)	Ø proximal (B)
Ø 7mm	Ø 11mm	Ø 7mm	Ø 13mm
Ø 8mm	Ø 12mm	Ø 8mm	Ø 14mm
Ø 9mm	Ø 13mm	Ø 9mm	Ø 15mm
Ø 10mm	Ø 14mm	Ø 10mm	Ø 16mm
Ø 11mm	Ø 15mm	Ø 11mm	Ø 17mm
Ø 12mm	Ø 16mm	Ø 12mm	Ø 18mm
Ø 13mm	Ø 17mm	Ø 13mm	Ø 19mm
Ø 14mm	Ø 18mm	Ø 14mm	Ø 20mm
Ø 15mm	Ø 19mm	Ø 15mm	Ø 21mm
Ø 16mm	Ø 20mm	Ø 16mm	Ø 22mm
Ø 17mm	Ø 21mm	Ø 17mm	Ø 23mm
Ø 18mm	Ø 22mm	Ø 18mm	Ø 24mm

In practice, the reamer will help in checking the **diameter of the narrowest part of the femoral istmus**, that is the region where the stem anchoring should be sought.

The stem size refers to the diameter taken at the proximal third of the stem, that is 4mm larger than the distal tip, therefore a first trial stem should be selected considering this criteria (ie. reamer Ø 12mm = stem Ø 16mm).

When using the 140mm straight stems, a set of calibrated Conical Reamers is available on request.





3 USE OF THE CONICAL REAMERS

An optional set of Conical Reamers allow to prepare the diaphysis for the **Straight Stems 140mm**. The reamers are available in diameters from 11 to 22mm with millimetric increment and fits a T - Handle with Hudson coupling (S11235).

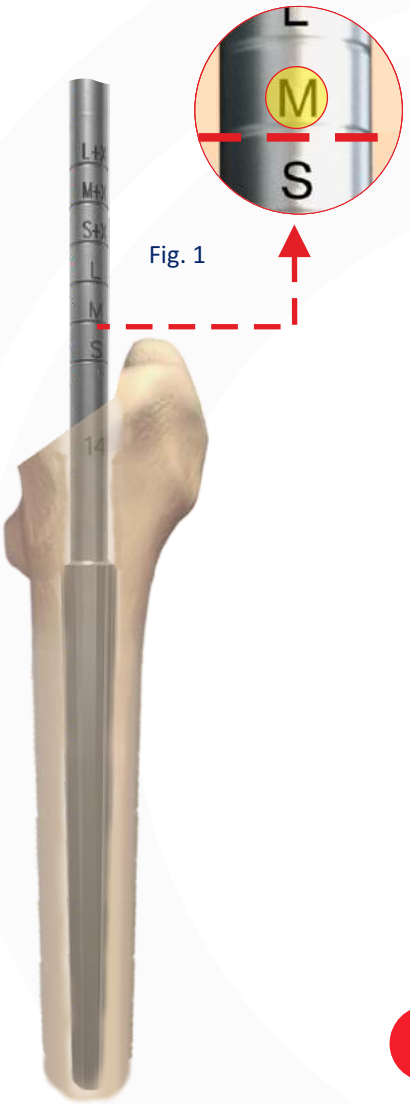


Fig. 1

After removal of the previously implanted prosthesis introduce the first Reamer, selecting a diameter compatible with the stem removed, and proceed in reaming the diaphysis increasing the diameter until achieve a strong resistence on the cortical walls (the instrument struggles to sink forward).

The sinking of the Reamer must also consider the length of the previous stem, in order to achieve a stable anchoring at least 7/8cm distally to the previous implant bed.

The graduated scale on the shaft (**Fig. 1**) indicates the ideal sinking level and gives a first indication of the size of *Diaphyseal Stem* and *Metaphyseal Body* to be used (in the example: Stem Ø 14mm with *Metaphyseal Body Medium - 60mm*).

Once determined the ideal diameter, proceed with the trial stem.

4 USE OF THE TRIAL COMPONENTS

The PM ProMotion modular revision prosthesis allows to carry out an intraoperative evaluation thanks to the trial components that exaclty reproduce the definitive implants :

- Trial Stems (straight or curved, in the different lengths and diameters)
- Trial Metaphyseal Bodies (in the 3 different lengths, standard and lateralized with offset)
- Trial Extension Body
- Trial Heads

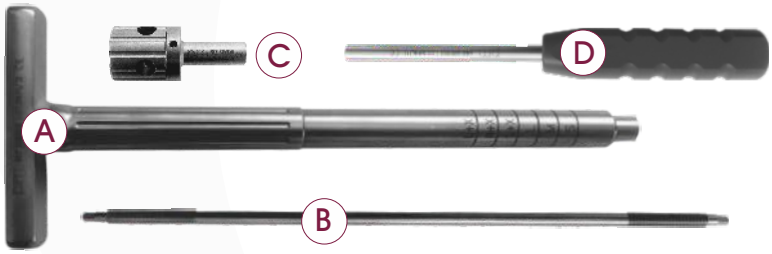
ASSEMBLING PROCEDURE 4.1

NOTE: the assembling procedure is the same for both the TRIAL and the IMPLANTABLE components.

The instruments provided allow the easy assembly and disassembly the modular components.

The Introducer/Extractor Handle is used for the introduction and extraction of both the trial and the definitive stems into the femoral diaphysis. The following instruments are to be used:

- (A) Introducer/Extractor Handle (S19305)
- (B) Guide Rod (S19309)
- (C) Knurled Screw - Short (S19306)
- (D) Screwdriver (S19302)



Connect the Guide Rod (B) to the Trial Stem, by screwing it in totally and then unlock. Slide the Introducer/Extractor Handle (A) onto the Guide Rod and e lock the assembly with the Knurled Screw - Short (C) (**Fig. 2**) tigthening it with the Screwdriver (D).

The connection between the Introducer/Extractor Handle and the stem is driven by two teeth (**Fig. 3**) that must match before tightening the assembly .

Fig. 2

Fig. 3

5 DETERMINATION OF THE SIZE

WARNING: whenever a Curved Stem is used make sure to insert the stem following the curve of the femur.
If the case, it would be advisable to ask for intra-operative x-ray control to verify the correct insertion.

The Trial Stem (of the size estimated with the preoperative planning or determined by the Conical Reamer whenever this option has been used) is connected to the Introducer/Extractor device and inserted into the femoral diaphysis by slightly impacting.
This step must be eventually repeated untill a stem guaranteeing a stable anchoring is found. The optimal size should ensure the maximum filling of the femoral canal and the stem could not sink down any further.

Whenever the diaphysis has been reamed, the Trial Stem will settle at the same sinking level of the last Reamer (or with a minimum deviation).

ATTENTION: whenever an hemi-diaphysectomy or fenestration should be necessary to remove the old stem, it would be advisable to place a cerclage wire to prevent fissuring before introducing the stem.

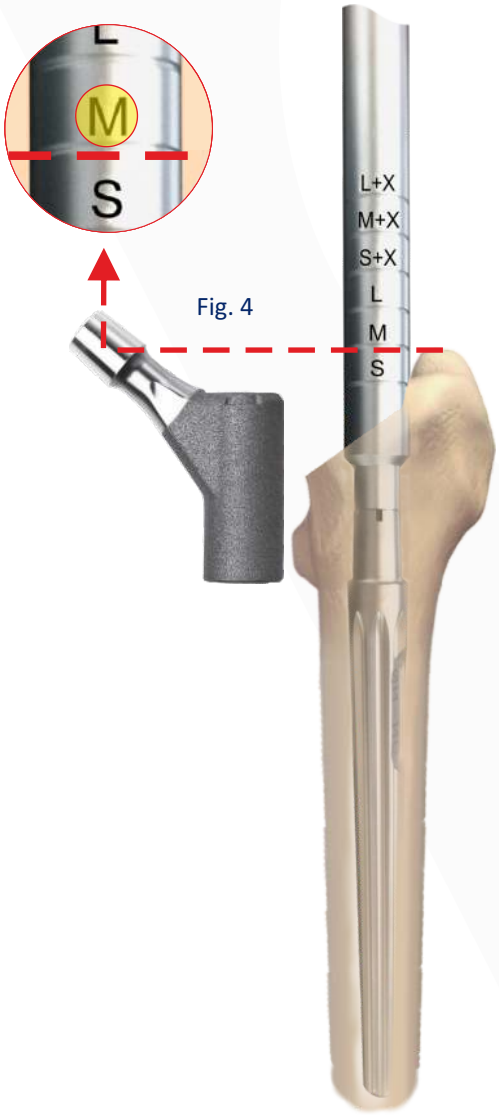


Fig. 4

Once established the correct seating of the Trial Stem, the length of the *Metaphyseal Body* to be used can be detected by the graduated scale on the Introducer/Extractor Handle, referring to the top of the *Greater Trochanter* (**Fig. 4**). This will correspond to the center of rotation of the ball head.

WARNING: it is important to be sure that the stem could not sink any further into the diaphysis. A stable anchoring will avoid sinking when the joint will be subjected to a load.

At this stage it is also possible to remove the Trial Stem (following the procedure described hereafter), replace it with the definitive stem and carry out the subsequent trial evaluations on it.

Unlock the Knurled Screw (**Fig. 5**) and remove the Introducer/Extractor Handle leaving the Guide Rod inserted in the Trial Stem. This will be used as a guide for the Reamer to prepare the housing for the Metaphyseal Body around the cone of the stem.

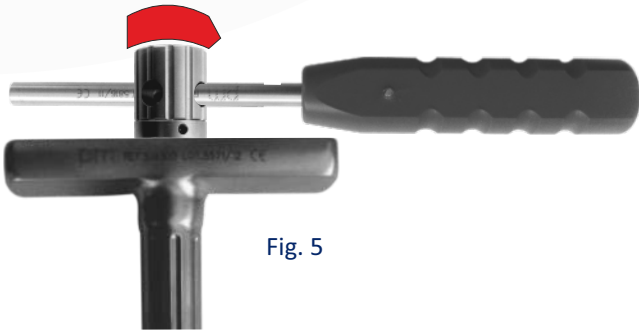


Fig. 5

Use the Reamer for Metaphyseal Body (S19301) inserting it onto the Guide Rod (**Fig. 6**) and start reaming manually or connecting the handle to a surgical power instrument (the handle fits AO connection) untill it will stop. This step is necessary to achieve the lodgement for the *Metaphyseal Body* around the cone of the *Diaphyseal Stem.*

It is important to start reaming from the top of the *Greater Trochanter*, in order to prepare the passage of the *Metaphyseal Body*.

WARNING: after the reaming, it is important to irrigate carefully the area around the cone and make sure to remove any bone debrise that could avoid a correct coupling of the *Metaphyseal Body*.

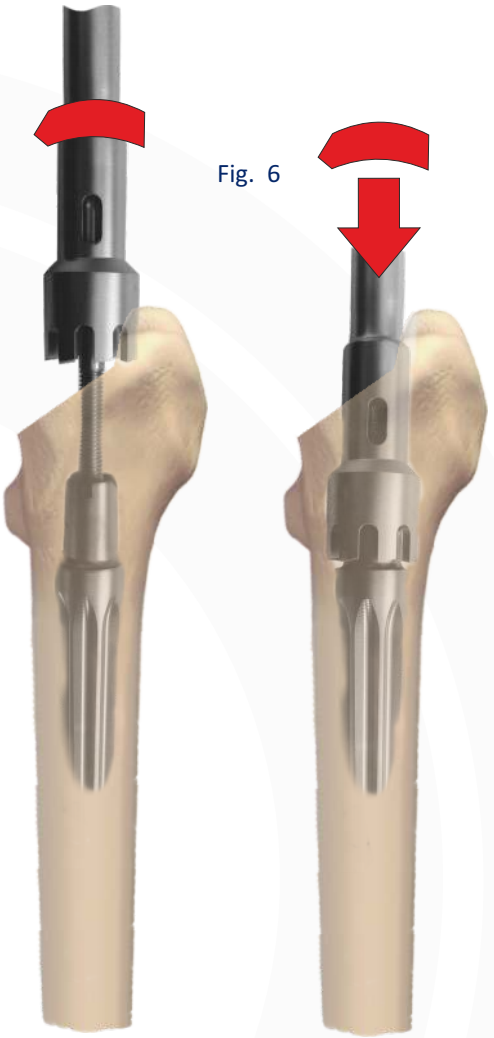


Fig. 6

ASSEMBLING OF THE TRIAL METAPHYSEAL BODY 6

After reaming, remove the Guide Rod and insert the Trial Metaphyseal Body (of the size previously determined) onto the Trial Stem still inserted in the diaphysis (**Fig. 7a**), providing the desired anteversion and locking it with the proper Locking Screw (S19097) and the Screwdriver Sw5 (S19310).

NOTE: the conical connection of the Trial Metaphyseal Body fits the cone of the definitive stems, that is larger than the trial. The Trial Metaphyseal Body therefore will not lock onto the Trial Stem cone and must be locked by a special locking screw.

Whenever the definitive stem has been already implanted, the locking screw will not be necessary and it will be possible to leave the Guide Rod in place to guide the insertion of the Trial Metaphyseal Body (using the Positioning Handle S19304) and lock the coupling by slightly impacting.

Whenever the Trial Extension Body should be required (S+X - M+X - L+X) select the proper one:

S19041 fitting the Trial Stem, recognizable by the double groove

S19042 fitting the definitive stem, recognizable by the single groove.

In this case the components locks onto eachother by taper connection and won't be necessary any locking screw.

S19041 S19042

Since the cone of the stem will be sunk deeper in the diaphysis, therefore less visible, it is advisable to use the Guide Rod to drive the insertion (**Fig. 7b**). Connect the selected Trial Metaphyseal Body together with the Trial Extension Body to the Positioning Handle (S19304) and insert the assembly along the Guide Rod. Once established the desired anteversion, slightly impact to secure the connection to the stem.

CAUTION: before to connect the *Trial Metaphyseal Body*, with or without the Extension Body, onto the Diaphyseal Stem make sure that any bone debrise nor soft tissue is present around the cone.

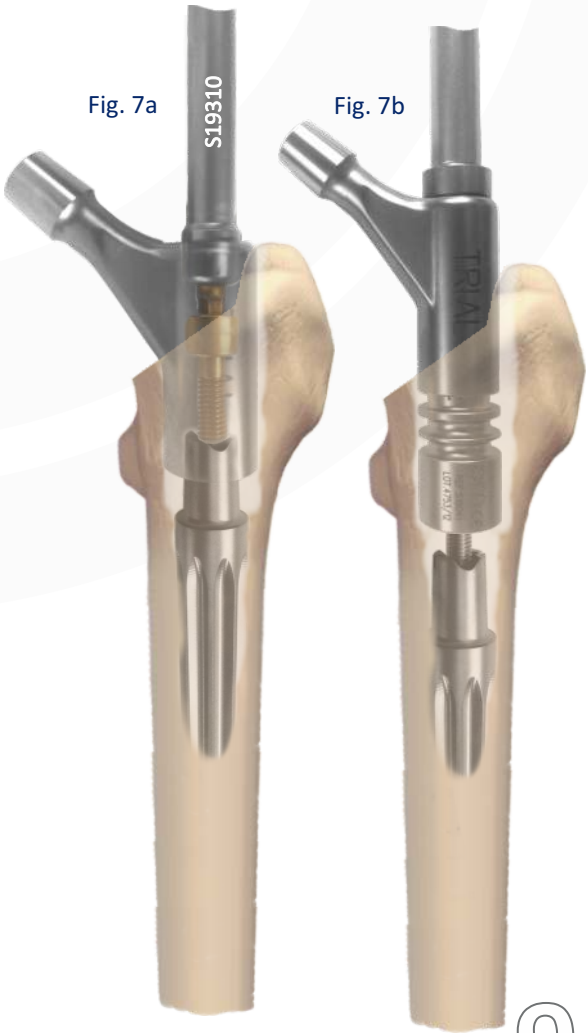


Fig. 7a Fig. 7b

7 TRIAL REDUCTION

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 / XL
BLU = MEDIUM
GREY = LONG

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

In case of use of a cemented Diaphyseal Stem refer to page 18.

REMOVAL OF THE TRIAL COMPONENTS 8

In case that the trial evaluation is satisfactory, it is possible to proceed with the removal of the trial components and the implantation of the definitive prosthetic parts. To do this, proceed as follow:

REMOVAL of the TRIAL STEM

Unlock the Locking Screw and remove the Trial Metaphyseal Body.

Re-insert the Guide Rod (B) into the Trial Stem (**Fig. 8a**) and re-position the Introducer/Extractor Handle (A) then lock the assembly with the Knurled Screw - Short (C) as shown at pag. 5.

Hit with a hammer the T Handle to remove the stem from the diaphysis (**Fig. 8b**).

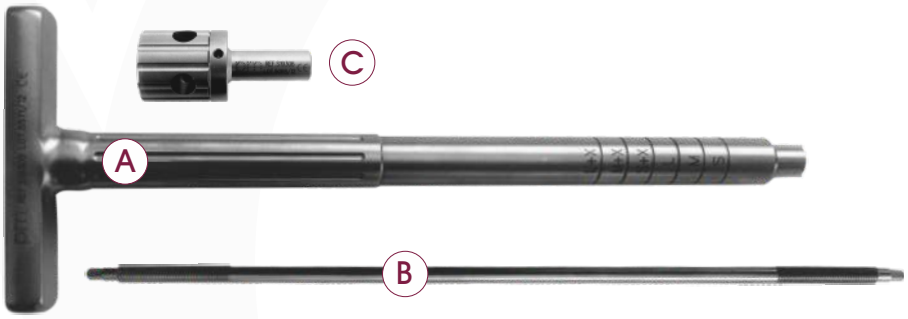


Fig. 8a

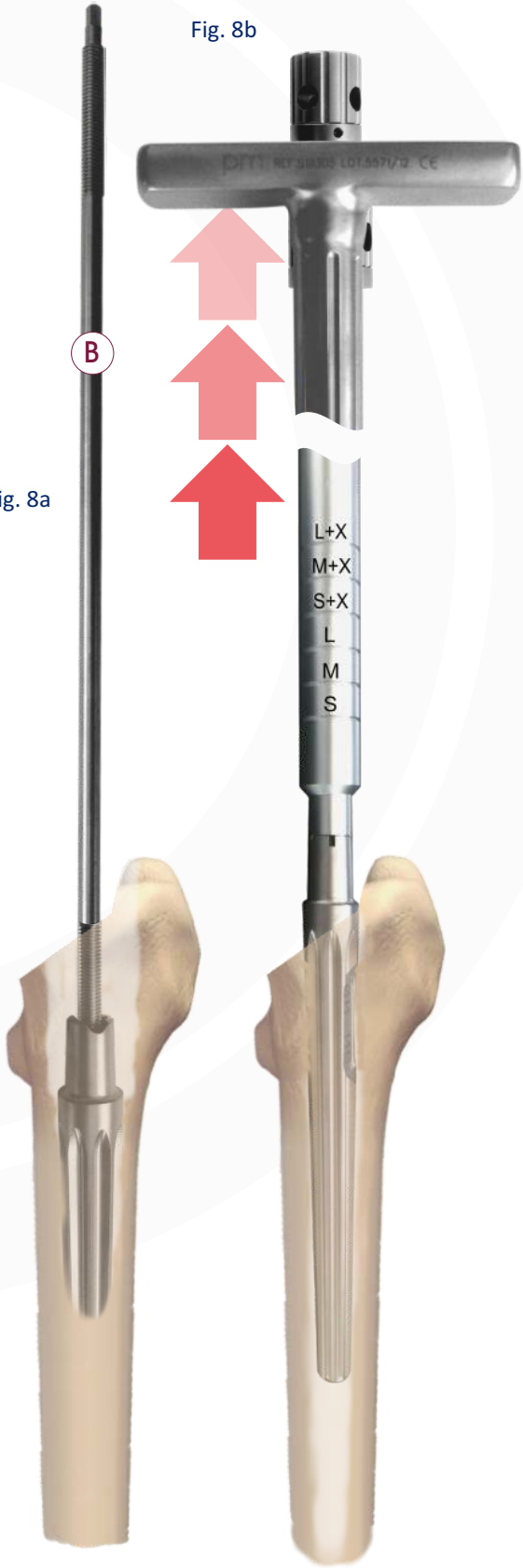


Fig. 8b

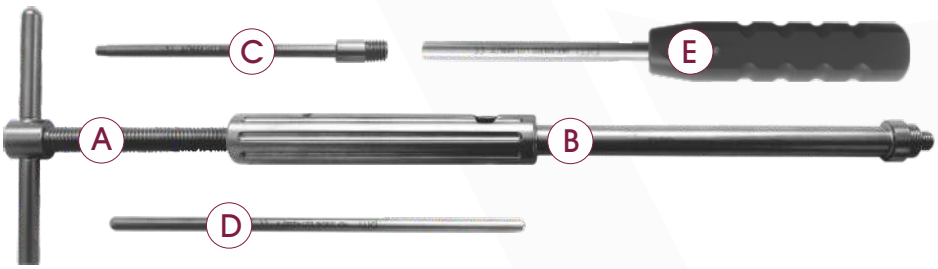
If the Extension Body is used, it will be necessary to remove it before to pull out the stem. To disconnect the Extension Body from the stem, please follow the procedure descrbed hereafter .

For the implantation of the definitive prosthesis skip to page 10.

REMOVAL of the EXTENSION BODY from the TRIAL STEM 8.1

The disassembling and removal procedure is the same for both the trial and definitive components.

Whenever the Trial Extension Body is used, it will be necessary its removal before to remove the stem. To disconnect the assembled parts, a special removal system is available. It is composed of:



- (A) Neck remover - Pressure Rod (S19314)
- (B) Neck Remover - Main Body (S19313)
- (C) Threaded Rod for Neck Removal (S19315)
- (D) Blunt Rod for Neck removal (S19316)
- (E) Screwdriver (S19302)

8.2 REMOVAL of the METAPHYSEAL BODY from the EXTENSION BODY

Screw the Threaded Pressure Rod (A) into the Extraction Body (B). Screw the Threaded Rod for Neck Removal (C) in the threaded hole on the top of the Extension Body (**Fig. 9a/b**) then secure the Extraction Body to the Trial Metaphyseal Body (**Fig. 9c**).

Fig. 9b

Fig. 9a

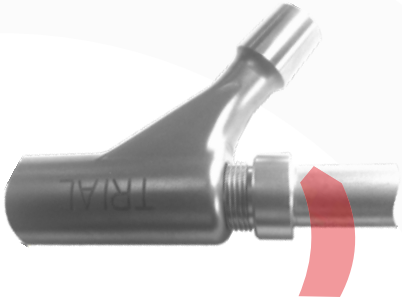


Fig. 9c

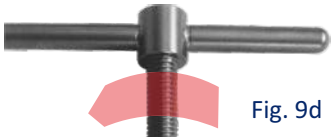
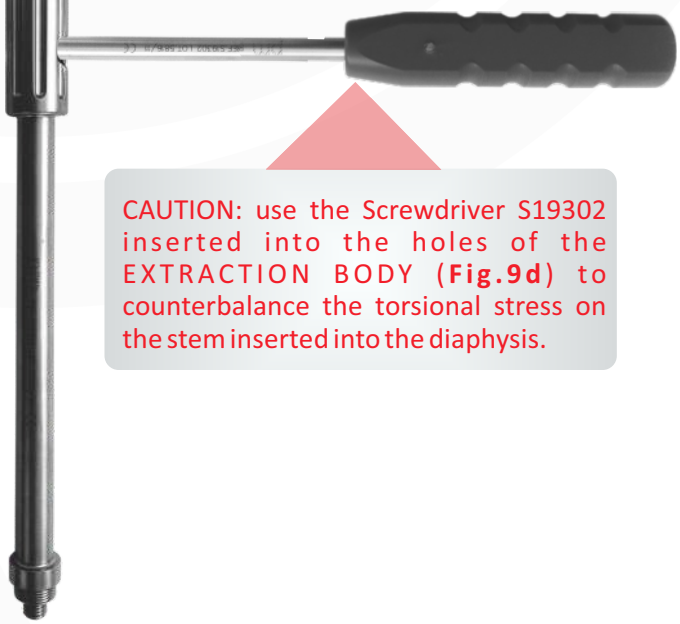


Fig. 9d

Fig. 9e

By turning clockwise the T handle of the Pressure Rod, this will push onto the Threaded Rod for Neck Removal, disconnecting the Metaphyseal Body from the Extension Body (**Fig. 9d/e**).



CAUTION: use the Screwdriver S19302 inserted into the holes of the EXTRACTION BODY (**Fig.9d**) to counterbalance the torsional stress on the stem inserted into the diaphysis.

REMOVAL of the EXTENSION BODY from the DIAPHYSEAL STEM 8.1

To remove the Extension Body from the Stem, insert the Blunt Rod for Neck removal (D) in the hole at the top of the stem cone (**Fig. 10a**) then connect the Extraction Body to the Extension Body (**Fig. 10b**).

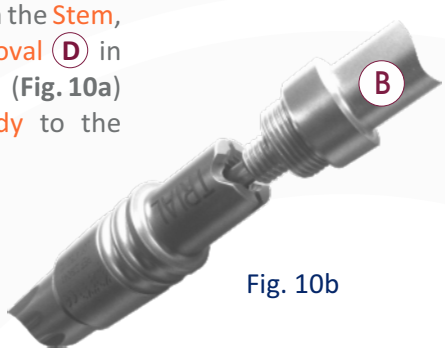


Fig. 10b

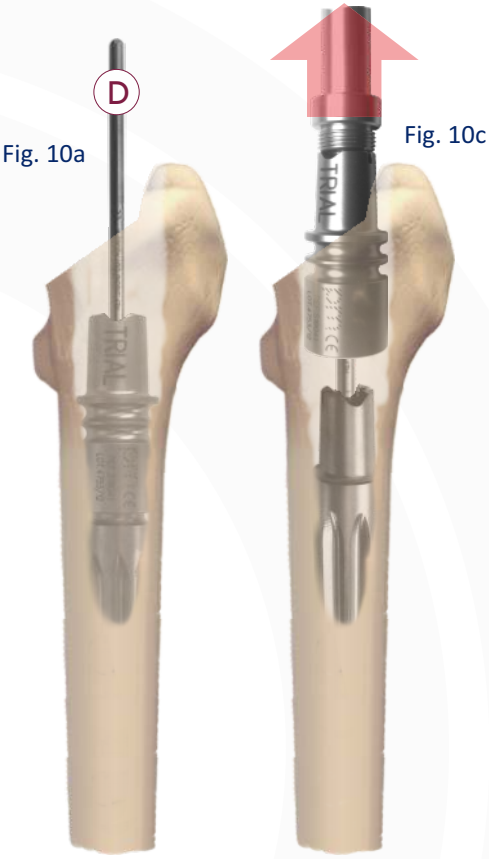


Fig. 10a

Fig. 10c

By turning clockwise the T handle of the Pressure Rod, this will push onto the Blunt Rod for Neck Removal, disconnecting the Extension Body from the Diaphyseal Stem (**Fig.10c**).

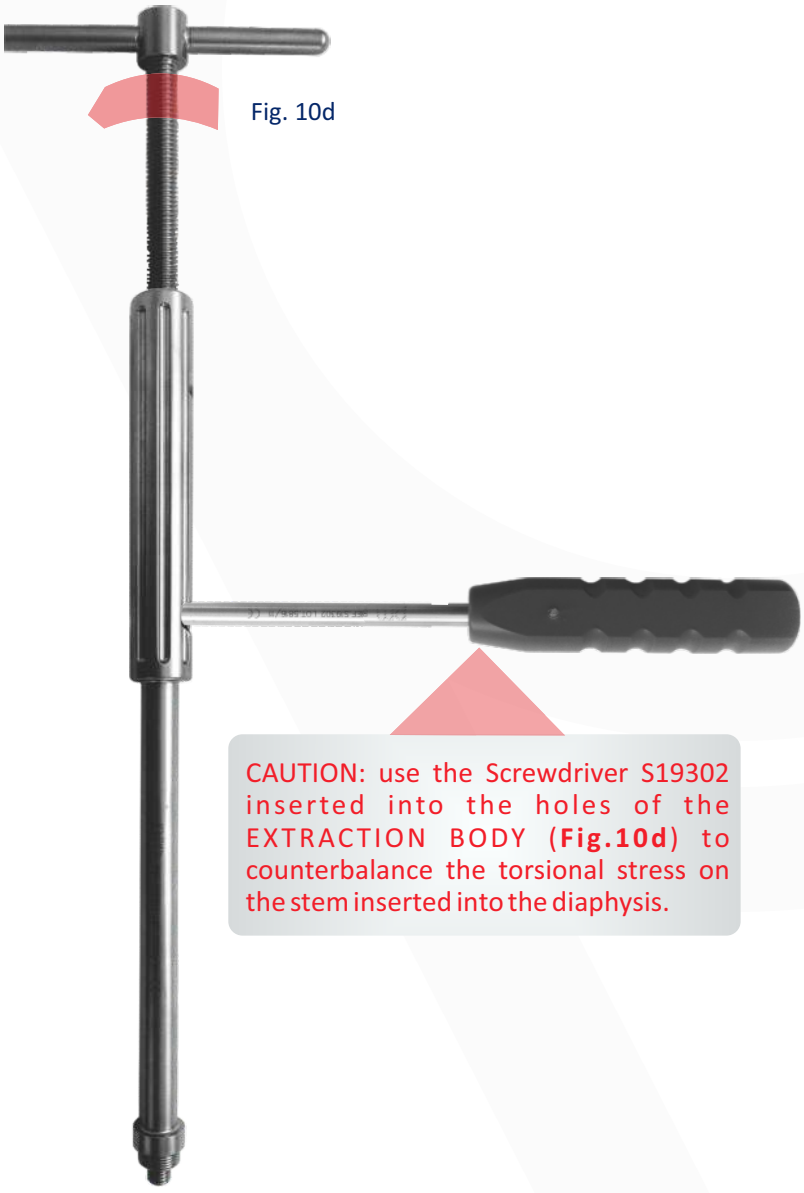


Fig. 10d

CAUTION: use the Screwdriver S19302 inserted into the holes of the EXTRACTION BODY (**Fig.10d**) to counterbalance the torsional stress on the stem inserted into the diaphysis.

9 IMPLANTATION of the DEFINITIVE PROSTHESIS

After the trial evaluation and establishment of the components to be used, the definitive prosthesis can be implanted.

The implantable *Diaphyseal stem* is inserted into the diaphysis using the same procedure described at page 5 e 6 (**Fig. 11**)
Remove the Introducer/Extractor Handle leaving the Guide Rod in place, connect the *Metaphyseal Body* of the selected size (and eventually the *Extension Body* if necessary) to the Positioning Handle and insert it onto the *Stem* sliding along the Guide Rod (**Fig. 12**).
After giving the desired anteversion, slightly impact the Positioning Handle to seat the *Metaphyseal Body* onto the *Stem*.

NOTE: whenever the *Extension Body* should be used, select the diameter better matching the proximal end of the *Stem*:

- ✓ Ø 20mm for stems till Ø 18mm;
- ✓ Ø 22mm for larger stems (19-22mm)

In case of use of a cemented Diaphyseal Stem refer to page 18.

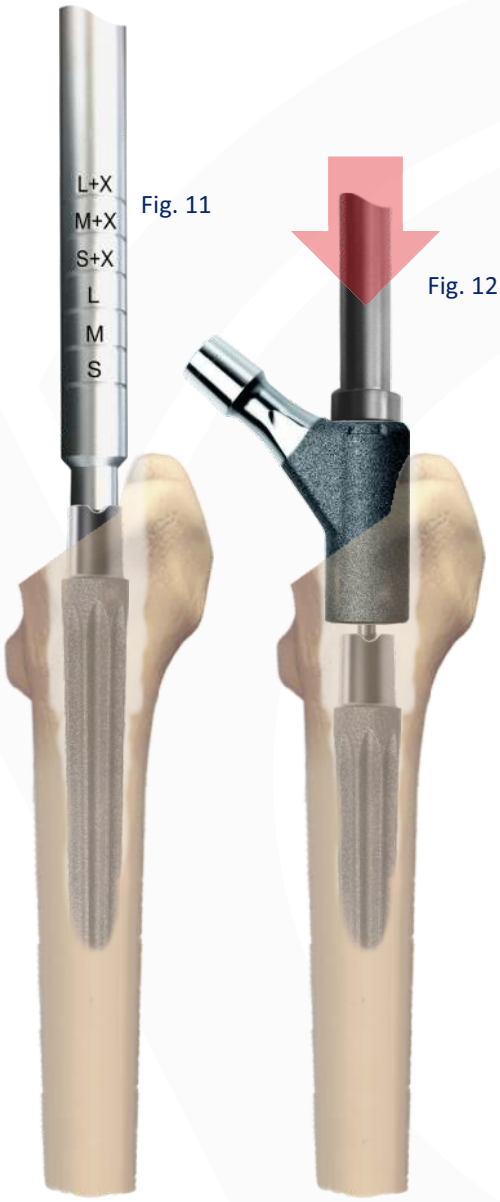


Fig. 11

Fig. 12

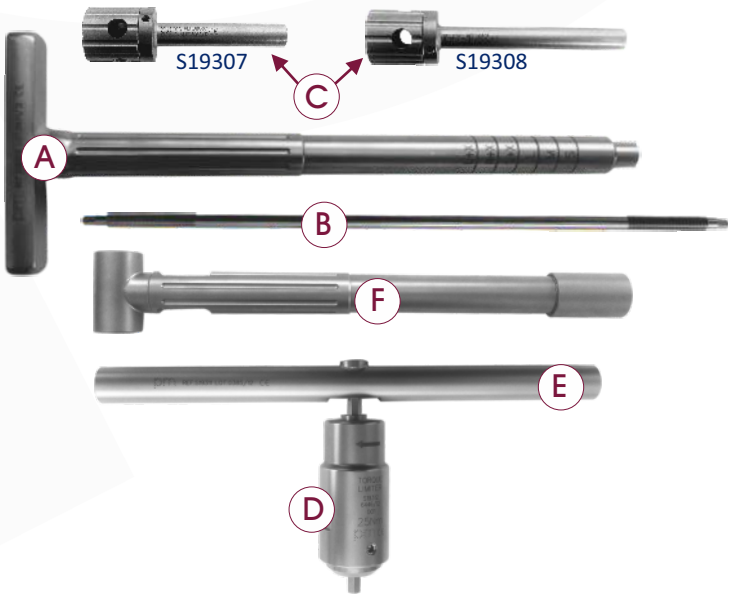
IMPORTANT: before inserting the Metaphyseal Body, with or without Extension Body, make sure that the area around the cone is free of any soft tissue or bone debrise that could impinge the component's coupling.

10 TIGHTENING OF THE COMPONENTS

To guarantee a safe and stable connection of the components, it is important to tighten the assembly before locking it with the *Locking Screw*.

This step is carried out using the following instruments:

- (A) Introducer/Extractor Handle (S19305)
- (B) Guide Rod (S19309)
- (C) Knurled Screw - Medium (S19307) or Long (S19308)
- (D) Torque Limiter (S19312)
- (E) T-Handle for tightening (S19311)
- (F) Anti-torsion Handle (S19303)



The Guide Rod (B) still connected to the *Stem* is used to tighten the components before the final locking with the Locking Screw.
Connect the Introducer/Extractor Handle (A) to the stem using the Medium Knurled Screw (C) (to tighten *Stem* and *Metaphyseal Body*) *or* Long (to tighten *Stem*, *Extension Body* and *Metaphyseal Body*).
Insert the Torque Limiter (D) connected to the T-Handle (E) into the hexagonal lodging on the top of the Knurled Screw.
Tighten the assembly (**Fig. 13**) by screwing the Knurled Screw turning the T-Handle clockwise untill the Torque Limiter unlocks indicating that the correct tensioning has been reached. This procedure is necessary to ensure the perfect coupling between the components before to lock the system with the *Locking Screw*.

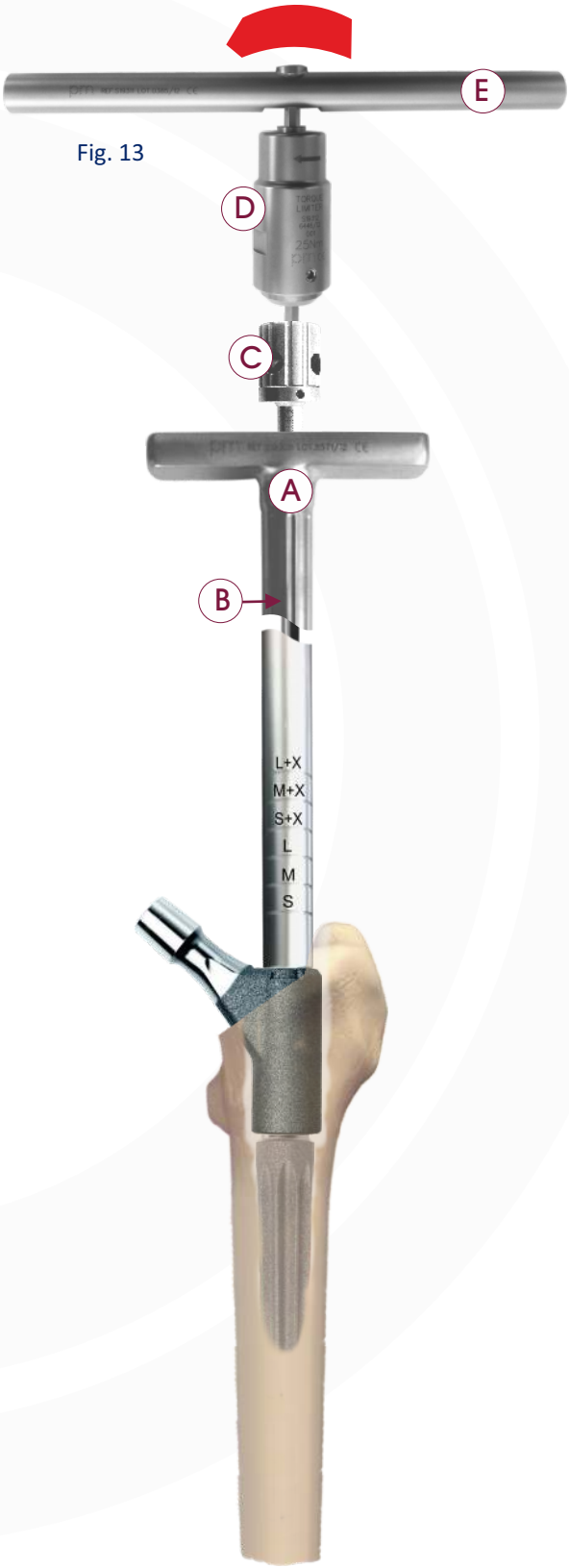


Fig. 13

WARNING:
the Torque Limiter needs to be checked periodically by the manufacturer to test the achievement of the expected torque. Before proceeding with its use, it is therefore necessary to CHECK THE EXPIRATION DATE marked on the device itself and, if necessary, return the instrument to the manufacturer for the necessary checks

In this step it is important to avoid transmission of any torsional stress on the implanted *Diaphyseal Stem* by counteracting it with the Counterholder Handle (F). This tool has two sleeves at the extremities, with plastic inner protection, to be used on the taper of the *Metaphyseal Body* (**Fig. 14a**) and a slot fitting the T Handle of the Introducer/Extractor (**Fig. 14b**).

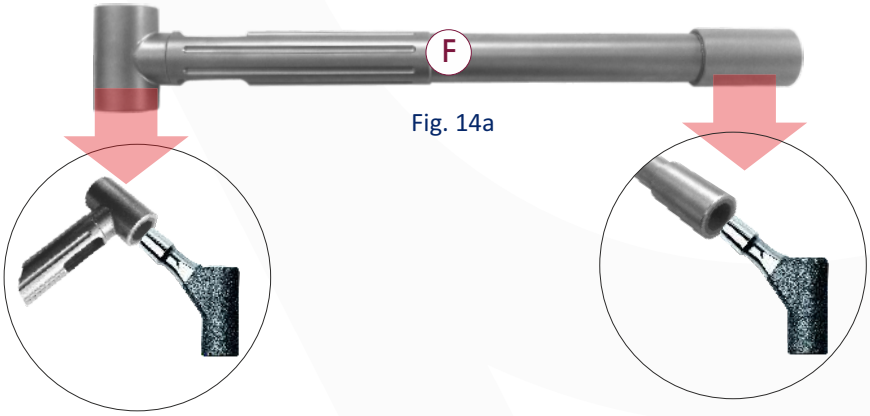


Fig. 14a

In the tightening stage it is possible to counterbalance the torsional stress by using the Counterholder Handle to grab the T handle of the Introducer/Extractor (**Fig. 14b**).

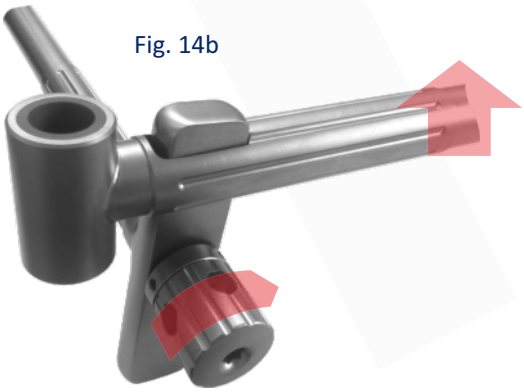


Fig. 14b

11 FINAL LOCKING

After the tightening phase the connection between all the components (*Diaphyseal Stem*, *Metaphyseal Body* and eventual *Extension Body*) is secured by the *Locking Screw*.

Utilize a *Locking Screw*

- SHORT if the assembly consist of two components (*Diaphyseal Stem* and *Metaphyseal Body of any length*)

- LONG if the assembly consist of three components (*Diaphyseal Stem, Extension Body* and *Metaphyseal Body of any length*).

Tighten the *Locking Screw* (**Fig. 15**) with the Sw5 Screwdriver (S19310), once again controlling the tensioning through the Torque Limiter and the T-Handle and always using the Counterholder Handle (S19303), grabbing the cone of the *Metaphyseal Body*, to avoid transimission of the torsion stresses on the implanted *Diaphyseal Stem*.

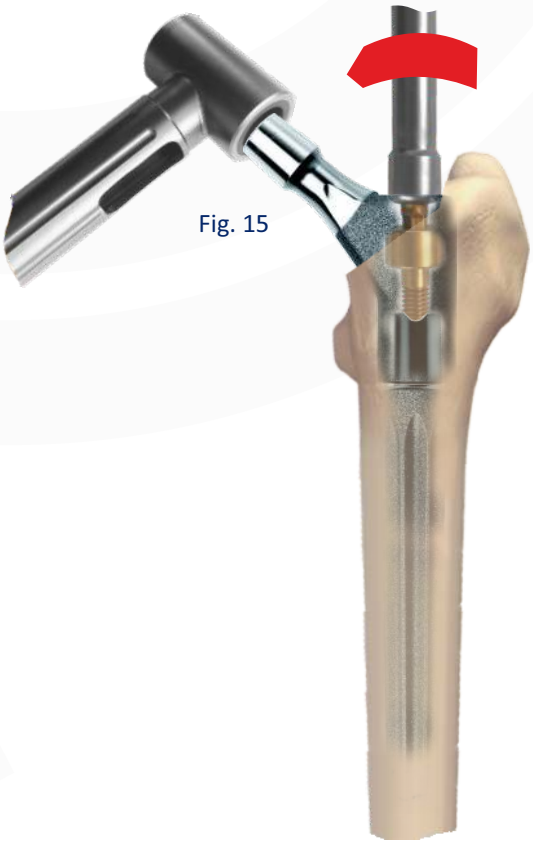


Fig. 15

The last step will consist in sealing the access hole of the *Metaphyseal Body* with the *Screw Cap* (**Fig. 16**) using the Sw5 Screwdriver (S19310) and once more the Counterholder Handle (S19303). In this case it won't be necessary to use the Torque Limiter .

It will always be possible, anyway, to disassemble intra-operatively the single definitive components by following the procedures described for the disassembling of the Trial Components.
The same procedures can be used also whenever, for any reason, it would be necessary to apply any post-operative correction to the implanted prosthesis (i.e. anteversion, length ecc.).

IMPORTANT: whenever the disassembly of the definitive components should be required, DO NOT re-use the same *Locking Screw* but replace it with a brand new device.

Fig. 16

In the case that the *Greater Trochanter* should be compromised or missing, it is possible to provide re-fixation of the *Gluteus Medius* muscle by assembling onto the *Metaphyseal Body* the *Trochanteric Module* (**Fig. 17**) and lock it with the proper *Screw Cap* (supplied in the same package) using the Torque Limiter as described for the *Locking Screw* at the previous page.

Fig. 17

POST-OP CARE 12

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 program regular check ups to veryfy the implant status.

APPENDIX 1 CEMENTED STEM IMPLANTATION

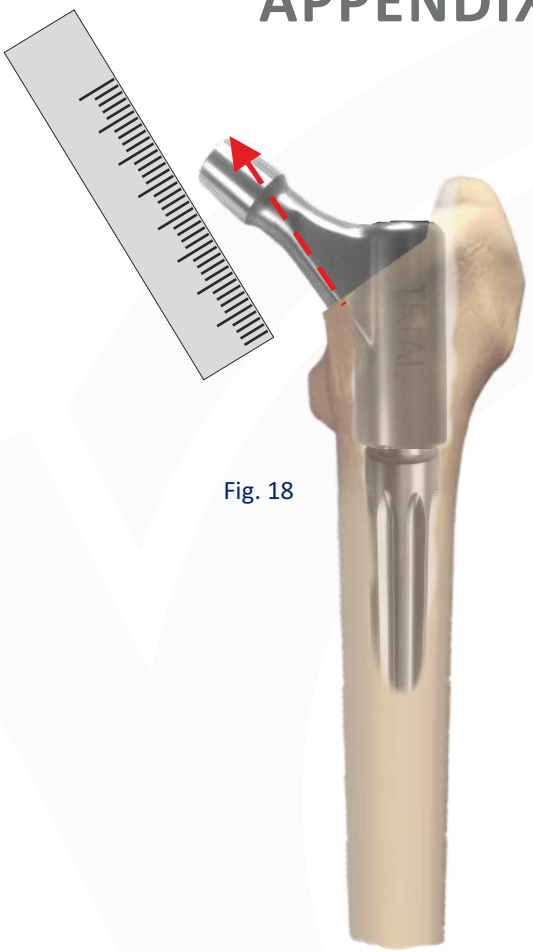


Fig. 18

After the trial evaluation has been carried out (refer to pages 6 to 10) it would be advisable, before removing the trial components, to measure the distance between the resection (or the Lesser Trochanter) and the top of the cone of the *Metaphyseal Body* in order to have a reference for the correct sinking of the stem(**Fig. 18**) since the cemented stem that will be used will be undersized compared to the Trial Stem (that is press-fit) .

Moreover, when selecting the stem diameter to be used, bear in mind that the cemented stems are only available in diameters 12, 14 and 16mm.

The following table could be a useful reference in the choice of the ideal size of the definitive stem :

Trial	Definitive
Ø 13mm Ø 14mm	Ø 12mm
Ø 15mm Ø 16mm	Ø 14mm
Ø 17mm Ø 18mm	Ø 16mm

After removal of the trial components, the corresponding implants (*Stem, Metaphyseal Body* and eventual *Extension Body*) are assembled on the nurse's table by following the procedure described in chapters 9, 10 and 11 (the presence of bone cement would make it difficult the assembly in-situ).

At surgeon's discretion the diaphyseal canal can be plugged with a cement restrictor.

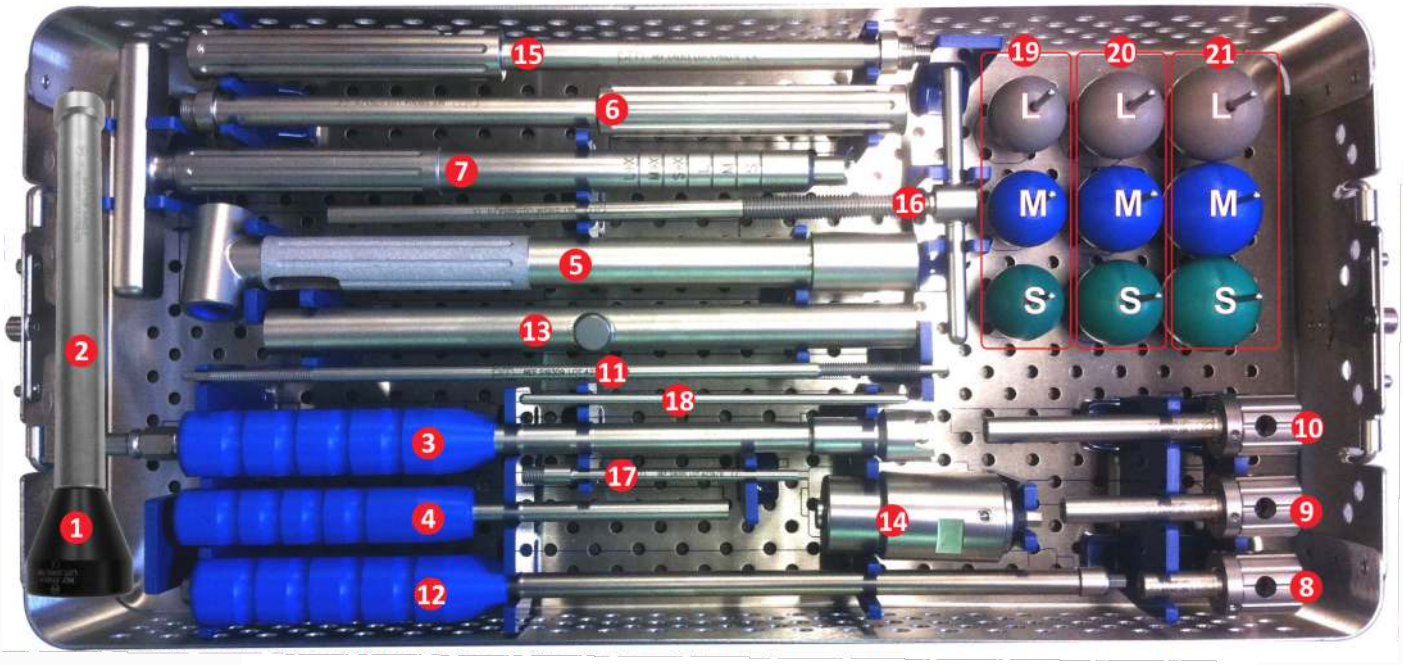
Fill the canal with bone cement and proceed with the insertion of the assembled prosthesis (**Fig. 19**) using the Positioning Handle (S19304) taking care to give the correct version and control the stem sinking with respect to the distance previously measured.

Fig. 19

Firmly hold the prostesis in place, removing the exceeding cement and applying a constant pressure until complete hardening of the bone cement.

Once the bone cement hardened, remove the Positioning Handle and seal the access hole of the *Metaphyseal Body* with the *Screw Cap* (as described at page 17).

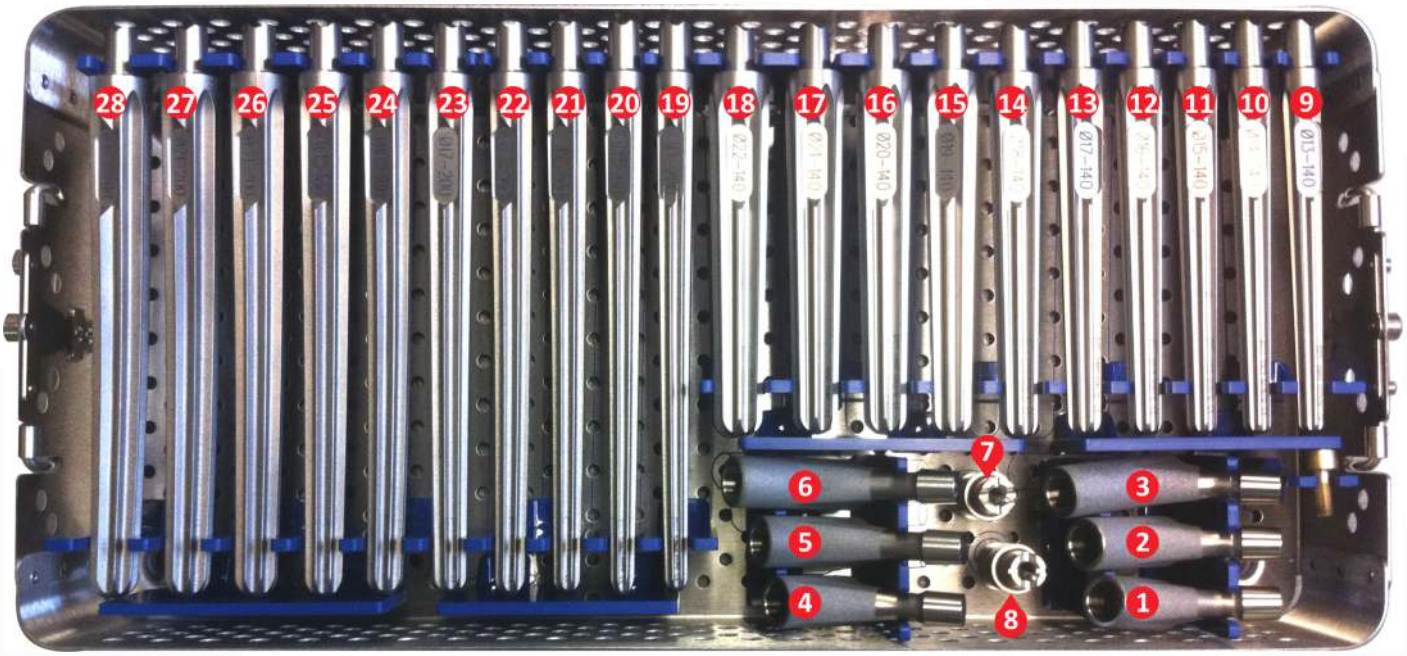
PM ProMotion Instruments Set S19000



	S19001	**PM ProMotion: Instruments Sterilization Case - Empty**
	S10014	HEAD IMPACTING END
2	S12011	UNIVERSAL IMPACTING HANDLE
3	S19301	PM ProMotion: Prosthetic Neck Cutter
4	S19302	PM ProMotion: Screwdriver SW 3,5mm
5	S19303	PM ProMotion: Counterholder
6	S19304	PM ProMotion: Prosthetic Neck Setting Handle
7	S19305	PM ProMotion: Introducer/Extractor Handle
8	S19306	PM ProMotion: Knurled Screw - SHORT
9	S19307	PM ProMotion: Knurled Screw - MEDIUM
10	S19308	PM ProMotion: Knurled Screw - LONG
11	S19309	PM ProMotion: Guide Rod for Insertion/Extraction
12	S19310	PM ProMotion: Screwdriver Sw5
13	S19311	PM ProMotion: "T" Handle
14	S19312	PM ProMotion: Torque Limiter
15	S19313	PM ProMotion: Neck Remover - Main Body
16	S19314	PM ProMotion: Neck Remover - Impression Rod
17	S19315	PM ProMotion: Impression Rod for Neck removal - Threaded
18	S19316	PM ProMotion: Impression Rod for Neck removal
	S20181	TRIAL HEAD Ø 28mm - SHORT Neck
19	S20182	TRIAL HEAD Ø 28mm - MEDIUM Neck
	S20183	TRIAL HEAD Ø 28mm - LONG Neck
	S20131	TRIAL HEAD Ø 32mm - SHORT Neck
20	S20132	TRIAL HEAD Ø 32mm - MEDIUM Neck
	S20133	TRIAL HEAD Ø 32mm - LONG Neck
	S20137	TRIAL HEAD Ø 36mm - SHORT Neck
21	S20138	TRIAL HEAD Ø 36mm - MEDIUM Neck
	S20139	TRIAL HEAD Ø 36mm - LONG Neck

WARNING:
the Torque Limiter needs to be checked periodically by the manufacturer to test the achievement of the expected torque. Before proceeding with its use, it is therefore necessary to CHECK THE EXPIRATION DATE marked on the device itself and, if necessary, return the instrument to the manufacturer for the necessary checks

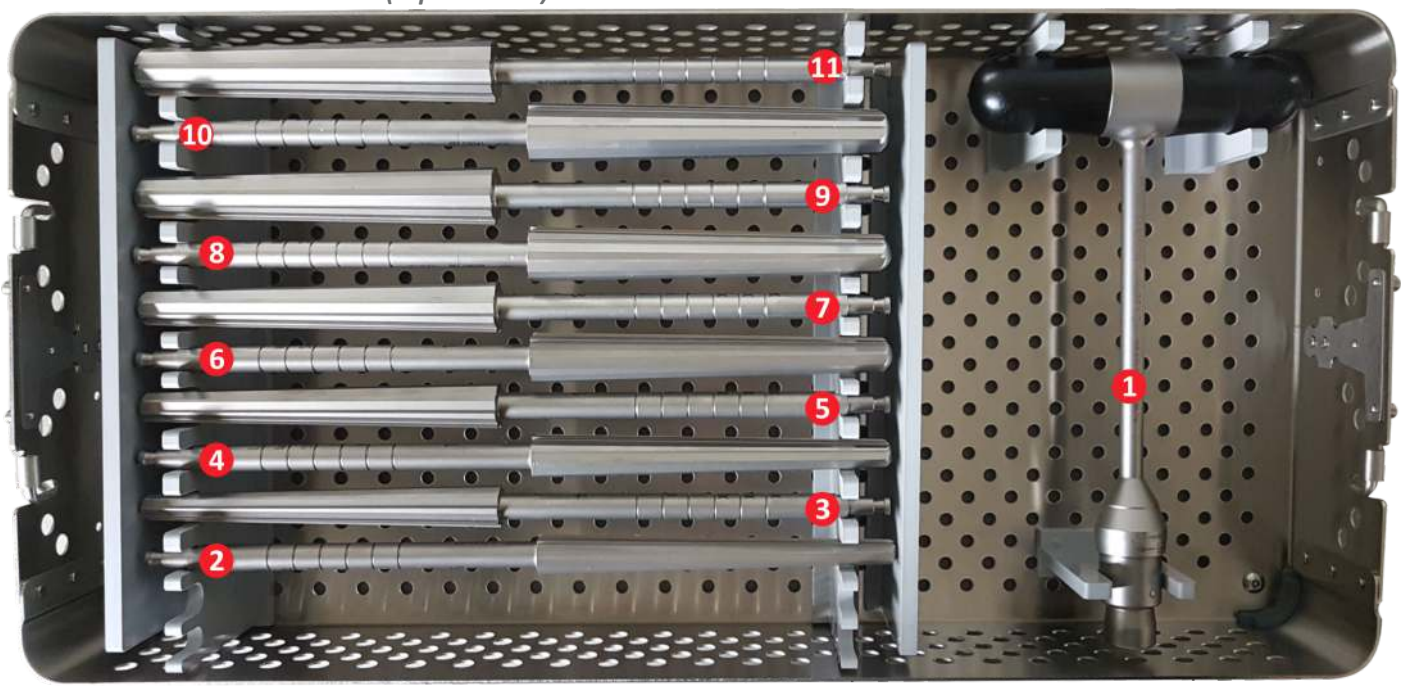
S19000 PM ProMotion Instruments Set



S19002 PM ProMotion: Trials Sterilization Case - Empty

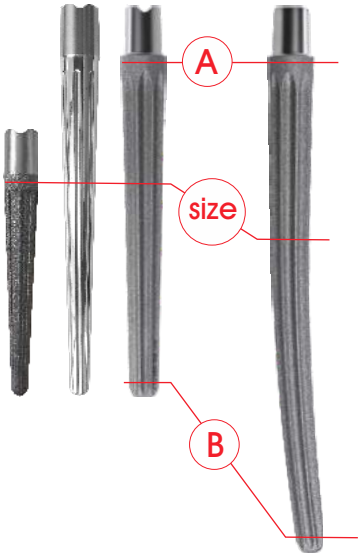
1 S19011 PM ProMotion: Trial Prosthesis Neck - SHORT
2 S19012 PM ProMotion: Trial Prosthesis Neck - MEDIUM
3 S19013 PM ProMotion: Trial Prosthesis Neck - LONG
4 S19021 PM ProMotion: Trial Prosthesis Neck Lateralized - SHORT
5 S19022 PM ProMotion: Trial Prosthesis Neck Lateralized - MEDIUM
6 S19023 PM ProMotion: Trial Prosthesis Neck Lateralized - LONG
7 S19041 PM ProMotion: Trial Extension Body for Trial Stem
8 S19042 PM ProMotion: Trial Extension Body for Implantable Stem
9 S19113 PM ProMotion: TRIAL Diaphyseal Stem Ø 13x140mm - STRAIGHT
10 S19114 PM ProMotion: TRIAL Diaphyseal Stem Ø 14x140mm - STRAIGHT
11 S19115 PM ProMotion: TRIAL Diaphyseal Stem Ø 15x140mm - STRAIGHT
12 S19116 PM ProMotion: TRIAL Diaphyseal Stem Ø 16x140mm - STRAIGHT
13 S19117 PM ProMotion: TRIAL Diaphyseal Stem Ø 17x140mm - STRAIGHT
14 S19118 PM ProMotion: TRIAL Diaphyseal Stem Ø 18x140mm - STRAIGHT
15 S19119 PM ProMotion: TRIAL Diaphyseal Stem Ø 19x140mm - STRAIGHT
16 S19120 PM ProMotion: TRIAL Diaphyseal Stem Ø 20x140mm - STRAIGHT
17 S19121 PM ProMotion: TRIAL Diaphyseal Stem Ø 21x140mm - STRAIGHT
18 S19122 PM ProMotion: TRIAL Diaphyseal Stem Ø 22x140mm - STRAIGHT
19 S19213 PM ProMotion: TRIAL Diaphyseal Stem Ø 13x200mm - CURVED
20 S19214 PM ProMotion: TRIAL Diaphyseal Stem Ø 14x200mm - CURVED
21 S19215 PM ProMotion: TRIAL Diaphyseal Stem Ø 15x200mm - CURVED
22 S19216 PM ProMotion: TRIAL Diaphyseal Stem Ø 16x200mm - CURVED
23 S19217 PM ProMotion: TRIAL Diaphyseal Stem Ø 17x200mm - CURVED
24 S19218 PM ProMotion: TRIAL Diaphyseal Stem Ø 18x200mm - CURVED
25 S19219 PM ProMotion: TRIAL Diaphyseal Stem Ø 19x200mm - CURVED
26 S19220 PM ProMotion: TRIAL Diaphyseal Stem Ø 20x200mm - CURVED
27 S19221 PM ProMotion: TRIAL Diaphyseal Stem Ø 21x200mm - CURVED
28 S19222 PM ProMotion: TRIAL Diaphyseal Stem Ø 22x200mm - CURVED

Conical Reamers Set (optional)



	S19003	**PM ProMotion: Reamers Sterilization Case - Empty**
1	S11235	T HANDLE (Hudson coupling)
2	S19233	PM ProMotion - Rigid Conical Reamer Ø 13x140mm - Att. Hudson
3	S19234	PM ProMotion - Rigid Conical Reamer Ø 14x140mm - Att. Hudson
4	S19235	PM ProMotion - Rigid Conical Reamer Ø 15x140mm - Att. Hudson
5	S19236	PM ProMotion - Rigid Conical Reamer Ø 16x140mm - Att. Hudson
6	S19237	PM ProMotion - Rigid Conical Reamer Ø 17x140mm - Att. Hudson
7	S19238	PM ProMotion - Rigid Conical Reamer Ø 18x140mm - Att. Hudson
8	S19239	PM ProMotion - Rigid Conical Reamer Ø 19x140mm - Att. Hudson
9	S19240	PM ProMotion - Rigid Conical Reamer Ø 20x140mm - Att. Hudson
10	S19241	PM ProMotion - Rigid Conical Reamer Ø 21x140mm - Att. Hudson
11	S19242	PM ProMotion - Rigid Conical Reamer Ø 22x140mm - Att. Hudson

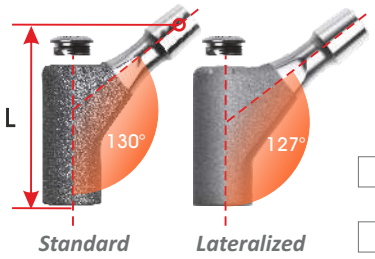
PM ProMotion - Diaphyseal Stems



Diameters A and B refers to cementless revision stems only

			CEMENTLESS				CEMENTED	
			STRAIGHT 140mm	STRAIGHT 200mm	CURVED 200mm	DISPLASY 100mm	STRAIGHT 140mm	STRAIGHT 200mm
Size Ø	Ø A	Ø B	Reference	Reference	Reference	Reference	Reference	Reference
11mm	13mm	7mm	19111*	19131	19211*	-	-	-
12mm	14mm	8mm	19112*	19132	19212*	-	19312	19412
13mm	15mm	9mm	19113	19133	19213	19513*	-	-
14mm	16mm	10mm	19114	19134	19214	19514*	19314	19414
15mm	17mm	11mm	19115	19135	19215	19515*	-	-
16mm	18mm	12mm	19116	19136	19216	19516*	19316	19416
17mm	19mm	13mm	19117	19137	19217	19517*		
18mm	20mm	14mm	19118	19138	19218	19518*		
19mm	21mm	15mm	19119	19139	19219	19519*		
20mm	22mm	16mm	19120	19140	19220	19520*		
21mm	23mm	17mm	19121	19141	19221	19521*		
22mm	24mm	18mm	19122	19142	19222	19522*		

PM ProMotion - Metaphyseal Body



Cap Screw included in the package

		Standard 130°	Lateralized 127° Offset 5mm
Size	Length L	Reference	Reference
SHORT	50mm	19011	19021
MEDIUM	60mm	19012	19022
LONG	70mm	19013	19023

Trochanteric Module

Cap Screw included in the package

Reference 19055

Extension Body

Ø mm	stem Size	Reference
20mm	from 13 to 18	19041
22mm	from 19 to 22	19042

Locking Screws

Size	Reference
SHORT	19097
LONG*	19098

*To be used with Extension Body

Informations

INTENDED PURPOSE: the PM ProMotion is a modular stem utilized in hip reconstruction interventions combined with a femoral head and an acetabular cup. Device anchorage is achieved through primary press fit stabilization or by using bone cement depending on the stem used. The PM ProMotion is a revision stem with distal anchorage, indicated in cases of revision due to various factors i.e. aseptic loosening and periprosthetic fractures, even in cases of serious bone loss in the proximal region of the femur, wherever the distal region of the femur present a structure still able to guarantee a correct and long lasting primary mechanical anchorage through the press fit technique.

MATERIALS: All the components are made of Titanium Aluminium Niobium forged alloy (Ti6Al7Nb) - ISO5832/11

SURFACE FINISHING:

Press-Fit Stems: Corundum sandblasted microstructured surface (ra 4-6µm).

Cemented Stems: polished surface.

STERILIZATION:

Method: Irradiation (*Beta or Gamma rays - nominal dose 25 kGy*) or vaporized Hydrogen Peroxide (*VH2O2*).

Validity: 5 years (*Beta*) - 10 years (*Gamma-VH2O2*).

CLASSIFICATION:

Class III or IIb 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

NOTES

NOTES

permedica
ORTHOPAEDICS

CHALLENGING EXCELLENCE IN TECHNOLOGY

www.permedica.it

Cod. TC062EN Rev. 03.2 - 2021/11