

Stem-M

Primary Hip Reconstruction
Cementless Short Stem

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■ Important Note

Lincotek Bologna S.r.l., does not practice medicine. This surgical technique / brochure has been developed in consultation with an experienced team of surgeons to provide their peers with general guidance when implanting the Predicate Acetabular System. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each patient individually.

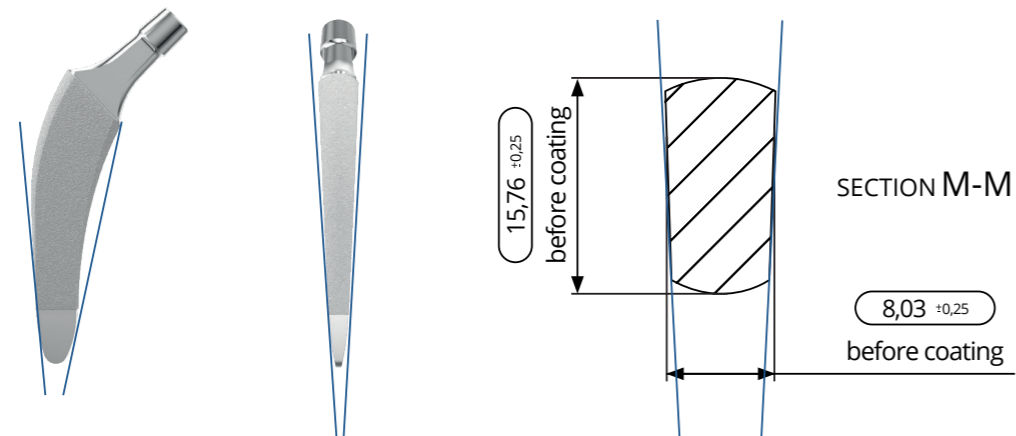
■ Stem-M



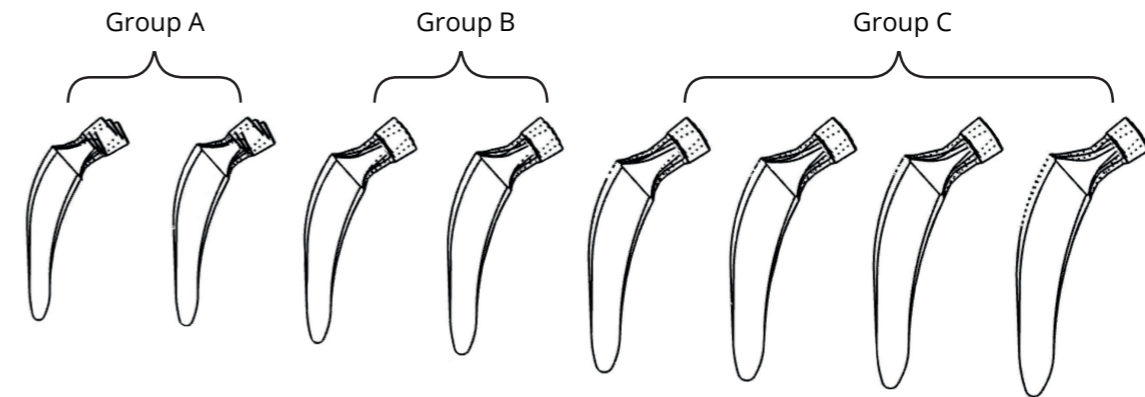
Uncemented short press-fit stem available in three different offsets, designed to be implanted with the same surgical technique as a conventional longer stem. Double coated with titanium plasma and calcium phosphate (CaP) or Hydroxylapatite (HA) on proximal and medial part of the stem to enhance primary stability and promote osteointegration. Smooth and rounded distal tip.

- Conventional short stem with standard technique
- Coated with Titanium Plasma Spray (ISO 5832-2) and CaP or HA
- Titanium Alloy Ti6Al4V ISO 5832-3;
- 8 cementless sizes, CCD 119°, 126°, 132°;
- Polished neck and smooth distal tip;
- Cross section of rectangular stem;
- Morse taper 12/14
- Variable neck length with size increase for a better anatomic match
- Triple tapered design

■ Three Tapers in Three Planes



■ Body and Neck Progression



■ Variability and Versatility

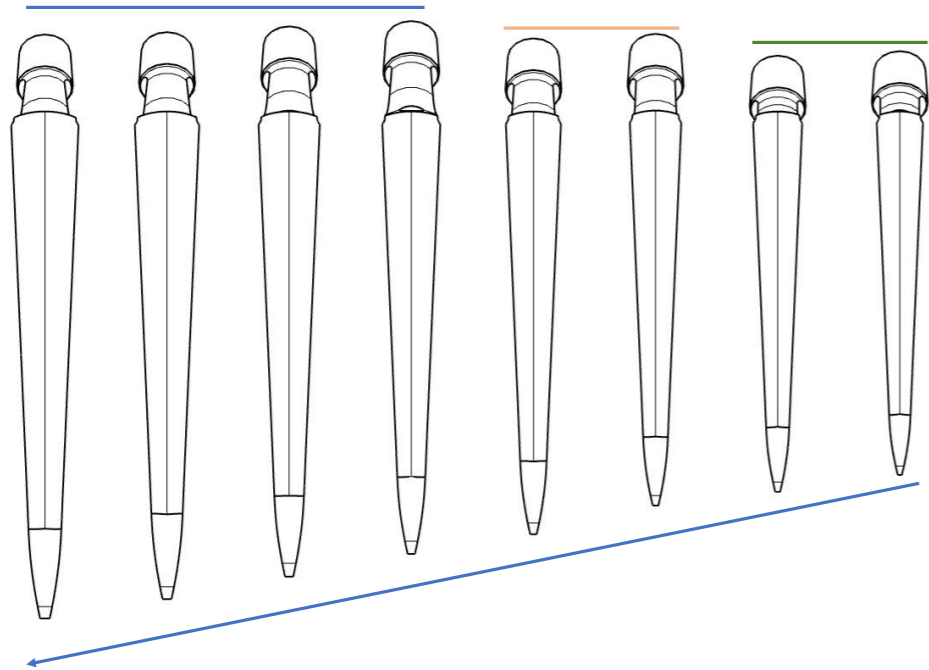


Size	Type	Lat Shoulder to Tip Length	Calcar to Tip Length	Calcar Section A	Calcar Section B	Offset	CCD Angle
1	LAT	89,1	72,7	23,7	10,2	39,1	119°
2	LAT	93,2	75,1	25	10,7	38,7	119°
3	LAT	96,8	78	26,3	11,3	43,5	119°
4	LAT	103,6	83,7	27,5	12,1	44,4	119°
5	LAT	108,4	87,7	28,5	12,7	46,9	119°
6	LAT	114	92,3	29,8	13,5	48,7	119°
7	LAT	119,5	97	30,5	14,2	49,9	119°
8	LAT	124,2	101,1	31,5	14,8	51,1	119°
1	MLA	89,1	72,7	23,7	10,2	36	126°
2	MLA	93,2	75,1	25	10,7	35,5	126°
3	MLA	96,8	78	26,3	11,3	41,7	126°
4	MLA	103,6	83,7	27,5	12,1	42,7	126°
5	MLA	108,4	87,7	28,5	12,7	44,8	126°
6	MLA	114	92,3	29,8	13,5	46,5	126°
7	MLA	119,5	97	30,5	14,2	47,7	126°
8	MLA	124,2	101,1	31,5	14,8	49	126°
1	STD	89,1	72,7	23,7	10,2	32,7	132°
2	STD	93,2	75,1	25	10,7	32,2	132°
3	STD	96,8	78	26,3	11,3	39,6	132°
4	STD	103,6	83,7	27,5	12,1	40,6	132°
5	STD	108,4	87,7	28,5	12,7	42,6	132°
6	STD	114	92,3	29,8	13,5	44,4	132°
7	STD	119,5	97	30,5	14,2	45,6	132°
8	STD	124,2	101,1	31,5	14,8	46,9	132°

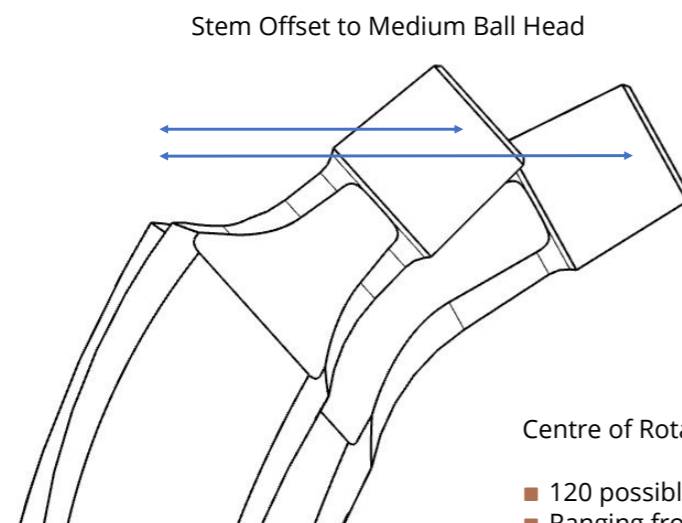
■ Stem Length & Neck Length

Stem M:

- Stem Body length from 89 to 124 mm;
- Neck: proportionally growing with stem size and available in 3 Versions: 119°-125°-132° CCD



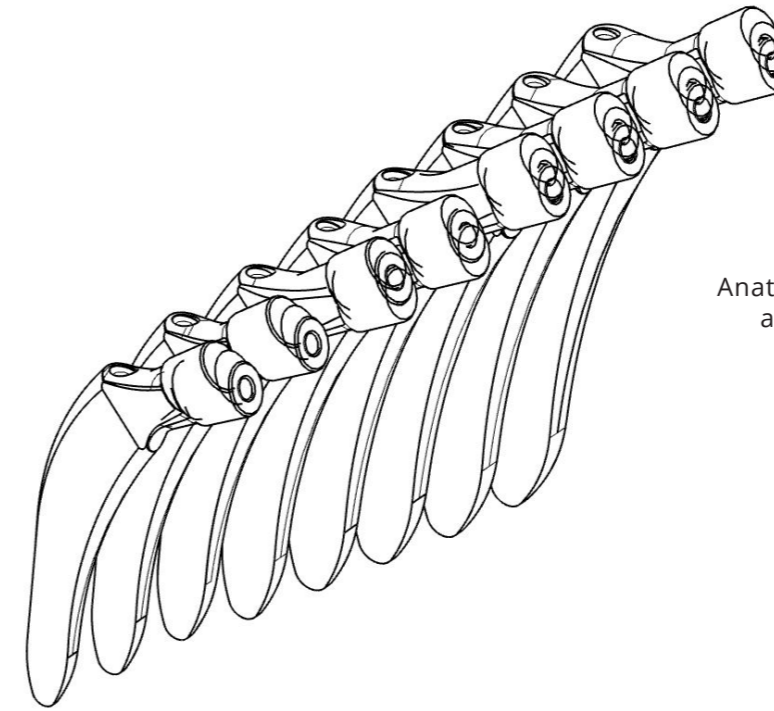
■ Offset



Centre of Rotation:

- 120 possible Stem Offsets
- Ranging from 26 mm to 55 mm

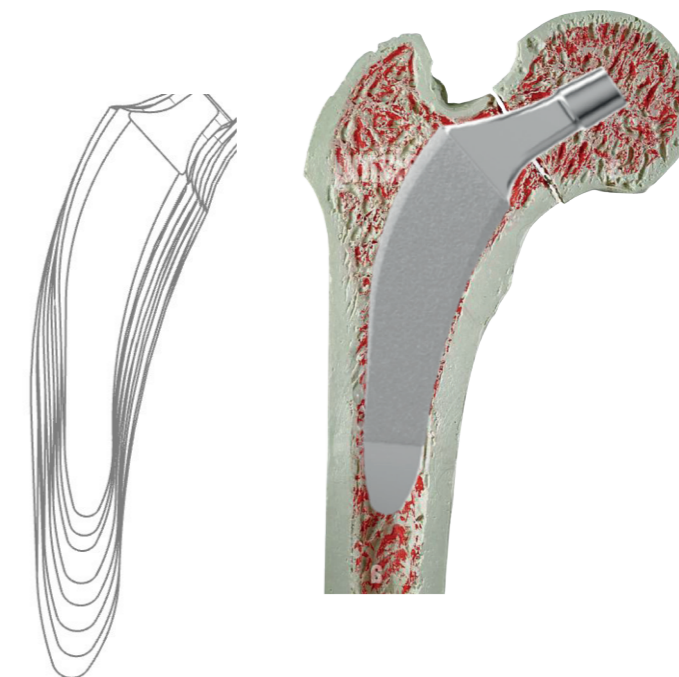
■ Stem-M Range



Anatomically growing to cover all possible surgical needs.

■ Stem-M Body

Stem body proportionally growing to achieve better fit and fill, with medial curvature anatomically shaped to match medial cortical bone and calcar curvature.



■ Indications

Indications according to IFU:

- Extensive primary and secondary destruction of the joint to the extent that the functional efficiency of the locomotive apparatus is reduced;
- Severe pathological condition affecting the articulation caused by degenerative and rheumatoid arthritis;
- Joint fracture or bone necrosis;
- Post-surgical conditions after previous operations with or without consequent use of a prosthesis.

■ Contraindications

- On-going inflammatory process in the peri-articular region;
- Severe loss of bone tissue such as to inhibit a primary stabilisation of the prosthesis;
- Degenerative changes in the patient's neurological condition;
- Severe instability in the ligament area that cannot be remedied;
- Foreseeable causes of fatigue of the implanted joint due to obesity or excessive physical activity;
- Severe osteoporosis;
- Bone cancer in the implant anchoring area;
- Alcohol and drug abuse;
- Allergy to the materials employed;
- Lack of collaboration by the patient.

Relative contraindications:

- Adiposity
- Lacking or foreseeable not assured compliance
- Foreseeable overload/overstressing of the joint prosthesis
- Osteoporosis

■ Risk Factors

Complications:

- Hematomas in the region of the operation;
- Late onset of acute infections in the region of the operation;
- Momentary or persistent functional alterations in the nerves of the anatomical area concerned;
- Venous thrombosis, pulmonary embolism, heart failure;
- Change in position and/or loosening of the prosthesis;
- Joint dislocation;
- Shortening or lengthening of the limb concerned;
- Pathological bone fracture caused by changes in load;
- Allergic reactions or metallosis in the peripheral region of the implant;
- Periarticular ossification.



■ Preoperative Planning

The device should be implanted only by surgeons familiar with the joint replacement procedures described in the specific surgical techniques.

Preoperative planning provides useful information for the correct placement of the implant but does not necessarily indicate the appropriate sizing.

The correct stem and cup size must be determined during surgery.

To achieve the best results preoperative planning using special templates (with specific magnification always advisable). It's suggested to do AP radiograph with adequate contrast.

The templates show both the profile of the cup and the center of rotation of the femoral head and the A-P main dimensions of the stem and the relative center of rotation according to the different head sizing.

In order to achieve successful hip replacement surgery, it is crucial to plan the procedure preoperatively, taking into consideration the patient's individual anatomy and level of physical activity.

The surgeon should conduct a thorough evaluation of the patient's clinical condition to determine the correct implant type and size, as well as its final intraosseous position.

To ensure optimal results, surgery should be planned in advance using appropriate templates, which must be compatible with the magnification factor of the X-rays.

Special X-ray templates are available in a standard 1.1:1 scale or in 1.15:1 scale. The implant size should be selected from adequate AP and ML X-rays, ensuring legibility and large enough to accommodate the whole template. A second X-ray of the unaffected joint can be helpful.

Improper preoperative planning can result in the selection of incorrect implant types or incorrect positioning of implants.

It is desirable to have a load-bearing, stable acetabular fossa with solid lateral osseous coverage for acetabular surgeries and to evaluate properly the femoral bone conditions to select the adequate stem type.

The inclination of the cup should not be significantly above or below 45°, and anteversion should not be significantly above or below 15°.

Deviating from these boundaries may lead to a reduced range of motion, potentially resulting in subluxation or dislocation of the joint.

The combined stem/cup anteversion should be around 30° to improve the range of motion and reduce the dislocation risk and any potential impingement risks.

During hip replacement surgery, various surgical approaches can be utilized to implant the components.

The following steps are applicable for both postero-lateral and other surgical access routes.

The patient is placed in a lateral position for the procedure. The incision is made postero-laterally, followed by opening of the fascia-lata. The external rotator muscles are then resected, and the joint capsule is incised.

The femoral head is dislocated dorsally to allow for easy access and removal of the head from the socket. This is achieved by flexing the hip and abducting the leg, which allows the femoral head to dislocate freely. These steps are critical for a successful hip replacement surgery, regardless of the surgical approach utilized.

Before acetabular reaming, it is essential to have a clear and direct view of the acetabular site, regardless of the surgical approach selected, and before femurs broaching a good visibility must be achieved and the relative position of the great trochanter and the calcar should be properly evaluated.

This requires the removal of any soft tissues and osteophytes that could obstruct visibility, allowing for a complete view of the entire acetabular socket and neck-femur region.

This is crucial to identify the presence of any cavitory or segmental defects and ensure accurate diagnosis and treatment.

Specific acetabular and femoral retractors are needed to facilitate acetabular exposure.

■ Choice of Stem Size and Stem Type

The stem size is selected in a way that, in frontal plane, the outline fills as much of the proximal femoral metaphysis as possible. In the sagittal plane, it must be ensured that the stem is suited to the anterior bow of the femur.

The stem is fixed proximally and therefore does not need to fit closely in the distal area. The size of prosthesis should be chosen so that the centre of rotation is correctly situated in the middle of the head respectively at a level with greater trochanter. Anteversion must be checked in the sagittal plane.

The stem size and the level for resection of the femoral neck should be selected such that the tip of the greater trochanter is level with the centre of the head of the prosthesis.

Lateralizing stems are available to achieve an anatomical reconstruction, even in case a high offset is required.

Preoperative planning gives an initial estimate but cannot conclusively determine the size of stem to be used.

This is decided intraoperatively.

■ Positioning of Patient and Surgical Approach

All surgical approaches can be used while implanting Stems. All the following steps apply for postero-lateral surgical approach and all other surgical access routes.

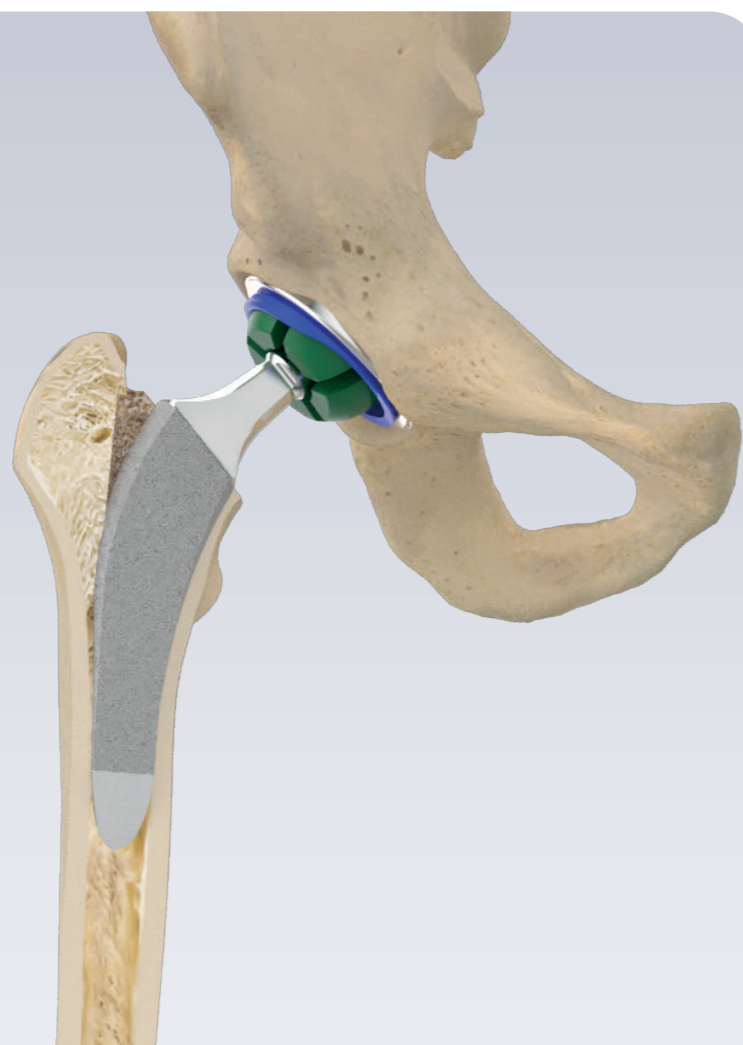
The patient lies on his/her side. The incision is done postero-laterally.

After opening of the "fascialata", external rotator muscles are resected and the joint capsule is incised.

Then, the femoral head is dislocated in dorsal direction so that it lies free.



Surgical Technique



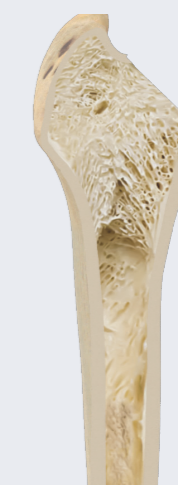
Determination of the Resection Level

The resection level has been defined in the pre-op planning. Resection should be sparing so that more bone can be resected later on if necessary.

The angle of resection is perpendicular to the femoral neck axis [► Fig.1]. Alternatively, a bone broach can be used to determine the resection level.

Then the resection is carried out at the planned level.

Fig. 1



Preparation of the Proximal Femur

The medullary canal is opened with the box chisel [► Fig.2]. This is done as laterally as possible to prevent varus positioning of the femoral component.

The bone broach is then used to compress the cancellous bone. This is an important step in the anchoring of the stem. Secure anchorage depends on a layer of compacted cancellous bone encompassing the implant.

To fix the bone broach in the handle open the lever and insert the bone broach [► Fig.3] with the medial side in the direction of the lever [► Fig.4].

Fig. 2

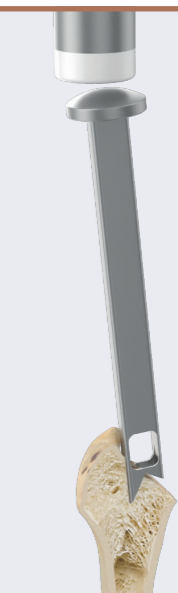
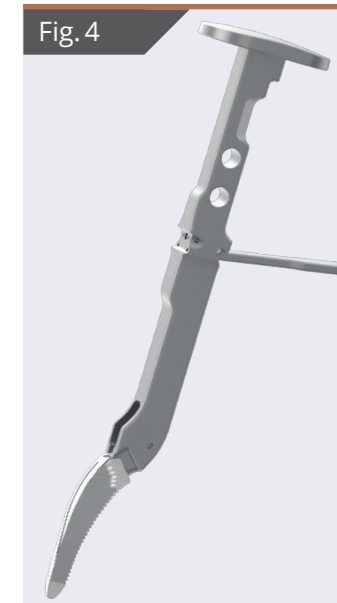


Fig. 3



Fig. 4



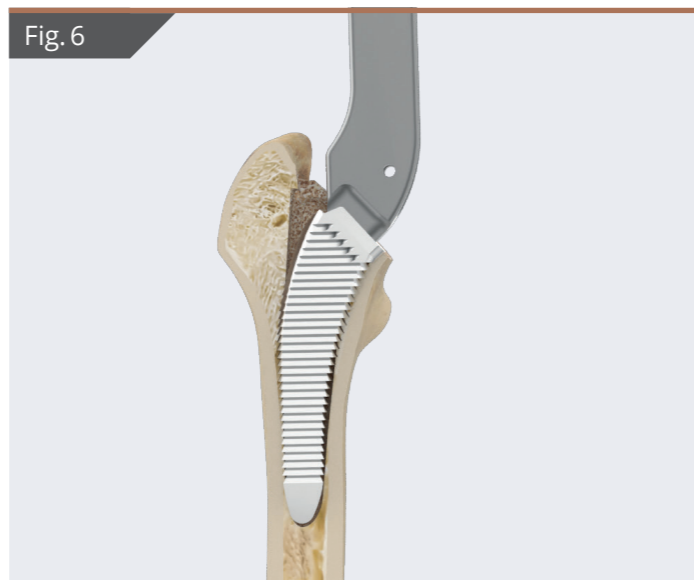
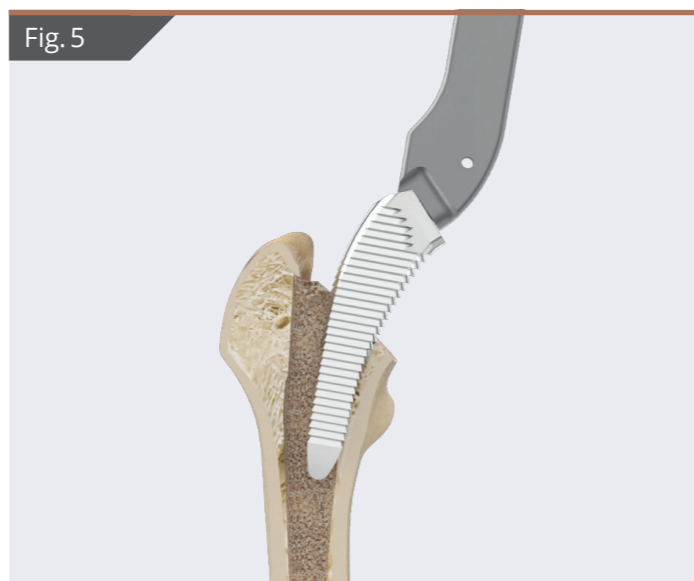
Close the lever. Start with the smallest bone broach [►Fig.5]. Take into account the anteversion of the stem required (usually 15°).

Lateral compressive stress (which may lead to thigh pain later on) in the distal femur is avoided by inserting the bone broach in an axial direction.

Drive in the bone broach until the junction surface of the broach is flush with the resected neck surface [►Fig.6].

Continue with progressively larger broach sizes until the bone broach is optimally seated in the femur (rotational stability, axial stability, implant level (height of center of rotation)).

When the optimal broach size is reached (which is not necessarily the same as planned preoperatively) remove the handle and leave the broach in place.



■ Trial Reduction

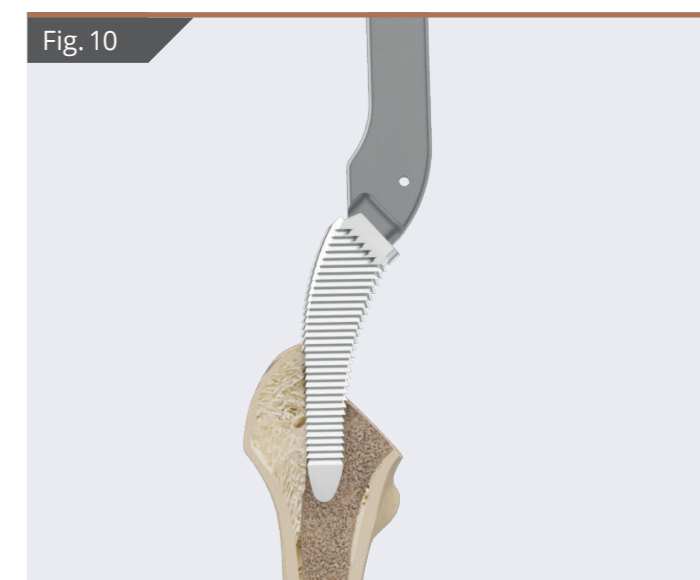
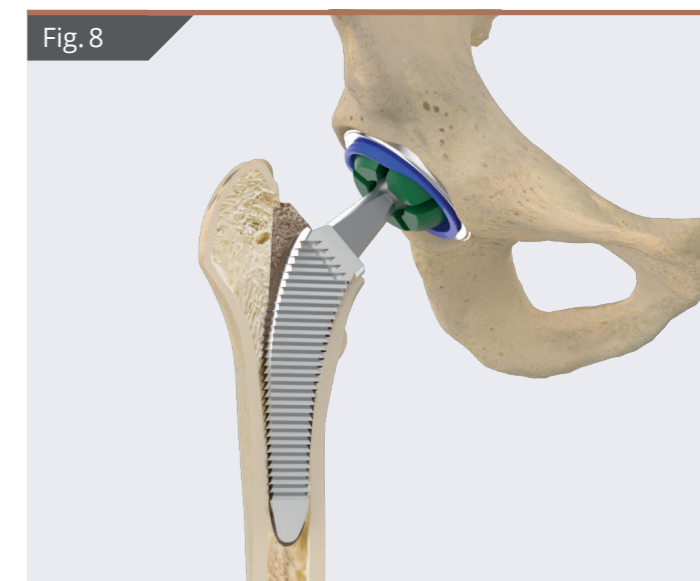
The acetabular cup is usually implanted before the stem. Trial reduction can then be carried out.

The inserted bone broach serves as a trial prosthesis on which the trial neck is inserted.

Select the appropriate trial neck segment according to the pre-op planning (stem types standard and lateralizing). The trial head is then placed on the trial neck [►Fig.7].

The stability and range of motion of the joint are examined with the help of the trial components [►Fig.8].

Finally, the trial head and neck segment are removed by hand [►Fig.9] and the bone broach is removed with the help of the handle [►Fig.10].

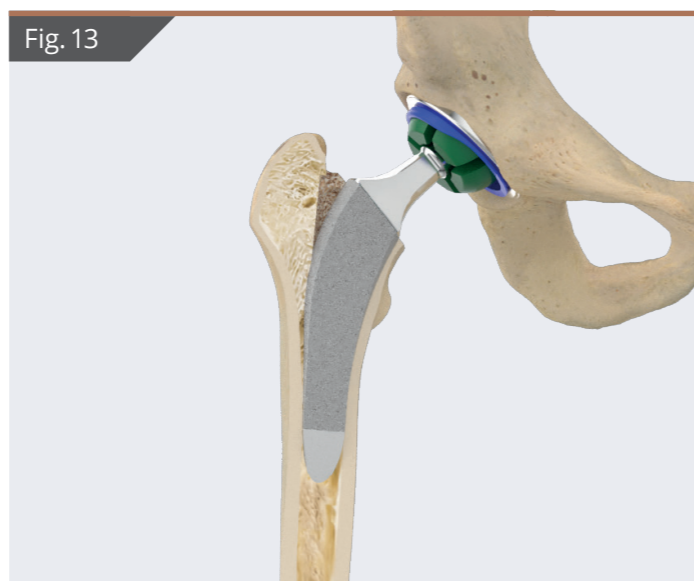
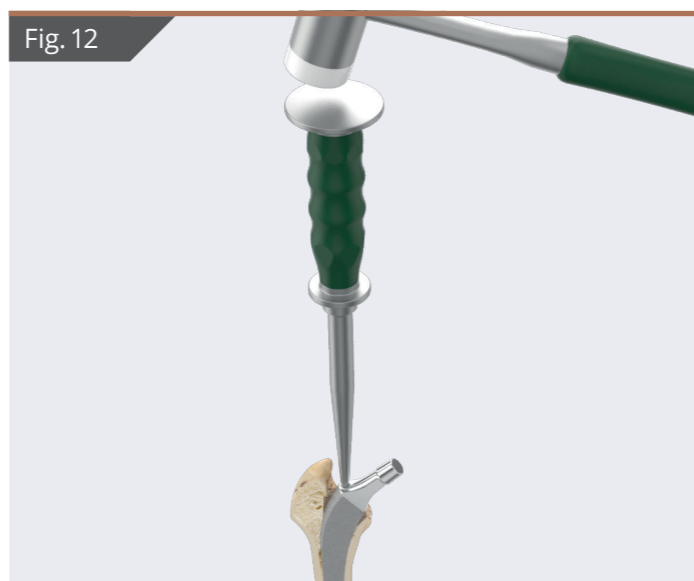


■ Inserting the Final Stem

Select the appropriate stem of the same size as the final bone broach and remove it from the sterile packaging. Position it into the femoral canal using the stem inserter. [▶ Fig.11].

Position the half-moon impactor [▶ Fig.12]. Drive in the stem with careful and controlled hammer blows until the transition line between the coating and the polished neck area corresponds to the profile of the last bone broach used.

For cemented stem: Select the appropriate stem of the same size as the final bone broach. The sizing of the implant is already adjusted to accommodate the bone cement. Cover the implant with bone cement. The bone cement final layer will be around 0.75 mm. Use the half-moon impactor to gently impact the stem, if needed adjust stem anteversion using the same half-moon impactor rotating the handle around its axis to fine the correct positioning.



■ Final Trial Reduction

At this point the correct head-neck-length can be checked again with the trial heads and trial liners [▶ Fig.13].

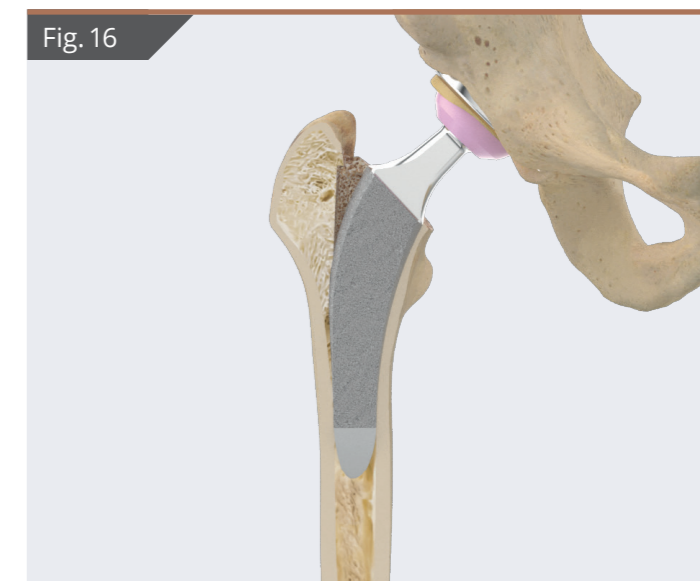
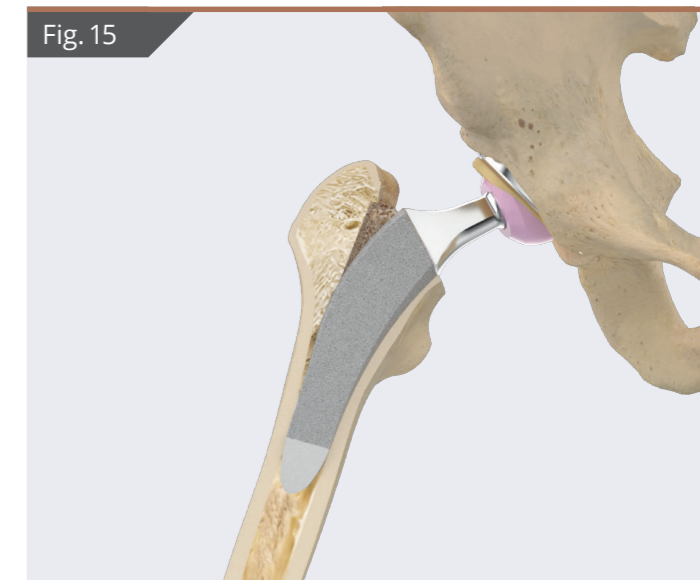
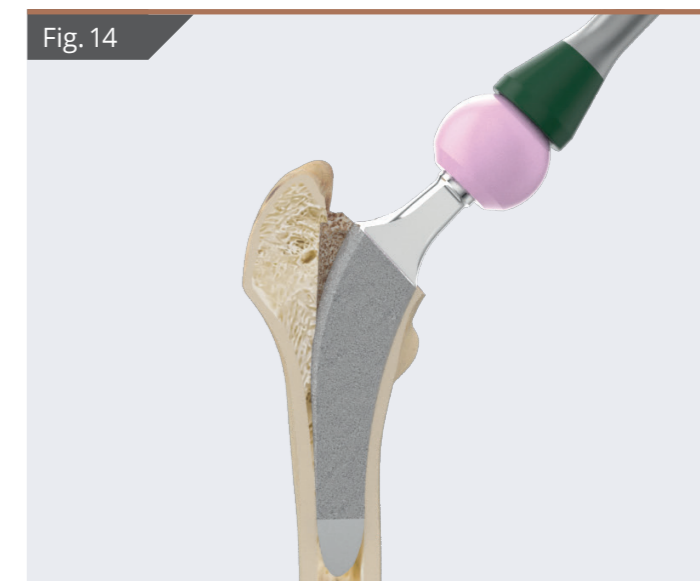
■ Final Head Implantation

Remove the appropriate prosthesis head (diameter, length, material) from the sterile packaging.

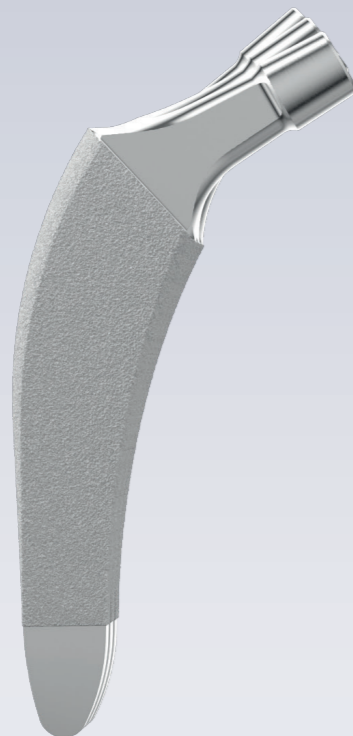
Clean and dry the taper of the stem thoroughly. This is particularly important with ceramic heads. Mount the head by hand using axial pressure and a turning motion.

Impact the head lightly if necessary, using the impactor for prosthesis heads [▶ Fig.14].

Reduction and suture:
Clean the joint surfaces thoroughly and then finally reduce the joint and test the final configuration and stability [▶ Fig.15] [▶ Fig.16].



Ordering Information Implants and Instruments



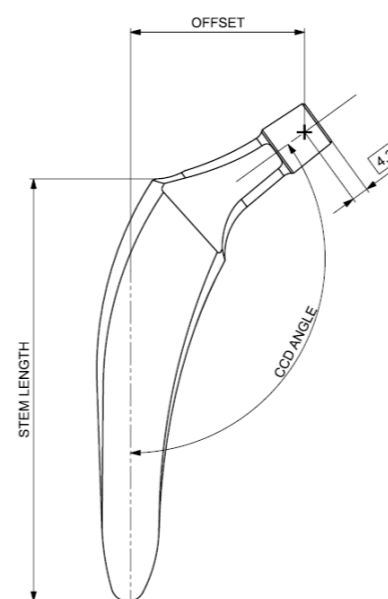
Stem-M: Cementless



Item Code	Description	Coating	Type	Main Material
XM01.1608.000.00	Stem-M Std 1 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1609.000.00	Stem-M Std 2 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1610.000.00	Stem-M Std 3 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1611.000.00	Stem-M Std 4 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1612.000.00	Stem-M Std 5 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1613.000.00	Stem-M Std 6 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1614.000.00	Stem-M Std 7 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1615.000.00	Stem-M Std 8 Ti-V + CaP	Ti-V + CaP	STD	Ti6Al4V - ISO 5832/3
XM01.1600.000.00	Stem-M Mla 1 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1601.000.00	Stem-M Mla 2 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1602.000.00	Stem-M Mla 3 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1603.000.00	Stem-M Mla 4 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1604.000.00	Stem-M Mla 5 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1605.000.00	Stem-M Mla 6 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1606.000.00	Stem-M Mla 7 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1607.000.00	Stem-M Mla 8 Ti-V + CaP	Ti-V + CaP	MLA	Ti6Al4V - ISO 5832/3
XM01.1592.000.00 *	Stem-M Lat 1 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1593.000.00 *	Stem-M Lat 2 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1594.000.00 *	Stem-M Lat 3 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1595.000.00 *	Stem-M Lat 4 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1596.000.00 *	Stem-M Lat 5 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1597.000.00 *	Stem-M Lat 6 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1598.000.00 *	Stem-M Lat 7 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3
XM01.1599.000.00 *	Stem-M Lat 8 Ti-V + CaP	Ti-V + CaP	LAT	Ti6Al4V - ISO 5832/3

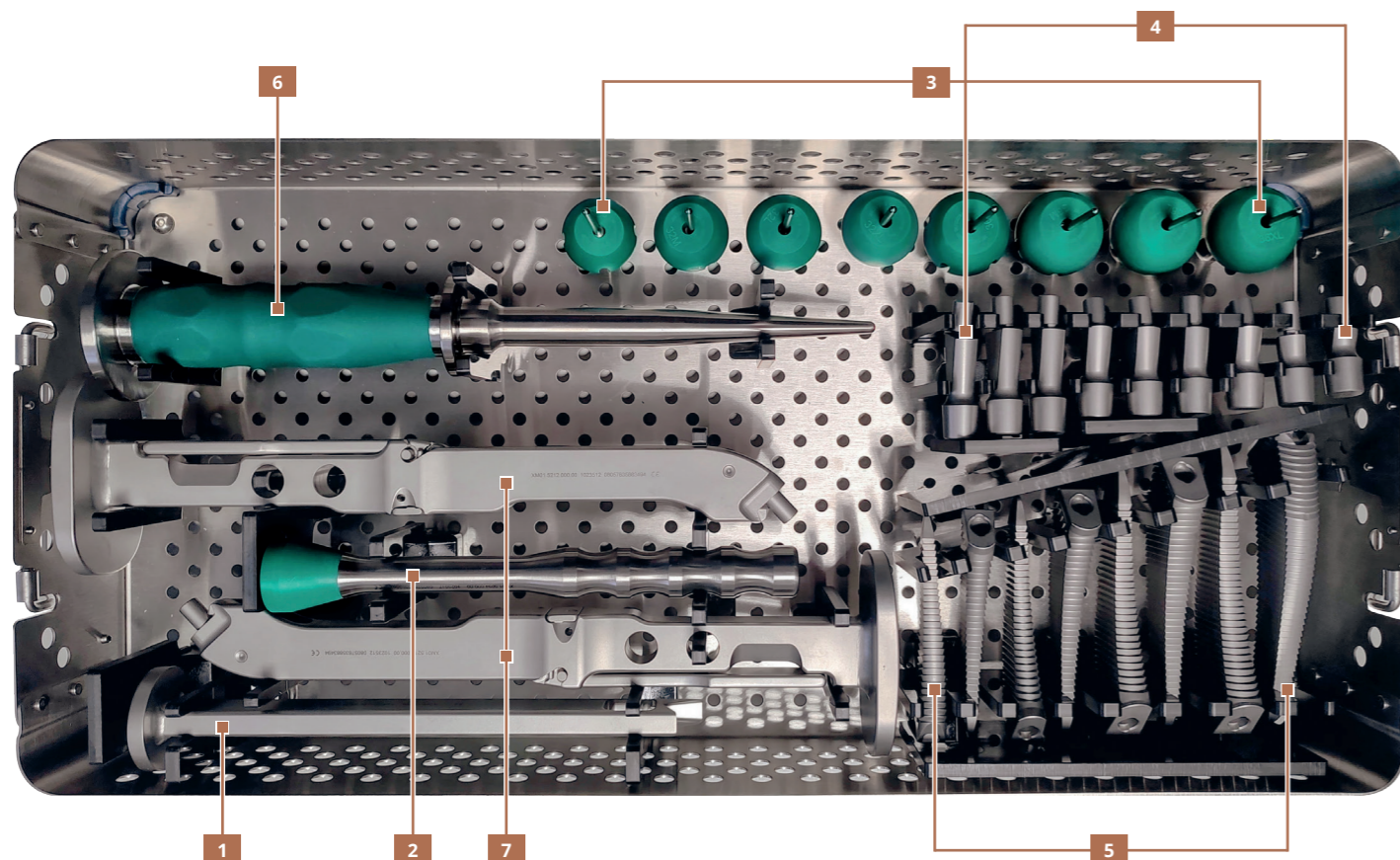
* Special request items

Stem Dimensions



Size	Type	Length (mm)	CCD Angle	Offset (mm)
1	STD	89	132	33
2	STD	93	132	32
3	STD	97	132	40
4	STD	104	132	41
5	STD	108	132	43
6	STD	114	132	44
7	STD	120	132	46
8	STD	124	132	47
1	MLA	89	124	36
2	MLA	93	124	36
3	MLA	97	125	42
4	MLA	104	125	43
5	MLA	108	126	45
6	MLA	114	126	47
7	MLA	120	126	48
8	MLA	124	126	49
1	LAT	89	119	39
2	LAT	93	119	39
3	LAT	97	119	44
4	LAT	104	119	44
5	LAT	108	119	47
6	LAT	114	119	49
7	LAT	120	119	50
8	LAT	124	119	51

Stem-M Instrument Set | B076.4008.000.00

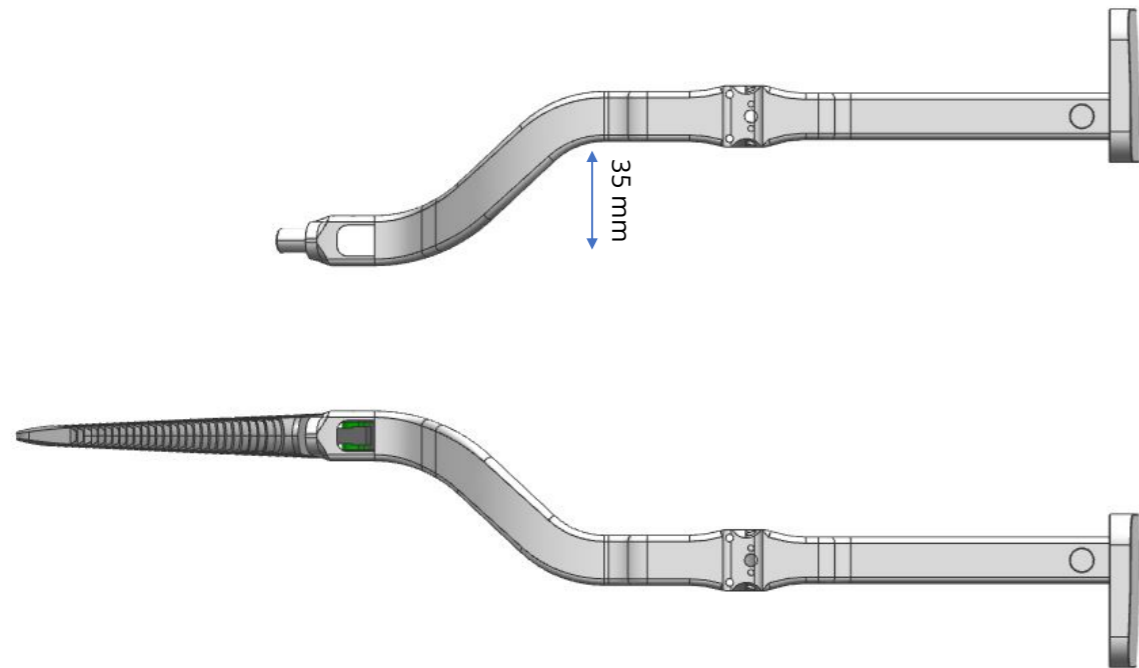


Set Content

No	Item Code	Description	Qty per SET
	BO76.4000.001.00	TRAY STEM P/M	1
	BO76.4009.003.00	TRAY Brackets Stem M	1
1	XM01.5090.000.00	Box Chisel	1
2	XM01.5094.000.00	Impactor For Prosthesis Heads	1
3	XM01.5104.000.00	Trial Ball Head 32S	1
	XM01.5105.000.00	Trial Ball Head 32M	1
	XM01.5106.000.00	Trial Ball Head 32L	1
	XM01.5107.000.00	Trial Ball Head 32XL	1
	XM01.5108.000.00	Trial Ball Head 36S	1
	XM01.5109.000.00	Trial Ball Head 36M	1
	XM01.5110.000.00	Trial Ball Head 36L	1
	XM01.5111.000.00	Trial Ball Head 36XL	1
4	XM01.5126.000.00	Trial Neck Std	1
	XM01.5127.000.00	Trial Neck Mla	1
	XM01.5128.000.00	Trial Neck Lat	1
5	XM01.5129.000.00	Broach 1	1
	XM01.5130.000.00	Broach 2	1
	XM01.5131.000.00	Broach 3	1
	XM01.5132.000.00	Broach 4	1
	XM01.5133.000.00	Broach 5	1
	XM01.5134.000.00	Broach 6	1
	XM01.5135.000.00	Broach 7	1
	XM01.5136.000.00	Broach 8	1
6	XM01.5206.000.00	Stem Impactor	1
7	XM01.5212.000.00	Broach Handle Male	2
	XM01.5216.000.00 *	Stem Extractor	1
	XM01.5098.000.00 *	Trial Ball Head 22S	1
	XM01.5099.000.00 *	Trial Ball Head 22M	1
	XM01.5100.000.00 *	Trial Ball Head 28S	1
	XM01.5101.000.00 *	Trial Ball Head 28M	1
	XM01.5102.000.00 *	Trial Ball Head 28L	1
	XM01.5103.000.00 *	Trial Ball Head 28XL	1
	XM01.5112.000.00 *	Trial Ball Head 40S	1
	XM01.5113.000.00 *	Trial Ball Head 40M	1
	XM01.5114.000.00 *	Trial Ball Head 40L	1
	XM01.5115.000.00 *	Trial Ball Head 40XL	1
	XM01.5211.000.00 *	Trial Ball Head 28XXL	1

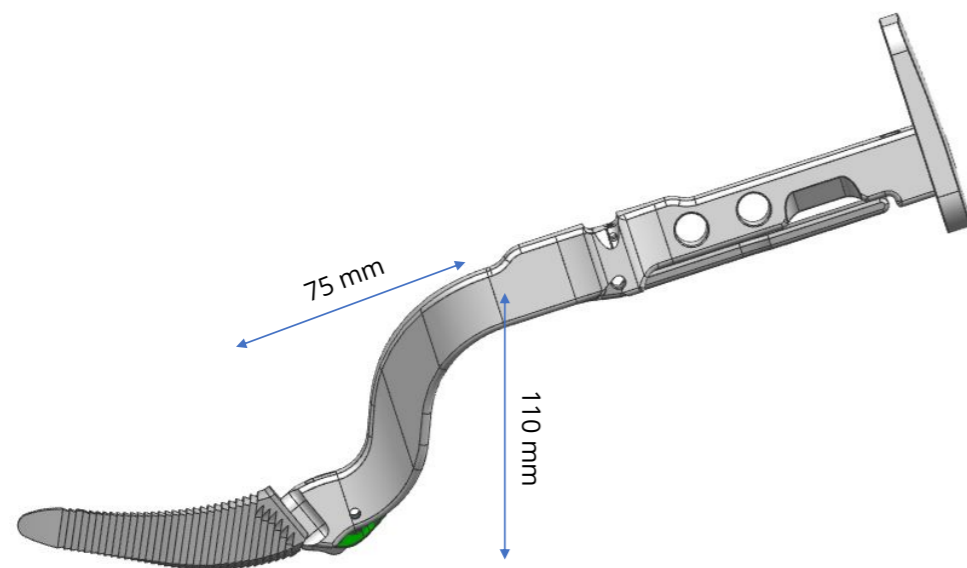
* Special request items not included in depicted standard set.

MIS Double Offset Broach Handles

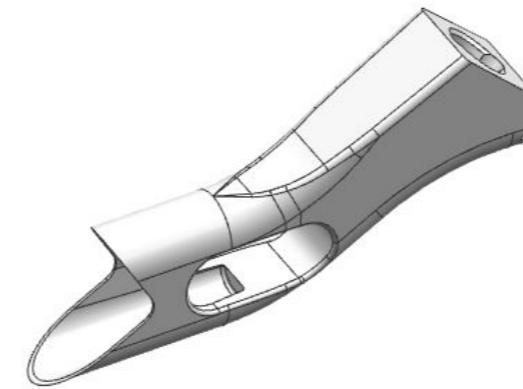


Set Content

Item Code	Description	Qty per SET
BO76.5516.000.00	Double Offset Handle - Right	1
BO76.5517.000.00	Double Offset Handle - Left	1
BO76.5518.000.00	Osteotome	1
BO76.5519.000.00	Stem Impactor Module	1
BO76.5514.000.00	Spoon Lever	1
BO76.5515.000.00	Teethed Curved Broach	1



Double Offset Broach Handles (common components with Traction-Bed): Components



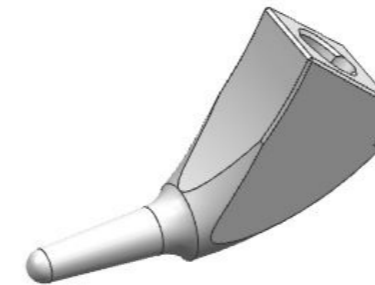
Osteotome for MIS

Item Code	Description
BO76.5518.000.00	Osteotome - M/N



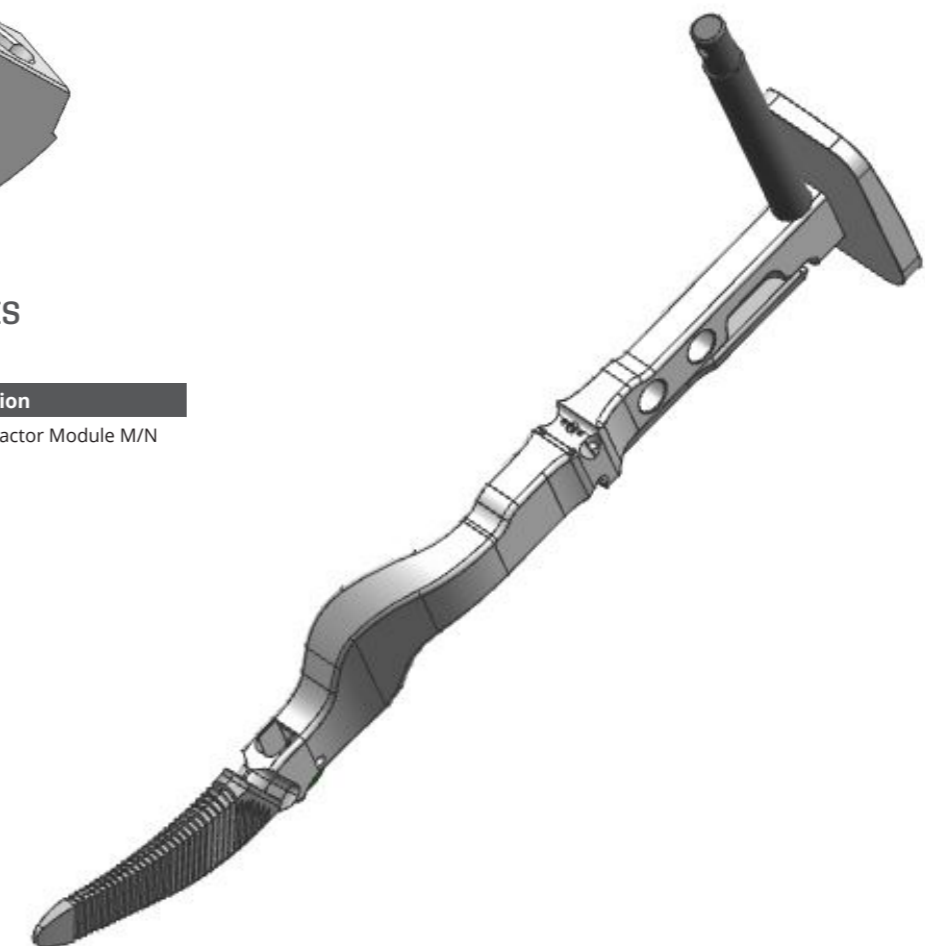
Direction Handle

Item Code	Description
BO76.5532.000.00	Alignment Rod



Stem Impactor for MIS

Item Code	Description
BO76.5519.000.00	Stem Impactor Module M/N



Contact Details


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