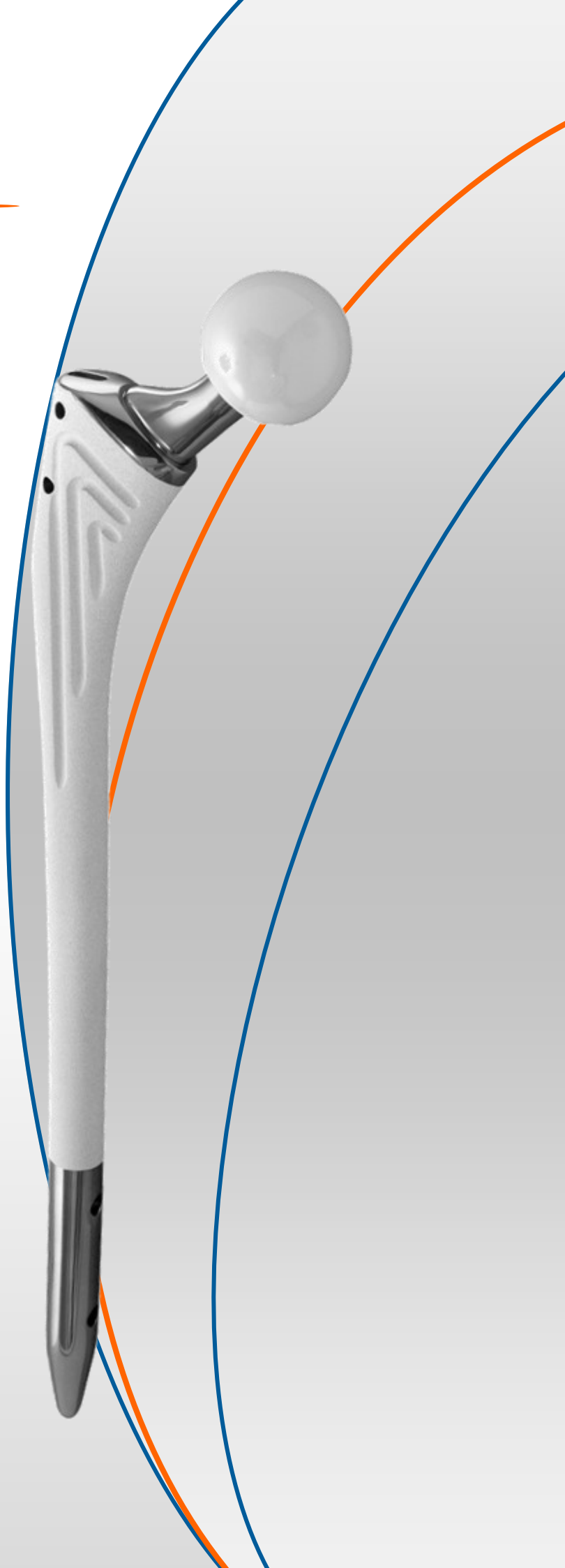
OPTIMAL®

Revision/reconstruction

cementless femoral stem



Surgical Technique
Conventional
Instrumentation

AMPLITUDE

OPTIMAL® REVISION/RECONSTRUCTION STEM: PRODUCTS

OPTIMAL® STEM

Revision

200 mm — 5 sizes

- Ø12 mm
  - Size 1
  - Size 2
  - Size 3
- Ø14 mm
  - Size 4
  - Size 5

Reconstruction

250 mm — 5 sizes

- Ø12 mm
  - Size 1
  - Size 2
  - Size 3
- Ø14 mm
  - Size 4
  - Size 5

Locking threaded pins:
Ø4.7 L 30 to 45 mm
(5 mm increments)

Modular necks

- Ante/Retro
- Lateral/Medial
- Lateral+ Medial+
- Lateral +10.5/ Medial +10.5

10/12 FEMORAL HEADS

Ceramic

Sizes
28 – 32 – 36 mm

BIOLOX® *delta*

Size	Head length
Ø 28 mm	S −3.5 mm M 0 mm L +3.5 mm
Ø 32 mm	S −4 mm M 0 mm L +4 mm
Ø 36 mm	S −4 mm M 0 mm L +4 mm

Ceramic revision

Sizes
28 – 32 – 36 mm

BIOLOX® *delta*

Size	Head length
Ø 28 mm	S −3 mm M 0 mm L +4 mm
Ø 32 mm	S −3 mm M 0 mm L +4 mm
Ø 36 mm	S −3 mm M 0 mm L +4 mm

Metal

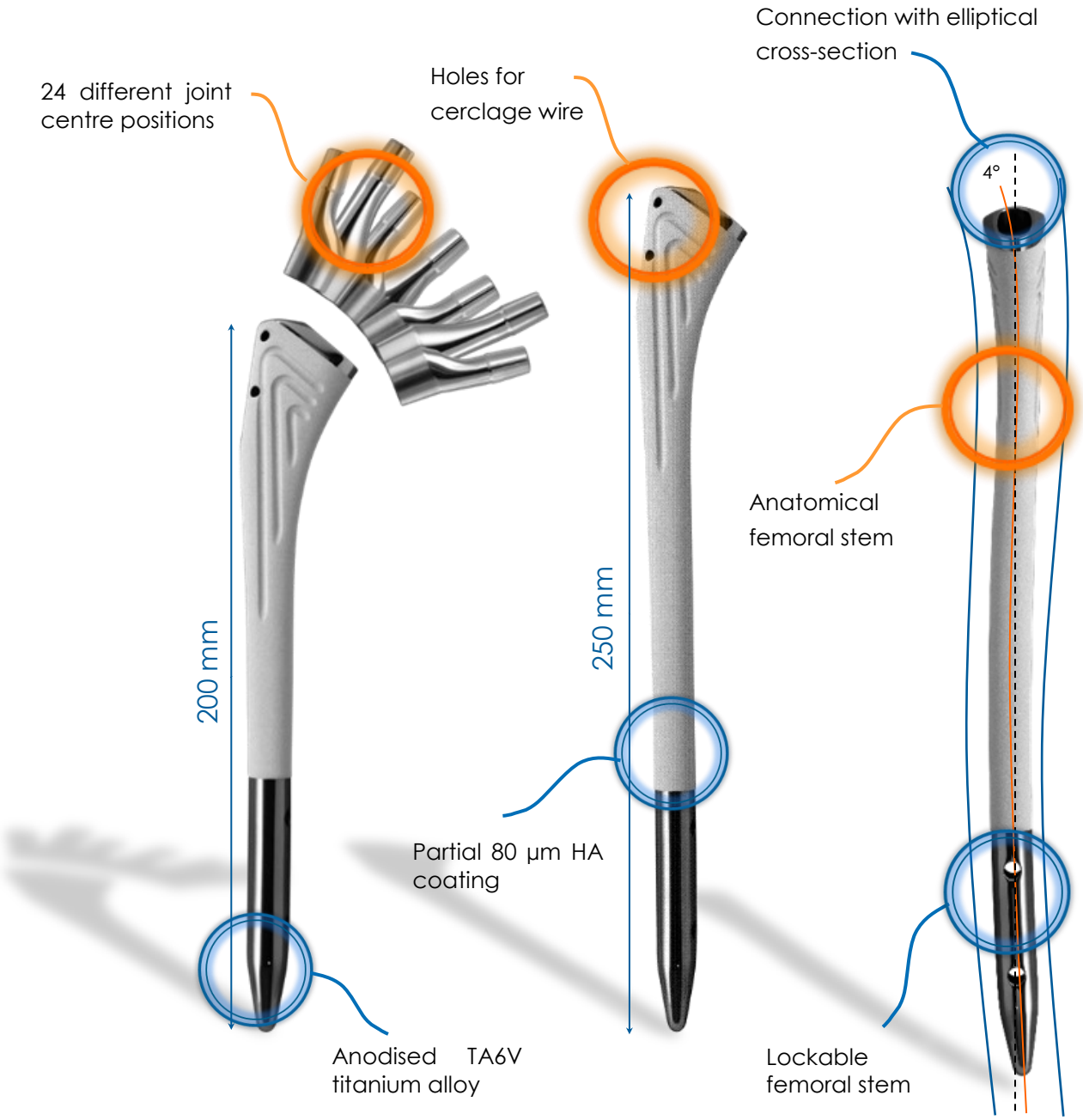
Sizes
22.2 – 28 – 32 mm

M30NW

Size	Head length
Ø 22,2 mm	S −2 mm M 0 mm L +2 mm
Ø 28 mm	S −3.5 mm M 0 mm L +3.5 mm XL +7.5 mm
Ø 32 mm	S −4 mm M 0 mm L +4 mm

OPTIMAL® REVISION/RECONSTRUCTION STEM

The OPTIMAL® stem is a cementless femoral stem indicated* for complex primary, revision and femoral reconstruction cases. It is an anatomical stem with a modular neck that is locked by threaded pins. It is available in two lengths: 200 mm and 250 mm.



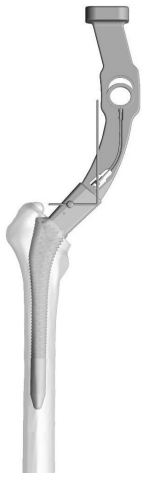
*The indications and contraindications are described in the IFU provided with this device.

SUMMARY OF SURGICAL TECHNIQUE

NON-LOCKING VERSION

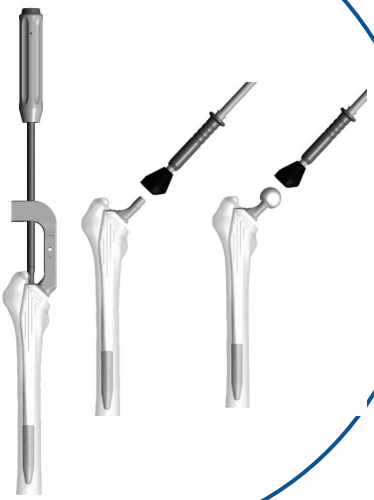
1 Preparation of greater trochanter and diaphysis

2 Intramedullary preparation



3 Trials

4 Insertion of chosen implants

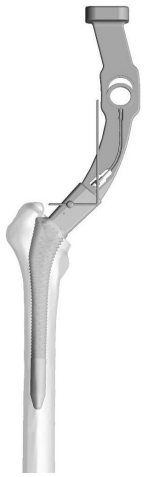


SUMMARY OF SURGICAL TECHNIQUE

LOCKING VERSION

1 **Preparation of greater trochanter and diaphysis**

2 **Intramedullary preparation**



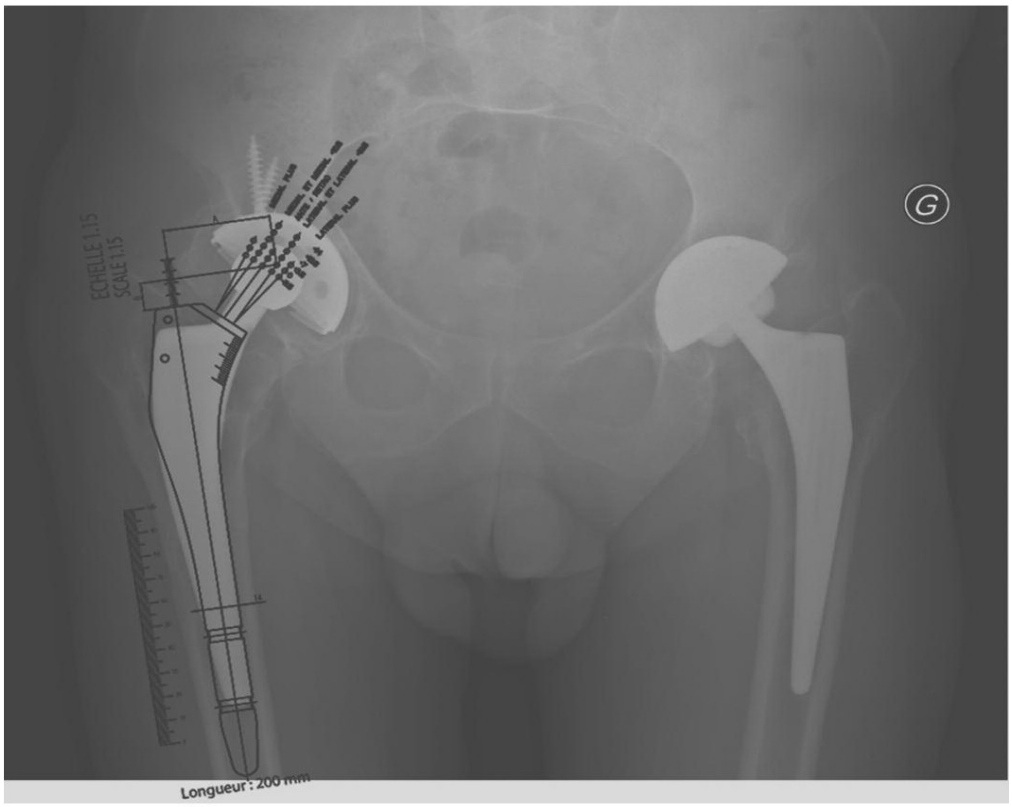
3 **Trials**

4 **Insertion of chosen implants**

IMPORTANT:

Refer to recommendations on page 28 to ensure good stem locking

PLANNING



The provided templates are superimposed over X-rays to:
- evaluate the metaphyseal bone loss in revision cases;
- locate the joint centre and infer the position of the replacement femoral head centre;
- decide on a reliable bony landmark, which can be identified intra-operatively, that will be used to identify the replacement joint centre. This landmark will be used throughout the procedure to recreate the joint centre's position in revision cases;
- estimate the size and length of the femoral stem to be implanted.

For primary arthroplasty cases or those without a pre-existing femorotomy, it will be necessary to:
- locate the femoral shaft axis;
- prepare the greater trochanter so it is not weakened when passing instruments and to avoid varus stem positioning.

For revision cases:
After having approached and exposed the existing implants, but before extracting the existing femoral stem, the bony landmark (e.g. greater trochanter, lesser trochanter, fracture line, femorotomy line, wire cerclage or a user-created landmark) selected during the preoperative planning will have to be confirmed.

REMINDER

The purpose of this surgical technique description is to provide instructions on how to use the instrumentation properly. The surgeon is fully responsible for choosing and performing the approach and surgical technique.

FEMORAL SHAFT PREPARATION

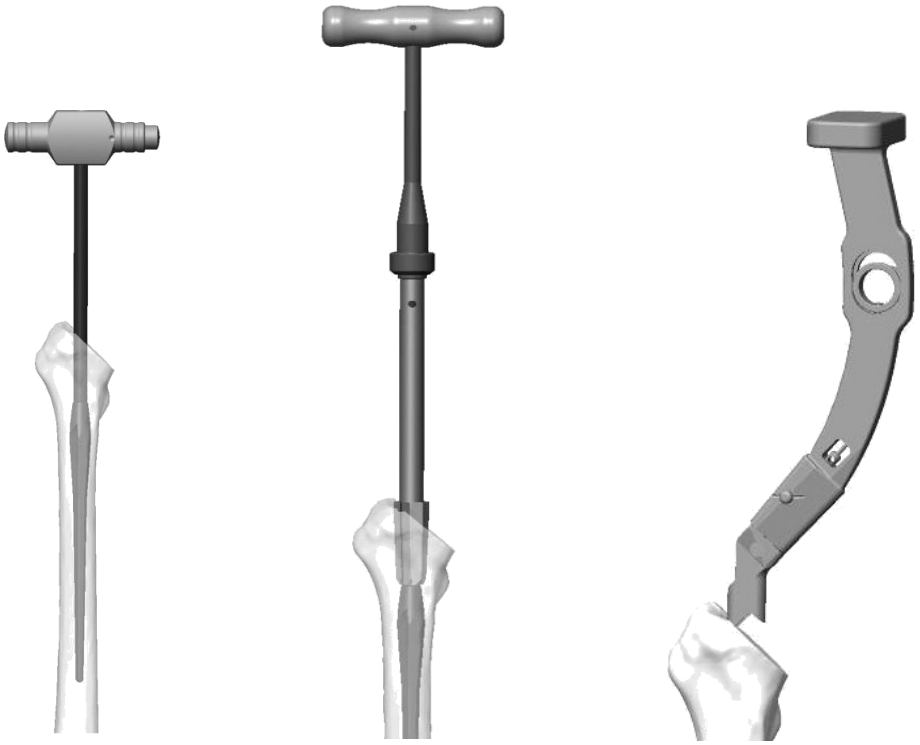
Expose the joint and cut the femoral neck using the surgeon's preferred method in cases of primary arthroplasty.

Place the reaming guide in the medullary canal.

Mount the smallest reaming head (9 mm diameter) on the flexible drive shaft and slide the entire unit on the reaming guide. Mount the surgical motor on the end of the drive shaft.

Ream the intramedullary canal using progressively larger reaming heads (1 mm increments) until the reamer makes contact with the cortex. The goal is to achieve press fit over enough of the shaft to provide good implant stability without the threaded pins. The diameter of the final reaming head must be 2 mm greater than the diameter of the stem being implanted.

GREATER TROCHANTER PREPARATION



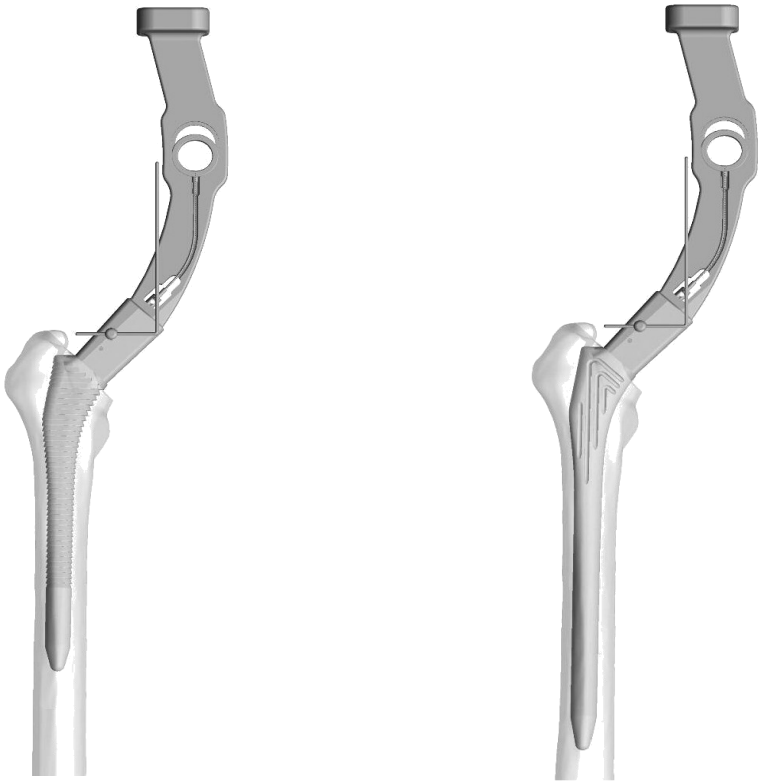
Assemble the removable handle with the trochanter reaming guide and stabilise the entire unit in the femoral shaft.

Remove the handle and push the trochanter reamer onto the guide.
The trochanter is prepared manually using the reamer holder.

NOTE

The trochanter can also be prepared using a box chisel mounted on the broach handle.

MEDULLARY CANAL PREPARATION



Mount the femoral broach corresponding to the operated side on the broach handle (grey broaches for left side and yellow broaches for right side).

Start with the size 1 broach and push it down into the femoral shaft; change to the next size up and repeat the procedure until satisfactory metaphyseal filling and stability are achieved. Check the depth by placing the blunt K-wire on the broach handle.

This K-wire represents a horizontal projection of the centre of the replacement femoral head with a lateralised neck and a medium length head to view the position of the joint centre relative to the previously selected bony landmark.

If the 200-mm long stem is being implanted: leave the final broach used in the femur to act as a trial implant and remove the broach handle.

If the 250-mm long stem is being implanted: remove the final broach used and replace it with the 250-mm long trial stem of the same size as the last broach. Place the trial stem onto the broach handle and push it into the femur, making sure not to force it in. The trial stem must be allowed to position itself. Check the depth using the blunt K-wire and remove the broach handle.

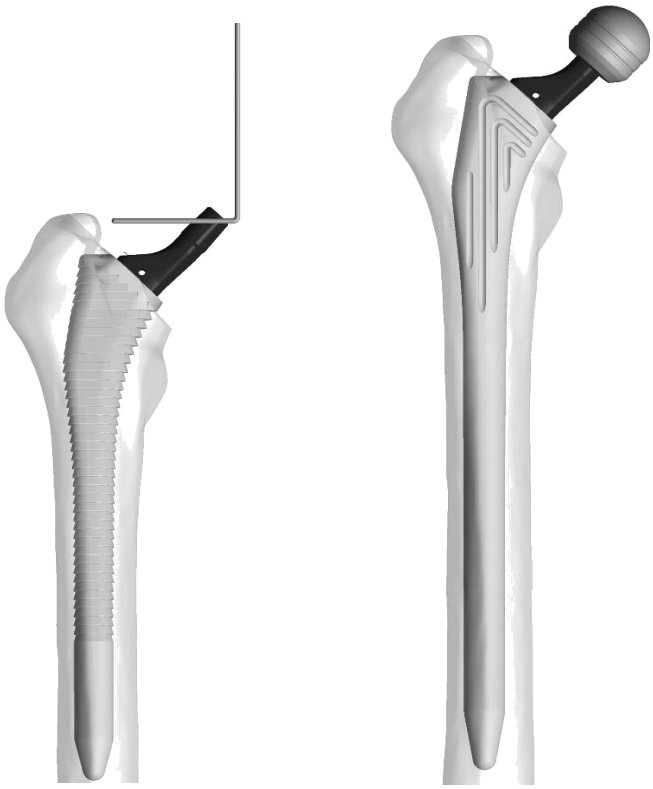
REMINDER

The final reamer must be 2 mm larger than the diameter of the stem being implanted.

NOTE

As progressively larger broaches are being used, make sure the reamed diameter corresponds to the broach's distal diameter. Refer to page 3 for the available stem diameter.

EXTRA-MEDULLARY TRIALS



Place the LATERAL trial modular neck (blue neck) onto the broach or trial stem.

Select and place a trial head of the desired length and diameter onto the neck.

Reduce using the modular neck-head impactor mounted on the universal handle.

Test the joint range of motion and stability to validate the extramedullary parameters.

If the joint range of motion and stability are unsatisfactory, redo the trials until the most appropriate trial modular neck and head are found to achieve the desired correction.

Remove the selected trial head and modular neck.

Use the broach handle to extract the broach or trial femoral stem.

On the back table, keep the selected components together (broach or trial stem with trial modular neck and trial head) until the final implant combination is ready.

Colour coding for trial heads:

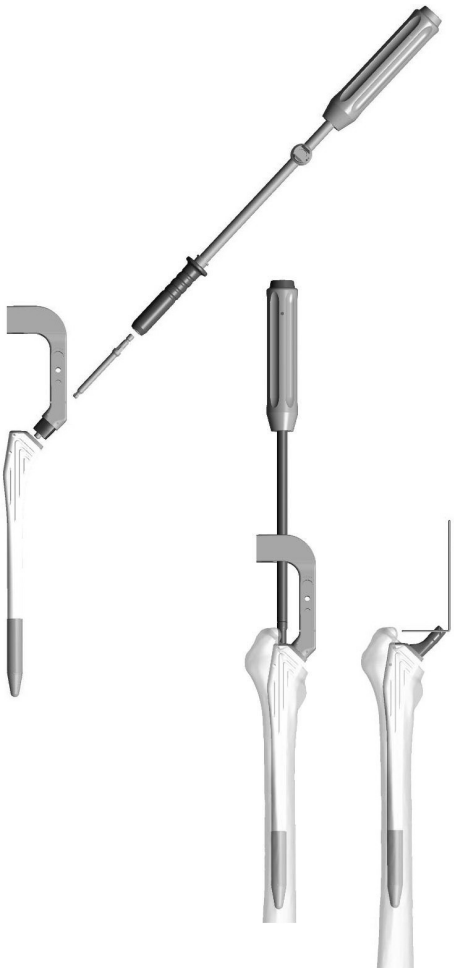
IMPORTANT:

Please comply with the following recommendations on acceptable modular neck/head combinations:

			FEMORAL HEADS			
			Short	Medium	Long	Extra-Long
MODULAR NECKS	L/M	Position Lateral& Medial	✓	✓	✓	✗
	Ante/Retro	Position anteverted & retroverted	✓	✓	✓	✓
	L+/M+	Position Lateral	90 kg max. patient weight	90 kg max. patient weight	90 kg max. patient weight	✗
		Position Medial	✓	✓	✓	✗
	L+10.5/M+10.5	Position Lateral & Medial	90 kg max. patient weight	90 kg max. patient weight	✗	✗

Table: Modular neck/femoral head combinations

NON-LOCKING VERSION: IMPLANTING THE CHOSEN STEM



Remove the protective elastomer cap from the oblong opening on the stem.

Assemble the implant holder with the selected stem using the spherical tip and universal handle. **Make sure everything is tight.**

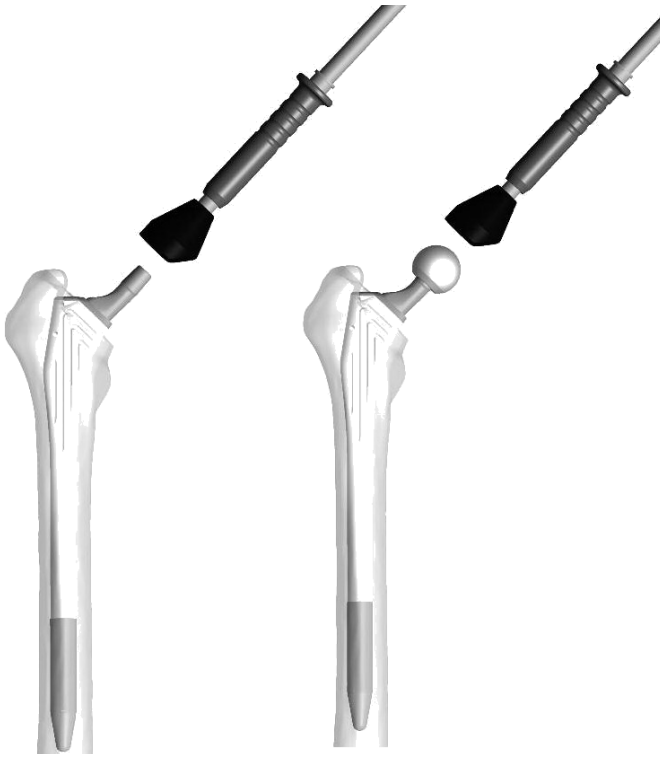
To ensure the stem is properly aligned when it is impacted into the femur, align the impactor carefully on the implant holder before impaction. A groove on the implant holder indicates the height of the centre of the femoral head with medium collar and a Lateral neck. Verify that the depth matches the one planned before the surgery.

Unscrew the implant holder.

Place the trial modular neck on the stem to validate the joint stability and range of motion. If these are unsatisfactory, change the trial neck.

Verify the height of the replacement head centre relative to the anatomical landmark by placing the blunt K-wire in the slot on the trial neck, which indicates the height of the centre of the head with medium collar and Lateral neck.

NON-LOCKING VERSION: IMPLANTING THE HEAD AND NECK



IMPORTANT:

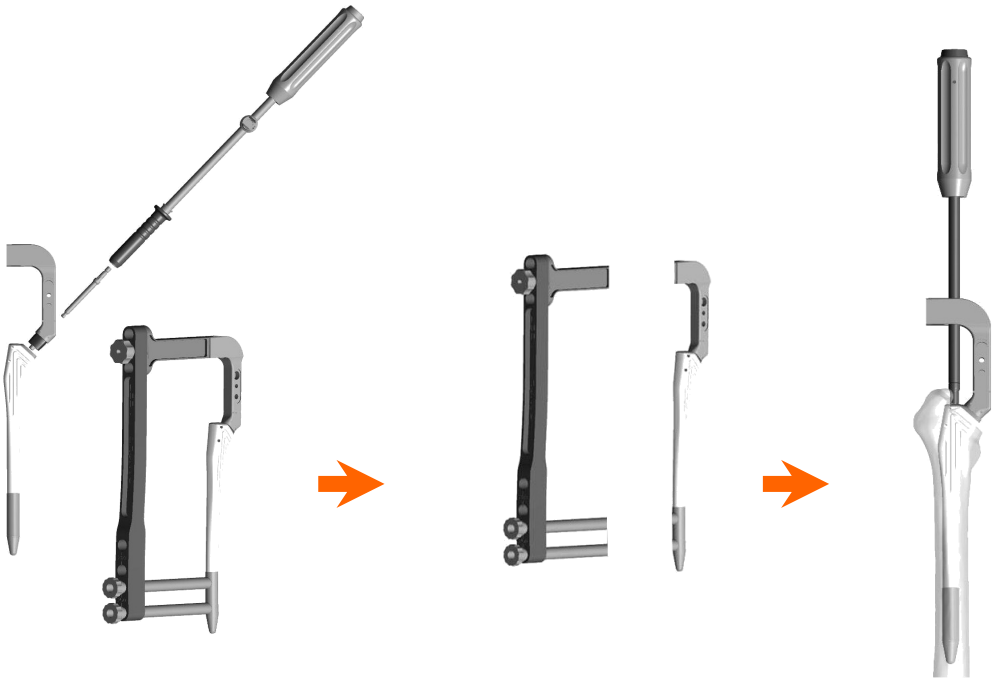
Make sure the connection between the stem and modular neck is clean and completely dry. The condition of the oblong Morse taper on the stem must be carefully inspected before inserting the modular neck. If the taper is damaged, the modular stem itself must be extracted and replaced.

Place the selected modular neck into the oblong opening, while maintaining the position validated during the trials and in accordance with the trial implants kept on the back table.

Impact the modular neck using the head-neck impactor mounted on the universal handle. The impactor has a cavity where the proximal part of the modular neck is inserted.

Use the head gripping tip to place the selected head onto the neck, then impact it with the head-neck impactor mounted on the universal handle. Reduce the joint.

LOCKING VERSION: IMPLANTING THE CHOSEN STEM



On the back table:
Remove the protective elastomer cap from the oblong opening on the stem.

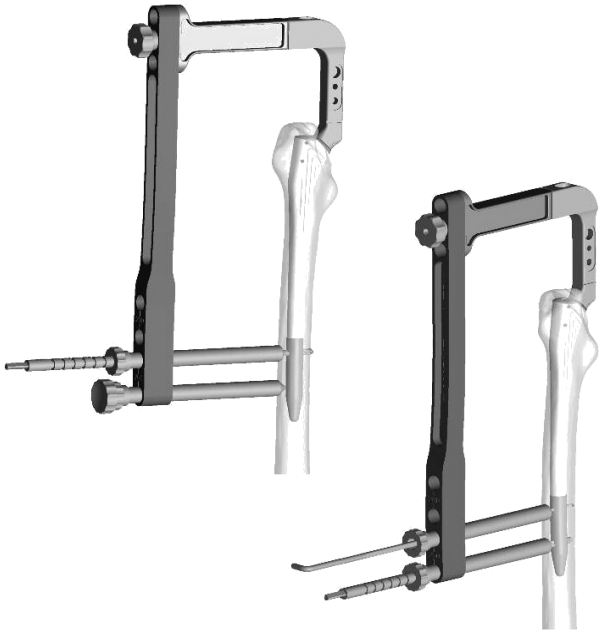
Assemble the implant holder with the selected stem using the spherical tip and universal handle. **Make sure everything is tight.**

Mount the offset shaft onto the alignment guide corresponding to the operated side, tighten everything with the clamping screw and then position the entire unit on the implant holder.

Make sure the drilling barrels and drill bits placed in the guide are aligned with the locking holes on the stem's shaft. The drilling level is indicated on the guide relative to the length of the stem being implanted. Remove the alignment guide and the offset shaft from the implant holder.

On the patient:
Align the impactor on the implant holder and then impact the stem into the femur. A groove on the implant holder indicates the height of the centre of the femoral head with medium collar and lateralised neck. Verify that the depth matches the one planned before the surgery.

LOCKING VERSION: LOCKING THE CHOSEN STEM



Once the stem is in place, put the offset shaft and drilling alignment guide back into the implant holder.

Secure everything together with the clamping screw.

Locate the two selected drilling levels on the alignment guide.

Install the two drilling barrels. Place the blunt drill guide in the proximal hole on the alignment guide.

Use a scalpel to make an incision in the skin then the fascia lata. **A wider incision should be made to make it easier to pass instruments.**

Push the blunt drill guide until it touches the bone. Remove the guide.

Make sure the barrel touches the bone.

Drill the proximal hole through both cortices using drill bit No. 1 for threaded pins. Leave the bit in place to stiffen the construct.

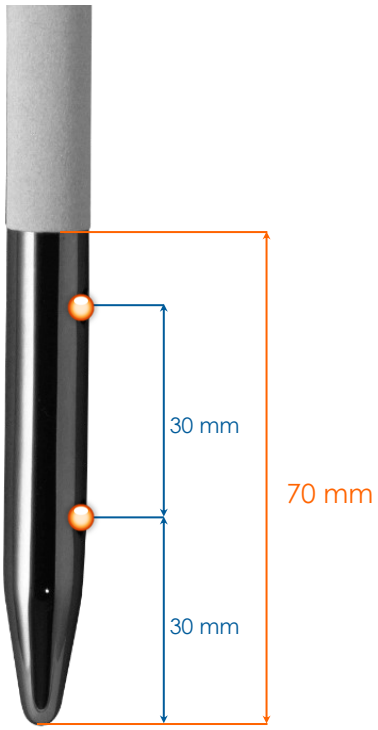
Place the blunt drill guide in the distal hole on the drilling alignment guide. Make an incision through the skin and fascia lata. Push the blunt drill guide until it touches the bone. Remove the guide.

Make sure the barrel touches the bone.

Drill the proximal hole through both cortices using drill bit No. 2 for threaded pins.

NOTE
A small incision can also be made to verify whether the drilling barrels touch the femoral cortex.

LOCKING VERSION: LOCKING THE CHOSEN STEM



Remove the proximal drill bit and use the threaded pin size gauge to determine the length of the threaded pin needed. The threaded pin is then inserted with the short H5 screwdriver (for stem locking). Continue turning the screw until the mark on the screwdriver is flush with the drilling barrel.

The second threaded pin is inserted the same way, except that the long H5 screwdriver is used.

Remove the stem locking frame (offset shaft, alignment guide and screw) and implant holder using the spherical tip and universal handle.

Place the trial modular neck on the stem to validate the joint stability and range of motion. If these are unsatisfactory, change the trial neck.

Verify the height of the replacement head centre relative to the anatomical landmark, by placing the blunt K-wire in the slot on the trial neck; the horizontal projection of the femoral head centre corresponds to the blunt K-wire and a lateralised neck and head with medium collar.

LOCKING VERSION: IMPLANTING THE HEAD AND NECK

IMPORTANT:

Make sure the connection between the stem and modular neck is clean and completely dry. The condition of the oblong Morse taper on the stem must be carefully inspected before inserting the modular neck. If the taper is damaged, the modular stem itself must be extracted and replaced.

Place the selected modular neck into the oblong opening, while maintaining the position validated during the trials and in accordance with the trial implants kept on the back table.

Impact the modular neck using the head-neck impactor mounted on the universal handle. The impactor has a cavity where the proximal part of the modular neck is inserted.

Use the head gripping tip to place the selected head onto the neck, then impact it with the head-neck impactor mounted on the universal handle. Reduce the joint.

IMPLANT EXTRACTION (MODULAR NECK AND STEM)

Neck:
Remove the femoral head by tapping around the underside of the head.

Place the neck disconnector over the modular neck, making sure the disconnector's mobile shaft is located just above the taper of the femoral head.

Tighten the mobile shaft with the H5 spherical tip mounted on the universal handle.

Mount the reamer holder on top of the disconnector.

Hold the disconnector with the 19 wrench and use the reamer holder to turn it until the neck is extracted.

Stem:
Once the modular neck has been extracted, screw the modular femoral stem extractor into the oblong opening on the stem using the H5 spherical tip mounted onto the universal handle.

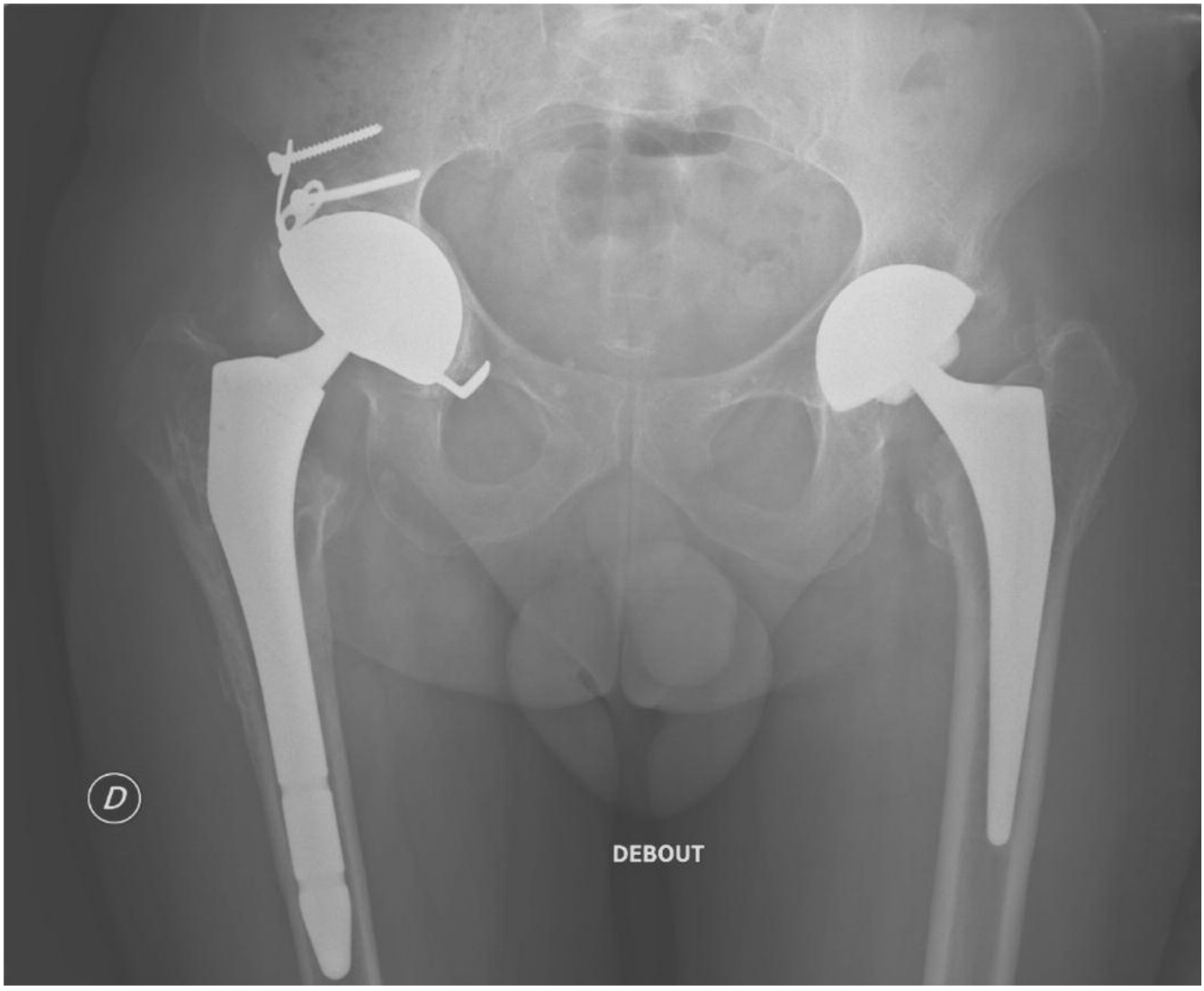
Make sure the extractor is aligned with the stem axis.

Place the shaft and slap hammer cylinder on the femoral stem extractor and then extract the stem. Keep the slap hammer aligned with the stem axis during extraction.

NOTE

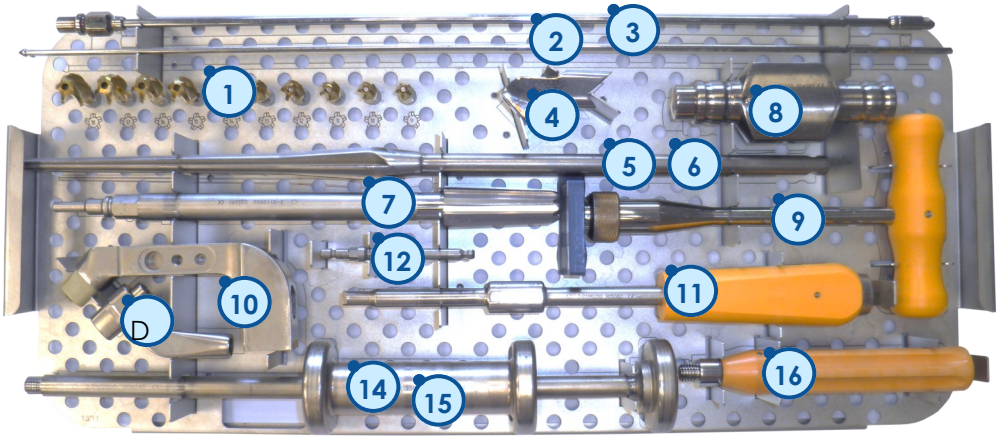
If the stem has been locked, extract the threaded pins with the H5 screwdriver (for OPTIMAL® stem locking) before attempting to extract the stem.

POSTOPERATIVE X-RAYS



INSTRUMENTATION

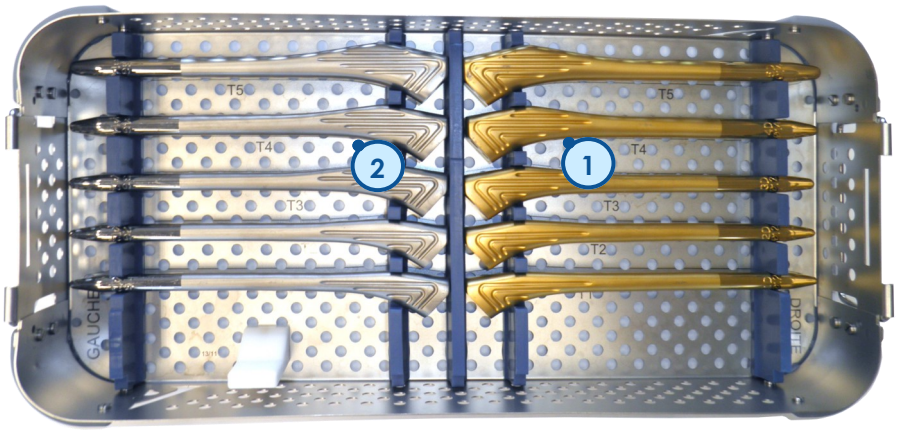
FEMORAL PREPARATION SET (TRAY) 2-0199963



Item	Name	Reference	Qty.
1	Reaming head **Ø9** mm to **Ø18** mm	MAL319009ONT MAL3190018ONT	1 of each
2	Flexible drive shaft Nitinol	MAF219004954701N	1
3	Flexible reamers reaming guide D3 lg 500 mm	2-0197300	2
4	Box chisel	2-0116300	1
5	Canal finder for trochanteric reamer 12x10	2-0197012	1
6	Canal finder for trochanteric reamer 18x10	2-0197018	1
7	Trochanteric reamer	2-0110900	1
8	Movable handle	2-0109300	1
9	Reamer handle	2-0103500	1
10	OPTIMAL stem prothesis handle	2-0196300	1
11	OPTIMAL stem impactor/orientator	2-0196200	1
12	Spherical tip H5	2-0115700	1
13	Modular femoral stem extractor - Optimal	2-0196900	1
14	Slap hammer shaft	2-0102900	1
15	Slap hammer cylinder	2-0103300	1
16	Holding handle	2-0104200	1

INSTRUMENTATION

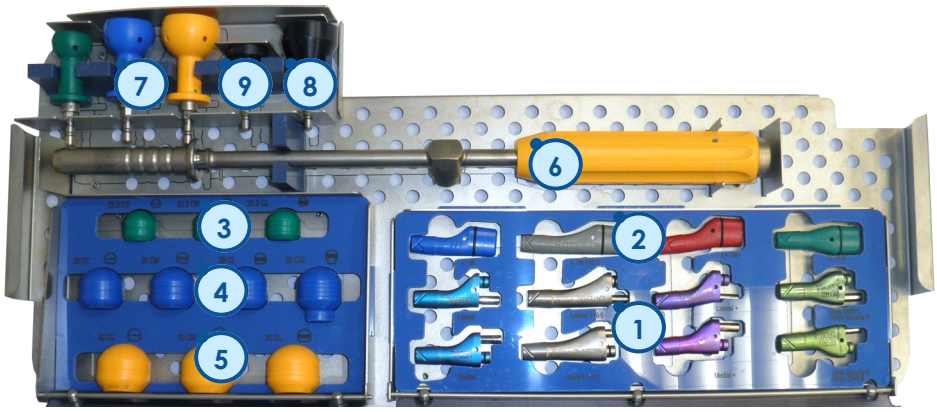
TRIAL STEM SET (TRAY) 2-0199963



Item	Name	Reference	Qty.
1	Trial OPTIMAL reconstruction stem - Right D 12 Size 1	2-0195901	1
1	Trial OPTIMAL reconstruction stem - Right D 12 Size 2	2-0195902	1
1	Trial OPTIMAL reconstruction stem - Right D 12 Size 3	2-0195903	1
1	Trial OPTIMAL reconstruction stem - Right D 14 Size 4	2-0195904	1
1	Trial OPTIMAL reconstruction stem - Right D 14 Size 5	2-0195915	1
2	Trial OPTIMAL reconstruction stem - Left D 12 Size 1	2-0196001	1
2	Trial OPTIMAL reconstruction stem - Left D 12 Size 2	2-0196002	1
2	Trial OPTIMAL reconstruction stem - Left D 12 Size 3	2-0196003	1
2	Trial OPTIMAL reconstruction stem - Left D 14 Size 4	2-0196004	1
2	Trial OPTIMAL reconstruction stem - Left D 14 Size 5	2-0196015	1

INSTRUMENTATION

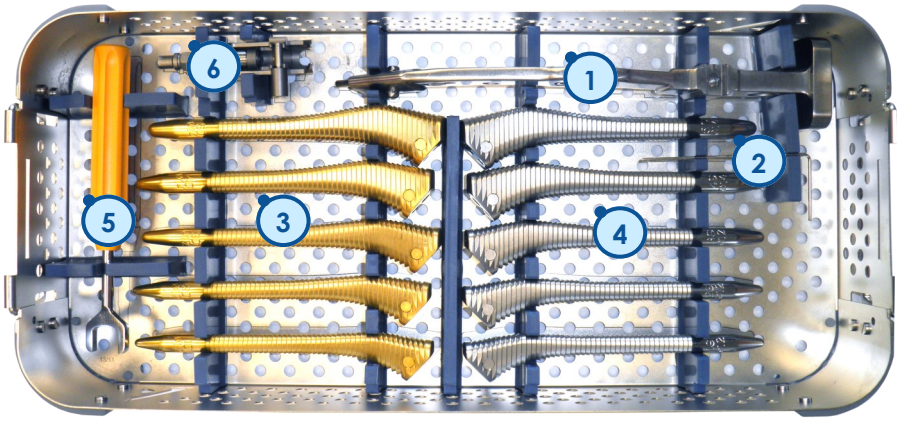
TRIAL HEAD AND NECK SET (TRAY) 2-0199963



Item	Name	Reference	Qty.
1	Modular trial neck on broach - LATERAL 10/12 Modular trial neck on broach - MEDIAL 10/12 Modular trial neck on broach - LATERAL PLUS 10/12 Modular trial neck on broach - MEDIAL PLUS 10/12 Modular trial neck on broach - ANTE LEFT/ RETRO RIGHT 8° 10/12 Modular trial neck on broach - ANTE RIGHT/RETRO LEFT 8° 10/12 Modular trial neck on broach - LATERAL +10,5 10/12 Modular trial neck on broach - MEDIAL +10,5 10/12	2-0116401 2-0116402 2-0116403 2-0116404 2-0116405 2-0116406 2-0116409 2-0116410	1
2	Modular trial neck on stem LATERAL/MEDIAL 10/12 Modular trial neck on stem ANTE / RETRO 8° 10/12 Modular trial neck on stem LATERAL + / MEDIAL + 10/12 Modular trial neck on stem LATERAL / MEDIAL +10.5 10/12	2-0116101 2-0116102 2-0116103 2-0116105	1
3	Trial head on stem Ø 22.2 short neck Trial head on stem Ø 22.2 medium neck Trial head on stem Ø 22.2 long neck	2-0100405 2-0100406 2-0100407	1
4	Trial head on stem Ø 28 short neck Trial head on stem Ø 28 medium neck Trial head on stem Ø 28 long neck Trial head on stem Ø 28 extra long neck	2-0100401 2-0100402 2-0100403 2-0100404	1
5	Trial head on stem Ø 32 short neck Trial head on stem Ø 32 medium neck Trial head on stem Ø 32 long neck	2-0100408 2-0100409 2-0100410	1
6	Universal holding wrench - Conventional/navigated	2-0117600	1
7	Femoral head gripping tip Ø 22.2 Femoral head gripping tip Ø 28 Femoral head gripping tip Ø 32	2-0104322 2-0104328 2-0104332	1
8	Femoral head and modular neck impactor	2-0115800	1
9	Impactor for Ø22.2 Heads	2-0101400	1

INSTRUMENTATION

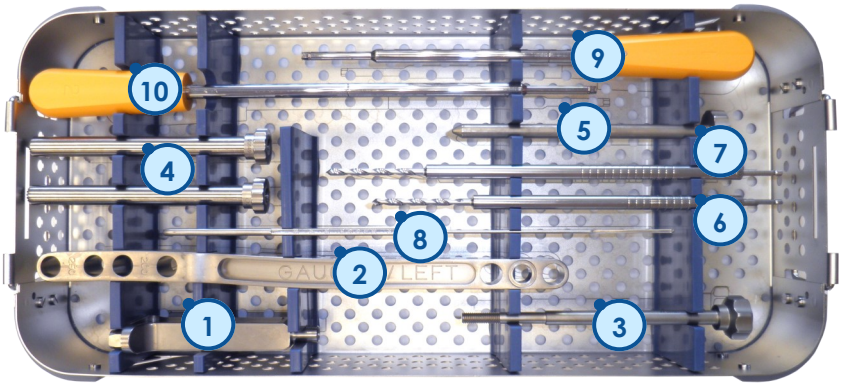
BROACH SET (TRAY) 2-0199963



Item	Name	Reference	Qty.
1	Straight broach handle conventional/navigation	2-0116901	1
2	Blunt K-wire Ø 2 A/P	2-0114000	1
3	OPTIMAL revision femoral broach - Right D12 Size 1	2-0195701	1
3	OPTIMAL revision femoral broach - Right D12 Size 2	2-0195702	1
3	OPTIMAL revision femoral broach - Right D12 Size 3	2-0195703	1
3	OPTIMAL revision femoral broach - Right D14 Size 4	2-0195704	1
3	OPTIMAL revision femoral broach - Right D14 Size 5	2-0195715	1
4	OPTIMAL revision femoral broach - Left D12 Size 1	2-0195801	1
4	OPTIMAL revision femoral broach - Left D12 Size 2	2-0195802	1
4	OPTIMAL revision femoral broach - Left D12 Size 3	2-0195803	1
4	OPTIMAL revision femoral broach - Left D14 Size 4	2-0195804	1
4	OPTIMAL revision femoral broach - Left D14 Size 5	2-0195815	1
5	19 mm wrench	2-0118400	1
6	Modular neck remover	2-0116200	1

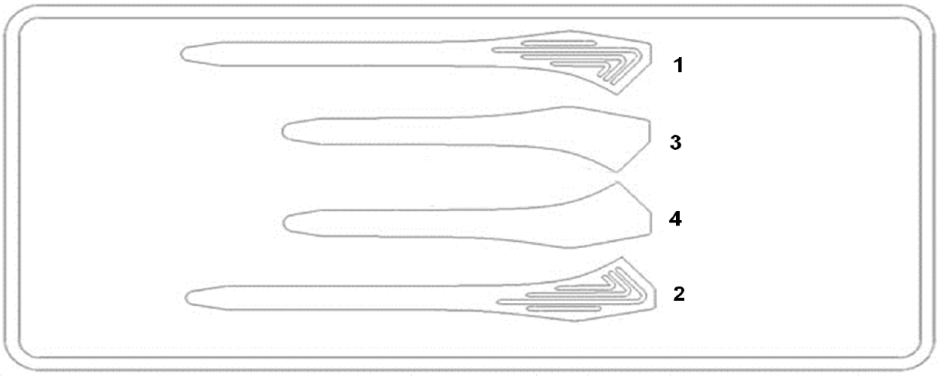
INSTRUMENTATION

LOCKING SET (TRAY) 2-0199963



Item	Name	Reference	Qty.
1	Offset shaft for OPTIMAL stem	2-0196400	1
2	Drilling alignment guide for OPTIMAL stem	2-0196700	1
3	Clamping screw for OPTIMAL stem drilling alignment guide	2-0196500	1
4	Drilling barrel	2-0109600	2
5	Blunt drill guide	2-0110600	1
6	Drill bit No. 1 for OPTIMAL threaded pin	2-0196600	1
7	Drill bit No. 2 for OPTIMAL threaded pin	2-0198000	1
8	OPTIMAL pin sizer	2-0197700	1
9	Short H5 screwdriver for OPTIMAL locking	2-0197800	1
10	Long H5 screwdriver for OPTIMAL locking	2-0197900	1

OPTIMAL® S5 Ø16 STEM SET 2-0199971



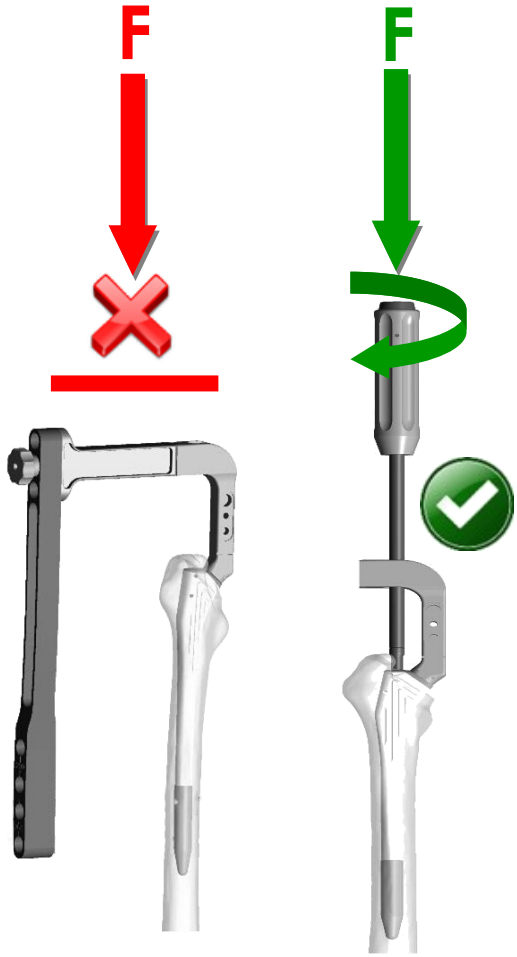
Item	Name	Reference	Qty.
1	Trial stem – size 5 right D16 for OPTIMAL reconstruction stem	2-0195905	1
2	Trial stem – size 5 left D16 for OPTIMAL reconstruction stem	2-0196005	1
3	Broach size 5 right D16 for OPTIMAL revision stem	2-0195705	1
4	Broach size 5 left D16 for OPTIMAL revision stem	2-0195805	1

RECOMMENDATIONS

1 STEM IMPACTION AND ORIENTATION

When implanting the stem, **do not impact the frame while it is mounted on the stem** as this may **jeopardise the alignment of the drilling barrels** (drill bits) with the holes in the stem.

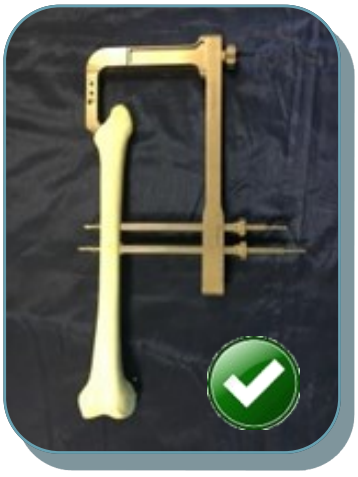
The frame **must be disassembled** after the trials on the back table and re-assembled after stem impaction. **Striking force should only be applied through the provided impactor.**



2 USE THE TWO DRILL BITS TO MAKE THE HOLES
AVOID PUTTING PRESSURE ON THE FRAME DURING DRILLING

It is **essential to use both drill bits from the instrumentation set** to make the holes where the threaded pins will be inserted. Leave drill bit No. 1 in place to stiffen the construct proximally and drill the second hole using drill bit No. 2, making sure to cross both cortices each time. Leave drill bit No. 2 in place while assembling the first threaded pin.

Avoid putting pressure on the frame during drilling as this could misalign the drill bit and jeopardise the frame's correct alignment.



NOTES

NOTES

Référence : TO.H.GB.104/1.0

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