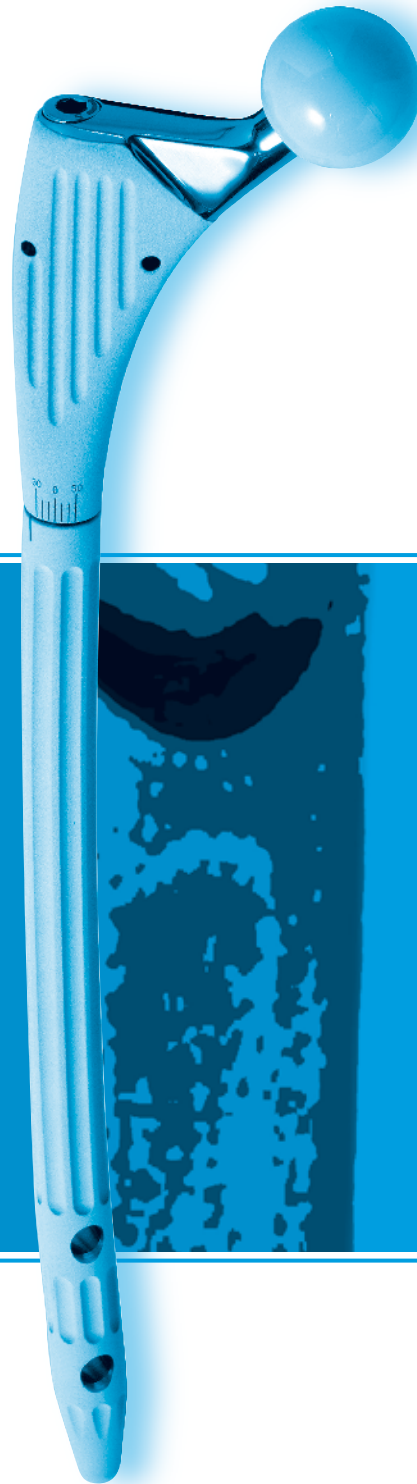


Surgical technique for conventional instrumentation



EXTREME[®]
Cementless reconstruction
femoral stem

AMPLITUDE 

Design of the EXTREME® femoral stem

- The EXTREME® stem product line has been designed for revision and extensive reconstruction cases.
- This cementless, lockable femoral stem allows independent adjustment and customised fit of the diaphysis and metaphyseal/epiphyseal components to optimise bone anchoring and joint stability.
- For femur reconstruction indications, the EXTREME® stem's modularity allows the following elements to be adapted to the patient:
 - Length
 - Diaphysis diameter
 - Diaphysis curvature
 - Metaphyseal filling
 - Metaphyseal torsion
 - Extramedullary anteversion.
- The two main components of the EXTREME® stem are assembled with a screw and two Morse tapers (small-angle taper technology).
- The quality of the impaction of the various modular components can be verified any time during the procedure with the provided instrumentation set.

Recommendations

IT IS NECESSARY TO VERIFY THE QUALITY OF THE IMPACTION BETWEEN THE MONOBLOCK EPIPHYSIS/METAPHYSIS AND THE DIAPHYSEAL NAIL.

- **Never strike the assembly screw during impaction. This screw must be tightened using the torque wrench provided in the AMPLITUDE instrumentation.**

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 the indication, surgical approach, surgical technique and postoperative protocol.

IMPORTANT: Flexible reamers will be needed in addition to the instrumentation set.



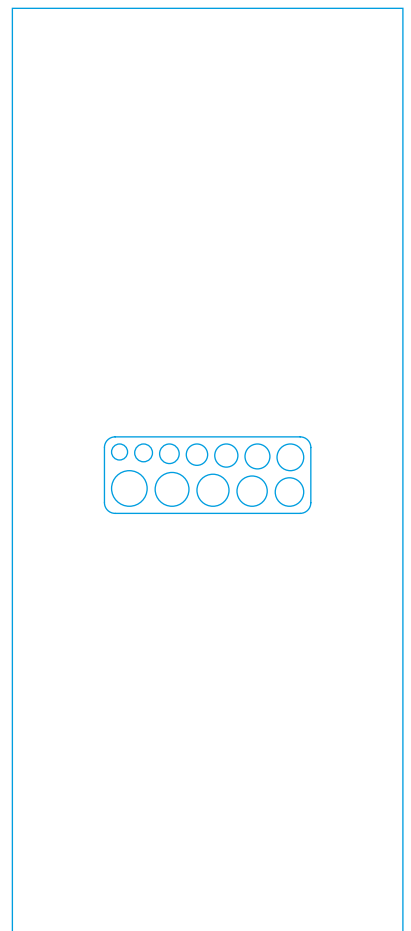
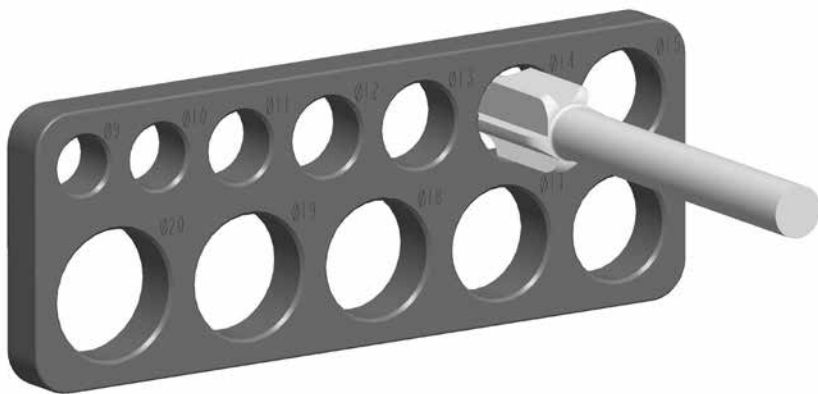
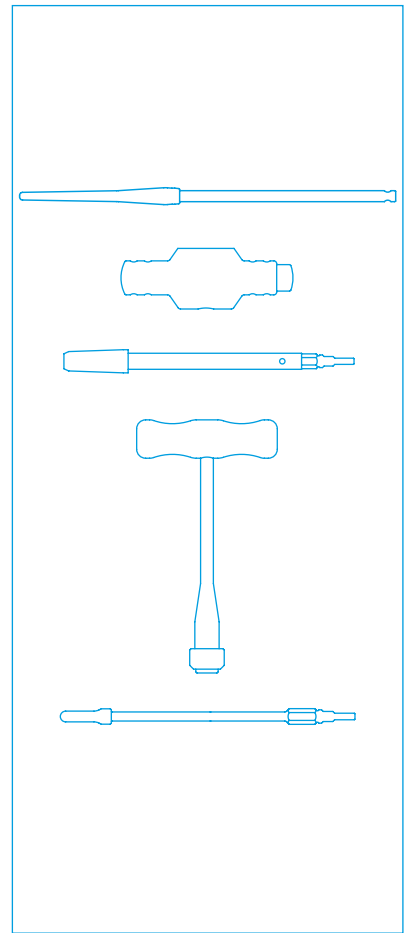
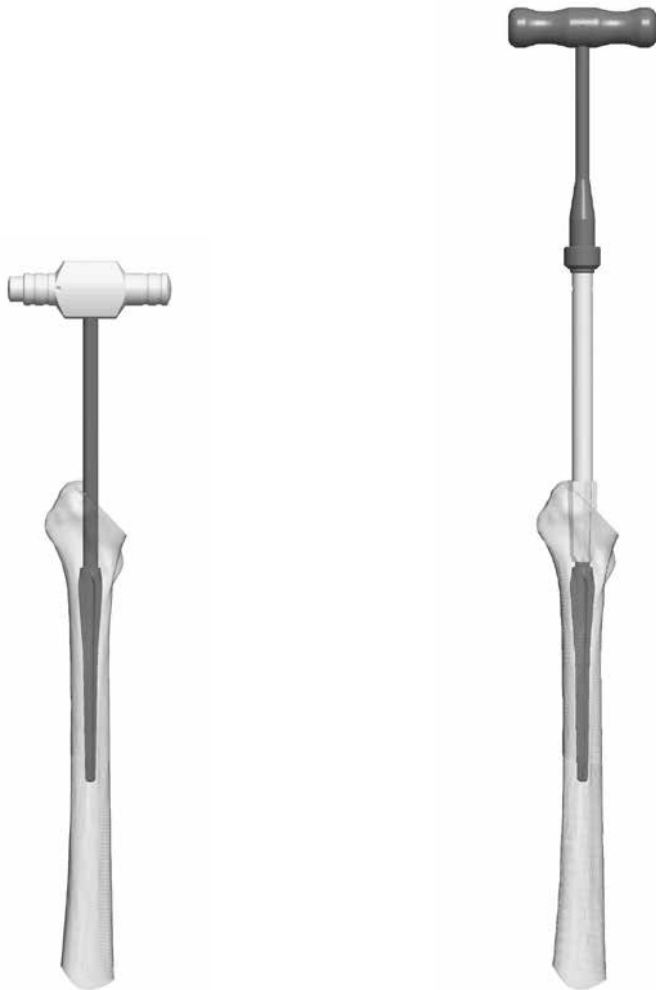
Preoperative planning

- Radiographs and templates are used to:
 - Estimate the metaphyseal bone loss;
 - Locate the centre of the hip joint (if changing the cup);
 - Select the height of the EXTREME® stem in the femur (same as or different to the stem being extracted);
 - The appropriate height is the distance between the horizontal projection of the centre of the planned femoral head and a reliable bone landmark. The provided instrumentation allows this measurement to be transferred and verified during the procedure (the horizontal projection of the femoral head centre corresponds to the blunt K-wire).
 - Determine the implant sizes, in particular the nail diameter;
 - Determine the screw length if the stem will be locked.
- Special case: if there is no proximal femur landmark to use when determining the implant position (e.g. multiple fractures), radiographs of the contralateral limb and the small ruler can be used for planning purposes. Transfer this information to the surgical procedure using the intramedullary gauge.

NB: Templates for the EXTREME® stem are available in 1x and 1.15x magnification. Please specify which one is preferred.

Intraoperative planning – Determining the height of the EXTREME® stem

- After having performed the surgical approach and exposed the joint, but before extracting the existing stem, the next step is to confirm:
 - The reliability of the femoral bone landmark (e.g. greater trochanter, lesser trochanter, fracture line, femorotomy line) chosen during the preoperative planning.
- Reminder:** For two-stage revision of infected stems, this femoral height landmark must be determined during the first stage, so it can be easily located during the second stage.
- The distance between the horizontal projection of the planned head centre and the chosen bone landmark. This distance will be transferred using the small ruler in the instrumentation set and can be verified at any point during the procedure.



Greater trochanter preparation

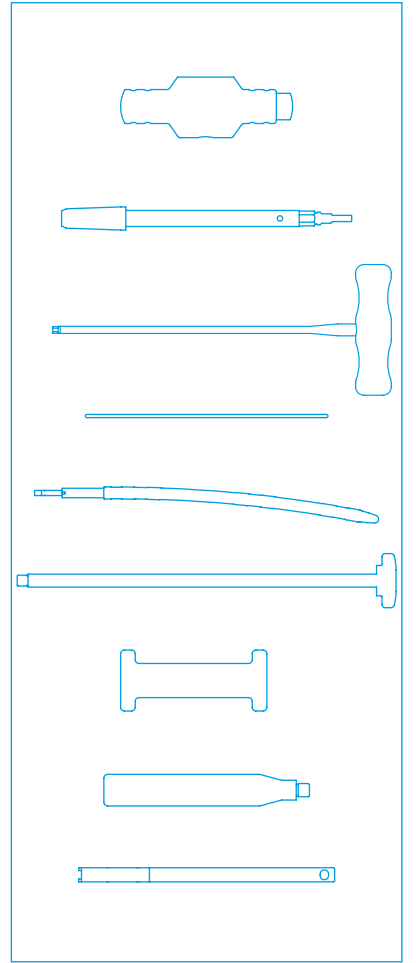
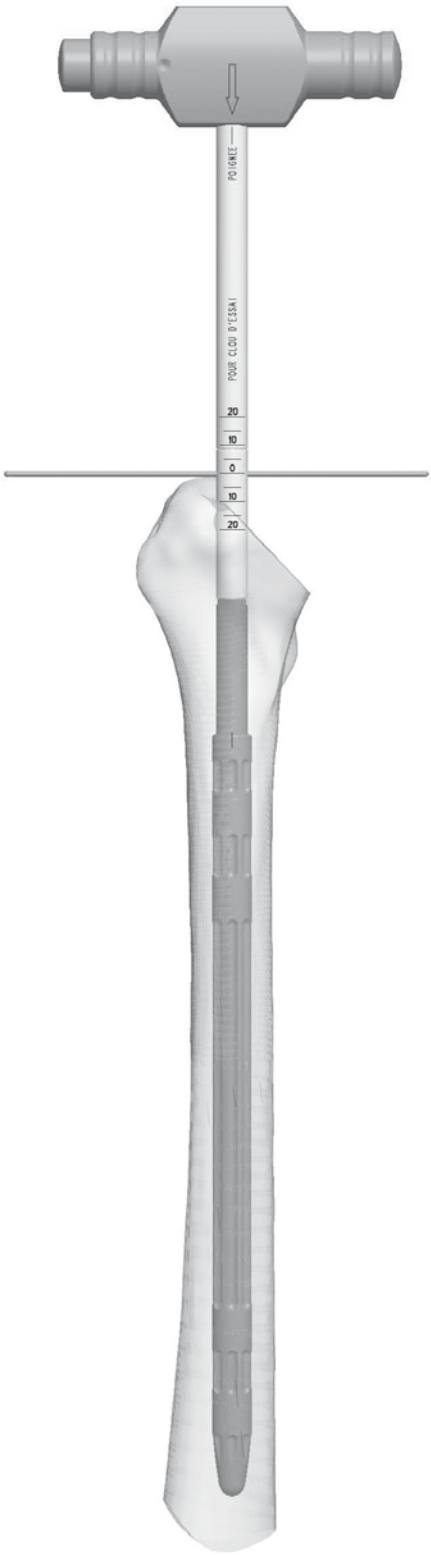
- With no prior femorotomy: it is essential to hollow out the greater trochanter to ensure it is not weakened by the instrumentation.
 - Assemble the removable handle with the trochanter reaming guide and stabilise the entire unit in the femur.
 - Remove the handle and push the trochanter reamer onto the guide. The trochanter is prepared manually using the reamer holder.

Note: If using a 10 or 12 mm diameter nail, after having used the trochanter reamer, you will need to use the reamer for Ø 10 mm or Ø 12 mm diaphyseal nail set up on the reamer holder. This will create a bevel in the area corresponding to the proximal flaring in the Ø 10 mm and Ø 12 mm nails. The reaming depth is determined using the line corresponding to the height of the femoral head centre (medium neck).

- If a femorotomy has been done: use bone nibblers to prepare the greater trochanter when closing the bone flaps on the implant at the end of the procedure.

Femoral shaft preparation

- If necessary, determine the reamer size using the provided reamer sizing tool.
- Prepare the medullary canal by inserting various flexible reamers with the guide until the desired diameter is reached. The aim is to match the diameter chosen during the preoperative planning to ensure the bone cortex is not too thin. The goal is to achieve press fit over enough of the shaft to provide good nail stability. The diameter of the final reamer must be 1.0 or 1.5 mm greater than the diameter of the nail being implanted.



Nail size selection

- The nail diameter and length were determined during the preoperative planning and during reaming. Use the trial nail to validate these measurements.
- Using the straight H5 screwdriver, assemble the trial nail extension piece on the trial nail of the chosen length and diameter. The diameter of the trial nail will be 1 mm or 1.5 mm less than the diameter of the last reamer used.
- Assemble the removable handle with the trial nail unit.
- Assemble the shaft for slap hammer, slap hammer weight and handle.
- Impact the trial nail into the diaphysis using the slap hammer. Make sure the nail's sagittal curvature is oriented correctly.
- The correct nail diameter is one that results in some resistance and a gradual descent during impaction.
- During impaction, the nail's position is defined by:
 - Rotation: the plane of the removable handle corresponds to the nail's frontal plane, which is required when impacting in the femur's frontal plane. Given the modularity between the neck and metaphysis components, some freedom in the nail's rotation is allowed to achieve a better intramedullary fit.
 - Depth: the blunt K-wire that crosses the extension piece for diaphyseal nail is a projection of the femoral head centre (medium neck). It must be positioned using the reliable bone landmark identified earlier in the procedure.

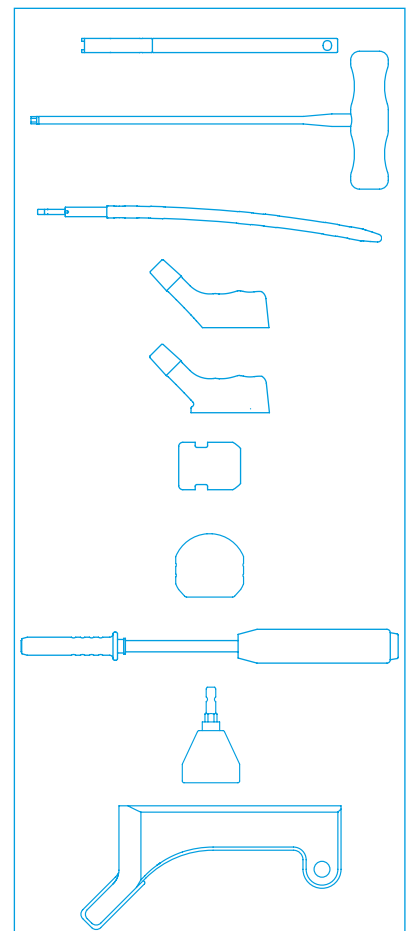
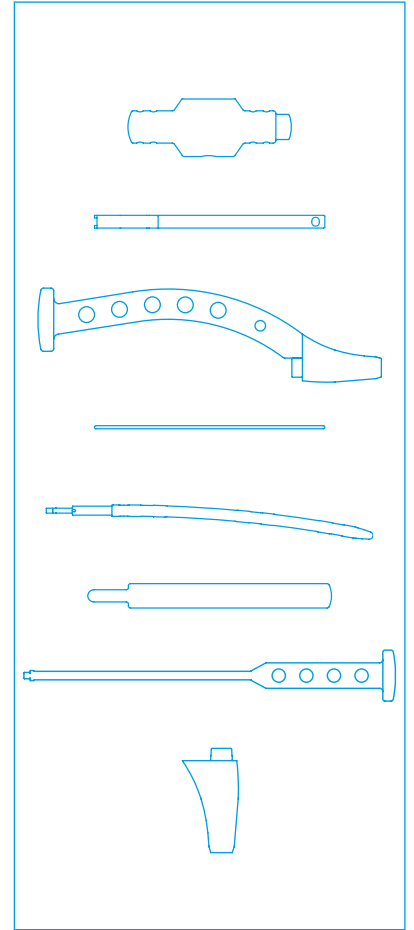
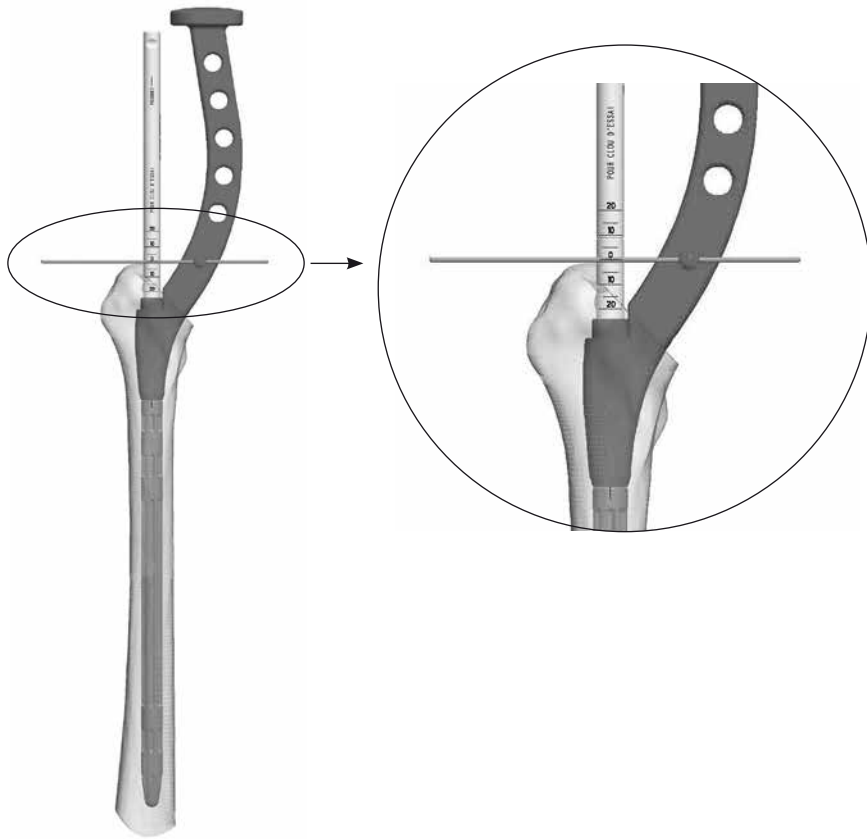
At this point in the procedure, the nail's stability will determine whether it needs to be locked.

Non-locked option (p. 10–13):

- Select the nail diameter that allows gradual descent into the shaft during impaction, while also providing satisfactory primary stability. The implantable nail has a 0.2 mm press-fit (at the diameter) relative to the trial nail, which ensures the femoral stem will be stable in the shaft.

Locked option (p. 14–19):

- If the nail descends into the shaft too easily to be spontaneously stable and the trial nail diameter cannot be increased any further (e.g. thin or weak cortices), use an implantable nail of the same diameter as the trial nail and then lock it.
- A femoral window will be needed to access the nail/metaphysis junction to remove any interposed bone or fibrous tissue.



OPTION: Non-locked

Metaphyseal preparation with trial nail

- Leave the trial nail and the extension piece in place in the femur at the chosen height.
- Remove the blunt K-wire and handle.
- Starting with a size 1 broach, insert the metaphyseal broaches on the extension piece while setting the desired anteversion. Continue this process with progressively larger broaches until the **best possible metaphyseal filling** is achieved.
- **Confirm that the metaphyseal broach is inserted as deep as possible against the trial nail:** place the blunt K-wire on the broach handle; it must line-up with the “o” mark on the trial nail extension piece (represents the horizontal projection of the femoral head centre). The metaphyseal broach now contacts the trial nail. Make sure the height is correct with each metaphyseal broach.
- Using the trial component holder, place the trial metaphysis of the size corresponding to the final broach used on the trial nail.
- **Confirm the trial metaphysis is inserted as deep as possible against the trial nail:** the top of the broach should be aligned with the mark on the trial nail extension piece.

Epiphysis preparation

- Remove the trial nail extension piece using the straight H5 screwdriver.
- Select a trial epiphysis of the **same size as the metaphysis** and position it by setting the anteversion/retroversion at 0°. Make sure the greater trochanter does not hinder the placement of the trial metaphysis.
- Secure all the components together using the lock-nut for trial components. Tighten it with the handle and straight H5 screwdriver. The components must be held tightly together to preserve the trial implant settings when they are extracted.
- Install the trial femoral head.

Trials

- Reduce the joint using the head impactor mounted on the universal handle.
- Test the range of motion and joint stability.

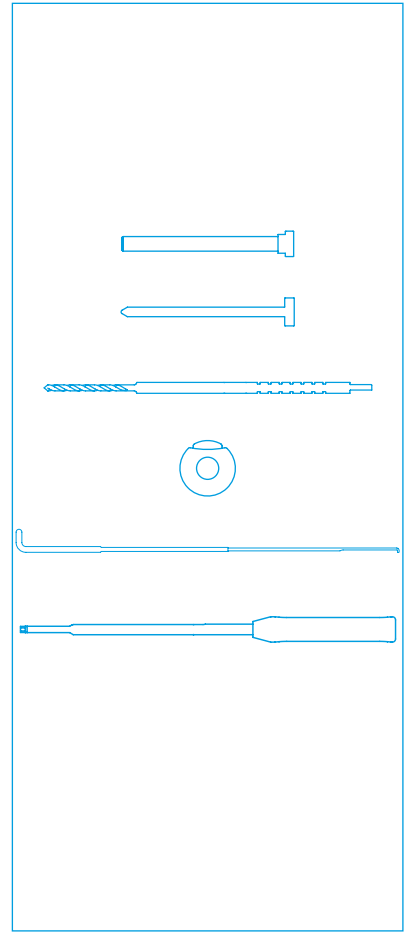
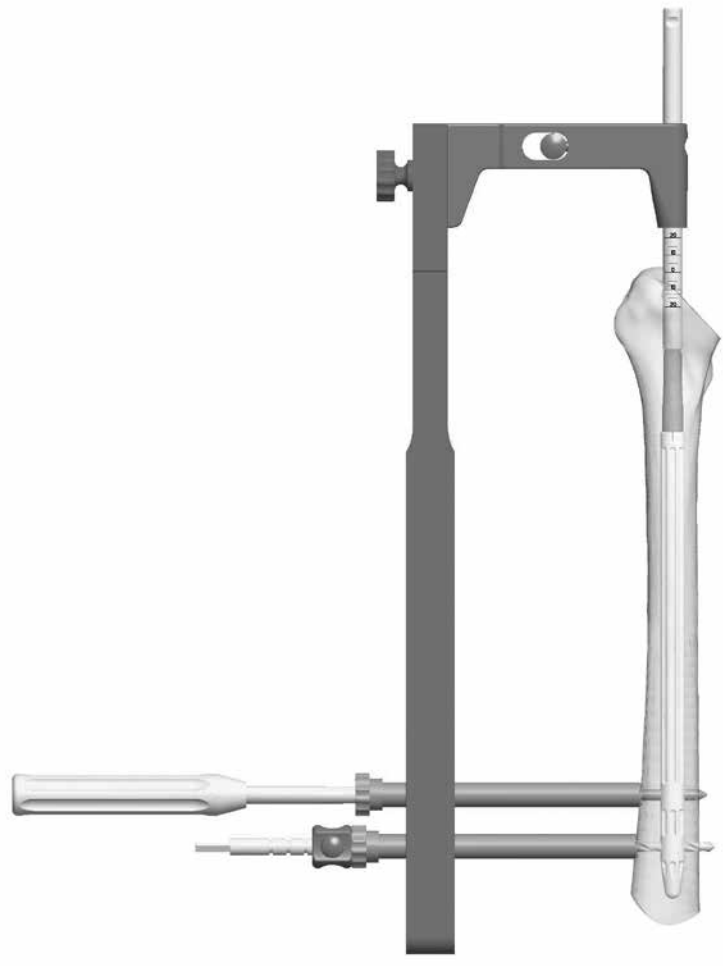
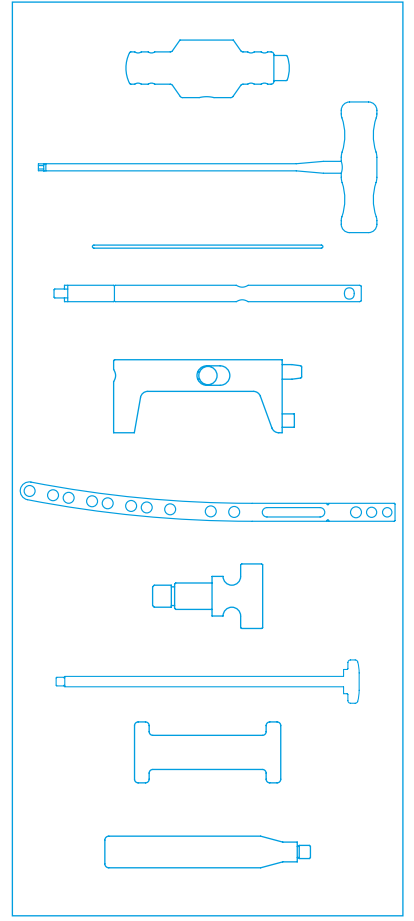
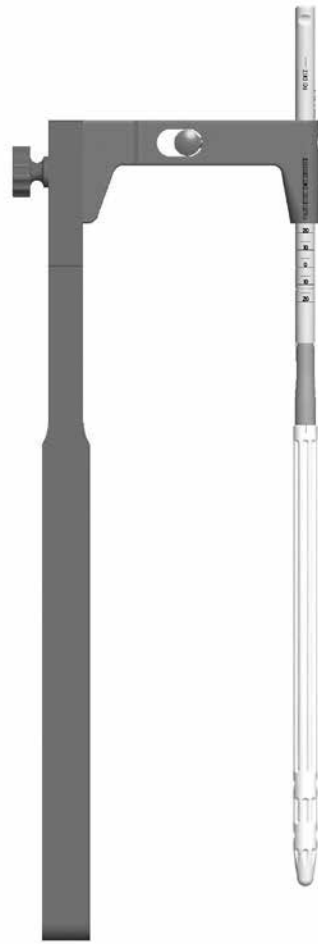
Placement of chosen femoral stem

- Remove all the trial components using the extractor tip for trial components assembled with the slap hammer. The tip fits in the lock nut. (Before starting, make sure the lock nut is fully tightened using the straight H5 screwdriver and handle).
- Prepare the final implant so it matches the trial components, including the nail's curvature:
 - Position the nail on the reconstruction femoral stem impaction plate.
 - Impact the monoblock epiphysis/metaphysis while reproducing the rotation determined with the trial implants (refer to graduations). Use the monoblock epiphysis/metaphysis impactor assembled on the universal handle.
 - Screw the monoblock implant holder with the H5 screwdriver on the implant, assembled with the slap hammer tip, the slap hammer weight and the handle.
- Impact the chosen implants into the femur. The graduations on the implant holder (corresponding to the horizontal projection of the femoral head centre) help to reproduce the depth of the trial implant relative to the chosen bone landmark.
- Unscrew the monoblock implant holder.
- Tighten the assembly screw using the screwdriver and then the torque wrench, until the wrench releases.
- Tighten the lock-nut using the straight H5 screwdriver or the torque wrench (no release).

Important!

**THE LOCK-NUT HAS REVERSE THREADS –
TURN IT COUNTERCLOCKWISE TO TIGHTEN IT.**

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



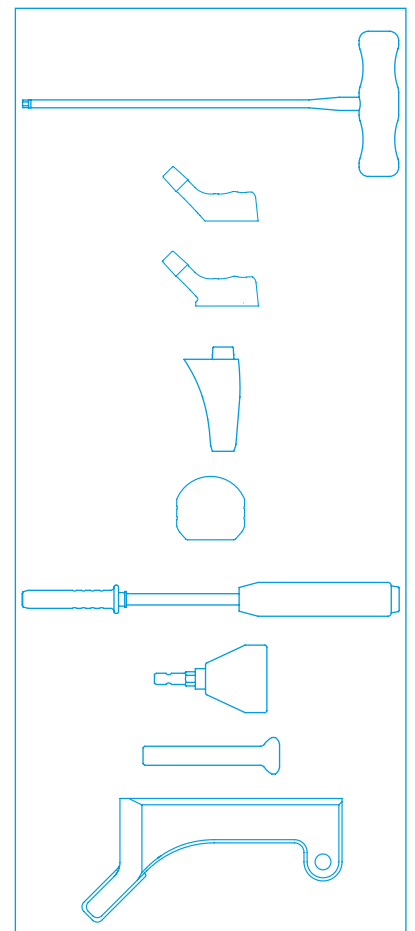
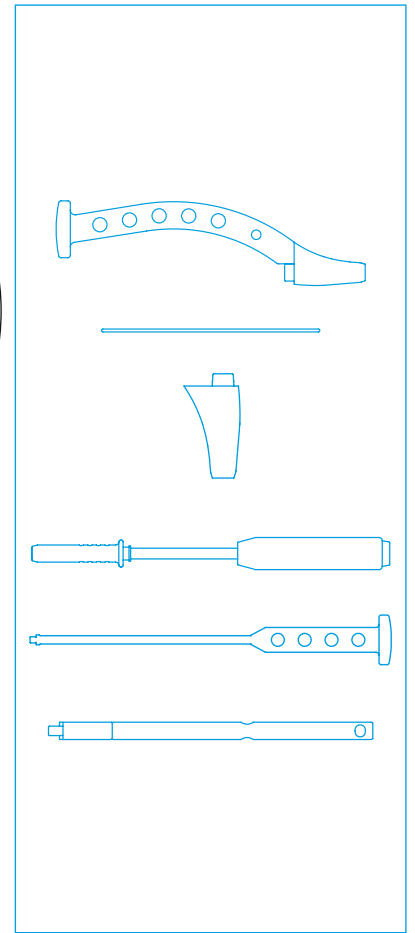
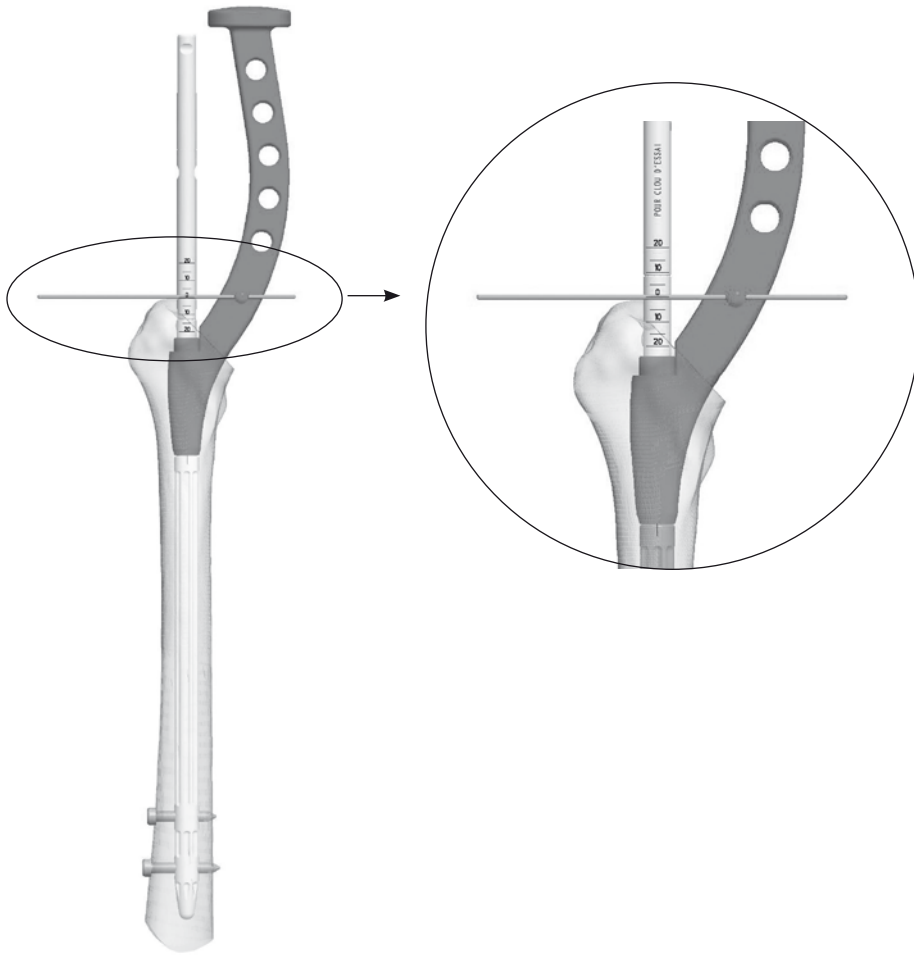
OPTION: Locked

Insertion of chosen nail

- Extract the trial nail.
- Prepare the implantable nail of the chosen size:
 - Screw the implantable nail extension piece on the chosen nail using the straight H5 screwdriver.
 - Assemble the entire unit on the offset shaft and locking guide. Make sure the nail's curvature is oriented correctly for the operated side.
- Insert the nail manually or with the slap hammer. Place the blunt K-wire in the implantable nail extension piece to show the horizontal projection of the head centre (medium neck) and to help set the planned height relative to the chosen bone landmark.

Locking of chosen nail

- Insert the two drilling barrels with blunt drill guide into the holes on the locking guide until they make bone contact. Remove the blunt drill guide.
- Drill the proximal hole first and leave the bit in place to stiffen the construct.
- Drill the second hole and leave this bit in place also.
- Remove the first drill bit and determine the length of screw needed using the screw sizer. Insert the screw using the screwdriver for stem locking. Continue turning the screw until the mark on the screwdriver is flush with the drilling barrel.
Note: if the screw length has been predetermined during the preoperative planning, place the removable stop on the drill bit using the screw length graduations. This stop will make the drilling of the second cortex safer.
- The same procedure can be used with the other screw(s).
- **Options for locking screw placement based on nail length and diameter: see page 22.**



Metaphyseal preparation (trial metaphysis)

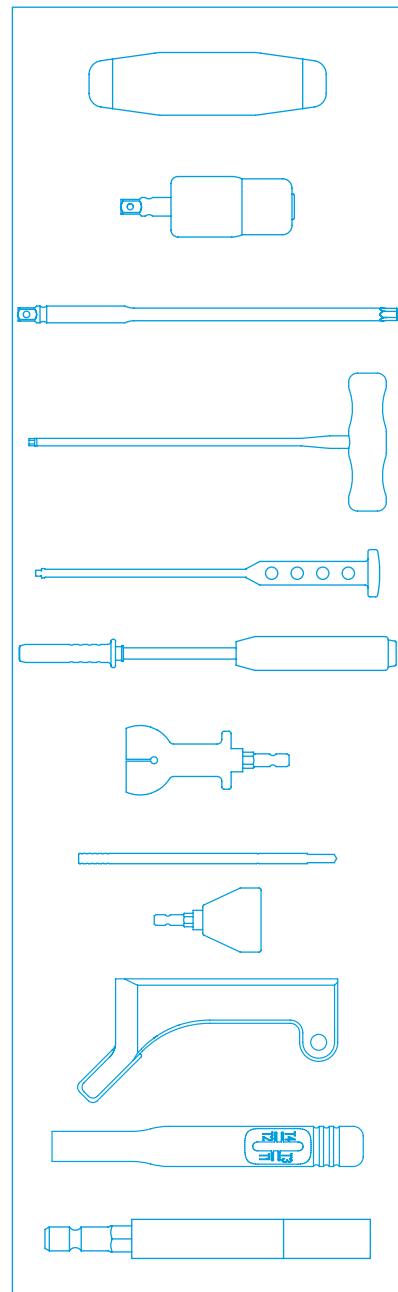
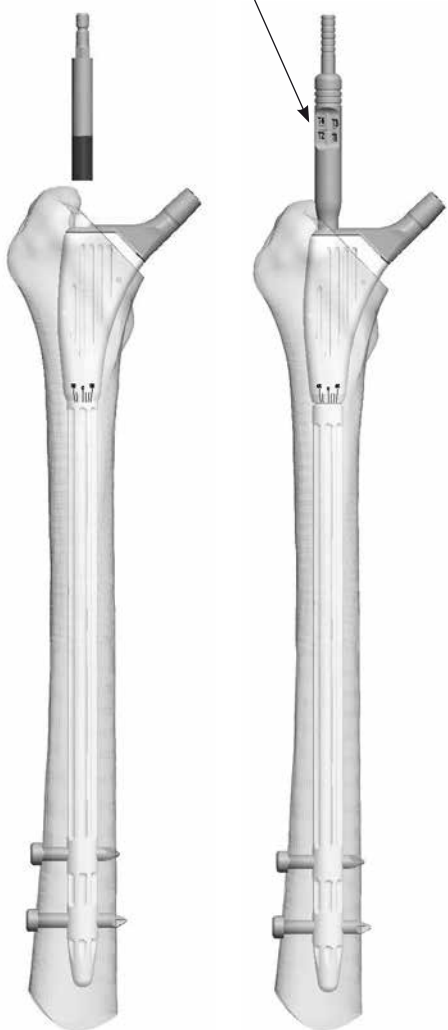
- Remove the locking frame once the nail has been locked in place.
- Starting with a size 1 broach, insert the metaphyseal broaches on the extension piece while setting the desired anteversion. Continue this process with progressively larger broaches until the **best possible metaphyseal filling** is achieved.
- **Confirm that the metaphyseal broach is inserted as deep as possible against the implantable nail:** place the blunt K-wire on the broach handle; it must line-up with the “o” mark on the implantable nail’s extension piece (represents the horizontal projection of the femoral head centre). The metaphyseal broach should rest against the nail; if it does not, remove any interposed bone or fibrous tissue. Make sure the height is correct with each metaphyseal broach.
- Using the trial component holder, place the trial metaphysis of the size corresponding to the final broach used on the trial nail.
- **Confirm the trial metaphysis is inserted as deep as possible against the trial nail:** the height of the broach should be aligned with the mark on the trial nail extension piece; if it is not, remove any interposed bone or fibrous tissue.

Epiphysis preparation (trial epiphysis)

- Remove the implantable nail extension piece using the straight H5 screwdriver.
- Select a trial epiphysis of the **same size as the metaphysis** and position it by setting the anteversion/retroversion at 0°. Make sure the greater trochanter does not hinder the placement of the trial metaphysis.
- Secure all the components together using the locking screw for trial components. Tighten it with the handle and straight H5 screwdriver.
- Install the trial femoral head.

Trials

- Reduce the joint using the head impactor mounted on the universal handle.
- Test the range of motion and joint stability.



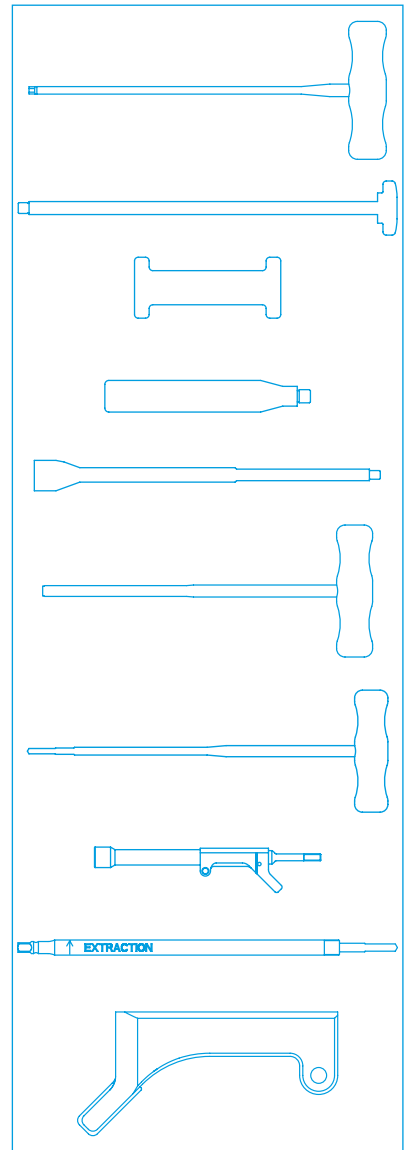
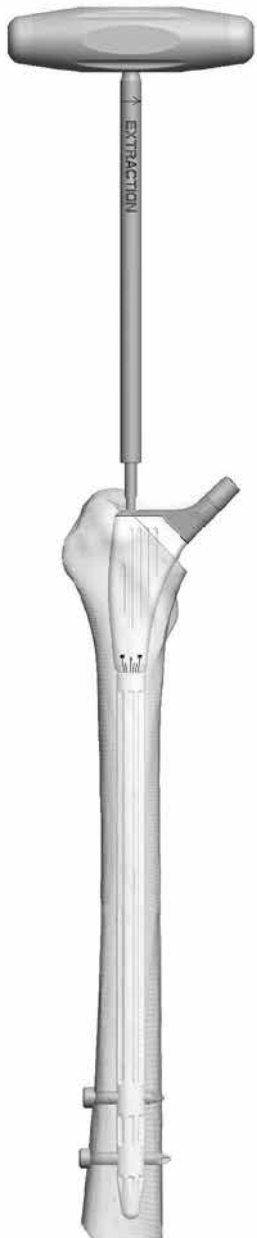
Placement of chosen femoral stem: Monoblock epiphysis/metaphysis

- Remove the trial components using the straight H5 screwdriver and the trial component holder.
- Place the chosen monoblock epiphysis/metaphysis on the nail.
- Assemble the monoblock epiphysis/metaphysis impactor with the universal handle and use it to impact the component.
- **Check the quality of the impaction using the metaphyseal impaction gauge and the monoblock epiphysis/metaphysis impaction indicator.** Set the impaction gauge in the monoblock epiphysis/metaphysis and slide the indicator on this gauge. Read the size of monoblock epiphysis/metaphysis in this window. This size must match the size of the implanted component.
- Tighten the assembly screw using the screwdriver and then the torque wrench, until the wrench releases.
- Tighten the lock-nut using the straight H5 screwdriver or the torque wrench (no release).

Important!

**THE LOCK-NUT HAS REVERSE THREADS –
TURN IT COUNTERCLOCKWISE TO TIGHTEN IT.**

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

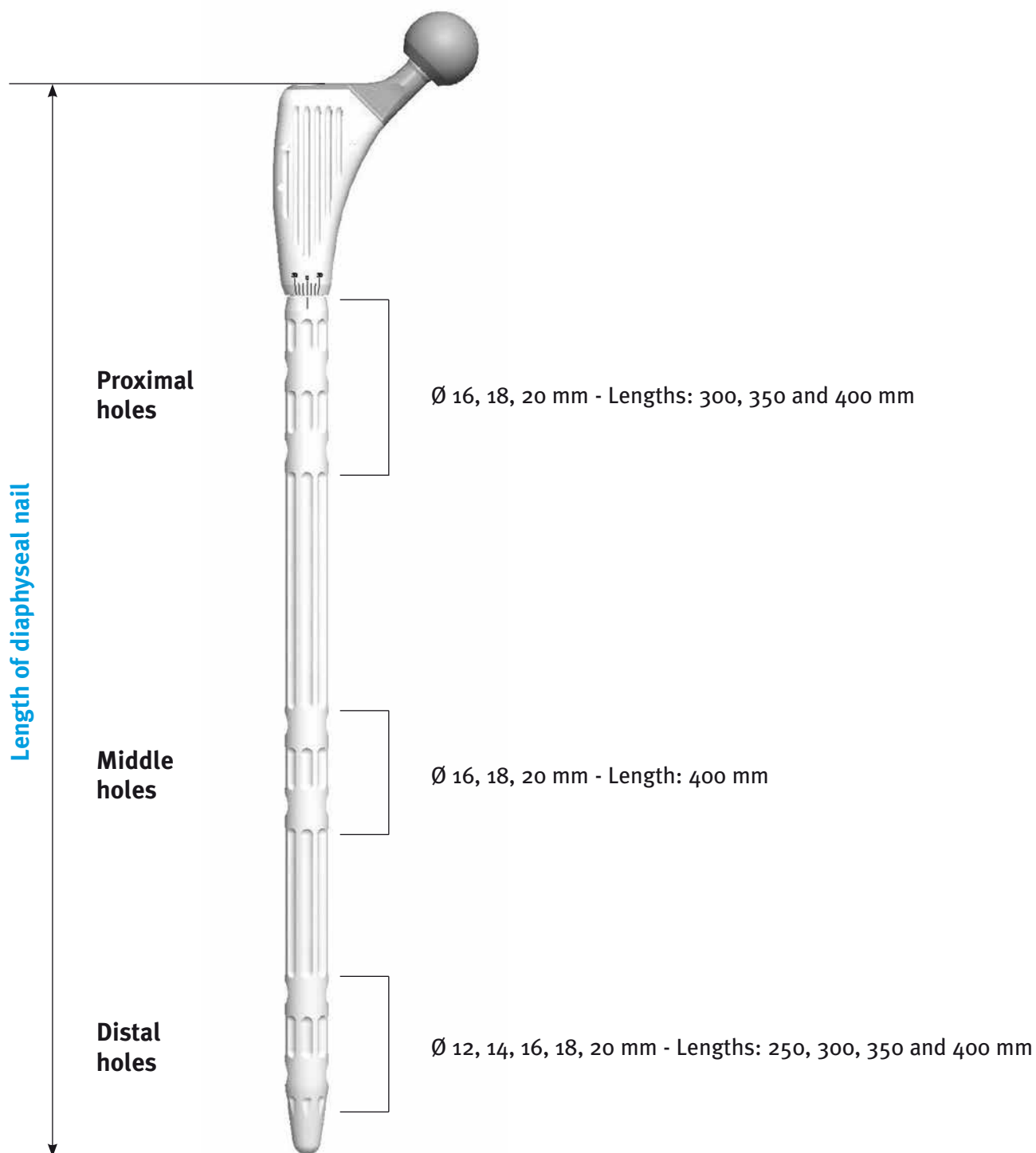


EXTREME[®] stem extraction

We recommend replacing all the components when performing a revision procedure.

- Remove the lock-nut and assembly screw using the straight H5 screwdriver and handle:
 - **Monoblock epiphysis/metaphysis component extraction:** Screw the extractor tip for monoblock epiphysis/metaphysis where the assembly screw was located and turn it until it disassembles.
 - **Nail extraction:** Remove any distal locking screws using the H5 screwdriver. After extracting the monoblock epiphysis/metaphysis, place the slap hammer tip on the nail. Add the slap hammer shaft and weight, and then use the slap hammer to extract the nail.
 - **Implant extraction:** After removing any distal locking screws with the H5 screwdriver, place the implant holder with slap hammer tip and weight where the assembly screw and lock nut were located. Use the slap hammer to remove the implant.

Locking options based on nail length and diameter



Note: The nail's length is the distance between the distal end of the nail and the top of the epiphysis (see above drawing).

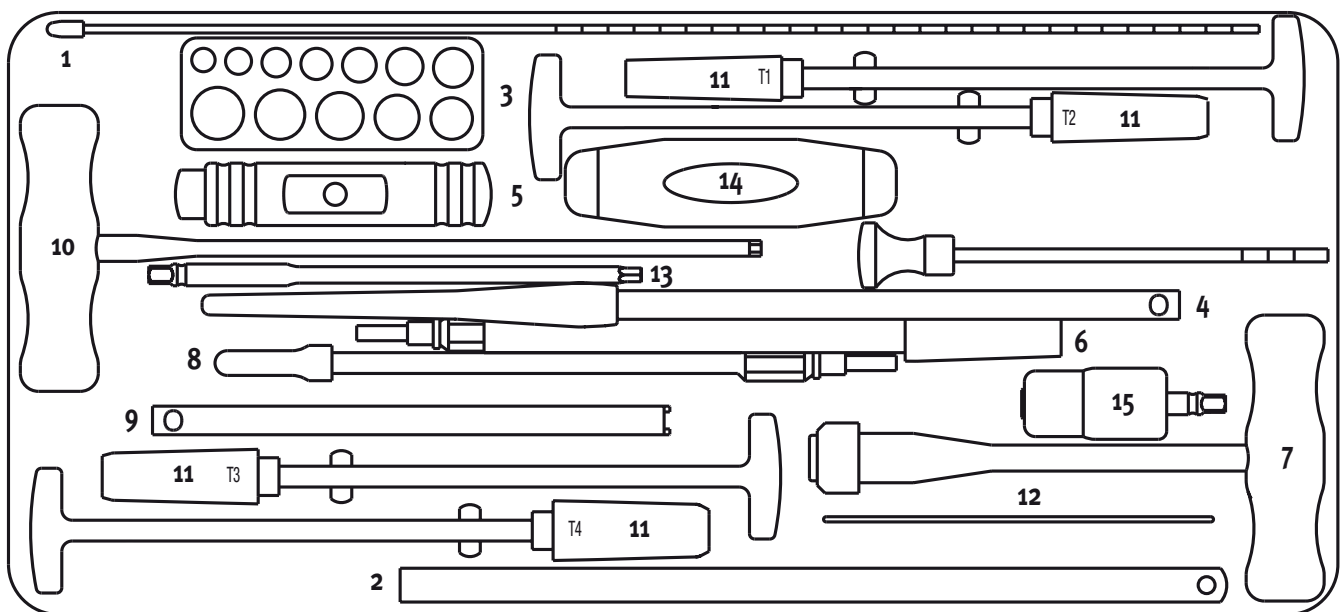
There are 4 trays in the EXTREME® instrumentation set:

- One common set (tray 1)
- One set for trial implants (tray 2)
- One set for stem locking (tray 3)
- One set for impaction and/or extraction of implants (tray 4)

An extraction set for the EXTREME® stem is also available for revision cases.

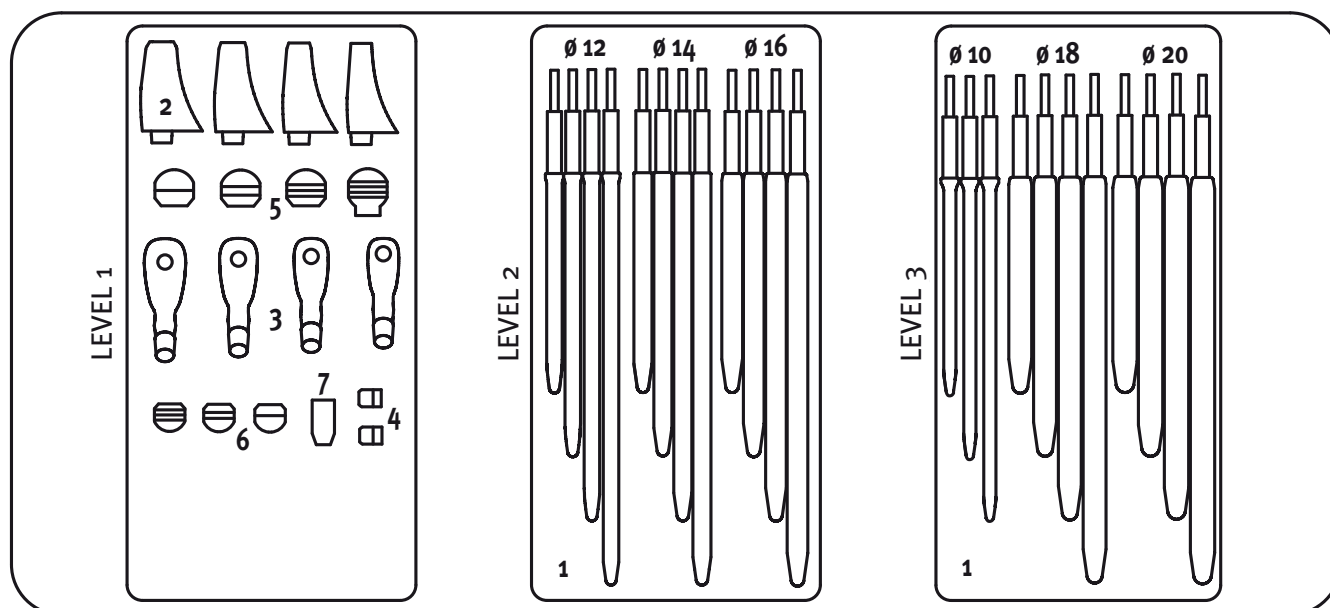
IMPORTANT: Flexible reamers will be needed in addition to the instrumentation set.

Common set (tray 1)



Item	Name	Product No.	Qty.
1	Intramedullary gauge	2-0112200	1
2	300-mm ruler (1-mm increments)	2-0111000	1
3	Reamer sizer	2-0112300	1
4	Guide for trochanter reamer	2-0110800	1
5	Removable handle	2-0109300	1
6	Trochanter reamer	2-0110900	1
7	Reamer holder	2-0103500	1
8	Reamer for femoral nail Ø10 & Ø12	2-0111900	1
9	Extension piece for trial femoral nail	2-0110700	1
10	Straight H5 screwdriver	2-0110100	1
11	Rasp handle for monoblock metaphysis size 1	2-0109401	1
11	Rasp handle for monoblock metaphysis size 2	2-0109402	1
11	Rasp handle for monoblock metaphysis size 3	2-0109403	1
11	Rasp handle for monoblock metaphysis size 4	2-0109404	1
12	Blunt K-wire Ø2 mm	2-0103000	1
13	Torque wrench shaft, H5	2-0019103	1
14	Universal handle	2-0119101	1
15	Torque wrench body	2-0119102	1

Trial implant set (tray 2)

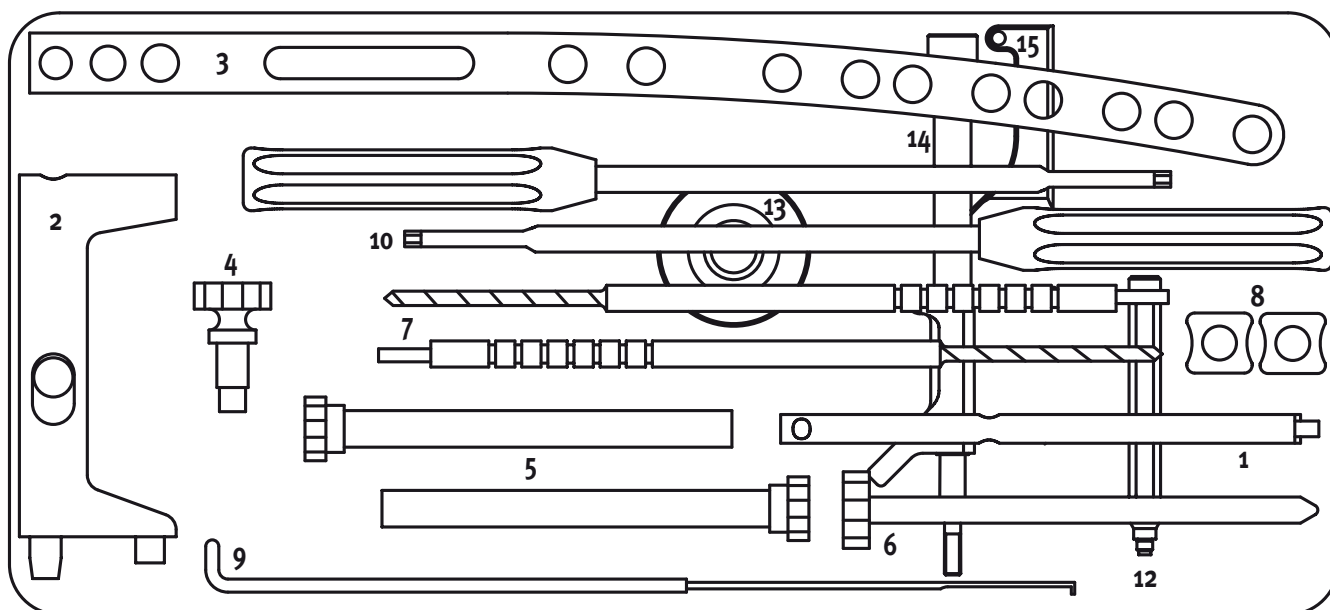


Item	Name	Product No.	Qty.
1	Trial femoral nail – Ø 10 Length 250 mm	2-0111101	1
1	Trial femoral nail – Ø 10 Length 300 mm	2-0111102	1
1	Trial femoral nail – Ø 10 Length 350 mm	2-0111103	1
1	Trial femoral nail – Ø 12 Length 250 mm	2-0111111	1
1	Trial femoral nail – Ø 12 Length 300 mm	2-0111112	1
1	Trial femoral nail – Ø 12 Length 350 mm	2-0111113	1
1	Trial femoral nail – Ø 12 Length 400 mm	2-0111114	1
1	Trial femoral nail – Ø 14 Length 250 mm	2-0111121	1
1	Trial femoral nail – Ø 14 Length 300 mm	2-0111122	1
1	Trial femoral nail – Ø 14 Length 350 mm	2-0111123	1
1	Trial femoral nail – Ø 14 Length 400 mm	2-0111124	1
1	Trial femoral nail – Ø 16 Length 250 mm	2-0111131	1
1	Trial femoral nail – Ø 16 Length 300 mm	2-0111132	1
1	Trial femoral nail – Ø 16 Length 350 mm	2-0111133	1
1	Trial femoral nail – Ø 16 Length 400 mm	2-0111134	1
1	Trial femoral nail – Ø 18 Length 250 mm	2-0111141	1
1	Trial femoral nail – Ø 18 Length 300 mm	2-0111142	1
1	Trial femoral nail – Ø 18 Length 350 mm	2-0111143	1
1	Trial femoral nail – Ø 18 Length 400 mm	2-0111144	1
1	Trial femoral nail – Ø 20 Length 250 mm	2-0111151	1
1	Trial femoral nail – Ø 20 Length 300 mm	2-0111152	1
1	Trial femoral nail – Ø 20 Length 350 mm	2-0111153	1
1	Trial femoral nail – Ø 20 Length 400 mm	2-0111154	1

Trial implant set (tray 2)

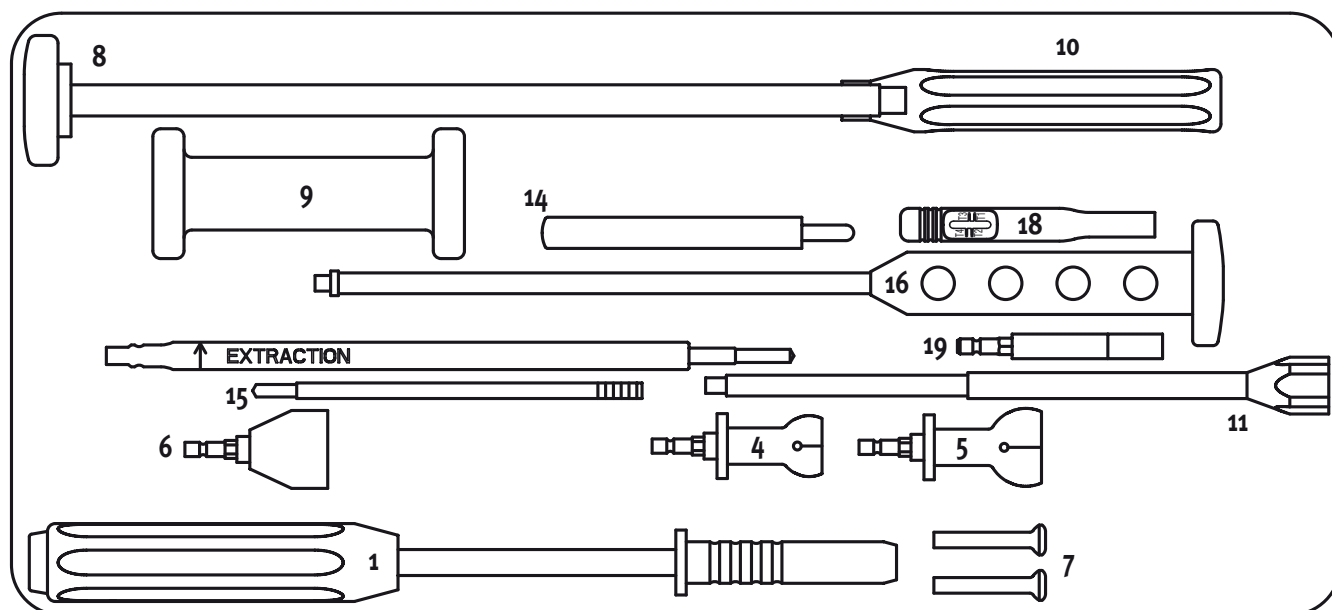
Item	Name	Product No.	Qty.
2	Trial standard metaphysis – Size 1	2-0111701	1
2	Trial standard metaphysis – Size 2	2-0111702	1
2	Trial standard metaphysis – Size 3	2-0111703	1
2	Trial standard metaphysis – Size 4	2-0111704	1
3	Trial epiphysis – Size 1	2-0111801	1
3	Trial epiphysis – Size 2	2-0111802	1
3	Trial epiphysis – Size 3	2-0111803	1
3	Trial epiphysis – Size 4	2-0111804	1
4	Lock nut for trial components	2-0110400	2
5	Trial head for stem Ø28, Short collar	2-0100401	1
5	Trial head for stem Ø28, Medium collar	2-0100402	1
5	Trial head for stem Ø28, Long collar	2-0100403	1
5	Trial head for stem Ø28, Extra-long collar	2-0100404	1
6	Trial head for stem Ø22.2, Short collar	2-0100405	1
6	Trial head for stem Ø22.2, Medium collar	2-0100406	1
6	Trial head for stem Ø22.2, Long collar	2-0100407	1
7	Extractor tip for trial components	2-0113700	1

Stem locking set (tray 3)

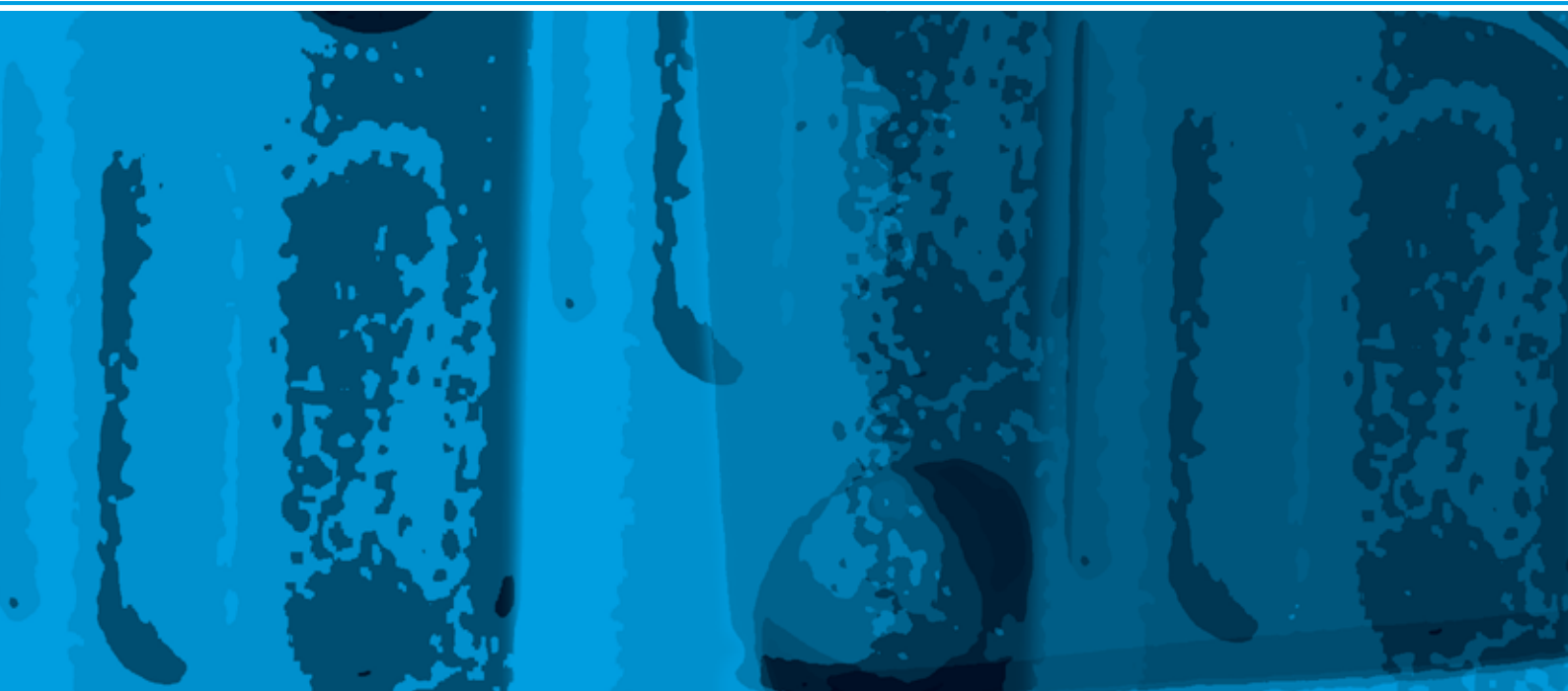


Item	Name	Product No.	Qty.
1	Extension piece for implantable femoral nail	2-0109200	1
2	Offset shaft	2-0109800	1
3	Locking guide	2-0109500	1
4	Screw for offset shaft	2-0109700	1
5	Drilling barrel	2-0109600	2
6	Blunt drill guide	2-0110600	1
7	Drill bit for locking screw	2-0111600	2
8	Removable drill stop	2-0111500	2
9	Screw depth gauge	2-0111200	1
10	Locking H5 screwdriver	2-0110000	2
12	Removable handle, length 150 mm	2-0191900	1
13	Impaction plate for reconstruction femoral stem	2-0118200	1
14	Wrench for EXTREME® epiphysis	2-0191700	1
15	Monoblock EXTREME® implant holder	2-0119900	1

Impaction and/or extraction set (tray 4)



Item	Name	Product No.	Qty.
1	Universal handle	2-0101000	1
4	Femoral head gripping tip Ø 22.2	2-0104322	1
5	Femoral head gripping tip Ø 28	2-0104328	1
6	Head impactor Ø 28 and Ø 32	2-0114200	1
7	Locking screw for trial components	2-0111300	2
8	Shaft for slap hammer	2-0102900	1
9	Weight for slap hammer	2-0103300	1
10	Handle	2-0104200	1
11	Slap hammer tip	2-0103200	1
14	Support rod	2-0110500	1
15	Impaction gauge for metaphysis	2-0113400	1
16	Trial component holder	2-0109900	1
17	Extractor shaft for Monoblock epiphysis-metaphysis	2-0119200	1
18	Impaction gauge for Monoblock epiphysis-metaphysis	2-0191500	1
19	Impactor for Monoblock epiphysis-metaphysis	2-0191600	1



AMPLITUDE 

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