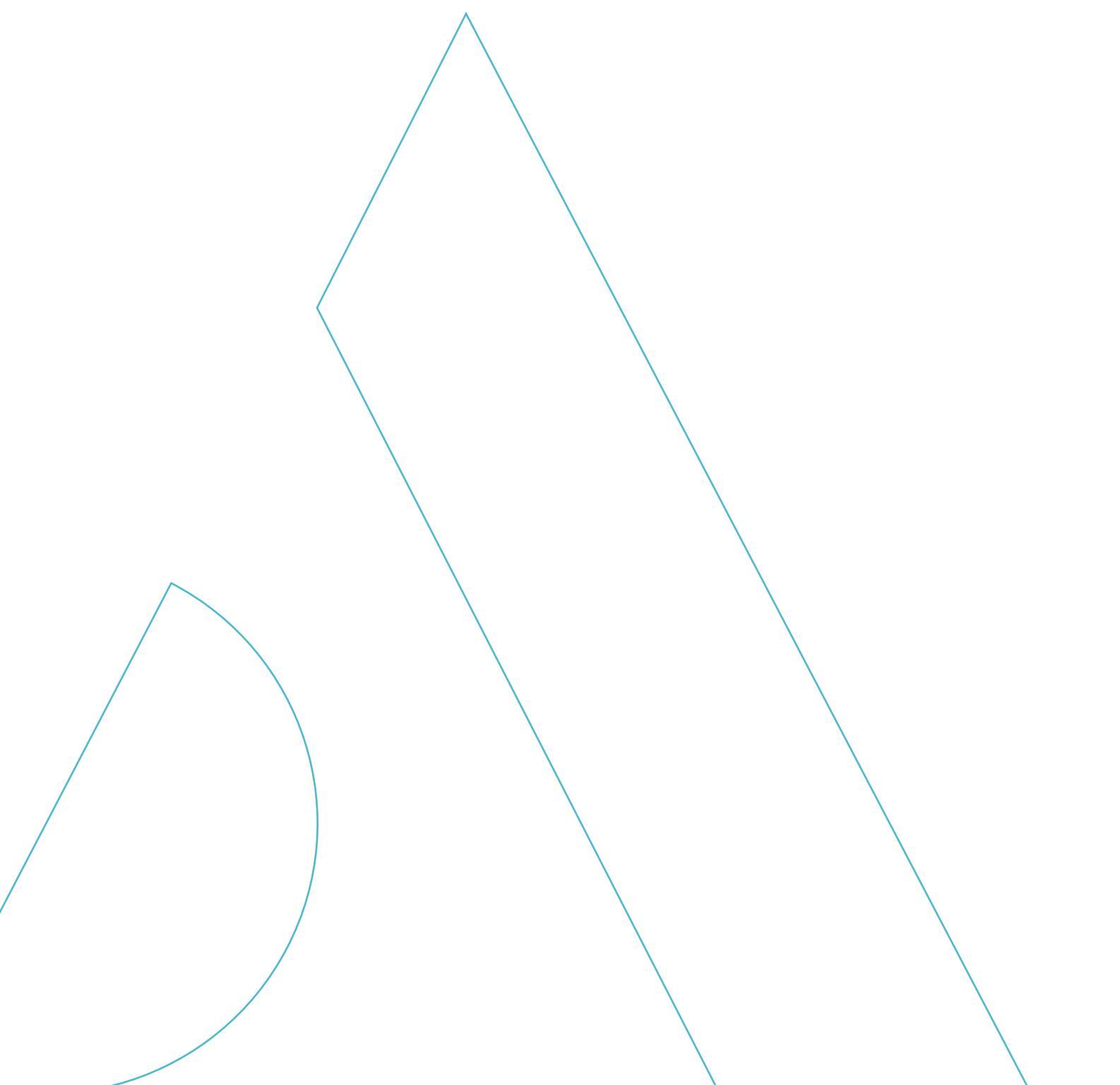


integrale
generic

amplitude



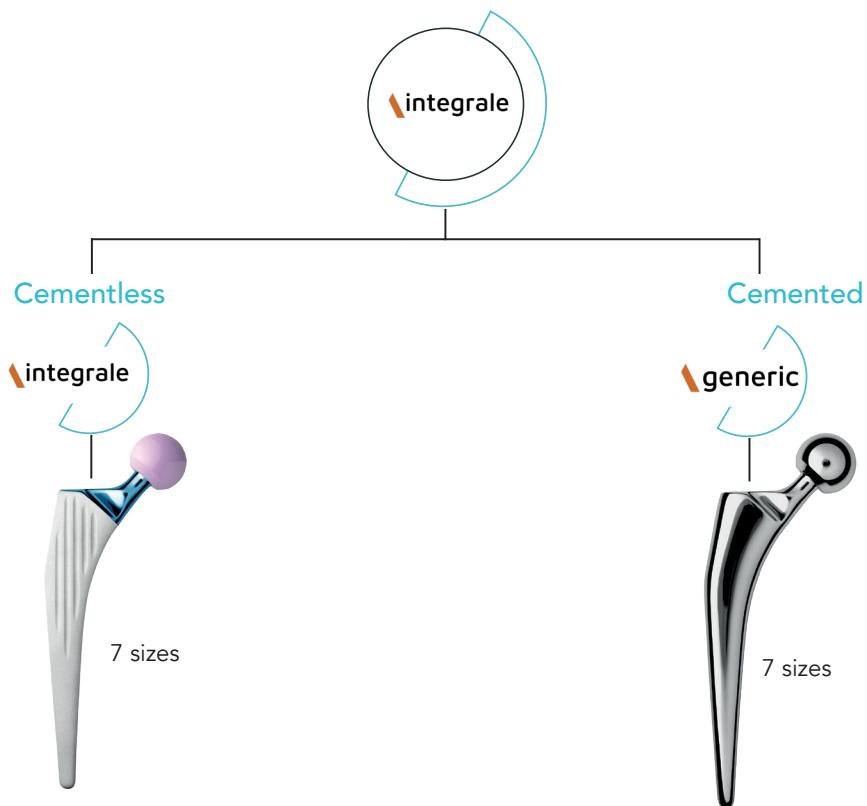
Surgical Technique



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Concept and Range



Size	Neck length	Size	Neck length	Size	Neck length
—	—	—	—	Ø 22,2 mm	SN -2 mm MN 0 mm CL +2 mm
Ø 28 mm	SN -3,5 mm MN 0 mm LN +3,5 mm	Ø 28 mm	SN -3 mm MN 0 mm LN +4 mm	Ø 28 mm	SN -3,5 mm MN 0 mm LN +3,5 mm XLN +7,5 mm
Ø 32 mm	SN -4 mm MN 0 mm LN +4 mm	Ø 32 mm	SN -3 mm MN 0 mm LN +4 mm	Ø 32 mm	SN +4 mm MN 0 mm LN +4 mm
Ø 36 mm	SN -4 mm MN 0 mm LN +4 mm	Ø 36 mm	SN -3 mm MN 0 mm LN +4 mm	—	—

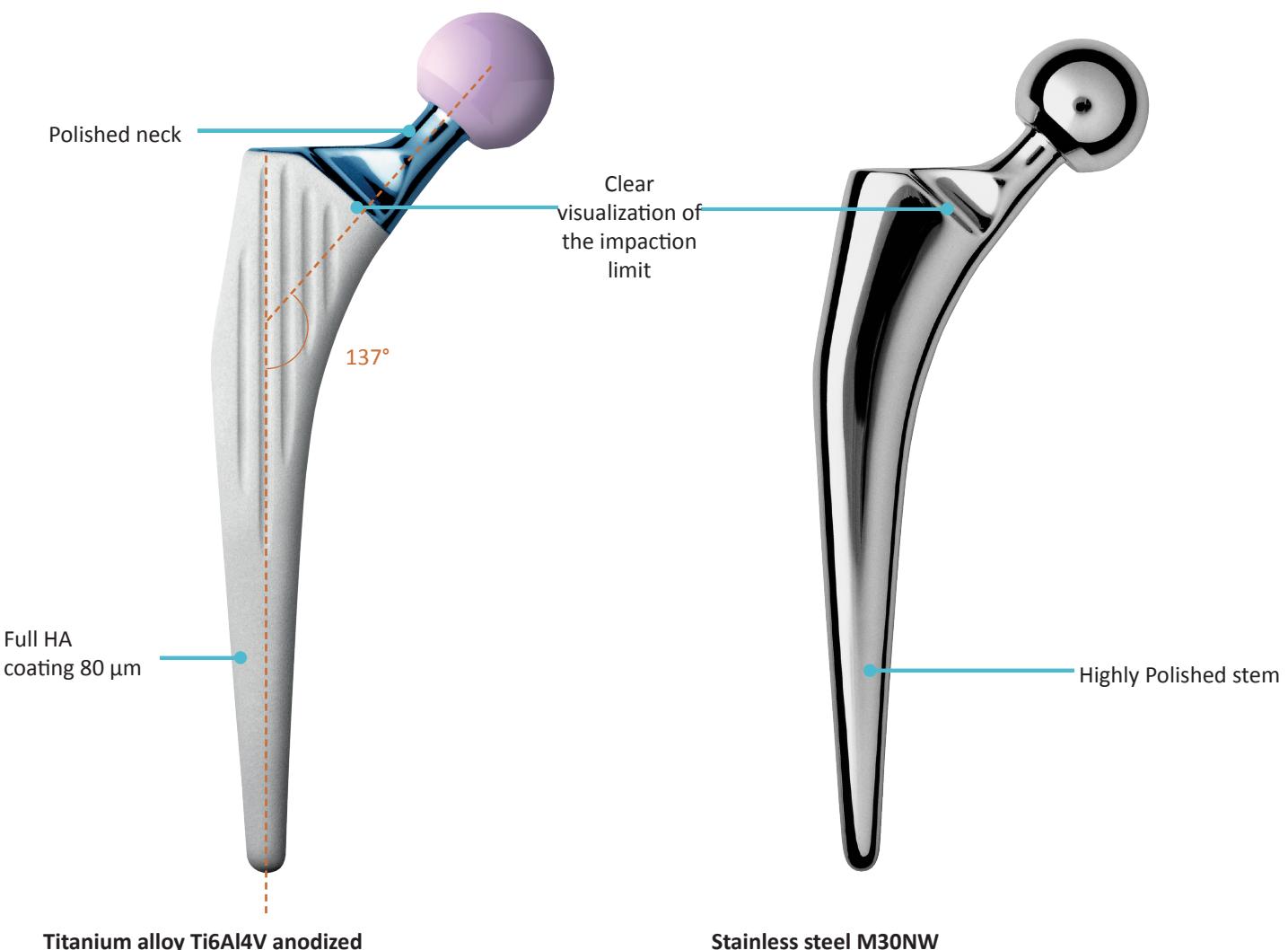
SN = Short Neck; MN = Medium Neck; LN = Long Neck; XLN = Extra-Long Neck
 Compatibilities are available on the IFU.



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Concept and Range

INTEGRALE and GENERIC femoral stems are straight stems and feature an avoid cross section. They are available in 7 sizes with homothetical progression. Their Neck-Shaft angle is 137° . Length and all intramedullary features are identical for all versions, except the coating.



Surgical technique overview



Surgical technique overview



1 Pre-operative planning



By means of radiological assessment and templates, it is possible to:

- Determine the position of the joint's centre.
- Choose the height of the GENERIC or INTEGRALE femoral stem (identical templates for 2 femoral stems). Note the distance between the horizontal projection from the centre of the femoral head with a medium neck and a reliable bone landmark. This measurement will be noted and checked throughout the operation with the instrumentation (horizontal projection of a medium neck head centre corresponds to the height of the blunt K-wire level).
- Assess the size of the implants.
- Assess the diaphyseal obturator location into the femoral canal (about 1 cm below the distal tip of the stem) if a GENERIC stem is used.

The GENERIC and INTEGRALE stems can be implanted with the same instruction component and the same surgical technique.

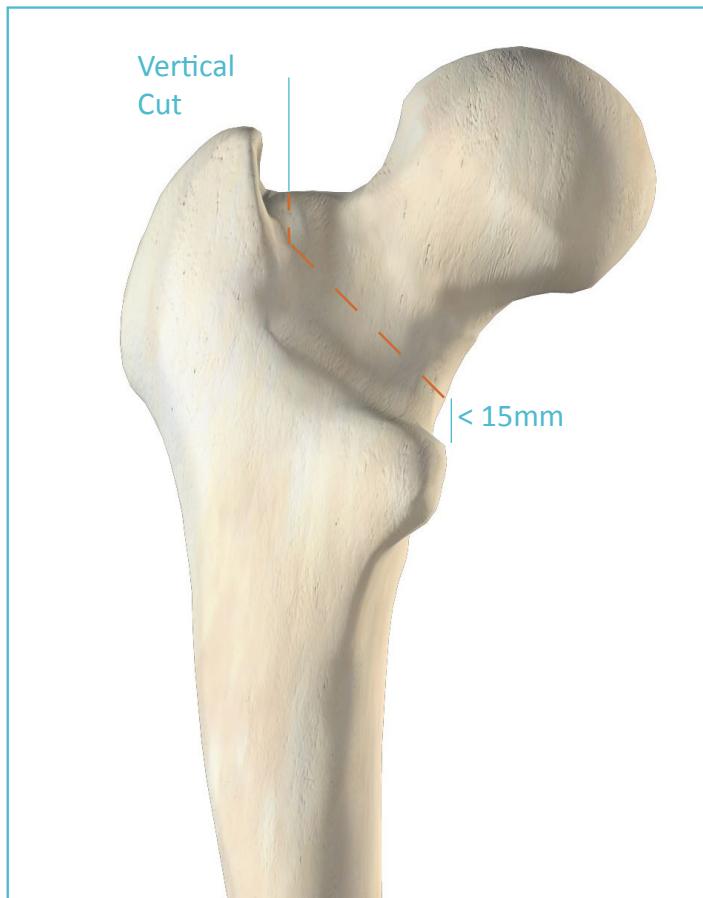
NOTE

Templates are provided at scale 1:15. Other magnifications and digital templates are available on request.

NOTE

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.

2 Femoral neck resection



Identify anatomical landmarks, lesser trochanter (LT), piriformis fossa, great trochanter (GT).

Determine the neck cut level as defined during preoperative planning. In most cases the distance from the neck cut to the LT is less than 15 mm.

Mark the cutting plane level onto the bone with reference to the anatomical landmarks. The neck can be cut before or after dislocation of the femoral head. Take care to protect the soft tissues and GT during neck cut.

In some cases, where the cut is lower, a second vertical cut is made at the base of the neck and GT. Further adjustment can then be made broach in situ.

3 Femoral canal preparation



Canal identification

Retraction of the gluteus medius and removal of lateral cortical bone at the piriformis insertion will allow true axial introduction of the instruments and stem.



Canal preparation

Assemble the 12*10 reamer on the T-handle. Push it down into the femoral canal to prepare it for broaching making sure to stay in the femoral shaft axis.

Assemble the 18*10 on the reamer holder and insert it in the diaphyseal canal in order to prepare the trochanter and reduce the risk of positioning the broaches in varus.



4 Broaching



Broaching is performed beginning with the smallest (size 1) broach. Assemble it to the broach handle adapted to surgical approach. The broach should be oriented in line with the femoral axis. Impact the broach down the femur.

The progressive preparation is performed using broaches of increasing sizes, until optimal metaphyseal fit good rotational and axial stability is achieved. The depth corresponds to the junction between the broach and the broach handle. Make sure this junction is visible when the last broach is inserted. It is possible to check the impaction level by inserting the blunt K-wire into the broach handle (horizontal projection of head centre with medium neck).

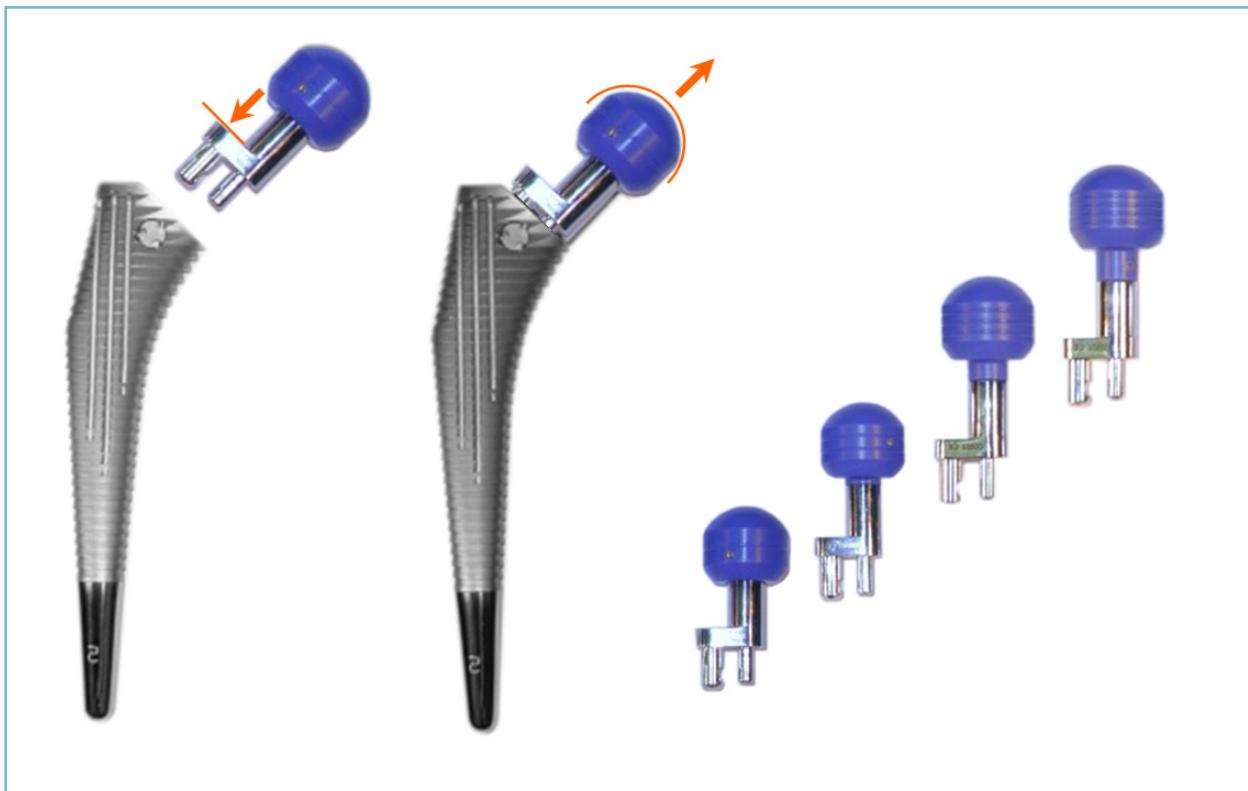
In order to prevent any varus position, attention must be paid to introduce the broaches in the anatomical axis.

The size of the last broach is usually the same as the size templated. Leave the last broach in the femur and remove the broach handle.

NOTE

It is important to have good femoral filling with the broach and good rotational stability.

5 Trials on broach



Place the trial neck on the selected broach (choose the required head diameter and neck length) by pressing the flat plane of the neck to engage the mechanism:



Reduce the head with the neck-head impactor assembled on the universal handle.

Test the range of motion, joint stability and then check the length to validate the extramedullary settings.

If the joint range of motion or stability are unsatisfactory, repeat the trials with a different trial neck until the desired stability and range of motion are achieved .

Remove the trial neck by pulling the head, and remove the broach from the femur using the broach handle.

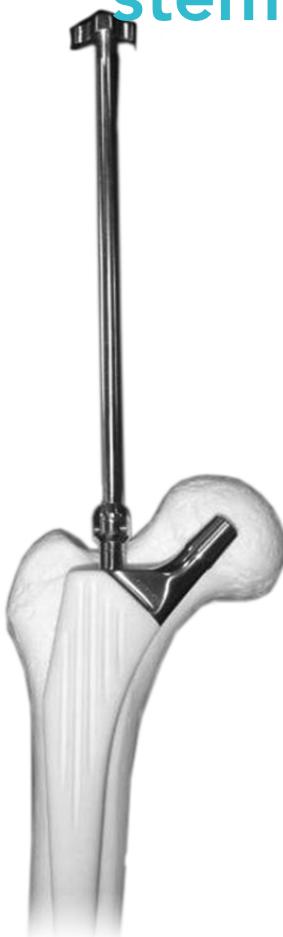
NOTE

The femoral neck can be recut directly on the broach.

NOTE

Keep the chosen broach and trial neck on the table to serve as a reference for the final implanted components.

6 Impaction of cementless femoral stems: integrale



Select the INTEGRALE femoral stem that matches the size validated during trials. Position manually the stem in the prepared femoral canal.

Place the stem impactor in the impaction oblong hole on top of the stem being implanted.

Impact the stem until adequate stability is achieved. The HA coating border corresponds to the impaction limit. During impaction, rotation can be controlled. Remove the stem impactor.

It is possible to check the height of the prosthetic head centre in relation to an anatomical landmark with the blunt K-wire inserted in the trochanter meter assembled to the extraction hole situated at the top of the stem. The horizontal projection of the K-wire corresponds to the centre of the prosthetic head with a medium neck.

Reduction trials can be performed using trial heads on the stem to validate stability and leg length.



NOTE

When using a GENERIC cemented stem,
follow instructions p.14.

7

Cement restrictor implementation



Wash and dry the intramedullar femoral cavity. Femoral canal obturation should be performed according to the surgeon's habits. The amplitude range offers the TEKSTOP bioabsorbable restrictor and a non-absorbable UHMWPE restrictor.

Introduce the cement restrictor according to following instructions depending on the model used:

TEKSTOP :

Based on femoral canal preparation, determine in the instrumentation the adequate trial «olive» diameter and assemble it on the handle by threading it completely (1).

Tighten the holding screw on the body of the inserter (2).

Compare the length with the validated broach by using a landmark that can be used to determine adequate insertion depth.

Insert in the femoral canal until determined depth is reached to assess the diameter. Repeat trials until diameter has been validated. Remove the trial «olive» by unthreading it.

Choose the TEKSTOP restrictor of the same size as the validated trial «olive» assemble it on the inserter and insert it in the femoral canal.

Unthread the holding screw (3) and pull the handle to leave the TEKSTOP restrictor in place (4).

Non-absorbable cement restrictor:

Assemble the non-absorbable restrictor on the introducer.

The graduation on the inserter indicates insertion depth. Compare with the validated broach by using a landmark that can be used to determine adequate insertion depth. Add 1cm to ensure positionning well below the stem.

Insert in the femoral canal until determined depth is reached.

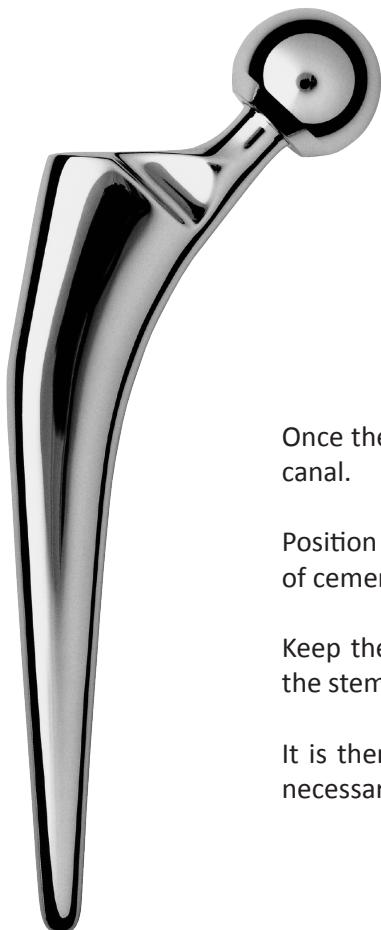
Remove the inserter to leave the restrictor in place.

NOTE

Follow the instruction for use of the cement being used

8

Impaction of cemented femoral stem: generic



Once the cement restrictor is in place, place the cement into the femoral canal.

Position the stem into the prepared femoral cavity and remove the excess of cement.

Keep the stem in place until complete cement polymerization thanks to the stem impactor.

It is then possible to perform new trials with trial heads on the stem if necessary (to validate neck length and articular stability).

NOTE

Follow instructions for use of the cement being used

9 Final head impaction



Select final femoral head that matches settings validated during trials.

Impaction of metallic head:

Make sure the stem taper is clean, dry and undamaged, then position the head manually until it is firmly seated on the taper.

Use the head impactor assembled on the universal handle to impact it axially. Reduce the joint.

Impaction of ceramic head:

Before placing the ceramic head onto femoral stem:

- Carefully rinse and dry the stem taper.
- Meticulously inspect the stem taper and female head taper, and remove any foreign body.

Manually place the head onto stem taper by gently turning it while pushing it along the taper axis until it is firmly seated.

Use the head impactor assembled on the universal handle to impact it axially. Reduce the joint.

Extraction of the implants (optional)



Remove the femoral head by tapping around the base of the head.

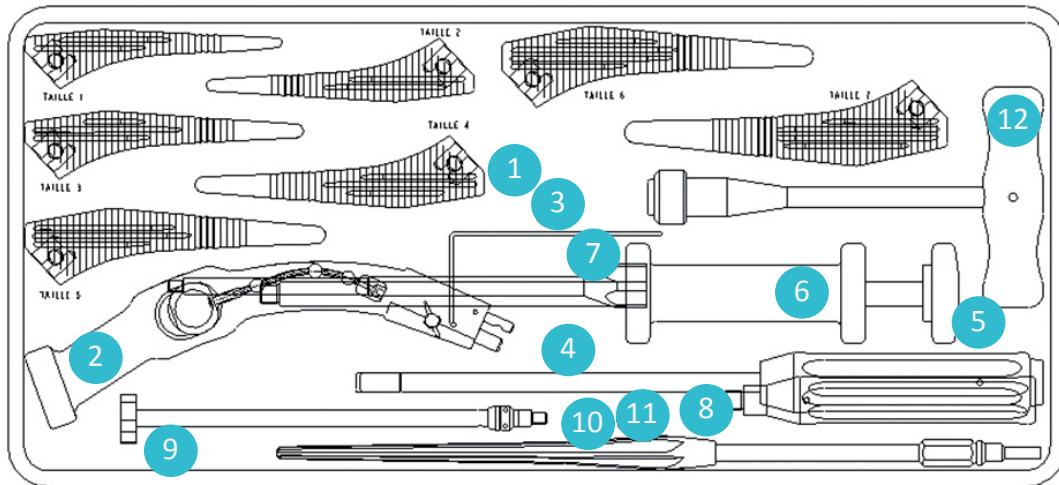
Assemble the slap hammer weight onto the slap hammer shaft and screw both components into the slap hammer tip.

Tightly screw the slap hammer tip into the upper portion of the stem and then extract it. Keep the slap hammer aligned with the stem axis during extraction.



Instrumentation

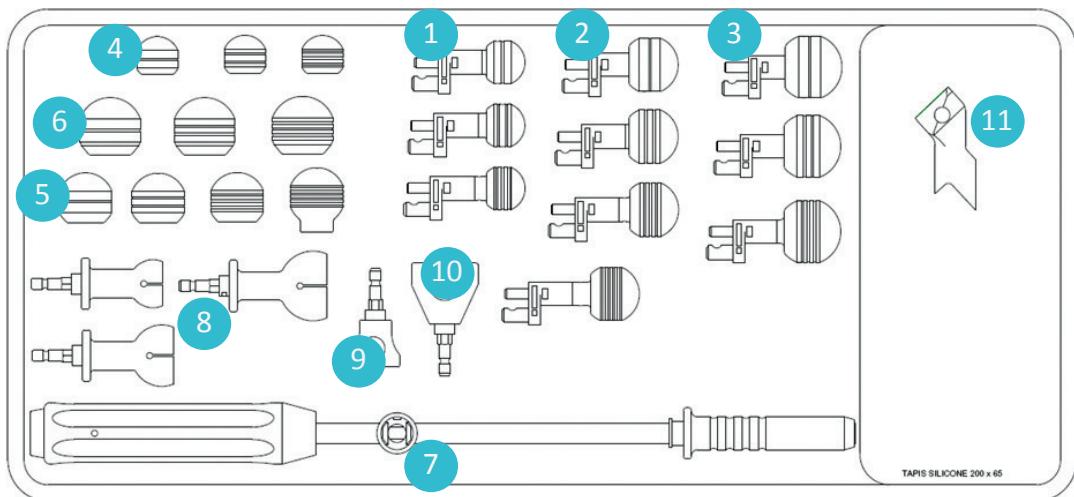
integrale, generic instruments set



Item	Description	Reference	Qty
1	Primary femoral broach size 1	2-0100201	1
1	Primary femoral broach size 2	2-0100202	1
1	Primary femoral broach size 3	2-0100203	1
1	Primary femoral broach size 4	2-0100204	1
1	Primary femoral broach size 5	2-0100205	1
1	Primary femoral broach size 6	2-0100206	1
1	Primary femoral broach size 7	2-0100207	1
2	Broach handle	2-0103100	1
3	Alignment Ø2 A/P	2-0114000	1
4	Monobloc femoral stem impactor	2-0100900	1
5	Slap hammer shaft	2-0102900	1
6	Slap hammer weight	2-0103300	1
7	Slap hammer tip	2-0103200	1
8	Holding handle	2-0104200	1
9	Trochanter size gauge	2-0103700	1
10	Reamer 12 x 10	2-0103612	1
11	Reamer 18 x 10	2-0103618	1
12	Reamer handle	2-0103500	1

Instrumentation

integrale, generic instruments set



Item	Description	Reference	Qty
1	Trial neck Ø22.2 Short, Medium and Long neck	2-0100505 to 2-0100507	1 of each
2	Trial neck Ø28 Short, Medium, long and Extra-long neck	2-0100501 to 2-0100504	1 of each
3	Trial neck Ø32 Short, Medium and Long neck	2-0100508 to 2-0100510	1 of each
4	Trial neck on stem Ø22.2 Short, Medium and Long neck	2-0100405 to 2-0100407	1 of each
5	Trial neck on stem Ø28 Short, Medium, long and Extra-long neck	2-0100401 to 2-0100404	1 of each
6	Trial neck on stem Ø32 Short, Medium and Long neck	2-0100408 to 2-0100410	1 of each
7	Universal handle - Conventional / navigated	2-0117600	1
8	Femoral head gripping tip Ø22.2	2-0104322	1
8	Femoral head gripping tip Ø28	2-0104328	1
8	Femoral head gripping tip Ø32	2-0104332	1
9	Impactor for Ø22.2 heads	2-0101400	1
10	Impactor for Ø28 and Ø32 heads	2-0114200	1
11	Box Chisel	2-0116300	1

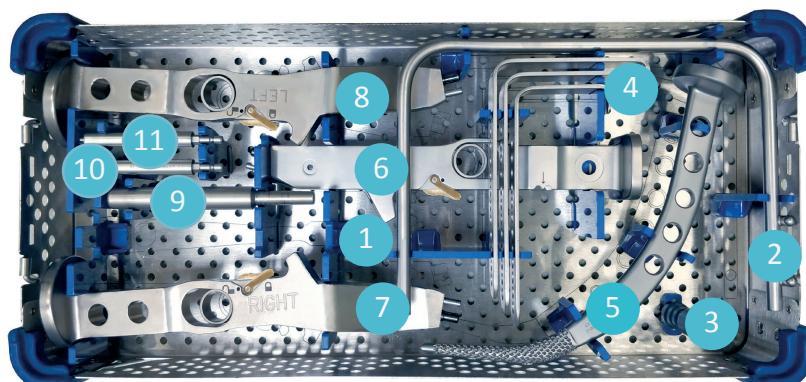
Instrumentation

Optional: Röttinger broach handles



Description	Reference	Qty
Offset left broach handle	2-0199001	1
Offset right broach handle	2-0199002	1

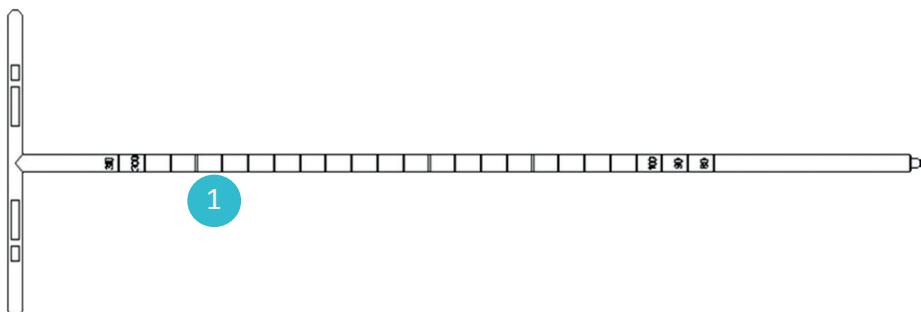
Anterior approach instrumentation set



Item	Description	Reference	Qty
1	Dual curvature Hohmann retractor	2-0199200	1
2	Charnley retractor frame	2-0199100	1
3	Valve fixation ring	2-0120700	1
4	Valve lengths 60, 80 and 100 for Charneley retractor frame	2-0122906 to 2-0122910	1 of each
5	Femoral preparation starter broach	2-0199300	1
6	Straight broach handle for HUETER approach - navigated	2-0123000	1
7	Offset broach handle for HUETER approach - Right	2-0123700	1
8	Offset broach handle for HUETER approach - Left	2-0123800	1
9	Holding rod 10 / 15	2-0126100	1
10	Impactor tip - Monobloc stem - Anterior approach	2-0198401	1
11	Impactor tip - Modular stem - Anterior approach	2-0198402	1

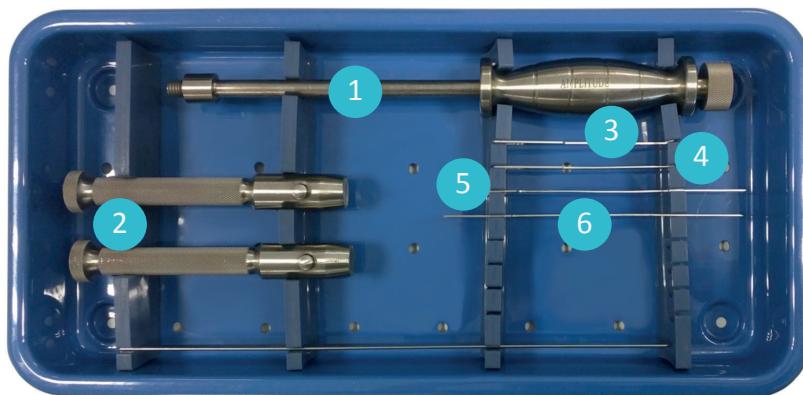
Instrumentation

Cement restrictor instrumentation set



Item	Description	Reference	Qty
1	Inserter for cement restrictor	2-0103400	1

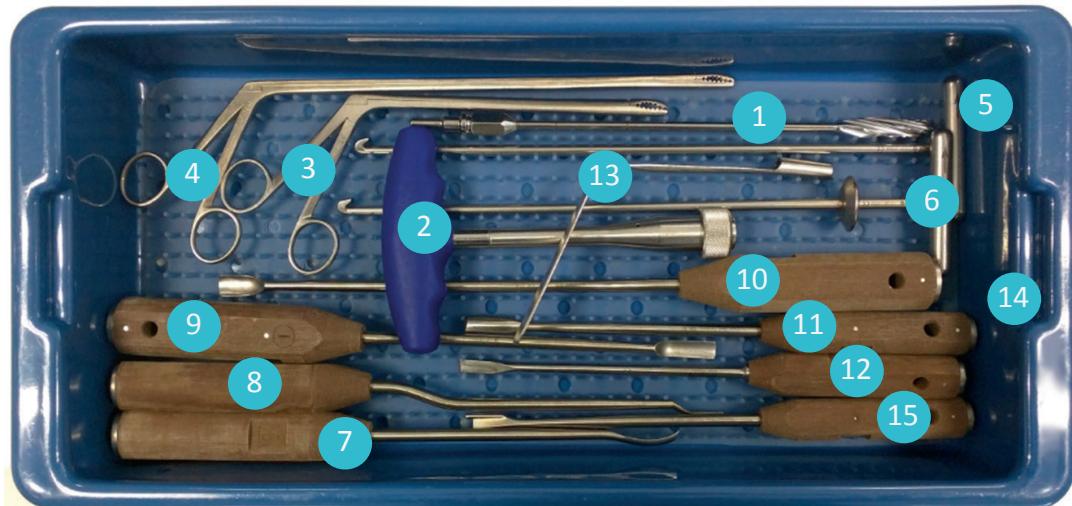
Cement stem extraction instrumentation set



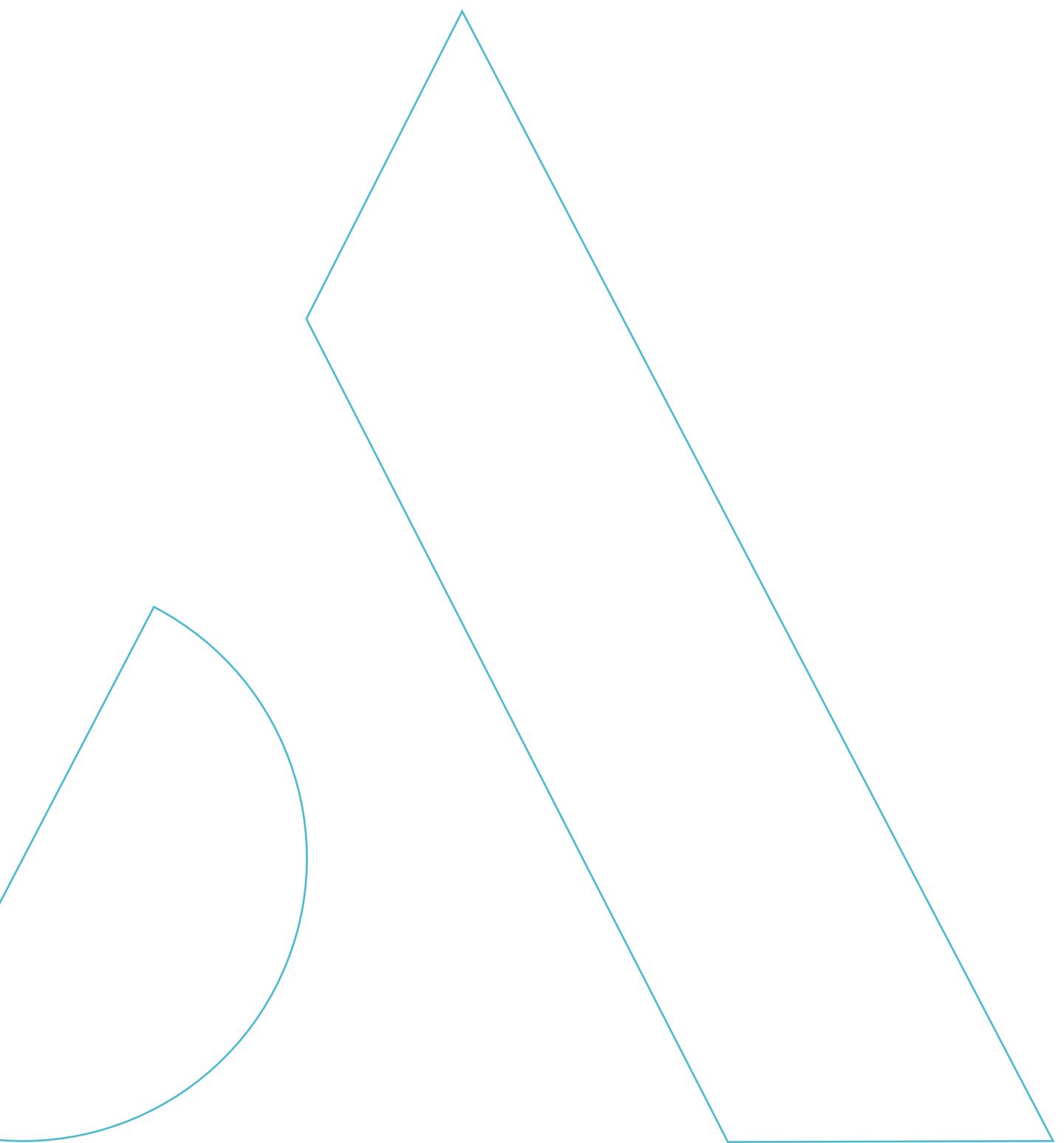
Item	Description	Reference	Qty
1	Extraction slap hammer	12-007-000	1
2	Quick release handle	10-020-000	2
3	Flexible chisel blade 8 mm - short	2-0198801	1
4	Flexible chisel blade 10 mm - short	2-0198803	1
5	Flexible chisel blade 8 mm - long	2-0198802	1
6	Flexible chisel blade 10 mm - long	2-0198804	1

Instrumentation

Cement extraction instrumentation set



Item	Description	Reference	Qty
1	Manual reamer 7 mm for handle 3.40.550	3-40 252	1
1	Manual reamer 8 mm for handle 3.40.550	3-40 253	1
1	Manual reamer 9 mm for handle 3.40.550	3-40 254	1
1	Manual reamer 10 mm for handle 3.40.550	3-40 255	1
1	Manual reamer 11 mm for handle 3.40.550	3-40 256	1
1	Manual reamer 12 mm for handle 3.40.550	3-40 257	1
1	Manual reamer 13 mm for handle 3.40.550	3-40 258	1
1	Manual reamer 14 mm for handle 3.40.550	3-40 259	1
2	Quick release handle	58-02-4008	1
3	Cement pincer - short	3-30-542	1
4	Cement pincer - long	3-30-543	1
5	Cement extraction curette	3-30-318	1
6	Cement extraction curette - 10 mm	3-30-319	1
7	Cement extracting chisel NEG 9 mm L 340 mm	3-30-312	1
8	Cement extracting chisel NEG 9 mm L 290 mm	3-30-309	1
9	Cement extracting chisel POS 9 mm L 340 mm	3-30-313	1
10	Cement extracting chisel NEG 11,5 mm L 400 mm	3-30-314	1
11	Lexer chisel 8 mm L 280 mm	3-30-304	1
12	Cup removal chisel 7.5 L 310 mm	3-30-316	1
13	Spiraled drill bit guide 6 mm	3-30-131	1
14	Spiraled drill bit 6 mm	3-40-297	1
15	Cement splitting blade 5 mm L 280 mm	3-30-307	1





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