





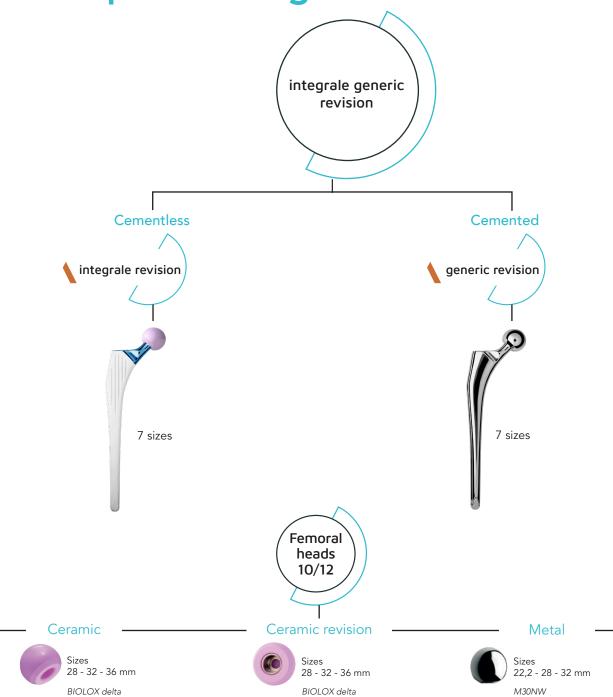
Surgical Technique



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Concept and range



| Size | Neck length |
|---------|-------------------------------------|
| - | - |
| Ø 28 mm | CC -3,5 mm CM 0 mm CL +3,5 mm |
| Ø 32 mm | CC -4 mm CM 0 mm CL +4 mm |

| Neck length |
|---------------------|
| _ |
| CC -3 mm CM 0 mm |
| CL +4 mm |
| CC -3 mm CM 0 mm |
| |

| Size | Neck length |
|-----------|-------------|
| Ø 22,2 mm | CC -2 mm |
| | CM 0 mm |
| | CL +2 mm |
| Ø 28 mm | CC -3,5 mm |
| • | CM 0 mm |
| | CL +3,5 mm |
| | CXL +7,5 mm |
| Ø 32 mm | CC +4 mm |
| | CM 0 mm |
| | CL +4 mm |

 $SN = Short\ Neck\ ;\ MN = Medium\ Neck\ ;\ LN = Long\ Neck\ ;\ XLN = Extra-Long\ Neck$



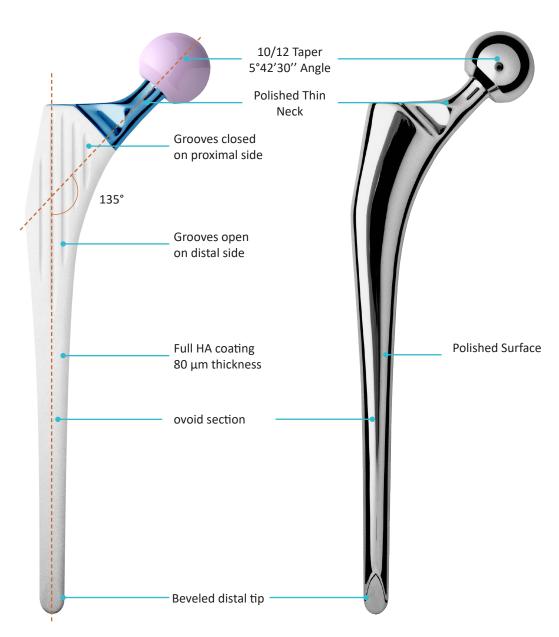
Concept and range

INTEGRALE revision and GENERIC revision are straight femoral stems. They feature an ovoid cross-section, identical to primary stems INTEGRALE and GENERIC. They are available in 7 sizes with homothetical evolution.

Neck-shaft angle of INTEGRALE revision and GENERIC revision is 135° for all sizes, and neck length is 37.5 mm (distance between neck cut level and femoral head centre with medium neck) for all sizes. This results in 3 mm lateralization in comparison with primary range.

INTEGRALE revision and GENERIC revision are in average 50 mm longer than primary stems (INTEGRALE, GENERIC) for the same size.



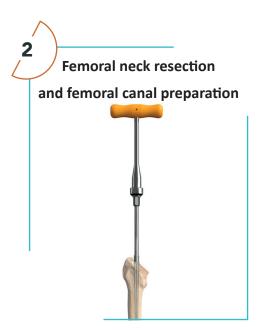


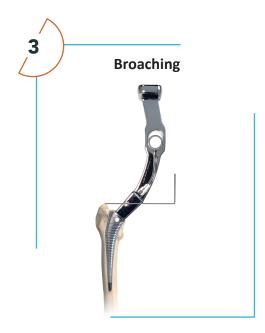
Material: Titanium alloy (Ti6Al4V) anodized

Material: Stainless steel (M30NW)

Surgical technique overview



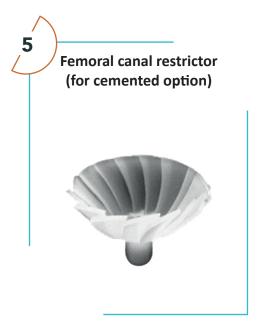


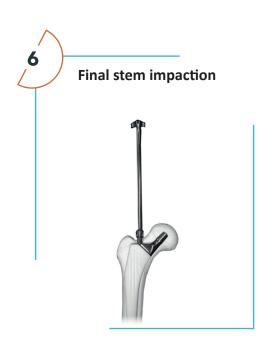






Surgical technique overview







Preoperative planning



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

- Determine the position of the joint's centre.
- Assess metaphyseal bone defect in revision cases.
- Choose the height of the GENERIC or INTEGRALE revision femoral stem (identical templates for the 2 femoral stems). None 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 revision stem is used.

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

NOTE

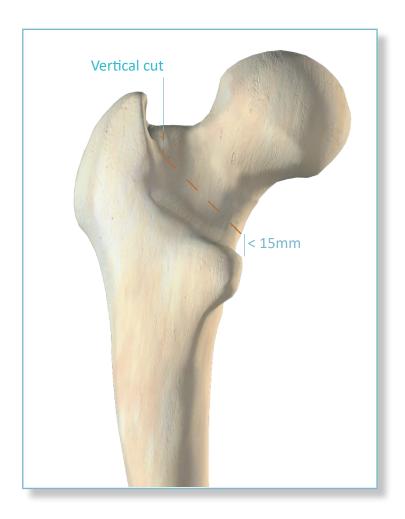
Templates are provided at scales 115%. Other magnifications and digital templates are available on request.

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.



Pemoral neck resection



Assess the anatomical landmarks, lesser trochanter, trochanteric fossae and greater trochanter.

Determine the level of the cervical cut, defined by the preoperative planning. This is usually 15mm above the lesser trochanter.

Identify the level of resection on the bone in relation to the selected landmarks. The neck can be cut before or after dislocation of the femoral head, taking care to protect the surrounding soft tissue.

When the cut is made lower down, a second vertical cut may be necessary at the base of the neck and greater trochanter. Adjustments can then be made with the broach in place if necessary.

Femoral canal preparation



Femoral canal preparation can be done either before or after acetabular preparation.

After exposing implants and before removing femoral stem in place, it is necessary to identify a reliable anatomical landmark (greater or lesser trochanter, fracture level, or create a landmark).

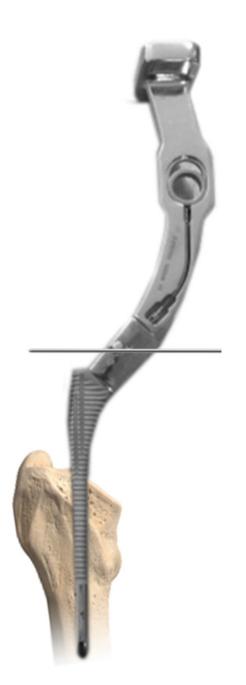
If no femorotomy is performed, diaphyseal axis should be identified and greater trochanter should be prepared in order to prevent any varus positionning of the stem.

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 reamer 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.



Broaching



Assemble the smallest size femoral broach (size 1) onto the appropriate broach handle for the approach being performed. The orientation of the broach must remain in the axis of the femur previously determined. Impact the broach into the femur.

Gradually increase the size of the broach to be lowered into the femur, until satisfactory metaphyseal filling, axial and rotational stability are obtained. The impaction level is represented of embedment is represented by the junction between the broach handle and the broach. It is recommended that this junction is visible with the last broach in place. To check the impaction level, insert the blunt K-wire into the broach handle (this represents the horizontal projection of the centre of the medium neck prosthetic head) and compare the height with the marker determined during preoperative planning.

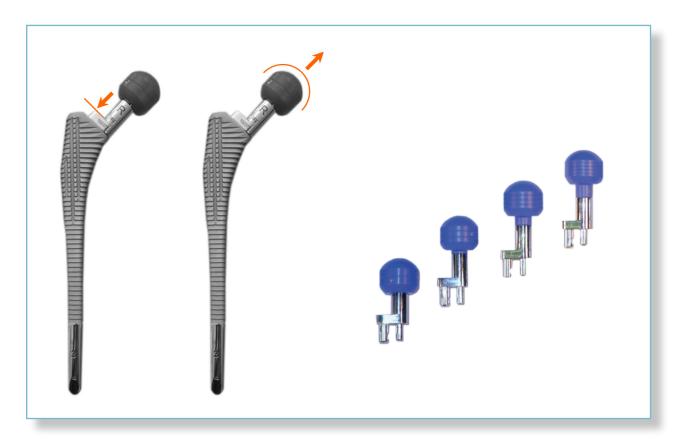
To avoid varus positioning, insert the broach according to the anatomical axis.

The size of the last broach usually corresponds to the implant size planned. Leave the last broach into the femur and remove the broach handle.

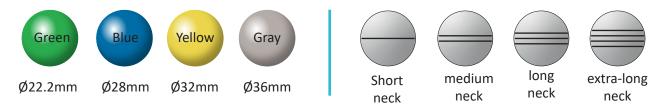
NOTE

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

4 Trials on broach



Place the revision 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 a different trial neck until the desired stability and range of motion are achieved.

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

NOTE

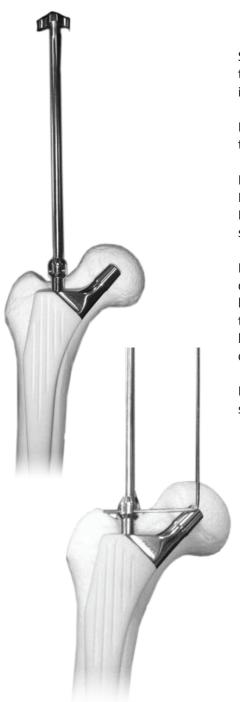
The femoral neck can be recut directly on the broach.

NOTE

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



Impaction of cementless femoral stems: integrale revision



Select the INTEGRALE revision 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 achevied. 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.

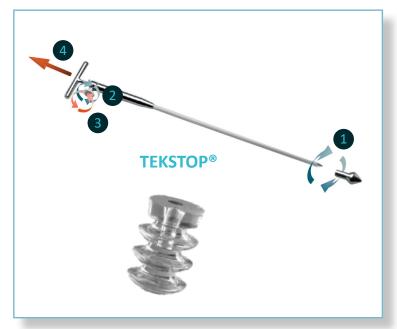
Reduction trials can be performed using trial heads on the stem to validate stability and leg length.

NOTE

When using a GENERIC revision cemented stem, follow instructions page 14.

Impaction of cemented femoral stem: generic revision

Cement restrictor insertion





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, absorbable restrictor, a one-size nonabsorbable UHMWPE restrictor, and a non-resorbable solid fin plug.

Introduce the cement restrictor 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

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 non-absorbable 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.

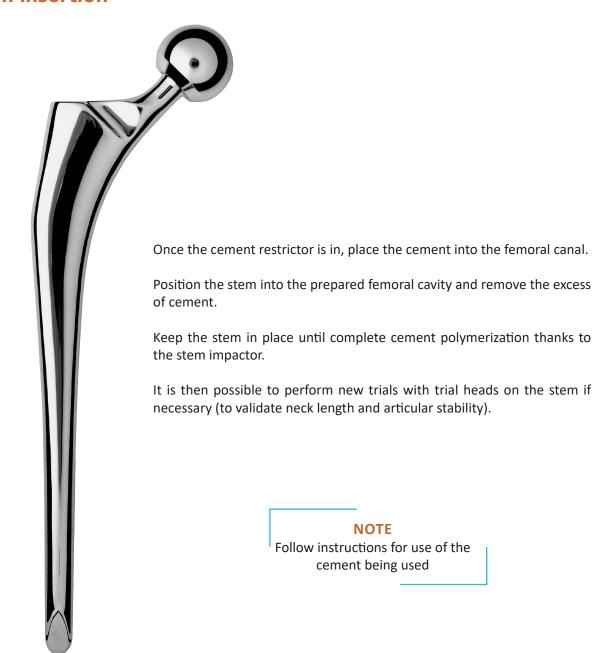
NOTE

Follow the instruction for use of the cement being used



7 Impaction of cemented femoral stem: generic revision

Stem insertion



8 Final head impaction



Impaction of metal 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 with a light blow in the axis .

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 implant (optional)

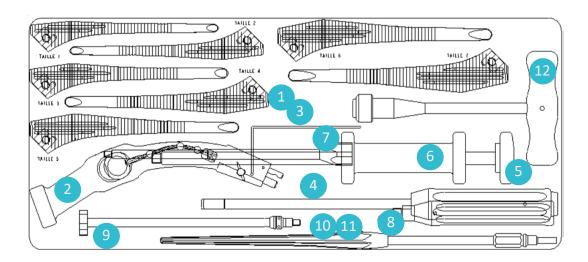


Remove the femoral head by tapping around the base of the head.

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.

Integrale, generic revision instruments set



| 1 Revision femoral broach size 1 2-0100301 1 Revision femoral broach size 2 2-0100302 1 Revision femoral broach size 3 2-0100303 1 Revision femoral broach size 4 2-0100304 1 Revision femoral broach size 5 2-0100305 1 Revision femoral broach size 6 2-0100306 1 Revision femoral broach size 7 2-0100307 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 4 Femoral stem impactor 2-0100900 | Qty |
|---|-----|
| 1 Revision femoral broach size 3 2-0100303 1 Revision femoral broach size 4 2-0100304 1 Revision femoral broach size 5 2-0100305 1 Revision femoral broach size 6 2-0100306 1 Revision femoral broach size 7 2-0100307 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| 1 Revision femoral broach size 4 2-0100304 1 Revision femoral broach size 5 2-0100305 1 Revision femoral broach size 6 2-0100306 1 Revision femoral broach size 7 2-0100307 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| 1 Revision femoral broach size 5 2-0100305 1 Revision femoral broach size 6 2-0100306 1 Revision femoral broach size 7 2-0100307 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| 1 Revision femoral broach size 6 2-0100306 1 Revision femoral broach size 7 2-0100307 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| 1 Revision femoral broach size 7 2-0100307 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| 2 Broach handle 2-0103100 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| 3 Alignment pin Ø2 A/P 2-0114000 | 1 |
| | 1 |
| A Femoral stem impactor 2.0100000 | 1 |
| - Temoral 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 |





Integrale, generic revision instruments set



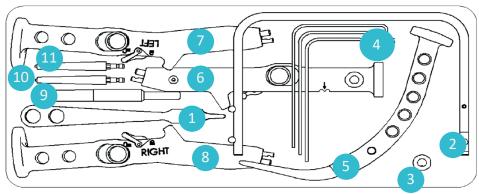
| Item | Description | Reference | Qty |
|------|--|---------------------------|-----------|
| 1 | Trial revision neck Ø22.2 Short, Medium and Long neck | 2-0100605 to 2-0100607 | 1 of each |
| 2 | Trial revision neck Ø28 Short, Medium, Long and Extra-long neck | 2-0100601 to 2-0100604 | 1 of each |
| 3 | Trial revision neck Ø32 Short, Medium and Long neck | 2-0100608 to 2-0100610 | 1 of each |
| 4 | Trial head on stem Ø22.2 Short, Medium and Long neck | 2-0100405 to 2-0100407 | 1 of each |
| 5 | Trial head on stem Ø28 Short, Medium, Long and Extra-long neck | 2-0100401 to 2-0100404 | 1 of each |
| 6 | Trial head on stem Ø32 Short, Medium and Long neck | 2-0100408 to 2-0100410 | 1 of each |
| 7 | Universal handle | 2-0101000 | 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 head | 2-0101400 | 1 |
| 10 | Impactor for Ø28 et Ø32 head | 2-0114200 | 1 |

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

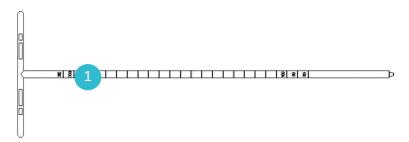


| Item | Description | Reference | Qty |
|------|---|---------------------------|-----------|
| 1 | Dual curvature Hohmann retractor | 2-0199200 | 1 |
| 2 | Charnley retractor frame | 2-0199100 | 1 |
| 3 | Valve fixation ring | 2-0120700 | 1 |
| 4 | Valve lengths 60, 80 and 100 for Charnley retractor 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 - non resorbable



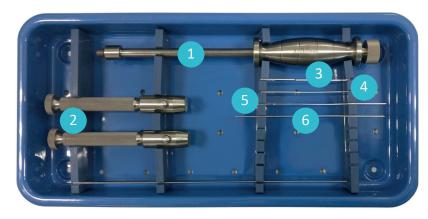
| Item | Description | Reference | Qty |
|------|--------------------------------|-----------|-----|
| 1 | Inserter for cement restrictor | 2-0103400 | 1 |

Cement restrictor instrumentation set - resorbable



| Item | Description | Reference | Qty |
|------|-----------------------------------|---------------|-----------|
| 1 | Trial Olive - 8 to 18 mm diameter | T067702 to 07 | 1 of each |
| 2 | Restrictor inserter | T067701 | 1 |

Cementless 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 |

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 spliting blade 5 mm L 280 mm | 3-30-307 | 1 |
| | | | |







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