

Expersus Femoral Stem cemented

SURGICAL INSTRUCTIONS



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INTRODUCTION AND PRODUCT DESCRIPTION

The Expersus Femoral Stem is a hip endoprosthesis for cemented anchorage in the femur. It is made of CoCrMo wrought alloy (ISO 5832-12) and comes with a 12/14 cone. The shaft can be combined with both metal and ceramic femoral heads. The cemented Expersus Femoral Stem has a smooth, fully polished surface.

In order to treat the various femoral anatomies of the patients, the Femoral Stem comes in 9 sizes with a standard 125° and standard 135° variant. The body of the stem has a triple tapered shape in order to ensure both self-clamping as well as the necessary rotational stability. There is therefore a wide range available for the reconstruction of the natural geometry of the joint using the biochemical parameters of centre of rotation, leg length and CCD angle.

All implant variants of the Expersus Femoral Stem can be used with the same instrument set. For the modular rasps there are two trial cones available with the corresponding offsets which serve the purpose of intraoperative trial reduction and are therefore used for confirming the preoperatively selected implant size and version. Compared to all cemented Expersus Femoral Stems, the rasps are oversized by 1 mm through an equal all-round cement coating.

Indications for the use of the Expersus Femoral Stem

- Advanced degeneration of the hip joint due to degenerative, post-traumatic, rheumatoid arthritis or congenital hip dysplasia
- Fracture or avascular necrosis of the femoral head
- Sequelae of earlier surgical procedures, e.g. osteosynthesis, articular reconstruction, arthrodesis
- Hemiarthroplasty or total hip prosthesis
- Certain cases of ankylosis

Contraindications for the use of the Expersus Femoral Stem

- Acute or chronic, local or systemic infection
- Severe muscle, nerve or vascular diseases endangering the extremity concerned
- Missing bone substance or poor bone quality that threatens the stable fit of the prosthesis
- Any underlying condition that might compromise the function of the implant
- Hypersensitivity to the materials used.

Note:

If femoral heads with a neck length of XL are used, the range of motion is reduced by approximately 30° and achieves flexion and extension values of between 80° and 100°.

Risks which may impair the success of the surgery

Potential risks associated with the procedure are:

- Disorders of the bone metabolism (osteoporosis, osteomalacia)
- Occurrence of fissures, in rare cases fractures of the femoral bone
- Circulatory disorders of the affected limb
- Neurological disorders of the affected limb
- Muscular dysfunction of the affected joint
- Overweight
- Alcohol or substance abuse
- Patient groups with mental disorders or addictions
- Pregnancy
- Growth in children and adolescents
- Expected extreme stresses due to work or sports
- Epilepsy or other causes of repeated accidents with an increased risk of fracture
- Joint deformities which complicate anchoring of the implant
- Weakening of the supporting structures due to a tumour
- High-dose administration of cortisone or cytotoxic drugs

- History or risk of infectious diseases with potential joint manifestation
- History of deep vein thrombosis and/or pulmonary embolism
- All general surgical risks

SURGICAL TECHNIQUE

The information provided in the Surgical Technique constitutes recommendations and notes only: the detailed implementation or the implementation options depend on the individual abilities and experience of the user.

For more detailed information about the implant system and the instruments, please see the respective Instructions for Use.

Preoperative planning

Preoperative planning can be used to:

- determine the resection plane
- determine the expected implant size and the correct offset
- reconstruct the optimum stem position with the biomechanical centre of rotation
- compensate for any difference in leg length

The final stem size is determined intraoperatively by the surgeon. These may differ from the size planned on the X-ray image.

For the preoperative planning there are X-ray templates available in an analogous shape with a magnification of 15% (Figure 1).

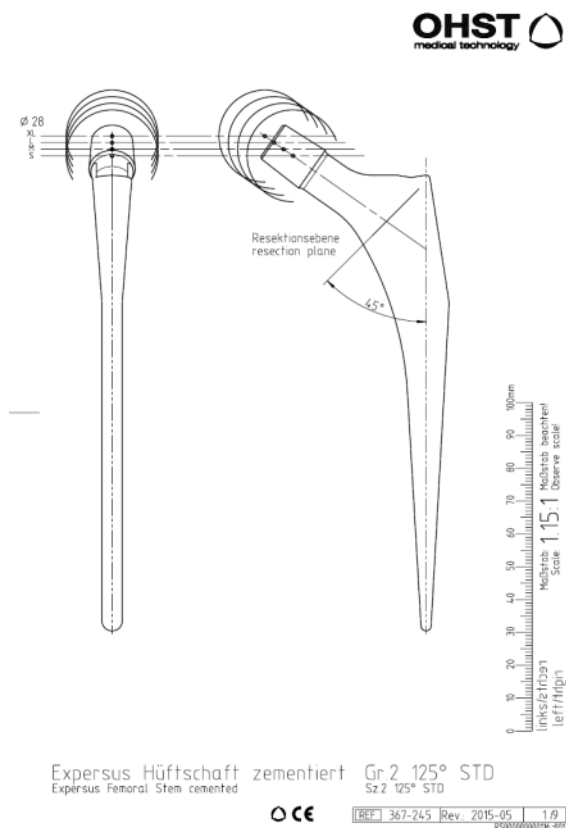


Figure 1: Example of an X-ray template for the cemented Expersus stem

Furthermore, digital X-ray templates at a scale of 1:1 for use with the planning software MediCAD* are available for downloading by default. Figure 2 shows a digital preoperative planning of an Expersus Femoral Stem cemented with a Primaro Cup.



Figure 2: Example of preoperative planning (using the MediCAD software)

* On request we will provide the digital X-ray templates in databases of other suppliers for digital planning software.

Approach to the hip

Any approach to the hip joint considered appropriate by the surgeon is possible. The surgeon should have a good view of the anatomical structures so that correct working with the instruments is not impeded.

Resection of the femoral head

- After opening the joint capsule and dislocating the femoral head from the cup, the femoral head is resected as determined in the preoperative planning (Figure 3).
- The femoral head must be removed in full.

Note:

In order to mark the resection plane, a femoral neck resection guide (see optional accessories) can be used.

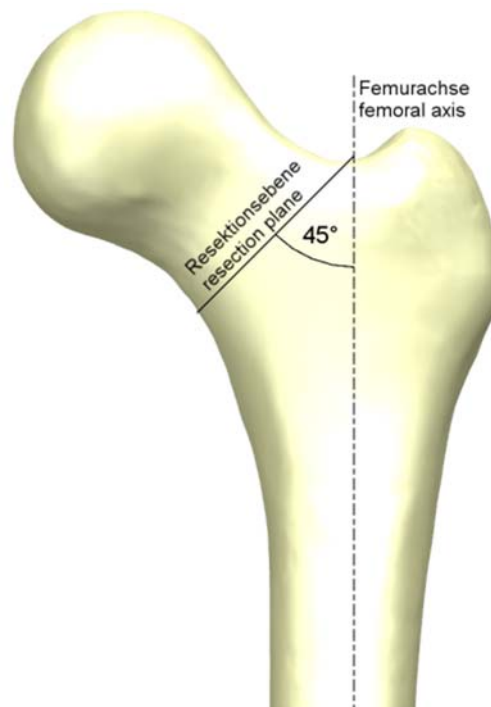


Figure 3: Resection of the femoral head

Opening of the medullary cavity

- Open the medullary cavity using the cavity chisel (Figure 4).

Note:

The cavity chisel has to be applied to the far lateral and dorsal side. This facilitates the subsequent driving in of the rasps in the direction of the femoral axis.

- Fracturing of the trochanter major must be avoided.
- The cavity chisel should be applied according to the desired antetorsion.



Figure 4: Opening of the medullary cavity with a cavity chisel

Note:

The medullary cavity opening can be opened further with the surgical awl (Figure 5).

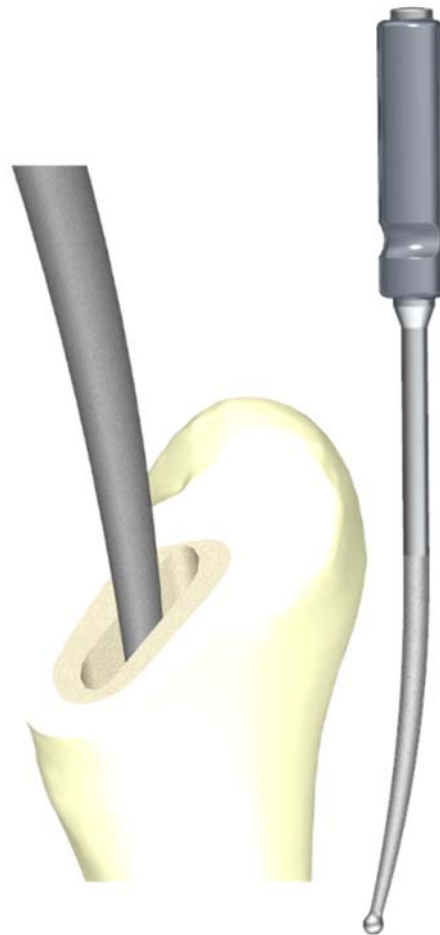


Figure 5: Surgical awl for extending the medullary cavity opening

Preparation of the femoral stem

After the medullary cavity has been opened, rasping of the femoral stem can begin (Figure 6).

- The first rasp determines the orientation of the following sizes. Care must be taken to ensure correct antetorsion already before the first rasp is applied.
- Antetorsion can be reviewed by means of the guide rod and rasp handle and is usually 10°-15°.
- The procedure is started with the smallest rasp size, which is connected to the rasp handle.
- After that, the subsequent rasps are used in ascending order until the preoperatively determined size is reached.
- The sizes of the rasps conform to the sizes of the implants.
- The correct position of the rasp inside the femur can be verified with an image converter.



Figure 6: Rasping of the femur

Note:

If during the rasping procedure the stem size does not correspond to the preoperatively determined size and if there is a difference of two or more sizes, the alignment of the axis may be incorrect or there may be an osseous obstruction present. In this case the selected stem might be too small and would therefore not provide the required stability.

Note:

On request, special rasp handles are available for the various access routes.

Trial reduction

The rasps are designed in such a way that they can also be used for trial reductions. The leg length, the range of motion and the tension of the ligaments can be checked by attaching the various trial cones and trials heads.

- Remove the handle from the rasp, which remains in the femur.
- Attach the trial cone to the rasp (Figure 7).

Note:

Trial cones with two offsets are offered for trial reductions of the various stem versions. The trial cones snap into place as soon as they are in their correct position.

Note:

Trial heads with various diameters are offered in the neck lengths S to XL for trial reductions..

- Attach the trial head to the trial cone by hand (Figure 8).
- After reduction, the definitive stability, mobility and muscle tension should be checked.



Figure 7: Trial reduction with a rasp and a trial cone



Figure 8: Trial reduction with a rasp, a trial cone and trial head (here neck length XL)

Note on removing the implants

Depending on the sterilisation method used, implants are packaged in a triple transparent pouch made of plastic laminated film (sterilisation by irradiation at least 25 kGy) or in a double transparent pouch made of Tyvek® (ethylene oxide sterilisation) with a carton.

The outer pouch of the triple transparent pouch packaging is to be removed by the non-sterile personnel together with the carton. For the double transparent pouch packaging, only the carton is to be removed by the non-sterile personnel. The second pouch must be opened such that the sterility of the inner pouch is not compromised. The inner pouch is removed and opened by the sterile personnel. The implant must then be presented to the surgeon, who can then directly remove the sterile implant.

Implantation of the cement restrictor

The cement restrictor is used depending on the preoperatively determined diaphyseal diameter of the medullary cavity. A special insertion instrument is available to insert the restrictor in the optimal depth in a controlled manner. Size 1 cement restrictor is recommended for medullary cavity diameters between 14 mm and 19 mm, or size 2 for diameters between 18 mm to 22 mm.

- Screw the cement restrictor onto the threaded rod of the insertion instrument and insert it into the medullary cavity (Figure 9).

Note:

The insertion depth can be read off the scale on the threaded rod.

Note:

The insertion depth should exceed the shaft length of the Femoral Stem prosthesis being implanted by a minimum of 5 mm, but no more than 20 mm.

Note:

During an X-ray control, the position of the cement restrictor in the femoral shaft can also be assessed based on the position of the radiopaque ring.

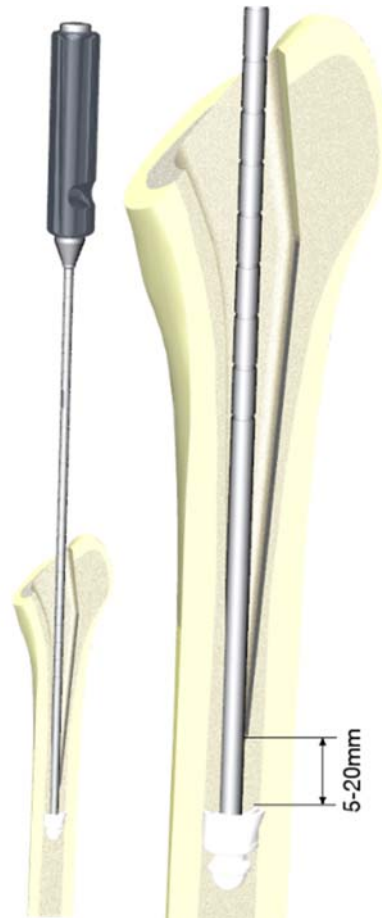


Figure 9: Insertion of the cement restrictor using the corresponding insertion instrument

- After that, remove the insertion instrument by rotating it anti-clockwise (Figure 10).

Note:

The implantation of the cement restrictor should always be completed before the bone cement is mixed.

- After the cement restrictor is inserted, the implant bed has to be rinsed and dried.
- The implantation of the Expersus Femoral Stem can then be continued.



Figure 10: Implanted cement restrictor

Implantation of the Expersus Femoral Stem

Note:

The cemented Expersus Femoral Stem is designed only for implantation with bone cement. It is imperative that user guides of the cement manufacturer are observed!

- Insert the cement using a modern cementing technique.
- Immediately after injection of the cement, insert the prosthesis into the implant bed up to the resection plane using the stem impactor (Figure 11).
- Apply mild pressure and wait until the bone cement has set (note manufacturer's instructions on setting times).
- Thoroughly clean and dry the prosthetic cone.
- Position the femoral head with the previously determined neck length (S to XL).
- Reduce the stem with the femoral head into the cup and check the range of motion, leg length and tension of the ligaments.
- The operation is routinely completed with the layer-by-layer wound closure.

Caution:

No femoral heads with a neck length greater than XL may be used!

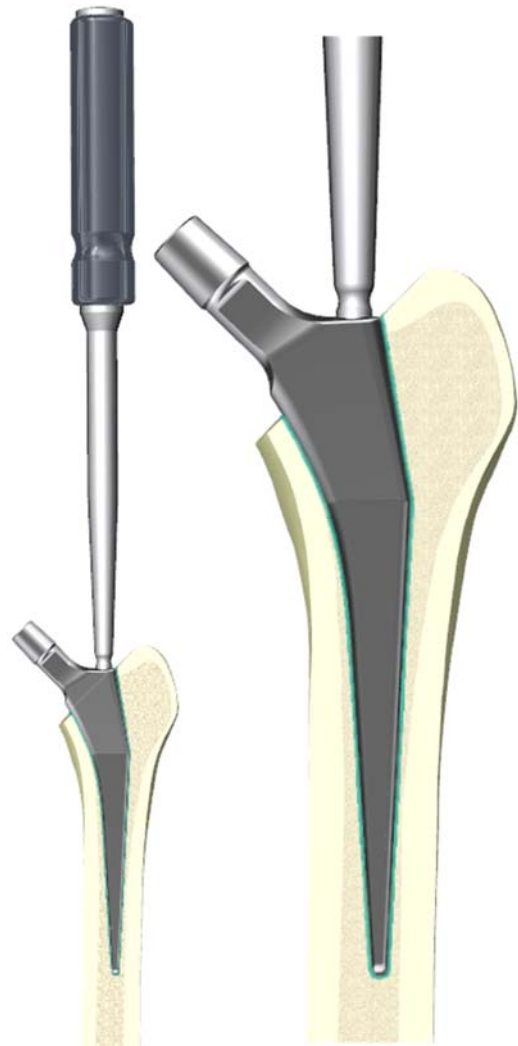


Figure 11: Implantation of the stem

IMPLANTS

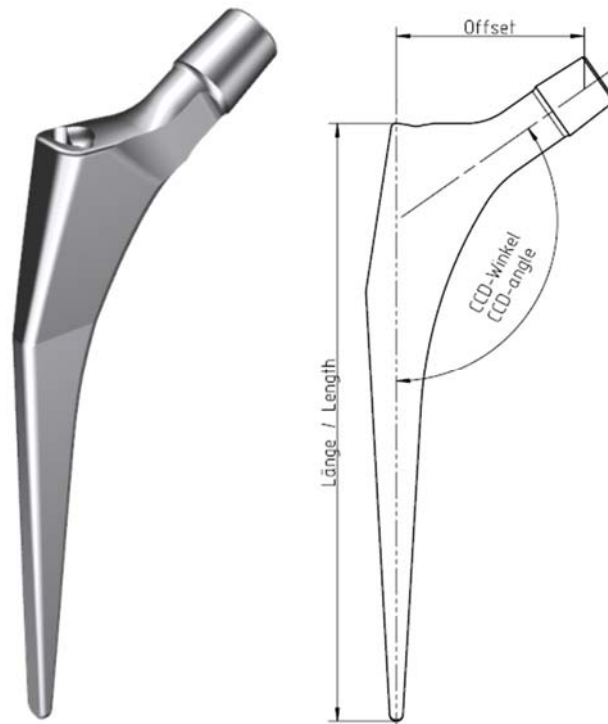


Figure 12: Expersus Femoral Stem cemented (left) and drawing of the Expersus stem with dimensions (right)

Expersus Femoral Stem cemented STD 125° (ISO 5832-12 CoCrMo)

Implant		Length [mm]	Offset [mm]	Art. no.
Expersus Femoral Stem size 2 STD, 125°, cemented	ISO 5832-12 CoCrMo	138.8	43.5	367-1326
Expersus Femoral Stem size 3 STD, 125°, cemented	ISO 5832-12 CoCrMo	144.0	45.5	367-1327
Expersus Femoral Stem size 4 STD, 125°, cemented	ISO 5832-12 CoCrMo	149.1	45.9	367-1328
Expersus Femoral Stem size 5 STD, 125°, cemented	ISO 5832-12 CoCrMo	153.1	46.7	367-1329
Expersus Femoral Stem size 6 STD, 125°, cemented	ISO 5832-12 CoCrMo	158.9	47.1	367-1330
Expersus Femoral Stem size 7 STD, 125°, cemented	ISO 5832-12 CoCrMo	163.9	47.9	367-1331
Expersus Femoral Stem size 8 STD, 125°, cemented	ISO 5832-12 CoCrMo	169.1	49.1	367-1332
Expersus Femoral Stem size 9 STD, 125°, cemented	ISO 5832-12 CoCrMo	179.0	50.4	367-1333
Expersus Femoral Stem size 10 STD, 125°, cemented	ISO 5832-12 CoCrMo	188.2	51.6	367-1334

Expersus Femoral Stem cemented STD 135° (ISO 5832-12 CoCrMo)

Implant		Length [mm]	Offset [mm]	Art. no.
Expersus Femoral Stem size 2 STD, 135°, cemented	ISO 5832-12 CoCrMo	138.8	38.8	367-1317
Expersus Femoral Stem size 3 STD, 135°, cemented	ISO 5832-12 CoCrMo	144.0	40	367-1318
Expersus Femoral Stem size 4 STD, 135°, cemented	ISO 5832-12 CoCrMo	149.1	40.8	367-1319
Expersus Femoral Stem size 5 STD, 135°, cemented	ISO 5832-12 CoCrMo	153.1	41.4	367-1320
Expersus Femoral Stem size 6 STD, 135°, cemented	ISO 5832-12 CoCrMo	158.9	41.8	367-1321
Expersus Femoral Stem size 7 STD, 135°, cemented	ISO 5832-12 CoCrMo	163.9	42.5	367-1322
Expersus Femoral Stem size 8 STD, 135°, cemented	ISO 5832-12 CoCrMo	169.1	43.5	367-1323
Expersus Femoral Stem size 9 STD, 135°, cemented	ISO 5832-12 CoCrMo	179.0	44.6	367-1324
Expersus Femoral Stem size 10 STD, 135°, cemented	ISO 5832-12 CoCrMo	188.2	45.6	367-1325

Cement restrictor (ISO 5834-2 UHMWPE)



Figure 13: Cement restrictor

Implant		Art.-No.
Cement Restrictor Size 1, Outer-Ø24mm	ISO 5834-2 UHMWPE	506-101
Cement Restrictor Size 2, Outer-Ø27mm	ISO 5834-2 UHMWPE	506-102

Unipolar heads (ISO 5832-9 implant steel)



Figure 14: Unipolar head

Implant		Nominal diameter	Neck length	Art. no.
Unipolar head 12/14 size S	ISO 5832-9 implant steel	Ø 40 mm to Ø 60 mm	-4 mm	155-140 to 155-160
Unipolar head 12/14 size M	ISO 5832-9 implant steel	Ø 40 mm to Ø 60 mm	0 mm	155-040 to 155-060
Unipolar head 12/14 size L	ISO 5832-9 implant steel	Ø 40 mm to Ø 60 mm	+4 mm	155-240 to 155-260

Femoral heads



Figure 15: Femoral heads

Implant		Diameter	Neck length	Art.-No.
Femoral Head 12/14	ISO 5832-12 CoCrMo	Ø 22 mm	S (-4 mm) M (0 mm) L (+4 mm)	030-2200 to 030-2202
Femoral Head 12/14	ISO 5832-9 Implant Steel	Ø 28 mm	S (-3,5 mm) M (0 mm) L (+3,5 mm)	020-2800 to 020-2803
Femoral Head 12/14	ISO 5832-12 CoCrMo		XL (+7 mm)	030-2800 to 030-2803
Bilox® delta Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic	Ø 28 mm	S (-3,5 mm) M (0 mm) L (+3,5 mm)	367-1140 to 367-1142
ELEC® Femoral Head 12/14	ISO 6474-1 Al ₂ O ₃ - Ceramic			384-001 to 384-003
ELEC®plus Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic			110230, 110240, 110250
ELEC®plus Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic			013-001 to 013-003
Femoral Head 12/14	ISO 5832-9 Implant Steel	Ø 32 mm	S (-4 mm) M (0 mm) L (+4 mm)	020-3200 to 020-3203
Femoral Head 12/14	ISO 5832-12 CoCrMo		XL (+8 mm)	030-3200 to 030-3203
Bilox® delta Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic	Ø 32 mm	S (-4 mm) M (0 mm) L (+4 mm) XL (+8 mm)	367-1143 to 367-1145 and 367-1149
ELEC® Femoral Head 12/14	ISO 6474-1 Al ₂ O ₃ - Ceramic	Ø 32 mm	S (-4 mm) M (0 mm) L (+4 mm)	384-004 to 384-006
ELEC®plus Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic	Ø 32 mm	S (-4 mm) M (0 mm) L (+4 mm)	110260, 110270, 110280, 110291
ELEC®plus Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic		XL (+8 mm)	013-004 to 013-007
Bilox® delta Femoral Head 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic	Ø 36 mm	S (-4 mm) M (0 mm) L (+4 mm) XL (+8 mm)	367-1146 to 367-1148 and 367-1150
ELEC® Femoral Head 12/14	ISO 6474-1 Al ₂ O ₃ - Ceramic	Ø 36 mm	S (-4 mm) M (0 mm) L (+4 mm)	384-007 to 384-009
ELEC®plus Hüftkopf 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic	Ø 36 mm	S (-4 mm) M (0 mm) L (+4 mm)	110300, 110310, 110320, 110330
ELEC®plus Hüftkopf 12/14	ISO 6474-2 Al ₂ O ₃ / ZrO ₂ - Ceramic		XL (+8 mm)	013-008 to 013-011

INSTRUMENTS

Expersus Femoral Stem Instrument Set (Art. no. 367-1493)

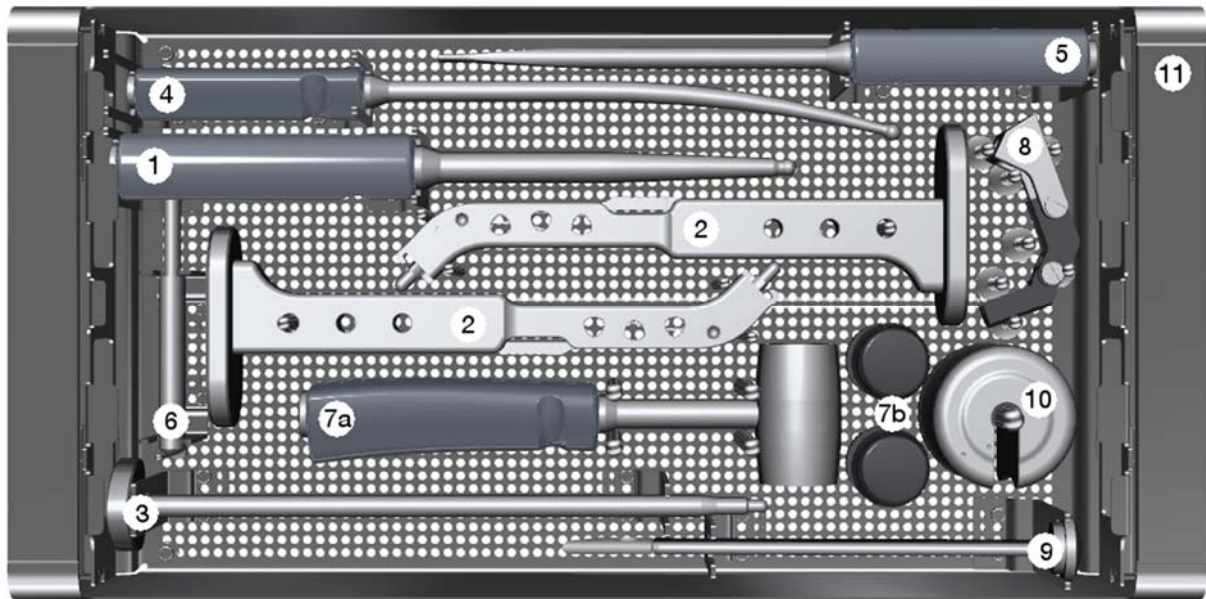


Figure 16: Expersus Femoral Stem Instrument Set

No.	Instrument	Art. no.
1	SPC Stem Impactor with silicone handle grey, L=300mm	271-301
2	Rasp handle straight L=253mm	271-321
3	Extractor Bar M8	367-1251
4	Opening broach	367-271
5	Biathlon Insertter	367-284
6	Guide rod Ø8mm L=120mm	506-015
7a	Hammer 1100g with silicone handle grey, L=250mm	506-072
7b	Impact Head for Hammer with Silicone Handle	506-072 II/II
8	Stem-Repositioner cone 12/14	506-073
9	Box chisel small 6mm x 20mm	506-091
10	Modular Weight	506-2107
11	Biathlon Stem Tray I	367-285

Rasp Instrument Set Expersus (Art. no. 367-1492)

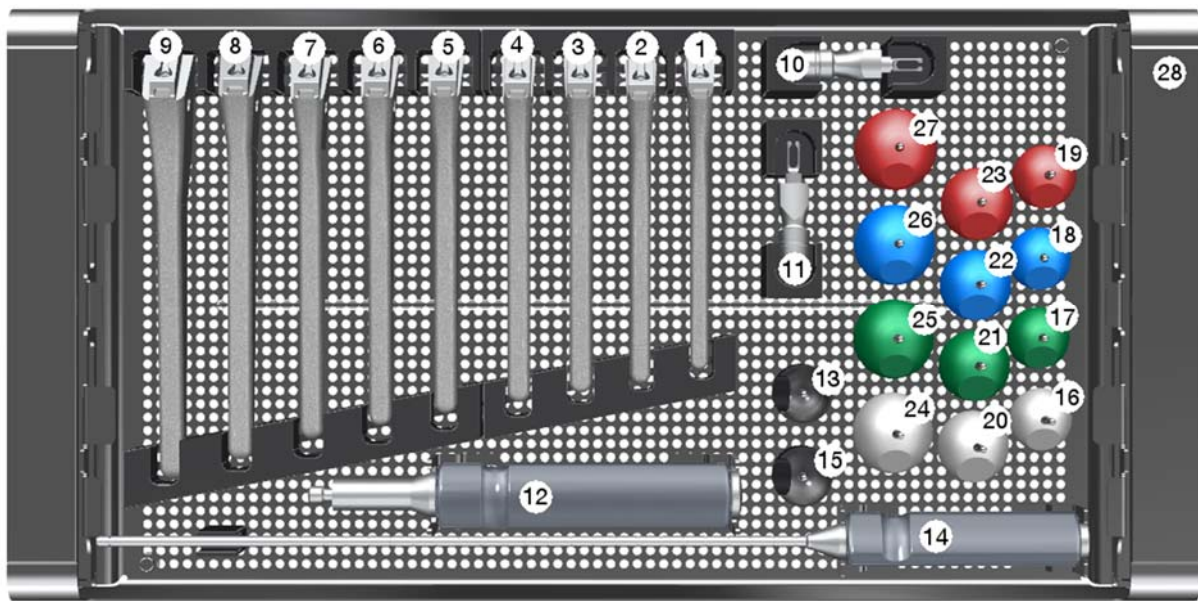


Figure 17: Rasp Instrument Set Expersus

No.	Instrument	Art. no.
1	Expersus rasp size 2	367-1380
2	Expersus rasp size 3	367-1381
3	Expersus rasp size 4	367-1382
4	Expersus rasp size 5	367-1383
5	Expersus rasp size 6	367-1384
6	Expersus rasp size 7	367-1385
7	Expersus rasp size 8	367-1386
8	Expersus rasp size 9	367-1387
9	Expersus rasp size 10	367-1388
10	Expersus trial cone 135°	367-1389
11	Expersus trial cone 125°	367-1437
12	Femoral Head impactor handle with silicone handle grey, L=192mm	506-060
13	Head End Ø28/Ø32mm for Femoral head impactor Handle	506-062
14	Insertion instrument for cement restrictor with silicone handle grey	506-100
15	Head End Ø 36mm for Femoral head impactor handle	506-1212
16	Trial head Ø28 12/14 S POM grey	512-280
17	Trial head Ø28 12/14 M POM green	512-281
18	Trial head Ø28 12/14 L POM blue	512-282
19	Trial head Ø28 12/14 XL POM red	512-283
20	Trial head Ø32 12/14 S POM grey	512-320
21	Trial head Ø32 12/14 M POM green	512-321
22	Trial head Ø32 12/14 L POM blue	512-322
23	Trial head Ø32 12/14 XL POM red	512-323

24	Trial head Ø36 12/14 S POM grey	512-361
25	Trial head Ø36 12/14 M POM green	512-362
26	Trial head Ø36 12/14 L POM blue	512-363
27	Trial head Ø36 12/14 XL POM red	512-364
28	Tray Rasp Instrument Set Expersus	367-1491

X-ray templates

Designation	Art. no.
X-ray template Expersus Femoral Stem cemented STD 135° KD28	367-244
X-ray template Expersus Femoral Stem cemented STD 125° KD28	367-245
X-ray template Expersus Femoral Stem cemented STD 135° KD32	367-072
X-ray template Expersus Femoral Stem cemented STD 125° KD32	367-073

Optional accessories

Designation	Art. no.
Femoral neck resection guide CCD 135°	367-006



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