



# OHST

medical technology



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## CE 0482

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## IMPLANT

### Expersus Femoral Stem

Before using the product, the user is under obligation to carefully study and comply with the following recommendations and information along with the information specific to the product.

The party introducing this product into circulation accepts no liability for direct or consequential damage resulting from careless use or handling, particularly noncompliance with the following user instructions or improper care or maintenance.

These implants may be used only by physicians with appropriate experience, practice and skills in hip arthroplasty. Familiarity with the surgical technique recommended for this system and its diligent application are indispensable in order to achieve the best possible result.

#### 1. Product description and implant materials

The Expersus femoral stem is a hip endoprosthesis for cementless and cemented anchorage in the femur. The cementless variant is manufactured from titanium alloy Ti6Al4V (ISO 5832-3) and the cemented variant from CoCrMo wrought alloy (ISO 5832-12). The Expersus femoral stem comes with a 12/14 cone. The shaft can be combined with both metal and ceramic femoral heads. Apart from the polished neck area, the cementless Expersus femoral stem has an all-round titanium plasma spray and hydroxyapatite coating. The cemented 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 inserted 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. The rasps are slightly undersized compared to all cementless Expersus femoral stems and oversized by 1 mm compared to all cemented Expersus femoral stems through an even all-round cement coating.

Product, packaging contents and materials used are specified on the product label. The implant must be implanted using a suitable surgical technique familiar to the surgeon. In this regard, attention must be given to the explanations concerning the particular surgical technique.

#### 1.1 Implant overview

Name	Material	Reference number
<b>Expersus femoral stem cemented</b>		
Expersus femoral stem size 2 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1317
Expersus femoral stem size 3 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1318
Expersus femoral stem size 4 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1319

<b>Name</b>	<b>Material</b>	<b>Reference number</b>
Expersus femoral stem size 5 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1320
Expersus femoral stem size 6 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1321
Expersus femoral stem size 7 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1322
Expersus femoral stem size 8 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1323
Expersus femoral stem size 9 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1324
Expersus femoral stem size 10 STD, 135°, cemented	ISO 5832-12 CoCrMo	367-1325
Expersus femoral stem size 2 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1326
Expersus femoral stem size 3 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1327
Expersus femoral stem size 4 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1328
Expersus femoral stem size 5 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1329
Expersus femoral stem size 6 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1330
Expersus femoral stem size 7 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1331
Expersus femoral stem size 8 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1332
Expersus femoral stem size 9 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1333
Expersus femoral stem size 10 STD, 125°, cemented	ISO 5832-12 CoCrMo	367-1334
<b>Expersus femoral stem cementless</b>		
Expersus femoral stem size 2 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1400
Expersus femoral stem size 3 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1401
Expersus femoral stem size 4 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1402
Expersus femoral stem size 5 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1403
Expersus femoral stem size 6 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1404
Expersus femoral stem size 7 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1405
Expersus femoral stem size 8 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1406
Expersus femoral stem size 9 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1407
Expersus femoral stem size 10 STD, 135°, cementless	ISO 5832-3 Ti6Al4V	367-1408
Expersus femoral stem size 2 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1409
Expersus femoral stem size 3 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1410
Expersus femoral stem size 4 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1411
Expersus femoral stem size 5 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1412
Expersus femoral stem size 6 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1413
Expersus femoral stem size 7 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1414
Expersus femoral stem size 8 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1415
Expersus femoral stem size 9 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1416
Expersus femoral stem size 10 STD, 125°, cementless	ISO 5832-3 Ti6Al4V	367-1417
<b>Cement restrictor</b>		
Cement restrictor size 1, external Ø24mm	ISO 5834-2 UHMWPE	506-101
Cement restrictor size 2, external Ø27mm	ISO 5834-2 UHMWPE	506-102

## 1.2 Instrument overview

The instruments of OHST Medizintechnik AG listed below must be used exclusively for implantation:

Name	Reference number
Expersus femoral stem instrument set	367-1493
Expersus femoral stem rasp instrument set	367-1492
Femoral Stem Extraction Instrument Set	206-010

## 1.3 Accessories

Name	Reference number
Surgical technique Expersus femoral stem cementless	50000351
Surgical technique Expersus femoral stem cemented	50000352
X-ray template Expersus femoral stem cementless STD 135° KD28	367-246
X-ray template Expersus femoral stem cementless STD 125° KD28	367-247
X-ray template Expersus femoral stem cementless STD 135° KD32	367-074
X-ray template Expersus femoral stem cementless STD 125° KD32	367-075
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
Instructions for Use Extraction Instrument Set	50000428
Instructions for use stem reducer	50000427
Implant passport	50000572

## 2. Handling

### 2.1 General information

This implant is part of a system and must only be used with the appropriate original system components. Only the instruments of the system listed above must be used for implantation. Before using the instruments the attached instructions for use (50000354) must be considered.

**Caution:** Implants must always be kept in their complete, unopened protective packaging. The packaging containing the implant must not be exposed to direct sunlight. Before inserting the implant, the packaging must be examined for damage, as this could affect sterility.

When unpacking the implant, its conformity with the designation on the packaging (art. no. / serial no. / size) must be checked. Compliance with the appropriate hygiene regulations is required during removal of the implant from the packaging. Care must be taken to protect all implant surfaces against damage, since this could be decisive for possible failure. The prosthesis must therefore not come into contact with objects which could damage its surface. Before use, every implant must be visually inspected for damage. Machining an implant can not only reduce its service life, but can also lead to immediate or subsequent failure of the prosthesis under stress. The implant must therefore neither be mechanically nor otherwise processed. Implants from damaged packaging, unsterile, contaminated, damaged or carelessly handled implants or implants subjected to unauthorized machining must not be used.

**Caution:** Implants are intended for single use only! Individual loads on the functional surfaces of an implant used for one patient modify the functional surfaces in a way that excludes any reuse. Detection of load-caused markings by visual methods only is not secured. After explantation, previous damages which exclude any reuse must therefore be assumed.

## 2.2 Authorised component combinations

The following femoral heads must be used for assembly with the implant:

**\* Caution:** The "Femoral Heads Biolox® forte" (ISO 6474) must not be combined with the „Expersus Femoral Stems cemented" (ISO 5832-12).

Nominal Ø	Name	Neck length	Reference number
Ø22 mm	Femoral Head CoCrMo ISO 5832-12, 12/14 S / M / L	-4 / 0 / +4 mm	030-2200 to 030-2202
Ø28 mm	Femoral Head Implant steel ISO 5832-9, 12/14 S / M / L / XL	-3,5 / 0 / +3,5 / +7 mm	020-2800 to 020-2803
	Femoral Head CoCrMo ISO 5832-12, 12/14 S / M / L / XL	-3,5 / 0 / +3,5 / +7 mm	030-2800 to 030-2803
	Femoral Head Biolox® forte* ISO 6474-1, 12/14 S / M / L	-3,5 / 0 / +3,5 mm	367-907 to 367-909
	Femoral Head Biolox® delta ISO 6474-2, 12/14 S / M / L	-3,5 / 0 / +3,5 mm	367-1140 to 367-1142
	ELEC® Femoral Head ISO 6474-1, 12/14 S / M / L	-3,5 / 0 / +3,5 mm	384-001 to 384-003
	ELEC®plus Femoral Head ISO 6474-2, 12/14 S / M / L	-3,5 / 0 / +3,5 mm	110230, 110240, 110250
	ELEC®plus Femoral Head ISO 6474-2, 12/14 S / M / L	-3,5 / 0 / +3,5 mm	013-001 to 013-003
Ø32 mm	Femoral Head Implant steel ISO 5832-9, 12/14 S / M / L / XL	-4 / 0 / +4 / +8 mm	020-3200 to 020-3203
	Femoral Head CoCrMo ISO 5832-12, 12/14 S / M / L / XL	-4 / 0 / +4 / +8 mm	030-3200 to 030-3203

<b>Nominal Ø</b>	<b>Name</b>	<b>Neck length</b>	<b>Reference number</b>
	Femoral Head BioloX® forte* ISO 6474-1, 12/14 S / M / L	-4 / 0 / +4 mm	367-920 to 367-912
	Femoral Head BioloX® delta ISO 6474-2, 12/14 S / M / L / XL	-4 / 0 / +4 / +7 mm	367-1143 to 367-1145, 367-1149
	ELEC® Femoral Head ISO 6474-1, 12/14 S / M / L	-4 / 0 / +4 mm	384-004 to 384-006
	ELEC®plus Femoral Head ISO 6474-2, 12/14 S / M / L / XL	-4 / 0 / +4 / +7 mm	110260, 110270, 110280, 110291
	ELEC®plus Femoral Head ISO 6474-2, 12/14 S / M / L / XL	-4 / 0 / +4 / +7 mm	013-004 to 013-007
Ø36 mm	Femoral Head BioloX® forte* ISO 6474-1, 12/14 S / M / L	-4 / 0 / +4 mm	367-930 to 367-932
	Femoral Head BioloX® delta ISO 6474-2, 12/14 S / M / L / XL	-4 / 0 / +4 / +8 mm	367-1146 to 367-1148, 367-1150
	ELEC® Femoral Head ISO 6474-1, 12/14 S / M / L	-4 / 0 / +4 mm	384-007 to 384-009
	ELEC®plus Femoral Head ISO 6474-2, 12/14 S / M / L / XL	-4 / 0 / +4 / +8 mm	110300, 110310, 110320, 110330
	ELEC®plus Femoral Head ISO 6474-2, 12/14 S / M / L / XL	-4 / 0 / +4 / +8 mm	013-008 to 013-011
Ø40 mm to Ø60 mm	Fracture head size S implant steel ISO 5832-9, 12/14	-4 mm	155-140 to 155-160
	Fracture head size M implant steel ISO 5832-9, 12/14	0 mm	155-040 to 155-060
	Fracture head size L implant steel ISO 5832-9, 12/14	+4 mm	155-240 to 155-260

We only guarantee compatibility of our products in combination with our own CE-marked products and with the products we have approved for combined use, for which the competent authority has issued its approval. In this regard, please note the instructions for use of the endoprosthesis manufacturers and the combination matrix approved by OHST.

Due to reasons relating the product safety and product liability, it is prohibited to use implants manufactured by OHST Medizintechnik AG in combination with components of other manufacturer that have not been approved by OHST.

## **2.3 Information for use**

The application of the implant is done with or without cement. A cement restrictor must be used for cemented applications. Before using the cement restrictor the corresponding instructions for use must be considered. The implant is equipped with a 12/14 cone to connect it with a femoral head. The femoral stem cone and the inner cone of the femoral head must be clean and intact when assembled. Before attaching the femoral head the cone should be cleaned carefully. The appropriate femoral head should then be attached by hand and fixed on the cone with the head insertion instrument and an appropriate hammer blow. When using ceramic femoral heads the corresponding instruction for use is also to be considered. After reduction, the definitive stability, mobility and muscle tension must be checked.

**Caution:** Please be hereby explicitly advised that, in case of an intraoperative change or revision of the femoral head, only femoral heads without a ceramic cone are to be used. This is valid irrespective of the materials used in the previous cone pairing.

**Caution:** If a ceramic component is damaged or fractured, complete revision of the prosthetic components at the earliest possible date is recommended. In this case, the use of metal femoral heads is contraindicated in revision surgery, as this may lead to serious and partly life-threatening complications. In the rare event of a fracture of the ceramic component, thorough debridement with removal of all visible ceramic particles as well as careful wound irrigation is absolutely essential during surgery.

If it should be necessary intraoperatively to remove the already inserted original prosthesis, a hip stem extractor is available. Before inserting the implant, the implant bed must be irrigated sufficiently. During implantation, ensure that all loose particles (e. g. bone splinters, friction particles from the instruments) are removed from the prepared implant bed.

The porous coating (TPS, Bonit®, CaP, HA) of the implant surfaces and the roughened surfaces must not come in contact with clothing or other fibre-shedding materials.

For the proper accomplishment of the cementing step the manufacturer data about the application of the bone cement must be considered. To lower the risk of severe cardiovascular complications (caused by BCIS = bone cement implantation syndrome), we recommend using vacuum-mixed bone cement.

**Caution:** When using high-frequency surgical instruments (e.g. cautery knife), it must be ensured that they do not come into contact with the implants or instruments. This can cause such severe damage to the implants or instruments that failure (e.g. fracture) may ensue. If an implant has been damaged, it must not remain in the patient but needs to be replaced by a new, intact implant. Damaged instruments may only continue to be used if they can still perform their intended function without compromise.

## **2.4 Surgical technique**

After opening the joint capsule and dislocating the femoral head from the cup, the femoral head is resected as determined in the preoperative planning and removed in full.

A femoral neck resection guide is optionally available for marking the resection plane. Then open the medullary cavity using the cavity chisel. The chisel has to be applied to the far lateral and dorsal side in order to facilitate the subsequent driving in of the rasps in the direction of the femoral axis. The cavity chisel should

be applied according to the desired antetorsion. Fracturing of the trochanter major must be avoided. The medullary cavity opening can be opened further with the surgical awl.

Once the medullary cavity has been opened, the femoral stem is rasped. The first rasp determines the orientation of the subsequent sizes. Care must be taken to ensure correct antetorsion already before the first rasp is applied. The 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. 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. On request, special rasp handles are available for the various access routes.

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 trial heads. Remove the handle from the rasp, which remains inside the femur, and attach the trial cone to the rasp. 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. Then attach the trial head to the trial cone by hand. Trial heads with various diameters are offered in the neck lengths S to XL for trial reductions. After reduction, the definitive stability, mobility and muscle tension should be checked.

When inserting the cemented Expersus femoral stem, the cement plug is implanted first and the cement inserted afterwards; this surgical step is not applicable to the cementless variant of the Expersus femoral stem.

The cement plug is used depending on the preoperatively determined diaphyseal diameter of the medullary cavity. A special insertion instrument is available to insert the plug in the optimal depth in a controlled manner. Size 1 cement plug 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 plug onto the threaded rod of the insertion instrument and insert it into the medullary cavity. The insertion depth can be read off the scale on the threaded rod and should protrude beyond the length of the stem of the prosthetic femoral stem to be implanted by at least 5 mm, but never more than 20 mm. It is also possible to gauge the position of the cement plug inside the femoral stem by means of an X-ray control based on the position of the radiopaque ring. After that, remove the insertion instrument by rotating it anti-clockwise. After the cement plug is inserted, the implant bed has to be rinsed and dried. The implantation of the cement plug should be completed before the bone cement is mixed. The cement is inserted using a modern cementing technique; in doing so, the instructions for use of the cement manufacturer must be observed.

Insert the prosthetic device into the implant bed up to the resection plane using the stem impactor. When using the cemented variant, this step has to be completed immediately after injection of the bone cement and gentle pressure is applied while waiting for the bone cement to harden. After that, thoroughly clean and dry the prosthetic cone and attach the femoral head with the previously determined neck length (S to XL).

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

Then 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.



### **3. Packaging and sterility**

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 instruments are supplied unsterile in protective packaging. They must be cleaned and sterilised prior to use in accordance with the respective instructions for use (50000354). The stated expiry date presumes that the packaging is intact and unopened and that the product is stored under suitable conditions.

**Caution:** The implants may not be resterilized! The reconditioning of components that have not been implanted but the packaging of which has been opened is permitted only at the manufacturer, because the components must pass through individual validated processes once again.

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.

### **4. Preoperative planning and postoperative care**

Preoperative planning by reference to X-rays, CT data and similar data is indispensable and provides important information about suitable implants, placement, possible component combinations and enables the size of the implant to be used to be preselected. The operation may be performed only if the patient's material compatibility has been determined. Use the X-ray templates for planning the operation. These are available for all sizes in a magnification of 1.15:1. In addition, X-ray templates with a 1:1 ratio are available in digital form. Trial prostheses for checking the correct seating (where applicable) and additional implants should be available in case another size is required or the intended implant cannot be used. Recognized procedures must be used for postoperative care.

### **5. Indications**

- 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

### **6. Contraindications**

- 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.

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

## **7. Risks and conditions that can impair the success of the operation**

Potential risks associated with the operation are:

- Disorders of bone metabolism (osteoporosis, osteomalacia)
- Occurrence of fissures, in rare cases fracture of the femoral bone
- Circulatory disorders of the affected limb
- Neurological disorders of the affected limb
- Muscle malfunction in the affected limb
- Overweight
- Alcohol or substance abuse
- Patient groups with mental disorders or addictions
- Pregnancy
- Growth in children and adolescents
- Anticipated extreme loading e.g. due to work and sport
- Epilepsy or other reasons for repeated trauma with an increased risk of fracture
- Joint deformities that make fixation of the implant difficult
- Weakening of the bearing structures by tumour
- High-dose ingestion of cortisone or cytostatics
- Previous or threatening infectious diseases with possible joint involvement
- Deep vein thrombosis and/or history of pulmonary embolism
- All general surgical risks

## **8. Undesirable effects**

The adverse events listed below are among the most typical and commonly occurring consequences of total hip arthroplasty:

- Change in position and loosening of the prosthesis
- Dislocation of the prosthesis
- Implant breakage
- Infection
- Venous thrombosis and pulmonary embolism
- Cardiovascular disorders
- Haematomas
- Paresthesia
- Numbness
- Swelling
- Nerve damage
- Muscle spasm
- Stiffness,
- Implant noises
- Reduced quality of life (pain, sleep disorders, ROM limitations; in particular also when lying down)
- Inflammation
- Oedem/fluids
- Metallosis

- Elevated metal ions in blood
- Coxa vara
- Osteolysis
- Heterotopic ossification
- Pseudotumours
- Cardiac arrhythmia, increased pulmonary vascular resistance, cardiac arrest (caused by BCIS = bone cement implantation syndrome)

## **9. Patient information, documentation**

The serial numbers of the implants used must be recorded in the patient's records. Appropriate labels are included with the packaging of the sterile implants.

The patient must be informed of the advantages and risks of the procedure. If the implant is regarded as the best solution for the patient, even though the contraindications described above partially apply to the patient, the patients should be informed about the possible effects of these circumstances and the anticipated risks. It should be explained to patients receiving a hip replacement that the life of the implant will depend on their weight and degree of activity. It is also recommended that the patient is informed of activities with which he can reduce the effects of these aggravating circumstances.

All the information given to the patient must be documented in writing by the surgeon. After surgery, the patient must be given an implant pass containing all necessary information concerning the implant. Adverse effects that are harmful to patients can arise during MRI investigations. Artefacts, heating of implant, induction of electrical currents and implant loosening are among the possible effects. The equipment manufacturer's instructions should be carefully studied before use. In case of doubt, comparable implants should be checked for their specific MRI suitability as part of an individual risk assessment. Patients should be informed of the risks.

## **10. Key to label symbols**

An explanation of the symbols used by OHST Medizintechnik AG can be found in the annex (p. 200).