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CE 0482

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IMPLANT

Bipolar Head

Before using the product, the user is under obligation to carefully study 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 or injury 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 and practice 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 bipolar head is a modular femoral head comprised of an outer shell made from implant steel (ISO 5832-1) or CoCrMo casting alloy (ISO 5832-4), a UHMWPE inlay (ISO 5834-2) and a UHMWPE safety ring (ISO 5834-2). The UHMWPE inlay has a radiopaque ring made of implant steel (ISO 5832-1) for fixation inside the outer shell of the bipolar head.

The bipolar head has a spherical internal contour with a diameter of 22 mm or 28 mm. The bipolar head comes in outside diameters of 38 mm to 60 mm.

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
Bipolar Head Ø38mm Head Ø22mm	ISO 5832-4 CoCrMo	150-038
Bipolar Head Ø39mm Head Ø22 mm	ISO 5832-4 CoCrMo	150-039
Bipolar Head Ø40mm Head Ø22mm	ISO 5832-4 CoCrMo	150-040
Bipolar Head Ø41mm Head Ø22mm	ISO 5832-4 CoCrMo	150-041
Bipolar Head Ø42mm Head Ø28mm	ISO 5832-4 CoCrMo	150-042
Bipolar Head Ø43mm Head Ø28mm	ISO 5832-4 CoCrMo	150-043
Bipolar Head Ø44mm Head Ø28mm	ISO 5832-4 CoCrMo	150-044
Bipolar Head Ø45mm Head Ø28mm	ISO 5832-4 CoCrMo	150-045
Bipolar Head Ø46mm Head Ø28mm	ISO 5832-4 CoCrMo	150-046
Bipolar Head Ø47mm Head Ø28mm	ISO 5832/4 CoCrMo	150-047
Bipolar Head Ø48mm Head Ø28mm	ISO 5832/4 CoCrMo	150-048
Bipolar Head Ø49mm Head Ø28mm	ISO 5832/4 CoCrMo	150-049
Bipolar Head Ø50mm Head Ø28mm	ISO 5832-4 CoCrMo	150-050
Bipolar Head Ø51mm Head Ø28mm	ISO 5832-4 CoCrMo	150-051

Name	Material	Reference number
Bipolar Head Ø52mm Head Ø28mm	ISO 5832-4 CoCrMo	150-052
Bipolar Head Ø53mm Head Ø28mm	ISO 5832-4 CoCrMo	150-053
Bipolar Head Ø54mm Head Ø28mm	ISO 5832-4 CoCrMo	150-054
Bipolar Head Ø55mm Head Ø28mm	ISO 5832-4 CoCrMo	150-055
Bipolar Head Ø56mm Head Ø28mm	ISO 5832-4 CoCrMo	150-056
Bipolar Head Ø57mm Head Ø28mm	ISO 5832-4 CoCrMo	150-057
Bipolar Head Ø58mm Head Ø28mm	ISO 5832-4 CoCrMo	150-058
Bipolar Head Ø59mm Head Ø28mm	ISO 5832-4 CoCrMo	150-059
Bipolar Head Ø60mm Head Ø28mm	ISO 5832-4 CoCrMo	150-060
Bipolar Head Ø42mm Head Ø28mm	ISO 5832-1 Implant Steel	151-042
Bipolar Head Ø44mm Head Ø28mm	ISO 5832-1 Implant Steel	151-044
Bipolar Head Ø46mm Head Ø28mm	ISO 5832-1 Implant Steel	151-046
Bipolar Head Ø48mm Head Ø28mm	ISO 5832-1 Implant Steel	151-048
Bipolar Head Ø50mm Head Ø28mm	ISO 5832-1 Implant Steel	151-050
Bipolar Head Ø52mm Head Ø28mm	ISO 5832-1 Implant Steel	151-052
Bipolar Head Ø54mm Head Ø28mm	ISO 5832-1 Implant Steel	151-054
Bipolar Head Ø56mm Head Ø28mm	ISO 5832-1 Implant Steel	151-056
Bipolar Head Ø58mm Head Ø28mm	ISO 5832-1 Implant Steel	151-058
Bipolar Head Ø60mm Head Ø28mm	ISO 5832-1 Implant Steel	151-060

1.2 Instrument overview

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

Name	Reference number
Instrument Set for Bipolar Head	367-041

1.3 Accessories

Name	Reference number
Surgical Technique Bipolar Head	50000574
X-Ray Template Bipolar Head HD 28 mm Even Sizes	367-2016
X-Ray Template Bipolar Head HD 22 mm	367-2017
X-Ray Template Bipolar Head HD 28 mm Uneven Sizes	367-2018
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 is required with the appropriate hygiene regulations 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 not therefore 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 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. Therefore, damage after explantation must be assumed which excludes any reuse.

2.2 Authorised component combinations

We guarantee compatibility of our products only in combination with our own CE-marked products and with the products we have approved for combined use and which have been authorised accordingly. 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

A femoral head with the same diameter of the ball diameter as shown in 1.1 is inserted into the bipolar head and secured with the UHMWPE safety ring. The bipolar head is used as a sliding partner with the acetabulum.

Caution The inner cone of the femoral head must absolutely match the cone of the femoral stem. The femoral stem cone and the inner cone of the femoral head have to be clean and free from defects during assembly.

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.

Before inserting the implant, the implant bed must be irrigated. During implantation, ensure that all loose particles (e. g. bone splinters, friction particles from the instruments) are removed from the prepared implant bed.

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 acetabulum, the femoral head is resected as determined in the preoperative planning and removed in full.

The femoral stem is prepared according to the surgical instructions of the hip stem system being used. After that, determine the size of the acetabulum using the trial bipolar heads in order to determine the size of the implant to be used. The outside diameter of the trial bipolar head corresponds to the outside diameter of the implant.

After preparation of the femoral stem, the leg length and range of motion can be reviewed by means of a trial reduction. This is done with the help of trial bipolar heads and trial femoral heads. The rasps of the OHST hip stem systems can also be used for trial reductions.

First remove the handle from the rasp left inside the femur and, if necessary, connect the trial cone to the rasp. Then place the trial femoral head with the trial bipolar head onto the rasp or onto the trial cone according to the preoperatively determined neck length. The trial bipolar head with the trial femoral head is in the correct position when the O-ring locks firmly into the groove. After the reduction, the definitive stability, mobility and muscle tension should be checked.

Afterwards, a femoral head size that fits the cone of the hip stem and the inlay of the bipolar head is placed onto the cone of the implanted hip stem prosthesis and fixed in place according to the instructions for use of the femoral head. Position the PE safety ring over the femoral head using the bipolar head forceps. After that, place the bipolar head onto the femoral head and fasten it with the PE safety ring, so that the latter locks into the nut provided in the PE inlay. The femoral head can now rotate safely inside the PE inlay without any risk of dislocation.

Caution: Prior to assembling the bipolar head, the femoral head always has to be mounted onto the stem cone to ensure a secure connection between the bipolar head, femoral head and hip stem.

After the implantation, reduce the femoral stem with the bipolar head into the acetabulum and check the range of motion and the leg length. Finish by closing the wound layer by layer in the preferred manner.

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 is indispensable and provides important information about suitable implants, placing and possible component combinations and enables the size of the implant to be used to be preselected. Surgery may only be performed once it has been established that the patient is able to tolerate the implant material. 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 should another size be required or the intended implant cannot be used. Recognized procedures must be used for postoperative care.

5. Indications

- Dislocated femoral neck fracture
- Osteonecrosis of the femoral head, only if the surface of the acetabular cartilage is still intact
- Secondary coxarthrosis without osteoarthrotic changes of the acetabulum
- Pseudarthrosis of the femoral neck
- Osteoarthrotic deformities of the femoral head
- Hemiarthroplasty
- Fractures that cannot be treated with osteosynthesis or that can lead to osteonecrosis of the femoral head

6. Contraindications

- Morphological changes of the acetabulum
- Hip dysplasia
- Acute or chronic infections, whether local or systemic
- Primary coxarthrosis
- 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 material used
- Local bone tumours that preclude stable fixation of the implant or that result in damage to the acetabulum

In case of breakage of a ceramic femoral head, the pairing of metal (femoral head) to polyethylene (acetabular component) as well as metal to metal is contraindicated in revision surgery.

7. Risk factors and conditions that may affect the success of the surgery

Caution: Clinical experience has shown that the presence of one or more of the following concomitant circumstances (risk factors) may lead to shorter service lives, more frequent complications or an altogether poorer outcome of hip arthroplasty. This list is by no means exhaustive.

General risk factors and conditions:

- Overweight
- Alcohol or substance abuse
- Patient groups with mental disorders or addictions
- Pregnancy
- 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

Risk factors and conditions specific to hip arthroplasty:

- Occurrence of fissures, in rare cases fractures
- Circulatory disorders of the affected limb
- Neurological disorders of the affected limb
- Muscle malfunction in the affected limb
- Muscle spasms or other spastic conditions
- 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 (e.g. bone cyst, non-ossifying fibroma)

8. Possible negative effects

The negative effects listed below are among the most typical and commonly occurring consequences of a surgical procedure:

- Infection
- Venous thrombosis and pulmonary embolism
- Cardiovascular disorders
- Haematomas
- Paresthesia
- Numbness
- Swelling
- Nerve damage
- Oedem/fluids

The negative effects listed below are among the most typical and most frequently occurring consequences of total hip arthroplasty:

- Change in position and loosening of the prosthesis

- Dislocation of the prosthesis
- Implant breakage
- Muscle spasm
- Stiffness
- Reduced quality of life (pain, sleep disorders, ROM limitations; in particular also when lying down)
- Metallosis
- Elevated metal ions in blood
- Osteolysis
- Heterotopic ossification
- Pseudotumours

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, although the contraindications described above partially apply to the patient, it is particularly important to point out to the patient the effects of these circumstances on the success. It must be explained to patients receiving a hip replacement that the life of the implant will depend on their weight and degree of activity. The patient has to be informed about 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. Adhesive labels are enclosed for documenting the implant used. 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. 141).