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**C € 0482**

**Zementstopper**

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**Cement Restrictor**

English 9

**Obturbateur à ciment**

Français 14

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## IMPLANT

### Cement Restrictor

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 cement restrictor is manufactured from ISO 5834-2 UHMWPE and is available in two sizes for the diameter range of 14 to 19 mm (size 1) or 18 to 22 mm (size 2). The cement restrictor is additionally equipped with a radiopaque ring made of ISO 5832-1 implant steel to improve radiological visibility. The cement restrictor is designed to act as a barrier against the unintended flow of bone cement into the distal medullary cavity during the implantation of cemented prosthetic hip stems.

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

Name	Reference number
Insertion instrument for Cement Restrictor with Silicone Handle, grey	506-100

##### 1.3 Accessories

Name	Reference number
Surgical Technique Cement restrictor	50000648
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 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 cement restrictor is used exclusively with cement in combination with a cemented prosthetic hip stem.

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.

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**

Prepare the femoral stem according to the surgical instructions of the hip stem system being used.

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 plug 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.

The insertion depth can be read off the scale on the threaded rod. To read off the insertion depth, the height of the cement restrictor (15.5 mm) and the distance between the hip stem and cement restrictor (min. 5 to max. 20 mm) must be added to the length of the stem used (shoulder of the implant to the distal tip).

During an X-ray examination, the position of the cement restrictor inside the femoral stem can also be assessed from the position of the radiopaque ring. After that, remove the insertion instrument by rotating it anti-clockwise.

The implantation of the cement restrictor should always be completed before the bone cement is mixed. After the cement restrictor is inserted, rinse and dry the implant bed.

Afterwards, continue the surgical procedure with the implantation of a hip stem as per the surgical instructions of the hip stem system being used.

## **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**

- Implantation of a prosthetic hip stem for cemented fixation

## **6. Contraindications**

- Medullary cross-sections with convex invaginations
- Severe muscle, nerve or vascular diseases endangering the affected extremity
- Acute or chronic infections, whether local or systemic
- Lack of bone substance or poor bone quality, which may impair stable seating of the implant
- Any concurrent illness that might compromise the functioning of the implant
- Hypersensitivity to the materials used

## **7. Conditions that can impair the success of the operation**

Potential risks in connection with the operation are:

- Disorders of bone metabolism (osteoporosis, osteomalacia)
- 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
- 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. Possible negative effects**

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 hip stem prosthesis
- Dislocation of the hip stem 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, 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. 107).