

Cement Restrictor

SURGICAL INSTRUCTIONS



CONTENTS

INTRODUCTION AND PRODUCT DESCRIPTION	4
Indications for the use of the Cement Restrictor	4
Contraindications for the use of the Cement Restrictor	4
Risks which may impair the success of the surgery	4
SURGICAL TECHNIQUE	5
Preparation of the femoral stem	5
Note on removing the implants	5
Implantation of the Cement Restrictor	5
Implantation of the hip stem	6
IMPLANTS	7
Cement Restrictor (ISO 5834-2 UHMWPE)	7
INSTRUMENTS	7
Insertion Instrument for Cement Restrictor	7

INTRODUCTION AND PRODUCT DESCRIPTION

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.

An insertion instrument which has been optimised for use with this implant ensures a safe surgical operation.

Indications for the use of the Cement Restrictor

- Implantation of a hip stem prosthesis for cemented anchorage

Contraindications for the use of the Cement Restrictor

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

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.

Preparation of the femoral stem

The femoral stem is prepared according to the surgical instructions of the hip stem system being used.

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 cement 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 1).

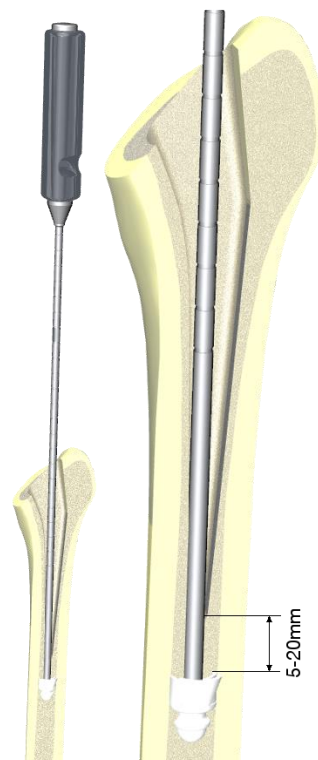


Figure 1: Insertion of the cement restrictor using the corresponding insertion instrument

Note:

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

To read off the insertion depth Y, the height of the cement restrictor H (15.5 mm) and the distance between the hip stem and cement restrictor X (min. 5 to max. 20 mm) must be added to the length L of the stem used (shoulder of the implant to the distal tip).

Example calculation (Figure 2):

$Y = \text{stem length } L + \text{cement restrictor height } H + \text{distance } X$

$Y = 140 \text{ mm} + 15.5 \text{ mm} + 10 \text{ mm} = 165.5 \text{ mm}$

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.

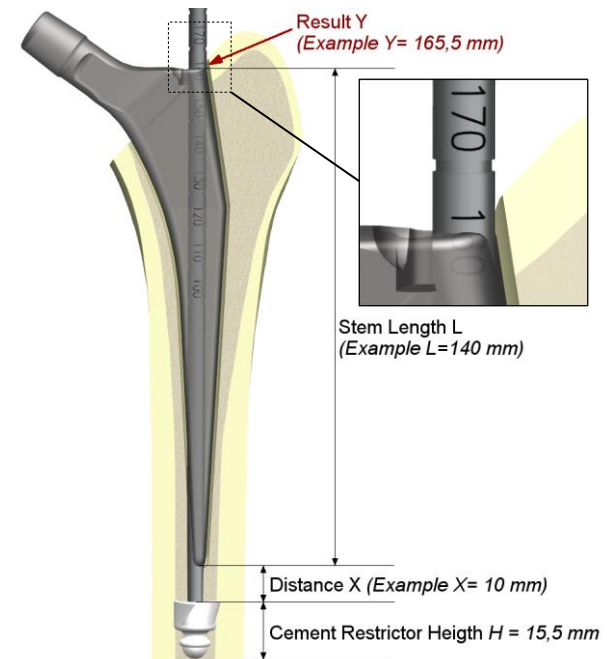


Figure 2: Reading off the Insertion depth

- After that, remove the insertion instrument by rotating it anti-clockwise (Figure 3).

Note:

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

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



Figure 3: Implanted Cement Restrictor

Implantation of the hip stem

The hip stem is implanted according to the surgical instructions of the hip stem system being used.

IMPLANTS



Figure 4: Cement Restrictor

Cement Restrictor (ISO 5834-2 UHMWPE)

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

INSTRUMENTS



Figure 5: Insertion Instrument for Cement Restrictor

Insertion Instrument for Cement Restrictor

Instrument	Art.-No.
Insertion Instrument for Cement Restrictor with Silicone Handle, grey	506-100



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Disclaimer

These surgical instructions are intended exclusively for specialists in medical technology.

It is not meant as information for medical lay persons.

The explanations about the products contained in the instruction manual are of general nature and do not constitute medical advice.

The instruction manual was created and compiled by medical experts and technically qualified employees of OHST AG to the best of their knowledge.

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