OHST
medical technology

Bipolar Head

SURGICAL INSTRUCTIONS

CONTENTS

INTRODUCTION AND PRODUCT DESCRIPTION

The principle of the bipolar head with different centers of rotation for the head and outer shell established itself as the standard of care for femoral neck fractures many years ago. The focus lies on providing a high degree of rotational freedom and low relative movements between the acetabulum and outer shell.
The large contact area and highly polished metal surface ensure the best possible protection of the acetabular cartilage. Different centers of rotation for the femoral head and outer shell of the bipolar head lead to self-centering of the implant. The removable safety ring provides optimal protection against dislocation of the joint.
23 sizes with varying diameters are available. Depending on the size, the bipolar head can be combined with femoral heads with a diameter of 22 mm or 28 mm.

Indications for use of the Bipolar Head

- 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

Contraindications for use of the Bipolar Head

- 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.

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)

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 anticipated size of the implant

The final size is determined intraoperatively by the surgeon. The size 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).

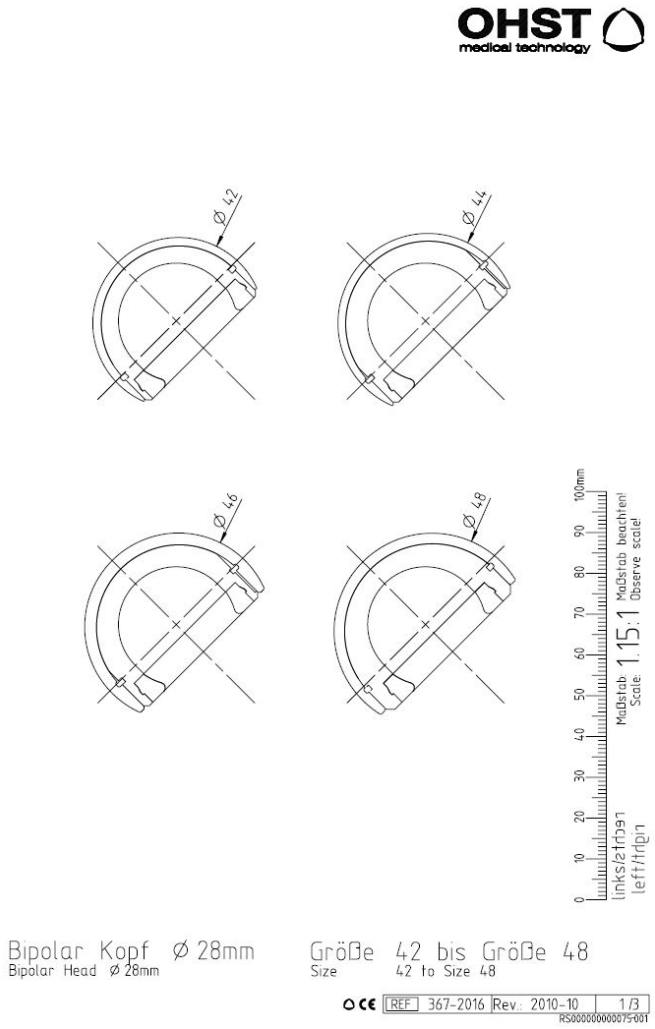

Figure 1: Example of an X-ray template for the bipolar head

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 a Müller straight stem with a bipolar head.

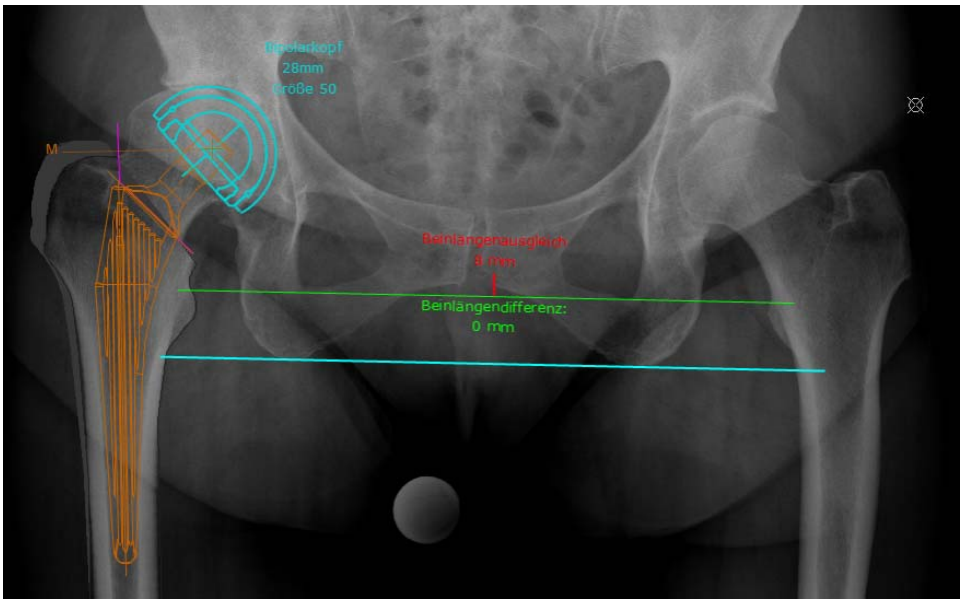

Figure 2: Example of preoperative planning (using the MediCAD software)

* 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

- Once the articular capsule has been opened and the femoral head has been dislocated from the acetabulum, the head is resected as determined in the preoperative planning (Figure 3).
- The femoral head must be removed in full.

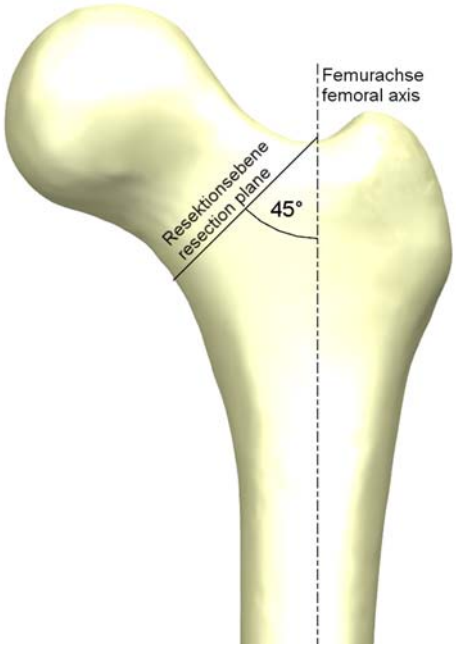

Figure 3: Resection of the femoral head

Preparation of the femoral stem

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

Determination of the implant size

- The size of the acetabulum is measured with trial bipolar heads in order to determine the size of the implant to be used (Figure 4).

Note:
The outside diameter of the trial bipolar head corresponds to the outside diameter of the implant.

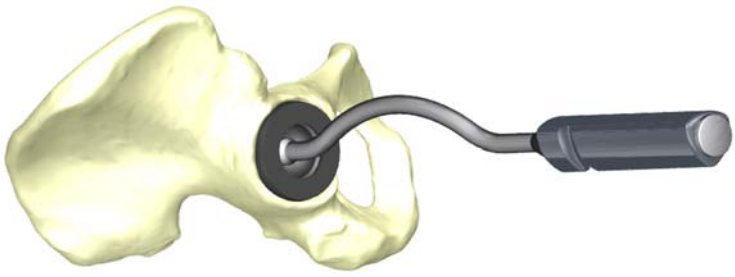

Figure 4: Determining the implant size with a trial bipolar head

Trial reduction

The rasps of the OHST hip stem system can be used for performing trial reductions.

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.

- Remove the handle from the rasp left inside the femur; if necessary connect the trial cone to the rasp (Figure 5).

Figure 5: Rasp with trial cone

- Place the trial femoral head onto the rasp or onto the trial cone according to the preoperatively determined neck length with the trial bipolar head (Figure 6).

Note:
The trial bipolar head with the trial femoral head is in the correct position when the O-ring locks firmly into the groove.

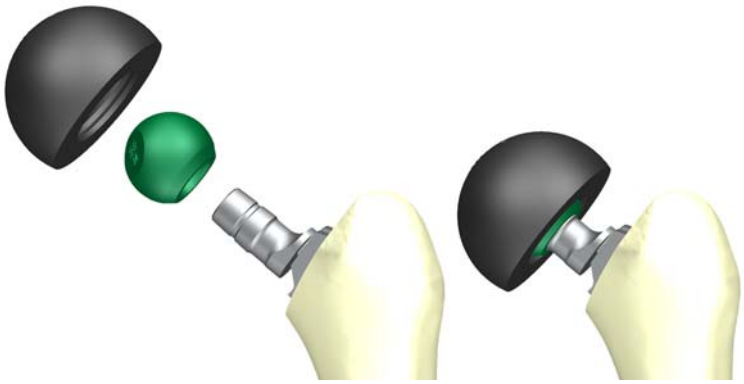

Figure 6: Trial reduction with trial bipolar head and trial femoral head

- After reduction, the definitive stability, mobility and muscle tension should be checked.

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

- 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 assembled according to the instructions for use of the femoral head (Figure 7).

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.

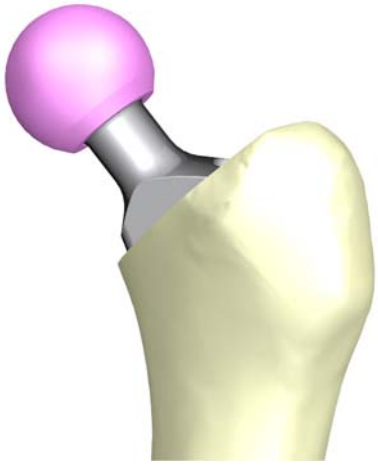

Figure 7: Implantation of a femoral head (here: Biolox®*delta* Femoral Head Ø28 M)

- The bipolar head forceps are used to position the PE safety ring over the femoral head (Figure 8).

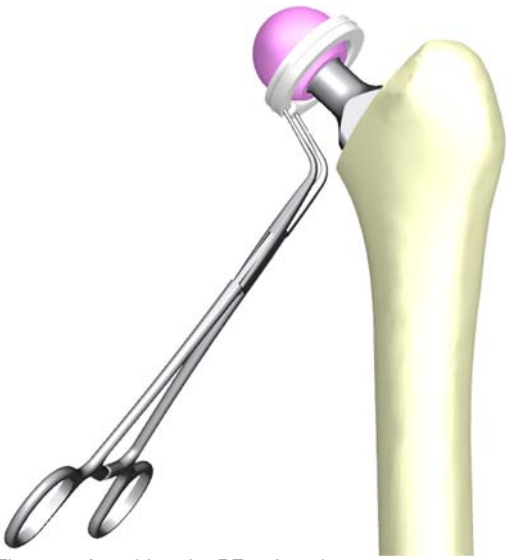

Figure 8: Attaching the PE safety ring

- After that, the bipolar head is placed onto the femoral head and fastened with the PE safety ring, so that the latter locks into the nut provided in the PE inlay (Figure 9).

Note:
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.

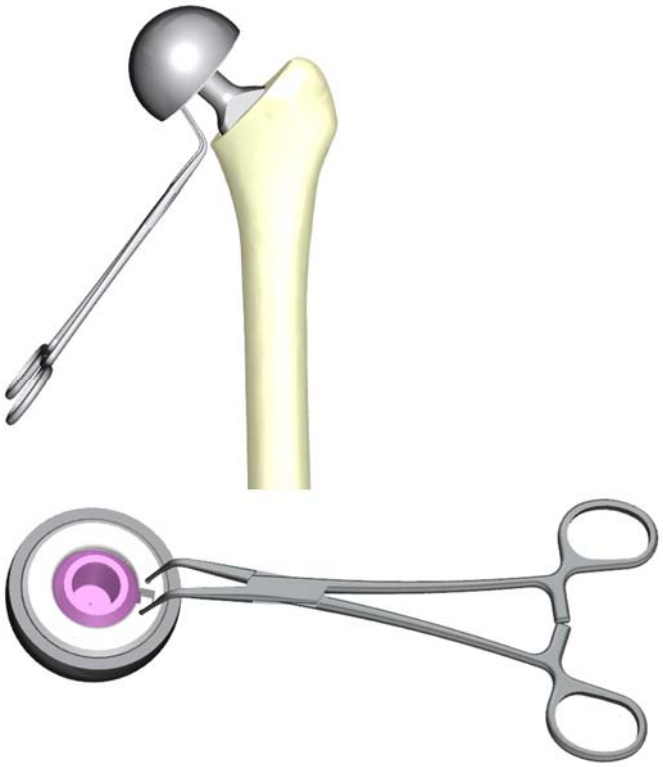

Figure 9: Mounting of the bipolar head by fastening the PE safety ring

- After implanting the bipolar head (Figure 10), reduce the stem with the bipolar head into the acetabulum.
- Check the range of motion and leg length.
- Close the wound layer by layer in the preferred manner.

Figure 10: Implanted bipolar head

IMPLANTS

Figure 11: Bipolar Head

Bipolar Head (ISO 5832-1 Implant Steel)

Implant		Art.-No.
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

Bipolar Head (ISO 5832-4 CoCrMo)

Implant		Art.-No.
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

Implant		Art.-No.
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
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

INSTRUMENTS

Instrument Set for Bipolar Head (Art. no. 367-041)

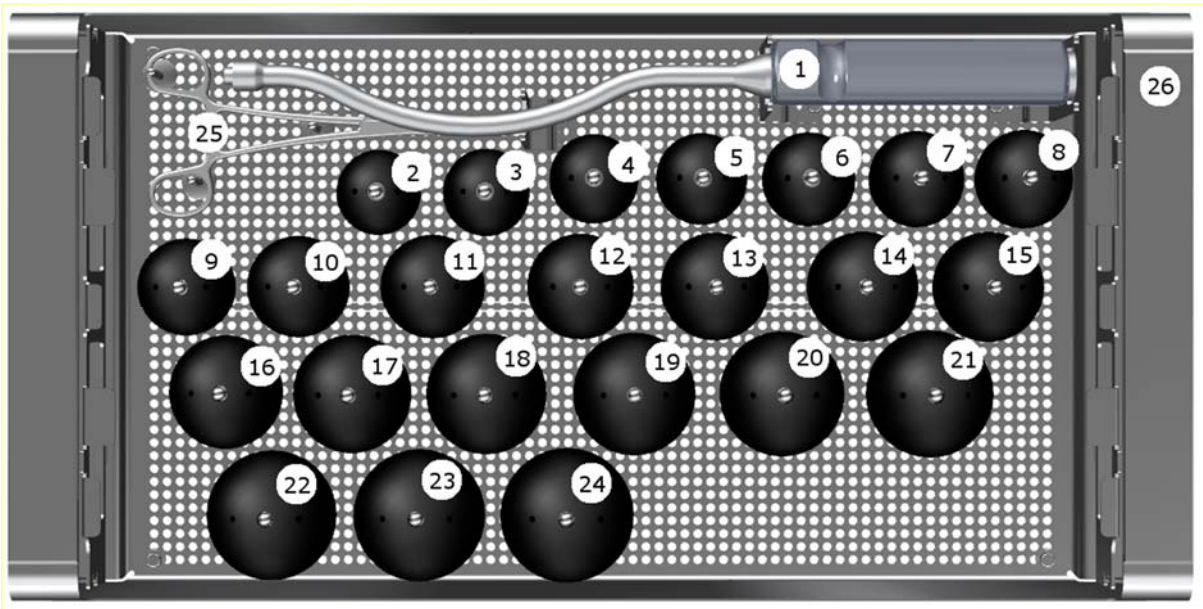

Figure 12: Instrument Set Bipolar Head

No.	Instrument	Art.-No.
1	Handle bent with Silicone Handle grey, L=377mm	600-300
2	Trial Bipolar Head Ø38mm HD 22mm Propylux black	600-338
3	Trial Bipolar Head Ø39mm HD 22mm Propylux black	600-339
4	Trial Bipolar Head Ø40mm HD 22mm Propylux black	600-340
5	Trial Bipolar Head Ø41mm HD 22mm Propylux black	600-341
6	Trial Bipolar Head Ø42mm HD 28mm Propylux black	600-342
7	Trial Bipolar Head Ø43mm HD 28mm Propylux black	600-343
8	Trial Bipolar Head Ø44mm HD 28mm Propylux black	600-344
9	Trial Bipolar Head Ø45mm HD 28mm Propylux black	600-345
10	Trial Bipolar Head Ø46mm HD 28mm Propylux black	600-346
11	Trial Bipolar Head Ø47mm HD 28mm Propylux black	600-347
12	Trial Bipolar Head Ø48mm HD 28mm Propylux black	600-348
13	Trial Bipolar Head Ø49mm HD 28mm Propylux black	600-349
14	Trial Bipolar Head Ø50mm HD 28mm Propylux black	600-350
15	Trial Bipolar Head Ø51mm HD 28mm Propylux black	600-351
16	Trial Bipolar Head Ø52mm HD 28mm Propylux black	600-352
17	Trial Bipolar Head Ø53mm HD 28mm Propylux black	600-353

18	Trial Bipolar Head Ø54mm HD 28mm Propylux black	600-354
19	Trial Bipolar Head Ø55mm HD 28mm Propylux black	600-355
20	Trial Bipolar Head Ø56mm HD 28mm Propylux black	600-356
21	Trial Bipolar Head Ø57mm HD 28mm Propylux black	600-357
22	Trial Bipolar Head Ø58mm HD 28mm Propylux black	600-358
23	Trial Bipolar Head Ø59mm HD 28mm Propylux black	600-359
24	Trial Bipolar Head Ø60mm HD 28mm Propylux black	600-360
25	Bipolar Head Forceps	150-000
26	Tray Trial Bipolar Heads	367-160

X-ray Templates

Designation	Art.-No.
X-Ray Template Bipolar Head HD 28 mm Even Sizes Scale 1.15:1	367-2016
X-Ray Template Bipolar Head HD 22 mm Scale 1.15:1	367-2017
X-Ray Template Bipolar Head HD 28 mm Uneven Sizes Scale 1.15:1	367-2018

OHST Medizintechnik AG
Grünauer Fenn 3
14712 Rathenow
Germany
Fon +49 (0) 3385 5420 0
Fax +49 (0) 3385 5420 99
E-Mail info@ohst.de
URL www.ohst.de