



Bipolar Head System

Partial Hip Replacement System
with / without cement

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■ Important Note

Lincotek Bologna S.r.l., does not practice medicine. This surgical technique / brochure has been developed in consultation with an experienced team of surgeons to provide their peers with general guidance when implanting the system. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training, experience and clinical evaluation of each patient individually.

■ Indications

Indications according to IFU:

- Extensive primary and secondary destruction of the joint to the extent that the functional efficiency of the locomotive apparatus is reduced;
- Severe pathological condition affecting the articulation caused by degenerative and rheumatoid arthritis;
- Joint fracture or bone necrosis;
- Post-surgical conditions after previous operations with or without consequent use of a prosthesis.

■ Contraindications

- On-going inflammatory process in the peri-articular region;
- Severe loss of bone tissue such as to inhibit a primary stabilisation of the prosthesis;
- Degenerative changes in the patient's neurological condition;
- Severe instability in the ligament area that cannot be remedied;
- Foreseeable causes of fatigue of the implanted joint due to obesity or excessive physical activity;
- Severe osteoporosis;
- Bone cancer in the implant anchoring area;
- Alcohol and drug abuse;
- Allergy to the materials employed;
- Lack of collaboration by the patient.

Relative contraindications:

- Adiposity
- Lacking or foreseeable not assured compliance
- Foreseeable overload/overstressing of the joint prosthesis
- Osteoporosis

■ Risk Factors

Complications:

- Hematomas in the region of the operation;
- Late onset of acute infections in the region of the operation;
- Momentary or persistent functional alterations in the nerves of the anatomical area concerned;
- Venous thrombosis, pulmonary embolism, heart failure;
- Change in position and/or loosening of the prosthesis;
- Joint dislocation;
- Shortening or lengthening of the limb concerned;
- Pathological bone fracture caused by changes in load;
- Allergic reactions or metallosis in the peripheral region of the implant;
- Periarticular ossification.



■ Preoperative Planning

The device should be implanted only by surgeons familiar with the joint replacement procedures described in the specific surgical techniques.

Preoperative planning provides useful information for the correct placement of the implant, but does not necessarily indicate the appropriate sizing.

The correct stem and cup size must be determined during surgery.

To achieve the best results, preoperative planning using special templates (with specific magnification always advisable).

It's suggested to do AP radiograph with adequate contrast.

The templates show both the profile of the cup and the center of rotation of the femoral head, and the A-P main dimensions of the stem and the relative center of rotation according to the different head sizing.

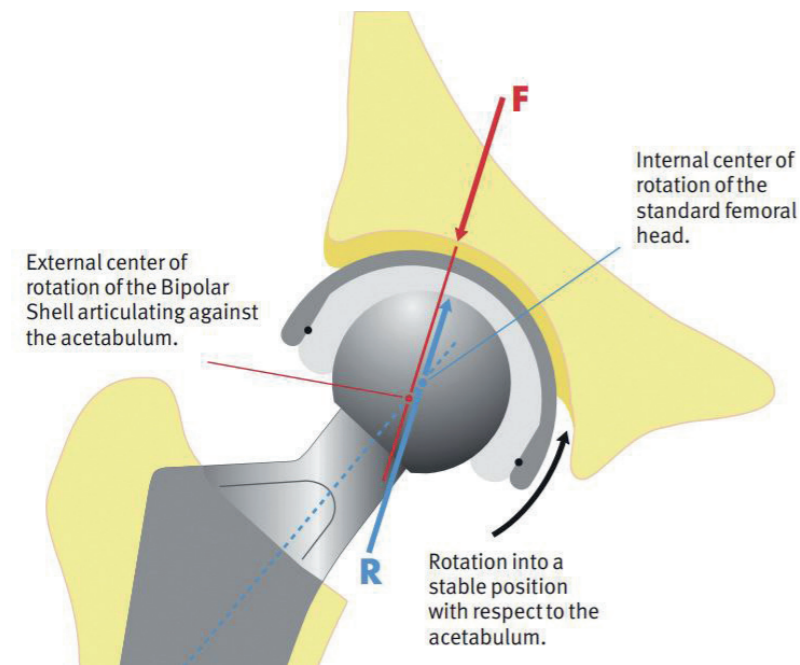
To achieve successful hip replacement surgery, it is crucial to plan the procedure preoperatively, taking into account the patient's individual anatomy and level of physical activity.

The surgeon should conduct a thorough evaluation of the patient's clinical condition to determine the correct implant type and size, as well as its final intraosseous position.

To ensure optimal results, surgery should be planned in advance using appropriate templates, which must be compatible with the magnification factor of the X-rays.

Special X-ray templates are available in a standard 1.1:1 scale or in 1.15:1 scale. The implant size should be selected from adequate AP and ML X-rays, ensuring legibility and large enough to accommodate the whole template.

A second X-ray of the unaffected joint can be helpful.



Improper preoperative planning can lead to incorrect implant types or incorrect positioning of implants.

During hip replacement surgery, various surgical approaches can be utilized to implant the components.

The following steps are applicable for both postero-lateral and other surgical access routes, but only postero-lateral approach will be shown in the following pictures.

The patient is placed in a lateral position for the procedure.

The incision is made postero-laterally, followed by opening of the fascia-lata. The external rotator muscles are then resected, and the joint capsule is incised.

The femoral head is dislocated posteriorly to allow easy access and removal of the head from the socket. This is achieved by flexing the hip and abducting the leg, which allows the femoral head to dislocate freely.

These steps are critical for successful hip replacement surgery, regardless of the surgical approach utilized.

Before proceeding with the Bipolar implantation, it is essential to have a clear and direct view of the acetabular site, regardless of the surgical approach selected. Before femurs broaching, good visibility must be achieved, and the relative position of the great trochanter and the calcar should be properly evaluated.

This requires the removal of any soft tissues and osteophytes that could obstruct visibility, allowing for a complete view of the entire acetabular socket and neck-femur region.

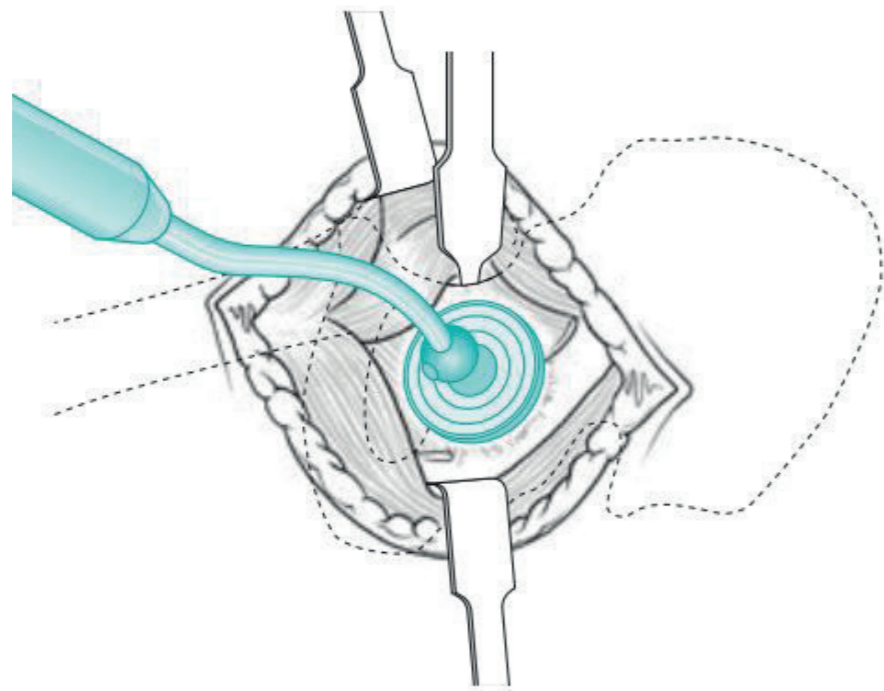
This is crucial to identify any cavitary or segmental defects and ensure accurate diagnosis and treatment.

Specific acetabular and femoral retractors are needed to facilitate acetabular exposure.

■ Choice of Stem Size and Stem Type

See surgical technique specific to stem being used.

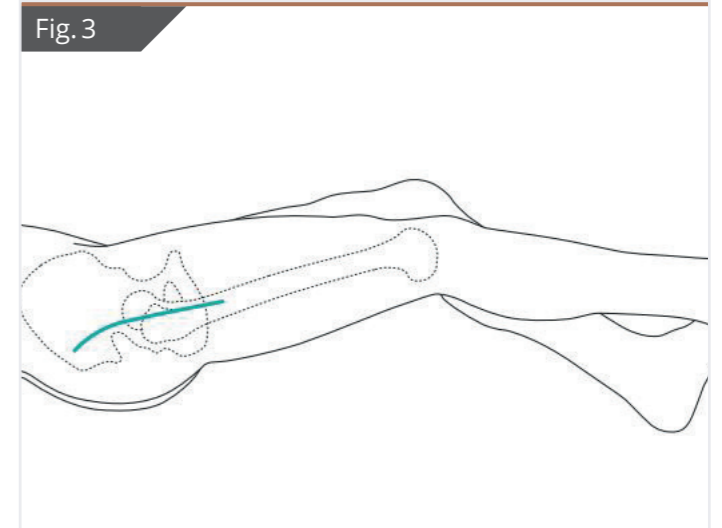
Surgical Technique



■ Positioning of Patient and Surgical Approach

Patient in lateral position. The skin incision is around 3cm posterior to the trochanteric crest, running in the line of fibers of the "gluteus medius" and the "fascia lata" [► Fig.3].

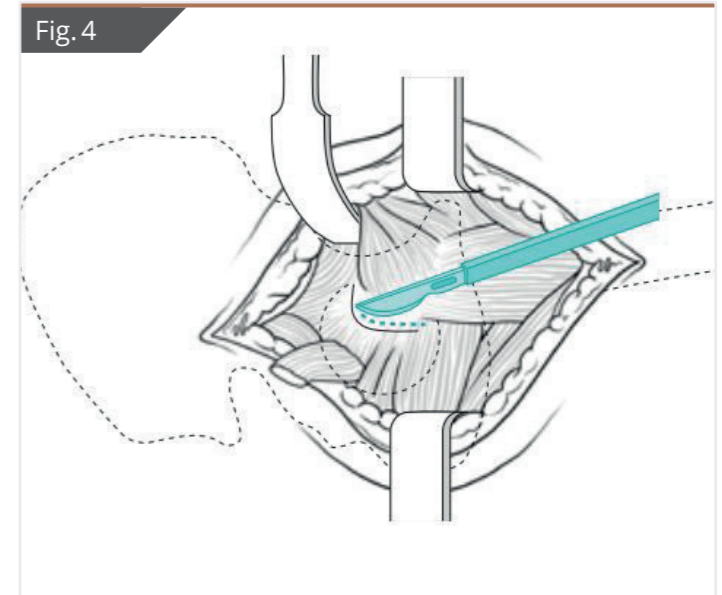
Fig. 3



■ Rotators management

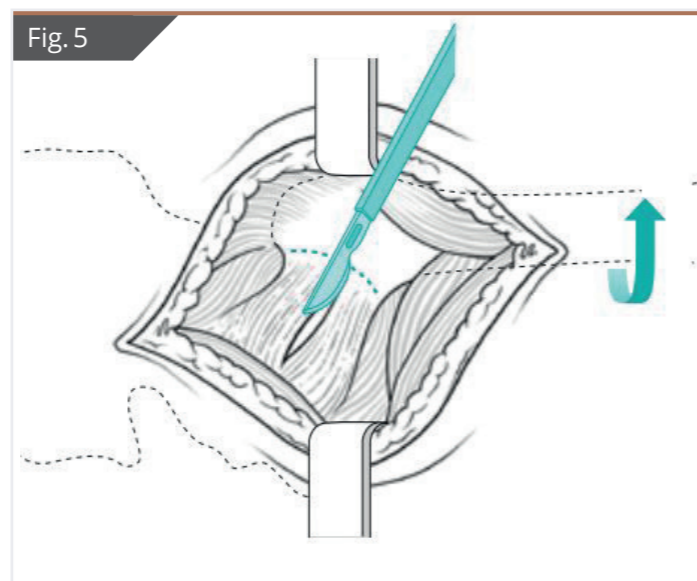
Divide the short external rotators, including piriformis, in their tendinous part at their insertion into the greater trochanter. Slight internal rotation of the limb assists exposure [► Fig.4].

Fig. 4



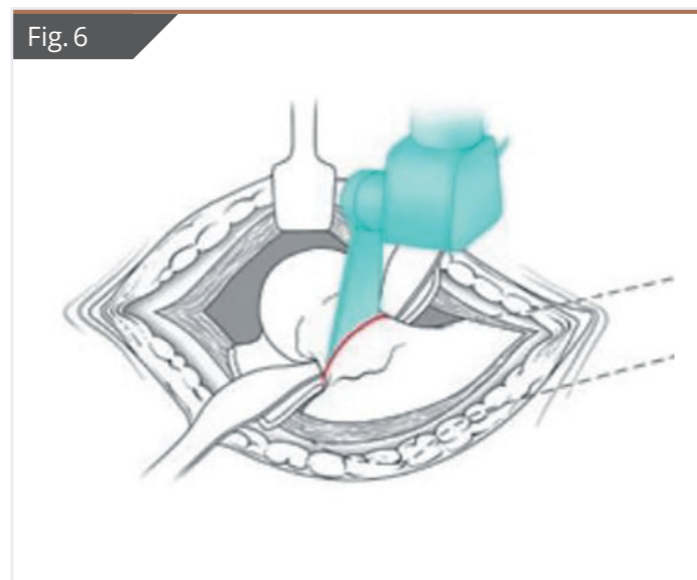
■ Capsule Incision

Incise the hip joint capsule in a T shape and suture after reduction. This is the best way to prevent dislocation [► Fig.5].



■ Femoral Neck Osteotomy

Following the dissection of soft tissue, proceed with the osteotomy of the femoral neck. Consult the relevant femoral stem surgical technique for detailed guidance [► Fig.6]. Once either the final femoral stem has been successfully implanted or when the broach and trial neck are properly positioned, proceed with the subsequent steps outlined in this Bipolar head surgical technique.



■ Explanted Femoral Head Measurements

For a preliminary verification of the explanted femoral head diameter, use the caliper (BO76.5516.000.00) provided with the instrument set, and compare the measured diameter with the originally planned head dimension [► Fig.7].

Always keep in mind that the explanted head could have been damaged, and there is a potential risk of underestimating the real diameter needed.

Therefore, use this information only for an initial selection of the correct bipolar head trial to be used for real acetabulum diameter evaluation and final trial reduction.



■ Trial Bipolar Head and Handle assembly

After getting an initial information of the explanted head diameter, proceed by selecting the correct trial bipolar head and assembling it to the trial bipolar handle (XM05.5147.000.00) by securing the selected trial bipolar head on the thread present on the tip of the handle [► Fig.8 a-b].

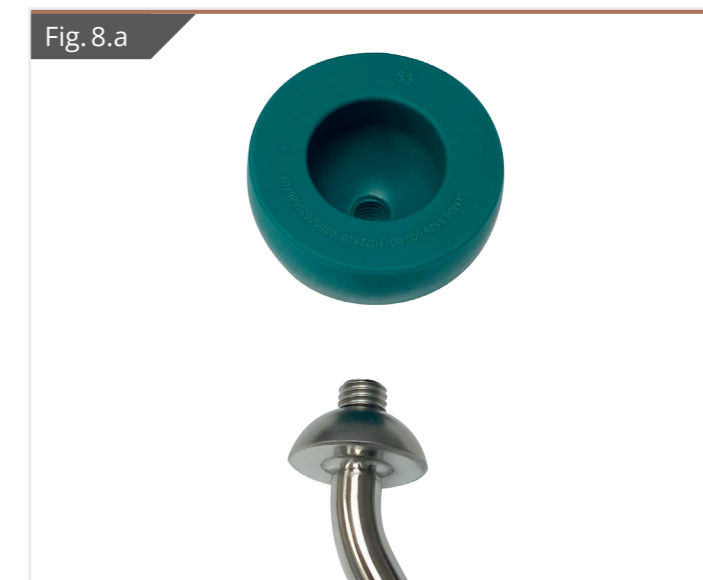


Fig. 8.b

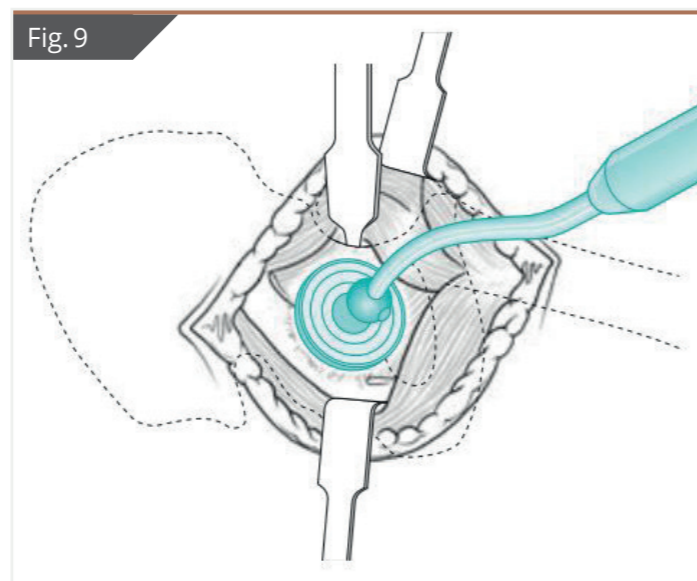


■ Trial Bipolar Head test in the acetabulum

Test the selected trial bipolar head into the exposed acetabulum by verifying the range of movement and stability of the selected size.

Proceed repeating step 9 with different trial ball heads until a good match is achieved and a satisfactory range of movement and stability is verified.

Use the selected bipolar trial head in the next steps for the actual trial reduction and final implant size selection [► Fig.9].



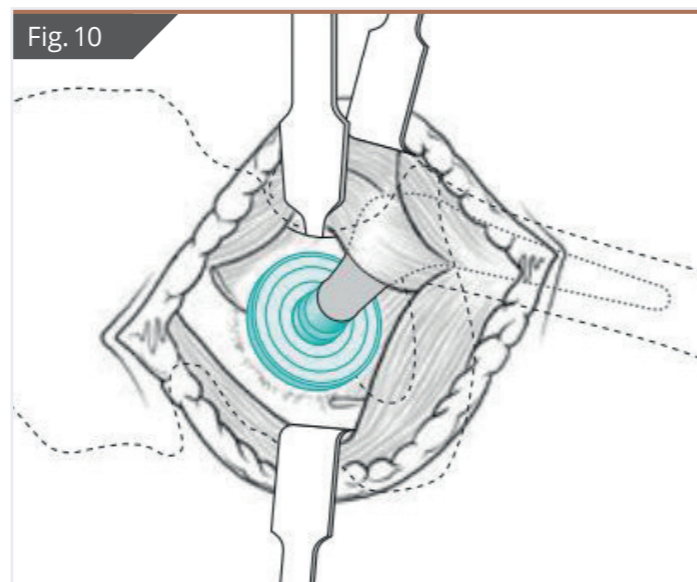
■ Trial reduction with trial Bipolar Head and trial Ball head

Upon confirming the appropriate bipolar head size, initiate the implant trial reduction [► Fig.10].

Disassemble the trial bipolar head from the handle and pair it with the trial ball head provided in the surgical set. Experiment with various ball head lengths as needed.

It's important to note that Bipolar heads are exclusively compatible with a ball head diameter of 28 mm.

This procedure can be conducted on either the already implanted final stem or on the trial neck positioned on the broach.



■ Bipolar final reduction

Additional reduction can be achieved by combining the chosen final Bipolar head with the trial ball head [► Fig.11].

It is advisable not to position the retentive ring during this stage, allowing for a final assessment of the appropriate sizing for both the bipolar head and the ball head.

This conclusive reduction can be conducted either with the final stem already in place or with the broach and trial neck positioned accordingly.



■ Bipolar implantation

Following the placement of the final stem, affix the retention ring around the neck of the stem, ensuring a secure fit by impacting the femoral head onto the stem.

Once the femoral head is in position, carefully encircle the stem neck with the retention (anti-luxation) ring [► Fig.12].

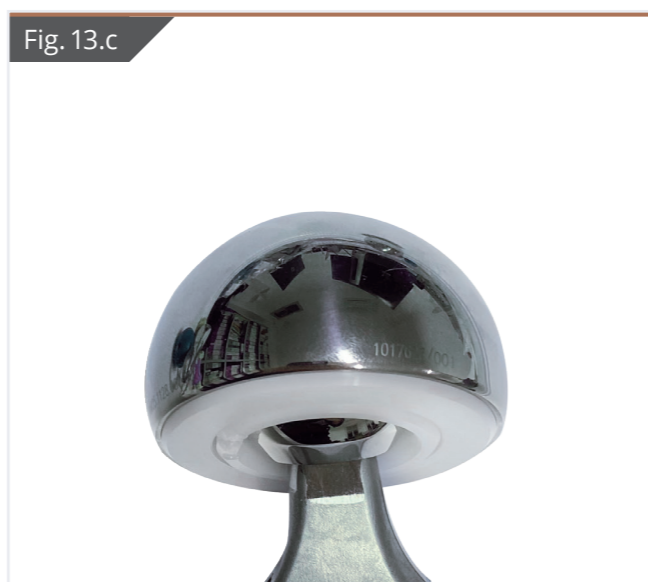
Subsequent to impacting the ball head, meticulously verify that the two holes of the ring are oriented not towards the ball head, but aligned with the resection plane of the femur.



■ Retention (anti-luxation) ring positioning

Use either your hands [▶Fig.13.a] or employ forceps [▶Fig.13.b] for positioning. When using your hands, exercise caution to avoid positioning the two holes of the ring towards the internal part of the Bipolar.

Opting for forceps eliminates the risk of misalignment, as they facilitate the correct approach to the Bipolar head. Once the ring is in position, gently press it with your fingers toward the Bipolar pole, allowing it to click into the liner. Upon correct placement, you'll observe the two holes, and the lower rim of the ring will align with the same plane [▶Fig.13.c].



■ Retention (anti-luxation) ring positioning

Avoid impacting the retention ring if the two holes are not visible [▶Fig.14.a-b]. If they are not visible, it indicates that the ring has been incorrectly positioned and must be reversed.



■ Retention (anti-luxation) ring removal with ball head (Tips and Tricks)

In the event that, for any reason the ring needs to be removed (such as instability during final reduction requiring a longer ball head or rigidity necessitating a shorter ball head), follow these steps:

- Insert one of the forceps tips into a hole, choosing the one more easily reachable based on your handedness. Subsequently, clamp the cut and plain area of the ring with the other forceps tips [▶ Fig.15.a-b].
- Once the forceps are closed and the ring is securely clamped, push the clamped ring extremities toward the center of the bipolar head, slightly moving the ring outside the equatorial plane of the bipolar head [▶ Fig.15.a-b]. After completing this maneuver, the ring will be loosened and can be easily extracted from its current position.
- Note that the ball head may limit the space for the ring's movement toward the center of the bipolar head, potentially complicating the process and requiring more strength for removal. In such cases, before repositioning the ring, carefully check for any damage. If damage is detected, discard the used ring and proceed to implant a new bipolar head.

Fig. 15.a

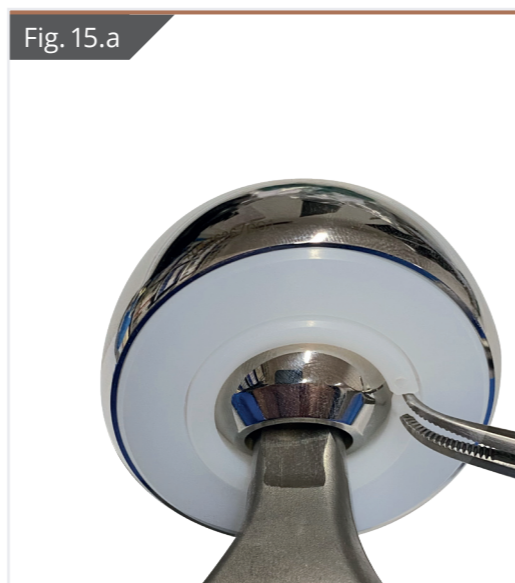


Fig. 15.b



■ Retention (anti-luxation) ring removal without ball head (Tips and Tricks):

- Insert one of the forceps tips into either hole, selecting the one more easily reachable based on your handedness (this may vary if you are left or right-handed). Subsequently, use the other forceps tip to clamp the cut and plain area of the ring [▶ Fig.16].
- Close the forceps, ensuring a secure grip on the ring, and then push the clamped ring extremities toward the center of the bipolar head, gently displacing the ring outside the equatorial plane of the bipolar head [▶ Fig.16]. Once this movement is executed, the ring will be loosened and can be effortlessly extracted from its current position.

Fig. 16

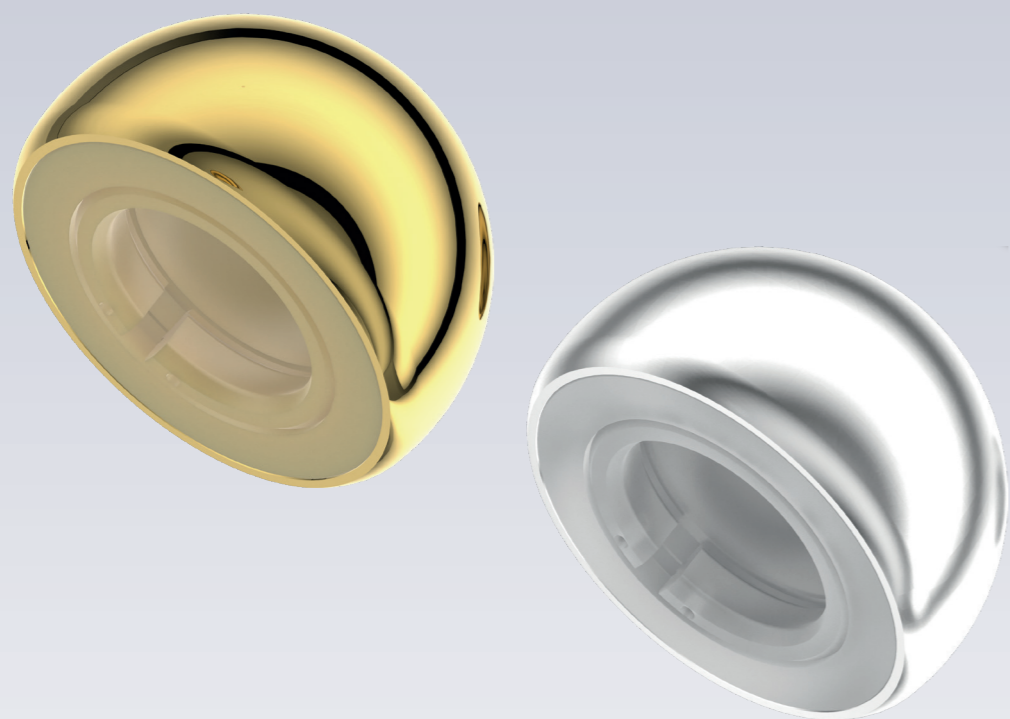


■ Implant reduction and suturing

Once the ring is in place and you are satisfied with the range of motion and stability, proceed with the final suturing.

Ordering Information

Implants and Instruments

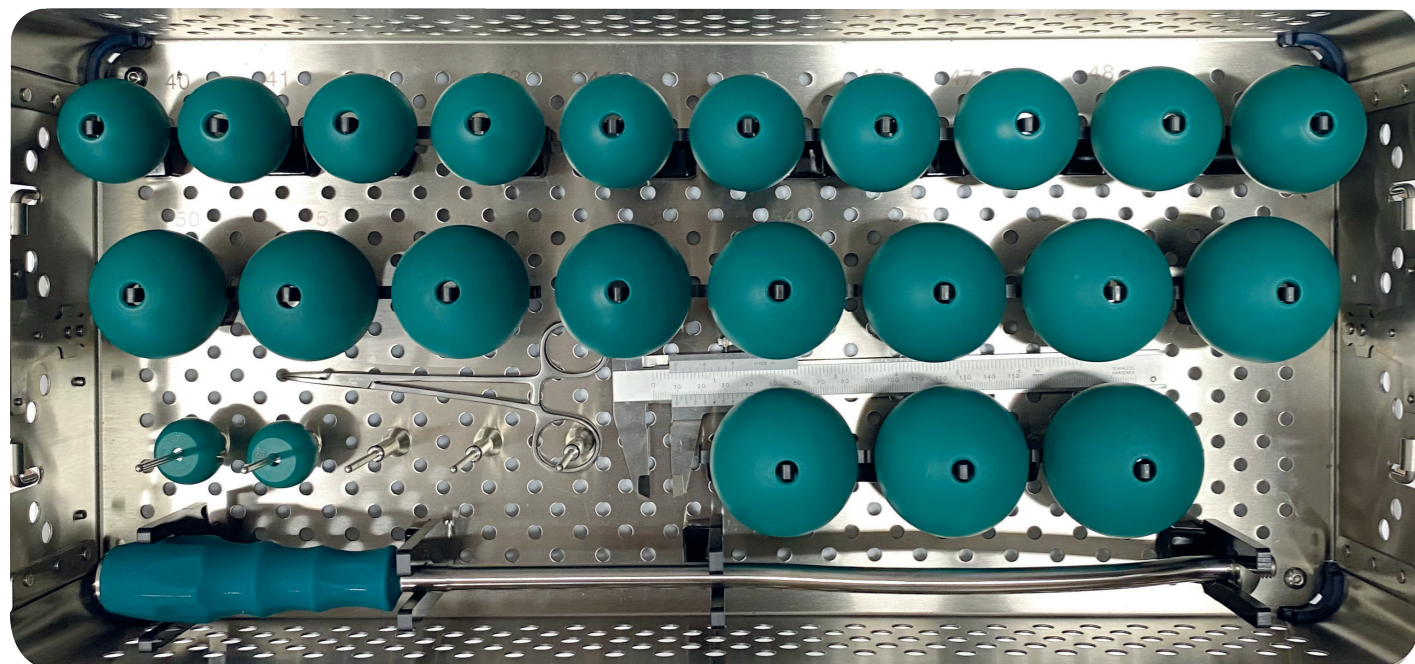


Item Code	Description	Coating	Diameter (mm)	Femoral Head (mm)
XM05.1116.000.00	Bipolar Head D.40	Any	40	28
XM05.1117.000.00	Bipolar Head D.41	Any	41	28
XM05.1118.000.00	Bipolar Head D.42	Any	42	28
XM05.1119.000.00	Bipolar Head D.43	Any	43	28
XM05.1120.000.00	Bipolar Head D.44	Any	44	28
XM05.1121.000.00	Bipolar Head D.45	Any	45	28
XM05.1122.000.00	Bipolar Head D.46	Any	46	28
XM05.1123.000.00	Bipolar Head D.47	Any	47	28
XM05.1124.000.00	Bipolar Head D.48	Any	48	28
XM05.1125.000.00	Bipolar Head D.49	Any	49	28
XM05.1126.000.00	Bipolar Head D.50	Any	50	28
XM05.1127.000.00	Bipolar Head D.51	Any	51	28
XM05.1128.000.00	Bipolar Head D.52	Any	52	28
XM05.1129.000.00	Bipolar Head D.53	Any	53	28
XM05.1130.000.00	Bipolar Head D.54	Any	54	28
XM05.1131.000.00	Bipolar Head D.55	Any	55	28
XM05.1132.000.00	Bipolar Head D.56	Any	56	28
XM05.1133.000.00	Bipolar Head D.57	Any	57	28
XM05.1134.000.00	Bipolar Head D.58	Any	58	28
XM05.1135.000.00	Bipolar Head D.59	Any	59	28
XM05.1136.000.00	Bipolar Head D.60	Any	60	28
XM05.1137.000.00	Bipolar Head D.40 TiNbN	TiNbN	40	28
XM05.1138.000.00	Bipolar Head D.41 TiNbN	TiNbN	41	28
XM05.1139.000.00	Bipolar Head D.42 TiNbN	TiNbN	42	28
XM05.1140.000.00	Bipolar Head D.43 TiNbN	TiNbN	43	28
XM05.1141.000.00	Bipolar Head D.44 TiNbN	TiNbN	44	28
XM05.1142.000.00	Bipolar Head D.45 TiNbN	TiNbN	45	28
XM05.1143.000.00	Bipolar Head D.46 TiNbN	TiNbN	46	28
XM05.1144.000.00	Bipolar Head D.47 TiNbN	TiNbN	47	28
XM05.1145.000.00	Bipolar Head D.48 TiNbN	TiNbN	48	28
XM05.1146.000.00	Bipolar Head D.49 TiNbN	TiNbN	49	28
XM05.1147.000.00	Bipolar Head D.50 TiNbN	TiNbN	50	28
XM05.1148.000.00	Bipolar Head D.51 TiNbN	TiNbN	51	28
XM05.1149.000.00	Bipolar Head D.52 TiNbN	TiNbN	52	28
XM05.1150.000.00	Bipolar Head D.53 TiNbN	TiNbN	53	28
XM05.1151.000.00	Bipolar Head D.54 TiNbN	TiNbN	54	28
XM05.1152.000.00	Bipolar Head D.55 TiNbN	TiNbN	55	28
XM05.1153.000.00	Bipolar Head D.56 TiNbN	TiNbN	56	28
XM05.1154.000.00	Bipolar Head D.57 TiNbN	TiNbN	57	28
XM05.1155.000.00	Bipolar Head D.58 TiNbN	TiNbN	58	28
XM05.1156.000.00	Bipolar Head D.59 TiNbN	TiNbN	59	28
XM05.1157.000.00	Bipolar Head D.60 TiNbN	TiNbN	60	28

Main Materials: UHMWPE - ISO 5834-1 & Stainless Steel - ISO 5832-1

■ Bipolar Head Instrument Set – Even & Odd Sizes

| B076.4007.000.00

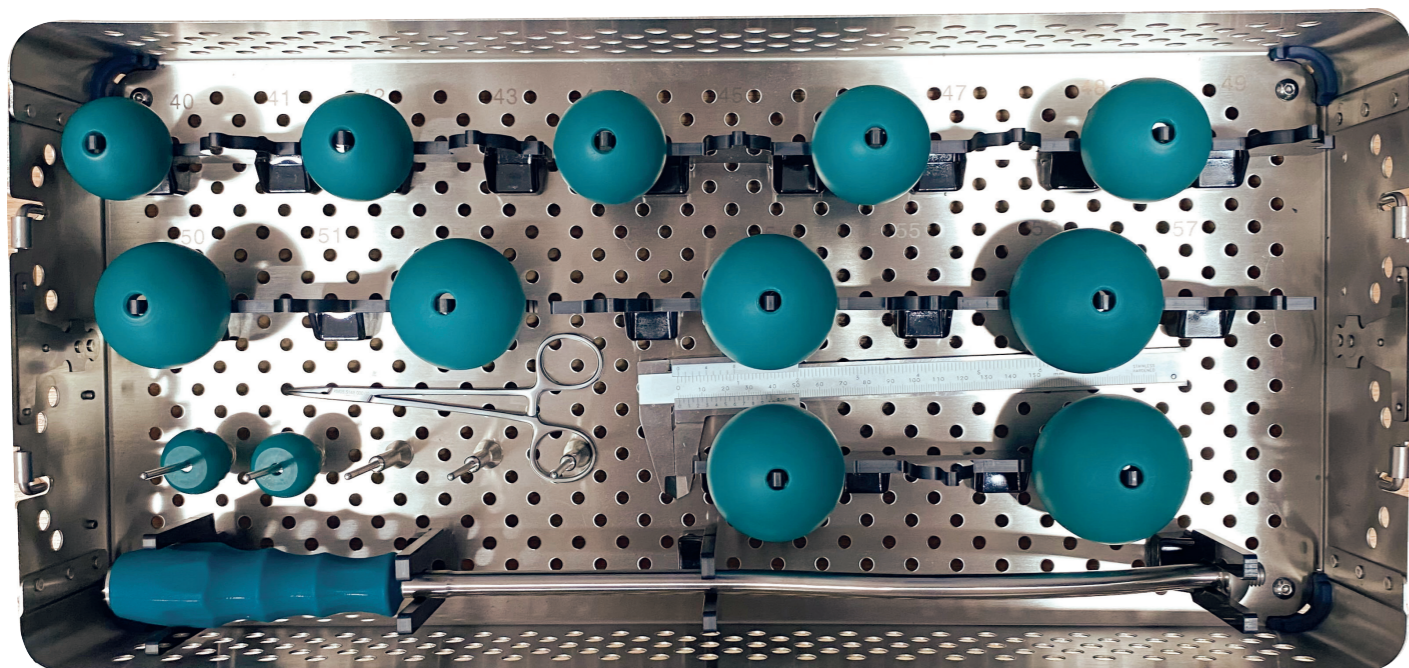


■ Set Content

No	Item Code	Description	Qty per SET
	BO76.4007.001.00	Bipolar Tray Empty	1
	XM01.5100.000.00	Trial Ball Head 28S / Testa Di Prova	1
	XM01.5101.000.00	Trial Ball Head 28M / Testa Di Prova	1
	XM01.5102.000.00	Trial Ball Head 28L / Testa Di Prova	1
	XM01.5103.000.00	Trial Ball Head 28XI / Testa Di Prova	1
	XM01.5211.000.00	Trial Ball Head 28XXL	1
	XM05.5116.000.00	Trial Bipolar Head diameter 40 mm	1
	XM05.5118.000.00	Trial Bipolar Head diameter 42 mm	1
	XM05.5120.000.00	Trial Bipolar Head diameter 44 mm	1
	XM05.5122.000.00	Trial Bipolar Head diameter 46 mm	1
	XM05.5124.000.00	Trial Bipolar Head diameter 48 mm	1
	XM05.5126.000.00	Trial Bipolar Head diameter 50 mm	1
	XM05.5128.000.00	Trial Bipolar Head diameter 52 mm	1
	XM05.5130.000.00	Trial Bipolar Head diameter 54 mm	1
	XM05.5132.000.00	Trial Bipolar Head diameter 56 mm	1
	XM05.5134.000.00	Trial Bipolar Head diameter 58 mm	1
	XM05.5136.000.00	Trial Bipolar Head diameter 60 mm	1
	XM05.5147.000.00	Bipolar Trial Head Handle	1
	XM05.5148.000.00	Positioning & Removing Forceps	1
	BO76.5516.000.00	Caliper	1
	XM05.5117.000.00	Trial Bipolar Head diameter 41 mm	1
	XM05.5119.000.00	Trial Bipolar Head diameter 43 mm	1
	XM05.5121.000.00	Trial Bipolar Head diameter 45 mm	1
	XM05.5123.000.00	Trial Bipolar Head diameter 47 mm	1
	XM05.5125.000.00	Trial Bipolar Head diameter 49 mm	1
	XM05.5127.000.00	Trial Bipolar Head diameter 51 mm	1
	XM05.5129.000.00	Trial Bipolar Head diameter 53 mm	1
	XM05.5131.000.00	Trial Bipolar Head diameter 55 mm	1
	XM05.5133.000.00	Trial Bipolar Head diameter 57 mm	1
	XM05.5135.000.00	Trial Bipolar Head diameter 59 mm	1

■ Bipolar Head Instrument Set – Only Odd Sizes

| B076.4008.000.00



■ Set Content

No	Item Code	Description	Qty per SET
	B076.4007.001.00	Bipolar Tray Empty	1
	XM01.5100.000.00	Trial Ball Head 28S / Testa Di Prova	1
	XM01.5101.000.00	Trial Ball Head 28M / Testa Di Prova	1
	XM01.5102.000.00	Trial Ball Head 28L / Testa Di Prova	1
	XM01.5103.000.00	Trial Ball Head 28XI / Testa Di Prova	1
	XM01.5211.000.00	Trial Ball Head 28XXL	1
	XM05.5116.000.00	Trial Bipolar Head diameter 40 mm	1
	XM05.5118.000.00	Trial Bipolar Head diameter 42 mm	1
	XM05.5120.000.00	Trial Bipolar Head diameter 44 mm	1
	XM05.5122.000.00	Trial Bipolar Head diameter 46 mm	1
	XM05.5124.000.00	Trial Bipolar Head diameter 48 mm	1
	XM05.5126.000.00	Trial Bipolar Head diameter 50 mm	1
	XM05.5128.000.00	Trial Bipolar Head diameter 52 mm	1
	XM05.5130.000.00	Trial Bipolar Head diameter 54 mm	1
	XM05.5132.000.00	Trial Bipolar Head diameter 56 mm	1
	XM05.5134.000.00	Trial Bipolar Head diameter 58 mm	1
	XM05.5136.000.00	Trial Bipolar Head diameter 60 mm	1
	XM05.5147.000.00	Bipolar Trial Head Handle	1
	XM05.5148.000.00	Positioning & Removing Forceps	1
	B076.5516.000.00	Caliper	1
	XM05.5117.000.00 *	Trial Bipolar Head diameter 41 mm	1
	XM05.5119.000.00 *	Trial Bipolar Head diameter 43 mm	1
	XM05.5121.000.00 *	Trial Bipolar Head diameter 45 mm	1
	XM05.5123.000.00 *	Trial Bipolar Head diameter 47 mm	1
	XM05.5125.000.00 *	Trial Bipolar Head diameter 49 mm	1
	XM05.5127.000.00 *	Trial Bipolar Head diameter 51 mm	1
	XM05.5129.000.00 *	Trial Bipolar Head diameter 53 mm	1
	XM05.5131.000.00 *	Trial Bipolar Head diameter 55 mm	1
	XM05.5133.000.00 *	Trial Bipolar Head diameter 57 mm	1
	XM05.5135.000.00 *	Trial Bipolar Head diameter 59 mm	1


* Special request items


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