



Foundation® Bipolar Unipolar

Surgical Technique



Bipolar Unipolar

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Table of Contents

Design Rationale	2
Indications	3
Contraindications	3
Preoperative Planning	4
Surgical Approach	4
Site Preparation	5
Trial Reduction	6
Stem Implantation	6
Assembly of Bipolar	7
Assembly of Unipolar	8
Disassembly of Bipolar	9
Disassembly of Unipolar	9

This brochure is presented to demonstrate a surgical technique. DJO Surgical, as the manufacturer of this device, does not practice medicine and cannot recommend this or any other surgical technique for use on a specific patient. The choice of the appropriate surgical technique is the responsibility of the surgeon performing the operation.

Foundation® Bipolar / Unipolar

Design Rationale

The Foundation Bipolar and Unipolar systems provide all the necessary options for hemi hip arthroplasty. These systems are easy to use and can be paired with any DJO Surgical stem.

Bipolar

Bipolar Heads (Modular insert packaged with shell)
FMP Modular CoCr Femoral Heads.

The Bipolar features a modular snap-fit design utilizing 22mm modular femoral heads in the 42mm and 43mm, and 28mm in sizes 44-64mm sizes.

Unipolar

Unipolar Heads

Modular Neck Adaptor Sleeves, available in -3.5mm, neutral, +3.5mm, +7mm, and 10.5mm options.



Bipolar



Unipolar

Indications

Joint replacement is indicated for patients suffering from disability due to:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis of the natural femoral head;
- Rheumatoid arthritis
- Correction of functional deformity
- Femoral fracture

This device may also be indicated in the salvage of previously failed surgical attempts.

Contraindications

Joint replacement is contraindicated where there is:

- Infection or sepsis;
- Insufficient bone quality which may affect the stability of the implant;
- Muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Skeletally immature patients and cases where there is a loss of abductor musculature, poor bone stock, poor skin coverage around the hip joint which would make the procedure unjustifiable;
- Osteomyelitis;
- Rapid joint destruction or bone absorption apparent on roentgenogram;
- Pathological conditions of the acetabulum, which would prevent achieving proper range of motion, appropriate head stability, and/or a well-seated and supported smooth articulation of the head within the acetabulum;
- Alcoholism or other addictions;
- Materials sensitivity;
- Loss of ligamentous structures;
- High levels of physical activity (e.g. competitive sports, heavy physical labor);
- Pregnancy (contraindicated for Metal on Metal applications only)

Surgical Technique

Bipolar / Unipolar

Preoperative Planning

Preoperative templates are provided for determining optimal component size, femoral neck resection level, and appropriate neck length. Radiographs should include a full A/P view of the pelvis including the proximal one-half of both femurs and a lateral view of the proximal half of the affected femur.

As with any surgical procedure, proper radiographs are required for accurate templating. Ideally, the A/P radiograph should be taken with 15-20 degree internal rotation of the femur. If the femur is not rotated or incorrectly rotated, the neck length and offset could be misjudged preoperatively.

A standard method of templating is used by aligning the center line of the femoral stem to the center of the femoral shaft and moving the template up or down to align to the center of rotation indicated on the template to the center of the femoral head. Because of the fracture, it may be necessary to template the unaffected hip to accurately estimate stem and bipolar/unipolar head size. Note the diaphyseal fill, the neck resection level, and the modular neck length estimation. On the template, the cemented stem is indicated by a solid black line, the cement mantle by an interrupted black line, and the press-fit stem by a solid purple line. The solid black line of the bipolar/unipolar template represents the outer dimension of the head and should be used to estimate femoral head size.

Surgical Approach

The Foundation Hip System is designed to accommodate any standard approach based on the surgeon's experience or personal preference.

Site Preparation

After the capsulotomy is performed and the fracture identified, the head/neck fragment is removed with the T-handled extractor (Figure 1). The external rotators and capsule are preserved for later repair. Gauge the size of the head by passing it through the head gauge plates (Figure 2). Choose the best fit. It is important for the head to fit firmly within the acetabulum. Too large of a head selection will result in the head articulating and loading along the rim of the acetabulum. The baton and selected head trial may be used to check for appropriate fit within the acetabulum (Figure 3). Prepare the femur for the stem. Consult the surgical technique specific to the stem that will be used.



Figure 1



Figure 2



Figure 3

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Bipolar / Unipolar

Trial Reduction

When preparation for the femoral stem is complete and the broach is in place, trialing for the Bipolar and Unipolar can be performed.

Bipolar

A trial reduction may be performed with the broach, corresponding head/neck adaptor, femoral head trial, and Bipolar/Unipolar head trial (Figure 4). The 22mm heads, for use in the 42mm and 43mm bipolar, have two options: neutral and +4mm; the 28mm heads have five options: -3.5mm, neutral, +3.5mm, +7mm, and +10.5mm. Choose the option which best establishes proper leg length and joint stability.



Figure 4

Unipolar

The Unipolar trial features a neck adaptor plug that fits into the Bipolar head trial (Figure 5 and 6). The neck adaptor trials correspond with the available neck sleeve adaptor options: -3.5mm, neutral, +3.5mm, +7mm, and +10.5mm.



Figure 5

Stem Implantation

The broach is removed and the appropriate size stem is implanted.

NOTE: Additional trialing may be performed with the appropriate femoral head trial or neck adaptor plug (Figures 6 and 7).



Figure 6



Figure 7

Assembly of Bipolar

Assemble the Impaction Plate and Impaction Post (Figure 8). Place the FMP® head over the Impaction Post (Figure 9). Place the poly liner over the head and press the liner over the head with your palm until the liner envelopes the head (Figures 10, 11).



Figure 8



Figure 9



Figure 10



Figure 11

Last, place the Bipolar shell over the liner/head combination and again use your palm to press downward until the liner locks into the shell (Figure 12). An impactor is also available to assist (Figure 13).



Figure 12



Figure 13

NOTE: Do NOT engage the poly liner into the Bipolar shell prior to inserting the FMP Head into the poly liner.

Surgical Technique

Bipolar / Unipolar

The femoral stem taper should be thoroughly cleaned and dried before accepting the modular bipolar assembly. The assembly is placed on the stem taper and impacted with the sleeve/head impactor (Figure 14).

The hip is reduced and evaluated again for stability. Range of motion and leg length are verified, and closure is initiated.

Assembly of Unipolar

Clean and dry the implanted stem taper and secure the appropriate neck adaptor with the sleeve/head impactor (Figures 15, 16).

Impact the Unipolar head component onto the adaptor sleeve (Figure 17).

The hip is reduced and evaluated again for stability. Range of motion and leg length are verified, and closure is initiated.



Figure 14



Figure 15



Figure 16



Figure 17

Disassembly of Bipolar

In the situation that removal of the Bipolar is necessary, utilize the Head Distractor. Hold the distractor in the headneck interface and impact (Figure 18).

Do not attempt to reuse any component in the assembly upon revision.

Disassembly of Unipolar

The modular neck adaptor sleeves are threaded at the base. This allows the sleeve to be disengaged from the Unipolar head or femoral stem taper in the situation that removal of the Unipolar sleeve is necessary. To disengage the neck adaptor sleeve from the femoral stem taper, fully thread the outer sleeve of the T-handle extractor into the neck adaptor sleeve. Once the outer sleeve is fully engaged, turn the T-handle clockwise until the sleeve disengages from the stem taper (Figure 19). It may be necessary to use the outer sleeve handle to apply counter pressure while turning the T-handle. If the taper lock is not released by the use of counter pressure only, the top of the T-handle may be struck sharply with a mallet. To disengage the neck adaptor sleeve from the Unipolar head, carefully thread the outer sleeve of the T-handle sleeve extractor into the adaptor sleeve until it is fully seated. Turn the T-handle clockwise until the adaptor sleeve disengages from the Unipolar head (Figure 20). Again, it may be necessary to apply counter pressure with the outer sleeve handle until the taper lock is released.



Figure 18



Figure 19



Figure 20

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Bipolar / Unipolar

Foundation Fracture Press-Fit 440 with and without Collar Stems Foundation Fracture Cemented 450 and 460 Stems

Femoral Stem Size	Stem Length	Neck Angle	Neck Length	Neck Offset
9.0	130mm	132°	34mm	40mm
10.5	135mm	132°	34mm	40mm
12.0	140mm	132°	34mm	42mm
13.5	145mm	132°	34mm	42mm
15.0	150mm	132°	37mm	45mm
16.5	155mm	132°	37mm	45mm

Distal Centralizer Diameters

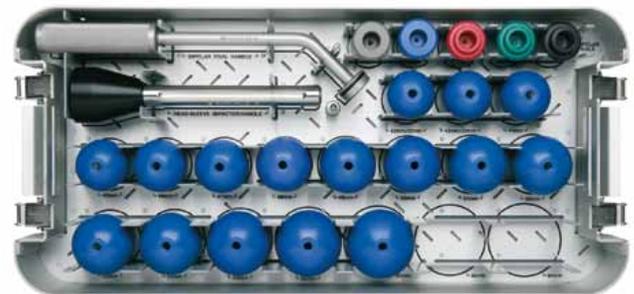
Distal Centralizer	Size Diameter
9.0	7.8mm
10.5	9.2mm
12.0	10.4mm
13.5	11.6mm
15.0	12.8mm
16.5	14.1mm
18.0	15.4mm

Bipolar/Unipolar Sizes Available

*42mm	48mm	54mm
*43mm	49mm	56mm
44mm	50mm	58mm
45mm	51mm	60mm
46mm	52mm	62mm
47mm	53mm	64mm

Femoral Head Trial Color

22/Neu	
22/+4.0	
28/-3.5	
28/Neu	
28/+3.5	
28/+7.0	
28/+10.5	



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CAUTION: Federal Law (USA)
restricts this device to sale by
or on the order of a physician.

See package insert for a
complete listing of indications,
contraindications, warnings,
and precautions.