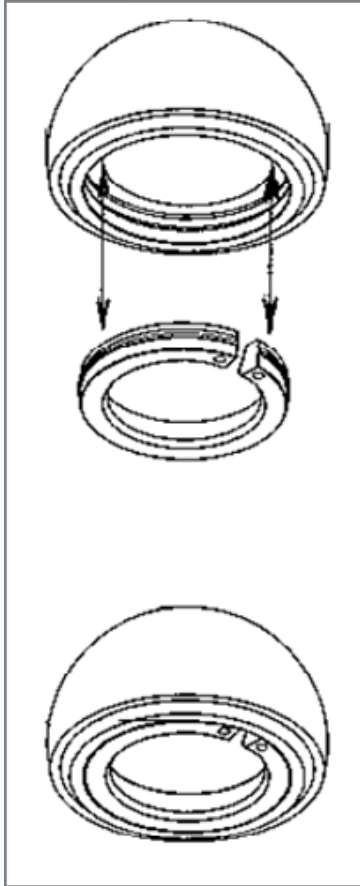


Bipolar System

Surgical Protocol and Product Specifications



Bipolar System



Bipolar Surgical Technique

After removal of the femoral head, the head diameter can be measured to determine the approximate size. Ligamentous structures and entophytes that could limit the range of motion can then be removed from the acetabulum. The appropriate sized trial head can be placed into the acetabulum to determine fit. The proper size has been determined when the trial has a snug fit in the acetabulum. Trial reduction to determine fit and range of motion can be performed with either the broach or femoral implant in place.

Once the appropriate size bipolar implant has been selected, it can be assembled. After opening the bipolar from the sterile package, the locking ring is removed with the bipolar ring clamp. The ring clamp is placed into the two holes on the locking ring and compressed to release the ring from the bipolar shell. Assembly may be completed by placing the femoral head into the bipolar shell, snapping the locking ring into the bipolar shell securely around the femoral head, and impacting the bipolar implant assembly after the femoral head has been aligned with the stem trunnion. Assembly may also be completed by placing the bipolar locking ring over the stem trunnion with the ring removal holes facing distally, placing the bipolar shell onto the femoral head implant, and snapping the locking ring into the bipolar shell securely around the femoral head.

The assembly is complete and the locking mechanism can now be checked by trying to remove the bipolar from the femoral head. Final reduction of the hip can now be accomplished.

Bipolar Removal

If required, the bipolar head can easily be removed with the bipolar ring clamp. The ring clamp is placed into the two holes on the locking ring and compressed, releasing the locking ring so that the bipolar head can be removed.

GENERAL PRODUCT INFORMATION

The bipolar head is CoCr alloy with a highly polished surface, which must be protected from marring at all times. The insert and snap ring are machined from UHMWPe (polyethylene). A 28mm diameter or a 22mm diameter femoral head must be used on the femoral stem. The bipolar head is available in a range of sizes. Assemble the snap ring over the trunnion on the stem. Place femoral head on trunnion, and then place the femoral head into the bipolar head. Secure snap ring into the bipolar.

PACKAGING

The assembled bipolar head is sterile barrier packaged in an inner foil pouch and placed in an outer Tyvek package. If the seal or package is breached, then the component should not be used.

CAUTION

Before using, the physician must understand the implant procedure.

INDICATIONS FOR USE

Fractures of the proximal femur.
Non-unions of proximal femoral neck fractures.
Aseptic necrosis of the femoral head.
Osteo-rheumatoid and post-traumatic arthritis of the hip with minimal distortion of the acetabulum.
Salvage of failed total hip arthroplasty.

CONTRAINDICATIONS

Any joint with active or suspected infection.
Any neuromuscular or mental disorders that could result in system failure from abuse.
Overweight patients who may over stress the components.
Any pathological conditions that would interfere with the performance of the system.

PRECAUTIONS

The patient must be informed of any life style modifications.
Proper selection and insertion of implants are mandatory.
The components must be protected during the procedure from mishandling and marring of the surfaces.

WARNINGS

Do not implant any damaged components.
Do not reuse implants.

ADVERSE EFFECTS

Heads have the potential for adverse effects including infection, loosening, fracture, disassembly and positional changes. Certain patients may experience reactions to polyethylene or bone cement. On rare occasions, amputation may be required due to complications. Wear debris can occur at the articulating surface.

STERILIZATION

The assembled bipolar head and the sterile barrier packaging are subjected to gamma sterilization. Do not use any component if the package has been breached.

Bipolar System

Product Specifications

Features

- CoCr Bearing Surface
- Self Centering Head through eccentric loading
- Simple disassembly with clamp
- For use with multiple offset femoral heads
- Additional special order sizes available



Femoral Head

22mm	28mm
SC1444	SC1151/ SC1152
	-5
-3.5	-3.5
+0	+0
+3.5	+3.5
	+7
	+10.5
	+12

Bipolar Head

OD mm / 22mm ID mm	OD mm / 28mm ID mm	
SC1866-40/22	SC1866-45/28	SC1866-56/28
SC1866-41/22	SC1866-46/28	SC1866-57/28
SC1866-42/22	SC1866-47/28	SC1866-58/28
SC1866-43/22	SC1866-48/28	SC1866-59/28
SC1866-44/22	SC1866-49/28	SC1866-60/28
	SC1866-50/28	SC1866-61/28
	SC1866-51/28	SC1866-62/28
	SC1866-52/28	SC1866-63/28
	SC1866-53/28	SC1866-64/28
	SC1866-54/28	SC1866-65/28
	SC1866-55/28	
Indicates Special Order Components		

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