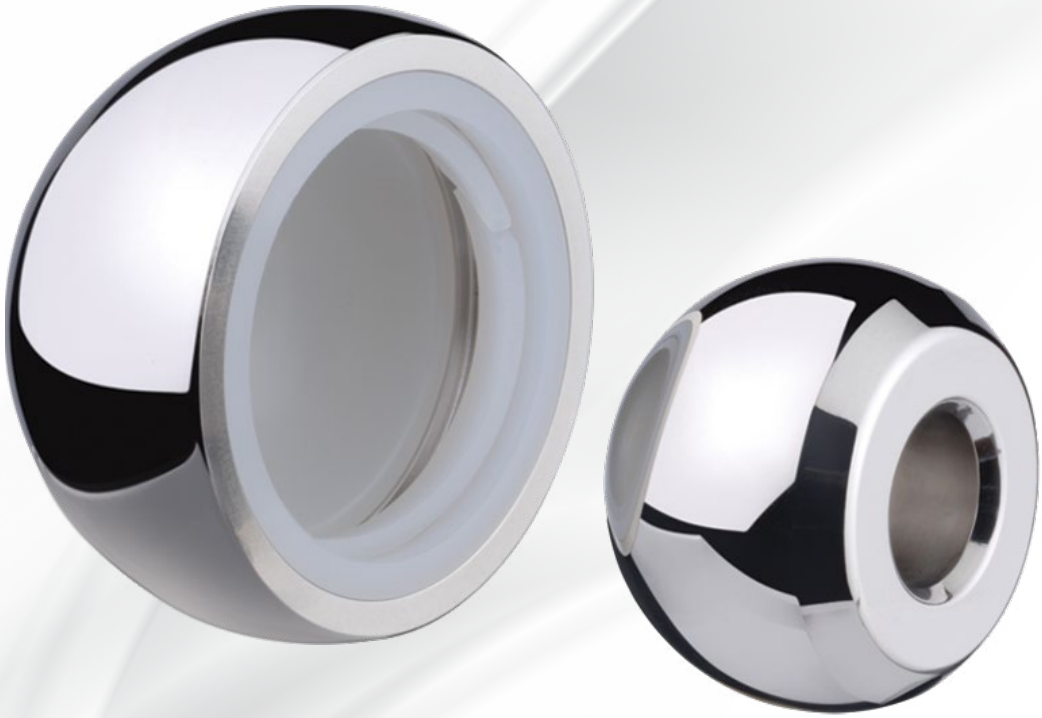
Gladiator® Bipolar
Acetabular System

Surgical Technique



MicroPort Orthopedics

Full Function, Faster®

Table of Contents

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience and patient condition. Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions for Use Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Package inserts can be found under:
Prescribing on microportortho.com

Indications

Indications

Bipolar cups should not be used in combination with skirted (hooded/collared) femoral heads as listed on page 3. Once a removal key has been used to disassociate a head from a bipolar cup, the head must be replaced with a new implant to avoid potential scratch damage.

IMPORTANT: *Prior to use of the system, the surgeon should refer to the product package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this Surgical Technique and the Instructions For Use package inserts are available on the website listed.*

Chapter 1

Design Features

DO NOT USE: *Bipolar Shells are* **not to be used** *with skirted (hooded / collared) femoral heads, which includes the following part numbers*:

Catalog No.	Ø [mm]	Size	Offset [mm]
26000020	28	X-Long	7
26000024	32	X-Long	7
26010003	22.25	Long	3.5
26010010	32	X-Long	7
26012804	28	X-Long	7
26012805	28	XX-Long	10.5
3614220500	22	Long	5
3614221000	22	X-Long	10
26010001	22.25	X-Long	7
26010011	32	XX-Long	10.5
260136XX	36	XX-Long	10.5

Gladiator® Bipolar Acetabular System is a bipolar hip implant design that features a cross-linked polyethylene bearing surface with a lock detail enhanced for strength. Historical concerns with traditional bipolar designs have included loosening of the insert, disassociation of the head from the shell, and osteolysis resulting from polyethylene wear. This system is designed to address these concerns to give surgeons greater confidence when using a bipolar implant.

There is an UHMWPE support ring inside the shell that is permanently fixed. There is also an UHMWPE locking ring that assembles above the support ring and locks into place once the head is inserted into the shell.

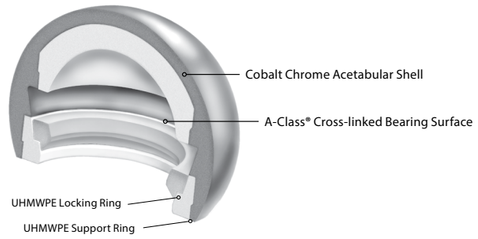


Figure 1

Figure 2 shows the locking ring in its "unlocked" position, without the head in the shell.

Figure 2

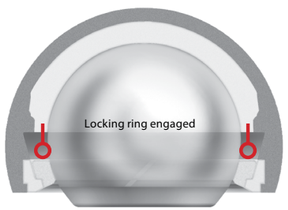


Figure 3 shows the head has been inserted. This causes the locking ring to engage and locks the head into place.

Figure 3

Chapter 2

Preoperative Planning

Figure 4

CAUTION: *Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively.*

Preoperative assessment of the appropriate size and position of the acetabular component will provide intraoperative guidance for acetabular reaming.

An A/P X-ray (Figure 4) of the pelvis will aid in leg length and offset assessment. Accurate templating requires good quality standardized radiographs of the pelvis and operated hip. Leg length discrepancies should be determined preoperatively and addressed intraoperatively.

Radiographic overlays for the Gladiator® Bipolar Cup System are available in 15 percent magnification.

Chapter 3

Surgical Technique

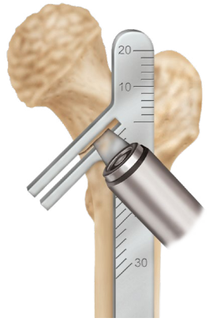


Figure 5

Figure 6

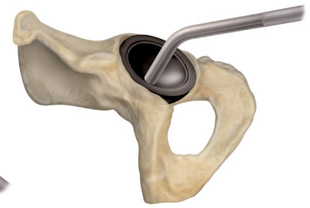


Figure 7

Figure 8

Figure 9

Figure 10

Femoral Neck Osteotomy

Approximately 10 - 20mm below the greater trochanter, resect the neck at a 45° angle to the longitudinal axis of the femur.

Sizing

Acetabular sizing is recommended using preoperative templates, the excised femoral head and the trial shells. When using trial shells, attach the acetabular sizer handle to the appropriate trial shell and size the acetabulum. When using the excised femoral head, use sizing calipers to determine the diameter of the head.

Gladiator® Bipolar Trial Shell
P/N GLBPT36-59

Acetabular Sizer Handle
P/N 48021006

Caliper
P/N 18410213

Note: *Femoral Preparation is described using as example the Profemur® Z Classic Hip Stem Surgical Technique.*

Femoral Canal Preparation

Using the box chisel, open the femoral canal. The box chisel should be lateralized to ensure a neutral orientation of the implant.

Starter Broach

Prepare the femoral canal with the initial Profemur® Z starter broach. Stay centered between the anterior and posterior cortices. Insert the broach using impactions until it rests 1-2mm below the level of the neck resection.

Profemur® Box Chisel
P/N PPR67704

Profemur® Z Starter Broach
P/N APA01070

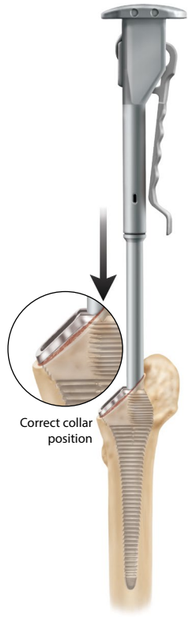


Figure 11

Figure 12

Figure 13

Femoral Broaching

Attach the preferred broach handle to the size 1 Profemur® Z broach. Using a mallet with short, controlled strokes, begin broaching.

Sequentially increase the broach sizes while broaching until an optimal fit is found. This will be denoted by a change in tone or resistance as the rounded corners of the broach contact the cortical bone of the femur. To verify a secure fit, attempt to rotate the broach relative to the femur. With proper cortical contact, the broach should not twist or move relative to the femur. At this point, leave the broach fully seated in the canal and detach the broach handle to allow for trial reduction.

Potential Differences between Broached and Templated Sizes

- The quality of bone plays an integral role in sizing. For soft bone, the broach may seat further than the template indicates. An implant larger than the templated size may be required. Patients with strong, healthy bone might require an implant smaller than the templated size.
- If a broach smaller than the size templated becomes tight, hard bone at the lateral femoral neck may be pushing the broach into varus. Use the lateral edge of the broach to restore a neutral position. Additional broaching may be necessary.
- If a broach is going in straight and still becomes tight with sizes smaller than templated, a repetitive in/out broach motion may clear excess medial and lateral bone. If still tight, the stem should be appropriately downsized until metaphyseal bone is engaged.

Slotted Broach Handle
P/N SLBROMAN

Profemur® Z Slotted Broach
P/N APA08001 - APA8009

Trial Reduction

After broaching, select the appropriate Profemur® trial neck and Gladiator® Bipolar trial head.

Place the trial head into the trial shell by lining up the flat portion of the trial head with the opening on the trial shell.

Place the appropriate Profemur® trial sleeve into the trial head. Place the construct onto the trial neck. A trial reduction may now be performed. Once a well balanced hip is achieved, remove the broach.

Summary of Neck Options

Straight necks create a neutral neck axis of 135˚. Varus necks decrease the inclination angle to 127˚; the femoral head shifts medially and inferiorly; leg length is shortened; offset is increased.

Profemur® Trial Neck
P/N APA11102

Gladiator® Bipolar Trial Head
P/N GLBPTH22-36

Profemur® Trial Sleeve
P/N APA0TSS3-APA0TSM0-APA0TSL3

Figure 14

Stem Insertion

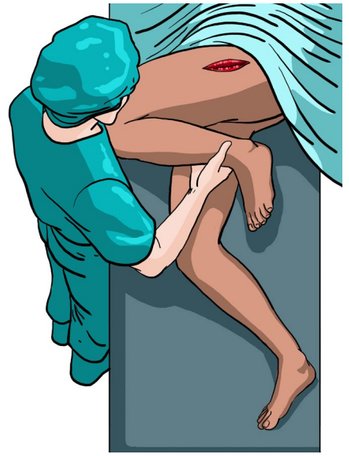
Insert the femoral implant into the canal and seat it as far as possible by hand while maintaining proper version. Place the tip of the final stem impactor into the dimple on the lateral shoulder and, with a mallet, fully seat the implant using short, controlled strokes.

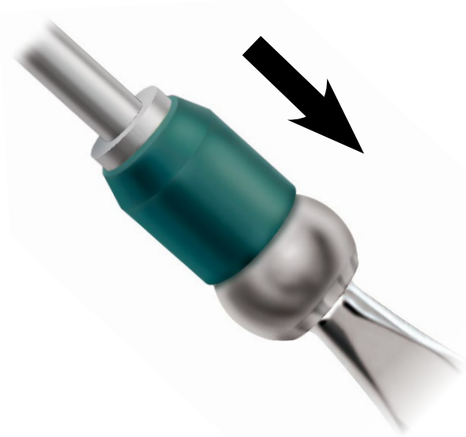
Typically, the implant is seated with the base of the polished neck at the resection cut.

Final Stem Impactor
P/N PPF60200

Final Trial Reduction

Perform a final reduction using a trial head and trial shell to reconfirm stability, range of motion and leg length. Once a well-balanced hip has been created with a trial head and trial shell, you can introduce the final head and shell implant.





Implant Assembly

Position the leg such that the knee is supported by an assistant on the opposite side of the table. By resting the patient's knee against the mid-section of the assistant, this will provide counter-force against the mallet blows to ensure the impaction load transfer to the neck junction.

Ensure the stem taper is clean and dry prior to assembly, and then affix the femoral head to the neck. Using the head impactor instrument, strike the impactor with **three very firm blows** with a mallet to securely fix the head to the neck.

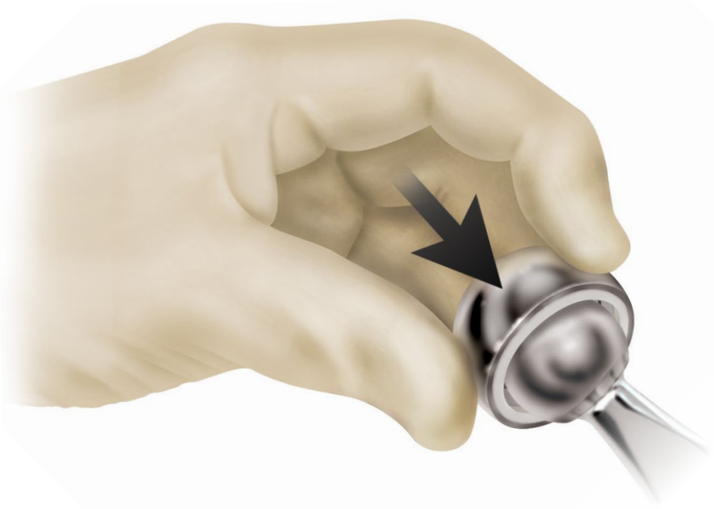


Figure 15

Gladiator® Bipolar Shell Seating

Place the bipolar shell implant onto the head. Apply a slight pressure to the shell and a clicking sound will confirm the shell is affixed to the head.

To verify that the Gladiator® Bipolar shell is fully seated, rotate and manipulate it repeatedly in a back and forth manner (along the axis of the femoral neck). The fully seated Gladiator® Bipolar shell should rotate freely and be secured locked onto the femoral head. Reduction can be performed.

Chapter 4

Implant Removal

Figure 16

Figure 17

Figure 18

Figure 19

Note: *If the removal of the implant is required due to revision, the surgeon should call the number on the back page of this surgical technique and select the option for customer service to receive instructions for returning the explanted device to the manufacturer for investigation.*

Implant Removal

Attach the removal key to the sizer handle. Place the removal key into the opening in the shell. The head will now disassociate from the shell with little force.

Femoral Head Removal

The femoral head is removed by placing a plastic tipped femoral head impactor under the femoral head and applying mallet blows upward until the femoral head is removed.

Gladiator® Bipolar Removal Key
P/N GLBPRK22-36

Implant Removal

Figure 20

Classic Stem Removal

The universal stem extractor and the corresponding slap hammer can be utilized to remove the stem. Thread the stem extractor onto the threaded end of the slap hammer. With the femoral head removed, position the stem extractor across the flats on the sides of the femoral neck, and remove the stem using repetitive upward blows delivered by the slap hammer.

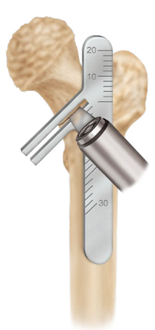
Universal Stem Extractor
P/N 4700SE05

Slap Hammer
P/N 4700SH0000

Chapter 5

Technique Overview

1. X-ray



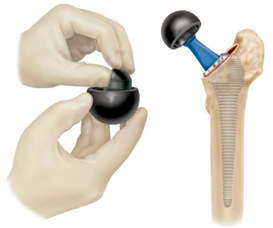
2. Femoral Neck Osteotomy

3. Sizing / Templating

4. Box Osteotome

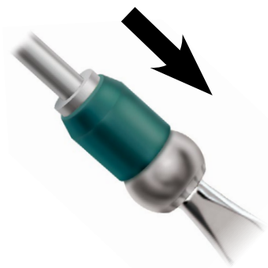
5. Starter Broach

6. Femoral Broaching

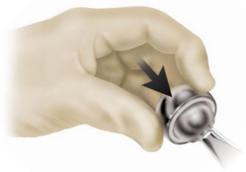


8. Trial Reduction

8. Implant Insertion



9. Femoral Head Assembly



10. Bipolar Shell Seating

Full ordering information can be found in the Gladiator Bipolar ordering guide (Document # 016388)

MicroPort Orthopedics

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