



Femoral Resurfacing System



## Femoral Resurfacing System

For demonstration purposes throughout this technique, a size 50mm femoral head is assumed. The 50mm sized head corresponds to two white markings on the instrumentation.



Instrumentation is consolidated and color-coded to promote efficiency during surgery as well as make it easier to identify the center of the femoral neck. All of the instrumentation necessary for a single implant size is depicted above.

The ReCap® Femoral Resurfacing System was developed in conjunction with John M. Cuckler, M.D., of Birmingham, Alabama; Thomas P. Gross, M.D., of Columbia, South Carolina; Thomas K. Donaldson, M.D., of Loma Linda, California; and Michael A. Jacobs, M.D., of Baltimore, Maryland.

This technique describes the surgical technique used by Thomas P. Gross, M.D. of Columbia, South Carolina. Biomet does not practice medicine and does not recommend this or any surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the prostheses in each individual patient. Biomet is not responsible for selection of the appropriate products and/or surgical technique(s) to be used on any individual patient.

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## Surgical Technique

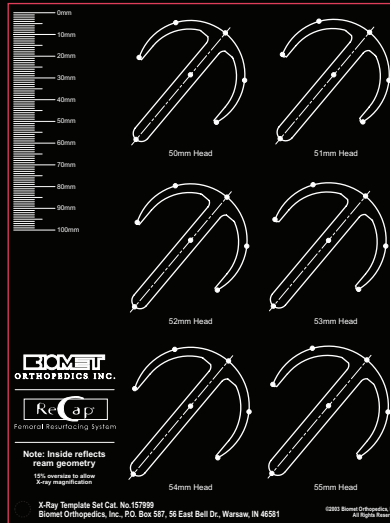


Figure 1

1

### Templating:

The femoral head is templated on Anterior/Posterior and Lateral x-rays for size and position. The implant template should match the circumference of the original femoral head. The template should be positioned so that the stem of the impant is **NOT** in varus. Take note of the color-coded markings on the chosen template as they will correspond to color-coded instrumentation during surgery (Figure 1).

2

### Surgical Approach:

Expose the femoral head through standard surgical incision (Figure 2). Both posterior and anterior approaches are possible based on the surgeon's preference.

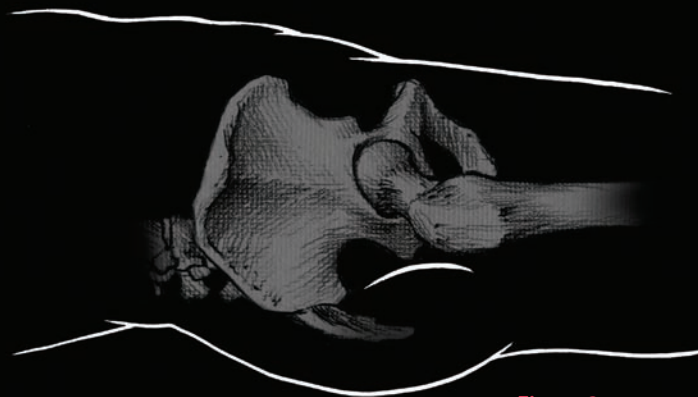


Figure 2



Figure 3a

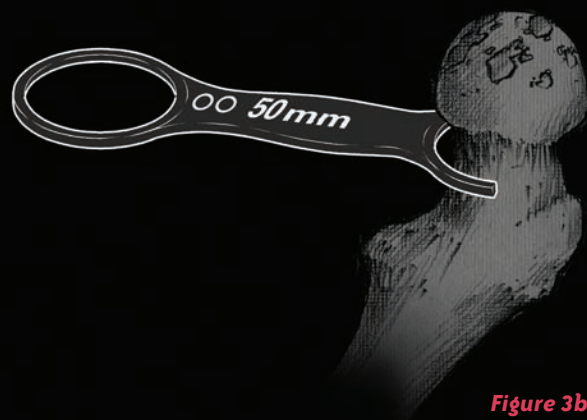


Figure 3b

### 3 Acetabular and Femoral Head/Neck Sizing:

Acetabular gauges (such as the ones used in the Endo II System) may be used to establish a size match between the resurfacing implant and the natural acetabulum. Select the femoral size that is closest to that of the natural acetabulum. If the acetabulum measures 50mm, the instruments with two white circular markings should be used. The ReCap® femoral resurfacing implants are available in 1mm increments (38mm to 60mm) to more closely match the implant to the natural acetabulum. The head sizing gauge can also be used to correlate the size of the acetabulum to the femoral instrumentation (Figure 3a). The neck sizing gauge (Figure 3b) is placed around the femoral neck and rotated to determine if contact with the femoral neck will occur when cylindrical reaming commences. If the neck sizing gauge does not fit around the femoral neck or is tight, select the next larger size until the neck sizing gauge fits loosely (approximately 2mm of play circumferentially).

### 4 Identifying Femoral Neck Center (Part 1):

Using a cauterizing marker, draw lines bisecting the femoral neck into two planes (anterior/posterior and medial/lateral). These lines should extend until they intersect at the top of the femoral head (Figure 4).

**Note:** The femoral head should be ignored when determining the location of the lines, as the femoral **neck** is to be used for referencing.

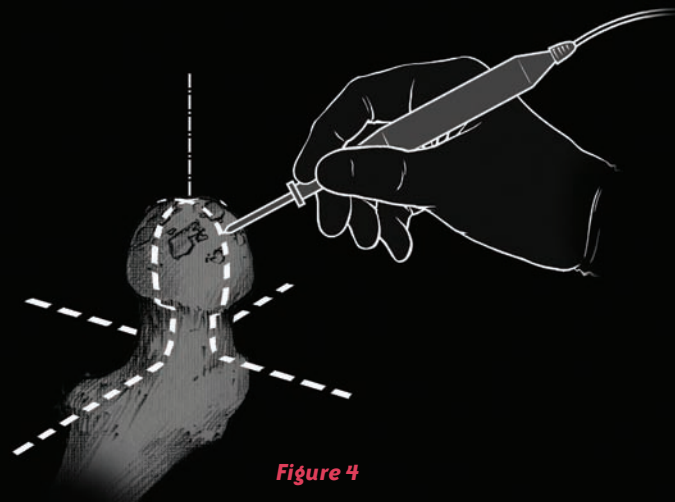
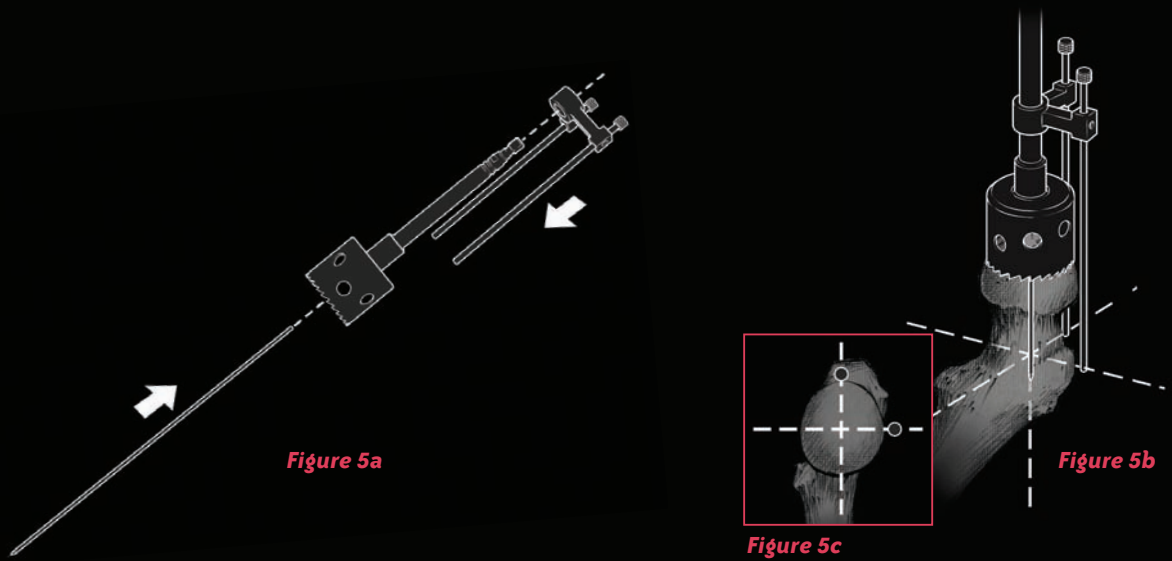


Figure 4

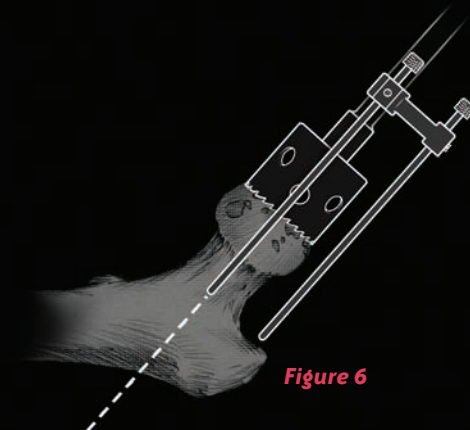


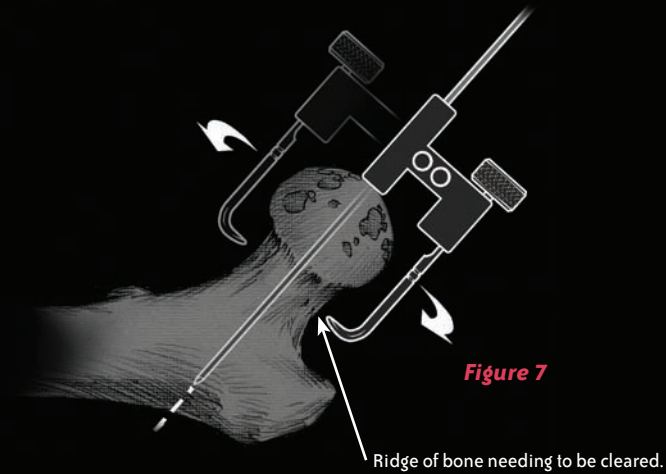
## 5 Identifying the Femoral Neck Center (Part 2):

Assemble the alignment guide tower (Figure 5a) and use it to verify the location of the femoral neck center. This is determined through visualization of the right angle rods extending from the alignment guide and their relationship to the previously cauterized marks bisecting the femoral neck (Figure 5b). The location of the entry point for the guide wire is usually superior and anterior to the perceived center of the femoral head (Figure 5c).

## 6 Guide Wire Placement:

Drill the guide wire through the femoral head into the center of the femoral **neck**. The wire should stop upon reaching the lateral cortex (Figure 6). It is common to have to reset the position of the wire, and the lateral cortex should not be perforated until the surgeon is satisfied with the wire's final location. The wire may be advanced through the lateral cortex after step 7 is completed.





**7 Neck Feeler Gauge:** Slide the color-coded neck feeler gauge onto the guide wire. Rotate the feeler gauge around the neck to ensure that the cylindrical reamer will not contact the femoral neck (Figure 7). The anterior/superior region of the femoral neck has a ridge of bone. It is important that the neck feeler gauge clear this ridge of bone in order to avoid notching with the cylindrical reamer. If the feeler gauge contacts the femoral neck in any place, the guide wire will need to be repositioned (repeat step 5).

**8 Advancement of Guide Wire:** When thoroughly satisfied with the positioning of the guide wire, it may then be advanced through the lateral cortex for added stability, although this is not an essential step (Figure 8).



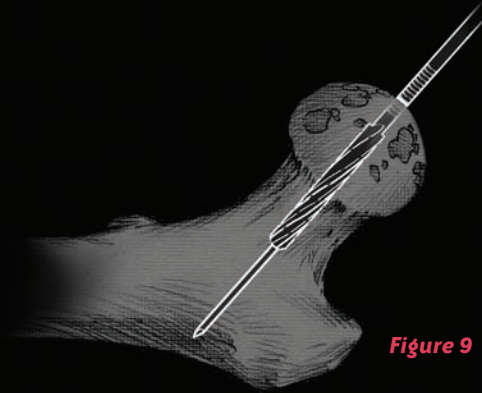


Figure 9

## 9 Cannulated Drilling:

Place the cannulated drill over the guide wire, then advance the cannulated drill into the femoral head stopping at the color-coded depth marking on the drill shaft (the second white marking for a size 50mm component) (Figure 9). The cannulated drill and guide wire may now be removed. (Alternatively, the remaining cuts may be made off of the initial K-wire using a cannulated spacer rod.)

## 10 Placement of the Guide Rod:

The standard (STD) length guide rod may now be inserted into the hole created by the cannulated drill, stopping when the collar rests on top of the femoral head (Figure 10). The standard length guide rod removes 6.5mm of bone from the articular surface of the femur. Additional guide rods of -3.0mm, +1.5mm, +3.0mm, +4.5mm and +6.0mm are available, to adjust the cut depth in order to adjust femoral length.

**Note:** These rods are used with the cylindrical and spherical reamers to remove bone. The -3.0mm rod removes 3.0mm **less** bone than the STD rod, while the +1.5mm, +3.0mm, +4.5mm and +6.0mm rods remove **more** bone than STD rod.

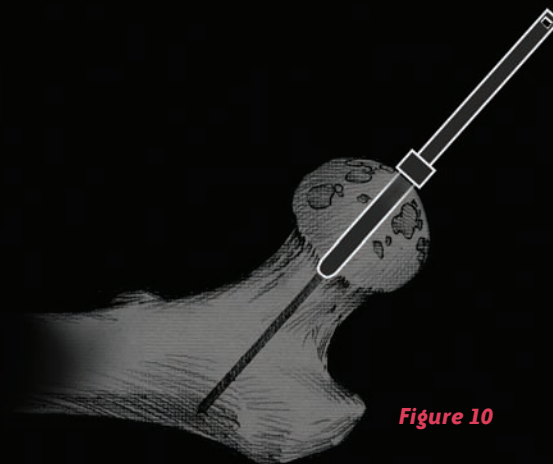
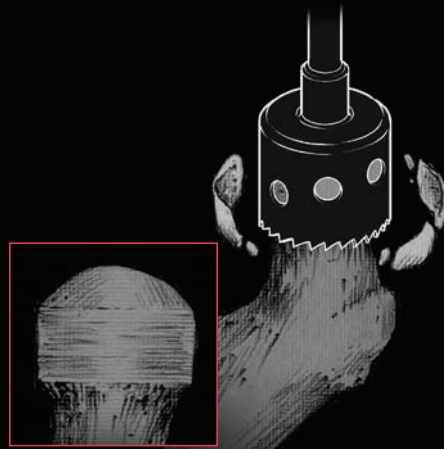



Figure 10



 Color markings are located at the top of the reamer shaft.

*Figure 11*

# 11

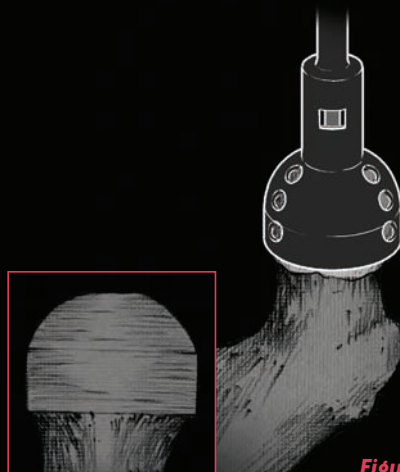
## **Cylindrical Reaming:**


Advance the appropriately sized cylindrical reamer over the guide rod and begin reaming the femoral head. It is often better to start several sizes larger than the expected size of the final femoral component and ream down to the chosen size (50mm). Use the holes on the side of the cylindrical reamer to verify when the reamer has bottomed on the guide rod collar. The tip of the cylindrical reamer, with the standard guide rod in place, will extend 5mm beyond the outer edge of the implant's articulating surface (Figure 11). Be sure not to advance the reamer too far, or notch the femoral neck. Should notching of the femoral neck occur, it is necessary to convert the resurfacing procedure to a total hip procedure, as notching of the femoral neck may negatively affect the survivorship of the resurfacing implant.

# 12

## **Spherical Reaming:**

Advance the appropriately sized spherical reamer over the guide rod. The spherical reamer is advanced until the spherical reamer bottoms on the collar of the guide rod (Figure 12). The midline marking of the window on the shaft of the spherical reamer may also be used to verify when the spherical reamer has bottomed out. Upon removal of the spherical reamer and guide rod, take a rongeur and remove the small peg of bone left on top of the femoral head.



 Color markings are located at the top of the reamer shaft.

*Figure 12*

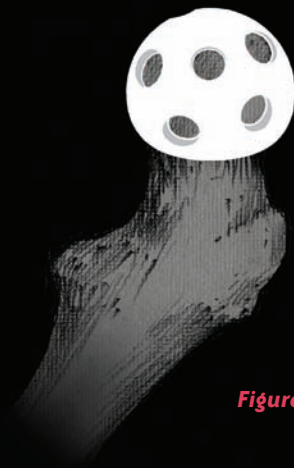


Figure 13

## 13 **Trialing the Femoral Implant:**

Place the appropriately sized head trial over the freshly prepared femoral head to check the fit of the implant and to perform a trial reduction. The trial will fit loosely. This gap allows a 0.5mm circumferential cement mantle or porous coating, depending on the implant choice. The holes in the trial are used to assess adequacy of reaming and defects remaining on the femoral head (Figure 13), which may be filled with cement or morselized bone graft depending on which implant option is used.

## 14 **Marking the Implant Seating Depth:**

With the head trial properly seated, mark the depth with a cauterizing marker or other marking device (Figure 14). This mark on the femoral neck may be used to verify seating depth for impacting the final implant.

**Note:** The bottom of the spherical reamer and the head trial is where the final implant will seat.

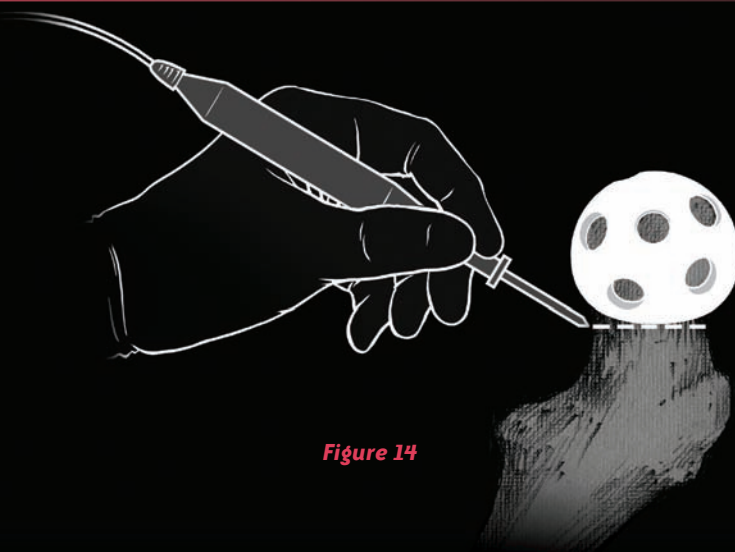


Figure 14

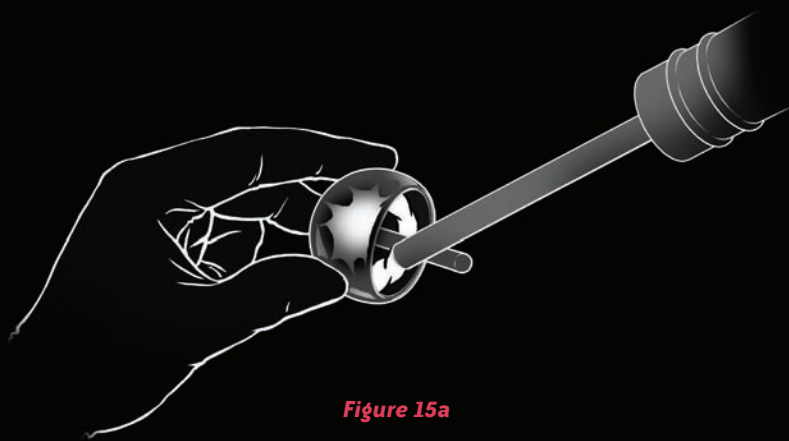


Figure 15a

# 15 Placing the Femoral Implant:

## a. Cemented Application:

Apply a thin layer of bone cement to the Interlok® surface on the inside of the femoral implant as well as to the femoral head (Figure 15a). Whether or not to cement the stem is controversial. Dr. Gross recommends inserting a suction tip into the stem hole in the femoral head in order to draw the cement into the porous bone. The femoral implant is then placed onto the femoral head (Figure 15b) and impacted until seated with the femoral head impactor (Figures 15c and 15d). There is a 0.5mm cement mantle built into the cemented implant (Figure 15e).

## b. Press-Fit Application:

Morselized bone graft may be impacted into defects on the surface of the femoral head. The appropriately sized press-fit implant should then be selected and the titanium porous plasma spray (PPS®) coating engaged through impaction onto the prepared femoral head.



Figure 15b



*Figure 15c*



*Figure 15d*

# 16

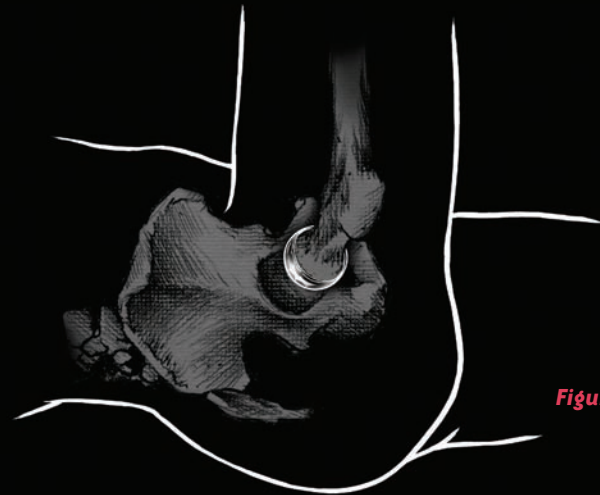
## **Reduction:**

Gently reduce the ReCap® femoral resurfacing implant into the natural acetabulum where it is designed to articulate with the acetabular cartilage (Figure 16).

This technique describes the surgical technique used by Thomas P. Gross, M.D. of Columbia, South Carolina. Biomet does not practice medicine and does not recommend this or any surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the prostheses in each individual patient. Biomet is not responsible for selection of the appropriate products and/or surgical technique(s) to be used on any individual patient.



*Figure 15e*



*Figure 16*

**Biomet® Femoral Head Resurfacing Prostheses**  
**Attention Operating Surgeon**

**DESCRIPTION**

Biomet® Femoral Head Resurfacing Prostheses are designed to replace the outer surface of the femoral head while preserving as much natural bone as possible. The device retains the diameter of the natural femoral head. The Femoral Head Resurfacing device is not cleared for use with an acetabular component in the United States.

**MATERIALS**

|                   |                 |
|-------------------|-----------------|
| Substrate         | CoCrMo Alloy    |
| Surfacing Coating | Ti-6AL-4V Alloy |

**INDICATIONS**

Cemented Femoral Head Resurfacing Device

- 1) Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
- 2) Rheumatoid arthritis

The device is a single use implant intended for use with bone cement.

Press-Fit Head Resurfacing Device

Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis, and rheumatoid arthritis.

The device is a single use implant intended for press-fit application.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness of the patient to follow instructions, including control of weight and activity level, 3) a good nutritional state of the patient, and 4) the patient must have reached full skeletal maturity.

**CONTRAINDICATIONS**

Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include: 1) uncooperative patient or patient with neurologic disorders who are incapable of following directions, 2) osteoporosis, 3) metabolic disorders which may impair bone formation, 4) osteomalacia, 5) distant foci of infections which may spread to the implant site, 6) rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram, 7) vascular insufficiency, muscular atrophy, or neuromuscular disease.

**WARNINGS**

Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris, or fatty tissues have lower adhesion strength to cement than implants handled with clean gloves. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.

Biomet joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

**PRECAUTIONS**

Specialized instruments are designed for Biomet joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Biomet recommends that all instruments be regularly inspected for wear and disfigurement.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

**POSSIBLE ADVERSE EFFECTS**

- 1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
- 2) Early or late postoperative, infection, and allergic reaction.
- 3) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
- 4) Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
- 5) Periarticular calcification or ossification, with or without impediment of joint mobility.
- 6) Inadequate range of motion due to improper selection or positioning of components.
- 7) Undesirable shortening of limb.
- 8) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
- 9) Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
- 10) Fretting and crevice corrosion can occur at interfaces between components.
- 11) Wear and/or deformation of articulating surfaces.
- 12) Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
- 13) Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
- 14) Intraoperative or postoperative bone fracture of the femoral neck and/or postoperative pain.

**STERILITY**

Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

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

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomet, P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683

Authorized Representative: Biomet UK, Ltd.  
Waterton Industrial Estates,  
Bridgend, South Wales  
CF31 3XA, U.K.

CE 0086

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# Ordering Information

## Implants

| ReCap® Resurfacing Heads |                    |      |
|--------------------------|--------------------|------|
| Cemented Part No.        | Press-Fit Part No. | Size |
| US157238                 | US157138           | 38mm |
| US157239                 | US157139           | 39mm |
| US157240                 | US157140           | 40mm |
| US157241                 | US157141           | 41mm |
| US157242                 | US157142           | 42mm |
| US157243                 | US157143           | 43mm |
| US157244                 | US157144           | 44mm |
| US157245                 | US157145           | 45mm |
| US157246                 | US157146           | 46mm |
| US157247                 | US157147           | 47mm |
| US157248                 | US157148           | 48mm |
| US157249                 | US157149           | 49mm |
| US157250                 | US157150           | 50mm |
| US157251                 | US157151           | 51mm |
| US157252                 | US157152           | 52mm |
| US157253                 | US157153           | 53mm |
| US157254                 | US157154           | 54mm |
| US157255                 | US157155           | 55mm |
| US157256                 | US157156           | 56mm |
| US157257                 | US157157           | 57mm |
| US157258                 | US157158           | 58mm |
| US157259                 | US157159           | 59mm |
| US157260                 | US157160           | 60mm |

## Instrumentation

### Head Sizing Gauges

|           |      |
|-----------|------|
| 31-500038 | 38mm |
| 31-500039 | 39mm |
| 31-500040 | 40mm |
| 31-500041 | 41mm |
| 31-500042 | 42mm |
| 31-500043 | 43mm |
| 31-500044 | 44mm |
| 31-500045 | 45mm |
| 31-500046 | 46mm |
| 31-500047 | 47mm |
| 31-500048 | 48mm |
| 31-500049 | 49mm |
| 31-500050 | 50mm |
| 31-500051 | 51mm |
| 31-500052 | 52mm |
| 31-500053 | 53mm |
| 31-500054 | 54mm |
| 31-500055 | 55mm |
| 31-500056 | 56mm |
| 31-500057 | 57mm |
| 31-500058 | 58mm |
| 31-500059 | 59mm |
| 31-500060 | 60mm |

### Neck Sizing Gauges

|           |         |
|-----------|---------|
| 31-500238 | 38–39mm |
| 31-500240 | 40–41mm |
| 31-500242 | 42–43mm |
| 31-500244 | 44–45mm |
| 31-500246 | 46–47mm |
| 31-500248 | 48–49mm |
| 31-500250 | 50–51mm |
| 31-500252 | 52–53mm |
| 31-500254 | 54–55mm |
| 31-500256 | 56–57mm |
| 31-500258 | 58–59mm |
| 31-500260 | 60mm    |

### Neck Alignment Guides

|           |        |
|-----------|--------|
| 31-500330 | Small  |
| 31-500331 | Medium |
| 31-500332 | Large  |

## Cannulated Instruments

|           |                       |
|-----------|-----------------------|
| 31-600385 | Stem Drill            |
| 31-500402 | Sleeve                |
| 31-500499 | -3.0mm<br>Guide Rod   |
| 31-500500 | Standard<br>Guide Rod |
| 31-500501 | +1.5mm<br>Guide Rod   |
| 31-500502 | +3.0mm<br>Guide Rod   |
| 31-500503 | +4.5mm<br>Guide Rod   |
| 31-500504 | +6.0mm<br>Guide Rod   |

### Guide Rod Removal Hook

US32-401111

### Steinmann Pins (pkg/6)

27-361678 1/8" x 9"

### Modular Head Impactor

31-476948

### Cylindrical Reamers

|           |         |
|-----------|---------|
| 31-500638 | 38/39mm |
| 31-500640 | 40/41mm |
| 31-500642 | 42/43mm |
| 31-500644 | 44/45mm |
| 31-500646 | 46/47mm |
| 31-500648 | 48/49mm |
| 31-500650 | 50/51mm |
| 31-500652 | 52/53mm |
| 31-500654 | 54/55mm |
| 31-500656 | 56/57mm |
| 31-500658 | 58/59mm |
| 31-500660 | 60mm    |

### Spherical Reamers

|           |         |
|-----------|---------|
| 31-500738 | 38/39mm |
| 31-500740 | 40/41mm |
| 31-500742 | 42/43mm |
| 31-500744 | 44/45mm |
| 31-500746 | 46/47mm |
| 31-500748 | 48/49mm |
| 31-500750 | 50/51mm |
| 31-500752 | 52/53mm |
| 31-500754 | 54/55mm |
| 31-500756 | 56/57mm |
| 31-500758 | 58/59mm |
| 31-500760 | 60mm    |

## Femoral Head Trials

|           |      |
|-----------|------|
| 31-500938 | 38mm |
| 31-500939 | 39mm |
| 31-500940 | 40mm |
| 31-500941 | 41mm |
| 31-500942 | 42mm |
| 31-500943 | 43mm |
| 31-500944 | 44mm |
| 31-500945 | 45mm |
| 31-500946 | 46mm |
| 31-500947 | 47mm |
| 31-500948 | 48mm |
| 31-500949 | 49mm |
| 31-500950 | 50mm |
| 31-500951 | 51mm |
| 31-500952 | 52mm |
| 31-500953 | 53mm |
| 31-500954 | 54mm |
| 31-500955 | 55mm |
| 31-500956 | 56mm |
| 31-500957 | 57mm |
| 31-500958 | 58mm |
| 31-500959 | 59mm |
| 31-500960 | 60mm |

### Template Set

157999

**BIOMET<sup>®</sup>**

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**Driven By Engineering**

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Form No. Y-BMT-928/093005/M