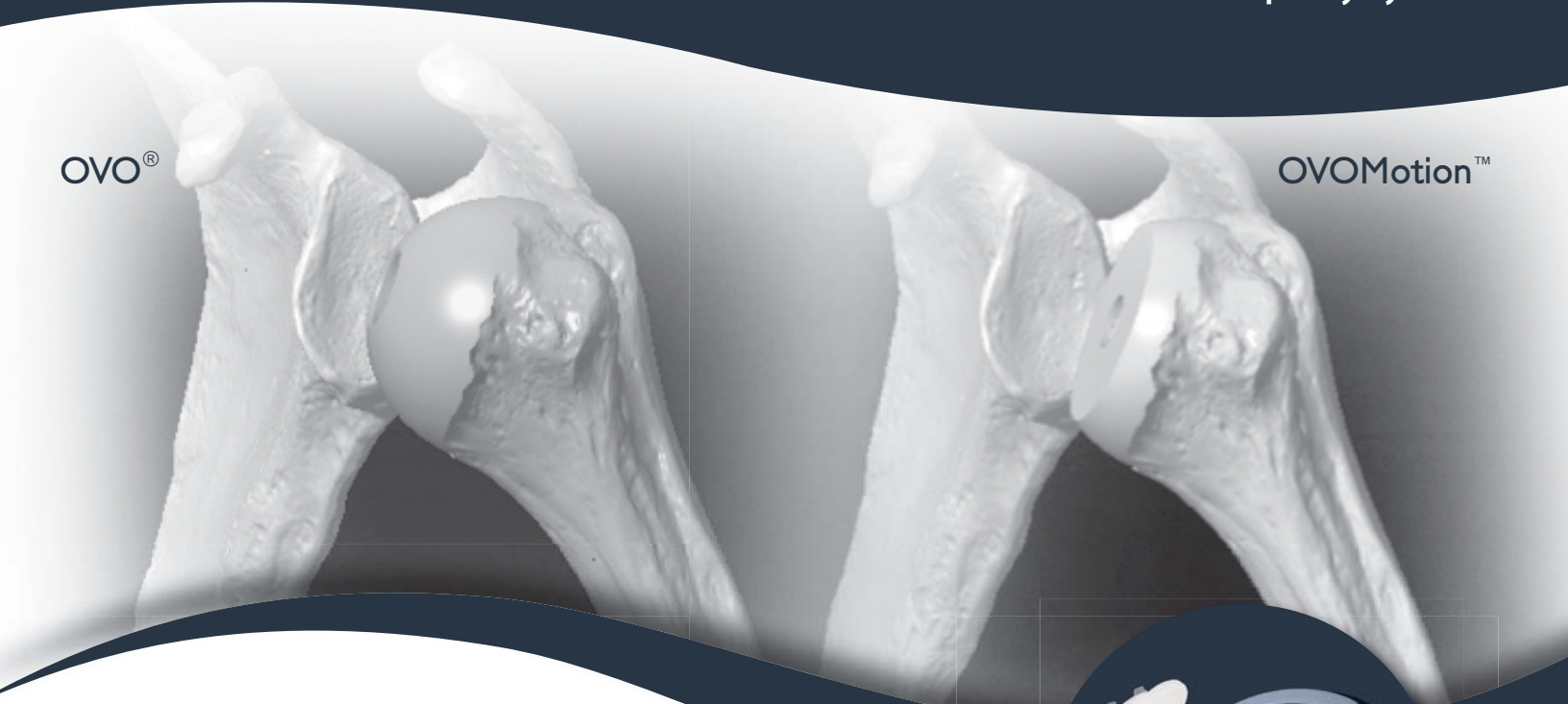
Technique Guide

OVO & OVOMotion Inlay
Shoulder Arthroplasty Systems



Anatomic

- **OVO & OVOMotion**
  Preserves volume, version and height of humeral head
- **Inlay Glenoid**
  Avoids lateralization & overstuffing
  Maintains glenohumeral stability & native soft tissue tension

Stability

- **OVOMotion**
  Epiphyseal crown supports the base and provides shear force protection
- **Inlay Glenoid**

Inlay: No loosening after 4000 cycles[1]
Superior biomechanical stability and resistance to gross loosening

Onlay: Gross loosening at a mean of 1126 cycles[1]
Significant increase in contact forces on the implant edge predisposing components to rocking horse phenomenon and loosening

Access

- **OVOMotion Glenoid Access**
  Humeral head access reamer optimizes visualization of the inferior and posterior glenoid border

1) Gagliano JR, Helms SM, Colbath GP, Przestrzelski BT, Hawkins RJ, DesJardins JD. A comparison of onlay versus inlay glenoid component loosening in total shoulder arthroplasty. J Shoulder Elbow Surg. 2017 Jul;26(7):1113-1120.

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Anterior Deltopectoral Approach

1. Beachchair position (tilt back to 45 degree angle).

2. Short deltopectoral incision (from coracoid tip to pectoralis major insertion).

3. This incision is utilitarian and can be converted to an extensile approach if necessary.

4. Develop skin flaps over pectoralis & deltoid.

5. Develop deltopectoral interval.
    a. The cephalic vein may go either medially or laterally. Lateral retraction of the cephalic vein can be beneficial because it preserves the venous outflow from the deltoid.
    b. Identify coracoid tip.
    c. Identify pectoralis major insertion.

6. Release subdeltoid and subacromial adhesions. Abducting the shoulder in order to relax the deltoid facilitates this step.

7. Retract the deltoid and pectoralis major muscles. This step is facilitated by the use of a blunt, multi-pronged self-retaining retractor.

8. Identify and develop the lateral border of the conjoined tendon. This step is assisted by flexion of the shoulder, which relaxes the conjoined tendon & facilitates exposure.

9. Retract the conjoined tendon medially. Take care to not injure the musculo-cutaneous nerve. A blunt, non self-retaining retractor under the conjoined tendon facilitates exposure while minimizing risk to the nerve.

10. Remove bursa from atop the subscapularis insertion.

11. Identify the anterior humeral circumflex vessels, which define the inferior aspect of the subscapularis. As needed, a 90 degree pediatric clamp is a useful tool to isolate the vessels. If necessary, a suture can be used to ligate the vessels.

12. Identify and protect axillary nerve. The axillary nerve lies deep to the anterior humeral circumflex vessels and superficial to the subscapularis muscle at the level of the glenoid. A rubber vessel loop can be used to protect/isolate the axillary nerve, if necessary.

13. Incise the subscapularis. Use of a needle tip electrocautery 1 cm lateral to the musculotendinous junction facilitates this step.
    a. Patients with anterior-inferior instability may be candidates for capsular shift and/or Bankart repair. In such cases, begin the subscapularis incision inferiorly and proceed superiorly in order to best differentiate the tendon from the underlying capsule.
    b. Alternatively, the subscapularis and capsule can be incised in one layer.
    c. Alternatively, the lesser tuberosity may be osteotomized with a sharp, 1 inch straight osteotome. This will allow bone to bone healing at the conclusion of the procedure.

14. Place #2 sutures using a Mason-Allen configuration into the edge of the subscapularis to help retract the tendon and for definitive repair at the conclusion of the procedure.
    a. A medium Cobb elevator and/or Metzenbaum scissors help to bluntly develop the layer between the subscapularis and the joint capsule. It is important to separate the subscapularis and the capsule medial to the joint line in order to address (if necessary) a Bankart lesion.

15. Release the rotator interval capsule between the upper border of the subscapularis and the anterior edge of the supraspinatus.

16. Incise the glenohumeral joint capsule along the anatomic neck with electrocautery.

17. If necessary, place a blunt "Cobra" or Hohman retractor between the axillary nerve and subscapularis/capsule in order to protect the axillary nerve.

18. Release the glenohumeral capsule from its insertion on the anatomic neck of the humerus anteriorly and inferiorly. External rotation and flexion of the shoulder facilitates capsular release and improves humeral head exposure.

19. Release the capsule completely off the anatomic neck until adequate exposure of the humeral head defect is achieved.

20. Place a humeral head retractor (i.e. Fukuda) to evaluate the glenoid and check for a Bankart lesion.

21. Perform the implantation of the OVOMotion™ Shoulder Arthroplasty System components as indicated.

22. Repair glenohumeral joint capsule and subscapularis as indicated.

23. Closure utilizing accepted practices.

Chapter One:

OVOMotion™

Shoulder Arthroplasty System

OVOMotion™ Shoulder Arthroplasty System

Description

The OVOMotion™ Shoulder Arthroplasty System includes:

1. Humeral articular component and a taper post fixation component that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface;
2. Glenoid component intended to articulate with the humeral component when both articular surfaces of the shoulder joint are affected.

The enclosed humeral articular component may be used with an appropriate Arthrosurface glenoid component (sold separately).

Materials

Articular Component:	Cobalt-Chronium Alloy (Co-Cr-Mo)
Undersurface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)

Indications

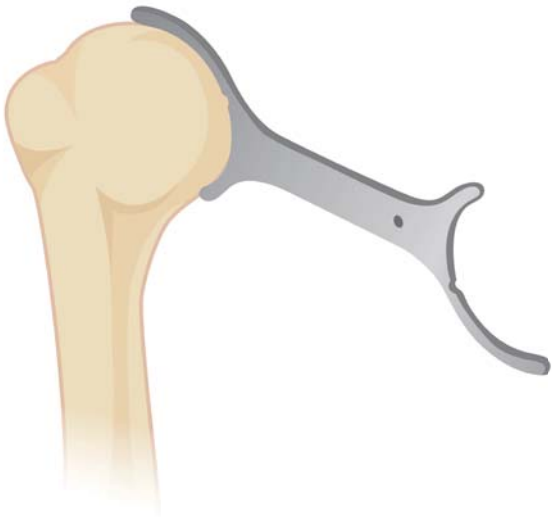
For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck and glenoid vault should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single-use implant intended to be used for hemiarthroplasty or in conjunction with the Arthrosurface glenoid component for total shoulder arthroplasty. Both humeral and glenoid components of the OVOMotion™ Shoulder Arthroplasty System are intended for cemented use only.

OVOMotion™ System Components

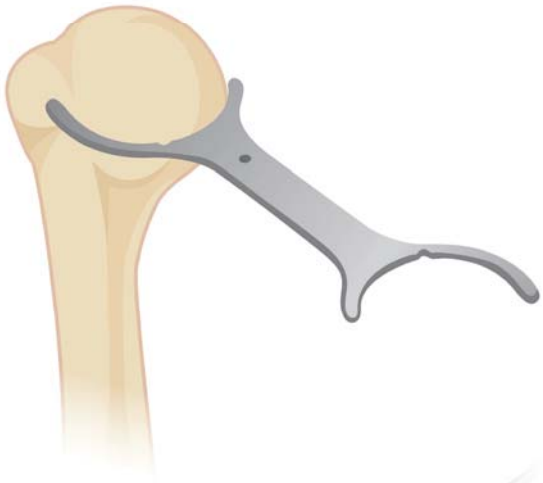
- Cobalt Chrome Component
  (Ovoid shapes, 7 offset choices)
- Ti Plasma Spray Undercoating
- Morse Taper:
  Interlocks the two components
- Titanium Fixation Component
  (Cannulated, Bead blasted)

Surgical Technique

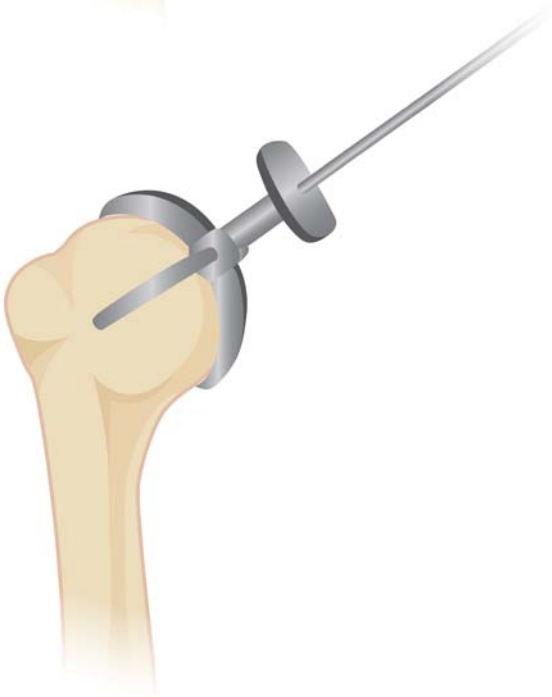
1. Remove osteophytes around the humeral head using a 3/4 inch osteotome and/or rongeur. There should be a smooth transition from the humeral neck to the humeral head.



2. Place the appropriate **Mapping Templates** over the articular surface and map the surface in both superior/ inferior and anterior/posterior planes. Utilize **Templates** to obtain the superior/ inferior diameter and anterior/ posterior diameter that best replicate the anatomy. Use the sizing card to record the diameters. The **Drill Guide** and **Surface Reamer** will be selected based on the anterior/posterior value. Place the **Surface Reamer** onto the humeral head to verify the **Surface Reamer** size and placement.

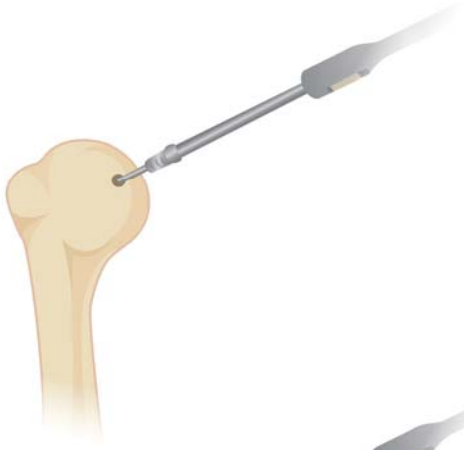


3. Utilizing the **Drill Guide** or the **Surface Reamer** as a guide, advance the 2.5mm **Guide Pin** into the bone using a Cannulated Powered Drill. Advance **Guide Pin** into bone until lateral humeral cortex is reached, with care to avoid penetrating through the lateral humeral cortex.

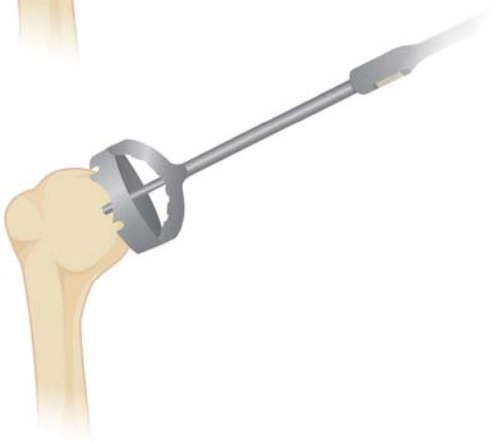


REMINDER: Start all Reamers and Drills off of the surface of the bone to avoid chipping.

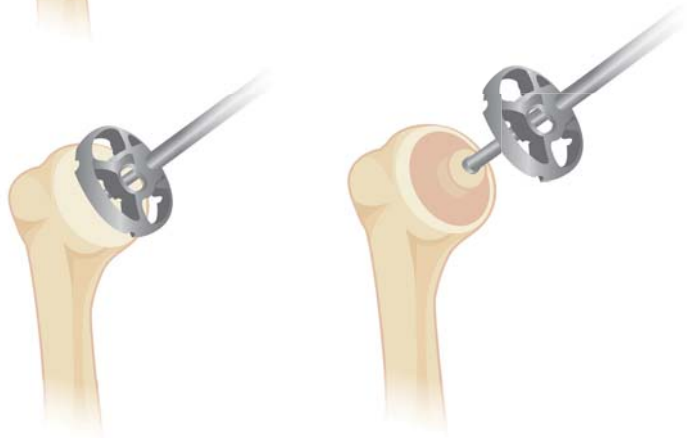
4. Using a powered drill, advance the **Centering Shaft** over the **Guide Pin** until the depth shoulder marking is at the height of the articular surface. The **Centering Shaft** can be placed slightly proud of the surface to compensate for surface flattening of the humeral head. The shoulder of the **Centering Shaft** represents the location of the crown of the implant.



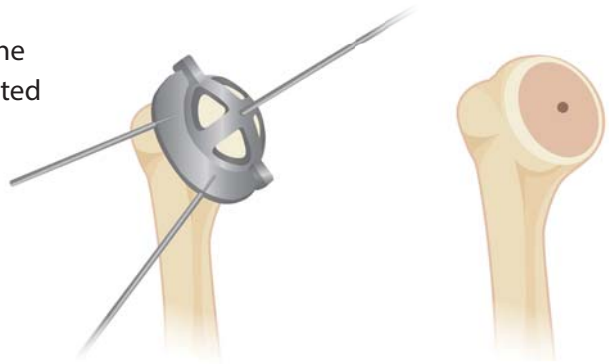
5. Using the **Surface Reamer** that matches the anterior/ posterior value, advance **Surface Reamer** over **Centering Shaft** until it reaches the stop on the **Centering Shaft**.



6. a) Repeat using the **Access Reamer.** Advance **Access Reamer** over **Centering Shaft** until it reaches the stop on the **Centering Shaft**.

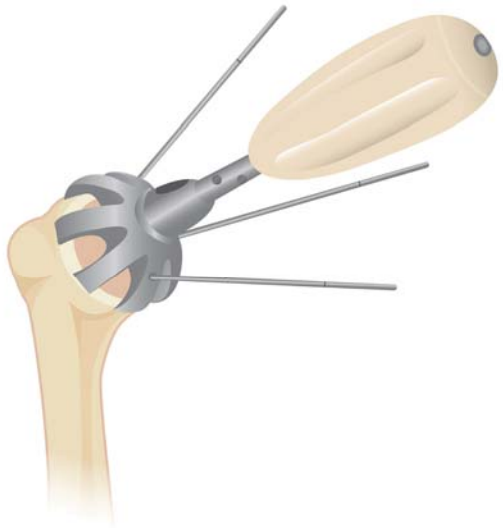


b) Or if preferred, utilize the **Sagittal Guide** to locate the sagittal saw cutting plane. Be sure all **Reamers** are started before engaging the humeral head.

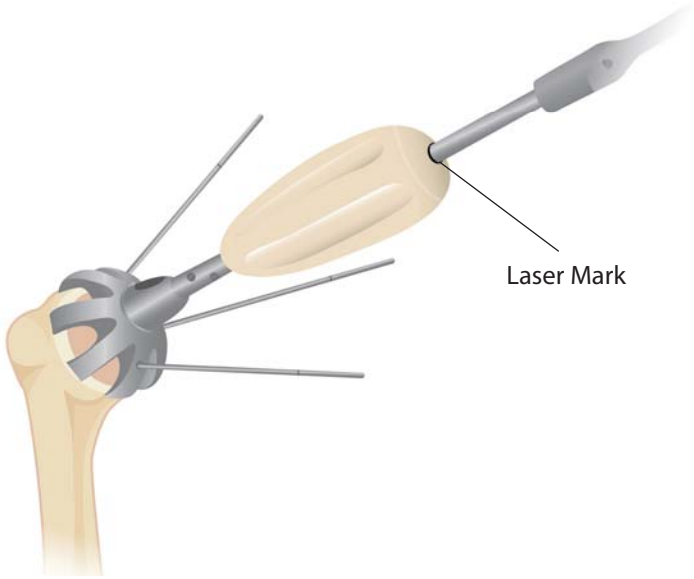


If performing the Inlay Glenoid GRS System proceed to Chapter Three prior to proceeding to next step. Refer to GRS Component label to select appropriate glenoid implant for use with the humeral component.

7. Assemble the **Guide Handle** onto the **Preparation Trial** and secure the Preparation Trial into position using the **Short Guide Pins**. The pins are critical to maintain the correct orientation of the final implant.

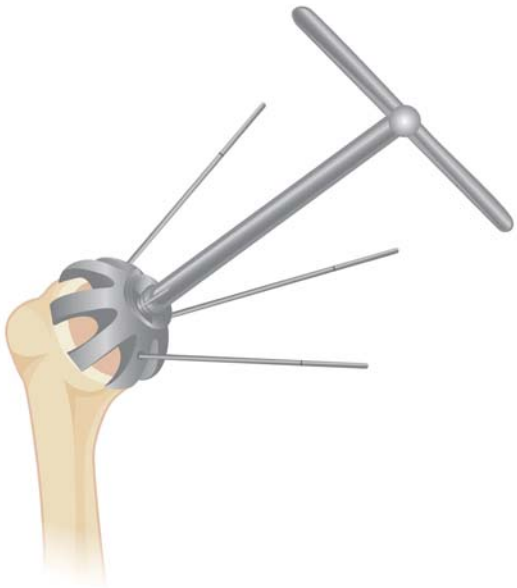


8. With the **Preparation Trial** fixed in place, insert the **Pilot Drill** through the center of the **Guide Handle** and advance until the laser mark indicated on the **Pilot Drill** meets the back of the handle. Leave **Pilot Drill** in place and unscrew and remove the **Guide Handle**.

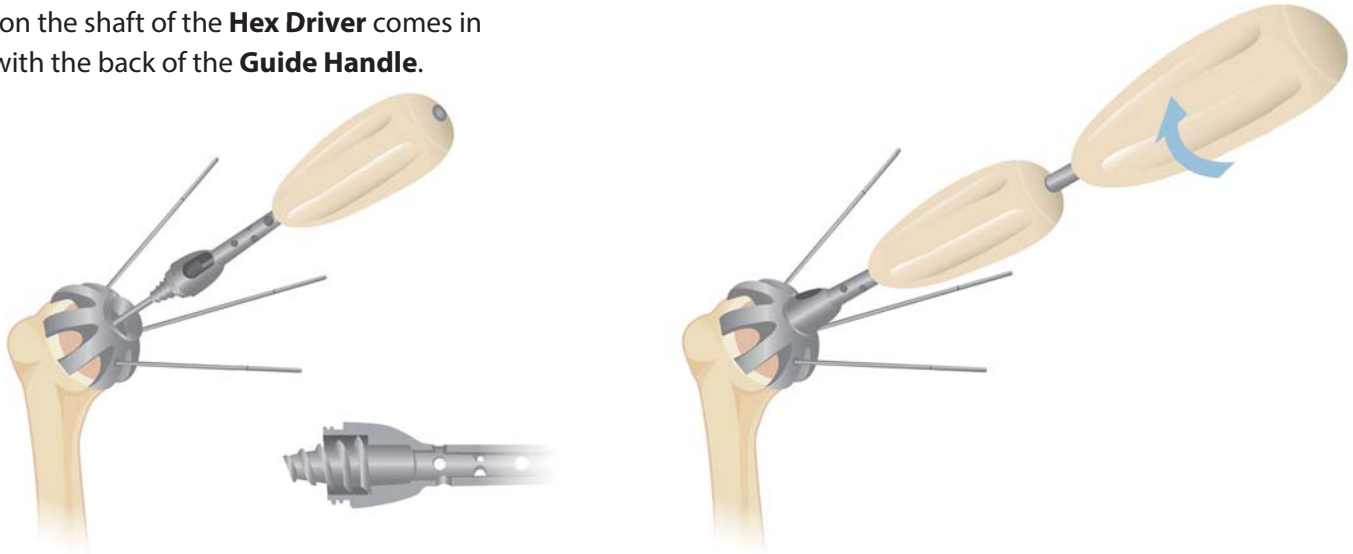


9 . Advance the **Tap** over the **Pilot Drill** until the laser mark on the **Tap** is even with the height marker on the **Preparation Trial**. Remove **Tap** and remove **Pilot Drill**. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and then inject the cement in a retrograde fashion from the end of the hole upwards.

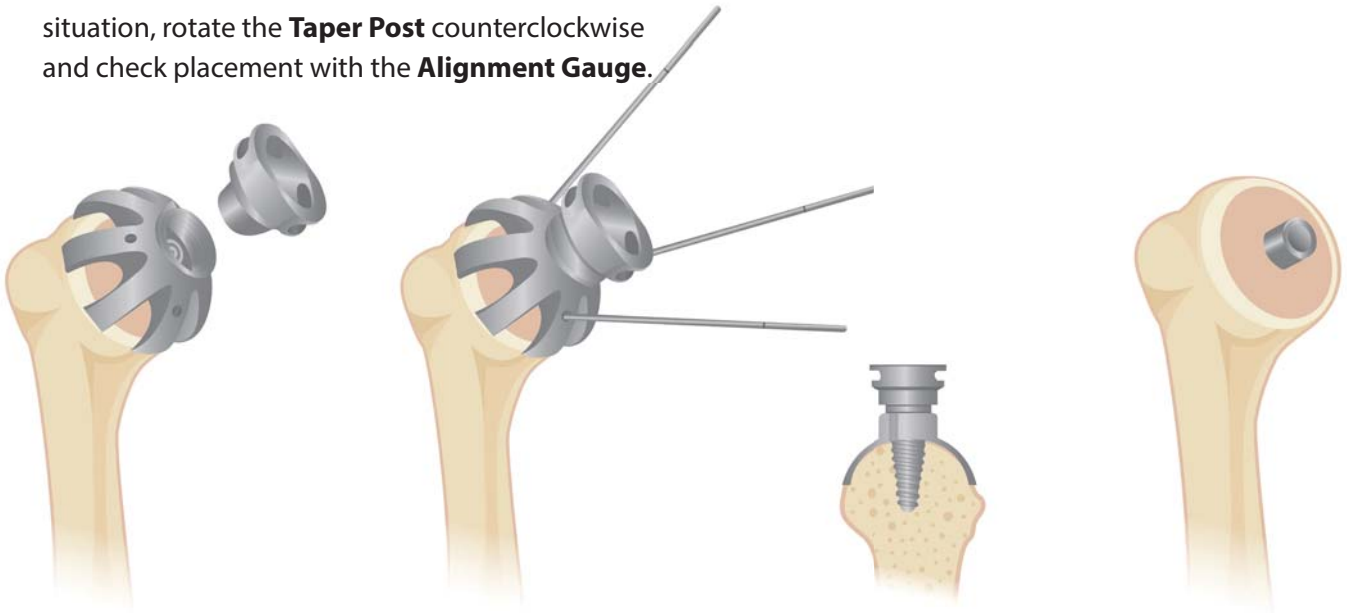
*Surgeon preference pending bone quality



10. Load the **Taper Post** into the distal end of the **Guide Handle** and attach the **Guide Handle** to **Preparation Trial**. Place the **Hex Driver** through the **Guide Handle** and advance the **Taper Post** until the stop on the shaft of the **Hex Driver** comes in contact with the back of the **Guide Handle**.

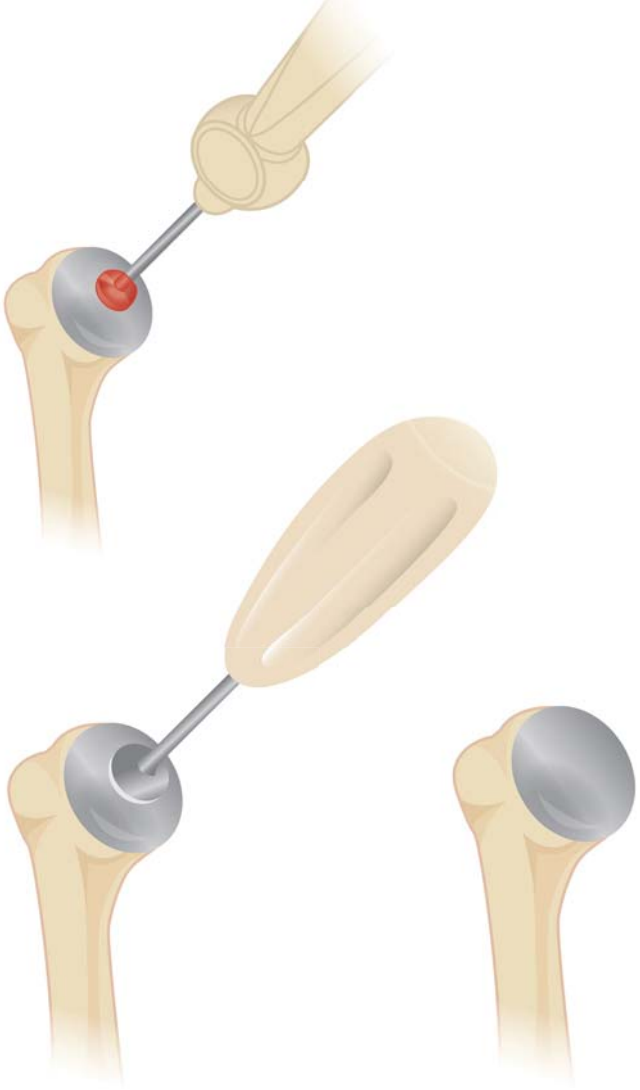


11. Use the **Alignment Gauge** to ensure that the **Taper Post** is seated at the proper depth. The **Alignment Gauge** is inserted into the **Preparation Trial**. The **Gauge** should meet resistance from the **Taper Post** and be flush with the edge of the **Preparation Trial**. If the **Gauge** is sitting proud then leave it in place and use the **Hex Driver** to rotate it until flush with the Trial. If the **Alignment Gauge** does not connect with the **Taper Post** then the **Taper Post** has been inserted too far into the bone. To address this situation, rotate the **Taper Post** counterclockwise and check placement with the **Alignment Gauge**.

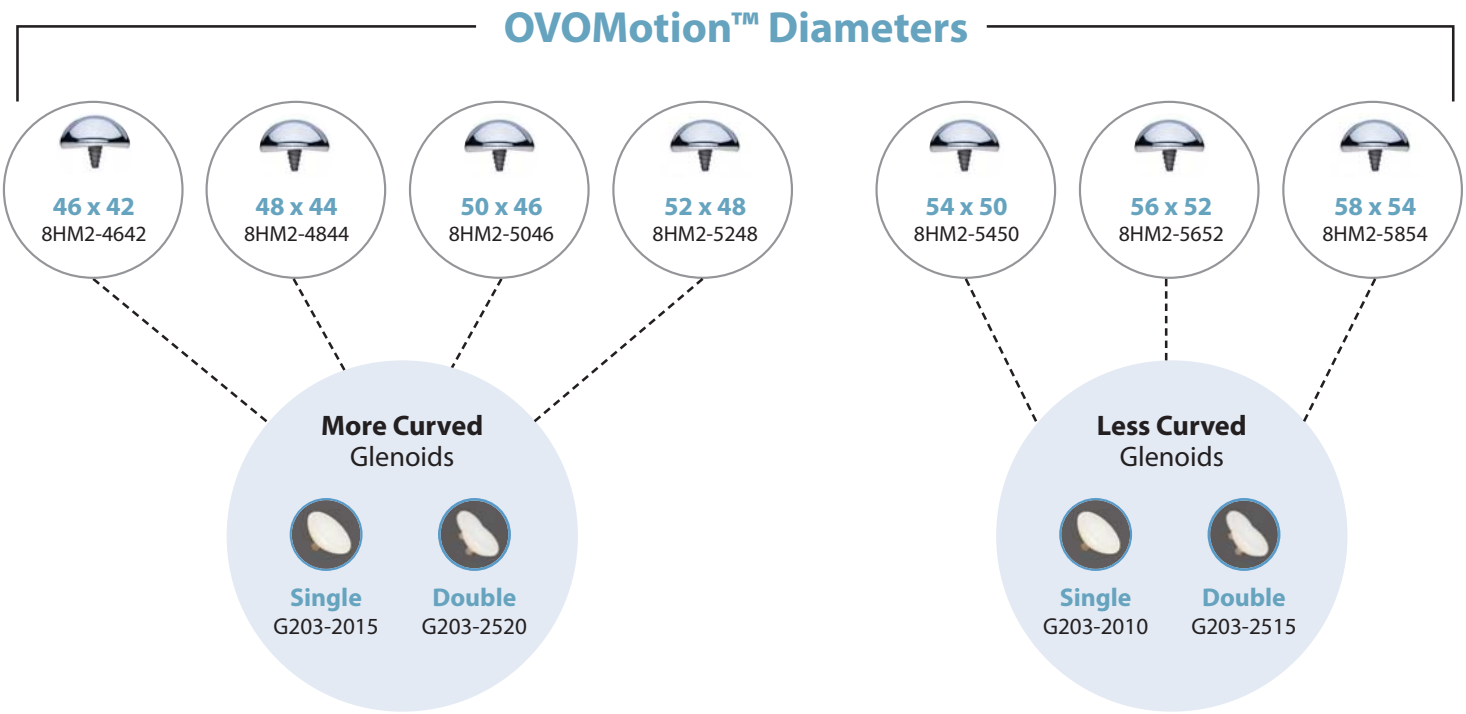


12. Prior to placing the **Humeral Articular Component** on the **Implant Holder** make sure that sufficient suction is present to hold the device onto the distal suction cup. Align the **Humeral Articular Component** on the **Implant Holder** with the etch mark in line with the superior offset of the **Humeral Articular Component**. Use the **Implant Holder** mark to align the implant in the proper orientation and insert onto taper of **Taper Post**.

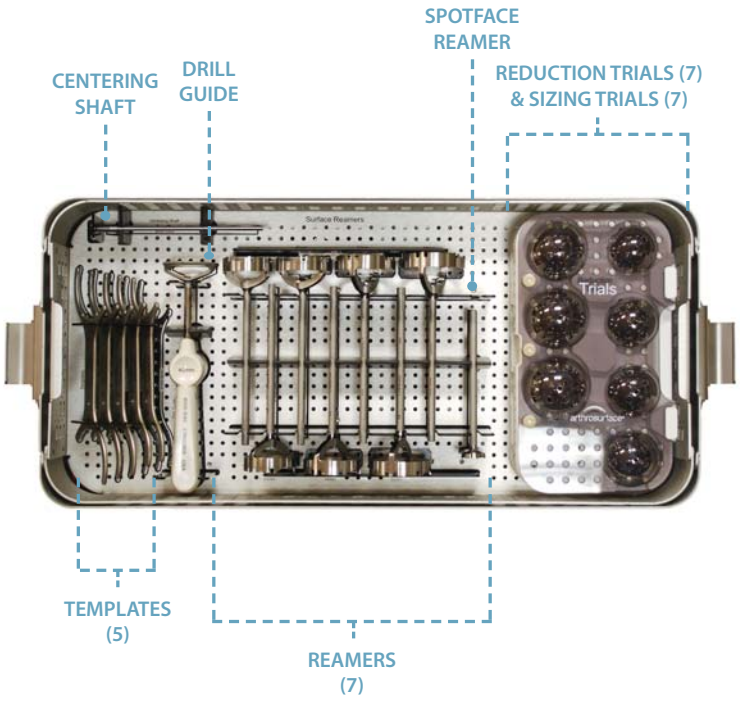
13. Firmly mallet the Impactor until the **Humeral Articular Component** is completely seated onto the **Taper Post**.

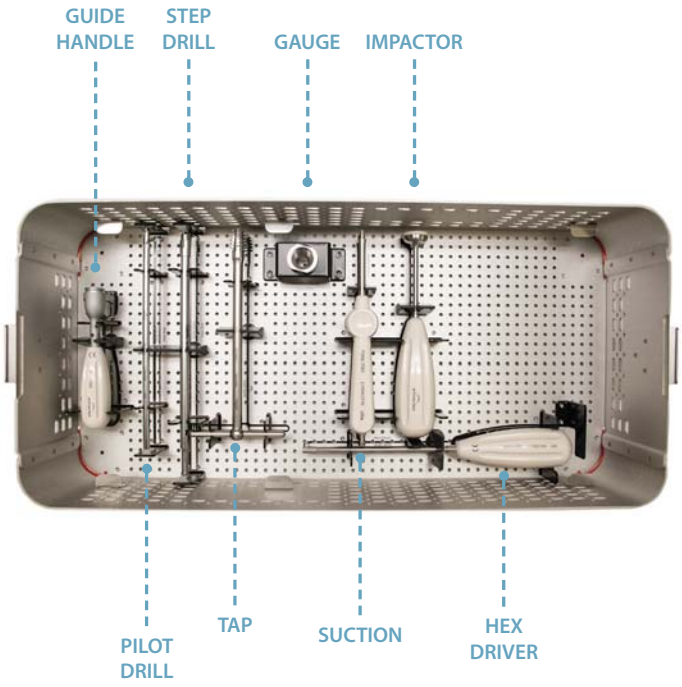


Matching OVOMotion™ Implant Diameters to Appropriate Glenoid

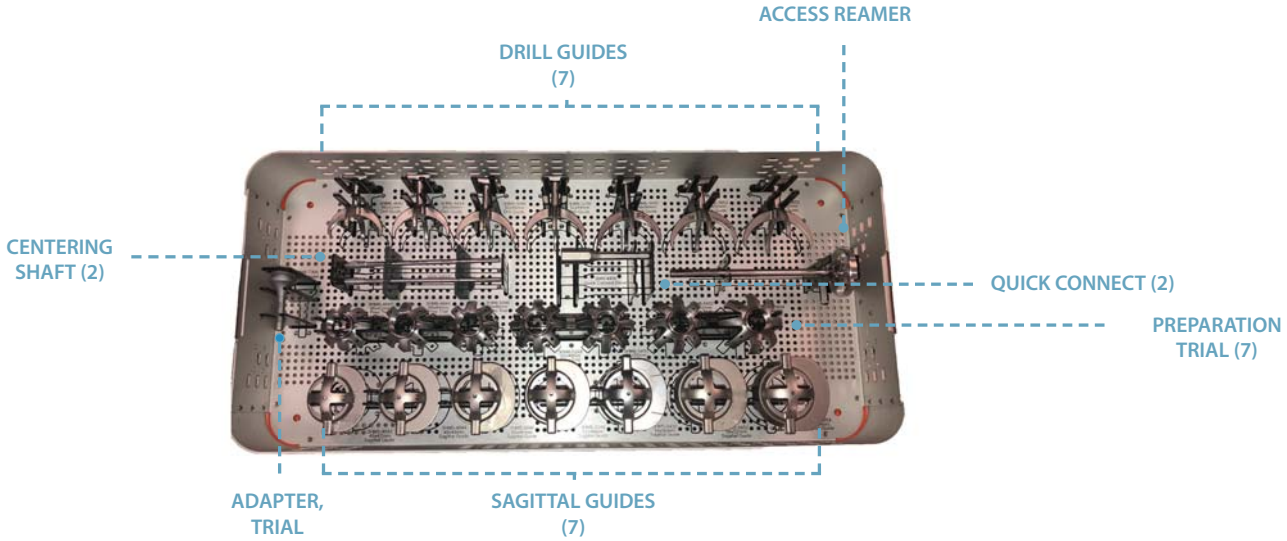


OVO® Instrumentation





OVOMotion™ Instrumentation



System Catalog (OVOMotion™)

Instrumentation System	
8000-5000	OVO Instrumentation Kit
8000-5100	OVOMotion Instrumentation Kit

Taper Post (Fixation Component)	
8156-0032-A	12.0mm x 32mm Includes 2.5mm guide wire, 2.0mm short guide pins and taper cleaner
8H00-0100	Pin Kit, Shoulder, OVO

Ovo Humeral Articular Components	
8HM2-4642	46mm x 42mm Offset
8HM2-4844	48mm x 44mm Offset
8HM2-5046	50mm x 46mm Offset
8HM2-5248	52mm x 48mm Offset
8HM2-5450	54mm x 50mm Offset
8HM2-5652	56mm x 52mm Offset
8HM2-5854	58mm x 54mm Offset

Chapter Two:

OVO®

Shoulder Arthroplasty System

Chapter One

OVO® Shoulder Arthroplasty System

Description

The OVO® Contoured Articular Prosthetic incorporates an articular component and a taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Materials

Articular Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Undersurface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)

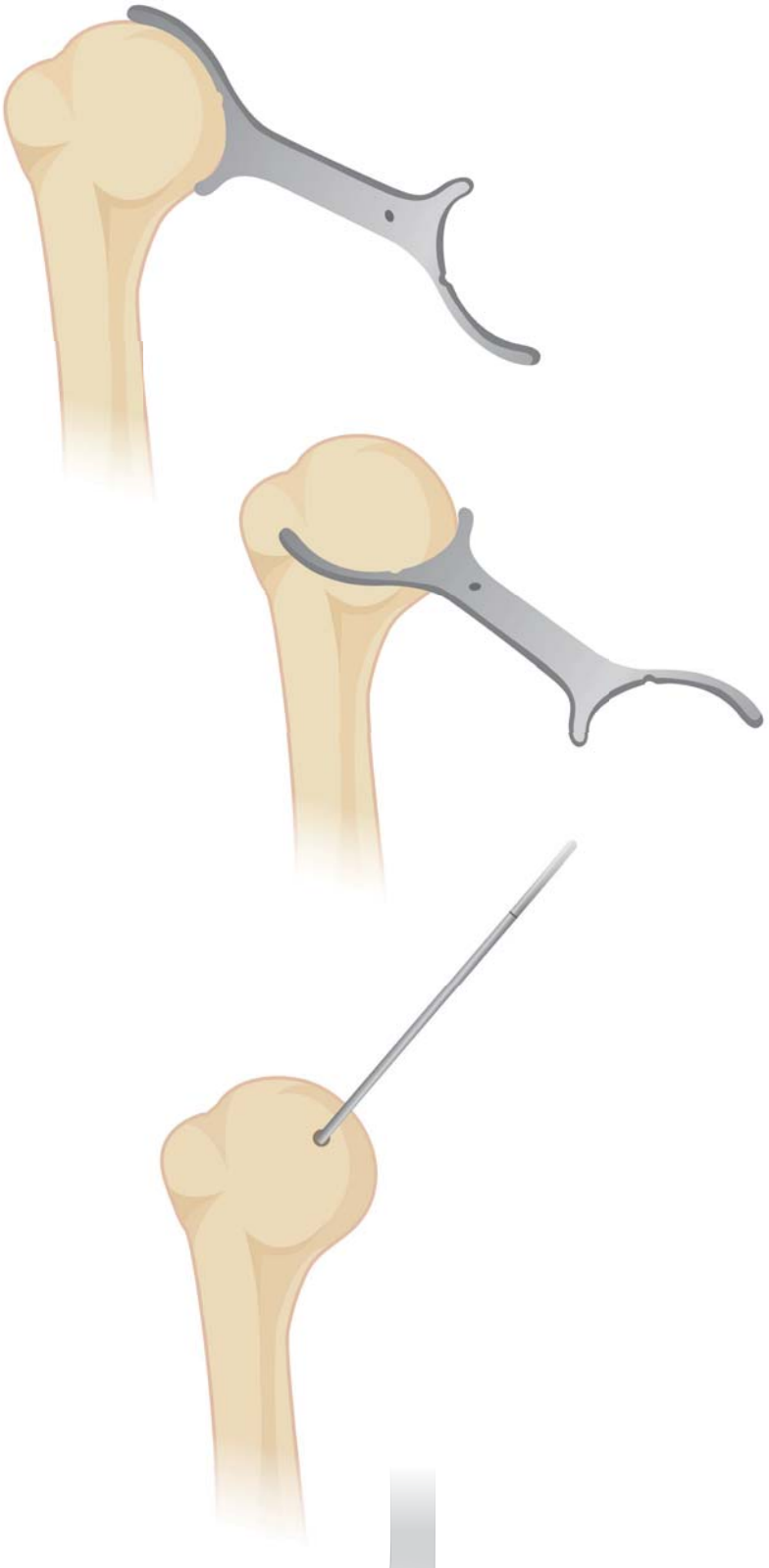
Indications

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be of sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single-use implant intended to be used with bone cement.

OVO® System Components

- Cobalt Chrome Component
  (Ovoid shapes, 7 offset choices)
- Ti Plasma Spray Undercoating
- Morse Taper:
  Interlocks the two components
- Titanium Fixation Component
  (Cannulated, Bead blasted)

Surgical Technique



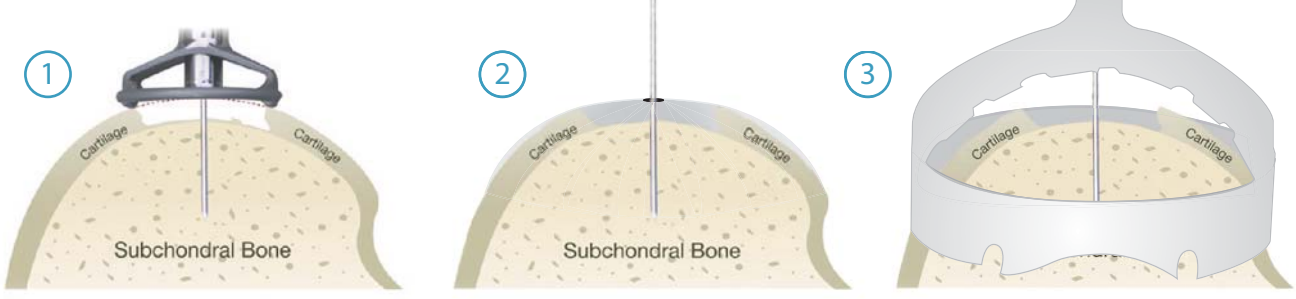
1. Remove all osteophytes around the humeral head using a 3/4 inch osteotome and/or rongeur. There should be a smooth transition from the humeral neck to the humeral head. Use the **Reduction Trial** to ascertain that all osteophytes have been adequately removed.

2. Place the appropriate **Mapping Templates** over the articular surface and map the surface in both superior/inferior and anterior/posterior planes. Utilize the **Templates** to obtain the superior/inferior diameter and anterior/posterior diameter that best replicate the anatomy. Use the **Sizing Card** to record the diameters. The **Surface Reamer** will be selected based on the anterior/posterior value. Place the **Reduction Trial** onto the humeral head to verify the **Reduction Trial** size and placement.

   *Note: The **Surface Reamer** and/or **Drill Guide** may also be used to assess correct pin location.*

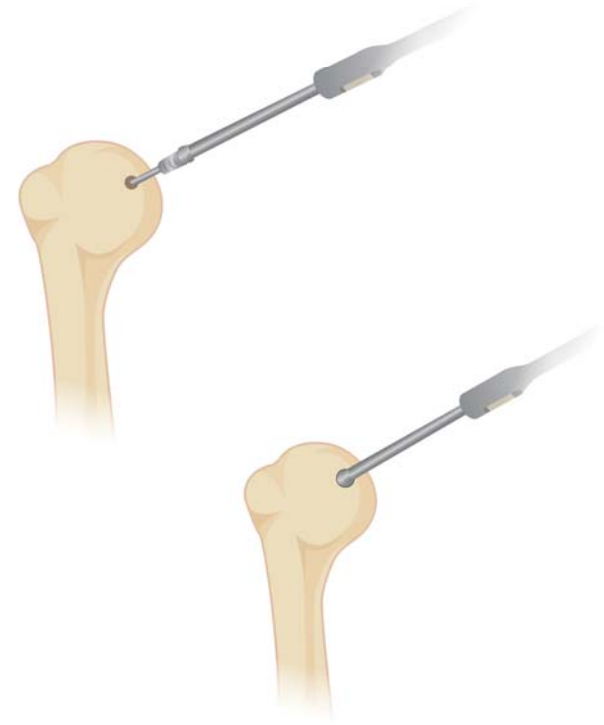
3. Locate the **Guide Pin** on head using option 1, 2, or 3 (see below). Place the **2.5 mm Guide Pin** into a cannulated powered drill and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** into the bone with care to avoid penetrating through the lateral humeral cortex.

Options:

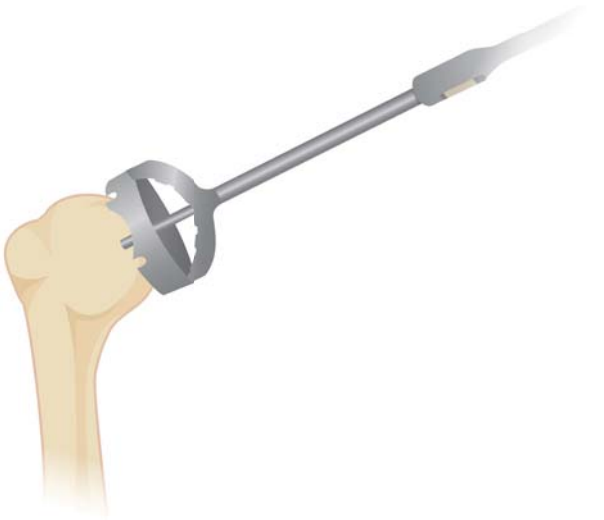


Drill Guide **Reduction Trial** **Shaft & Reamer**

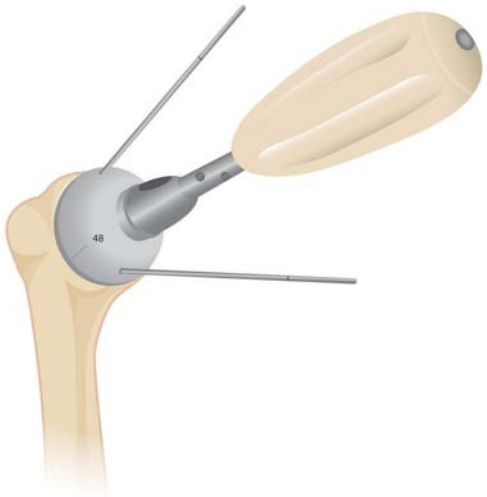
4. Using a cannulated powered drill, advance the **Centering Shaft** over the **Guide Pin** until the distal shoulder of the **Centering Shaft** marking is at the height of the articular surface. The **Centering Shaft** can be placed slightly proud to the surface to compensate for a flattened humeral head. The shoulder of the **Centering Shaft** sets the peak height representing the location of the crown of the implant.



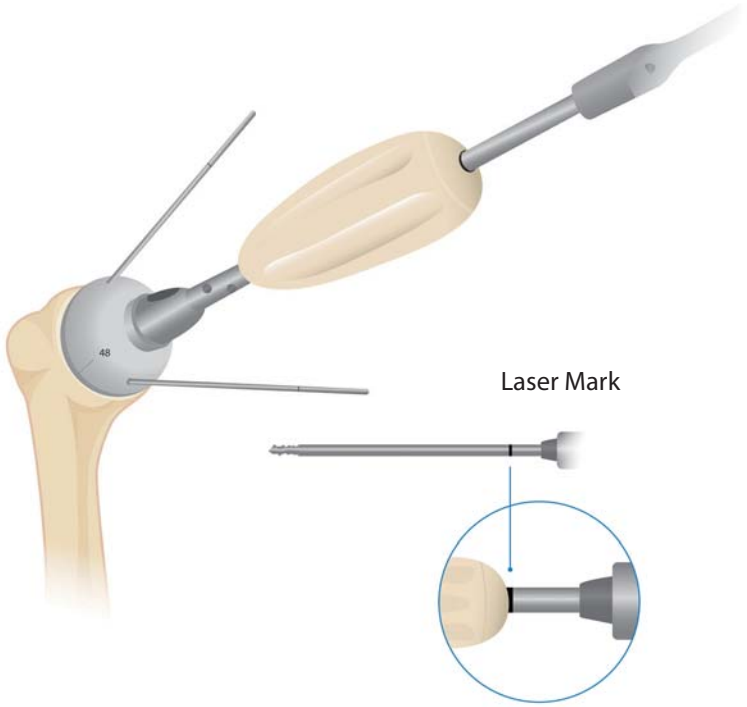
5. Using the **OVO Reamer** that matches the anterior/posterior value, advance the **OVO Reamer** over the **Centering Shaft** until it reaches the stop on the **Centering Shaft**. If using an **Inlay Glenoid Component**, repeat using the **Crown Reamer** to provide additional access for the **Glenoid** instruments. Be sure the **OVO Reamer** is started before engaging the humeral head.



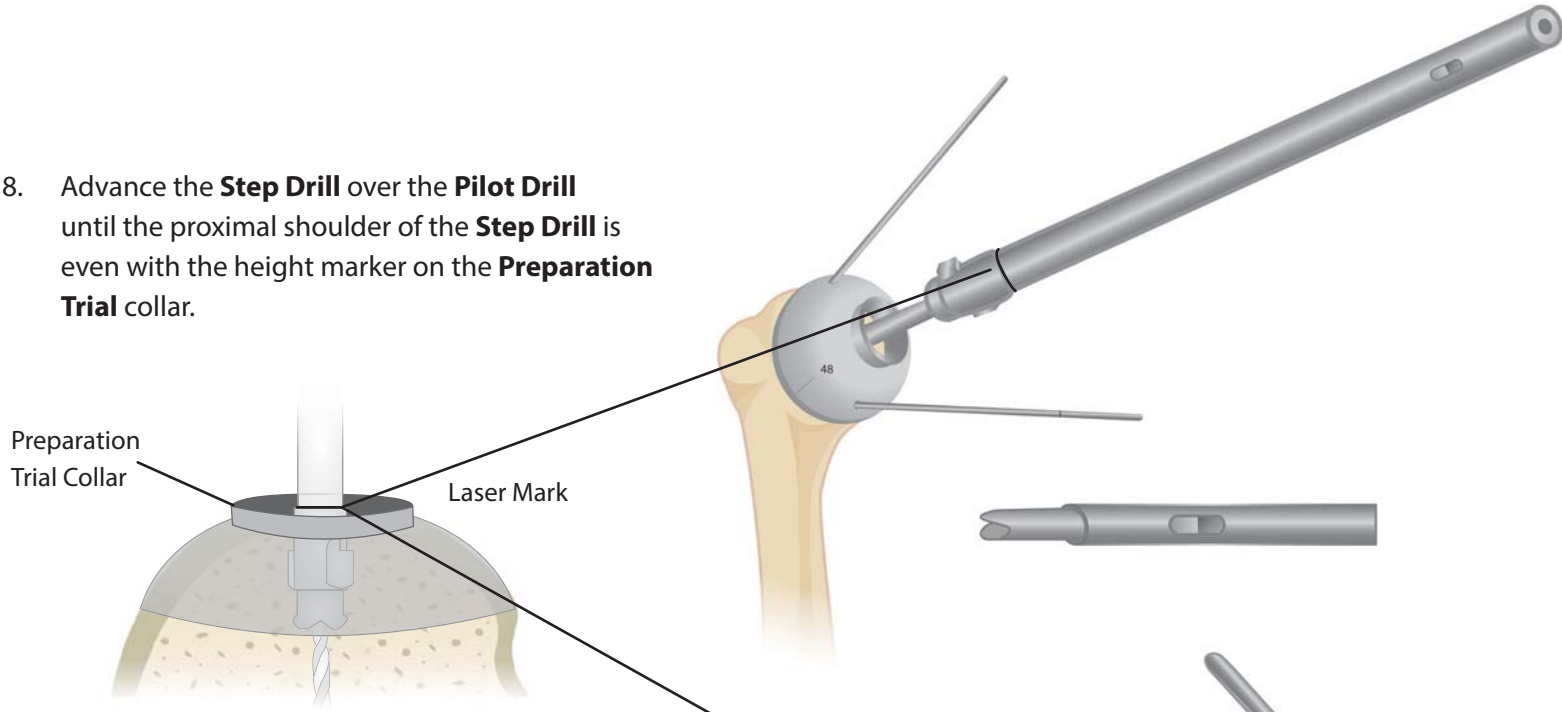
6. Place the appropriate **Reduction Trial** onto the prepared humeral surface and perform a range of motion evaluation. Assemble the **Guide Handle** onto the **Preparation Trial** and secure the **Preparation Trial** into position using at least two **Short Guide Pins**. The pins are critical, keeping the trial stable so that the correct orientation of the final implant can be maintained.



7. With the **Preparation Trial** fixed in place, insert the **Pilot Drill** through the center of the **Guide Handle** and advance until the laser mark indicated on the **Pilot Drill** meets the back of the handle. Leave the **Pilot Drill** in place and unscrew and remove the **Guide Handle**.



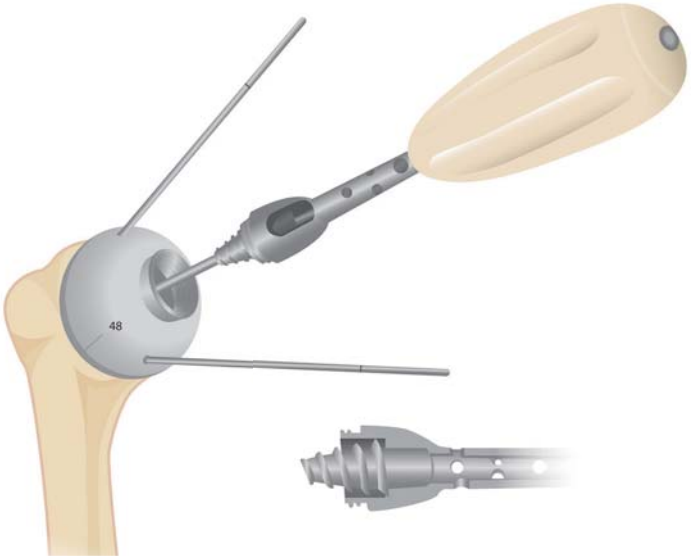
8. Advance the **Step Drill** over the **Pilot Drill** until the proximal shoulder of the **Step Drill** is even with the height marker on the **Preparation Trial** collar.



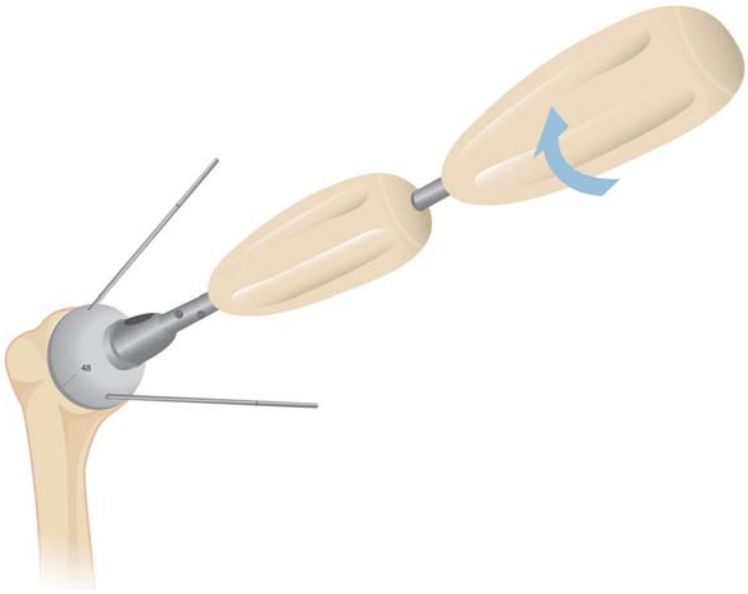
9 . Advance the **Tap** over the **Pilot Drill** until the laser mark on the **Tap** is even with the height marker on the **Preparation Trial** collar. Remove the **Tap** and **Pilot Drill**.

*Surgeon preference pending bone quality

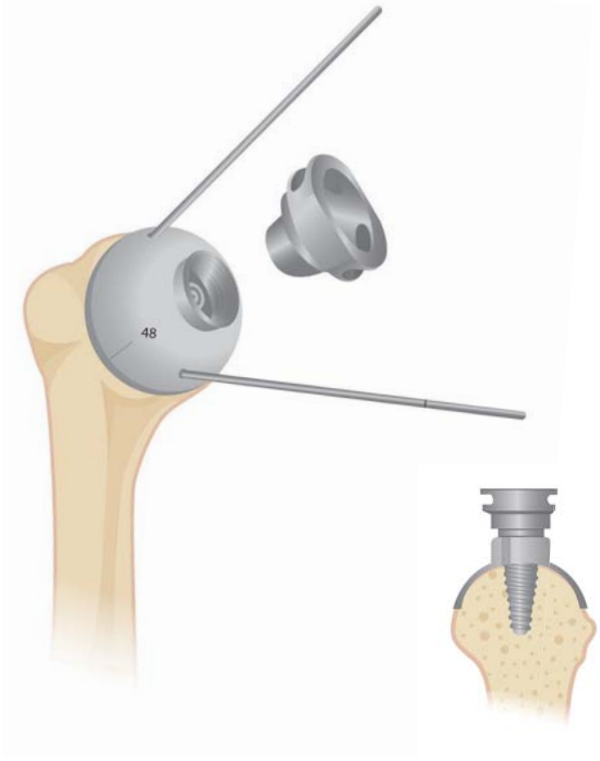
10. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and inject the cement in a retrograde fashion from the end of the hole upwards. Load the **Taper Post** into the distal end of the **Guide Handle** and attach the **Guide Handle** to the **Preparation Trial.** Place the **Hex Driver** through the **Guide Handle** and advance the **Taper Post** until the stop in the shaft of the **Hex Driver** comes in contact with the back of the **Guide Handle**. Be careful NOT to advance the screwdriver once it contacts the handle as it will move the screw in and away from the **Morse Taper**.



11. Use the **Alignment Gauge** to ensure that the **Taper Post** is seated at the proper depth. The **Alignment Gauge** is inserted into the **Preparation Trial**. The **Gauge** should meet resistance from the **Taper Post** and be flush with the edge of the **Preparation Trial**. If the **Gauge** is sitting proud then leave it in place and use the **Hex Driver** to rotate it flush with the **Trial**. If the Alignment Gauge does not connect with the **Taper Post** then the **Taper Post** has been inserted too far into the bone. To address this situation, rotate the **Taper Post** counterclockwise and check placement with the **Alignment Gauge**. Place the **Reduction Trial** into the defect that matches the offset profile of the chosen **OVO Articular Component**. Confirm the fit of the **Reduction Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Reduction Trial** is proud at the edge of the articular cartilage, re-ream the area until the **Reduction Trial** is flush or slightly recessed.

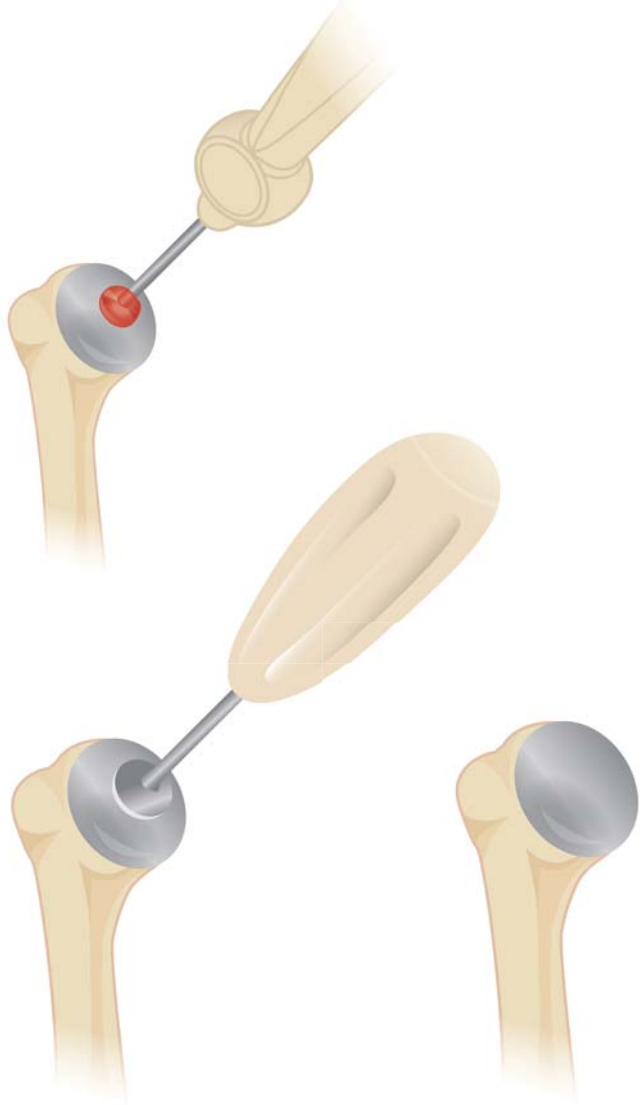


IF PERFORMING THE GLENOID:
Proceed to Step 1 in Chapter Three

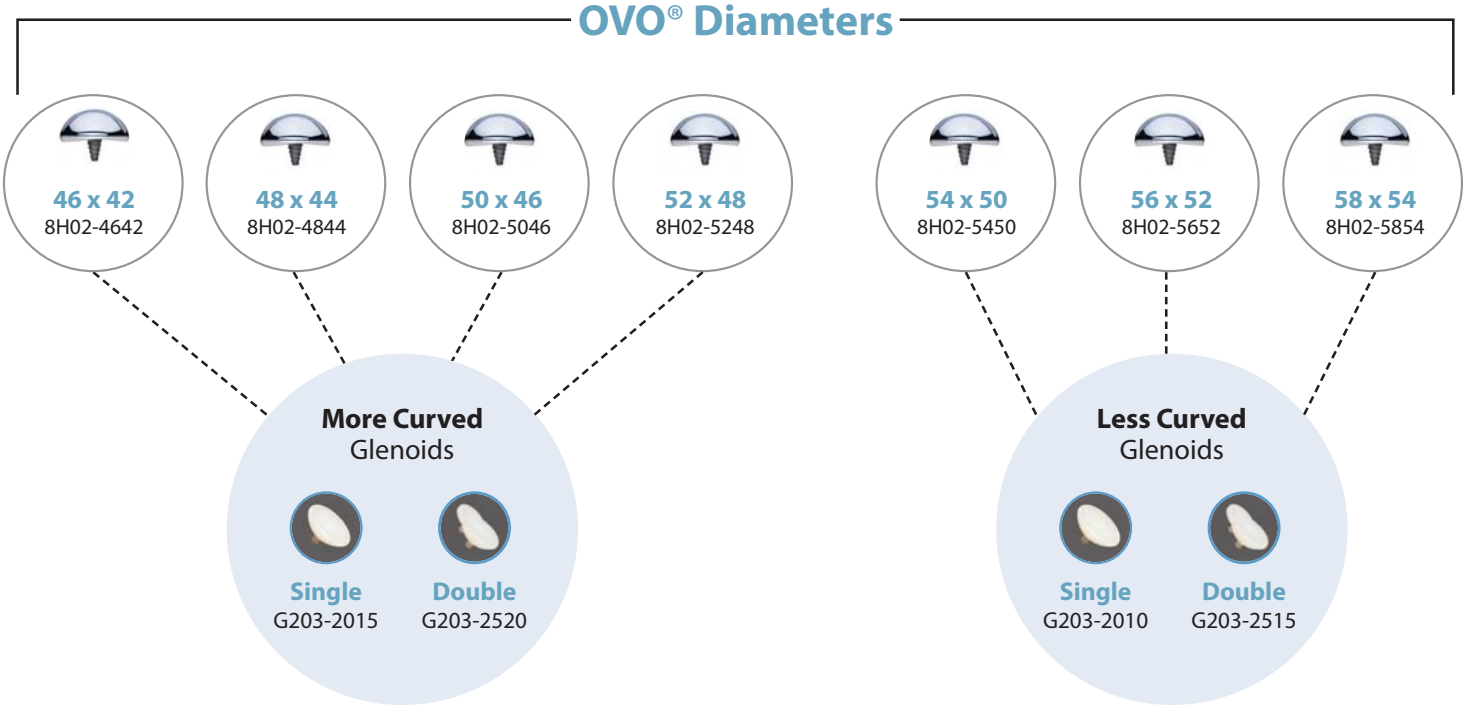


12. Prior to placing the **OVO Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device onto the distal suction cup. Align the **OVO Component** on the **Implant Holder** with the etch mark inline with the superior offset of the **OVO Component**. Use the **Implant Holder** mark to align the implant in the proper orientation and insert onto the taper of the **Taper Post**.

13. Firmly mallet the **Impactor** until the **OVO Component** is completely seated onto the **Taper Post**.

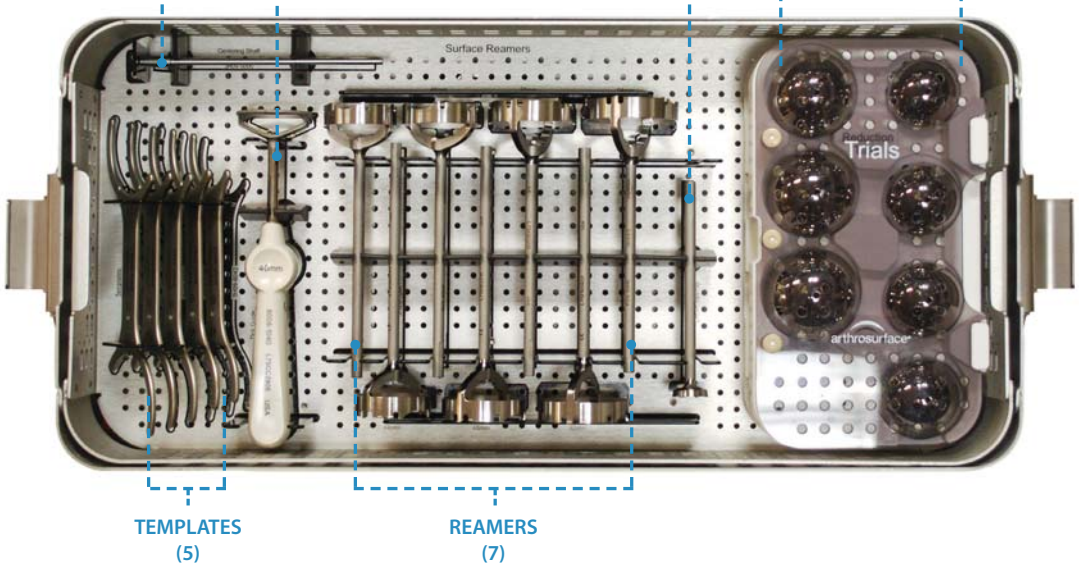


Matching OVO® Implant Diameters to Appropriate Glenoid

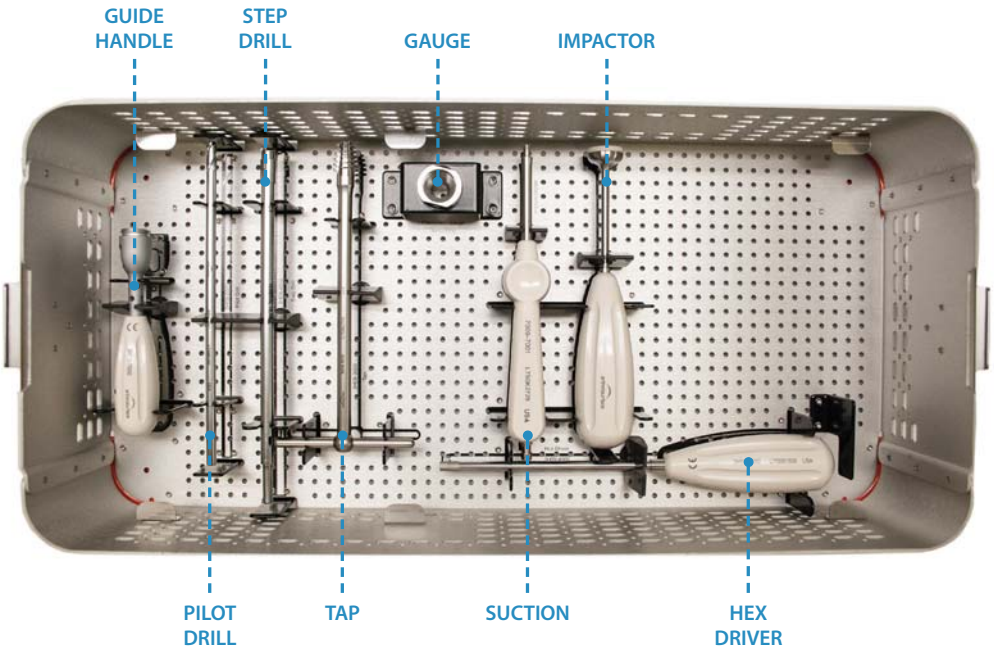


OVO® Instrumentation

Upper Tray



Lower Tray



System Catalog (OVO)

Instrumentation System	
8000-5000	OVO Instrumentation Kit

Taper Post (Fixation Component)	
8156-0032-A	12.0mm x 32mm includes 2.5mm guide wire, 2.0mm short guide pins and taper cleaner
8156-0032-W	15.6mm x 32mm includes 2.5mm guide wire, 2.0mm short guide pins and taper cleaner

Ovo Humeral Articular Components	
8H02-4642	46mm x 42mm Offset
8H02-4844	48mm x 44mm Offset
8H02-5046	50mm x 46mm Offset
8H02-5248	52mm x 48mm Offset
8H02-5450	54mm x 50mm Offset
8H02-5652	56mm x 52mm Offset
8H02-5854	58mm x 54mm Offset

Chapter Three:

Inlay Glenoid

Inlay Glenoid Replacement

Description

The Contoured Articular Prosthetic incorporates an articular component and a taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

The Inlay glenoid component is intended to interface and articulate with the humeral component when both articular surfaces of the joint are affected.

Materials

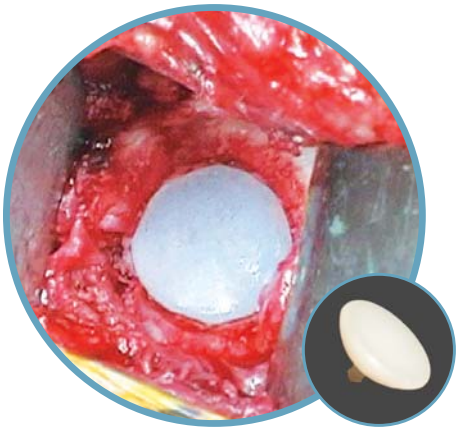
Glenoid Component: Ultra High Molecular Weight Polyethylene (UHMWPE)

Indications

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be sufficient bone stock to support loading. The rotator cuff should be intact or reconstructible. The device is a single-use implant intended to be used with bone cement.

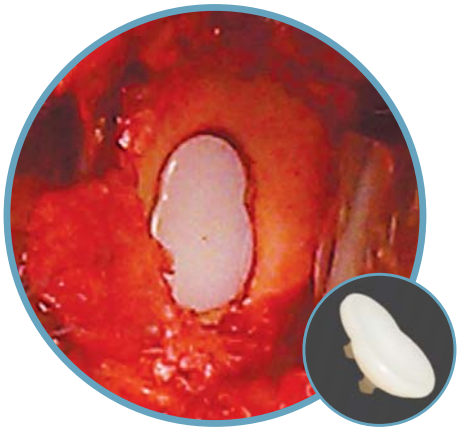
Inlay Glenoid System Components

- Ultra High Molecular Weight Polyethylene (UHMWPE)
- Inlay design
- Labrum preserving
- Two offset choices per component



Single

Partial Glenoid Component

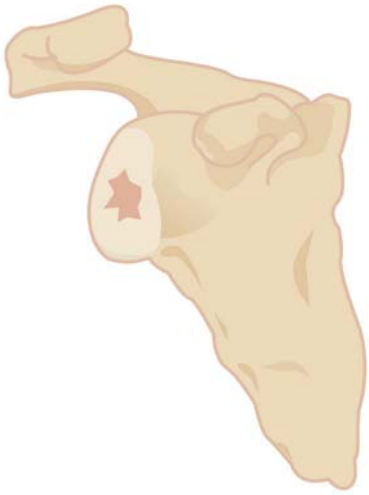


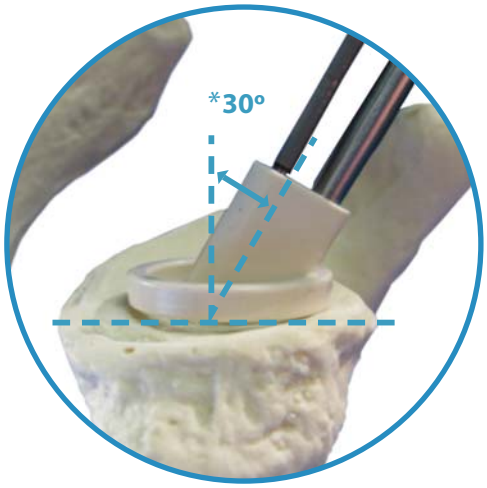
Double

Full Glenoid Component

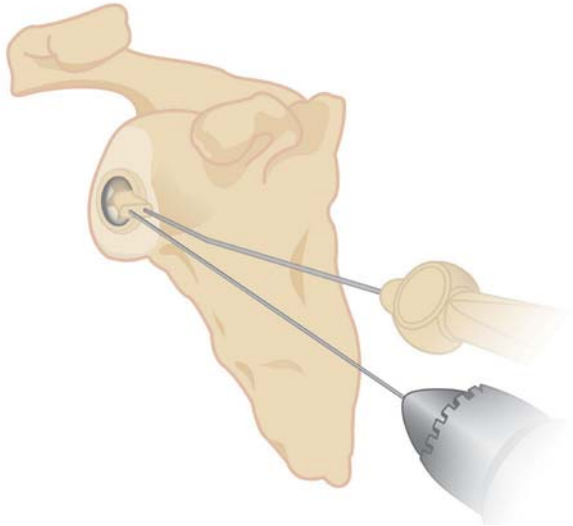
Surgical Technique

1. Use the **Drill Guide** to locate the intended implant position on the glenoid surface. Position the **Drill Guide** central to the inferior aspect of the glenoid lesion. Place the tip of the **Guide Pin** into the **Drill Guide** and advance the **Guide Pin** into the bone to the depth of the single etch mark using a cannulated power drill. The **Guide Pin** will be positioned slightly offset posteriorly. This is normal for the system as the **Reamer** begins to cut anterior first.

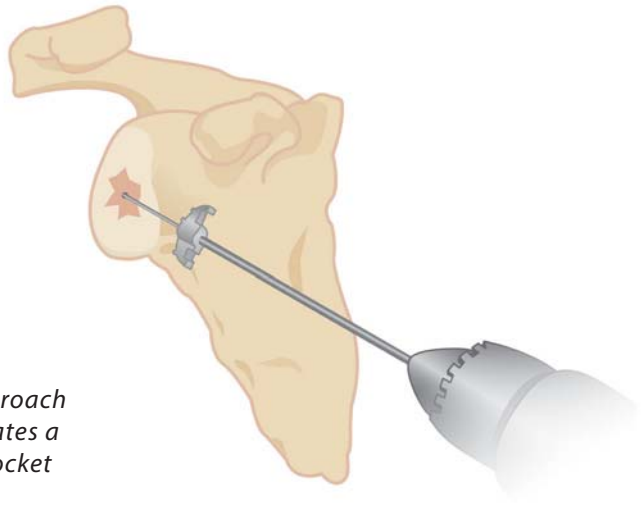


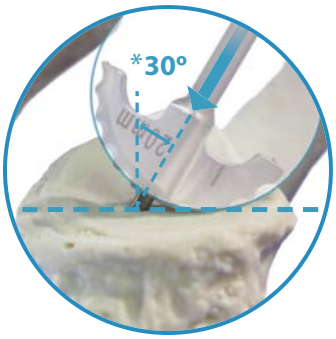


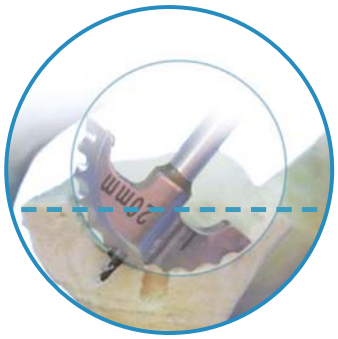
*This sets up angled approach for spherical reaming



2. Introduce the **Inferior Glenoid Reamer** over the **Guide Pin** and carefully advance under power until the **Inferior Glenoid Reamer** depth stop makes contact with the proximal end of the **Guide Pin.** Be sure to ream and visually check the depth of the reamer using the **Inferior Glenoid Trial.**





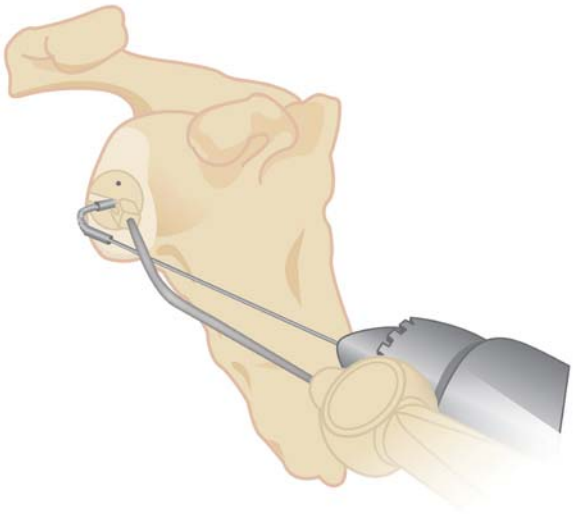


*Angled approach & ream creates a spherical socket

3. With the **Inferior Glenoid Trial** in place over the **Guide Pin,** confirm that the trial is flush or slightly recessed to the remaining glenoid fossa. Position the **Inferior Glenoid Trial** and place the **Flexible Peg Drill** into the central hole. Advance the **Flexible Peg Drill** to the stop to make the tunnel for the peg of the **Single Glenoid Component**.

   Note: Do not allow the **Flexible Peg Drill** to engage with any other hardware. Do not run the **Flexible Peg Drill** in reverse. These actions can cause the **Flexible Peg Drill** to break.

   If using the Single Glenoid Component only,** ***proceed to Step 7

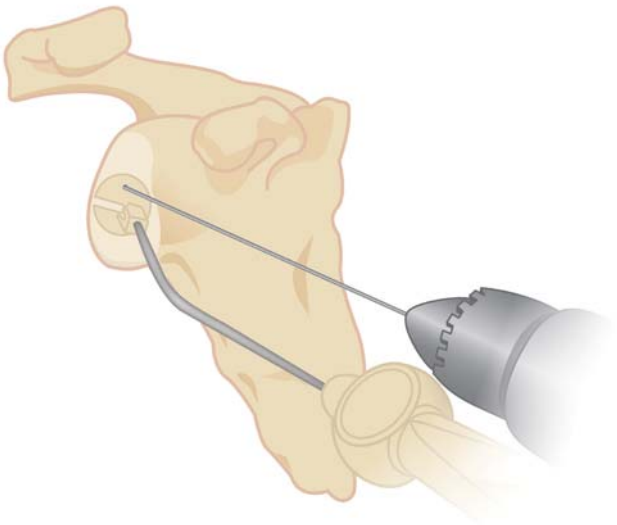


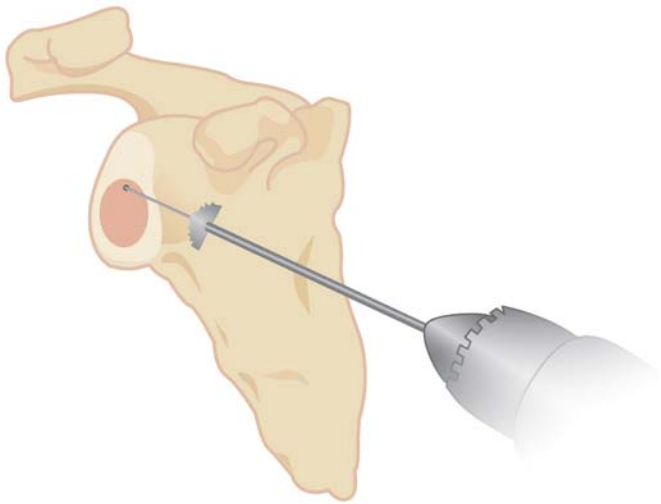
Flexible Peg Drill

4. If using the larger **Double Glenoid Implant**, place the **Inferior Glenoid Trial** in its proper orientation. Advance the **Guide Pin** into the superior hole of the **Inferior Glenoid Trial** and drill to the proximal line of the double etch mark using a cannulated powered drill.

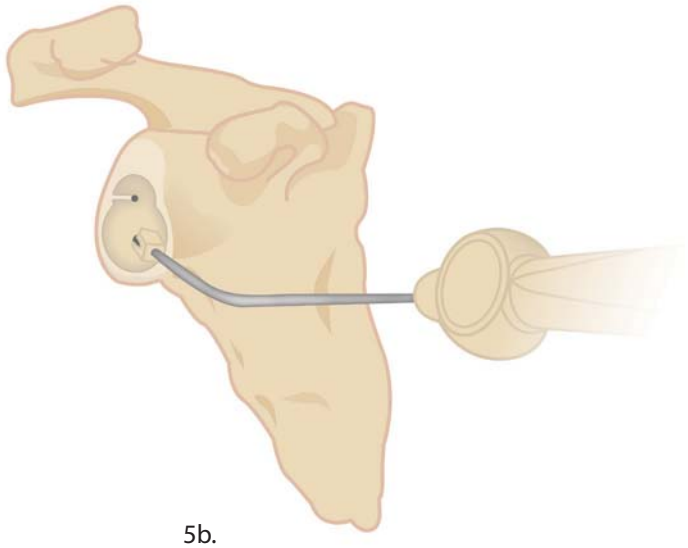
5. a) Introduce the **Superior Glenoid Reamer** over the **Guide Pin** and carefully advance under power until the **Superior Glenoid Reamer** depth stop makes contact with the proximal end of the **Guide Pin**. Be sure to ream carefully and visually check the depth of the reamer using the **Double Glenoid Trial**.

   b) Position the **Double Glenoid Trial** and confirm that the **Double Glenoid Trial** is flush or slightly recessed to the remaining glenoid fossa**.**



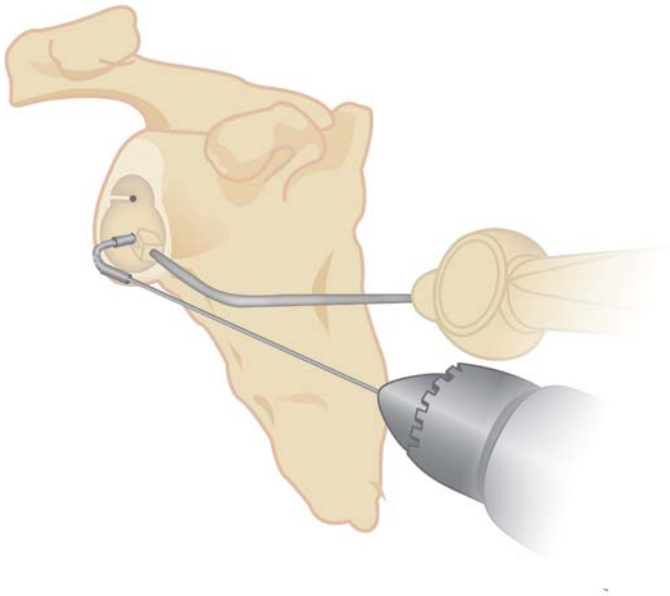


5a.



5b.

6. With the **Double Glenoid Trial** in position, advance the **Flexible Peg Drill** into both central holes of the **Double Glenoid Trial** to make bone tunnels for the **Double Glenoid Component** pegs.

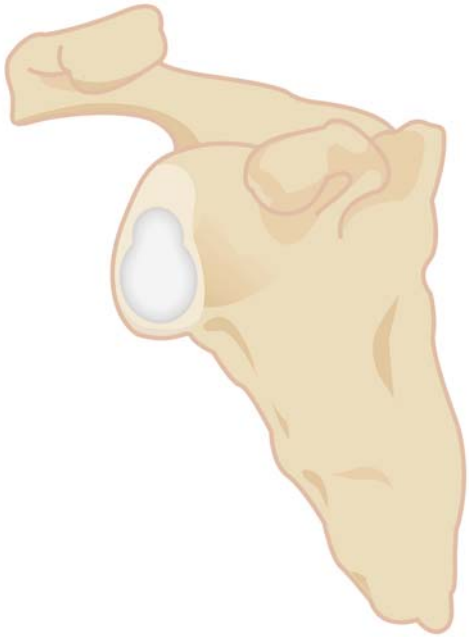


7. Use the **Angled Gouge** and mallet to create several small cement channels around the periphery of the glenoid fossa to aid with cement fixation.

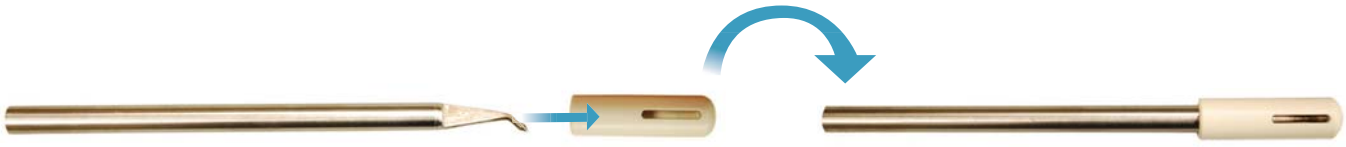
Angled Gouge

8 . Apply a small amount of low-viscosity bone cement into the prepared glenoid surface. Using the **Cement Finger Cap**, apply pressure to the cement in the glenoid fossa to make sure the cement fills the peg holes and gouge channels.

Cement Finger Cap



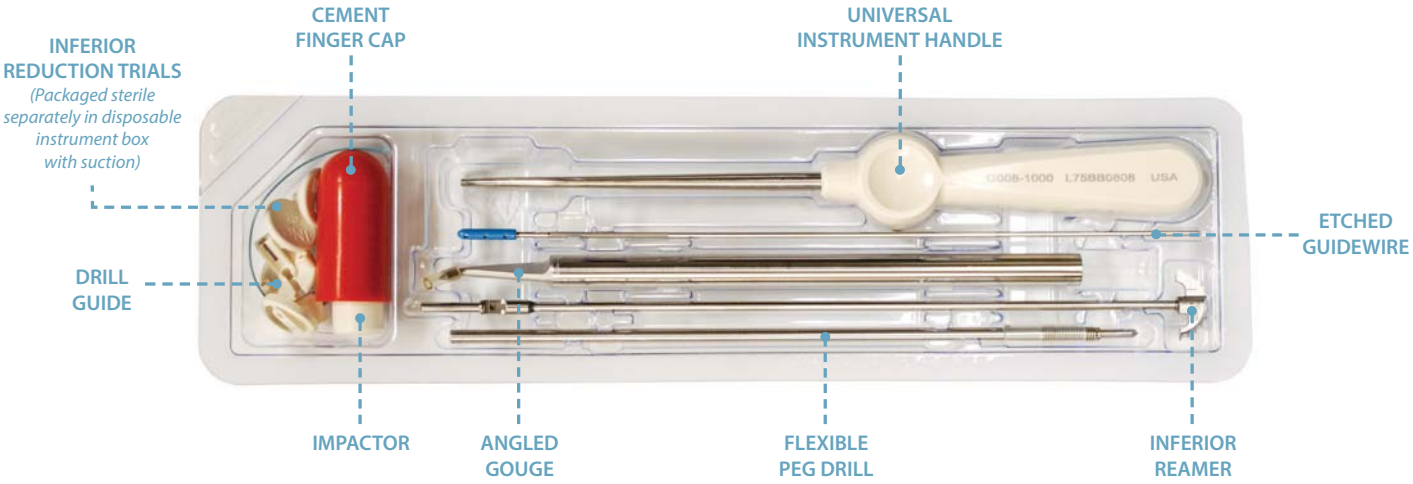
9 . Place the **Inlay Glenoid Implant** into position and use the **Glenoid Impactor** to secure the glenoid implant into position making sure the implant fits flush or slightly recessed to the surrounding glenoid fossa. The **Glenoid Impactor** is created by sliding the **Slotted Impactor Tip** over the end of the **Angled Gouge**. Maintain firm pressure on the implant until the bone cement sets. Remove any excess bone cement.



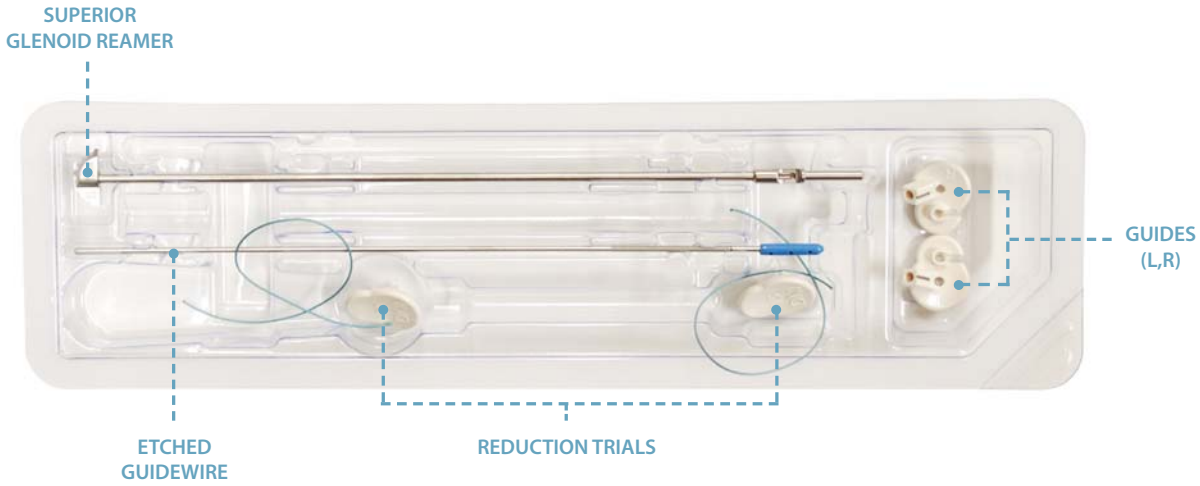
Angled Gouge Tip Impactor

Inlay Glenoid Replacement Instrumentation

Inferior Tray



Superior Tray



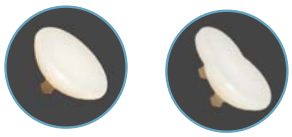
System Catalog

Inlay Glenoid Instrumentation System	
G007-1400	2.0mm Glenoid Guide Pin (sterile)
G000-0100	Inferior Glenoid Instrument Kit (sterile, disposable)
G000-0200	Superior Glenoid Instrument Kit (sterile, disposable)
G000-0300	15mm Reamer Pack, Glenoid (sterile, disposable)

Inlay Glenoid Component		Matching Ovo Head Diameters
Inferior Glenoid Component - Single		
G203-2010	19mm x 20mm Glenoid Comp. 1.0mm Offset	(58-54mm)
G203-2015	19mm x 20mm Glenoid Comp. 1.5mm Offset	(52-46mm)
Superior Glenoid Component - Double		
G203-2515	20mm x 25mm Glenoid Comp. 1.0mm Offset	(58-54mm)
G203-2520	20mm x 25mm Glenoid Comp. 1.5mm Offset	(52-46mm)

Arthrosurface Shoulder Systems

Inlay Glenoid



OVOMotion

OVO

40

35

Asymmetrical

30

25

Warnings

Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixation of the device. Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned. When placing implant, carefully trim articular cartilage debris or osteophytes around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments.

All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Accepted practices in postoperative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to postoperative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

These implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. Their safety in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

These implants are intended to be fitted and installed with the corresponding instrument set. Use of instruments from other systems may result in improper implant selection, fitting and placement, which could result in implant failure or poor clinical outcome. Instruments should be regularly inspected for any signs of wear or damage. Surgeon or Physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.

Possible Adverse Effects

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
2. Infection or allergic reaction.
3. Loosening, migration or loss of fixation of implant.
4. Fretting and crevice corrosion can occur at the interface between the implant components.
5. Fatigue fracture of the implants as a result of bone resorption around the implant components.
6. Wear and damage to the implant articulating surface.
7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
8. Intraoperative or postoperative bone fracture.
9. Postoperative pain or incomplete resolution of preoperative symptoms.
10. Periarticular calcification or ossification, with or without impediment of joint mobility.
11. Incomplete range of motion due to improper selection or positioning of components.
12. Transient nerve palsy.
13. Embolism.

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