Comprehensive®
Reverse Shoulder System
Mini Humeral Tray

Surgical Technique Addendum

ZIMMER BIOMET
Your progress. Our promise.®

Table of Contents

Introduction

Building on the history and clinical success of the Comprehensive Reverse Shoulder design, the Comprehensive Reverse Mini Humeral Tray continues the trend of market leading solutions. Offering a smaller Humeral Tray diameter with offset options for lateralizing the Humeral Tray with respect to the stem (Figure A).

This surgical technique addendum will describe the reverse shoulder procedure on the humeral side, and will include both the trialing and the implantation of the Mini Humeral Tray and associated Bearing. This addendum is to be used in conjunction with Comprehensive Reverse Shoulder System Surgical Technique: 0173.1-GLBL-en.

Preoperative Considerations

Preoperative evaluation of the humerus and glenoid using the Comprehensive Humeral Tray, Bearing and Glenosphere x-ray templates helps determine the size of the prosthesis and potentially the level of the head resection for a primary reverse shoulder, prior to surgery.

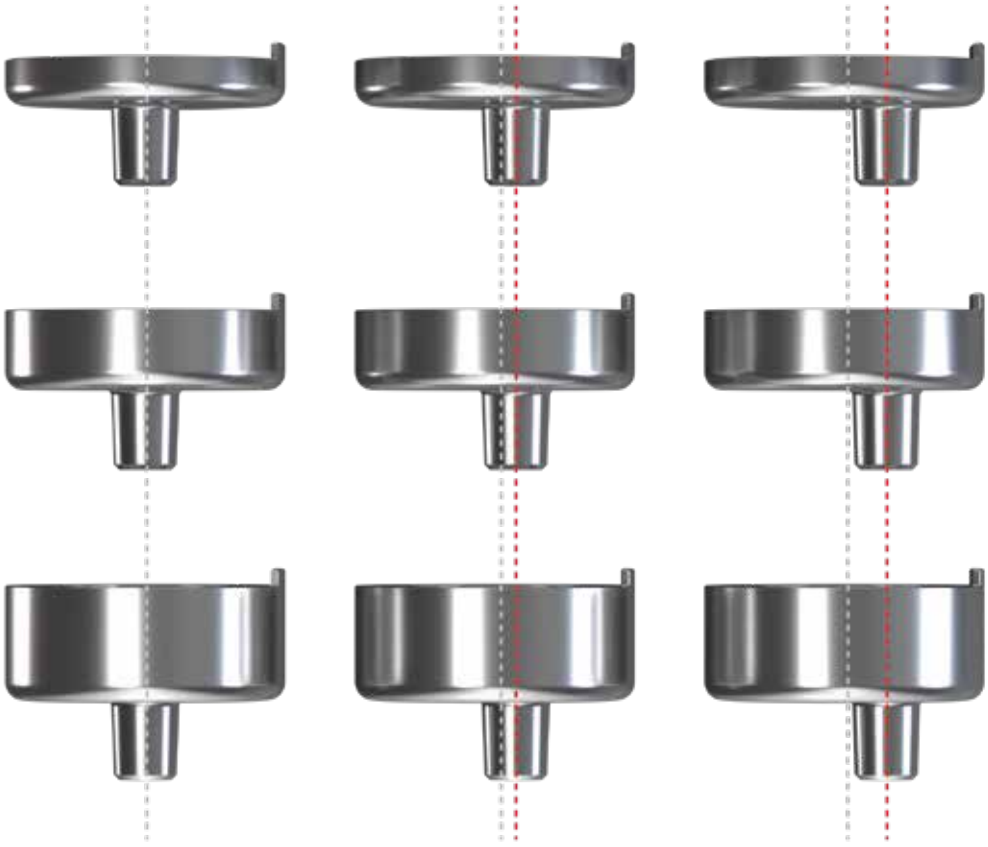


Figure A
Mini Humeral Tray Options

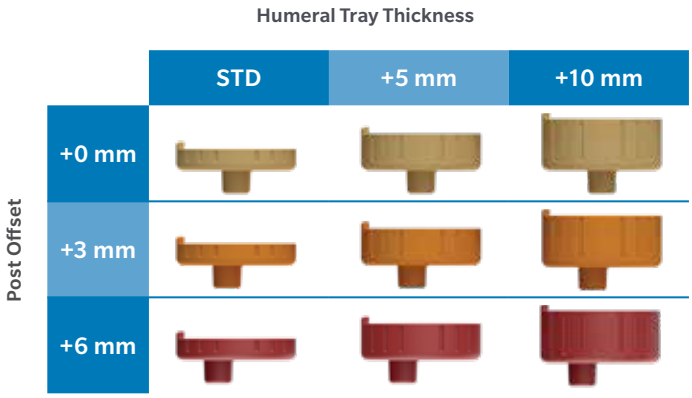


Figure 1

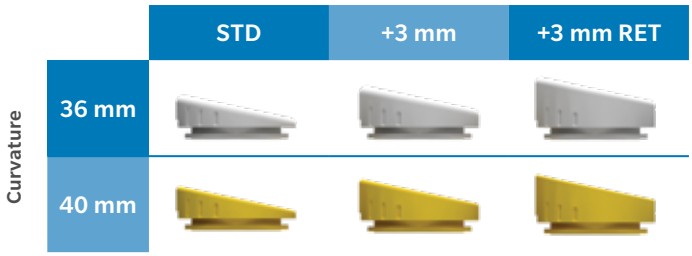


Figure 2

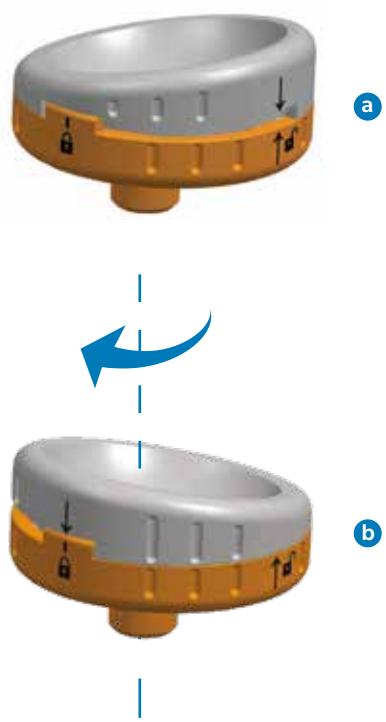


Figure 3

Tray and Bearing Trialing

Trials Selection

Start with a standard thickness, centered post (+0) Humeral Tray Trial and a standard Bearing Trial of appropriate radius of curvature.

Depending on desired deltoid tensioning, build up the height of the Humeral Tray and/or Bearing Trials as necessary. Depending on desired post-offset, choose the appropriate Tray.

Note: The Tray Trials are color-coded (bone, orange, and green) based on post-offsets. The darker color indicates more offset. Each offset is available in three thickness configurations (Figure 1).

Note: The Bearing Trials are color-coded (grey and yellow) and come in the following curvature and thickness configurations (Figure 2).

Trials Assembly

Make sure that Trials are clean before assembling them. Bring the Trials together such that the arrow on the bearing points toward the arrow on the tray next to the unlock mark (a). Then rotate the Bearing over the Tray clockwise until the arrow on the bearing points to the line above the lock mark on the tray (b). The Trials are now locked in place and may be used for trial range of motion (Figure 3).

Note: A larger post offset would result in the humerus moving further medially.

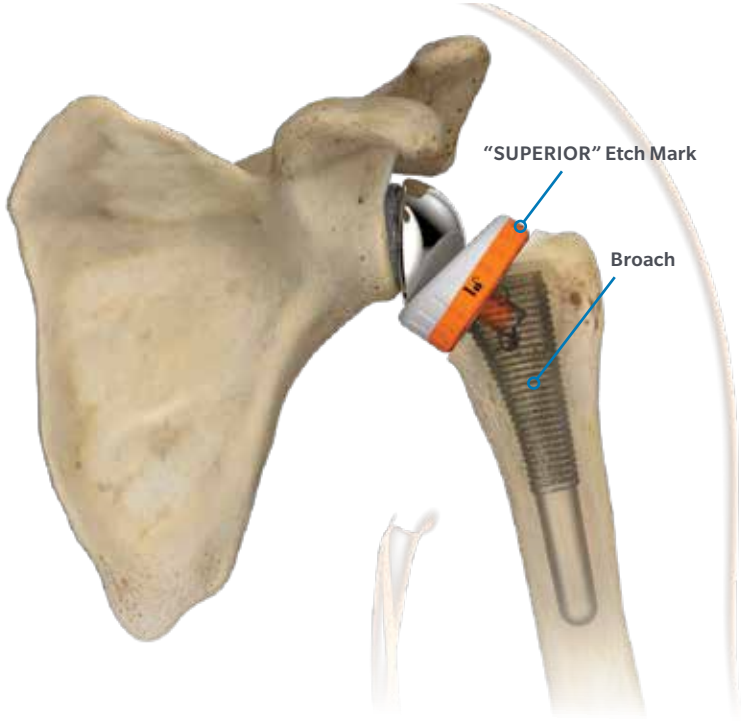


Figure 4
Trial Range of Motion

Trial Range of Motion

Noting the "SUPERIOR" marking on the Humeral Tray Trial, place the assembly into the Broach (Figure 4). Perform a trial reduction to assess range of motion and implant size selection. The trial reduction should show limited distraction (1 mm or less).

Note: The assembled Humeral Tray/Bearing Trial will not engage the Broach if the Broach is counter-sunk and/or does not match the version/inclination of the humeral cut. If the Broach is counter-sunk and/or does not match the humeral cut version/inclination, re-position the Broach higher or remove the appropriate amount of bone in order for the assembled Humeral Tray/Bearing Trial to seat.

Technique Tip: Shoe Horn may be helpful in reducing the joint.

Note: Additional humeral resection and subsequent re-reaming and re-broaching may be required if the joint is extremely difficult to reduce. Releases of pectoralis major and additional deltoid attachment site may also be helpful.

Note: For cases of extreme instability, +3 mm Retentive Humeral Bearings are available. Retentive Bearings capture more of the glenosphere and have polyethylene walls which are 2– 3 mm higher than standard +3 mm Bearings, but do not add any additional joint space.

Note: Check to ensure that Trial Bearing and Trial Tray do not move respective to each other during trial range of motion.

Comprehensive Reverse Tray

3 Shoe Horn

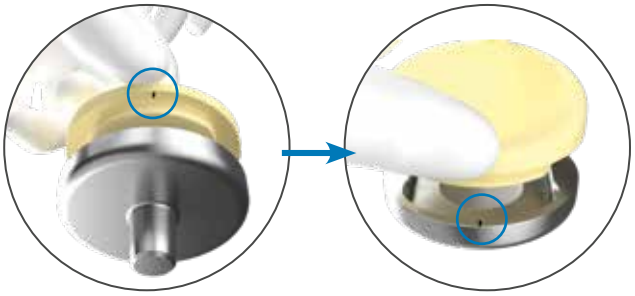


Figure 5
(Superior Side)

Figure 6
(Superior Side)

Figure 9
Snap Together by Hand

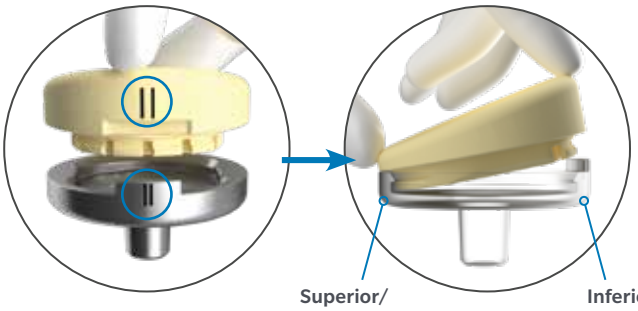


Figure 7
(Inferior Side)

Figure 8

Figure 10
(Optional - Use Poly Impactor to Assemble)

Tray and Bearing Implantation

Tray and Bearing Implant Assembly

Position the definitive Bearing Implant in the definitive Humeral Tray Implant such that the single etch marks on the superior side (Figure 5 and 6) and the double etch marks on the inferior side (Figure 7) of the implants align together.

Then, on the superior side, insert the solid toe of the Bearing under the lip of the Tray (Figure 8).

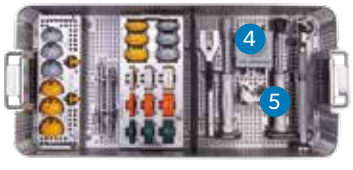
Note: The Bearing cannot be used after it has been inserted and then removed.

Next, on the inferior side, "snap" the assembly together either by hand or the Poly Impactor.

By Hand: Manually press the inferior side of the engaged Bearing into the Tray. Ensure the Bearing is fully seated within the Tray (Figure 9).

By Impactor tool: Place the engaged Bearing and Tray on the Offset Orientation Block. With two firm strikes of the Poly Impactor, impact the Bearing into the Tray. Ensure the Bearing is fully seated within the Tray (Figure 10).

Comprehensive Reverse Tray



4 Offset Orientation Block with Versa-Dial® Taper Impactor Base

Top Bottom

5 Poly Impactor

Figure 11
Insert Tray/Bearing Implant

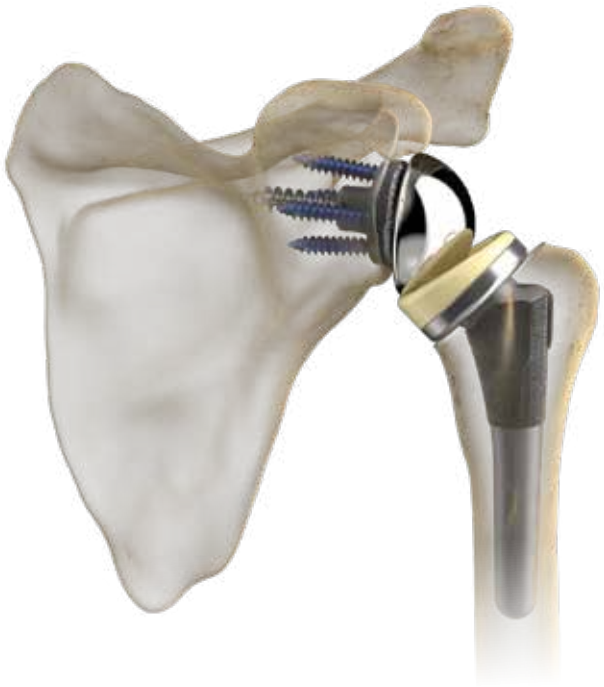


Figure 12
Final View

Tray/Bearing Implant Insertion

Clean and dry the reverse Morse taper of the Stem. The Humeral Tray is marked "SUPERIOR" to aid in positioning the Tray/Bearing with respect to the Stem. When inserted correctly, the thicker portion of the polyethylene Bearing should be inferior.

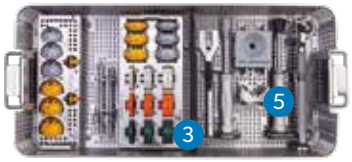
With two firm strikes of the Poly Impactor, impact the assembled definitive Humeral Tray/Bearing into the Comprehensive Stem (Figure 11).

Final Reduction

Reduce the joint with the aid of the Shoe Horn and assess the final range of motion with the compatible Zimmer Biomet reverse shoulder glenoid construct. The final reduction (Figure 12) should show limited distraction (1 mm or less). Impingement should not be present in either adduction or abduction. If impingement occurs in abduction, a greater tuberosity osteotomy or tuberoplasty may be necessary.

Note: There is some evidence that the subscapularis improves the stability of the implant. When possible, the subscapularis should be repaired at the completion of the procedure, as long as it does not significantly reduce external rotation.[1]

Comprehensive Reverse Tray



5 Poly Impactor

3 Shoe Horn

Figure 13

Figure 14

Revision Options

Bearing Removal/Exchange

If a Humeral Bearing needs to be replaced, the Bearing may be exchanged/revised without Tray removal.

To remove a Humeral Bearing, place an osteotome between the Bearing and Tray directly above the Tray's double etch marks (Figure 13). A firm, angled strike at this location will disengage the Bearing from the Tray.

Insert the new Humeral Bearing into the Humeral Tray. In order to ensure the Tray taper is seated properly after Bearing exchange, the Bearing/Tray assembly must be impacted into the Stem. With two firm strikes of the Poly Impactor, impact the assembled definitive Tray/Bearing into the Stem.

Note: The Bearing cannot be used after it has been inserted and then removed.

Tray Removal

The Humeral Tray/Bearing assembly may be removed with the Humeral Tray Removal Fork. It is preferable to place one of the removal fork arms between the Humeral Tray and Stem collar, which will act as a wedge and disengage the taper from the Stem (Figure 14).

Comprehensive Reverse Revision Tray

6 Humeral Tray Removal Fork

Instrument Lifespan

For information in determining whether a reusable instrument is no longer suitable for use, reference Reusable Instrument Lifespan Manual (1219.1-GLBL-en).

Indications and Contraindications

INDICATIONS

Comprehensive Reverse Shoulder products are indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

Comprehensive Reverse Shoulder products are indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Titanium glenospheres are intended for patients with Cobalt Alloy material sensitivity. The wear of these devices has not been tested but, based on pin on disk testing, the wear rate is inferior to that of cobalt alloy glenospheres. A Cobalt Alloy glenosphere is the recommended component for reverse shoulder arthroplasty patients without material sensitivity to cobalt alloy.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

CONTRAINDICATIONS

Absolute contraindications include infection, sepsis, and osteomyelitis.

Relative contraindications include:

1. Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow 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.

Compatibility

Comprehensive® Mini Humeral Trays are compatible with ASHCOM™ and Segmental Revision System (SRS), as well as the Comprehensive Humeral Stems including Micro, Mini, Standard, Revision and Fracture.

For more information, please refer to the Zimmer Biomet Product Compatibility website: http://www.zimmerbiomet.com/medical-professionals/" www.zimmerbiomet.com/medical-professionals/support/product-compatibility.html#shoulder.

References

1. Werner BC. Wong AC. Mahony GT. Craig EV, Dines DM, Warren RF, Gulotta LV. Clinical Outcomes After Reverse Shoulder Arthroplasty With and Without Subscapularis Repair: The Importance of Considering Glenosphere Lateralization. *J Am Acad Orthop Surg*. 2018 Mar 1:26(5)e114-e119.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information. Check for country product clearances and reference product specific instructions for use.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with a health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

ZIMMER BIOMET

Your progress. Our promise.®

1998.1-GLBL-en-REV1118

Legal Manufacturer
Zimmer, Inc.
1800 West Center Street
Warsaw, Indiana 46580
USA
1-800-348-2759 (US only)
+1-574-372-4999
zimmerbiomet.com

Legal Manufacturer
Biomet Orthopedics
P.O. Box 587
56 E. Bell Drive
Warsaw, Indiana 46581-0587
USA