Comprehensive®
Reverse Shoulder System
Mini Humeral Tray

Surgical Technique Addendum

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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

Intended Purpose

Intended Use
These devices are intended for reverse shoulder joint arthroplasty.

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.

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.

Intended Purpose

Intended Use
The Zimmer Biomet Reverse Shoulder products are intended for shoulder joint arthroplasty.

INDICATIONS

Reverse Application:

Zimmer Biomet 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.

The Zimmer Biomet Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

The titanium Glenosphere components are indicated for patients with suspected cobalt alloy sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A Titanium Glenospheres is not recommended for patients who lack suspected material sensitivity to cobalt alloy.

The humeral components are indicted for either cemented or uncemented (biological fixation).

Compatible Glenoid Baseplate components are intended for cementless applications with the addition of screw fixation.

CONTRAINDICATIONS

- This device is contraindicated for the following:
- Local/systemic infection
- Presence of significant injury to the upper brachial plexus
- Paralysis of the axillary nerve
- Marked bone loss
- Nonfunctional deltoid or external rotator muscles
- Any neuromuscular disease compromising the affected limb that would render the procedure unjustifiable

Introduction

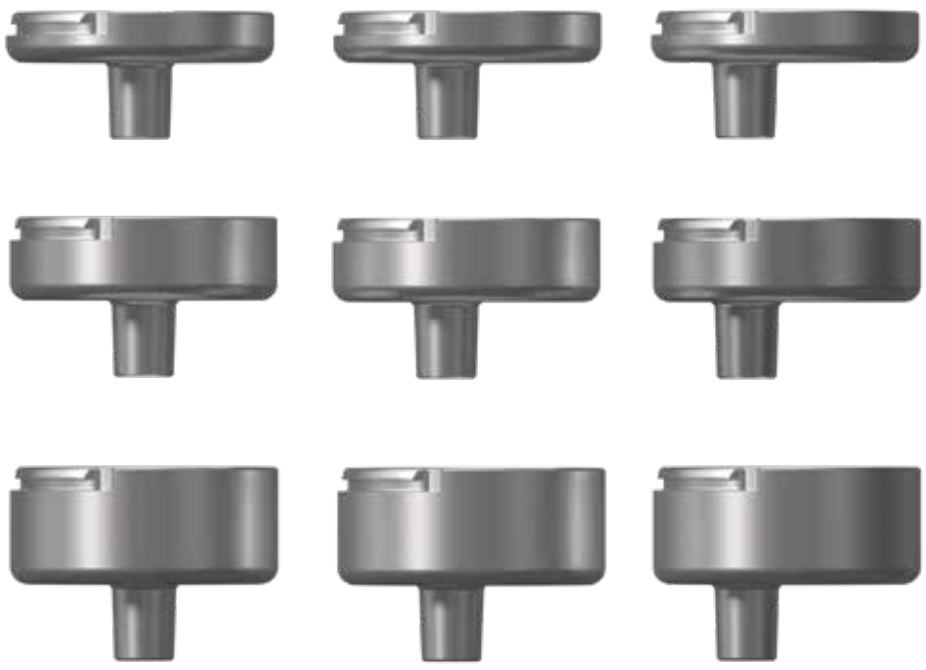
Building on the history and clinical success of the Comprehensive Reverse Shoulder design, the latest Comprehensive Reverse Humeral Tray with Alliance Humeral Bearing continues the trend of market leading solutions. Offering a Humeral Tray with offset options for lateralizing the Humeral Tray with respect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

This surgical technique addendum will describe reverse shoulder tray/bearing trialing and implantation, as well as 32 mm glenosphere trialing and implantation.

This addendum is to be used in conjunction with the Comprehensive Reverse Shoulder System Surgical Technique.

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.



Neutral Offset **3 mm Offset** **6 mm Offset**

Figure A

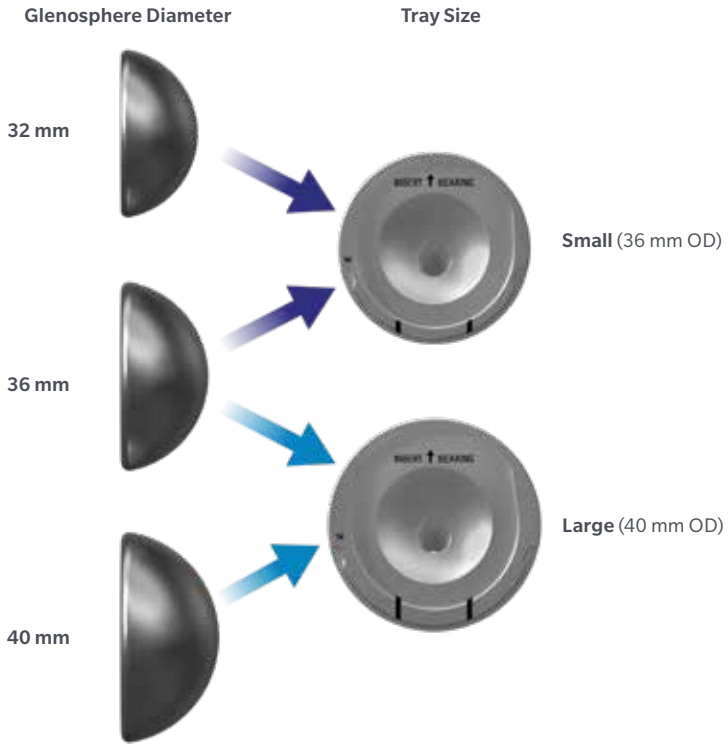


Figure 1

Figure 2

32 mm Glenosphere Compatibility

The 32 mm Glenosphere is compatible with an Alliance Humeral Bearing and a small diameter (SM) humeral tray. This glenosphere is not compatible with any Comprehensive Reverse humeral trays or the large diameter (LG) Identity Reverse humeral tray (Figure 1).

32 mm Glenosphere offerings

The new 32 mm glenospheres and 32 mm glenosphere taper adapter enable variable offset that ranges between 0–3 mm. The offset value corresponds to the following letters:

A	**0 mm**
B	**1 mm**
C	**2 mm**
D	**3 mm**

Additionally, lateralization choices include Standard, +3 mm and +6 mm options depending on preference (Figure 2).

Figure 3

Figure 4

Figure 5

32 mm Glenosphere Trialing

Insert the blue 32 mm Adapter Trial into the Glenosphere Trial such that the screw head is visible through the slot on the articular surface (Figure 3). Advance the screw until it locks the Adapter Trial in place, then back off by a quarter turn of the Hex Driver to enable in-situ setting of final offset.

Glenosphere trials are marked with an arrow to show offset direction (Figure 4).

When determining the amount and orientation of glenosphere offset, keep in mind that placing the offset inferiorly may reduce the likelihood of scapular notching. Using the Hex Driver, advance the screw until the Adapter Trial locks in place.

Insert the glenosphere trial assembly into the base plate, ensuring full seating. When desired positioning of the Glenosphere Trial is determined, tighten the Adapter Trial screw with the Hex Driver through the slot in the articulation (Figure 5).

Perform a trial range of motion.

Figure 6

Figure 7a

Figure 7b

32 mm Glenosphere Trialing (cont.)

Remove the Glenosphere Trial assembly from the Baseplate. Note the amount of offset by referencing the A, B, C, and D indicators on the underside of the Glenosphere Trial (Figure 6). This offset value will be referenced when preparing the definitive implant.

32 mm Glenosphere Implant Assembly

Place the glenosphere implant into the Impactor Base. Ensure the components are clean and dry. The adapter implant is packaged and pre-assembled to a disposable impactor. Insert the Taper Adapter into the Glenosphere such that the Taper Adapter etch mark aligns to the offset letter determined during trialing (Figure 7a). The arrow marking on the Impactor can be used to align the Taper Adapter to the Glenosphere implant (Figure 7b). For example, if trialing indicated a fully offset glenosphere (position D), the Taper Adapter implant should align to the letter D on the Glenosphere implant.

Note: The 32 mm Taper Adapter implant cannot be removed from the 32 mm Glenosphere implant.

Figure 8

Figure 9

Use two firm mallet strikes to engage the taper junction (Figure 8).

Glenosphere Inserter Assembly

The new modular Glenosphere Inserter has size-specific frames to ensure optimal fit with the implant. These come in 32 mm, 36 mm and 40 mm sizes with the size engraved on each frame (Figure 9). Note that one prong has an engraved arrow.

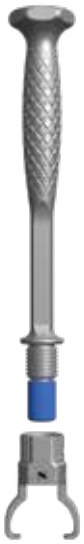


Figure 10a

Figure 10b

Figure 11

Glenosphere Inserter Assembly (cont.)

Thread the appropriately sized Frame to the Glenosphere Inserter (Figure 10a), advancing the threads until the plastic tip is aligned to the base of the prongs (Figure 10b). Do not advance the threads beyond this point or it may prevent mating with the Glenosphere implant assembly.

Implant Insertion

Place the Glenosphere assembly into the orientation block. Rotate the Glenosphere until the implant reaches the point that is furthest on the orientation block scale. This orientation will represent the direction of maximum offset (Figure 11).

Figure 12a

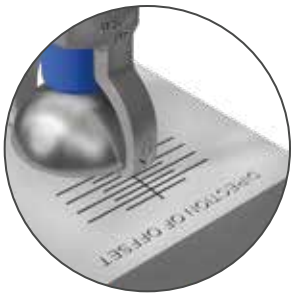


Figure 12b

Slide the Frame prongs onto the Glenosphere such that the prong with the engraved arrow aligns to the maximum offset (Figure 12a and 12b). Holding the Frame static, rotate the Inserter handle clockwise to advance the threads and rigidly mate implant to instrument.

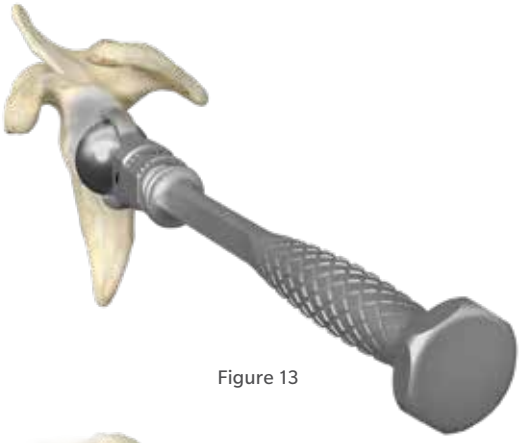


Figure 13

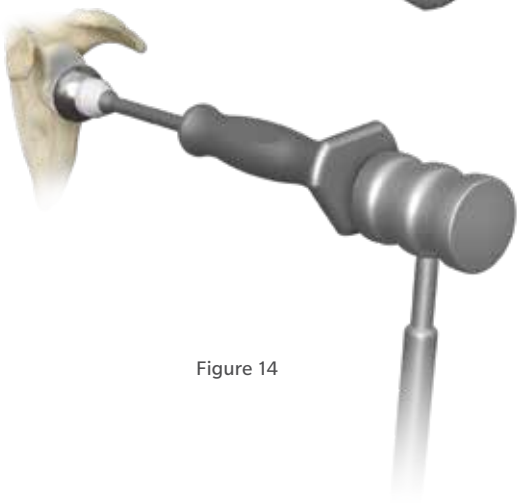


Figure 14

Clean and dry the base plate female taper. Insert the Glenosphere implant assembly into the base plate in the same orientation as the trial (Figure 13). Using a mallet, firmly strike the Inserter. To disengage the Inserter, rotate the handle counterclockwise. Slide the Inserter out from behind the Glenosphere.

Use a mallet and the concave Glenosphere Impactor to ensure robust taper engagement (Figure 14).

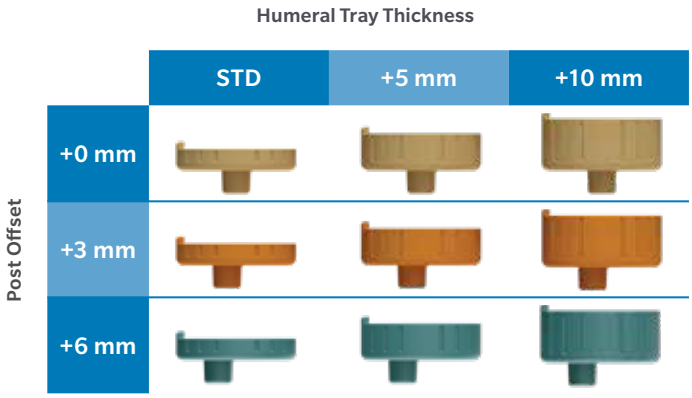


Figure 15

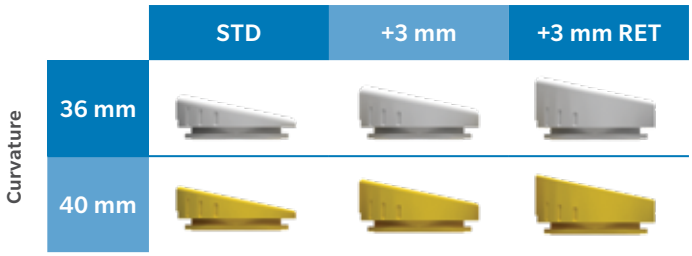


Figure 16

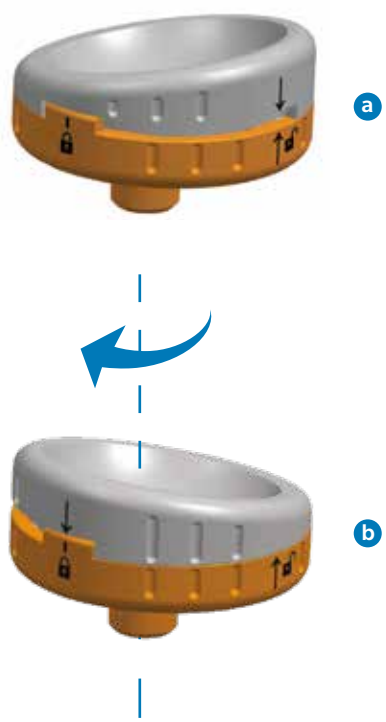


Figure 17

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 15).

Note: The Bearing Trials are color-coded (grey and yellow) and come in the following curvature and thickness configurations (Figure 16).

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 17).

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

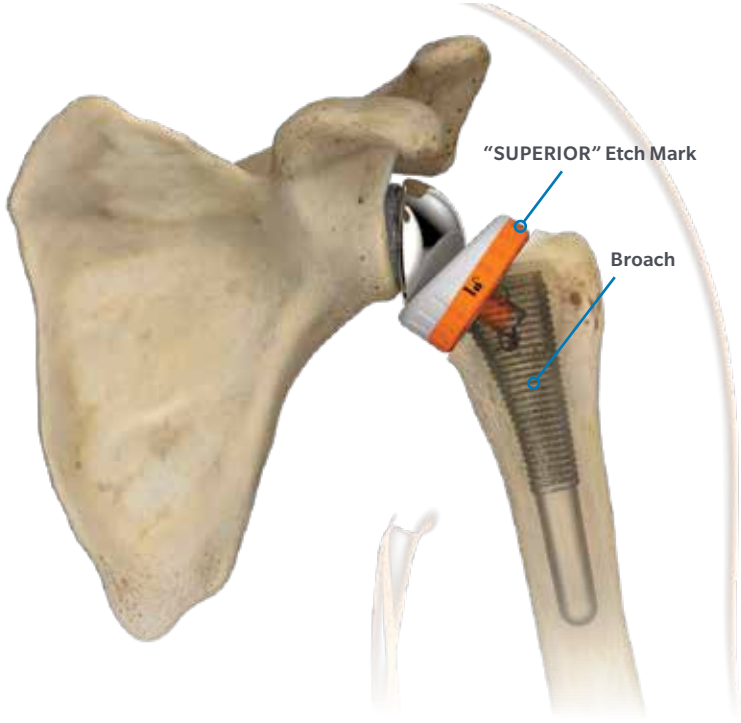


Figure 18

Trial Range of Motion

Noting the "SUPERIOR" marking on the Humeral Tray Trial, place the assembly into the Broach (Figure 18). 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.

Figure 19a

Figure 19b

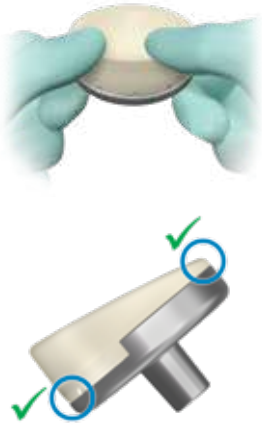


Figure 20

Figure 21

Tray and Bearing Implantation

Tray and Bearing Implant Assembly

To mate the Bearing and Tray implants, align the arrow etch mark on the bottom of the Humeral Bearing to the arrow etch on the top of the Humeral Tray (Figure 19a). Tilt the Bearing so that the lateral "toe" tucks into the lateral undercut of the Humeral Tray (Figure 19b).

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

Using thumb pressure, press down on the medial side of the Bearing to seat the implant (Figure 20). The Bearing will make an audible click when it fully seats into the Humeral Tray.

Optional 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 21).

Figure 22

Figure 23

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 22).

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 23) 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]

Figure 24

Figure 25

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 anteriorly at the Bearing/Tray junction where the Tray is thickest. (Figure 24). Using a mallet, firmly strike the osteotome to disengage the Bearing.

To insert the new Humeral Bearing into the Humeral Tray, align the arrow etch markings on the bottom of the Bearing and the top of the Humeral Tray. Tilt the bearing so that the lateral "toe" engages into the lateral undercut of the Humeral Tray. Using both thumbs, press down on the medial side of the Bearing to seat the implant. The Bearing will make an audible click when it fully seats.

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 25).

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 ordering information, please refer to document 5470.1-GLBL-en

Please refer to the Instructions for Use and the package label for the products to be used with this surgical technique.

Products within this system are under the design control of various legal manufacturers. Refer to the product labeling of each device for the legal manufacturer.

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