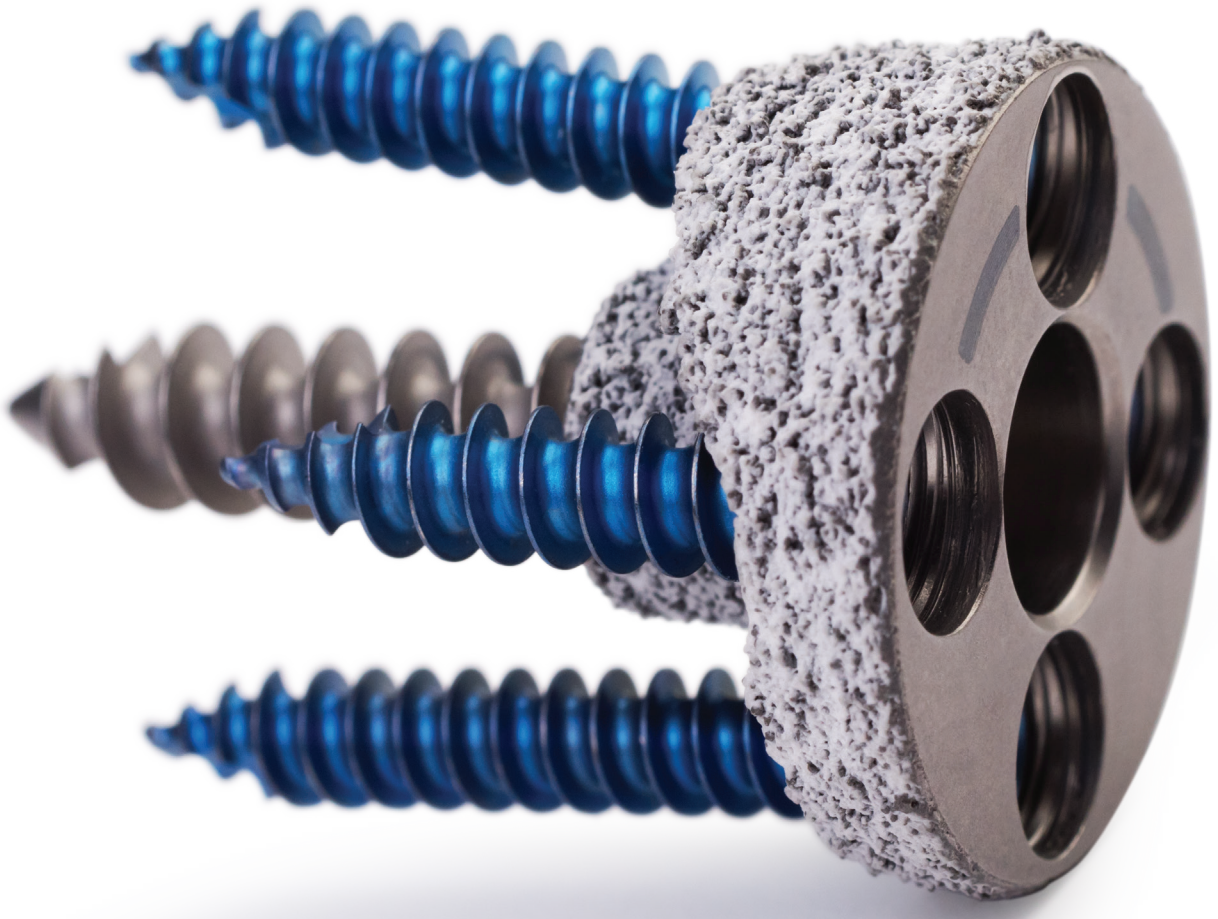
ZIMMER BIOMET
Moving You Forward.™

Comprehensive® Reverse Shoulder System Augmented Baseplate

with Off-Axis Instrumentation

Surgical Technique Addendum



INTENDED USE

These devices are intended for shoulder joint arthroplasty.

INSTRUMENT LIFESPAN

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

INDICATIONS

Zimmer Biomet 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.

The Comprehensive 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.

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 stem components 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.

Adaptive

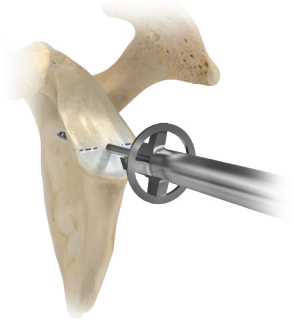
Building on the history and clinical success of the Comprehensive Reverse Shoulder design, the Comprehensive Reverse Augmented Baseplates continue the trend of market leading solutions. Offering relevant sizing of augments with maximum versatility in placement, the Comprehensive Reverse Baseplate Augments utilize a familiar circular baseplate design with three separate buildup options (small, medium and large). The Augmented Baseplates can be placed in any orientation to address a multitude of glenoid erosion and deformity cases. The surgical technique and instrumentation have been developed with the goal of creating a simple, intuitive, and consistent set of steps. The reference peg feature allows for controlled augment preparation and matching augment placement. This match between augment preparation and implant placement helps maximize full bony support while minimizing bone removal.

In order to meet the needs and demands of reverse shoulder patients, bone scans and wear pattern analysis was used to determine optimal sizing of components with the goal of maximizing fit, performance and durability.*

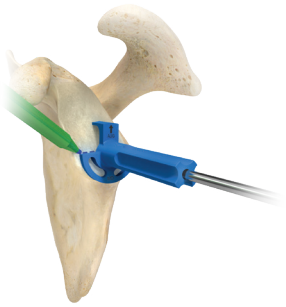
*Data on file at Zimmer Biomet - ZTM_BI_0117_18

Technique Summary

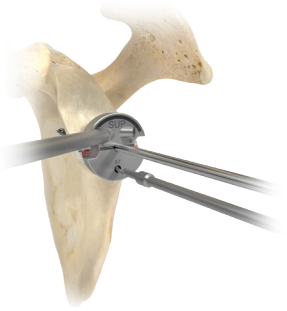
1. Place pin at desired version and inclination



2. Ream glenoid to 50%

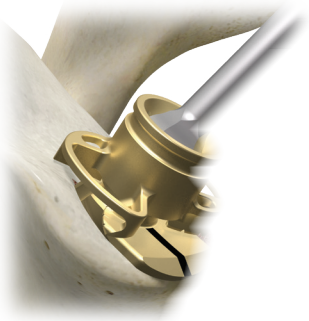


3. Choose augment size and orientation



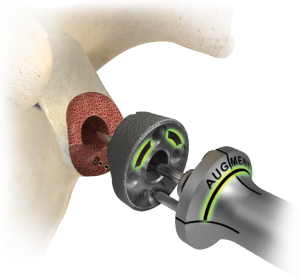
4. Drill augment positioning hole

5. Place augment reamer guide



6. Ream low side glenoid

7. Trial augment baseplate



8. Place augmented baseplate

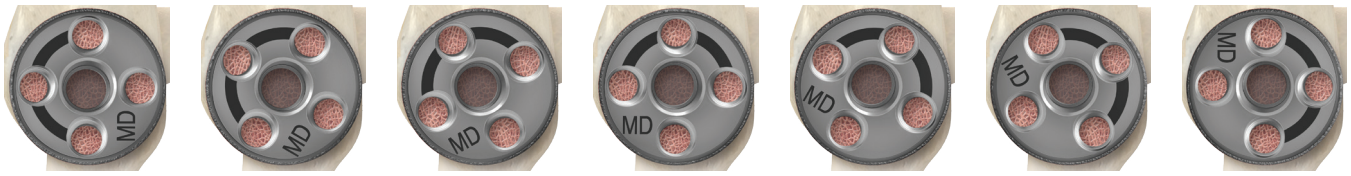
Superior

Anterior

Posterior

Dialing Options

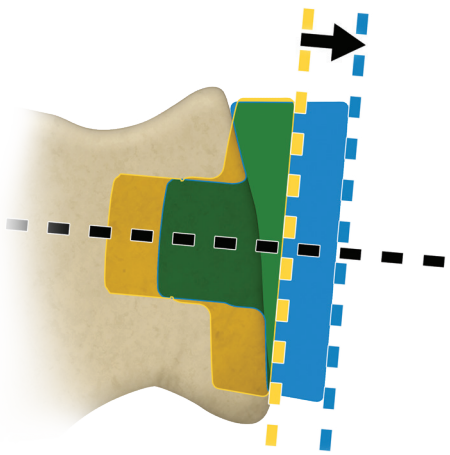
Anterior ⟷ Superior ⟷ Posterior



The augmented baseplate design allows for the treatment of a wide spectrum of glenoid bone wear conditions. The circular design of the baseplate allows for rotation to address bone deficiency in any direction while multiple augment sizes are available to manage glenoid wear with minimal bone removal.

Multiple augment sizes are provided to address the defect directly.

In the rare case where the glenoid defect exceeds the limitation of the augmented baseplate, implants such as the Comprehensive Vault Reconstruction System (VRS) are available through the Zimmer Biomet Patient Matched Implant Group. For more information on the VRS glenoids, reference the Comprehensive VRS Surgical Technique.



Solid Yellow = Bone Preserved
Yellow Hash = Face of Mini Baseplate
Blue Hash = Face of Augmented Baseplate
Arrow = Increased Lateralization

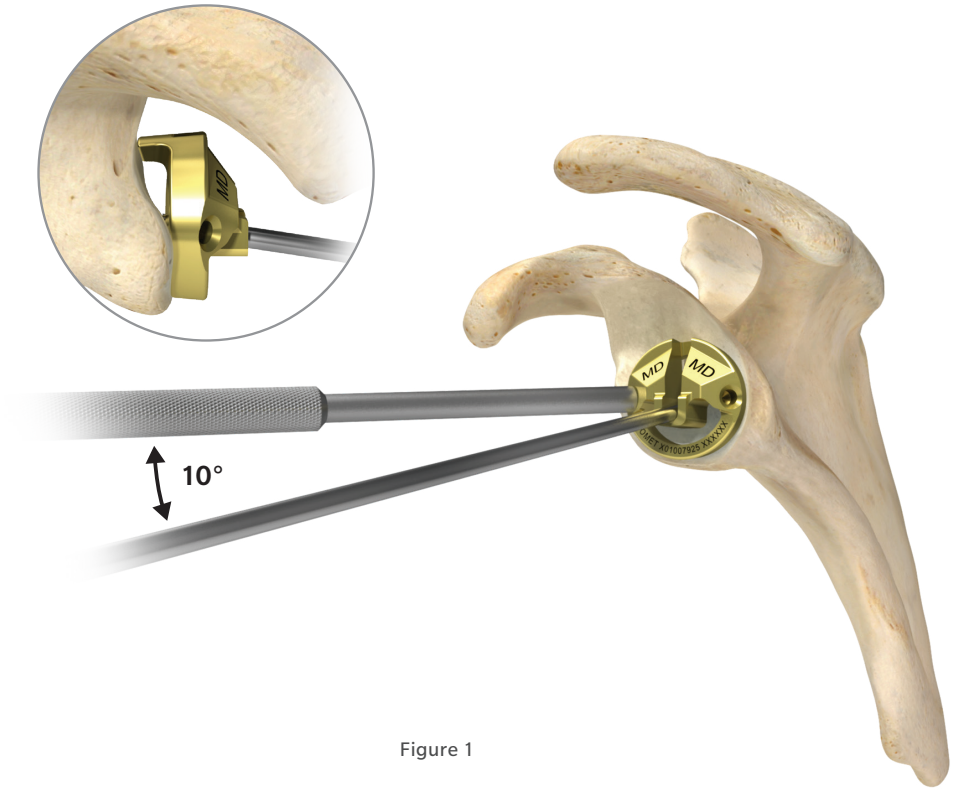


Figure 1

Initial Pin Placement

Select the appropriate pin placement guide based on the amount of glenoid erosion. Determine which guide (non-augmented, small, medium, or large) will best align the initial Stienmann pin in the desired version and inclination, and attach to the threaded glenoid guide handle. The “left” and “right” moniker on the pin placement guide relates to the side of the guide of which the kickstand extends, and does not relate to the anatomic side shoulder. It is recommended to aim for the central axis of the scapula with 10° of inferior tilt. Insert a 3.2 mm Steinmann pin into the glenoid at the desired angle and position, ensuring the pin engages or perforates the medial cortical wall (Figure 1). A completely secure Steinmann pin is essential to ensure the subsequent reamer has a stable cannula over which to ream. A 10 degree inferior tilt has been built into the pin placement guide, however you will need to account for any glenoid defects or asymmetric wear when placing the Steinmann pin. When the Steinmann pin is placed correctly within the guide, it will lie flush with the inferior slot of the guide.

Ideally, the pin placement guide should be centered over the inferior glenoid. However, in glenoid deformity cases and situations with poor bone quality, the Steinmann pin should be placed into the best possible bone stock, keeping in mind the Versa-Dial® glenosphere can be offset up to 4.5 mm in any direction.

Note: For the 36 mm standard glenosphere, the offset range is 1.5–3.5 mm.

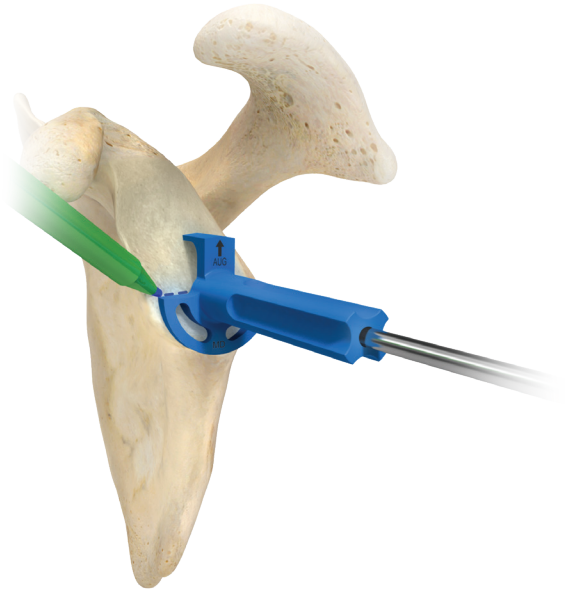


Figure 2

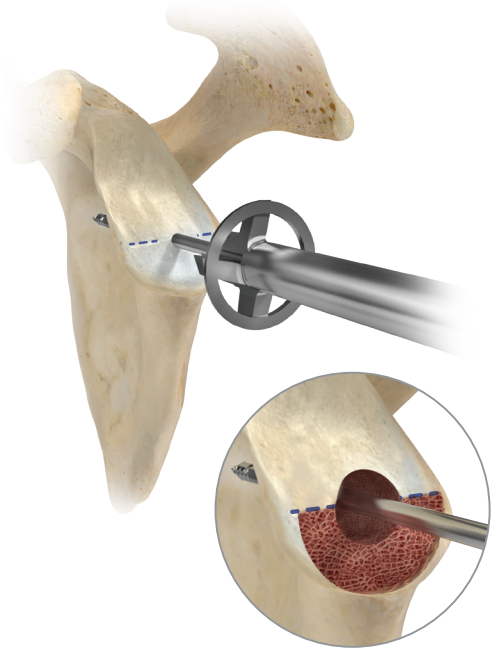


Figure 3

High Side Glenoid Preparation

The glenoid is prepared in two stages. The first stage prepares the high side (less deficient) of the glenoid. The second stage prepares the low side (more deficient) of the glenoid to accept the augmented portion of the baseplate.

To begin preparation of high side of the glenoid, position the augment sizer over the Steinmann pin and onto the face of the glenoid. Dial the augment sizer with the small, medium or large tab in the appropriate direction to ensure the maximum defect is being addressed so the baseplate will lie in the desired orientation. Mark the 50% line on the face of the glenoid (Figure 2).

Using the Comprehensive Mini Baseplate Reamer, ream the glenoid until the high side half has been fully prepared. It is critical the high side half of the glenoid is reamed to at least 50% (use Steinmann pin as reference) as this prepares the necessary bone for the augmented baseplate to be fully supported (Figure 3).

Position the augment sizer instrument over the Steinmann pin and onto the face of the glenoid as a reference to ensure at least 50% of the glenoid face has been reamed. If less than 50% of the glenoid face has been reamed, repeat baseplate reaming until 50% ream is achieved and confirm with the appropriate augment sizer.

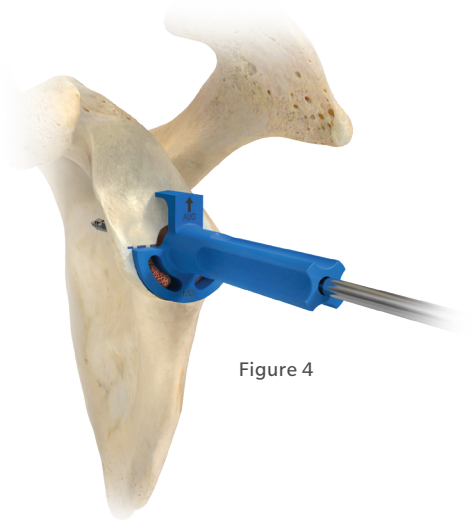


Figure 4

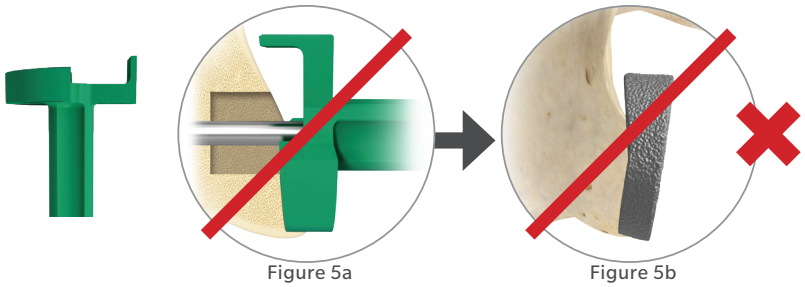


Figure 5a

Figure 5b

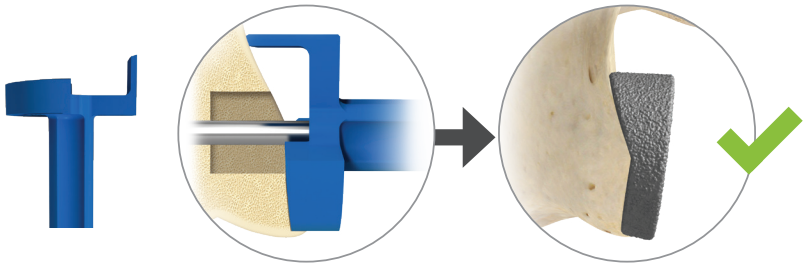


Figure 5c

Figure 5d

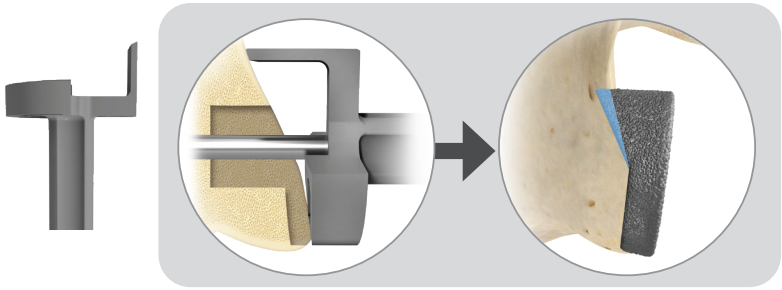


Figure 5e

Figure 5f

Augment Sizing

The following steps will serve as the final decision on sizing based on intraoperative evaluation of the glenoid after reaming.

After the glenoid face has been reamed to 50%, the augment sizer is placed over the Steinmann pin and rotated to the deepest point of the defect (Figure 4). The augment sizer will assist in determining which size augment (SM/MD/LG) will be used. Start with the small augment sizer and seat with the kickstand making contact with the deepest point of the low side. If the small augment sizer contacts the defect on the glenoid face, then that is the appropriate augment size. If the small sizer kickstand does not contact the glenoid (Figure 5a), proceed to the medium augment sizer and re-evaluate (Figure 5c). If medium sizer kickstand does not contact the glenoid, proceed to the large sizer and re-evaluate (Figure 5e). The smallest augment sizer that contacts the deepest point of the low side should be the augment size chosen. Augment sizing should always start with the small and progress to the medium and large to minimize bone removal. The next larger size implant may also achieve sufficient contact but remove more bone than required (Figure 5e and 5f).

Note: If using the large augment sizer and the kickstand is not contacting the deepest point of the defect, then additional reaming of the high side of the glenoid is necessary.

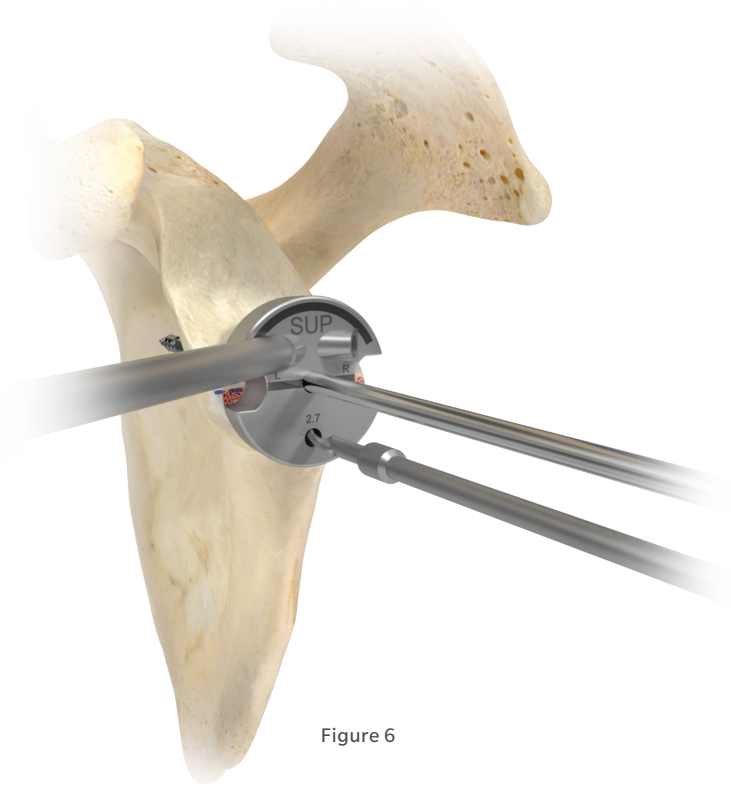


Figure 6

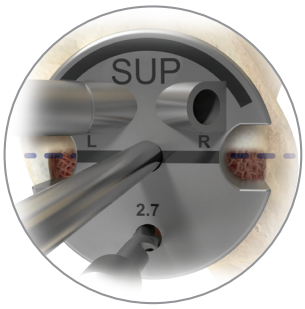


Figure 6a

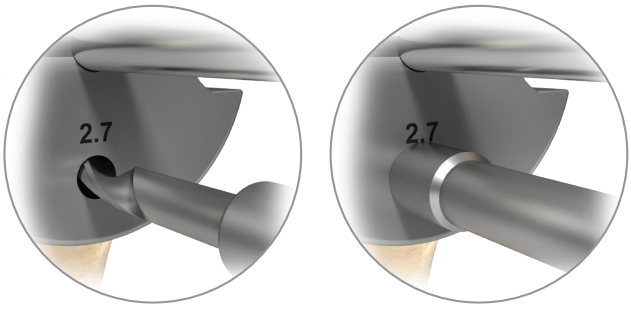


Figure 6b

Reference Peg Preparation

Drilling of the 2.7 mm hole in the following step will determine augment orientation during baseplate insertion.

Position the 2.7 mm peg drill guide on the glenoid with the half-circle etch in the location where the augment is desired (Figure 6). Care should be made that all soft tissue is clear of the drill guide to allow for proper seating before use. Reference the windows to ensure that the center line on the 2.7 mm peg drill guide is aligned with the 50% bone reamed in the previous step (Figure 6a). Drill the 2.7 mm hole opposite of the augment etch ensuring the drill has bottomed out on the drill guide (Figure 6b). Remove the 2.7 mm drill and drill guide.

Figure 7a

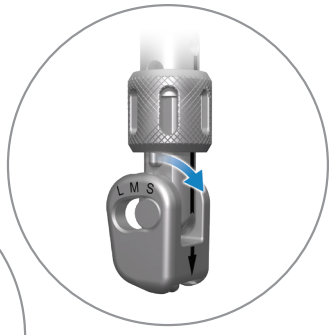


Figure 7b

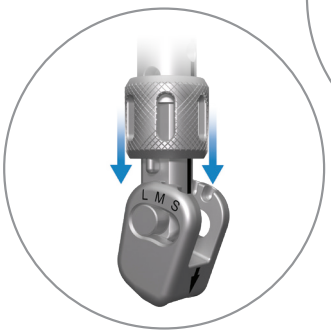


Figure 7c

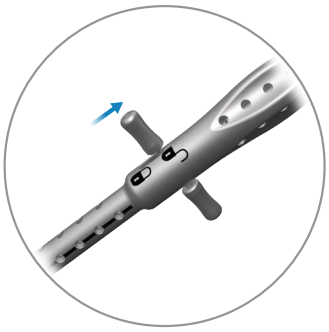


Figure 8a

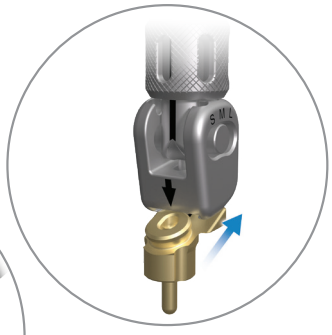


Figure 8b

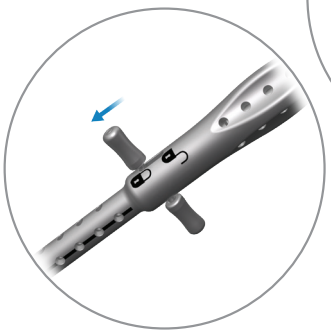


Figure 8c

Augment Reamer Guide Placement

Utilize the correct reamer guide size based on the corresponding augment size. Adjust the distal working end of the Off-Axis Inserter/Remover to the corresponding size-specific orientation. Do this by pulling back on the spring-loaded locking sleeve (Figure 7a) and rotating the distal end of the Inserter to the appropriate position (Figure 7b). Lock the position by releasing the locking sleeve (Figure 7c) and confirm the sleeve is fully seated. Attach the reamer guide to the Off-Axis Inserter/Remover by pulling up the Inserter/Remover handle into the "Unlocked" position (Figure 8a) and sliding the guide into place, gripping the reamer guide by its collar (Figure 8b). Lock the guide into place by moving the Inserter/Remover handle to the bottom-most "Locked" position (Figure 8c). Place the Augment Reamer Guide into the prepared center post hole, ensuring alignment between the backside alignment peg and the peg hole (Figure 9a,b). Return the inserter to the "Unlocked" position and remove the inserter from the surgical site by sliding the working end off of the guide boss and out of the surgical site (Figure 9c). Confirm full seating and stability of the guide.

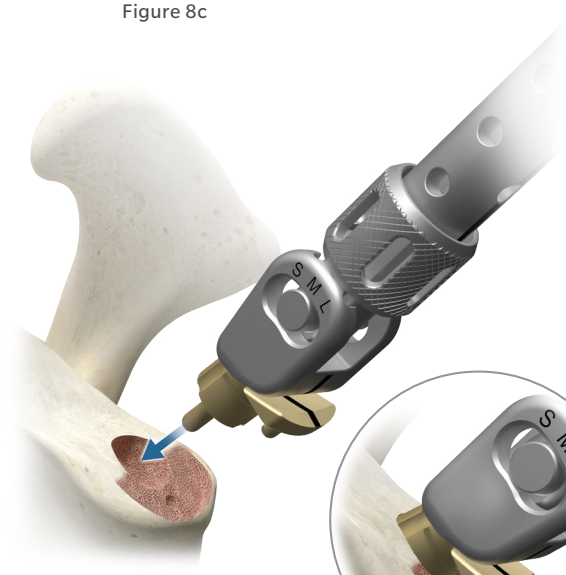


Figure 9

Figure 9a

Figure 9b

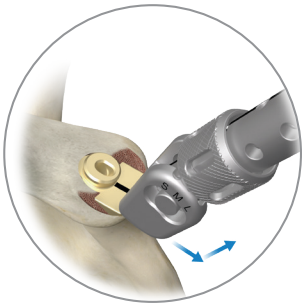


Figure 9c

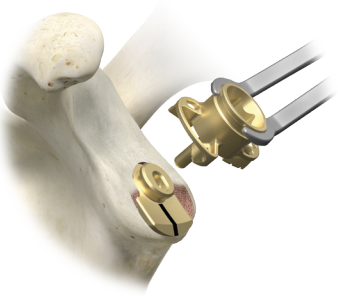


Figure 10a

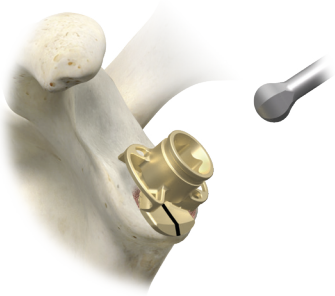


Figure 10b

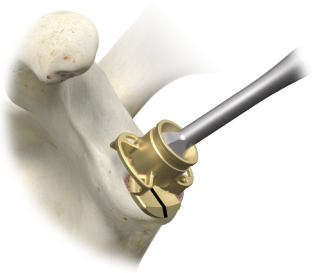


Figure 10c

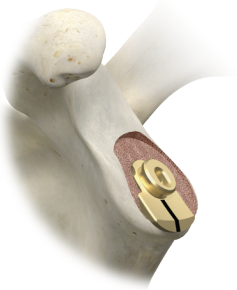
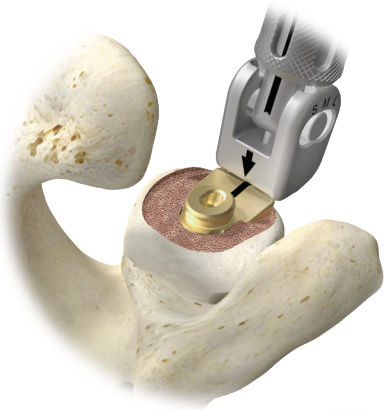


Figure 10d



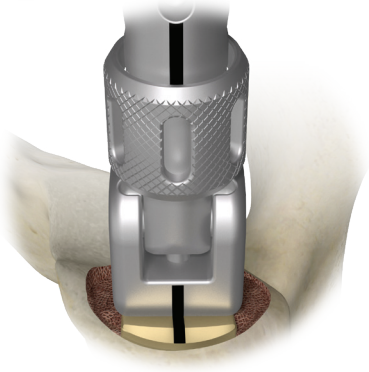


Figure 11

Augment Reaming

To ream the glenoid, utilize the correct reamer size for the corresponding augment. Glenoid reaming can be performed by hand or using power. Attach the Augment Off-Axis Reamer to the Augment Reamer Guide Inserter. Place the pilot tip of the Augment Off-Axis Reamer into the Reamer Guide hole (Figure 10a). Connect the Universal Ball Hex Driver to the reamer (Figure 10b). If necessary, remove glenoid osteophytes to allow proper seating of reamer. Prior to establishing contact with the bone, slowly begin rotating the reamer. Ream the glenoid fully until the reamer bottoms out on the guide (Figure 10c). The glenoid has now been prepared for the augmented baseplate (Figure 10d).

Reamer Guide Removal Using Inserter

When removing the reamer guide using the Off-Axis Inserter/ Remover, ensure that the inserter is in the "Unlocked" position. Align the arrow to the orientation line of the guide and slide the distal end of the inserter over the guide boss, using the lasermark alignment features as a guide shown in Figure 11. Release the handle and allow it to move forward into the locked position, securing the reamer guide within the inserter.

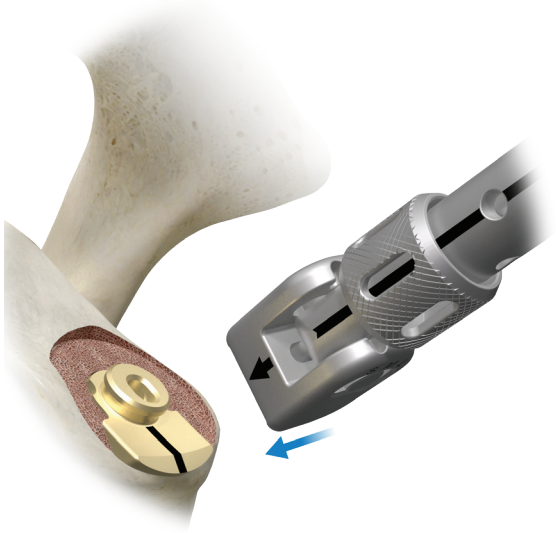


Figure 12

Figure 13

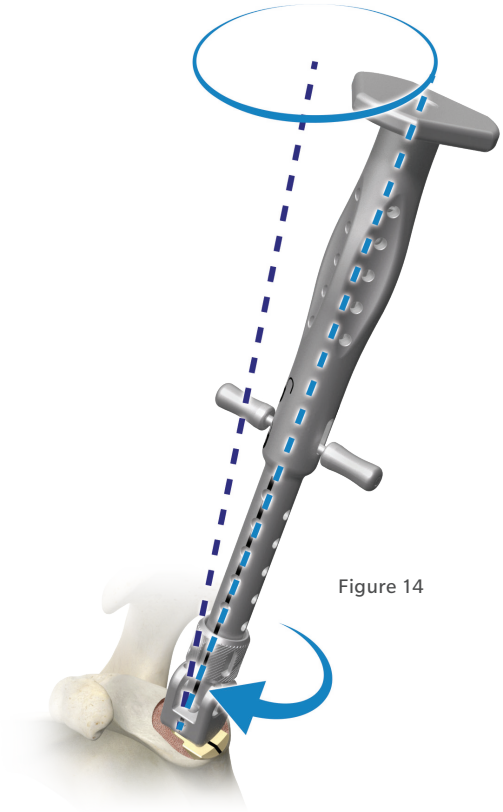


Figure 14

Figure 15

Reamer Guide Removal Using Inserter (cont.)

In the case that patient anatomy and/or clocking orientation (Ex. Anterior/superior defect) prevents you from aligning and approaching the reamer guide as shown in the previous Figure 11, the circular shape of the reamer guide boss will allow you to attach the Inserter/Remover at any orientation and rotate into an aligned position.

Approach the reamer guide from the orientation desired. Slide the working end of the Inserter/Remover fully over the reamer guide boss as shown in Figure 12 & 13. While keeping the Inserter/Remover disengaged, rotate the Inserter/Remover carefully about the reamer guide until you are able to obtain a correct orientation as shown in Figure 14. Release the handle and allow the Inserter/Remover to engage onto the reamer guide and ensure the reamer guide is fully captured as normal (Figure 15).

Note: Rotate the Inserter/Remover carefully, allowing the proximal end of the Inserter/Remover to rotate without disturbing the reamer guide seating (Figure 14)

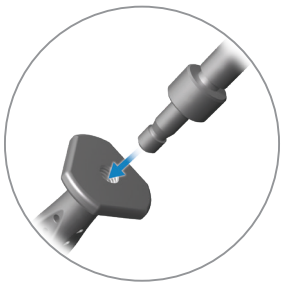


Figure 16

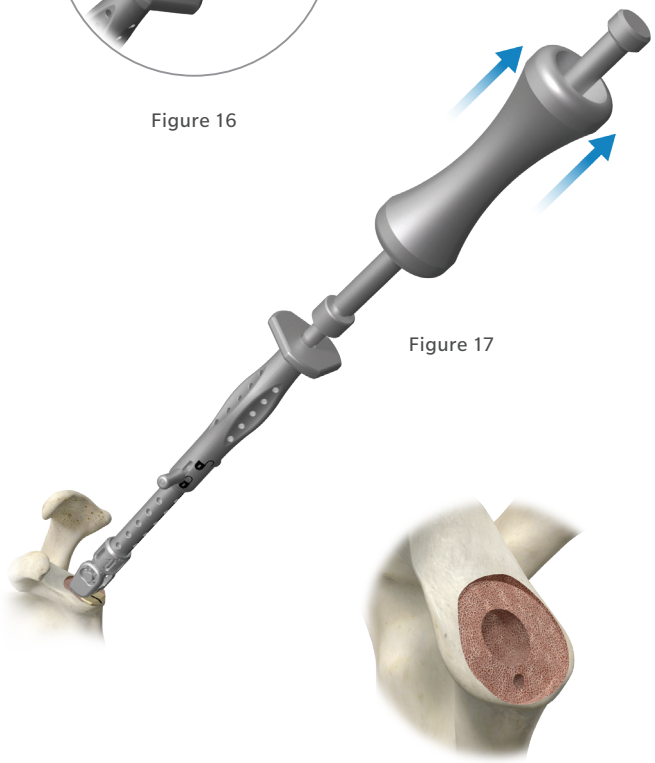


Figure 17

Figure 18

Reamer Guide Removal Using Inserter (cont.)

Optional Slaphammer-Assisted Removal

In the case of a tightly captured guide, the Off-Axis Inserter/Remover is able to accept a slaphammer via threaded attachment. To utilize, locate the threaded feature at the proximal end of the inserter and thread on the attachment fully (Figure 16). Use the assembly to fully remove the reamer guide from the glenoid surface (Figure 17). Disengage the inserter to detach guide and dispose. Figure 18 shows the prepared glenoid after removal of the guide.

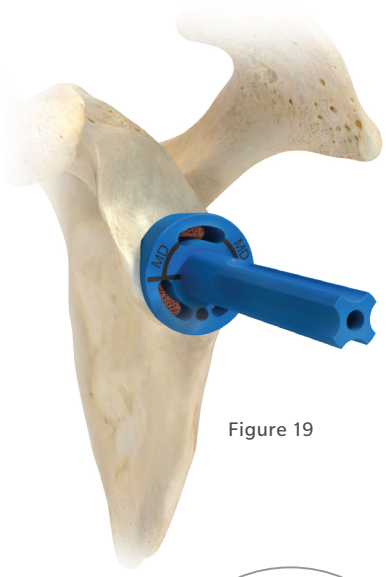


Figure 19

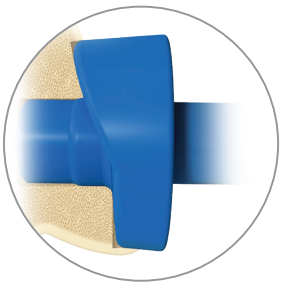


Figure 19a

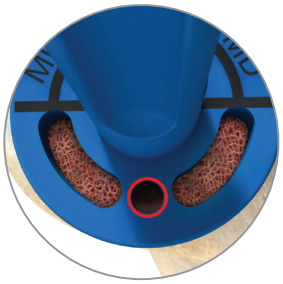


Figure 19b

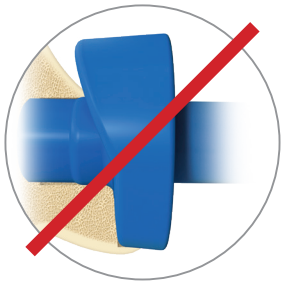


Figure 19c

Augmented Baseplate Trialing

Using the required augment baseplate trial (SM/MD/LG), position the augment baseplate trial into the prepared glenoid and ensure the trial seats fully (Figure 19 and 19a). To guide in trialing, the initial 3.2 mm Steinmann pin may be reinserted. The augment baseplate trial contains an alignment hole that should sit directly above the 2.7 mm peg hole when properly positioned (Figure 19b). If the augment baseplate trial does not fully seat (Figure 19c), additional reaming may be needed to ensure full contact of the augmented baseplate.

Note: The outer diameter of the augment baseplate trial is intentionally undersized to allow proper seating past surrounding soft tissues.

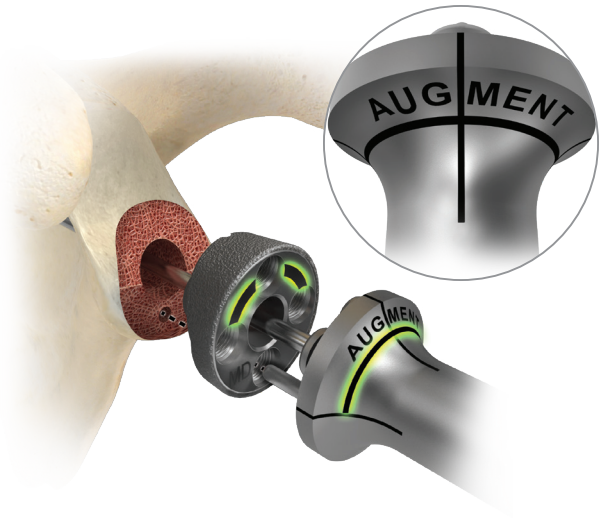


Figure 20

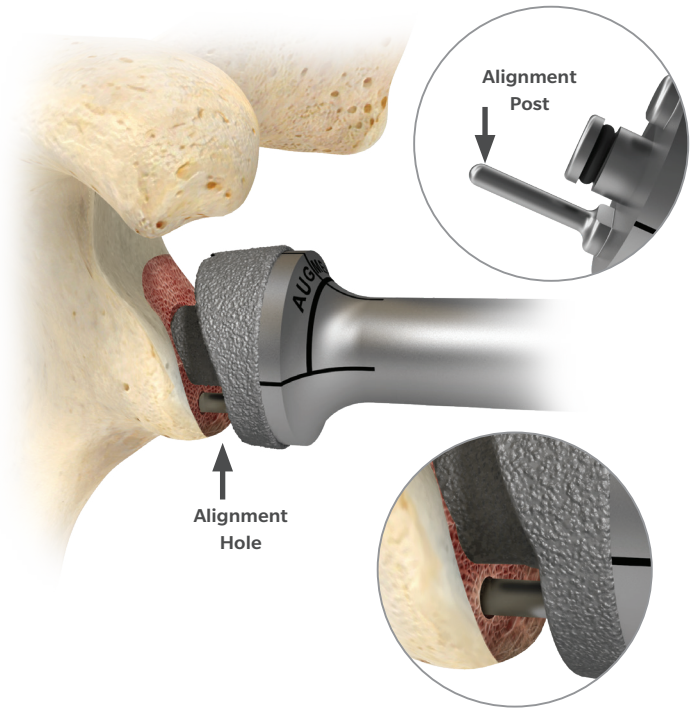


Figure 21

Augmented Baseplate Insertion

Place the augmented baseplate onto the end of the baseplate impactor, ensuring the augment of the baseplate is aligned with the "augment" label on the baseplate inserter (Figure 20).

Note: Application of saline or other appropriate lubrication to impactor tip o-ring should aid in distraction of impactor from baseplate after impaction.

Note: Re-insertion of the Steinmann pin to assist with alignment during impaction is optional.

Position the alignment post of the baseplate impactor so it engages in the 2.7 mm alignment hole on the glenoid, which is directly opposite of the bone prepared for the augment (Figure 21). When the alignment post is in the correct orientation, the half-circle etch and augment label on the inserter should match the glenoid bone prepared for the augmented aspect of the baseplate.

Note: The Comprehensive Mini Taper Adaptor comes packaged with the Comprehensive Augmented Baseplate.

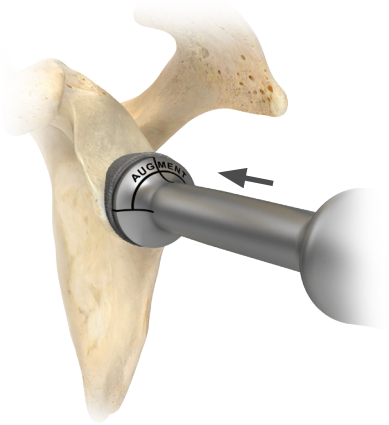


Figure 22

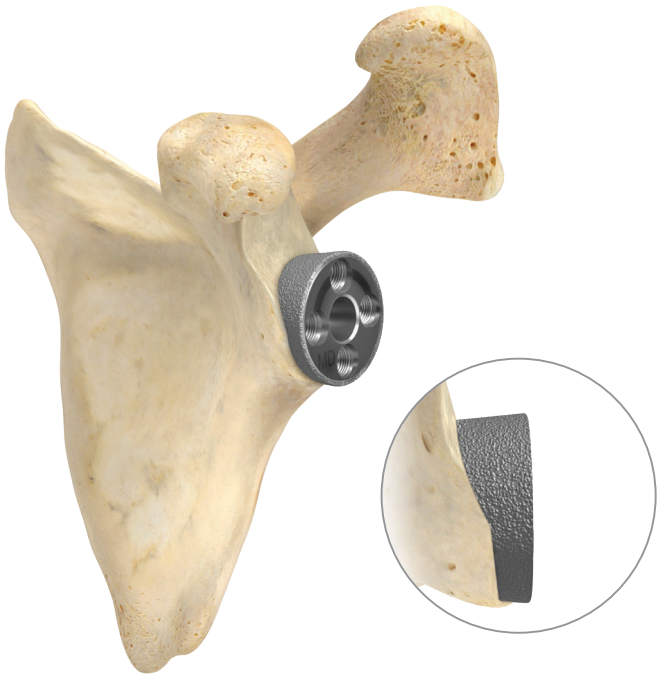


Figure 23

Baseplate Insertion (cont.)

Once aligned, impact the augmented baseplate into the glenoid and remove the augmented baseplate inserter (Figure 22). The back of the augmented baseplate should be fully seated on the face of the glenoid surface (Figure 23). Visual confirmation can be attained by checking for gaps between the reamed glenoid surface and baseplate at the screw holes.

Note: While assessing range of motion with the Glenosphere trial and humeral trial, adjustments may be made to the glenosphere size or position, in order to minimize the potential for component impingement. If Augmented Baseplate removal is necessary, the extractor peripheral screws should not go through the augment portion of the baseplate.

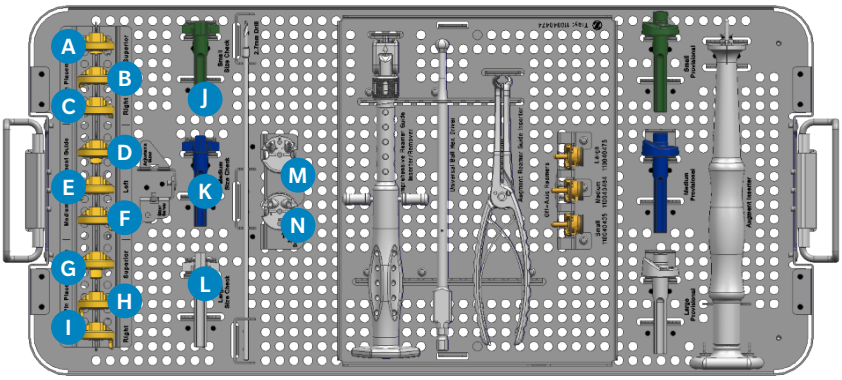
Note: As is with any Morse taper, ensure taper is clean and dry before impaction of the definitive glenosphere later in the procedure.

Baseplate Screw Fixation

Compression of the augmented baseplate is important and is achieved mainly with a 6.5 mm central screw. To achieve this compression of the baseplate, the distal threads of the central screw should perforate the anterior cortex of the scapula. For the surgical steps in determining the adequate lengths of both the 6.5 mm central compression screw as well as the 4.75 mm peripheral locking or non-locking screws proceed to the Comprehensive Reverse Surgical Technique.

Note: Due to the buildup of the augment of the baseplate, there is limited angulation for a non-locking peripheral screw in the hole that passes through the augment. Therefore, only the fixed angle drill guides should be used through this peripheral hole, even if a 4.75 mm non-locking compression screw is desired. The variable angle drill guide may be used through the remaining three holes if desired.

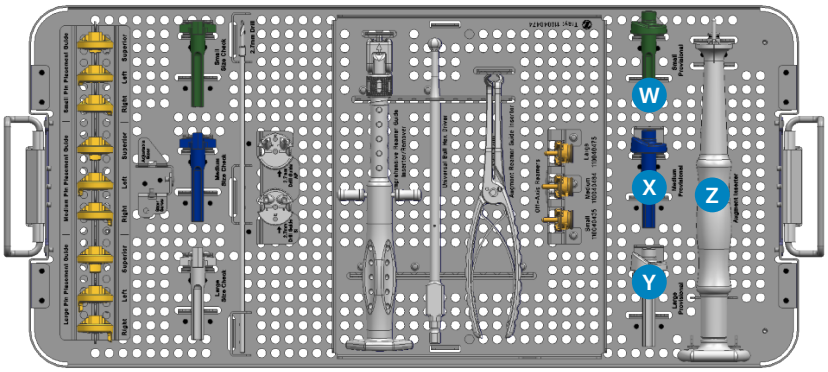
Ordering Information



110029768 Augmented Baseplate Instrument Case
110028919 Augmented Baseplate Instrument Case Lid

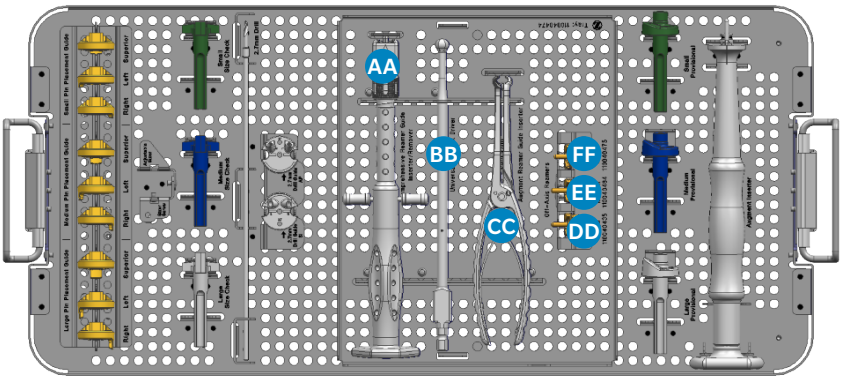
Instruments

Product	Description	Label	Size	Part Number
	**Pin Placement Guide**	A	Small Superior	110029094
		B	Small Right	110029091
		C	Small Left	110040010
		D	Medium Superior	110029095
		E	Medium Right	110029092
		F	Medium Left	110040020
		G	Large Superior	110029096
		H	Large Right	110029093
		I	Large Left	110040030
	**Augment Sizer**	J	Small	110040110
		K	Medium	110040120
		L	Large	110040130
	**Anterior/Posterior Drill Guide**	M	2.7mm	110040200
	**Superior/Inferior Drill Guide**	N	2.7mm	110040201



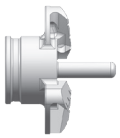
110029768 Augmented Baseplate Instrument Case
110028919 Augmented Baseplate Instrument Case Lid

Product	Description	Label	Size	Part Number
	**Augment Provisional**	W	Small	110040510
		X	Medium	110040520
		Y	Large	110040530
	**Augment Baseplate Inserter**	Z	–	110040600



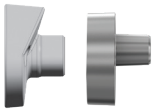
110040474 Augmented Off-Axis Instrument Tray

Instruments

Product	Description	Label	Size	Part Number
	**Off-Axis Inserter/Remover**	AA	–	110040239
	Universal Ball Hex Driver	BB	–	110037010
	**Augment Reamer Guide Inserter**	CC	–	SBGL3700
	**Augment Off-Axis Reamer**	DD	Small	110040435
		EE	Medium	110040484
		FF	Large	110040475

Ordering Information

Implants

Product	Description	Size	Part Number
	**Augmented Baseplate Implant with Taper Adapter***	Small	110032410
		Medium	110032420
		Large	110032430

Disposables

Product	Description	Size	Part Number
	Drill with Stop	2.7mm	110040202
	**Augment Off-Axis Ream Guide**	Small	110040240
		Medium	110040241
		Large	110040242

Notes

Please refer to the Instructions for Use and the package label for the products to be used with this (Comprehensive Reverse Shoulder System Surgical Technique).

For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the Instructions for Use or contact your local representative; visit www.zimmerbiomet.com for additional product information.

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