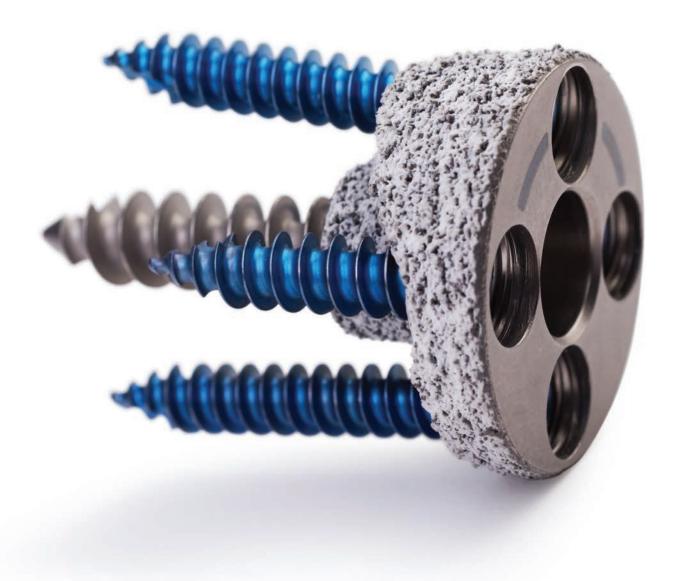


Comprehensive® Reverse Shoulder System Augmented Baseplate

Surgical Technique Addendum



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 unique 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.







Technique Summary



1. Place pin at desired version and inclination



3. Choose augment size and orientation



5. Place augment reamer guide and bushing



7. Trial augment baseplate



2. Ream glenoid to 50%



4. Drill augment positioning hole

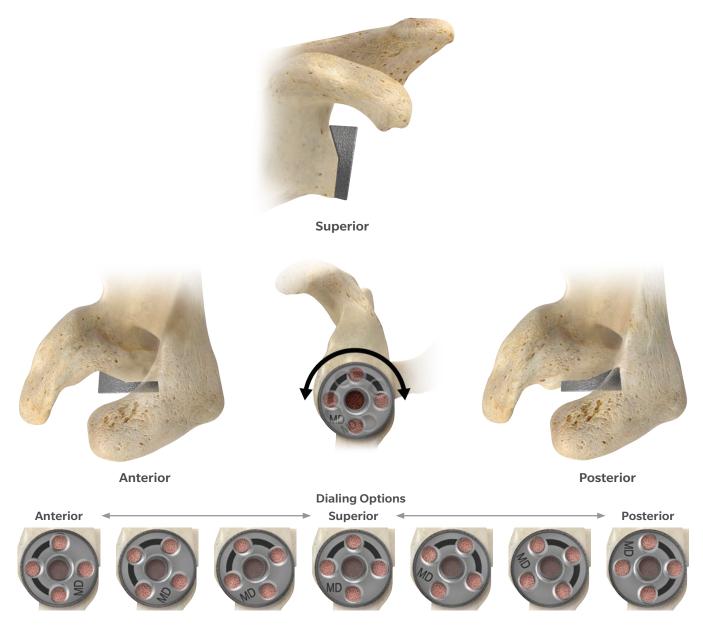


6. Ream low side glenoid



8. Place augmented baseplate

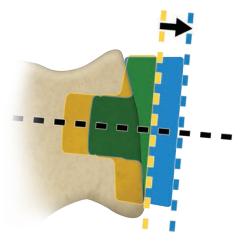
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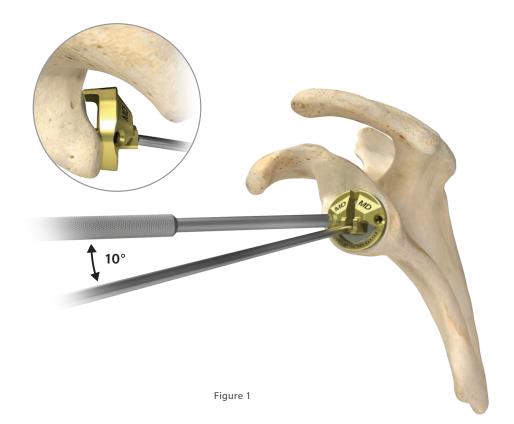
The augmented baseplate design allows for the treatment of a wide spectrum of glenoid bone wear conditions. The circular design of the baseplate allows for rotation to address bone deficiency in any direction while multiple augment sizes are available to manage glenoid wear with minimal bone removal.

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 0469.2-GLBL-en-0817.



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



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

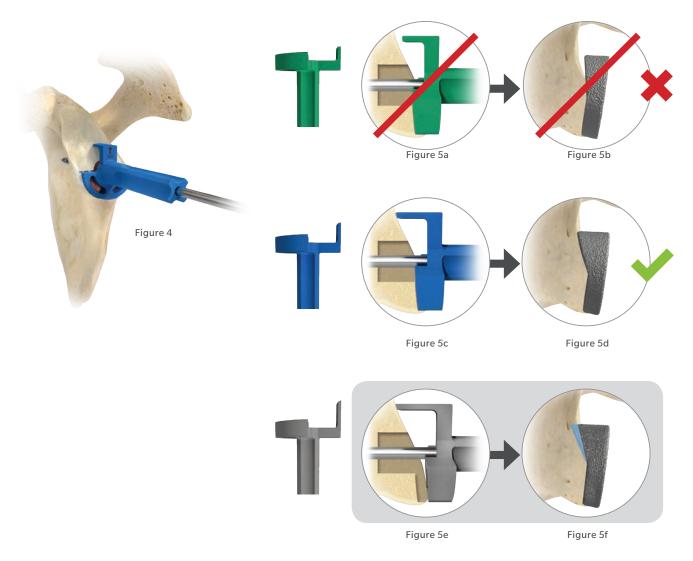
Figure 3

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.



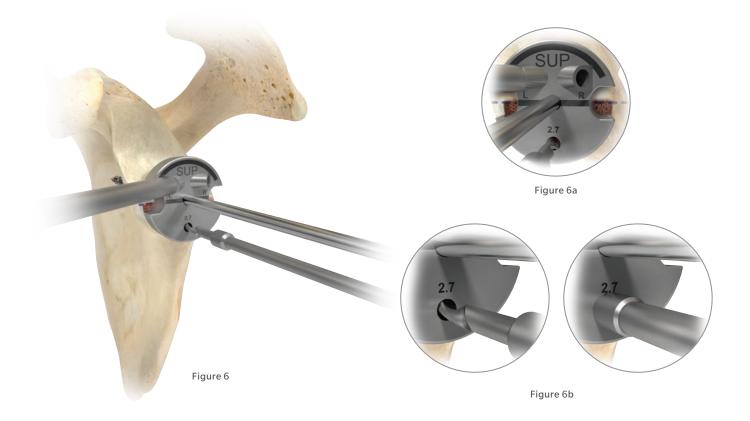
Augment Sizing

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).

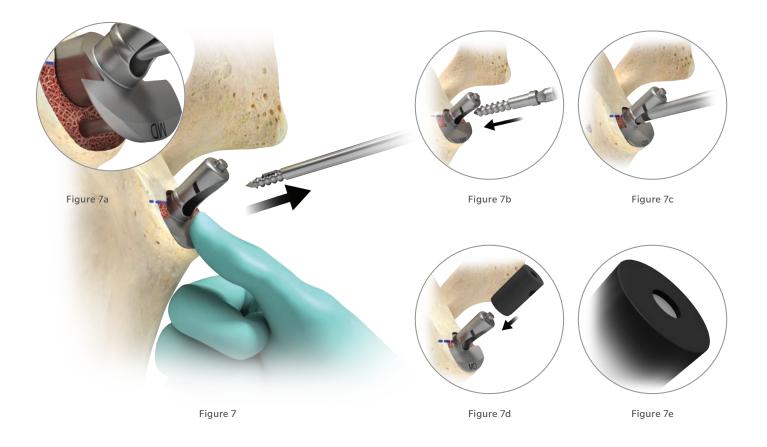
Note: If using the large augment sizer and the kickstand is not contacting the deepest point of the defect, then additional reaming of the high side of the glenoid is necessary.



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.



Augment Reamer Guide Placement

Place the appropriate augment reamer guide over the Steinmann pin onto the prepared glenoid (Figure 7a) taking care to align the reamer guide post with the 2.7 mm drilled hole. Remove the 3.2 mm Steinmann pin (Figure 7). Using the 3.5 hex driver under hand power, insert the 4.75 mm guide screw until it is fully seated within the augment reamer guide (Figure 7b). The etch line on the driver should line up with the etch line on the reamer guide when completely seated as a warning when the screw is close to bottoming out in the reaming guide (Figure 7c). The Reamer Guide is fully seated when the flange is in full contact with the supporting bone.

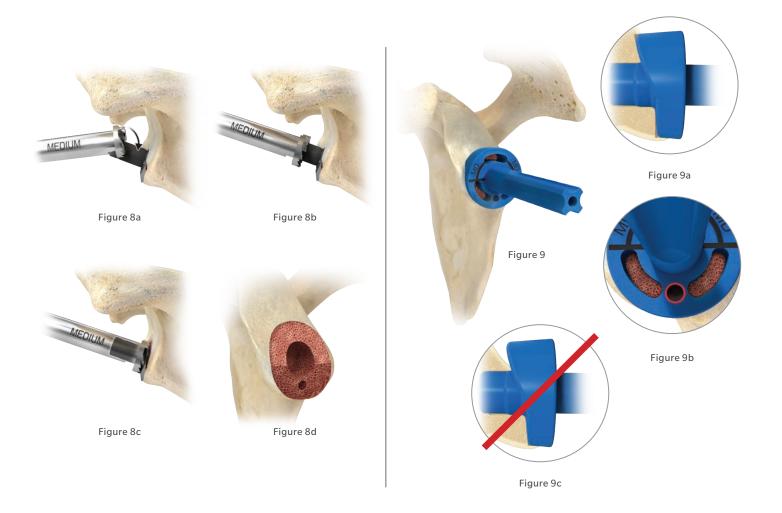
- Note: Do not over tighten the 4.75 mm guide screw as this may depress the reamer guide into the glenoid bone
- Note: If the reamer guide does not initially fully seat with digital pressure, proceed with the 4.75 mm guide screw as this will draw the reamer guide down to the glenoid bone.

The 4.75 mm guide screw has been engineered with the same pitch as the definitive 6.5 mm central screw, ensuring the final screw achieves purchase into undisturbed bone. The 4.75 mm guide screw is designed to provide additional reamer guide fixation during reaming for the augment along with serving as a tap for the 6.5 mm central screw.

Once the 3.5 mm hex driver has been removed, insert the reamer guide bushing onto the reamer guide post (Figure 7d) and make sure it is completely down. Reamer guide bushings are packaged single sterile so if a second is needed, a new sterile bushing should be opened.

Note: When the bushing is completely seated, the top of the reamer guide will sit below the top of the bushing hole (Figure 7e).

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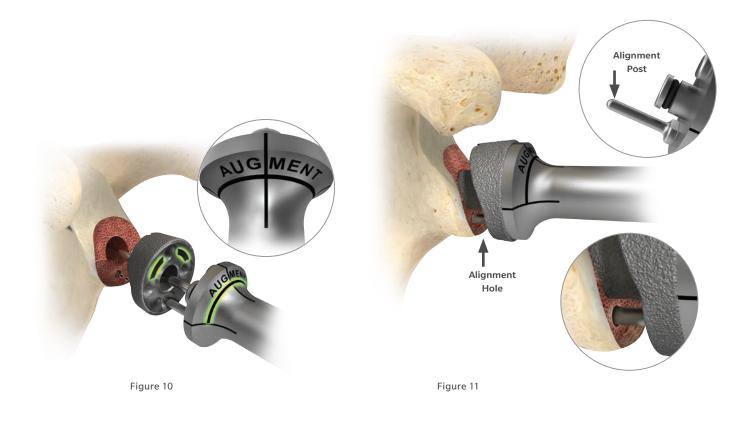
Low Side Glenoid Preparation

Position the required size augment reamer (SM/ MD/LG) over the augment reamer guide bushing (Figure 8a). Ensure the reamer is fully captured on the reamer guide bushing before beginning to ream (Figure 8b and 8c). If necessary, remove glenoid osteophytes to allow proper seating of reamer. Start rotation of reamer head before engaging bone, and advance the reamer until it bottoms out on the reamer guide bushing. When bottomed out, the appropriate bone has been prepared to accept the augmented baseplate of choice. Take care to remove the reamer in-axis with the reamer guide post so to not disturb the reamer guide. Remove the reamer guide bushing, 4.75 mm guide screw, and the augment reamer guide. The glenoid has now been prepared for the augmented baseplate (Figure 8d).

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 9 and 9a). 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 9b). If the augment baseplate trial does not fully seat (Figure 9c), 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.



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 10).

- 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 11). When the alignment post is in the correct orientation, the halfcircle 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 13

Figure 12

Baseplate Insertion (cont.)

Once aligned, impact the augmented baseplate into the glenoid and remove the augmented baseplate inserter (Figure 12). The back of the augmented baseplate should be fully seated on the face of the glenoid surface (Figure 13). Visual confirmation can be attained by checking for gaps between the reamed glenoid surface and baseplate at the screw holes.

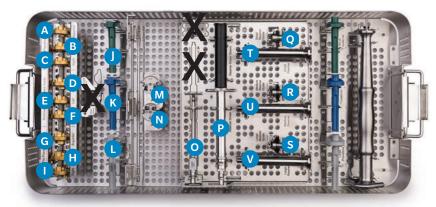
- Note: While assessing range of motion with the Glenosphere trial and humeral trial, adjustments may be made to the glenosphere size or position, in order to minimize the potential for component impingement. If Augmented Baseplate removal is necessary, the extractor peripheral screws should not go through 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 6.5mm 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 (0173.1-US-en-REV0216).

● 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

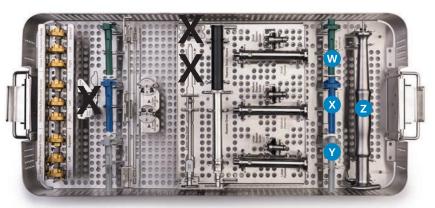


110029768 Augmented Baseplate Instrument Case 110028919 Augmented Baseplate Instrument Case Lid

Instruments

Product	Description	Label	Size	Part Number
	Pin Placement Guide	А	Small Superior	110029094
		В	Small Right	110029091
		С	Small Left	110040010
		D	Medium Superior	110029095
		E	Medium Right	110029092
		F	Medium Left	110040020
		G	Large Superior	110029096
		Н	Large Right	110029093
		I	Large Left	110040030
	Augment Sizer	J	Small	110040110
		К	Medium	110040120
		L	Large	110040130
	Anterior/Posterior Drill Guide	Μ	2.7mm	110040200
	Superior/Inferior Drill Guide	Ν	2.7mm	110040201
	Ream Guide Screw Hex Driver	0	3.5mm	110040301
	Cannulated Glenoid Reamer Shaft	Р		110004200
-	Augment Reamer Guide	Q	Small	110040210
		R	Medium	110040220
		S	Large	110040230
	Augment Reamer	Т	Small	110040410
		U	Medium	110040420
		V	Large	110040430

"X" indicates instrument is not included. For future expansion.



110029768 Augmented Baseplate Instrument Case 110028919 Augmented Baseplate Instrument Case Lid

Product	Description	Label	Size	Part Number
	Augment Provisional	W	Small	110040510
		Х	Medium	110040520
		Y	Large	110040530
and mercent in	Augment Baseplate Inserter	Z	_	110040600

"X" indicates instrument is not included. For future expansion.

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 Ream Guide Screw	-	110040300
• —	Augment Ream Guide Bushing	-	110031869

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-REV0417).

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.

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:

- Uncooperative patient or patient with neurologic disorders who is incapable or unwilling to follow directions.
- 2. Osteoporosis.
- 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.

Notes	

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.

Zimmer Biomet does not practice medicine. This technique was developed in conjunction with health care professionals. 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.

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0468.1-GLBL-en-REV0219

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