

Comprehensive[®] Vault Reconstruction System

Surgical Technique



Table of Contents

Evolution of a Patient-matched Implant.....	6
Preoperative Planning / 3D PDF.....	7
Screw Trajectory Planning	8
Final Design Notification	10
Glenoid Preparation For Implants with Outer Boss Geometry	12
Boss Reaming	14
Excess Bone and Soft Tissue Removal / Glenoid Trialing	15
Glenoid Placement / Initial Glenoid Stability.....	15
Central Screw Selection / Insertion	17
Peripheral Screw Selection / Insertion	19
Salvage Hemi-Arthroplasty / Removal of VRS Glenoid	20
Instrument / Implant Listing	21
Indications / Contraindications.....	26

Comprehensive VRS Overview

For today's orthopedic surgeons, emergency reconstructive cases or extreme variations in anatomy that may require the development of an implant specifically designed to meet one patient's needs are becoming commonplace. Since its inception in 1977, Zimmer Biomet's PMI® Patient-Matched Implant department has reinforced the foundation of solid engineering to address the most complicated cases of bone loss and deformity. Using computed tomography, the Comprehensive Vault Reconstruction System (VRS) is able to address significant scapular bone loss in an expedited manner. Its unique union of technology and personal attention allows surgeons and patients to benefit from the most advanced orthopedic designs available.

Severe cases of glenoid bone loss often require an implant to specifically match the patient's anatomy. The Comprehensive VRS glenoid implant is designed using a CT scan of the patient's severe bone defect. Case managers are then able to create patient-matched implants to fill bone voids using PPS® coated titanium which provides high strength and flexibility and allows for biologic fixation. When the Comprehensive VRS is used, it is often the final option to repair the patient's severely deficient shoulder.

This surgical technique should be studied prior to and used in association with the operation. As with other surgical procedures, errors of technique are more likely when the method is being learned. The Comprehensive VRS may be more complex due to many variable factors including reduced bone and tissue quality, difficulty of exposure, and variability between the date of the CT scan and the date of the procedure.

Exposure

Glenoid exposure has often been described as the most difficult part of total shoulder arthroplasty. Optimal glenoid exposure can be difficult and requires careful attention to detail.

Meticulous attention needs to be paid to proper anesthetics in order to ensure the patient's muscles are properly relaxed. Careful release of key soft tissue structures, removal of peripheral osteophytes on the humerus, appropriate humeral head cut, and key placement of specific retractors can all lead to excellent glenoid visualization and access. During these difficult cases, meticulous care needs to be taken not to disturb the anatomy while placing retractors and is especially true when using the VRS implant due to reduced bone and tissue quality.

For additional information and advice from surgeons experienced with Zimmer Biomet's Comprehensive Shoulder, please review *Key Steps to Glenoid Exposure*. This technique can be ordered through Zimmer Biomet's literature supplier using *BMET0500.0*.

Deltoid Mobilization

To start, ensure the deltoid is fully mobilized proximally, and the subacromial space is cleared of any scar tissue between the deltoid and underlying rotator cuff. The deltoid should be mobilized in the mid-aspect and distally. Special attention should be made to identify the axillary nerve on the undersurface of the deltoid.

Comprehensive VRS Overview (cont.)

Humeral Head Cut

Because the humerus is funnel-shaped, a more aggressive humeral head cut can help with adequate glenoid exposure. A slightly more aggressive head cut makes the humerus narrower, which decreases the amount of bone that has to be retracted behind the glenoid.

In cases where the rotator cuff is still intact, the humeral head cut should exit just above the rotator cuff insertion without violating it.

Inferior Capsule Release

With the arm placed in an adducted and externally rotated position, release the inferior capsule off the proximal humerus. Use cautery directly on the bone with progressive external rotation of the arm. A Darrach-type retractor can be used to smooth the humerus.

Labral and Capsular Release

With a wide variety of retractors available for glenoid exposure, typically a wide Bhattman retractor is placed posteriorly. A Fukuda retractor is also a viable option. Split the labrum and stump of the biceps tendon at the 12 o'clock position. A knee retractor can be placed between the labrum and the subscapularis. After removal of the anterior labrum, a thin Bhattman retractor is placed along the anterior glenoid rim. The labrum is then removed superiorly, anteriorly, and inferiorly. In general, the posterior labrum is also excised, but a formal posterior capsular release is not always necessary with total shoulder arthroplasty.

In cases where the labrum and subscapularis are no longer intact, simply clear away any soft tissue off the bone while still protecting the bony surface. Release any visible scar tissue without violating the bone stock and clean up bony surfaces carefully using curette.



Step 1:
3D reconstruction
from CT scan



Step 2:
Computer aided design used
to create implant proposal



Step 3:
Prototype implant created



Step 4:
Final implant manufactured

Evolution of a Patient-matched Implant

Zimmer Biomet's reputation for high quality custom implants begins with its engineers and dedicated 24-hour PMI manufacturing facility. The success of each implant starts with accurate reconstruction of the patient's CT scan data into a 3-D bone model. Please reference Zimmer Biomet's PMI CT protocol (0807.2-GLBL-en-REV0419). Working with the surgeon, an implant proposal is designed and can be sent out digitally, via 3-D PDF file or as a rapid prototype model. Upon surgeon approval of the proposal, the final implant is manufactured for surgery.

Patient anatomy may change over time. It is the operating surgeon's responsibility to determine if the implant is suitable for the patient. It is recommended that if more than 6 months have passed between the original CT scan used for implant design and the surgery, an additional CT scan be conducted to confirm the anatomy.

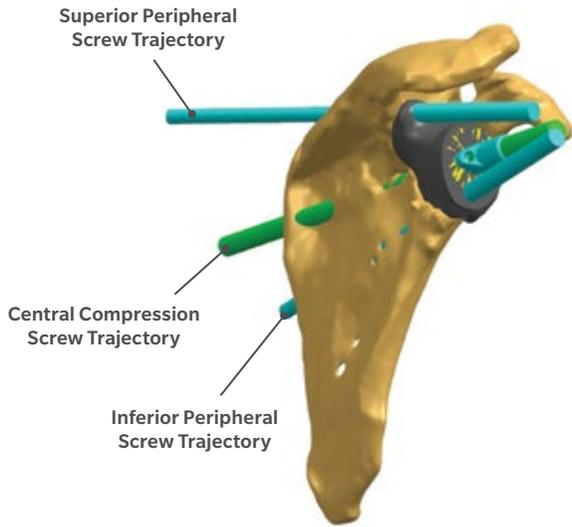


Figure 1

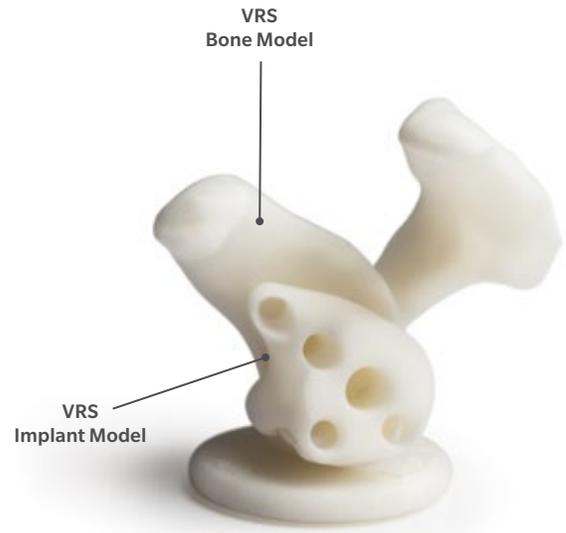


Figure 2

Preoperative Planning/3D PDF

The Comprehensive VRS Glenoid is created from 3D CT imaging which offers preoperative planning, visualization and the development of patient-specific implants. Surgeons will be able to view and manipulate the pre-operative plan from any computer. The plan features patient-specific images for the Comprehensive VRS Glenoid detailing the implant position, implant orientation, screw trajectory, size of the implant, and recommended bone removal, if necessary (Figure 1). Surgeons will communicate directly with a case manager from the Zimmer Biomet PMI team to update the plan. The surgeon is required to approve the proposal before the Comprehensive VRS Glenoid will be manufactured.

With each Comprehensive VRS Glenoid, the surgeon will receive a patient-specific bone model, implant model, and if necessary, a custom boss reaming guide. The implant model, bone model and custom boss reaming guide are all constructed from a sterilizable material, intended as single use disposable instruments and can be used as tools for the initial plan review (Figure 2).

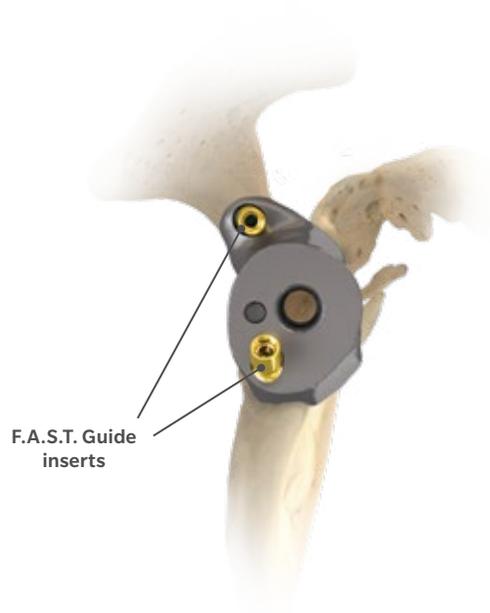


Figure 3

Screw Trajectory Planning

During the initial design of the VRS implant, a PMI case manager will prepare a plan detailing screw trajectories and estimated screw lengths. The PMI case manager will discuss with the surgeon any necessary modifications to the preoperative plan. Careful consideration should be given as to what type of screw trajectory is most appropriate for any given location in the preoperative planning stages, as well as intra-operatively. Factors to consider when selecting a screw for a given location include:

- Bone quality
- Bone depth
- Screw lengths
- Soft tissue and other anatomic structures in the screw vicinity
- Ability to gain adequate exposure to drill for the screw along the axis of the hole
- Relationship between the direction of physiological loading and the axis of the screw
- Desired screw compression
- Promotion of load sharing between the screw and backside of the implant

The Comprehensive VRS is pre-assembled with F.A.S.T. Guide[®] inserts (Figure 3) that are aligned for fixed screw trajectories and allows for easy drilling. F.A.S.T. guides come in two colors to distinguish proper locations to use for initial fixation of the implant with shortened wires. Gold F.A.S.T. Guide inserts are placed strategically for fixation prior to central screw placement while the green F.A.S.T. Guide inserts mark where additional peripheral screws will be placed.

Non-Locking Screw



Figure 4

Fixed Locking Screw



Figure 5

Central Screw

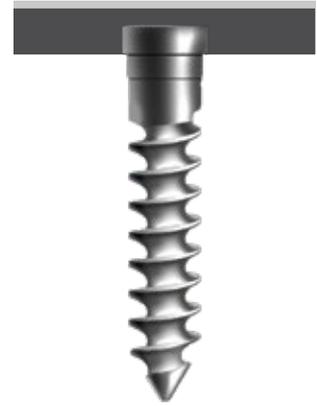


Figure 6

Screw Trajectory Planning (cont.)

All peripheral screw holes accept the 4.75 mm fixed locking and 4.75 mm fixed non-locking screws ranging from 15 mm to 45 mm in length in 5 mm increments. **Non-locking screw trajectories will match the pre-operative plan and will not be designed to have six degrees of angulation built in (Figure 4).**

Locking screws can only be drilled for and inserted along the fixed axis of the threads (Figure 5). Pre-assembled F.A.S.T. Guide inserts are aligned for fixed screw trajectories.

The central screw hole will accept the standard Comprehensive 6.5 mm central compression screw ranging from 20 mm to 50 mm length in 5 mm increments (Figure 6).

ZIMMER BIOMET
FRM022040 VAULT RECONSTRUCTION SYSTEM (VRS) PROPOSAL REV 1

Today's Date:	Side:	Case Number:	Revision:
Patient Name:	Physician Name:		
Patient ID:	Engineer Name:		

The devices below will be provided by PMI:

Part Numbers:	Part Description:	Materials:
110027734	Comprehensive VRS Glenoid with F.A.S.T. guides assembled (sterile)	Ti-6Al-4V and Porous Coat
110031378	Comprehensive VRS Mini Taper Adaptor (sterile)	Ti-6Al-4V
110019066	Comprehensive VRS bone and implant model (non-sterile, but can be sterilized)	Polyamide

Note: VRS implant and models expire 6 months after date of manufacture

Implant Image:



Additional Comments:

All other implants and instruments must be arranged & provided by distributorship including but not limited to:

- 6.5mm Central Screws and 4.75mm Peripheral Screws
- Comprehensive VRS looser set 110030060 L (SMS) or 999101
- 110028045 – VRS 2.7mm 4” drill bits QTY: 2
- Comprehensive Reverse and Comprehensive Reverse Mini Instrument Set
- Comprehensive Reverse Implants

Technique(s):

- Comprehensive Vault Reconstruction System (VRS) Surgical Technique (0469.1-US-en)
- Bone removal may be necessary
- Additional information on specific technique for this case will be provided on FRM022042 Final Design Notice Vault Reconstruction System (VRS).

Warning(s):

- *If there is anything currently in the glenoid that could cause discrepancies during CT reconstruction or additional bone loss during removal, the VRS may not fit as designed. Please consider a two stage to remove the glenoid component before the design of the VRS.*

ZIMMER BIOMET
FRM022040 VAULT RECONSTRUCTION SYSTEM (VRS) PROPOSAL REV 1

- Patient anatomy may change over time. It is the operating physician's responsibility to determine if the implant is suitable for the patient. It is recommended that if more than 6 months have passed between the original CT scan used for implant design and the surgery, an additional CT scan be conducted to confirm the anatomy.

I have reviewed the surgical technique and acknowledge any and all indications/contraindications/warnings above. I acknowledge that the device design was the result of engineering requirements and physician input, and all features are necessary for treatment of the patient by result of the collaborative design process.

Physician Signature:	Date:
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Reject – Do not sign above and please provide additional comments below or to the PMI Engineer:

Figure 7

Proposal Notification

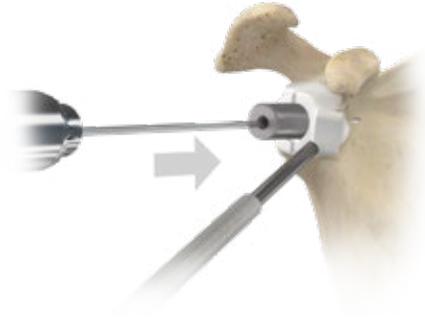
Upon review of the plan, the surgeon will receive a proposal notification describing the final implant specifications before the PMI team will manufacture the VRS implant (Figure 7).

Within the proposal notification, the surgeon will notice that the case manager has carefully laid out and described the details of the F.A.S.T. Guide trajectories, information and summaries on screw placement and provided a list of what instrumentation will be used to implant the Comprehensive VRS.

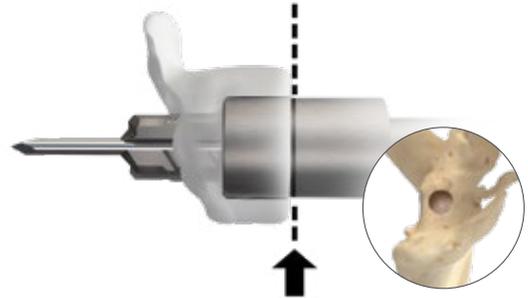


For implants with a boss

1. Place ream guide and central pin



2. Ream glenoid until reamer bottoms out on guide

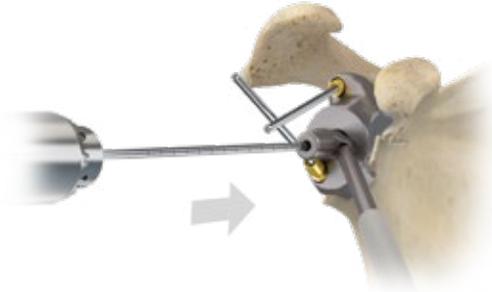


For all implants

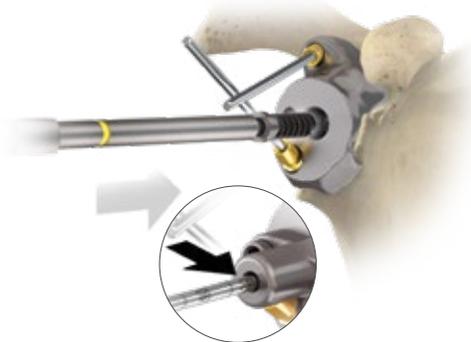
3. Place glenoid implant



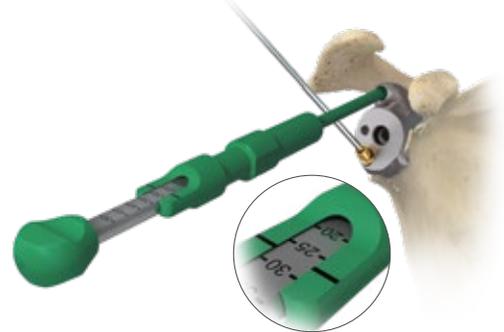
4. Insert peripheral drills and drill central hole



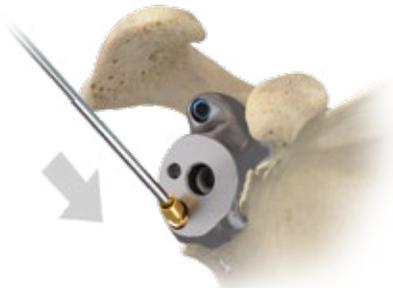
5. Insert central screw



6. Remove F.A.S.T. Guides and drill peripheral holes

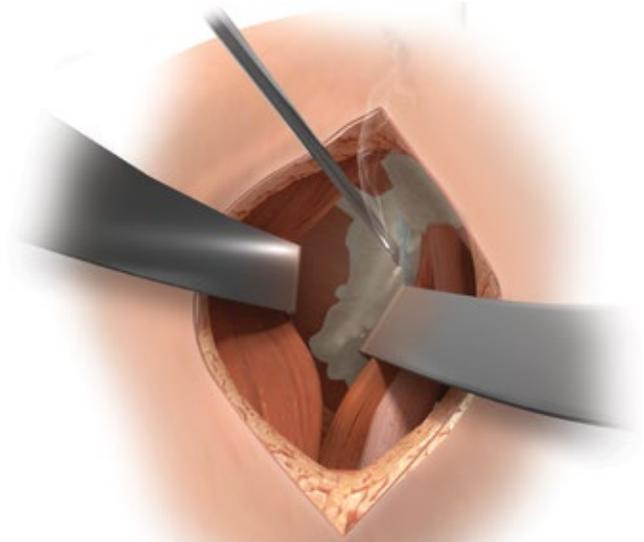
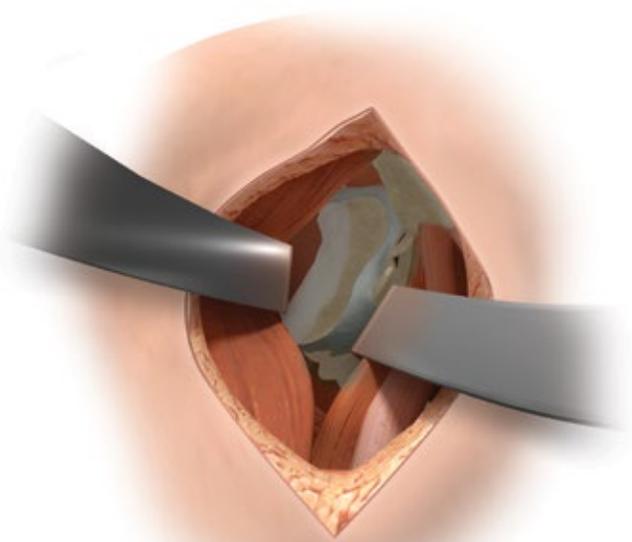


7. Insert peripheral screws



8. Insert and impact glenosphere





Glenoid Preparation (For implants with Mini Baseplate outer boss geometry)

***If boss removal is not required, see page 15.**

Once visualization of the glenoid is achieved, prepare the anatomy and remove as much soft tissue in and around the glenoid as needed to allow for optimal Comprehensive VRS central boss reaming guide fit and placement. Specifically, remove the entire capsulolabral complex on the anterior and inferior rim of the glenoid, approximately 1 to 7 o'clock on a right shoulder, however, patient anatomies and soft tissue removal will vary. If the capsulolabral complex has been eroded away, remove any remaining scar tissue without disturbing the underlying bone stock.

ⓘ **Note:** Comprehensive VRS central boss reaming guides and implants are designed to register on the bony landmarks that were previously referenced to build them. The reaming guide was designed with a thumb pad, or pressure point, to help align the guide when direct thumb pressure is applied to this point on the guide. Be sure to provide sufficient superior/posterior directed pressure when securing the guide. The reaming guide will fit firmly on the glenoid if the soft tissue is sufficiently removed and will not toggle once correct placement is found. If the placement of the reaming guide is not firm, it may be necessary to remove additional soft tissue or superficial bone until the reaming guide is secure on the glenoid.

ⓘ **Note:** The provided patient specific bone model can serve as an excellent reference for adequate soft tissue removal.



Figure 8

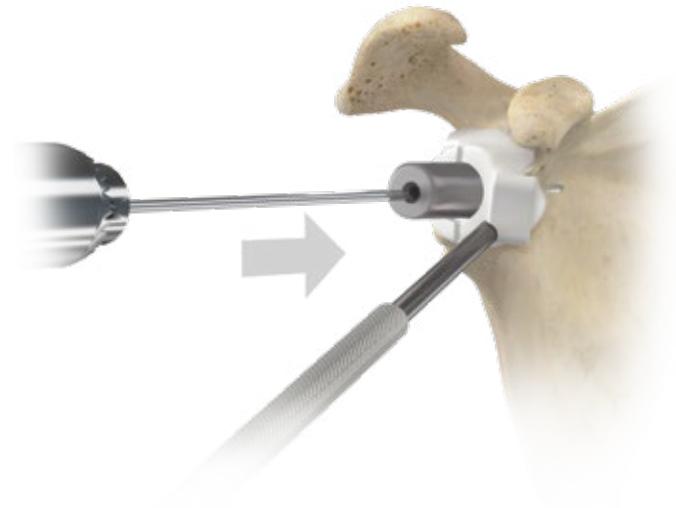


Figure 9

Glenoid Preparation (For implants with Mini Baseplate outer boss geometry) (cont.)

Attach the threaded glenoid guide handle to the Comprehensive VRS central boss reaming guide. **Great care should be taken to retain all pathologic bone stock and not to violate the bony structures referenced by the boss reaming guide.** Any changes to the anatomy can alter the intended position of the boss reaming guide. The boss reaming guide will fit firmly on the glenoid and should not toggle when correct placement is established (Figure 8).

Place the Comprehensive VRS K-wire insert into the boss reaming guide. Introduce a 3.2 mm Steinmann pin into the Comprehensive VRS K-wire insert ensuring the pin engages or perforates the medial cortical wall (Figure 9). A completely secure Steinmann pin is essential to ensure the subsequent reamer has a stable cannula over which to ream. Remove the Comprehensive VRS K-wire insert in preparation for boss reaming.

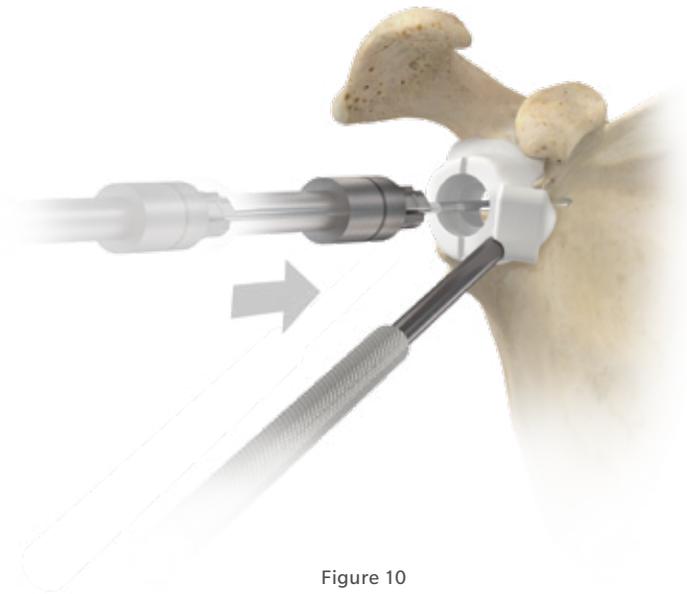


Figure 10

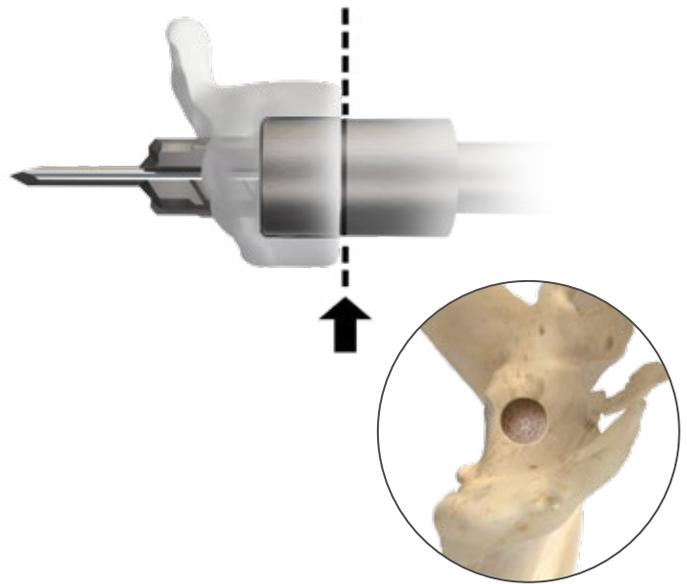


Figure 11

Boss Reaming

Position the cannulated central boss reamer over the Steinmann pin (Figure 10). Ream the glenoid until the reamer has bottomed out against the guide and the etch mark on the reamer is flush with the reaming guide (Figure 11). Remove the cannulated boss reamer, Steinmann pin, and boss guide.

ⓘ **Note:** Steinmann pin can remain in the glenoid to assist with implant placement, if desired.

ⓘ **Tip:** Delicate abrasion of the glenoid surface may be performed to enhance initial fixation. However, if the bone bed is delicate, the glenoid surface should not be abraded as this could alter implant fit. Subchondral bone should be preserved for support purposes.

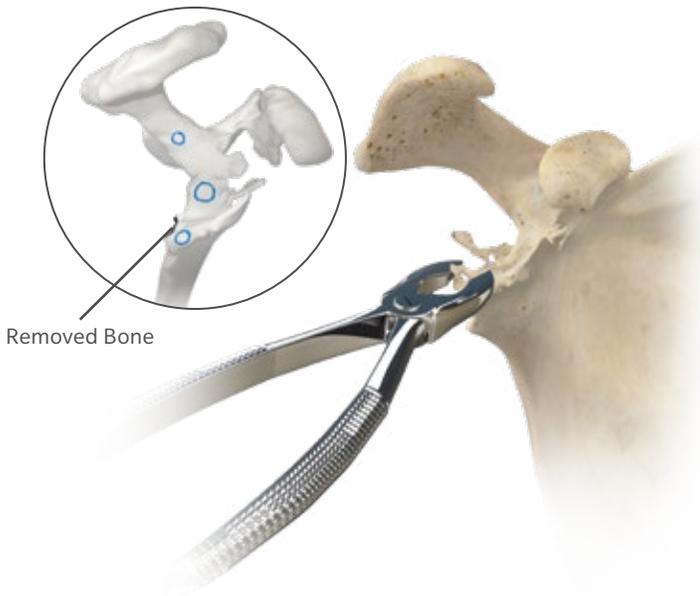


Figure 12



Figure 13

Excess Bone & Soft Tissue Removal

Bone will only be removed if determined necessary during preoperative planning. The bone model will be marked by the case manager, highlighting sections of bone that needs to be removed for proper implant seating. (Figure 12). **Great care should be taken not to violate the bony structures referenced by the bone model.**

It is also important to remove the appropriate amount of soft tissue to ensure proper placement and alignment of the Comprehensive VRS implant. Prepare the anatomy and remove as much soft tissue in and around the glenoid as needed to allow for optimal Comprehensive VRS implant fit and placement. Specifically, remove the entire capsulolabral complex on the anterior and inferior rim of the glenoid, approximately 1 to 7 o'clock on a right shoulder.

ⓘ **Note:** Comprehensive VRS implants are designed to register on the bony landmarks that were previously referenced to build them. The implant will fit firmly on the glenoid and will not toggle once correct placement is found.

ⓘ **Note:** The provided patient specific bone model can serve as an excellent reference for adequate soft tissue removal.

Glenoid Placement

ⓘ **Important:** It is recommended that the surgeon inspect the Comprehensive VRS implant and confirm the number of pre-assembled F.A.S.T. Guide inserts matches the number that was approved in the final design notification. Following the surgery, ensure all F.A.S.T. Guide inserts are removed, collected, and counted prior to screw insertion. Confirm the number of F.A.S.T. Guide inserts counted matches the number listed on the final design notification.

Apply saline or other appropriate lubrication to inserter tip o-ring which should aid in distraction of the Comprehensive VRS Inserter from the glenoid implant after insertion is complete. Place the Comprehensive VRS Glenoid onto the end of the inserter and use a 3.5 mm hex driver to secure the connection with the inserter screw (Figure 13). Attach the threaded handle to the inserter.

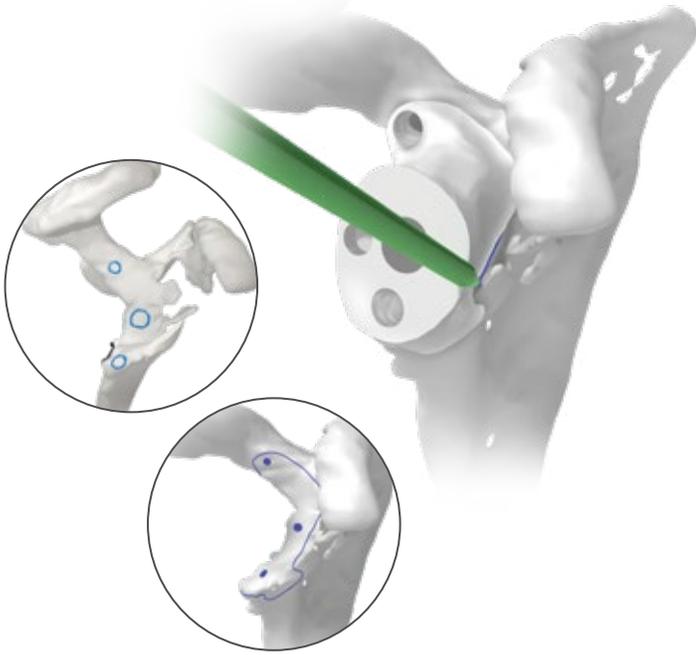


Figure 14

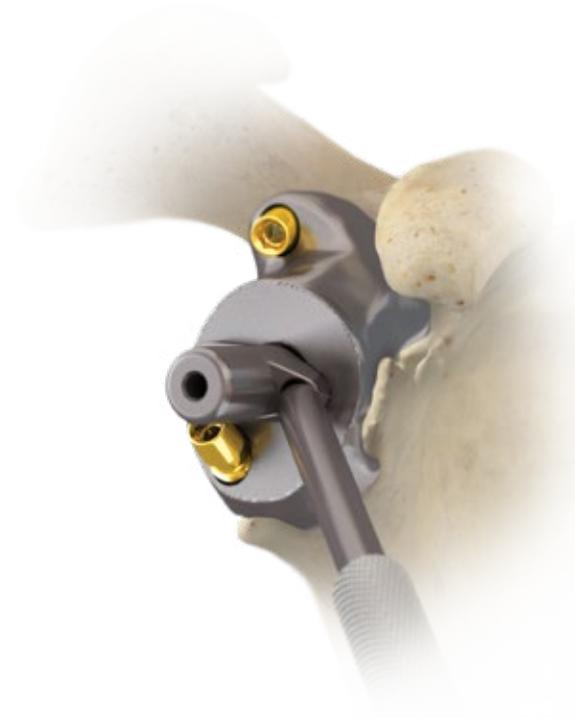


Figure 15

Glenoid Trialing

Position the Comprehensive VRS implant into the prepared glenoid cavity utilizing the anterior lip to assist with orientation and positioning (Figure 14). The implant will fit firmly on the glenoid and should not toggle when correct placement is established. Ensure screw trajectories and peripheral edge of implant correlate with the bone as portrayed on the bone model.

ⓘ **Note:** DO NOT screw the implant model into the glenoid.

Navigate the Comprehensive VRS implant into the prepared glenoid cavity utilizing the anterior lip to assist with orientation and positioning (Figure 15). The implant will fit firmly on the glenoid and should not toggle when correct placement is established. Reference the screw holes on the implant to align trajectories with planned screw placement.

Impaction is not recommended but, if necessary, can be performed lightly to assist with implant seating. The back of the glenoid component should be fully

seated onto the face of the glenoid surface. Visual confirmation can be attained by checking for gaps between the glenoid at the screw holes. The implant should be seated on the glenoid with no visible movement. A small nerve hook may aid in confirming complete seating of the component.

ⓘ **Note:** Comprehensive Reverse Mini impactor may be used over the K-wire on the Comprehensive VRS inserter to assist with light impaction.

Initial Glenoid Stability

In order to acquire initial implant stability, two or more 2.7 mm drills (4 or 6 inch length options) should be inserted, starting with the pre-assembled gold F.A.S.T. Guide inserts.

ⓘ **Note:** Gold-colored F.A.S.T. Guide inserts trajectories have been confirmed to not interfere with the inserter.

ⓘ **Note:** Verify that the two 2.7 mm drill bits achieve solid bone purchase before placement of the central compression screw.

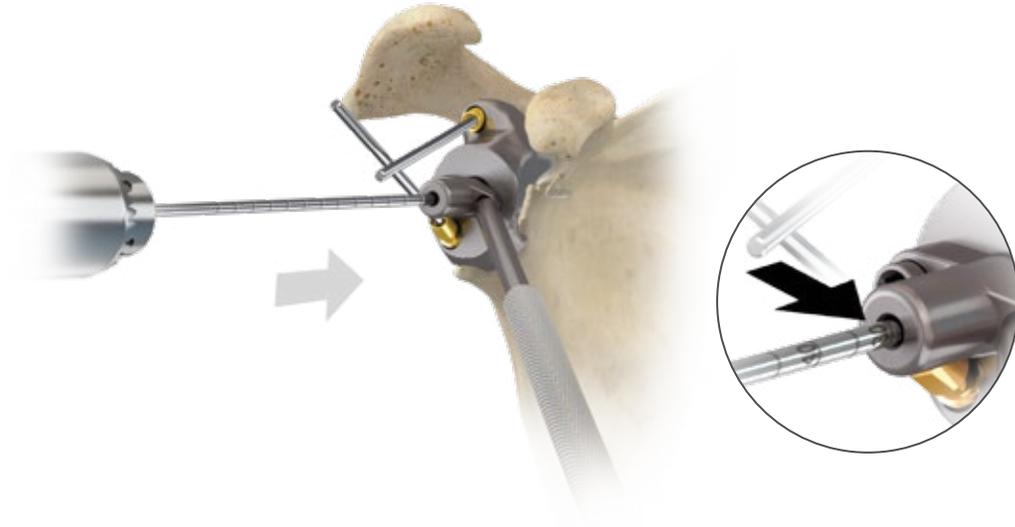


Figure 16

Central Screw Selection/Insertion

Use the central screw drill to drill a 3.2 mm diameter hole to the desired depth. Read the corresponding depth marking on the 3.2 mm diameter drill from the back of the Comprehensive VRS Inserter (Figure 16).

- Note:** A Comprehensive Mini Baseplate central screw depth gauge is included in the Comprehensive Mini Baseplate instrument set. However, in most cases, the F.A.S.T. Guide inserts will interfere with the central screw depth gauge. The measurement of the central screw should be taken from the back of the Comprehensive VRS Inserter.

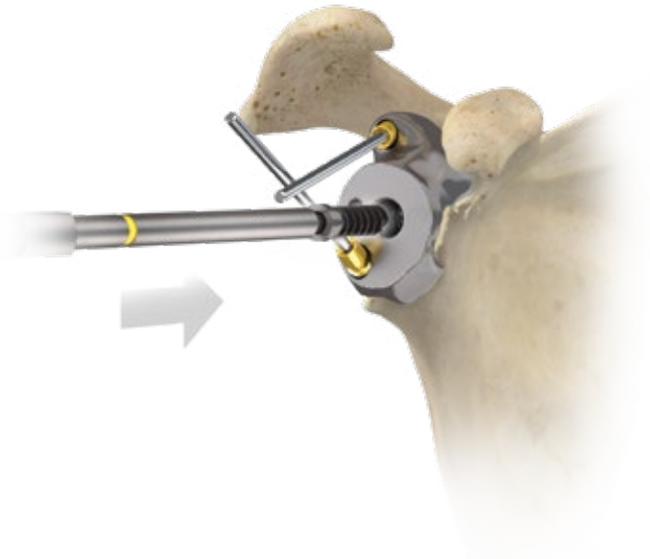


Figure 17

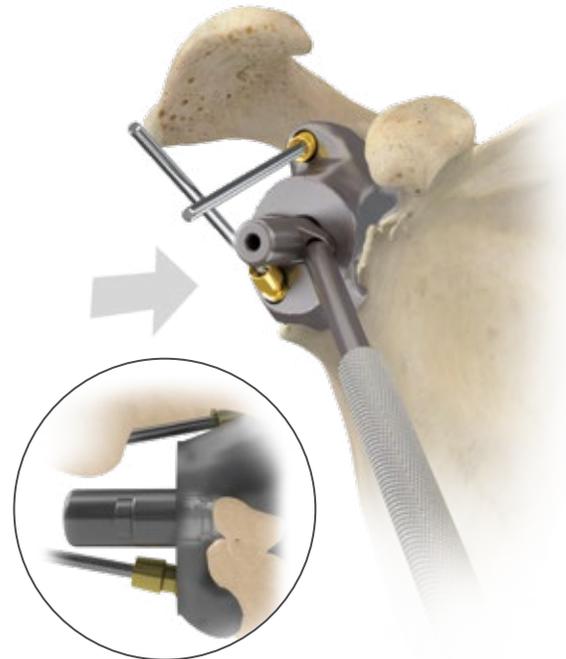


Figure 18

Central Screw Selection/Insertion (cont.)

Insert the desired length 6.5 mm central screw (Figure 17) and completely tighten with the 3.5 mm hex driver. To verify the 6.5 mm screw is fully seated into the implant, attach the Comprehensive VRS inserter to the guide handle and insert into the reverse Morse taper of the baseplate. If the inserter sits flush on the baseplate without rocking or toggling, the central screw is completely and correctly seated (Figure 18).

ⓘ **Note:** Pay close attention to initial implant placement. While tightening the 6.5 mm screw, do not allow implant to rotate.

ⓘ **Note:** If the guide does not sit flush, the central screw is not completely seated. Additional effort should be made to inspect for unwanted soft tissue or debris behind the screw head, then, fully seat the central screw. A fully seated central screw provides the best compression and fixation, as well as helps ensure that the male taper of the glenosphere will fully engage.

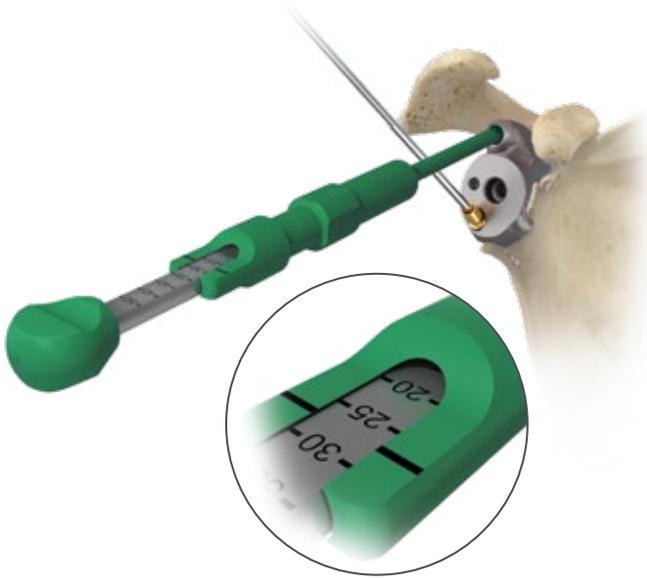


Figure 19

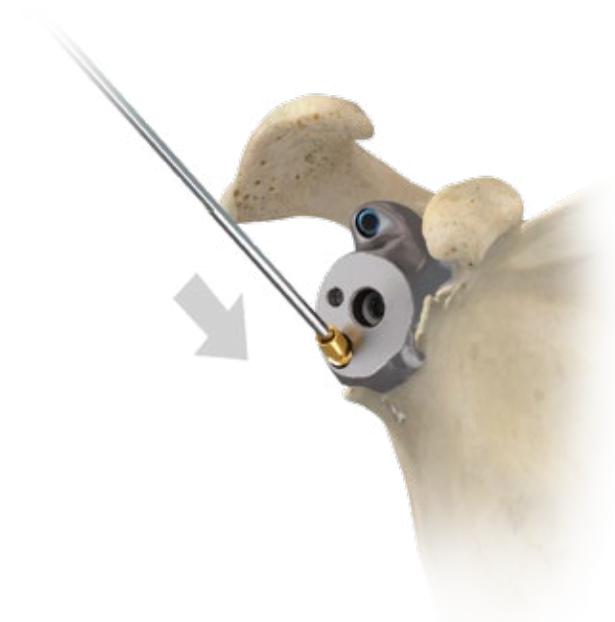


Figure 20

Peripheral Screw Selection/Insertion

Pre-assembled F.A.S.T. Guide inserts are designed to match the non-diverging trajectory of the locking screws. For peripheral screws, drill directly through the F.A.S.T. Guide inserts using the 2.7 mm drill bits (Figure 20).

For either screw type, completely remove the associated drill guide. Check the screw depth with the Comprehensive VRS peripheral screw depth gauge (Figure 19) and insert the corresponding peripheral screw with the 3.5 mm hex driver. Repeat until all peripheral screws are inserted and then fully tighten in an alternating fashion.

For glenosphere insertion, refer to the standard Comprehensive Reverse Shoulder System Surgical Technique. (0173.1-GLBL-en-REV1018)

- ⓘ **Note:** Screw trajectories will match the pre-operative plan and will not be designed to have six degrees of angulation built in.
- ⓘ **Note:** If using the F.A.S.T. Guide inserts or a fixed-angle threaded peripheral drill guide, either the locking or non-locking 4.75 mm peripheral screws may be used.
- ⓘ **Note:** Ensure all F.A.S.T. Guide inserts are removed, collected, and counted prior to screw insertion. Confirm the number of F.A.S.T. Guide inserts counted matches the number listed on the final design notice.

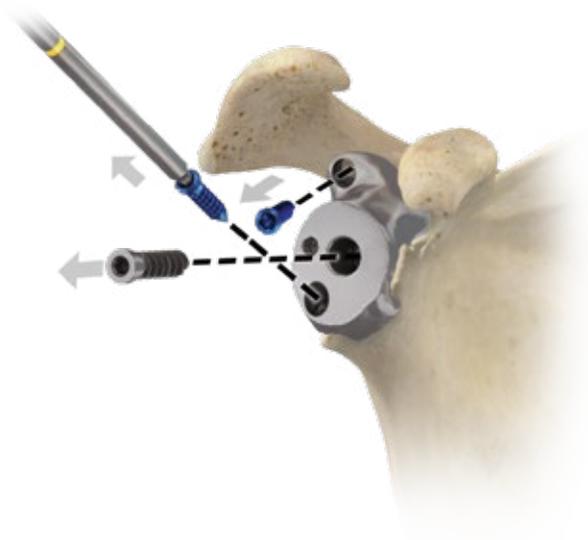


Figure 21

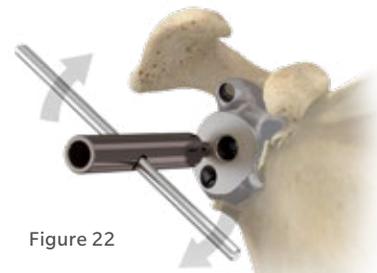


Figure 22



Figure 22a

Salvage Hemi-Arthroplasty

When converting from a Comprehensive VRS, the surgeon may choose a salvage hemi-arthroplasty for a patient. A salvage reverse to hemi-arthroplasty conversion may be accomplished without removing the Comprehensive stem.

Removal of VRS Glenoid

ⓘ **Note:** For glenosphere removal, refer to the standard Comprehensive Reverse Shoulder System Surgical Technique. (0173.1-GLBL-en-REV1018)

The peripheral and central screws should be removed with a 3.5mm hex driver (Figure 21). For removal of the VRS Glenoid, utilize the Comprehensive VRS extractor by threading it into the extractor hole on the implant (Figure 22). The extraction bar can be inserted into the extractor thru-hole and turned clockwise to tighten the extraction connection. Once secure, a slap hammer can be attached to the Comprehensive VRS extractor and used to remove the implant (Figure 22a). It may be desirable to use autograft/allograft material on the glenoid at this time, before proceeding to complete the salvage hemi-arthroplasty.

ⓘ **Note:** Bone/implant interface may be compromised due to poor bone quality.

Implants

Product	Description	Size	Part Number
	Comprehensive VRS Glenoid (PPS)		110027734
	Versa-Dial® Glenosphere Standard	36 mm	115310
	Versa-Dial Glenosphere +3 mm	36 mm	115313
	Versa-Dial Glenosphere +6 mm	36 mm	115316
	Versa-Dial Glenosphere Standard	41 mm	115320
	Versa-Dial Glenosphere +3 mm	41 mm	115323
	Versa-Dial Glenosphere +6 mm	41 mm	115326
	Versa-Dial Glenosphere Standard (Titanium)	36 mm	TI-115310
	Versa-Dial Glenosphere +3 mm (Titanium)	36 mm	TI-115313
	Versa-Dial Glenosphere +6 mm (Titanium)	36 mm	TI-115316
	Versa-Dial Glenosphere Standard (Titanium)	41 mm	TI-115320
	Versa-Dial Glenosphere +3 mm (Titanium)	41 mm	TI-115323
	Versa-Dial Glenosphere +6 mm (Titanium)	41 mm	TI-115326
	Humeral Tray Standard - Titanium	44 mm	115340
	Humeral Tray +5 mm - Titanium	44 mm	115345
	Humeral Tray +10 mm - Titanium	44 mm	115348
	Cobalt Chrome Standard Tray	44 mm	115370
	Cobalt chrome +5 Tray	44 mm	115375
	Cobalt chrome +10 Tray	44 mm	115378
	ArComXL® Standard Humeral Bearing	44-36 mm	XL-115363
	ArComXL +3 mm Humeral Bearing	44-36 mm	XL-115364
	ArComXL Retentive +3 Humeral Bearing	44-36 mm	XL-115365
	ArComXL Standard Humeral Bearing	44-41 mm	XL-115366
	ArComXL +3 mm Humeral Bearing	44-41 mm	XL-115367
	ArComXL Retentive +3 mm Humeral Bearing	44-41 mm	XL-115368
	E1® Standard Humeral Bearing	44-36 mm	EP-115393
	E1 +3 mm Humeral Bearing	44-36 mm	EP-115394
	E1 Retentive +3 mm Humeral Bearing	44-36 mm	EP-115395
	E1 Standard Humeral Bearing	44-41 mm	EP-115396
	E1 +3 mm Humeral Bearing	44-41 mm	EP-115397
	E1 Retentive +3 mm Humeral Bearing	44-41 mm	EP-115398

Implants (cont.)

Product	Description	Size	Part Number
	Comprehensive Humeral Stem - Micro	4 mm	113604
	Comprehensive Humeral Stem - Micro	5 mm	113605
	Comprehensive Humeral Stem - Micro	6 mm	113606
	Comprehensive Humeral Stem - Micro	7 mm	113607
	Comprehensive Humeral Stem - Micro	8 mm	113608
	Comprehensive Humeral Stem - Micro	9 mm	113609
	Comprehensive Humeral Stem - Micro	10 mm	113610
	Comprehensive Humeral Stem - Micro	11 mm	113611
	Comprehensive Humeral Stem - Micro	12 mm	113612
	Comprehensive Humeral Stem - Micro	13 mm	113613
	Comprehensive Humeral Stem - Micro	14 mm	113614
	Comprehensive Humeral Stem - Micro	15 mm	113615
	Comprehensive Humeral Stem - Micro	16 mm	113616
	Comprehensive Humeral Stem - Micro	17 mm	113617
	Comprehensive Humeral Stem - Micro	18 mm	113618
	Comprehensive Humeral Stem - Micro	19 mm	113619
	Comprehensive Humeral Stem - Micro	20 mm	113620
	Comprehensive Humeral Stem - Mini	4 mm	113624
	Comprehensive Humeral Stem - Mini	5 mm	113625
	Comprehensive Humeral Stem - Mini	6 mm	113626
	Comprehensive Humeral Stem - Mini	7 mm	113627
	Comprehensive Humeral Stem - Mini	8 mm	113628
	Comprehensive Humeral Stem - Mini	9 mm	113629
	Comprehensive Humeral Stem - Mini	10 mm	113630
	Comprehensive Humeral Stem - Mini	11 mm	113631
	Comprehensive Humeral Stem - Mini	12 mm	113632
	Comprehensive Humeral Stem - Mini	13 mm	113633
	Comprehensive Humeral Stem - Mini	14 mm	113634
	Comprehensive Humeral Stem - Mini	15 mm	113635
	Comprehensive Humeral Stem - Mini	16 mm	113636
	Comprehensive Humeral Stem - Mini	17 mm	113637
	Comprehensive Humeral Stem - Mini	18 mm	113638
	Comprehensive Humeral Stem - Mini	19 mm	113639
	Comprehensive Humeral Stem - Mini	20 mm	113640

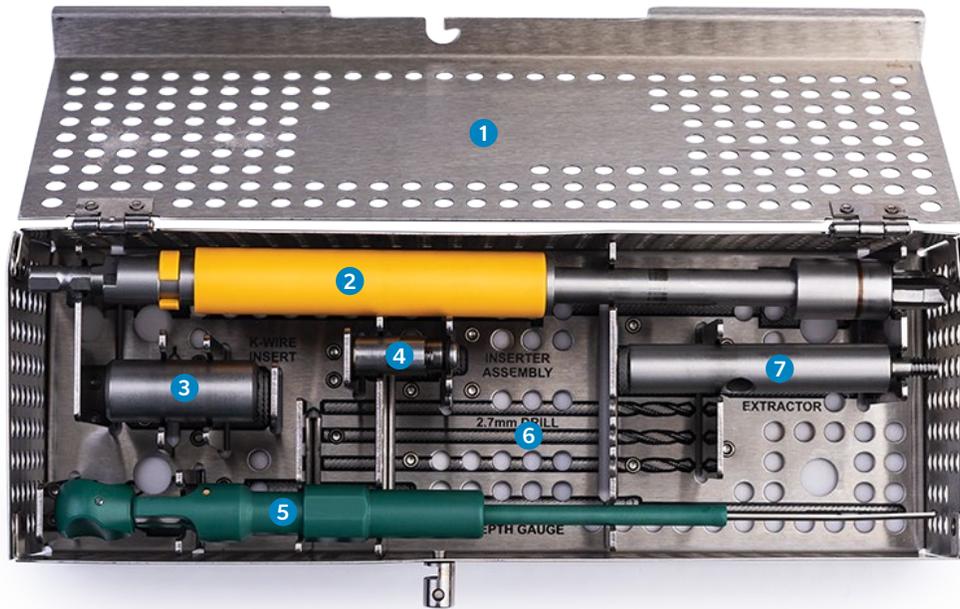
Implants (cont.)

Product	Description	Size	Part Number
	Comprehensive Humeral Stem - Standard	4 mm	113644
	Comprehensive Humeral Stem - Standard	5 mm	113645
	Comprehensive Humeral Stem - Standard	6 mm	113646
	Comprehensive Humeral Stem - Standard	7 mm	113647
	Comprehensive Humeral Stem - Standard	8 mm	113648
	Comprehensive Humeral Stem - Standard	9 mm	113649
	Comprehensive Humeral Stem - Standard	10 mm	113650
	Comprehensive Humeral Stem - Standard	11 mm	113651
	Comprehensive Humeral Stem - Standard	12 mm	113652
	Comprehensive Humeral Stem - Standard	13 mm	113653
	Comprehensive Humeral Stem - Standard	14 mm	113654
	Comprehensive Humeral Stem - Standard	15 mm	113655
	Comprehensive Humeral Stem - Standard	16 mm	113656
	Comprehensive Humeral Stem - Standard	17 mm	113657
	Comprehensive Humeral Stem - Standard	18 mm	113658
Comprehensive Humeral Stem - Standard	19 mm	113659	
Comprehensive Humeral Stem - Standard	20 mm	113660	
	Comprehensive Humeral Stem – Fracture PPS	4 mm	12-113554
	Comprehensive Humeral Stem – Fracture PPS	6 mm	12-113556
	Comprehensive Humeral Stem – Fracture PPS	8 mm	12-113558
	Comprehensive Humeral Stem – Fracture PPS	10 mm	12-113560
	Comprehensive Humeral Stem – Fracture PPS	12 mm	12-113562
	Comprehensive Humeral Stem – Fracture PPS	14 mm	12-113564
	Comprehensive Humeral Stem - Revision	4 mm	113664
	Comprehensive Humeral Stem - Revision	6 mm	113666
	Comprehensive Humeral Stem - Revision	8 mm	113668
	Comprehensive Humeral Stem - Revision	10 mm	113670
	Comprehensive Humeral Stem - Revision	12 mm	113672
	Comprehensive Humeral Stem - Revision	14 mm	113674

Implants (cont.)

Product	Description	Size	Part Number
	6.5 mm Central Screw 3.5 Hex	20 mm	115394
	6.5 mm Central Screw 3.5 Hex	25 mm	115395
	6.5 mm Central Screw 3.5 Hex	30 mm	115396
	6.5 mm Central Screw 3.5 Hex	35 mm	115397
	6.5 mm Central Screw 3.5 Hex	40 mm	115398
	6.5 mm Central Screw 3.5 Hex	45 mm	115399
	6.5 mm Central Screw 3.5 Hex	50 mm	115400
	4.75 mm Fixed Locking Screw 3.5 Hex	15 mm	180550
	4.75 mm Fixed Locking Screw 3.5 Hex	20 mm	180551
	4.75 mm Fixed Locking Screw 3.5 Hex	25 mm	180552
	4.75 mm Fixed Locking Screw 3.5 Hex	30 mm	180553
	4.75 mm Fixed Locking Screw 3.5 Hex	35 mm	180554
	4.75 mm Fixed Locking Screw 3.5 Hex	40 mm	180555
	4.75 mm Fixed Locking Screw 3.5 Hex	45 mm	180556
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	15 mm	180557
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	20 mm	180558
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	25 mm	180559
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	30 mm	180560
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	35 mm	180561
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	40 mm	180562
	4.75 mm Fixed Non-Locking Screw 3.5 Hex	45 mm	180563

VRS Instrument Set



	Description	Part Number
	1 Comprehensive VRS Instrument Loaner Set	999101 / 110030060_L
	2 Comprehensive VRS Central Boss Reamer	110019063
	3 Comprehensive VRS K-Wire Insert	110019065
	4 Comprehensive VRS Inserter	110019068
	5 Comprehensive VRS Depth Gauge	110028059
	6 Comprehensive VRS Short 2.7 mm Drills (ordered separately)	110028045
	7 Comprehensive VRS Extractor	110019067
	Comprehensive VRS Reaming Guide, Bone Model, and Implant Model (Patient-Specific)	110031178
	Comprehensive VRS Bone and Implant Model (Patient-Specific)	110019066
	Comprehensive VRS Mini Taper Adaptor (Sterile)	110031378
	Comprehensive VRS Glenoid with F.A.S.T. guides assembled (sterile)	110027734

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.

The Comprehensive Vault Reconstruction System glenoid baseplate components are intended for cementless application with the addition of screw fixation in patients with unusual anatomy and/or extensive bone loss which precludes the use of a standard glenoid baseplate component.

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.

Comprehensive Shoulder humeral stems 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.

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Check for local product registrations and product-specific instructions for use. See the package insert for each patient-specific product.

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