OsseoFit™ Stemless Shoulder System

Anatomic

Surgical Technique

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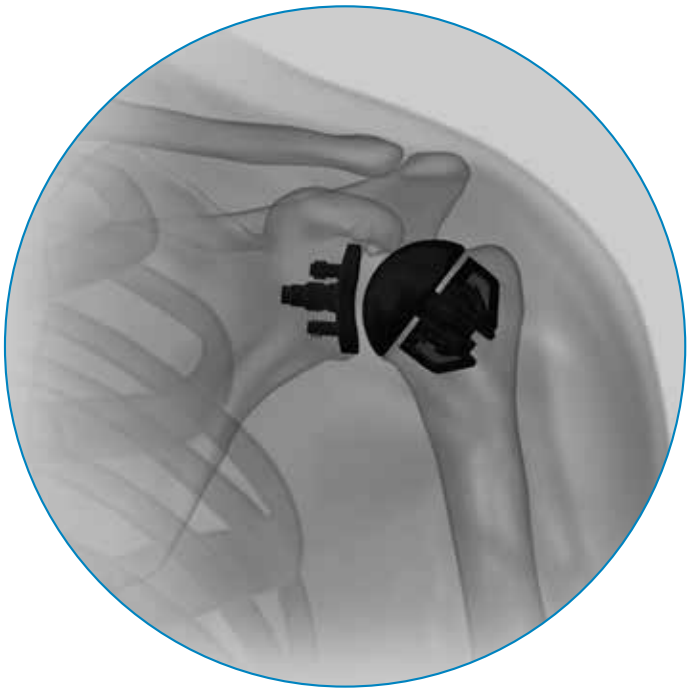
Table of Contents

Introduction

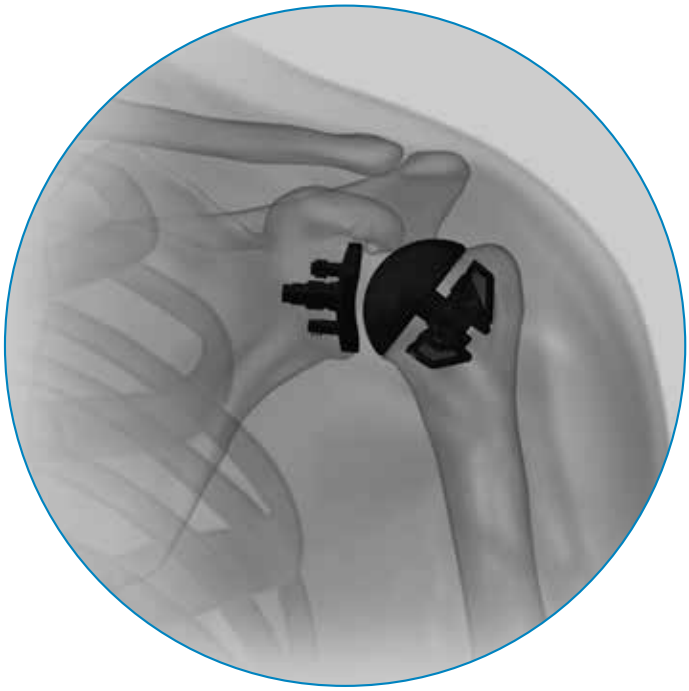
The OsseoFit™ Stemless Shoulder System is a versatile anatomic total shoulder. With a patient inspired fin design, backed by extensive humeral anatomy research, the OsseoFit System provides Left and Right specific implants to help maximize fixation while offering a bone-sparing solution. Five (5) implant sizes allow surgeons to meet a wide variety of patient anatomies, and each of these sizes offer an Inlay and Onlay design.

The OsseoFit Stemless Implants utilize OsseoTi® Porous Metal Technology, which mimics the architecture of human cancellous bone and is designed for stable and biological fixation[^1*]. Each fin on the stemless implant creates a press-fit during insertion and contains a fully porous window.

The OsseoFit Implant design features also include anterior suture holes to offer a solution to repair the subscapularis muscle. Instrumentation, cases and designated sports medicine kits were designed to simplify and complement the surgical workflow. This technique focuses on the surgical steps to implant the OsseoFit Stemless anatomic total shoulder.



Onlay Implant Design



Inlay Implant Design

1. Gupta, G. OsseoTi Porous Metal For Enhanced Bone Integration: an Animal Study. Biomet Form No. BMET0718.1-GBL.

*Animal studies are not necessarily indicative of clinical performance.

Indications & Contraindications

INTENDED USE
The OsseoFit Stemless Shoulder Implants are intended for shoulder joint arthroplasty.

INDICATIONS
Anatomic Total Shoulder applications:

- Osteoarthritis.
- The patient must be anatomically and structurally suited, as evident by scapula and proximal humerus closure, to receive the implants.

OsseoFit Stemless Shoulder Humeral Components have a porous surface and are indicated for uncemented biological fixation applications.

Compatible Glenoid components are intended to be implanted with bone cement. The porous posts may be inserted without bone cement.

Compatible Convertible 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, Sepsis, and Osteomyelitis.
- Inadequate humeral bone which may lead to poor implant fixation. Clinical examples where inadequate humeral bone may be observed include but are not limited to Osteoporosis, extensive Avascular Necrosis, Rheumatoid Arthritis, and Metaphyseal bony defects (including large cysts).
- Humeral bone fracture.
- Osteomalacia.
- Malunion or non-union of the tuberosities of the proximal humerus.
- Irreparable cuff tear.
- Revision of any stemmed or stemless prosthesis.
- Any neuromuscular disease compromising the affected limb.

SYMBOLS
Symbols have been established for the following:

SIZE	SZ
SMALL	S or SM
MEDIUM	MED
LARGE	LG
LEFT	LT
RIGHT	RT
SUPERIOR	SUP

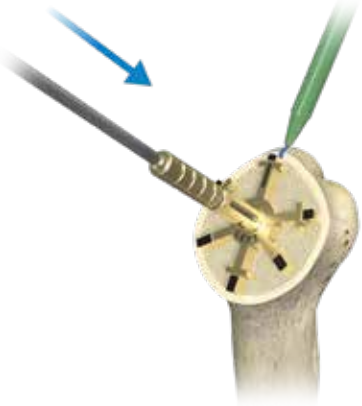
Please refer to the Instructions for Use and the package label for the products to be used with this Surgical Technique.

CE Mark in Surgical Technique is not valid unless there is a CE Mark on the product label.

Surgical Technique Summary

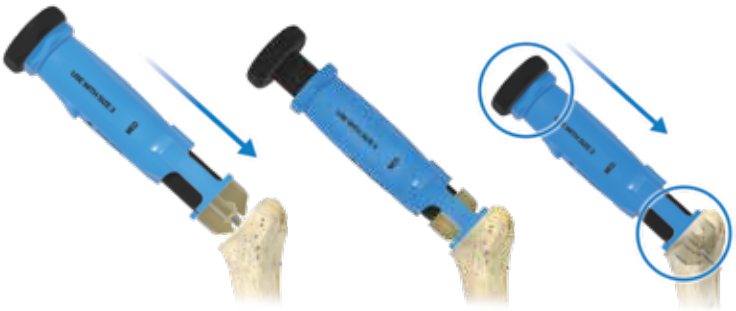
1. Humeral Head Resection

2. Humeral Protection During Glenoid Preparation

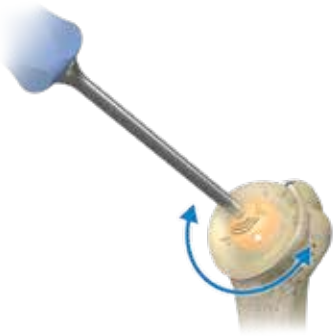


3. Humeral Sizing

4. Humeral Bone Preparation – Boss Reaming



5. Humeral Bone Preparation - Broaching



6. Humeral Head Trialing

7. Implant Insertion

8. Humeral Head Implantation

Figure 1

Pre-operative Considerations

Prior to surgery, obtain patient imaging to evaluate bony anatomy for any deformities or acquired bone loss. Recommended x-rays include A/P, scapular Y and axillary views. A CT scan can be used to assess bone quality and identify any humeral bone issues, which may affect implant selection. The system includes x-ray templates to estimate stemless humeral implant size prior to surgery.

Intra-operative Considerations

The patient must have adequate bone stock/quality to support the fixation of the implant. Final bone quality assessment is determined intra-operatively and therefore, preparations for a back-up stemmed prosthesis option should be considered prior to surgery.

Note: If performing a Lesser Tuberosity Osteotomy (LTO) to release the subscapularis, ensure there will be adequate bone stock available for subsequent implant seating.

Patient Positioning

Place the patient in a beach chair position on the edge of the the operating table (Figure 1). Extend the operative shoulder over the edge of the table so the arm can be brought into full extension and adduction. The use of the armrest is optional.

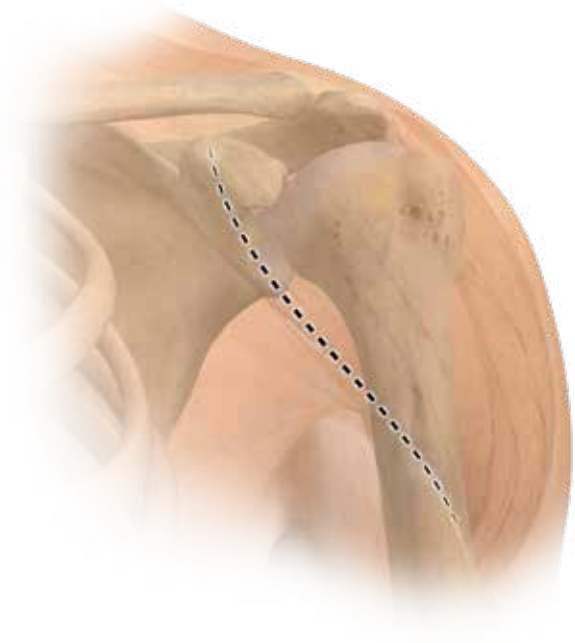


Figure 2

Figure 3

Initial Incision

Utilize an extended deltopectoral anterior incision with an optional biceps tenodesis beginning immediately above the coracoid process and extending distally and laterally, following the deltopectoral groove along the anterior border of the deltoid (Figure 2).

Laterally retract the deltoid muscle, identify the anterior structures and externally rotate the humerus. Release the subscapularis based on surgeon preference (Figure 3).

Note: If performing a Lesser Tuberosity Osteotomy (LTO) to release the subscapularis, ensure there will be adequate bone stock available for subsequent implant seating.

Externally rotate and extend the humerus to expose the humeral head, while protecting the axillary nerve.

Figure 4

Figure 5

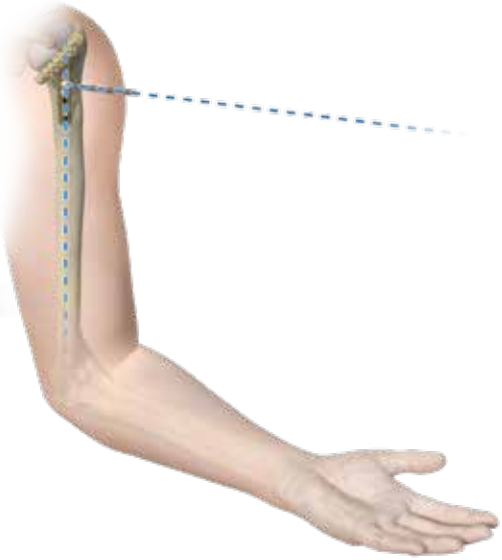


Figure 6

Humeral Head Resection

Expose the humeral head and identify the anatomic neck landmarks, removing any unwanted osteophytes to restore the humerus to near native anatomy and to reveal the articular margin. Two humeral head resection techniques are possible with Anatomic OsseoFit Stemless Shoulder Instrumentation:

- A Fixed Angle Resection targeting 135° inclination and 30° retroversion.
- An Anatomic Resection targeting the native inclination and version angles (Anatomic Resection Guide).

See Appendix 1 – Anatomic Humeral Head Resection for Anatomic Humeral Head Resection instructions.

Fixed Angle Resection:
Select the Extramedullary (EM) Resection Guide appropriate for the operative shoulder (Left/Right). Gold colored instrumentation (i.e., EM Resection Guide, Implant Sizers, and Humeral Broaches) are intended for use on Left operative shoulders (Figure 4). Insert the version rod into the 30° version hole on the Guide's Post. An additional threaded hole attachment is located at 0° version and is for reference only. Position the EM Resection Guide on the humerus so the Guide Post is aligned with the humeral shaft (Figure 5), ensuring the 30° version rod is aligned with the forearm flexed at 90° (Figure 6).

Figure 7

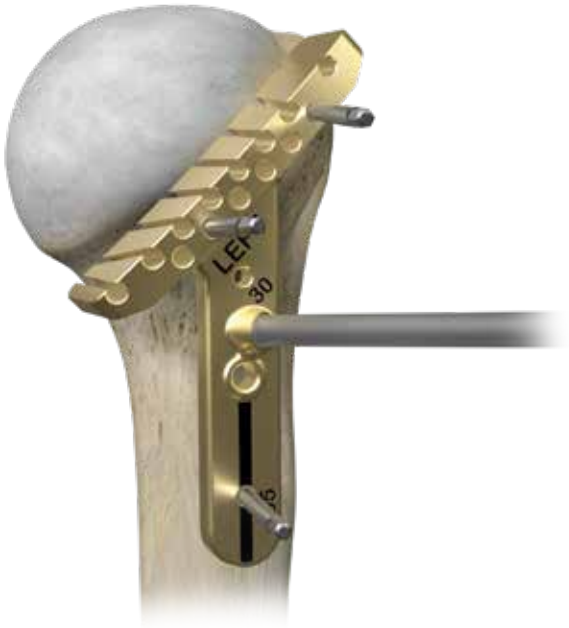


Figure 8

Humeral Head Resection (cont.)

Note: While establishing EM Resection Guide positioning, ensure the cutting path will not violate the supraspinatus and infraspinatus. If desired, an optional Tissue Probe may be used to check the cutting path/resection plane around the humerus prior to cutting (Figure 7).

The EM Resection Guide includes pin slots located on the guide's post (above or below the version rod threaded holes), at the cutting surface, and below the cutting surface (Figure 8). Use of the cutting surface pin slots can provide additional assistance to achieve a flush resection. Sterile, single-use Hex Pins of 70 mm and 100 mm lengths are available. Each box contains three (3) Hex Pins. Place a Hex Pin in the Hex Driver and insert the first Hex Pin through a pin slot located near the lateral edge of the EM Resection Guide. The first pin defines the humeral head resection version. Upon the first pin placement, check to ensure proper version was maintained.

Drive a second Hex Pin through a pin slot, targeting the medial portion of the head. The second pin defines the humeral head resection inclination. Place at least one additional Hex Pin to provide a sufficient and stable cutting surface across the entire proximal humerus. Additional pins may be placed for added stability.

Note: Inserting angled pins will provide EM Resection Guide stability during head resection. Ensure at least one pin is placed through an angled slot. Refer to Figure 9 on the next page for the straight and angled slot locations.

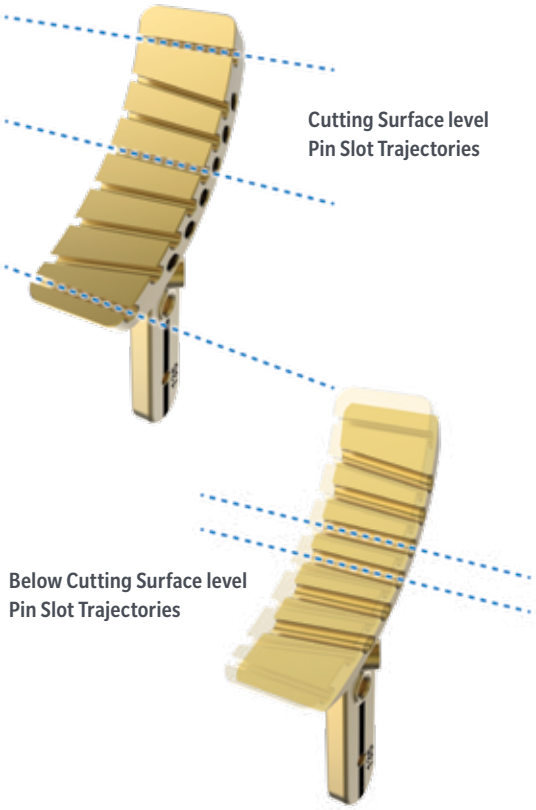


Figure 9

Figure 10

Figure 11

Humeral Head Resection (cont.)

Note: The lateral-most, center, and medial-most pin slots at the cutting surface have straight trajectories. The two center pin slots below the cutting surface also have straight trajectories (Figure 9). All straight trajectory pin holes are denoted by dotted lines in Figure 9 . All other pin slots at or below the cutting surface have an angled trajectory.

Resect the humeral head by cutting on top of the EM Resection Guide through the far side of the humeral head (Figure 10). A flush resection is important to ensure uniform contact with the Reference Foot to be used in subsequent surgical steps (Figure 11). Remove the EM Resection Guide and Hex Pins from the resected humerus.

Note: When using the cutting surface pin slots, a flush resection has been achieved when the Hex Pins are fully visible across the entirety of the resection surface. If the pins are not fully visible, resect enough bone to visualize them to ensure a flush resection in the targeted 135° inclination and 30° retroversion.

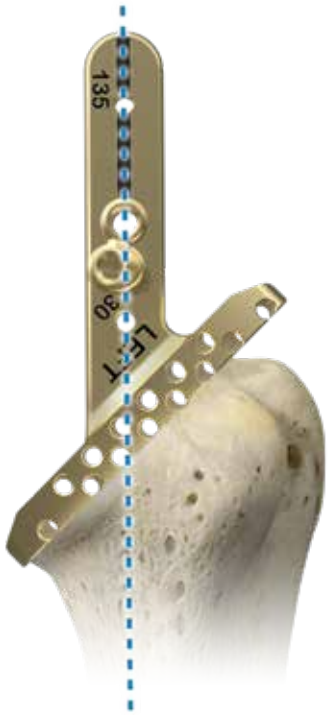


Figure 12

Humeral Head Resection (cont.)

Note: The resection angle's inclination of 135° may be verified by flipping the EM Resection Guide upside down and placing on top of the resection surface. The Guide Post should be aligned with the humeral shaft (Figure 12). If an adjustment to the resection is necessary, use the EM Resection Guide or Calcar Planer to perform the adjustment.

Figure 13

Figure 14

Perform Bone Quality Test

To assess the bone quality, use the pad of your thumb to press on the humerus in a direction that is perpendicular to the resected humeral surface (Figure 13). If you can depress your thumb into the humerus without much resistance, then primary stability of the stemless implant may be insufficient. In this case a stemmed prosthesis can provide more optimal fixation.

Glenoid Options

Prior to preparing the glenoid, utilize the Humeral Resection Covers by selecting the size that most closely fits the resection surface (Figure 14).

Reference the Alliance® Glenoid or Comprehensive® Convertible Glenoid Surgical Techniques on zimmerbiomet.com for glenoid preparation and implantation instructions.

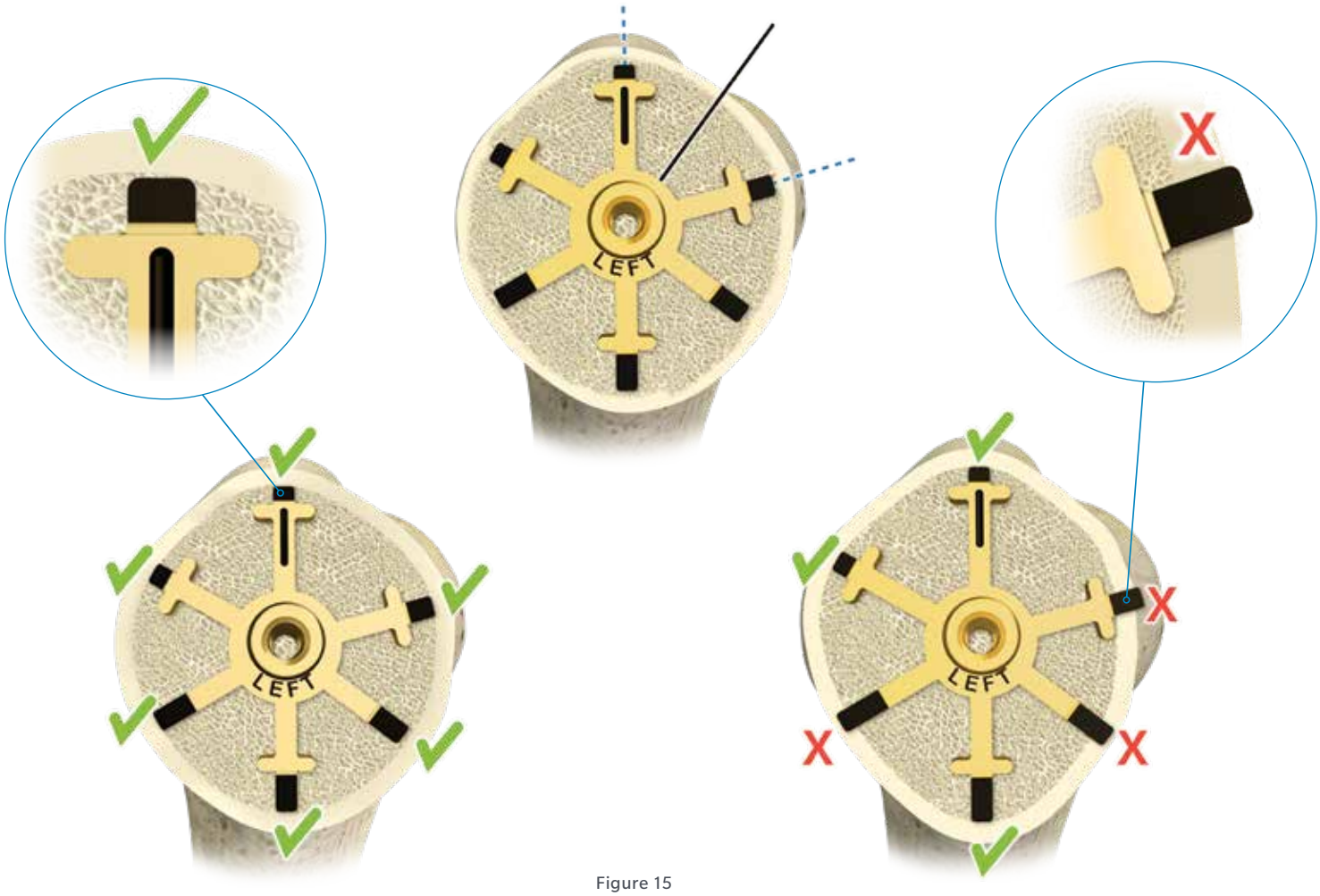


Figure 15

Humeral Sizing

After preparing the glenoid, remove the Humeral Resection Cover. The size of the OsseoFit Humeral Implant will be determined by laying a Humeral Sizer onto the resection surface.

The Humeral Sizer is designed to assist the surgeon in selecting the implant that optimizes fixation in the cancellous bone without violating the inner cortical rim.

Orient the Humeral Sizer so the bicipital groove bisects the Superior and Anterior Fins (Figure 15). The Gold regions (Silver Regions for right Humeral Sizers) of the Humeral Sizer match the corresponding Implant size exactly. The Humeral Sizer's extensions are designated by the black laser etched regions that extend beyond each fin. The Humeral Sizer that is completely contained in the cancellous bone without extending over the inner cortical rim is the appropriate size (Figure 15).

Note: If a Lesser Tuberosity Osteotomy (LTO) was performed to release the subscapularis, confirm there is adequate bone stock available for subsequent implant seating.

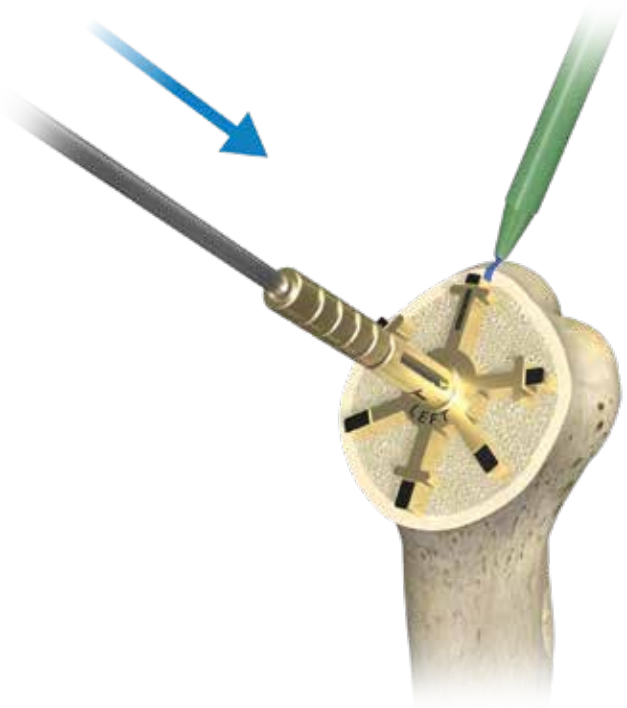


Figure 16

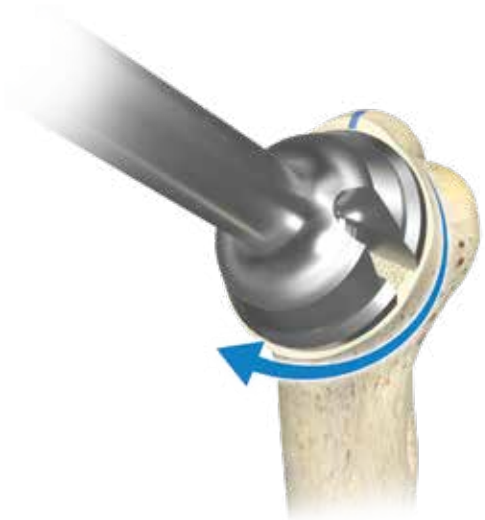


Figure 17

Humeral Sizing (cont.)

Note: Selecting a Humeral Sizer that exceeds the inner cortical rim, may result in impingement of the cortical wall with the final implant at or below the resection surface.

Insert the Central Steinmann Pin into the center of the Humeral Sizer, through the lateral cortex of the humerus. Mark the Humeral Sizer's superior fin location on the bone with a surgical marker (Figure 16).

Note: Avoid deep penetration of the lateral humeral cortex with the pin to avoid potential injury to the axillary nerve, as it courses around the lateral side of the humerus. A retractor (i.e., Brown Retractor) may be placed on the lateral side of the humerus to avoid potential injury to the axillary nerve. Once inserted, ensure that the soft tissue structures and instrumentation do not impinge against the Central Steinmann Pin and cause loosening within the cancellous bone.

Remove the Humeral Sizer, leaving the Central Steinmann Pin in place.

The size (i.e., Size 1, 2, etc.) of the Humeral Sizer used will correspond with subsequent size specific instrumentation and final implant.

Note: If desired, use the Calcar Planer to refine the resection surface. Attach the Planer Blade that most closely matches the diameter of the resection surface to the barrel of the Calcar Planer. Place the Calcar Planer over the Central Steinmann Pin and ensure rotation of the Calcar Planer prior to contacting bone. Apply slight pressure and plane the resection surface (Figure 17). Remove the Calcar Planer leaving the Central Steinmann Pin in place. Confirm the size of Humeral Sizer is still appropriate after planning.

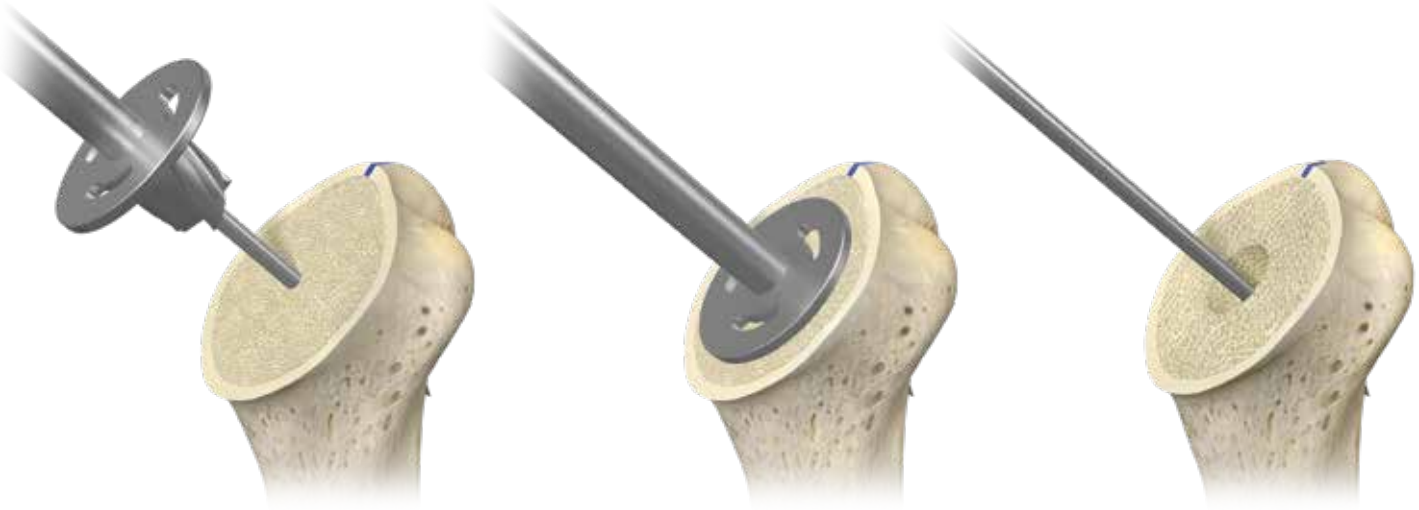


Figure 18

Humeral Bone Preparation

Using the Boss Reamer, ream over the Central Steinmann Pin until the reamer bottoms out on the resected surface (Figure 18).

Note: The Boss Reamer should be moving before it comes in contact with bone. Do not press on the bone after the reamer has bottomed out. Place a retractor on the lateral side of the humerus to avoid any potential injury to the axillary nerve.

Remove the Boss Reamer, leaving the Central Steinmann Pin in place.

Figure 19

Figure 21

Figure 20

Figure 22

Humeral Bone Preparation (cont.)

The Reference Foot must be assembled to the Broach Inserter properly to ensure the Broach is seated flush with the resection surface, while maintaining proper version and inclination angles. Considering the size of the Humeral Sizer previously used (i.e., Size 1, 2, etc.), select the appropriate size Reference Foot using Table 1, which provides the component size compatibility for each respective Reference Foot. Confirm both sides of the Reference Foot contact the cortical rim, with minimal overhang or underhang (Figure 19).

Table 1. Reference Foot Size Compatibility

Reference Foot Size	Component Size
Small (S)	Size 1
	Size 2
Medium (MED)	Size 3
Large (LG)	Size 4
	Size 5

Orient the Broach Inserter Alignment Rail with the selected Reference Foot Alignment Groove (Figure 20). Slide the Broach Inserter completely into the Reference Foot (Figure 21).

Select the Broach size corresponding to the Humeral Sizer used to place the Central Steinmann Pin. Align the Broach's superior fin with the superior indicator line on the Broach Inserter and push the Broach completely onto the assembly until it is flush with the Broach Inserter (Figure 22). The Broach Trunnion will engage with the corresponding recess on the Broach Inserter.

Figure 23

Figure 24

Figure 25

Figure 26

Humeral Bone Preparation (cont.)

After assembling the Broach, insert and slide the assembly over the Central Steinmann Pin until the Broach touches the resection surface (Figure 23). Next, slide the Reference Foot down until there is uniform contact with the resection surface (Figure 24).

Note: Ensure the Central Steinmann Pin does not move deeper during assembly and/or impactions. A retractor (i.e., Brown Retractor) may be placed on the lateral side of the humerus to avoid potential injury to the axillary nerve.

While maintaining alignment of the superior fin markings on the bone and assembly (Figure 25), impact the assembly until the Inserter Strike Plate bottoms out and is flush on the Reference Foot (Figure 26). This indicates the top surface of the Broach Fins are flush with the resection level.

During impaction, ensure the Reference Foot maintains uniform contact with the resection surface (i.e., not tilting in any direction) and does not subside into the bone.

Figure 27

Figure 28

Humeral Bone Preparation (cont.)

Optional: Prior to removing the Inserter-Reference Foot Assembly from the Broach, it may be helpful to mark the location of the Reference Foot's bottom inferior edge on the bone with a surgical marker (Figure 27). This marking can be useful for alignment, along with the superior fin markings during implant insertion.

Disengage the Inserter-Reference Foot Assembly from the Broach by axially pulling on the assembly. Next, remove the Central Steinmann Pin from the bone (Figure 28).

Note: The anti-rotation trunnion feature on the Broach will be proud of the resection surface. The top surfaces of the Broach Fins are intended to be flush with the resection (Figure 28).

Note: Set the Reference Foot aside as it will be used for subsequent definitive implant insertion.

Perform Broach Stability Test:
If the Broach is unstable after impaction, then primary stability of the stemless implant may not be sufficient. In this case, a stemmed prosthesis would provide more optimal fixation.

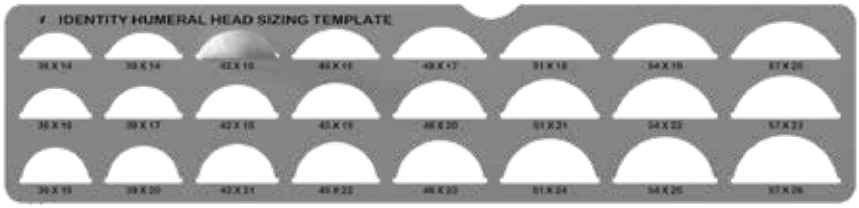


Figure 29

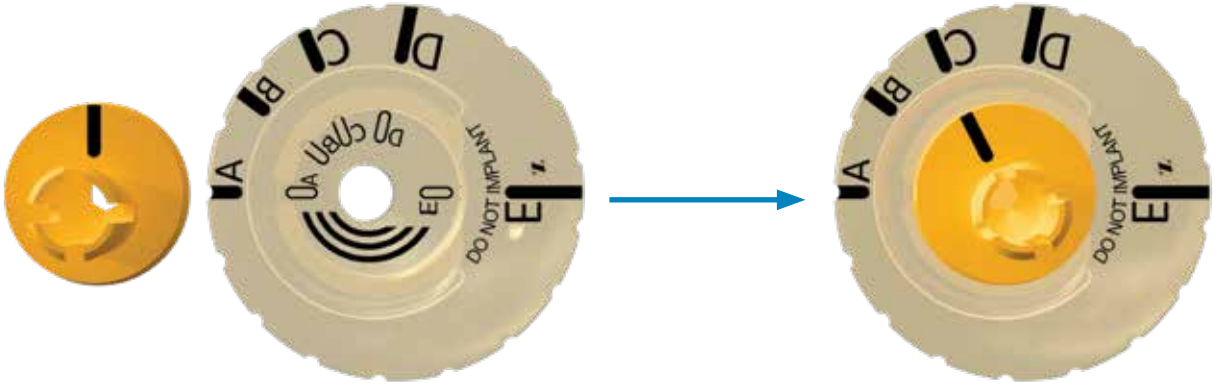


Figure 30a

Figure 30b

Humeral Head Trialing

Using the Humeral Head Sizing Template, determine the best size match by sliding the resected humeral head through the template slots (Figure 29). Pay particular attention to head height. Once the proper height has been determined, confirm the best diameter size match. Humeral heads come in varying heights for each of the eight different diameters. Alternately, use the resected humeral head and mate the resection surface to the underside of a Head Trial that best matches the head height and diameter.

Select the yellow plastic (radel) OsseoFit Humeral Head Offset Trial from the instrument set. To assemble the Offset Trial to the Identity Humeral Head Trial, turn the Head Trial upside down (Figure 30a). Place the Offset Trial into the Head Trial and push down by hand until it snaps in place (Figure 30b).

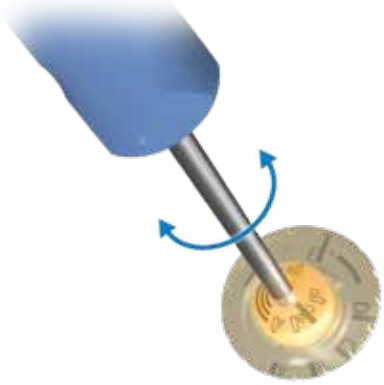


Figure 31

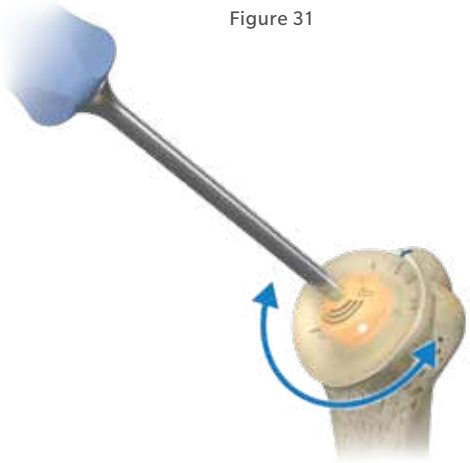


Figure 32

Figure 33

Figure 34

Humeral Head Trialing (cont.)

Turn the Humeral Head Trial assembly right side up. Using the Hex Driver through the hole in the articular surface, rotate the Offset Trial until the etch mark points to the letter "A" on the Head Trial. Note that offset letters are only on one side of the head trial. The other side has concentric semi-circle etch marks. Ensure the Offset Trial etch line is dialed on the side with letters (Figure 31).

Place the Humeral Head Trial assembly into the Broach until it is fully seated (Figure 33). Without touching the Head Trial, use the Hex Driver to rotate the trial assembly (both parts together) to see if it attains proper head coverage (Figure 32). Pay particular attention to ensure the superior portion of the head trial is above the superior portion of the greater tuberosity, and that it aligns to the anterior and posterior borders of the humeral resection.

If the Head Trial does not cover the resection surface on one side, then there is not enough offset. To increase the offset, hold the Head Trial in place while advancing the Offset Trial to a higher offset letter (i.e., "B", "C", "D", or "E"). Using only the Hex Driver, rotate the trial assembly (both parts together) until best fit is found.

If the Head Trial tends to "overhang" the resected bone (Figure 34), then there is too much offset. To reduce the offset, hold the Head Trial in place while using the Hex Driver to rotate the Offset Trial to a lower letter. Using only the Hex Driver, rotate the trial assembly (both parts together) until best fit is found. If the Head Trial will not rotate, check to ensure there is no bony prominence or soft tissue interference.

Figure 35

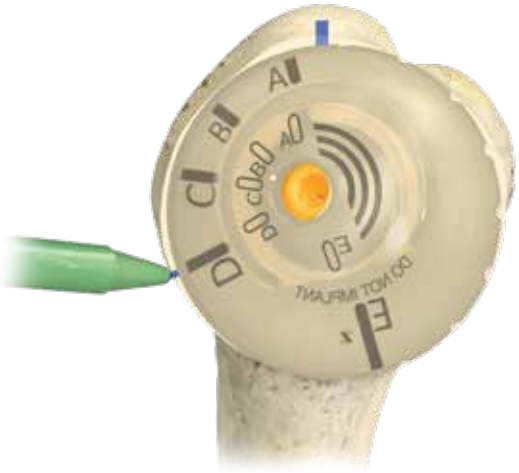


Figure 36

Figure 37

Humeral Head Trialing (cont.)

With the Head Trial in final position, reduce the joint and perform a trial range of motion.

Keeping the head trial assembly in final position, look through the translucent head trial to determine which letter ("A", "B", "C", "D" or "E") aligns with the Offset Trial etch mark (Figure 35). Keep in mind the etch mark can be between two letters. Mark the proximal humerus in line with the Offset Trial etch mark (Figure 36).

Remove the Head Trial assembly from the Broach.

To disassemble the Head Trial assembly, place the construct with the flat surface facing down over the Assembly Block concave cavity. Place the Hex Driver into the Offset Trial hex hole. Push down on the Hex Driver handle to disengage the Offset Trial (Figure 37).

Figure 38

Figure 39

Implant Insertion

After trialing, insert and engage the Slap Hammer with the Broach until the collar of the Slap Hammer bottoms out on the top surface of the Broach. Be sure to not overtighten the assembly once the collar has bottomed out. Lightly slide the handle of the Slap Hammer to remove the Broach from the humerus (Figure 38). During removal, use caution to ensure the Slap Hammer remains on-axis and there is no tilting to preserve the prepared bone.

Ensuring the tip of the Implant Inserter is clean and dry, orient and slide the Implant Inserter completely into the same Reference Foot size used for Broach insertion (Figure 39). See Table 2 below for reference. Select the implant size corresponding to the Broach size used to prepare the bone and the operative shoulder. Ensure the implant taper is clean and dry.

Table 2. Reference Foot Size Compatibility

Reference Foot Size	Component Size
Small (S)	Size 1
	Size 2
Medium (MED)	Size 3
Large (LG)	Size 4
	Size 5

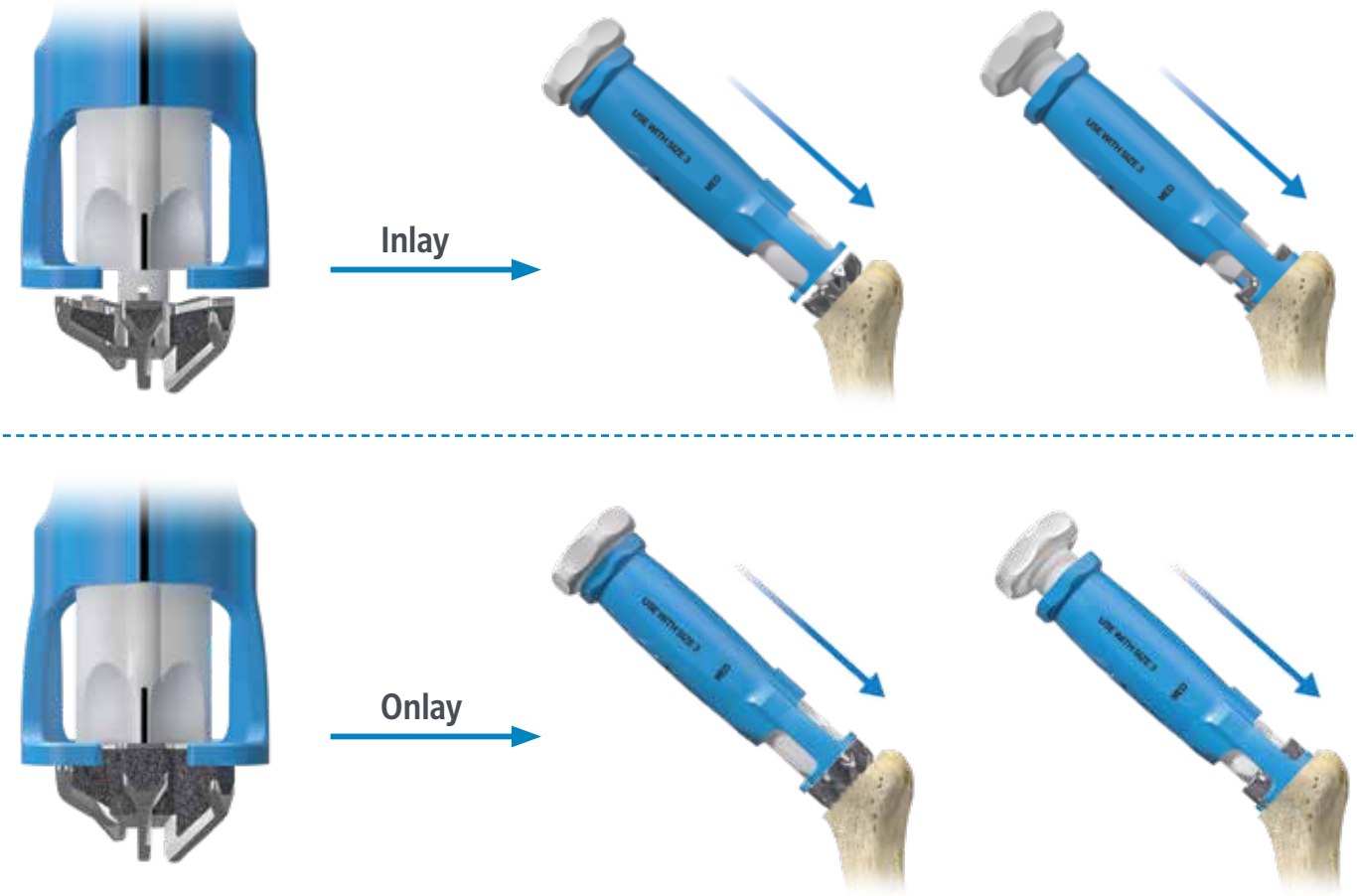


Figure 40

Implant Insertion (cont.)

Align the Implant's superior fin with the superior indicator line on the Implant Inserter. Push the Implant onto the Inserter until secure (Figure 40 Left).

Note: Only the top surface of the Onlay Implant will be flush with the inserter.

The Inlay Implant will **NOT** be flush and only needs to be pushed onto the Inserter until it is secure.

Introduce the assembly to the resection surface and engage the implant fins with the prepared bone cavity (Figure 40 Center). Once the Implant is engaged with the prepared bone cavity, slide the Reference Foot down until there is uniform contact with the resection surface (Figure 40 Right). Confirm the superior fin markings are aligned on the Reference Foot, implant and bone. If marked, confirm the location of the Reference Foot using the bottom inferior edge marking.

Figure 41

Figure 42

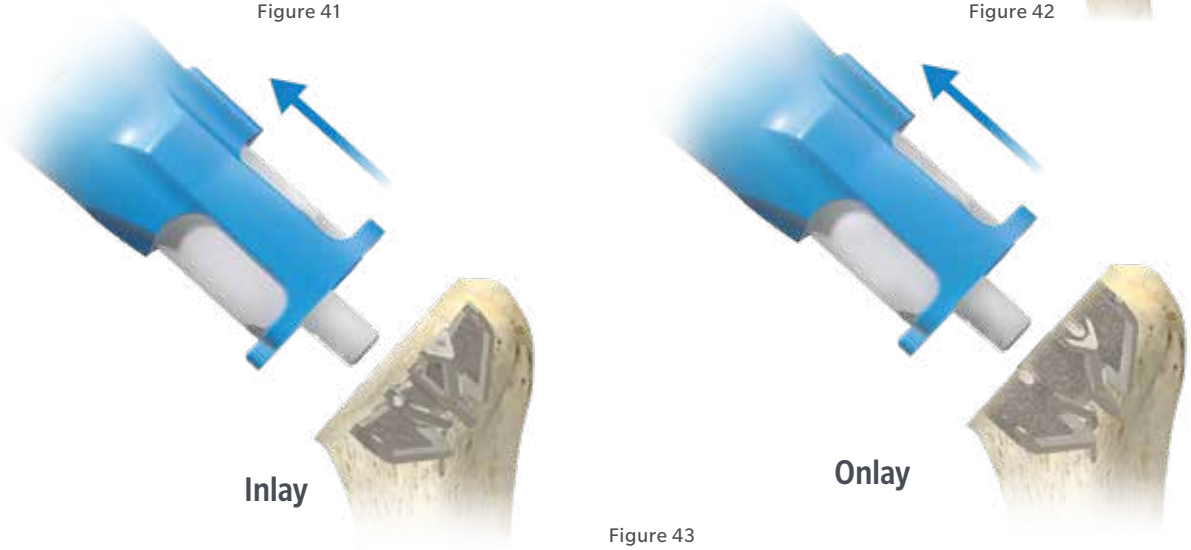


Figure 43

Implant Insertion (cont.)

While maintaining alignment of the superior fin markings on the bone and assembly (Figure 41), impact the assembly until the Inserter Strike Plate bottoms out and is flush on the Reference Foot (Figure 42). This indicates the implant has reached the appropriate seating depth.

During impaction, ensure the Reference Foot maintains uniform contact with the resection surface (i.e., not tilting in any direction) and does not subside into the bone.

To disengage the Inserter-Reference Foot Assembly from the implant, a small rotational force may be applied while axially pulling on the assembly (Figure 43).

Note: The center boss of the Onlay Implant will be slightly proud of the resection surface and the top surfaces of the Implant's fins will be flush with the resection (Figure 43 Right). The Inlay Implant will be below the resection surface (Figure 43 Left).

Figure 44

Figure 45

Humeral Head Implantation

To replicate the humeral head offset determined during trialing, reference the letter indicated from the Offset Trial. Select a Humeral Head Implant that matches the diameter and height of the final head trial used. On a sterile field table that provides rigid support, place the Humeral Head into the concave surface of the Impactor Base (Figure 44).

The Humeral Head Adapter Implant comes packaged with a Disposable Impactor. Prior to seating the Head Adapter into the Humeral Head, ensure the mating taper junctions are clean and dry. Rotate the Head Adapter so the etch mark aligns to the offset letter determined during trialing (Figure 44).

For example, if the Offset Trial etch mark points to "D," align the Head Adapter etch mark to point to "D." Or if the trial etch mark is in between "B" and "C," align the Head Adapter etch mark in between letters "B" and "C".

Assemble and impact the Disposable Impactor to seat the Humeral Head Adapter Implant into the Humeral Head (Figure 45).

Note: In the event the Humeral Head Adapter has been engaged in an incorrect position, a new Humeral Head Adapter and a new Humeral Head must be used.

Figure 46

Figure 47

Figure 48

Humeral Head Implantation (cont.)

Remove the assembled head from the Impactor Base. Use a marker to denote the chosen offset letter location on the articular surface (Figure 46). Be sure to clean and dry all taper junctions prior to assembly. Place the Humeral Head construct into the humeral taper opening of the OsseoFit Implant, with the chosen offset letter mark aligned to the mark previously made on the proximal humerus (Figure 47). Prior to impaction, confirm maximum coverage of the resected surface.

Place the Head Impactor on the Humeral Head in perpendicular alignment to the plane of resection. Visually confirm the presence of a small gap between the bottom of the Humeral Head and the resection surface. This small gap will be reduced through the final impactions. Using a Mallet, strike the Head Impactor at least twice until the Humeral Head is flush with the resection (Figure 48). Visually confirm uniform seating.

Note: The absence of a small gap, prior to impaction, between the bottom of the Humeral Head and the resection surface may suggest the implant has subsided too deeply. This may prevent proper taper assembly and a stemmed prosthesis may be recommended.

Figure A1.1

Figure A1.2

Figure A1.3

Figure A1.4

Appendix 1 – Anatomic Humeral Head Resection

Expose the humeral head and identify the anatomical neck landmarks, removing any unwanted osteophytes to restore the humerus to near native anatomy and to reveal the articular margin.

Assemble the Resection Guide by sliding the rectangular-shaped Anatomic Resection Guide Carriage onto the Anatomic Resection Guide Arm (Figure A1.1). The components are properly assembled when the single- and double-spike tips align towards each other. Place the single-spike tip at the posterior-lateral edge of the articular margin, being careful not to violate the supraspinatus insertion (Figure A1.2).

Note: The Anatomic Resection Guide Arm is not intended to rest on top of the humeral head.

Slide the Anatomic Resection Guide Carriage so that the flat surface of the double-spikes aligns to the articular margin, just anterior to the supraspinatus (Figure A1.3). Squeeze the Anatomic Resection Guide assembly together to ensure stable anterior and posterior contact with humeral bone.

Sterile, single-use Hex Pins of 70 mm and 100 mm lengths are available. Each box contains three (3) Hex Pins. Place a Hex Pin in the Hex Driver and insert it through the Anatomic Resection Guide pin hole until it reaches the far cortical wall (Figure A1.4). The first Hex Pin defines humeral resection version.

To disengage the Anatomic Resection Guide assembly from the Hex Pin, hold the Anatomic Resection Guide Arm with one hand while sliding off the Anatomic Resection Guide Carriage with the other hand. Leave the Hex Pin in the bone.

Figure A1.5

Figure A1.6

Figure A1.7

Figure A1.8

Appendix 1 – Anatomic Humeral Head Resection (cont.)

Select the Extramedullary (EM) Resection Guide appropriate for the operative shoulder (Left/Right). Gold colored instrumentation (i.e., EM Resection Guide, Implant Sizers, and Humeral Broaches) are intended for use on Left operative shoulders (Figure A1.5). Slide the lateral-most pin slot of the EM Resection Guide over the inserted Hex Pin until the EM Resection Guide contacts the humerus (Figure A1.6).

Note: While establishing EM Resection Guide positioning, ensure the cutting path will not violate the supraspinatus and infraspinatus. If desired, an optional Tissue Probe may be used to check the cutting path/resection plane around the humerus prior to cutting (Figure A1.6).

Pivot the EM Resection Guide about the lateral Hex Pin until the top of the cutting surface aligns with the articular margin (Figure A1.7). If necessary for best fit to the anterior humerus, disengage the EM Resection Guide from the Hex Pin and reposition it through a different pin slot near the lateral edge.

Note: The post of the EM Resection Guide may not align with the humeral shaft for an anatomic resection as it represents a 135° neck angle. Figure A1.8 shows an example of a patient's anatomic neck angle being greater than 135°.

Figure A1.9

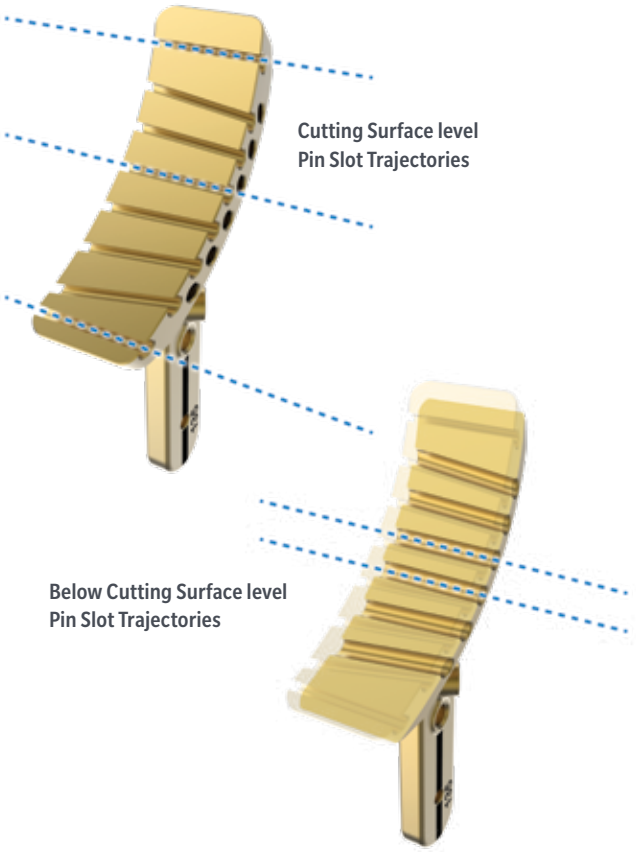


Figure A1.10

Appendix 1 – Anatomic Humeral Head Resection (cont.)

The EM Resection Guide includes pin slots located on the Guide Post (above or below the Version Rod Threaded Holes), at the cutting surface, and below the cutting surface (Figure A1.9). Use of the cutting surface Pin slots can provide additional assistance to achieve a flush resection. Once positioned, drive a second Hex Pin through a Pin slot, targeting the medial portion of the head. The second pin defines the humeral head resection inclination. Place at least one additional Hex Pin to provide a sufficient and stable cutting surface across the entire proximal humerus. Additional pins may be placed for added stability.

Note: Inserting angled pins will provide EM Resection Guide stability during head resection. Ensure at least one pin is placed through an angled slot.

Note: The lateral-most, center, and medial-most pin slots at the cutting surface have straight trajectories. The two center pin slots below the cutting surface also have straight trajectories (Figure A1.10). All straight trajectory pin holes are denoted by dotted lines in Figure A1.10. All other pin slots at or below the cutting surface has an angled trajectory.

Figure A1.11a

Figure A1.11b

Appendix 1 – Anatomic Humeral Head Resection (cont.)

Resect the humeral head by cutting on top of the EM Resection Guide through the far side of the humeral head (Figure A1.11a). A flush resection is important to ensure uniform contact with the Reference Foot to be used in subsequent surgical steps (Figure A1.11b). Remove the EM Resection Guide and Hex Pins from the resected humerus.

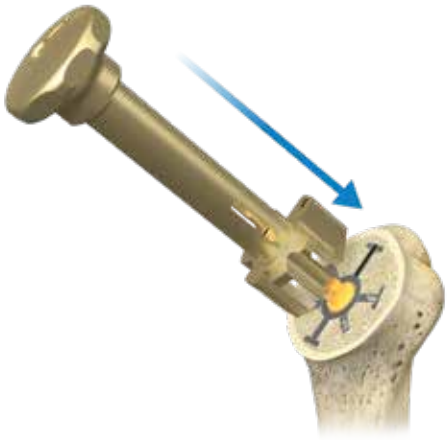
Note: When using the cutting surface pin slots, a flush resection has been achieved when the Hex Pins are fully visible across the entirety of the resection surface (see top pin in Figure A1.11b). If the pins are not fully visible, resect enough bone to visualize them to ensure a flush resection.

Proceed to "Perform Bone Quality Test" section above on Page 12.

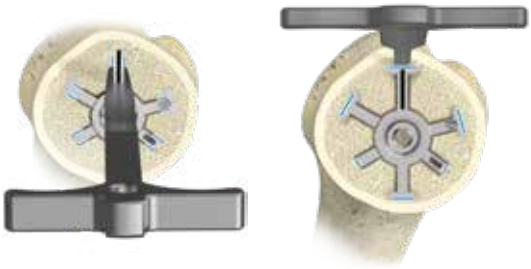
Appendix 2 - Revision Surgical Technique

Revision Surgical Technique Summary

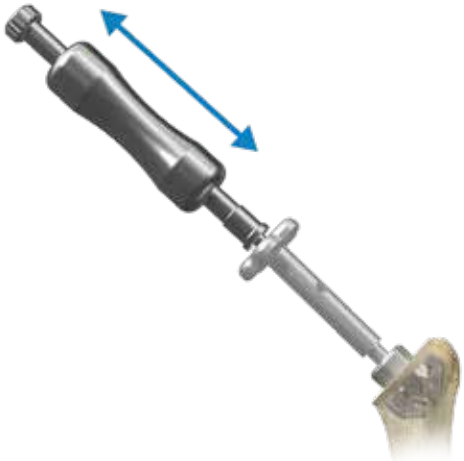
1. Humeral Head Removal



2. Freeing Implant-Bone Connections (Silhouette Cutter and Guide)



3. Freeing Implant-Bone Connections (Osteotomes)



4. Implant Extraction

Figure A2.1

Figure A2.2

Anatomic Revision Steps

Humeral Head Removal

Place the Humeral Head Remover Base between the under surface of the Humeral Head and the OsseoFit Humeral Head Adapter. Firmly tap the end of the instrument until contact with the taper adapter is achieved (Figure A2.1). Insert the Thin Humeral Fork into the back of the Humeral Head Remover Base and firmly tap the end of the instrument until the Humeral Head separates (Figure A2.2).

If the Thin Humeral Fork does not reach the underside of the Humeral Head, replace the Thin Humeral Fork with the Thick Humeral Fork, and firmly tap the end of the instrument until the Humeral Head separates.

Figure A2.3

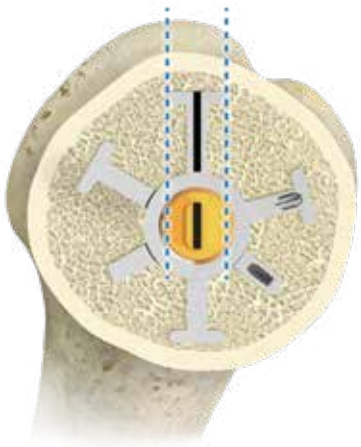


Figure A2.4

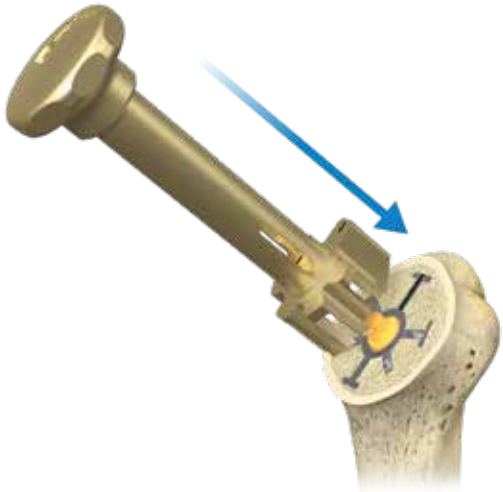


Figure A2.5

Freeing Implant-Bone Connections

After the Humeral Head has been removed from the implant, orient and insert the Silhouette Cutter Guide into the implant taper (Figure A2.3). The Silhouette Cutter Guide is secured within the implant taper via a press-fit connection, similar to the primary Broach and Implant Inserters. Ensure the etch mark on the Silhouette Cutter Guide aligns with the superior fin and marking of the implant (Figure A2.4).

Use Table A2.1 to identify the appropriate size Silhouette Cutter. Gold colored instrumentation (i.e., Silhouette Cutters) are intended for use on Left operative shoulders. If the implant size is unknown, use the Small Silhouette Cutter.

Table A2.1. Silhouette Cutter Size Compatibility

Silhouette Cutter Size	Implant Size
Small (S)	Size 1
	Size 2
Large (LG)	Size 3
	Size 4
	Size 5

Align the superior fin markings of the Silhouette Cutter, Silhouette Cutter Guide and implant. Advance the Silhouette Cutter over the Silhouette Cutter Guide by carefully impacting with a mallet (Figure A2.5).

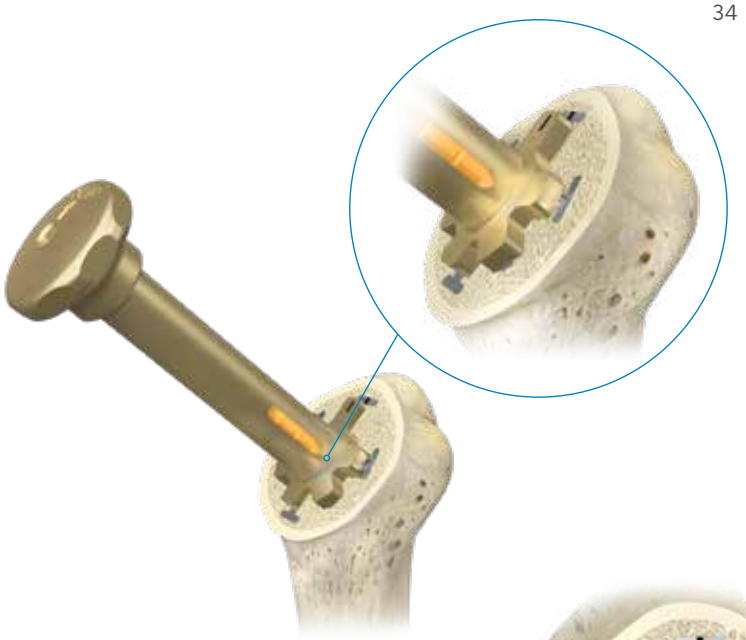


Figure A2.6a

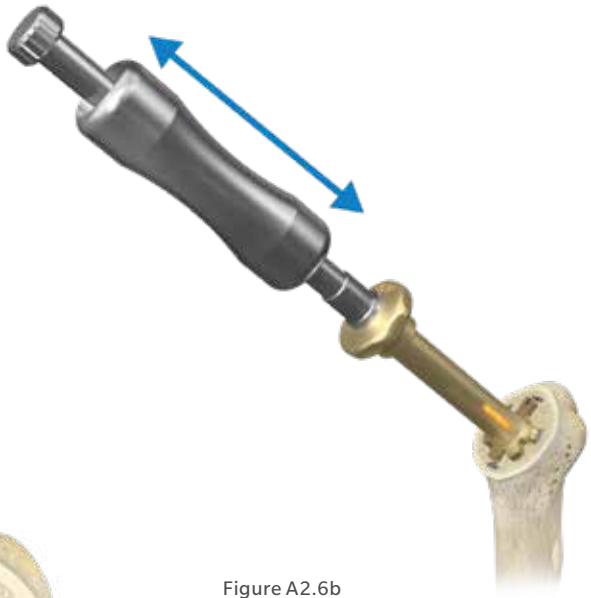


Figure A2.6b

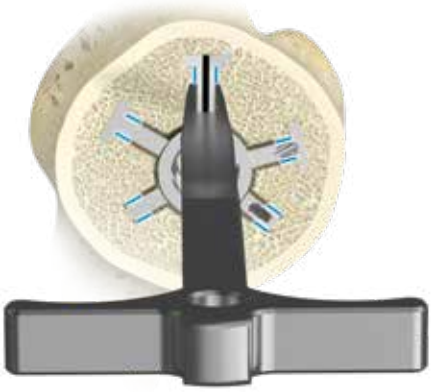


Figure A2.7

Freeing Implant-Bone Connections (cont.)

Impact the Silhouette Cutter until it is flush with the resection (Figure A2.6a). To remove the Silhouette Cutter, thread the Slap Hammer into the Strike Plate of the Silhouette Cutter. Lightly slide the Slap Hammer Handle until the Silhouette Cutter has been removed from the bone (Figure A2.6b). During removal, use caution to ensure the Slap Hammer remains on-axis and there is no tilting. To disengage the Silhouette Cutter Guide from the implant taper, a small rotational force may be applied while axially pulling on the Guide.

The Goal Post Osteotome can be used to free the remaining implant-bone connections on the inner portions of the implant fins as needed (Figure A2.7). Align the Goal Post Osteotome Blades over an implant fin and impact to the desired depth. During removal, use caution to ensure the Goal Post Osteotome remains on-axis.

Note: Alternatively to using the Silhouette Cutter, the Goal Post Osteotome can be used to free all implant-bone connections along the entire inner portion length of the implant fins.

Figure A2.8

Figure A2.9a

Figure A2.9b

Freeing Implant-Bone Connections (cont.)

To free the implant-bone connections on the outer edges of the implant fins, use the Straight Osteotome (see blue regions in Figure A2.8). Orient the Straight Osteotome on the outer edges of the implant fins and impact to the desired depth (Figure A2.8). Use caution during impaction to ensure the cortical wall is not damaged/perforated. During removal, ensure the Straight Osteotome remains on-axis.

Note: Alternatively, the Straight Osteotome can be used to free all implant-bone connections on the outer edges of the implant fins and around the center boss region of the implant.

Implant Extraction

After the implant-bone connections have been freed, insert the Extractor Base into the implant taper until secure (Figure A2.9a and Figure A2.9b)

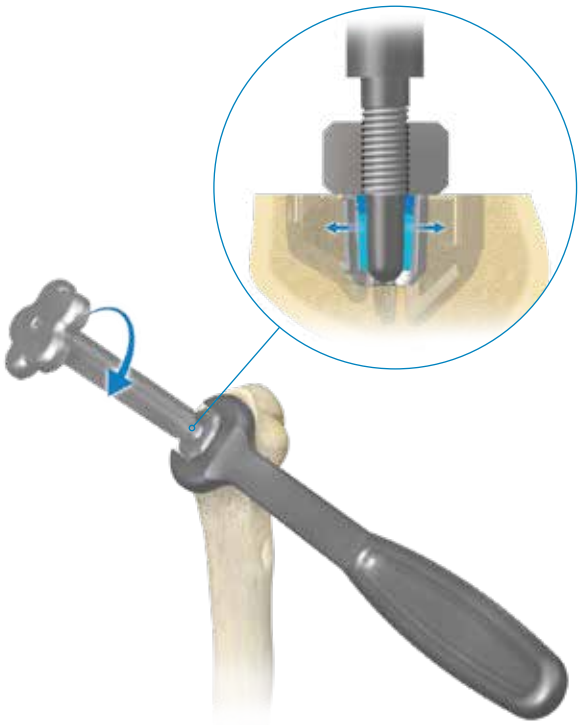


Figure A2.10

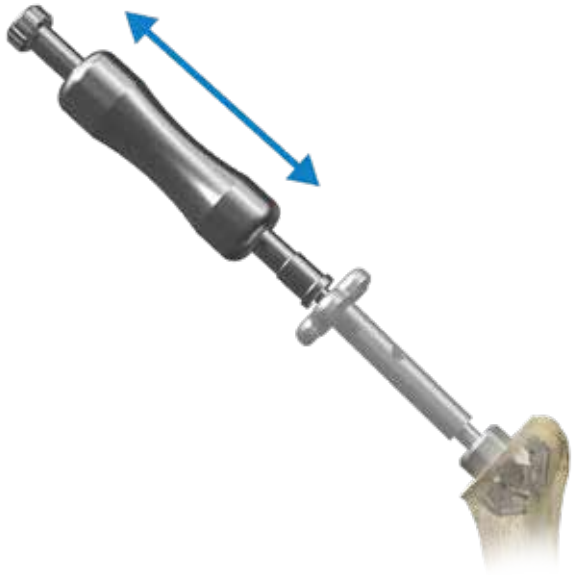


Figure A2.11

Implant Extraction (Cont.)

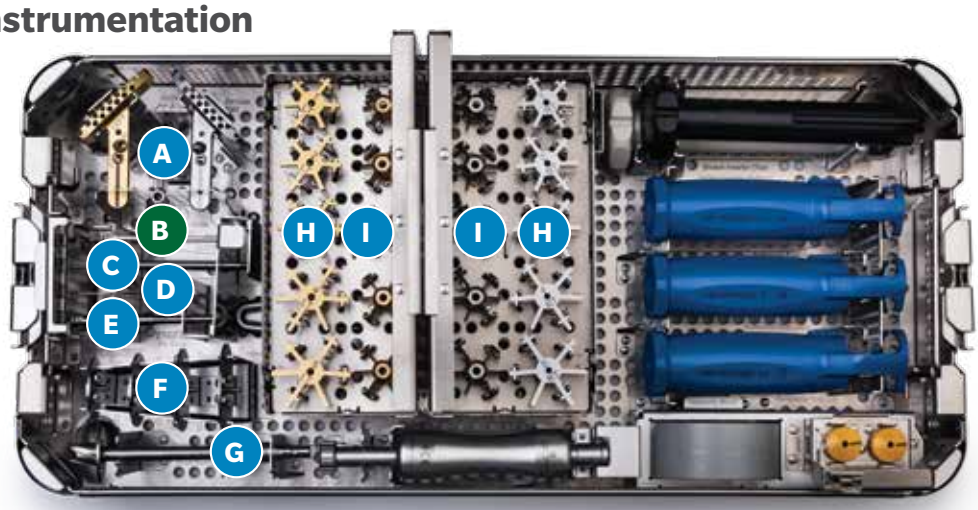
Once the Extractor Base is secured in the implant taper, assemble the Humeral Wrench onto the outer surface of the Extractor Base. Using the Humeral Wrench as a counter-torque, insert and tighten the Extractor Screw (Figure A2.10). Ensure the implant does not spin within the bone when tightening the Extractor Screw.

Once the Extractor Screw is secured into the Extractor Base, thread the Slap Hammer into the handle of the Extractor Screw. Lightly slide the Slap Hammer Handle until the implant has been removed from the bone (Figure A2.11). During removal, use caution to ensure the Slap Hammer remains on-axis and there is no tilting.

OsseoFit Implants

Product	Description	Side	Size	Part Number
	**OsseoFit Onlay Anchor Implant**	Left	Sz 1	00-5380-000-11
			Sz 2	00-5380-000-12
			Sz 3	00-5380-000-13
			Sz 4	00-5380-000-14
			Sz 5	00-5380-000-15
		Right	Sz 1	00-5380-000-21
			Sz 2	00-5380-000-22
			Sz 3	00-5380-000-23
			Sz 4	00-5380-000-24
			Sz 5	00-5380-000-25
	**OsseoFit Inlay Anchor Implant**	Left	Sz 1	00-5380-000-31
			Sz 2	00-5380-000-32
			Sz 3	00-5380-000-33
			Sz 4	00-5380-000-34
			Sz 5	00-5380-000-35
		Right	Sz 1	00-5380-000-41
			Sz 2	00-5380-000-42
			Sz 3	00-5380-000-43
			Sz 4	00-5380-000-44
			Sz 5	00-5380-000-45
	**OsseoFit Humeral Head Adapter**	-	-	00-5380-000-00

OsseoFit Instrumentation

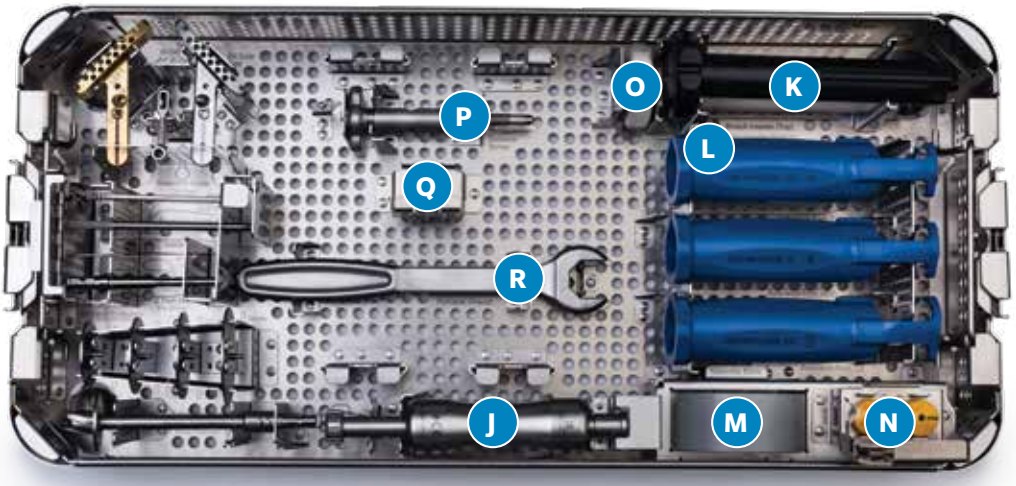


OsseoFit Primary Instrument Case (00-5381-100-00)

● Optional

Label	Product	Description	Side	Size	Part Number	Quantity
A		OsseoFit EM Resection Guides	Left Right	-	00-5381-003-10 00-5381-003-20	1 1
B (Optional)		Anatomic Resection Guide	-	-	SBHS0195 SBHS0196	1 1
C		Comprehensive Version Rod	-	-	407395	2
D		Tissue Probe	-	-	994500111	1
E		2.7 mm Hex Pin Driver	-	-	SBHS0199	1
F		OsseoFit Humeral Protectors	-	36 mm 42 mm 48 mm 54 mm	00-5381-001-01 00-5381-001-02 00-5381-001-03 00-5381-001-04	1 1 1 1
G		OsseoFit Boss Reamer	-	-	00-5381-006-00	1
H		OsseoFit Implant Sizers	Left	Sz 1 Sz 2 Sz 3 Sz 4 Sz 5	00-5381-004-11 00-5381-004-12 00-5381-004-13 00-5381-004-14 00-5381-004-15	1 1 1 1 1
			Right	Sz 1 Sz 2 Sz 3 Sz 4 Sz 5	00-5381-004-21 00-5381-004-22 00-5381-004-23 00-5381-004-24 00-5381-004-25	1 1 1 1 1
I		OsseoFit Humeral Broaches	Left	Sz 1 Sz 2 Sz 3 Sz 4 Sz 5	00-5381-007-11 00-5381-007-12 00-5381-007-13 00-5381-007-14 00-5381-007-15	1 1 1 1 1
			Right	Sz 1 Sz 2 Sz 3 Sz 4 Sz 5	00-5381-007-21 00-5381-007-22 00-5381-007-23 00-5381-007-24 00-5381-007-25	1 1 1 1 1

*Caddy Lid removed for clarity for Instruments H and I.

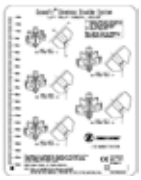
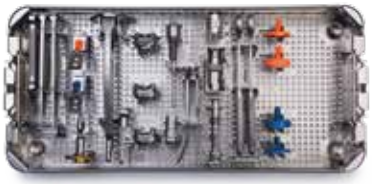


OsseoFit Primary Instrument Case (00-5381-100-00) (cont.)

Label	Product	Description	Side	Size	Part Number	Quantity
J		OsseoFit Slap Hammer	-	-	00-5381-011-00	1
K		OsseoFit Monoblock Broach Inserter	-	-	00-5381-008-00	1
L		OsseoFit Reference Feet	- - -	S MED LG	00-5381-008-01 00-5381-008-02 00-5381-008-03	1 1 1
M		Impactor Base	-	-	407281	1
N		OsseoFit Humeral Head Offset Trial	-	-	00-5381-015-00	2
O		OsseoFit Implant Inserter	-	-	00-5381-008-04	1
P		OsseoFit Revision Extractor Screw	-	-	00-5381-016-00	1
Q		OsseoFit Revision Extractor Base	-	-	00-5381-016-01	1
R		Humeral Wrench	-	-	SBRV9006	1

*Instruments located below OsseoFit Shoulder Instrument Caddy (Broaches and Sizers). Caddy removed for clarity for Instruments P, Q, and R.
**Lid removed for clarity for Instruments N and Q.
Check with local representative to confirm item availability.

Accessory Device

Product	Description	Size	Part Number	Case Number
	OsseoFit X-Ray Template Set • Onlay Anchor (Left & Right) • Inlay Anchor (Left & Right)	-	XRAY0005381	-
	Identity Humeral Head Implants – Cobalt Chrome	-	ST111100304	-
	Identity Humeral Head Implants - Titanium	-	ST111100305	-
	Hex Pin 2.7mm x 70mm 3 Box (Sterile, Single Use)	-	SBHS1070	-
	Hex Pin 2.7mm x 100mm 3 Box (Sterile, Single Use)	-	SBHS1100	-
	Comprehensive Nano Pin 3.2mm (Sterile, Single Use)	-	110045821	-
	Comprehensive Nano Calcar Planer	-	31-406991	593691
	Calcar Planer Blades	38mm 42mm 46mm 50mm 54mm 58mm	406661 406662 406663 406664 406665 406666	595259
	Identity Humeral Head Case • Humeral Head Trials • 3.5mm Hex Driver • Humeral Head Impactor • Humeral Head Sizing Template	-	-	KT111100309
	Identity Revision Case • Humeral Head Remover Base • Humeral Head Remover Thin • Humeral Head Remover Thick • Straight Osteotome	-	-	KT111100311
	OsseoFit Revision Silhouette Cutter Guide	-	00-5381-009-20	-
	OsseoFit Revision Silhouette Cutters	Small Left Large Left Small Right Large Right	00-5381-010-11 00-5381-010-12 00-5381-010-21 00-5381-010-22	-
	OsseoFit Revision Goal Post Osteotome	-	00-5381-009-10	-

Reference 4943.1-GLBL-en for the OsseoFit Stemless Shoulder System Ordering Guide.

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