

EXACTECH | SHOULDER

Operative Technique Addendum



equinox[®]

Humeral Augmented Tray Operative Technique Addendum
to Equinox[®] Platform Shoulder System



TABLE OF CONTENTS

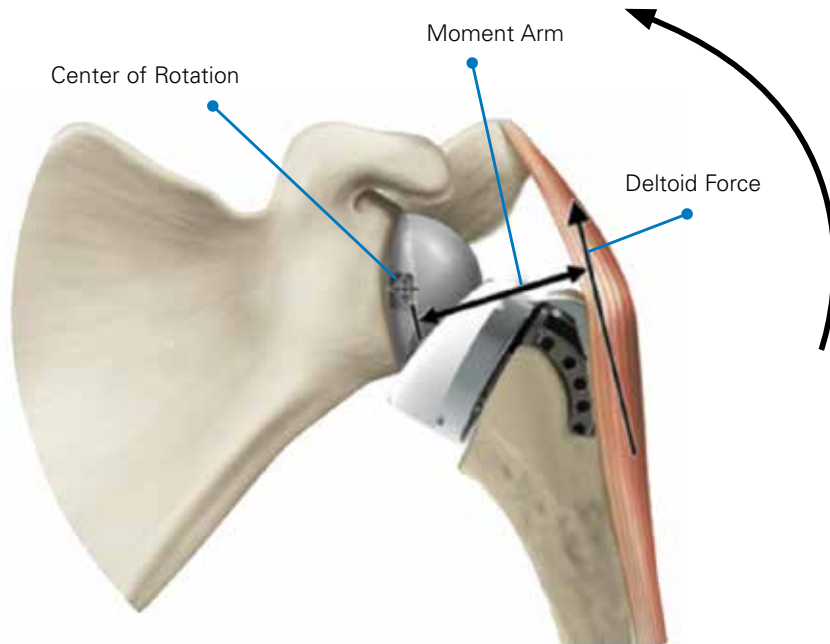
EQUINOXE HUMERAL AUGMENTED TRAY – PRODUCT OVERVIEW	1
DEVICE DESCRIPTION.....	1
PRODUCT FEATURES HAT CONFIGURATIONS EQUINOXE STEM COMPATIBILITY.....	2
OPERATIVE TECHNIQUE PROCEDURAL OVERVIEW FLOWCHART	3
DETAILED OPERATIVE TECHNIQUE	4
OPTION ONE:	
HAT Implantation to a Well-Fixed Equinoxe Standard or Fracture Stem	4
OPTION TWO:	
HAT Implantation in Primary or Revision Procedure	
Where Adequate Humeral Stem Fixation Can Be Achieved	16
IMPLANT & INSTRUMENT LISTING	30
IMPLANT SPECIFICATIONS	33
REFERENCES	34

NOTE

The Equinoxe Humeral Augmented Tray (HAT) implants are inserted using steps included in this operative technique. The HAT operative technique presents an addendum to the Equinoxe Platform Shoulder System, Equinoxe Platform Shoulder System with Ergo Instruments and Equinoxe Platform Fracture Stem Shoulder System operative techniques to include the Equinoxe HAT.¹⁻³

Please refer to the reverse shoulder section of the Equinoxe Platform Shoulder System operative technique¹⁻³ for information related to patient positioning, surgical approaches, and the preparation of the humerus and glenoid. The HAT is inserted using steps similar to what is used to insert the standard Equinoxe Reverse Shoulder humeral tray and liner. The steps described in this addendum address the specific HAT steps.

The Equinoxe Humeral Augmented Tray is anatomically designed to improve joint mechanics and stability by providing increased deltoid muscle wrapping.



DEVICE DESCRIPTION

The Humeral Augmented Tray (HAT) is intended for use in total shoulder arthroplasty in skeletally mature patients with proximal humeral bone loss. Specifically the HAT is used in combination with Equinoxe Reverse Shoulder System components to compensate for proximal humeral bone loss in the presence of an intact medial calcar, irreparable or grossly deficient rotator cuff and a functional deltoid muscle.

One of the overall goals of this anatomically-designed implant is to improve joint mechanics and stability by providing increased deltoid muscle wrapping and adequate soft tissue tensioning in patients with proximal humeral bone loss.

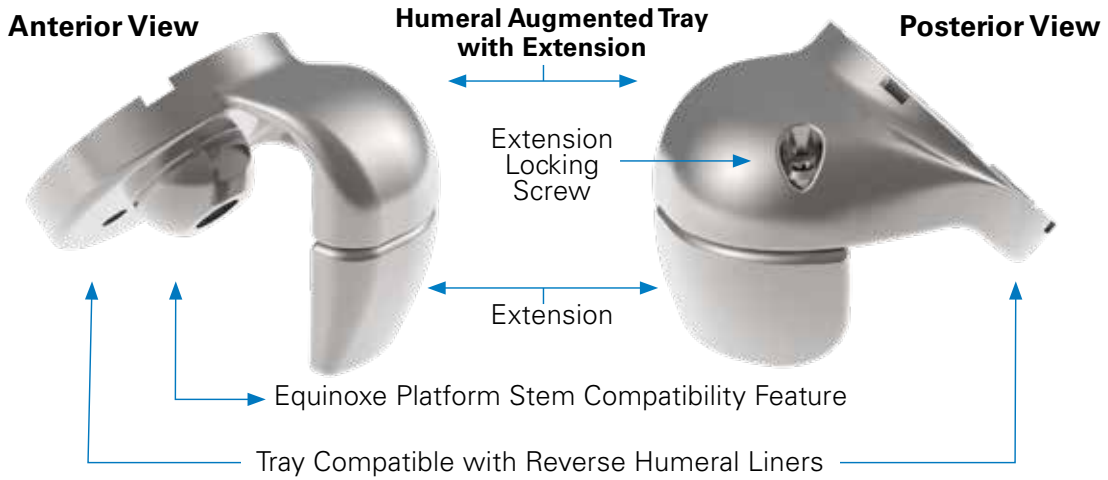
The HAT consists of a humeral tray component, modular extension and locking screw for use in primary and revision cases.

To accommodate patients' various anatomical needs, the HAT is anatomically designed with two offsets and multiple lateralizations of left and right humeral trays and left and right modular extensions. Per surgeon evaluation, the modular extension, secured with a locking screw, is used to replace greater and more severe proximal humeral bone loss than can be adequately addressed with the use of a humeral tray component alone. When the modular extension is used, the locking screw must be used to secure it to the humeral tray component. All three components are manufactured from Titanium Alloy (Ti-6Al-4V E.L.I.).

EQUINOXE HUMERAL AUGMENTED TRAY – PRODUCT OVERVIEW

PRODUCT FEATURES | HAT CONFIGURATIONS | EQUINOXE STEM COMPATIBILITY

PRODUCT FEATURES



HAT CONFIGURATIONS

Bone Loss / HAT without Extension



Bone Loss / HAT with Extension



EQUINOXE STEM COMPATIBILITY

HAT Construct without Extension

Standard Stem



Fracture Stem



HAT Construct with Extension

Standard Stem



Fracture Stem



EQUINOXE HUMERAL AUGMENTED TRAY – PRODUCT OVERVIEW

OPERATIVE TECHNIQUE PROCEDURAL OVERVIEW FLOWCHART



OPTION 1

HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem

Well-Fixed Stem Procedure



Humeral Prep with a Well-Fixed Equinox Standard or Fracture Stem From aTSA (left) or rTSA (right)

OPTION 2

Primary or Revision of Non-Equinox Stem with HAT Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

Primary or Revision HAT Procedure



Humeral Prep Primary Procedure or Revision (aTSA or rTSA)

HAT CUTTING GUIDES

HAT Only Cut Guide



OR



HAT Extension Cut Guide

TRIALING

Trialing-HAT Without Extension



OR



Trialing-HAT With Extension

IMPLANTATION OF FINAL CONSTRUCT



HAT ASSEMBLY ONTO STEM



IMPLANTATION OF FINAL CONSTRUCT



OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem



Figure 1a
Anatomic
Articulating
Components

Figure 1b
Reverse
Articulating
Components



Figure 2
Remove the
Humeral Head

Figure 3
Disengage the Torque
Defining Screw and Remove
the Replicator Plate

HUMERAL PREP WITH A WELL-FIXED STEM

Remove anatomic (*Figure 1a*) or reverse (*Figure 1b*) humeral articulating components. For reverse, see next page.

If an anatomic construct, remove only the **Humeral Head**, **Torque Defining Screw** and **Anatomic Replicator Plate** (*Figures 2 and 3*).

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem



Figure 4
Remove the Humeral Liner



Figure 5
Remove the Reverse Torque Defining Screw
and Humeral Adapter Tray

If it is a reverse construct, remove only the **Humeral Liner**, Reverse Torque Defining Screw and **Humeral Adapter Tray** (Figures 4 and 5).

The above implant components are described in the Equinox Platform Shoulder System operative techniques.¹⁻³

Once the anatomic or reverse humeral components are removed, leave only the Equinox stem in place, ensuring the stem is well-fixed.

DETAILED OPERATIVE TECHNIQUE

HAT STEM CUT GUIDE ARM

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem



Figure 6
Stem Cut Guide Arm



Figure 7
Assemble Stem Cut Guide Arm
to Well-Fixed Stem

HAT STEM CUT GUIDE ARM

To ensure no bony structure will obstruct the HAT implant or the HAT Extension from seating properly, cutting guides for both the tray and the extension are provided.

Place the bowl feature of the **HAT Stem Cut Guide Arm (319-26-00)** (Figure 6) onto the implanted humeral stem and tighten the 3.5mm hex screw to secure the guide arm at the center line of the stem using the **3.5mm Hex Driver**. Ensure that the dimple on the Stem Cut Guide Arm is aligned with the divot on the well-fixed stem (Figure 7).

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem

Cut Guide Assembly for
HAT Body Only

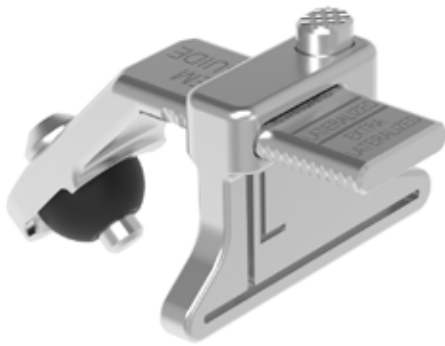


Figure 8
Stem Cut Guide Arm
Assembled to the HAT Body
Cut Guide

Cut Guide Assembly for
HAT Body + Extension



Figure 9
Stem Cut Guide Arm
Assembled to the HAT
Extension Cut Guide

ASSEMBLE THE HAT BODY CUT GUIDE OR THE EXTENSION CUT GUIDE TO STEM CUT GUIDE ARM

The amount of bone removal needed to accommodate the HAT and optional extension can be determined at this time. Connect the HAT Stem Cut Guide Arm to either the **HAT Body Cut Guide (319-27-00)** (Figure 8) or the **Extension Cut Guide (319-28-00)** (Figure 9) by depressing the button on top of Cut Guide to allow for locking and releasing of the two components.

Ensure the appropriate left or right side is positioned so that the "L" (left) or "R" (right) labeling, respectively, is facing outward and is able to be read by the user.

Note: In Figures 8 and 9, Stem Cut Guide Arm is not shown secured to the stem for convenience of illustration.

DETAILED OPERATIVE TECHNIQUE

ASSEMBLE THE HAT BODY CUT GUIDE OR THE EXTENSION CUT GUIDE TO STEM CUT GUIDE ARM

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem

**Cut Guide Assembly for
HAT Body Only**



Figure 10
Cut the Humerus with the HAT
Body Cut Guide in Place

**Cut Guide Assembly for
HAT Body + Extension**



Figure 11
Cut the Humerus with the HAT
Extension Cut Guide in Place

Once the **Cut Guide Assembly** is secured to the well-fixed standard or fracture stem, using a small width saw blade, **using a recommended saw blade 10mm X 1.19mm thickness**, cut the bone in both the horizontal and vertical cut guide slots (*Figures 10 and 11*).

Note: When using the HAT/Extension cut guides, avoid contacting the humeral stem with the saw blade. The posterior soft tissues should be protected using a retractor.

Once the tuberosity resection is complete, remove the Cut Guide Assembly by loosening the 3.5mm hex screw on the HAT Stem Cut Guide Arm. A rongeur or free-hand saw technique can be used to remove any remaining bone fragments on the cut surfaces. An even cut surface is necessary to ensure the final implant will seat properly.

OPTION ONE: HAT Implantation to a Well-Fixed Equinoxe Standard or Fracture Stem

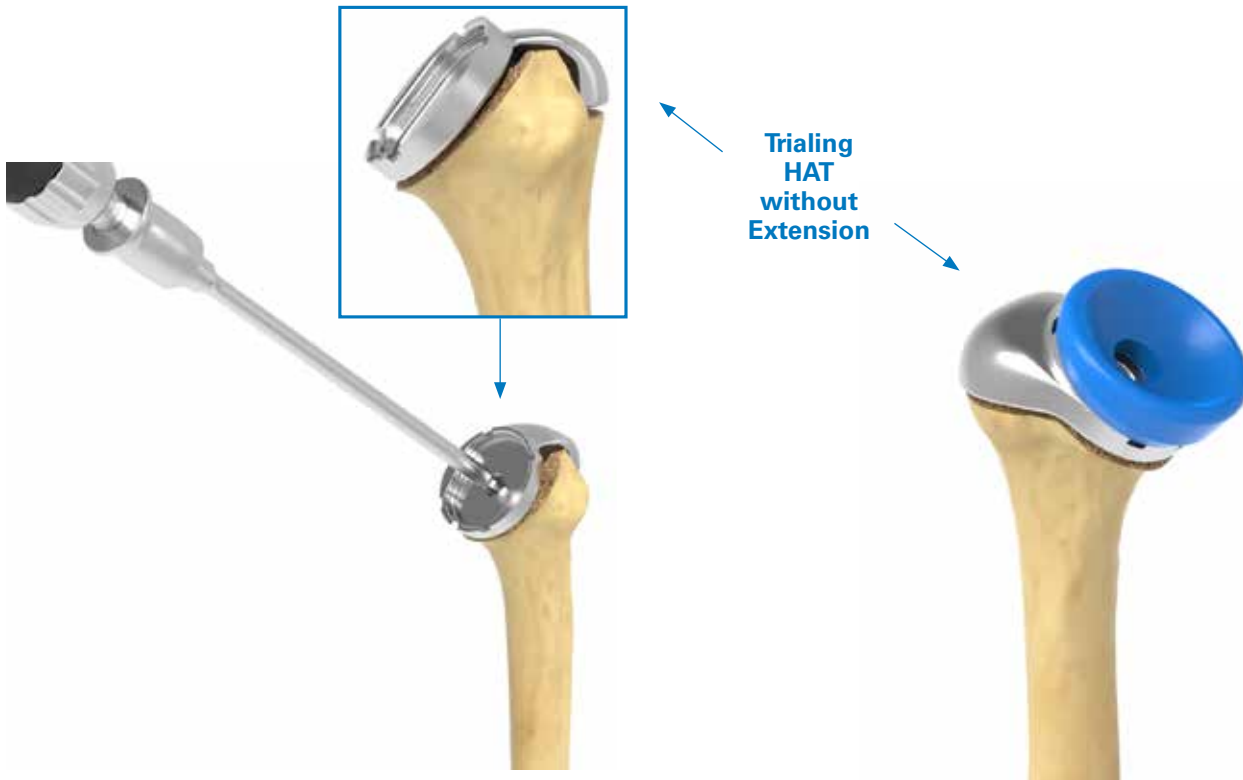


Figure 12

Attach the HAT Trial without Extension to the Stem

Figure 13

Assemble the Humeral Liner Trial to the HAT Trial without Extension

TRIALING – HAT WITHOUT EXTENSION

Use the **HAT Trials (321-24-01,02,11,12,21,22)** and **+5 Tray Trial (321-10-05)** to determine the offset (0 or +5) and lateralization of the final implant. Attach the desired HAT Tray Trial to the humeral stem by threading the 3.5mm captured hex screw into the humeral stem screw hole using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08) (Figure 12).

To insert the **Humeral Liner Trial (321-36-XX, 321-38-XX, 321-40-XX, 321-42-XX and 321-46-XX)** into the tray trial, the underside asymmetric connecting feature should be appropriately aligned and the liner/tray trials should be pressed together until the C-spring engages (Figure 13).

Note: Ensure the fully seated HAT Trial does not contact the remaining humeral bone.

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem



Figure 14

Remove the Humeral Liner Trial and HAT Trial without Extension

The stability of the implant is assessed during a trial reduction. The shoulder should be placed through a range of motion to assess the stability of the construct. To disengage the liner trials, insert the tip of the **Humeral Liner Removal Tool (Legacy: 321-15-11 or Ergo: 321-19-11)** into the recessed region of the tray trial and turn the handle of the instrument like a key until the spring that connects the humeral liner trials and tray trials is disengaged, thereby freeing the humeral liner trial. Remove the HAT Tray Trial by unthreading the 3.5mm captured hex screw using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08) (Figure 14).

Note: The assembled humeral component has a humeral neck angle of 145 degrees because the Humeral Liner adds 12.5 degrees to the stem's 132.5-degree neck angle.

Note: Trial size should be chosen to ensure that the best possible coverage of the bone resection surface is achieved, and the trial does not contact the cortex. Removing humeral bone and trialing may be an iterative process to ensure that the trials can be fully seated without contacting any remaining humeral bone.

OPTION ONE: HAT Implantation to a Well-Fixed Equinoxe Standard or Fracture Stem

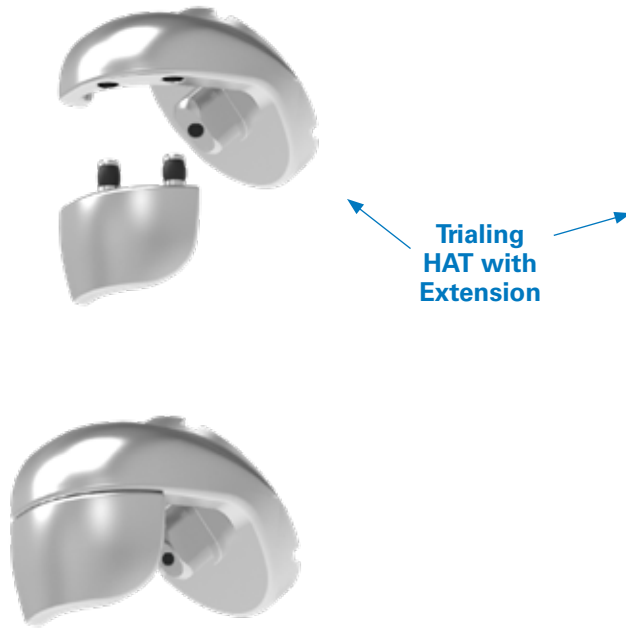


Figure 15

Connect the Extension Trial to the HAT Trial



Figure 16

Assemble the Humeral Liner Trial

TRIALING – HAT WITH EXTENSION

For more severe proximal humeral bone loss than can be addressed with HAT only implant, the HAT offers an extension. In addition to the HAT Trials (**321-24-01,02,11,12,21,22**) and +5 Tray Trial (321-10-05), the HAT instrumentation also includes the **HAT Extension Trials (321-20-01,02)**. To use, connect the HAT Extension Trial to the tray trial through the two mating posts on the extension trial (*Figure 15*). Once the HAT Extension Trial is attached to the HAT Tray Trial, the construct is attached to the implanted humeral stem by threading the 3.5mm captured hex screw into the humeral stem screw hole using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08).

To insert the Humeral Liner Trial (321-36-XX, 321-38-XX, 321-40-XX, 321-42-XX and 321-46-XX) into the tray trial, the underside asymmetric connecting feature should be appropriately aligned and the liner/tray trials should be pressed together until the C-spring engages (*Figure 16*).

Note: Ensure the fully seated HAT with Extension Trial construct does not contact the remaining humeral bone.

OPTION ONE: HAT Implantation to a Well-Fixed Equinoxe Standard or Fracture Stem



Figure 17

Remove the Humeral Liner Trial and HAT Trial with Extension Trial

The stability of the implant is assessed during a trial reduction. The shoulder should be placed through a range of motion to assess the stability of the construct. To disengage the liner trials, insert the tip of the Humeral Liner Removal Tool (Legacy: 321-15-11 or Ergo: 321-19-11) into the recessed region of the tray trial and turn the handle of the instrument like a key until the spring that connects the humeral liner trials and tray trials is disengaged, thereby freeing the liner trial. Remove the HAT Tray Trial by unthreading the 3.5mm captured hex screw using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08) (Figure 17).

Note: The assembled humeral component has a humeral neck angle of 145 degrees because the humeral liner adds 12.5 degrees to the stem's 132.5-degree neck angle.

Note: Trial size should be chosen to ensure that the best possible coverage of the bone resection surface is achieved, and the trial does not contact the cortex. Removing humeral bone and trialing may be an iterative process to ensure that the trials can be fully seated without contacting any remaining humeral bone.

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem



Figure 18
HAT Back Table Assembly

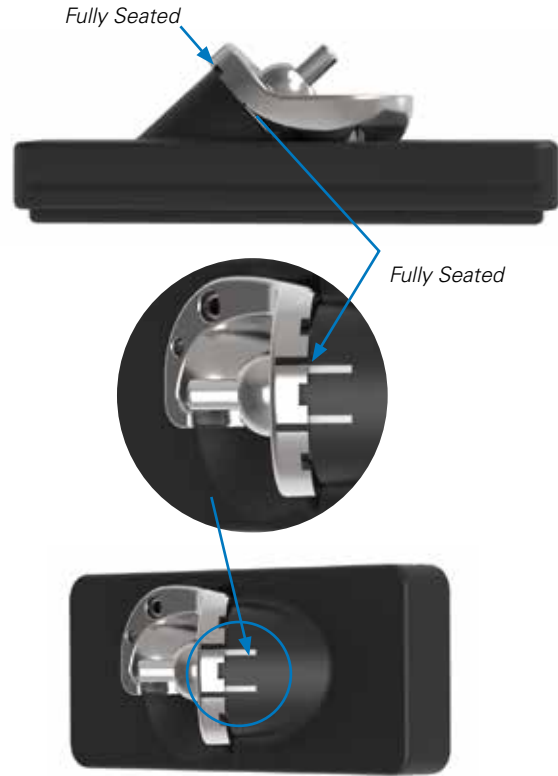


Figure 19
HAT Implant Seated onto Back Table Assembly
Ensuring Laser Marks Align

HAT IMPLANT AND EXTENSION ASSEMBLY

Once the implant size has been determined from the tray trials and extension trials, follow the steps below to assemble the extension to the tray implant:

1. Assemble the **HAT Back Table Assembly** into the **Universal Back Table Stand (Legacy: 315-15-22 or Ergo: 321-15-48/321-19-22 [legs])** (*Figure 18*).

2. Seat the final HAT implant onto the HAT Back Table Assembly. Ensure that the two laser marks on the implant align to the two laser marks on the back table assembly, allowing the HAT implant to fully seat (*Figure 19*).

OPTION ONE: HAT Implantation to a Well-Fixed Equinox Standard or Fracture Stem



Figure 20

Assemble Extension Onto HAT Body and Impact with Extension Impactor



Figure 21

Drive Locking Screw with T-10 Screw Driver Assembled to Torque-Limiting Driver

3. Align the **Left Extension (320-20-01)** or **Right Extension (320-20-02)** to the seated implant on the Back Table Assembly. Connect the **Extension Impactor (319-23-00)** to the **Impactor Handle (Legacy: 321-07-05 or Ergo 321-09-05)**, hold the Impactor Handle vertically and use a mallet to strike the Impactor Handle and the Extension directly in line with the taper (*Figure 20*).

WARNING: Don't assemble or disassemble devices in the surgical field.

4. Remove the HAT implant and Extension from the Back Table Assembly.

5. To secure and lock the extension onto the implant, place the **Extension Locking Screw** through the hole in the HAT and tighten using the **T-Handle Torque-Limiting Driver 802-001** and **T-10 Screw Driver (341-01-38)** assembly (*Figure 21*).

Note: The Extension Locking Screw should be fully tightened prior to final HAT and Extension insertion and attachment to the well-fixed stem (see next page). Two screws are packaged with the Extension in case one becomes unusable before assembly.

OPTION ONE: HAT Implantation to a Well-Fixed Equinoxe Standard or Fracture Stem



Figure 22

Assemble the Implant to the Stem
Using the Reverse Torque Defining Screw



Figure 23

Final Implant - HAT with Standard Stem or Fracture Stem
with or without Extension

FINAL HAT IMPLANTATION

To implant the final implant with or without the extension, assemble the HAT only or HAT with Extension to the already well-fixed Equinoxe stem *in situ* by engaging the **Reverse Shoulder Torque Defining Screw (320-20-00)** (Figure 22) and impacting the humeral liner as described in the Equinoxe Platform Shoulder System operative techniques (Figure 23).¹³

Note: Ensure the fully seated HAT only or HAT with Extension construct does not contact the remaining humeral bone.

DETAILED OPERATIVE TECHNIQUE

HAT IMPLANTATION IN PRIMARY OR REVISION PROCEDURE WHERE ADEQUATE HUMERAL STEM FIXATION CAN BE ACHIEVED

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

HAT IMPLANTATION WITH EQUINOXE STANDARD OR FRACTURE STEMS

Standard Stem



Figure 24a
Standard Stem
and HAT Assembly

Figure 24b
Standard Stem and
HAT with Extension
Assembly

Fracture Stem



Figure 25a
Fracture Stem
and HAT Assembly

Figure 25b
Fracture Stem and
HAT with Extension
Assembly

For implantation of a stem with the HAT, surgeons can choose to use either the Equinoxe platform standard (Figures 24a & 24b) or fracture (Figures 25a & 25b) stems with or without the extension (Figures 24-25).

Note: Equinoxe Standard and Fracture stems are the only two stems compatible with the HAT device.

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Standard stem shown above with Humeral Augmented Tray and Extension Assembly.

HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Figure 26

HAT Stem Cut Guide Arm for Stem Trial or Final Stem



Figure 27

HAT Broach Cut Guide Arm for Female Broach Trial









HUMERAL PREP PRIMARY PROCEDURE

Please refer to the Equinox operative techniques¹³ for stem trialing and broaching.

For humeral preparation, it is important to note the different instrumentation available in the HAT instrument set for either stem trialing (*Figure 26*) or female broach trialing (*Figure 27*). See *Table 1* on page 19 for further information.

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

Table 1: Cut Guide and Arm Selection Matrix

HUMERUS TRIALS	HAT EXTENSION TRIALS		STEM CUT GUIDE ARM	BROACH CUT GUIDE ARM	HAT BODY CUT GUIDE	HAT EXTENSION CUT GUIDE
						
FEMALE BROACH	WITHOUT EXTENSION		NO	YES	YES	NO
	WITH EXTENSION		NO	YES	NO	YES
STEM TRIAL &/OR STEM	WITHOUT EXTENSION		YES	NO	YES	NO
	WITH EXTENSION		YES	NO	NO	YES

Note: Two Cut Guide Arms are provided for compatibility with either a female broach or a stem trial. Female broaches come with the Ergo (Instruments) Primary/Reverse Operative Technique (00-0000121) and legacy stem trials with the Primary/Reverse Operative Technique (718-01-30).^{1,2} Cut guides for the HAT only or HAT with Extension are compatible with either Cut Guide Arm.

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

Fracture Stem Trial



HAT Stem Cut Guide Arm

Figure 28

Assemble Stem Cut Guide Arm to Stem Trial or Final Stem



HAT Broach Cut Guide Arm

Figure 29

Assemble Broach Cut Guide Arm to Female Broach

HAT CUT GUIDE ARMS

Select and Assemble Either The HAT Stem or Broach Cut Guide Arm to Humeral Component

Select either the **Stem Cut Guide Arm (319-26-00)** (Figure 28) or the **Broach Cut Guide Arm (319-24-00)** (Figure 29) as determined by humeral prep procedure.

Connect either the Stem Cut Guide Arm or Broach Cut Guide Arm to the humeral component and tighten the 3.5mm central hex screw using the 3.5mm Hex Driver (321-19-08) ensuring that the dimple on the Stem Cut Guide Arm is aligned with the divot if using the stem or stem trial.

Note: The Broach Cut Guide Arm (319-24-00) may be used for the HAT humeral prep only when using the female broaches. See Table 1 on page 19 for further information.

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

Cut Guide Assembly for HAT Body Only



Figure 30

Cut Guide Arm Assembled to the HAT Body Cut Guide

Cut Guide Assembly for HAT Body + Extension



Figure 31

Cut Guide Arm Assembled to the HAT Extension Cut Guide

ASSEMBLE THE HAT BODY CUT GUIDE OR THE EXTENSION CUT GUIDE TO STEM/BROACH CUT GUIDE ARM

The amount of bone removal needed to accommodate the HAT and optional extension can be determined at this time. Connect either the HAT Body Cut Guide (319-27-00) (Figure 30) or the Extension Cut Guide (319-28-00) (Figure 31) to either the stem or Broach Cut Guide Arm (Figure 28 or 29) by depressing the button on top of the cut guide to allow for locking and releasing of the two components. Ensure the appropriate left or right side is positioned so that the “L” (left) or “R” (right) labeling, respectively, is facing outward and able to be read by the user.

Once the Cut Guide Assembly is secured to the humeral component, using a small width saw blade, **using a**

recommended saw blade 10mm X 1.19mm thickness, cut the bone in both the horizontal and vertical cut guide slots (Figures 30 and 31).

Note: When using the HAT/Extension cut guides, avoid contacting the humeral stem, stem trial or broach with the saw blade. The posterior soft tissues should be protected using a retractor.

Once the tuberosity resection is complete, remove the Cut Guide Assembly by loosening the 3.5mm hex screw on the Cut Guide Arm. A rongeur or free-hand saw technique can be used to remove any remaining bone fragments on the cut surfaces. An even cut surface is necessary to ensure the final implant will seat properly.

DETAILED OPERATIVE TECHNIQUE

TRIALING - HAT WITHOUT EXTENSION

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

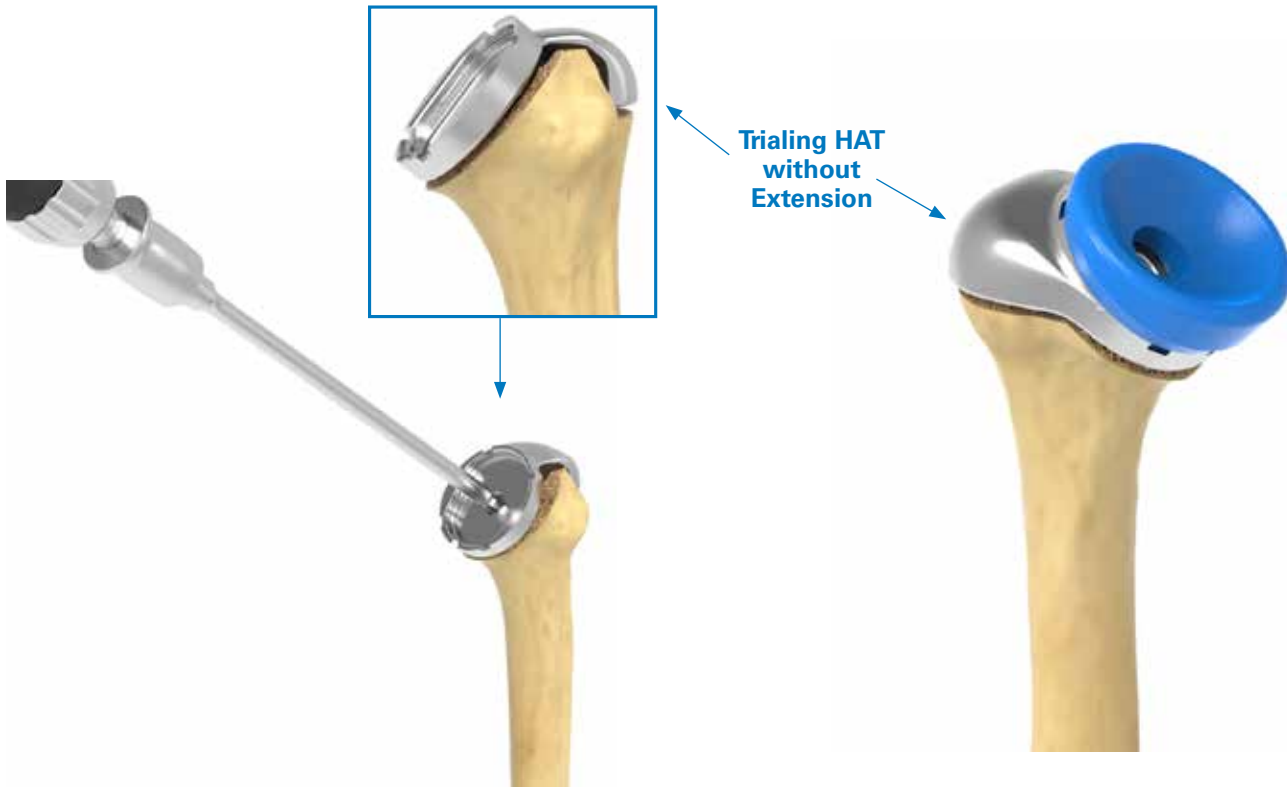


Figure 32

Attach the HAT Trial to the Stem Trial or Female Broach

Figure 33

Assemble the Humeral Liner Trial

TRIALING - HAT WITHOUT EXTENSION

Use the HAT Trials (321-24-01,02,11,12,21,22) and +5 Tray Trial (321-10-05) to determine the offset (0 or +5) and lateralization of the final implant. Attach the desired HAT Tray Trial to the humeral stem trial by threading the 3.5mm captured hex screw into the humeral stem screw hole using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08) (Figure 32).

Note: The HAT Trials are cross-compatible with either a standard stem/stem trial or female broach trial.

To insert the Humeral Liner Trial (321-36-XX, 321-38-XX, 321-40-XX, 321-42-XX and 321-46-XX) into the tray trial, the underside asymmetric connecting feature should be appropriately aligned and the liner/tray trials should be pressed together until the C-spring engages (Figure 33).

Note: Ensure the fully seated HAT Trial does not contact the remaining humeral bone.

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Figure 34

Remove the Humeral Liner Trial and HAT Trial without Extension

The stability of the implant is assessed during a trial reduction. The shoulder should be placed through a range of motion to assess the stability of the construct. To disengage the liner trials, insert the tip of the Humeral Liner Removal Tool (Legacy: 321-15-11 or Ergo: 321-19-11) into the recessed region of the tray trial and turn the handle of the instrument like a key until the spring that connects the humeral liner trials and tray trials is disengaged, thereby freeing the liner trial. Remove the HAT Tray Trial by unthreading the 3.5mm captured hex screw using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08) (Figure 34).

Note: The assembled humeral component has a humeral neck angle of 145 degrees because the Humeral Liner adds 12.5 degrees to the stem's 132.5-degree neck angle.

Note: Trial size should be chosen to ensure that the best possible coverage of the bone resection surface is achieved, and the trial does not contact the cortex. Removing the humeral bone and trialing may be an iterative process to ensure that the trials can be fully seated without contacting any remaining humeral bone.

DETAILED OPERATIVE TECHNIQUE

TRIALING - HAT WITH EXTENSION

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

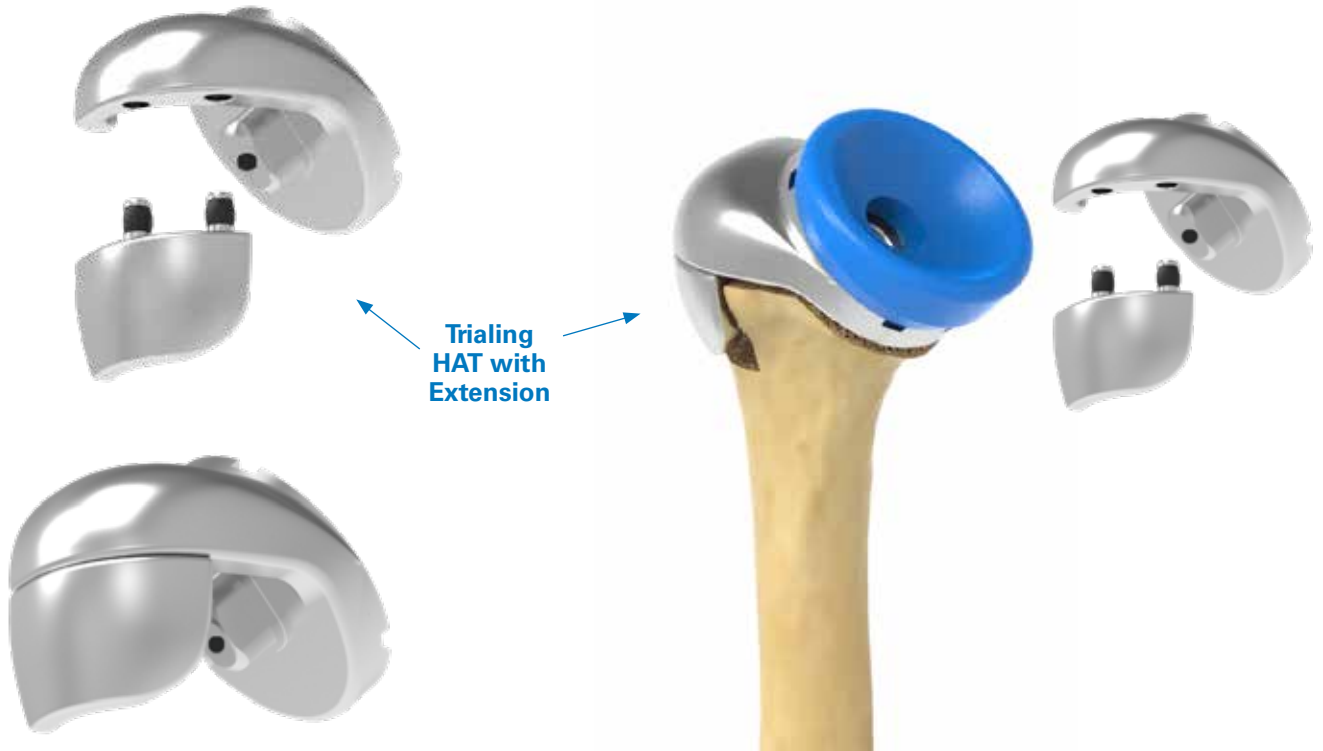


Figure 35

Connect the Extension Trial to the HAT Trial

Figure 36

Assemble the Humeral Liner Trial

TRIALING - HAT WITH EXTENSION

For more severe proximal humeral bone loss than can be addressed with HAT only implant, HAT offers an extension. In addition to the HAT Trials (321-00-01,02,11,12,21,22) and +5 Tray Trial (321-10-05), the HAT instrumentation also includes the HAT Extension Trial (321-20-01,02). To use, connect the HAT Extension Trial to the HAT Trial through the two mating posts on the extension trial (Figure 35). Once the HAT Extension Trial is attached to the HAT Tray Trial, the construct is attached to the inserted stem trial/female broach by threading the 3.5mm captured hex screw into the stem trial/female broach screw hole using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08).

Note: The HAT Trials are cross-compatible with either a standard stem/stem trial or female broach trial.

To insert the Humeral Liner Trial (321-36-XX, 321-38-XX, 321-40-XX, 321-42-XX and 321-46-XX) into the tray trial, the underside asymmetric-connecting feature should be appropriately aligned and the liner/tray trials should be pressed together until the C-spring engages (Figure 36).

Note: Ensure the fully seated HAT with Extension Trial construct does not contact the remaining humeral bone.

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Figure 37

Remove the Humeral Liner Trial and HAT Trial with Extension Trial

The stability of the implant is assessed during a trial reduction. The shoulder should be placed through a range of motion to assess the stability of the construct. To disengage the liner trials, insert the tip of the Humeral Liner Removal Tool (Legacy: 321-15-11 or Ergo: 321-19-11) into the recessed region of the tray trial and turn the handle of the instrument like a key until the spring that connects the humeral liner trials and tray trials is disengaged, thereby freeing the liner trial. Remove the HAT Tray Trial by unthreading the 3.5mm captured hex screw using the 3.5mm Hex Screw Driver (Legacy: 321-15-08 or Ergo: 321-19-08) (Figure 37).

Note: The assembled humeral component has a humeral neck angle of 145 degrees because the Humeral Liner adds 12.5 degrees to the stem's 132.5-degree neck angle.

Note: Trial size should be chosen to ensure that the best possible coverage of the bone resection surface is achieved, and that the trial does not contact the cortex. Removing the humeral bone and trialing may be an iterative process to ensure that the trials can be fully seated without contacting any remaining humeral bone.

DETAILED OPERATIVE TECHNIQUE

HAT IMPLANT AND EXTENSION ASSEMBLY

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Figure 38
HAT Back Table Assembly

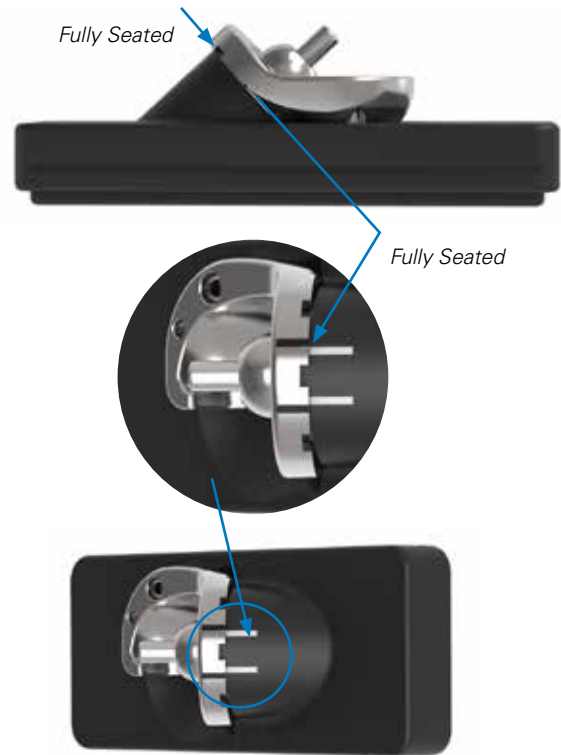


Figure 39
HAT Implant Seated onto Back Table Assembly
Ensuring Laser Marks Align

HAT IMPLANT AND EXTENSION ASSEMBLY

Once the implant size has been determined from the tray trials and extension trials, follow the steps below in order to assemble the extension to the implant:

1. Assemble the HAT Back Table Assembly into the Universal Back Table Stand (Legacy: 315-15-22 or Ergo: 321-15-48/321-19-22 [legs]) (Figure 38).

2. Seat the final HAT implant onto the HAT Back Table Assembly. Ensure that the two laser marks on the implant align to the two laser marks on the back table assembly, allowing the HAT implant to fully seat (Figure 39).

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved

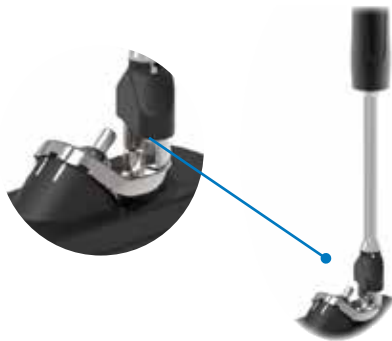


Figure 40

Assemble Extension onto HAT Body and Impact with Extension Impactor



Figure 41

Drive Locking Screw with T-10 Screw Driver Assembled to Torque-Limiting Driver



Figure 42

Lock Reverse Torque Defining Screw

3. Align the Left Extension (320-20-01) or Right Extension (320-20-02) to the seated implant on the HAT Back Table Assembly. Connect the Extension Impactor (319-23-00) to the Impactor Handle (Legacy: 321-07-05 or Ergo 321-09-05), hold the Impactor Handle vertically and use a mallet to strike the Impactor Handle and the Extension directly in line with the taper (Figure 40).

WARNING: Don't assemble or disassemble devices in the surgical field.

4. Remove the HAT implant and Extension from the Back Table Assembly.

5. To secure and lock the extension onto the implant, place the Extension Locking Screw through the hole in the HAT and tighten using the T-Handle Torque-Limiting Driver 802-001 and T-10 Screw Driver (341-01-38) assembly (Figure 41).

Note: The Extension Locking Screw should be fully tightened prior

to final HAT and Extension insertion. Two screws are packaged with the Extension in case one becomes unusable before assembly.

HAT AND EXTENSION ASSEMBLY ONTO STEM

The HAT/Extension and humeral stem can be assembled *in vivo* as described in option one or by utilizing the back table assembly stand first and then placing the construct into the humerus with cement. The disadvantage of this technique is that further implant trialing is not possible. Utilizing the Stem Back Table Insert (Legacy: 321-15-23 & Ergo: 321-19-23 / 321-19-24/321-19-25), the final **Humeral Augmented Tray [(LEFT: 320-00-01, 320-05-01, 320-00-11, 320-05-11, 320-00-21, 320-05-21) or (RIGHT: 320-00-02, 320-05-02, 320-00-12, 320-05-12, 320-00-22, 320-05-22) and optional Extension [(LEFT: 320-20-01) or (RIGHT: 320-20-02)]** is attached to the humeral stem using the Reverse Torque Defining Screw (320-20-00) (Figure 42).

DETAILED OPERATIVE TECHNIQUE

IMPLANTATION OF THE FINAL CONSTRUCT WITH OR WITHOUT EXTENSION

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Figure 43
HAT Full Assembly Impactor



Figure 44
Connect Impactor Handle and Retroversion Bar to the HAT Full Assembly Impactor

IMPLANTATION OF THE FINAL CONSTRUCT WITH OR WITHOUT EXTENSION

In order to implant the HAT and stem as a construct, connect the **Retroversion Bar (301-05-20)** to the **HAT Full Assembly Impactor (319-25-00)** (Figure 43), then connect the HAT Full Assembly Impactor to the Impactor Handle (Legacy: 321-07-05 or Ergo: 321-09-05) (Figure 44).

WARNING: Don't assemble or disassemble devices in the surgical field.

The HAT Full Assembly Impactor will sit within the recessed portion of the HAT tray (Figure 45 - see next page).

OPTION TWO: HAT Implantation in Primary or Revision Procedure Where Adequate Humeral Stem Fixation Can Be Achieved



Figure 45

Impact Stem with HAT/Extension Into Humerus with Full Assembly Impactor and Retroversion Bar



Left: Fracture Stem

Right: Standard Stem

Figure 46

Final Implant - HAT with Standard Stem or Fracture Stem with or without Extension

The Retroversion Bar should be used to ensure proper implant version (*Figure 45*).

Use a mallet to impact the impactor handle strike plate until the implant is fully seated. Once the stem is fully seated with the HAT securely attached, remove the HAT Full Assembly Impactor from the tray and implant the Humeral Liner per standard operative techniques (*Figure 46*).^{1,3}

Note: Ensure the fully seated HAT only or HAT with extension construct does not contact the remaining humeral bone.

















Note: Take precaution to ensure humeral bone is not damaged during stem insertion.

IMPLANT & INSTRUMENT LISTING

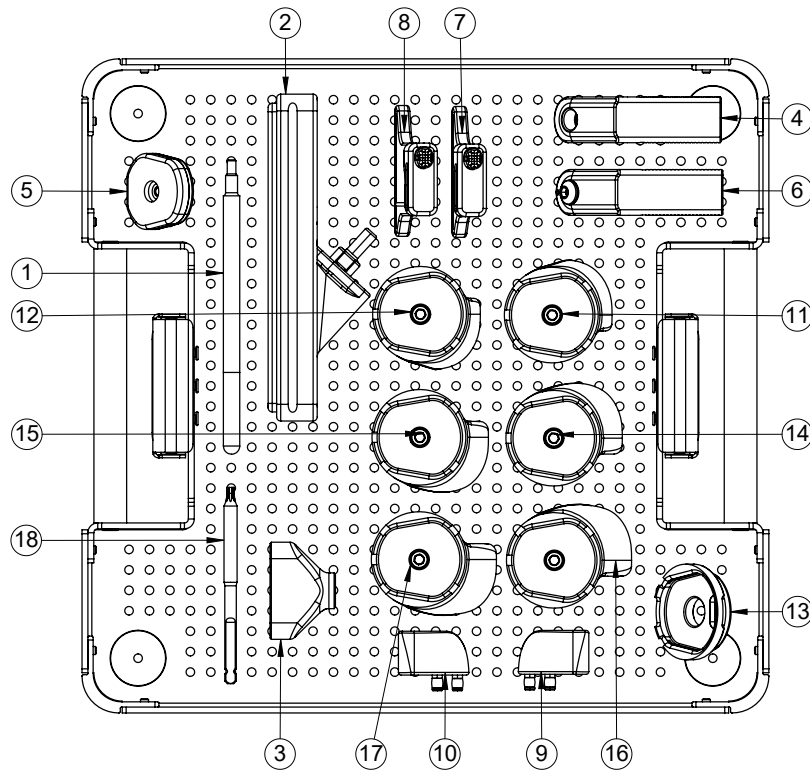
IMPLANTS KIT-320HAT

PART NUMBER	DESCRIPTION	
320-00-01	HAT, +0 Standard, Left	
320-00-02	HAT, +0 Standard, Right	
320-05-01	HAT, +5 Standard, Left	
320-05-02	HAT, +5 Standard, Right	
320-00-11	HAT, +0 Lateralized, Left	
320-00-12	HAT, +0 Lateralized, Right	
320-05-11	HAT, +5 Lateralized, Left	
320-05-12	HAT, +5 Lateralized, Right	
320-00-21	HAT, +0 Extra Lateralized, Left	
320-00-22	HAT, +0 Extra Lateralized, Right	
320-05-21	HAT, +5 Extra Lateralized, Left	
320-05-22	HAT, +5 Extra Lateralized, Right	
320-20-01	Left Extension Implant and Screws	
320-20-02	Right Extension Implant and Screws	

INSTRUMENTS KIT-321HAT

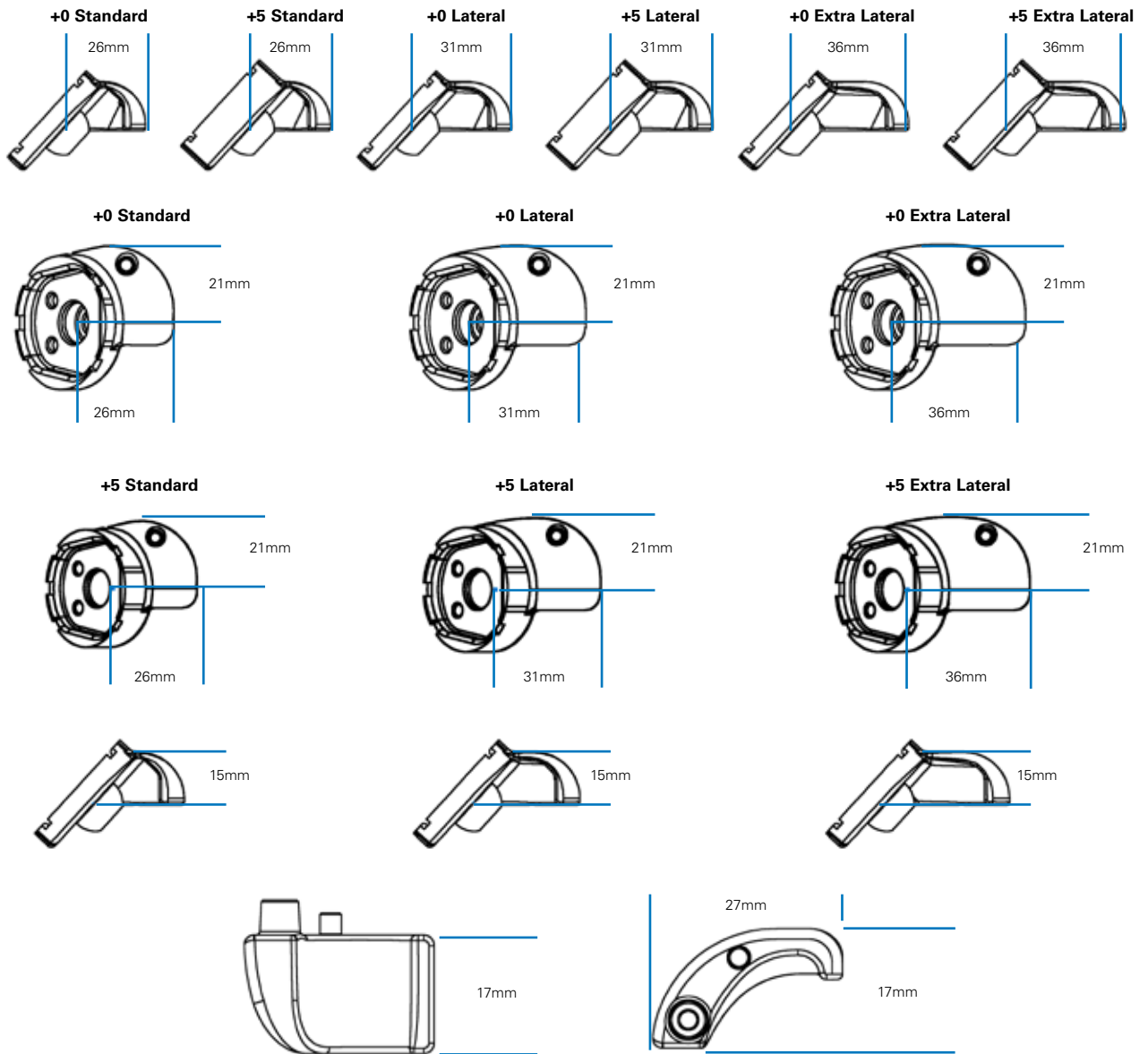
PART NUMBER	DESCRIPTION	
321-24-01	HAT Trial, +0 Standard Left	
321-24-02	HAT Trial, +0 Standard Right	
321-24-11	HAT Trial, +0 Lateralized, Left	
321-24-12	HAT Trial, +0 Lateralized, Right	
321-24-21	HAT Trial, +0 Extra Lateralized, Left	
321-24-22	HAT Trial, +0 Extra Lateralized, Right	
321-20-01	HAT Left Extension Trial	
321-20-02	HAT Right Extension Trial	
319-22-00	HAT Back Table Assembly	
319-23-00	HAT Extension Impactor	
319-24-00	HAT Broach Cut Guide Arm	
319-25-00	HAT Full Assembly Impactor	
319-26-00	HAT Stem Cut Guide Arm	
319-27-00	HAT Body Cut Guide	
319-28-00	HAT Extension Cut Guide	
802-001	T-Handle Torque-Limiting Driver	
301-05-20	Retroversion Bar	
321-10-05	Humeral Adapter Tray Trial +5	
341-01-38	T-10 Screw Driver	

IMPLANT & INSTRUMENT LISTING



#	PART NUMBER	DESCRIPTION
1	301-05-20	Ergo Retroversion Bar
2	319-22-00	Back Table Assembly
3	319-23-00	Extension Impactor
4	319-24-00	Broach Cut Guide Arm
5	319-25-00	Full Assembly Impactor
6	319-26-00	Stem Cut Guide Arm
7	319-27-00	Cut Guide, Tray Augment
8	319-28-00	Cut Guide, Extension
9	321-20-01	Left Extension Trial
10	321-20-02	Right Extension Trial
11	321-24-01	HAT Trial, Captured Screw, +0 Std, Left
12	321-24-02	HAT Trial, Captured Screw, +0 Std, Right
13	321-10-05	Humeral Adapter Tray Trial, +5
14	321-24-11	HAT Trial, Captured Screw, +0 Lat, Left
15	321-24-12	HAT Trial, Captured Screw, +0 Lat, Right
16	321-24-21	HAT Trial, Captured Screw, +0 Extra Lat, Left
17	321-24-22	HAT Trial, Captured Screw, +0 Extra Lat, Right
18	341-01-38	T-10 Driver

HUMERAL AUGMENTED TRAY AND EXTENSION IMPLANT SIZES



IMPLANT	CENTER OF HUMERAL HEAD TO LATERAL OVERHANG	CENTER OF HUMERAL HEAD TO TOP OF HAT SUPERIOR ASPECT	CENTER OF HUMERAL HEAD TO POSTERIOR ASPECT OF HAT	HAT EXTENSION
0 Standard Tray	26MM	15MM	21MM	WIDTH 27MM HEIGHT 17MM
+5 Standard Tray	26MM			
0 Lateralized	31MM			
+5 Lateralized Tray	31MM			
0 Extra Lateralized Tray	36MM			
+5 Extra Lateralized Tray	36MM			

REFERENCES

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EXACTECH, INC.
2320 NW 66TH COURT
GAINESVILLE, FL 32653 USA

+1 352.377.1140
+1 800.EXACTECH
+1 352.378.2617 (FAX)
www.exac.com