AFFINITI® Glenoid

Balanced Through Simplicity

SURGICAL TECHNIQUE

TORNIER

SCIENTIFIC VISION. SURGICAL LEADERSHIP.

The Affiniti® Shoulder System was developed in collaboration with:

John Brems, MD
Cleveland, OH

R. Sean Churchill, MD
Milwaukee, WI

Ed Fehringer, MD
Omaha, NE

Brian Holloway, MD
Knoxville, TN

Edwin Spencer, MD
Knoxville, TN

Proper surgical procedures and techniques are the responsibility of the medical professional. Individual surgeon evaluation of the surgical technique should be performed based on his or her personal medical training and experience. This essential product information does not include all of the information necessary for selection and use of a device. Please see full labeling on package insert for all necessary information.

Table of Contents

Anatomic Design

Anatomic pear-shape mimics that of the native glenoid, reducing overhang and the risk of soft-tissue abrasion

Two varying peg patterns to accommodate anatomy and provide optimal stability

- Tighter pattern for the 40/44
- Wider spread for the 48/52/56

Two central peg lengths

- Shorter central peg for smaller anatomy reducing the risk of perforating the vault (Size 40/44)
- Longer central peg for larger anatomy (Size 48/52/56)

Unique Central Peg

Provides excellent initial fixation

- Fins closest to articular surface buttress cortical wall providing exceptional immediate fixation
- Press-fit central peg minimizes cement usage reducing the risk of thermal necrosis
- Minimally cemented peripheral pegs counteract rotational forces

Enhances long-term fixation

- Fins on the central post allow for bone growth for long-term biologic fixation

Consistent Mismatch

When paired by size, the Affiniti glenoid and humeral heads create a 3mm radial mismatch which reproduces glenohumeral kinematics and reduces wear

INDICATIONS

The Affiniti Total and Hemi-Shoulder System is indicated for

- Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
- Fracture/dislocation of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
- Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component).

Hemi-shoulder replacement is also indicated for

- Ununited humeral head fractures
- Avascular necrosis of the humeral head
- Rotator cuff tear arthropathy

CONTRAINDICATIONS

Total or Hemi-shoulder

- Lack of quality bone to seat and support the implant, including that resulting from skeletal immaturity or osteoporosis.
- Metal allergies or sensitivity
- Infection at or near the site of implantation
- Distant or systemic infection

Total Shoulder

- Lack of sufficient sound muscle or rotator cuff to seat and support the implant

Pre-Operative Planning

Pre-Operative Planning

A careful analysis of X-rays and axial CT scan views is recommended before surgery to evaluate the following parameters:

Osteophytes

Anterior and, more importantly, posterior glenoid wear

Location, orientation and depth of the medullary canal.

Exposure

Exposure

With the arm slightly adducted and internally rotated a posterior retractor (Darrach or Fukuda) is placed on the posterior glenoid border as the proximal humerus is dislocated posteriorly and inferiorly. A Hohmann retractor placed in the subscapular fossa is used to complete the exposure.

A complete anterior glenoid release is performed by sharply excising the remaining labral tissue and releasing the capsule from the 12 o'clock position down to the 6 o'clock position.

If preoperatively the humerus rests in a fixed posteriorly subluxed position, then the posterior capsule may be stretched out sufficiently so that a posterior capsular release for exposure may not be necessary. If after releasing the entire anterior capsule down to 6 o'clock on glenoid face the shoulder is still tight, then additional capsule is released around the posterior inferior corner and up the posterior side until the humerus can be adequately retracted for exposure. The glenoid retractor then is moved upward if more of the posterior release needs to be completed.

Note: The axillary nerve must be protected during the inferior capsulectomy.

SIZE THE GLENOID

Selection of the appropriately sized glenoid is determined using the sizing disks. Once the appropriate size has been selected, align the sizer disk on the glenoid and mark the center (Fig 1). Five sizers are available in the set (40, 44, 48, 52, 56). Matching the glenoid and humeral head sizes will ensure 3mm of radial mismatch.

Note: If significant posterior erosion exists, final sizing of the glenoid should be performed after all reaming is complete.

Fig 1

Head Diameter (Implant)	Glenoid Size (Implant)	Reamer	Center Drill Bit	Peripheral Drill Guide	Trial Glenoid	Color Code
40 mm	40	40	40/44	40/44	40	Rust
44 mm	44	44	40/44	40/44	44	Green
48 mm	48	48	48/52/56	48/52/56	48	Black
52 mm	52	52	48/52/56	48/52/56	52	Blue
56 mm	56	56	48/52/56	48/52/56	56	Yellow

DRILL PILOT HOLE

Freehand drill the center pilot hole using the starter/peripheral drill bit and straight driver (Fig 2). Placement of the surgeon's finger in the subscapularis fossa along the glenoid neck helps verify proper alignment of the starter drill.

Fig 2

If reaming of the glenoid is necessary, select the appropriately sized glenoid reamer as determined by sizer disk. Attach the reamer to either the straight driver or articulated driver.

Using the Articulated Driver

1) To use the articulated driver, attach the reamer in the unlocked straight position.

2) Once attached, pivot the reamer and insert the tip of the reamer into the central hole of the glenoid (Fig 3).

Fig 3

3) Once the reamer tip is seated, use the handle as a lever and retract the reamer shaft into the straight position (Fig 4/Unlocked). Slide the outer sleeve into the locked position (Fig 4/Locked).

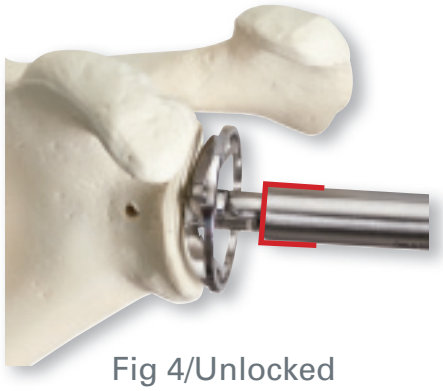


Fig 4/Unlocked

Caution: The articulated driver can only be used in the straight locked position.

Always begin by hand reaming and advance to a power reamer only if necessary. Engage the reamer prior to seating on the glenoid surface and then ream applying gentle pressure.

The reamer should remain perpendicular to the medullary canal. The goal of reaming is to obtain a bony surface that matches the backside of the glenoid component.

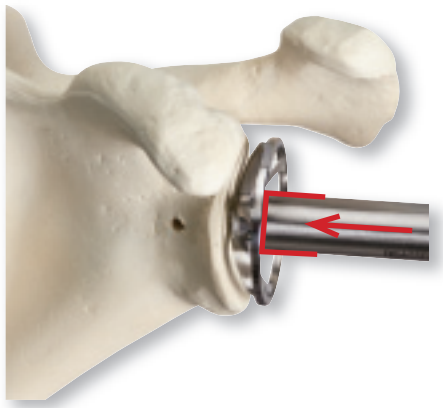


Fig 4/Locked

However, it is not advisable to ream down to cancellous bone because of the limited glenoid bone stock.

Over agressive reaming should be avoided to prevent possible glenoid fracture.

ENLARGE CENTRAL HOLE

Using the straight driver and appropriately sized center drill bit, as determined by the size disk, drill the center hole to the maximum depth allowed. (Fig 5)

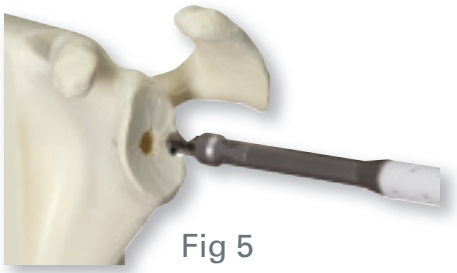


Fig 5

DRILL PERIPHERAL PEG HOLES

According to the glenoid size the peripheral peg pattern varies to provide better rotational stability.

Two peripheral drill guides are available (40/44 and 48/52/56).

Select the guide that corresponds with the center drill used in the previous step and attach the optional handle to the appropriate side (Left or Right).

Insert the post of the drill guide into the center hole until the backside of the drill guide is fully seated on the reamed surface of the glenoid. After verifying proper rotation by checking the location of the peripheral peg holes, seat this securely using the tamp and mallet.

Fig 6

Using the starter/peripheral drill bit and straight driver, drill the anterior or superior hole. Be sure to drill to the maximum depth allowed by the guide. The maximum depth is obtained when the drill bit collar contacts the drill guide.(Fig 6)

Insert an anti-rotation peg using the peg inserter/remover and then drill the remaining anterior or superior hole, inserting an additional anti-rotation peg. Complete this step by drilling the posterior hole and removing anti-rotation pegs and peripheral drill guide. (Fig 7)

Fig 7

Note: For the posterior hole the straight driver may work as a retractor against the proximal humerus in order to obtain the desired drill angle. The previously placed anti-rotation pegs provide the stability of the guide during this process.

INSERT TRIAL GLENOID

The trial glenoid component is used to check for appropriate size, coverage and positioning. Insert the trial by either using the grasper superiorly and inferiorly or by freehand placement. (Fig 8)

Three windows on the trial glenoid component allow visualization of the implant bone interface. Use these windows to ensure the trial sits flush on the prepared surface of the glenoid.

The trial component is then removed and the peg holes and glenoid surface are carefully cleaned and dried.

Fig 8

IMPLANT GLENOID PROSTHESIS

Cementing of the three peripheral holes is then performed. This is completed by syringe pressurization of the cement into the three peripheral holes.

Reamed bone from the glenoid or backside of the humeral head may be used as a graft between the fins on the central post to facilitate bony integration. **No cement is placed in the central hole.**

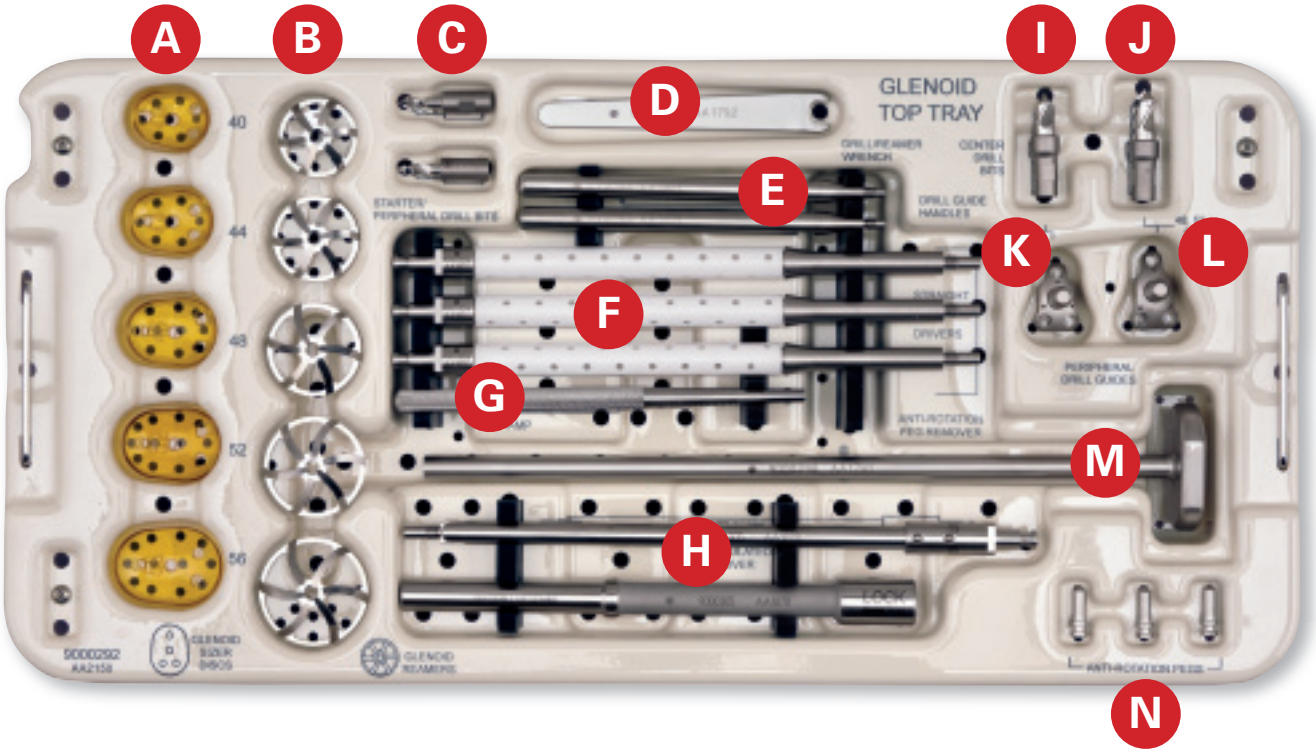
The final implant is inserted into the joint and aligned either using the grasper or freehand (Fig 9). To seat the glenoid place a thumb in the middle of the implant and with the proper alignment verified, apply pressure. To complete the insertion two impactor tips are available (40/44 and 44/52/56).

Using the appropriately sized tip, impact the implant until there is complete contact with the perimeter of the glenoid (Fig 10). Apply direct pressure on the component until the cement has hardened.

Fig 9

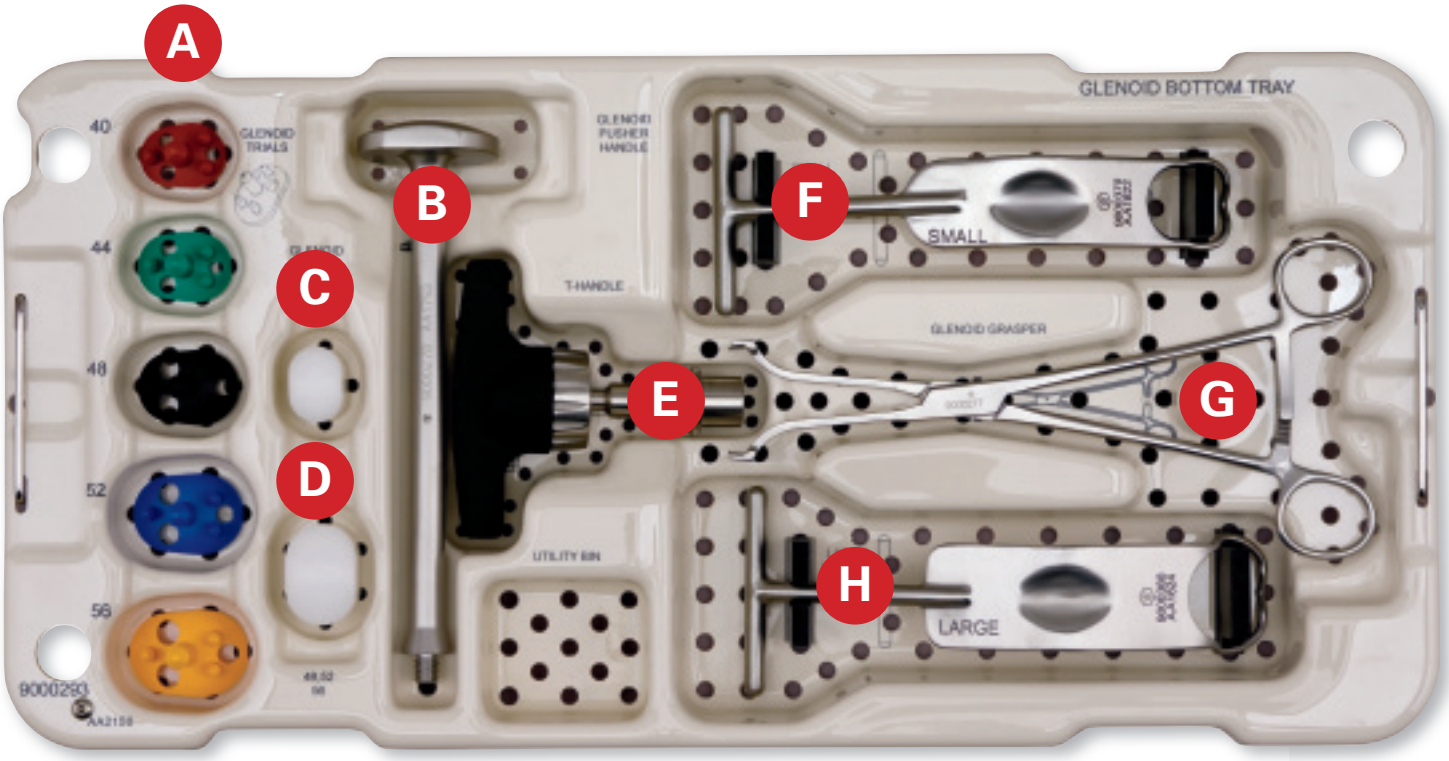
Fig 10

Glenoid Top Tray



Instrument	Catalog #	Description
A	9000340	40 Glenoid Sizer
A	9000344	44 Glenoid Sizer
A	9000348	48 Glenoid Sizer
A	9000352	52 Glenoid Sizer
A	9000356	56 Glenoid Sizer
B	9000440	40 Glenoid Reamer
B	9000444	44 Glenoid Reamer
B	9000448	48 Glenoid Reamer
B	9000452	52 Glenoid Reamer
B	9000456	56 Glenoid Reamer
C	9000255	Glenoid Starter/Peripheral Drill Bits
D	9000295	Glenoid Drill/Reamer Wrench
E	9000294	Glenoid Drill Guide Handles
F	9000304	Glenoid Straight Drill/Reamer Drivers
G	9000323	Tamp
H	9000305	Glenoid Articulated Driver
I	9000301	Glenoid Center Peg Drill Bit - Short 40,44
J	9000284	Glenoid Center Peg Drill Bit - Long 48,52,56
K	9000296	Glenoid Peripheral Drill Guide - Small 40,44
L	9000303	Glenoid Peripheral Drill Guide - Large 48,52,56
M	9000298	Glenoid Antirotation Peg Remover
N	9000297	Glenoid Antirotation Pegs

Glenoid Bottom Tray



Instrument	Catalog #	Description
A	9000200	40 Peg Glenoid Trial
A	9000201	44 Peg Glenoid Trial
A	9000202	48 Peg Glenoid Trial
A	9000203	52 Peg Glenoid Trial
A	9000204	56 Peg Glenoid Trial
B	9000278	Glenoid Pusher
C	9000282	Glenoid Pusher Tip - Small 40,44
D	9000322	Glenoid Pusher Tip - Large 48,52,56
E	9000264	T Handle w/ Hudson End
F	9000379	Small Fukuda Retractor
G	9000277	Glenoid/Trial Grasper
H	9000380	Large Fukuda Retractor

Notes

Notes

GLENOID IMPLANTS

Catalog #	Description
0020060	40 Pegged Glenoid
0020061	44 Pegged Glenoid

Catalog #	Description
0020062	48 Pegged Glenoid
0020063	52 Pegged Glenoid
0020064	56 Pegged Glenoid

TORNIER

Distributed by:
Tornier, Inc.
Edina, MN 55435
USA
+1 888 867 6437
+1 281 494 7900
www.tornier-us.com

3000050RA - 12/2008