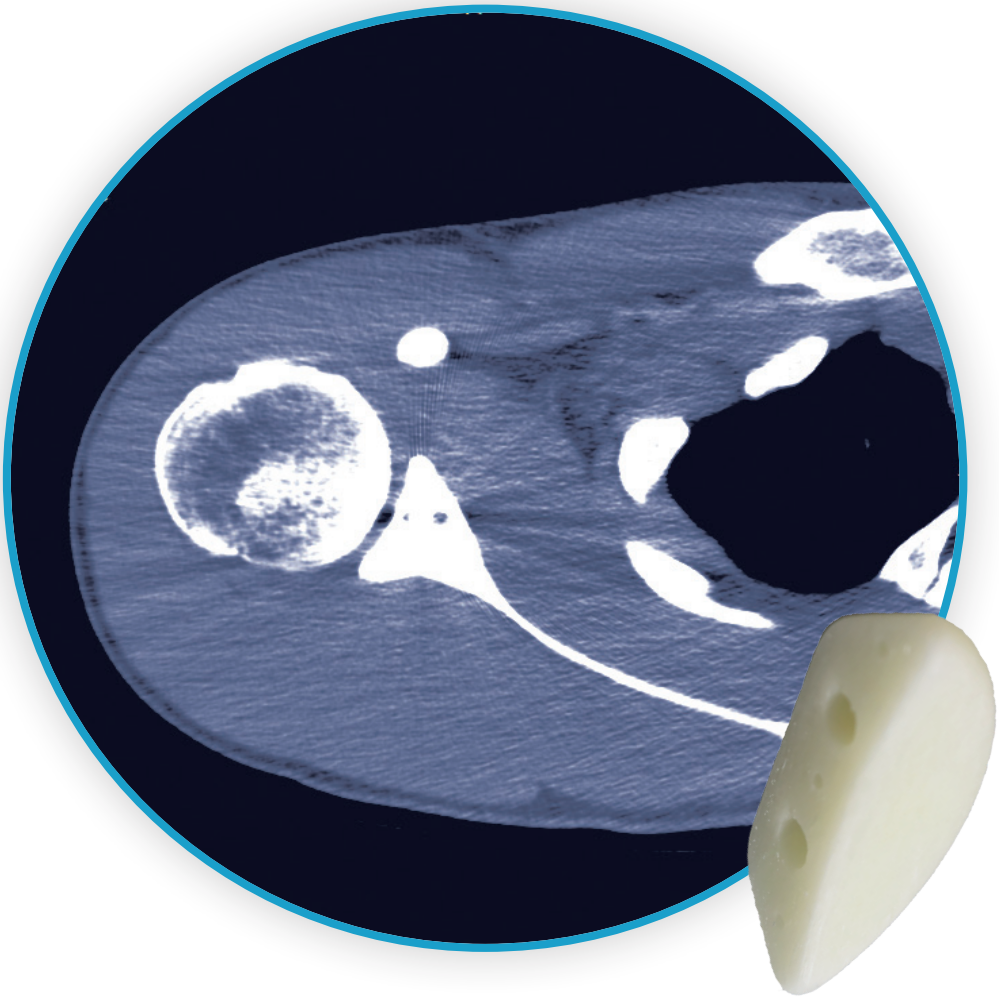
ANIKA

Glenojet® Allograft System

Surgical Technique Guide



ANIKA arthrosurface

Glenojet Introduction

The Glenojet Allograft System was created to replace and augment anterior glenoid bone loss associated with trauma, recurrent dislocation or an unstable shoulder.

- Pre-shaped, pre-drilled human cortical allograft designed to match the contours of the glenoid defect
- May reduce operative and preparation time compared to traditional lataret procedures.
- Sling effect can still be achieved without the need for dissecting the coracoid.
- Effective revision option as the patient's coracoid is still intact.

"The current body of Level IV data suggests that allograft reconstruction for glenoid bone loss provides excellent clinical outcomes, low rates of recurrent instability, and high osseous incorporation rates with no evidence of graft resorption."

Sayegh ET, Mascarenhas R, Chalmers PN, Cole BJ, Verma NN, Romeo AA. Allograft reconstruction for glenoid bone loss in glenohumeral instability: a systematic review. Arthroscopy. 2014 Dec;30(12):1642-9. doi: 10.1016/j.arthro.2014.05.007. Epub 2014 Jul 4.

Description

The Glenojet Allograft System consists of a shaped human tissue cortical bone allograft. Sterile, single-use instruments are available and are intended to facilitate positioning and implant site preparation for the Glenojet Allograft.

Sterility

The Glenojet Allograft is sterilized by exposure to gamma radiation. The Glenojet System Instruments are sterilized by exposure to gamma radiation. Do not resterilize any components. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date.

Indications for Use

Intended to be used for the repair, replacement, or reconstruction of musculoskeletal defects including bony pathologies associated with shoulder instability, such as anterior glenoid bone loss, bony Bankart, glenoid fracture or engaging Hill-Sachs lesions. Patient selection factors to be considered include:

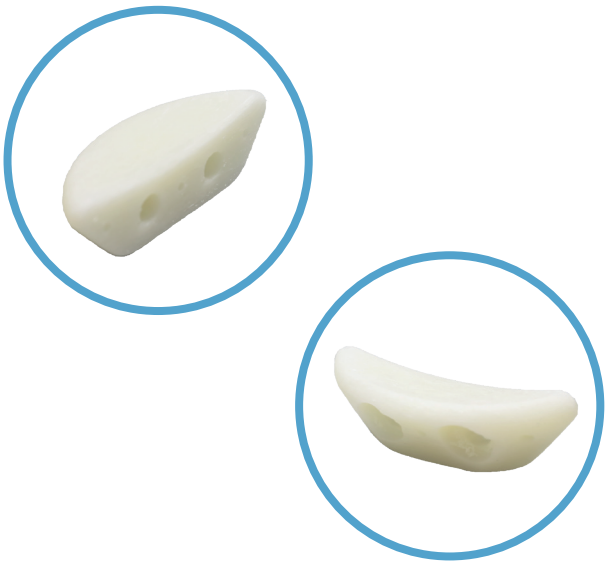
1. Need to obtain pain relief and improve function.
2. Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

Anterior Deltopectoral Approach

Glenojet Allograft System

1. Beachchair position (tilt back to 30-45 degree angle).
2. Short deltopectoral incision (from coracoid tip to pectoralis major insertion).
3. This incision is utilitarian and can be converted to an extensile approach if necessary.
4. Identify coracoid tip. Identify pectoralis major insertion.
5. Develop deltopectoral interval.
   a. The cephalic vein may go either medially or laterally. Lateral retraction of the cephalic vein can be beneficial because it preserves the venous outflow from the deltoid.
   b. Identify coracoid tip.
   c. Identify pectoralis major insertion.
6. Release subdeltoid and subacromial adhesions. Abducting the shoulder in order to relax the deltoid facilitates this step.
7. Retract the deltoid and pectoralis major muscles. This step is facilitated by the use of a blunt, multi-pronged self-retaining retractor.
8. Identify and develop the lateral border of the conjoined tendon. This step is assisted by flexion of the shoulder, which relaxes the conjoined tendon & facilitates exposure.
9. Retract the conjoined tendon medially. Take care to not injure the musculocutaneous nerve. A blunt retractor under the conjoined tendon facilitates exposure while minimizing risk to the nerve.
10. Remove bursa from atop the subscapularis insertion. The subscapularis can be dealt with in a number of ways. It can either be split in line with its fibers and separated from the underlying capsule, it can be tenotomized leaving 1-2 cm attached to the tuberosity for repair, or it can be peeled from the tuberosity and separated from capsule.

    Alternatively, the lesser tuberosity may be osteotomized with a sharp, 1 inch straight osteotome. This will allow bone-to-bone healing at the conclusion of the procedure.
11. A glenoid retractor must be placed on the anterior glenoid neck to give exposure and access to the glenoid. The conjoined tendon is retracted medially to allow flush placement of the glenoid guide on the glenoid face. Alternatively, if one wants to use the sling effect of the conjoined tendon as part of this repair procedure, it can be released from the coracoid tip, stay sutures placed in the end of the tendon and then later attached to the Glenojet implant. Detachment of the conjoined tendon facilitates glenoid exposure. Address any glenoid pathology with Glenojet System as indicated.

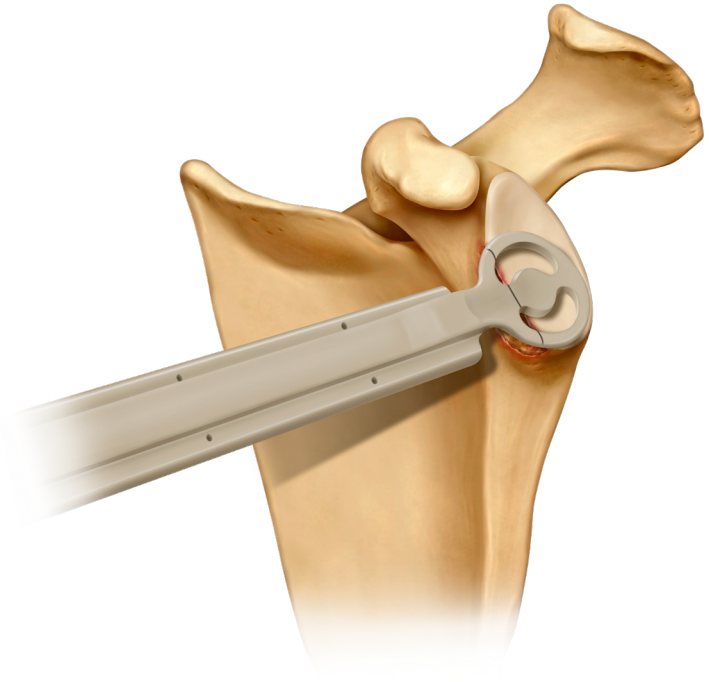


Surgical Technique

Implantation of the Glenojet Allograft System

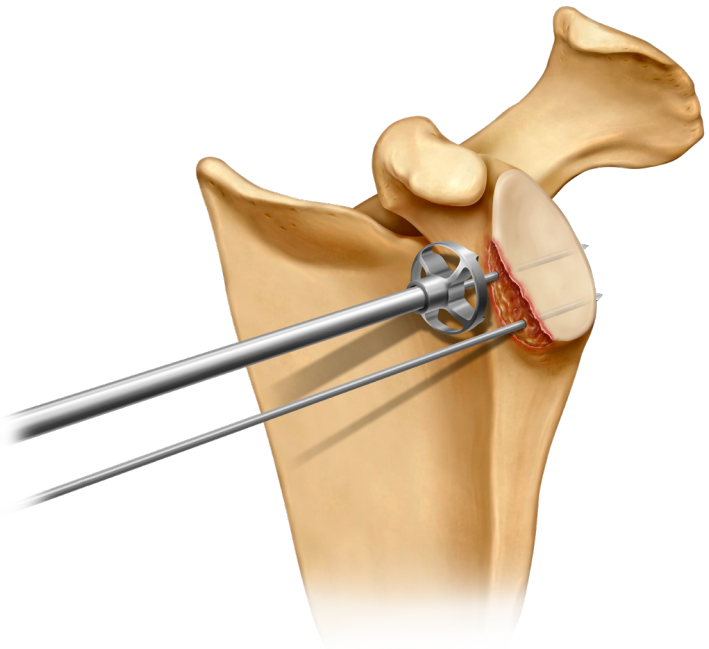
Step 1

Use **Drill Guide** to locate graft position on anterior glenoid surface. Position **Drill Guide** central to inferior aspect of glenoid so that the convex distal surface of the **Drill Guide** conforms with glenoid articular surface. (The laser mark on the **Drill Guide** should be positioned in-line with the anterior glenoid fracture plane. Position the guide flush with the articular surface to assure graft anatomic placement). Place tip of first **Guide Pin** into the **Drill Guide** and advance **Guide Pin** into bone to the depth of the etch mark using a pin driver. (The etch mark inserts the guide pin to the end of the circular Drill Guide, which should be close to or just through the posterior cortex of the glenoid). Repeat for second **Guide Pin**.



Step 2

Introduce **Reamer** over first **Guide Pin** and advance under power until the **Reamer** depth stop makes contact with the proximal end of the **Guide Pin**. Be sure to start **Reamer** before contacting bone. Repeat reaming step over second **Guide Pin**.



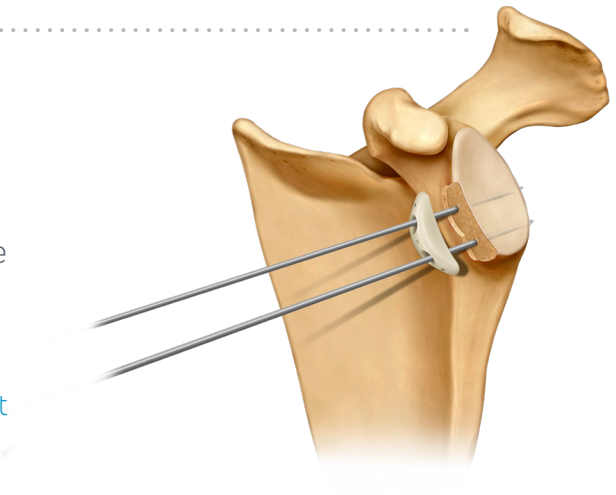
Surgical Technique

Implantation of the Glenojet Allograft System

Step 3

Position the **Glenojet Graft** so that both **Guide Pins** pass through the pre-drilled holes in the **Glenojet Graft** and the concave surface of the **Glenojet Graft** is continuous with the surface of the native glenoid.

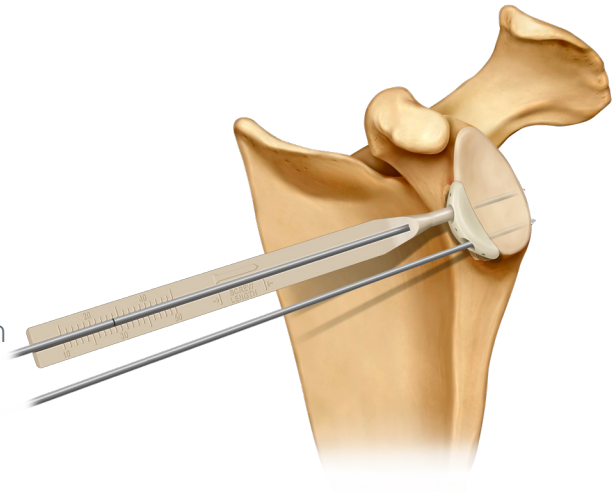
Note: Suture holes are supplied in the graft to allow for placement of suture configuration so capsule can be placed at the edge of the glenoid depending on surgeon preference. As previously stated, the conjoined tendon can be attached with sutures to the graft if one prefers to provide a sling effect similar to a latarjet procedure.



Step 4

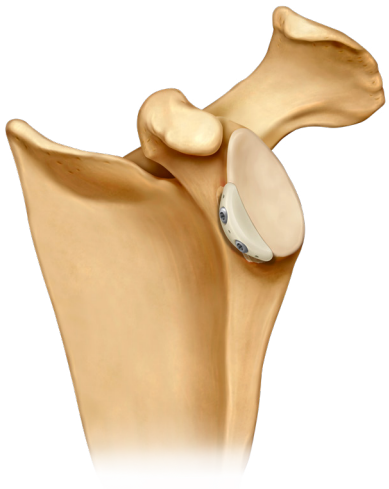
Introduce **Depth Gauge** over the **Guide Pin** to determine appropriate length of cortical bone screw to engage posterior cortex of glenoid through the pre-drilled holes in the **Glenojet Graft** and along the pilot hole created by the **Guide Pin**.

Note: A 3.5mm or 4.0mm cortical bone screw may be used at the surgeon's discretion based upon patient morphology.



Step 5

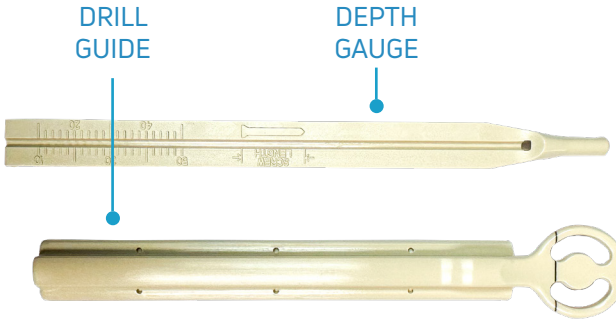
Remove inferior and superior **Guide Pins**. Insert **Bone Screws**, alternating between inferior and superior screws until they are both tightened. Graft and screw final position may be confirmed radiographically.



Instrumentation

Glenojet Allograft System

G500-1000
Sterile Disposable Glenojet Instrument Kit



2.0mm
GUIDE PINS (2)

G500-2000
Sterile Disposable Glenojet Reamer

DISPOSABLE
REAMER

System Catalog

Glenojet Bone Grafts	
G500-0200	10MM X 29MM (Ø33mm Glenoid)
G500-0300	12MM X 32MM (Ø36mm Glenoid)

4.0mm Cortical Screws & Hex Driver	
G501-1024	4.0mm x 24mm, Cortical Screw, Solid, Partially Thread
G501-1026	4.0mm x 26mm, Cortical Screw, Solid, Partially Thread
G501-1028	4.0mm x 28mm, Cortical Screw, Solid, Partially Thread
G501-1030	4.0mm x 30mm, Cortical Screw, Solid, Partially Thread
G501-1032	4.0mm x 32mm, Cortical Screw, Solid, Partially Thread
G501-1034	4.0mm x 34mm, Cortical Screw, Solid, Partially Thread
GS09-2000	Hex Driver, 2.5mm

Glenojet Instrument Kits	
G500-1000	Disposable Drill Guide, Depth Gauge & 2.0mm Non-threaded Guide Pins
G500-2000	Disposable Reamer (Ø 20mm)

Warnings

Proper surgical techniques are the responsibility of the medical professional. The Glenojet Instruments are furnished as tools to facilitate positioning and implant site preparation for the Glenojet Allograft. Each surgeon must evaluate the appropriateness of the instruments and techniques for each patient based on his or her own medical training and expertise. As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy or high dosage radiation therapy. Every patient is different and patient results may vary. Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post operative instructions and activity restrictions.

Caution

United States Federal law restricts this device to sale by or on the order of a physician.

Precautions

All Glenojet Allograft System components are for single patient use and should never be reused. Inspect components prior to use for damage during shipment or storage. Verify that components are within expiry date on package label. Expired product should be properly discarded. Reuse of these single patient use components may potentially result in serious patient harm. Examples of hazards related to the reuse of these components include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Possible Adverse Effects

General risks and complications may include, but are not limited to: infection, allergic reaction, loosening or loss of fixation of the graft, poor integration of the graft bleeding, injury to nerves, etc.

Complications may occur with tissue transplantation and surgeons should discuss these possible adverse events with their patients:

- Transmission of disease of unknown etiology
- Transmission of unknown infectious agents including, but not limited to, HIV, Hepatitis, syphilis and bacteria
- Immune rejection of HCT/P

Refer to the Glenojet Allograft package insert for additional potential adverse effects.

Any adverse outcomes potentially related to this tissue allograft must be promptly reported to Anika, Inc.

Shoulder Portfolio

OVO

Asymmetrical

40

Symmetrical

Asymmetrical

35

Symmetrical

Asymmetrical

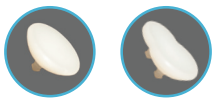
30

Symmetrical

25

Symmetrical

GRS



✶ *The Inlay Gleniod Replacement system glenoid component is currently not available in all markets.*

GLS

Notes

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www.anika.com | Anika. Restore Active Living.® | Stay Active®

AML-900-436 REV 02

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