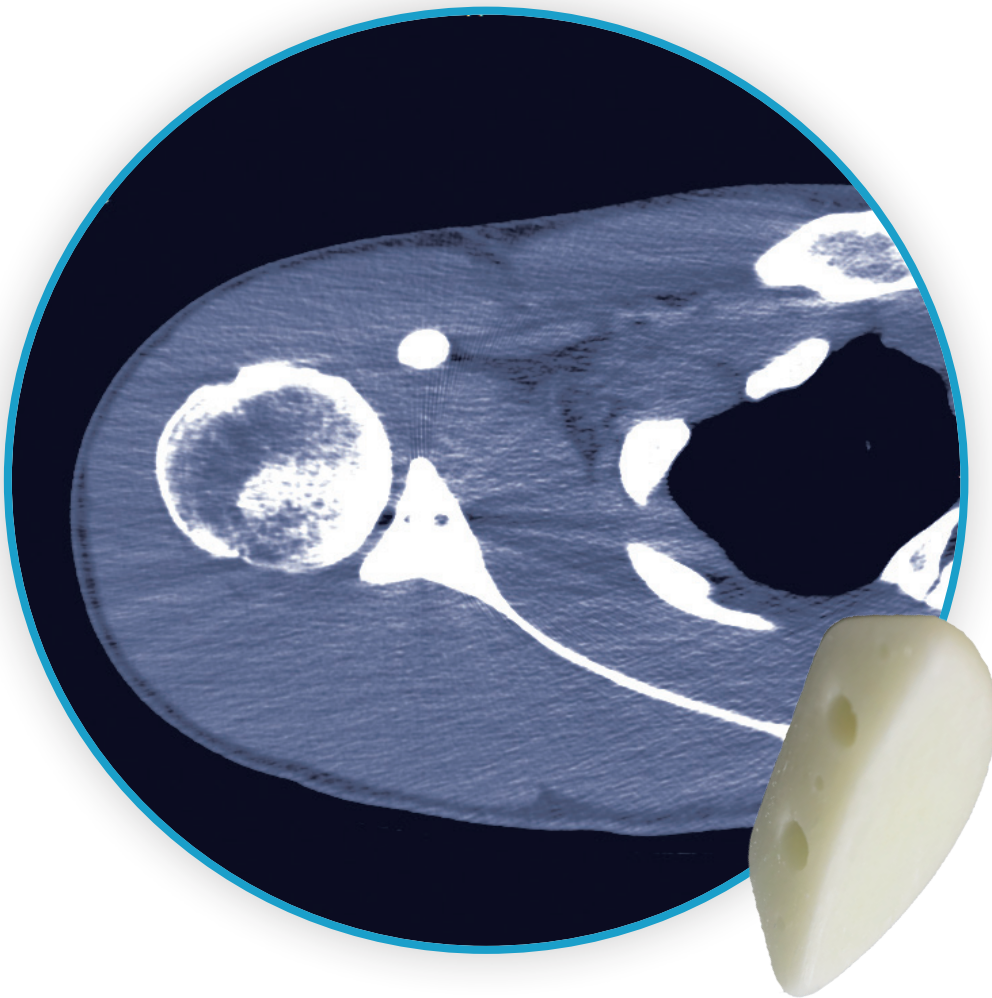


Glenojet[®] Allograft System

Surgical Technique Guide



arthrosurface

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Glenojet Introduction

The Glenojet Allograft System was created to replace and augment anterior glenoid bone loss associated with trauma, recurrent dislocation or unstable shoulder. It eliminates the procedural steps and surgical time associated with autograft bone harvesting and preparation and is a great alternative to a Latarjet procedure.

- Pre-shaped, pre-drilled human cortical allograft reduces operative and prep time.
- Sling effect can still be achieved without the need for dissecting the coracoid.
- Excellent revision option for failed Latarjet.

The cortical bone graft used in the Glenojet is identical in materials and processing to cortical bone grafts that have been used in hundreds of thousands of cervical spinal fusions with over 9 years of clinical history.

“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.”

Arthroscopy. 2014 Dec;30(12):1642-9. doi: 10.1016/j.arthro.2014.05.007. Epub 2014 Jul 4.

Description

The Glenojet Glenoid Laterjet System consists of a shaped human tissue cortical bone allograft; and a single-use, sterile instrument kit containing a Drill Guide and a Reamer to facilitate accurate placement of the graft. The Glenojet Shaped Human Tissue Allograft is 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. Refer to the Glenojet Shaped Human Tissue Allograft package insert for additional instructions for use. The Glenojet Instruments are intended to facilitate positioning and implant site preparation for the The Glenojet Shaped Human Tissue Allograft.

Sterility

The Glenojet Shaped Human Tissue Allograft is sterilized by exposure to gamma radiation. The Glenojet Glenoid Laterjet 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.

Anterior Deltopectoral Approach

Glenojet Latarjet 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 musculo-cutaneous nerve. A blunt, non self-retaining 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.

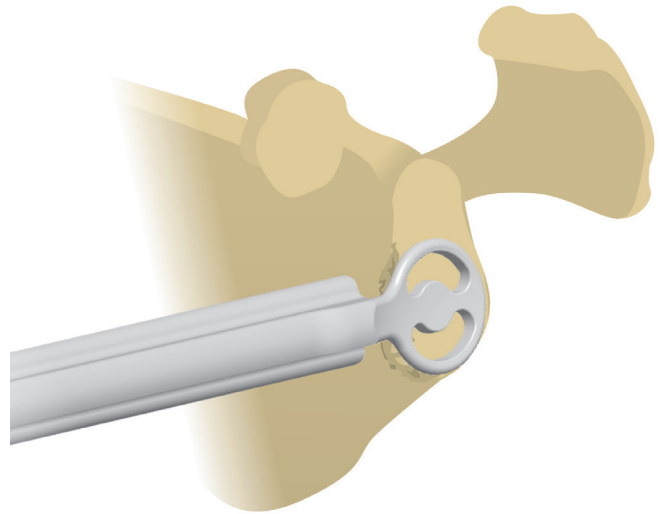


Surgical Technique

Implantation of the Glenojet Laterjet System

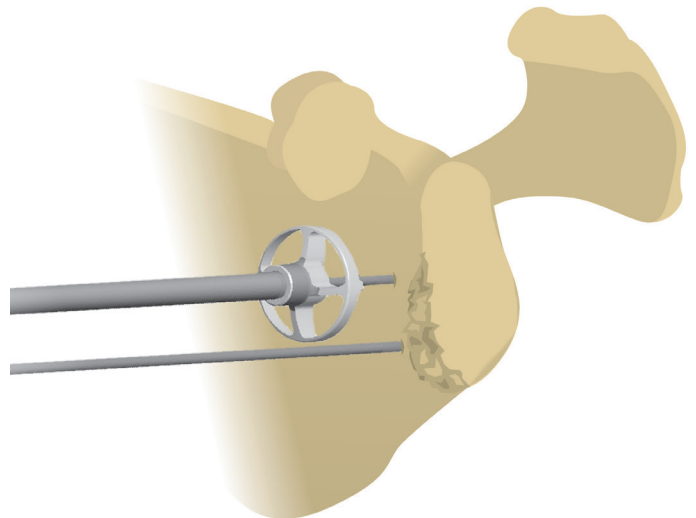
Step 1

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 cannulated powered drill. (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**. Repeat for second **Guide Pin**.

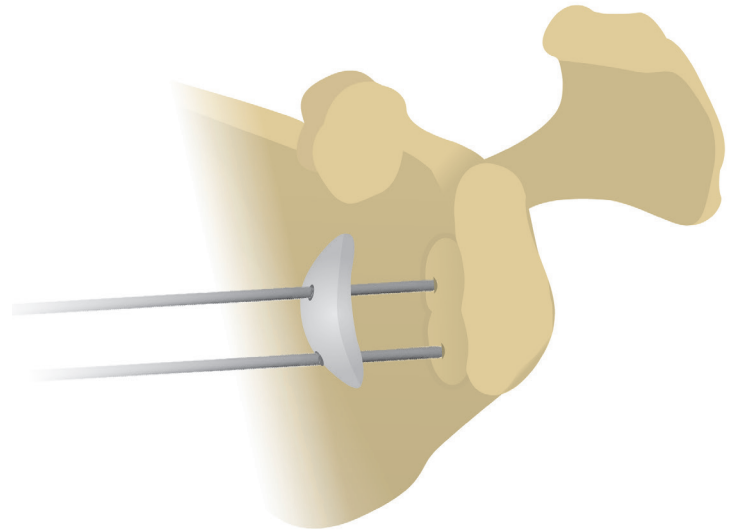


Surgical Technique

Implantation of the Glenojet Laterjet System

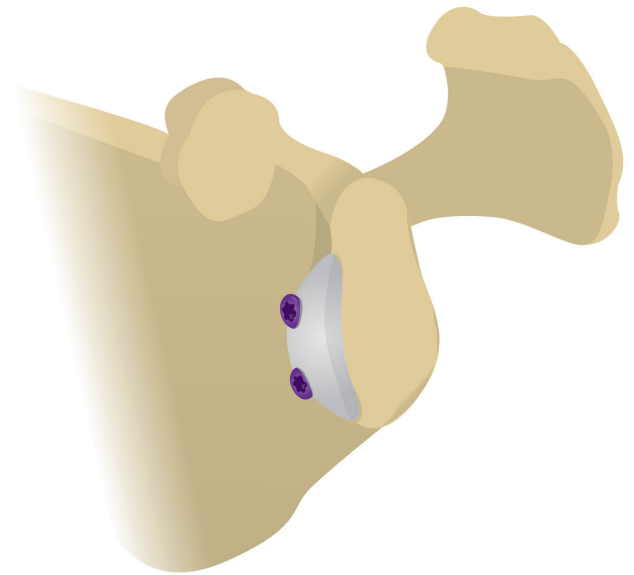
Step 3

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



Step 4

Remove inferior **Guide Pin**. Determine appropriate length 3.5mm Cortical Bone Screw (not supplied) to engage posterior cortex of glenoid thru the pre-drilled holes in the **Glenojet Graft** and along the pilot hole created by the **Guide Pin**. Deliver the inferior 3.5mm Cortical Bone Screw. Repeat for the superior screw location. Confirm graft and screw final position radiographically.

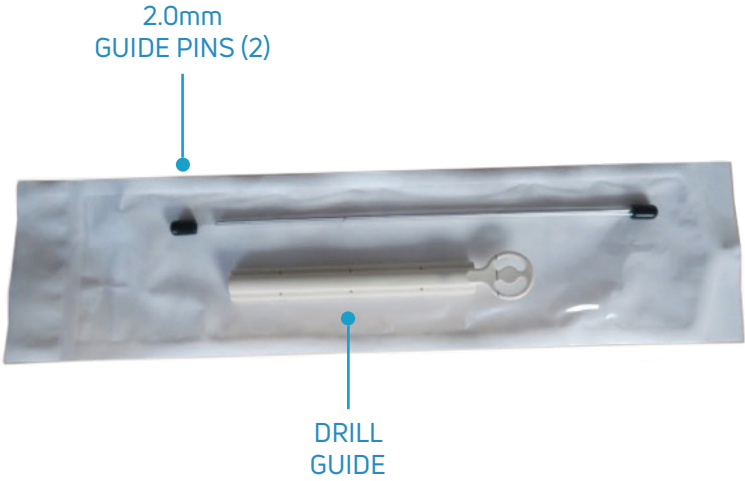


Note: Suture Holes are supplied in the graft to allow for placement of suture configuration so capsule can be of the graft or edge of glenoid depending on surgeon preference. As previously stated, the conjoined tendon can be attached with sutures to the graft if one prefers to provide a sling effect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

Instrumentation

Glenojet Latarjet System

G500-1000 Disposable Sterile Product



G500-2000 Disposable Sterile Product



System Catalog

Instrumentation Systems

G500-1000	Drill Guide & 2.0mm Pins
G500-2000	Disposable Reamer

Glenojet Bone Grafts

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

Warnings and Precautions

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 Shaped Human Tissue 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 an physician.

Precautions

All Glenojet Glenoid Latarjet 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 Shaped Human Tissue 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

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Asymmetrical

40



Symmetrical

Asymmetrical

35



Symmetrical

Asymmetrical

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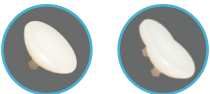
Symmetrical

25



Symmetrical

GRS



★ The Inlay Glenoid Replacement system glenoid component is currently not available in all markets.

GLS



Notes

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28 Forge Parkway, Franklin, MA 02038

1-508-520-3003 | stayactive@anika.com

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

This product is covered by one or more of U.S. Patent Nos. 6,520,964, 6,610,067, 6,679,917 and other patents pending.

This pamphlet and information is intended for markets where regulatory approval has been granted.

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System designed and manufactured in the U.S.A. | Printed in the U.S.A.

PN 3001-3020 REV D

