arthrosurface®

glenojet

Glenoid Latarjet System
Instructions for Use

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Description

The Glenojet™ Glenoid Latarjet 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.

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.

Contraindications

Absolute contraindications include:

1. Inflammatory degenerative joint disease, rheumatoid arthritis, infection, sepsis, and osteomyelitis.
2. Patients that have a known sensitivity to implant alloys typically used in orthopedic bone screws.

Relative contraindications include:

1. Uncooperative patient or patient incapable of following preoperative and postoperative instructions.

2. Metabolic disorders which may impair the formation or healing of bone.
3. Infections at remote sites which may spread to the implant site.
4. Rapid joint destruction or bone resorption visible on roentgenogram.
5. Chronic instability or deficient soft tissues and other support structures.
6. Vascular or muscular insufficiency.

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™ 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.

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 Arthrosurface, Inc.

Sterility

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

The Glenojet™ Glenoid Latarjet 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.

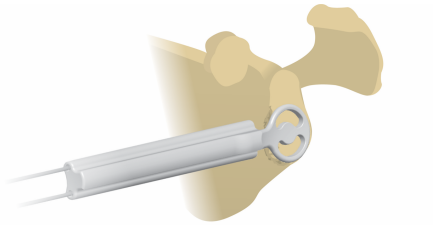
Caution

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

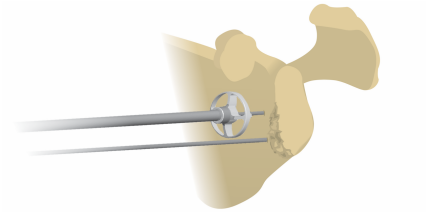
Instructions for Use

Implantation of the Glenojet™ Glenoid Latarjet System shaped human tissue bone allograft

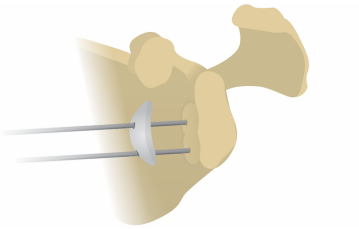
1. Use **Drill Guide** to locate graft position on anterior glenoid surface. Position **Drill Guide** central to inferior aspect of glenoid so that the convex distal surface of the **Drill Guide** conforms with glenoid articular surface. Place tip of first **Guide Pin** into the **Drill Guide** and advance **Guide Pin** into bone to the depth of the etch mark using a cannulated powered drill. Repeat for second **Guide Pin.**



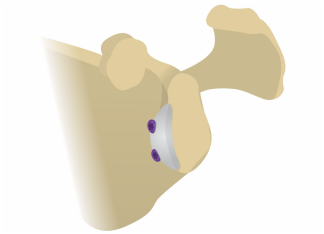
2. Introduce **Reamer** over first **Guide Pin** and advance under power until the **Reamer** depth stop makes contact with the proximal end of the **Guide Pin**. Repeat for second **Guide Pin**.



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.



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.



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