TSY™ SHOULDER PLATE
Bone Graft Stabilization System

Endoscopically Guided Subchondral Intraosseous Osteotomy and Bone Graft Stabilization of the Humeral Head
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Dear Colleagues:

Osteonecrosis of the humeral head can be viewed as a disease with a variety of pathologic presentations likely to require surgical intervention. Although occurring less frequently than osteonecrosis of the femoral head, the goals of treatment are relief of pain, maintenance of shoulder joint congruency and range of motion, and delay or prevention of total or hemi shoulder arthroplasty. The ideal treatment for early stages will preserve the natural humeral head, with the chosen treatment modality being influenced by the age of the patient and the stage of disease with an emphasis on the presence and degree of collapse, as well as the size and location of the lesion.

Variable success rates (range, 33% to 95%), depending on the stage of disease, have been achieved with core decompression of the femoral head, under the guise that the procedure decreases intraosseous pressure and improves intraosseous circulation. Whereas extrapolation of clinical data from the hip to the shoulder may be common, treatment options for early stage disease are limited. However, with continued clinical success using an endoscopically guided approach to ensure thorough debridement of the femoral head, OSI formally offers an identical approach for osteonecrosis of the humeral head.

The endoscopically guided approach used with the TSY™ Shoulder Plate Bone Graft Stabilization System (BGSS) is specifically designed to assist those surgeons who determine that thorough debridement and nonvascularized bone-grafting is the best treatment modality for a given patient. The endoscopic approach enhances the surgeon’s ability to identify and debride necrotic bone within the humeral head while minimizing the soft-tissue dissection. The TSY™ Shoulder Plate stabilizes the fresh autologous cancellous bone and bone marrow, preventing micromotion of the graft composite, thereby assisting its incorporation into the surrounding host bone through primary bone healing.

The following monograph introduces the TSY™ Shoulder Plate BGSS and the surgical technique used to maximize procedural efficiency.

Orthopedic Sciences, Inc.

Suggested Reading


**Diagnosis of Osteonecrosis**

The diagnosis of osteonecrosis of the shoulder should be confirmed with a complete and thorough history and physical examination along with appropriate radiographic studies. Plain film radiographs are essential to making the diagnosis and should include a true AP, an internally and externally rotated AP, and an axillary view. Additionally, a MRI, which is <90% sensitive and specific, may be obtained to allow one to characterize the extent of involvement of the necrotic lesion on T1 and T2 weighted images. However, a CT scan should be obtained if the MRI is nondiagnostic. Importantly, the surgeon must rule out rotator cuff and subacromial disease.

**Preoperative Lesion Localization**

Using the transparencies, align the tracing of the implant along the lateral cortex of the proximal humerus. Choose the tracing that has a barrel angle that best causes the central axis of the implant barrel to pass through the centroid of the necrotic lesion, as shown in Figure 3. The implant choice (130° to 140°, in increments of 5°) is based on the location of the lesion within the humeral head and not the native head-shaft angle of the proximal humerus.
**Surgical Technique**

**Patient Positioning**

The patient is positioned supine or in the beach chair position on a fracture table, having the entirety of the affected extremity prepared free. A bump should be placed under the patient’s shoulder. Obtain fluoroscopic images prior to preparing and draping the patient to ensure unobstructed visualization of the humeral head in the externally rotated, internally rotated, and axillary views. Please see Figures 4 & 5.

**Intraoperative Lesion Localization**

Starting at the tip of the acromion, a direct lateral deltoid splitting 3cm to 4cm incision is fashioned over the proximal humerus. The incision should not extend more than 5cm distal to the acromion and extreme care should be exercised to avoid injury to the axillary nerve. The multipennate anatomy of the deltoid will facilitate splitting of its fibers. Carry the dissection down to the lateral cortex juxtainferior to the insertion of the supraspinatus. Use the angle-guide/guide plate that matches the barrel angle determined preoperatively. Align the chosen angle-guide along the lateral cortex of the proximal humerus approximately 1.5cm distal to the insertion of the supraspinatus. Advance the threaded-tip 3.2mm guide wire toward and up to the centroid of the necrotic lesion using a power drill. The guide wire should be inserted just superior to the inferior margin of the humeral head and inferior to the greater tuberosity. Once the guide wire is inserted, do not rotate the arm without first retracting the soft tissue, as doing so will bend the guide wire and/or split the humeral head. See Figure 6. Disengage the drill and angle-guide from the guide wire.
**Intraoperative Lesion Localization**

Obtain an externally rotated and axillary view to ensure proper placement of the guide wire in the anterior and posterior planes of the humeral head. One should observe a sufficient amount of bone circumferential to the guide wire in all planes to make certain that the compression screw will remain buried within the humeral head once placed therein (3.5mm on either side of the guide wire in two planes). As shown in Figure 6, confirm that the angle established between the lateral cortex of the proximal humerus and the guide wire is within 130° to 140°, in increments of 5°. The angle guide/guide plate is used to confirm that the true implant will lie flush against the lateral cortex of the proximal humerus PRIOR to establishing a portal of entry. If 1 of the 3 guide plates cannot be shown to lie flush against the lateral cortex in the AP view, adjustments should be made until proper alignment is achieved before establishing the portal of entry.

**Establish The Portal of Entry**

Pass the 12mm OD reamer over the guide wire to establish a portal of entry in the lateral cortex of the proximal humerus. The base of the reamer has an enlarged diameter to ensure that the insertion of the reamer is no more than 17mm. See Figure 8.

**Retrieval of the Antecedent Core of Bone**

Insert the core-retrieval guide into the portal of the proximal humerus as shown in Figure 9. Attach the disposable 8mm ID x 6" coring trephine to its insertion handle. The OD of the coring trephine is 9mm.
Using pronosupination, insert the coring trephine into the humeral head over the guide wire. Advance the trephine into the humeral head up to the tip of the guide wire. Use fluoroscopy to observe the depth of insertion. After verifying appropriate placement of the coring trephine under fluoroscopic guidance, pass the wire crimp over the guide wire causing it to engage the proximal end of the insertion handle. Taking hold of the insertion handle and the wire crimp, remove the coring trephine and the guide wire from the humeral head as a unit. The antecedent core of bone will remain in the coring trephine having the guide wire centrally positioned therein. The guide wire can now be removed from the coring trephine in a retrograde fashion. Importantly, the antecedent core of bone may be returned to the humeral head in a reverse direction after thorough debridement.
RETRIEVAL OF THE ANTECEDENT CORE OF BONE

Advance the plunger/bone tamp into the trephine to disengage the core of bone. See Figures 9 through 13. Obtain autologous cancellous bone and bone marrow from the iliac crest. Ensure that a sufficient amount of bone is obtained to fill the humeral head defect.

INSERTION OF THE ENDOSCOPIC PORTAL

Advance the endoscopic portal into the proximal humerus. The endoscopic portal should be inserted so as to allow its proximal portion to be exposed over the skin of the shoulder. Exercise extreme caution and do not rotate the arm, as doing so may fracture the proximal humerus. The endoscopic trephine is passed through the endoscopic portal and up to the lesion within the humeral head.
**Endoscopic Evaluation of Subchondral Bone**

The flexible 5.4mm endoscopic is passed through the endoscopic trephine. The bone within the humeral head should be well visualized on the video monitor. Use the trumpet valves to irrigate the humeral head cavity. Catalog the location of any necrotic bone to four endoscopic quadrants; superior, inferior, anterior, and posterior. A small orientation mark, parallel to the side opening of either the endoscopic or working trephine serves as an aid to spatial orientation during endoscopic evaluation of the bone. See Figure 16.

**Debridement of the Humeral Head**

Using the 7mm or 9mm burr, debride the humeral head as shown in Figure 17. Use fluoroscopy to visually observe the position of the burr. After a cavity has been created within the humeral head, the endoscopic trephine may be re-inserted into the humeral head. The 5.4mm endoscope is re-inserted into the humeral head to evaluate the extent of debridement and to identify bleeding bone and its location.
ENDOSCOPIC EVALUATION OF SUBCHONDRAL BONE

A small orientation mark parallel to the side opening of either trephine serves as an aid to spatial orientation during endoscopic debridement and visualization.
Endoscopic Debridement of the Humeral Head

Endoscopic grasping forceps may be passed into the humeral head for biopsy and debridement purposes as shown in Figure 19. The valve on the endoscope may be used to irrigate the humeral head to allow one to identify bleeding bone. The objective is to view the subchondral bone in submerged and evacuated environments.

Obtain Contrast Study

The contrast material can be attached to the portal on the endoscope. Open the valve mechanism on the portal and gently press the trumpet valve on the endoscopic tubing to draw contrast material into the humeral head. Obtain fluoroscopic images to verify that the cartilage was not violated during the debridement process by observing the absence of extravasation of contrast material into the shoulder joint.

Fig. 19
Bone Grafting of the Humeral Head

Using the funnelated trephine, pass morselized cancellous bone and bone marrow into the humeral head cavity until it is completely filled with healthy bone. Use the plunger to firmly pack the cancellous bone and to elevate any areas of joint depression. Use fluoroscopy to aid the reduction process. Use extreme caution to ensure that any areas of joint depression are not over reduced. Position the area of the humeral head to be reduced against the glenoid during the reduction process. The antecedent core of bone may be returned to the humeral head in a reverse direction. The broach may be used to facilitate displacement of the bone graft into the humeral head.
**Surgical Technique**

**Determine the Length of the Compression Screw**

Insert the depth gauge into the humeral head over the core retrieval guide and advance the measuring rod until the bone graft is advanced to a stable position. This will require only a minimal amount of force. Once the bone graft is in a stable position, one should slightly compress the bone graft AND while still compressing, determine the length of the compression screw. The 20mm screw provides 5mm of static compression; the 17.5mm screw provides 2.5mm of static compression; and the 15mm screw provides 0mm of static compression. It is important to ensure that the bone graft is in a stable position when the screw length is determined. See Figure 22. If the measured length of the compression screw is greater than 20mm, more bone graft should be packed into the humeral head. When advancing the compression screw into the humeral head, always use the restricted screwdriver to ensure that the bone graft is not over compressed.

**Placement of True Implant**

Engage the compression screw of the appropriate length to the true implant such that the head of the compression screw is flush with one end of the implant barrel. The barrel angle of the implant should be identical to the barrel angle determined preoperatively. Advance the implant into the portal of entry. The implant is then rigidly fixed to the humerus using standard AO technique. The first and second screw holes of the implant should be drilled with a 3.2mm drill bit for placement of two 4.5mm cortical screws. See Figure 23.
**Placement of True Implant**

Use the restricted screwdriver to advance the compression screw into the humeral head. The compression screw will stabilize and contain the bone graft and further induce extravasation of marrow stem cells into the surrounding host bone. The restricted screwdriver will allow a maximum of 5mm of static compression with the 20mm compression screw leaving 10mm of engagement between the compression screw and the implant barrel. A 7mm set screw is then used to lock the compression screw in place. Intraoperative plain film radiographs are obtained along with fluoroscopic images as necessary. The wound is closed in layers and a drain may be used at the surgeon’s discretion.

*Fig. 24*
### Implants

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
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<tbody>
<tr>
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<td>130° Shoulder Plate Implant</td>
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<td>TSY-140</td>
<td>140° Shoulder Plate Implant</td>
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### Compression Screws

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<tr>
<td>CSY-015</td>
<td>15mm Compression Screw Implant</td>
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<td>CSY-017</td>
<td>17.5mm Compression Screw Implant</td>
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<td>20mm Compression Screw Implant</td>
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### Set Screw

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### Cortical Screws

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<td>CS-028</td>
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<td>CS-050</td>
<td>50mm 4.5 Cortical Screw</td>
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### INSTRUMENTS

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<td>Trial Plate 140°</td>
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<td>SPT-200</td>
<td>Shoulder Plate Core Retrieval Guide</td>
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<tr>
<td>SRM-012</td>
<td>12mm Reamer</td>
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<tr>
<td>SD-270</td>
<td>Unrestricted Compression Screwdriver</td>
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<td>SD-170</td>
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<td>PP-170</td>
<td>Placement Probe</td>
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<td>HD-170</td>
<td>4.5 Cortical Screwdriver</td>
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<td>AD-170</td>
<td>Assembly Screwdriver</td>
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**Orthopedic Sciences**

- SD-270
- SD-170
- PP-170
- HD-170
- AD-170

**Surgical Technique**

- ST-130
- ST-135
- ST-140
- SPT-200
- SRM-012
## Instruments

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<tr>
<td>BR-080</td>
<td>Broach</td>
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<td>GT-170</td>
<td>Graft Placement Plunger</td>
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<tr>
<td>CG-170</td>
<td>Compression Screw Depth Gauge</td>
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<td>BT-170</td>
<td>Assembly Screwdriver</td>
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<tr>
<td>GF-170</td>
<td>Funnelated Trephine</td>
</tr>
<tr>
<td>HPS-2101</td>
<td>Bone Tool Handle</td>
</tr>
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<td>CH-170</td>
<td>Insertion Handle</td>
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PURPOSE
Use of the TSY™ Shoulder Plate BGSS provides the orthopaedic surgeon a means for stabilizing a bone graft within the humeral head and neck to assist healing of an intraosseous fracture. The TSY™ is intended to stabilize a bone graft within the humeral head and neck to assist healing of an intraosseous fracture.

DESCRIPTION
The TSY™ BGSS consists of a reamer, a broach, guide wires, a series of angle guides, a depth gauge, and trephines and curettes in a variety of shapes and sizes intended to assist in core decompression/debridement of osteonecrotic bone within the humeral head, and a bone plate having a bone barrel, attachment screws, and a bone graft compression screw having a set screw intended to stabilize a bone graft placed within the humeral head and neck. The bone plate and barrel, and the compression screw and set screw are generally known as the TSY™.

The TSY™ bone graft stabilization implant is fabricated from 316L medical grade stainless steel as designated by the American Society for Testing and Materials (ASTM) specification F138.

Orthopedic Sciences, Inc., expressly warrants that the TSY™ bone graft stabilization implant and accompanying instrumentation and components, which comprise the TSY™ Shoulder Plate BGSS, are fabricated from the foregoing material specifications. No other warranties, expressed, or implied, are made.

Do not use the TSY™ BGSS with components from any other manufacturer. None of the TSY™ implant components should ever be reused under any circumstances.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:
When used as a bone graft stabilization system, in skeletally mature patients, the TSY™ is indicated for an intraosseous fracture within the humeral head and neck where bone grafting with bone graft stabilization is required.

CONTRAINDICATIONS:
Contraindications include, but are not limited to:
1. An intraosseous fracture extending into the cortical surface of the humeral neck (a humeral neck fracture).
2. Poor quality of proximal humeral bone such that rigid fixation of the TSY™ plate to the bone cannot be achieved.
3. Signs of local inflammation.
4. Fever or leukocytosis.
5. Pregnancy.
6. Any other medical or surgical condition which would preclude the potential benefit of core decompression/debridement of the humeral head with bone grafting and bone graft stabilization, such as advanced arthritis, septic arthritis, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood cell count (WBC), or a marked left shift in the WBC differential count.
7. Suspected or documented metal allergy or intolerance.
8. Any case not needing core decompression/debridement of the humeral head and neck followed by bone grafting.
9. Any neuromuscular deficit, which could interfere with the patient’s ability to limit weight bearing.
10. Mental, physical or neurological conditions which may impair the patient’s ability to cooperate with the postoperative regimen.
11. Any patient unwilling to follow postoperative instructions.

POTENTIAL ADVERSE EVENTS:
All of the possible adverse events associated with core decompression/debridement of the humeral head without bone grafting are possible. With bone grafting and bone graft stabilization, a list of potential adverse events includes, which may be clinically related rather than device related, but is not limited to:
1. Early or late loosening of any or all of the components of the implant.
2. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, and/or autoimmune disease.
3. Pressure on the skin from the components in patients with inadequate soft-tissue coverage over the implant possibly causing skin penetration, irritation, pain, and/or bruising. Tissue damage caused by improper positioning and placement of the implant or instruments.
4. Injury to the axillary nerve.
5. Fracture of the humeral head from over compressing the bone graft.

6. Infection, early or late, deep or superficial.
7. Conditions attributable to nonunion, such as diabetes, inhibited revascularization and poor bone formation can cause loosening of the device or loss of rigid fixation with the bone.
8. Delayed union or nonunion of the intraosseous fracture site.
9. Neurovascular injury may occur as a result of the surgical trauma.
10. Bone loss or a decrease in bone density, possibly caused by stress shielding.
11. Bone graft donor site complications including pain, fracture, or wound healing problems.
12. Hemorrhage, hematoma, stroke, wound dehiscence, wound necrosis, damage to blood vessels, or other types of cardiovascular system compromise.
13. Development of respiratory problems, e.g., pneumonia, atelectasis, bronchitis, a pulmonary embolism.
15. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING AND PRECAUTIONS:

WARNING:
The safety and effectiveness of plates and screws to assist healing of bone fractures have been established. Autologous bone is the only graft material that is osteoconductive, osteoinductive, and osteogenic. The safety and effectiveness of this device to stabilize demineralized bone and/or synthetic bone substitutes to assist healing of bony fractures is not known.

PRECAUTION:
The use of the TSY™ BGSS and the implantation of the TSY™ should be performed only by experienced orthopaedic surgeons trained in the use of surgical implants for ORIF of a fracture and shoulder surgery because this is a technically demanding procedure requiring strict adherence to technique to ensure that the TSY™ implant will lie flush against the proximal humerus and simultaneously stabilize the bone graft placed within the humeral head and neck without injury to the axillary nerve.

An intraosseous fracture within the humeral head and neck does not extend into the cortical surface, therefore, the angle of the implant chosen for bone graft stabilization must match the angle subtended by the portal of entry in the humeral head and the lateral cortical shaft of the proximal humerus. Preoperatively, the operating surgeon should always use the transparencies to estimate the angle of the implant to be used to stabilize the bone graft. The TSY™ BGSS instrumentation allows the surgeon to ensure that the angle subtended by the portal of entry in the humeral neck and the cortical shaft of the proximal humerus is between 130º and 140º, in increments of 5º. As with any surgical procedure, a successful result is not always achieved in every case. This device system is not intended to be used without bone graft. Preoperative and operating procedures, including knowledge of surgical technique, good fluoroscopic images during surgery, and proper selection and placement of the implant are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect results. Patients who smoke have been shown to have an increased incidence of a nonunion of transosseous fractures (fractures extending into the cortical surface of the bone). Poor outcomes in patients with a history of smoking that undergo core decompression/debridement followed by bone grafting and bone graft stabilization have not been specifically addressed in the literature. These patients, as well as malnourished patients and patients that abuse alcohol and/or suffer from chemical dependency may be at risk for a poor outcome and should be warned of this consequence. Patients taking high dose steroids for medical reasons should be particularly warned of the potential for a poor outcome, as steroids have been shown to decrease the activity of osteoblast. The TSY™ is not designed to address deficiencies in the rotator cuff mechanism. A rotator cuff tear identified on MRI or suspected on plain film radiographs must be addressed to promote a good outcome after stabilization of bone graft within the humeral head.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the warnings and precautions given in this document must be conveyed to the patient.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:
SURGICAL TECHNIQUE

PREOPERATIVE:
1. Only patients that meet the criteria described in the indications should be selected.
2. The operating surgeon should always use the transparencies to template the affected humeral head to determine the most likely angle of the implant to be used to stabilize the bone graft within the humeral head and neck.
3. Patient positioning is extremely important. The surgeon must ensure that unobstructed fluoroscopic images of the humeral head can be obtained in both the AP and the lateral view.
4. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
5. Care should be used in the handling and storage of the implant component. The implants and instruments should be protected during storage, especially from corrosive environments.
6. An adequate inventory of implants should be available at the time of surgery, normally a quantity more than what is expected to be used.
7. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment.
8. All instruments must be cleaned and sterilized before use. Additionally, sterile components should be inspected for package integrity before use.
9. The TSY™ BGSS instruments (described in the DESCRIPTION section of this document) are not to be combined with components from another manufacturer. Different metal types should never be used together.

INTRAOPERATIVE:
1. The surgical dissection should proceed in a manner so as to expose 3 to 4 centimeters of the lateral cortical surface of the proximal humerus. This will ensure that soft-tissue will not be interposed between the bony surface of the proximal humerus and the guide plate true implant.
2. To ensure that the angle subtended by the portal of entry in the humeral neck and the lateral cortex of the proximal humerus is between 130º and 140º, use the drill guide and the guide plates as described in the TECHNIQUE MANUAL.
3. Only use the threaded-tip 3.2mm guide wire to enter into the humeral neck in preparation for retrieval of the antecedent core of cancellous bone.
4. Before establishing the portal of entry in the humeral neck with the reamers, make certain that the true implant will lie flush against the proximal humerus by evaluating the angle created with the threaded-tip 3.2mm guide wire under fluoroscopy. Evaluate this angle by passing the guide plate over the guide wire as described in the TECHNIQUE MANUAL.
5. Although harvesting bone graft from the ipsilateral greater tuberosity may be performed, it is recommended that bone graft be taken from the ipsilateral iliac crest. Additionally, a substantial quantity of cancellous bone graft and bone marrow can be harvested from the iliac crest.
6. The harvested cancellous bone should completely fill the defect created by core decompression/debridement of the humeral head and neck, having a portion of the bone graft extending into the core tract within the humeral neck. The degree to which the bone graft extends into the humeral neck will ultimately determine the length of the compression screw. The surrounding host bone may more readily incorporate morselized cancellous bone, as morselization increases the surface area of the bone graft.
7. Only use the depth gauge provided with the TSY™ BGSS instrumentation to determine the length of the compression screw. Use fluoroscopy while determining the length of the compression screw to observe where the head of the compression screw will be positioned once placed in the humeral neck. If the compression screw length is determined to be greater than 20mm, more bone graft should be placed into the humeral head and neck defect. The compression screw is not intended to fill the defect within the humeral head and neck that was created by core decompression/debridement.
8. Before closing the soft-tissues, the attachment screws and the set screw should be tightened firmly. Recheck the tightness of the attachment screws and the set screw after finishing to make certain that none loosened during the tightening process. Failure to do so may cause loosening of the implant.

POSTOPERATIVE:
The physician's postoperative directions and warnings to the patient are extremely important.
1. Detailed instructions on the use and limitations of the TSY™ BGSS should be given to the patient. If a pendulum exercises or a partial load-bearing program is recommended before bony union, the patient must be made aware of the importance of complying with such a program. Active patients should be asked to decrease, modify, or eliminate activities, during the fracture-healing phase, that substantially increase the joint reactive force of the shoulder joint.
2. To view the maximum chances for a successful surgical result, the patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or nonsteriodals or anti-inflammatory medications such as aspirin during the inflammatory phase of the bone graft healing process.
3. As a precaution, before patients with implants receive any subsequent surgery (such as a dental procedure), prophylactic antibiotics may be considered, especially for high-risk patients.
4. Adequate postoperative management to avoid fracture, refracture, or other complications should follow implant removal.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the TSY™ true implant or any of its components should never be reused under any circumstances.

PACKAGING:
Packages for each of the sterile components should be intact upon receipt. If a loaner or consignment system is used, the instrumentation set should be carefully checked for completeness. All components, including the instruments, should be carefully checked to ensure that there is no damage before use. Damaged packages or products should not be used, and should be returned to Orthopedic Sciences, Inc.

CLEANING AND DECONTAMINATION:
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated and handled with care. Improper use or handling may lead to damage and possible improper functioning of the device.

STERILIZATION:
The TSY™ true implant (bone plate and bone barrel, compression screw and set screw) is provided sterile, and the integrity of its packaging should be inspected before use. Further, unless marked sterile and clearly labeled as such, the TSY™ BGSS instruments described in this insert are provided nonsterile and must be sterilized prior to use. These products are recommended to be steam sterilized by the hospital using one of the two sets of process parameters below:

<table>
<thead>
<tr>
<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>PreVacuum</td>
<td>270°F (131°C)</td>
<td>4 Minutes</td>
</tr>
</tbody>
</table>

Use only sterile products in the operative field. Always immediately resterilize all instruments used in surgery. This process must be performed before handling or (if applicable) returning any instrumentation to Orthopedic Sciences, Inc.

PRODUCT COMPLAINTS:
Any Healthcare Professional (e.g. customer or user of the TSY™ BGSS), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify the distributor or Orthopedic Sciences, Inc., at the address below. Further, if any of the implanted components ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of malfunctioning, the distributor should be notified immediately. If any of Orthopedic Sciences' product ever malfunctions and may have contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, facsimile or written correspondence. When filing a complaint, please provide the component name, part number, lot number, your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:
If further information is needed or required, please contact Orthopedic Sciences, Inc:

ORTHOPEDIC SCIENCES, INC.
Customer Service Division
Orthopedic Sciences, Inc.
3020 Old Ranch Parkway, Suite 325
Seal Beach, CA 90740
Telephone: 562.799.5550
Telefax: 562.793.5333

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For product availability, labeling limitations, and/or more information on any Orthopedic Science’s products, contact your ORTHOPEDIC SCIENCES Sales Associate: 562.799.5550.

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See package insert for labeling limitations.