Endoscopically Guided Core Decompression and Bone Grafting of the Femoral Head
Dear Colleagues:

Osteonecrosis of the femoral head can be viewed as a disease with a variety of pathologic presentations likely to require surgical intervention. The goals of treatment are relief of pain, maintenance of hip joint congruency and range of motion, and delay or prevention of total hip arthroplasty. The ideal treatment for earlier stages will preserve the natural femoral 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, size and location of lesion (necrotic angle), and acetabular involvement.1-4.

Variable success rates (range, 33% to 95%) have been achieved with core decompression (CD), under the guise that the procedure decreases intraosseous pressure and improves intraosseous circulation.4 Importantly, Brown et al.5 characterized the ideal location of a decompressing core tract in a finite-element model, however, these investigators did not elucidate the extent of debridement of necrotic bone one could achieve with a 9mm to 10mm core tract with respect to increasing necrotic angles.

In 1995, Urbaniak et al. reported on 103 patients having had a free vascularized fibula graft (FVFG). After a median duration of follow-up of seven years, (range, 4.5 to 12.2 years), approximately one-third required conversion to a total hip arthroplasty.6 FVFG as described by Urbaniak7 creates a core tract in the femoral neck ranging in diameter from 16mm to 19mm, thus substantially improving the amount of necrotic bone that can be debrided from the femoral head, e.g., a precollapse lesion with a combined necrotic angle of < 200º. Prolonged non-weight bearing and the fibula stabilize the fresh autogenous cancellous bone packed into the femoral head, with the FVFG further supporting the subchondral bone and theoretically increasing vascularity.

The endoscopically guided core decompression approach used with the Titanium-Hip Tool™ Bone Graft Stabilization System (T-BGSS) is specifically designed to assist those surgeons who determine that CD 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 femoral head without having to increase the diameter of the core tract beyond 9mm or having to use the soft-tissue dissections characteristic of “the light bulb”8 or “the trapdoor”9 procedures. The Titanium-Hip Tool™ plate and compression screw stabilize the fresh autogenous cancellous bone (preventing its micro-motion) thereby assisting its incorporation into the surrounding viable host bone within the femoral head.

The goal of the endoscopic approach is to extend the debridement process up to vascularized bone, i.e., prepare the host bed for bone graft while maintaining a narrow core tract in the femoral neck. Additionally, the Titanium-Hip Tool™ plate and compression screw stabilize the fresh autogenous cancellous bone and prevent its micro-motion, as would be required in primary bone healing.

The following monograph introduces the Titanium-Hip Tool™ BGSS and the surgical technique used to maximize procedural efficiency.

Sincerely,

Don P. Sanders, MD, MSPH
Associate Professor, King/Drew Medical Center
South Bay Orthopedic Specialists
Torrance, California

REFERENCES
Diagnosis
The diagnosis of osteonecrosis 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 an AP and frog-leg lateral of the affected hip. Additionally, an MRI, which is 99% sensitive and specific, may be obtained to allow one to characterize the extent of localization of the necrotic lesion on T1 and T2 weighted images.

Preoperative Lesion Localization
Using the transparencies, align the tracing of the implant along the lateral cortex of the proximal femur. Choose the tracing that has a barrel angle that best causes the central axis of the implant barrel to pass through the central portion of the necrotic lesion, as shown in Figure 3. The implant choice (130° to 150°, in increments of 5°) is based on the location of the lesion within the femoral head and not the native neck-shaft angle of the proximal femur. The trial implant used for instrumentation and decompression/debridement will have a barrel angle identical to the true implant used to stabilize the decompressed femoral head.
**Patient Positioning**

The patient is positioned supine on a fracture table having the entire lower extremity prepared free. Obtain fluoroscopic images prior to preparing and draping the patient to ensure unobstructed visualization of the femoral head in the AP and frog-leg lateral views. Please see Figure 4. The supine position allows gravity drainage of the femoral head during irrigation and endoscopic visualization.

**Intraoperative Lesion Localization**

A direct lateral incision is fashioned over the proximal femur. The incision should be at least 3cm to 4cm in length and may vary depending on the patient’s body habitus. Carry the dissection down to the lateral cortex juxtainferior to the vastus ridge. The vastus lateralis and the peristeme are elevated a sufficient distance distally and anteriorly to ensure that both the trial and the true implant will lie flush against the lateral cortex. Use the angle-guide that matches the barrel angle determined preoperatively. Align the chosen angle-guide along the lateral cortex of the proximal femur. Advance the threaded-tip 3mm guide wire toward the central portion of the necrotic lesion passing through the femoral neck using a power drill. The guide wire should be inserted at a level superior to the lesser trochanter and advanced into the femoral neck and head to a position juxtainferior to the necrotic lesion. See Figure 5.

Disengage the drill and angle-guide from the guide wire. Obtain a frog-leg lateral view to ensure proper placement of the guide wire. See Figure 6. It is important to show the guide wire completely superimposed by the femur in the frog-leg lateral view. 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 femoral neck once placed therein (4.5mm on either side of the guide wire in two planes).
**Intraoperative Lesion Localization**

Pass the guide plate over the guide wire, as shown in Figure 7, to confirm that the angle established between the lateral cortex of the proximal femur and the guide wire is within 130° to 150°, in increments of 5°. The angle of the trial implant used for instrumentation should match the angle of the guide plate that best shows the guide plate flush against the lateral cortex of the proximal femur in the AP view. The guide plate is used to allow the surgeon to confirm that the trial implant and thus the true implant will lie flush against the lateral cortex of the proximal femur PRIOR to establishing a portal of entry. If 1 of the 5 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 the portal of entry in the lateral cortex of the proximal femur. The base of the reamer has an enlarged diameter to ensure that the insertion of the reamer is no more than 45mm. See Figure 8. The 12.5mm OD reamer may be used to increase the portal diameter.

**Retrieval of the Antecedent Core of Bone**

Insert the trial implant into the portal of entry in the proximal femur as shown in Figure 9. A Lowman clamp may be used to secure the trial implant to the bone. Attach the 9mm OD x 8mm ID x 8” coring trephine to its insertion handle.
**Retrieval of the Antecedent Core of Bone**

Using pronosupination, insert the coring trephine into the femoral neck over the guide wire. Advance the trephine into the femoral neck 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 and crimp the wire. Taking hold of the insertion handle and the wire crimp, remove the coring trephine and the guide wire from the femoral neck 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.
**RETRIEVAL OF THE ANTECEDENT CORE OF BONE**

Advance the plunger/bone tamp into the trephine to disengage the antecedent core of bone. After the femoral head has been debrided, the core of bone can be manually returned to the femoral neck in a reverse direction sending the necrotic segment of bone to pathology. See Figures 13 and 14. Further, although one may use the cancellous bone within the greater trochanter to graft the cavity within the femoral head, obtaining bone from the iliac crest will avoid placing an additional stress riser on the proximal femur. Figure 15 shows the femoral head having been prepared for endoscopic visualization and debridement. Importantly, the Bone Tool™ can be used to harvest several fresh autogenous cancellous cores of bone from the iliac crest.
Debridement of the Femoral Head

After retrieval of the antecedent core of bone, insert the endoscopic portal into the proximal femur. Pass the endoscopic trephine into the femoral neck over the endoscopic portal. A 5.5 mm flexible endoscope is passed into the femoral head to visually localize the necrotic bone. The trumpet valves on the endoscopic tubing may be used to irrigate and enhance visualization. See Figure 16. Using the special burs and curettes, debride the femoral head as shown in Figure 17. Use fluoroscopy to visually observe the placement of the special bur or curette. After a cavity has been created within the femoral head, the endoscopic trephine or working trephine may be re-inserted into the femoral head as shown in Figures 18 and 19.
**Debridement of the Femoral Head**

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

**Fig. 18**

**Endoscopic Subchondral Femoral Head Quadrants**

- **RIGHT HIP**
  - Visual Field is toward the Acetabulum
  - Rt. A Quadrant: Posterosuperior, medial/lateral
  - Rt. B Quadrant: Anterosuperior, medial/lateral
  - Rt. C Quadrant: Posteroinferior, medial/lateral
  - Rt. D Quadrant: Anteroinferior, medial/lateral

- **LEFT HIP**
  - Visual Field is toward the Acetabulum
  - Lt. A Quadrant: Anterosuperior, medial/lateral
  - Lt. B Quadrant: Posterosuperior, medial/lateral
  - Lt. C Quadrant: Anteroinferior, medial/lateral
  - Lt. D Quadrant: Posteroinferior, medial/lateral

**Fig. 19**
**Surgical Technique**

**Debridement of the Femoral Head**

Endoscopic grasping forceps may be passed into the femoral head for biopsy and debridement purposes as shown in Figure 20. The valve on the endoscope may be used to irrigate the femoral 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 femoral 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 hip joint.
**Bone Grafting of the Femoral Head and Neck**

Using the funnelated trephine, pass cancellous bone into the decompressed/debrided femoral head until the cavity is completely filled with viable bone. The bone graft should be packed into the femoral head with the trial implant fixed to the proximal femur with a Lowman clamp. Insert the antecedent core of bone into the femoral neck using the plunger/bone tamp. The broach may be used to facilitate displacement of the bone graft into the femoral head cavity. See Figures 21 and 22.
Determine the Length of the Compression Screw

Insert the depth gauge into the trial implant and advance the measuring rod into the femoral neck until the antecedent core of bone is advanced to a stable position. This will require only a minimal amount of force. Slightly compress the antecedent core of bone once the core is in a stable position, AND while still compressing the core, determine the length of the compression screw. Compression screws provide 5mm of static compression. The antecedent core of bone must be in a stable position when the compression screw length is determined. See Figure 23. If the measured length of the compression screw is greater than 65mm, more bone graft should be packed into the femoral head and neck.

Placement of True Implant

Remove the trial implant from the proximal femur. Engage the compression screw of the measured length into 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 true implant should be identical to the barrel angle of the trial implant. Advance the true implant into the portal of entry. The true implant is then rigidly fixed to the femur with a 4.5mm cortical screw using standard AO technique. The plate is designed to engage a cerclage wire, if desired, to stabilize the plate against the proximal femur using one cortex of fixation per cortical screw, or the device may be used as a standard side plate using two cortices of fixation per cortical screw. See Figure 24.
**Placement of True Implant**

If it is determined that an additional screw for fixation is necessary, the second screw hole of the true implant should be drilled with a 3.2mm drill bit for placement of the second 4.5mm cortical screw. Using fluoroscopy, advance the smooth 2.5mm guide wire into the femoral head passing through the cannulated portion of the compression screw and the antecedent core of bone. The cannulated screwdriver is then used to advance the compression screw into the femoral neck to compress the antecedent core of bone and bone graft. The compression screw will stabilize the bone graft and the antecedent core of bone. The special cannulated screwdriver will only allow up to a maximum of 5mm of compression leaving 35mm of engagement between the compression screw and the implant barrel. The 2.5mm guide wire ensures that the antecedent core of bone is compressed symmetrically within the femoral neck. A 7mm set screw is then placed into the implant barrel to ensure that the compression screw remains seated. The 2.5mm guide wire is then removed. 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.
### Implants

#### Hip Plate Implant

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Description</th>
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<tr>
<td>TP-130LP</td>
<td>130° Titanium Hip Plate Low Profile Implant</td>
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<td>140° Titanium Hip Plate Low Profile Implant</td>
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#### Compression Screws

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<tr>
<th>Part No.</th>
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<tr>
<td>TS-040</td>
<td>40mm Titanium Compression Screw Implant</td>
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<td>TS-055</td>
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#### Set Screw

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<td>7mm Titanium Set Screw Implant</td>
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#### Cortical Screws

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<td>TS-028</td>
<td>28mm Titanium 4.5 Low Profile Cortical Screw</td>
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<td>PP-170</td>
<td>Placement Probe</td>
</tr>
<tr>
<td>CH-170</td>
<td>Insertion Handle</td>
</tr>
<tr>
<td>BT-170</td>
<td>Bone Tamp/Plunger</td>
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<tr>
<td>WC-170</td>
<td>Guide Wire Crimp</td>
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![Image of surgical instruments](image-url)
Surgical Technique

INSTRUMENTS

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<td>TR-150</td>
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<td>AD-170</td>
<td>Assembly Screwdriver</td>
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<tr>
<td>SD-170</td>
<td>Compression Screwdriver</td>
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<tr>
<td>HPS-2101</td>
<td>Bone Tool Handle</td>
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<tr>
<td>GF-170</td>
<td>Funnelated Trephine</td>
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<tr>
<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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Trial Plate

Assembly Screwdriver

Compression Screwdriver

Funnelated Trephine

Bone Tool Handle

Graft Placement Plunger

Compression Screw Depth Gauge
Purpose

Use of the Titanium-Hip Tool™T-BGSS provides the orthopaedic surgeon a means for stabilizing a bone graft within the femoral head and neck to assist healing of an intraosseous fracture. The Titanium-Hip Tool™T-BGSS is intended to stabilize a bone graft within the femoral head and neck to assist healing of an intraosseous fracture.

Description

The Titanium-Hip Tool™T-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 necrotic bone within the femoral 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 femoral head and neck. The bone plate and barrel, and the compression screw and set screw are generally known as the Titanium-Hip Tool™.

The Titanium-Hip Tool™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 Titanium-Hip Tool™bone graft stabilization implant and accompanying instrumentations and components, which comprise the Titanium-Hip Tool™T-BGSS are fabricated from the foregoing material specifications. No other warranties, expressed, or implied, are made.

Do not use the Titanium-Hip Tool™T-BGSS with components from any other manufacturer. None of the Titanium-Hip Tool™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 Titanium-Hip Tool™is indicated for an intraosseous fracture within the femoral 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 femoral head and neck (a femoral neck fracture).
2. Signs of local inflammation.
3. Fever or leukocytosis.
5. Any other medical or surgical condition which would preclude the potential benefit of core decompression/debridement of the femoral 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.
6. Suspected or documented metal allergy or intolerance.
7. Any case not needing core decompression/debridement of the femoral head and neck followed by bone grafting.
8. Any neuromuscular deficit which could interfere with the patient’s ability to limit weight bearing.
9. Mental, physical or neurological conditions which may impair the patient’s ability to cooperate with the postoperative regimen.
10. Any patient unwilling to follow postoperative instructions.

Adverse Events:

When used as a bone graft stabilization system, adverse events may be necessary to correct some of these potential adverse events.

Warning and Precautions:

Warning: The safety and effectiveness of plates and screws to stabilize autograft and undemineralized allograft bone to assist healing of bony 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 denmineralized bone and/or synthetic bone graft substitutes to assist healing of bony fractures is not known.

Precaution: The use of the Titanium-Hip Tool™T-BGSS and the implantation of the Titanium-Hip Tool™should be performed only by experienced orthopaedic surgeons trained in the use of surgical implants for ORIF of a fracture and hip surgery because this is a technically demanding procedure requiring strict adherence to technique to ensure that the Titanium-Hip Tool™implant will lie flush against the proximal femur and simultaneously stabilize the bone graft placed within the femoral head and neck.

An intraosseous fracture within the femoral 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 femoral neck and the lateral cortical shaft of the proximal femur. 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 Titanium-Hip Tool™T-BGSS instrumentation allows the surgeon to ensure that the angle subtended by the portal of entry in the femoral neck and the lateral cortical shaft of the proximal femur is between 130º and 150º in increments of 5º.

As with any surgical procedure, a successful result is not always achieved in every case. The 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.

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.
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 femoral hip to determine the most likely angle of the implant to be used to stabilize the bone graft within the femoral head and neck.
3. Patient positioning is extremely important. The surgeon must ensure that unobstructed fluoroscopic images of the hip can be obtained in both the AP and the frog-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 Titanium-Hip Tool™-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 subtrochanteric portion of the proximal femur. This will ensure that soft-tissue will not be interposed between the bony surface of the proximal femur and the trial/true implant.
2. To ensure that the angle subtended by the portal of entry in the femoral neck and the lateral cortex of the proximal femur is between 130º and 150º, insert instruments of 3º to 5º use the drill guides and the angle guides as described in the TECHNIQUE MANUAL.
3. Only use the threaded-tip 3mm guide wire to enter into the femoral neck in preparation for retrieval of the antecedent core of cancellous bone.
4. Before establishing the portal of entry in the femoral neck with the reamer, make certain that the trial/true implant will lie flush against the proximal femur by evaluating the angle created with the threaded-tip 3mm guide wire under fluoroscopy. Evaluate this angle by passing the angle guide over the guide wire as described in the TECHNIQUE MANUAL.
5. Although harvesting bone graft from the ipsilateral greater trochanter has been described; 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 femoral head and neck, having a portion of the bone graft extending into the core tract within the femoral neck. The degree to which the bone graft extends into the femoral 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 Titanium-Hip Tool™-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 femoral neck. If the compression screw length is determined to be greater than 65mm, more bone graft should be placed into the femoral head and neck defect before removal of the trial implant. The compression screw is not intended to fill the defect within the femoral head and neck that was created by core decompression/debridement.
8. Before closing the soft-tissues, 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:
1. Detailed instructions on the use and limitations of the Titanium-Hip Tool™-BGSS should be given to the patient. If a toe-touch or a partial weight-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 hip joint.
2. To allow 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 nonsteroidal or anti-inflammatory medications such as aspirin during 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 Titanium-Hip Tool™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 instrument 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 Titanium-Hip Tool™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 Titanium-Hip Tool™-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>250º F (121º C)</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>PreVacuum</td>
<td>270º F (131º 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 Titanium-Hip Tool™-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:
For product availability, labeling limitations, and/or more information on any Orthopedic Sciences products, contact your ORTHOPEDIC SCIENCES Sales Associate, or call ORTHOPEDIC SCIENCES Customer Services: 562.799.5550