INSTRUCTIONS FOR USE (IFU)
&
SURGICAL TECHNIQUE GUIDE (STG)

Orbitum Staple System

Indications For Use:

The Orbitum X and VI Staple System is intended to be used for fixation such as: Lisfranc arthrodesis, mono or bi-cortical osteotomies in the forefoot, first metatarsophalangeal arthrodesis, Akin osteotomy, midfoot and hindfoot arthrodesis or osteotomies, fixation of osteotomies for hallux valgus treatment (Scarf and Chevron), and arthrodesis of the metatarsocuneiform joint to reposition and stabilize metatarsus primus varus.

Description:

The Orbitum X and VI Staple System is a single use bone staple intended for fracture and osteotomy fixation and joint arthrodesis of the hand and foot. Orbitum Staples are constructed from titanium alloy (Ti-6Al-4V ELI per ASTM F136) and consist of multiple radially dispersed legs connected by a single bridge.

Orbitum Staples are available in multiple sizes, ranging from 12-24 millimeters in diameter/width and 8-12 millimeters in length. The Orbitum implants come as a set or system, for implanting the device.

Two separate methods for hole making are included in each Orbitum Staple System: a Punch, with awl-like points dispersed radially in coincidence with the pattern of the staple's legs, and a template for drilling when more delicate hole making strategies are required. Orbitum Staple System Sets include two temporary fixation pins for use with the drill template. In addition, the set includes a 1.5 mm drill for use if desired.

A surgical sizing template is provided to assist with preoperative selection of the most appropriately sized implant. Clinical Use Examples include:

I. Hand & Wrist Surgery:

Intracarpal and interphalangeal arthrodesis, Carpal, metacarpal, and phalangeal fracture or osteotomy fixation. Distal radius fracture fixation, Corrective osteotomies of the distal radius, Capital and sub capital distal ulna fracture fixation, Carpal fracture fixation, Radio-carpal and intercarpal joint arthrodesis, Phalangeal, metacarpal, and carpal bone fixation, Arthrodesis of finger joints, Corrective osteotomies of phalangeal and metacarpal bones, Shortening osteotomies of the ulna shaft, Total arthrodesis of the wrist.

II. Foot Surgery:

Bunionectomy, tibiotarsal, Lisfranc's, calcaneocuboidal, and talonavicular arthrodesis, hind, mid, or forefoot bone fracture or osteotomy fixation.

a) *Foot* - Fracture fixation, arthrodesis, and osteotomies of the hind-foot, mid-foot, and fore-foot, Fracture fixation of the talus, Ankle arthrodesis
b) *Fore Foot* - Akin, Bunion, MP Arthrodesis
c) *Mid Foot* - Navicular Cuneiform Fusion, Lisfranc Arthrodesis, Lapidus, Opening/Closing Wedge, Base Wedge
d) *Rear Foot* - Talar/Navicular Arthrodesis, Calcaneal/Cuboid Arthrodesis, Subtalar Arthrodesis

III. General Skeletal Surgery:

Bone fragment retention, Adjunct fracture, osteotomy, or arthrodesis fixation in the femur, tibia, humerus, ulna, radius, clavicle, ribs, pelvis, scapula, and sternum.

Contraindications Include:

- Infection.
- Patient conditions including blood supply limitations, obesity and insufficient quantity or quality of bone.
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
- Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

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

Materials:

The Orbitum Staple System staples are manufactured from a Titanium alloy (Ti-6Al-4V ELI per ASTM F136). The instruments are made of surgical grade stainless steel (ISO 7153-1 and ASTM F899).

Adverse Effects:

In all surgical procedures, the potential for complications and adverse reactions exists. The risks and complications with these implants include:

- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and / or loosening
- Pain, discomfort, or abnormal sensations due to the presence of an implant
- Nerve damage resulting from surgical trauma.
- Bone necrosis or bone resorption
- Delayed or nonunion of bone fragments
- Allergic reaction to the implant materials

Warnings & Precautions:

- Carefully inspect product packaging and all device components for damage prior to use. Do not use any device if it appears defective, damaged, or otherwise compromised. Sterility cannot be assured with unintended sterilization methods. Acceptable surgical practices should be followed in post- operative care. Patients should be made aware of post- operative limitations and that physical and/or weight bearing activities have been implicated in premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery. Orbitum Staples have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or migration in the MR environment.
- For safe and effective use of the Orbitum Staple System, the surgeon should be familiar with the recommended surgical procedure for the devices. Improper selection, placement, positioning, or fixation of the implant may result in unusual loading conditions which could affect the long-term service life of the implant(s). Correct selection of Orbitum Staples is critical. The most appropriately sized implant must be selected based on the needs of each individual patient. Use of the largest possible size of implant is preferred for the best results and care should be taken to ensure proper positioning of the implant. Failure to do so may result in loosening, bending, cracking, or fracture of the device, injury to the patient's bone, or both. Orbitum Staples and instruments must always be handled with care. Avoid contact with other tools or objects which could damage the device's surface.

Patient Selection:

The surgeon is responsible for patient selection. When considering use of the Orbitum Staple System, ensure that the patient's weight, occupation, activity level, and/or presence of any degenerative diseases are evaluated. The surgeon is responsible for understanding all indications and contraindications associated with each patient's individual surgical requirements. The surgeon must evaluate each procedure Orbitum Staples are being considered for based on his or her own training and experience. The physician must determine if the device is appropriate for patients having any of the following physical or emotional conditions:

- Drug and/or alcohol and/or smoke addiction and/or abuse.
- Infectious disease
- Malignancy
- Local bone tumor
- Systemic or metabolic disorders or replacement.
- Compromised wound healing.
- Obesity
- Demonstrated psychological instability, inappropriate motivation, or attitude.
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement.
- Lack of understanding that a metallic implant is not as strong as normal healthy bone, and will bend, loosen, or fracture if excessive demand is placed on it.
- Lack of understanding that their preoperative capacity may not be fully recovered, even after successful implantation.

It is the responsibility of the surgeon to provide each patient with appropriate information prior to surgery. The surgeon should discuss all possible risks versus potential benefits of the treatment with each patient, outlining realistic expectations for postoperative improvement of the patient's preoperative condition. The surgeon must ensure the patient does not have unrealistic expectations regarding the results which may be provided by the procedure and/or Orbitum Staples or implants. The patient should clearly understand all applicable warnings, precautions, possible intraoperative and postoperative complications, and possible adverse effects associated with the procedure to make an informed decision. Each patient should be informed that Orbitum Staples are manufactured from Titanium alloy, which may cause reactions and/or other complications. The patient should be informed that the life expectancy of the device is difficult to accurately predict once implanted, and that successful outcomes cannot be guaranteed.

Preoperative Planning Information:

Careful preoperative planning must be conducted based on radiographic findings. Never attempt a surgical procedure with defective, damaged, or otherwise compromised implants or instruments. Inspect all components preoperatively to ensure that the device components and instruments are appropriate for use. It is the physician's responsibility to determine the correct size of Orbitum Staple to be implanted. The physician should always have a full inventory of Orbitum Staple sizes on hand at the time of surgery to ensure availability of the optimum size for the patient. If any of the components are damaged during attempted implantation, additional Orbitum Staples of the same size should be available. Alternate fixation methods should also be available for use if the Orbitum Staple cannot be successfully implanted. Handling of the Orbitum Staple System and instruments must be performed in accordance with aseptic handling practices to maintain sterility throughout use.

Care and Handling:

The Orbitum Staple System should be received in an intact, clearly labeled package. Carefully inspect product packaging and all device components for damage prior to use. Damaged packages or products should not be used and should be returned to the manufacturer. All packaging material must be removed prior to use.

Limitations on Processing:

Repeated processing has minimal effect on these implant and instruments. End of life is normally determined by wear and damage due to use.

Sterilization:

The Orbitum Staple System is supplied non-sterile and must be sterilized at the surgical facility prior to use. Proper sterilization techniques cannot be assured with unintended sterilization methods.

Method	Time	Temperature	Dry Time
Pre-vacuum	4 minutes	270° F (132° C)	30 minutes

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

After Cleaning:

A minimum drying time of 30 minutes, after sterilization, is recommended. Drying times may vary according to load size and should be increased for large loads. Dry, thoroughly and promptly, after both cleaning and sterilization.

Inspection and Function Testing All instruments:

If instruments have been disassembled prior to cleaning reassemble prior to use. Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged. Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored, or damaged instruments.

Packaging:

Instruments may be loaded into the specified Orbitum Staple System instrument trays, or general-purpose trays. Wrap the trays using an appropriate method with no more than two layers of sterilization wrap that are FDA cleared for pre-vacuum steam sterilization.

Storage:

Orbitum implants and instruments should not be subjected to storage temperatures of more than 76.7°C or 170°F. Instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

MRI Safety Information

The Orbitum Staple has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Orbitum Staple in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Basic Surgical Technique Guide

Implant Size Selection:
The Orbitum Clinical Sizer is used to determine the most appropriate size of Orbitum Staple for use during the preoperative planning process. The Orbitum Clinical Sizer may be used in conjunction with radiographic images, or as a visual template, held near or against the patient's unbroken skin prior to surgery.

Exposure/Preparation:
A variety of surgical approaches as well as single or multiple incisions may be utilized for exposure, depending upon the specific patient anatomy and surgical requirements. The fracture, osteotomy, or joint to be fused is prepared in standard fashion, ensuring adequate exposure of subchondral surfaces or raw bone ends for successful arthrodesis or osteotomy healing. The bone surfaces are then brought into apposition with any angulational concerns, gaps in approximation, or remaining high points addressed at this time. Clamps, pins, or manual pressure may be used to maintain position while preparing for implant insertion. No provisional fixation may be required if the construct is adequately stable independently.

Templating:
The Orbitum Surgical Sizer is provided for templating the exact position and orientation of the implant.
Care is to be taken to ensure proper alignment of the staples bicortical and monocortical legs, ensuring that no leg enters the fusion site, nor will be placed outside of the bone ends. Locations of the staple's legs and bridge may be marked at this time using a marking pen or electrocautery if desired.

Hole Preparation:
Entry holes for the implant may now be prepared using either the Punch or Drill Template and K-Wires or 1.5 mm drill.

Punch Method:
The Punch is brought into the surgical site, and its points aligned with the predetermined desired orientation of the implant's legs. Punches are provided for each implant size.
Careful, deliberate, raps with the mallet are then used to pierce the cortex with the punch's points, until base of the points begins to contact the bone surface. The lengths and widths of the Punch's points are sized to provide optimal interference between implant and bone, ensuring effective fixation of the implant.

Drill Method:
The Drill Template is brought into the surgical site, and holes aligned with the predetermined desired orientation of the implant's legs. K-Wires may be used to hold the Drill Template in proper alignment at this time, if desired, while the remaining entry holes are created. To ensure an interference fit between implant and bone, it is important that the K-Wires and/or 1.5 mm Drill are used to just puncture the cortex on the near side of the surgical site. Fixation may be compromised if entry holes are excessively large or deep, as this may preclude adequate interference between implant and bone.

Inspection:
Once entry holes have been made and the Punch and/or Drill Template removed, the Surgical Clinical Sizer may be brought back into the surgical site for final inspection of the hole pattern and orientation if desired.
Note - K-Wires and/or 1.5 mm Drills are only to be used within the holes provided in the Drill Template. K-Wires and/or 1.5 mm Drills are NOT to be templated using the Clinical Sizer.

Initial Insertion:
The Orbitum Staple, loaded onto the appropriate Inserter, may now be brought into the surgical site, and the legs aligned with the pre-drilled holes in the previously determined orientation. A mallet may be used to begin impaction of the staple into the bone, using a firm, deliberate, rapping technique. Repeated impaction is continued until the monocortical spikes begin to contact the bone, at which point the Inserter is to be removed. The Orbitum Staple is released from the Inserter by giving the handle a gentle tilt (~5° away from the central axis of the implant) in the 12 o'clock, 6 o'clock, 3 o'clock, or 9 o'clock directions, and then lifting directly away from the implant.

Final Seating:
Final seating of the Orbitum Staple is then performed using the Tamp, mating the Tamp's tapered nose with the chamfer of the implant's central hole or by tapping about the bridge of the implant with the Tamp in 12 o'clock, 3 o'clock, 6 o'clock, and 9 o'clock positions sequentially. This approach is continued with firm, deliberate, raps with the mallet until the implant is seated to its final desired position.

Verification and Closure:
Final confirmation of the Orbitum Staples desired placement, anatomic alignment, and fusion surface apposition should be performed using fluoroscopy. Once placement has been verified, the site may be irrigated and incision closed in standard manner.

Retrieval and Analysis of Removed Implants:
The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant during handling and shipping. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent the spread of bloodborne pathogens. Please contact Fuse Medical customer service prior to the return of removed implants.

Postoperative Management:
The patient should be provided with detailed written instructions regarding postoperative care and the use and limitations of the device. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until there is evidence of stability. Patients who are obese, noncompliant, or could be predisposed to delayed union or nonunion must make use of auxiliary support during the postoperative period. Patients should be warned of the risks of performing any activities involving walking or lifting without assistance.
The patient should be advised that any noncompliance with postoperative instructions could lead to loosening, bending, or breakage of the implant, potentially requiring additional surgeries for revision or removal. The patient should be instructed to report any unusual changes near the operative site to his or her surgeon immediately. If any evidence suggestive of implant loosening or failure presents, an accelerated schedule of follow-up visits with the surgeon is advised and new warnings and instructions presented to the patient to further restrict activities if necessary.
The patient should be encouraged to receive prompt medical attention for any infection which may occur, either at the operative site or any other part of the body.

Symbol Glossary

Symbol	Title/ Standard	Meaning
Rx only	21 CFR 801.109b Prescription Only	Indicates that a practitioner licensed by the law of the state in which the practitioner practices to use or order the use of the device
REF	ISO 15223-1 5.1.6 Catalogue Number	Indicates the manufacturers catalogue number so that the medical device can be identified.
LOT	ISO 15223-1 5.1.5 Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified
MATL	Material	Indicates the material of the device
QTY	Quantity	Indicates the quantity of devices.
	ISO 15223-1 5.4.2 Do not re-use	Indicates a medical device that is intended for one single use only.
	ISO 15223-1 5.2.8 Do not use if package is damaged	Indicates a product should not be used if the package is damaged or opened and the user should consult the instructions for use for additional information.
	ISO 15223-1 5.4.3 Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 5.4.3 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
NON STERILE	ISO 15223-1 5.2.7 Non-sterile	Indicates a medical device that has not been subjected to a sterilization process
	ISO 15223-1 5.1.1 Manufacturer	Indicates the medical device manufacturer.
MD	ISO 15223-1 Medical Device Symbol	Indicates that the item is a medical device.
UDI	ISO 15223-1 5.7.10 Unique Device Identifier	Indicates a carrier that contains unique device identifier information.

Additional Information:

Comments, questions, or concerns regarding the use of this device should be directed to the following:

Website	www.FuseMedical.Com
Email	Info@FuseMedical.Com
Phone	469-862-3030
Postal	Attn: Customer Service CPM Medical Consultants, LLC 4343 Sigma Road, Suite 500 Farmers Branch, TX 75244
Website	www.FuseMedical.Com

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