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INSTRUCTIONS FOR USE

ORBITUM X and VI Staple System

Description

Fuse Medical's *ORBITUM X and VI* Staple is a single- use bone staple intended for fracture and osteotomy fixation and joint arthrodesis of the hand and foot. ORBITUM X and VI implants 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 Staple implants are available in multiple sizes, ranging from 12-20 millimeters in diameter/width and 8-12 millimeters in length. The ORBITUM Staple implants come as a set or system, for implanting the device.

Two separate methods for holemaking 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 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.

Indications for Use

The *ORBITUM X and VI* Bone Staple is indicated for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

ORBITUM X and VI Implants are 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.

Contraindications

Contraindications include, but are not limited to:

- Acute or chronic, local or systemic infections.
- Pathological conditions of bone which could impair the ability to securely fix the staple, such as osteopenia.
- Comminuted bone surface which could militate secure staple fixation.
- Physical conditions which would preclude adequate implant support or retard healing, such as blood supply impairment, insufficient bone quality or quantity, or previous infection.
- Mental conditions which preclude cooperation with the rehabilitation regimen.

Warnings

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* implants 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.**

Precautions

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* implants 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 best results and care should be taken to ensure proper positing 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 implants and instruments must always be handled with care. Avoid contact with other tools or objects which could damage the device's surface.

Sterilization

ORBITUM Staple System is supplied non-sterile and must be sterilized at the surgical facility prior to use. Sterilization instructions provided on page 4 must be followed.

Sterility cannot be assured with unintended sterilization methods.

Packaging

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 CPM Medical, LLC. All packaging material must be removed prior to use.

Storage

ORBITUM implants and instruments should not be subjected to storage temperatures in excess of 76.7°C or 170°F.

Clinical Use Examples

Hand Surgery – Intracarpal and interphalangeal arthrodesis, carpal, metacarpal, and phalanges fracture or osteotomy.

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

- Foot
  - Fracture fixation, arthrodesis, and osteotomies of the hind-foot, mid-foot, and fore-foot
  - Fracture fixation of the talus
  - Ankle arthrodesis
- Hand & Wrist
  - Distal radius fracture fixation
  - Corrective osteotomies of the distal radius
  - Capital and subcapital 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
- Fore-Foot
  - Akin
  - Bunion
  - MP Arthrodesis
- Mid-Foot
  - Navicular Cuneiform Fusion
  - Lisfranc Arthrodesis
  - Lapidus
  - Opening/Closing Wedge
  - Base Wedge

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- Rear-Foot
  - Talar/Navicular Arthrodesis
  - Calcaneal/Cuboid Arthrodesis
  - Subtalar Arthrodesis
- Hand Surgery
  - Intracarpal and interphalangeal arthrodesis
  - Carpal, metacarpal, and phalangeal fracture or osteotomy fixation
- Foot Surgery
  - Bunionectomy
  - Tibiotarsal, Lisfranc's, calcaneocuboidal, and talonavicular arthrodesis
  - Hind, mid, or fore-foot fracture and osteotomy fixation
- 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

Patient Selection Information

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* implants 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.
- Lacks an 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.
- Lacks an 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 not have unrealistic expectations regarding the results which may be provided by the procedure and/or *ORBITUM* implant or implants. The patient should clearly understand all applicable warning, precautions, possible intraoperative and postoperative complications, and possible adverse effects associated with the procedure and implants in order to make an informed decision. Each patient should be informed that *ORBITUM* implants 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* Staple Sets of the same size should be available.

Alternate fixation methods should also be available for use in the event that the *ORBITUM* Staple cannot be successfully implanted.

Handling of the *ORBITUM* implants and instruments must be performed in accordance with aseptic handling practices to maintain sterility throughout use.

Basic Surgical Technique Guide

Implant Size Selection

The *ORBITUM Clinical Sizing Template* is used to determine the most appropriate size of *ORBITUM* implant for use during the preoperative planning process. The *ORBITUM Clinical Sizing Template* 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 Sizing Template is provided for templating the exact position and orientation of the implant.

Care is to be taken to ensure proper alignment of the staple's 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.

Temporary Fixation Pins 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 Sizing Template may be brought back into the surgical site for final inspection of the hole pattern and orientation if desired.

* *NOTE* – K-Wires, Temporary Fixation Pins, and/or 1.5 mm Drills are only to be used within the holes provided in the Drill Template. K-Wires, Temporary Fixation Pins, and/or 1.5 mm Drills are NOT to be templated using the Surgical Sizing Template.

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Initial Insertion

The *ORBITUM* Staple implant, loaded onto the appropriate Insertion Rod, 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 Insertion Rod is to be removed.

The *ORBITUM* implant is released from the Insertion Rod 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, and 9 o'clock directions, and then lifting directly away from the implant.

Final Seating

Final seating of the *ORBITUM* implant 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* implant's 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.

Postoperative Care

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.

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Removal

If removal becomes necessary, the surgical site should be exposed in the standard manner, ensuring visualization of the entire top of the implant can be achieved.

An osteotome or elevator may be used to lift the implant's bridge from the top of the bone surface, and removal completed by grasping the center of the implant using forceps.

Warranty Information

All *ORBITUM S*taple implants and instruments are guaranteed for materials, function, and workmanship for a single patient use.

CPM Medical, LLC shall not be liable, expressly or implied for any damage which might arise or be caused, whether by the customer or by any users of the product, as a result of:

- Misuse, mishandling, and/or improper operation.
- Attempted repairs and/or modifications performed other than by CPM Medical, LLC or a CPM Medical, LLC authorized repair facility.
- Use in any manner or medical procedure other than those for which it is designed; and any special, indirect, and/or consequential damages of any kind and however causing arising from the sale or use of the product.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND/OR STATURORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS, AND/OR SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON CPM MEDICAL LLC'S PART.

Return Conditions

In the event the device must be returned for any reason, return the product in the original packaging. Contact Customer Service or an authorized CPM Medical, LLC representative to receive a return authorization number prior to return shipment.

CAUTIONS:
The *ORBITUM* Staple System components provided **NON-STERILE** should be cleaned and sterilized before use, unless the individual packaging states otherwise.

Automated cleaning may not be effective. A thorough, manual cleaning process is recommended.

Cleaning agents with chlorine or chloride as an active ingredient are corrosive to stainless steel and should not be used.

Saline solution has a corrosive effect on stainless steel and should not be used.

Use only neutral pH cleaning agents and detergents.

ORBITUM implants are single use. Therefore these guidelines are not intended for **USED ORBITUM** implants or **DISPOSABLE**, single use instruments.

The *ORBITUM* Staple System has not been evaluated for safety and compatibility in the MR environment. The ORBITUM Staple System has not been tested for heating or migration in the MR environment.

Limitations on Reprocessing:

Repeated processing has limited effect on REUSABLE instruments.

End of life is normally determined by wear and damage due to use.

INSTRUCTIONS

Removal of gross contamination: The effectiveness of subsequent decontamination processes depends on prior removal of gross soil as it may be impaired by dried or coagulated protein. Gross soil should be removed under running water using a mechanical aid such as a brush with rigid nylon bristles. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and continuously draining. Instruments should not be held under a running tap, as this is likely to result in splashing. Operatives should wear protective equipment including gloves and goggles. Care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from all cannulations and obscure holes in the instruments.

Preparation for decontamination: Disassemble all components to provide maximum exposure for cleaning.

Cleaning –Automated
Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used as a follow-up method to manual cleaning.

Cleaning-Manual

1.Disassemble all components before cleaning

2. Completely submerge instruments in enzyme solution and allow to soak for a minimum of 20 minutes. Use a soft-bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, and appropriately sized soft-bristled brush (e.g. pipe cleaner brush).

3. Remove the devices from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas.

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4. After manual cleaning, and all visible blood, soft tissue, and bone have been removed, ultra-sonic cleaning may be used. Place prepared cleaning agents in a sonication unit. Completely submerge device in cleaning solution and sonicate for a minimum of 10 minutes at 45-50 kHz.

5. Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse

stream. Thoroughly and aggressively flush lumens, holes and other difficult-to-reach areas. Use de-ionized water for final rinse of all components.

6. Repeat the sonication and rinse steps above until all visible contamination has been removed.

7. Thoroughly and promptly, remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe. Allow the tray and components to dry for a minimum of 15 minutes. The tray and components must be thoroughly dry prior to sterilization cycle.

Disinfection: Disinfection is only acceptable as an adjunct to full sterilization for reusable surgical instruments.

Maintenance, inspection, and testing
Carefully inspect each device to ensure that all visible blood and soil have been removed. Inspect lumens to confirm that all foreign material has been removed.
Visually inspect for damage and/or wear.

Note: If any damage or wear is noted that impairs the function of the instrument, contact your Meditech representative for a replacement.

Packaging:
This set of components may be loaded into a dedicated tray, supplied by the manufacturer, for sterilization.

Sterilization:

Thoroughly clean ORBITUM Instrument Trays prior to sterilization and visually inspect the tray and all components for any remaining debris prior to sterilization. Repeat the cleaning process if the visual inspection produces any evidence of debris

ORBITUM Staple System components provided **NON-STERILE** should be autoclave sterilized using the sterilizer manufacturer's instructions and the institution's procedures for ensuring sterility. The sterilization cycle should occur in a calibrated autoclave.

DO NOT STACK ORBITUM instrument trays during sterilization

***ORBITUM* Staple System components should be sterilized utilizing a pre-vacuum steam autoclave for a minimum of 4 minutes at 270°F (132°C.)**

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).

Drying:

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.

Storage:

Store components in a clean, dry, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and extremes in humidity and temperature.

The instructions provided above have been validated by CPM Medical, LLC as being CAPABLE of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing as actually performed, using equipment, materials, and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. Any deviation by the re-processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

MRI Safety Information

The ORBITUM BONE 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 BONE STAPLES in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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