ORTHONOVIS BPSS ANKLE FRACTURE SYSTEM

INSTRUCTION FOR USE (IFU)

Caution: Federal Law restricts this device to sale by or on the order of a Physician.

General:
The OrthoNovis BPSS Ankle Fracture System is to be used as an aid to the treatment of certain types of fractures, fusions or osteotomies that lend themselves to the principle of plate and/or screw fixation. Like every type of orthopaedic implant, it cannot be assumed to be uniformly effective without risk. Use of these implants is not a substitute for normal tissue healing. The OrthoNovis BPSS Ankle Fracture System is designed to provide additional constraint of movement of a fractured, fused or osteotomized bone and are intended only as an aid to fix the fracture in place during the healing process.

Basic Design Features:
The BPSS Ankle Fracture System include implants designed for fixation of certain fractures, fusions or osteotomies. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate variations in patient size and sites of application. BPSS Ankle Fracture System Plates and Screws are manufactured from 316L medical grade implant quality stainless steel, grade 2 commercially pure titanium per ISO 5832-2 and grade 5 commercially pure titanium (Ti-6Al-4V) per ISO 5833-3 and/or ASTM F1472. BPSS Ankle Fracture System plates should only be used with the appropriate size screws.

Indications, Contraindications, Adverse Effects:
Patient selection and sound surgical principles apply to the use of the BPSS Ankle Fracture System in a given clinical setting. The decision to use an implant as well as the size and shape of the implant used must be based on sound medical judgment that takes into consideration factors such as the circumstances and configuration of the injury. As with plate and screw fixation in general, the surgeon must implement post-operative patient protocol measures to avoid excessive force on implant until bone healing has taken place. This includes protection of the fracture, fusion or osteotomy when appropriate, and instructions to the patient to avoid excess loading of the extremity until sufficient healing has taken place.

Specific Indications:
Specific fractures, fusions or osteotomies with configurations that would otherwise lend themselves to the general principle of bone plate fixation with this class of implants may be appropriate for use with this device.

The distal fibular plate is intended for use in internal fixation of the distal fibula. The one-third tubular plate is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, distal fibula, small bones in the ankle, fore, mid-and hind-foot in adult patients. The 4.0 cannulated screw is intended for fracture fixation of small and long bones. **The system is not intended for spinal use.**

Contraindications: ***The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:***
1. Any active or suspected latent infection or marked local inflammation in or about the affected area.
2. Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
3. Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices.
4. Material sensitivity, documented or suspected.
5. Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
6. Patients having inadequate tissue coverage over the operative site.
7. Implant utilization that would interfere with anatomical structures or physiological performance.

Contraindications may be relative or absolute. Users of this device must carefully weigh the advantages against possible complications and consider the patient's entire clinical exam in addition to the items listed above.

Possible Adverse Effects: In any surgical procedure, the potential for adverse reactions exists. Possible adverse effects particular to orthopaedic devices are listed below. These do not include all adverse effects which can occur with surgical procedures.

1. Loosening, bending, cracking or fracture of any component with or without loss of fixation in bone, possibly in association with blood supply limitations, insufficient quality or quantity of bone, osteoporosis, delayed union, nonunion, excess activity, or any of the factors listed previously.
2. Loss of anatomic position with resulting nonunion, malunion, or delayed union.
3. Infections.
4. Hematoma.
5. Stiffness of the adjacent joint with or without degenerative changes.
6. Tendinitis or tendon rupture.
7. Scarring.
8. Chronic regional pain syndrome.
9. Local bursitis and pain from prominent hardware.

The adverse effects listed here are not specific to the OrthoNovis BPSS Ankle Fracture System and are in principle observed with any implant.

Warnings and Precautions:
1.Use caution in the handling and storage of implants. Cutting, bending, or scratching the surface of metal components impairs the strength and fatigue life of the implant. Implants should be stored away from corrosive agents and environments. If implants appear damaged, they should not be implanted.
2. Implantation in patients with the contraindications specified previously should be avoided. It is important to preoperatively assess the radiographic configuration of the fracture, fusion or osteotomy prior to considering implantation of this device. In addition, all other relevant medical and social factors should be considered in order to determine whether a patient is an appropriate candidate for this device.
3. Allergies to component materials should be considered and tested, if appropriate, prior to using this device. See material composition under the general regulatory information section.
4. A full inventory of instruments and implants should be available prior to initiation of the surgical procedure. Components should be tested in trial assembly prior to implantation.
5. Surgeons are advised to review the product-specific surgical technique prior to performing surgery. Surgeons should also be fully familiar with the biomechanics and surgical principles inherent to the use of this device, and proper selection and placement of the device are important considerations in successful utilization of this device.
6. Any adjacent soft tissue structures should be checked to ensure that abrasive rubbing against components will not occur.
7. Size and position of implants should be checked radiographically prior to completion of the surgical procedure.
8. These devices are intended for single use only. Violation of this could potentially result in loss of performance, function, fit or device failure, and could potentially result in infection.
9. Excessive or improper insertion angle can potentially deform or adversely affect the strength and fatigue life of the implant.
10.OrthoNovis plates should not be bent near the locking screw hole, as it may distort the hole threads which prohibits insertion of the screw.
11.OrthoNovis plates should not be repeatedly bent at the same location or bent to excessive angles as it may potentially lead to premature plate fatigue, loss of performance or breakage in situ.
12.OrthoNovis screws must be inserted by hand, and are not advised to be placed under powered equipment. Possible risks using screws under power include stripping, bending, cracking or fracturing of the implant and/or instrument. For screws where power equipment may be used, the surgeon must carefully control of the speed and power of insertion. It is inappropriate to use power equipment with smaller sizes of OrthoNovis screws. It is the responsibility of the surgeon to ensure safe use.
13.OrthoNovis plates should only be used with the appropriate size OrthoNovis screws. OrthoNovis has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
14.Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative protocol prescribed by the surgeon should be strictly followed to avoid adverse stresses applied to the device.
15. Removal of OrthoNovis plates and screws may be warranted if deemed medically necessary in order to avoid possible adverse effects. Temporary joint spanning plates, such as bridge plates, must be periodically monitored and removed once bone healing has occurred.
16.These devices have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment.

Recommendations for Cleaning and Sterilization:

The following recommendations are for processing Orthonovis reusable surgical instruments. OrthoNovis products supplied in a non-sterile condition must be cleaned and steam sterilized prior to surgical use. Prior to cleaning and/or sterilization, remove and dispose of all original disposable packaging (e.g., silicone sleeves, tip guards, pouches, bags, tubes, etc.) Component devices must be disassembled prior to cleaning, disinfection and sterilization.

Cleaning:

Unused OrthoNovis implants that have been soiled by blood, tissue, and/or bodily fluids or matter, must be processed according to the following cleaning procedures. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve cleanliness.

1. Upon point of use, immediately after the surgical procedure, remove as much debris as possible from each instrument using a water moistened gauze pad or surgical towel to prevent organic debris from drying. Exchange the gauze and/or towel as necessary when it becomes soiled.
2. Rinse the soiled device under lukewarm running tap water (22° C - 43° C) for a minimum of two (2) minutes. Remove gross soil using a soft-bristled brush or clean, soft, lint free cloth. Note: Remove additional soil from challenging design features (i.e., holes, lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common cleaning tools. Never use metal brushes or steel wool for cleaning.
3. Prepare an enzymatic cleaning solution presoak (such as Johnson & Johnson Enzol Enzymatic Detergent) per the manufacturer's instructions.
4. Fully immerse the instruments in the fresh, newly prepared enzymatic cleaning solution and soak for twenty (20) minutes.
5. Use a soft-bristled brush to gently clean the submerged device paying particular attention to crevices, lumens, mated surfaces, and other hard-to-clean areas. Brush for a minimum of 15 seconds or longer to remove debris. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush) if needed to remove debris. Note: The enzyme solution should be replaced when it becomes grossly contaminated (bloody and/or turbid).
6. Remove the device from the cleaning solution and rinse with lukewarm, running tap water (22° C – 43° C) for a minimum of three (3) minutes, including to ensure all regions including difficult-to-reach areas are flushed. After rinsing, ensure debris is removed from the instrument. If debris remains, use a syringe to flush the device or repeat rinsing until debris is removed.
7. Prepare an enzymatic cleaning solution presoak (such as Johnson & Johnson Enzol Enzymatic Detergent) per the manufacturer's instructions and fully immerse all devices within the container of enzymatic cleaning solution and place the container in the sonication unit.
8. Actuate the joints, handles, and other movable device features to expose areas to the cleaning solution several times. Sonicate for ten (10) minutes.
9. Fully immerse the device in a basin with clean lukewarm tap water (22° C - 43° C) for rinsing. Gently agitate the device for a minimum of one (1) minute. Actuate the joints, handles, and other movable device features to expose areas to the water several times. Pass a soft bristled brush through any crevices or lumens.
10. Repeat steps 8 and 9 with freshly prepared cleaning solution if there is a sign of blood or soil in the tap water bath.
11. Remove the devices from the rinse solution and rinse with lukewarm (22° C – 43° C) deionized water for a minimum of three (3) minutes ensuring all regions including difficult-to-reach areas are flushed. After rinsing, ensure debris is removed from the instrument. If debris remains, repeat Steps 7 through 11.
12. Dry the device using a clean, soft, lint-free cloth or clean compressed air. Visually inspect the device; no visible soil should be left on the device. Note: Thorough drying of devices prevents corrosion from mineral content, condensate and residual agents.

Sterilization:

OrthoNovis recommends the following sterilization procedures for non-sterile implants and re-usable instruments. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve sterility.
1. Place clean and unused implants and screws into the designated slots of the designated caddies. Disassemble instruments and place them inside the designated caddy. Carefully close the caddy covers.
2. Place properly cleaned and dried instruments into the designated slots inside the sterilization tray. Disassemble instruments and place components inside the sterilization tray. Where possible, hinged instruments should be in the open position.
3. Place the implant and screw caddies into the designated locations inside the sterilization tray. Carefully close the implant tray and clamp to seal.
4. Wrap the instrument tray with commercially available CSR wrap.
5. Place wrapped instrument tray in steam sterilizer, sterilize for 4 minutes in 132oC pre-vacuum cycle with 20-minute dry time.
6. Upon cycle completion, remove the wrapped instrument tray from the sterilizer and place the tray on a padded surface to prevent condensation during cooling.
7. Store the sterilized instrument tray in a clean and dry area.

NOTE: Prior to reuse, instruments must be inspected for signs of wear, damage and proper function. If an instrument is suspected to be damaged it must not be used and Orthonovis, Inc. must be contacted for a replacement.

NOTE: These parameters have been validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and updated sterilization parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms. 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).

NOTE: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as-needed basis.

NOTE: The above recommendations are for processing Orthonovis reusable medical devices. Reusable devices include the stainless steel and titanium systems (including plates, screws, external fixation, surgical instruments, instrument trays and lids).

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REFERENCES to relevant literature may be obtained by contacting OrthoNovis, Inc. at cs@orthonovis.com

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