Orthonovis ONX Large External Fixation System Instruction For Use (IFU)

Instruction For Use

Recommendations for the Care and Handling for OrthoNovis, Inc., ONX Large External Fixation System

DESCRIPTION:

The ONX Large External Fixation System includes a variety of components including clamps, rods, posts and pins that, when used in conjunction, provide the surgeon a broad range of frame construct options that can be used to stabilize/immobilize fractures or surgically created instability of the femur, tibia, knee joint, ankle, and pelvis. The clamps, fabricated from titanium and stainless steel, are offered in the following configurations: open rod clamp, closed rod clamp, adjustable rod pin clamp, rod pin clamp, and multiple pin clamp. The open rod clamp, closed rod clamp, adjustable rod pin clamp, and rod pin clamp are used to connect rods to pins or to connect a rod to another rod. The large multiple pin clamp is used to connect rods to multiple bone pins. The rods are 11mm in diameter and are provided in a range of lengths. All rods are fabricated from radiolucent carbon fiber to provide strength and rigidity while minimizing interference with x-rays. The bone pins incorporate fixation threads and are offered in three diameters and in three lengths with self-drilling tips. All bone pins are available in either titanium alloy or stainless steel. All ONX Large External Fixation System components are intended for single use only.

IMPORTANT NOTE:

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. Individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-label use) should be aware that such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL:

Materials in the ONX Large External Fixation System components are as follows:

- Bone pins: Titanium Alloy or 316LVM Stainless Steel
- Rods: Reinforced Carbon Fiber
- Clamps: Titanium Alloy and 316L Stainless Steel
- Posts: 316L Stainless Steel.
- Accessory components: Silicone (USP Class VI), polyphenylsulfone (Radel R5500) or vinyl
- All Titanium Alloy conforms to ASTM F136 (Ti-6Al-4V ELI). All Stainless Steel conforms to ASTM F138.

GENERAL CONDITIONS OF USE:

The safe implantation of external fixation systems requires an in-depth knowledge of human anatomy as well as common anatomical variations along with a thorough understanding of the specific clinical circumstances. The use of the ONX Large External Fixation System should be performed only by experienced surgeons with specific training in the use of external fixation. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this system. The ONX Large External Fixation System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. After bone healing occurs, these devices serve no functional purpose and should be removed. The decision regarding when to remove the external fixation device is made between the surgeon and the patient with due regard to treatment options.

INDICATION FOR USE:

The ONX Large External Fixation System is indicated for the following:

- Stabilization/fixation of:
  - Long bone fractures in tibia and femur
  - Fractures of pelvis and ankle
  - Peri-articular and intra-articular fractures of knee and ankle
- Joint arthrodesis
- Non-unions and mal-unions
- Osteotomies

CONTRAINDICATIONS:

- Insufficient quantity or quality of bone which would inhibit appropriate fixation of the external fixation system.
- Patients with a suspected or documented metal allergy or intolerance.
- Compromised vascularity that would inhibit the blood supply to the operative site.
- Recent or active infection.

WARNINGS, PRECAUTIONS, POTENTIAL RISKS and POTENTIAL ADVERSE EFFECTS:

These warnings do not include all possible adverse surgical effects, but are particular to metallic fixation devices. Explain general surgical risks to the patient before surgery.

WARNINGS

1. The patient should be advised that the device cannot and does not replicate a normal healthy bone. The device can break or become damaged as a result of trauma or strenuous activity. The ONX Large External Fixation System has a finite expected service of life.
2. The surgeon must discuss all relevant risks, including the finite lifetime of the device with the patient, when necessary.
3. All non-sterile devices must be cleaned and sterilized before use.
4. All ONX Large External Fixation components are intended for single use only.
5. The compatibility of different product systems has not been tested and is considered “off-label” for use.
6. Bone pin placement requires accurate anatomic alignment to avoid damage to nerves, blood vessels and tendons.
7. Pre-drilling should be done using a low drill speed to minimize heat that can injure bone and soft tissue.
8. Use caution when handling the sharp tip of the Bone Pin. If the Bone Pins are to be cut, the pin ends should be held by the surgeon or an assistant during this process. Eye protection is recommended for all operating room personnel.
9. As with all percutaneous skeletal fixations, pin track care is important in reducing the incidence of infection.

PRECAUTIONS

1. Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
2. Patient cooperation and participation are important to effective use of the ONX Large External Fixation System. Advise your patient to report adverse or unanticipated effects as soon as possible.
3. Skeletal pin security in bone and device integrity should be routinely checked by the surgeon. Pin track infections need prompt recognition and treatment and may require early device removal.
4. Adequately instruct the patient. Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the system limitations, and to limit physical activities.

POTENTIAL RISKS:

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper component size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present component size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No component can be expected to withstand indefinitely the unsupported stress of full weight bearing. Components can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the component may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate component longevity. Notches, scratches or component bending during the surgery may also contribute to early failure. Fully inform patients of the component failure risks.
2. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The

amount of metal compounds released into the body system will also increase. Internal fixation devices that come into contact with other metal objects, must be made from like or compatible materials.

POTENTIAL ADVERSE EFFECTS:

1. In addition to the obvious risk that any orthopaedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:
2. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopaedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopaedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long-term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
3. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While formation wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
4. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Ti-6AL-4V ELI) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

TECHNICAL DETAILS, MRI SAFETY:

The ONX Large External Fixation System has not been evaluated for safety and compatibility in the MR environment. The ONX Large External Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ONX Large External Fixation System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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).

CAUTION: Federal Law USA restricts this device to sale by or on the order of a physician.

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