BLUE OCEAN
GLOBAL

INSTRUCTIONS FOR USE

IMPORTANT MEDICAL INFORMATION: Excelsior External Fixation System

Please read this before using the Excelsior External Fixation System product. This instruction applies to the Excelsior External Fixation System and supplemental surgical instruments ("instruments") for external fixation. These instructions are designed to assist in using the system, and are not a reference for surgical techniques.

DESCRIPTION

Blue Ocean Global manufactures a modular External Fixation system for aid in fracture fixation and soft bony or tissue correction.

INDICATIONS

The Excelsior External Fixation System is indicated for adult and pediatric (greater than 2 through 21 years of age) patients for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (e.g. orthoplastic surgery)
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures
- Bone transport

The Excelsior External Fixation System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction practices
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
- Lisfranc dislocations
- Ankle distraction (arthrodiastasis)
- Septic fusion

The Excelsior Translation Device is not intended for weight bearing applications. Patients must remain non weight bearing on the Excelsior External Fixation frame when the Excelsior Translation Device is used for transport applications.

CONTRAINDICATIONS

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized.

In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic, and patients with a history of infection
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the devices
- Osteopathies with reduced bone substance that could affect the function of the devices
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment. The risk of breakage of a fixation device is greater in older patients with mental deficiency, alcoholics or drug addicts or patients who, for other reasons, may ignore the necessary restrictions and precautions to be observed while using the device.
- Known or suspected sensitivity to device materials
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or device failure can occur

The Excelsior Translation Device is not intended for weight bearing applications. Patients must remain non weight bearing on the Excelsior External Fixation frame when the Excelsior Translation Device is used for transport applications.

The Excelsior External Fixation System is indicated for prescription use only.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation, migration, subluxation, fracture of the device, or premature loss of fixation with the bone which may result in nerve and soft tissue damage
- Delayed union, non-union, or malunion resulting in breakage of the construct. If healing is delayed, or does not occur, the construct may eventually break due to the increased loading.
- Acute post-operative wound infections and late infections with possible sepsis and osteomyelitis, including chronic drainage of the Schanze screw sites following removal of the device.
- Migration, subluxation of the implant with resulting reduction in range of movement
- Thrombosis or embolism
- Avascular necrosis
- Tissue necrosis, wound hematoma and delayed wound healing
- Excessive surgical bleeding
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Shortening of the affected bone/fracture site.
- Bone loss or reduced bone density due to a reduction in the tension applied to the bone.
- Fractures resulting from unilateral joint loading
- Edema or possible compartmental syndrome.
- Premature bone callus consolidation during distraction.
- Possible tension affecting the soft tissues and/or the fixation during manipulation of the callus (e.g. corrections of deformities and/or elongation).
- Fracture of regenerated bone, or at the Schanze screw holes, following removal of the device.
- Bone damage due to erroneous Schanze screw selection.
- Bone deformities or talipes equinus.
- The persistence or recurrence of the initial condition subject to treatment.
- Abnormal growth cartilage development in skeletally immature patients.
- Pressure on the skin caused by external components when the free space is insufficient.
- Secondary bony sequestration due to rapid perforation of the cortex with accumulation of heat and bone necrosis.
- Nerve or vascular damage following the insertion of Schanze screws or wires.

All possible complications listed here are not typical of Blue Ocean Global products but are in principle observed with any implant. Promptly inform Blue Ocean Global in the event that complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Blue Ocean Global with the explant(s) in a cleaned, disinfected and sterile condition. Blue Ocean Global cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent non-compliant patient behavior.

WARNINGS

- The patient must be informed that a second minor surgery for the removal of the fixation system is required.
- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- The implants and guide wires are intended for single use only.
- Guide wires and Schanze screws are to be treated as sharps.
- Do not reuse used single use components or accessories. Reuse of used single-use external fixators may lead to reduced biomechanical properties and/or fatigue breakage of the devices.
- Do not use other manufacturer's instruments or implants in conjunction with the Excelsior External Fixation System.
- Improper use of the Translation Device may result in patient injury due to device failure and breakage resulting in delayed or non-union of fracture healing.

MR SAFETY INFORMATION

The Excelsior External Fixation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Excelsior External Fixation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

CLEANING

1. The Excelsior System components, accessories and instruments are provided non-sterile. The health care professional is to follow the institutions procedures for automated cleaning and disinfection prior to sterilization by the institutions validated procedures.
2. Begin by rinsing the instruments with cold tap water to eliminate gross soil.
3. Check that the container for the cleaning is clean and there are no visible foreign objects. Fill the container with demineralized water and the enzymatic cleaning agent solution at a concentration of 0.5% V/V (5mL/L) at 40-45°C.
4. Gently soak the contaminated instruments in the solution where solution reaches all surfaces, including holes and hollow parts for 5 minutes then remove instruments from the solution. In the case of cannulated instruments, it is recommended to use a syringe to inject the cleaning agent solution directly into the holes before dipping the instruments into the solution.
5. Use a soft-bristled brush to remove visible residues and, in the case of cannulated instruments, inject cleaning solution again directly into the holes several times
6. Rinse the instruments for at least two (2) minutes under the jet of cold running water, in the case of cannulated instruments it is recommended to direct the jet of water inside the hole(s).
7. Thoroughly dry the instruments with a clean soft lint-free cloth
8. If the device still has visible residues at the end of the preventive cleaning, the procedure will be repeated before moving to the next cleaning phase
9. Prepare an ultrasonic bath with demineralized water and a decontaminant solution at a concentration of 0.5% V/V (5mL/L) at 40-45°C.
10. Soak the instruments in the ultrasonic bath, making sure that all surfaces are completely immersed in the solution and activate the ultrasound for at least five (5) minutes
11. Remove the instruments from the ultrasonic bath and proceed with an intense and accurate rinsing for at least two (2) minutes with cold running water. In case of cannulated instruments, it is recommended to direct the jet of water inside the hole(s).
12. Proceed to a final rinse with cold demineralized water to avoid the formation of stains and halos on the instruments.
13. Dry the instruments immediately and completely with a sterile lint-free cloth or filtered-compressed air.
14. Visually inspect all visible internal and external surfaces. If necessary, repeat the cleaning phase until the instruments are visibly cleaned.

Cleaning Notes

- Contamination must not be allowed to dry on the instruments, otherwise cleaning can be difficult.
- Components and/or Instruments are not to be placed in physiological saline solution, as prolonged contact with this medium can lead to corrosion and changes to their surfaces.
- Freshley prepared cleaning materials must always be used.
- Do not use metal brush or scouring agents for the cleaning of components and instruments. Resulting damage may affect structural integrity of the system.
- To avoid water stains, a final rinsing with desalinated water is recommended.
- Dry the components and/or instruments immediately.

HANDLING AND STERILIZATION

1. The Excelsior External Fixation System is provided non-sterile and MUST be sterilized prior to use.
2. The health care practitioner is to follow the institution's validated sterilization procedures. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling.
3. Health care institutions validated procedures should be in accordance with ANSI/AAMI ST79:Current Edition Comprehensive guide to team sterilization and sterility assurance in health care facilities and/or ISO SO 17665-1 Sterilization of health care products – Most heat for the development, validation and

routine control of a sterilization process for medical devices internationally recognized standards to provide a 10^{-6} sterility assurance level (SAL) or national specifications should be followed if they supersede the international standards.

4. Validated chamber load configurations should be followed.
5. Ensure a FDA-cleared or legally marketed sterilization wrap is used for sterilization.
6. Prior to sterilization, verify that all components and instruments are in their open and unlocked position within the instrument tray(s). The following validated steam autoclave is recommended:

Recommended Steam Sterilization Parameters				
Device Set	Cycle	Temperature	Exposure Time	Dry Time
Excelsior Instrument Case + ½ pins and wires	Pre-Vacuum	270°F (132°C)	4 min	50 min
	Pre-Vacuum[1]	273°F (134°C)	3 min	
Excelsior 2 Rods, Plates & Struts	Pre-Vacuum	270°F (132°C)	4 min	30 min
	Pre-Vacuum[1]	273°F (134°C)	3 min	
Excelsior 3 Rings & Foot Plates	Pre-Vacuum	270°F (132°C)	4 min	30 min
	Pre-Vacuum[1]	273°F (134°C)	3 min	
Pre-Built Frame inside Excelsior	Pre-Vacuum	270°F (132°C)	4 min	40 min
	Pre-Vacuum[1]	273°F (134°C)	3 min	

[1] 134°C setting is for outside the USA **only**

7. Any system component that has been used is not to be reprocessed, recleaned or re-sterilized after use on patients. System components that have not been used on a patient may be reprocessed, re-cleaned and/or re-sterilized according to health care institution procedure. Dispose of used components in accordance with the heath care institutions procedures for disposal of used medical devices. Dispose of implantable half pins and wires in accordance with the health care institutions procedures for biohazardous sharps.
8. The Excelsior System instruments may be reprocessed then reused. The health care professional is to follow the institutions procedures for automated cleaning, disinfection and sterilization by the institutions validated procedures.

INSPECTION AND FUNCITONAL TESTING

Instruments should be inspected for any damage or wear over time. Check for smooth movement of assemblies. Cutting edges should be free of nicks and have a continuous edge. Lond slender instruments should be straight and free of distortion. Instruments should be removed of any excessive moisture with a clean, absorbent, and non-shedding wipe. If the user notices any damage or wear, discontinue use of the instrument and/or component.

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Excelsior External Fixation System. Refer to Excelsior External Fixation System Surgical Technique for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Blue Ocean Global by phone, 786-784-7841.

STORAGE AND SHELF LIFE

Store the Excelsior System at room temperature. The Excelsior System is supplied non-sterile and is composed of stainless steel, titanium and aluminum, materials that do not degrade over time if stored properly. The health care facility is to establish a shelf life for sterilized components, accessories and tools based upon the type of sterile wrap or rigid container used and the recommendations of the sterile wrap or rigid container manufacturer. Do not use sterilized components if the sterile wrap is compromised.

REMOVAL

For the removal of the frame, use a Jacob's Chuck to remove the Half Pins and cut the Smooth/Reduction Wires with provided Wire Cutter. After removal of all Wire and Half Pins, slide the frame off the patient. Refer to the Surgical Instructions for Use.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Blue Ocean Global immediately. Blue Ocean Global should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

Blue Ocean Global
12550 Biscayne Boulevard, Suite 110
Miami FL 33181
Tel: 786-784-7841

IFU Revision XX (MM-YYYY)

USE OF SYMBOLS ON LABELS

Symbol	Description
	Manufacturer
	Catalogue Number
	Batch Code
	Date of manufacture
	Prescription use only
	Caution
	Non-sterile
	MR unsafe

Symbol	Description
	Consult instructions for use or consult electronic instructions for use
	Do not re-use