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ARBOR™ EXTERNAL FIXATION SYSTEM

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IMPORTANT INFORMATION ON THE ARBOR™ EXTERNAL FIXATION SYSTEM

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION ON THE ARBOR™ EXTERNAL FIXATION SYSTEM

DESCRIPTION

The ARBOR™ External Fixation System is comprised of Schanz pins, external fixation clamps, and bars. The pins and bars are available in various sizes, and the fixation clamps are available in several designs all capable of use with any size pins and bars.

ARBOR™ pins and clamps are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F138, F139, F899, F1058, F1295, F1472, F1537, and F2229. ARBOR™ pins are also available with hydroxyapatite (HA) coating as specified in ASTM F1185. ARBOR™ bars are manufactured from carbon fiber reinforced epoxy.

INDICATIONS

The ARBOR™ External Fixation System is indicated for use in construction of an external fixation frame for the treatment of pediatric and adult fractures and/or reconstruction of long bones, small bones (including metacarpal and metatarsal), and the pelvis.

The ARBOR™ External Fixation System is intended for:
- Stabilization of open or closed fractures with soft tissue injuries;
- Polytrauma;
- Vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures;
- Arthrodesis and osteotomies with soft tissue problems;
- Revision procedures where other devices have been unsuccessful including failures of total joints;
- Neutralization of fractures stabilized with limited internal fixation;
- Non-unions/septic non-unions;
- Intraoperative reduction/stabilization tool to assist with indirect reduction;
- Correction of deformity; and
- Unilateral rectilinear bone segment transport or leg lengthening.

WARNINGS

The correct implant selection is extremely important. Failure to use the appropriate implant for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the implant and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

Implanting metals and alloys in the human body subjects them to an aggressive chemical environment of salts, acids, and proteins, which can cause corrosion. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Thus, mixing of implant components from different manufacturers is not recommended, for metallurgical, mechanical and function reasons.

PRECAUTIONS

The implantation of external fixation devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

External fixation pins must never be reused. An explanted implant must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage. For reprocessing instructions for non-implanted, reusable devices (e.g. clamps, bars), refer to the REPROCESSING section below.

Surgeons must respect the neurovascular anatomy of the fixation site. Care must be taken to avoid these structures when placing fixation pins, to avoid serious injury.

MRI SAFETY INFORMATION

Non-clinical testing demonstrated that the ARBOR™ External Fixation System is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:
- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2-W/kg in the Normal Operating Mode of operation for the MR system
- The entire device must be visible outside the MRI bore
- Under the scan conditions defined, the ARBOR™ External Fixation System is expected to produce a maximum temperature rise of 2°C after 15-minutes of continuous scanning when the device is visibly out of the coil.

Artifact Information

In non-clinical testing, the image artifact caused by the ARBOR™ External Fixation System extends approximately 43mm from this implant when imaged using a gradient echo pulse sequence and a 3.0 Tesla MRI system.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:
- Patients in whom no screws can be inserted due to a bone or soft tissue disease.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of external fracture fixation devices:
- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. External fixation devices are load-sharing devices which are intended to hold fracture bone surface in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalicia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.
- Improper alignment can cause a malunion of the bone and bending, cracking or even breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, deep or superficial.
- Edema.
- Septic arthritis.
- Pin loosening.
- Pin breakage or movement at the fracture site caused by use of too few pins or pins that are too small.
- Excessive motion at the fracture site caused by failure to tighten the component parts of the device.
- Bone separation induced by rapid drilling of the bony cortex.
- Chronic drainage of bone screw or wire sites after device removal.
- Inadequate fracture reduction because of failure to pin the bone segments correctly.
- Thrombosis.
- Ankle stiffness.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Nerve damage due to surgical trauma.
- Metal sensitivity, or allergic reaction to a foreign body.
- Decrease in bone density, pain, discomfort, or abnormal sensations due to the presence of the device, and vascular changes.

CAUTIONS

Pre-operative
- Pins are single patient use only.
- Pins that came in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

Intraoperative
- Discard all damaged or mishandled implants.
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- Implants are available in different versions, varying for example in length, diameter, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- Implants which consist of several components must only be used in the prescribed combination (refer to the ARBOR™ Surgical Technique Guide).
- After the procedure, check the proper positioning of all implants.
- Do not use components from this system in conjunction with components from any other manufacturer unless otherwise specified (refer to the ARBOR™ Surgical Technique Guide).

Postoperative

- These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason, postoperative instructions and warnings to patients are extremely important.
- The injured limb should be kept elevated.
- Depending on the construct and surgeon preference, full weight bearing walking may be started immediately.
- In the event of a delay in bone consolidation or if such consolidation does not take place, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular postoperative examinations (e.g. x-ray checks) are advisable.
- Patients who cannot follow the recommendations of the physician because of a mental or neuromuscular disorder must have additional postoperative follow-up.
- Advise the patient of daily cleaning of pin-skin interface.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

Informing the Patient

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually on correct behavior and activity after the implantation.

Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid refracture.

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

These implants and instruments may also be provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Pins and sterile-packed instruments are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any pins or single use instruments that may have been accidently contaminated.

Sterile-packed pins and instruments that have become nonsterile but have not been used or contaminated may be resterilized using the instructions for nonsterile devices in the STERILIZATION section below.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

REPROCESSING

- PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED.
- Repeated reprocessing has minimal effect on reusable devices. End of life is normally determined by wear and damage due to use.
- Remove gross soiling by submerging the device into cold water (<40°C) immediately after use. Do not use fixating detergent or hot water as this can cause the fixation of residua which may influence the result of the reprocessing process. Remove surface contamination with paper tissue.
- Follow hospital protocols when handling contaminated and bio-hazardous materials. Devices should be cleaned within 30 minutes after use to minimize the potential of staining, damage and drying.
- Do not attempt to resterilize. Globus Medical, Inc. will not accept devices for reprocessing that have been reprocessed or sterilized by other facilities.
- Pack the devices in a biohazard bag and ship to Globus Medical, Inc. for reprocessing.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, container/pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. 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 FDA for the selected sterilization cycle specifications (time and temperature). Sterile implants meet pyrogen limit specifications.

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal Law (USA) Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	ATTENTION, SEE INSTRUCTIONS FOR USE		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		