Instructions for Use

WishBone Medical Smart Correction System with a Computer Assisted Web Application

Manufacturer:
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CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Rx only	• **Caution: Federal law restricts this device to sale by or on the order of a physician.**
5.1.1	• **Manufacturer**
5.1.3	• **Date of Manufacture**
5.4.2	• **Single-use**
REF 5.1.6	• **Catalog number**
LOT 5.1.5	• **Lot number**
QTY	• **Quantity**
5.4.4	• **Caution: See instructions for use**
STERILE R 5.2.4	• **Sterile – Irradiation**
STERILE EO .2.3	• **Sterile – ethylene oxide**
5.1.4	• **Use by date**
5.2.6	• **Do not resterilize**
LATEX	• **Not made with Natural Rubber Latex**
5.2.8	• **Do Not Use If Package is Damaged**
NON STERILE 5.2.7	• **Non-Sterile**

Symbols: ISO-15223

Note: External Fixation should be used by surgeons who have a thorough knowledge of the anatomy, physiology and surgical principles required for this procedure. Prior to initial use of external fixation applications, physicians are encouraged to obtain instruction from experienced/trained surgeons in a lab or by observing application of circular hexapod techniques.

DESCRIPTION

The WishBone Medical Smart Correction® System is a multilateral hexapod circular external fixator device used to stabilize and maintain alignment of complicated fractured bones, soft tissues and/or congenital deformity repairs of an extremity. The Smart Correction System is a modular system and facilitates a multitude of different frame configurations to serve a wide variety of patient needs.

The system consists of rings, foot plates, compression/distraction struts, half pins, wires, clamps, nuts, bolts and instruments. An individualized configuration should be designed for each case to suit the specific application. Refer to supporting instruction information provided by WishBone Medical or component information assembly instructions, and surgical techniques for each individual external fixation system. Unless outlined in supporting instructional information, each External Fixation System is designed as a system and does not allow the substitution of components from other systems or manufacturers.

The *Smart Correction* System has a computer assisted program to aid the surgeon in preplanning the frame's structure and postoperatively to provide a schedule for strut adjustments.

Important note for medical professionals and OR staff: These instructions for use do not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information (corresponding Surgical Technique, Important Information and device-specific label).

MATERIALS

The materials used for the anchoring devices, connectors and bridge elements are common biocompatible materials used in external fixation device and implanted medical devices. Anchorage implants are made from 316 LVM Stainless Steel. Instruments and other frame assembly elements are made from stainless steel, titanium, aluminum, silicone, PTFE, epoxy adhesive, PPSU, tungsten carbide and acetal copolymer (POM). If not specifically labeled sterile, the components supplied are non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile external fixation devices, remove the original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning is completed prior to sterilization.

INTENDED USE

The WishBone Medical *Smart Correction* System is intended for use in pediatric subgroups (except newborns) and adult patients for the treatment of open and closed fractures, arthrodesis and pseudoarthrosis of long bones, limb lengthening, deformity and angular correction, bony or soft tissue defect correction, and malunions. This is accomplished by construction of an external fixator frame and a computer assisted planning and correction application. Based on surgeon input of examination and radiographic measurements, the software provides a schedule of adjustments for the fixator frame.

INDICATIONS FOR USE

The *Smart Correction* System is indicated for pediatric subpopulations (excluding newborns) and adults for the following:

- Joint contracture resulting in loss of range of motion.
- Fractures and disease which generally may result in joint contractures or loss of range of motion.
- Fractures requiring distraction.
- Open and closed fracture fixation, including fractures of long bones (intracapsular, intertrochanteric, supracondylar, condylar).
- Correction of bony or soft tissue defects.
- Correction of bony or soft tissue deformities.
- Joint arthrodesis.
- Infected fractures or nonunion.
- Limb Lengthening by epiphyseal or metphyseal distraction.
- Pseudoarthrosis of long bones.

CONTRAINDICATIONS

- Patients who are unwilling or incapable of following postoperative care instructions or materials. Express Strut prescription is to be made at the surgeon's discretion. Patients that may attempt unauthorized adjustments and patients with mental, physical, or neurological conditions which may impair the ability to cooperate with the postoperative regimen may not be suitable for use of these devices.
- Not intended for spine applications.

CONDITIONS PRESENTING INCREASED RISK OF FAILURE

Contraindications may be absolute or relative and are left to the discretion of the surgeon. As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include: Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, irreparable damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy / hypersensitivity reactions, and side effects associated with hardware prominence, malunion, non-union.

POTENTIAL ADVERSE EFFECTS

Any surgical procedure has the potential for complications. Possible reactions may include but are not limited to:

- Infection or painful, swollen, or inflamed implant site.
- Nerve, soft tissue, or vessel damage caused by wire or half pin insertion.
- Superficial or deep pin tract infection, osteomyelitis, and septic arthritis.
- Premature bone consolidation during distraction osteogenesis.
- Failure of bone to regenerate satisfactorily, development of nonunion or pseudarthrosis.
- Loosening, dislocation, or breakage of the half pins, wires, or other components including inadvertent injury to the patient or operating room personnel caused by the wire (e.g., projective wire from tip cutting during surgery).
- Allergic reaction(s) to the implant(s) material.
- Skin pressure problems caused by external components.
- Persistent drainage after wire removal; chronic wire site osteomyelitis.
- Fracture of regenerated bone or fracture through a hole after removal of the device
- Joint contracture, subluxation dislocation or loss of range of motion.
- Reoccurrence of the initial condition requiring revision surgery.
- Abnormal growth plate development in patients who are not skeletally mature, including premature fusion, and slowed or accelerated growth.
- Limb length discrepancy.
- Bone deformity.
- Loss of bone mass due to stress shielding.
- Bone sequestration secondary to rapid drilling of the bony cortex, with heat build-up and bone necrosis.
- Excessive motion at the fracture site due to failure to tighten the component parts of the device; improper tensioning of wires, flexion from use of too few pins or pins that are too small.
- Neurologic complication with palsy.
- Early or late postoperative infection and allergic reaction.
- Edema or possible compartmental syndrome.
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
- Loss of anatomical position with non-union or malunions with rotation or angulation.

WARNINGS

- Each component that leaves the OR with the patient is disposable device and is intended for single-use only.
- Single-use devices should not be reused due to risks of breakage, failure, or patient infection.
- Surgeon must be familiar with the device and should review the surgical technique for safe effective use.

- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient based on injury, weight, compliance, etc. Releasing Express Strut locking nut may result in free motion and destabilize the construct; for noncooperative patients or pediatric patients, the Standard Strut may reduce the risk of collapse. If the patient unintentionally adjusts or collapses construct, contact your physician immediately.
- Particular care should be taken to avoid half pins and wires entering the joints or damaging the growth plates in children.
- Too much force may cause component breakage. Inspect all components for damage and wear prior to use.
- Intraoperative fracture or instrument breakage can occur. Instruments which have been used extensively or with excessive force are susceptible to fracture. Examine all instruments for wear and damage prior to surgery. Replace where necessary.
- Use caution when handling the sharp tips of wires. The tip of the wire should be held when clipped. Eye protection is recommended for operating room personnel.
- Wire and pin placement requires strict anatomical consideration to avoid damage to nerves, muscles, tendons, and vessels.
- The fixation must be applied at such a distance from the skin as to allow post-surgical swelling and cleansing, bearing in mind that the stability of the fixation device depends on the distance between it and the bone. Additional equipment might be required for the application and removal of the fixation devices, such as wire-cutters, hammers, and electric drills.
- Appropriate technique for insertion of wires and half pins should be used to prevent heat necrosis of tissue and bone. Pre-drilling for half pin placement with the appropriate drill is recommended.
- Care should be taken to avoid the growth plate and joints during half pin insertion in pediatric patents.
- Half pin size should be no larger than 1/3 the size of the bone.
- Pin/wire site care is crucial in reducing infections.
- Due to the design of the half pins, the pins should not be backed out following insertion as they may lose purchase.
- Ensure all bridge connectors, half pins and wires are tightened properly per the surgical technique.
- Periodic postoperative follow-up and radiographs are recommended during the distraction phase.
- The surgeon must evaluate the integrity of the construct at follow-up visits.
- Patient/caregiver should understand the importance of postoperative follow up during the distraction period.
- The patient/caregiver must be instructed regarding the use and maintenance of the fixation device and care of the wire/pin sites. WishBone Medical provides a Patient/Caregiver Instructions for Use IFU-SCPC:
  - Make the adjustments or get help in making the adjustments as needed.
  - Identify on the prescription when to return for a strut change and for follow-up visits.
  - Check periodically that the strut reference lengths are according to the prescription.
  - Report if adjustment schedule cannot be met.
  - Report any adverse or unexpected effects (strut breakage or disengagement, components damage, clip dislodgement, lost prescription).

DEVICE PRECAUTIONS

- Surgeons and OR staff should be familiar with the components within the system. All components should be inspected and sterilized before application in surgery. Damage to the surface of metal components can result in breakage during the procedure. Any damaged components should be removed from the system and replaced.
- Use extreme care in handling and storing components. Cutting, bending, or scratching the surface of components can reduce the strength and fatigue life of the device. Any components damaged during the course of the treatment should be replaced.
- The WishBone Medical *Smart Correction* system must not be used with other components from another manufacturers. It is unknown as to the metallurgy, design, or mechanics interaction of multiple systems.
- Proper fixation and assembly of components are essential. All wires and miscellaneous parts should be securely fastened with the appropriate instrument. Wires should be tensioned as specified in the surgical technique.
- The proper wire diameter should be used to ensure sufficient wire strength and to maintain appropriate axial stiffness of the apparatus.
- The diameter of the rings, assembled half rings or frames, are recommended to be about 50-60mm larger in diameter than the limb to avoid any skin contact initially and during correction process.
- Wire/pin security in bone, wire tension, and device frame integrity should be routinely checked. The gap at a fracture site should be reassessed during healing. Adjustments should be made as necessary.
- The patient should be instructed to report any adverse or unanticipated effects to the physician as soon as possible and should also be advised of the distraction and adjustment requirement.
- Preoperative planning for the *Smart Correction* System is faciitated via special software and programs. Accurate inputs are critical for accurate results. Verify and double check all input parameters.
- Intraoperative placement of the *Smart Correction* System according to preoperative plans is key to achieving predetermined results. If intraoperative conditions require a change to frame placement (eccentricity) or size (parameters), new strut lengths should be calculated by entering the new inputs into the program. Small changes may affect accuracy of outcome.
- Touch down weight bearing may be allowed postoperatively. Weight bearing may be increased as the callus thickens.

POSTOPERATIVE

- The surgeon will determine controlled axial motion and weight bearing for the patient.
- Routine monitoring of the half pins and frame integrity is necessary.
- Patients must understand and receive instructions on the required hygiene for wires and half pins to avoid or minimize pin site infection.
- Patients undergoing distraction osteogenesis, the physician will determine the rate, but normally 1mm distraction per day is recommended. The 1mm is achieved by ¼ mm turns of compression/distraction at 6 hour intervals.
- Adverse effects should be reported to the physician immediately.
- The surgeon will assess the fracture site during the postoperative healing time and make adjustments as necessary.

MAGNETIC RESONANCE (MR) STATEMENT

The MR environment presents risks to patient with metal implants. Physicians should consider the risks when recommending MR imaging for patients with metal implants.

The WishBone *Smart Correction* System components have not been evaluated for safety and compatibility in MR environment. The System has not been tested for heating, migration or image artifact in the MR environment. Scanning a patient who has this device may result in patient injury. The *Smart Correction* System does not claim MR compatibility.

CLEANING AND STERILIZATION

All components provided non-sterile must be steam sterilized prior to use. The sterility instructions are recommended for the care, maintenance, cleaning, and sterilization of reusable and single-use, non-sterile medical devices produced by WishBone Medical. All devices not used in surgery must be considered soiled, and be cleaned and sterilized prior to use in another surgery.

Some components are provided sterile and do not require additional processing.

Please refer to WishBone Decontamination and Sterilization IFU-RI for complete cleaning and sterilization instructions and use on www.WishBoneMedical.com/IFU.

The *Smart Correction* system has **not been evaluated for radiation (gamma, e-beam) sterilization**.

SOFTWARE

The web-based WishBone Medical *Smart Correction* System Software is intended to aid the surgeon in his/her use of the *Smart Correction* product. It can be accessed at www.click2correct.com.

* The software is not validated for use with the foot rings at this time.

The surgeon uses the WishBone Medical *Smart Correction* software program Click2Correct™ preoperatively to plan a template for the trauma/deformity correction. It is important to enter accurate data for correct results. The template is used to verify the suitability of the frame for the existing deformity/fracture.

The frame is placed intraoperatively on the patient according to the Click2Correct™ preoperative plan in order to achieve the predetermined results.

If intraoperative conditions require changing placement of the frame (eccentricity) or strut measurements, the surgeon should enter the new data into the software program. It is important to enter even minor changes to ensure the accuracy of the final result.

The surgeon will utilize the *Smart Correction* software program for postoperative adjustment of the struts. This will assist the surgeon in creating the patient's prescription schedule. The prescription may be revised using the software after subsequent patient follow-up visits based on surgeon examination and X-rays.

DEVICE INTENDED TO BE USED BY A TRAINED PHYSICIAN

This description alone does not provide sufficient background for direct use of WishBone Medical products. Instruction by a surgeon experienced in handling these products is highly recommended.

IMPLANT REMOVAL – ANALYSIS OF IMPLANT

Upon removal of frame components and implants, hospital procedures should be followed.

FOR FURTHER INFORMATION

Please contact WishBone Medical, Inc. or your authorized representative for further information about this product.

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