METALOGIX

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METALOGIX INSTRUCTIONS FOR USE REVOLUTION EXTERNAL PLATING SYSTEM

IMPORTANT MEDICAL INFORMATION

SPECIAL NOTE

External fixation should be used only under the directions of physicians who have a thorough knowledge of the anatomy, physiology, and surgical principles involved. Physicians are strongly encouraged to obtain instruction from experienced clinicians or to observe surgical application of the apparatus prior to its initial use.

DESCRIPTION & INDICATIONS FOR USE

The Metalogix External Plating System is designed for human use and consists of a series of open external plates and hardware, intended for use with Metalogix Half-Pins, Smooth Wires and/or Truss Wires. When used with other System components this device stabilizes open and/or unstable fractures of long bones including intracapsular, intertrochanteric, supracondylar, or condylar. It is also used for joint fusions, limb lengthening and deformity corrections which involve cutting the bone. The Metalogix Revolution External Plating System components are designed to withstand the stresses of full weightbearing, particularly in unstable fractures or in the presence of nonunion, delayed union or incomplete healing. The use of external supports (e.g., walking aids) and toe-touch walking is recommended as a part of the treatment. The system consists of various modules to be applied to sites along the humerus, forearm, femur, tibia, fibula, and foot. When used correctly, the Metalogix Revolution External Plating System maintains limb function, minimizes surgical trauma to anatomical structures, preserves the blood supply and osteogenic potential of the tissues, and where indicated, provides for the application of dynamization to enhance the fracture healing process. All Metalogix devices are intended for use by professional Health Care Providers (Surgeons) who are trained in Orthopedic applications. Surgeons who supervise the use of Metalogix devices must have full awareness of orthopedic fixation procedures as well as adequate understanding of the philosophy of the Metalogix's External Plating System.

INDICATIONS

The Revolution External Plating System is indicated for treatment of a variety of broken or deformed bones:

- Stabilizes open and/or unstable fracture of complex proximal and/or distal tibial fractures
- Fusions of the joints and bone (hand, foot, long-bone)
- Correction of bone or soft tissue deformities
- Correction of segmental or non-segmental bone, soft tissue defects or bone loss
- Neutralization of fractures stabilized with limited internal fixation
- Adult and Pediatric subgroups except newborns

CONTRAINDICATIONS

The Revolution External Plating system is not designed or sold for any use except as indicated. Use of the system is contraindicated in the following situations:

- Patient with compromised immune system
- Non-compliant patient who would not be able to ensure proper frame adjustment or wire and pin care
- Any fracture, where rigid fixation or reduction cannot be achieved by means of external fixation

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WARNINGS

1. 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.
2. Pre-Operation or preliminary assembly of the External Plating System is recommended to reduce operative times and to assure an adequate supply of components prior to surgery.
3. Intraoperative fracture or instrument breakage can occur. Instruments which have been used extensively or with excessive force are susceptive to fracture. Examine all instruments for wear and damage prior to surgery and replace where necessary. Single use devices should not be reused due to risks of breakage, failure, or patient infection.
4. Medial or lateral, anterior or posterior translation may occur if the body of the fixator is not placed parallel to the diaphysis.
5. Wire and pin placement requires strict anatomical consideration to avoid damage to nerves, muscles, tendons, and vessels. Wires should be gently pushed through soft tissue, not drilled, to reduce the possibility of soft tissue injury.
6. Half-Pin or Wire drilling through the bone should be done slowly to avoid heat necrosis of surrounding tissues and bone.
7. Use caution when handling the sharp tips of Wires or Half-Pins. The tips of the Wire or end of the Half-Pin should be held when they are being clipped off. Eye protection is recommended for operating room personnel.
8. Pin/Wire site care is crucial in reducing infections.
9. Periodic postoperative follow-up and radiographs are recommended.
10. Any device inserted into the patient, such as: Half-Pins, Wires, Drill Bits, and in general any device which is labelled “single use only” **MUST NOT BE REUSED**.

PRECAUTIONS

1. 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 treatment should be considered for replacement.
2. Unless specified, only components from the same system should be used together.
3. Proper fixation and assembly of components is essential. All Wires, Half-Pins and Hardware parts should be securely fastened with the appropriate instrument.
4. Wires should be tensioned to the appropriate kg as indicated for by surgeon knowledge and training.
5. No attempt should be made to insert any wire more than once; since the tip may have become blunt and is the only cutting surface, undesirable heating of the bone may occur.
6. Appropriate Metalogix instrumentation should be used to apply Half-Pins and Wires correctly.
7. To tension Wires, the handle of the wire tensioning device should be opened, and the device fully inserted over the Wire against the face of the slider unit, ensuring that at least 8 cm (80mm) of wire protrudes into the tensioning device.
8. Wires mounted on an opened plate should be tensioned to a maximum of 130 kg.
9. While tightening the Wire Fixation Bolt, it is important not to lever the wire tensioning device, which might cause breakage of the wire. Also, when tightening the wire fixation bolt, it is recommended to use the spherical nuts as that will reduce the stress on the bolt.
10. Security of Wire/Pin in the 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.
11. The inner space of the open plates is recommended to be about 4 cm (40mm) larger than the maximum diameter of the operated limb segment to accommodate swelling.
12. Weight bearing may be allowed postoperatively according to physician recommendations.
13. Physician’s frame dynamization and physical therapy guidelines should be followed.
14. Additional equipment may be required for fixation application and removal such as wire cutters, mallet and power drill.
15. Nuclear Magnetic Resonance Imaging (MRI) should not be used in any segment to which a fixator is applied.
16. 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, compression and adjustment requirement.
17. All patients must receive instruction on the maintenance of their fixator and pin site care.
18. The fracture site gap should be reassessed periodically during healing and adjustments to the frame made as necessary. Persistent separation of the fracture ends may lead to delay in bone union.
19. In patients undergoing distraction osteogenesis, the rate of distraction should be controlled and adjusted in accordance with the rate of ossification and monitored radiologically.

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POSSIBLE ADVERSE EFFECTS

1. Damage to nerves or vessels resulting from insertion of wires and pins
2. Infection including persistent drainage of the pin tracts, or after wire removal; chronic pin/wire site osteomyelitis
3. Edema or swelling, possible compartment syndrome
4. Joint contracture, loss of range of motion or reduction, joint subluxation or dislocation
5. Septic arthritis and osteomyelitis
6. Loosening or breakage of the Pins, Wires, or other components including inadvertent injury to the patient or operating room personnel caused by the cutting tip of Half-Pin or Wire (e.g., projectile from tip cutting during surgery)
7. Intractable pain or delayed unions or both
8. Persistence or reoccurrence of the initial condition requiring treatment
9. Reoperation to replace a component or the entire apparatus
10. Reaction to foreign bodies such as: Half-Pins, Wires, or other components
11. Tissue thermal necrosis occurring during Pin or Wire insertion or at the Pin/Wire tissue junction
12. Excessive operative bleeding or muscle tendon impalement
13. Skin pressure problems caused by external components
14. The intrinsic risks associated with anesthesia
15. Premature consolidation during bone elongation
16. Secondary equinus contracture
17. Failure of bone to regenerate satisfactorily; development or persistence of nonunion or pseudoarthrosis
18. Fracture of regenerated bone or fracture through a Hal-Pin or Wire hole after removal of the device
19. Abnormal growth plate development in patients who are not skeletally mature, including premature fusion, and slowed or accelerated growth
20. Loss of bone mass due to “stress shielding”
21. Limb length discrepancy
22. Bone sequestration secondary to rapid drilling of the bony cortex, with heat build-up and bone necrosis
23. 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
24. Ankle stiffness if multiple transfixion pins are used in tibial fractures
25. Thrombosis, late erosion or arteriovenous fistulas
26. Persistent drainage after Wire/Pin removal; chronic Wire/Pin site osteomyelitis
27. Bone deformity
28. Inability to compress the bone surface if the Pins/Wires are not securely seated in bone

MRI SAFETY INFORMATION

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

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

MATERIALS

The Metalogix Revolution External Fixation System is comprised of titanium, stainless steel, aluminum alloy, and plastic components. The components that come into contact with the patient are the percutaneous Pins (Half-Pins), Wires, Drill Bits and Trocar Guides used during insertion. These are manufactured from surgical grade materials.

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STERILE & NON-STERILE PRODUCT

Metalogix provides the Revolution fixation device NON-STERILE.

If not specifically labeled sterile, the components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile external fixation devices, remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

STERILIZATION

The recommended, validated sterilization cycles are:

Method	Cycle	Temperature	Exposure Time	Drying Time
Dynamic Air Removal Steam Cycle	Pre-Vacuum (Dynamic Air removal)	132°C (270°F)	4min	30min

Containment devices should be wrapped with an FDA cleared central supply wrap or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

NOTE: Store in a dry environment. The devices should never be stored in a wet or moist condition.

CLEANING INSTRUCTIONS

<table>
<tr><td>Point of Use</td><td>Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a damp cloth. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning.</td></tr>
<tr><td>Containment/ Transportation</td><td>Universal precautions for handling contaminated/biohazardous materials should be observed. Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.</td></tr>
<tr><td>Preparation of Cleaning Agents</td><td>Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.</td></tr>
<tr><td>Automated Cleaning</td><td>1. Pre-rinse devices under warm, running, potable tap water for two (2) minutes to remove gross debris.
2. Completely submerge the instruments in an ultrasonic cleaning bath filled with enzymatic detergent solution and ultrasonicate for ten (10) minutes.
3. Remove any remaining debris from crevices using a cleaning brush. Pay close attention to threads, crevices, seams, lumens, and any hard-to-reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks, or spring-loaded features to free trapped soil. If the components of the device can be retracted, retract or open the part while cleaning the area. Bend or flex devices with flexible shafts under the cleaning solution while brushing the flexing areas. Clean lumens with a long, narrow, soft-bristled brush.
4. Place the devices in a wire mesh basket and process within a mechanical washer using the following validation parameters:
<table>
<tr><th>Treatment</th><th>Time (mm:ss)</th><th>Temperature</th><th>Cleaning Solution</th></tr>
<tr><td>Enzymatic Wash</td><td>04:00</td><td>60°C</td><td>Enzyme Presoak and Cleaner</td></tr>
<tr><td>Wash</td><td>02:00</td><td>Warm Tap Water</td><td>Neutral Detergent</td></tr>
<tr><td>Rinse</td><td>02:00</td><td>70°C</td><td>N/A</td></tr>
<tr><td>Dry</td><td>15:00</td><td>80°C</td><td>N/A</td></tr>
</table>
5. Visually inspect the devices. Repeat cleaning if visible soil remains.</td></tr>
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Maintenance	1. Lubricate hinges, threads and other moving parts with a commercial water-based surgical grade instrument lubricant (such as instrument milk) to reduce friction and wear. 2. Discard blunt or damaged instruments.
Packaging	Sets of instruments may be loaded into dedicated instrument trays or general-purpose sterilization trays for sterilization. Use standard medical grade, FDA approved steam sterilization wrap following the AAMI double wrap method (AAMI ST79).
Sterilization	1. Steam sterilize using either validated method: a) Gravity cycle for 15 minutes at a minimum temperature of 132°C (270°F). b) Pre-vacuum cycle for 4 minutes at a minimum temperature of 132°C (270°F). 2. Allow to dry for a minimum of 30 minutes.
Storage	Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

SINGLE-USE DEVICE

DO NOT REUSE

Products intended for single-use must not be re-used. Re-use or reprocessing (e.g., cleaning and re-sterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness, or death. Re-use for unintended instruments may create a risk of contamination e.g., due to the transmission of infectious material from one patient to another. This could result in injury or death to the patient or user.

The only products in the Revolution Plating System that are reusable are **Instruments**:

900100	Wire Tensioner x Ratcheting
900103	Wrench T-Handle x AO
900104	Wrench Slotted 90 Deg. Tubular x 10mm
900105	Wrench Open End/Swivel End x 10mm
900106	Wrench Standard x 10mm
100404	Trocar & Sheath 4-6mm

All other items are considered single-use devices.

NOTE: Only external parts of the system are reprocessed. The pins that are inserted through the bone are single use implants that are not reprocessed.

The re-use of “SINGLE USE” non-implantable device cannot guarantee the original mechanical and functional performances, compromising the effectiveness of the products and introducing health risks for the patients.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.
If the implant will be returned to Metalogix, LLC. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

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