AMDT SixFix™ Hexapod Fixator

Instructions for Use

Description

The AMDT SixFix Hexapod is a multilateral circular external fixator with two rings/footplates that connect with a Hexapod Strut assembly that includes six telescopic struts. Each strut can be independently lengthened or shortened relative to the rest of the frame to provides six different axes of movement. The rings' positions are adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space. The AMDT SixFix Hexapod provides the surgeon a valuable tool to correct difficult congenital deformities and trauma cases.

Indications

The SixFix Hexapod and Deformity Analysis and Correction Software (DACS) are intended to be used for 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; open and closed fracture fixation; pseudo-arthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; infected fractures or nonunions.

Contraindications

1. Physiologically or psychologically inadequate patient.
2. Possibility for conservative treatment.
3. Failure to obtain patient's consent.

Conditions presenting an increased risk of failure include:

- Active infection
- Inadequate skin, bone or neurovascular status
- Irreparable tendon systems
- Growing patients with open epiphyses
- Patients with high levels of activity
- Fevers and white blood cells
- Obesity

Patient Selection

Use of surgical hardware requires consideration of the following general characteristics:

- Good condition of the patient
- Good neurovascular status
- Adequate skin coverage
- Possibility of a functional musculotendinous system
- Adequate bone stock to receive an implant
- Availability of post-operative therapy
- Cooperative patient

Warnings

External fixators are intended for single use only.

MR Safety Information

The AMDT SixFix Hexapod Fixator 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 AMDT SixFix Hexapod Fixator in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Precautions

Pre-operative Precautions

1. Proper understanding of the devices and technique is essential. Please refer the SixFix Hexapod Operative Technique for instructions regarding fixator assembly and implantation of the half pins and wires.
2. Patient selection should be in accordance with the listed indications and contraindications for use of the device.

3. Misuse of the device or patient noncompliance may adversely affect performance. In no case will this device replace a healthy bone structure.
4. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
5. The proper wire diameter should be used to ensure sufficient wire strength and to maintain appropriate axial stiffness of the apparatus. The 2.0 mm wires are usually recommended for the tibia and femur in normal adults, while the 1.8 mm wires are usually recommended for the upper limbs and pediatric lower limb applications.
6. The diameter of the rings, assembled partial rings or frames, are recommended to be about 4 cm larger than the maximum diameter of the operated limb segment to accommodate swelling.
7. 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.
8. External fixators are intended to be left in place for stabilization until complete healing is achieved. After healing is complete, removal should be considered. However, early removal should be considered in the following situations:
    - Pain due to implants
    - Infection
    - Implant breakage

FOLLOW-UP

1. Examine implantation under image intensifier.
2. Assessment of motor activity
3. Check proper tightening of all locking components.

POST-OPERATIVE PRECAUTIONS

Warnings and directions to patients regarding:

- Restricted physical activity.
- Adverse effects.
- Knowing that no metal device will ever be as strong as a healthy bone.
- AMDT does not recommend immersing the SixFix frame assembly in corrosive solutions such as sodium hypochlorite or in solutions that could deposit precipitates on or within the SixFix assembly subcomponents.

ADVERSE EFFECTS

In any surgical procedure, the potential for complications exists. The risks and complications with this device include:

- Infection or painful, swollen or inflamed implant site.
- Fracture of the device.
- Loosening or dislocation of the implant requiring revision surgery.
- Abnormal pain and sensations due to the device
- Allergic reaction to implant material.
- Infection
- Neurologic complication with possible palsy
- Pseudarthrosis.

PACKAGING

All components and instruments are provided non-sterile. All components should be cleaned, decontaminated and sterilized by steam autoclaving before use.

Any component with damaged packaging should be discarded.

Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

STERILIZATION INFORMATION

All components and instruments are provided non-sterile. Remove all original packaging and labeling inserts prior to initial sterilization. It is important that adequate cleaning of instrumentation used in surgery be carried out prior to re-sterilization. Refer to AMDT SixFix Hexapod Fixator Instrumentation Instructions for Use for information regarding cleaning and sterilization of instrumentation.

Surgical instruments and non-sterile fixator components should be placed in the sterilization trays and the tray should be wrapped with an FDA cleared wrap.

The weight of the sterilization tray should not exceed 25 pounds, per AAMI ST 77. Before packaging the instruments for sterilization, the instruments should be dry. Surgical instruments and non-sterile fixator components should be sterilized according to the following parameters:

Method	Temperature	Time	Drying Time
Pre-vacuum	270°-275°F (132°-135°C)	4 minutes	45 minutes

The specified steam sterilization parameters result in a sterility assurance level (SAL) of 10^{-6}. These parameters were validated according to ISO 17665-1:2006 "Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices." This cycle is not for use in prion inactivation.

STORAGE CONDITIONS

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

MANUFACTURER

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

SYMBOLS GLOSSARY

Symbol	Reference ID*	Meaning
	2493	Catalogue number
	2492	Batch code/number
	3082	Indicates medical device manufacturer
	2497	Date of manufacturer
	1641	Consult instructions for use
	0434A	Caution, consult the instructions for use for important cautionary information
	1051	Single use - Do not reuse
	2502	Sterilized by irradiation
	2609	Non-sterile

* ISO 7000: Graphical Symbols For Use On Equipment - Registered Symbols. If a symbol is added from another standard, please note the standard in the table.