AMDT SixFix® Circular Fixation System
Instrumentation Instructions for Use

Description

The AMDT SixFix Circular Fixation System is a multilateral circular external fixator that includes rings, arches, foot rockers, struts, threaded rods, stanchions, and assembly accessories. When used as a hexapod, two rings/footplates are connected with a SixFix 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 Circular Fixation System is 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; pseudarthrosis 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.

Instruments (non-sterile)

The AMDT SixFix Circular Fixation System Fixator does not utilize any instruments that are specific for this device. The general instruments used with the SixFix Circular Fixation System include a Wire Tensioner, Hex Drivers, Wrenches, Quick Connect Pin Chuck/Power Adaptors, Screw Guide/Tissue Protector, Pin Extender/Adaptor, T-Handle for Pins and other common instrumentation.

For non-sterile external fixation components and instruments, remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

Cleaning

1. Rinse with cold tap water to remove gross contamination.
2. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
3. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
4. Rinse with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
5. Bathe in a detergent solution prepared per manufacturer directions for 5 minutes
6. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
7. Rinse thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
8. Sonicate for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions
9. Rinse thoroughly /flush with RO/DI water.
10. Dry with a clean, soft, absorbent, disposable cloth.
11. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary re-clean until it is visibly clean.

Reuse Life

After cleaning, all instruments should be visually inspected for deterioration such as corrosion, discoloration, pitting or cracked seals. If any of these conditions are seen, contact a company representative for a replacement part.

Sterilization

The fully loaded implant and instrument tray is recommended to be steam sterilized by the hospital using 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

Instruments can best be sterilized effectively when stored and sterilized in the AMDT SixFix Circular Fixation System Instrument Tray.

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
	2607	Use by date
	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.