Instructions For Use are subject to change,
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Instructions for the Safe Processing of the

Pitkar External Fixation System- ALFA Fixator System
Appliances and Instruments

Manufacturer name	S.H. PITKAR ORTHOTOOLS PVT. LTD. EL-32, "J" Block, MIDC Bhosari, Pune 411026, India Tel: +91 20 40706464 Fax: +91 20 46768107 Email: info@pitkar.net
Method code	Processing of the Pitkar External Fixation System medical devices
Symbol	⚠Attention, see instructions for use
Device(s)	All the Pitkar ALFA Fixator System products NOT SUPPLIED "STERILE"**.** (IMPLANTS ARE SINGLE USE AND INSTRUMENTS ARE RE-USABLE)
Description	Pitkar Orthotools manufactures a variety of fixation devices intended to aid in the alignment and stabilization of fractures to the skeletal system until healing has occurred. Pitkar External Fixation System- ALFA Fixator components are intended to be used on adult or pediatric patients as required. As a general rule it is better to avoid operating on children under the age of five. In the children above age 10, the rail 300 mm may be more appropriate. The pediatric system is designed for use in children under the age of 10. Implant & appliances Components within the ALFA fixation system are for single use only. The S.H.Pitkar Orthotools Pvt. Ltd. does not claim MRI safety.
Indications	The device should be used for following indications: 1. Open and closed fracture fixation 2. Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; 3. Pseudoarthrosis of long bones; 4. Limb lengthening; 5. Infected fractures or non-unions; and 6. Correction of long bone deformities.
Contraindications	1. Active infection. 2. Patient conditions including blood supply limitations, insufficient quantity or quality of bone. 3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. 4. Foreign body sensitivity where material sensitivity is suspected, testing is to be completed prior to implantation of the device.
Warnings	1. Proper understanding of the device and technique are essential. Physicians are strongly encouraged to obtain instructions from experienced clinicians or to observe surgical application of the apparatus 2. Prior to initial use of the Rail Fixation system. 3. Patient selection should be in accordance with the listed indications and contraindications for use of the Rail Fixation system. 4. Preliminary frame assembly is recommended to reduce operative time and to assure an adequate supply of components before surgery. 5. All of the device components should be sterilized before use 6. Single use devices should not be reused due to risks of breakage, failure or patient infection 7. Select an appropriate size of the fixator and template. 8. Select an appropriate type of Clamps. 9. Select Tapered half pins of correct devise, lengths. 10. Select an appropriate size of Drill bits 11. Proper fixation of components is essential.

	12. Ensure that all components are securely tightened or fastened with appropriate Instruments. 13. Taper half pin placement should be in strict anatomical consideration avoiding damage to nerves and vessels. 14. The selection of the taper half pin should be to ensure sufficient pin strength and to maintain appropriate axial stiffness of the apparatus. 15. The taper half pin should be gently pushed through soft tissue, not drilled. 16. Physiologic use of the affected limb and weight bearing when appropriate is advocated. 17. Apparatus integrity should be checked routinely. 18. The patient should be instructed to report any adverse or unanticipated effects immediately to the physician. 19. The post-operative follow-ups and radiographs are recommended during the distraction phase. This frequency may be reduced to monthly during the fixation phase. 20. Adequate care should be taken during the treatment. The skin around the tapered half pin should be cleaned with saline. The skin around the pin should then be covered with sterile gauze. 21. The joint function should be checked regularly while the fixator is in place. Should there be a degree of joint stiffness, it should be overcome by regular programme of physiotherapy. 22. Dynamisation: The time point at which Dynamisation should commence will depend upon various factors like type of fracture, bone fixator distance, weight of the patient, the extent of fracture repairs and physical condition of the patient. 23. The fixator should be removed only after clinical radioluscence evidence of fracture healing. 24. To ensure full follow up of the case, X-ray should be taken at one or two months from final healing and removal of fixator.
Possible Adverse Effects	1. Edema or swelling; possible compartment syndrome. 2. Joint contracture or loss of range of motion. 3. Premature consolidation during bone elongation. 4. Loosening of the taper half pin or joining of the pin. 5. Poor result caused by patient non-compliance. 6. Bone deformity. 7. Intractable infection 8. Fracture of regenerated bone. 9. Skin pressure problems caused by external components. 10. Limb length discrepancy. 11. Implants are single use only. No metallic surgical implant should be reused. Any metal implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patters which may lead to fatigue failure.
MRI Information	The ALFA Fixation System components have not been evaluated in the MR environment. The Device has not been tested for heating or migration in the MR environment. The risks associated with a passive implant in an MR environment has been evaluated and are known to include heating, migration, and image artifacts at or near the implant site. Scanning a patient who has this device may result in patient injury.
STORAGE AND HANDLING	1. Packaged implants & 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. 2. Care must be exercised in handling of wrapped cases or individual implants &instruments to prevent damage to the sterile barrier. 3. The health care facility should establish a shelf life for sterilized implants &instruments based upon the type of sterile wrap or rigid container used. 4. Sterile implants & instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised Note: Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned,

	repackaged and sterilized.
RISKS DUE TO THE RE-USE OF "SINGLE USE" IMPLANTABLE DEVICE*	The "SINGLE USE" implantable device* of ALFA Fixation System is identified through symbol reported on the product label. After the removal from the patient, the implantable device* has to be dismantled. The re-use of implantable device* introduces contamination risks for users and patients. The re-use of implantable device* cannot guarantee the original mechanical and functional performances compromising the effectiveness of the products and introducing health risks for the patients. (*): Implantable device: Any device intended to be totally/partially to be introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. Product/s shall be stored in their original packages, in specific area protected against warmth source, humidity and dust, at Standard Conditioning Atmosphere. Product/s shall be protected from direct sunlight, ionizing radiation, extreme temperatures, particulate or microbial contamination. Product/s shall be protected during the transport to avoid potential damage. They do not require controlled temperature transport.
INSTRUCTIONS FOR REPROCESSING OF REUSABLE DEVICES (INSTRUMENTS) FOR SUBSEQUENT RE-USE	
GENERAL	•All Pitkar medical devices must be sterilized prior to surgical use. •A new product means any device taken out of its original Pitkar packaging.
NOTE	Pitkar has validated reprocessing of reusable device & advices do not reprocess reusable devices more than 250 times.
AT THE POINT OF USE	The drying of gross soil (blood, tissue and/or debris) on devices following surgical use should be avoided. It is preferred that gross soil is removed from devices following use and in preparation for transportation to a processing area. Gross soil can be removed using sponges, cloths, or soft brushes. Water and/or cleaning detergents (labelled for use on medical devices) may be used. If gross-soil cannot be removed at the point of use, the devices should be transported to prevent drying (e.g., covered with a towel dampened with purified water) and cleaned as soon as possible at a designated processing area.
PREPERATION BEFORE CLEANING	It is recommended that devices should be reprocessed as soon as is reasonably practical following surgical use. Instruments must be cleaned separately from instrument trays and cases. Care should be taken in the handling and cleaning of sharp devices. These are recommended to be cleaned separately to reduce risks of injury. All devices with lumens need to be manually flushed to remove debris and brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brush size should be approximately the same diameter of the lumen to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the lumen. Refer to any technique guides or other supplemental information for specific device lumen diameters. After brushing, rinse with water by flushing and blow clean compressed air through all lumens.
CLEANING-AUTOMATED	Equipment required: 1. Washer/disinfector from Getinge (Getinge 46 series, 46-4). 2. Getinge Clean Enzymatic Liquid 3. Getinge Disinfection AB 4. Getinge Clean Rinse Aid liquid. Instructions: 1. Before the automated processing, rinse the re-usable instruments under running water. No residues from the cleaning/disinfection agent should be transferred to the Washer/disinfector. 2. Place the instruments in a suitable instrument rack. 3. Place the instrument rack in the Washer/disinfector so that the spray jet comes into direct contact with the instruments.

	4. Pour in the cleaning/disinfection agent according to the specifications of the manufacturer and Washer/disinfector manufacturer. 5. Normally the preset parameter settings of the installed programs are used, but in special cases it may be necessary to adjust certain parameters for matching to a specific wash process. Set parameters are as follows: Pre-wash- at 50°C with tap water. Enzyme wash- at 50°C with 0.5% Wash-neutralization with warm tap water Rinse - with warm distilled water Chemical disinfection with distilled water, at 90°C for at least 5 min. Automatic drying, at 90°C for 30 min Procedure: 1. Open the door and take out the loading trolley. 2. Check and clean the strainer filter. A dirty coarse strainer may prevent water from circulating and create the conditions for the growth of bacteria. 3. Fill the detergent container with Getinge Clean Enzymatic Liquid solution (Dosing – 5ml/lit.) and surfactant container with Getinge Clean Rinse Aid solution (Dosing – 0.5 ml/lit.). 4. Use distilled water for washing and disinfecting process. 5. Load the washing crates with instruments to be cleaned. Maximum weight allowed is 50 Kg. 6. Load the trolley in washing chamber of machine. Make sure that the rotary washer arms can rotate freely without touching the instruments. 7. Close the door and make sure that the door handle is in the locked position. 8. Put 'ON' the main switch to start the machine. 9. Select suitable program P1 to P6 from control panel using selection keys. 10. Start the washing program by pressing 'START' key on control panel. Monitor the washing program for temperature, yellow lamp indicator showing cycle is in process and status of cycle displayed on control panel screen. 11. Green lamp indicator will lit after completion of washing program. 12. Put 'OFF' the main switch to stop the machine. 13. Open the door and unload the trolley from washing chamber. 14. Close the door and forward cleaned instruments for next procedure. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.
CLEANING-ULTRASOUND	Equipment required: • An ultrasonic washer with lid which will hold enough liquid so that the items of equipment to be cleaned can be fully immersed. • A sufficient number of supporting racks or trays for stacking items to be processed. • A timing device. • A compatible water-detergent solution at dilution and temperature, recommended by manufacturer. • A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility. • Ultrasonic cleaning solution- Spectra UCP Procedure: • Ensure the ultrasonic washer is clean and dry prior to use. • Wear protective equipment, fill the fluid reservoir with sufficient water/disinfectant to ensure complete immersion of items. • Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used; • Use the 2% Spectra UCP or equivalent phenolic disinfectant solution as per the guidelines provided by the disinfectant manufacturer • Switch on ultrasonic cleaner and proceed as per routine procedure. • Switch off, lift the lid, remove the item and drain before transferring to a clean-rinse receptacle. • Rinse thoroughly for 15 minutes with distilled water as per the routine

<table>
<tr><td></td><td>procedure to ensure the proper cleaning of instruments
• Place the cleaned instrument in a drying cabinet for 15 minutes
• Complete the documentation.
• Proceed with sterilization.</td></tr>
<tr><td>MAINTENANCE AND INSPECTION</td><td>Instruments should be visually inspected under ambient lighting, to verify that the devices do not have visible soil, damage or moisture.
Inspect devices for:
• Lack of moisture- If moisture is detected, manually drying should be performed.
• Cleanliness- If any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
• Damage- including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear.</td></tr>
<tr><td>PACKAGING</td><td>• The package should be prepared using the AAMI double wrap or equivalent method. . The sterilization wrap used should be FDA cleared.
• Sterilization Containers: Instruments may be loaded into a dedicated (Pitkar) instrument tray, or general-purpose sterilization tray. Cutting edges should be protected and the recommended content or maximum weight not exceeded as indicated by manufacturer i.e. 22 lbs</td></tr>
<tr><td>STERILIZATION INSTRUCTION</td><td>• Steam (moist heat) sterilization shall be performed in a locally approved, gravity cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8.
• The steam sterilizer should be installed and maintained in compliance to manufacturer’s instructions and local requirements.
• Sterilize by steam autoclaving, utilizing a gravity cycle as following –
<table><tr><td>Steam Sterilizer Type</td><td>Gravity</td><td>Gravity</td></tr><tr><td>Minimum Exposure Temperature</td><td>121°C (250°F).</td><td>132°C (270°F).</td></tr><tr><td>Pressure</td><td>15 psi</td><td>30 psi</td></tr><tr><td>Minimum Exposure Time</td><td>30 Minutes</td><td>15 Minutes</td></tr><tr><td>Drying Time</td><td>30 Minutes</td><td>30 Minutes</td></tr><tr><td>Drying temperature</td><td colspan="2">Between 60°C to 100°C</td></tr></table>
The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Extended drying within the sterilizer or in an external drying cabinet in accordance with manufacturer’s instructions may be necessary. Do not exceed 140°C (284°F) during drying.</td></tr>
<tr><td>ADDITIONAL INFORMATION</td><td>• Cleaning agent information: Examples of detergents that have been used during cleaning validations.
• The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance.</td></tr>
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Disclaimer: "The instructions provided above have been validated by Pitkar as being a true description of the preparation of a device for first clinical use or for re-use or multiple use devices.
The institution or practitioner bears full responsibility for using cleaning and sterilization methods other than Pitkar recommendation for reusable devices for subsequent use**.**

EC REP

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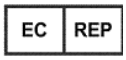
Symbol	Meaning	Symbol	Meaning
	Caution, consult accompanying documents		Batch code
	Date of manufacture		Manufacturer
	Do not reuse		Non sterile
	Do not use if package is damaged		Catalogue Number
	Humidity limitations		Temperature limit
	Authorized representative in the European Community		Use by date
	"CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician."		Protect from moisture

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