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Instructions for the Safe Processing of the

Pitkar External Fixation System- Rail Fixation System Appliances and Instruments

Manufacturer name	S.H. Pitkar Orthotools Pvt. Ltd. EL-32, J Block, MIDC Bhosari, Pune 411026, India Phone- +91-20-40706464, Fax - +91-20-46768107
Method code	Processing of the Pitkar Fixation Fixation System medical devices
Symbol	⚠Attention, see instructions for use
Device(s)	All the Pitkar Rail Fixation System products NOT SUPPLIED "STERILE"
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- Rail Fixation 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 Rail 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. Fracture fixation 2. For correcting diaphyseal deformities, metaphyseal deformities with or without shortenings 3. Correction of bony or soft tissue deformities 4. Limb Lengthening 5. For treating non-union and mal-union 6. Bone transport application
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 Rail 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.
INSTRUCTIONS FOR PROCESSING NEW DEVICES SUPPLIED "NON-STERILE" PRIOR TO THEIR FIRST USE	
General	•Unless supplied sterile, all Pitkar medical devices must be sterilized prior to surgical use. •A new product means any device taken out of its original Pitkar packaging.
Recommended decontamination process	The following sequence of processes is recommended for rendering the External Fixation System-Rail Fixation System devices which are supplied non-sterile safe for their first clinical use: •CLEANING •STERILIZATION
Preparation for cleaning of used devices	•Used fixators should be disassembled completely, and all cams and bushes discarded since they are not re-usable.

Preparation for cleaning of new products	• When applicable, the device should be disassembled completely. - Wherever possible, all parts of disassembled devices should be kept together in one container. - For disassembly/reassembly the specific instrumentation should be used as described in detail in the Operative Manuals.
STEP 1: Cleaning of new products	• REMOVE products from their original packaging. All equipment should be carefully examined prior to use to assure proper working condition. • CLEAN with a woven-non woven tissue soaked using a solution of 70% medical grade alcohol and 30% distilled water or with compatible detergent. • Detergents with fluoride, chloride, bromide, iodide or hydroxyl ions MUST NOT be used**.** • RINSE with sterile distilled water.
STEP 2: Drying	HAND-DRY carefully, using absorbent, non-shedding cloth or industrial hot hair dryer, or place into drying cabinet.
STEP 3: Sterilization of new products	•Prior to surgical use, new products should be cleaned as described at Step 1. •PACKAGING: Where products are to be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use, an appropriate medical grade packaging material should be used.Ensure that the pack is large enough to contain the instruments without stressing the seals. •STERILIZATION CONTAINERS: Instruments may be loaded into a dedicated instrument tray, or general-purpose sterilization tray. Ensure that cutting edges are protected and do not exceed the recommended content or maximum weight indicated by manufacturer. •PRECAUTIONS: Fixators can be sterilized in the assembled state as long as ball-joints, central body locking nut and clamp locking screws are left untightened. If any joints are tightened, they may sustain damage from thermal expansion during the sterilization process. •STERILIZATION: Sterilize by steam autoclaving, utilizing a pre-vacuum cycle. Pitkar recommends the following cycle: Steam autoclave 132-135°C (270-275°F), minimum holding time 10 minutes. •Any other validated pre-vacuum autoclave cycle may be used in alternative.
INSTRUCTIONS FOR REPROCESSING OF REUSABLE DEVICES FOR SUBSEQUENT RE-USE	
General	•Unless supplied sterile, all Pitkar devices must be sterilized prior to surgical use. •PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED. •Repeated reprocessing has minimal effect on reusable instruments. End of life is normally determined by wear and damage due to use.
Recommended decontamination process	The following sequence of decontamination processes is recommended for reprocessing re-usable Pitkar External Fixation System- Rail Fixation System medical devices and rendering them safe for subsequent clinical use. • CLEANING • DISINFECTION • STERILIZATION
Preparation at the point of use of used devices	• All used surgical instruments should be regarded as contaminated. Their handling, collection and transportation should be strictly controlled to minimise any possible risks to patients, personnel and any area of the healthcare facility. • It is recommended that instruments are reprocessed as soon as is reasonably practicable following use. • Ensure that items are securely and safely packaged during transport to the decontamination area.
Preparation for cleaning of used devices	• Used fixators should be disassembled completely, and all cams and bushes discarded since they are not re-usable. • All components should be inspected, since damage to the surface of metal components can reduce the strength and fatigue resistance and may lead to corrosion. • Wherever possible, all parts of disassembled devices should be kept together in one container. • For disassembly/reassembly, the specific instrumentation should be used as described in detail in the Operative Manuals.

	• Cleaning is an essential pre-requisite to ensure effective disinfection or sterilization. • The preferred method of decontamination of used devices is mechanical cleaning followed by disinfection. • Where an automated washer-disinfector is not available, manual cleaning may be used, followed by disinfection.
	MANUAL CLEANING (BY IMMERSION) Equipment required: • a sink (not hand wash basin) or receptacle which will hold enough detergent so that the item of equipment to be cleaned can be fully immersed; • a detergent solution. Pitkar **r**ecommends use of a 0,3% enzymatic detergent solution, immersion for 30 minutes at 40°C (104°F). Detergents with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used; • a receptacle to contain rinse water; • a drainage surface; • a clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer); • a brush and jet washer.
	Procedure: • Ensure that the cleaning receptacle is clean and dry. • Wearing protective equipment, fill the receptacle with sufficient water/detergent solution. • Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of devices that have holes or recesses or are cannulated. • Brush, wipe, agitate, irrigate, jetwash or hand spray the item to dislodge and remove all visible dirt, ensuring that the action is performed beneath the surface of the solution. • Remove the items from the solution and drain. • Remove any residue with a brush in running water. • Soak in sterile distilled water to remove traces of hard water. • Remove item from rinse water and drain. • Carefully hand-dry using absorbent, non-shedding cloth or an industrial hot air dryer, or place in a drying cabinet. • Complete the necessary documentation. • Proceed with disinfection.
	MECHANICAL CLEANING (USING AN AUTOMATED WASHER) • Mechanical cleaning followed by disinfection is the preferred method of decontamination of used devices. • If a washer-disinfector is used, it must have a validated cycle. • Ensure that the washer-disinfector and all services are operational. • Select and start a cycle according to the recommendations of the washer manufacturer • Detergents with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used. • Proceed with disinfection.
STEP 2: Disinfection	**DISINFECTION PROCEDURE (MANUAL)** Equipment required: • a sink (not hand wash basin) or receptacle which will hold enough disinfectant so that the item of equipment to be cleaned can be fully immersed; • a compatible water/disinfectant solution at dilution and temperature recommended by its producer. Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] MUST NOT be used; Pitkar recommends use of 3% hydrogen peroxide, with immersion, for 3 hours at room temperature; • a receptacle to contain rinse water; • a drainage surface; • a clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (drying cabinet or industrial hot air dryer); • a brush and jet washer.

	Procedure: • Wearing protective equipment, fill the receptacle with sufficient disinfectant solution to ensure complete immersion of the item. • Carefully immerse all components in the solution in order to displace trapped air; it is important to ensure that the cleaning solution reached all surfaces, including those of cannulated devices. • Leave the items for the time required (3 hours with 3% Hydrogen Peroxide). • Remove the items from the solution and drain. • Remove any residue with a brush in running water. • Soak in sterile distilled water to remove traces of hard water. • Remove item from rinse water and drain. • Carefully hand-dry using absorbent, non-shedding cloth or industrial hot hair dryer, or place in a drying cabinet. • Complete the necessary documentation. • Proceed with sterilization.
	DISINFECTION PROCEDURE (AUTOMATIC) Equipment required: • A thermal washer-disinfector, cabinet or continuous process type. • A sufficient number of racks for stacking items to be processed. • A compatible disinfectant and rinse aid. Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used; Pitkar recommends use of 0,5% phenolic disinfectant solution at 80°C (176°F). The validated cycle time is 80 minutes. • A drainage surface. • A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.
	Procedure: • Ensure the washer-disinfector and all services are operational. • Wear protective equipment, load the rack/machine ensuring that the loading configuration does not impede the cleansing process. • Select and start a cycle according to the recommendation of the washer manufacturer. On completion on the cycle, ensure that all stages and parameters have been achieved; remove the load and visually check and inspect the cleanliness of the item, drain off excessive water and dry if necessary. • Complete the documentation. • Proceed with sterilization.
	DISINFECTION PROCEDURE (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.
	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; Pitkar recommends use of 0,5% phenolic disinfectant solution immersion at 50°C (122°F) for 15 minutes (ultrasound frequency 50/60 Hz). • Switch on and leave for required time to degas the water. • Remove lid and carefully immerse the item in the fluid ensuring that any air contained within the item is displaced. Irrigate cannulated devices. • Re-place the lid and leave for the time recommended (15 minutes). • Switch off, lift the lid, remove the item and drain before transferring to a clean-rinse receptacle.

	• Rinse thoroughly with clean water, ensuring irrigation of lumen devices, and drain. • Carefully hand-dry using absorbent, non-shedding cloth, industrial hot air dryer or place in a drying cabinet. • Complete the documentation. • Proceed with sterilization.
STEP 3: Drying	Carefully hand-dry using absorbent, non-shedding cloth or industrial hot air dryer, or place in a drying cabinet.
STEP 4: Inspection, maintenance and testing	All instruments and product components should be visually inspected for cleanness and any signs of deterioration that may cause failure in use (such as cracks or damage to surfaces) and functions tested before being sterilized (see detailed Operative Technique Manuals and Instructions for use). Particular attention should be given to: • Cannulated devices (NB: cannulated drill-bits are single-patient use only) 1. Cutting edges: Discard blunt or damaged instruments 2. Hinged instruments: check for smooth movement of hinges without excessive "play".Locking mechanisms should be checked for action. • If a component or instrument is believed to be faulty, damaged or suspect, it should NOT BE USED. • When instruments form part of an assembly, check assembly with matching components. • Lubricate all parts, except for cam, bush and ball-joint coupling with lubrication oil for medical applications whenever required (see detailed Operative Technique Manuals).
STEP 5: Sterilization	• PACKAGING: Where products are to be packaged to maintain their sterility after sterilization and to prevent damage of the instrument prior to use, an appropriate medical grade packaging material should be used. The pack should be large enough to contain the instruments without stressing the seals. • 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. • PRECAUTIONS: Fixators can be sterilized in the assembled state as long as ball-joints, central body locking nut and clamp locking screws are left untightened. If any joints are tightened, they may sustain damage from thermal expansion during the sterilization process. • STERILIZATION: Sterilize by steam autoclaving, utilizing a pre-vacuum cycle. Pitkar recommends the following cycle: Steam autoclave 132-135°C (270-275°F), minimum holding time 10 minutes. • Any other validated pre-vacuum autoclave cycle may be used in alternative. • Processed items should be stored in clean and secure stores to avoid damage or tampering.

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 of multiple use devices. It remains the responsibility of the reprocessor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This normally requires validation and routine monitoring of the process. The cleaning, disinfection and sterilization processes should be adequately recorded. Likewise any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences and should also be appropriately recorded".

EC REP

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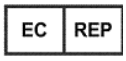
Symbol	Meaning	Symbol	Meaning
	Caution, consult accompanying documents		Batch code
	Date of manufacture		Manufacturer
	Do not reuse		Non sterile
	Do not use if package is damaged		Catalogue Number
	Humidity limitations		Temperature limit
	Authorized representative in the European Community		Use by date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

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