Instructions For Use are subject to change, the most current version of each Instruction For Use is always available online, Important information – please read prior to use.

Pitkar External Fixation System- Rail fixator System
Single Use Appliances

Manufacturer name	S.H. PITKAR ORTHOTOOLS PVT. LTD. Gat No 36 & 37 RMK Industrial Park II, Jadhavwadi, Navlakh Umbare, Taluka Maval, Pune, Maharashtra, India, 410507 Email: info@pitkar.net
Method code	Processing of the Pitkar External Fixation System- Rail fixator system
Symbol	⚠Attention, see instructions for use
Device(s)	All the Pitkar Rail fixator System products NOT SUPPLIED "STERILE
Associated device systems with these instructions for use	Rail, Swivel Clamp, Ball And Socket Clamps, Metafacial Clamp, T Clamp, End Cap, Bolt, C D Unit.
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. 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.
Intended Use	Pitkar External Fixation System- Rail 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.
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.
Population	1. For Adult Assembly: Population to be adult males and females for given indications 2.For Pediatric Assembly: Population to be between age of 5 to 10 for given indications 3. It is recommended to avoid operating on children under the age of five, in case of pediatric 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. 5. Patients having over weight or obesity 6. Pregnant patient
Warnings	**Pre-Operative:** 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 prior to initial use of the RAIL Fixation system. 2. Patient selection should be in accordance with the listed indications and contraindications for use of the RAIL Fixation system. 3. Preliminary frame assembly is recommended to reduce operative time and to assure an adequate supply of components before surgery. 4. All of the device components should be sterilized before use 5. Single use devices should not be reused due to risks of breakage, failure or

	patient infection **Intra-Operative:** 6. Select an appropriate size of the fixator and template. 7. Select an appropriate type of Clamps. 8. Select Tapered half pins of correct devise, lengths. 9. Select an appropriate size of Drill bits 10. Proper fixation of components is essential. 11. Ensure that all components are securely tightened or fastened with appropriate Instruments. 12. Taper half pin placement should be in strict anatomical consideration avoiding damage to nerves and vessels. 13. The selection of the taper half pin should be to ensure sufficient pin strength and to maintain appropriate axial stiffness of the apparatus. 14. The taper half pin should be gently pushed through soft tissue, not drilled. **Post-Operative:** 15. Physiologic use of the affected limb and weight bearing when appropriate is advocated. 16. Apparatus integrity should be checked routinely. 17. The patient should be instructed to report any adverse or unanticipated effects immediately to the physician. 18. The post-operative follow-ups and radiographs are recommended during the distraction phase. This frequency may be reduced to monthly during the fixation phase. 19. 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. 20. 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 program of physiotherapy. 21. 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. 22. The fixator should be removed only after clinical radioluscence evidence of fracture healing. 23. 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.
STORAGE AND HANDLING	1. Packaged appliances 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 appliances to prevent damage to the sterile barrier.

<table>
<tr><td></td><td>3. The health care facility should establish a shelf life for sterilized appliances based upon the type of sterile wrap or rigid container used.
4. Sterile appliances 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.</td></tr>
<tr><td>RISKS DUE TO THE RE-USE OF "SINGLE USE" APPLIANCES</td><td>The "SINGLE USE" appliances of Rail Fixation System are identified through symbol reported on the product label. After the removal from the patient, the appliances have to be dismantled.

The re-use of appliances introduces contamination risks for users and patients. The re-use of appliances cannot guarantee the original mechanical and functional performances compromising the effectiveness of the products and introducing health risks for the patients.

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.</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.
• Packaging material to be used- Woven fabric, nonwoven materials, peel pouches of plastic and/or paper, made of a variety of materials, including paper, cellophane, polyethylene, Tyvek and various paper-plastic combinations;
• Wrapping Technique- Packages can be wrapped in two ways, sequential or simultaneous. When sequential wrapping is done, the items are wrapped twice, creating a pack within a pack. When a pack is wrapped simultaneous the package is wrapped once with a special double layered synthetic nonwoven material bound on the sides.
• There are two folding techniques commonly used for wrapping sterile packages. They are the envelope fold, most commonly used for smaller items, and instrument sets and the square fold, which is commonly used on larger packs.
• Tape (other than sterilization indicator tape) should not be used to secure packages, nor should safety pins, paper clips, staples, or other sharp objects. With wrapped packages, the information should go on the sterilization indicator tape.
• Sterilization Containers: Appliances 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 ISO 17665-1
• 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 –

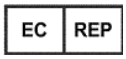
<table>
<tr><td>Steam Sterilizer Type</td><td>Gravity</td><td>Gravity</td></tr>
<tr><td>Minimum Exposure Temperature</td><td>121°C (250°F).</td><td>132°C (270°F).</td></tr>
<tr><td>Pressure</td><td>15 psi</td><td>30 psi</td></tr>
<tr><td>Minimum Exposure Time</td><td>30 Minutes</td><td>15 Minutes</td></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</td></tr>
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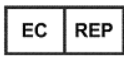
	100°C (212°F) during drying.

PITKAR IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE SINGLE USE OF THE IMPLANTABLE DEVICES. The institution or practitioner bears full responsibility for any subsequent use of these devices.

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



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

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