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- Ring 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- RING fixator system
Symbol	⚠Attention, see instructions for use
Device(s)	All the Pitkar RING Fixator System products NOT SUPPLIED "STERILE
Associated device systems with these instructions for use	Half ring, 5/8 ring, Foot ring, Arches, Nut, Bolt, Threaded rod, Hinges, Telescopic rod, Post male & female, Universal joint, Washer, Block for half pin, Sleeve, Socket, Plate, Rotational and Translational Device
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 Ring 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- Ring Fixator components are intended to be used on adult or pediatric patients as required.
Indications	1. Fracture fixation (Open & Closed) 2. Pseudoarthroses of long bones(Both congenital and acquired) 3. Limb lengthening by epiphyseal or metaphyseal distraction. 4. Correction of bony or soft tissue deformities. 5. Correction of bony or soft tissue defects.
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.
Warnings	Pre-Operative: • 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 Ring Fixator. • Patient selection should be in accordance with the listed indications and contraindications for use of the Ring fixator. • Preliminary frame assembly is recommended to reduce operative time and to assure an adequate supply of components before surgery. • Correction of varus, Valgus, Procuratum and Recurvatum movement of limb segments during distraction should be planned for preoperatively by selecting an appropriate prophylactic ring tilt and strategically positioning wires with stoppers, fulcrums and hinges. • All of the device components should be sterilized before use. • Single use devices should not be reused due to risks of breakage, failure or patient infection. Intra-Operative: 1. Wire placement requires strict anatomical consideration avoiding damage to

	nerves and vessels. 2. The proper wire diameter should be used to ensure sufficient wire strength and to maintain appropriate axial stiffness of the apparatus. The 1.8mm wires are usually recommended for the tibia and femur in normal adults, while the 1.5mm wire usually recommended for the upper limb and pediatric lower limb applications. 3. The wire should be gently pushed through soft tissue, not drilled, to reduce the possibility of nerve or vessel injury. 4. Wire drilling of the bone should be done slowly to avoid heat necrosis of surrounding tissue and bone 5. Caution should be used in handling the sharp tips of the wires. The tip of the wire should be held with a surgical sponge or soft cloth when clipped for removal. It is recommended that eye protection devices be worn by operating room personnel. 6. The diameter of the rings or assembled half rings are recommended to be used about 3cm larger than the maximum diameter of the operated limb segment. Ring sizes smaller or larger should not be used. 7. The wires should not be bent, scratched or marred during frame assembly. Bending can be avoided by using various types of washers to build the ring to the wire. 8. Appropriate tension should be applied to the regular wires at least 100kg. And no greater than 130kg. 9. Wires with stoppers or "olives" are not always placed under tension, depending upon the application. 10. The limb segments should be twisted carefully to verify completion of the corticotomy: The tibia should only be externally rotated to prevent undue traction on the peroneal nerve. 11. Proper fixation of components is essential. All wires and miscellaneous parts (bolts, rods, nuts, etc.) should be securely fastened with the appropriate instrument. Post-Operative: • Physiologic use of the affected limb and weight bearing when appropriate is advocated. • Meticulous wire-site care is crucial in reducing wire- tract infection. A suggested course is to surround the site with antiseptic soaked foam sponges. Persistent infection may necessitate wire removal. • The average recommended rate of bone or soft tissue distraction is 1mm/day, accomplished by 1/4mm movement every 6 hours. However, rates slower than this may be needed in situations of delayed consolidation, or faster than this in cases of premature consolidation of hinges are used. • Wire tension and frame integrity should be checked routinely. Some component bending or breakage may occur during use. • The patient should be instructed to report any adverse or unanticipated effects immediately to the physician. The patient should be instructed about apparatus distraction and adjustment. • Weekly to every other week post - operative follow-ups and radiographs are recommended during the distraction phase. This frequency may be reduced to monthly during the fixation phase.
Possible Adverse Effects	• Damage to nerves or vessels caused during insertion of the wires or during elongation of an anatomical segment. • Superficial or deep wire tract infection • Edema or swelling; possible compartment syndrome. • Joint contracture or loss of range of motion. • Septic arthritis and osteomyelitis. • Premature consolidation during bone elongation. • Loosening or breakage of the wires. • Poor result caused by patient non-compliance. • Bone deformity. • Intractable pain. • Fracture of regenerated bone. • Joint subluxation or dislocation.

	• Foreign body reaction to wires or other components. • Tissue necrosis occurring during wire insertion. • Persistent drainage after wire removal; chronic wire site osteomyelitis. • Skin pressure problems caused by external components. • Limb length discrepancy. • Inadvertent injury to the patient or operating room personnel caused by the wire. (e.g. Projectile wire from tip cutting during surgery) • 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 Ring 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. 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.
RISKS DUE TO THE RE-USE OF "SINGLE USE" APPLIANCES	The "SINGLE USE" appliances of Ring Fixation System is identified through symbol reported on the product label. After the removal from the patient, the appliances has 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.
PACKAGING	• 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

<table>
<tr><td></td><td>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 100°C (212°F) during drying.</td></tr>
</table>

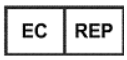
PITKAR IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE SINGLE USE OF THE IMPLANTABLE DEVICES. The institution or practitioner bears full responsibility for any subsequent use of these devices.

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

EC REP

Obelis S.A.
Bd, General Wahis 53
1030 Brussels, Belgium
Tel: + (32) 2.732.59.54
Email: mail@obelis.net

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		

Issue date: 03.11.2017
Rev. No. & date: 07/04.01.2025