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.

SSCP is available in the European database on medical devices (Eudamed), it is linked to the Basic UDI-DI.
URL to the Eudamed public website: https://ec.europa.eu/tools/eudamed

Pitkar External Fixation System- DeftFix 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 DeftFix System medical devices
Symbol	⚠Attention, see instructions for use
Device(s)	All the Pitkar DeftFix 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. The DeftFix is a Hexapod based system, designed to enable three-dimensional movement of bone segments, which is designed to be used with Pitkar Ring Fixation System to make multiplanar adjustments as required by varying the length of 6 programmable struts. The rings position is adjusted either in fast mode or gradually in precise increments to perform bone segment repositioning in three-dimensional space. Pitkar DeftFix System components are intended to be used on adult or pediatric patients as required. Pitkar DeftFix System indicated for the following treatments in adults, and in both children (3-12) and adolescents (12-21) in which the growths of plates have fused or will not be the crossed with the hardware. The S.H. Pitkar Orthotools Pvt. Ltd. does not claim MRI safety.
Material	Implants namely SS Pins (HA coated and non-coated) are manufactured from implant grade stainless steels (per ASTM F138) & Titanium non coated Pins are manufactured from implant grade Titanium (per ASTM F136) which is commonly used materials in orthopedic implants. Appliances are single use and manufactured from Aluminium & SS304. Instruments are reusable and manufactured from Standard Specification for Wrought Stainless Steels for Surgical Instruments (ASTM F899 -2012)
Indications	The device should be used for following indications: 1. Open and closed fracture fixation 2. Pseudoarthrosis or non-union of long bones 3. Limb lengthening by epiphyseal or metaphyseal distraction 4. Correction of bony or soft tissue deformities 5. Correction of segmental or nonsegmental bony or soft tissue defects 6. Post-Traumatic joint contracture which has resulted in loss of range of motion
Contraindications	The DeftFix system is not to use except as indicated. Use of system in contraindicated in the following situation: 1. Patients with mental or physiological impediment, unwilling or incapable of following postoperative care instructions and prescriptions for strut advance
Warnings	• 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 DeftFix fixator. • All the device components should be sterilized before use. • Single use devices should not be reused due to risks of breakage, failure or patient infection. • Bending, cutting, scratching of fixation devices will reduce the structural integrity of the frame.

	• Specialized instruments should be used for application; instruments with prolonged use must be examined prior to surgery.
	• Patient must be informed regarding removal surgery of fixation device.
	• Inspection of device prior to surgery is important; if found to be defective, DO NOT USE IT.
	• Advancement of screws on struts accompanies with a clicking noise. However, the noise can disappear after wear. Hence, patient must be able to follow prescription, even without sound.
	• After the strut is fully advanced, it should not be removed.
	• If the prescription required the screw to advance further, the strut should not be collapsed. Instead, the advance screw can be reset, while retaining strut position.
	• Fixation must be applied such that there is distance from the skin to accommodate swelling, cleansing, etc., bearing in mind, distance from bone is necessary parameter for stability of device.
	• DeftFix has not been evaluated in the MR environment for safety and compatibility.
	• The patient/caregiver must be instructed by the physician to:
	• Make the adjustments or get help in making the adjustments as needed.
	  • Identify on the prescription when to return for a strut change and for follow-up visits.
	  • Check periodically that the strut reference lengths are according to the prescription.
	  • Report if adjustment schedule cannot be met.
	  • Report any adverse or unexpected effects (strut breakage or disengagement, components damage, clip dislodgement, lost prescription).
	• The surgeon must evaluate the integrity of the construct at follow-up visits.
	• The fracture or bone gap must be checked periodically during treatment, making any necessary adjustments to the fixation device. An excessive or persistent gap can delay consolidation.
	• This device is not approved for fixing or attachment by means of screws to posterior elements (pedicles) of the cervical, thoracic or lumbar spinal column.
	• It is essential that special care be taken to ensure that the screws or wires do not penetrate joints or growth cartilage in pediatric patients.
	• Removal of the device: the surgeon should decide when it is time to remove the fixation device. Before final removal, temporary removal of a section of the frame is advised to check the strength of the healed regenerate segment.
	• While using the DeftFix system for deformity correction, the surgeon should keep the following in mind:
	  • Patient weight: an obese or overweight patients place loads on the device that could cause breakage or bending.
	  • Patient occupation or activity: the risk of bending or breakage of an internal or external bone fixation device during post-operative rehabilitation may increase if the patient carries out activities that involve lifting or heavy muscular activity, as these movements subject the device to forces that could cause it to break.
	  • Mental condition of the patient: the risk of breakage of a fixation device is greater in older patients, or patients with mental deficiency, alcoholics or drug addicts or patients who, for other reasons, may ignore the necessary restrictions and precautions to be observed while using the device.
	  • Debilitated patients: debilitated persons who have difficulty in using weight support devices can be at risk during post-operative rehabilitation.

Possible Adverse Effects	• Loosening, bending or breakage of the fixation device(s) or loss of fixation or migration which may result in nerve, soft tissue, or organ damage, including perforation through the skin or other hemorrhaging. • Loss of anatomical position with non-union or malunions with rotation or angulation. • Corrosion with localized tissue reaction or pain. Infection, local or systemic. • Pain, discomfort or abnormal sensations of the nervous system resulting from the presence of the device. • Cardiovascular disorders including venous thrombosis, pulmonary embolism, or

	myocardial infarction. • Bone loss or reduced bone density due to a reduction in the tension applied to the bone. Nerve or vascular damage following the insertion of wires or screws. • Deep or surface infections of the bone screw site, osteomyelitis, septic arthritis, including chronic drainage of the bone screw sites following removal of the device. • Oedema or possible compartmental syndrome. • Joint constriction, subluxation, dislocation or loss of motor movement. • Premature bone callus consolidation during distraction. • Possible tension affecting the soft tissues and/or the fixation during manipulation of the callus (e.g., corrections of deformities and/or elongation). • Lack of satisfactory bone regeneration, the development of mal-union or nonunion. • Fracture of regenerated bone, or at the bone screw holes, following removal of the device. • Loosening or breakage of the bone screws. • Bone damage due to erroneous bone screw selection. • Bone deformities or talipesequinus. • The persistence or recurrence of the initial condition subject to treatment. • New surgery to replace a component or the entire fixation frame. • Abnormal growth cartilage development in skeletally immature patients. • Foreign body reactions due to bone screws or components of the fixation frame. • Tissue necrosis secondary to the insertion of bone screws. • Pressure on the skin caused by external components when the free space is insufficient. • Limb dysmetria. • Excessive surgical bleeding. • Intrinsic risks associated with anaesthesia. • Unmanageable pain. • Secondary bone sequestration due to rapid perforation of the cortex with accumulation of heat and bone necrosis. Vascular disorders, including thrombophlebitis, pulmonary embolism, wound hematoma, avascular necrosis.
MRI Information	The Pitkar DeftFix 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.
Important	• Some surgical cases cannot be resolved with positive result. Improper use, medical reasons, or failure of device may cause additional complications. This may require surgery to remove or replace the device. • Knowledge of surgical techniques, presurgical procedures, and selection and positioning of external fixation device are important factors for the success of the DeftFix fixator. • Selection and screening of patients while bearing in mind the physical/mental limitations of individual is important while planning optimal route of therapy. Patient's ability to comply with surgeon's instructions and follow prescribed treatment has significant influence on the results of the device. If a candidate is found to exhibit contraindications, DO NOT USE the DeftFix fixator.
Software	The DeftFix is a circular external fixator based on Ilizarov principles. The frame consists of a hexapod made up of six variable length struts. The relative strut lengths determine the position of the rings in space. Because the rings are attached to bone segments, their position indirectly determines the position of the bone segments. This software needs three sets of parameters to perform the calculation for strut length adjustments. With these sets of parameters, the computer will be able to calculate appropriate strut adjustments for surgeon's review and approval. For further information, see Software Manual DeftFix, Doc: Software/ External Fixator/ DeftFix, Rev. no. 02/20.05.2021 DeftFix software web-page can be accessed on a web-browser by a surgeon user with

	the web address: www. DeftFix.com. The software asks for login information to let users use the software.
Software requirements	Computer Specifications: Processor speed of 1.5 GHz or higher, RAM of 4 GB or higher OS Specifications: Windows 10 or higher, Ubuntu 18 (Linux) or higher Display Settings: Screen resolution of 1024 x 768 or higher Browser -Google Chrome v84 or higher / Mozilla Firefox v79 or higher Browser Settings: Must support 128-bit SSL encryption. JavaScript enabled Internet Connection: A high-speed wireless, cable or DSL connection is recommended
Precautions	Accurate inputs are critical for accurate results. Verify and double check all input parameters. Intraoperative placement of the DeftFix Fixator according to preoperative plans is imperative to achieve predetermined results. If intraoperative conditions require a change to frame placement or size, new strut lengths will be calculated by entering the new inputs into the program. Small changes may affect accuracy of outcome.
Notice to Users and Patients-Serious-incident reporting	Any serious incident that has occurred in relation to this device should be reported to the S.H. PITKAR ORTHOTOOLS PVT. LTD., Email: info@pitkar.net and the competent authority of the Member State in which the user and/or patient is established.
Warnings	The software should be used only after careful study of the see Software Manual DeftFix, Doc: Software/ External Fixator/ DeftFix, Rev. no. 02/20.05.2021. All instructions in the DeftFix manual related to Software use should be followed precisely. The software should be only used in conjunction with the hardware of the DeftFix fixation device. It is not compatible with any other fixation devices. Only a trained surgeon should operate the software and device. Maximum accuracy of all parameters is required to be input into the software. The appropriate parameter values and method of their measurement is defined in the Software Use guideline in Software Manual DeftFix, Doc: Software/ External Fixator/ DeftFix, Rev. no. 02/20.05.2021. Special attention must be paid to scaling of images to achieve a successful result. Improper use of Software may result in erroneous calculations. Software diagrams should be checked to correspond with deformity seen in X-rays or clinically. Surgeon must carefully review prescriptions of the strut lengths adjustment calculations made by the software. Patients must be able to read prescription clearly and must understand the values of adjustments. When using Software, it is important to save the file after each step.
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 Pitkar DeftFix 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

<table>
<tr><td></td><td>shall be protected from direct sunlight, ionizing radiation, extreme temperatures, particulate or microbial contamination. Product/s shall be protected during the transport to transport. avoid potential damage. They do not require controlled temperature.</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: 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.

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<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.

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<tr><td>ADDITIONAL INFORMATION</td><td>Non sterile appliances and implants are supplied in “cleaned condition” and “ready to sterile”. Do not clean the Non sterile appliances and implants.</td></tr>
<tr><td>DISPOSAL</td><td>Disposal must be performed in accordance with national, regional, and local environmental and public health regulations.</td></tr>
</table>

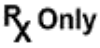
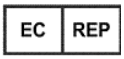
PITKAR IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE SINGLE USE OF THE IMPLANTABLE DEVICES. The institution or practitioner bears full responsibility for any subsequent use of these devices.

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

EC REP

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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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