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

Pitkar DeftFix System

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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 growth 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 are single use and manufactured from implant grade stainless steels (per ASTM F138) which is commonly used materials in orthopedic implants. Appliances are single use and manufactured from Aluminium. 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**:** • 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 is 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 patient places 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 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 B**rowser** -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.
Warnings	The software should be used only after careful study of the see Software Manual DeftFix, Doc : Software/ External Fixator/ DEFTFIX 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 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 Intramedullary Locking Nail System-PFNA IIis 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.
INSTRUCTIONS FOR REPROCESSING OF REUSABLE DEVICES FOR SUBSEQUENT RE-USE	
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 areused, 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 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.
MAINTENANCE AND INSPECTION	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.
PACKAGING	• 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

<table>
<tr><td></td><td>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.
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<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.

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</table>

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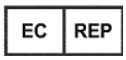
Symbol	Meaning	Symbol	Meaning
	Caution, consult accompanying documents		Batch code
	Date of manufacture		Manufacturer
	Do not reuse		Non sterile
	Do not use if package is damaged		Catalogue Number
	Humidity limitations		Temperature limit
	Authorized representative in the European Community		Use by date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

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