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.

Intramedullary Locking Nail- PFNA II

Manufacturer Name	S.H. PITKAR ORTHOTOOLS PVT. LTD. EL-32, "J" Block, MIDC Bhosari, Pune 411026, India Tel: +91 20 40706464 Fax: +91 20 46768107 Email: info@pitkar.net
Method Code	**Processing of the Intramedullary Locking Nail-PFNA IIMedical Devices**
Symbol	Attention, see instructions for use
Device(s)	The Intramedullary Locking Nail SystemNOT SUPPLIED "STERILE"
Limitations and restrictions on reprocessing	PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED.(IMPLANTS ARE SINGLE USE AND INSTRUMENTS ARE RE-USABLE)

INSTRUCTIONS FOR PROCESSING NEW DEVICES SUPPLIED "NON-STERILE" PRIOR TO THEIR FIRST USE	
Please read these instructions for use, and the corresponding Surgical Technique Guide carefully before use. Ensure that you are familiar with the appropriate surgical technique, Doc No. Operative / IM Nail/ PFNA II Rev. 01/14.12.2020	
INTENDED USE	Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of bones in various anatomical regions such as proximal femur, femoral shaft.
Associated device systems with these instructions for use	PFNA II Nail Short & Long, PFNA II Blade, Interlocking screw, Cap screw for PFNA II nail.
DESCRIPTION AND INDICATIONS FOR USE	The Intramedullary Locking Nail System-PFNA IIis comprised of non-sterile, single use, titanium alloy components & each implant as mentioned has specific indication depending on bone size & application such as. • Pertrochanteric fractures (31-A1 and 31-A2) • Intertrochanteric fractures (31-A3) • High subtrochanteric fractures (32-A1) • Low and extended subtrochanteric fractures • Ipsilateral trochanteric fractures • Combination fractures (in the proximal femur) • Pathological fractures of femur
MATERIALS	Titanium Alloy (Ti-6Al-7Nb)
CONTRAINDICATIONS	Contraindications include, but are not limited to: 1. Patients, in whom co-operation or mental competence is lacking, thereby reducing patient compliance. 2. Lack of bone substance or poor bone quality jeopardizing stable seating of implants. 3. Insufficient blood circulation. 4. Acute or chronic infections, either local or systemic. 5. Previous infection or risk of infection. 6. Any coexisting diseases that might endanger the function of the implant. 7. Patient's sensitivity to implant material. 8. Severe Osteoporosis.

	9. Metabolic disorders of patient. 10. Drug use & alcoholism. 11. Low subtrochanteric fractures 12. Femoral shaft fractures 13. Isolated or combined medial femoral neck fractures 14. Isolated or combined medial femoral neck fractures
NOTE FOR USE	Do not use PITKAR products in conjunction with those of other manufacturers, unless otherwise specified, as the combination is not converted by the necessary validation.
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. • Patient selection should be in accordance with the listed indications and contraindications for safe use of the implant. • These implants have been designed for usage in surgical theatre of public hospital and Private clinics. • All of the device components should be sterilized before use. • Reuse of any implant previously implanted is not permitted. • Check the marking on the implant corresponds to labelling (Make, batch number, size, length & necessary description is always marked on implant) • Each implant should be visually inspected for any defects like scratches, bend or cracks before implantations. Implants indicating such defects should not be used under any circumstances. • Under no circumstances should the user modify the implants • The operation should be planned carefully based on X rays findings. X rays provide adequate information about size & type of implant required for the said application. • The hospital must keep a record of available implants including catalogue number & batch number to ensure that fast action is taken in case of product recalls by the company. The article catalogue number & batch number of each single implant must be recorded in the operation report & patients medical record for the purpose of trace ability. • Suitable implant selection is prime issue in delivering satisfactory results. Complications arising out of negative indications or unsatisfactory surgical accuracy or technique, improper selection of implants cannot be attributed to manufacturer or supplier. • The surgeon must inform patient about the longevity & stability of implants depending upon the weight, behaviour & activity & about possible adverse effects. • Single use devices should not be reused due to risks of breakage, failure or patient infection. • 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. **Intra-Operative**: • Select an appropriate size of the implant & related instruments. • Select an appropriate type of implant. **Post-Operative:** • Physiologic use of the affected limb and weight bearing when appropriate is advocated. • Apparatus integrity should be checked routinely. • The patient should be instructed to report any adverse or unanticipated effects

	immediately to the physician. • The patient must be advised on limitations of metallic implants. • The post-operative follow-ups and radiographs are recommended during the distraction phase. This frequency may be reduced to monthly during the fixation phase. • The implant should be removed only after clinical radioluscence evidence of fracture healing & bone resuming its normal function. Physician concern is responsible for this decision. • To ensure full follow up of the case, X-ray should be taken at one or two months from final healing and removal of implant.
POSSIBLE ADVERSE EVENTS	• Displacement or loosening of implant. • Infections. • Venous thrombosis and pulmonary embolism. • Cardiovascular disorders. • Poor result caused by patient non-compliance. • Allergic reactions. • Pseudoarthrosis. • Haematoma. • Delayed wound healing. • Various forms of corrosion & wear
MRI SAFETY INFORMATION	The Intramedullary Locking Nail Systemhave not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. They have not been tested for heating, migration, or image artifact in the MR environment., unless specified otherwise on the instructions for use and/or the operative technique they are used with.
STORAGE AND HANDLING	1. Packaged implants &instrumentsshould 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 &instrumentpackages 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.
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 are used, 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 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.

<table>
<tr><td>MAINTENANCE AND INSPECTION</td><td>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</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.
• SterilizationContainers: 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</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</td></tr>
<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.</td></tr>
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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 or multiple use devices.
The institution or practitioner bears full responsibility for using cleaning and sterilization methods other than Pitkar recommendation for reusable devices for subsequent use**.**

EC REP

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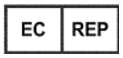
Symbol	Meaning	Symbol	Meaning
	Caution, consult accompanying documents		Batch code
	Date of manufacture		Manufacturer
	Do not reuse		Non sterile
	Do not use if package is damaged		Catalogue Number
	Humidity limitations		Temperature limit
	Authorized representative in the European Community		Use by date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

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