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.

STERILE HYDROXYAPATITE COATED TAPERED HALF PIN FOR EXTERNAL FIXATION SYSTEM
Single use implant

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 Tapered Half Pin – External Fixation System Medical Devices**
Symbol	Attention, see instructions for use
Device(s)	All the PITKAR Hydroxyapatite Coated Tapered Half Pin for External Fixation System are SUPPLIED "STERILE"
Limitations and restrictions on reprocessing	PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED.

INSTRUCTIONS FOR PROCESSING NEW DEVICES SUPPLIED "NON-STERILE" PRIOR TO THEIR FIRST USE	
DESCRIPTION	PITKAR Hydroxyapatite Coated Tapered Half Pin are intended to be used in association with PITKAR External Fixation System for long and small bone fixation. They are available in different thread designs, thread and shaft diameters and lengths in order to be applied according to the anatomical site (i.e., upper limb, lower limb, pelvis, hand and foot), bone dimensions and quality. They are available in stainless steel and titanium. PITKAR Tapered Half Pins are intended for professional use only. Surgeons who supervise the use of PITKAR Tapered Half Pins must have full awareness of orthopedic fixation procedures as well as understanding of bone screw surgical applications and post operative management.
INTENDED USE	Hydroxyapatite Coated Tapered Half Pin are indicated for use with external fixation system
MATERIALS	The PITKAR Hydroxyapatite Coated Tapered Half Pin are manufactured from surgical grade stainless steel are plasma-sprayed with a thin coating of hydroxyapatite over the threaded portion. This coating has been shown in clinical trials to enhance fixation at the pin-bone interface and to reduce the incidence of pin loosening. Furthermore, osteointegration with direct contact between the bone and the screw thread was seen on histologic examination.
CONTRAINDICATIONS	The PITKAR Hydroxyapatite Coated Tapered Half Pin are not designed or sold for any use except as indicated. Contraindications include, but are not limited to: 1. Presence of infection (systematic or localized) 2. Patients with mental or physiological conditions who are unwilling or incapable of following postoperative care instructions. 3. Patients with severe osteoporosis*, patients who are HIV positive and patients with severe, poorly controlled diabetes mellitus. 4. Patients with foreign body sensitivity or allergies to the implant material. Where material sensitivity is suspected, tests should be made prior to implant insertion. 5. As defined by the World Health Organization: "Bone mineral density of 2.5 standard deviations or more below the mean peak bone mass (average of young, healthy adults) in presence of one or more fragility fractures". 6. Patients having over weight or obesity 7. Pregnant patient
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	1. Particular care should be taken that Pins do not enter the joints or damage the growth plates in children. 2. Any device implanted into the patient, such as pins, and in general any device which is labeled "single use only" MUST NOT BE RE-USED". 3. PITKAR Hydroxyapatite Coated Tapered Half Pin length and thread length should be selected in accordance with bone dimensions. Thread length should be such that at least one full thread will remain outside the entry cortex and the screw tip will project just beyond the second cortex. Excessive penetration of the second cortex by any type of screw should be avoided, because of the risk of soft tissue damage. Tapered Half Pins should never be inserted so that the smooth shank penetrates the entry cortex, because of the risk of damage to the bone. 4. In case of pin, the screw thread tapers, for example, from 6.0 to 5.0mm between shaft and the tip of the standard Tapered Half Pins, or from 6.0 to 5.6mm in the External Fixation System. Any attempt to back out a Tapered Half Pin once it has been inserted may cause it to become loose. 5. Pin diameter should be selected in accordance with bone diameter. The maximum diameter of the Pin thread should not be greater than one third of the bone diameter (e.g., 6-5 or 6-5.6mm bone screw for bone diameter greater than 20mm). 6. For per-drilled bone screws, per-drilling with appropriate drill bits and drill guides prior to screws insertion through the screw guide is imperative. Blunt drill bits can cause thermal damage to the bone and always be discarded. 7. Pin with a thread diameter of 5.00mm or above should never be inserted with a power tool, but always by hand or with a hand drill. Self-drilling screws with smaller thread diameters may be inserted with a power drill at low speed. 8. The Hydroxyapatite Coated Tapered Half Pin are designed to be self-drilling, and direct insertion with a hand drill is advised in most cases. However, when insertion of self-drilling screws is performed in diaphyseal bone, pre-drilling is recommended; use a 4.8mm drill bit through a drill guide when a bone is hard; when the bone quality is poor, or in the metaphyseal region where the cortex is thin, a 3.2 mm drill bit should be used. Screw insertion, whether or not pre-drilling has been performed, should always be with the hand drill or T Wrench only and through a screw guide. It is important that, moderate force is applied for the screw to gain entry into the first cortex. Insertion can be completed with the T Wrench. Diaphyseal bone screws should always be inserted in the center of the bone axis, to avoid weakening it. In all cases the surgeon should be mindful of the amount of torque required to insert the screw. It seems tighter than usual, it is safer to remove the screw and clean it, and drill the hole again with a 4.8mm drill bit, and even it has already been used. 9. For more stable fixation of a fracture with a fixator, we recommend that the nearest tapered half pin is applied fairly close to the fracture margin (a minimum of 2cm is recommended) and that these distances are equal on both sides of the fracture. 10. Appropriate Tapered Half Pin instrumentation should be used to insert pins correctly. 11. Meticulous pin site hygiene is required. 12. All patients must receive instruction on pin site care. 13. Patients should be instructed to report any adverse or unanticipated effects to the treating surgeon. 14. Care should be taken during usage of thread diameter 4.5-3.5mm Tapered Half Pins with a long shaft, since the risk of fatigue or other failure may be slightly higher than with our standard tapered half pin range. Particular care should be taken during pin insertion if the bone is hard. PITKAR suggests using three pins rather than two to spread the load. If the patient is heavy, weightbearing should be limited.

	15. The device is not approved for pin attachment or fixation to the posterior elements (pedicles) of the cervical thoracic or lumbar spine.
POSSIBLE ADVERSE EVENTS	1. Nerve or Vessel damage resulting from insertion of tapered half pins. 2. Superficial or deep tapered half pin infection, osteomyelitis, or septic arthritis, including chronic drainage of tapered half pin sites after device removal. 3. Oedema or swelling, possible compartment syndrome. 4. Joint Contracture, subluxation, dislocation or loss of range of motion. 5. Fracture through tapered half pin holes after device removal. 6. Loosening or breakage of the tapered half pin. 7. Bony damage due to inappropriate tapered half pin selection. 8. Foreign body reaction to tapered half pin. 9. Tissue necrosis secondary to tapered half pin insertion. 10. Pressure on the skin caused by external components when clearance in inadequate. 11. Excessive operative bleeding. 12. Intrinsic risks associated with anesthesia. 13. Intractable pain. 14. Bone sequestration secondary to rapid drilling of bony cortex with heat build-up and bone necrosis. 15. Vascular disorders including thrombophlebitis, pulmonary embolus, wound ematomas, avascular necrosis.
IMPORTANT	A successful result is not achieved in every surgical case. Additional complications may develop at any time due to improper use, medical reasons or device failure which require further surgical intervention to remove or replace the tapered half pin. Preoperative and operative procedures including knowledge of surgical techniques and proper selection and placement of the tapered half pin are important considerations in the successful utilization of tapered half pins by the surgeon. Proper patient selection and the patient's ability to comply with physician instructions and follow prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations. If a surgical candidate exhibits any contraindications or is predisposed to any contraindications, DO NOT USE PITKAR tapered half pins.
MRI SAFETY INFORMATION	The PITKAR Hydroxyapatite Coated Tapered Half Pin have 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 of the tapered half pin external fixation system they are used with.
STORAGE AND HANDLING	1. Sterile PITKAR Hydroxyapatite Coated Tapered Half Pin 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 Sterile PITKAR Hydroxyapatite Coated Tapered Half Pin to prevent damage to the sterile barrier. 3. Sterile PITKAR Hydroxyapatite Coated Tapered Half Pin should be carefully examined prior to opening to ensure that package integrity has not been compromised
PRE-USE INSPECTION	1. Carefully examine the sterile packaging (pouch/blister and protective seals) of the orthopedic half pin immediately before opening. 2. Do not use the device if the packaging is torn, punctured, cracked, unsealed, wet, or if the sterile barrier appears compromised or unintentionally opened in any way. 3. If any damage or premature opening is detected, the device must be **immediately rejected and treated as non-sterile**. Do not attempt to use the half pin on a patient, as a compromised sterile barrier introduces a severe risk of deep bone or surgical site infection.

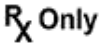
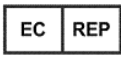
RISKS DUE TO THE RE-USE OF "SINGLE USE" IMPLANTABLE DEVICE*	The "SINGLE USE" implantable device* of PITKAR Hydroxyapatite Coated Tapered Half Pin is identified through symbol reported on the product label. After the removal from the patient, the implantable device* has to be dismantled. The re-use of 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 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.
STERILE & NON-STERILE Product	Hydroxyapatite Coated Tapered Half Pin are gamma sterilized at 25 KGay.
DISPOSAL	• Immediately upon removal from the patient, place the half pins directly into a rigid, puncture-resistant, leak-proof sharps container specifically approved for biohazardous medical waste. • Following explantation, half pins are heavily contaminated with blood, tissue, and potentially infectious biological agents. They must be handled as hazardous medical waste. Healthcare professionals must wear appropriate Personal Protective Equipment (PPE). • Do not dispose of half pins in standard clinical waste bags or municipal trash. Final disposal of the sharps container must be carried out by authorized medical waste personnel in strict accordance with institutional protocols and local, regional, and national regulations for infectious clinical sharps waste.

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		Sterile
	Catalogue Number		Humidity limitations
	Do not re-sterilize (only for sterile product)		Use by date (only for sterile product)
	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		Protect from moisture

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