Device Description
The Simple Locking Intra-Medullary (SLIM) system consists of intramedullary fixation devices for use in long bones. The solid shaft, beveled point, and pre-determined or blank length options rods are designed for easy insertion in the medullar canal. Anchorage of the device is achieved through a conical cortical thread to obtain a stable fixation in the epiphyses or cortical bone, which aims to reduce the risk of migration. Internal features, such as a hexagonal drive and an internal mechanical thread in the head of the device, are designed for capture and guidance during insertion and retrieval. Additional proximal and distal locking holes allow supplemental pinning when required to ensure fixation with Locking Pins or Locking Pegs when required, and the Bullet Screws allow fixation of smaller diameter shafts that cannot be cross-pinned due to their size.
The SLIM, single-use, implants are manufactured in medical grade Stainless Steel (SS316L, ASTM F138). The rods are available in seven diameters: 2.0, 2.6, 3.2, 4.0, 4.8, 5.6 and 6.4 mm, from 80mm up to 400 mm in length, and allow the end user to customize the length of the rod.

Intended Use
The SLIM System is intended as a temporary implant for alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities, or have sustained fractures due to trauma or disease. This includes the femur, tibia, humerus, ulna and fbula of the pediatric population (child and adolescent), and patients with small intramedullary canals afected by skeletal displasias, osteogenesis imperfecta or other bone diseases.

Contraindications
Do not use in any situation that is not described in the Intended Use section of this insert.
Devices should not be used in patients with:
- Active or suspected latent infection or marked local inflammation in or about the affected area.
- Osteoporosis, insufficient quality or quantity of bone/soft tissue
- Compromised vascularity inhibiting adequate blood supply to the operative site.
- Documented or suspected material sensitivity.
- Sepsis
- Patients with abnormal neurological or mental conditions
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

Surgeons should warn patients about these contraindications and limitations when appropriate.

Adverse Effects
The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:
- Pain, discomfort or abnormal sensations due to the presence of the device.
- Irritation or inflammation of surrounding soft tissue or skin over implant if coverage is insufficient
- Limb shortening or residual deformity with nonunion or malunion
- Metal sensibility and/or allergic reaction to a foreign body.
- Nerve damage due to the surgical trauma
- Bone resorption due to stress shielding.
- Postoperative bone fracture and pain.
- Infection, both deep and superficial
- Unrecognized joint penetration
- Inadequate healing
- Necrosis of bone
- Possible neurovascular injury
- Possible blood circulation or vessel damage, or avascular necrosis (AVN)
- Cessation of growth of the operated portion of bone
- Bony formation around implant making removal difficult or impossible
- Persistent instability
- Nonunion or delayed union of bone fracture or bony fusion
- Migration resulting in injury to soft tissue, visceral organs, or unrecognized joint penetration
- Corrosion of implants

Additional injuries can occur as a result of postoperative trauma. Device breakage, loosening, and/or migration can occur as a result of early weight bearing or muscle activity. It may be necessary to perform additional surgery in order to correct adverse effects or reactions which may not be related to the actual system.
These adverse effects include important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

Warnings
- Implants are single use items. Please note that single use device (SUD) which comes into contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed.
- Metal implants should never be reimplanted. Although appearing undamaged, the device may have small defects or internal stresses which may eventually lead to implant failure.
- Correct implant handling is extremely important. Avoid contouring of metallic implants. Discard all damaged or mishandled implants
- Continuous screening with an image intensifier (fluoroscopy) during guide wire insertion and whenever cannulated instruments are advanced over a guide wire is recommended to prevent unintended guide wire advancement and penetration into the surrounding tissues.
- Failure to use largest possible components or improper positioning/insertion of the device during implantation can increase the possibility of migration, loosening, bending, cracking, or fracture of the device or bone, or both.
- Device breakage or damage can occur when implant is subjected to increased loading associated with delayed union, non-union, or incomplete healing. Proper consolidation should be observed prior to full weight bearing.
- Contouring and bending of an implant may reduce its fatigue strength causing failure under load.
- Improper insertion of the device during implantation can increase the possibility of loosening or migration.
- Bullet Screws, Locking Pins and Pegs included in the Simple Locking IntraMedullary (SLIM) System should not be used as stand-alone implants.
- The diameter of the Bullet Screws, Locking Pins and Pegs should be selected in accordance with bone diameter. The maximum screw, pin or peg diameter should not be greater than one third of the bone diameter.
- The patient's mobility should be restricted at the region of the osteotomy or fracture to allow bony union. If a nonunion develops, the implants should be removed. If a solid fusion of bone does not occur, the site should be immobilized until solid bony fusion can be achieved. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to healing of the fracture. Due to normal metal fatigue these stresses can cause eventual bending or breakage of the device.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management to avoid re-fracture or recurrent deformity.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged implants and instruments, and to take into account the risk of infection if a cut appears.
- Pega Medical advises against the use of another manufacturer's component with any Pega Medical component. Any such use will negate the responsibility of Pega Medical for the performance of the resulting mix.
- Early removal of Implant may cause the risk of re-fracture and the possible complications of an additional operation.

The surgeon should be aware and the patient informed of the following information and limitations.
- Compliance of the patient may affect the results of the fixation,
- Patients should be warned to avoid any sudden change in position, strenuous activity, or falls. To achieve a successful union, the patient should not be exposed to mechanical vibrations, wether intrinsic or extrinsic, that may lead to loosening of the device. The patient should be warned of this possibility and instructed to restrict physical activities especially those causing any type of mechanical stress on the area that is being secured by the system. The patient should avoid any type of sport activities or strenuous work during the postoperative or post implant removal healing period.

Complications and/or failure are more likely to occur in
- Physically active patients
- Debilitated patients or patients unable to follow instruction or use weight supporting devices
- Patients that suddenly change position, fall, or are exposed to mechanical vibrations.

MRI Safety Information for the SLIM System:
In non-clinical testing, the SLIM implants were determined to be MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

Static Magnetic Field Strength (B0)	1.5 T and 3 T	
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm) or less	
RF Excitation	Circularly Polarized (CP)	
RF Transmit Coil Type	Body Coil: See scan region limitations below	
	Local Coils: Head transmit-receive coil, no restrictions on local transmit-receive coils that the device is not within	
Operating Mode	Normal Operating Mode	
Maximum Whole Body SAR	See details below	
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)	
Anatomical Isocenter Landmarks	< 50 cm from center of bone that device is implanted in	≥ 50 cm from center of bone that device is implanted in
1.5 T SAR and Scan Durations	1 W/kg whole body average SAR for 10 minutes of continuous RF. (a sequence or back to back series/scan without breaks) with a 20 minute cooling period between scans for one hour of scanning	2 W/kg whole body average SAR for 60 minutes of continuous RF. (a sequence or back to back series/scan without breaks)
3 T SAR and Scan Durations	Only use local transmit-receive coils that device is not within	
Image Artifact	The presence of this implant may produce an image artifact. Optimization of MR imaging parameters to compensate for the presence of this device may be necessary.	

- The presence of other implants or the health state of the patient may require a modification of the MR conditions.
- If information about a specific parameter is not included, there are no conditions associated with that parameter.

CAUTION: Federal law (USA) and most other countries' laws restrict this device to sale by or on the order of a physician.

Surgical Technique
Standard surgical technique for the placement of the intramedullary nails is recommended. Pre-operative procedures, knowledge of applicable surgical techniques, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.The surgical technique manual details every step and should be carefully followed.

Device Lifetime and Retrieval
Removal or replacement of the implant is recommended subsequent to normal follow-up after the bone has consolidated and the deformity correction has been achieved. Routine removal of internal fixation devices may reduce the occurrence of symptomatic complications of implant breakage, implant loosening and implant related pain. If removal is favorable, Pega Medical recommends the retrieval of implants in order to avoid bone reduction and weakening, particularly in young and active patients. Ensure that consolidation is complete prior to the removal of the device. Although the final decision to retrieve the implants falls on the surgeon, a maximum Device Lifetime of 5 years for the implant has been defined to ensure material stability. The Surgical Technique manual details retrieval steps and should be carefully followed.

Cleaning and Sterilization Instructions for Implant Components
All implants are provided clean, but are NON-STERILE when shipped from Pega Medical. The instructions below should be followed for sterilizing items supplied non-sterile. Apply a standard cleaning protocol that is approved by the hospital before implant sterilization. All metallic implants can be steam sterilized following the instructions and parameters listed below:

Note for USA only: Sterilization wraps, pouches, indicators and sterilization trays should be FDA cleared for the sterilization cycle parameters.
- The implant trays of the SLIM system should be sterilized wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques.
- Implant components of the SLIM System should be sterilized using sterilization pouches.
- Devices should be dry before packaged for sterilization

Method	Steam
Sterilization type	Prevacuum
Minimal temperature	270°F (132°C)
Minimal cycle time	4 minutes
Minimal drying time	30 minutes

Warning: Do not stack trays during sterilization
Other sterilization methods and cycles may also be suitable. However, validation of any alternative method using appropriate laboratory techniques is advised.

Cleaning, Sterilization and Re-sterilization Instructions for Instruments
Reusable instruments must be cleaned and sterilized prior to every use. The instrument tray and instruments of the SLIM system should be sterilized wrapped in two layers of 1-ply polypropylene wrap using sequential wrapping techniques.
Please refer to document entitled: "Guidance for Instrument Care" for further information and instructions regarding cleaning, sterilization and re-sterilization of instruments.

For any further questions, please contact Pega Medical

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

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ISO 15223-1

Manufacturer / Fabricante / Fabricant

Caution: law prohibits dispensing without prescription

See instruction for use / Ver instrucciones de uso / Lire les instructions avant usage

Catalogue number / Número de catálogo / Numéro de catalogue

Do not reuse / No reutilizar / Ne pas réutiliser

Medical device / Dispositivo Médico / Dispositif médical

Non sterile / No estéril / Non stérile

Authorized representative / Representante Autorizado / Représentant Autorisé

Batch number / Número de lote / Numéro de lot

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Simple Locking Intramedullary System

CE 0413

SLIM-IFU-AU Rev.F
(2021/11)

Printed in Canada