

INTRODUCTION

Patient Information Leaflet

This leaflet includes important information about The Simple Locking Intra-Medullary (SLIM) System (SLIM Nail). It will help you understand how the SLIM Nail works as well as the benefits and risks associated with this medical device. Follow your surgeon's advice even if it differs from what is in this leaflet. If you need further information, your surgeon can answer any questions you may have, or you can contact us at: feedback@pegamedical.com.

Please read this leaflet carefully and keep it in a safe place so that you may refer to it in the future if needed.

What is the SLIM Nail?

The SLIM Nail is a rod that is placed inside the medullary canal of the long bones to stabilize the bone allowing to heal the fracture. The SLIM Nail is manufactured in medical grade Stainless Steel.

It includes the following model references:

LENGTH (mm)	SLIM Rods							
	DIAMETER (mm)	2.0	2.6	3.2	4.0	4.8	5.6	6.4
80	SLM-20-080	SLM-26-080	SLM-32-080					
90	SLM-20-090	SLM-26-090	SLM-32-090					
100	SLM-20-100	SLM-26-100	SLM-32-100					
110	SLM-20-110	SLM-26-110	SLM-32-110					
120	SLM-20-120	SLM-26-120	SLM-32-120	SLM-40-120	SLM-48-120			
130	SLM-20-130	SLM-26-130	SLM-32-130	SLM-40-130	SLM-48-130			
140	SLM-20-140	SLM-26-140	SLM-32-140	SLM-40-140	SLM-48-140			
150	SLM-20-150	SLM-26-150	SLM-32-150	SLM-40-150	SLM-48-150			
160	SLM-20-160	SLM-26-160	SLM-32-160	SLM-40-160	SLM-48-160	SLM-56-160	SLM-64-160	
170	SLM-20-170	SLM-26-170	SLM-32-170	SLM-40-170	SLM-48-170	SLM-56-170	SLM-64-170	
180	SLM-20-180	SLM-26-180	SLM-32-180	SLM-40-180	SLM-48-180	SLM-56-180	SLM-64-180	
190	SLM-20-190	SLM-26-190	SLM-32-190	SLM-40-190	SLM-48-190	SLM-56-190	SLM-64-190	
200	SLM-20-200	SLM-26-200	SLM-32-200	SLM-40-200	SLM-48-200	SLM-56-200	SLM-64-200	
220	SLM-20-220	SLM-26-220	SLM-32-220	SLM-40-220	SLM-48-220	SLM-56-220	SLM-64-220	
240	SLM-20-240	SLM-26-240	SLM-32-240	SLM-40-240	SLM-48-240	SLM-56-240	SLM-64-240	
260	SLM-20-260	SLM-26-260	SLM-32-260	SLM-40-260	SLM-48-260	SLM-56-260	SLM-64-260	
280	SLM-20-280	SLM-26-280	SLM-32-280	SLM-40-280	SLM-48-280	SLM-56-280	SLM-64-280	
300				SLM-40-300	SLM-48-300	SLM-56-300	SLM-64-300	
320				SLM-40-320	SLM-48-320	SLM-56-320	SLM-64-320	
340				SLM-40-340	SLM-48-340	SLM-56-340	SLM-64-340	
360						SLM-56-360	SLM-64-360	
380						SLM-56-380	SLM-64-380	
400						SLM-56-400	SLM-64-400	

What is it indicated for?

- The SLIM Nail is a temporary implant used to:
- Straighten deformed bones
- Prevent or stabilize fractures

Who is it indicated for?

- Children 18 months and older as well as adults

For which bones is the system indicated?

Femur, Tibia, Humerus, Ulna and Fibula.

What is the intended performance of the SLIM Nail?

The SLIM Nail is a small diameter nail that can be fixed at both extremities of the bone. The small size of this nail allows it to be used in small diameter bones including bones with diseases.

The fixation features at both extremities improve stabilization of fractures and can help for faster healing.

The straight shape of the SLIM Nail allows for insertion of the implant without impaction which can potentially decrease tissue trauma with the intention of reducing pain and recovery time for the patient.

It is a load-sharing device; patients can rapidly ambulate, as the nail helps distribute the stress and load the fracture to help it heal.

Are there any possible undesirable side effects following the surgery?

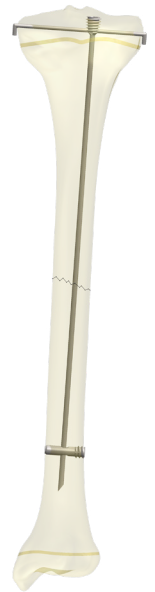
Rodding is major surgery, and as with any major surgical procedure, although uncommon, there are potential side effects including:

- Irritation or inflammation of surrounding soft tissue or skin over implant if coverage is insufficient
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Metal sensibility and/or allergic reaction
- 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
- Risk of growth disturbances
- Corrosion of implants

What kind of complications can occur from use of the SLIM Nail?

Although uncommon, some complications can occur such as:

- Migration of the implant
- Nail bending or breakage due to excessive loading or impact
- Delayed union, non-union, shortening, or Inadequate healing
- New bone deformity
- Bony formation around implant making removal difficult



Are there any risks that could arise from the interaction of the SLIM Nail with other equipment and precautions to be taken?

The SLIM Nail has not been evaluated for safety and compatibility in the Magnetic Resonance environment. Speak to your surgeon about whether you can have MRI scans. You should inform the technicians performing the scan that you have an implant.

How long is the immobilization time?

For all bones – femur/tibia/humerus – immobilization time is usually around 3 to 4 weeks or until bone healing starts to be apparent.

How long after surgery will it take to recover normal use of the limbs?

The length of the recovery period is determined by many factors such as the extent of the surgery, the patient's age and activity level. Each case is particular, and some patients will recover faster than others. In general, the patient can start standing activities three to four weeks after surgery.

What kind of rehabilitation is needed after surgery?

Physical therapy is required for most children after rodding surgery. Some physicians prescribe physical therapy during the recovery period to keep up muscle strength in limbs not affected by the surgery. Other times, physical therapy, sometimes beginning in the swimming pool, is employed after the cast is removed to help the individual regain strength.

What type of follow-up is needed after surgery?

Routine follow-up is recommended to avoid post-operative complications. Your doctor will instruct you to return for additional visits to monitor your progress. You should follow-up as proposed by your orthopaedic surgeon.

If you have any problems, you should see an orthopedic doctor right away and inform him or her that you have an orthopedic implant.

Are there any symptoms that could indicate that the device is not properly functioning?

Please call your doctor if you develop any of the following symptoms:

- Pain, discomfort, or abnormal sensations due to the presence of the device
- Swelling, numbness, general weakness, or fever
- loss of function/range of motion
- Postoperative re-fracture or inadequate healing
- Drainage continues from the site of your incision

What precautions should be taken if I experience any of the above symptoms?

- Consult your health care professional immediately.
- Use the prescribed medications to help minimize the risk of infection and inflammation.
- Do not engage in any strenuous activity until your doctor says it is okay to do so.
- Do not lift any heavy objects; try not to bend, as this can cause undue stress on your implant.

How long will the SLIM implant last?

Your surgeons may decide to remove the SLIM implant once the fracture or osteotomy has fully healed. Otherwise, the SLIM Nail may need to be removed or replaced if significant growth has occurred or if a complication has arisen such as breakage, migration, or recurrence of deformity. Else, it is recommended to remove or replace the nail after 5 years of implantation to ensure material stability.

Nevertheless, the final decision rests with the surgeon. Any decision to remove the device should take into consideration the potential risks of a secondary surgical procedure. Device removal should be followed by adequate postoperative management.

Is there anything that could affect the lifetime of the SLIM implant?

- Trauma, Infection, early weight bearing could shorten the device lifetime.
- Follow recommendations from your surgeon to limit physical activities, particularly those causing any type of mechanical stress on the affected area. This is especially important during the postoperative or post implant removal healing period.
- Avoid any sudden change in position, strenuous activity, or falls.
- Proper post-operative care and regular follow-up with healthcare professional and following the instructions for use will contribute to lengthen the device lifetime.

Is there any precaution that should be taken near the expected device lifetime?

Continue with the regular post-operative monitoring with the surgeon and follow their recommendations.

What is the SLIM Nail made of?

The SLIM Nail is manufactured in medical grade Stainless-Steel (316L, ASTM 138). This is a biocompatible material made according to standards recognized by regulatory authorities. This is one of the most common Stainless-Steel grades used for implantable devices.

Is there any manufacturing residual that could pose a risk?

The SLIM Nail is meticulously decontaminated following a process validated according to medical industry standards that removes any manufacturing residue well below tolerable exposure values, thus maximizing safety.

Contact information in case of serious incident:

Any serious incident that occurs with the use of the SLIM Nail should be reported to Pega Medical and the Therapeutic Goods Administration (TGA) to the contact information below:

Pega Medical, Inc.

1111 Autoroute Chomedey
Laval, QC H7W 5J8 Canada
Email: feedback@pegamedical.com
Phone: 1-450-688-5144
Toll Free: 1-877-739-6358
Website: www.pegamedical.com

Therapeutic Goods Administration (TGA)

Email: iris@health.gov.au
Phone: 1800 809 361 (free call within Australia)

Users who are deaf or have a hearing or speech impairment can call through the National Relay Service:

- TTY or computer with modem users phone 1800 555 677 then ask for 1800 809 361
- Speak and listen (speech to speech relay) users phone 1800 555 727 then ask for 1800 809 361

For further information, visit TGA's website: <https://www.tga.gov.au/medical-devices-ivd>