Pega Medical™

Fassier-Duval
Telescopic IM System™

Patient Information Leaflet

INTRODUCTION

This leaflet includes important information about the Fassier-Duval Telescopic Intramedullary System (FD Nail). It will help you understand how the FD 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 FD Nail?

The FD Nail is a telescopic rod fixed within both extremities of the long bone that elongates while normal growth occurs.
The FD Nail is manufactured in medical grade Stainless Steel.

It includes the following model references:

	FEMALE		MALE		
COMPONENTS	SIZE Ø (mm)	Femur	Tibia/Humerus	Long Thread	Short Thread	Pin Locking (LON)
		Catalog	Catalog	Catalog	Catalog	Catalog
	3.2	F032-SS	T032-SS	M032-SS-100	M032-SS-50	M032-SS-LON
	4.0	F040-SS	T040-SS	M040-SS-110	M040-SS-60	M040-SS-LON
	4.8	F048-SS	T048-SS	M048-SS-120	M048-SS-70	M048-SS-LON
	5.6	F056-SS	T056-SS	M056-SS-130	M056-SS-85	M056-SS-LON
	6.4	F064-SS	T064-SS	M064-SS-150	M064-SS-100	M064-SS-LON

What is it indicated for?

The FD Nail is a temporary implant used to:
- Straighten deformed bones
- Prevent or stabilize fractures
- Correct limb length discrepancy
- Support your natural growth

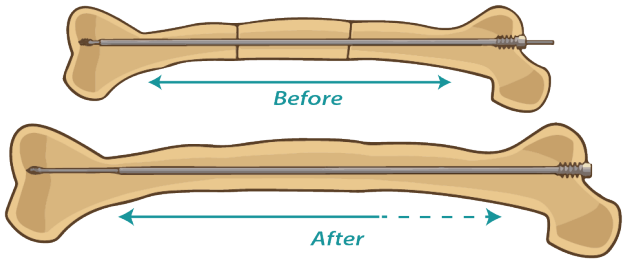
Who is it indicated for?

- Children 18 months and older suffering from Osteogenesis Imperfecta (OI), or younger if the child exerts pressure on his limbs to stand, causing repetitive fractures or bowed bones.
- For children and small stature patients in cases of limb length discrepancy.

For which bones is the system indicated?

Femur, Tibia and Humerus.

The nail *extends* as you grow



Are there any special operating instructions for the use of the FD Nail?

The FD Nail does everything on its own and will extend as you grow. Each component of the FD Nail is fixed at each extremity of the bone. As the bone grows, the nail will extend like an antenna.

What is the intended performance of the FD Nail?

The FD Nail provides a long telescopic range, which translates into several years of growth before exchanging the nail might become necessary. Moreover, its screw-type fixation and traversal interlocking options provide improved stabilization. When compared to non-telescoping implants, the FD Nail is shown to have a lower rate of complications and 7.8x longer duration before re-operation[1].
The single-entry point compared to dual-entry points favours bone and joint preservation, decreases tissue trauma and minimizes blood loss during surgery[2]. With shorter rehabilitation times, fewer scars and less pain, recovery is faster.
It is a load-sharing device; patients can rapidly ambulate as indicated by the operating surgeon, and 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:
- 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

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

The risk of post-operative complications is reduced compared to other devices, and so is the re-operation rate. However, some complications can occur such as:
- Non telescoping of the rod,
- Migration of the implant,
- Nail bending or breakage due to excessive loading or impact,
- Delayed union, non-union or shortening
- New bone deformity
- Risk of growth disturbances

[1] Spahn, Kimberly M. MD, et al. Fassier-Duval Rods are Associated With Superior Probability of Survival Compared With Static Implants in a Cohort of Children With Osteogenesis Imperfecta Deformities, Journal of Pediatric Orthopaedics: May/June 2019 - Volume 39 - Issue 5 - p e392-e396
[2] Cho, T-J., et al. "Fracture in long bones stabilised by telescopic intramedullary rods in patients with osteogenesis imperfecta." The Journal of bone and joint surgery. British volume 93.5 (2011): 634-638.

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

The FD 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 under the protection of an Ankle-Foot Orthoses (AFOs) or a Knee-Ankle-Foot Orthoses (KAFOs) braces.

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 FD implant last?

It depends on the age of the patient. In a very young patient, the rod may have to be exchanged for a larger one due to bone growth. Otherwise, the FD Nail will only need to be replaced if complications arise such as breakage, migration or recurrence of deformity. Otherwise, it is recommended to remove or replace the nail after 5 years of implantation to ensure good 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 with your surgeon. Device removal should be followed by adequate postoperative management.

Is there anything that could affect the lifetime of the FD 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 instruction 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.

Is there any manufacturing residual that could pose a risk?

The FD is meticulously decontaminated following a cleaning 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 FD 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