PATIENT INFORMATION LEAFLET

Lync®, osteosynthesis intramedullary implants

Your surgeon has implanted a Lync® implant and provided you with the associated Implant Card. Please see below the main related information.

☐ Ref. CM010030 (UDI-DI: 03700879509631) – lync® S0° - Straight 

☐ Ref. CM010031 (UDI-DI: 03700879509648)– lync® S10° - Bent 

☐ Ref. CM010010 (UDI-DI: 03700879500423)– lync® M0° - Straight 

☐ Ref. CM010011(UDI-DI: 03700879500430) – lync® M10° - Bent 

☐ Ref. CM010040(UDI-DI: 03700879509655) – lync® DIP – Straight 

I. LYNC® IMPLANT INFORMATION

The Lync® implant is implanted to allow fusion of toes phalanxes for the correction of deformities or arthritis.

Raw material: Unalloyed titanium

Expected lifetime

The **lync®** implant is designed to remain in your body and is not intended to be explanted unless required by your surgeon. It must ensure its function during the bone consolidation period, that takes usually around 3 months after implantation.

Precautions and warnings

Follow your surgeon's recommendations for post-operative follow-up protocol. It is not recommended to load the treated toe immediately after the operation. If necessary, immobilization might be necessary during the bone consolidation.

The materials used in the implant may interfere with medical MRI/CT scans. The safety of the device, including heating or migration, has not been assessed in a magnetic resonance environment.

BE SURE TO INFORM THE MEDICAL STAFF OF THE PRESENCE OF AN IMPLANTED DEVICE IN THE EVENT OF AN EXAM OF THIS NATURE.

Possible side effects:

- Pain
- Pseudoarthrosis and non-union
- Allergic reaction to Titanium

In case of complication, it might be necessary to remove the implant. Please refer to your surgeon.

II. LYNC® IMPLANT CARD: MEANING OF SYMBOLS

Please see below the meaning of the symbols displayed on your implant card.

	Patient information website	REF	Device reference
	Name and address of the manufacturer	MD	Device name
LOT	Unique Device Identifier	UDI	UDI as AIDC or Human Readable

III. ADVERSE EVENT REPORTING

EUROPE

Any serious incident in relation to the implant shall be reported to the manufacturer and to your national regulatory authority for health products.

For additional information regarding Lync® implant, please refer to the Summary of Safety and Clinical Performances (SSCP) publicly available :

- On Eudamed website, by using the Basic UDI-DI: 370087950TF2B04020008 Eudamed Website: https://ec.europa.eu/tools/eudamed/#/screen/search-device

- On request to Novastep (via e-mail) until EUDAMED is fully functional: regulatory-InfFA@enovis.com

Access to our patient webpage:

AUSTRALIA

Any serious incident in relation to the implant shall be reported to the manufacturer and to Competent Authority: TGA.

TGA Website: Reporting adverse events for medical devices | Therapeutic Goods Administration (TGA)

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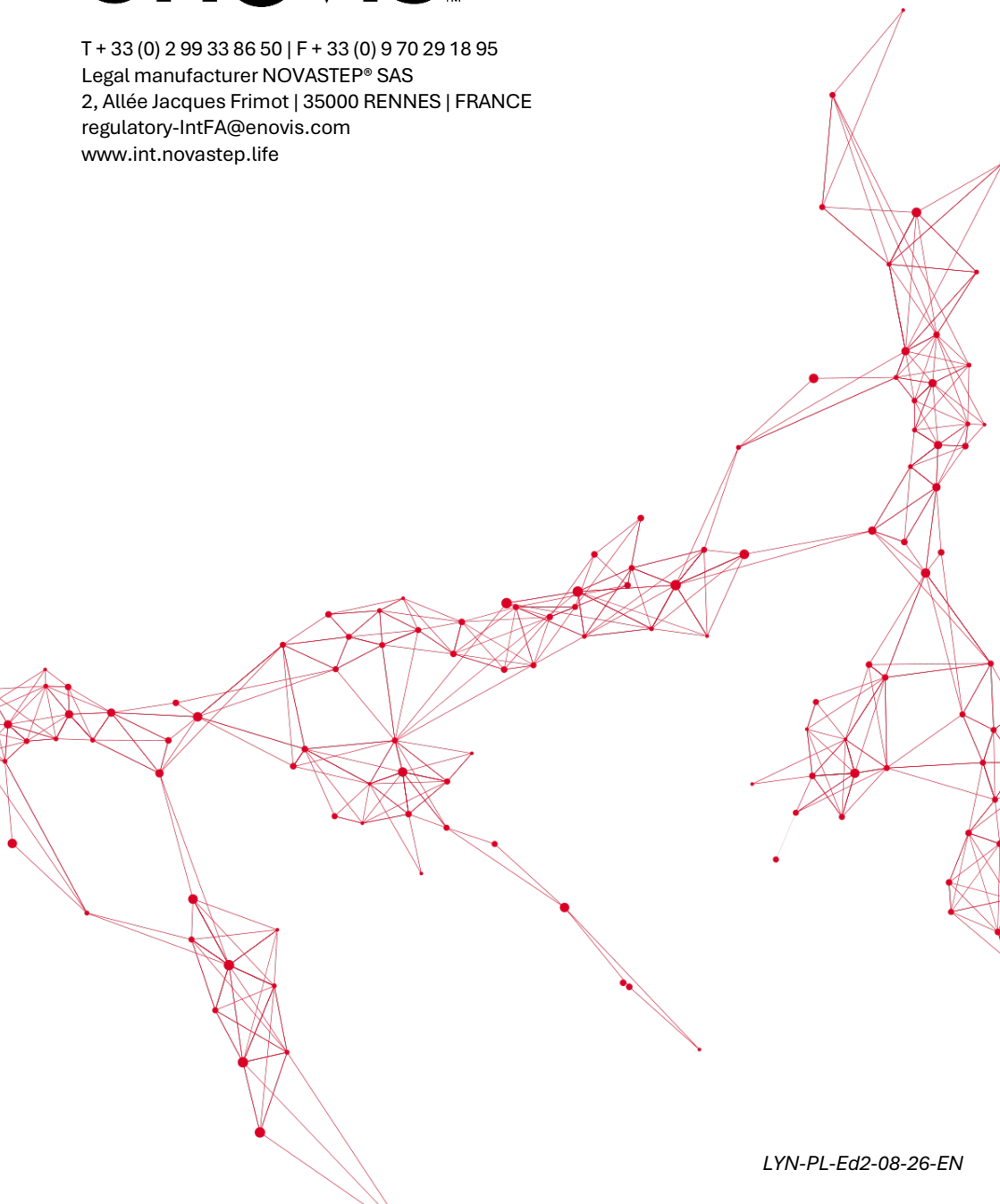
www.int.novastep.life



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