novastep®
Your foot & ankle company

PATIENT INFORMATION LEAFLET

Lync®, Intramedullary implant for hammertoe correction

READ CAREFULLY THIS LEAFLET BEFORE SURGERY
IT CONTAINS IMPORTANT INFORMATION

What is in this leaflet:

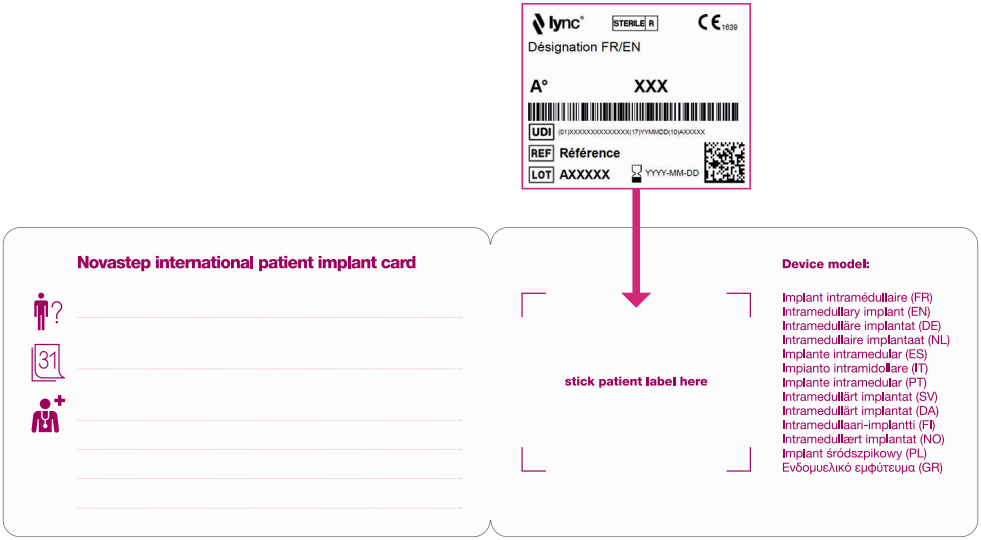
I. INDICATIONS FOR IMPLANT CARD COMPLETION AND USE

Instruction for completion:

The below information should be filled by the healthcare institution/provider.

Patient Name or ID	Date of implantation	Healthcare center or doctor

In addition, once implanted, stick one of the 5 patient labels on the implant card, as described below:



Logotypes signification:

	Website with information for patients
	Name and adress of the manufacturer
LOT	Lot number / batch code

REF	Device reference
MD	Device name
UDI	UDI as AIDC or Human Readable

II. INFORMATION ABOUT DEVICE IMPLANTED

Your surgeon can tick the box corresponding to the device you have been implanted with:

☐ Ref. CM010030 – Lync® S0° - Straight 

☐ Ref. CM010031 – Lync® S10° - Bent 

☐ Ref. CM010010 – Lync® M0° - Straight 

☐ Ref. CM010011 – Lync® M10° - Bent 

☐ Ref. CM010040 – Lync® DIP – Straight 

Materials: Anodized pure titaniumT40 grade 2.

III. INTENDED USE

Lync® Intramedullary implant is intended for inter-digital fusion of fingers and toes and small bone fusion. It is particularly indicated for:
- Proximal Interphalangeal arthrodesis: fusion of the first joint of the small toes for the correction of the hammertoe / claw toe deformity;
- Proximal Interphalangeal arthrodesis or Distal Interphalangeal arthrodesis: fusion of the first or second joint in the digits of the foot or the hand.

These implants are intended for adults and teenager patients.

Your surgeon can give more details. The decision to implant is left to your surgeon after evaluation of the risks/benefits balance and after discussion between you and your surgeon.

IV. WARNINGS AND PRECAUTIONS

Precautions:

- Follow your surgeon's recommendations for post-operative follow-up protocol. Immediate load-bearing just after the operation is not recommended. Immobilization might be necessary during osteosynthesis process, that generally takes between 6 to 8 weeks.
- The follow-up treatment as well as the decision of whether to retain or explant the implant is the responsibility of your surgeon. In case of complications, it might be necessary to remove the implant.
- Implants are designed to remain in the body at long term but can be removed if needed, at surgeon's discretion.
- The implants contain metals which may provoke an immune system response characterized by an allergic reaction. In case of any suspicion of sensitivity to the device, carry out preoperative tests.
- Never perform an intramuscular injection near the implant.
- The device is radio-opaque. Its correct positioning may be verified by X-ray inspection.

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.

PLEASE INFORM PERSONNEL ABOUT THE IMPLANTED DEVICE.

You must be informed about the factors that could compromise the success of the surgery and post operative results:

- Metabolic disease reducing the patient's resistance or leading to progressive bone degradation.
- Localized bone tumors.
- Severe bone deformity causing incorrect positioning of the implants or a weakened attachment.
- Severe osteoporosis.
- The practice of high-risk sports or activities exposing the implant to excessive or repeated stress.
- Bone disease, systemic or metabolic disorders and infectious diseases.
- Senility, mental disease, addictive behavior.
- Overweight.
- Risk of incompatibility with other implants.
- Risk of articular conflict.

V. DEVICE EXPECTED LIFE TIME

The Lync® intramedullary implants must ensure their function during 6 to 8 weeks which corresponds to the osteosynthesis period.
The removal of the Lync® intramedullary implants can be done, at surgeon's discretion.
The device's lifetime corresponds to its implantation duration.

Please refer to the surgeon advice for the follow-up.

VI. CONTRA-INDICATIONS

The conditions listed below are not recommended:
. Severe muscular, neurological or vascular deficiency in the extremity concerned;
. Bone destruction or poor bone quality, likely to impair implant stability;
. Known or suspected allergy to any of the device components;
. Pregnancy;
. Diabetes;
. Acute or chronic infections.

These conditions should be discussed with your surgeons. Any pathology, even if not listed above, must be mentioned to your surgeon beforehand.

VII. POSSIBLE SIDE EFFECTS

You must be informed about the side effects in relation to the device that might occur.
Please consult your surgeon if any doubt.

Possible side effects during implantation of osteosynthesis devices:
. Delayed consolidation, pseudoarthrosis.
. Rupture or deformation of all or part of the implant.
. Infection, bruising, venous thrombosis, pulmonary embolism, cardiovascular problems.

REPORTING ADVERSE EVENTS:

Any serious incident in relation to the device shall be reported to the manufacturer and to the Competent Authority.
TGA website: https:/www.tga.gov.au

KEEP THIS LEAFLET

If you have any further questions, ask your surgeon.
If you experience any side effect including possible side effects not listed in this leaflet, talk to your surgeon.

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