THORACIC RECONSTRUCTION SYSTEM TRIONYX® INSTRUCTIONS FOR USE

Fabricant : NEURO FRANCE Implants
ZA LE BOURG – 25 RUE DES ECOLES
41160 LA VILLE AUX CLERCS - FRANCE
Phone: (33) 02 54 80 90 90
Fax: (33) 02 54 80 83 33
Email: neurofrance@neuro-france.net

Important information for the medical practitioner:
The practicing physician should carefully read the instructions and advice as well as the recommendations before using the thoracic reconstruction system TRIONYX®.

1. Description of the system

- The TRIONYX® system is composed of sternal plates, sternal staples, and long rod-staple junction screw with long brake insert.
- The sternal plates and the long rod-staple junction screw with long brake insert are made of Ti 6-Al 4-V titanium alloy according to the ISO 5832-2 standard. The sternal staples are made of T40 pure titanium according to the ISO 5832-2 standard. The brake insert are made of PEEK Optima®.
- The TRIONYX® system is available in non-sterile condition.

Origin neither human, nor animal – Non absorbable.

2. Intended use

The TRIONYX® system is intended for massive reconstruction after sternal and/or manubrial removal. It allows the protection of the vital organs (heart, large vessels, and lungs).

3. Expected clinical performance

- Restoration of thoracic rigidity in over 90% of cases, limiting post-operative morbidity and mortality.
- Preservation of ventilatory mechanics in over 90% of cases.
- Prevention of paradoxical respiration in over 90% of cases.

4. Indications

The TRIONYX® thoracic reconstruction system is intended for the treatment of sternal disorders in adults, such as:

- Sternal and/or manubrial bone tumour.

5. Contraindications

The treatment of choice is determined by the practitioner who has the required skills, knowledge and experience.
Factors which may compromise the implantation include (but are not limited to):

- Severe osteoporosis
- Active infectious process or significant risk of infection (compromised immune system)
- Morbid obesity
- Pregnancy
- Hyperactivity
- Mental illness
- Brittle bone disease
- Suspected or documented allergy or intolerance to the constituent materials of the implant
- Any case not described in the indications.

6. Use

- Please consult the surgical technique before use.
- Anterior surgical approach.

7. General precaution

The surgeon is solely responsible for the surgery. The surgeon should carefully review the guidelines, advice and recommendations before using the thoracic osteosynthesis system TRIONYX®. To obtain a stable fixation and without constraint, he must know perfectly the handling of the ancillary material to preform staples to reproduce the healthy thoracic anatomy at the best. **This forming phase is essential to limit or even eliminate any system failure (bone fracture and/or fracture of the implant, unscrewing of the screw of the staple on the plate) due to excessive torsion, an insufficient modeling bringing excessive stress on the implant, and an insufficient tightening of the rod-staple junction screw.**

8. Warning / Operating precautions

- The surgeon must be fully experienced in the use of the TRIONYX® implants, the application method, the instruments and the surgical technique.
- The components of the TRIONYX® range must not be associated with devices from other ranges.
- The use of other ancillary and/or an incorrect use of ancillary required to fit the TRIONYX® implants is highly proscribed because it may lead to a deterioration of implants that will limit the optimization of the desired function.
- Although allergic reactions are extremely rare, it is recommended to make an allergy check-up on patients with a particularly strong predisposition to allergies.
- The TRIONYX® system must be used under perfectly sterile conditions.
- The implants are for single use only and should never be reused. Reuse may lead to the degradation of device performances, contaminations and cross-infections.
- All implants extracted from the patient, damaged or having been incorrectly used should be disposed of once it has been soiled or contaminated with blood or body tissues.
- There are no known risks of mutual interferences between the implant and other medical devices.
- The implants are made of titanium alloy Ti 6-Al 4-V, T40 titanium or PEEK Optima® which are non-magnetic materials. Patients can be exposed to electromagnetic or magnetic fields without any real risks.
- The patient must notify that he has an implant before any exposure to electromagnetic or magnetic fields.
- The patient has to be informed of the risks of the surgical intervention by the medical staff (contraindications, adverse effects/complications, precautions, limited lifetime of the medical device). The patient should follow the advices and recommendations from the surgeon (radiological examinations, limited physical activities, …) during the postoperative phase.
- It is recommended to limit physical activity after the surgery or for life to allow bone fusion. If not, the implant may break or otherwise be damaged necessitating revision surgery. The implant should not be exposed to extreme movements of mechanical vibrations for example.
- All modifications (aspect, pain…) at the implant site must be reported to the medical practitioner. The medical practitioner should also be informed of all type of incidents like a fall for instance, even when there are no visible signs at the implant site.

9. Adverse effects / complications

The potential adverse effects or complications are :

- Superficial or deep infection of the implantation site, skin necrosis
- Hypersensitivity reaction to the implants
- Pain, sensation of discomfort or stiffness
- Vascular, cardiac or pulmonary damage due to the surgical procedure
- Displacement, fracture and/or expulsion of the implant requiring a further procedure
- Material and/or bone stress fracture
- Death.

10. Storage conditions

Store the implant in a dry environmment and at room temperature.

11. Sterilization

The TRIONYX® **implants** and the **ancillary** are supplied non-sterile. They must be sterilized under the responsibility of the person responsible for sterilization in the healthcare facility. Sterilization must be carried out in an autoclave.

Method: Sterilization by steam (moist heat)
Recommended minimum duration: 18 minutes
Recommended minimum temperature: 134°C

It is recommended to check the sterilization indicators and the integrity of the packaging before opening.

12. Disposal of implants

Implants must be disposed of according to the relevant hygiene and waste disposal guidelines of the healthcare facility for medical/biohazard waste.

13. Additional informations

Put on the market: June 2016
Additional informations can be obtained from NEURO FRANCE Implants.

Examples of symbols used on the labels:

LOT	Batch number	NON STERILE	Non-sterile
REF	Catalogue number	2	Single use
	Manufacturer	CE 0459	CE marking with Notified Body identification number
	Warning ! Consult accompanying documents		

Claims:
All claims or malfunction reports should be addressed immediately by phone, fax, email or letter to NEURO FRANCE Implants.

Please read the instructions carefully.
These implants are class IIb medical devices and are marked :

CE 0459

Our notified body is the GMED.