THORACIC OSTEOSYNTHESIS SYSTEM
ThoRib® / ThoRib® PECTUS
INSTRUCTIONS FOR USE

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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 osteosynthesis system ThoRib®/ThoRib® PECTUS.

1. Description of the system

- The ThoRib® system is composed of different types of staples and rods, ThoRib® connectors (spinal connection), rod-staple junction screws (normal or long) with brake insert (normal or long), and locking-nut screws. The ThoRib® PECTUS system is composed of a Pectus staple, PECTUS reinforced rods and long rod-staple junction screw with long brake insert.
- The various rods of the system, the ThoRib® connectors, the rod-staple junction screws (normal or long) and the locking-nut screws are made of titanium alloy Ti 6-Al 4-V according to ISO 5832-3 standard. The various staples of the system are made of T40 pure titanium according to ISO 5832-2 standard. Only the brake insert (normal or long) on the rod-staple junction screws (normal or long) is made of PEEK Optima®.
- The ThoRib® and ThoRib® PECTUS systems are both available in non-sterile and sterile condition.

Origin neither human, nor animal - Non absorbable.

2. Intended use

ThoRib® implants are intended for thoracic reconstruction after rib removal. They allow costal bridging and the repair of rib fractures in the case of traumas. ThoRib® PECTUS implants are intended for the treatment of deformities and malformations of the chest wall (Pectus excavatum, carinatum and arcuatum).

Note: Under no circumstances should ThoRib® implants be used to treat deformities and malformations of the chest wall. Only the PECTUS range is intended for this type of indication.

3. Expected clinical performance

Restoration of thoracic rigidity in over 90% of cases, following:

- Wide resection of a chest wall bone tumour
- Thoracic trauma.

Correction of sternal deformity in over 90% of cases.

4. Indications

The ThoRib® thoracic osteosynthesis system is intended to be used for:

- ► Severe chest trauma
- ► Chest wall and/or sternal tumour

The ThoRib® PECTUS thoracic osteosynthesis system is intended to be used for:

- ► Deformities and malformations of the chest wall (pectus excavatum, carinatum and arcuatum)."

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
- ThoRib® PECTUS System should not be used in children under 17 years old (past puberty)
- 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 ostheosynthesis system ThoRib®/ThoRib® PECTUS. To obtain a stable fixation and without constraint, he must know perfectly the handling of the ancillary material to preform staples and rods (thoracic staple, PECTUS staple, thoracic rod, PECTUS rod) to reproduce the healthy 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 rod) 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 ThoRib® and ThoRib® PECTUS implants, the application method, the instruments and the surgical technique.
- The components of the ThoRib® or ThoRib® PECTUS 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 ThoRib® and ThoRib® PECTUS implants is highly proscribed because it may lead to a deterioration of the 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.
- In the case of an extensive ThoRib® PECTUS system, it is recommended to use maximally 4 Pectus staples and 2 Pectus rods.
- The ThoRib® 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 advice 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 implants in their original packaging in a dry environment and at room temperature, UV light protected.

11. Sterilization

- Implants and ancillary supplied non-sterile

The ThoRib® or ThoRib® PECTUS **implants** and the **ancillary** supplied non-sterile 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.

- Implants supplied sterile

The ThoRib® or ThoRib® PECTUS **implants** are delivered sterile under double vacuum packaging in a fully-labelled filmed cardboard box. Sterilization is effected by gamma radiation at a dose of 25 kGy minimum by a cobalt-60 source.

> **Caution:** Do not use this implant in the following case: loss of vacuum indicating a deterioration of the packaging, which implies that the sterile barrier has been compromised.

It is recommended to check the integrity of the packaging at all levels before use and also to check the expiration date.

Product labels are placed inside the packaging to ensure traceability in healthcare facilities.

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 Information

Put on the market: June 2012 (non sterile) / February 2015 (sterile)
Additional informations can be obtained from NEURO FRANCE Implants.

Examples of symbols used on the labels:

STERILE R	Sterile by radiation		Manufacturer
REF	Catalogue number		Manufacturing date
LOT	Batch number		Do not use if package is damaged
	Use before		Warning ! Consult accompanying documents
	Single use	CE 0459	CE marking with Notified Body identification number
NON STERILE	Non-sterile		

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.