

CERVICO-THORACIC OSTEOSYNTHESIS SYSTEM CTJ (CTJ+ INCLUDED) INSTRUCTIONS FOR USE

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Important information for the practitioner :

The practitioner should carefully study the guidelines and advice and recommendations before using cervicothoracic osteosynthesis CTJ (CTJ+ included).

1. Description of the material

- The CTJ system consists of monoaxial and polyaxial thoracic screws, hooks, 5 mm diameter bars, articulated cross links, connectors, and nuts. The CTJ + system consists of CTJ + monoaxial screws, 3mm diameter bars and CTJ + nuts.
- The entire system is made of titanium alloy Ti 6-Al 4-V in accordance with the ISO 5832-3 standard.
- The CTJ system is available in a non-sterile state.

Origin neither human nor animal - Non absorbable.

2. Proper Usage

The CTJ osteosynthesis system is intended to perform a fixation between vertebrae by posterior cervico-thoracic arthrodesis. The CTJ + osteosynthesis system is intended to achieve a reduction of thoracic vertebral deformations anterolaterally. These systems are made by assembling interconnected components. The Implants are not intended to withstand anatomic mechanical stresses beyond one year without bone grafting and / or anterior fusion.

3. Expected Clinical Performance

- Decreased clinical ODI and VAS pain scores by 15% at 12 months post operatively
- Stabilization of the operated spine level (s).

4. Indications

The CTJ cervico-thoracic osteosynthesis system is intended for the reduction, fixation of spinal disorders in children aged 12 and over or in adult such as :

- Degenerative spine
- Spinal deformities.
- Tumor
- Trauma

The CTJ + cervico-thoracic osteosynthesis system is intended for the temporary or permanent dynamic reduction of spinal disorders, anterolaterally, in children aged 12 and over such as :

- Spinal deformities.

5. Contraindications

The choice of treatment belongs to the practitioner who has the training and experience necessary for it.

Factors compromising implantation (non-exhaustive list) :

- Severe osteoporosis
- Active infectious process or significant risk of infection (immunity compromised)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy

- Hyperactivity
- Mental illness
- Any other medical or surgical condition that would exclude the potential benefit of spinal implant surgery.
- Anomalies, elevation of the rate of sedimentation unexplained by other diseases, increase in the number of white blood cells.
- Allergy or intolerance to the materials constituting the suspected or documented implant.
- All cases where implant components chosen for use would be too large or too small to achieve a positive result.
- Any patient with insufficient tissue coverage at the operative site, or inadequate bone stock or bone quality.
- Any patient in whom the use of the implant would interfere with the expected anatomical structures or physiological performance.
- Any patient not wishing to follow postoperative instructions.
- Severe bone resorption, osteomalacia
- Any case not described in the indications.

6. Use

- Consult the surgical technique before each use.
- The surgical approach is the posterior or anterolateral (only with CTJ +).
- The choice of use of the different screw sizes of the CTJ system must take into account the patient's corpulence and the level to be osteosynthesized. The practitioner is strongly advised to use pedicular implants with diameters and lengths adapted to the area to be osteosynthesized.

7. General warning

The surgeon is solely responsible for the operation. He should carefully study the guidelines and advice as well as recommendations before using CTJ implants. To have a stable fixation, he must know perfectly the handling of ancillary equipment and recommendations for use.

8. Warnings / Operating Precautions

- The surgeon must be fully familiar with CTJ implants, the method of application, the instruments and the surgical technique.
- The components of the CTJ range must not be associated with devices of other ranges.
- The use of different ancillary components and / or incorrect use of the ancillaries necessary for the installation of the CTJ system is strongly contraindicated since this can lead to damage to the implants and thus limit the optimization of the desired function.
- Although allergic reactions are very rare, it is recommended to check the allergic level of the patients with particularly strong ground.
- The CTJ system must be used under perfectly sterile operating conditions.
- Our implants are for single use and should never be reused. Reuse can result in decreased device performance, contamination, and cross-infection.
- Any implant removed from the patient, damaged or misused, should be removed as soon as it has been in contact with blood or body tissue.
- There is no known risk of reciprocal interference between the implant and other medical devices.
- The implants are made of titanium alloy Ti 6-Al 4-V which is a non-magnetic material. They pose no real risks to patients when exposed to electromagnetic and magnetic environments.
- The patient must declare that he is an implant holder before exposure to electromagnetic and magnetic environments.
- The patient will be informed by the medical staff of the risks generated by the surgical procedure (contraindications, adverse effects / complications, precautions to take, limited life of the device). He must also respect the surgeon's advice and recommendations (radiological checks, limited physical activity, etc.) during the postoperative phase.
- For proper consolidation, it is advisable to limit physical activity after placing the medical device and carrying heavy loads. Otherwise, the implant could rupture or damage which would require re-operation. The

implant should not be exposed to excessive movements of mechanical vibrations for example.

- Any changes (appearance, pain,...) at the implanted site should be reported to the practitioner. All types of accidents such as a fall, for example, should be reported to the practitioner even if no external sign at the implanted site is visible.

9. Undesirable effects / complications

The undesirable effects or potential complications are :

- Neurological pain
- Durotomy
- Risk of infection of the implantation site
- Neurological and / or vascular damage related to the surgical procedure
- Pedicular and / or laminar fracture
- Fatigue fracture of the material
- Death.

10. Implant storage condition

The implants should be stored in a dry place at room temperature.

11. Sterilization

CTJ implants and ancillaries are delivered non-sterile. They must be sterilized under the responsibility of the sterilization manager of the health facility. Sterilization must be performed by autoclaving.

Method: Sterilization with steam (moist heat). Minimum recommended time: 18 minutes

Minimum recommended temperature: 134° C

It is recommended to check the sterilization indicator (s) before opening and the integrity of the sterilization packaging.

12. Implant Disposal

The disposal and rebut of the implant follows the same procedures in the facility as hospital waste.

13. Additional information

Date of placing on the market : April 2010

Further information can be obtained from NEURO FRANCE Implants.

Explanation of symbols used on product labeling :

	Lot Number		Non-sterile
	Catalog Number		Do not reuse
	Manufacturer		CE marking with the Notified Body's identification number
	Attention! Consult attached documentation		

Complaints :

Any complaint or report of malfunction must be made immediately by telephone, fax, email or mail to NEURO FRANCE Implants.

Please read the instructions carefully.

These implants are class IIb medical devices and are marked :

Our notified body is the GMED.