EUROS
COMMITTED TO CARE

E.SPINE® -E.SPINE® TANIT®

INSTRUCTIONS FOR USE

NI.DAU1026A1-2025/06/06



0. REVISION

Version & date	Modifications	URL internet
A1 2025/06/06	Creation	-

1. DESCRIPTION

> The E.SPINE® system including the E.SPINE® TANIT® system is a set of implants for correcting and temporarily stabilizing the thoracolumbar-sacral spine (T1-S1) using a posterior approach, in order to achieve arthrodesis. The system is intended for skeletally mature or immature patients and shall be implanted by healthcare professional.

> The E.SPINE® system is composed of:

- Pedicle screws available in various lengths and diameters, in a standard or reduction version. The pedicle screws as provided are monoaxial, and they can be converted into polyaxial screws in accordance with the operating technique instructions;
- Hooks available in different shapes tailored to fit the fixation site, and in different heights;
- Locking screws;
- Ø5.5 rods available in different lengths, different materials, and in straight or pre-curved versions;
- Ø6 pre-bent rods available in different materials;
- Rod-Connector available in straight or pre-bent version and in different lengths compatible with Ø5.5-6 rods;
- Transverse links available in different shapes and different lengths;
- Connectors available in different shapes (standard, reduced, end-to-end, side-to-side, for Ø5.5 rods and Ø5.5-6 rods);
- E.SPINE® TANIT® ilio-sacral fixing system comprising:
  - Ilio-sacral connectors available in standard, standard wide, reduction, wide reduction, closed and wide closed ;
  - Ilio-sacral screws available in different lengths.

> This set of components comprises a modular system, allowing the surgeon to adjust the assembly of the system to the anatomy and the pathology of the individual patient.

> The materials used to manufacture this product satisfy current standard requirements (see the end of this leaflet).

2. INDICATIONS

> The E.SPINE® system is intended for posterior spinal surgery for the following indications:

- Adult deformities (adult degenerative scoliosis, hyperkyphosis);
- Pediatric deformities (neuromuscular scoliosis, congenital malformations, isthmic spondylolisthesis, Adolescent Idiopathic Scoliosis, syndromic scoliosis);
- Degenerative pathologies (disc herniation, degenerative disc disease, stenosis, listhesis);
- Trauma (lumbar and thoracic) ;
- Tumors (primary or metastasis);
- Revision surgery.

> It is worth noting that, certain implant components from E.SPINE® system, as PEEK rods, are specifically excluded for use in pediatric patients. PEEK rods are preferred for arthrodesis on few levels.

> The E.SPINE® TANIT® iliosacral system is intended for posterior spinal surgery for the following indications:

- Severe paediatric neuro-muscular deformities (neuromuscular scoliosis).

3. CONTRAINDICATIONS

The list of contraindications includes:

- Acute or chronic infections, local to the operative site or systemic;
- Signs of local inflammation;
- Pathological obesity;
- Pregnancy;
- Non reducible scoliosis;
- Patients whose physical, mental or medical condition would prevent a positive surgical outcome or would lead to a risk behavior for the product;
- Suspected or proven allergy or intolerance to the implanted materials;
- Inadequate tissue coverage over the operative site;
- Severe osteoporosis, inadequate bone stock, poor bone quality or anatomical definition likely to

affect the stability of the devices;
- Use in combination with already implanted competitive systems;
- Patient unwilling to cooperate with the post-operative instructions;
- Total sacral agenesis (for E.SPINE® TANIT® system).

4. WARNINGS / CAUTIONS

> The use of these products is reserved for surgeons with sufficient skills and experience in spinal surgery. The product must be used under the conditions specified by the manufacturer for the designated purpose.

> Prior to use, surgeons shall be trained to the assembly and installation techniques and shall have read EUROS documentation. Insertion must be carried out in accordance with the recognised surgical technique. The surgeon is responsible for ensuring that the operation proceeds smoothly and correctly.

> Compliance with preoperative and intraoperative procedures, including knowledge of surgical techniques and the selection and proper positioning of devices, are important factors in the successful use of this device or system by the surgeon. Furthermore, the selection of a suitable patient together with the latter's cooperation are essential factors for a successful outcome.

Patients who present contra-indications must be turned down.

> The surgeon should take into consideration factors that may affect the performance of the device or system:
- The patient's weight, activity level and occupation
- The patient's bone state (osteoporosis, tumors);
- The patient's allergies;
- The patient's diseases and disorders (infectious diseases, mental or neuromuscular disorders);
- The patient's addiction (drug, alcoholism or nicotine).

The surgeon must assess the patient's physical and mental state and decide whether the latter is suited to having the device fitted, can stand up to the operation and follow a suitable rehabilitation program.

> The manufacturer is not liable for any complications arising from incorrect diagnosis, incorrect choice of device, the incorrect assembly of components of the device and/or incorrect operating techniques, the limitations of treatment methods or inadequate aseptic conditions.

> Reporting an incident:

Any healthcare professional wishing to make a complaint or express their dissatisfaction in terms of the quality, identification, reliability, safety, efficacy and/or the performance of EUROS device must inform EUROS.

In the case of a serious incident or risk of a serious incident liable to lead to or that may have led to death or to severe deterioration in the state of health of a patient or user, EUROS must be notified immediately by phone, fax or email (complaints@euros.fr). The competent authority of the Member State in which the user/or patient is established must be notified in case of a serious incident in relation to the device.

For any additional information involving the devices, please contact EUROS or your distributor.

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5. PRECAUTIONS

> Caution should be exercised when handling the devices. The devices must not be scratched or damaged in any way whatsoever. Damaged devices and those with damaged packaging must not be used and should be returned to EUROS.

> Devices must be kept in its original sealed packaging in a clean, dry location. Store the sterile products between 10 and 30°C. During transport, temperatures of up to 40°C for short periods can be tolerated. The packaging must not be directly exposed to the sun's rays or extreme temperatures.

> Devices are for single use only and must not be reused. The reuse of a single use device that has come into contact with blood, bone, tissue or other body fluids may cause injury to the patient or user. The risks associated with the reuse of a single-use device may include, but are not limited to, mechanical failure and the transmission of infectious

agents.

> Devices must only be used with the instruments specified by EUROS in the reference surgical technique.

> Metal rods must not be bent several times. Repeated bending poses risks of premature rod rupture.

> If growth assembly is used, repeated locking of the domino threaded pins to the rod in a concentrated area may create incipient cracks.

> In the event of any disposal due to an error of storage or use, or to excision, devices should be disposed of following the disposal method for hospital waste in accordance with the procedures in force in the establishment.

> Using all means available such as X-rays and templates, the surgeon must ensure that, by guaranteeing the concordance of scales between the X-rays and the templates, the implantation of the device will cause no risks of impingement with other implants already in the patient's body.

6. EXPECTED PERFORMANCE AND BENEFITS

The E.SPINE® implants are osteosynthesis devices which are used to stabilize the spine during the period of healing of bone. During this period the device performances are insured;

> Technical performances

- Resisting to mechanical loads during the time to fusion under normal conditions of use:
  - As anchors: resist the pullout loads, resist the per-operative loads (screw insertion, removal);
  - As link between vertebras: Resist the flexion, traction and torsion loads of the spine ;
  - As assemblies/interconnections between different components: Resist the flexion, traction and torsion loads of the spine.
- Enabling stabilization of the spine and maintain correct alignment of the spine:
  - Being anchored to the vertebras;
  - Rigidly linking the vertebras together while providing load sharing construct.
- Being adapted to all deformities and anatomies:
  - Dimensions of the implant must be compatible with small and large stature patients and must avoid any prominence when used in deformed spine.
- Answering the implantation constraints:
  - Biocompatible ;
  - Being easily cleaned and sterilized;
  - Being easily implantable and removable by posterior approach.

> Clinical performances

- Improvement and/or maintain of coronal Cobb angle,
- Restoration and/or maintain of sagittal balance;
- Fusion.

> Clinical benefits

- Restoration of vertebral column stability and physiological position;
- Decreased pain;
- Quality of life improvement.

7. ADVERSE EFFECTS / RESIDUAL RISKS

The list of potential adverse events includes :

- Migration of the implant;
- Breakage of the implant;
- Patient's reaction to a foreign body;
- Instability and degeneration of adjacent segments;
- Pseudoarthrosis;
- Vertebral fracture;
- Superficial and/or deep infection;
- Injury to surrounding soft tissues (vascular, nervous, visceral, muscular);
- Dural leakage;
- Neurological injury ;
- Surgical complications (thrombosis, pulmonary embolism, myocardial infarction, bursitis, seroma, hematoma, difficulty healing);
- Pain;
- Superficial wounds;
- Correction loss/wrong spinal balance (Flatback syndrome);
- Delayed wound union;
- Inflammatory reactions;
- Contamination;
- Formation of erythema or edema;
- Implant rejection;
- Implant loosening;

- * absorption of a toxic substance by the body, cellular damage, convulsion;
- *Cancer, tumor, immunological, and neurological disorders, genetic defects, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity.

Treatment of certain undesirable side effects could necessitate additional surgery.

**Note: these residual risks are related to the device biocompatibility. The biological risk assessment report demonstrated that the biological risk was controlled and considered acceptable for the EUROS products.*

8. INFORMATION TO BE PROVIDED TO THE PATIENT

> The surgeon must inform the patient that the device's safety and durability will be affected by her/his weight, behaviour, namely the physical activities.
Before leaving the care facility, the patient must receive instructions and warnings from the surgeon regarding the treatment and therapy to follow, and any restriction on physical and sporting activity or practices.
The surgeon must inform the patient of all physical and psychological limitations inherent in the use of the device, as well as the need for regular medical follow-up.

> MRI safety: The surgeon must inform the patient the devices are MR unsafe.

> The surgeon must inform the patient to report any incident in relation to the devices to the surgeon.

> CMR substances: The surgeon must inform the patient that for the CoCr rod contain more than 0.01% (weight/weight) of cobalt identified as a carcinogenic and toxic for reproduction substance according to the regulation 1272/2008, 1907/2006 and 2020/2096. However, the cobalt chromium alloy has long clinical history and remains more performant than rods in other materials when confronted to scoliosis that requires stable correction.
Our biological risk assessment report demonstrated that the biological risk was controlled and considered acceptable.

> The surgeon should inform the patient about the residual risks available in section 7 of these instructions for use.

9. CHOICE OF DEVICE / DEVICE COMPATIBILITY

> The selection of the size or shape of the implants for each patient is essential for the success of the procedure.

> The surgeon is responsible for the choice of implants, depending on the patient and the size of their vertebrae and on the correction sought by the surgeon. This choice may require preoperative planning.
The surgeon may also make use of our instrumentation to help determine the optimum implant size to use.

> Information on device size and shape is provided on the device packaging and on the device itself. The surgical team must check this information before the surgery.

COMBINATION OF DEVICES

> The E.SPINE® system can be combined only with compatible implants in accordance with the manufacturer's recommendations and must not be used with other posterior stabilization systems. The only combinations of prosthetic elements allowed are those of EUROS devices.

> Ø6 rods are only compatible with connector-rods and Ø5.5-6 connectors.

> Final locking of PEEK rods must be performed using the 6.5Nm self-breaking locking screws.

> Correct locking of the anchors (hooks, pedicle screws, etc.) on the rods must be checked:

- The rod must be locked by locking screws on its smooth section: avoid the hexagonal section for metal rods; avoid locking on a strongly curved section of the rod;
- The rod must protrude on either side of the interconnection with the anchorage points.

Partial locking or locking on the non-smooth section of the rod may lead to unintentional loosening.

10. MRI SAFETY INFORMATION

> MR unsafe: The devices have not been tested for safety and compatibility in the MR environment. The safety of the devices in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury. Patients with these devices should not be scanned.

11. CLEANING, DECONTAMINATION AND STERILIZATION

> E.SPINE® implants may be supplied sterile or non-sterile (which will be clearly marked on their labels).

> For instruments used to insert implants, see the relevant package leaflet for information on cleaning and sterilisation.

Sterile devices

> E.SPINE® implants delivered sterile are sterilised by gamma irradiation at a sterility assurance level (SAL) of 10^{-6}

> Inspect every package before use. Do not use the component if the integrity of the double envelope ensuring the maintenance of sterility has been compromised (loss of vacuum, damaged envelopes, damaged seal area), or if the expiry date has elapsed.

> Once the package has been opened, the device must never be re-sterilised. Any re-sterilisation may have adverse effects on the device materials and cause premature defects.

Non-sterile devices

> All E.SPINE® implants delivered non-sterile must be cleaned and sterilised before use. It is the responsibility of the healthcare facility to carry out the cleaning and sterilisation of the implant prior to its implantation, in accordance with the recommended method that follows.
If the device is delivered in packaging, the plastic envelope must be removed before any procedure.

> In order to maintain optimal functionality and safety of the device, it is essential to avoid: the use of metal brushes, scouring pads or objects that could impair the device, the use of chlorine-based chemicals, acids or organic or ammonia-based solvents.

Washer/disinfector cycle:

It is recommended that a cycle be run that is specifically for the inactivation of prions.

Step	Duration	Parameters	Agent used
Pre-washing	2min	Softened cold water <40°C	N/A
Washing	5min	Softened hot water 70°C	ALKA ONE
1st rinse	2min	Softened hot water	N/A
2nd rinse	2min	Reverse osmosis purified water	N/A
Thermal disinfection using a drying product	3min	93°C	DECONEX 64 NEUTRADRY
Drying	60min	110°C	N/A
Cooling	Minimum 2 min*		N/A

*2 minutes is given as a guide to avoid burns

In the case of patients with suspect or diagnosed TSE, the cleaning and decontamination procedure must be carried out in accordance with the instructions of Directive DGS/RI3/2011/449.

Sterilization cycle for medical devices:

Local or national specifications must be followed where steam sterilization requirements are stricter or more conservative than those listed in the table.

EUROS-approved sterilization conditions are listed in the table below:

Method	Type of Cycle	Pressure
Steam[1]	Pre-vacuum	3 bars
Temperature	Exposure time	Minimum drying time[2]
134°C	18 min	30 min

[1] Steam sterilization parameters recommended in accordance with Directive DGS/RI3/2011/449.

[2] Minimum drying times have been validated using sterilizers equipped for vacuum drying. Drying cycles using ambient atmospheric pressure may require longer drying times. Please refer to the manufacturer's recommendations.

NOTE:

The sterilizer manufacturer's operating instructions and instructions for load configuration must be followed absolutely.

12. ADDITIONAL INFORMATION

The Summary of Safety and Clinical Performance is available upon request (email: qualite@euros.fr ; Tel : +33 4 42 71 42 71).
E.SPINE basic UDI-DI: 37004372R003BH

13. MEANING OF THE SYMBOLS

List of symbols applicable for the implants covered by these instructions for use:

	Sterilized using irradiation Double sterile barrier system
	Do not reuse
	Do not re-sterilise
	Caution
	Non-sterile
	Batch code
	Keep dry
	Keep away from sunlight
	Storage temperature limitation
	Use-by date
	Do not use if package is damaged and consult the instructions for use
	Catalogue number
	Manufacturer
	Date of manufacture
	Consult the instructions for use
	Carcinogenic, mutagenic, toxic for reproduction or endocrine disruptor
	MR Unsafe
	Medical device
	UDI

14. MEANING OF THE ABBREVIATIONS

Qty: quantity - fr: French - en: English - it: Italian - es: Spanish - de: German - nl: Dutch – pt : Portuguese – no : Norwegian
CoCr: Cobalt-Chromium alloy
Ti6Al4V ELI : aluminum-vanadium alloy titanium
PEEK: Polyetheretherketone

15. MATERIAL

Pedicle screw, hook, looking screw, rod-connector, transverse link, connector, TANIT screw and connector	100% Ti6Al4V ELI (ISO 5832-3)
Rod	100% Ti6Al4V ELI (ISO 5832-3) Or PEEK LT1 6Ba Or CoCr (ISO 5832-12)

MATERIAL CHEMICAL COMPOSITION

Ti6Al4V ELI (ISO 5832-3 and ASTM F136) [%m/m]

C	Al	V	H
≤0.08	5.5 to 6.5	3.5 to 4.5	≤0.012
O	N	Fe	Ti
≤0.13	≤0.05	≤0.25	Balance

Co28Cr6Mo (ISO 5832-12 and ASTM F1537) [%m/m]

Cr	Mo	Ni	Fe	
26 to 30	5 to 7	≤1	≤0.75	
C	Si	Mn	N	Co
≤0.14	≤1	≤1	≤0,25	Balance

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