EUROS
COMMITTED TO CARE

NEMOST

INSTRUCTIONS FOR USE

NI.DAU1027A1-2025/12/19



EN

0. REVISION

Version & date	Modifications	URL internet
A1 2025/12/19	Creation	-

1. DESCRIPTION

> The NEMOST growing domino is a device designed to correct spinal deformation and maintain this correction during growth to minimize scoliosis progression.
The NEMOST growing domino is a device for paediatric use.

> The NEMOST growing domino consists of a rod that slides along the domino in one direction.

> This system must be combined with posterior anchors from the E.SPINE® range (pedicle screws, hooks and/or other rod connections). The assembly thus made constitutes a modular system, allowing the surgeon to adapt the assembly to the anatomy and pathology of the patient.

> The NEMOST growing domino is available in two growth reserve lengths. It should be implemented bilaterally.

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

2. INDICATIONS

The list of indications includes:

- idiopathic scoliosis ;
- congenital scoliosis ;
- neuromuscular scoliosis ;
- syndromic scoliosis .

This surgical treatment should only be considered in the case of progressive spinal deformation, which does not respond little or no to orthopaedic treatments, in a growing child (RISSER 0) and with first surgical intention.

3. CONTRAINDICATIONS

The list of contraindications includes:

- signs of local inflammation;
- acute or chronic, local or systemic infections ;
- non-reducible scoliosis ;
- pathological obesity ;
- allergy or intolerance to implanted materials;
- insufficiency or absence of tissue coverage.

The NEMOST implant should not be used in a spine that has already been instrumented or fused.

4. WARNINGS / CAUTIONS

> The use of this product 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:

- inadequate pedicle anatomy,
- trauma or tumours at the fixation zones;
- severe osteoporosis, bone destruction or poor bone quality;
- malnutrition;
- weight, level of activity;
- patients and/or parents (or the holder(s) of parental authority) who are not willing or unable to comply with the postoperative care instructions.

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.

> It is strongly recommended that an accurate clinical examination be performed to actively and passively assess the flexibility of the deformation and its reducibility (including potential pelvic obliquity) and to consider pre-surgery and/or intra-surgery pull-up where appropriate.

> The crenelated part of the implant must not be bent or come into contact with clamps or other instruments that may damage the implant in any way. It must not be cut as burrs may prevent it from sliding into the domino body.

> The smooth part of the rod can be bent, but not repeatedly, to avoid weakening it. The smooth rod area at the inlet of the growing domino must not be bent or twisted (as this may damage the PEEK bushing inside the system).

> The domino locking principle is based on the tightening of two screws. It is essential to tighten them in accordance with the reference operating technique with the instrument provided for this purpose.

> The implant must be manipulated with ancillary equipment adapted to the diameter of the chosen rod (Ø5.5mm or Ø6mm rods) and must only be assembled with bone anchors intended for chosen diameter rods (Ø5.5mm or Ø6mm rods).

> The implant must not be combined with a mounting containing PEEK rods.

> The locking ring must be removed after fitting in accordance with the reference operating technique.

> In order to maximize the effectiveness of the implant, it is important to pay particular attention to the correct positioning of the implant. The implant should be positioned bilaterally as described in the reference surgical technique. It is recommended to position the rod so that it is parallel to the sagittal plane and oriented along the growth axis of the spine.

> Assembly recommendations are detailed in the operating technique.

> Generally speaking, the 80mm rods can be used in children under 10 years of age and mainly when the assembly is extended to the pelvis.

> Chest positioning is not recommended to reduce the risk of bursitis and other skin irritation. The bend of the rod should be as close as possible to the

anatomical curvature of the spine.

> The surgeon has a responsibility to judge the patient's growth potential.

> It should be noted that the performance of the device may be impaired in case of a history of spine surgery.

> Surgery should be performed under neuromonitoring in order to eliminate any risk of excessive spinal distraction and nerve damage.

> 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.

> Postoperative patient manipulations (e.g., lifting) must be considered to avoid significant pulling of the assembly. Significant asymmetric efforts should be avoided.

> 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

> Technical performances

- Resistance to mechanical stress under normal operating conditions:
  - Axial compressive resistance;
  - Interconnection resistance.
- Meet implantation requirements
  - Biocompatible;
  - Sterilized ;
  - Easily implantable and removable by posterior route.

> Clinical performances

- allow correction of the spinal deformation and to maintain correct alignment of the spine:
  - Provide adequate structural rigidity to limit movement;
  - Allow multiple levels of thoracic and/or lumbar instrumentation.
- Enabling the growth of the spine through the growth mechanism:
  - Enable controlled growth;
  - Adapt to different anatomies.

> Clinical benefits

- Correction of spinal curvature, Cobb angle correction and maintenance,
- Improvement of alignment of the spine in all three planes of the space,
- Spinal growth preservation.

7. ADVERSE EFFECTS / RESIDUAL RISKS

The list of potential adverse events includes :

- prominence of the implant;
- implant migration;
- rupture or implant coming apart;
- blockage of the device preventing its growth;
- Irritation, Inflammatory reaction, stings, burns, skin erosion;
- early onset fusion;
- sagittal imbalance;
- Deformation angle increase;
- instability and degeneration of adjacent segments;
- proximal junctional kyphosis;
- crankshaft phenomenon;
- metallosis;
- pseudarthrosis;
- vertebral fracture;
- superficial and/or deep infection;
- damage to surrounding soft tissues (vascular, nervous, visceral, muscle);
- dural leak;
- neurological injury (including paralysis, radiculopathy, pain...);
- paralysis;
- other general and surgical complications (thrombosis, pulmonary embolism, myocardial infarction, bursitis, seroma, haematoma, difficulty in healing);
- pain;
- Immune reaction, allergy, formation of erythema or edema or implant rejection;
- *Intoxication, 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 and the parent(s) (or the holder(s) of parental authority) 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 and the parent(s) (or the holder(s) of parental authority) 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 and the parent(s) (or the holder(s) of parental authority) 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 and the parent(s) (or the holder(s) of parental authority) that the devices are MR unsafe.

> The surgeon must inform the patient and the parent(s) (or the holder(s) of parental authority) to report any incident in relation to the devices to the surgeon.

> The surgeon should inform the patient and the parent(s) (or the holder(s) of parental authority) 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 NEMOST growing domino is available with two different reserve growth lengths.

> The surgeon is responsible for selecting the most suitable implant based on the patient's growth potential and the deformation to be corrected.

> Information on device size 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 NEMOST growing domino is to be used with a later stabilization system in the E.SPINE®EUROS range.
All combination with devices of other manufacturer is forbidden.

10. STERILITY

> The NEMOST growing domino is supplied sterile (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.

> For the additional fixings system and for instruments used to insert implants, see the relevant leaflet for information on sterilisation.

11. ADDITIONAL INFORMATION

The Summary of Safety and Clinical Performance is available upon request (email: qualite@euros.fr; Tel : +33 4 42 71 42 71).
NEMOST Basic UDI-DI: 37004372R004BK

12. 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
	Caution

EN

LOT	Batch code
	Keep dry
	Keep away from sunlight
	Storage temperature limitation
	Do not re-sterilise
	Use-by date
	Do not use if package is damaged and consult the instructions for use
REF	Catalogue number
	Manufacturer
	Date of manufacture
	Consult the instructions for use
MD	Medical device
UDI	UDI

13. MEANING OF THE ABBREVIATIONS

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

14. MATERIAL

Connector domino (crenellated rod included)	99,8-99,84 %(m/m) Ti6Al4V ELI (ISO 5832-3 and ASTM F136) + 0,16 - 0,2 %(m/m) PEEK OPTIMA® LT1 (ASTM F2026)
Smooth rod	100% (m/m) Ti6Al4V ELI (ISO 5832-3 and ASTM F136)

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

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