POST-MARKETING CLINICAL MONITORING STUDY OF THE NEMOST V2 GROWTH DOMINO

Protocol

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Medical device: NEMOST

Study No.: EC-304-02

IDRCB No. 2025-A01794-45

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Document history:

Document version	Date	Modifications
A	09/18/2025	Creation
B	10/08/2025	Modifications requested by the ANSM when the application was not approved
C	12/11/2025	Modification following feedback from the CPP
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E	12/17/2025	Modification following feedback from the CPP
F	12/19/2025	Addition of the date on which the CPP issued its favorable opinion.

SUMMARY

Study title	Post-marketing clinical surveillance study of the NEMOST V2 growth domino NEMOST V2
Sponsor	EUROS SAS
Study number	EC-304-02
IDRCB Number	2025-A01794-45
Type of study	Post-marketing clinical follow-up
Rationale	The NEMOST spinal implant is a growth domino intended for the surgical treatment of progressive scoliosis in children. As part of post-marketing surveillance, EUROS is conducting a prospective study to collect clinical and radiological data on the NEMOST growth domino.
Study Design	Clinical prospective multicenter multicenter of post-marketing This study is interventional, non-randomized, and non-controlled. This study is interventional, non-randomized, and uncontrolled.
Objectives	The primary objective of this clinical study is to monitor intraoperative and postoperative complications related to the NEMOST growth domino, as well as any medical or surgical intervention related to the NEMOST growth domino during a 5-year postoperative follow-up in patients treated for progressive childhood scoliosis. The secondary objective of this clinical study is to monitor the performance of the NEMOST growth domino during a 5-year postoperative follow-up in patients treated for progressive scoliosis in children.
Inclusion criteria for inclusion	• Idiopathic, congenital, neuromuscular, syndromic scoliosis: progressive spinal deformity, not treated by orthopedic treatment, as a first-line surgical option. • The patient and those with parental authority are informed of their participation in the study and have given their consent • Participants aged 5 to 17 years, with the exception of patients still in growing
Exclusion criteria	The list of contraindications includes: • signs of local inflammation; • acute or chronic infections, local or systemic; • non-reducible scoliosis; • morbid obesity;

	• allergy or intolerance to implanted materials; • insufficient or absent tissue coverage. The NEMOST implant should not be used in a spine that has already been instrumented or fused.
Evaluation parameters (primary and secondary)	Complication monitoring data include the nature, incidence, and severity of any complications related to the NEMOST growth domino and any medical or surgical procedures related to the NEMOST growth domino. The NEMOST growth domino performance monitoring data are scoliosis correction (Cobb angle), thoracolumbar growth (T1-T12 and T1-S1 segment length), pelvic obliquity, thoracic kyphosis, lumbar lordosis, EOSQ-24 score, and pulmonary function (EFR).
Investigators	• Necker Enfants Malades Hospital, Paris: Dr. Miladi • Pellegrin University Hospital, Bordeaux: Dr. Boissière • Pellegrin University Hospital, Bordeaux: Prof. Lefevre • Women's and Children's Hospital, Hospices Civils de Lyon: Dr. Cunin • Lenval Foundation, Nice: Dr. Solla • Armand Trousseau Hospital, Paris: Prof. Vialle • Armand Trousseau Hospital, Paris: Dr. Gaumé
Staff	According to data in the literature, the average rate of intraoperative and postoperative complications is 56%. With a desired power of 90%, the number of subjects required is 66 patients. Assuming an additional 20% loss to follow-up, a minimum of 82 patients will need to be included. The inclusion period to reach this number is 36 months from the first inclusion. A maximum of 140 patients is expected in this study, due to the recruitment potential of the centers.
Start and end dates	Start: 12/19/2025 Recruitment: Maximum 3 years Follow-up: 5 years End: 12/19/2033
Statistics	The statistical analysis will be descriptive and comparative, and will be carried out on the follow-up population using methods appropriate to the nature of the criteria, whether quantitative or qualitative, and to the distribution of the data. The risk of type 1 is set at α = 5% (two-tailed test).

LIST OF ABBREVIATIONS

ABBREVIATIONS	DEFINITIONS
ANSM	French National Agency for Medicines and Health Products Safety
CPT	Total Lung Capacity
CV	Vital Capacity
CE	European Conformity
CNIL	French Data Protection Authority
CPP	Committee for the Protection of Individuals
CSP	Public Health Code
DM	Medical device
(e)CRF	(electronic) Case Report Form
EFR	Respiratory function test
EIG	Serious adverse event
EOS	Early-Onset Scoliosis
EOSQ-24	Early-Onset Scoliosis Questionnaire – 24
items BMI	Body Mass Index
SCAC	Post-marketing clinical follow-up
EU	European Union

SUMMARY

1. INTRODUCTION

1.1 RATIONALE

Scoliosis is a three-dimensional deformity of all or part of the spine (cervical, thoracic, or lumbar) consisting of a progressive relative displacement of one vertebra in relation to its adjacent vertebra, occurring in all three planes of space (frontal, sagittal, and coronal) without loss of osteoligamentous continuity. In the frontal plane, the curvature of scoliosis is measured by the Cobb angle [COB48]. In the horizontal plane, it is vertebral rotation accompanied by a hump that is visible on clinical examination. In the sagittal plane, it is hyperlordosis, flat back, or even hollow back.
Idiopathic scoliosis in children and adolescents, secondary congenital scoliosis, neuromuscular scoliosis, and syndromic scoliosis appearing before the age of 5 are grouped under the term "early onset scoliosis" (EOS) [BES10].
In children, some cases of scoliosis remain very mild, worsening very little, very slowly, or not at all, and may even regress spontaneously. Other cases of scoliosis, on the other hand, are progressive and sometimes progress very rapidly.
This rapid progression is linked to spinal growth, which is at its maximum during the first five years of life [AKB05,BES10] . During this period, the T1-S1 length increases by 10 cm (2 cm per year) [AKB05] . The thoracolumbar spine reaches two-thirds of its adult length by the age of 5 [AKB05] . Growth then slows between the ages of 5 and 10, before increasing again during puberty [AKB05] .
In children, scoliosis is considered progressive when the Cobb angle worsens by 5° on two X-rays taken 4 or 6 months apart [HAS08]. A curvature greater than 30° is considered progressive from the outset [HAS08].
The impact of these major scoliotic curvatures is significant, with respiratory failure posing a threat to life in the medium term [BES10]. The impact on walking and sitting is also significant, leading to difficult living conditions.

The management of infantile and juvenile scoliosis remains one of the most difficult problems in pediatric orthopedics. Some cases are not very progressive and are stabilized by orthopedic treatment [BES10]. Others progress very rapidly, escaping orthopedic treatment [BES10]. If orthopedic treatment fails, surgical treatment is indicated [AKB05]. In these cases, early surgery is sometimes considered before the age of 10 [AKB05].
There are two main surgical treatment options: arthrodesis and instrumentation without grafting [AKB05]. Arthrodesis before the age of 10 has extremely serious consequences: by blocking trunk growth, it leads to limited respiratory function.
On the contrary, non-surgical instruments can partially correct the deformity and prevent the progression of scoliosis, while maintaining spinal growth during treatment [AKB05,ATI15,FAR10, JAI17,JAY16,MCE11,MCE12]. Nowadays, non-fusion techniques are most commonly used in the treatment of progressive scoliosis in prepubescent children when conservative treatments have failed. Growth rods allow the spine to grow while correcting the deformity in order to mitigate the respiratory, digestive, and functional consequences associated with major spinal deformity [AKB05,JAY16,MCE11,MCE12] . When maximum spinal growth is achieved, arthrodesis may be performed [AKB05,BES10,FAR10,JAI16,MCE11, MCE12].

During the treatment period, from the initial surgery to the final arthrodesis, growth rods may require reoperations for lengthening or replacement [AKB05,ATI15,BES10,FAR10,JAY16,MCE11,

[MCE12]. Reoperations are indicated when the Cobb angle worsens by 10° to 20° [BLA01,LI10,MIL13, WAN12, ZHA12].

More recently, automatic or magnetic growth rods have been developed, eliminating the need for repeat surgeries to lengthen the spine while maintaining curvature correction and allowing patients to continue growing.

The NEMOST growth domino, combined with a posterior stabilization system, is one such automatic growth device.

1.2 PRODUCT INFORMATION

The NEMOST growth domino is a thoracolumbar device designed to correct and control the progression of scoliosis while maintaining spinal growth. It is implanted with the E.SPINE posterior stabilization system.

The NEMOST growth domino consists of two titanium rods inserted into a double parallel tunnel connector. The main rod consists of a smooth section and a serrated section. The connector slides over the serrated section in a unidirectional manner in the direction of distraction, locked in compression. The smooth section is designed to be fixed to one end of the spine using fasteners from the E.SPINE range. The serrated section of the rod constitutes
the "growth reserve," the length of which will be chosen based on the patient's residual growth potential.

The NEMOST maintains a constant distraction force between two fixation points on the spine thanks to the anti-return effect of its connector on the partially serrated rod. The rod's growth reserve allows for a total expansion of 50 mm or 80 mm, depending on the size chosen, in increments of 1 mm.

The growth domino is made of titanium alloy (Ti6Al4V ELI).

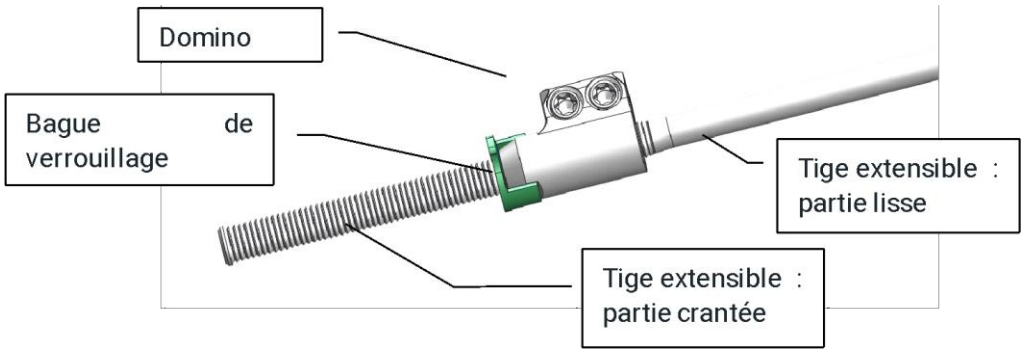

Figure 7: NEMOST device

1.3 EXPECTED BENEFIT/RISK RATIO

1.3.1 Expected complications

Complications associated with the surgical implantation of a NEMOST implant include the following:

- implant prominence;
- implant migration;
- implant rupture or disassembly;
- blockage of the device preventing its growth;

- irritation, inflammatory reaction, burns, skin erosion;
- proximal junctional kyphosis;
- crank phenomenon;
- metallosis;
- Superficial and/or deep infection;
- damage to surrounding soft tissue (vascular, nervous, visceral, muscular);
- neurological injury (including paralysis, radiculopathy, pain, etc.);
- other general and nonspecific surgical complications (thrombosis, pulmonary embolism, myocardial infarction, bursitis, seroma, hematoma, difficulty healing);
- pain;
- immune reaction, allergy, erythema or edema formation, or implant rejection;
- intoxication, cell damage, convulsions;
- Cancer, tumor, immunological and neurological disorders, genetic defects, non-hereditary adverse effects on offspring, and/or impairment of male or female reproductive function or capacity.

Treatment of certain adverse side effects may require additional surgery.
*Note: these residual risks are related to the biocompatibility of the device. The biological risk assessment report demonstrated that the biological risk was controlled and considered acceptable for EUROS products.

1.3.2 Expected benefits

The clinical performance of the NEMOST implant is presented in the clinical evaluation report "EVCR-A304-01-H":

As a result, the expected benefits of the NEMOST implant are as follows:

-correction and maintenance of curvature and Cobb angle

-improvement of spinal alignment in all three planes

-preservation of spinal growth.

1.4 CONCLUSION AND PURPOSE OF THE STUDY

EUROS is conducting a multicenter, interventional, prospective post-marketing clinical follow-up study on the NEMOST implant.

This clinical study will involve collecting clinical and radiological data to monitor complications and performance related to the implant.

2. ECTIVE OBJECTIVES AND EVALUATION PARAMETERS

2.1 PRIMARY OBJECTIVE

The primary objective of this clinical study is to monitor intraoperative and postoperative complications

postoperative complications related to the NEMOST growth domino, as well as any medical or surgical interventions related to the NEMOST growth domino during a 5-year postoperative follow-up period in patients treated for progressive childhood scoliosis.

2.2 SECONDARY OBJECTIVES

The secondary objective of this clinical study is to monitor the performance of the NEMOST growth domino during a 5-year postoperative follow-up in patients treated for progressive scoliosis in children.

2.3 PRIMARY END POINTS

Complication monitoring data include the nature, incidence, and severity of any intraoperative and postoperative complications related to the NEMOST growth domino and any medical or surgical intervention related to the NEMOST growth domino.

A bilateral revision of NEMOST, i.e., removal of the two bilateral dominoes initially implanted, will result in closure of the patient's file in the study. A unilateral revision of NEMOST, i.e., the removal of only one of the two dominoes initially implanted, or the revision of another component of the assembly, will be considered minor and recorded as a complication.

In cases where patients have difficulty traveling for follow-up visits, a telephone interview or a questionnaire by mail/email may be conducted to collect information on any complications that have occurred since the last visit and the status of the implant (in place or revised).

2.4 SECONDARY EVALUATION PARAMETERS

2.4.1 Clinical parameters

The quality of life of patients prior to surgery and at each post-operative visit will be assessed using the EOSQ-24 questionnaire.

A pulmonary function test (PFT) will be performed if the patient is able to do so.

Spinal ankylosis is inferred if the following three parameters are observed: no progression of scoliosis, no rod breakage, and follow-up for more than 2 years.

2.4.2 Radiological parameters

The performance monitoring data for the NEMOST growth domino are the correction of

scoliosis (Cobb angle), thoracolumbar growth (T1-T12 and T1-S1 segment length), pelvic obliquity, thoracic kyphosis, and lumbar lordosis.

3. EXPERIMENTAL DESIGN AND METHODOLOGY

3.1 TYPE OF STUDY

This study is a post-marketing clinical follow-up based on data, multicenter, interventional, prospective, and uncontrolled.

The observation period is the time between the preoperative visit and a maximum of 5 years of postoperative follow-up, i.e. 10 visits: preoperative visit, operative report, postoperative visits at 3 months +/- 3 months, 6 months +/- 3 months, 1 year +/- 3 months, 1.5 years +/- 3 months, 2 years +/- 6 months, then every year +/- 6 months up to 5 years .

The study will be conducted by the following investigators at the following centers:

- Necker Enfants Malades Hospital, Paris: Dr. Miladi
- Pellegrin University Hospital, Bordeaux: Dr. Boissière
- Pellegrin University Hospital, Bordeaux: Prof. Lefevre
- Hôpital Femme Mère Enfant, Hospices Civils de Lyon: Dr. Cunin
- Lenval Foundation, Nice: Dr. Solla
- Armand Trousseau Hospital, Paris: Prof. Vialle
- Armand Trousseau Hospital, Paris: Dr. Gaumé

3.2 STUDY POPULATION

3.2.1 Calculation of the number of patients

The number of subjects required is calculated using the following Cochran formula:

$$n = \frac{z^2\, p(1-p)}{e^2}$$

where:
n = sample size
z = 1.96 (for a 95% confidence interval)
p = 0.56 (incidence of intraoperative and postoperative complications 56%)
e = 0.05 (chosen margin of error 5%)
therefore n=379

〖n'〗 ^ =n /(1+(n+1)/N)

where:
n' = recalculated sample size
N = 80 (parent mother)
n = 379 (sample size) therefore
n'=66
According to data in the literature, the rate of intraoperative and postoperative complications is 56%.

With a desired power of 90%, the number of subjects required would be 66 cases.

Assuming a 20% loss to follow-up rate at 5 years, the **minimum** number of patients to be included is 82. As the centers have a higher recruitment capacity, the **maximum total number** of patients included will be 140.

3.2.2 Patient selection

It is planned to prospectively include a total of 140 patients in this post-marketing clinical follow-up marketing follow-up during an inclusion period of up to 36 months.

During the inclusion period, investigators must systematically and consecutively include all eligible patients who meet the inclusion and exclusion criteria listed in the following paragraph.

The study and its inclusions will begin as soon as a favorable opinion is obtained from the CPP. Upon receipt of this

approval, patients will be enrolled prospectively.

3.2.3 Eligibility criteria

Inclusion criteria:

- Idiopathic, congenital, neuromuscular, syndromic scoliosis: progressive spinal deformity, not treated by orthopedic treatment, as a first-line surgical option.
- The patient and legal guardians are informed of their participation in the study and have given their consent.
- Participants aged 5 to 17 years, with the exception of patients who are still growing (Sharawat 2016; Cheung and Luk 2017; Henderson et al. 2007; Era et al., n.d.).

The methods used to diagnose scoliosis are clinical and radiological examinations performed on the patient up to the preoperative consultation. A Cobb angle >10° is a diagnosis of scoliosis.

The participant's growth potential is diagnosed based on bone age: RISSER, triradiate cartilage, wrist X-rays, age of first menstruation. The literature reports that bone age can be 2 to 5 years different from chronological age. Thus, a patient over 17

years of age may still have growth potential. (Sharawat 2016; Cheung and Luk 2017; Henderson et al. 2007; Era et al., n.d.).

Exclusion criteria:

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

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

3.2.4 Assignment of a patient number

A unique number will be assigned to each patient sequentially according to the chronology of the surgical procedure.

The patient number will consist of the investigation center number, followed by a unique, incremental number on the next two digits, followed by the first letter of the patient's last name and the first letter of the patient's first name on the last two digits.

A list of included patients will be kept up to date and maintained by the investigators.

The pseudo-anonymity of patients will be guaranteed throughout the study.

3.3 STUDY PROCEDURE

3.3.1 Duration of the study

Patients will be included prospectively and followed up for a postoperative period of 5 years ( ).

Inclusions will be closed when the desired number of patients has been reached and may not exceed 36 months.

Start: 12/19/2025 Recruitment:
Maximum 3 years Follow-up: 5
years
Expected end date: 12/19/2033

3.3.2 Data collected

Data will be collected during visits that are part of the patients' routine medical follow-up, with the exception of the EOSQ-24 score, which is not usually collected, and recorded by the

investigators in an electronic case report form (eCRF) dedicated to the study, based on the patients' medical records

and the completed questionnaire.

Data collected at the preoperative visit:

- Date of visit
- Month and year of birth
- Age, gender, weight
- RISSER test
- First period
- General medical history and treatments
- Orthopedic history of the spine
- Etiology
- Patient profile: Hypotonic or spastic
- EOSQ-24 clinical score
- Radiographic data measured on a seated or standing front/profile X-ray: Cobb angle, T1-T12 length, T1-S1 length, pelvic obliquity, thoracic kyphosis, lumbar lordosis.
- EFR pulmonary function: sitting or lying down, measurement of Total Lung Capacity (TLC, mL) and Vital Capacity (VC, mL)

Data collected during the procedure (operative report):

- Date of procedure
- Age, weight
- Duration of procedure
- Length of hospital stay
- Bipolar surgical technique: T1 to S1
- Size, type, and method of attachment of implants, growth reserve
- Associated procedures
- Difficulties associated with implant placement instruments
- Complications and possible treatment(s)
- Immediate postoperative radiographic evaluation. Radiographic data measured on a sitting/standing X-ray: Cobb angle, T1-T12 length, T1-S1 length, pelvic obliquity, thoracic kyphosis, lumbar lordosis.

Data collected during post-operative visits:

No additional post-operative appointments for patients are scheduled.

As part of this study, no visit frequency is defined by the protocol other than the usual practice: 3 months +/- 3 months, 6 months +/- 3 months, 1 year +/- 3 months, 1.5 years +/- 3 months, 2 years +/- 6 months, then every year +/- 6 months up to 5 years .

Some tests are not routinely performed: EOSQ-24 score. These procedures are non-invasive and do not involve any significant burden.

The data collected during postoperative visits are as follows:

- Date of visit and follow-up
- Age, weight
- General complications, local complications, mechanical complications, and their treatment(s). Postoperative mortality and morbidity at 30 days to be determined according to the Clavien-Dindo classification.
- Radiographic measurements (seated/standing X-rays depending on patient's ability): Cobb angle, T1-T12 length, T1-S1 length, pelvic obliquity, thoracic kyphosis, lumbar lordosis.
- Growth reserve of the rods or consumption
- EOSQ-24 questionnaire for the patient's parents or the patient if they are capable.
- At least one EFR between 1 and 3 years of age if the patient is able
- Deduction of spinal ankylosis: no fracture, no progression of scoliosis, follow-up > 2 years
- Arthrodesis performed?

If the patient is unable to travel for personal or medical reasons, a letter, email, or phone call may be made to provide the following information:

- *The date of contact and postoperative follow-up*
- *EOSQ-24 clinical score*
- *The occurrence of any complications and any treatments*

Summary of visits:

Visit data	Patient data (age, sex, etiology, etc.)	Scores	Radiology	Complications	EFR
Pre-operative	x	x	x		x
Surgery/hospitalization			X	x	
3 months +/- 3		x	x	x	

months					
6 months +/- 3 months		x	x	x	
1 year +/- 3 months		x	x	x	x
1.5 years +/- 3 months		x	x	x	x
2 years +/- 6 months		x	x	x	x
3 years +/- 6 months		x	x	x	x
4 years +/- 6 months		x	x	x	
5 years +/- 6 months		x	x	x	

Data collected during the final visit:

- Date of visit and postoperative follow-up at closure
- Reason for closure:
  - Patient lost to follow-up after 3 reminders
  - Patient deceased
  - Bilateral revision
  - Normal completion of study

4. INCIDENTS (SAIs) AND COMPLAINTS

In accordance with the Public Health Code (Art. R. 1413-67), a serious adverse event (SAE) is any adverse event that has resulted in one of the following outcomes:
a) death,
b) serious deterioration in the subject's state of health, resulting in:
i. a life-threatening illness or injury,
ii. permanent damage to a bodily structure or function,
iii. hospitalization or prolonged hospitalization,
iv. medical or surgical intervention to prevent a life-threatening illness or injury or permanent impairment,
v. a chronic illness,
c) Fetal distress, fetal death, or congenital physical or mental abnormality. (MDR Regulation, Article 2(58))

Device failure (DF): Any deficiency related to the identity, quality, durability, reliability, safety, or performance of an investigational device, including a failure, misuse, or deficiency in the information provided by the manufacturer. (MDR Regulation, Article 2(59))

The sponsor shall record in full:

a) any adverse event of a type defined in the clinical investigation protocol as being decisive for the evaluation of the results of the clinical investigation;
b) any serious adverse event;
c) any device defect that could have led to a serious adverse event in the absence of appropriate measures or intervention, or if circumstances had been less favorable;
d) any new information concerning an event referred to in points (a) to (c).

The investigator undertakes to inform the clinical project manager at EUROS without delay using the SIE reporting form (by email:clinique_rachis@euros.fr). The clinical department is responsible for forwarding the information as soon as it becomes aware of it to the Materiovigilance department via the addresscomplaints@euros.fr , in accordance with the provisions described in Articles 87 to 90 of the MDR.

5. STATISTICS

The primary objective of this clinical study is to monitor intraoperative and postoperative complications related to the NEMOST growth domino, as well as any medical or surgical intervention related to the NEMOST growth domino during a postoperative follow-up period of up to 5 years in patients treated for progressive childhood scoliosis.

The secondary objective of this clinical study is to monitor the performance of the NEMOST growth domino during a 5-year postoperative follow-up in patients treated for progressive scoliosis in children.

5.1 GENERAL CONSIDERATIONS

The statistical analysis will be performed using XLSTAT software and will follow the detailed statistical analysis plan defined in advance.

The statistical analysis will be descriptive and comparative, and will be performed using methods appropriate to the nature of the criteria, whether quantitative or qualitative, and to the distribution of the data.

It will enable the characteristics of the patients to be defined, any differences to be described, and compare the type of population with the series in the literature.

In the event that subgroup analyses are performed, parametric statistical tests and Conventional nonparametric methods will be implemented.

5.2 POPULATION ANALYSED

The patient population included will correspond to all patients for whom, at a minimum, data from the intraoperative visit are available.

The analysis reports will include data from all patients who received the implant under study.

The follow-up population will correspond to the population of patients included for whom data from at least one postoperative visit will be available. Missing data will not be replaced.

5.3 STATISTICAL METHODS

5.3.1 Descriptive analysis

Qualitative parameters will be analyzed and presented by their absolute frequency (n) and relative frequency (%).

Quantitative parameters will be analyzed and presented by the number of observations, the mean, the median, minimum, and maximum.

The descriptive analysis will be performed in each interim report, once a year until the final report at 5 years.

The analysis of the primary endpoint will be descriptive, as it will consist of collecting all intraoperative and postoperative complications, as well as any reoperations or revisions, and calculating their incidence: number of events/total number of patients, as well as the number of patients with at least one event/total number of patients. These proportions will be monitored at each timepoint of the study.

Descriptive analyses in subgroups may be performed given the expected number of patients (140): indications, E.SPINE TANIT implants, etc.

5.3.2 Comparative analysis

A comparison of clinical parameters will be performed between preoperative and postoperative data at each interim report, once a year, for up to 5 years, particularly in terms of changes in the EOSQ-24 score. A comparison of radiological parameters will be performed between the preoperative and immediate postoperative periods once a year, for up to 5 years.

Lung function assessed between 1 and 3 years of follow-up will be compared with preoperative function at the 3-year interim analysis.

Quantitative variables will be compared using Student's t-test or, if the conditions for applying for this test are not met (normality of distributions), by a Wilcoxon test. The risk of the^{1st}species will be set at α = 5% (two-tailed test).

5.4 MAIN ANALYSIS CRITERIA

The analysis of intraoperative and postoperative complications, as well as any medical

or surgical intervention, will be performed on the follow-up population. It will be descriptive and presented by the frequency of occurrence of the various complications and revisions.

5.5 SECONDARY ANALYSIS CRITERIA

The analysis of clinical and radiological evaluation parameters will be performed on the follow-up population follow-up population. It will be descriptive and comparative.

6. RIGHT OF ACCESS TO DATA AND SOURCE DOCUMENTS

6.1 DEFINITION OF SOURCE DATA

All assessments reported in the CRF must be consistent with the source data contained in the patient's medical record.

6.2 DATA CONFIDENTIALITY

6.2.1 Preservation of subject pseudo-anonymity

Patient privacy will always be maintained. The pseudo-anonymity of the subject will always be preserved, and only authorized persons will have access to personally identifiable information.
All personal data collected and processed as part of the study will be compiled by the investigator with appropriate precautions to ensure confidentiality.
In all presentations of the results of this study at meetings or in publications, the identity of the subjects will remain confidential and all data will be pseudonymized.

6.2.2 Access to source data

In accordance with the laws and regulations in force (Articles L.1121-3 and R.5121-13 of the Public Health Code), the Investigator shall provide direct access to source documents to the Sponsor's Monitor(s) and/or Auditor(s) or those designated by the Sponsor, as well as to the applicable regulatory authorities for the purpose of conducting the inspection.
These persons are bound by professional secrecy and will not disclose personal identity or personal medical information.
As soon as the Investigator is informed of a future inspection by the authorities, he/she shall inform the Promoter and will authorize the Promoter to participate in this inspection.
The confidentiality of the verified data and the pseudo-anonymity of patients must be respected

during these inspections.

6.3 COMPLETION OF CASE REPORT FORMS (CRFs)

The investigator is responsible for the correct and adequate recording of all observations and other data relevant to the study in the eCRF designed specifically for the study. The sponsor will provide an eCRF accessible online.

An eCRF must be completed for each patient included in the study. The completed eCRF is the exclusive property of the Sponsor and shall not be made available in any form to third parties without the Sponsor's written permission, except to representatives authorized by the Sponsor or the relevant regulatory authorities.

The investigator or his/her representative designated by the task delegation list shall record patient data in the eCRF as accurately as possible. The investigator shall ensure that all data are entered promptly after evaluation, are complete, accurate, and consistent with the source documents, in accordance with the specific instructions accompanying the eCRF designed specifically for this study.

6.4 STUDY MONITORING

The Investigator is responsible for conducting the study in accordance with this assessment protocol, Good Clinical Practices, and applicable regulations.

Practices and the regulatory provisions in force.

The Investigator must comply with the procedures required by this plan. The Investigator agrees to provide all information requested in the CRF in a correct and comprehensible manner, in accordance with the instructions given, and authorizes direct access to source documents to persons authorized by the Sponsor.

The Sponsor of this study is accountable to the health authorities and must take all necessary measures to ensure the proper conduct of the study with regard to ethics, compliance with the protocol, and the integrity and validity of the data recorded in the CRFs.

As part of this study, the sponsor reserves the right to conduct (or appoint a company to conduct) monitoring visits.

In this case, during the study, the center will be contacted by a representative of the monitoring team through site visits, letters, or phone calls to verify the progress of the study,

the investigator's and patients' compliance with the protocol requirements, and any emerging issues emerging issues.

Monitoring visits are scheduled at a frequency appropriate to the available data.

6.5 DOCUMENT RETENTION

The investigator shall retain all study files until notified by EUROS SAS that the files may be destroyed or returned to the Sponsor. If the investigator withdraws responsibility for this retention, he/she must first transfer this responsibility to a person willing to accept it. If these documents are to be moved to another location, the Sponsor must be notified.

6.6 PATIENT ACCESS TO DATA

In accordance with legal provisions, patients who so wish may have access to their data at the end of the research. They may also have access to the overall results of the study. They must submit their request in writing to the investigator and will receive a response within 30 working days.

7. QUALITY CONTROL AND INSPECTION

7.1 QUALITY CONTROL

The investigator is responsible for the correct and adequate recording of all observations and other data relevant to the study.

7.2 INSPECTIONS BY REGULATORY AGENCIES

In order to remain in compliance with the evaluation protocol and applicable legal and regulatory requirements, the investigator must grant access to the sponsor for the purpose of conducting an audit and to the competent authorities for the purpose of conducting an inspection, where applicable (CSP Article R5121-13).

The investigator agrees to allow auditors/inspectors direct access to source documents, given that these individuals are bound by professional secrecy and will not disclose personal identity or personal medical information.

As soon as the investigator is informed of a future inspection by the authorities, he shall inform the sponsor

sponsor and authorize the sponsor to participate in this inspection.

The confidentiality of the verified data and the pseudo-anonymity of the patients must be respected during these inspections.

8. ETHICAL AND REGULATORY PROVISIONS

This study is conducted in accordance with ethical principles based in particular on the Declaration of Helsinki, in compliance with the Public Health Code and Regulations (EU) 2016/679 and 2017/745.

8.1 REGULATORY CONSIDERATIONS

The Sponsor certifies that, in accordance with Regulation (EU) 2016/679, the processing of data collected in the context of this study is necessary for the purposes of ensuring high standards of quality and safety of medical devices, based on Union law or Member State law.

Similarly, in accordance with Regulation (EU) 2017/745 and ISO 14155:2020, this prospective clinical study falls within the scope of post-market clinical follow-up (PMCF) of the NEMOST implant. It falls within the scope of PMFIS investigations on a CE-marked medical device, any class, used for its intended purpose with additional non-burdensome and non-invasive procedures. The additional examinations to standard practice are the EOSQ-24 score. The protocol will therefore be submitted to an ethics committee (CPP) for approval.

8.2 ETHICAL CONSIDERATIONS

In accordance with Regulation (EU) 2017/745, this study falls within the scope of SCAC investigations on CE-marked medical devices, any class, used for their intended purpose with additional non-burdensome and non-invasive procedures and therefore requires notification to the ANSM (French National Agency for Medicines and Health Products Safety) and authorization from a human subjects review committee (CPP).

8.3 NATIONAL COMMISSION FOR INFORMATION TECHNOLOGY AND LIBERTIES (CNIL)

This interventional clinical study complies with the MR-001 reference methodology established by the CNIL. The Sponsor certifies that it has submitted a single declaration of compliance with the methodology

MR001 (No. 2218623).

8.4 HEALTH DATA HUB

In accordance with the legal provisions in force for studies, the study will be registered on the public Health Data Hub database.

8.5 CLINICAL TRIALS.GOV

The study will also be registered in the clinicaltrials.gov database.

8.6 PATIENT CONSENT AND PARENTAL AUTHORITY PARENTAL AUTHORITY

1. The informed consent shall be in writing, dated and signed by the person conducting the interview (preoperative visit) referred to in paragraph 2(c), by the holders of parental authority after they have been duly informed in accordance with paragraph 2. The signature of the minor participant is not required, but his or her information is and his or her assent must be obtained. The participant and the holders of parental authority shall be given a copy of the document or other means of documentation, as appropriate, by which they have given their informed consent. Informed consent shall be documented. The minor participant and the holders of parental authority shall be given adequate time to consider their decision to participate in the clinical investigation.

2. The information provided to the minor participant and the holders of parental authority to obtain their informed consent:

a) enable the participant and the holders of parental authority to understand:
i) the nature, objectives, benefits, consequences, risks, and disadvantages of the clinical investigation;
ii) the rights and safeguards of the participant regarding his or her protection, in particular his or her right to refuse to participate in the clinical investigation and his or her right to withdraw from it at any time without prejudice and without having to justify his or her decision;
iii) the conditions under which the clinical investigation is to be conducted, including the expected duration of the subject's participation in the clinical investigation; and
iv) any alternative treatments, including follow-up measures if the subject's participation in the clinical investigation is terminated;
b) are complete, concise, clear, relevant, and understandable to the subject and those with parental authority of parental authority;
c) are provided during a preliminary interview with a member of the research team who is duly qualified under national law;

3. The minor participant takes part in the informed consent procedure. In the absence of such consent, the minor participant shall not be included in the study.

consent, the minor participant shall not be included in the study.

A clinical investigation may be conducted on minors only if, in addition to the conditions laid down in Article 62(4), all of the following conditions are met:
a) the informed consent of their legal guardians has been obtained; L 117/60 EN Official Journal of the European Union 5.5.2017
b) the minors have received, from the investigators or members of the investigation team trained or experienced in working with children, the information referred to in Article 63(2) in a manner appropriate to their age and mental maturity;
c) the explicit wish of a minor participant, who is capable of forming an opinion and assessing the information referred to in Article 63(2), to refuse to participate in the clinical investigation or to withdraw from it at any time, is respected by the investigator;
d) no inducement or financial benefit is offered to the participant or those with parental authority, except for compensation for expenses and loss of income directly related to participation in the clinical investigation;
e) the clinical investigation is intended to study treatments for a condition that only affects minors, or the clinical investigation is essential in relation to minors in order to validate data obtained in clinical investigations on persons capable of giving informed consent or by other research methods;
f) the clinical investigation relates directly to a condition affecting the minor concerned or is of such a nature that it can only be conducted on minors;
g) there are scientific grounds for believing that participation in the clinical investigation will result in a direct benefit to the minor participant that outweighs the risks and burdens involved;
h) the minor participates in the informed consent process in a manner appropriate to his or her age and mental maturity;
i) if, during a clinical investigation, the minor reaches the age at which he or she is legally competent to give informed consent as defined by national law, his or her informed consent is obtained before that participant can continue to participate in the clinical investigation.

In accordance with point 3b), three separate information and consent forms are available depending on the age of the participants: 5-7 years, 8-11 years, 12-17 years.

9. STORAGE OF DOCUMENTS AND DATA RELATED TO THE STUDY

9.1 CONFIDENTIALITY

All data collected as part of the study protocol will be entered into a computer system by the sponsor in accordance with the French Data Protection Act (Article 40 of January 6, 1978), which complies with European Directive 95/46/EC.

9.2 PERSONAL DATA CIRCUIT

In accordance with Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data, the data collected as part of the study protocol will be pseudonymized (according to the process described in §. 3.1.2.

Assignment of a patient number*)* then collected on paper and transcribed into a password-protected database. This database will be hosted and backed up on a file server (with access protected by Active Directory accounts and in a building with physical access secured by a code and alarm). The database will be transferred to RC Informatique via a secure transfer (SSH connection with asymmetric encryption and in a building protected by magnetic badge access and video surveillance).

9.3 PROPERTIES OF THE RESULTS

The Sponsor is the sole owner of the study data and results. It reserves the right to use them in any form whatsoever, to submit them to the Health Authorities of any country.
In the event that the study generates results that could be patented, the Sponsor shall be solely entitled to file such a patent, in its name and at its expense.

9.4 ARCHIVING

The investigator must retain all study documents that he or she has completed until the closing visit. completion.
EUROS SAS will archive all study documents for 15 years after the end of the study. After this period, the database will be destroyed.

10. PUBLICATIONS

Any information resulting from the study will be considered confidential and must not be disclosed without the prior consent of the Sponsor.
The results of the study may be published or presented by the Investigator or the experts responsible for the analyses, in collaboration with the Sponsor, with the latter's written consent. The Sponsor may use the results of the study for any publication or communication, with the written consent of the Investigator or the experts responsible for the analyses if they are cited.

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12. APPENDICES

12.1 LIST OF INVESTIGATORS

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12.2 INFORMATION AND CONSENT FORM ADDRESSED TO PARENTS AND CONSENT FOR PARTICIPANTS AGED 5 TO 7

Hello,
You have a curve in your back. This is called scoliosis.
The doctor who is treating you, Professor/Doctor _____, will perform an operation to help your back become straighter.
During the operation, the doctor will insert metal implants into your back. One of these implants is called NEMOST. It is manufactured by a company called EUROS.
The doctor also invites you to participate in a study called "Post-marketing surveillance study of the NEMOST V2 growth domino." This study is managed by Euros and Dr. Solla in Nice and bears the number 2025-A01794-45.
This study is used to check how you are doing after the operation. You will see the doctor as planned, sometimes have photos taken of your back (X-rays), and answer a few questions. It is the same as what you would have done anyway. The only difference is that the doctor will write the information in a special notebook for 5 years.
You can say yes or no to participating. If you say no, no one will be upset. You will still receive the same level of care. Since you are still a child, your parents must also agree.
If you say yes, but one day you no longer want to participate, you can stop. Just tell your doctor or your parents.

Your doctor is available if you have any questions. Thank you very much for reading this information.

Participant consent
Last name, First name: _____
Consent given: ☐
Date

12.3 INFORMATION AND CONSENT INFORMATION ADDRESSED TO PARTICIPANTS AGED 8 TO 11

Hello,
You have a deformity of the back called scoliosis. The professor/doctor _____ will perform an operation to correct this deformity. The operation will proceed as follows: after putting you to sleep, your surgeon will open your back to straighten it. To ensure that your back remains straight, your surgeon will use metal rods called NEMOST, manufactured by EUROS. These rods will remain attached to your back and will help you grow and keep your back as straight as possible.
Your surgeon is also participating in a study managed by EUROS that monitors how children fare after scoliosis surgery. The study is being conducted at the hospital. _____ and managed by Dr. Solla (Nice Hospital). The study has been assigned the national number 2025-A017094-45.
If you agree to participate, nothing will change in your medical care: you will see your doctor as usual, undergo the same tests (such as X-rays), with a few additional questions, and nothing will be painful. The only difference is that information about your surgery and your condition will be recorded in a special notebook and stored on a computer without your name, to protect your privacy.
Participation is voluntary:

- You can say yes or no.
- Your parents must also agree.
- If you refuse, nothing will change in terms of your care.
- Even if you agree, you can change your mind later without having to justify your decision.

The study lasts 5 years. The device has all the necessary approvals, so participating does not put you at any additional risk.
If you have any questions, your surgeon can explain everything to you.

Participant consent
Last name, First name: _____
Consent given: ☐
Date Signature [optional but not mandatory]

12.4 INFORMATION AND CONSENT INFORMATION ADDRESSED TO PARTICIPANTS AGED 12 TO 17

Hello,

You have a spinal deformity called scoliosis, and the professor/doctor _____ will operate on you to treat this deformity. During the operation, after opening your back and correcting your scoliosis, your surgeon will use materials such as screws and rods to keep your back straight. He has chosen to use a rod called NEMOST, which is manufactured by EUROS.
Your surgeon is participating in a study entitled "*Post-marketing surveillance study of the NEMOST V2 growth domino*." EUROS SAS is the sponsor. The purpose of this study is to monitor your health after your scoliosis surgery. This study is being conducted at the hospital _____, a French center with extensive experience in treating scoliosis in children. This study is managed by Dr. Solla (Nice Hospital). The study's national number is 2025-A017094-45.
Your surgeon has just asked you to participate in this study. This information sheet is intended to explain the purpose and procedure of this study.

To monitor your health, the doctor needs to see you for a consultation and will also ask you to undergo a number of additional tests. These tests are no different from those you already undergo and are not painful. They include, for example, an X-ray or a questionnaire.
If you agree to participate in this study, the medical follow-up you receive will be exactly the same as if you were not participating. The only difference if you participate is that details about your scoliosis, the operation, and the results of the tests you have had will be recorded in a medical notebook.
If you do not wish to participate in this study, the doctor will see you for your appointment as planned and will offer you the same medical care. However, the medical record will not be completed.

The information recorded in the medical logbook will be stored on a computer, but no one will be able to link it to your name. You will be able to check it if you wish. You will also be able to access the results of this study. All you need to do is ask your doctor.

This study is expected to last five years. The device has obtained all the necessary authorizations, so there is no additional risk in participating in this study.

Participation in this study is entirely voluntary. You are free to accept or refuse to participate without this affecting your relationship with the people (doctors, nurses, etc.) who monitor your health. As you are not yet 18 years old, your parents must also indicate whether or not they agree to your participation. If

you refuse or your parents refuse, you are not required to give any explanation. Even if your parents agree, you can still accept or refuse to participate, after asking any questions you may have.
If you agree to participate, you must have read and understood this document. An equivalent document is also given to your parents or legal guardians, who must also agree. If you need further explanation, your surgeon is available to answer your questions. If you agree, tell your parents and your doctor. You do not have to give your answer right away; you can take a few days to think about it, ask questions, and discuss it with your parents before giving your final consent.

If you change your mind later, you can stop participating in the study at any time without having to give an explanation.

Your surgeon remains available if you require further clarification. We appreciate your cooperation.

Participant's consent
Last name, First name: _____
Consent given: ☐
Date Signature [optional but not mandatory]

12.5 INFORMATION NOTICE FOR PARENTS OR LEGAL GUARDIANS

Dear Sir or Madam,

Dr./Prof. _____[Name, First name of the investigating physician] is offering your child the opportunity to participate in a study that aims to evaluate NEMOST growth rods in the treatment of progressive scoliosis. Your child is free to participate or not. You can take the time you need to read the information below, discuss it with your child and your treating physician, and ask the research physician, known as the investigator, any questions you may have. Once you have received satisfactory answers to your questions and had sufficient time to consider the matter, you can then decide whether or not to allow your child to participate in the research.

Your child's condition can be treated in several ways, including surgical correction of the scoliosis and the insertion of rods to maintain the correction. Since your child is still growing, growth rods are an option. From among all the implants available, the doctor has chosen the CE-marked NEMOST implant, manufactured and marketed by EUROS SAS (ZE Athélia III, 13600 La Ciotat).

As part of your child's treatment, we are offering them the opportunity to participate in a clinical study entitled "Post-marketing surveillance study of the NEMOST V2 growth domino." This study is being conducted at _____[name and address of the center]. Its purpose is to monitor any complications and the performance of the NEMOST device. EUROS SAS is the sponsor of the study. The study is coordinated by Dr. Solla (Nice Hospital). The study has been assigned the national number 2025-A017094-45. It is an interventional clinical study that involves collecting clinical and radiological data for a maximum period of 5 years after surgery. This study will involve 140 patients in 5 different centers. All consultations and examinations are part of your child's usual medical follow-up. There are no risks associated with this clinical study, as the device has already been approved and is commercially available, and no additional invasive procedures will be necessary. There are no additional costs and/or medical procedures. At each consultation, the surgeon will ask you questions to determine your quality of life score using the Early Onset Scoliosis Questionnaire-24 (EOSQ-24) and will take an X-ray of your child. At certain visits, a lung function assessment will be performed. If you have difficulty traveling to the consultations, we will offer you the option of answering these questions by phone, email, or mail. The data collected will concern the preoperative visit, the operative report, and a maximum of 8 postoperative visits (postoperative visits at 3 months, 6 months, 1 year, 1.5 years, 2 years, and then every year until 5 years postoperatively). The preoperative visit you are currently attending allows the doctor to assess whether your child could participate in the research or not, based on criteria relating to their condition or age.

In accordance with Article L. 1121-4 of the French Public Health Code, this research has been authorized by the French National Agency for Medicines and Health Products Safety (ANSM) and received a favorable opinion from the Committee for the Protection of Persons on December 19, 2025. The processing of your personal data in the context of this research complies with a methodology established by the French Data Protection Authority (CNIL).

Your child's participation in this research is voluntary: you are free to accept or refuse their participation in this study and you can withdraw them from the study at any time without having to give a reason and without incurring any liability or prejudice as a result. All you need to do is notify the investigator. Your decision to allow or refuse your child's participation will have no impact on their medical care, the quality of their treatment, or their relationship with the investigator. In order for your child to participate in the research, you must first give your free and informed consent. "Informed" means that you will have received clear and understandable information about the issues and conduct of the research and about your child's rights as a participant and your rights as a parent or guardian. You will be informed

by the investigator monitoring your child of any new information concerning the research that could change your decision to participate. You have the right to obtain, during or at the end of the research, information concerning your child's health held by the investigator. If you wish, you may be informed of the overall results of this research in accordance with the provisions of Article L. 1122-1 of the Public Health Code, once it has been completed, by contacting the investigator.

If you agree to your child participating in the research, their personal data, including their health data, will be processed* by the sponsor, in their capacity as data controller. The following data will be collected: general data (age, weight), data on their medical conditions, clinical scores, radiographic results, and any complications. This processing is authorized because it is necessary for scientific research purposes. The data controller must implement appropriate measures to guarantee your child's rights and freedoms, in particular by only collecting data that is strictly necessary for the research.

Your child's personal data will be treated confidentially, in accordance with the amended law of January 6, 1978, known as the "Data Protection Act," and in accordance with the General Data Protection Regulation (GDPR). The data will be pseudonymized, meaning that your child will be identified by a code number for research purposes, without mentioning their first and last names. Only the investigator will keep the list of correspondences between the code and their name. Information concerning their identity (surname, first name) will only be known to the medical team caring for them, as well as to the persons carrying out the quality control of the research mandated by the sponsor, by the health or control authorities, and by the sponsor's data protection officer if you contact them [by email:rgpd@euros.fr , by post: EUROS SAS, Z.E. Athelia, 13600 La Ciotat]. These individuals are bound by professional secrecy. You have the right to access your child's data through the investigator and request that it be corrected or completed. You may also request that the processing of the data be restricted (i.e., ask the sponsor to temporarily freeze the use of your data). Even if you agree to your child participating in the research, you may object at any time to the processing of their data for the purposes of the research. In this case, no further information about them will be collected. You may also exercise your right to have data that has already been collected erased, but this may not be possible if it would make it impossible or seriously compromise the achievement of the research objectives. In addition, certain data intended to ensure the quality and safety of the research (e.g., adverse effects of the products being tested) must be collected by the sponsor. You will not be able to exercise your right

to object to or erase this data. You may exercise your rights at any time without having to justify your decision. As the sponsor does not have access to your identity, we recommend that you first contact the investigator using the contact details provided in this notice. If you wish, you may also exercise your rights by contacting the sponsor's data protection officer (by email:rgpd@euros.fr , by mail: EUROS SAS, Z.E. Athelia, 13600 La Ciotat, France), who will handle your request in coordination with the physician and professionals involved in the study. In this case, your identity (first name, last name) will be made available to the sponsor's data protection officer. If you are unable to exercise your rights, you also have the right to lodge a complaint regarding the processing of your personal data with the Commission nationale de l'informatique et des libertés (CNIL), which is the competent supervisory authority in France for data protection.

EUROS SAS undertakes not to transfer data concerning your child outside the European Union and to archive all study documents for 15 years after the end of the study. After this period, the documents will be destroyed.

The surgeon remains at your disposal for any further information you may require. Thank you for your cooperation.

CONSENT FORM

We, the undersigned,

Mr., Mr./Ms. , (*surname, first name of the holder of the*)……...

Mr. Mr./Ms. , (last *name, first name of holder of the*)……...

*[**If there is only one holder of parental authority, they must certify this manually** I, the undersigned, Mrs., Ms., Mr. (surname, first name of the sole holder of parental authority) certify that I am the sole holder of parental authority]*……

freely accept freely that our child (first name, first name of the child)**……..is participating in the research study entitled "Post-marketing surveillance study of the NEMOST V2 growth domino"**

organized by EUROS in collaboration with the hospital.....and which us has was proposed by the Dr. Prof.*, (surname, first name, phone number, department*)

…....., physician in this search.

- We have read the information sheet explaining the purpose of this research, how it will be conducted, and what our child's participation will involve.
- our child has been informed and has not refused to participate in this research,
- We had the opportunity to ask the doctor any questions we wanted, and he explained the potential risks and constraints associated with our child's participation in this research.
- we received appropriate answers to all our questions,
- We have had sufficient time to make our decision.
- We understand that our child's participation is voluntary and that we may withdraw our consent at any time without incurring any liability or prejudice to the quality of care provided to him or her. We will then inform the attending physician whether or not we wish the data collected up to the time of our decision to be used.
- We are aware that our child's participation may also be interrupted by the doctor if necessary.
- Before participating in this research, our child underwent a medical examination appropriate to the research, the results of which were communicated to us.

- We understand that in order to participate in this research, our child must be covered by social security. We confirm that this is the case.
- We have been informed that his participation in this research will last for **five years after the procedure.**
- Our consent does not in any way release the doctor treating our child as part of the research or the hospital from all of their responsibilities, and our child retains all of their rights guaranteed by law.
- We acknowledge that we have the right to access, rectify, restrict and, where applicable, object to and erase our child's personal data. These rights may be exercised in the first instance with the investigator who is monitoring our child as part of this research and who knows their identity.
- We understand that this research has been authorized by the French National Agency for Medicines and Health Products Safety (ANSM) and has received a favorable opinion from the Committee for the Protection of Persons.
- The overall results of the research will be communicated to us at the end of the research, if we request them from the investigator.
- After the research has begun, we may request additional information from Dr./Prof. .
- Two original copies of this consent form have been drawn up: one has been given to us, the second is kept by the investigator. They will be kept in the study file for at least 15 years after the end of the research.
- We have been informed about how our child's personal data may be collected, used, and shared as described in this document.

Signature of the legal guardians Last name,	Doctor's signature
First name: _____	Last name, First name: _____
Date Signature:	_____ Date
Last name, First name: _____	Signature:
_____ Date	
Signature	

Participant's consent
Last name, First name: _____
Consent given: ☐

Date	Signature [optional]

This document must be completed in duplicate, with the original to be kept *for 15 years* by the investigator, and the second given to the person giving consent.