\*\*\*PLEASE DELETE THIS TOP BANNER BEFORE USING OR SUBMITTING THIS INFORMED PATIENT CONSENT FORM TO A PATIENT OF YOUR HOSPITAL\*\*\*

This Informed Patient Consent form is being proposed for use in conjunction with your participation in the EUROSPINE Spine Tango Registry (the “ST Registry”), and your rights and duties to comply with applicable data protection laws and regulations when obtaining and documenting each of your patient’s informed consent for the use of their data. Such patient informed consent must also comply with General Terms and Conditions of the EUROSPINE Spine Tango Registry (the “ST General Terms”).

EUROSPINE and its registry hosting provider, NEC Software Solutions UK Ltd (“NEC”) will only gather data from the Participant to the ST Registry upon execution of the Informed Patient Consent form in substantially the version appearing below. Any changes to the form may result in a suspension of your access to the ST Registry if either EUROSPINE or NEC reasonably believe that changes to the form fail to comply with Section 4 of the ST General Terms, or applicable data protections laws or regulations.

**Please be sure to indicate whether Patient has provided his/her consent in the (describe the Spine Tango Live system). If the Informed Patient Consent form is modified in any material way, EUROSPINE reserves the right to be provided with a copy of the form, for its internal records. EUROSPINE**

If in doubt as to whether any proposed changes to the form are material, please communicate with your EUROSPINE contact prior to using the amended form.

\*\*\*PLEASE DELETE THIS TOP BANNER BEFORE SUBMITTING THIS DOCUMENT TO THE TEAMING PARTY\*\*\*

**Informed Patient Consent**

**Informed consent of patient about external data processing of <<*please insert hospital name*>> in <<*please insert place of hospital*>> by EUROSPINE, the Spine Society of Europe and NEC Software Solutions UK Ltd (hereinafter "NEC") in the United Kingdom.**

1. **Who are we and for what purposes do we collect, use and process your personal data?**

The hospital <<please insert hospital name>> and the registry hosting provider NEC work together under the direction and supervision of EUROSPINE, the Spine Society of Europe, c/o Pfister Treuhand AG, Bankstrasse 4, 8610 Uster-Zürich, Switzerland by centrally collecting medical data in the European spine registry “Spine Tango”. The hospital transfers your data via an electronic application service provider network to NEC for storage and evaluation.

The data pool is evaluated for quality assurance regarding the performance of various spinal implants and treatments, allowing malfunctioning implants to be identified and the hospitals involved and all patients who received those implants to be contacted for a follow-up examination. The registry therefore facilitates improved consumer protection.

1. **What personal data do we collect?**

Based on your explicit consent and pursuant to Article 9 (2) (a) GDPR, the hospital can centrally archive all relevant medical data. This includes data from admission, surgery/treatment, rehabilitation, and follow-up examinations recorded by the various hospital departments. Consequently, to the extent authorised by applicable law, this consent refers to all data generated during hospitalisation or outpatient treatment, including your contact details and medical and health data.

1. **Who has access to your data?**

In addition to the hospital collecting your data, NEC (in the United Kingdom) as service provider, as well as EUROSPINE (in Switzerland) as registry owner will have access to your personal data solely to fulfil the registry purposes outlined above.

Other hospitals can request access to data stored by NEC from EUROSPINE for research purposes. If the request is granted, the hospitals will only receive access to anonymised data. Furthermore, implant suppliers can request access to data stored by NEC from EUROSPINE for quality assurance purposes. If the request is granted, the hospitals will only receive access to aggregated data.

1. **For how long do we retain your personal data?**

EUROSPINE will keep your personal data as long as necessary to fulfil the purposes outlined above or as required by applicable law.

1. **How do we secure your data?**

The transferred data are protected from being accessed by unauthorised persons with the necessary and appropriate technical and organisational measures. The NEC and EUROSPINE staff are bound by a confidentiality obligation.

Your personal data may be transferred to a country that may not provide the same level of data protection as provided by your home country. In such cases, EUROSPINE will conclude a data transfer agreement based on the EU model clauses with the hospitals or service providers concerned in order to ensure an adequate level of data protection.

1. **How can you exercise your rights?**

We have appointed <<please insert contact information>> as the contact person with whom you can exercise your rights.

You may have certain rights against EUROSPINE and the hospital to request (1) access to your personal data, (2) rectification of your personal data, (3) erasure of your personal data, (4) restriction of processing of your personal data, (5) portability of your personal data, (6) objection to the processing of your personal data (including objection to profiling), and (7) objection to automated decision making (including profiling).

Furthermore, you may withdraw your consent at any time with no influence on the contract governing your medical treatment by contacting [health\_servicedesk@necsws.com](mailto:health_servicedesk@necsws.com). However, the withdrawal does not affect the lawfulness of any previous data processing. You may exercise these rights by contacting the appointed contact person. If we are unable to provide the requested data or information or make the changes you requested, we will provide the reasons for such decisions.

If consent is denied, the hospital will not transfer your personal data to NEC or EUROSPINE and it will not be processed or evaluated. If consent is withdrawn, NEC and EUROSPINE will cease to process your personal data and delete it from storage.

1. **Consent**

I was given the opportunity to ask questions. [optional] These questions were answered fully and comprehensively by ………………..

**Therefore, and in light of the above, I release the hospital from professional medical secrecy and consent of my own free will to my personal data being collected, used, transferred and processed as stated above.**

Date/place Signature of patient Patient’s name (print)

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Signature of parent or guardian if the patient is under … years old (the local age necessary for this consent)

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