GENERAL TERMS AND CONDITIONS

OF THE EUROSPINE SPINE TANGO REGISTRY

between

EUROSPINE, the Spine Society of Europe
c/o Pfister Treuhand AG
Bankstrasse 4
8610 Uster
Switzerland
(the "**EUROSPINE**")

And

(the "**Participant**")

(each a "**Party**" and together the "**Parties**")

Content

1. Participant's Capacity

The Participant can be either an individual or a legal entity. If the Participant is an individual they should be a member of EUROSPINE (in any one of the approved membership categories). If the Participant is a legal entity, it can authorize any of its employees or members of its departments to participate in Spine Tango in accordance with this agreement ("Agreement") (such employee or member referred to as "Authorised User") provided that Participant guarantees Authorized Users' compliance with Participant's obligations under this Agreement and shall be responsible for any of Participants' Authorised User's failure to comply with the terms of this Agreement, including without limiting the generality of the foregoing, section13. For legal entities, at least one Authorised User should be a member of EUROSPINE. If Participant does not meet these membership criteria, EUROSPINE membership shall be obtained within 12 months of signature of this Agreement.

2. Spine Tango registry

2.1 Mission Statement

The Registry, as defined further below, gathers data from international participants to provide across countries performance benchmarking and a collective evidence base of treatment effectiveness, patient safety and best practice. EUROSPINE aims to establish Spine Tango as a standard of care for any patient undergoing spinal surgery.

2.2 Vision

EUROSPINE's vision is to make the Spine Tango registry ("Registry") the leading spine registry in Europe.

2.3 Background & History of Spine Tango

Innovations in spinal surgery demand continuous evidence assessing the efficiency, safety and effectiveness of new techniques and technologies.

Spine Tango, the international Spine Registry of EUROSPINE, was established in 2002 to address this need. Since its inception, there have been a growing number of hospitals and centres contributing to the Registry.

It is in the interest of patients, surgeons, providers and industry to have in place effective data collection and analysis on implant performance. This enables assessment of real world evidence on the safety and effectiveness of implants and treatments.

Changes in device regulation is driving greater need for high quality longitudinal data on implant performance and outcome. A registry offers opportunity to provide a cost effective mechanism to support this, although to date, there has been a lack of linkage between device and outcome data.

2.4 Major purposes of the Registry

The major purposes of the Registry are:

- Evidence of performance and quality assurance
    - of spinal care for individual user, departments, hospitals, national modules,
    - of spinal care across countries, and
    - of spinal implants;
- Research (with anonymised patient data).

2.5 Definitions

The Core Outcome Measures Index (COMI) is a short, multidimensional outcome instrument, with excellent psychometric properties, that has been recommended for use in monitoring the outcome of spinal interventions from the patient's perspective.

The Database is the result of the collection of independently gathered data through the Registry, arranged in a systematic or methodical way.

Spine Tango's Dictionary of Terms refers to documents published on the Spine Tango webpage which provide a glossary of terms used in the Spine Tango data collection tools.

Documentation is the written and/or online descriptions of the Platform's features, functions and methods of operation and (where relevant) the user instructions for the Services made available to the Participant by EUROSPINE and/or the Host.

Currently, NEC Software Solutions UK Limited (NEC) is the host of the Registry. NEC is an information services provider specialising in secure data collection, data management and informatics services across public sector bodies. Based in the UK, NEC is an NEC Group Company, with offices around the world. EUROSPINE reserves the right to appoint another host of the Spine Tango registry. EUROSPINE shall inform the Participant about the new host prior to the change becoming effective. NEC or any future host shall be referred to as "Host" throughout this Agreement.

Platform is the online platform provided by the Host in order to host Spine Tango.

Software is the online software made available by the Host for use by the Participant as part of the Services.

Spine Tango or Registry is an international, web-based registry of clinical data and outcomes from surgical and conservative spinal interventions.

Spine Tango Task Force is the steering committee of the Registry consisting of an international board of spinal surgeons, non-surgical therapists and researchers. The Task Force is also responsible for representation of the interests of the users to the Executive Committee of EUROSPINE.

2.6 Registry content

Surgery form: Being initially a purely surgical registry, Spine Tango has been developed around one core questionnaire for primary and revision surgeries. The form is suitable for documentation of all spinal pathologies, levels, accesses and surgical techniques and is concise. A follow-up form is also available.

Implant documentation is enabled within the Spine Tango surgery form and is required for implant-based surgery.

Patient-reported outcome: There has been a significant shift in political and consumer requirements for validated surgical outcomes. With this in mind the Core Outcome Measures Index (COMI), originally proposed by R. Deyo et al. (1998), was developed by a group at the Schulthess Clinic and at Balgrist Hospital, Zurich, Switzerland (Mannion AF, Grob D, Boos N et al.) for back and neck pain (two separate instruments) and is now the official outcome instrument for the Spine Tango community. Similar to the physician-based documentation, the COMI is short (7 items), comprehensive and easy for patients to fill in.

Conservative form: The "Spine Tango conservative form" is a documentation form for the most important non-surgical treatment options. One of the main goals in the development of the

conservative form was to enable meaningful comparisons between surgical and conservative patient outcomes.

3. Joining the Spine Tango Registry

The Host will provide remote assistance to all Spine Tango participants, particularly new starters. On-site assistance may additionally be provided to facilitate set-up and training in the use of the system. Charges may be applied for on-site assistance.

4. Participant's right and duties

4.1 Compliance with the General Data Protection Regulation (GDPR) and other national laws and regulations

The Participant shall ensure that all necessary agreements and approvals are obtained from their institution (and can be made available on demand) in respect to any local laws, guidelines, "best practices", ethical requirements, etc. In particular, the Participant is explicitly responsible for obtaining and documenting each patient's informed consent for the use of their data for purposes of research and quality assurance in the Registry and warrants that it has obtained all necessary consents and approvals required for processing all information relating to an identified or identifiable natural person to be processed under this Agreement.

Furthermore, the Participant commits to document their cases in the Registry in accordance with good clinical and epidemiological practice standards.

Participant is considered a data controller regarding the collection, pseudonymization and transfer of personal data of its patients prior to and at time of submission of its data to the Registry. The Participant may enter personal data of the patient to the Registry, although it is not required to do so. Participant shall decide in its sole discretion whether personal data of the patient may be required for the identification of the patient at the time of submission to the Registry. The Participant may, at its sole option, enter data in a pseudonymized form and retain the key for the pseudonymization of its data. Unless otherwise agreed with Participant, EUROSPINE will not have access to Participant's key used by it for the pseudonymization of its data.

If personal data is submitted by the Participant along with clinical data, EUROSPINE shall maintain them in the Registry database for the Participant's sole use (e.g. identification of the patient). Any personal data submitted by the Participant (whether or not pseudonymized by Participant) will be strictly anonymized by EUROSPINE prior to EUROSPINE 's pooling of said data with clinical data into the Registry, for quality assurance (reports) and research.

EUROSPINE shall not attempt to re-identify any pseudonymized patient personal data submitted by Participant. In the event pseudonymized patient personal data, for whatever reason, becomes identifiable to EUROSPINE or Host, EUROSPINE agrees to immediately notify Participant, to immediately remove the reference to that patient and to preserve, at all times, the confidentiality of information pertaining to such patient. EUROSPINE shall ensure that the Host to whom it provides/discloses the pseudonymized patient personal data agrees in writing to be bound by the same restrictions and conditions that apply to EUROPSINE with respect to such patient personal data.

EUROSPINE may in certain cases be considered to be a joint controller with regard to the personal data submitted by Participant to the Registry (both pseudonymised and data entered into the register without pseudonymisation). In such cases, EUROSPINE will comply with all legal obligations which it

may be subject to in its capacity as a controller, including but not limited to the requirement allowing a data subject to assert his/her rights under applicable law.

Host is considered to be the processor of the personal data stored within its hosting IT infrastructure. EUROSPINE has entered into a data processing agreement with the Host pursuant to Article 28 of the GDPR, which obliges the Host to process personal data in accordance with the rules of the GDPR. Each Party agrees to comply with all applicable obligations under the GDPR, and other national laws and regulations applicable to the parties' data processing activities, including technical and organizational measures and to protect the rights of the data subjects under chapter 3 GDPR (information, rectification and erasure, data portability, objection, as well as automated decision-making in individual cases) within the statutory periods.

Additional information regarding the Parties' rights and obligations respecting data processing can be found in the FAQ on Data Protection and Information Security attached hereto as Annex 1, as may be amended by EUROSPINE from time to time and the Data Processing Agreement entered attached hereto as Annex 2.

4.2 Requirements for Participant

The Participant hereby agrees that by signing this Agreement it acknowledges that no data which has been submitted, aggregated and anonymized for use by the Registry can be withdrawn/removed at a later date, irrespective of Participant's withdrawing for any reason from Spine Tango participation and terminating this Agreement. Only (i) data entered and subsequently found to be "fraudulent" or (ii) identifiable patient data residing on the Spine Tango Registry which has become subject to a patient's request to rescind his/her consent for use by Participant will be removed from the data pool. If such data has already been used in existing publications, and has markedly influenced those published findings, this shall be addressed as an addendum in the relevant journal or publication. [The reason for insisting on the retention of all data in the Registry is that any data that has been published, based on a given data set, must be readily accessible to underpin the evidence and be available should inspection be requested. Although an electronic copy of the specific dataset will be stored separately in the database, the original data must be traceable within the Registry at all times. However, removal of clinic related identifiers, such as name and address, and all names of registered colleagues and patients are subject to submission of a written request to EUROSPINE.

4.3 Data ownership and use of the data

A Ownership

Each Participant and its authorized users retain ownership of data they have entered into the Registry and may use them for the purposes of scientific publication or quality assurance. This also applies for Participant and their groups of users that wish to use their combined data for, inter alia, hospital, multi-centre or national data analysis.

The anonymized data pool is owned by EUROSPINE. EUROSPINE determines how the data is to be processed, including access controls. EUROSPINE only pools the data submitted by the Participant without personal patient identification identifiers, from all Participants and stores the pooled data in an anonymized (for example aggregated) way for quality assurance (reports) and research purposes, as specified in this Agreement.

B Use of the data

Should the Participant have a proposal for a study that requires/involves data from the whole data pool, the Participant may apply for an access to the data of the whole data pool and submit a summary of the proposed study for approval to the Spine Tango Task Force.

If approved, the major participants contributing the data (≥20%) for the proposed study shall be invited by the authors to join the study and co-author the paper, conditional upon their effective contribution to the work. The first author shall be the judge of "effective contribution" and the subsequent rights of authorship. Should a dispute arise in relation to "effective contribution" the Spine Tango Task Force shall be the final arbiter whose decision shall be final and binding upon the parties.

Following approval of a study protocol by the Spine Tango Task Force, Participant shall have access to EUROSPINE's anonymized international data pool for research purposes. The access will be given only for purposes of the approved study and may not be extended to other studies or analyses. Any misuse of the data will result in an immediate termination of this Agreement, the exclusion of the Participant from the Spine Tango community and the immediate withdrawal of access to the Registry.

Each Spine Tango based publication shall mention in the Material and Methods section

- EUROSPINE, the Spine Society of Europe, as the owner of the Registry, and
- NEC Software Solutions, as the host of the Registry.

Furthermore, all Spine Tango Participants, which contributed data to the study, should be acknowledged by hospital name and country.

Participant shall use a common language for completion of the Spine Tango forms in accordance with the definitions given in the Spine Tango's Dictionary of Terms. [Adherence to the Spine Tango Dictionary of Terms is important to ensure consistent and systematic data collection, and to avoid any wording/phrasing from being interpreted differently by different users.] Constructive comments and feedback on the dictionary are encouraged and welcomed, especially if Participant encounters any inconsistencies or ambiguities.

Participant is strongly encouraged to use the COMI as a patient-related outcome instrument, given that it is available in the necessary language.

5. Quality of the data and audits

Auditing of the Registry data, including verification of data accuracy and the proportion of total cases submitted to the Registry, is essential to ensure that Registry data is reliable. Any such audit shall be performed in such a manner as to avoid unreasonable interference with Participant's operations; and the audit shall be limited to verification of data accuracy and compliance with the terms of this Agreement. EUROSPINE and the Host will be monitoring the quality of the entered data using regular data analyses and other approaches.

Participant agrees to on-site auditing of their Registry practices at the prior request of EUROSPINE, which may not exceed six (6) person-hours of hospital resources per year. Cost of additional efforts shall be discussed between the parties and agreed upon before the audit occurs. On site audits may be conducted to measure quality of data documentation, compliance with this Agreement and completeness. Participants will receive notice of any audit at least one month in advance. Participant also agrees to on-site auditing by an independent party contracted by EUROSPINE who shall be made known to Participant in due advance (all independent auditors will be bound by medical confidentiality). As part of any audit, Participant will be required to provide the methodology and means by which they verify the number of cases they have operated upon or treated in a given year

(e.g. clinic information system, operating room report, personal agenda, and billing procedure) in order to calculate the percentage of patients with data sets submitted to the Registry.

Honesty, truthfulness and integrity are explicitly required of Participant and all participants in the Registry community. Strict enforcement of EUROSPINE's standard is essential in order to ensure the integrity of the dataset, and its value to other participants and EUROSPINE. EUROSPINE retains the right to exclude Participant from Registry participation if serious data quality problems are demonstrated through monitoring, and are not corrected during a reasonably long period of time set in the appropriate warnings. In the case of proven fraudulent behaviour the Participant's entire data set will be removed from the Registry and their current and previous participation will be terminated. Participant's name will be deleted from the published list of participants. This step will only be taken after an investigation by the EUROSPINE Executive Committee. The EUROSPINE Executive Committee has discretion to conduct the investigation as it deems appropriate. In the event of such an investigation, Participant must comply with the Executive Committee's requirements and requests.

6. Accreditation

In order to be acknowledged by EUROSPINE as an "Accredited Spine Tango Participant" Participant must comply with the completion rates for data input described below. The final decision for recognition as an "Accredited Spine Tango Participant" will be made by the Spine Tango Task Force based on the data completion compliance proven by an on-site audit.

To be and continue to be acknowledged as an Accredited Spine Tango Participant, Participant must obtain ≥80% "case" documentation rate (completeness).

A surgical "case" is defined as a preoperative COMI form, the surgical intervention form, and at least one postoperative COMI and physician follow-up form at an interval of ≥3 months after treatment. For the non-surgical participants, a conservative "case" is defined as a pre-treatment COMI form, the conservative treatment form and an end of treatment assessment with a COMI form. Where Accredited Participants already have a set-up in place that relies on other established outcome questionnaires (e.g. Oswestry, RMDQ, NDI etc.) they will not be compelled to change to the COMI form; however, where feasible, they will be encouraged to use the COMI form in addition to their own chosen outcome instrument(s) and must as a minimum include two 0-10 pain scales for axial pain and referred pain. Having at least one instrument in common between all centres (pain scale) will facilitate comparison. It may also allow "calibration" of the data collected using outcome instruments other than the COMI.

Participant may apply to become accredited as an "Accredited Spine Tango Participant" after a minimum of 12 months' participation in the Registry. If Participant believes that they have reached the necessary standards and that these can be maintained in the long term, an application letter must be sent to the Spine Tango Task Force with documented proof indicating the annual surgical or treatment volume (e.g. hospital or departmental annual report). If compliance is deemed inadequate, assistance will be offered in an attempt to remedy the shortcoming. Accreditation will be affirmed on an annual basis.

7. Promotion

The Spine Tango community aims to foster an atmosphere of open exchange, support and assistance for all users. Participants and their administrators are encouraged to share their Spine Tango expertise and know-how with other participants.

8. Benefits for the Participant and duties of EUROSPINE

Each participant has their own database of individual Registry activity for the purposes of, inter alia, quality assurance, outcomes research, and implant monitoring. The database can be exported at any time, for example to perform further statistical analyses beyond those offered by the online statistics. Each individual database is part of the Registry data pool, which means that the work of each participant offers value to the wider community beyond that which it offers to the participant. Benefits of Registry participation include:

Automatically managed electronic patient-reported outcome measures, online statistics and benchmarking of local performance with the anonymous data pool of all other Participants is available without the need for any statistical software or data handling knowledge.

Annual Registry report in electronic format (within the 1st quarter of the following year).

Annual hospital report with benchmark in electronic format (within the 1st quarter of the following year).

Annual user report with benchmarking in electronic format (within the 1st quarter of the following year).

Ongoing remote support for the users. On-site support may be available, however, charges may apply.

Access to diverse questionnaire and templates (e.g. study protocol template, informed patient consent template) to assist with participation and research study.

A large international network of clinicians and researchers, open to collaboration.

Access to EUROSPINE's anonymized international data pool for research purposes.

The EUROSPINE is collaborating with industry stakeholders to establish and maintain an extensive database of spinal implant. The implant database will facilitate compliance with EU medical device regulations.

EUROSPINE commits for continuous development of the Registry to ensure that Participants benefit from the most up-to-date technical solutions and best-practice approaches for Registry processes.

9. Additional benefits for the Accredited Spine Tango Participant

For the period during which the Participant is an Accredited Spine Tango Participant, the Participant shall have access to the following data:

Annual hospital report with benchmark based on the data from Accredited Spine Tango Participants only, in electronic format (within the 1st quarter of the following year).

Annual user report with benchmark based on the data from Accredited Spine Tango Participants only, in electronic format (within the 1st quarter of the following year).

Yearly accreditation with a certificate confirming status as "EUROSPINE Spine Tango Accredited Participant".

All accredited Participants will be listed on the EUROSPINE website and Spine Tango website on an annual basis.

Use of logo indicating status of "EUROSPINE Spine Tango Accredited Participant".

10. User fee

A. Participation in the Registry and basic services are free of charge. No user fee is collected.
B. Individual services (technical features, customized reporting, support on-site etc.) for the users may be provided by the Host. Any such services can be arranged through a separate bilateral agreement between the Participant and the EUROSPINE. Similarly, specific requirements regarding technical and content set-up of the Registry (e.g. national modules of the Registry) can be arranged through a separate bilateral agreement between the user and EUROSPINE.

11. Third parties (industry, insurance companies, political bodies, societies etc.).

Any requests for research data from a third party (non-commercial, academic only) must be made to the Spine Tango Task Force. The Spine Tango Task Force will consider the application and any requirement for further authorisations (e.g. ethical approval). EUROSPINE will also consider potential breaches of GDPR and any other legal or contractual obligation including issues of consent. The data will only be released when the Spine Tango Task Force is satisfied that it is appropriate and legal to do so. Individual patient-level data shall under no circumstances be released to commercial entities. Individual anonymized patient-level data may be released to other third parties for research purposes only (with limited use according to the study protocol, and only upon presentation of ethical approval of the responsible authority). For all other purposes only aggregated data can be released. Prior to releasing any data to a third party (which would be in an anonymized format), the third party shall agree vis-à-vis EUROSPINE to EUROSPINE's terms and conditions regarding the use of any such data, including the purpose and permitted scope of use.

EUROSPINE explicitly retains the right to provide implant suppliers with standardized reporting for quality assurance purposes using anonymized patient data in aggregated format and to collect fees for such services. EUROSPINE intends to use any income generated through such a reporting service for the following:

- coverage of ongoing Registry costs (including further developments),
- (re)coverage of all previous EUROSPINE's investment into the Registry, and
- reinvestment to develop and build the Registry.

Re-identification of a hospital or a user in such reporting may be allowed based on a written consent from the involved hospital only. Re-identification of an individual patient will not be permitted under any circumstances.

12. Ceasing from participation

Participant is free to cease participation at any time. The Participant's name will remain on the year-list of participants and Accredited Spine Tango Participants published on the website for the years corresponding to the period of participation.

13. Terms of use of the Platform

These are the terms under which the Participant agrees to use the Platform.

By using the Platform, the Participant confirms full acceptance of the terms of use and agrees to comply with them. If the Participant does not agree to these terms of use, the Participant must not use the Platform.

13.1 Changes to these terms

EUROSPINE may revise these General Terms and Conditions from time to time. Participant shall be advised in writing in advance of the proposed revisions or modifications, and hereby acknowledges and agrees that by submitting new data after the coming into force of the revised General Terms and Conditions, Participant has agreed to be bound thereby. The revised General Terms and Conditions will be published online. Participant further acknowledges that changes to the General Terms and Conditions may affect the Participant's Registry practices.

13.2 Accessing the Platform

Participant acknowledges and agrees that neither the Host nor EUROSPINE guarantee that Participant's use of the Platform will be uninterrupted or error-free, or that the Platform, the Documentation and/or the information obtained by Participant through the Platform or the Registry will meet the Participant's requirements.

Participant acknowledges and agrees that neither the Host nor EUROSPINE are responsible for any delays, delivery failures, or any other loss or damage resulting from the transfer of data over communications networks and facilities, including the internet, and the Participant acknowledges that the Platform may be subject to limitations, delays and other problems inherent in the use of such communications facilities.

Participant acknowledges and agrees that the Host' and EUROSPINE's boundary of responsibility for interfaces (i) initiated by the Host to a third party application, ends where a message leaves the Host' architecture; and (ii) initiated by third party applications, starts where a message enters the Host' architecture.

Participant has a non-exclusive, non-transferable right to use the Platform and the Documentation solely for Participant's internal business operations and solely for the term of this Agreement. Participant is responsible for making all arrangements necessary to enable access to the Platform. Participant is also responsible for ensuring that all persons who access the Platform through the Participant's internet connection are aware of these terms of use and other applicable terms and conditions and that they comply with them.

13.3 Participant's username and password

Participant will be provided with a unique username and password as part of its security procedures. Participant must treat such information as confidential and must not disclose it to any third party.

Participant acknowledges and agrees that EUROSPINE has the right to disable any username or password, whether chosen by Participant or allocated to them, at any time if in EUROSPINE's reasonable opinion a Participant has failed to comply with any of the provisions of this section 13. The Host shall notify the Participant if any of Participant's Authorised Users have their access disabled in this way

If the Participant knows or suspects that anyone other than the Participant knows a user identification code or password, the Participant must promptly notify the Registry at health_servicedesk@necsws.com.

13.4 Intellectual property rights

Participant acknowledges and agrees that it shall have no right to any intellectual property rights in the Platform, the Documentation, the Registry including all materials published on the Registry, all reports and results generated or provided during the course of using the Platform. This property is

protected by copyright laws and treaties around the world. All such rights of the Host, EUROSPINE and third parties are reserved.

13.5 Third party links and resources in the Host's site

Where EUROSPINE's site contains links to other sites and resources provided by third parties, these links are provided for the Participant's information only. Neither EUROSPINE nor the Host have control over the contents of those sites or resources and therefore the Host and EUROSPINE are not responsible for them.

13.6 Limitations of liability

Except as expressly and specifically provided in these terms of use, all warranties, representations, conditions and all other terms of any kind whatsoever implied by statute or common law are, to the fullest extent permitted by applicable law, excluded.

Participant acknowledges and agrees that the Host' or EUROSPINE's liability under this Agreement and in connection with Participant's use of the Registry shall be excluded except as set forth below:

Nothing in these terms of use excludes the liability of the Host and/or EUROSPINE for (a) death or personal injury caused, with respect to the Host's liability by the Host's and with respect to EUROSPINE's liability by EUROSPINE's negligence or (b) for fraud or fraudulent misrepresentation.

Subject to the foregoing in this section, Participant acknowledges and agrees that neither the Host nor EUROSPINE shall be liable whether in tort (including for negligence) for breach of statutory duty, contract, misrepresentation, restitution or otherwise for any loss or damage whatsoever, including (i) loss of profits; (ii) loss of business; (iii) depletion of goodwill and/or similar losses; or (iv) loss or corruption of data or information; or (v) pure economic loss; or (vi) for any special, indirect or consequential loss, costs, damages, charges or expenses, in each case however arising in relation to the use of the Platform, Documentation and/or Registry.

In no event shall the Host and/or EUROSPINE be liable for any inaccuracy or incompleteness of third party data.

Neither the Host nor EUROSPINE assumes any responsibility for the content of websites linked on the Platform. Such links should not be interpreted as endorsement by the Host and/or EUROSPINE of those linked websites. Neither the Host nor EUROSPINE will be liable for any loss or damage that may arise from Participant's use of them.

13.7 Uploading content from the Platform

Participant shall not upload, access, store, distribute or transmit any material during the course of Participant's use of the Platform that:

- is unlawful, harmful, threatening, defamatory, obscene, infringing, harassing or racially or ethnically offensive;
- facilitates illegal activity;
- depicts sexually explicit images;
- promotes unlawful violence;
- is discriminatory based on race, gender, colour, religious belief, sexual orientation, disability; or
- in a manner that is otherwise illegal or causes damage or injury to any person or property;

and both the Host and EUROSPINE reserve the right, without liability or prejudice to any other rights the Host and/or EUROSPINE may have against Participant, to disable the Participant's access to the Platform, the Documentation and/or the Registry. The Host and EUROSPINE have the right to remove any content Participant uploads to the platform if, in their opinion, it does not comply with these terms of use.

The Participant warrants that any such contribution made by Participant does comply with those standards, and the Participant will be liable to the Host and/or EUROSPINE and indemnify the Host and/or EUROSPINE for any breach of that warranty.

The Host and/or EUROSPINE also individually have the right to disclose Participant's identity to any third party who is claiming that any content posted or uploaded by Participant to the platform constitutes a violation of their intellectual property rights, or of their right to privacy.

The Host and/or EUROSPINE will not be responsible, or liable to any third party, for the content or accuracy of any content posted by Participant or any other user of the Platform.

13.8 Restriction on use

The Participant shall only use the anonymized data pool and reports accessed or obtained as a result of using the Platform solely for Participant's own internal business operations and shall not link or combine the EUROSPINE data or reports with any other dataset without EUROSPINE's prior written consent.

13.9 Participants Obligations

Participant shall not

- attempt to reverse compile, disassemble, reverse engineer or otherwise reduce to human-perceivable form all or any part of the Platform and/or the Documentation, except as may be allowed by any applicable law which is incapable of exclusion by agreement between the parties; or
- attempt to copy, modify, duplicate, create derivative works from, frame, mirror, republish, download, display, transmit, or distribute all or any portion of the Platform and/or the Documentation in any form or media or by any means; or
- access all or any part of the Platform and/or the Documentation in order to build a product or service which competes with the Platform and/or the Documentation; or
- use the Platform and/or the Documentation to provide services to third parties, other than any third parties who are be expressly set out by agreement between Participant on the one side and the Host and EUROSPINE on the other side as being permitted to receive and use the Platform and/or the Documentation; or
- license, sell, rent, lease, transfer, assign, distribute, display, disclose, or otherwise commercially exploit, or otherwise make the Platform and/or the Documentation available to any third party except the Participant's Authorised Users; or
- attempt to obtain, or assist third parties in obtaining, access to the Platform and/or the Documentation, other than as provided under this clause 13; or
- access, store, distribute or transmit any viruses during the course of their use of the Platform and/or the Documentation.

14. Patient identifiable data

If the Participant is using and/or accessing the Platform in Participant's capacity as, or on the authorised behalf of, a treating physician (a "Hospital User") Participant will have access to certain

patient identifiable data held on the platform. In this regard Participant agrees, in addition to its rights and duties described in section 4, to treat such personal data in accordance with all applicable data protection laws and regulations, rules, codes of practice and guidelines issued from time to time regarding the use of personal data and in particular Participant will:

- keep such personal data confidential and not disclose it to any third party unless required by law; and
- not to copy or process such personal data,

other than for the purposes of that patient's healthcare.

Hospital Users must remove any patient identifiable data from any images or documents prior to uploading them to the platform.

15. Indemnity

The Participant shall indemnify and hold harmless EUROSPINE against any claims, actions, proceedings, losses, damages, expenses and costs (including without limitation court costs and reasonable legal fees) arising out of or in connection with the Participant's use of the Services and/or Documentation other than in accordance with the provisions of this Agreement, provided that:

- the Participant is given prompt notice of any such claim; and
- EUROSPINE provides reasonable co-operation to the Participant, at the Participant's expense.

If EUROSPINE requests Participant to defend the claim, including, at EUROSPINE's choice, to take over the party position of EUROSPINE, to supplement it or represent it in any kind of proceedings, as provided by the rules of procedure applicable to the proceedings in question, or to settle the claim in, at EUROSPINE's choice, Participant's and/or EUROSPINE's name, and Participant refuses any such request for no reasonable grounds

- EUROSPINE is free to conclude any settlement it reasonably deems fit at Participant's costs;
- Prior to concluding any settlement at Participant's costs, EUROSPINE shall obtain the Participant's consent, such consent not to be unreasonably withheld; and
- Participant accepts that EUROSPINE does not have to prove, in any potential claim against Participant to receive compensation as per this clause, any statement made in any judgment against it.

16. Third-party rights

Nothing in this Agreement shall be interpreted or construed as conferring to a party which is not a signatory to this Agreement a right to enforce any term of this Agreement or as conferring a right to claim to such third party provided, however, that the Host shall have the right to assert rights under this Agreement directly against Participant respecting the unauthorized or improper access to the Platform and/or use of the Software in contravention of the terms of use, and more specifically, regarding Sections 13.7 and 13.8.

17. Applicable law and jurisdiction

This Agreement, its subject matter and its validity and any disputes or claims arising out of or in connection with it, including non-contractual disputes or claims, are governed by Swiss law. Participant acknowledges and agrees that the courts in Uster, Canton of Zurich, Switzerland will have exclusive jurisdiction to settle all and any dispute or claim that arises out of or in relation to this Agreement, its subject matter or its validity, including non-contractual disputes or claims.

18. Notices

Any notice required to be given under this Agreement shall be in writing and shall be sent by registered mail or international courier service to the other party to the following address:

If to Participant:	If to EUROSPINE:
	EUROSPINE, the Spine Society of Europe c/o Pfister Treuhand AG Bankstrasse 4 8610 Uster Switzerland

Address changes have to be notified without delay to the other party. As long as no such notification of change of address is received, notifications hereunder are validly made to the last valid address in accordance with this clause.

19. Duration and terms of termination this Agreement

The Agreement comes into force upon its signature by both parties. The duration of the Agreement is not limited and shall cover all duration of participation of the Participant in the Registry. The Agreement can be terminated by either party at any time by giving the other 30 days prior notice.

[Remainder of page intentionally left blank]

20. Execution

EUROSPINE, The Spine Society of Europe		**[Insert Participant Name]**
by:		
Name:	Thomas Blattert	Name:
Place, date:	Ingolstadt, 1 November 2022	Place, date:
Capacity:	EUROSPINE President 2021-2022	Capacity
Signature:		Signature:

Name:	Everard Munting
Place, date:	Ottignies, 1 November 2022
Capacity:	EUROSPINE President 2019-2021
Signature:	

Annex 1 - FAQ on Data Protection and Information Security

1. How is compliance with the General Data Protection Regulation (GDPR) and other rules warranted?

It is the responsibility of the individual or organisation (the 'Participant') to ensure that all necessary agreements are obtained from their institution (and can be made available on demand) in respect to any local laws, guidelines, 'best practice', ethical requirements, etc. In particular, the Participant is explicitly responsible for obtaining and documenting each patient's informed consent for the use of the patient's data for the specific purposes of research and quality assurance in the Registry. The participant must also warrant that all necessary consents and approvals required for processing all information relating to an identified or identifiable natural person to be processed under this agreement have been obtained.

Upon registration of a new patient, the registry platform requires a confirmation that informed patient consent has been obtained freely and unambiguously, thus signifying an agreement to the processing of personal data relating to the patient.

2. What data are collected?

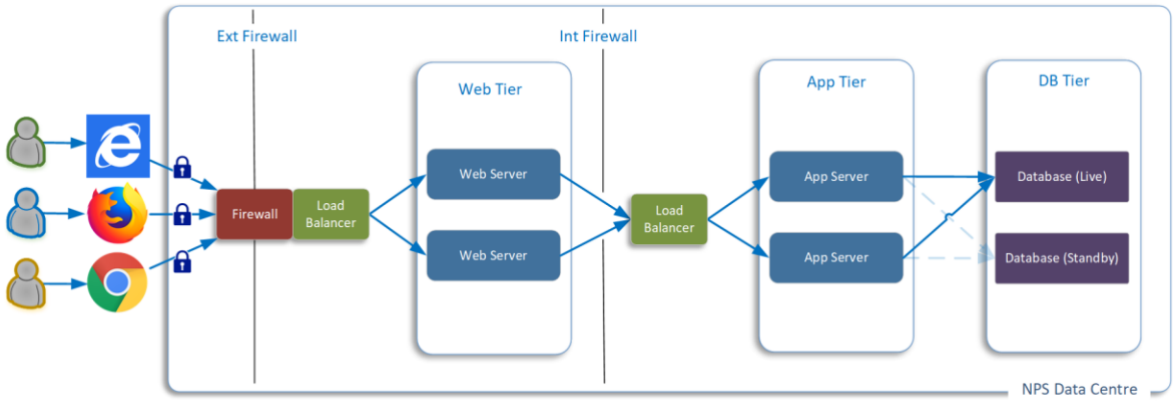
The registry data is comprised out two separately processed parts:

- Patient identifiable data
  - Patient first name
  - Patient last name
  - Gender
  - Date of Birth
  - Medical record number (MRN), a unique number provided by the participant
- Clinical data on patients' diagnosis, treatment and outcome

The registry platform requires a unique MRN, the patient's birthdate and their gender to be entered before a new patient record can be created in the system. A patient's first name and last name are not mandatory and do not need to be provided when creating a new patient record. However, providing a patient's first name and last name will enable a patient's record to be more easily identified by the participant. The patient identifiable and clinical data are hosted in separate databases and combined when the participant logs onto the system.

3. Where are the data hosted?

The following diagram shows the infrastructure used to host the Spine Tango solution. The service is hosted by NEC Software Solutions UK Ltd (formerly known as Northgate Public Services (UK) Limited) in one of its UK data centres.



NEC' Health Platform provides a minimum of a web server, application server and database server. To provide greater security, resilience and the ability to run reports without affecting data entry, the solution has been specified to provide redundancy throughout the infrastructure. This means that failure in any single component will not result in service interruption.
The entire database is encrypted with further encryption being provided to those data fields holding patient identifiable data. A very limited number of NEC staff have access to the database for the purposes of data management. Developers and network managers have access to the server on which the data resides but cannot view the data itself. Data sent from local clients to the database are sent via the Internet with the link being encrypted using a Secure Sockets Layer (SSL). This protects the data in transit.

4. How are the hosted data protected?

The secure and confidential handling of patient and clinical data is a fundamental part of the Spine Tango service provided by NEC. In delivering services to their clients, NEC manages confidential data relating to millions of citizens and patients in the UK and overseas. This not only involves technical solutions to protect the data, but also robust processes and procedures surrounding data access, based upon legislation and industry best practice. Given the nature of the data processed by NEC, security and governance are afforded the highest priority.

4.1 What security accreditation does the data processor have?

NEC is accredited to the following:

- ISO/IEC 27001:13, ISO/ISEC 9001.
- The UK government's Cyber Essentials.
- National Health Service (NHS) Data Security and Protection Toolkit (completed annually and required to process NHS data).
- NEC is also compliant with the UK Government's Information Technology Infrastructure Library (ITIL), a set of detailed practices for IT service management.
- NEC' data centres and back up and disaster recovery facilities are also ISO/IEC 27001:13 accredited.

NEC is registered on the Information Commissioner's Office Data Protection Public Register under Registration Number Z5666588 (https://ico.org.uk/ESDWebPages/Entry/Z5666588).

4.2 What information security best practice standards does the data processor follow?

NEC adopts information security best practice standards which require it to:

- Undertake regular Information Security Risk Assessments.
- Comply with all legal obligations under a variety of different legislation, regulations, directives and codes of conduct.
- Maintain and test all Business Continuity and Disaster Recovery plans.
- Provide regular Security Awareness training to all staff.
- Provide standards for the acceptable use of information assets.
- Report any actual or suspected breach of the Security Policies and Standards to the Information Security Manager, who investigates all incidents, and to EUROSPINE as the data controller.
- Review the Information Security Management System performance at regular intervals.

In addition, NEC undertake other, physical and procedural methods to protect data. These include but are not limited to:

- Continuous assessment of our processes under our ISO/IEC accreditations.

- The encryption of all data at the database level and the encryption of sensitive data at the data field level. This exceeds the recommendations set out in the UK Cabinet Office's guidance published in 'Electronic Government Services for the 21st Century'.
- Limiting access to data to only those staff working on delivery of the Spine Tango service, and also further restricting access to sensitive data.
- Processing data on the servers, not downloading it to, or storing it on, local computers.
- Never transmitting sensitive data by email over the public Internet.
- Regular penetration testing of services by an external, independent company.

4.3 Are staff aware of their responsibilities regarding data security and information governance?

The need for confidentiality when handling data is included in contracts of employment for all NEC employees.

There is a high level of organisational awareness and understanding of the needs for patient confidentiality within NEC and all staff are required to undertake mandatory annual training which covers data protections, data security, and data governance.

In addition, all staff within NEC' Health business undertake further mandatory annual training as required by the National Health Service (NHS) in order to achieve compliance with the NHS Data Security and Protection Toolkit, necessary in order to process NHS data.

All staff are vetted as part of the recruitment process.

4.4 Who ensures compliance with policies?

NEC Data Protection Officer - NEC' governance model includes a named Data Protection Officer (DPO). This is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information sharing. The DPO plays a key role in ensuring NEC satisfies the highest practical standards for handling patient identifiable information.

Acting as the 'conscience' of the organisation and championing Information Governance, the DPO supports NEC by ensuring that all programmes and projects operate in line with national guidelines and lawful and ethical processing of information. This role is particularly important in relation to running of national and international systems and services. The DPO does not sit within the service management hierarchy, retaining an independent role and thus ensuring exclusive focus in the interest of Information Governance best practice.

Security and Compliance Department - NEC' Security and Compliance Department is responsible for implementing written policies and procedures, conducting risk assessments, undertaking internal monitoring and audit against both internal policies and external standards, and ensuring that staff are familiar with the appropriate compliance and security standards, and ensuring that staff complete the mandatory annual training.

All services are subject to security and compliance reviews starting at the design stage, through implementation, and into the operation stage. The reviews check not only adherence with policies but include physical security checks, including regular (monthly) penetration testing.

Audits - NEC runs a full information security internal audit programme and are externally audited by the UKAS accredited audit body, the British Standards Institute, (BSI), which independently audits NEC compliance to ISO 27001. This audit reviews our security management controls and ensures these meet the required standard.

5. What are the information governance arrangements for Spine Tango?

For Spine Tango, the EUROSPINE Spine Tango Task Force (STTF) is the Data Controller and NEC is the Data Processor. Each have clearly defined roles and processes regarding the handling and management of all data.

As the data processor, NEC acts under the direct instruction of the Data Controller, the EUROSPINE Spine Tango Task Force (STTF) and within the appropriate legal framework. NEC also provides support and advice to the STTF in relation to the requirements of that legislation.
Both NEC and the STTF acknowledge the need to maintain robust and independent records of processing activities under their respective responsibilities. Accordingly, all of the processing to be carried out by NEC on behalf of the STTF will ensure sufficient guarantees in terms of expert knowledge, reliability and resources, to implement technical and organizational measures, which will always meet the requirements of the GDPR.

6. Who can access Spine Tango Data?

Anyone with a legitimate interest in using Spine Tango data can request access to it. All requests for data, whether data requests, research requests or Freedom of Information (FOI) requests, will be passed to the STTF for consideration and resolution. NEC will only release data to third party requestors when instructed to do so by the STTF and following agreement as to the exact data fields that will be provided. All requests for data are logged and the use of the data is subject to strict terms and conditions, including the destruction of the data at the expiry of the data sharing agreement.
Record level data may be provided for research purposes strictly earmarked but would normally be provided in a pseudo-anonymised format.

6.1 Non-commercial and academic use

Upon receipt of a request for non-commercial or academic use, the STTF will consider the application and ensure that any associated ethics, or other, approvals have been obtained or if they are required. Once the request has been considered and approved, STTF will agree with NEC the details of the data to be released and then instruct NEC to release the data. Where NEC has concerns over the release of the data (e.g. potential non-compliance with the GDPR, lack of patient consent), these will have been raised with STTF at an early stage. NEC and STTF will ensure that the release and use of the data falls meets the requirements of the appropriate legislation.

6.2 Commercial use

Data can be requested for commercial use but would only be provided as aggregated data. Record-level data will not be provided. Even so, such commercial use should always be strictly limited to the specified use or purpose indicated at the time of obtaining the informed patient consent.

6.3 Conditions of use

The data released will be appropriate to the needs of the study/research and subject to the Spine Tango Code of Conduct. Before the release of any data, the requestor will be required to formally agree EUROSPINE Terms and Conditions which will include the specific purpose and permitted scope for use of the data, the length of the agreement, the actions to be carried out with the data at the end of the agreement and any general requirements, e.g. the requirement to acknowledge EUROSPINE as the source of data; the condition prohibiting the publication of record-level data.
No data shall be used for sales or marketing purposes.

Annex 2 Data Processing Agreement (DPA)

1. General

This DPA constitutes an integral part of the GENERAL TERMS AND CONDITIONS OF THE EUROSPINE SPINE TANGO REGISTRY agreed upon between EUROSPINE, the Spine Society of Europe and _____(Participant) (referred to hereafter collectively as the "GTCs").

The Parties undertake to comply with the applicable data protection legislation, namely the EU general data protection regulation 2016/679 (GDPR), applicable European Union Member State data protection laws and regulations, and the Swiss Federal Act on Data Protection (FADP) and its Ordinance (together “the applicable data protection laws”). Specifically, the Parties shall process personal data only for purposes of complying with and implementing the GTCs (and this DPA) and solely to the extent necessary to do so. When performing data processing, the Parties shall adhere to the principles of proportionality, use of the data solely for its designated purpose, transparency and good faith. The Parties undertake to ensure that data processing activities are carried out exclusively within the EU, the EEA or Switzerland.

2. Personal data

Personal data means (i) any patient identifiable data provided by Participant to EUROSPINE as defined under the GTCs; and (ii) any information defined under Article 5 FADP.

EUROSPINE shall refrain from using personal data for its own purposes or for any purpose other than those referred to in the GTCs.

3. Technical measures

The Parties undertake to put in place all reasonable and necessary technical and organisational measures to protect personal data, specifically in order to prevent unauthorised third party access to data or loss, damage, erasure or destruction thereof. The protective measures taken must comply at least with the requirements set forth in Article 32 GDPR.

The technical and organisational measures must ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services. In addition to digitised information and data security, access to the premises on which data are processed must be protected.

The Parties are aware of the legal requirements applicable to technical and organisational measures and each shall bear fully responsible within its respective area for ensuring that these offer a sufficient level of protection, having regard to the relevant risks.

4. Outsourced processing and involvement of third parties

The purpose of processing personal data as covered in this DPA concerns Participant’s participation in Spine Tango, the international Spine Registry established by EUROSPINE, and more fully described at Section 2.4 of the GTCs. EUROSPINE shall process personal data exclusively in accordance with the activities and service descriptions (i.e. the data processing) set out in the GTCs. Any changes to the GTCs must be stated in writing. EUROSPINE shall maintain a record of data processing activities pursuant to Article 30 GDPR and shall actively support Participant in complying with the duties set forth in Articles 32 to 36 GDPR (data security measures, reporting personal data breaches to the supervisory authority, notifying the data subject affected by a personal data breach, data protection impact assessment, prior consultation). EUROPSINE shall inform Participant immediately if it believes that any instruction contravenes applicable data protection laws. It may defer implementation of the instruction until confirmed or amended by Participant.

The Parties warrant that all necessary legal basis for processing of personal data (consent etc.) are applicable.

The Parties warrant that the staff responsible for processing data and other auxiliary agents shall be prohibited from processing data except in accordance with each Party’s instructions.

Third parties may only be engaged as subcontractors for the processing of personal data in relation to the provision of services as set forth in the GTCs, which is deemed provided under the GTCs, and further provided that said third parties shall process data only for the purposes described in the GTCs. The Host identified in Section 2.5 of the GTCs is the only subcontractor authorized to process data on behalf of EUROSPINE. Any other third party will require the prior written approval of the other Party prior to being authorized to process data under the GTCs or this DPA. Any third parties involved in the provision of services shall be subject to the same obligations as the Parties in relation to the processing of personal data. The Parties warrant that they will impose their respective obligations on any third parties. They shall remain responsible for compliance with these obligations.

5. Rights of data subjects

The Parties undertake to honour and guarantee the rights of data subjects regarding said data subject's personal identifying or personal data. Specifically, a data subject shall have the right of access, the right of erasure, the right of rectification, the right to have a block placed on the personal data, and the right of data portability (Articles 12 et seq GDPR) of their personal data. If any personal data cannot be erased owing to a statutory or business requirement, including the anonymization of said data (as stated in the GTCs), such data will be excluded from the rights described herein. If the accuracy or absence of any personal data cannot be proven, they shall be flagged with a comment to the effect that they have been disputed. The Parties undertake that, upon request by the data subject, they shall provide the personal data that the data subject furnished for processing in a commonly-used, machine-readable format. If a data subject approaches EUROSPINE with any request for rectification, erasure or access, EUROSPINE shall clearly indicate to data subjects that all requests concerning data subject's rights are to be directed to Participant. The Parties shall support each other to the extent agreed in handling requests by data subjects.

6. Process documentation

The Parties shall operate documentation and escalation processes for any personal data breaches and shall also maintain a record of data processing activities.

7. Data Protection Officer

The Parties shall each appoint a contact for all issues relating to data protection (so-called "Data Protection Officer").

8. Notification duties and control rights

The Parties shall inform each other promptly in the event that they discover any personal data breach in relation to the provision of the contractual services as stated in the GTCs. The Parties shall also report any such breach within 72 hours to the competent supervisory authority. Participant shall have the right to carry out an audit either itself or through an independent auditing firm selected and appointed by Participant. The formal conditions shall be determined in accordance with the GTCs.

9. Duty of retention, erasure and return

After the purpose has been fulfilled, and otherwise upon termination, expiry or notice to terminate the GTCs, EUROSPINE retain all personal data, if any, for the prescribed statutory archival period in a manner compliant with the applicable data protection laws, and if necessary provide them to Participant free of charge. Upon the completion of processing, and otherwise upon termination of this DPA (and the GTCs), EUROSPINE shall, subject to its rights of ownership and use set forth under Sections 4.3 and 13.4 of the GTCs, deliver to Participant or destroy or securely erase in accordance with the applicable data protection laws and in consultation with Participant all personal data in its possession.

10. Liability

Each party shall be liable applicable data protection laws and regulations for any damage suffered by the other, or the data subjects as a result of improper use of the data or any other breach of the applicable data protection laws for the processing of personal data whether under the GTCs or otherwise.