SPINE TANGO
The international Spine Registry
Our Vision

Spine surgery is a heavily technology driven medical discipline with a lack of sufficient evidence for many therapies. Whenever new innovations enter the market they should be carefully surveyed and monitored since neither laboratory testing nor randomised controlled trials provide the final conclusive information about the product performance and its safety in the multitude of the different clinical and post-market settings, i.e. in reality. Accordingly, opinion leaders in spinal surgery recommend consistent and consequent documentation of treatment outcomes and rigorous post-market surveillance of implants for adverse events. Eurospine, the Spine Society of Europe has partnered up with an international leader in the field of medical registries and has developed a common language for recording and reporting treatments and outcomes for and of spinal pathologies. In order to identify rare adverse events fast and increase the power of our observations, a joint database for all participants is equally important. This vision triggered the development of Spine Tango, the only international spinal registry to date. Spine Tango can meanwhile look back at a 15 years history and over 80’000 documented cases from more than 50 hospitals. We are looking forward to welcoming you as a contributing new member in this visionary endeavour.

T. Pigott, MD,
head of the Spine Tango committee

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Info
www.eurospine.org
→ click on PROFESSIONALS
→ click on SPINE TANGO
Why a registry?

“All patients must be followed in order to assess the benefit or complications of a certain treatment.”
Ernest Codman, 1931

A well run registry communicates valuable information:

**Quality Management**
– to assess the quality of treatments and implants

**Drive Improvement**
– to benchmark “own” approach against peers’ techniques

**Provide Security**
– verification system for regulatory authorities to review

**Patient Counselling**
– to provide patients factual evidence of treatment choices

**Fiscal Prudence**
– to supply invaluable data for cost benefit analysis

**Early Warning**
– alert to implant failures or to trends—negative & positive

**Save Time**
– deliver convenient access to overview of operative activities

“Documentation is considered as indespensible for surgeon self-assessment and evaluation of value of the various surgical methods.”
Maurice E. Müller, 1963
Why participate in the Spine Tango registry

<table>
<thead>
<tr>
<th>Simple two page, low complexity questionnaire</th>
<th>Easy and convenient to administer and maintain</th>
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<tr>
<td>Questionnaire for non-surgical therapies within the same project</td>
<td>Enables outcome comparison of surgical and conservative treatments in the framework of the same registry</td>
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<td>Modern outcome questionnaires for neck and back pain</td>
<td>Short yet comprehensive outcome assessment for improved patient compliance</td>
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<td>You can add your own data sets and forms</td>
<td>Customized data sets provide more specialized information</td>
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<td>Same questionnaire and data structure for all participating nations</td>
<td>Direct comparisons on national, international and inter-continental scale</td>
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<td>Online and offline data collection</td>
<td>Better integration into hospital workflow</td>
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<td>Full online system using an Application Service Provider (ASP)</td>
<td>No local software installation or management—seamless updates</td>
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<td>National filter modules—national web address, national administrative autonomy, PC web server</td>
<td>Safe in the knowledge it never leaves your national environment—identifiable data remains within national boundaries</td>
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<td>Centralized data pool—consolidation of clinical, implant and picture data in one database</td>
<td>Saves time—all the data comes in one consistent format from one database</td>
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<td>Global research network and backbone for implementation of multi center studies</td>
<td>Greater power to your clinical studies</td>
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<tr>
<td>Content developed by Spine Society of Europe</td>
<td>You are safe in the knowledge that all systems are based on sound expertise from International opinion leaders</td>
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<td>Institute for Evaluative Research in Medicine, University of Bern</td>
<td>Academic clearing house with years of experience in building registries—your access to constant innovation</td>
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Questionnaires - the 2011 generation

Online and paper-based data collection and scanning with optical mark reader

**Physician Forms:**
- ST Surgery 2011
- ST Staged Surgery 2011
- ST Followup 2011
- ST Adult Deformity Add-on
- ST Adolescent Scoliosis Add-on
- ST Conservative Therapy 2011

**Patient Forms:**
- COMI Back - COMI Back Conservative
- COMI Neck - COMI Neck Conservative
Statistics and reports

1. **Spine Tango online statistics**
   1. Query mask for creation of patient samples and output variables
   2. Graphical output format
   3. Table output format

2. **Spine Tango print tool**
   4. Question-answer print format
      Soon to come: customizable print templates for generation of surgical reports and discharge letters
Implant tracking

The number and diversity of implants available on the market makes it highly desirable to precisely document the implant used, and to correlate it with the clinical and radiographic outcome in short-, mid-, and long-term follow-ups. As of 2016 the EU commission will release the new MEDDEV, which categorizes spinal implants as risk class III, just like hip, knee or shoulder arthroplasties. This increases the pressure on suppliers to generate and demonstrate more clinical safety and performance data to the notified bodies. Registries with large datasets and precise implant documentation can hence become a valuable source of information. Numerous variables are needed to describe an implant so precisely as to be able to accurately identify it. This is a very time consuming effort, and hence is not possible for daily use in a clinical setting. Therefore, Spine Tango has interfaced a barcode-based implant tracking system, which is capable of accurately identifying and tracking orthopaedic implants. This system, called Secure Data Integration Concept (SEDICO) can integrate all major implant producers` catalogues. With SEDICO, all main components used and implanted in a patient are scanned by the OR staff and automatically identified to the respective case using the hospital code, medical record number of the case, location and date of operation and scan. One set of the data is used for ordering and inventory purposes, and another copy with supplier name, implant description and lot numbers and the linking parameters is sent to the MEMdoc portal with a dedicated interface. In the event that the SEDICO system is not available in a hospital, an inexpensive MEMdoc barcode scanner for direct implant scanning inside the patient`s implant subform can be used. Finally, the documentation system also offers updated electronic catalogues of the major implant producers where the implanted components can be searched and linked. Last but not least, possibilities to simply type-in article numbers or fill-in the implant description of other producers are also available online.

SEDICO reordering and documentation process

1. SCAN Scanning of the implant barcode
2. TRANSMIT Transmission of the scanned data
3. RECEIVE Reception of the scanned data at the clearing center
4. CONFIRM E-mail or fax confirmation sent to the operating theatre or purchasing department
5. INTEGRATE (optional) Integration of the order into the hospital’s ERP
6. DOCUMENT Linking of implant data to clinical documentation
7. PROCESS Order processing by the supplier
Security

Spine Tango makes use of the latest security technology developed for the MEMdoc documentation portal of the University of Bern Institute for Evaluative Research in Medicine. The model of the MEMdoc portal and its module system is designed around the principle of data separation. The MEMdoc central server, housed at the University of Bern, hosts the main application and the central database containing all study definitions and clinical study data. Satellite MEMdoc-Module servers located throughout the world to store all personal data about users, institutions and patients. At the core of the system is an innovative and patent-pending architecture in which the web browser of the client is used as a hub to seamlessly segregate and integrate the data between the MEMdoc-Module and the MEMdoc central server. This design provides tightly integrated communication between the servers while increasing the security and privacy of both systems. This has been accomplished using a light weight JSON server and incorporation of SSL encryption on each module. Flexible data sharing options have been designed to restrict or expand data access to suit individual needs. Finally, data consistency is controlled through systematic validation of received data and a rollback in case of errors.

Read more about Spine Tango data security on the Spine Tango web page under “Literature”.

![MEMdoc and MEMdoc-Module Data Segregation and Web Service](image)