Spine Tango Industry Update Meeting. June-2025

Agenda:

1. Actions and updates from previous meeting
   a) Assessing Fusion
   b) Implant Related Reoperations
   c) Implant catalogue completeness update
   d) Implant report: comparator groups update
   e) Implant Report changes

2. Registry update

3. Update on the Spine Atlas Initiative

4. International Spine Registries (ISR) updates

5. Expanding the use and utility of Spine Tango

6. Q & A Session

1A. Action from previous meeting: Assessing Fusion

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Capturing Fusion Assessment outcomes within the registry

Today (based on the principle of minimum efforts)

- The surgeon can select "non-union" as a complication on the follow-up form (= failure of bone consolidation at least 6 months after surgery). Otherwise, bony consolidation is assumed. Thus, the rates of (assumed) fusion are assessed by identifying cases with non-union.
- Question 1: Is this measure sufficient?
- If not --> Question 2: How should fusion/non-fusion shall be documented (with minimum effort)?
- Depending on how focused/granular the documentation of fusion rates should be, it may be reasonable to do this only for a selected, limited patient population as a nested study.

Proposed approach:

1. **Timing of evaluation:** 6M, 12M, 24M post-op, other / please specify

2. **Was fusion intended:** yes, no

3. **Imaging-based fusion:** yes/taking place, no, not assessable, no adequate imaging

4. *(Optional)* **Imaging modality used:** CT, x-ray, dynamic X-ray

1B. Implant Related Reoperations – new request

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The coding matrix for the implant-related revisions (based on the 2025 form version)

Cause for the revision	Other surgical measures=hardware removal	Implant-related revision
another originally planned surgery	no	no
	yes	yes
neurocompression, non-union, instability, superficial or deep infection, wound healing problem, spinal imbalance, CSF-leak, failure to reach therapeutic goals, adjacent segment pathology	no	no
	yes	yes
implant malposition, implant migration or loosening, implant breakage, implant assembly failure, hardware removal	yes/no	yes
other /to specify	no	will depend on the specification; used words like implant, hardware, osteosynthesis in the specification are hints for an implant-related revision
	yes	yes

1C. Implant database update

- **71** Manufacturers

- Overall database completeness: **75.5%**

- Vital data to support enhanced comparative analysis for SOTA purposes

- Aiming to continue liaising with partners to populate missing attribute data

- Thank you for your continued support

1D. Comparator group enhancement proposals (SOTA)

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Spinal Devices - Excluding Fusion Devices

Spinal Components	Highest-Level			Lowest-Level
Field Name (overall completion)	Implant Joint Type	Level	*Surgical Approach	Component Type
Answer Option/s	Spine	Thoracic, Cervical, Lumbar	Anterior, Lateral, Posterior	Artificial Disc, Cable, Cage, Connector, Plate, Rod, Screw, Vertebral Body Replacement (VBR), Other
Completion Rate	100%	100%	61.6%	75.27%
Location of Data	Device Database	Device Database	Device Database / *Surgery Form (CRF)	Device Database

Consider how to; group answer options in larger categories; handle multiselect answer options; and identify not required answer options.

*Surgical Approach can be taken from the form answers rather than the component database, making it c.90% complete.

1D. Comparator group enhancement proposals (SOTA)

Spinal Fusion Devices

Fusion Systems	Highest-Level				Lowest-Level
Field Name (overall completion)	**Fusion**	**Implant Joint Type**	**Level**	**Surgical Approach***	**Component Type**
Answer Option/s	A-IF, OLIF, PLIF, TLIF, XLIF, Other Interbody fusion, Posterolateral fusion, Posterior fusion	Spine	Thoracic, Cervical, Lumbar	Anterior, Lateral, Posterior	Artificial Disc, Cable, Cage, Connector, Plate, Rod, Screw, Vertebral Body Replacement (VBR), Other
Completion Rate	c.90%	100%	100%	61.6%	75.27%
Location of Data	*Surgery Form (CRF)	Device Database	Device Database	Device Database	Device Database

Consider how to; group answer options in larger categories; handle multiselect answer options; and identify not required answer options.

*Fusion can be taken from the device database rather than the Surgery Form (CRF), which is c.63% complete.

1E. Implant Report change Requests Under Review

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PROMs analysis changes

- Provide mean scores by post operative intervals, e.g. 6M, 1 year, 2 year, etc. **Due in November-25**
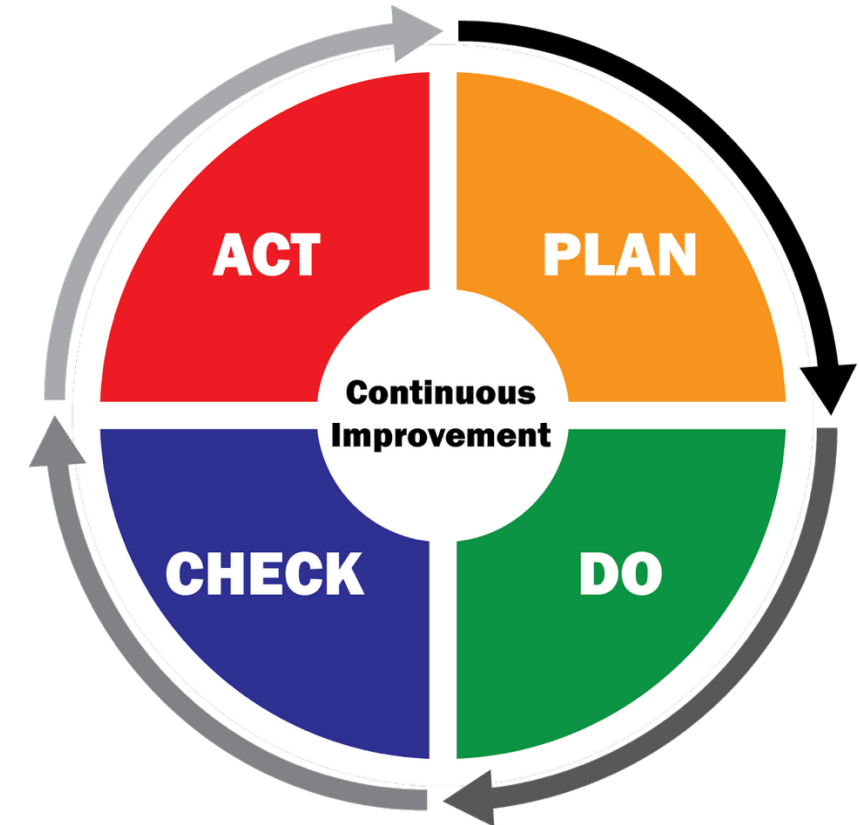
Surgery 2025 Form (CRF) inclusion

- Surgery 2025 (CRF) form now included in reports from June-25. Some minor changes requested on data mappings which are going through approvals.

Implant related reoperations

- Drafting proposal which would include an additional set of reoperation tables to include those which are subject implant related. Release date TBC

Comparator group enhancements (SOTA)

- Subject to on-going consultation, data availability and volume feasibility for defined groups. Consultation paper to be produced. Release date TBC

2. Registry update

- 12.5% more surgeries in Q1 2025 vs. Q1 2024

- Spine Atlas Initiatives (SAI) as a catalysator for further participants

- Why hospital participates – key benefits
  - Quality assurance:
    - Performance record
    - Reports
    - Certification
  - Research
    - Automatised electronic collection of PROMs
    - Own research through access to international data and statistical service at no cost
    - Co-authorship of external publications (incl. SAI)
    - Visibility (incl. SAI)
    - EUROSPINE is assessing the idea of a research grant for a Spine Tango based study

Can MedTech create additional incentives for its customers (through info/education, financial benefits, human resources, sponsoring research grants, funding specific research, and the like)?

3. Update on the Spine Atlas Initiative (SAI)

- Standardised framework for cross-border data exchange incl. existing registry integration

- Population-based insights into distribution and treatments of spinal pathologies

- Generation of real-world evidence on implant/device use as part of optional data set

- Inaugural Data call 2025 (LDS) nearing close: 50 + hospitals/ registries across all regions submitted data already

- Expansion of the low-barrier annual data calls for 2026 and beyond planned - broader user base and new clinical topics

4. International Spine Registries (ISR) updates

- The International Spine Registries (ISR) have shared the policy papers with all Spine Registries.
  - Collating responses to the implementation process at registries.

- Update to the PROMs policy paper.
  - ODI is a 'paid' for PROM for registries.

- The Agenda Setting Group to meet next month to discuss agenda for next meeting in October.

- Data definition on MDS data items has commenced.

- Ability to provide a centralised implant library is ongoing.

- The next ISR meeting is being held as a pre-day course on 21st October, in Copenhagen, at the EUROSPINE conference.

5. Increasing the utility of Spine Tango

- Idea of a call for research questions among MedTech

- Engaging MedTech customers
  - Minimal dataset
  - Nested studies

Industry Feedback – Q&A