

What are the requirements and expectations (from regulators, medtech and notified bodies) and how they can be met

Emin Aghayev, EUROSPINE

Requirements of the regulators, medtech and notified bodies

- «sufficient clinical evidence» on each medical device
- device level data (not assembly-/construct- and not brand-level)
- good quality / valid data (complete, reliable, robust, sufficient follow-up rate etc.)

The primary goal is to increase **patient safety!**

(sample) Implant report

Sample Implant

Reason for Reoperation

Reason for Reoperation

| | |
|--|-----|
| Number of Reoperations at Any Level | 768 |
| Number of Reoperations at the Same Level | 215 |

| Reason for Reoperation | Any Level | | | Same Level | | |
|-------------------------------------|-----------------|--------------|---------------|-----------------|--------------|---------------|
| | Percent (Count) | Mean (Years) | Range (Years) | Percent (Count) | Mean (Years) | Range (Years) |
| Adjacent Segment Pathology | 21.9% (168) | 1.0 | 0.0-6.4 | 17.7% (38) | 0.9 | 0.0-4.0 |
| Failure To Reach Therapeutic Goals | 10.9% (84) | 0.9 | 0.0-6.6 | 19.1% (41) | 0.7 | 0.0-6.6 |
| Hardware Removal | 15.2% (117) | 1.0 | 0.0-6.3 | 22.3% (48) | 0.9 | 0.0-3.3 |
| Implant Failure | 13.3% (102) | 0.6 | 0.0-6.3 | 16.3% (35) | 0.5 | 0.0-1.9 |
| Implant Malposition | 3.9% (30) | 0.6 | 0.0-3.1 | 5.6% (12) | 0.3 | 0.0-1.4 |
| Instability | 15.1% (116) | 0.6 | 0.0-4.0 | 17.7% (38) | 0.5 | 0.0-4.0 |
| Neurocompression | 15.1% (116) | 0.8 | 0.0-5.8 | 20.9% (45) | 0.5 | 0.0-4.0 |
| Non-Union | 13.7% (105) | 1.1 | 0.0-6.6 | 23.7% (51) | 1.3 | 0.0-6.6 |
| Other | 12.8% (98) | 0.5 | 0.0-4.5 | 22.8% (49) | 0.3 | 0.0-2.8 |
| Postoperative Infection Deep | 7.0% (54) | 0.3 | 0.0-3.2 | 9.3% (20) | 0.2 | 0.0-1.3 |
| Postoperative Infection Superficial | 2.0% (15) | 0.2 | 0.0-2.0 | 4.2% (9) | 0.1 | 0.0-0.6 |
| Sagittal Imbalance | 6.5% (50) | 0.9 | 0.0-5.4 | 6.0% (13) | 0.8 | 0.0-2.8 |
| Unknown | 45.1% (346) | 1.1 | 0.0-6.7 | 27.0% (58) | 0.8 | 0.0-6.6 |

Any operation occurring after the first primary surgery is classified as a reoperation. Reason for reoperation is only available where the operation has been classified as a repeat surgery, and hence the number of reoperations may differ from the total number of available reoperation reasons. Please also note that multiple reoperation reasons may be listed for one procedure.

Implant database

- EUROSPINE, in partnership with medtech has developed an implant classification architecture which specifies the attributes which are collected for implantable devices.
- The implant catalogue is feed by medtech.
- Missing implants in the database can be requested by participating hospitals.
- The article number is the unique article identifier. All other attributes and classifications are linked to it.

Spine Prosthesis Architecture

| Implant Joint Type | Component Group | Component Type | Metal Composition | Other Composition | Revision Specific | Surgical Approach | Fusion System | Brand Name |
|--------------------|---|----------------------------------|---|--|-------------------|--|------------------|---|
| Spine | Cervical (Yes/No) Lumbar (Yes/No) Thoracic (Yes/No) | Artificial Disc | Titanium Titanium Alloy Cobalt Chrome Stainless Steel Tantalum Titanium/Cobalt Chrome Titanium/Titanium Alloy Other N/A | Ultra High Molecular Polyethylene (UHMWPE) Carbon Polyurethane Silicone PEEK Ceramic Peek/Titanium Other N/A | Yes / No | Anterior Posterior Lateral All N/A | Yes No N/A | From Existing Non static List Based Upon Component Type |
| | | Cable | | | | | | |
| | | Cage | | | | | | |
| | | Connector | | | | | | |
| | | Plate | | | | | | |
| | | Rod | | | | | | |
| | | Screw | | | | | | |
| | | Vertebral Body Replacement (VBR) | | | | | | |
| | | Custom | | | | | | |
| | Accessories | Other | | | | | | |

75 manufacturers
~200k devices

How does the implant registration work?



Added implants

| | | | |
|------------------|-----------------------|----------------|---------------------|
| Manufacturer | [REDACTED] | Barcode (GTIN) | 0100885074459950172 |
| Catalogue Number | G2911232 | Lot number | 0396641W |
| Description | 12 X 32 CA [REDACTED] | | |

- Select out of your **favourite list**
- **Search** it in the catalogue
- **Scan** the implants barcode or QR-code
- Request a missing implant

Patient M.R.N. : Confidential Id : 3000413000000212598 Born : 01/01/2020 Gender : Male Surgery SIRIS plus Spi...

Admission / Pathology ●
 Surgery ●
Implants ▲
 Surgical measures ●
 Hospital stay ●

Save Submit

Favourites

| Name | | User Name ↑ | | | |
|--------------|-----|--------------|---|---|---|
| USS II PA | (1) | Aghayev Emin | ↓ | 👁 | 🗑 |
| Mein Favorit | (1) | Aghayev Emin | ↓ | 👁 | 🗑 |

10 Items per page 1 - 2 of 2 items

Catalogue search

Manufacturer

Brand

Description

Barcode (GTIN) Catalogue Number

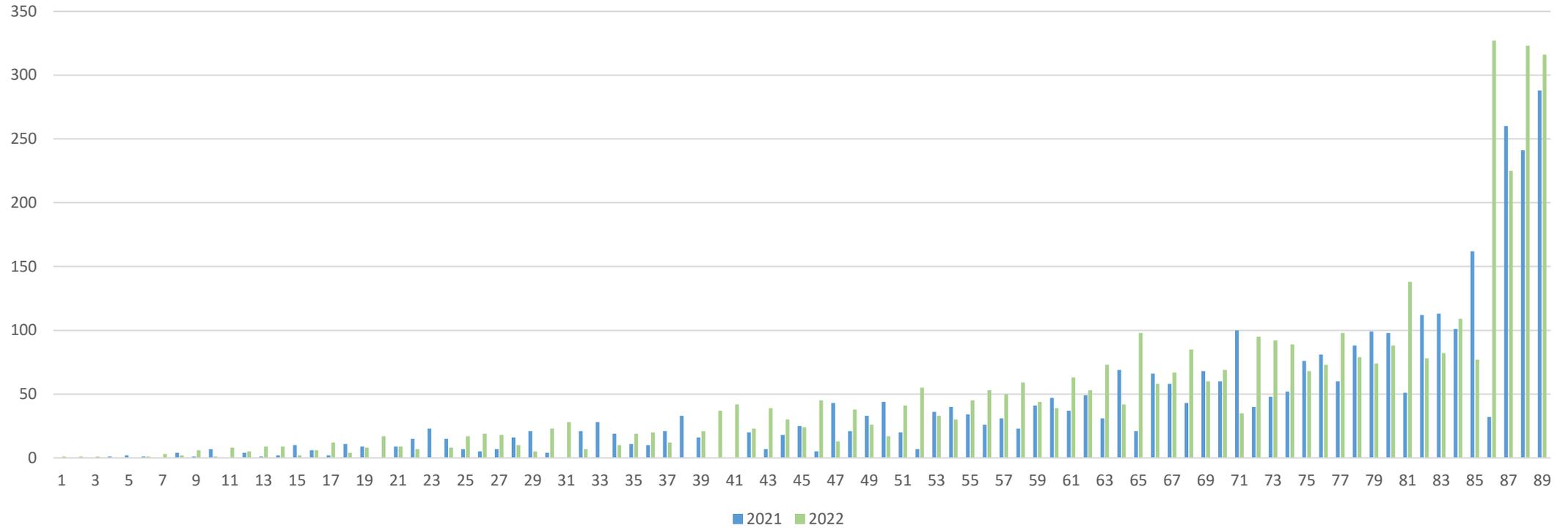
Request missing implant Reset Search

Search results

27.11.2023

Swiss Spine Implant Registry since 2021

Number of surgeries per hospital



National Spine Registries

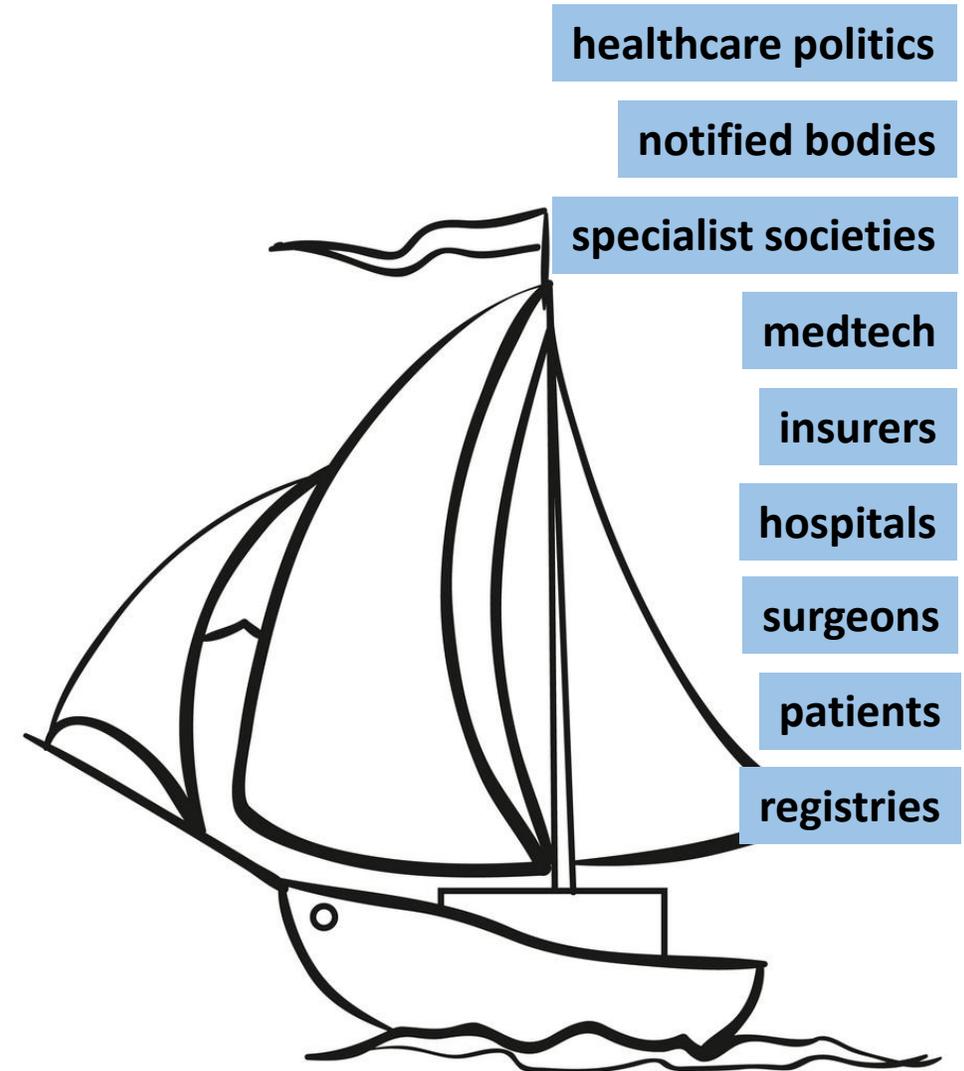


Changing world



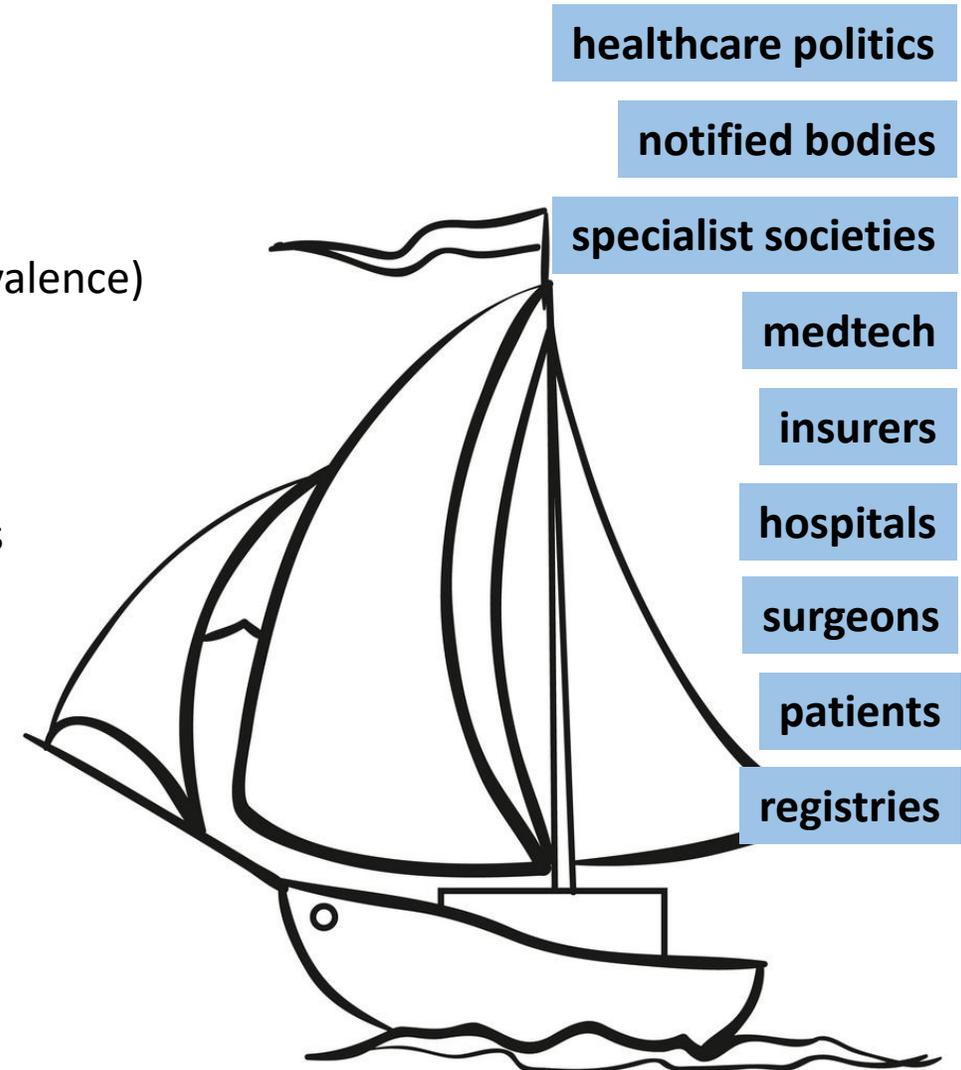
[image source](#)

Treatment efficacy
Treatment efficiency
Patient safety



Benefits of common standards

- ability to (efficiently) merge data from different regions
 - big picture incl. epidemiological figures (incidence, prevalence)
 - robust analyses
 - reach earlier the level of significance
- compare treatment outcomes regardless of national borders
- learning from each other and avoid repeating mistakes



Joining forces

- The implant catalogue is used in the international Spine Tango and in the Swiss Implant registry
- EUROSPINE offer its use to other spine registries



Thank you
