EUROSPINE's position on the implementation of the new EU MDR

For close to 25 years now, EUROSPINE, the Spine Society of Europe has been operating as a professional, non-profit organisation focused on the advancement of spine research and treatment. Its primary mission since its inception has been to promote the exchange of information and ideas related to the research, prevention and treatment of spinal problems, and to coordinate and support the ongoing efforts of European countries and national spine registries in this field.

The main focus has been on research to (i) improve the understanding of spinal disorders and related problems, and (ii) to develop more effective treatments and strategies for patient care for back pain and other spinal disorders. By bringing together experts from different fields and fostering collaboration, EUROSPINE aims to make significant advances in the prevention, diagnosis and treatment of spinal problems.

In addition to the foregoing, our Statutes authorize our Society's Executive Committee to represent the views of the Society and its members to governmental and any other health related organisation to promote and facilitate the aims and the objectives of the Society, and by extension, the patients who depend on the medical profession in the prevention, diagnosis and treatment of spinal injury and disease. Our Society continues to partner and collaborate with universities, public and private clinics, and lastly, health industry players, including medical device manufacturers, who notwithstanding their "for profit" profiles, share our commitment to providing and maintaining the highest quality of spine care and treatment techniques.

With the coming into force of the new EU MDR (which replaces the 2017 regulation and repeals two prior directives on medical and implantable devices), our Society is joining a large chorus of concerned spine care professionals, clinicians, surgeons and manufacturers of medical devices in raising the alarm on the implications and potential for unintended and undesirable effects with a regulatory scheme that was initially intended to improve quality and transparency of data for medical devices placed on the EU market.

While the new EU MDR is positioned as a more rigorous and improved set of regulations, designed to beef up product safety, hygiene and post-market surveillance, it will also have a huge impact on quality management systems (QMS), and is more strict and more evidence based. The rationale has been based on more overt transparency and consistency throughout the entire device design and product cycle and thereafter, and has been redesigned to address recalls regarding defective or inefficient marketed devices.

While non-profit charitable institutions, such as ours, and medical device manufacturers may come across as strange bedfellows in confronting the challenges posed by the EU MDR, our shared concerns intersect directly when taking into consideration the impact of the new EU MDR on both patient care, and the spine care specialists entrusted with the delivery of products and procedures designed to ensure optimal patient care. While not exhaustive, EUROSPINE is marshalling its efforts to join a growing number of multidisciplinary parties to address:

1. Potential significant barriers to collecting the necessary clinical evidence to ensure that niche and legacy products are maintained on the market. For both these categories of products, the high evidentiary bar can result in a lack of benchmarks for safety, performance and clinical benefit, due to a lack of literature or other baseline data to enable a scientifically valid evaluation. Thus, our spine surgeon members will lose

possibilities that ensure optimal solutions for their patients due to a lower variety of available implants, instruments and modern procedural solutions.

2. Fear in the spine surgical fields that research and development funding will flee from the EU in favour of more favourable jurisdictions requiring less types and levels of clinical evidence, thereby accelerating certification. This affects both the private sector (especially SMEs with limited R&D budgets) and the public sector hospitals and research centres.
3. An exodus of tomorrow's new generation of medical professionals who will choose to work and conduct research in jurisdictions not hampered by a lack of guidance and certitude in the types and levels of scientific evaluation required to bring products and procedures to market.
4. A competitive disadvantage when comparing the roles and responsibilities of governing regulatory bodies in the EU [whereby the EMA must issue scientific opinions to notified bodies via a consultative process prior to awarding a CE mark] versus other jurisdictions such as the US FDA, where streamlined procedures such as 510Ks can allow an accelerated demonstration of safety and efficacy to establish equivalence to a marketed product. The EU MDR will impose tougher rules to establish equivalence.
5. Serious challenges regarding Notified Bodies: a crisis that continues to grow as notified bodies are understaffed and increasingly unable to define valid clinical evidence to determine which outcome measures will clearly correlate with the desired safety, performance and clinical benefit parameters that medical device manufacturers will require to place their products in the EU market.

The future outlook:

From the EUROSPINE perspective, we remain committed to maintaining the highest quality of spine care and treatment techniques, and as part of this commitment, we have implemented several quality assurance activities that may well serve the medical community at large when confronting the challenges of the new EU MDR.

One of the most significant quality assurance tools developed by Eurospine is the Spine Tango registry. It is an international spine surgery registry that comprehensively documents the procedures, used implants, complications and patient reported outcomes. The Spine Tango registry enables spine care providers and Med Techs to monitor and compare a wide range of parameters between participating institutions and countries over varying and even lengthy periods of time. With Spine Tango, early detection of quality deviations through registered complications and reoperations becomes easy, and the analysis of their relationship to the employed implants on a granular level is possible.

Eurospine and Spine Tango also play a leading role in the International Spine Registry Group established in London in 2013, which includes all the world's largest national spine registries. It aims to create and promulgate common operating principles between registries utilized in different countries. Consistent registration of commonly defined diagnoses, procedures, potential complications, granular implant data and as well as large-scale and long-term follow-up of patient outcomes according to internationally agreed principles will enable the collection of large and homogenous data pools. With such data, even more reliable analysis of correlations between procedures, complications and used implants will help healthcare providers, manufacturers and notified bodies to assess the performance and safety of implantable medical devices.

It is hoped that by improving the patient reported outcome measures and increasing participation by national spine repositories and their myriad participating hospitals, clinicians and researchers, we can assist the medical device manufacturers in collecting the necessary quality clinical data to establish to the notified bodies that there exists a clear correlation between an outcome measure, and the extent to which the device has affected this outcome.

To conclude:

Our Society firmly believes that the EU Commission must act quickly to address the prevalent uncertainties in the proposed new MDR that risk undermining the implementation of an actionable framework for the promised benefits for both patient care, and the spine care specialists entrusted with the delivery of products and procedures designed to ensure optimal patient care.

Signed on behalf of the **Executive Committee of EUROSPINE**:

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- Vice-President Yann Philippe Charles, Professeur des Universités (France)
- President Elect Jörg Franke, Prof. Dr. med. habil. (Germany)
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Signed on behalf of the **European Spine Society Advisory Board (EuSSAB)** and its members:

- Polish Spine Surgery Society: President Tomasz Potaczek, MD, PhD / EuSSAB Representative Bartosz Limanówka MD, PhD
- Swiss Society of Spinal Surgery: President Cordula Netzer, MD, Dr.med., MBA / EuSSAB Representative Raoul Heilbronner, MD, Dr.med.
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