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Italian National Spine Registry: spinal implants' classification and building of the spinal medical device dictionary

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Background

The number of spinal surgery procedures is constantly growing. Due to their strong impact on patient safety and on public health, the Italian National Implantable Protheses Registry (RIPI) started the Italian National Spine Registry (RIDIS) project. RIDIS Medical Device (MD) Dictionary is a database of spinal implants' technical data. The data will be uploaded by manufacturers and distributors through a web-platform and the information will be free-consulted by manufacturers and surgeons. The aim of this study is to describe the methodology followed to design the taxonomy of spinal implants at the base of the future Dictionary.

Materials and Methods

A first draft of the taxonomy was proposed by the surgeons participating in the RIDIS project panel. Then, it was compared with the specific categories of the Italian National Classification of Medical Devices (recently adopted at European level) to highlight the main technical characteristics. The minimum dataset of technical characteristics essential to assess the device performance were selected referring to MD datasheets.

Results

Five categories of spinal devices were defined. The categories include spinal fixation systems, interbody and corpectomy cages, total or partial discal prostheses, implantable stents, cements for augmentation kyphoplasty and neurostimulators for chronic spinal pain. Each category includes more detailed specifications such as spinal section involved, geometry, size and material.

Discussion/Conclusion

The achieved results give the basis for the future implementation of the spinal implantable devices database, needed for a complete identification and characterisation of the implanted devices collected in the registry.

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