# Registries might support updating and improvement of the national MD classification CND: an example for spinal devices.

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## Introduction

The Italian Implantable Prostheses Registry (RIPI) is a set of registries, which includes the Italian Arthroplasty Registry (RIAP) and the Italian Spinal Implant Registry (RIDIS). They are based on a medical device (MD) classification system critical for the registries' activity, MD surveillance and vigilance. The Italian MD classification (CND) is a hierarchical classification divided into subgroups with homogeneous properties. Since 2016, RIAP has constantly updated the CND of joint prostheses cooperating with the Ministry of Health.
In 2019, the Medical Device Coordination Group (MDCG) selected the CND as a reference for the European Medical Device Nomenclature (EMDN). Indeed, due to its structure, purpose, and characteristics, it was adopted in EUDAMED as a basis for creating the EMDN nomenclature.
This study aims to propose CND updating system by taking advantage of the knowledge acquired in designing the RIDIS-MD Library.

## Materials and Methods

The RIDIS-MD Library design followed three steps: 1) selection of the devices of interest made by the expert panel (including surgeons), 2) a thorough analysis of the technical datasheets and definition of the MD taxonomy, 3) discussion and agreement with the manufacturers. Specific categories and classes defined by the RIDIS taxonomy were then selected for CND updating.

## Results

The analysis results pointed out the need to: a) split the class "Spinal Cages" into "Intersomatic cages" and "Corpectomy cages"; b) add the new class "System for sacroiliac or pelvic stabilisation/fixation" to the classes "Prostheses, cervical fixation systems" and "Thoracolumbosacral spine, fixation systems" already existing.

## Discussion

The study showed how general classification systems adopted at a national or international level can benefit from the constant work performed by implant registries to design and maintain updated MD Libraries. Therefore, a close interaction between registries and regulatory bodies should be promoted for a better MD identification and characterisation to enhance patient safety.