

MedTech Europe's Reflection Paper on the terms of MDR Article 18.3

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Industry welcomes the use of an implant card (IC) and patient information (so called patient leaflet or brochure) for implantable devices as regulated in Article 18 of the MDR (Regulation (EU) 2017/745). The implant card will contain the key information about the implant and will be a convenient record for the patient. However, the MDR Art.18.3. sets a series of exceptions which are not of immediate general understanding.

With the present paper MedTech Europe intends to give examples of devices which are covered by the terms used in MDR Art.18.3

MDR Art.18 lists implant categories which are exempted from the obligation to provide an implant card and related information:

"The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors"

This was done, it is industry understanding, to avoid imposing the burden derived by the obligation of providing an implant card where this would not have an increased positive impact on the overall safety of the patient in which the device is implanted, e.g, during first responder or emergency clinical staff intervention.

The general nature of the terms used, however, has left the interpretation of these terms to the stakeholders (Manufacturers, Notified Bodies and Competent Authorities), with the obvious danger of dis-harmonization.

MedTech Europe wishes to contribute to give examples of devices falling in these categories based on the experience of its members and based on the kinds of implants currently placed on the European market. With this clarification, we hope to ensure an aligned approach to Art.18 for all actors concerned, since diverging interpretations have occurred in the past and led to unnecessary confusion.

Product group	Intended Use	Reference term
Lead adaptor	Pacemaker, Nerve stimulator etc. lead connector adaption	Connectors
Lead extender/connector	Pacemaker, Nerve stimulator etc. lead extension	Connectors
Intramedullary nail end cap	Used to cap the hole at the end of intramedullary nails.	Screws

Tape/ligature	General soft tissue approximation and/or ligation (e.g. circular suture or ligation of the cervix).	Sutures
Blanking plugs for acetabular screw and apical holes	To close holes in joint replacement acetabular component.	Screws
Pledgets /absorbable (sponge) pledgets	Used for wound closure. Intended to be used as a suture buttress, between the suture and the tissue surface to increase the load bearing area	Sutures
Intramedullary nail	Fixation (Osteosynthesis)	Pins
Nails	Fixation	Pins
Nails system	Fixation	Pins and screws
Suture anchors	Fixation	Sutures and screws
Pin plug	Pacemaker, Nerve stimulator etc. connector hole sealing. Used to seal unused connector ports of an IPG. An accessory to/or part of an existing implanted system. It does not cause any incremental impact on medical treatment beyond that which is already established for the existing implant. . No individual application, rather they aid in the implantation and/or repair of leads and cardiac implantable electronic devices (CIEDs). Intended to be implanted as part of the lead system. Used to seal unused connector ports of an IPG	Connectors
Lead End cap	Pacemaker, Nerve stimulator etc. lead sealing	Connectors
Percutaneous Extension	Implanted and exiting the skin during a "buried trial", in which it is used for less than 30 days- the most common use	Connectors
Occipito-Cervical and Cervical Spinal Plates	Intended to provide stabilization of the occipitocervical junction and cervical spine to promote fusion	Plates
Thoracolumbar and Lumbosacral Spinal and Buttress Plates	Intended to provide stabilization of the thoracolumbar and lumbosacral spine to promote fusion Intended to stabilize and buttress bone graft as an aid to spinal fusion	Plates
Interspinous Spacers/Plates	Intended for use as a space holder between the spinous processes in the non-cervical spine (T1-S1). Controls the segmental extension and distracts the interspinous space	Plates
Pectus support bar	This is a plate that is bent to contour the chest wall for the correction of Pectus Excavatum	Plates
Archbar	Archbar intended to work together with screws and wires to achieve temporary fixation of the maxilla and mandible to provide indirect or passive stabilization of fractures and maintenance of occlusion in the oral and maxillofacial region.	Plates
Cervical and Thoracolumbar Interbody Cages (including	Used to secure spacing between the vertebral bodies during the time it takes fusion to be	Wedges

both non-expandable and expandable cages)	achieved but do not replace the function of a natural disc	
Cervical and Thoracolumbar Interbody Cages (pre-filled with Class III graft material)	Used to secure spacing between the vertebral bodies during the time it takes fusion to be achieved but do not replace the function of a natural disc	Wedges
Cerclage wire/cable sleeve	The cerclage wires/cables are passed through holes and the sleeves are crimped to fasten and maintain the position on individual wire/cables.	Connectors
Augment, buttress, shim, Femoral and tibial sleeve, cone, filler block	Intended to be used with hip and knee implants, particularly in revision surgery, to replace deficient/missing anatomic structures (e.g. bone defects/voids) and for re-aligning/reinforcing existing structures in order to facilitate load transfer	Wedges
Dynamic Pedicle Screw/Rod and Pediatric Growing Rod Systems (non-fusion devices)	Expandable devices function as static devices once locked in place in situ	Screws
Cervical and non-cervical Screw (pedicle and non-pedicle)/Hook/Rod/Connector (including transverse/cross connectors) Fixation Systems and the components that make up these systems	Intended to provide segmental stabilization of the spine to promote fusion	Screws
Dental implant	Intended to be surgically implanted into alveolar and/or basal bone of the mandible or maxilla to provide support and a means of retention for a dental prosthesis (e.g., bridge, single-tooth, overdenture)	Screws (Please refer as well to Team-NB-Position paper on Dental Implants-20200311-V1)
Dental implant abutment	Intended to connect endosseous dental implants with dental restoration to restore chewing function	Connectors (Please refer as well to Team-NB-Position paper on Dental Implants-20200311-V1)

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.

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References*:

Medical Devices Regulation: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505>