PROCEED® Surgical Mesh
PROCEED® Ventral Patch

HerniaMesh

Product Information Re Transition from MDD to MDR

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Reimagining how we heal™

Agenda

1. Objective and Scope
2. Product Details
3. Details of Key Changes
4. Medical Devices Regulation (MDR) Article 18 – Implant Cards
5. Product Information
6. Further Information

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Objective & Scope

Objective | PROCEED® Ventral Patch and PROCEED® Surgical Mesh

Background

- PROCEED® Ventral Patch and PROCEED® Surgical Mesh is a sterile synthetic mesh device with absorbable and non-absorbable components and are used to repair hernias that need added support. Please see slide 10 and 11 for changes in indications for use.
- All Labeling and Marketing assets must be updated to comply to the new Medical Device Regulation (MDR).

Objective

After reading this document, you will be able to:

- Identify the SKUs in scope
- Provide references to product information and IFU document link.
- Understand indication and labelling changes
- Understand EU MDR Article 18 Implant Card requirements

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Product Details

Scope | PROCEED® Surgical Mesh

The SKU(s) below are in scope for this submission

PROCEED® Surgical Mesh -11 SKU

Product Code	Product Description
PCDB1	PROCEED® Surgical Mesh- Rectangle
PCDD1	
PCDJ1	
PCDR1	
PCDW1	
PCDL1	PROCEED® Surgical Mesh- Square
PCDM1	
PCDN1	PROCEED® Surgical Mesh- Oval
PCDG1	
PCDH1	
PCDT1	

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Scope | PROCEED® Ventral Patch

The SKU(s) below are in scope for this submission 

Product Code	Product Description
PVPS	PVP SMALL 4.3CM X 4.3CM
PVPM	PVP MEDIUM 6.4CM X 6.4CM

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Details of Key Changes

PROCEED® Surgical Mesh- Changes in Indications for Use

MDD vs MDR

MDD

INDICATIONS

PROCEED® Surgical Mesh is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.

MDR

Indications / Intended Use

PROCEED® Surgical Mesh is indicated for the repair of abdominal wall hernias that require the addition of a reinforcing material to obtain the desired surgical result.

- **Narrowing of Indication statement**

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PROCEED® Ventral Patch- Changes in Indications for Use

MDD vs MDR

MDD

INDICATIONS

PROCEED® Ventral Patch is indicated for the repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.

MDR

Indications / Intended Use

PROCEED® Ventral Patch is indicated for the open repair of ventral hernias that require the addition of a reinforcing material to obtain the desired surgical result.

➢ **Narrowing of Indication statement**

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Medical Devices Regulation (MDR) Article 18 - Implant Cards

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EU MDR Article 18

What does Article 18 of the Regulation Say?

Implant card and information to be supplied to the patient with an implanted device

1. The manufacturer of an implantable device shall provide together with the device the following:

a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;

b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonable foreseeable external influences, medical examinations or environmental conditions;

c) any information about the expected lifetime of the device and any necessary follow-up;

d) any other information to ensure safe use of the device by the patient, including the information in point (u) of Section 23.4 of Annex 1.

IMPLANT CARD

PATIENT INFORMATION

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EU MDR Article 18

What does Article 18 of the Regulation Say?

Implant card and information to be supplied to the patient with an implanted device

The information referred to in the first subparagraph shall be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by any means that allow rapid access to that information and shall be stated in the language(s) determined by the concerned Member State. The information shall be written in a way that is readily understood by a lay person and shall be updated where appropriate. Updates of the information shall be made available to the patient via the website mentioned in point (a) of the first subparagraph.

In addition, the manufacturer shall provide the information referred to in print (a) of the first subparagraph on an **implant card delivered with the device.**

2. Member States shall require health institutions to make the information referred to in paragraph 1 available, by any means that allow rapid access to that information, to any patients who have been implanted with the device, together with the implant card, which shall bear their identify.
3. **The following implants shall be exempted from the obligation laid down in this Article; sutures, staples, dental filings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors**. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom.

Bulk at the hospital is NOT an option

Well-established technologies are EXEMPT from Article 18

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EU MDR Article 18 | Implants Cards

Elements to fulfill Article 18 requirements – Aligned across HMD

Content

All elements need to be provided in 25 languages
***ICG does not need include Icelandic - 24 languages**

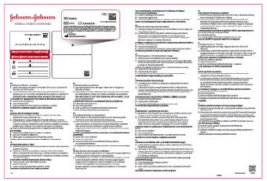
Implant Card

- Title: **International Implant Card**
- Patient website URL
- Space for *Implant Card Label and* for HCP to write information

Implant Card Label

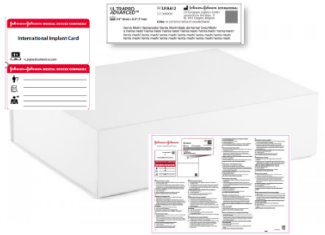
- Product name, REF
- Device type category
- Lot number, UDI, legal manufacturer

Implant Card Guide*



- Instructs the HCP how to complete the Implant Card
- Symbol legend

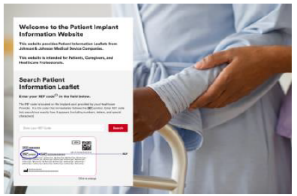
Delivered with the Product



Patient Information Leaflet

- Describes the implant in lay person terms
- HCP provides to the patient
- Warnings, lifetime, information on safe use

Delivered via e-platform
Download & print from website



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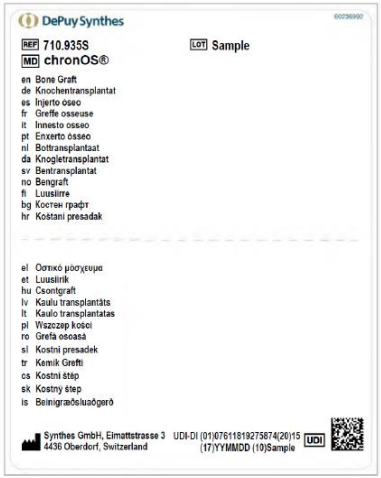
EU MDR Article 18 | Implants Cards

How does the Implant Card get to the Patient?

Implant Card (IC) – Credit Card format

HCP adds ICL to IC

Large Implant Card Label (ICL)



Information specific to patient, date and Health Care Institution

HCP assembles, fills in and gives to patient

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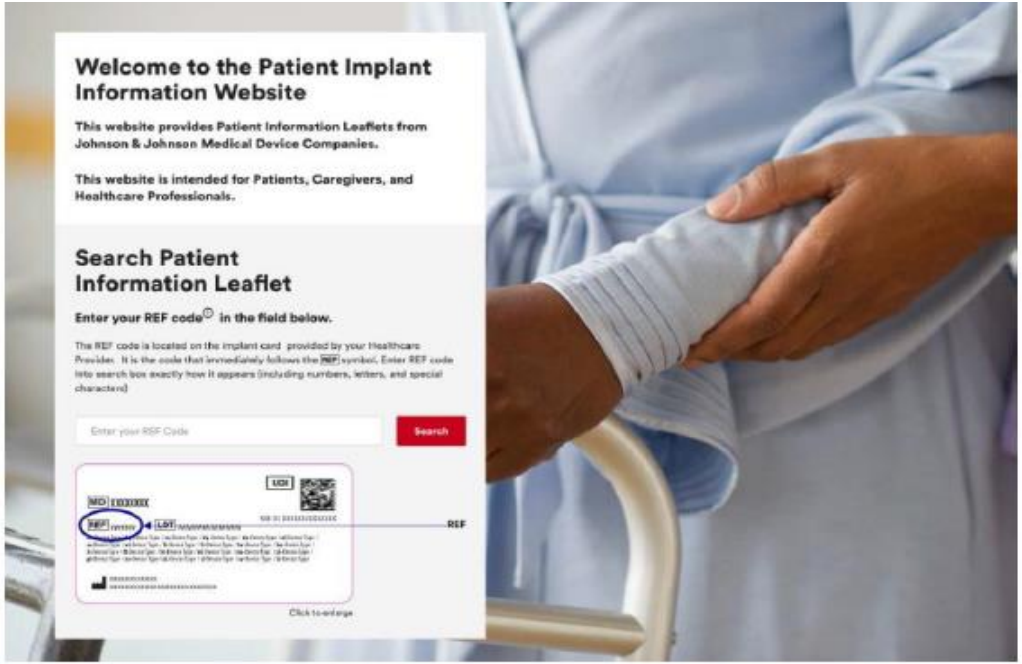
EU MDR Article 18 | Implants Cards

How does the Patient obtain the Patient Information Leaflet (PIL)?

Patient

- Visits Patient Implant Information Website ic.jnjmedicaldevices.com
- Enters REF number from the Implant Card

ic.jnjmedicaldevices.com



NOTE: Franchise uploads multilingual PIL (PDF).
REF code is the only way a patient can search for their PIL.

Product Information

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Product Information | Reference Documents

- For the most up to date **Surgical Technique Guides** and **Product Catalogues** linked to these brands, please contact your local Customer Service Team or Johnson & Johnson MedTech Sales Representative.

- Should you have any **medical**, **scientific** or **technical** questions, please submit them to our Medical Affairs team via the **Medical Information Requests (MIR)** portal link:
  - Medical Information Request (MIR)

- The **EU MDR Resource Centre** retains other relevant MDR information can be found via the following link:
  - EU MDR Resource Centre

- For more information about products and information please refer to the e-IFU page of this document.

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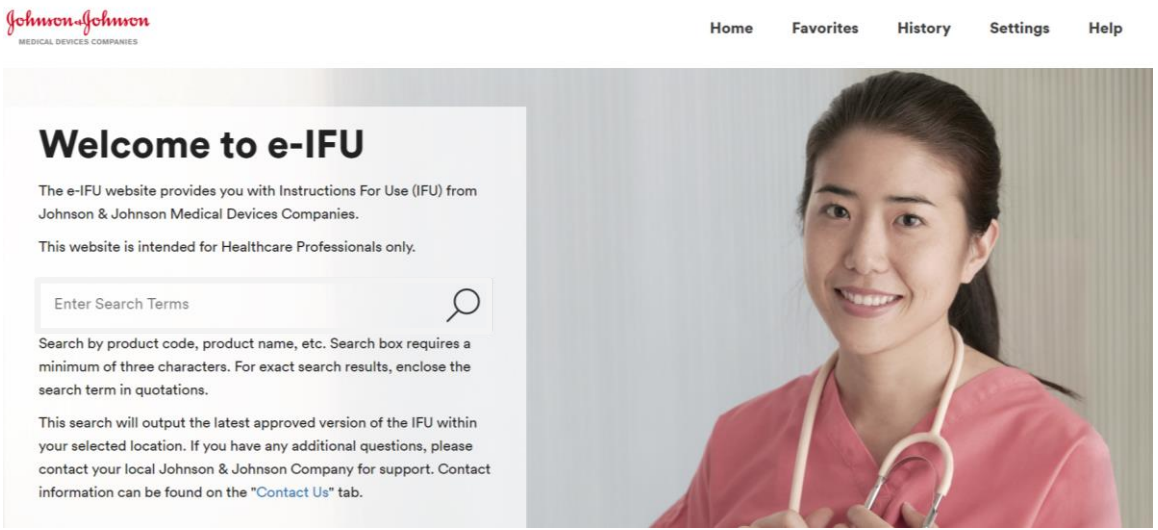
Product Information | Reference Documents (IFU)

Use portal link below, with this information the relevant IFU(s) can be found with the SKU:
MDR: https://www.e-ifu.com/

ePIL (Patient Information Leaflet) on www.ic.jnjmedicaldevices.com

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.



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Further Information

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Restricted Substance (RS) Primer & Fact Sheet

Note:
Presence of Restricted Substance (RS) such as cobalt, Hazardous Substance (HS) symbols have been added to the IFU and labels.

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Thank you.

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If you have questions, please contact your local customer service team or Johnson & Johnson MedTech sales representative. Alternatively, if you have any medical, scientific or technical questions please submit these questions to our Medical Affairs team via the Medical Information Requests (MIR) portal: Medical Information Request (MIR).

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