Instructions for Use (IFU) and Electronic Instructions for Use (eIFU)

Ensuring healthcare providers and patients understand and use medical device products safely and effectively is a focus of the EU Medical Devices Regulation (EU MDR).

The term “instructions for use” within the EU MDR, refers to the information provided by the manufacturer to inform the user of a device’s intended purpose and proper use and of any precautions to be taken. EU MDR requirements in other areas, such as clinical indications, may have a direct effect on the format and contents of a device’s IFU. This factsheet helps HCPs understand EU MDR requirements for IFUs and the approach Johnson & Johnson MedTech (JJMT) is taking to meet those requirements.

IFUs are required for all class IIb and class III medical devices. Other class devices are exempted if the devices can be used safely without any instructions. Some products will include a paper-based version of the IFU, which carries the respective details relevant to the device and will be in an official EU language determined by the Member State in which the device is used.

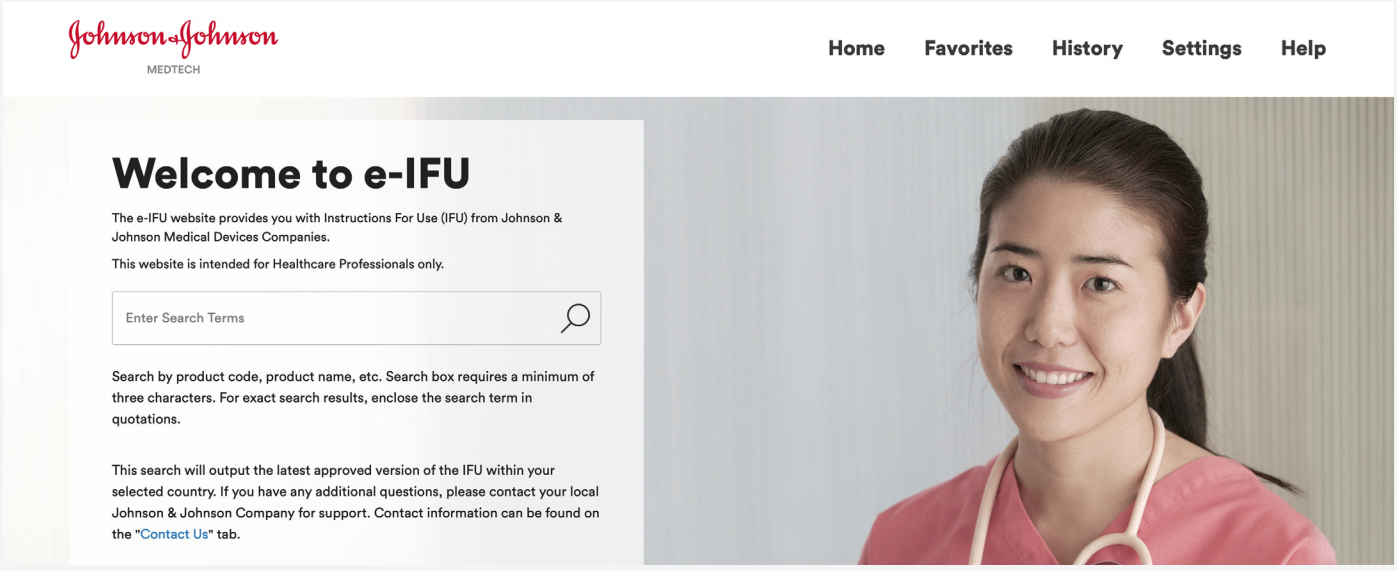
Electronic Instructions for Use (eIFU)

eIFUs are acceptable for all devices when coupled with a paper IFU. However, some devices are eligible for eIFU in place of a paper IFU. They include:

- Implants & active implants and their accessories
- Fixed installed devices
- Devices with built-in system displaying instructions
- Software covered by the EU MDR

These JJMT products will no longer carry a paper IFU, instead the IFU is provided online via this website, www.e-ifu.com. The latest version of the IFU will be displayed on the website and previous versions will be available by selecting the “Version” option.

Countries outside of the EU that leverage the CE Mark may not allow an eIFU. In those cases, a paper IFU (outserted) will be provided even though the eIFU symbol is available on the packaging.



Johnson & Johnson MedTech eIFU website

IFUs and Changes to Clinical Indications

Medical devices are grouped into four classes under EU MDR as follows:

- Class I - low-risk
- Class Im (measuring device) – low risk
- Class Is (sterile device) – low risk
- Class IIa – medium risk
- Class IIb – medium to high risk
- Class III – high risk

However, EU MDR up-classifies certain devices and has a wider scope. Some products may require changes to clinical indications due to increased clinical evidence requirements to comply with the new regulation. IFUs will be updated for changes to clinical indication claims or intended use as well as any changes to surgical technique guides.

IFUs and Restricted Substances

EU MDR also requires that IFUs and eIFUs be updated to indicate the presence of carcinogenic, mutagenic, or toxic to reproduction (CMR) substances or endocrine-disrupting substances in certain medical devices above certain concentrations. This labelling requirement does not mean a device is unsafe. The fact that it has been CE Marked means that both the manufacturer and the notified body have established a positive benefit-risk ratio.

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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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