MedTech Europe
from diagnosis to cure

Let’s Go Digital: Instructions For Use

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Instructions for use come with every medical device and provide the intended user with information on safe and effective use of the device.

Right now, European regulations mandate the use of paper Instructions for Use (IFU) for most medical devices. Almost every device that gets delivered to a doctor or a hospital, therefore, comes with printed instructions, whether it is a catheter, dermal filler or perfusion equipment.

Some of these IFUs can be hundreds of pages long – in one language. Translations further increase the large amount of paper needed. Data shows that to make paper IFU for 10 medtech companies 6 billion trees need to be cut down in a year. This roughly accounts for trees spread over the size of Belgium or Costa Rica.

But did you know that…

…we could get rid of mountains of paper needed to make paper IFUs and stop billions of trees being cut down every year to make paper by adopting electronic Instructions for Use (eIFU)?

Why eIFU?

Besides being environmentally friendly, eIFU are accessible, searchable and adaptable.

- **Accessible** – eIFU are available whenever the user needs them. They enable easy handling and opening. Surgeons and teams can read them prior to procedures.
- **Searchable** – eIFU allow the user to quickly find specific information, select a preferred language, increase font as needed and adjust view. They can also include illustrations and videos.
- **Adaptable** – They can be easily updated so that the user has the most up-to date information.

They have the potential to **significantly help manufacturers supply their devices faster**, which will increase accessibility to treatments for patients.

Help spread the word to make eIFU available for medical devices!

What if I prefer paper?

As per the European eIFU Regulation, you can always request a paper copy of IFU for the product. The manufacturer must make the paper copy available to you, free of charge.

What happens if the website of a manufacturer temporarily does not work or becomes inaccessible?

You will find a customer line number on the device label for such cases.

The European eIFU Regulation makes provisions for risk mitigation to prevent such situations from happening alltogether.

What is the situation like in other countries?

- Most major jurisdictions worldwide already allow eIFU for medical devices used by professionals. The United States, for instance, has allowed the use of eIFU for 20 years for all prescription devices.
- Other countries include Canada, Japan, South Korea, Brasil, Singapore, Saudi Arabia and more.

How long does it take to…

… issue a new version of eIFU?

- Any changes to e-IFU can be implemented within a matter of weeks (most frequently up to 2 weeks) and all language versions for all EU Member States are updated simultaneously.

… issue a new paper IFU?

- Implementation of changes, translations, printing, and shipping to all users takes approximately 3-6 months depending on the nature of the updates.

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