Fresenius Kabi Australia Pty Limited

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16 April 2024

Dear Healthcare Professional.

As per the Therapeutic Goods (Medical Devices) Regulations 2002 From 1 December 2021, all implantable medical devices are required to have patient information materials available in the form of both Patient Implant Card (PIC) and Patient Information Leaflet (PIL). Our records show that we supply the following class IIb implantable medical devices to your healthcare facility.

- 7755642 ENFit Freka PEG FR 9
- 7755643 ENFit, Freka PEG FR 15
- 7755644 ENFit, Freka PEG FR 20
- 7755645 ENFit, Freka FCJ FR 9

The TGA allows the PIC and PIL to be supplied either in hard copies implemented into the packaging at the time of manufacture, or made available electronically, separate to the packaged device, to be readily accessible by Healthcare professional and patient.

Fresenius Kabi is in the process of finalisation and implementation of the PIC and PIL into the packaging for the above mentioned implantable medical devices. In the interim, we have created PIC's and PIL's which can be downloaded from our website and provided to the patient in print form or by website link.

Please complete the PIC information by referring to the primary packaging label of the device and provide the completed PIC & PIL to the patient after surgery.

Link to Product Page	Patient Implant Card link	Patient Information Leaflet link
Freka® PEG 7755642, 7755643, 7755644	Freka® PEG PIC	Freka® PEG PIL
Freka® FCJ 7755645	Freka® FCJ PIC	Freka® FCJ PIL

Should you have any questions or comments, please don't hesitate to contact your local Fresenius Kabi Account Manager, or you may call our Customer Service Support Team on 1300 304 384 in Australia or 0800 144 892 in New Zealand.

Kind regards,

Carolyn Kirker
Infusion & Nutrition Systems Product Manager

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