

To Whom It May Concern

Marketing Information Letter

Freka® Button Extension Sets 1, 30 cm, angled, ENFit	7981397
Freka® Button Extension Sets 2, 30 cm, straight, ENFit	7981398

Fresenius Kabi has launched Freka® Button Extension Sets for Freka® Belly Button with the new ENFit connector. The Freka® Button Extension Sets are available either with straight connector or with angled connector to be connected with the Freka® Belly Button. It is indicated for the administration of enteral nutrition and/or medication only.

The Freka® Button Extension Sets are classified as single use – disposables Medical Devices. Single use can be stated as "One patient and one application".

Microbiological tests showed that the Freka® Button Extension Sets can be used for up to 2 weeks. For hygienic and functional reasons it is recommended to replace them at least every 2 weeks. The Freka® Button Extension Sets have to be flushed after each administration with min. 20 ml of water. During feeding breaks they should be stored in a dry and clean environment and protected from direct sun light (please see also the label and IFU information).

For critical patients it is recommended to replace the Freka® Button Extension Sets every 24 hours.

Bad Homburg, 02.02.2017



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