

Rolta soft

General description of the device/Intended purpose

Rolta soft is a single-use device used by healthcare professionals and instructed lay persons in a non-invasive context. It can be used where a padding effect is required, i.e. compression therapy or immobilization with stiff materials such as splints or casts, for up to long-term on intact skin on humans.

Rolta soft is a synthetic padding bandage, made of crimped polyester fibres that are permeable to air and can be torn off by hand. Rolta soft protects the covered body parts from mechanical damage due to the properties of the synthetic fibres.

Application/Indication

Rolta soft is used where a padding effect is required, i.e. compression therapy or immobilization with stiff materials such as splints or casts.

Reference Numbers

REF	Name	Dimensions	Bandages per folding box
932043	Rolta soft	6 cm x 3 m	6
932048	Rolta soft	6 cm x 3 m	50
932045	Rolta soft	10 cm x 3 m	6
932049	Rolta soft	10 cm x 3 m	30
932047	Rolta soft	15 cm x 3 m	4
932050	Rolta soft	15 cm x 3 m	20
932051	Rolta soft	25 cm x 3 m	10

Contraindications

Don't use Rolta soft in case of intolerance to one of its ingredients.

Single use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Rolta soft should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Incident reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

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Product Performance Characteristics

Property	First layer
Elongation	ca. 90 %
Thickness	ca. 2,2 mm
Width	6, 10, 15, 25 cm
Area weight	ca. 80 g/m ²
Pad effect (200 N load)	> 75
Air permeability	> 3500 mm/s


Labelling

Lot-No. with 9-digit code


e.g.:

	9	001	01	17	1
explanation definition	[9 = 2019] year	[999-000] serial production order	for internal purposes only		

Date of Manufacture

e.g.:  **2019** **04** **01**
year month day

Use-by date

e.g.:  **2024** **04** **01**
year month day

Shelf life: 5 years

Medical Device



Unique Device Identifier



Latest date of revision: 2020-05-25