

Omnisilk

General Product Description

Omnisilk spool plasters are non-active, non-invasive, single-use, self-adhesive, non-sterile devices consisting of an adhesive coated backing material (carrier material) attached to a core spool.

The main constituents of these products are:

- Backing / carrier material: White Riging silk fabric
- Medical grade adhesive: Synthetic rubber based adhesive / Hotmelt (transparent)
- Spool: polystyrene

The products are intended for humans, without restrictions (in age group, weight range, health status or condition), for a single use by healthcare professionals and lay-users, in contact with intact skin (healthy skin), and short-term (60 minutes ≤ Duration ≤ 30 days, acc. to MDR) / prolonged use (24 hours < Duration ≤ 30 days, acc. to ISO 10993-1:2018) duration of use.

The products do not contain resorbable components, medicinal products / drug substances (derived from human blood or plasma or not), tissues or cells of human or animal origin, radioactive substances, nanomaterials or other hazardous components.

The products are packed in cardboard folding boxes, either single spools or as multipacks.

Application/Indication

Omnisilk is a surgical fixation tape for the fixation of any kind of non self-adhesive wound dressings (like wound pads, traditional gauzes), especially for coverage of large surfaces, as well as for the fixation of tubes of cannulas, probes and/or catheters.

Reference Numbers

Omnisilk international range

Packaging	Dimensions	Labelling type	Name	Reference number
P1	1.25cmx5m	Folding box	Omnisilk	900430
P1	2.5cmx5m	Folding box	Omnisilk	900431
P1	2.5cmx9.2m	Folding box	Omnisilk	900419
P1	5cmx5m	Folding box	Omnisilk	900432
P1	5cmx9.2m	Folding box	Omnisilk	900420

Omnisilk

Omnisilk Russian OTC range

Packaging	Dimensions	Labelling type	Name	Reference number
P10	1.25cmx5m	Folding box + Display	Omnisilk	900494
P10	2.5cmx5m	Folding box + Display	Omnisilk	900484
P10	5cmx5m	Folding box + Display	Omnisilk	900554

Omnisilk OTC, language circle R, B, CR, SL

Packaging	Dimensions	Labelling type	Name	Reference number
P10	2.5cmx5m	Folding box + Display	Omnisilk	900483

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 our products 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.

Omnisilk

Product Performance /Material Characteristics

Nonwoven (standard performance) 1				
Property	Test method	Unit	Requirements of EN 13795 (critical reas)	Test results
Visual inspection	TM00 0001	-	Not required	OK
MVTR	TM00 0188	g/m2/24h		>3600
Peel adhesion	TM00 0090-02	N/25mm		12 ± 5
Unwinding	PH383/001	N/25mm		<15

Labelling

Lot-No. with 8-Digit Code

e.g.:



0

year

12

week of production

XXXXX

for internal purposes only

Manufacturing Date

e.g.:



2020
year

03
month

01
day

00:00
Hour

Use-by-Date

e.g.:



2025
year

03
month

01
day

Shelf Life: 5 years

Medical Device



Unique Device Identification (UDI)



Latest Date of Revision: 2020-05-29