

Stülpa® and TubeGaze

MEDICAL DEVICE

General Product Description/Intended Purpose

Stülpa® and TubeGaze are single-use, non-sterile tubular bandages used by instructed lay-user and healthcare professionals on intact skin as inner lining to protect skin from zinc paste bandages, support cast, adhesive and cohesive bandages; or used as outer lining to protect primary wound dressings / compression bandages or for fixation of dressings in combination with other fixation aids.

Stülpa® and TubeGaze are considered a medical device in Class I.

Application/Indication

The densely-knitted, tubular construction serves to protect skin from zinc paste bandages, support cast, adhesive and cohesive bandages. Furthermore, Stülpa® and TubeGaze can be used for dressing protection and fixation of dressings with other fixing aids.

Catalogue Numbers

Brand	REF	Size	Pieces per foldingbox	Dimensions	
				Width (cm)	Total length (m)
Stülpa® Rolls	427110	0	1	1,5 ± 0,3	15 ± 0,75
	427111	1	1	2,5 ± 0,4	
	427112	2	1	6,0 ± 0,6	
	427113	3	1	8,0 ± 0,8	
	427114	4	1	10,0 ± 1,0	
	427115	5	1	12,0 ± 1,2	
	427146	6	1	15,0 ± 1,7	
	427147	7	1	21,0 ± 2,1	
	427148	8	1	24,0 ± 2,4	
Stülpa® Ready-for-use-bandages	427211	1	20	2,5 ± 0,4	≥ 0,34
	427213	3	10	8,0 ± 0,8	≥ 0,72
	427214	4	10	10,0 ± 1,0	≥ 0,82
	427261	1	50	2,5 ± 0,4	≥ 0,34
	427253	3	10	8,0 ± 0,8	≥ 0,72
	427254	4	10	10,0 ± 1,0	≥ 0,82
TubeGaze Rolls	427000	01	1	1,5 ± 0,3	20 ± 1,0
	427001	12	1	2,5 ± 0,2	
	427002	34	1	4,0 ± 0,3	
	427003	56	1	6,0 ± 0,3	
	427004	78	1	8,0 ± 0,4	
	427005	T1	1	10,0 ± 0,5	

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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

In order to minimise the risk of potential infection hazards, or environmental pollution, disposable components of Stülpa® and TubeGaze 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 (EU) 2017/745 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.

Product Performance Characteristics

Property	Stülpa® Rolls	Stülpa® Ready-for-use-bandages	TubeGaze
Material composition	100 % Viscose	100 % Viscose	100 % Cotton (bleached)
Color	White	White	White
Optical brighteners	No	No	No
Area weight [g/m ²]	Size 0 + 1: 220 ± 25 Size 2: 200 ± 25 Size 3-5: 190 ± 25 Size 6: 185 ± 25 Size 7-8: 165 ± 25	Size 1: 220 ± 25 Size 3 – 4: 190 ± 25	size 01: 185 + 35/- 25 all other: 185 ± 25
Number of courses per 10 cm	55 -5/+8	55 -5/+8	50 ± 8
Elongation in CD [%]	size 0: 350 ± 100 size 1: 350 ± 100 size 2: 350 ± 100 size 3: 350 ± 100 size 4: 330 ± 100 size 5: 350 ± 100 size 6: 350 ± 100 size 7: 280 ± 80 size 8: 280 ± 80	Size 1: 350 ± 100 Size 3: 350 ± 100 Size 4: 330 ± 100	01: ≥ 300 all other: 300 + 100/ - 50

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Labelling

Lot-No. with 9-Digit Code

e.g.:



9

year

999

week
of production

XXXXX

for internal purposes only

Date of manufacture

e.g.:



2025

year

01

month

01

day

Use-by Date

e.g.:



2030

year

01

month

01

day

Shelf Life: 5 years

Medical Device



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