

Stülpa®-fix



Spec.-No.: D 2.4400
 Department: **COM-DGM**
 Date: 2018-12-03

1. General Product Description

Stülpa-fix is a seamless warp knitted tubular bandages made from bleached cotton and elastic threads covered by PA yarn. The elasticity causes a slight pressure to make the bandage fixating.

Stülpa®-fix carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class I medical device.

A conformity assessment has been performed for Stülpa®-fix and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use of Stülpa®-fix, therefore, is ensured if the product is used in line with the intended purpose (see 2. Application/Indication).

2. Application / Indication

Stülpa-fix is a non-sterile permanently elastic net tubular bandage for use on human skin. It is for single-use and can be used by lay persons and health professionals in clinical and home environment as a secondary dressing for short-term or long-term treatment of acute and chronic wounds for application in combination with primary dressings.

Dressing retention can be done on all parts of the body depending on size.

3. Presentations

Stülpa®-fix, stretched length 25 m

Size	Application	Size recommendation
1	adult's hands and feet and children's hands and feet	3 – 10 cm
2	adult's hands, arms and feet and children's arms, legs, hands and feet	5 - 20 cm
3	adult's arms, legs and feet and children's arms and legs	10 - 40 cm
4	adult's legs, heads and arms and children's legs, heads and trunks	20 - 65 cm
5	adult's heads, trunks and legs and children's heads and trunks	40 - 90 cm
6	adult's trunks	70 - 120 cm
7	adult's trunks	105 - 150 cm

4. Product Characteristics

Material:	68 % cotton bleached 24 % polyamide 8 % elastane
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5. Product Requirements

Dimensions:	
Width unstretched:	
size 1	approx. 1,5 cm
size 2	approx. 2,0 cm
size 3	approx. 3,0 cm
size 4	approx. 5,0 cm
size 5	approx. 6,5 cm
size 6	approx. 8,5 cm
size 7	approx. 11,5 cm
Length stretched:	25 ± 1,5 m

Construction:	Warp knitted fabric
Elongation cross direction:	size 1: 1100 ± 200 size 2: 1100 ± 150 size 3: 950 ± 150 size 4: 900 ± 100 size 5: 900 ± 100 size 6: 900 ± 100 size 7: 825 ± 100
Elongation machine direction	120 ± 20 %
Residual elongation after multi-cycle stress:	< 60 %
Residual elongation after stress with 1,2 kg for 60 min:	< 140 %
Amount of loops per tube:	Size 1: 16 size 2: 24 ± 1 size 3: 36 ± 1 size 4: 60 ± 2 size 5: 76 ± 2 size 6: 100 ± 2 size 7: 140 ± 2
Amount of courses per 10 cm (stretched):	41 ± 3
Weight per area:	250 ± 50 g/cm ²

Sterilizability:

Ethylene oxide sterilization according to DIN EN ISO 11135 with validated process.

Steam sterilization at 134 °C for 10 min according to DIN EN ISO 17665 with validated processes with the following restrictions:

Stretched length: decrease of appr. 5 %

Elongation in machine direction: increase of appr. 35 %

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Elongation in cross direction: decrease appr. 10 %

6. Labelling

The Lot is created by iLISS- system.

Example:

Lot. - No.	7	123	28	17	1
Definition	Last figure of the current year	Serial production order	Internal code		

Expiry date  Year - Month - Day
 Example 2020 – 03 – 01
 Shelf life: 5 years

Production date  Year – Month – Day
 Example 2017 – 03 – 01

7. Packaging

Stülpa®-fix are packed into dispensers and then into transport cartons. The transport cartons are sealed with adhesive tape and packed onto euro pallets.

Date: 03th December 2018

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