

3213 Easy Donning Sleeve

MD Medical Device

Construction and Function

The Easy donning sleeve is used for easier donning of lower limb prostheses with a valve opening. It is made of a lightweight material with low friction qualities and reduces the pain prosthesis wearers may experience when donning their prosthesis.

Intended Use

The product is to used solely for lower limb prosthetic fittings.

The product can be used for prostheses with a valve opening.

⚠ WARNING

Keep and store out of reach of small children – Danger of suffocation due to lack of oxygen supply!

⚠ CAUTION

Using the product without following the instructions for use

Deteriorating health condition and damage to the product because of failure to follow the safety information

Observe the safety information in these instructions for use.

⚠ CAUTION

Single use user only!

Skin irritation, formation of eczema or infections due to contamination with germs.



⚠ NOTICE

- Impaired functionality may occur due to mechanical damage (such as sharp valve opening).
- Check the product for damage prior to each use.
- Do not use the product if its functionality has been impaired.

Application

⚠ NOTICE

Use of powder (baby powder, talcum powder)

Loss of function of prosthetic components due to clogging with particles or deprivation of low friction properties.

Avoid contact with powders.

- 1) Fully spread out the donning sheath
- 2) Turn one half of the donning sheath into the other half, so that the strap is facing out
- 3) Pull the donning sheath over the residual limb, avoiding any wrinkles
- 4) Slide into the prosthetic socket and guide the pull-strap through the valve opening in the socket.
- 5) Pull the donning sheath out through the valve opening in the socket, dividing the donning sheath into 4 quadrants.
- 6) Evenly pull the donning sheath in each quadrant to reduce bunching, and to evenly pull the limb/skin into place within the socket to ensure a good fit.
- 7) Perform very slight (not moderate or large) pumping movements with the residual limb to aid donning the socket. If moderate or large pumping occurs, it is possible to pull the limb out of optimal placement while donning the socket!

⚠ Only use and don prosthesis in a very secure location and scenario. Be sure to have a means to keep stable while using!

Cleaning ⚠ NOTICE

Use of improper cleaning agents can incrementally damage the product over time with repeated washings.

- 1) Wash the product in warm water with very mild, odor free soap
- 2) Allow the product to air dry completely. Do not expose to direct heat sources to dry out (no direct sunlight, stove, heater)

Dispose of product in accordance with local and national regulations.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.



Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, sand



Liability

The manufacturer will only assume a warranted claim of the product if used in accordance with the description and instructions provided. The manufacturer will not accept any claim for damage caused by disregard of this document.

CE Conformity

This product meets the requirements Council EU 2017/745 (EU) for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

Useful Life

Service life of the product is covered by the warranty period.

Counter Indications

There are no counter indications.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

P / N	Size	W / L
3213-S	Donning Sleeve, S	28cm / 96cm
3213-M	Donning Sleeve, M	34cm / 97cm
3213-L	Donning Sleeve, L	40cm / 104cm

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