

pedilay[®]med

GERBRAUCHSANWEISUNG

für **Pedilay[®]med** erstellt am 23.03.2020 durch Pedilay[®] Care GmbH.
Version 1.2; ersetzt 12.06.2019

GERBRAUCHSFERTIGER FUSSVERBAND

passend für rechten oder linken Fuß

INSTRUCTIONS FOR USE

for **Pedilay[®]med** issued 23.03.2020 by Pedilay[®] Care GmbH.
Version 1.2; replaces 12.06.2019

READY FOR USE FOOT BANDAGE

fits on the right or left foot

ENGLISH

Foot Care.
Simply Better.

Pedilay Care GmbH
www.pedilay.care

Medizinprodukt
Medical Device



WHAT IS PEDILAY® MED?

WHAT IS IT USED FOR?

Pedilay® med is a ready for use foot bandage, covering the foot up to the ankle, to support medical treatments. The purpose of **Pedilay® med** is to act as a biocompatible physical layer to protect and support the skin. **Pedilay® med** is intended to be used alone or in conjunction with other products for medical treatment.

In case of use as a secondary or tertiary dressing on injured skin, **Pedilay® med** acts as an additional physical layer. **Pedilay® med** can help retain layers underneath and absorb excess fluids.

Pedilay® med can be used for patients who receive temporary or long-term medical foot treatment, or who are bedridden or have limited mobility.

THE ADVANTAGES

- easy and quick to put on and take off
- designed for sensitive feet
- adapts to any foot shape
- imperceptible seams
- low-friction material

INFORMATION AND SAFETY

Pedilay® med should always be recommended by a healthcare professional and non-medical users should be provided with initial instruction.

Only use **Pedilay® med** as described in the instructions for use. Any other use is considered improper and may result in property damage or personal injury.



Pedilay® med as a primary layer:
on intact, uninjured skin.



Pedilay® med as a secondary layer:
on injured skin or open wounds with
a primary layer underneath (e.g. plaster)



Pedilay® med must not be used:
directly on injured skin or open wounds
without primary layer underneath
(e.g. plaster)

In case of any uncertainty regarding use of **Pedilay® med** or if health condition worsens, immediately discontinue use and seek medical advice. Please report all serious events to **Pedilay® Care GmbH** and the **German Federal Institute for Drugs and Medical Devices (BfArM)**: Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn, Germany.

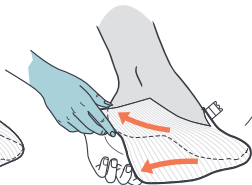
APPLICATION FOR RIGHT OR LEFT FOOT



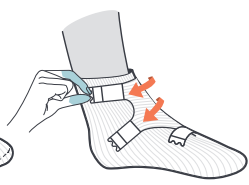
1. Open tabs and slip **Pedilay® med** over the toes.



2. Pull **Pedilay® med** backwards over the foot.



3. Stretch **Pedilay® med** to the foot length and pull upwards over the heel.



4. Close all tabs in the desired position.

CLOSURES

ANKLE

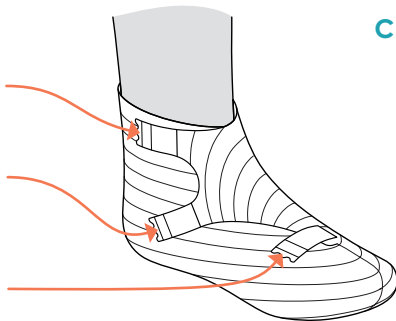
runs parallel to the cuff

INSTEP

runs along the instep, diagonally towards the heel

FOREFOOT

runs along the forefoot



CORRECT FIT

- low compression
- no hollow areas
- no pressure
- no wrinkles
- no gaps

SIZING CHART

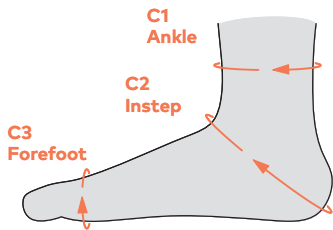
Note:

Non-medical users are recommended to try and choose the correct size in accordance with a healthcare professional.

Shoe sizes and foot dimensions only serve as a guide for size selection of **Pedilay®med**. Other factors can require the selection of a different size in individual cases.

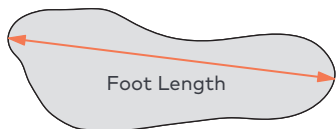
SIZE	Shoe Size	37 – 42 (EU)
	Foot Length	20 – 26 cm
S	CIRCUMFERENCES:	
	C1 Ankle	20 – 31 cm
	C2 Instep	21 – 25 cm
	C3 Forefoot	20 – 26 cm

MEASURING CIRCUMFERENCES



SIZE	Shoe Size	41 – 46 (EU)
	Foot Length	25 – 32 cm
L	CIRCUMFERENCES:	
	C1 Ankle	30 – 36 cm
	C2 Instep	23 – 29 cm
	C3 Forefoot	25 – 28 cm

MEASURING FOOT LENGTH



SIZE SELECTION

The following factors may require a different size of **Pedilay® med**:

LARGER PRODUCT SIZE REQUIRED

skeletal deformities

e.g. Hallux valgus, Charcot foot, clubfoot

extremely voluminous feet

e.g. edema, diabetic foot syndrome

swelling of the foot

e.g. with edemas, inflammations

underlying layers

e.g. foams, compression bandages

SMALLER PRODUCT SIZE REQUIRED

skeletal deformities

e.g. claw toes, hammer toes

amputations

e.g. toe-, forefoot-, midfoot- or hind-foot amputation

INDICATIONS FOR WRONG SIZE

Pedilay® med feels tight or causes a feeling of numbness. The material has lost its wave structure and appears transparent. Seams or elastic fibres leave permanent pressure marks. The tabs can no longer be closed.

HYGIENE AND DISPOSAL

For optimal hygienic care, change **Pedilay® med** :

- **daily** in case of acute, infectious and exuding wounds
- when it is **soiled or soaked**
- if the material has become **worn-out or ripped**
- latest **after 3 days**

Dispose the used **Pedilay® med** **immediately** after change as regular household waste.



Single use



Do not wash



Special precautions are recommended for infectious wounds:

- Use **disposable gloves** or **disinfect your hands** before & after use
- Dispose **Pedilay® med** in a **lockable waste container**
- In stationary facilities, the **respective operational and legal regulations may apply**



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