# COMPRESSION for chronic



venous disease and PAD / Diabetes

Yes, certainly!

mediven® angio

Safety in treatment – down to the toes.

Unique, soft padding from above the ankles down to the tip of the sport sports

# mediven® angio

Safety in treatment – down to the toes.





The unique solution for patients with chronic venous disease and concomitant PAD and / or diabetes.

#### Solid ribbed structure

Ideal ratio between resting and working pressure

Optimised compression effect on the venous system with due regard to the arterial vascular status and / or absent sensitivity to pressure and pain

#### Merino-Plush in the entire foo

Unique padding from the tip of the toes up to above the ankle

 Reduction of pressure peaks and avoidance of lesions at bony predilection sites (e.g. ankle, metatarsal heads)

#### Extra long, flat seam

Seam ends proximally of the metatarsophalangeal joints I and V

Reduction of pressure peaks to avoid lesions developing on the toes and their joints

Available length	Colours		CCL
AD (knee-high)	Caramel	Black	CCL 1
	Caramel	Black	CCL 2

# Safe and indication-appropriate treatment



#### Chronic venous disease (CEAP COs – C5)

#### approx. 98 % of the over 60-year-old<sup>2</sup>

#### **Clinical diagnosis**

- · Venous reflux
- Venous hypertension

#### Patient-individual criteria

- Severity of venous disease
- Oedema
- · Weight / BMI



Compression therapy with mediven® round knit (e.g. mediven plus) – patient-individual care

#### Chronic venous disease (CEAP COs – C5) and mild to moderate PAD

#### approx. 21 % of the over 65-year-old3

#### Further clinical diagnosis<sup>3,4</sup>

- Fontaine-Stadium I II
- Ankle-brachial pressure index (ABPI) < 0.9 and > 0.5
- Ankle artery pressure > 60 mmHg
- No palpable foot pulses

#### Patient-individual criteria

- General tissue atrophy
- Trophic skin disorder
- · Sandpaper-like hyperkeratosis



Compression therapy with mediven angio unique and safe

#### ✓ Unique product

- Merino-Plush in the entire foot
- Solid ribbed structure
- Extra long, flat toe seam

#### Chronic venous disease (CEAP COs – C5) and diabetes mellitus Type 2 / diabetic PNP

#### approx. 20,5 % of the over 60-year-old<sup>5</sup>

#### Further clinical diagnosis

- Paresthesia
- Hypaesthesia
- Analgesia

#### Patient-individual criteria

- Tropic oedema
- Hyperkeratosis in pressure-exposed areas
- Dry skin

#### Clinical trial

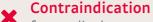
- Stable microcirculation
- No skin lesions
- No abrasions
- No pressure points
- High wearing comfort

Confirmed for compression classes 1 and 2



#### Chronic venous disease and severe PAD

Chronic venous disease and diabetic foot syndrome (DFS)



for medical compression therapy<sup>4</sup>

No treatment

with medical compression stockings

<sup>1</sup> Rother U et al. Safety of medical compression stockings in patients with diabetes mellitus or peripheral arterial disease. BMJ Open Diab Res Care 2020;8:e001316.

<sup>2</sup> Rabe E et al. Bonner Venenstudie der Deutschen Gesellschaft für Phlebologie. Phlebologie 2003;32:1–14.

<sup>3</sup> Lawall H et al. S3-Leitlinie zur Diagnostik, Therapie und Nachsorge der peripheren arteriellen Verschlusskrankheit. Online available at:
https://www.awmf.org/leitlinien/detail/ll/065-003.html (Last access 2020, Dec 28th).

<sup>4</sup> Rabe E et al. S2k-leitlinie: Medizinische Kompressionstherapie der Extremitäten mit Medizinischem Kompressionstrumpf (MKS), Phlebologischem Kompressionsverband (PKV) und
Medizinischen adaptiven Kompressionssystemen (MAK). Online available at: https://www.awmf.org/leitlinien/detail/ll/037-005.html (Last access 2020, Dec 28th).

<sup>5</sup> Bericht der nationalen Diabetes-Surveillance 2019. Diabetes in Deutschland. Robert Koch-Institut.

Intended purpose mediven angio: Round-knitted medical compression stocking used for compression of the lower extremities, mainly for the treatment of disorders of the venous system.

## Infographic of the mediven® angio study:

Safety in medical compression therapy

- in patients suffering from venous leg edema
- and co-existing mild to moderate PAD or diabetes mellitus





#### 94 study participants

 $(0^7 n=67/9 n=27)$ 



Measurement 5

t (h)

#### **Healthy subjects**

(historical control group)

n = 5

#### thereof

Patients with venous leg edema

+ PAD

n = 45

 $(0^7 \text{ n}=30 / 9 \text{ n}=15:$ Ø Age: 68.8 years)

#### Patients with **venous leg edema** + diabetes mellitus type 2

n = 44

 $(0^7 \text{ n}=35/9 \text{ n}=9)$ : Ø Age: 66.1 years)

#### Inclusion criteria

- · No leg edema
- No PAD

Patient population

- Ankle brachial pressure index 1
- Palpable foot pulses
- · No diabetes mellitus
- · Venous leg edema
- PAD (Rutherford category 1-3, Fontaine stadium II)
- No palpable foot pulses
- Ankle brachial pressure index <0.9 and >0.6
- Systolic ankle pressure > 60 mmHg
- No diabetes mellitus

- · Venous leg edema
- Diabets mellitus type 2
  - University of Texas Wound classification system grade 0
  - Pallesthesia score > 6
- No PAD
  - Palpable foot pulses

#### **Endpoints**

#### Primary endpoint:

Safety

- in general (MCS-related (serious) adverse events)
- Microcirculation

#### Secondary endpoint:

Wearing comfort

#### Measurement 1 Measurement 2 0 \

Without MCS

MCS (mediven® angio) CCL1 (Application on one leg)

Measurement 3 Measurement 4

> MCS (mediven® angio) CCL2 (Application on the same leg)

## **Procedure**

#### Measurements:

- Parameters of microcirculation: sO<sub>2</sub>, rHb, relative blood flow, blood flow velocity
- Three measuring points: big toe (M1) lateral ankle joint (M2) dorsal calf (M3)
- Four measuring positions: supine sitting standing + provocation test with elevated leg\*

#### The application of MCS in patients with venous leg edema AND with PAD or diabetes mellitus is safe

#### Safety (in general)

#### No (serious) adverse events

occured during the course of the study

- → no skin lesions
- → no abrasions
- → no pressure points

#### Safety (microcirculation)

#### **Stable microcirculation** in the

physiological positions (sitting, standing\*\*) upon application of MCS of CCL1 and CCL2 - comparable to the healthy subjects

#### Wearing comfort

#### High wearing comfort

CCL1: 1.84

(mean value; standard deviation: 0.84)

CCL2: 2.10

(mean value; standard deviation: 0.92)

Likert-type scale 1-10:

1 = optimal wearing comfort 10 = massive impairment

PAD = peripheral arterial disease, MCS: medical compression stocking, sO,: oxygen saturation of hemoglobin, rHb: relative hemoglobin amount

\* provocation test in 65 cm elevated leg position
\*\* A reduced perfusion in the elevated, not physiological leg position (= provocation test) could also be shown in healthy subjects.

Results

Study design

# mediven® angio

Safety in treatment – down to the toes.

#### medi tip

Due to product features and the results of the clinical trial we recommend mediven angio for:

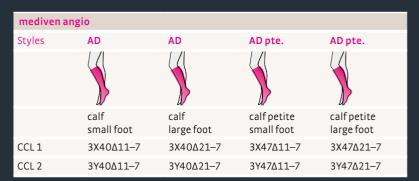
- Women / men with chronic venous disease
- Concomitant mild to moderate peripheral arterial disease (PAD)
- · Concomitant diabetes mellitus

#### **Indications**

 $\bullet$  Chronic venous diseases stages I to III according to Widmer or COs – C5 according to CEAP

# Material Medium Compression classes CCL 1, 2 Standard colours S = Standard M = Made-to-measure\* Caramel

\* Delivery period up to 10 working days.

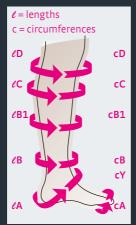


 $\Delta$  = Please add **1** for colour caramel and **5** for colour black Please choose the size on the last digit of the article number from 1 to 7.

ℓD

petite

#### Measurement chart



Standa	ard sizes	1	II	III	IV	٧	VI	VII
Circumferences in cm	cD	27 – 33	29 – 36	32 – 39	34 – 42	36-45	38-48	40-50
	cC	28 – 34	30 – 37	33 – 40	35 – 43	37 – 46	39 – 49	41-51
	cB1	23 – 27	24 – 29	26 – 32	29 – 35	31-37	33 – 39	35 – 41
	сВ	18 – 20	20 – 22	22 – 24	24 – 26	26 – 28	28 – 30	30 – 32
	cY	26 – 31	28 – 33	29 – 35	31-37	32 – 38	33 – 40	34 – 42
	cA	17 – 22	19 – 24	21-26	23 – 29	25 – 32	27 – 34	28 – 35
ngths	Product lengths		Footlengths					
	ℓD regular	39 – 44 cm	small foot	closed up to 2	toe, 5 cm ê shoe s	sizes 36 – 40		

from 25 cm  $\hat{=}$  shoe sizes 40 - 46

34 – 38 cm

large foot

 $<sup>^{6}</sup>$  Please note that this recommendation does not replace a doctor's diagnosis or professional advice from a specialist medical retailer.

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