Instructions for Use
English

comprimed® GRADIENT 100 6

6-level gradient system for
intermittent pneumatic compression therapy

passion for compression

www.comprimed.de

BÖSL

Content

Manufacturer

Bösl Medizintechnik GmbH
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If you have any questions or problems with the device or the sleeves, please contact the manufacturer. Visit our website: www.boesl-med.de. You will find the latest version of these instructions for use in the download area.

General safety regulations

Please read the instructions for use before putting the device into operation and observe the list of indications and contraindications. If anything is unclear, ask your doctor or specialist retailer before commencing therapy.
The system meets the relevant safety regulations including EN 60601-1:2006/A1:2013, VDE0750:2013-12.

General safety warnings

Electrical devices can be dangerous if used incorrectly.
The device housing may be opened by authorized experts only. Repairs may only be carried out by authorized specialist retailers or the manufacturer. Under no circumstances may unauthorized persons open the device. For safety reasons, the device and the sleeves must not be modified or altered by the user. Failure to heed these warnings will void the warranty. In case of device malfunction, please contact Customer Service. This also applies to the fuses of the power socket on the rear device panel. These may be replaced only by authorized experts and never by the patient or the operator. The device must not be used in the presence of flammable gases such as anesthetic agents. The sleeves are biocompatible but should be used only on healthy skin. If you have open wounds of any kind, speak to your doctor before using the device. Open wounds must be covered completely during use. Should you nevertheless experience problems, contact your doctor immediately. Any product equipped with cables, hoses, etc. poses a potential strangulation hazard. Hoses and cables that are accessible to the patient should always be stored and used with caution and out of the reach of small children.
Use the sleeves only on the extremities to be treated (arm, leg, hips, upper body). Never pull the sleeves over the head.

Safety precautions

For your own safety and to protect the device, the following precautions must be observed:

- During use, check the device regularly to ensure that it is operating properly and that the sleeves have been applied correctly.
- Keep the device out of the reach of pets and small children.
- Keep the device away from liquids and protect it from moisture. Do not expose the device and the sleeves to excessive soiling, dust, moisture, open flames, cigarette ash, etc. and irradiation (e.g., sunlight).
- The device consists of precision and electronic components. Protect the device and the accessories from impact, dirt, and electromagnetic interferences. Do not drop the device.
- Turn off the power switch before cleaning or inspecting the device and remove the power plug from the socket in order to disconnect it completely from the mains.
- Use only commercial cleaning agents to clean the device.
- Clean the device only with a dry cloth, never with a damp cloth.
- Make sure the device is clean and dry before placing it into storage.
- Never inspect the device using sharp objects.
- Use only the sleeve combinations and the appropriate extensions specified by BÖSL Medizintechnik (see also section “The sleeves and further accessories”). Proper device function can only be guaranteed if the correct devices and sleeve combinations are used.
- Use of this device in the immediate vicinity of other devices or stacked with other devices should be avoided, as this could result in faulty operation. If this form of use is necessary, both this device as well as the other devices should be monitored to ensure proper function.
- The use of accessories other than those provided can result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and can lead to faulty operation.

Intended purpose

The control units from BÖSL Medizintechnik GmbH are active medical devices that are used in conjunction with sleeves for intermittent pneumatic compression. Taking into consideration the treatment parameters specified by the doctor, the control units are suitable for the treatment of disorders related to venous and lymphatic obstruction according to the following indications, taking into account the contraindications. The operational safety of the control units is guaranteed only when used as intended by an informed user. The user groups include patients, doctors, nurses, physical therapists, and relatives, which means that the control units can be used in professional health care facilities as well as in the home environment. There are no restrictions regarding the patient population. Children and people in need of assistance can be treated under professional guidance and supervision.

Indications

- Prophylaxis of thromboembolism
- Post-thrombotic syndrome
- Crural ulcer
- Venous edema
- Post-traumatic edema
- Lymphedema
- Lipedema
- Mixed forms of edema
- Peripheral arterial occlusive disease (with close monitoring)
- Sensory deficits in hemiplegia

Contraindications

- Decompensated heart failure
- Extensive thrombophlebitis, thrombosis or suspected thrombosis
- Erysipelas
- Severe, uncontrolled hypertension
- Acute soft tissue trauma of the extremities
- Neuropathy
- Occluding processes in lymphatic drainage
- Compartment syndrome
- Acute phlegmon

Undesirable effects

While the sleeves have been shown to be biocompatible under Parts 1, 5 and 10 of DIN EN ISO 10993, in very rare cases

- skin irritation
- allergic reactions

can occur. In these cases, please talk to your doctor. If in doubt, use the sleeves only on top of clothing.

The noises emitted by the system during operation may be perceived as minor noise pollution.
After use, marks may appear on the skin, which will however disappear by themselves.

Reporting of incidents

If serious incidents (death, severe deterioration in health) occur in connection with the device described in these instructions for use, they must be reported by the user to the manufacturer and the competent authority.
The competent authority in Germany is:
Federal Institute for Drugs and Medical Devices (BfArM)
Kurt-Georg-Kiesinger-Allee 3, 53175 Bonn
Phone: +49 (0)228 99 307-0
www.bfarm.de
For information on the competent body outside of Germany, please contact the authorities in your respective country.

Maintenance

The device and sleeves are maintenance-free. Neither the patient nor any other operator is required to perform any maintenance work.

Cleaning

Device care and cleaning should be done only with a dry cloth (please do not subject the device to chemical dry-cleaning). Commercial cleaning agents may be used.

Disinfection

Disinfection of the treatment sleeves must be carried out after use and/or before each patient change. In this regard, please perform wipe disinfection as recommended by the German Robert Koch Institute (see “Liste der vom Robert Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren”). For more information and instructions, please refer to our leaflet “Cleaning and disinfection instructions”.

Warranty

The manufacturer offers a two-year warranty for the device and accessories, provided defects are due to material and/or manufacturing errors. The manufacturer considers itself responsible for effects on the safety, reliability, and performance of the device only if: extensions, new settings, modifications or repairs are carried out by persons authorized by the manufacturer, the electrical installation of the respective room in which the device is used meets the requirements of the VDE (Association of German Electricians), and the device is used in accordance with the instructions for use.
In case of device malfunction, please contact the supplier directly. When used properly, the typical, average useful life of the device and the accessories is 10 years.

ElektroG (German Electrical and Electronic Equipment Act)

Correct disposal of waste equipment (electronic waste)
(With separate collection systems in the countries of the European Union and in other European countries)

The marking on the device, on accessories and/or on the respective documentation states that the device and its accessories must not be disposed of with regular household waste after the end of their service life. Please dispose of this device and its accessories separately from other waste in order not to jeopardize the environment or human health through uncontrolled waste disposal. Potentially contaminated sleeves are to be disposed of in regular household waste with a corresponding note and after consultation with the manufacturer. Please help us dispose of waste equipment and accessories correctly in order to promote the sustainable recycling of material resources.

Private users should contact the retailer from whom they purchased the device, or the competent authority for information as to where they can return the waste equipment and/or the accessories to ensure environmentally friendly disposal. Commercial users should contact their supplier and proceed according to the conditions of the purchase agreement. This device and electronic accessories must not be disposed of with other industrial waste.

The device is disposed of as electronic waste and must not be thrown away in regular household waste. Return the device to the collection points of the public waste disposal authorities.

Symbols

Information

CAUTION!
This symbol indicates hazards that can lead to health impairments, injuries, permanent bodily injury or death. Follow the occupational safety instructions closely and take particular caution in these cases.

Manufacturer

2015

Year of manufacture

Refer to instruction manual.
To ensure safe device operation it is necessary that the instructions for use are read and understood completely, as improper use can pose an unacceptable risk.

LOT

Batch code

SN

Serial number

IP21

Protected against solid objects with a diameter ≥ 12.5 mm and against vertically falling drops of water

CE 0197

CE marking with identification number of the Notified Body

Fuse

~

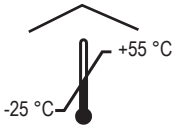
Alternating current

Disposal/WEEE

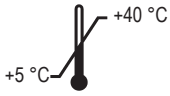
Keep away from rain

Class II equipment

Device classification
Type BF applied part



Ambient temperature for transport and storage.
Transport and storage outside the specified temperature ranges can lead to damage of the device and thus to a hazard for the patient, user, or third persons.

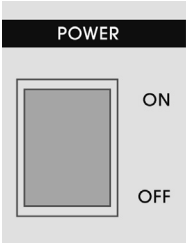


Ambient temperature for use.
Device operation outside the specified temperature ranges can lead to damage of the device and thus to a hazard for the patient, user, or third persons.

Symbols

Pressure settings/pressure indicator
20–100 mmHg

Timer 10–60 min



On/Off switch

Technical data

The model **comprimed ®100** is designed for use in a home environment with a direct connection to a public supply network.

To ensure correct operation of the device and its connection to the power supply grid, please use a country-specific mains adapter, where necessary, corresponding to the device specifications (not included in the scope of delivery).

Continuous pressure setting
20–100 mmHg
(accuracy approx. 15 %)

Interval/pause
set to 15 sec.

Nominal voltage	~ 230V
Nominal frequency	50/60 Hz
Nominal current	0.2 A
	2 x T 1.6 H 250V

Dimensions:
W – 23 cm, H – 15 cm, D – 21 cm
Weight: 3.2 kg

Device classification:
Type BF applied part –
treatment sleeves 

Protection class:
Class II equipment 

Environmental conditions for transport and storage:
The environmental conditions for transport and storage are -25 °C to +55 °C with humidity: 15 % to 93 % rH.

Environmental conditions for use:
The environmental conditions for use are +5 °C to +40 °C,
humidity: 15 % to 93 % rH
atmospheric pressure: 700 to 1060 hPa

Electromagnetic compatibility (EMC)

comprimed ®100 meets the EMC requirements for medical devices set forth in EN 60601-1-2. In addition, it meets the limits for mains voltage distortion for medical electrical devices pursuant to EN 61000-3-2 and EN 61000-3-3.

If electromagnetic interferences compromise the performance of the comprimed®100, the therapeutic effect may be reduced.

The comprimed®100 device is designed for use in an electromagnetic environment as indicated below. Customers or users of the comprimed®100 should ensure that the device is operated in a corresponding environment.

Guidelines and manufacturer's declaration — Electromagnetic emissions

Emission measurements	**Conformity**
RF emissions according to CISPR 11	Group 1
RF emissions according to CISPR 11	Class B
Harmonic current emissions according to IEC 61000-3-2	Class A
Emissions of voltage fluctuations/flicker according to IEC 61000-3-3	Conforms

The comprimed®100 device is designed for use in a home environment with a direct connection to a public supply network.

Interference testing		**Compliance level**
Electrostatic discharge (ESD) according to IEC 61000-4-2	+/- 6 kV contact discharge +/- 15 kV air discharge	+/- 6 kV contact discharge +/- 15 kV air discharge
Electrical fast transients/bursts according to IEC 61000-4-4	+/- 2 kV at 100 kHz for power supply lines	+/- 2 kV at 100 kHz for power supply lines
Impulse voltages/surges according to IEC 61000-4-5	+/- 0.5 kV, +/- 1 kV voltage line to line +/- 0.5 kV, +/- 1 kV, +/- 2 kV voltage line to earth	+/- 0.5 kV, +/- 1 kV voltage line to line +/- 0.5 kV, +/- 1 kV, +/- 2 kV voltage line to earth
Voltage dips, short interruptions and voltage fluctuations according to IEC 61000-4-11	Voltage dips: 0 % U_T; 1/2 cycle at 0 to 315 degrees 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles single phase Voltage interruptions: 0 %U_T; 250/300 cycles	Voltage dips: 0 % U_T; 1/2 cycle at 0 to 315 degrees 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles single phase Voltage interruptions: 0 %U_T; 250/300 cycles
Magnetic field at power frequency (50/60 Hz) according to IEC 61000-4-8	30 A/m	30 A/m

Interference testing	**IEC 60601 test level**	**Compliance level**
Conducted RF disturbances according to IEC 61000-4-6	3 V at 0.15 MHz to 80 MHz, 6 V in ISM and amateur radio bands between 0.15 MHz to 80 MHz, 80 % AM at 1 KHz	6 $V_{effective\ value}$ across entire frequency range
Radiated RF disturbances according to IEC 61000-4-3	10 V/m; 80 MHz to 2.7 GHz; 80 % (compliance level also 10V)	10 V/m; 80 MHz to 2.7 GHz; 80 % (compliance level also 10V)

The field strength should be less than 3 V/m across the frequency range of 150 kHz to 80 MHz

The tested RF frequencies correspond to the following radio services:

Test frequency	Frequency band (MHz)	Service	Immunity test level (V/m)
385	380 to 390	TETRA 400	27
450	430 to 470	GMRS 460, FRS 460	28
710 745 780	704 to 787	LTE band 13, 17	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	28
1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900;GSM 1900; DECT; LTE band 1, 3, 4, 25; UMTS	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	9

Customers or users of the **comprimed®100** can help prevent electromagnetic interferences in order to minimize damages. To this end, portable high-frequency radio devices, including their accessories, should not be used within a distance of 30 cm to the parts and cables of the **comprimed®100**. Failure to follow these instructions can lead to a reduction in performance.

Troubleshooting

Fault
No function:
Is the device connected to the power supply?
-> Connect power cord

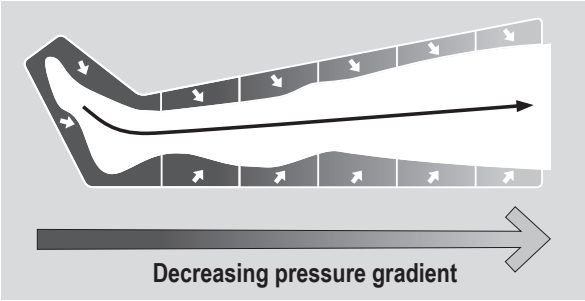
Is the device switched on?
-> Switch on device

Fault
Sleeves are not filled or vented:
Are all hoses connected to the device?
-> Connect hoses

Are unused connections closed with a dummy connector?
-> Connect dummy connector

Mode of action of the comprimed®100 device

The **comprimed®100** gradient system is designed for the treatment of disorders related to venous and lymphatic obstruction. The characteristic function of the **comprimed®100** is the intermittent build-up of pressure. The sleeves exert intermittent gradient pressure on the extremities (arms and legs). The 6 chambers of the sleeves are filled with air one by one, starting from the foot or the hand. The pressure that is built up in the process decreases over various pressure ranges from the first to the last chamber. This gradient treatment pressure exerts a physiologically efficient drop in pressure. The liquid that is mobilized by means of the pressure inside the chambers can flow out unhindered and without returning.



The air chambers remain filled with air until the top chamber has reached a specified pressure level. The pressure then escapes simultaneously from all air chambers before the process of inflation is restarted after a set interval. The intermittent compression acts on the individual layers of tissue and on the blood and lymph vessels inside them. Congestion in the tissue is reduced, venous and lymphatic return is supported, and metabolism and gas exchange are improved.

Treatment recommendations

During the treatment the patient should lie down in a comfortable and relaxed position. To further support the treatment effect, the legs or arms being treated can be slightly elevated. At the start of the therapy, a low pressure setting should be selected and subsequently increased as needed. The pressure setting must never be so high that the patient experiences discomfort or pain. The treatment should feel relaxing and pleasant.

Technical instructions for installation

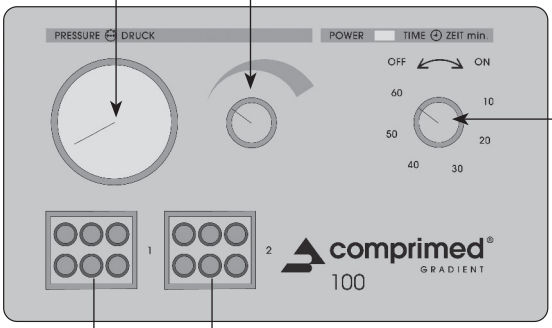
- After removal from the packaging, the device is ready for operation.
- Visually inspect the device for external damage.
- Do not use the device if there is visible damage.
- Place the device onto a flat and solid surface, e.g., a table.
- Connect the power cord to the power line (**B2**) and then to the socket (power supply).
- Connect the device to a power supply that corresponds to the specifications.
- To ensure correct operation of the device and its connection to the power supply grid, please use a country-specific mains adapter, where necessary, corresponding to the device specifications (not included in the scope of delivery).
- Position the device in such a way that the patient or the operator can pull out the power cord during treatment, if necessary.
- Do not cover the air vents (**B1**) on the device with cloths, blankets or other objects. Do not stack devices. Do not use device as a storage surface.
- Remove the dummy connector from the connection jacks to be used (**A4** and/or **A5**).
- Connect the sleeves to the connection jacks (**A4** and/or **A5**) and apply the sleeves.
- All of the device features can be used safely by the patient.
- Switch the On/Off switch **(A3**) to “ON”, control light comes on.
- Use the pressure regulator (**A2**) to set the desired mean treatment pressure and check it using the manometer (**A1**) (continuous adjustment).
- Once the treatment is completed, dial the pressure regulator (**A2**) back to “0”.
- Switch the On/Off switch (**A3**) to “OFF”.
- To better vent the sleeves after the treatment, disconnect the hoses from the treatment device.

Design of the comprimed®100 device

Front of device

A1
Manometer to verify pressure setting (mmHg)

A2
Pressure regulator to set mean treatment pressure

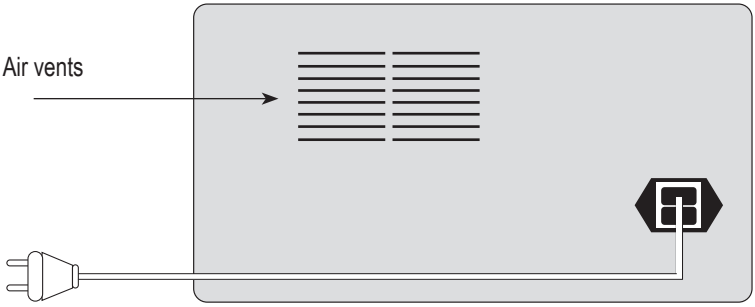


A3
Timer 10–60 min, automatic switch-off
On/Off switch

A4 **A5**
2 connection jacks for leg/arm sleeves

Rear of device

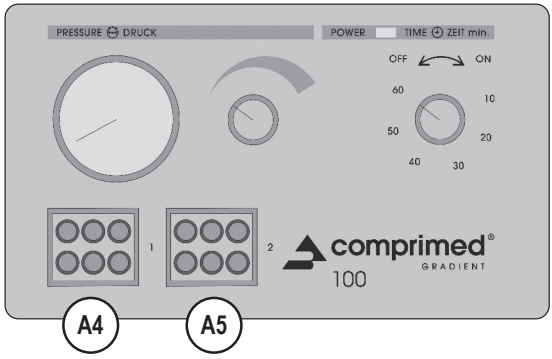
B1 Air vents



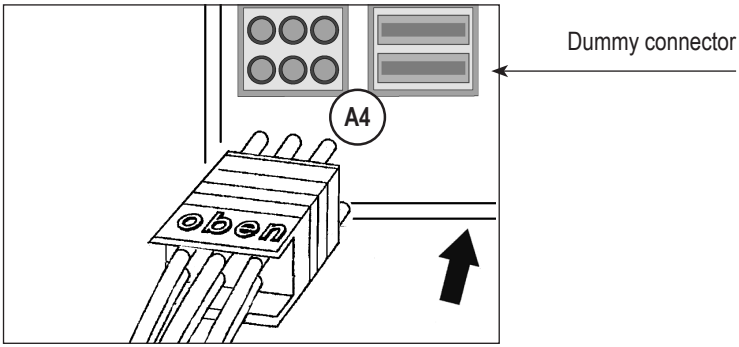
B2
Power line ~ 230 V 50/60 Hz
with device protection fuse 2 x T 1.6A H 250V

Connecting the sleeves

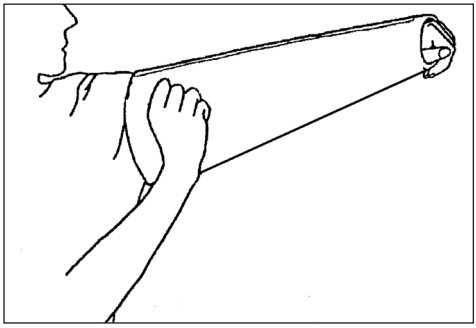
- Up to two sleeves can be connected to the device at the same time.
- Either two leg sleeves or two arm sleeves or one leg and one arm sleeve.
- Insert the hose connectors of the treatment sleeves into the connection jacks (**A4** or **A5**).
- Please note the markings ‘top’ and ‘bottom’ on the hose connectors!
- To ensure that the individual chambers can be filled with air, the air hoses of the sleeves must not be bent.
- The connection jacks (**A4** or **A5**) that are not required for the duration of the treatment must be closed with the dummy connectors provided.



A4/A5 2 connection jacks for sleeves

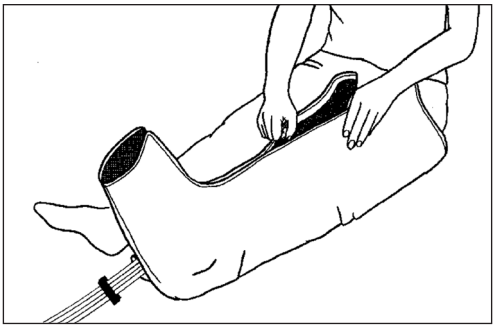


Applying the sleeves



The arm sleeve
Apply the sleeve and close the zipper completely.
The zipper should not be opened under pressure.

The leg sleeve
Apply the sleeve and close the zipper completely. The Velcro fastener additionally prevents possible opening of the zipper. The zipper should not be opened under pressure.



Connecting the extension

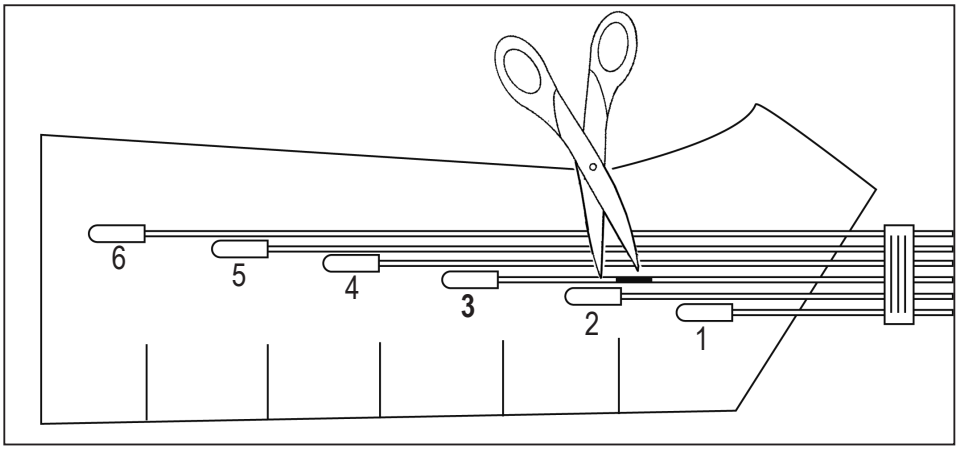
Extension

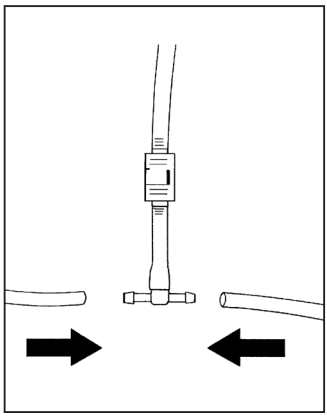
The extension extends the circumference of the leg sleeve by 13 cm. It is attached to the sleeve using side zippers.

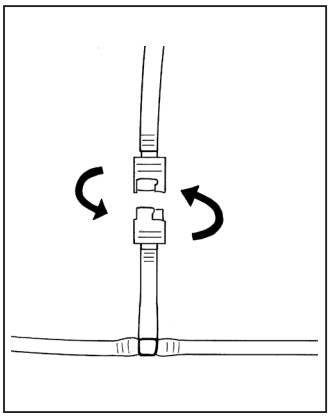
Assembly instructions

How to assemble the extension:

Cut the hose of the third air chamber at the marked spot (black line) and connect the connecting piece of the extension.







When removing the extension, disconnect it at the hose coupling.

The sleeves and further accessories

6-chamber leg sleeve
Size M
Thigh circumference up to 70 cm
Length 85 cm
Art. No. 630

Size L
Thigh circumference up to 83 cm
Length 85 cm
Art. No. 640

Extension for leg sleeve
Size M and **L**
with 1 air chamber,
extension 13 cm
Art. No. 1240

6-chamber arm sleeve
Upper arm circumference up to 60 cm
Length 71 cm
Art. No. 650

The sleeves are made of easy-care nylon/polyurethane fabric.

Please use only the supply lines approved by the manufacturer.

Notes

CE 0197

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Made in Germany

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