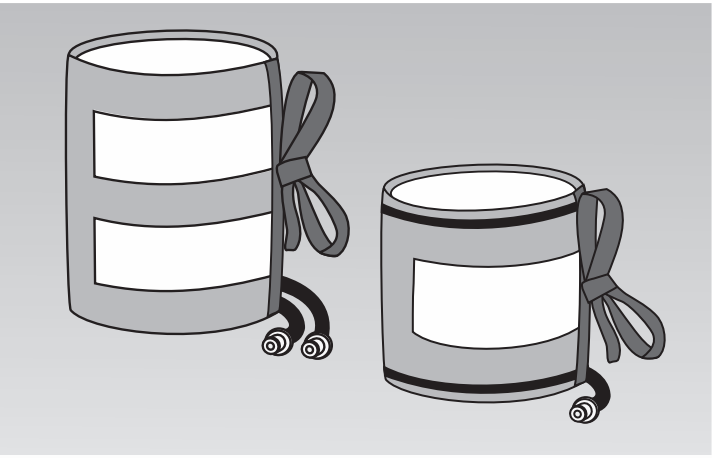
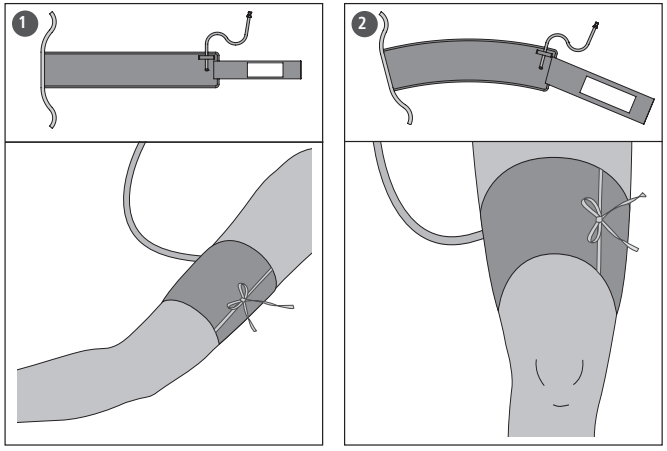
VBM Medizintechnik



Tourniquet Dispo Cuff

for blood occlusion in upper or lower extremities



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English

INTENDED USE - TOURNIQUET DISPO CUFF

Tourniquet Dispo Cuffs are tourniquet cuffs which are used during surgical procedures to ensure a temporary bloodless field in the patient's upper or lower extremities.

INTENDED USE - EXTENSION TUBING

The extension tubing allows the sterile zone of the Tourniquet Dispo Cuff to be extended.

LOCATION OF USE

Rooms that are suitable for surgical procedures.

INDICATION / CONTRAINDICATION

Indications and contraindications depend on the application and therefore on the selected Dispo Cuff.

Possible indications for blood arrest:

- Rectification of certain fractures
- Arthroscopy of knee, hand, finger or elbow
- Bone grafting
- Kirschner wire removal
- Traumatic or non-traumatic amputations
- Removal of tumours or cysts
- Subcutaneous fasciotomy
- Nerve damage
- Ligament repair
- Replacement or revision of knee joint, wrist or finger joint
- Correction of a hammer toe
- Podiatry

No other indications are known.

Possible contraindications for blood arrest:

- Open fractures of the extremities
- Post-traumatic lengthy hand reconstruction
- Severe crushing injuries
- Elbow surgery with concomitant excessive swelling
- Severe hypertension
- Skin transplant
- Impaired circulation (e.g. peripheral arterial disease)
- Diabetes mellitus

No other contraindications are known.

The physician must, in each individual case, assess the indications and contraindications in the light of his or her expert knowledge.

SAFETY INSTRUCTIONS

- Read the instructions for use carefully before using the product and follow them.
- This product must only be used by a physician, or by medically trained personnel working under the instruction of a physician.
- The user and/or the patient must report all serious adverse events that have occurred in connection with the product to the manufacturer and to the competent authority of the EU member state in which the user and/or patient is practising/residing (or the competent authority of the country concerned if an event occurs outside of the EU).
- Prior to each use, the products must be subjected to a visual inspection (see section "Visual inspection"). Damaged products must not be used.
- Maximum application time: 2 hours
- It is not permitted to make any changes to the product.
- The Dispo Cuff has been designed and tested for use with Tourniquets from the manufacturer. If the user uses a Tourniquets from other manufacturers, then the manufacturer accepts no liability for the product.
- The Dispo Cuff is designed for a max. cuff pressure of 600 mmHg when in place on the patient. If exposed to a higher cuff pressure, the Dispo Cuff will be irreversibly damaged.
- The product is intended for single use and must not be reused and/or reprocessed. The function of the product is impaired by reprocessing. Any reuse entails a potential infection hazard.
- The product is sterile (ethylene oxide).
- The product must not be used if the packaging is damaged or the expiration date has expired.

PREPARATION PRIOR TO USE

Select the correct cuff size for the respective extremity.

VISUAL INSPECTION

- Check the packaging for damages.
- Check the product for damages (cracks, breaks, kinks and loose particles).

Damaged products must not be used.

APPLICATION

CAUTION

- The duration of the blood arrest is at the physician's discretion. A max. of 2 hours is normally recommended.
- In order to ensure reliable blood arrest while avoiding exposure of the patient to unnecessary stress, an appropriate cuff target pressure must be selected for the Dispo Cuff, depending on the cuff size, the extremity and the systolic blood pressure.
- The user must check the current pressure of the Dispo Cuff at regular intervals. If the target pressure deviates from the current pressure of the Dispo Cuff, then appropriate action must be taken in response.
- Avoid kinking of cuff tubes.
- All tube connections must snap firmly into place.

- Apply thin padding under the Dispo Cuff to avoid pressure sores and injury to the skin.

In order to ensure that the cuff tubes are not located in the operating field, they must point proximalward (pictures 1 + 2).

CAUTION

To ensure reliable blood arrest, the bladder of the Dispo Cuff must overlap on the extremity. However, too much overlap can result in cuff rolling

- Apply Dispo Cuff tightly on the extremity, but without using force. Two fingers should fit between the extremity and the Dispo Cuff.
- After applying the Dispo Cuff, additionally secure it with the colour-coded cuff ties (pictures 1+ 2).

Option: The sterile zone of the Dispo Cuff can be extended by means of the extension tubing. Connect the extension tubing to the cuff tube.

- Connect the cuff tube or extension tubing to the Tourniquet.
- All tube connections must snap firmly into place.
- Prior to cuff inflation the extremity must be exsanguinated.
- Inflate the cuff with the lowest necessary pressure required to occlude the blood flow.

In order to avoid possible chemical burns, fluids must be prevented from getting under the Dispo Cuff.

- Disinfect the skin and drape the operating field.
- Before commencing the surgical procedure, make sure by means of palpation or auscultation that the arterial blood flow has been occluded.

WARNING

IVRA (intravenous regional anaesthesia)

- Connect the blue cuff tube to the blue connection of the Tourniquet. Connect the red cuff tube to the red connection of the Tourniquet.
- After administration of the local anaesthetic, a minimum occlusion time of 20 minutes must be considered in order to prevent a toxic reaction.
- In the event of pressure loss in the inflated cuff chamber the second cuff chamber must immediately be inflated.

CAUTION

- After use, completely deflate the Dispo Cuff and immediately remove cuff and padding from the extremity in order to prevent the risk of venous congestion.

- Disconnect the cuff tube from the Tourniquet.

SHELF LIFE

Expiration date: See label on the product.

STORAGE AND TRANSPORT CONDITIONS

CAUTION

- Protect from heat and store in a dry place.
- Keep away from sunlight and light sources.
- Store and transport in the original packaging.

DISPOSAL

The used or damaged products must be disposed of in accordance with the applicable national and international statutory regulations.

ARTICLE NUMBERS

REF	Tourniquet Dispo Cuff
20-34-700SLZ-1	Single Cuff, 20 cm
20-34-710SLZ-1	Single Cuff, 30 cm
20-34-711SLZ-1	Single Cuff, 35 cm
20-34-712SLZ-1	Single Cuff, 46 cm
20-34-715SLZ-1	Single Cuff, 46 cm
20-34-722SLZ-1	Single Cuff, 61 cm
20-34-727SLZ-1	Single Cuff, 76 cm
20-34-728SLZ-1	Single Cuff, 86 cm
20-34-729SLZ-1	Single Cuff, 107 cm
20-30-710SLZ-1	Double Cuff, 30 cm
20-30-712SLZ-1	Double Cuff, 46 cm
20-30-722SLZ-1	Double Cuff, 61 cm
	Accessories
20-39-100-1	Extension tubing for Tourniquet Dispo Cuffs, length 100 cm

PRODUCT SPECIFICATIONS

REF	Width	Colour coding	Shape	Weight (incl. packaging)	Packaging unit
20-34-700SLZ-1	5 cm	-	Straight	0.69 kg	10
20-34-710SLZ-1	6 cm	blue		0.81 kg	
20-34-711SLZ-1	8 cm	yellow		0.90 kg	
20-34-712SLZ-1	10 cm	red		1.06 kg	
20-34-715SLZ-1	12 cm		Tapered	1.84 kg	
20-34-722SLZ-1		green		1.95 kg	
20-34-727SLZ-1		dark blue		2.10 kg	
20-34-728SLZ-1		brown		2.68 kg	
20-34-729SLZ-1		dark red		3.65 kg	
20-30-710SLZ-1		blue	Straight	1.58 kg	
20-30-712SLZ-1	15 cm	red		1.74 kg	
20-30-722SLZ-1		green		2.35 kg	
20-39-100-1	-	-	-	0.47 kg	5

Conversion of pressure units: 1 hPa = 1.01973 cmH_2O = 0.75006 mmHg

SYMBOL DESCRIPTION

	EN - Manufacturer
	EN - Date of manufacture
	EN - Use-by date
REF	EN - Catalogue number
LOT	EN - Batch code
MD	EN - Medical Device
	EN - Consult instructions for use
	EN - Caution
	EN - Do not use if package is damaged
STERILE EO	EN - Sterilized using ethylene oxide
	EN - Do not re-use
	EN - Keep away from sunlight.
	EN - Keep dry
Rx only	EN - Caution: Federal law restricts this device to sale by or on the order of a physician. For USA and Canada only.
CE 0123	EN - CE marking with identification number of the notified body.