Instructions for use

Multi-use cuffs

ulrich medical

Manufacturer

ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
Germany
Phone: +49 (0)731 9654-0
Fax: +49 (0)731 9654-199
tourniquets@ulrichmedical.com
www.ulrichmedical.com

Product number	Name
UT 1317-xx Single Port cuff with orange connector	
UT 1317-2XS	Cuff 2XS, orange connector, 250 x 55 mm
UT 1317-XS	Cuff XS, orange connector, 290 x 70 mm
UT 1317-S	Cuff S, orange connector, 495 x 85 mm
UT 1317-M	Cuff M, orange connector, 600 x 100 mm
UT 1317-L	Cuff L, orange connector, 710 x 120 mm
UT 1317-XL	Cuff XL, orange connector, 950 x 150 mm
UT 1317-2XL	Cuff 2XL, orange connector, 1090 x 100 mm
UT 1317-3XL	Cuff 3XL, orange connector, 1310 x 120 mm
UT 1317-IVRA-I	Cuff IVRA-I, orange connector, 500 x 150 mm
UT 1321-xx Single Port cuff with standard connector	
UT 1321-2XS	Cuff 2XS, standard connector, 250 x 55 mm
UT 1321-XS	Cuff XS, standard connector, 290 x 70 mm
UT 1321-S	Cuff S, standard connector, 495 x 85 mm
UT 1321-M	Cuff M, standard connector, 600 x 100 mm
UT 1321-L	Cuff L, standard connector, 710 x 120 mm
UT 1321-XL	Cuff XL, standard connector, 950 x 150 mm
UT 1321-2XL	Cuff 2XL, standard connector, 1090 x 100 mm
UT 1321-3XL	Cuff 3XL, standard connector, 1310 x 120 mm
UT 1321-IVRA-I	Cuff IVRA-I, standard connector, 500 x 150 mm
UT 1322-xx Dual Port cuff with standard connector	
UT 1322-2XS	Dual port cuff, 250 x 55 mm
UT 1322-XS	Dual port cuff, 290 x 70 mm
UT 1322-S	Dual port cuff, 495 x 85 mm
UT 1322-M	Dual port cuff, 600 x 100 mm
UT 1322-L	Dual port cuff, 710 x 120 mm
UT 1322-XL	Dual port cuff, 950 x 150 mm
UT 1322-2XL	Dual port cuff, 1090 x 100 mm
UT 1322-3XL	Dual port cuff, 1310 x 120 mm
UT 1322-IVRA-I	Dual port cuff, 500 x 150 mm

Table 1. Identification

Table of contents

1 About this document

These instructions for use and any associated supplemental sheets are part of the products UT 1317-xx, UT 1321-xx, and UT 1322-xx and are valid until they are replaced by a later version of the instructions for use. These instructions for use describe safe and proper use of the products.

- ▶ Read the instructions for use before using the products.
- ▶ Keep the instructions readily available with the products at all times.
- ▶ Read the other applicable documents before using the products.

1.1 Warnings

Information intended to alert you to hazards to the patient and/or user and/or product is labeled as follows:

DANGER!
Danger indicates a dangerous situation that will lead to severe injury or death if it is not avoided.

- ▷ Measure to take to prevent hazards referred to in a warning.

WARNING!
Warning indicates a dangerous situation that can lead to severe injury or death if it is not avoided.

- ▷ Measure to take to prevent hazards referred to in a warning.

CAUTION!
Caution indicates a dangerous situation that can lead to mild or moderate injuries if it is not avoided.

- ▷ Measure to take to prevent hazards referred to in a warning.

1.2 Text markings

Text passages are marked as follows:

Marking	Meaning
▶	Instructions for use. These indicate actions you need to perform.
▷	Measure to take to prevent hazards referred to in a warning.
1. 2.	Multi-step instructions. ▶ Follow them sequentially.

Table 2. Text markings

1.3 Abbreviations

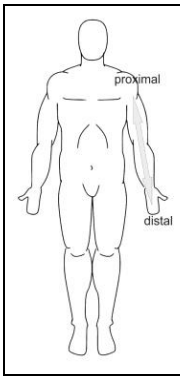
Abbreviation	Meaning
IVRA	Intravenous Regional Anesthesia
mmHg	Millimeters of mercury
OP	Operation
CDM	Cleaning and disinfection machine
UV	Ultraviolet

Table 3. Abbreviations

1.4 Terms

The following instructions use abbreviated terms:

- "Cuff", if referring to all cuff types.
- "IVRA cuff", if referring to a two-chamber cuff.
- "Single Port cuff", if referring to a single-chamber or double-chamber cuff with one hose per chamber.
- "Dual Port cuff", if referring to a single-chamber or double-chamber cuff with two hoses per chamber.



Term	Meaning	Assigned color
proximal	Towards the torso (towards the heart)	red
distal	Away from the torso (away from the heart)	blue

Table 4. Explanation of terms

2 Symbols on product and packaging

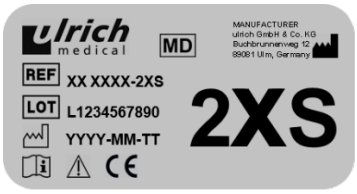
Symbol / Term	Meaning
	Caution
	Consult instructions for use
	CE-mark
	Manufacturer
	Date of manufacture
REF	Catalogue number
LOT	Batch code
Qty.	Quantity
MD	Medical Device
	Keep dry
	Keep away from sunlight
	Direct part marking (example: 2XS)

Table 5. Symbols on product and packaging

3 Intended purpose

3.1 Intended purpose

The intended use of the ulrich medical tourniquet cuff, in conjunction with a compatible tourniquet, is the temporary regulation of arterial blood flow in the upper and lower extremities, including complete blood arrest. The duration and amount of applied pressure are the sole responsibility of the physician according to current knowledge obtained from research and technology.

3.2 Indications

The tourniquet cuff is used on extremities in surgery on extremities as well as for applications in vascular surgery, trauma surgery, neurosurgery, and plastic surgery. An additional application in anesthesia is IVRA.
The cuff is used for the following applications:

- Fractures
- Removal of metal or implants
- Finger, knee, and elbow prostheses
- Arthroscopy
- Tendon correction
- Carpal tunnel syndrome
- Hammer toes
- Amputation
- Varicose veins
- Removal of benign tumors
- Removal of cysts

The following cuffs are suitable for IVRA:

- UT 1317-IVRA-I
- UT 1321-IVRA-I
- UT 1322-IVRA-I

3.3 Contraindications

ulrich medical tourniquet cuffs must only be used on patients who do not have any of the following contraindications:

- Inflammations
- Malignant tumors
- Severe arteriosclerosis
- Severe crush injury
- Severe hypertension
- Diabetes mellitus
- Thrombosis
- Compound fractures of the extremities
- Fresh skin transplants
- Severe brain injury
- Neuromuscular damage
- Crush injuries
- Peripheral arterial disease
- Patients carrying the sickle cell gene
- Tissue ischemia

3.4 Patient group

No restrictions. See contraindications.

3.5 Users

Only medically trained specialist personnel are permitted to operate the device.

3.6 Function and principle of action of the medical device

The single-chamber and double-chamber Single Port cuff as well as the single-chamber and double-chamber Dual Port cuff for tourniquets are used to establish blood arrest in the upper or lower extremities in order to create a relatively blood-free surgical site. As a result of high pressure generated by a tourniquet, the cuff blocks arterial blood flow into the extremity as well as venous return blood flow out of the extremity.
Depending on the cuff type, it is connected to the tourniquet as follows:

- Single-chamber and dual-chamber Dual Port cuff (only for third-party devices): Pressure is established by means of the air inlet / outlet hose, and the pressure is monitored with the measuring hose.
- Single-chamber and double-chamber Single Port cuff: Both functions (establishing and monitoring pressure) are performed by means of the same hose. Two different connectors are available for connecting to the tourniquet.
  The cuff can be used without padding between it and the patient. At the user's discretion, thin padding can be used.

4 Safety notes

DANGER! Failure to comply with these safety notes can result in the patient's death.

- ▷ Read the safety notes before using the product and comply with them.

DANGER! Insufficient expertise regarding the product or the procedure can result in the patient's death.

- ▷ Ensure that the cuff is only applied by qualified medical personnel with adequate knowledge.

WARNING! Loss of cuff function due to incorrect assembly. Nerve damage due to inhomogeneous distribution of pressure on nerves is possible.

- ▷ During assembly, verify that the bladder and foil are correctly positioned in the sleeve.
- ▷ Reusable cuffs must only be used if they are correctly assembled and in proper condition.

DANGER! Selecting an incorrect cuff size or applying pressure for an incorrect duration or at an incorrect level can result in the patient's death.

- ▷ The physician is solely responsible for the duration and level of pressure during blood arrest. The duration of blood arrest depends on the diagnosis, the surgical technique and the patient's constitution (age, weight, skin and tissue condition, vascular condition and blood pressure, shape and size of the extremity, general constitution, obesity, etc.).
- ▷ Perform a pre-operative examination of the patient in order to identify risk factors, and to be able to correctly select a cuff and correctly specify the pressure to be applied during blood arrest.
- ▷ Monitor the cuff and the tourniquet during the blood arrest.

CAUTION! An improperly applied cuff can result in tissue damage to the patient.

- ▷ In order to prevent injury, make sure that no skin folds form under the applied cuff.
- ▷ Do not apply excessive starting pressure when applying the cuff, especially when using size 2XL and 3XL cuffs.
- ▷ In order to prevent severe skin injuries, irritation and abrasions, do not turn or move cuffs that have already been applied and pressurized. To correct the position: Depressurize the cuff, open the cuff closure, reapply the cuff in the correct position and refill it.
- ▷ Only remove the cuff from the patient after it has been completely vented.

CAUTION! External influences can damage the cuff and result in loss of function during use. Risk of infection due to prolonged operation time.

- ▷ Before each use, verify that the product is in operable, proper condition.
- ▷ Protect the bladder from mechanical damage and UV radiation.
- ▷ Protect the cuff against pre-operative skin treatment products, which can reduce cuff service life.

CAUTION! Inhomogeneous pressure distribution in tissue or the cuff becoming detached due to insufficient overlap of the two ends of the cuff. Risk of infection due to prolonged operation time.

- ▷ When putting the cuff on, make sure that the end of the cuff completely covers the red mark that indicates the required amount of overlap.

CAUTION! The cuff must not be disconnected from the tourniquet when under pressure and with hoses pinched off. Risk of infection due to prolonged operation time.

- ▷ Ensure that the cuff pressure is constantly monitored by a tourniquet. Hoses must not be pinched off.

CAUTION! Improper placement of connecting hoses can impair their functionality. Risk of infection due to prolonged operation time.

- ▷ Make sure that all connection hoses are neither kinked nor pinched off.

CAUTION! Incompatible accessories or hose combinations will lead to loss of functionality. Risk of infection due to prolonged operation time.

- ▷ Only the accessories listed in the accessory list may be used.
- ▷ Do not use hose combinations consisting of multiple hoses or connectors.

CAUTION! Incompatible tourniquet results in loss of function. Risk of infection due to prolonged operation time.

- ▷ 1-hose cuffs must only be connected to a compatible tourniquet for 1-hose cuffs.
- ▷ 2-hose cuffs must only be connected to a compatible tourniquet for 2-hose cuffs.

DANGER! Improperly performed IVRA use can lead to anesthetic entering systemic circulation and resulting in the patient's death.

- ▷ Only allow IVRA with a double-chamber cuff to be performed by a physician.
- ▷ Comply with the instructions for use for the anesthetic. Comply with the manufacturer's instructions regarding the administration time for the local anesthetic and the minimum duration of local anesthesia with blood arrest.
- ▷ In order to achieve the same degree of vessel compression, pressurize double-chamber cuffs to higher pressure than single-chamber cuffs.
- ▷ Do not vent the cuff until the local anesthetic has been completely absorbed by the tissue. Slowly reduce the pressure in the cuff, in stages if necessary, in order to avoid rapid infiltration of metabolites after releasing blood arrest.
- ▷ Ensure that the proximal chamber is pressurized before the local anesthetic is administered.

CAUTION! Pre-operative skin treatment products in the area where the cuff is applied can cause chemical burns and skin irritation.

- ▷ Ensure that no skin treatment products (disinfectants) are in the area where the cuff is applied, and that none have accumulated there or can enter there. If necessary, apply a rubber tourniquet on the distal side of the area where the cuff will be applied.

CAUTION! The cuff's resistance to aging is reduced by frequent cleaning, disinfection and sterilization processes, as well as increased periods of downtime. Risk of infection due to prolonged operation time.

- ▷ The product may be cleaned / disinfected and sterilized a maximum of 50 times.

CAUTION! Using a non-sterile cuff increases the patient's risk of infection.

- ▷ After removing the packaging from a brand-new product, and before using it for the first time, prepare it for clinical use (machine cleaning and sterilization).
- ▷ Only use cuffs that have been cleaned / disinfected and sterilized.
- ▷ Make sure that the cleaning / disinfection and sterilization process has been validated.
- ▷ Handle all sterile components carefully in order to ensure their sterility.

CAUTION! High temperatures under surgical lamps can lead to heat buildup.

- ▷ Take into account the need to reduce the duration of blood arrest at high temperatures. Do not actively warm children during blood arrest.

5 Description

5.1 Single-chamber Single Port cuff

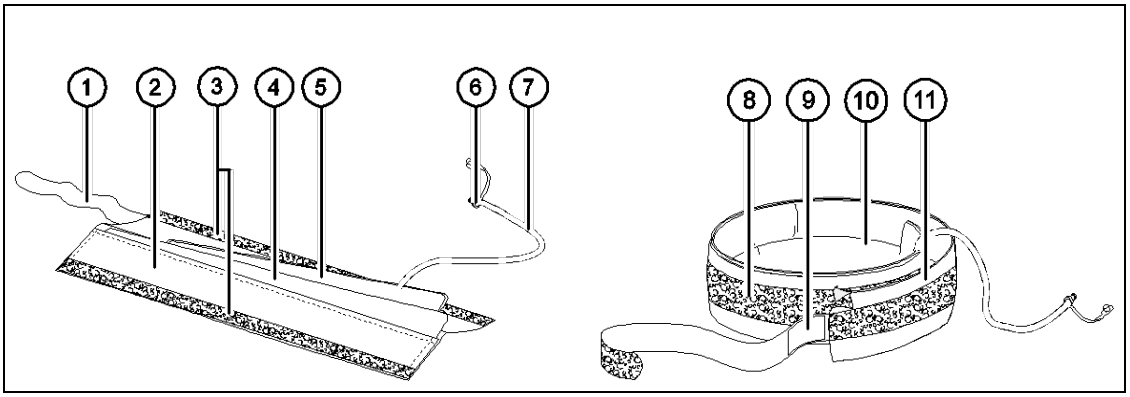


Figure 1. Single-chamber Single Port cuff

1 Velcro strap of the cuff closure
2 Fabric sleeve (with pocket)
3 Velcro
4 Foil
5 Bladder
6 Connector with sealing cap
7 Cuff hose
8 Velcro strap of the cuff closure
9 Direct part marking
10 Interior side
11 Exterior side

5.2 IVRA double-chamber Single Port cuff

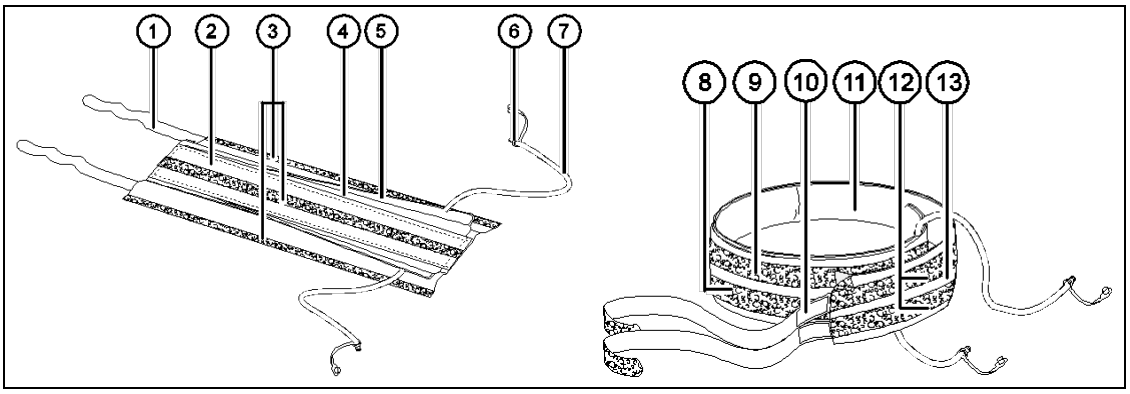


Figure 2. Double-chamber Single Port cuff

1 Velcro strap of the cuff closure
2 Fabric sleeve (with pocket)
3 Velcro
4 Foil
5 Bladder
6 Connector with sealing cap
7 Cuff hose
8 Distal chamber (blue)
9 Proximal chamber (red)
10 Direct part marking
11 Interior side
12 Velcro strap of the cuff closure
13 Exterior side

5.3 Single-chamber Dual Port cuff

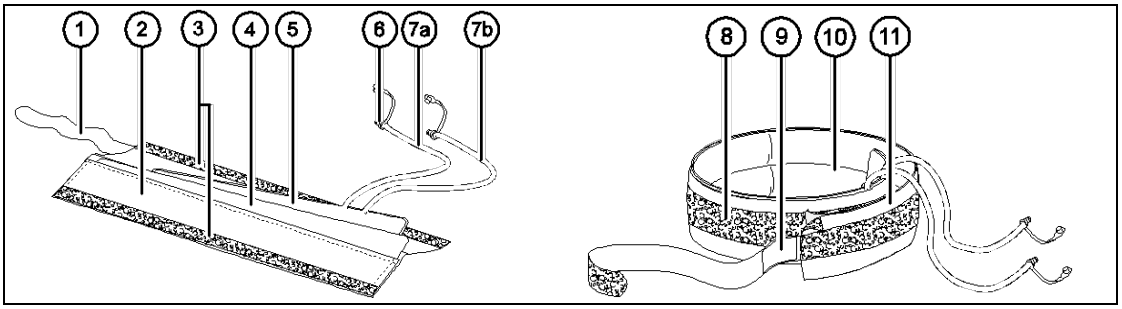


Figure 3. Single-chamber Dual Port cuff

1 Velcro strap of the cuff closure
2 Fabric sleeve (with pocket)
3 Velcro
4 Foil
5 Bladder
6 Standard connector with sealing cap
7 Cuff hoses:
  7a Air inlet / outlet hose
  7b Measuring hose
8 Velcro strap of the cuff closure
9 Direct part marking
10 Interior side
11 Exterior side

5.4 IVRA double-chamber Dual Port cuff

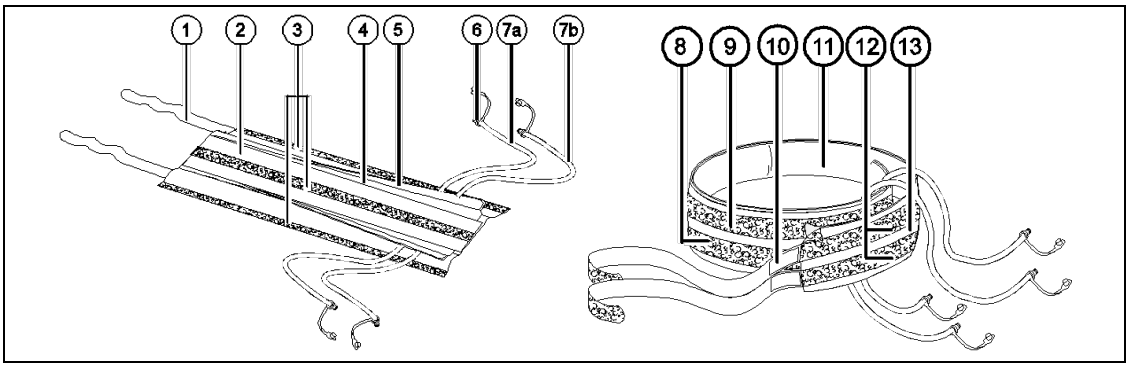


Figure 4. Double-chamber Dual Port cuff

1 Velcro strap of the cuff closure
2 Fabric sleeve (with pocket)
3 Velcro
4 Foil
5 Bladder
6 Standard connector with sealing cap
7 Cuff hoses:
  7a Air inlet / outlet hose
  7b Measuring hose
8 Distal chamber (blue)
9 Proximal chamber (red)
10 Direct part marking
11 Interior side
12 Velcro strap of the cuff closure
13 Exterior side

5.5 Connector variants

The single-chamber / double-chamber Single Port cuffs are available with two different connectors for the connection to the tourniquet.

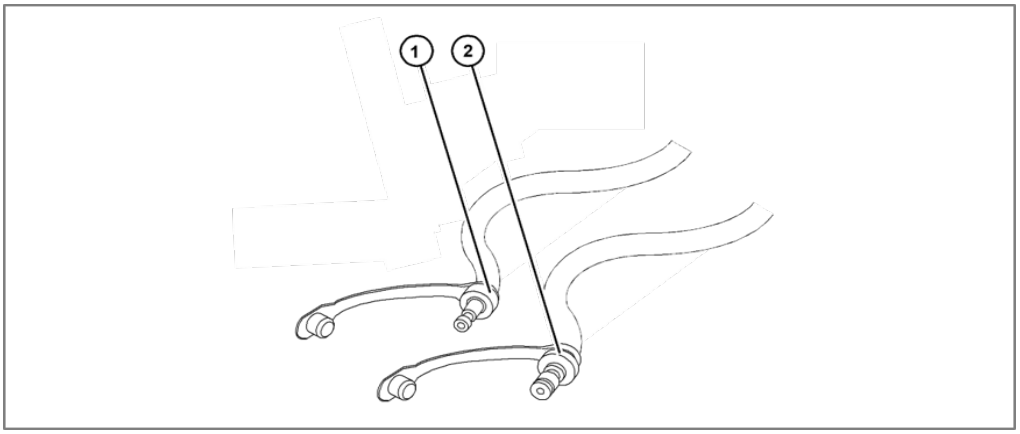


Figure 5. Connectors

1 Orange connector
2 Standard connector

6 Preparation for first use, assembly and disassembly

6.1 Visual inspection and functional test before use

CAUTION! External influences can damage the cuff and result in loss of function during use. Risk of infection due to prolonged operation time.

- ▷ Before each use, verify that the product is in operable, proper condition.
- ▷ Protect the bladder from mechanical damage and UV radiation.
- ▷ Protect the cuff against pre-operative skin treatment products, which can reduce cuff service life.

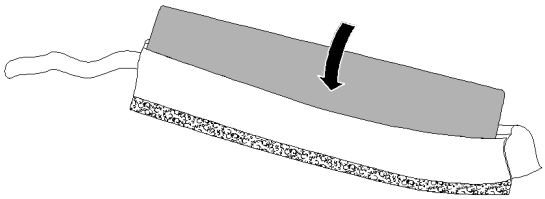
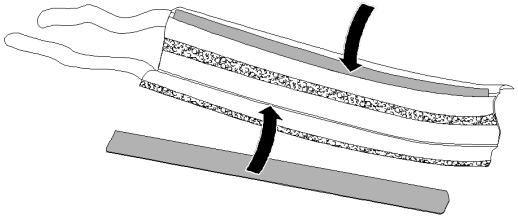
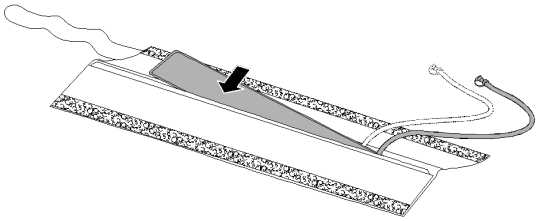
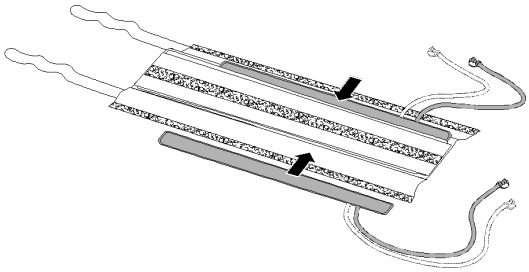
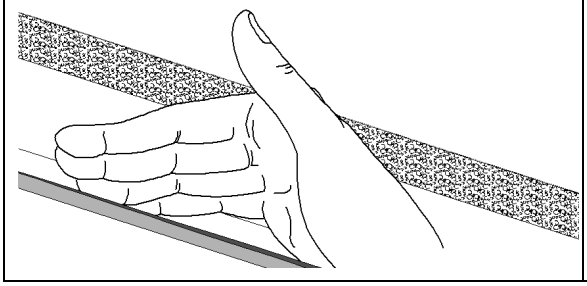
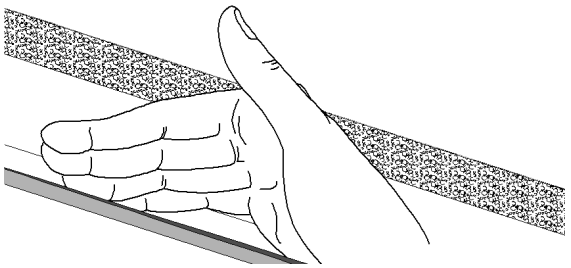
Before each use, a visual inspection and functional test of the cuff must be performed in the following sequence:

1. Before bringing it into the operating room: Ensure that all information on the cuff's direct part marking is completely legible.
2. Ensure that there are no cracks / tears, holes or damaged stitching.
3. For standard connectors: Check that O-rings on the connectors are properly positioned and functional. Ensure that the O-rings are free from cracks / tears.
4. Ensure that the cuff closure and Velcro are intact and free of foreign bodies (e.g., cotton or leftover bandage material).
5. Test to ensure that the Velcro has adequate resistance to being pulled apart.
6. No longer use cuffs that are damaged or defective.
7. Perform a functional test on the tourniquet. Comply with the tourniquet's instructions for use.

6.2 Assembly

WARNING! Loss of cuff function due to incorrect assembly. Nerve damage due to inhomogeneous distribution of pressure on nerves is possible.

- ▷ During assembly, verify that the bladder and foil are correctly positioned in the sleeve.
- ▷ Reusable cuffs must only be used if they are correctly assembled and in proper condition.

Assembling a single-chamber cuff	Assembling an IVRA double-chamber cuff
1. Place the foil in the pocket. 	1. Place one foil each into the two pockets. 
2. Insert bladder into the pocket under the foil. The bladder should be towards the side of the cuff that touches the patient's skin. 	2. Place one bladder under the foil in each of the two pockets. The bladders should be towards the side of the cuff that touches the patient's skin. 
3. Ensure that the foil and bladder are flush with each other. 	3. Ensure that the foil and bladder are flush with each other. 

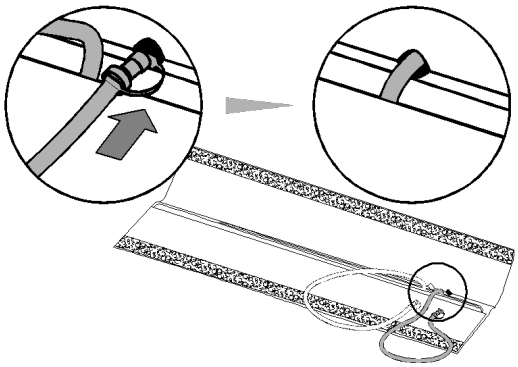
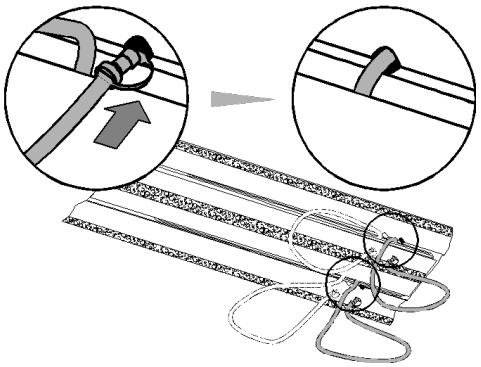
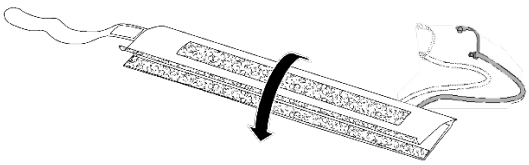
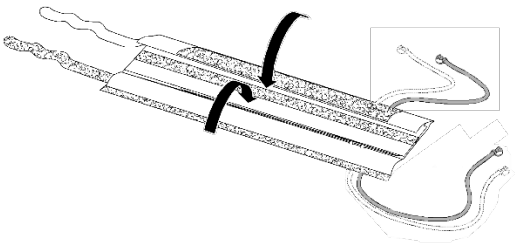
Assembling a single-chamber cuff	Assembling an IVRA double-chamber cuff
4. Push the cuff hose(s) through the openings in the pocket, and pull them towards the outside. ► Take care that the cuff hose is not kinked. 	4. Push the cuff hose(s) for the bladder on each side through the openings in the pockets, and pull them towards the outside. ► Take care that the cuff hose is not kinked. 
5. Carefully close the Velcro closure. 	5. Carefully close the Velcro closures. 
6. Ensure that the two sides of the Velcro closure are flush with each other.	6. Ensure that the two sides of the Velcro closure are flush with each other.

Table 6. Assembly

6.3 Disassembly

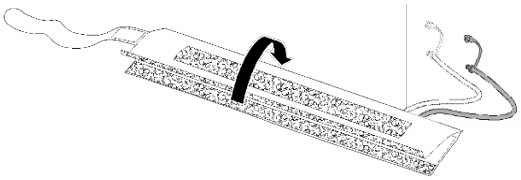
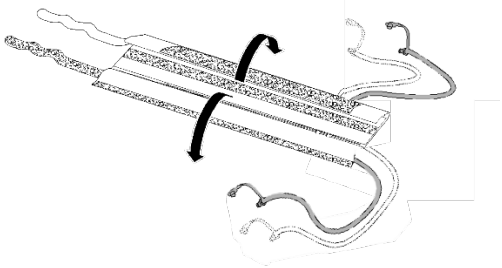
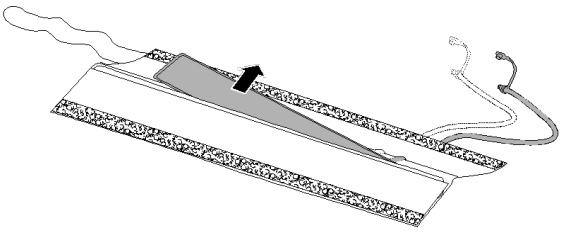
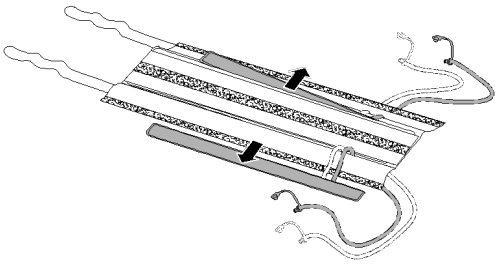
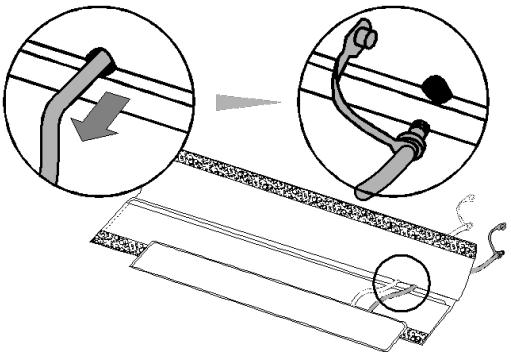
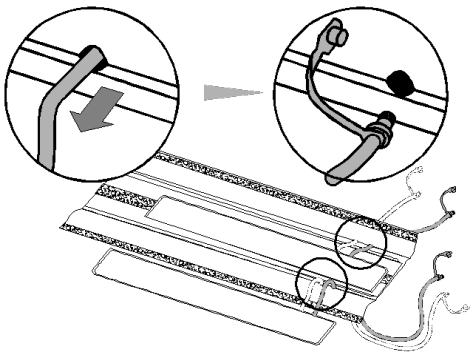
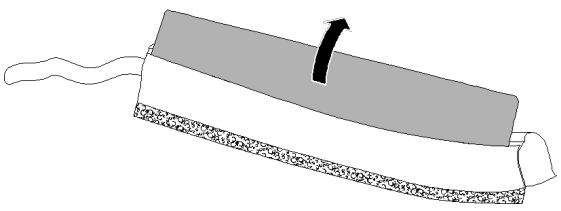
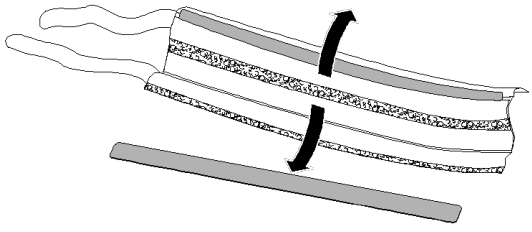
Disassembling a single-chamber cuff	Disassembling an IVRA double-chamber cuff
1. Pull the fabric sleeve's Velcro closure apart and open the cuff. 	1. Pull the fabric sleeves' Velcro closures apart and open the cuff. 
2. Remove the bladder from the pocket. 	2. Remove the bladder from each of the two pockets. 
3. Pull the cuff hose(s) through the openings. 	3. Pull the cuff hose(s) through the openings. 
4. Remove the foil from the pocket. 	4. Remove the foil from each of the pockets. 

Table 7. Disassembly

7 Using the cuffs

DANGER! Insufficient expertise regarding the product or the procedure can result in the patient's death.

- ▷ Ensure that the cuff is only applied by qualified medical personnel with adequate knowledge.

CAUTION! Incompatible accessories or hose combinations will lead to loss of functionality. Risk of infection due to prolonged operation time.

- ▷ Only the accessories listed in the accessory list may be used.
- ▷ Do not use hose combinations consisting of multiple hoses or connectors.

CAUTION! Improper placement of connecting hoses can impair their functionality. Risk of infection due to prolonged operation time.

- ▷ Make sure that all connection hoses are neither kinked nor pinched off.

Caution! The cuff must not be disconnected from the tourniquet when under pressure and with hoses pinched off. Risk of infection due to prolonged operation time.

- ▷ Ensure that the cuff pressure is constantly monitored by a tourniquet. Hoses must not be pinched off.

7.1 Reduce the amount of blood present in the tissue

Reduce the amount of blood present in the tissue as instructed by the treating physician. Possible measures to be taken are:

- ▶ Elevate the patients' extremities.
- ▶ Wrap the patients' extremities with an Esmarch bandage (or a roll-on cuff as described by Löfqvist).

7.2 Apply the cuff

DANGER! Selecting an incorrect cuff size or applying pressure for an incorrect duration or at an incorrect level can result in the patient's death.

- ▷ The physician is solely responsible for the duration and level of pressure during blood arrest. The duration of blood arrest depends on the diagnosis, the surgical technique and the patient's constitution (age, weight, skin and tissue condition, vascular condition and blood pressure, shape and size of the extremity, general constitution, obesity, etc.).
- ▷ Perform a pre-operative examination of the patient in order to identify risk factors, and to be able to correctly select a cuff and correctly specify the pressure to be applied during blood arrest.
- ▷ Monitor the cuff and the tourniquet during the blood arrest.

CAUTION! Pre-operative skin treatment products in the area where the cuff is applied can cause chemical burns and skin irritation.

▷ Ensure that no skin treatment products (disinfectants) are in the area where the cuff is applied, and that none have accumulated there or can enter there. If necessary, apply a rubber tourniquet on the distal side of the area where the cuff will be applied.

CAUTION! Inhomogeneous pressure distribution in tissue or the cuff becoming detached due to insufficient overlap of the two ends of the cuff. Risk of infection due to prolonged operation time.

▷ When putting the cuff on, make sure that the end of the cuff completely covers the red mark that indicates the required amount of overlap.

CAUTION! An improperly applied cuff can result in tissue damage to the patient.

▷ In order to prevent injury, make sure that no skin folds form under the applied cuff.

▷ Do not apply excessive starting pressure when applying the cuff, especially when using size 2XL and 3XL cuffs.

▷ In order to prevent severe skin injuries, irritation and abrasions, do not turn or move cuffs that have already been applied and pressurized. To correct the position: Depressurize the cuff, open the cuff closure, reapply the cuff in the correct position and refill it.

▷ Only remove the cuff from the patient after it has been completely vented.

The following graphics show how to use the Single Port and Dual Port cuffs. The hose highlighted in gray (see Figure 7, p. 23; Figure 9, p. 24; Figure 10, p.25) is the second hose for the Dual Port cuff. This hose is not present for the Single Port cuff.

Circumference of the extremity	Cuff size
10–18 cm	2XS
14–21 cm	XS
21–40 cm	S / IVRA
40–49 cm	M

Circumference of the extremity	Cuff size
49–57 cm	L
57–78 cm	XL
78–97 cm	2XL
97–117 cm	3XL

Table 8. Cuff size and circumference

1. Ensure that the end of the cuff completely covers the red mark (a) that indicates the required amount of overlap and reaches as far as the beginning of the Velcro (b).
   - If there is too much overlap:
     - ▶ Use a smaller cuff size.
   - If there is too little overlap:
     - ▶ Use a bigger cuff size.

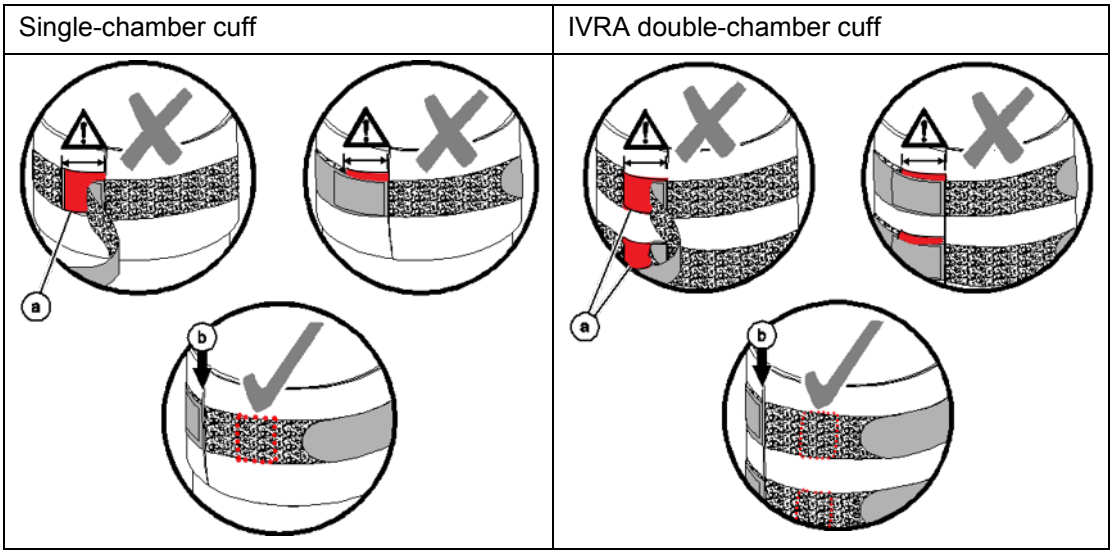


Figure 6. Ensure adequate cuff overlap

2. Optional: Thin padding can be placed under the cuff at the user's discretion.
3. Place the cuff around the extremity. For a double-chamber cuff, ensure that the red proximal chamber (a) points towards the heart and the blue distal chamber (b) points to the surgical site.

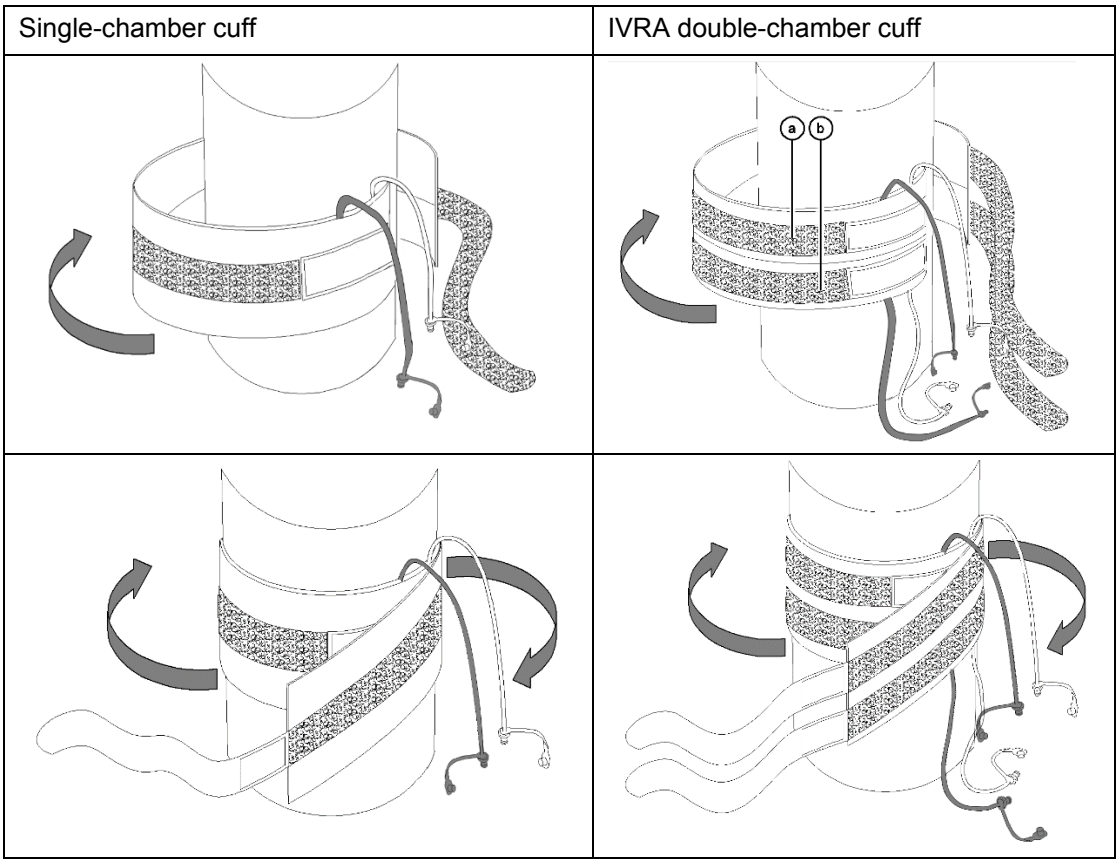


Figure 7. Apply the cuff

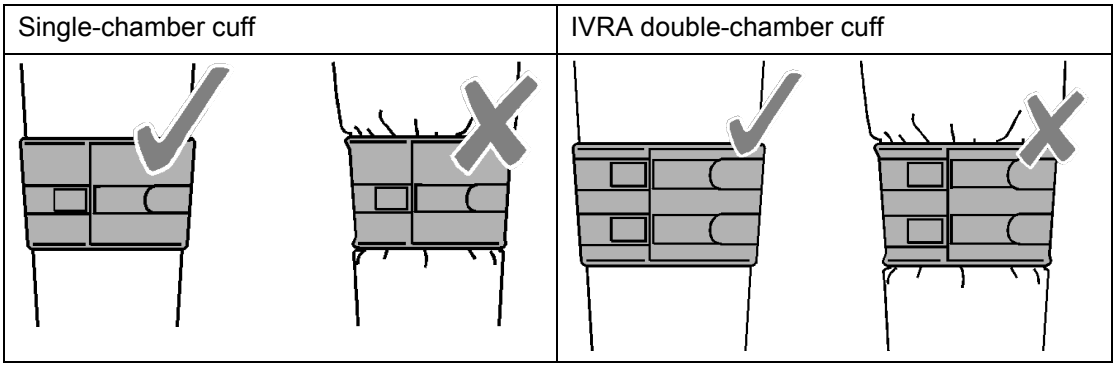


Figure 8. Check that the positioning of the cuff has not caused tissue folds

4. Close the cuff closure.

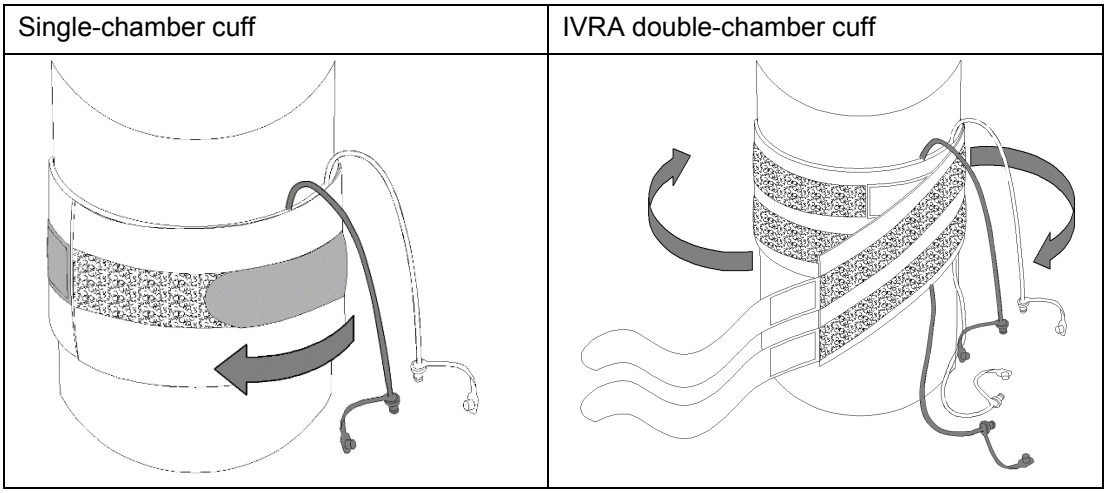


Figure 9. Close the cuff closure

5. Connect the cuff hose(s) (a) to the connection hoses (b) to the tourniquet.
   - Make sure the connection configuration is correct.
   - Comply with the tourniquet's instructions for use.
   - A click must be clearly heard in the socket on the connection hose when inserting the connector on the cuff hose.
   - If possible, during use you should arrange the cuff hoses so that they lead away from the surgical site.

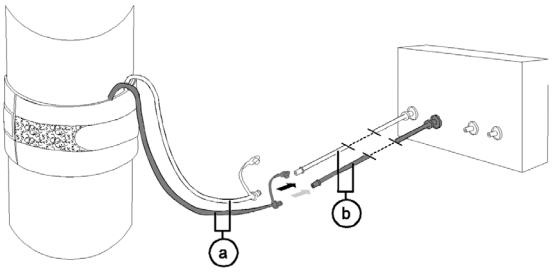
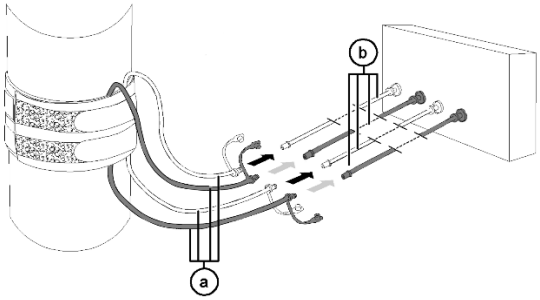
Single-chamber cuff	IVRA double-chamber cuff
	

Figure 10. Connect to tourniquet

7.3 Blood arrest

CAUTION! Incompatible tourniquet results in loss of function. Risk of infection due to prolonged operation time.

- ▷ 1-hose cuffs must only be connected to a compatible tourniquet for 1-hose cuffs.
- ▷ 2-hose cuffs must only be connected to a compatible tourniquet for 2-hose cuffs.

CAUTION! High temperatures under surgical lamps can lead to heat buildup.

- ▷ Take into account the need to reduce the duration of blood arrest at high temperatures. Do not actively warm children during blood arrest.

Single-chamber cuff

1. Pre-select the pressure on the tourniquet. Comply with the tourniquet's instructions for use. When establishing blood arrest, comply with the tourniquet's instructions for use.
2. Pressurize the cuff. Adjust the pressure in an individualized way for the patient in order to prevent nerve / muscle damage due to excessive pressure. Use the minimum pressure necessary.

3. Use two fingers to grip under the cuff and check whether you can distinctly feel counterpressure.
   ▶ Test on the proximal side.

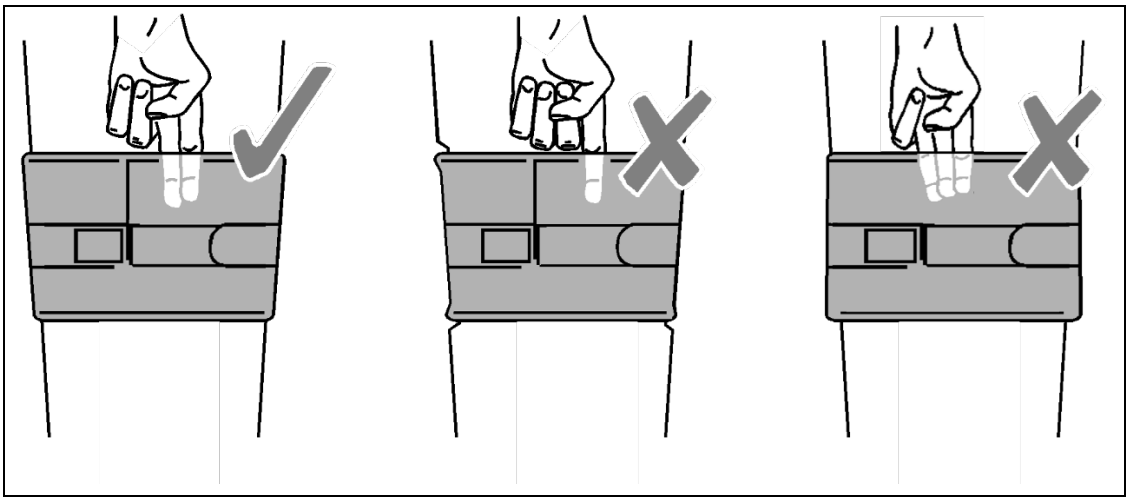


Figure 11. Testing for counterpressure

4. Monitor the cuff and tourniquet.
5. Regularly monitor the duration on the tourniquet.

Double-chamber cuff

DANGER! Improperly performed IVRA use can lead to anesthetic entering systemic circulation and resulting in the patient's death.

- ▷ Only allow IVRA with a double-chamber cuff to be performed by a physician.
- ▷ Comply with the instructions for use for the anesthetic. Comply with the manufacturer's instructions regarding the administration time for the local anesthetic and the minimum duration of local anesthesia with blood arrest.
- ▷ In order to achieve the same degree of vessel compression, pressurize double-chamber cuffs to higher pressure than single-chamber cuffs.
- ▷ Do not vent the cuff until the local anesthetic has been completely absorbed by the tissue. Slowly reduce the pressure in the cuff, in stages if necessary, in order to avoid rapid infiltration of metabolites after releasing blood arrest.
- ▷ Ensure that the proximal chamber is pressurized before the local anesthetic is administered.

1. Check the bladders for leaks: Pre-select the pressure on the tourniquet and pressurize both bladders.
   ▶ If no leaks were found: Vent the distal chamber. The proximal chamber's bladder can remain pressurized if the correct pressure has already been selected for the blood arrest.
   ▶ If leakage was found: Remove the cuff from the patient. Use a new cuff. Repeat the leak check.
2. Pre-select the pressure on the tourniquet. Comply with the tourniquet's instructions for use.

3. Pressurize the proximal chamber (red).
4. Use two fingers to grip under the cuff and check whether you can distinctly feel counterpressure.
   - ▶ Test on the proximal side.

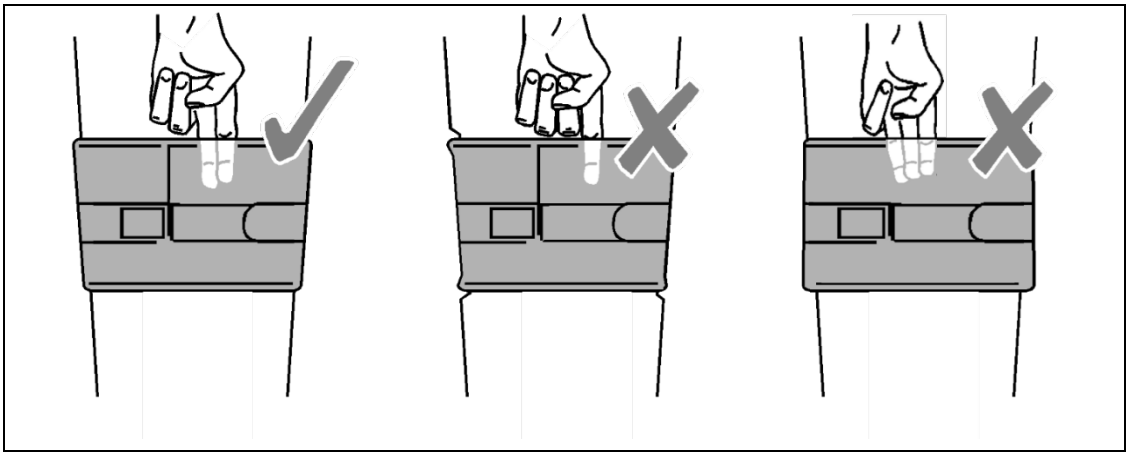


Figure 12. Testing for counterpressure

5. If possible, feel the artery to check that the vessel is sufficiently compressed.
6. Have a physician administer the local anesthetic. Wait for the onset of action of the anesthetic.
7. Pressurize the distal (blue) chamber. Check for counterpressure (as described in point 4) on the distal side.
8. Vent the proximal (red) chamber.
9. Monitor the cuff and tourniquet.
10. Regularly monitor the duration on the tourniquet.

7.4 Terminate blood arrest

7.4.1 Vent the cuff

- ▶ Vent the cuff in multiple steps with the tourniquet. Comply with the tourniquet's instructions for use.
- ▶ Slowly reduce the pressure in the cuff, in stages if necessary, in order to avoid rapid infiltration of metabolites after releasing blood arrest.
- ▶ For IVRA: Do not vent the cuff until the local anesthetic has been completely absorbed by the tissue.
- ▶ For IVRA: Comply with the manufacturer's instructions regarding the administration time for the local anesthetic and the minimum duration of local anesthesia with blood arrest.

7.4.2 Remove the cuff

1. Terminate blood arrest on the tourniquet. Comply with the tourniquet's instructions for use.
2. Disconnect the cuff hose(s) from the connection hose(s) and the tourniquet.
3. Open the cuff closure.
4. Remove the cuff from the extremity.
5. Clean / disinfect and sterilize the cuff.

8 Cleaning / Disinfection and Sterilization

CAUTION! Using a non-sterile cuff increases the patient's risk of infection.

- ▷ After removing the packaging from a brand-new product, and before using it for the first time, prepare it for clinical use (machine cleaning and sterilization).
- ▷ Only use cuffs that have been cleaned / disinfected and sterilized.
- ▷ Make sure that the cleaning / disinfection and sterilization process has been validated.
- ▷ Handle all sterile components carefully in order to ensure their sterility.

CAUTION! The cuff's resistance to aging is reduced by frequent cleaning, disinfection and sterilization processes, as well as increased periods of downtime. Risk of infection due to prolonged operation time.

- ▷ The product may be cleaned / disinfected and sterilized a maximum of 50 times.

The cuffs must be cleaned, disinfected, and sterilized before each use; note that this also includes the initial use after receiving the cuff, because all cuffs are shipped in non-sterile condition. Effective cleaning and disinfection is required for effective sterilization.

- ▶ To ensure proper sterilization, only use adequate, validated device- and product-specific procedures for cleaning / disinfection and sterilization, and perform regular maintenance on equipment (cleaning and disinfecting machines and steam-sterilizers) and inspect them upon each cycle to verify that validated parameters are complied with.

Using an excessive amount of cleaning agent can damage the materials.

- ▶ National statutory regulations, national and international standards and guidelines as well as your own facility's hygiene rules for cleaning / disinfection must be followed.
- ▶ Test cleaning / disinfection and sterilization procedures per DIN EN ISO 17665 for their suitability for cleaning / disinfection and sterilization and compatibility with the cuff.
- ▶ Do not use any cleaning agents that contain solvents.
- ▶ Only use suitable cleaning agents (neutral, enzymatic or mildly alkaline cleaning agents (up to pH 10.5)).
- ▶ Only use process chemicals that have been tested and approved (e.g., VAH / DGHM or FDA approval or CE mark) and that have been recommended by the chemical manufacturer with regard to their compatibility with materials. Comply with the manufacturer's instructions regarding temperature, concentration and exposure time.
- ▶ Do not use hydrogen peroxide.

8.1 Machine cleaning

When selecting the cleaning / disinfection machine, make sure that its effectiveness has been tested (e.g., VAH / DGHM or FDA clearance and/or CE mark with regard to DIN EN ISO 15883). Cleaning and disinfection was validated with the following programs and cleaning agents / disinfectants:

- Cleaning temperature and dwell time: 60°C, 10 minutes
- Disinfection temperature and dwell time: 93°C, 5 minutes
- Cleaning agent: Neodisher® mediclean forte
- Neutralizer: Neodisher® Z

8.1.1 Preparation

- ▶ Make sure that each connector is sealed with its sealing cap in order to prevent fluid from entering the bladder.
- ▶ Make sure that the product is always disassembled for cleaning (see section 6.3 p.20).
- ▶ Remove coarse contaminants from the cuffs. Use running water or a disinfectant solution to manually remove contamination. Only use a soft brush or a clean, soft cloth; do not use metal brushes or steel wool.

8.1.2 Cleaning

1. Put the individual parts into the CDM.
2. Perform cleaning and disinfection.
   - ▶ Make sure that the cleaning and disinfection temperature complies with the validated procedure.
   - ▶ Comply with the CDM's instructions for use.
3. After cleaning, inspect the product for cleanliness and functionality.

8.2 Sterilization

Use a steam-sterilizer in accordance with DIN EN 13060 and/or DIN EN 285. The following cycle for steam sterilization with a fractionated vacuum process was validated:

- Temperature and dwell time: 134°C, 8 minutes
- Drying time: 15 minutes
- ▶ When using other temperatures, dwell times must be adjusted accordingly.
- ▶ Always assemble the product before sterilizing it (see section 6.2 p.18).
- ▶ Before sterilization, allow the cuffs to dry at room temperature.

Performing sterilization

1. Pack the product. Use suitable sterile packaging for steam-sterilizers (see DIN EN ISO 11607 / EN 868-2).
   - ▶ Make sure that the direct part marking is not covered, and is legible.
   - ▶ Make sure that the sterilization agent has access to all surfaces.
2. Put the product in the sterilizer.
3. Perform sterilization. Make sure that the sterilization temperature and dwell time comply with the validated cycle.

8.3 Storage

- The product must be stored dry, away from sunlight, and at room temperature.
- After sterilization, the reusable cuffs must be stored clean and dry in their sterile packaging.

9 Maintenance and repair

Damaged reinforcing foil

- ▶ Replace with an original replacement part.

Damaged bladder and fabric sleeve

- ▶ Replace and dispose of the damaged cuff.

Repairs

The product does not contain any parts that can be repaired by the user.

- ▶ Dispose of defective cuffs or parts.

10 Troubleshooting

Error	Cause	Resolution
Pressure does not build up in the cuff.	Connector is defective or is not inserted. Tourniquet is defective. Bladder is defective.	▶ Check the connection to the tourniquet. ▶ If necessary, replace the cuff. ▶ Check the tourniquet.
Cuff cannot be vented.	Cuff hose is kinked or pinched. Tourniquet is defective.	▶ Check the cuff hose for kinks or pinching. ▶ Disconnect the cuff. ▶ Check the tourniquet.
Cuff loses pressure during the blood arrest.	Bladder is defective. Connection hose is defective. Hose or connector is defective. Tourniquet is defective.	▶ Adjust the pressure. ▶ For standard connectors: Check the seal on the connector after the operation is over. ▶ Replace a defective bladder or hose after the end of the operation. ▶ Check the tourniquet.
Cuff comes open. Cuff is worn out.	Foreign bodies need to be cleaned out of the cuff closure. Frequent use and cleaning / disinfection / sterilization.	▶ Clean the Velcro with a Velcro cleaning comb (300,001). ▶ If necessary, replace the cuff.
Cuff slips in the distal direction.	Cuff overlap is inadequate. Extremity is highly conical.	▶ Inspect the cuff overlap (see section 7.2 p.21) and select a larger cuff where necessary. ▶ If necessary, use a conical single-use cuff (UT 1332-XL/ UT 1330-XL).

Error	Cause	Resolution
Cuff no longer has a round fit.	Foil is deformed.	▶ Replace foil.
Cuff does not fit around the extremity.	Incorrect cuff size was selected.	▶ Select a suitable cuff size. ▶ Determine the size as needed with a cuff size tape.

Table 9. Troubleshooting

11 Reporting incidents

All complaints in connection with the safety, efficacy or performance of the product must be reported by the user to ulrich medical (complaint@ulrichmedical.com) or the local distributor within 72 hours.

If one or more components of the system should have a malfunction (i. e. one or more of the performance specifications are not met or the intended performance is not achieved for other reasons) or if it is suspected that this may be the case, then ulrich medical (complaint@ulrichmedical.com) or the local distributor should be notified immediately (within 24 hours).

If one or several components of the system have ever failed and possibly led or contributed to the death or severe injury of a patient, then ulrich medical or the local distributor should be notified by telephone immediately.

Please use the Medical Device Vigilance Report Form from ulrich medical to report product complaints, malfunctions or product failure. It is available at: www.ulrichmedical.com/vigilancereport.

12 Accessories and replacement parts

Ordering address

As a customer, you can order all listed accessory parts from your authorized distributor.

Authorized Distributor / Customer Service

The address can be found on the rear side of the instructions for use.

Accessory item

Catalog number	Description
Connection hoses for cuffs	
UT 1276-300	Connection hose for cuff, 650 mmHg, orange, length 3 m, cannot be sterilized
UT 1276-500	Connection hose for cuff, 650 mmHg, orange, length 5 m, cannot be sterilized
UT 1277-300	Connection hose for cuff, 650 mmHg, orange, length 3 m, can be sterilized
UT 1277-500	Connection hose for cuff, 650 mmHg, orange, length 5 m, can be sterilized
UT 1187-500	Connection hose 5 m orange male – safety female, cannot be sterilized, without protective caps
UT 1188-500	Connection hose 5 m safety male – orange female, can be sterilized, with protective caps
UT 1321-300	Connection hose for cuff, standard connector, length 3 m, cannot be sterilized
UT 1321-500	Connection hose for cuff, standard connector, length 5 m, cannot be sterilized
UT 1278-500	IVRA-Connection hose, length 5 m, cannot be sterilized
Cuff accessories	
UT 1315	Cuff Size Tape
300,001	Velcro cleaning comb

Table 10. Accessories

Spare foil	
UT 132X-XS-F	Spare foil, 270 x 47 mm
UT 132X-S-F	Spare foil, 470 x 65 mm
UT 132X-M-F	Spare foil, 560 x 80 mm
UT 132X-L-F	Spare foil, 670 x 100 mm
UT 132X-XL-F	Spare foil, 910 x 130 mm
UT 132X-2XL-F	Spare foil, 1050 x 80 mm
UT 132X-3XL-F	Spare foil, 1270 x 100 mm

Table 11. Replacement parts

13 Technical information

Characteristic	Value
Medical device class	I
Bladder pressure	Maximum 650 mmHg
Materials with skin contact	
Cuff hose	EPDM
Cuff sleeve	Polyester, rayon, and polyamide
Connectors	
Orange connector	Suitable for orange ulrich medical connector (Rectus connector) for 650 mmHg maximum
Standard connector	Suitable for CPC quick connection

Table 12. Technical information

14 Combination with other devices

14.1 ulrich medical tourniquets

Characteristic	Value
Type name	UT 1380-E elsa, mein Tourniquet, 1-channel with compressor and rechargeable battery UT 1380-EP elsa, mein Tourniquet, 1-channel with printer UT 1380-H heidi, mein Tourniquet, 2-channel with compressor and rechargeable battery UT 1380-HP heidi, mein Tourniquet, 2-channel with printer UT 1380-S sophie, mein Tourniquet, 2-channel for connecting to a CGS UT 1380-SP sophie, mein Tourniquet, 2-channel with printer
Maximum pressure	600 mmHg
Connector compatibility	Orange ulrich medical connector (Rectus connector)

Table 13. Combination an ulrich medical tourniquet

14.2 Third-party tourniquets

Characteristic	Value
Type name	Third-party tourniquets
Maximum pressure	600 mmHg
Connector compatibility	Standard CPC connector

Table 14. Combination with third-party tourniquet

14.3 ulrich medical connection hoses

Characteristic	Value
Type name	UT 118X-XXX; UT 127X-XXX; UT 1321-XXX ulrich medical connection hose (see section 11 p. 34)
Connector compatibility	Orange ulrich medical connector (Rectus connector) Standard CPC connector

Table 15. Combination with ulrich medical connection hoses

14.4 Cuff Size Tape

Characteristic	Value
Type name	UT 1315 Cuff size tape
Cuff compatibility	Suitable for ulrich medical single-use and reusable cuffs

Table 16. Combination with cuff size tape

15 Disposal

The system and/or system components can also be disposed of by means of the clinic's own disposal system.

The European List of Wastes is the basis for the disposal of medical waste in the European Union. If necessary, jurisdictions from the national down to the municipal level can issue their own waste rules that must be complied with.

Outside the European Union, the appropriate country-specific regulations for disposal of medical waste must be complied with.

Type of disposal	Includes	Waste code*
Electronic waste	Displays, printed circuit boards, motors, power supply units, switches, sensors, terminals	20 01 36
Batteries Note: Return batteries to the manufacturer for disposal (BattG)	Lead Lithium-ion	20 01 33
Metal recycling / plastic recycling	Structural attachments, cables, housing, tray	20 01 39 20 01 40
Packaging	Separation of cardboard, paper and plastics	15 01 01 15 01 02 15 01 05 15 01 06
Items with patient contact	Single use items, cuffs, mouthpieces	16 03 04 16 10 02 18 01 04 18 01 01 20 01 11
Items without patient contact	Single use items, cuffs, mouthpieces	16 03 04 20 01 11 18 01 01

Table 17. General disposal instructions including the waste codes for the European Union

* Waste codes according to the currently applicable European List of Wastes Regulation (AVV).

16 Service

- When reporting malfunctions or defects please specify the reusable cuffs' lot numbers.

Germany

ulrich GmbH & Co. KG
Tourniquet Customer Service
Buchbrunnenweg 12
89081 Ulm
Phone: +49 (0)731 9654-111
Fax: +49 (0)731 9654-2808
E-mail: service@ulrichmedical.com
Internet: www.ulrichmedical.com

Technical hot line (8:00 am – 5:00 pm CET)

Authorized Distributor / Customer Service

The address can be found on the rear side of the instructions for use.

Authorized Distributor / Customer Service

CE

patented
or/and
pat. pend.

ulrich GmbH & Co. KG | Buchbrunnenweg 12 | 89081 Ulm | Germany
Phone: +49 (0)731 9654-0 | Fax: +49 (0)731 9654-199
tourniquets@ulrichmedical.com | www.ulrichmedical.com