ATMOS
MedizinTechnik

Instructions for Use

Cuff

English



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CE

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1 Introduction

1.1 Notes on Instructions for Use



These Instructions for Use are part of the products mentioned in chapter (‘1.2 These Instructions for Use are valid for the following products:’ on page 5) and remain valid until they are replaced by a later revision of the Instructions for Use.

These Instructions for Use are designed for training and instructing new operating personnel in the use of the system and also for use as a reference manual. This document may be reprinted, either in part or in whole, only with the written permission from ATMOS.

These Instructions for Use must always be kept available near the product.



Care, periodic tests, regular cleaning, and proper application are essential. They ensure the operational safety and usability of the product.



Read the chapter ‘Notes for your safety’ on page 11 before using the product for the first time. This will help you to avoid potentially dangerous situations.

The products bear the CE marking CE in accordance with the European Medical Device Regulation (MDR) 2017/745.

The Declarations of Conformity and our General Terms and Conditions can be viewed on our website at www.atmosmed.com.

The quality management system applied at ATMOS has been certified according to the international standard EN ISO 13485.

1.2 These Instructions for Use are valid for the following products:

Cuff 2XS, orange connector	UT 1317-2XS
Cuff XS, orange connector	UT 1317-XS
Cuff S, orange connector	UT 1317-S
Cuff M, orange connector	UT 1317-M
Cuff L, orange connector	UT 1317-L
Cuff XL, orange connector	UT 1317-XL
Cuff 2XL, orange connector	UT 1317-2XL
Cuff 3XL, orange connector	UT 1317-3XL
Cuff 2XS, standard connector	UT 1321-2XS
Cuff XS, standard connector	UT 1321-XS
Cuff S, standard connector	UT 1321-S
Cuff M, standard connector	UT 1321-M
Cuff L, standard connector	UT 1321-L
Cuff XL, standard connector	UT 1321-XL
Cuff 2XL, standard connector	UT 1321-2XL
Cuff 3XL, standard connector	UT 1321-3XL

Size	Circumference of the extremity	Colour coding	Length x width	Weight	Connector	Art. no.
2XS	100 to 180 mm	Grey	250 x 55 mm	66 g	Standard	UT 1321-2XS
	4 to 7 in		10 x 2 in		Orange	UT 1317-2XS
XS	140 to 210 mm	Light blue	290 x 70 mm	100 g	Standard	UT 1321-XS
	5.5 to 8.5 in		12 x 3.5 in		Orange	UT 1317-XS
S	210 to 400 mm	Red	495 x 85 mm	190 g	Standard	UT 1321-S
	8.5 to 16 in		19.5 x 4 in		Orange	UT 1317-S
M	400 to 490 mm	Green	600 x 100 mm	276 g	Standard	UT 1321-M
	16 to 19.5 in		23.5 x 4 in		Orange	UT 1317-M
L	490 to 570 mm	Dark blue	710 x 120 mm	320 g	Standard	UT 1321-L
	19.5 to 22.5 in		30 x 4 in		Orange	UT 1317-L
XL	570 to 780 mm	Brown	950 x 150 mm	640 g	Standard	UT 1321-XL
	22.5 to 30.5 in		34 x 4 in		Orange	UT 1317-XL
2XL	780 to 970 mm	Black	1090 x 100 mm	500 g	Standard	UT 1321-2XL
	30.5 to 38 in		42 x 4 in		Orange	UT 1317-2XL
3XL	970 to 1170 mm	Orange	1310 x 120 mm	690 g	Standard	UT 1321-3XL
	38.2 to 46 in		42 x 4 in		Orange	UT 1317-3XL

1.3 Explanation of pictograms and symbols

In the Instructions for Use

⚠ DANGER	Warning of a hazard that will result in death or serious injury. Observe the necessary measures.
⚠ WARNING	Warning of a hazard that could result in death or serious injury. Observe the necessary measures.
⚠ CAUTION	Warning of a hazard that may result in minor or moderate injury. Observe the necessary measures.
NOTICE	Indicates a hazard that may result in damage to the product or other property if not avoided. Observe the necessary measures.
⚠	Warning of a hazard that could cause serious injury or death.
1.	Call for action. Proceed step by step.
☞	Useful information on handling the device.
»	Result of an action.

On the device and packaging

	Consult instructions for use
	Warning; pay special attention
CE	This device complies with the relevant requirements of EU directives.
	Manufacturer
	Date of manufacture Country of manufacture
REF	Reference number
UDI	Unique Device Identifier of a medical device
MD	Medical device
LOT	Batch code
	Keep dry

	Keep away from sunlight
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

UDI application identifier

(01)	UDI-DI: Identification of the manufacturer and the device
(10)	Batch code
(11)	Date of manufacture

1.4 Intended purpose

Product name:	• Cuff 2XS, orange connector • Cuff XS, orange connector • Cuff S, orange connector • Cuff M, orange connector • Cuff L, orange connector • Cuff XL, orange connector • Cuff 2XL, orange connector • Cuff 3XL, orange connector • Cuff 2XS, standard connector • Cuff XS, standard connector • Cuff S, standard connector • Cuff M, standard connector • Cuff L, standard connector • Cuff XL, standard connector • Cuff 2XL, standard connector • Cuff 3XL, standard connector
Main functions:	The cuffs for tourniquets are used to create an artificial blood arrest in the upper or lower extremities in order to achieve a relatively bloodless surgical site. By building up high pressure generated by a tourniquet, the cuffs stop arterial blood flow to the extremity and venous blood return from the extremity. Thin padding must be used under the cuffs at the discretion of the user.

Intended use:	The intended use of the cuffs, 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.
Intended users / user profiles:	Trained healthcare professionals (e.g. operating theatre assistants). Users must not be hard of hearing or deaf and must have adequate eyesight.
User training:	The cuffs may only be used by persons who have received medical training.
Intended patient target groups:	Patients of all age groups with and without restrictions. There are no restrictions apart from the contraindications. The typical patient group consists of patients undergoing surgery on the extremity. The indications are examples of such patient groups.
Medical conditions to be diagnosed, treated or monitored:	Not applicable. Use of cuffs is not dependent on a medical condition. Use of cuffs is defined by the indication.
Organ(s) applied to:	Upper and lower extremities
Duration of application:	For short-term use (max. 24 h) on the patient
Use environment:	Cuffs are used in the surgical environment of a professional healthcare facility. Cuffs are used in surgery/orthopaedics of the extremities in the fields of vascular surgery, trauma surgery, neurosurgery, and plastic surgery.
Patient selection criteria:	The patient group consists of patients undergoing surgery on one or more extremities.
Indications:	Cuffs are used for the following indications: • 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 tumours • Removal of cysts

Medical contra-indications:	Cuffs may only be used on patients who do not have any of the following contraindications: • Inflammations • Malignant tumours • 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 ischaemia
Other contra-indications:	• No application in emergency and rescue situations • No use in the homecare area that is not supervised by healthcare professionals • No use in non-medical areas
Undesirable side-effects:	The following complications may occur during or after use of cuffs: • Hyperaemia with a risk of haemorrhage • Muscle oedema • Paralyses • Acid-base regulation disorder • Shock due to metabolite influx after spontaneous return of blood flow • Crushed nerve (especially the peroneal or ulnar nerve); consequence: paralysis
Warnings:	See chapter '2 Notes for your safety' on page 11 in the valid instructions for use of the product.
The product is:	Not active
Sterility / specific microbial state:	Non-sterile product
Single-use device / reprocessing:	• The cuffs are intended for multiple use. • For information on reprocessing, cleaning and disinfection, refer to chapter '5 Reprocessing' on page 24.

1.5 Product description

Reusable cuffs for tourniquets are used to create an artificial tourniquet on the upper or lower extremities in order to achieve a relatively bloodless surgical field. By building up high pressure generated by a tourniquet, the cuffs block arterial blood flow to the extremity and venous blood return from the extremity.

1.6 Transport and storage

Transport the product only in packaging that provides sufficient protection.

If you notice any transport damage:

1. Document and report the transport damage.
2. Fill in the form QD 434 'Product Complaint / Return Shipment'.
3. Send in the product to ATMOS.

Environmental conditions of the product for transport and storage: see chapter '11 Technical Data' on page 34.

2 Notes for your safety

The safety and performance of the cuff comply with the relevant General Safety and Performance Requirements in accordance with Regulation (EU) 2017/745 on medical devices (MDR) and the generally accepted state of the art.

2.1 General safety instructions

Report any serious incidents that occur in connection with this product to the manufacturer and your national competent authority.

Make yourself familiar with the product in good time, so that you can use it at any time.

Never operate the product if it exhibits any obvious safety defects.

The product will meet the safety requirements of users, patients and third parties only if it is fully functional. Therefore, observe the following instructions on your product.

Read and observe the safety instructions carefully before using the product.

2.2 Danger to users, patients and third parties

⚠ DANGER

Your patient can be severely injured!

- Read and observe the safety instructions before using the product.
- Insufficient expertise regarding the product or procedure can cause the death of the patient.
- Make sure the cuff is applied only by health care professionals with sufficient knowledge.
- Incorrect selection of the cuff size as well as the duration or level of the applied pressure can cause the death of the patient.
- The duration and level of the pressure applied to occlude the blood flow are the sole responsibility of the physician. The duration of blood flow occlusion depends on the diagnosis, the surgical technique, and the patient's condition (age, weight, skin and tissue condition, vascular status and blood pressure, shape and size of the extremity, general condition, obesity, etc.).
- Subject the patient to a preoperative examination to identify risk factors and determine the correct selection of the cuff and the pressure while blood flow is occluded.
- Monitor the cuff and tourniquet while blood flow is occluded.

⚠ WARNING

Avoid improper use!

Your patient can be severely injured.

- The cuff should be applied only by healthcare professionals.
- To monitor the duration of blood flow occlusion, the cuff may be used only with a tourniquet device equipped with the appropriate alarm and safety features and an integrated timer.

⚠ WARNING

Ensure that the product is functional and ready for use at all times!

Your patient can be severely injured.

- Ensure that the product is always ready for use.
- Always carry out a function check before each use.
- ATMOS recommend always having a spare cuff ready at hand.

⚠ WARNING

Loss of function of the cuff due to incorrect assembly. Nerve damage possible due to inhomogeneous pressure distribution on the nerve!

Your patient can be severely injured.

- Observe the correct position of the bladder and foil in the fabric sleeve when fitting the cuff.
- The cuff may be used only in correctly assembled, perfect condition.

⚠ WARNING

Tissue damage and serious injuries to patients can be caused by applying a cuff inappropriately!

Your patient can be severely injured.

- To avoid injuries, make sure no skin folds are created under the applied cuff.
- Do not exert any high pre-tension when applying the cuff, in particular when using size 2XL and 3XL cuffs.
- Do not turn or move the cuff with the pressure applied to avoid serious skin injuries, irritation and abrasion. To correct the position: deflate the cuff, open the cuff fastener, reapply the cuff in its correct position and inflate it again.
- Remove the cuff from the patient only when it is fully deflated.
- To prevent chemical burns or skin irritation caused by preoperative skin treatment agents or irrigation solutions during surgery, the cuff should be thinly padded (e.g., with cotton wool) and then sealed distally.
- The cuff should be applied as proximally as possible in order for plenty of muscle and tissue mass to be between the nerves and vessels and cuff.
- The cuff must not be disconnected from the tourniquet while it is inflated and the hoses are clamped. Increased risk of infection due to extended surgery time!
- Make sure the cuff pressure is always monitored by a tourniquet. The hoses must not be clamped.
- Improperly routed connection hoses can impair functionality. Increased risk of infection due to extended surgery time!
- Ensure that no connection hoses are kinked or clamped.

⚠ WARNING

External influences can damage the cuff, which can result in loss of function during the application. Increased risk of infection due to extended surgery time!

Deadly diseases may be transmitted.

- Check the product for proper condition and functionality before every use.
- Protect the bladder from mechanical damage and UV radiation.
- Protect the cuff from contact with preoperative skin treatment agents, as these will reduce the service life of the cuff.
- Use only cleaning agents and disinfectants that are suitable for the reprocessing of medical devices. Use disinfectants whose effectiveness has been confirmed by recognised test procedures (e.g., according to VAH, DGHM, or RKI listing).

⚠ WARNING

Inhomogeneous pressure distribution in the tissue or detachment of the cuff on its own due to insufficient overlapping of the cuff ends. Increased risk of infection due to extended surgery time!

Deadly diseases may be transmitted.

- When putting on the cuff, make sure the end of the cuff fully covers the red mark indicating the required overlap.

⚠ WARNING

Incompatible accessories or hose combinations will result in a loss of function. Increased risk of infection due to extended surgery time!

Deadly diseases may be transmitted.

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

⚠ WARNING

Incompatible tourniquets will result in a loss of function. Increased risk of infection due to extended surgery time!

Deadly diseases may be transmitted.

- Connect the cuff only to a compatible tourniquet.

NOTICE

Frequent cleaning, disinfection, sterilisation, and prolonged storage times reduce the ageing resistance of the cuff. Damage to the product due to incorrect handling!

The product may become damaged.

- Reprocess the product no more than 50 times.
- Always carry out a function check before each use.
- ATMOS recommend always having a spare cuff ready at hand.

⚠ CAUTION

An increased risk of infection of the patient is caused by using cuffs that have not been reprocessed!

Your patient can be injured.

- Reprocess the brand new product clinically after removing the transport packaging and before using it for the first time (see chapter ‘5 Reprocessing’ on page 24).
- Use only clinically reprocessed cuffs.
- Ensure that a validated reprocessing procedure is in place.

⚠ CAUTION

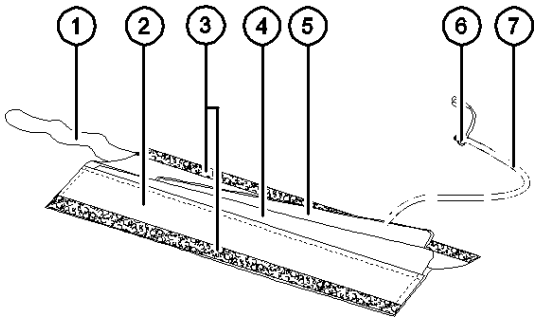
High temperatures under surgical lights can cause heat accumulation!

Your patient can be injured.

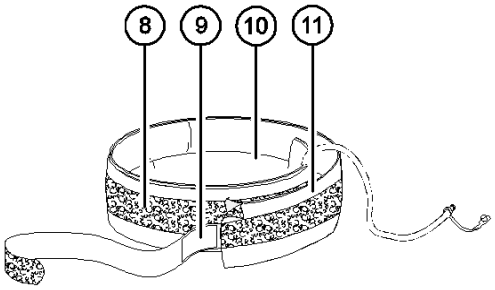
Consider reducing the duration of blood flow occlusion at high temperatures. Do not actively warm children while blood flow is occluded.

3 Description

3.1 Cuff



1. Hook strip of the cuff fastener
2. Fabric sleeve (with pocket)
3. Hook-and-loop strip
4. Foil
5. Bladder
6. Connector with protection cap
7. Cuff hose



8. Loop strip of the cuff fastener
9. Direct marking
10. Skin side
11. Outside

3.2 Connector versions

The cuffs are available with two different connectors for connection to the tourniquet.



1. Orange connector
2. Standard connector

4 Using the cuff for the first time

4.1 Visual and functional inspection before application

⚠ WARNING

External influences can damage the cuff, which can result in loss of function during the application. Increased risk of infection due to extended surgery time!

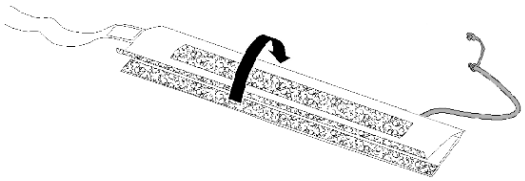
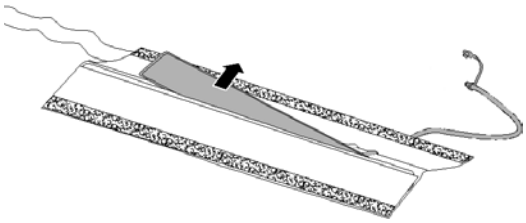
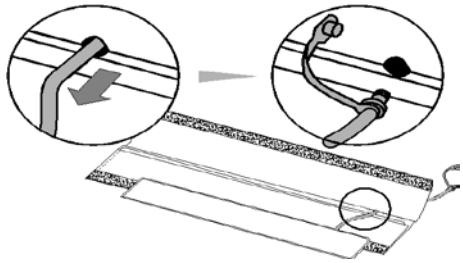
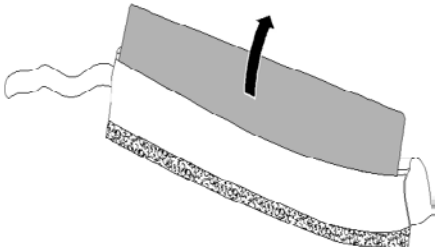
Your patient can be injured.

- Check the product for proper condition and functionality before every use.
- Protect the bladder from mechanical damage and UV radiation.
- Protect the cuff from contact with preoperative skin treatment agents, as these will reduce the service life of the cuff.

The cuff is to be subjected to a visual and functional inspection with the following procedure before each use:

1. Before bringing the cuff into the operating theatre, ensure that all information on the cuff's direct marking is fully legible.
2. Ensure that the cuff shows no tears, holes, or damaged seams.
3. With standard connectors: Check that the sealing rings on the connectors are correctly seated and functioning properly. Ensure that the sealing rings do not show any cracks.
4. Ensure that the cuff and the hook-and-loop strip are intact and free from foreign matter (e.g., cotton fibres or bandage remnants).
5. Check and ensure that the fastening strength of the hook-and-loop strip is sufficient.
6. Do not use damaged or defective cuffs any longer.
7. Conduct a functional check on the tourniquet. Observe the tourniquet's Instructions for Use.

4.2 Disassembly

Disassembling the cuff	
	1. Open the hook-and-loop strip of the fabric sleeve and then open the cuff.
	2. Remove the bladder from the pocket.
	3. Pull the cuff hose through the openings.
	☞ Remove the foil from the pockets.

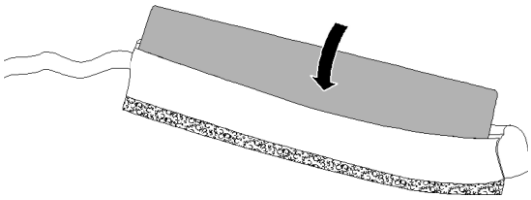
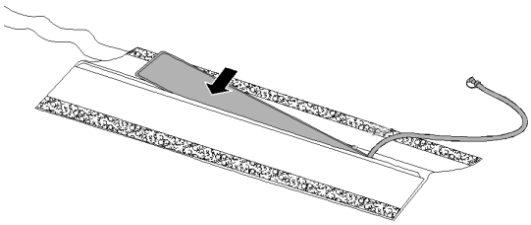
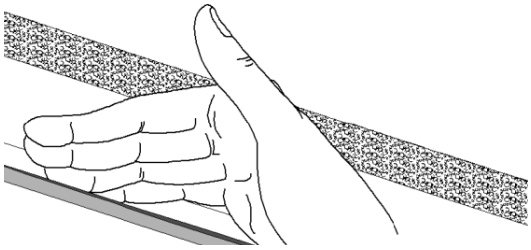
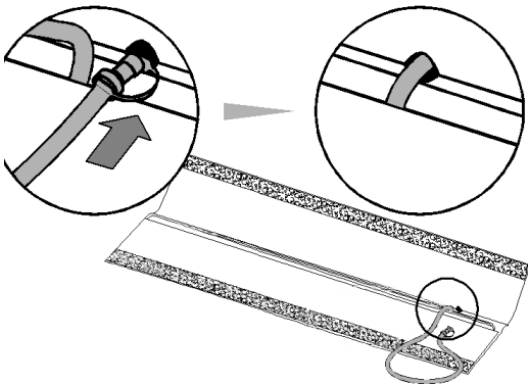
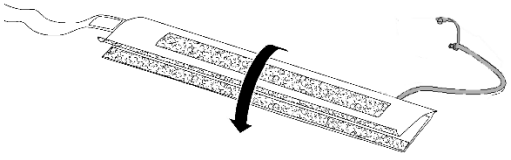
4.3 Assembly of the cuff

⚠ WARNING

Loss of function of the cuff due to incorrect assembly. Nerve damage possible due to inhomogeneous pressure distribution on the nerve!

Your patient can be severely injured.

- Observe the correct position of the bladder and foil in the sleeve when assembling the cuff.
- The cuff may be used only in correctly assembled, perfect condition.

Assembling the cuff	
	1. Insert the foil in the pocket.
	2. Insert the bladder in the pocket under the foil. The bladder lies on the skin side.
	3. Make sure the foil and bladder are flush.
	4. Push the cuff hose through the openings of the pocket and pull it through to the outside. ☞ Make sure the cuff hose is not kinked.
	5. Close the hook-and-loop strip carefully. 6. Make sure both parts of the hook-and-loop-strip are flush.

4.4 Applying the cuffs

⚠ DANGER

Insufficient expertise regarding the product or procedure can cause the death of the patient!

Your patient can be severely injured.

- Make sure the cuff is applied only by health care professionals with sufficient knowledge.

⚠ WARNING

Incompatible accessories or hose combinations will result in a loss of function. Increased risk of infection due to extended surgery time!

Deadly diseases may be transmitted.

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

⚠ CAUTION

Improperly routed connection hoses can impair functionality. Increased risk of infection during surgery time!

Your patient can be injured.

- Ensure that no connection hoses are kinked or clamped.

⚠ CAUTION

The cuff must not be disconnected from the tourniquet while it is inflated and the hoses are clamped. Increased risk of infection due to extended surgery time!

Your patient can be injured.

- Make sure the cuff pressure is always monitored by a tourniquet. The hoses must not be clamped.

Before applying the tourniquet, the patient's medical history must be taken by the physician. The correct selection and application of the tourniquet cuff, as well as the level of applied pressure and the duration of application, depend on the patient's condition (skin and tissue condition, vascular status and blood pressure, shape and size of the extremity, general condition, obesity, etc.) and are the sole responsibility of the physician.

4.4.1 Establishing a bloodless field

Establish a bloodless field according to the specifications of the treating physician. Possible measures are:

» Bring the patient's extremities into an elevated position.

» Wrap the patient's extremities with an Esmarch bandage (alternatively a roll cuff).

4.4.2 Applying the cuff

⚠ DANGER

Incorrect selection of the cuff size as well as duration or level of the applied pressure can lead to the death of the patient!

Your patient can be severely injured.

- The duration and level of the pressure applied to occlude the blood flow are the sole responsibility of the physician. The duration of blood flow occlusion depends on the diagnosis, the surgical technique, and the patient's condition (age, weight, skin and tissue condition, vascular status and blood pressure, shape and size of the extremity, general condition, obesity, etc.).
- Subject the patient to a preoperative examination to identify risk factors and determine the correct selection of the cuff and the pressure while blood flow is occluded.
- Monitor the cuff and tourniquet while blood flow is occluded.

⚠ CAUTION

Preoperative skin treatment agents in the area where the cuff is applied can cause chemical burns and skin irritations!

Your patient can be injured.

- Make sure no preoperative skin treatment agents (disinfectants) are where the cuff is applied or can accumulate there or flow into the area of application. If necessary, seal the application area of the cuff distally.

⚠ CAUTION

Inhomogeneous pressure distribution in the tissue or detachment of the cuff on its own due to insufficient overlapping of the cuff ends. Increased risk of infection due to extended surgery time!

Your patient can be injured.

- When putting on the cuff, make sure the end of the cuff fully covers the red mark indicating the required overlap.

⚠ CAUTION

Tissue damage to patients can be caused by applying the cuff inappropriately!

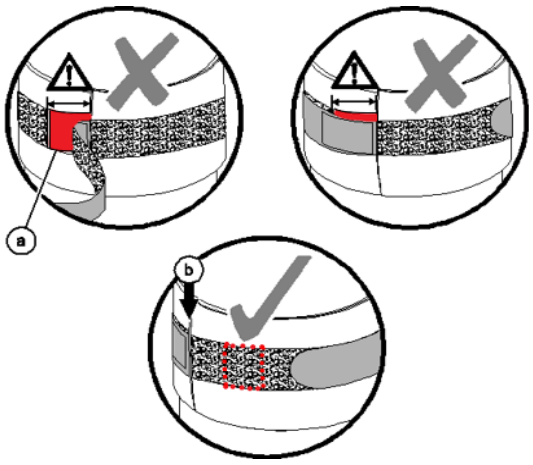
Your patient can be injured.

- To avoid injuries, make sure no skin folds are created under the applied cuff.
- Do not exert any high pre-tension when applying the cuff, in particular when using size 2XL and 3XL cuffs.
- Do not turn or move the cuff with the pressure applied to avoid serious skin injuries, irritation and abrasion. To correct the position: deflate the cuff, open the cuff fastener, reapply the cuff in its correct position and inflate it again.
- Remove the cuff from the patient only when it is fully deflated.

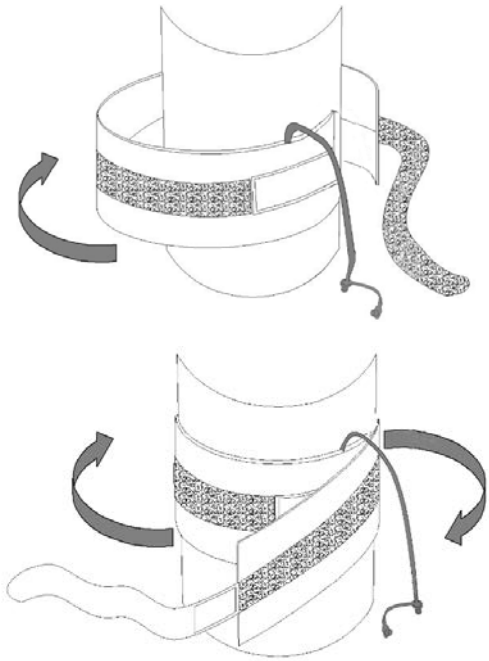
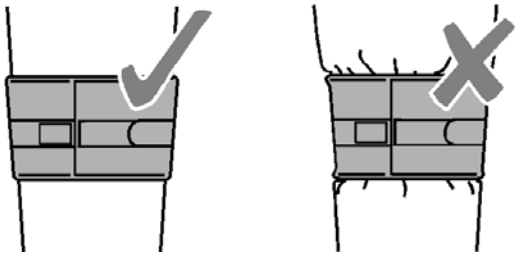
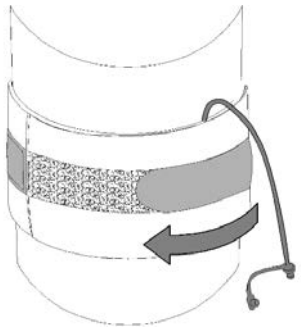
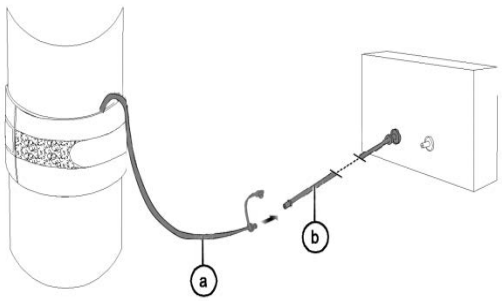
The selection of the cuff size is based on the circumference of the extremity. The following table shows the available cuff sizes, depending on the circumference of the extremity. The individual cuff sizes are also colour-coded. To determine the correct cuff size, it is recommended to use the UT 1315 cuff size tape.

Circumference of the extremity	Cuff size	
10 - 18 cm	2XS	Grey
14 - 21 cm	XS	Light blue
21 - 40 cm	S	Red
40 - 49 cm	M	Green
49 - 57 cm	L	Dark blue
57 - 78 cm	XL	Brown
78 - 97 cm	2XL	Black
97 - 117 cm	3XL	Orange

Applying the cuff



1. Make sure the end of the cuff fully covers the red mark (a) for the necessary overlapping and reaches up to the beginning of the loop strip (b).
   - In the event of excess overlapping:
     » Use a smaller cuff size
   - In the event of insufficient overlapping:
     » Use a larger cuff size
2. Optional: If necessary, pad the cuff thinly at the user's discretion.

	3. Lay the cuff around the extremity.
	4. Check the cuff fitting for skin folds.
	5. Close the cuff fastener.
	6. Connect the cuff hose (a) to the connection hose (b) leading to the tourniquet. • Ensure the hoses are attached to the correct connectors. • Observe the tourniquet's Instructions for Use. • You must clearly hear the connector on the connection hose click when plugging it onto the cuff hose. • If possible, route the cuff hoses away from the surgical site during use.

4.5 Occlusion of blood flow

⚠ CAUTION

Incompatible tourniquets will result in a loss of function. Increased risk of infection due to extended surgery time!

Your patient can be injured.

- Connect the cuff only to a compatible tourniquet for cuffs.

⚠ CAUTION

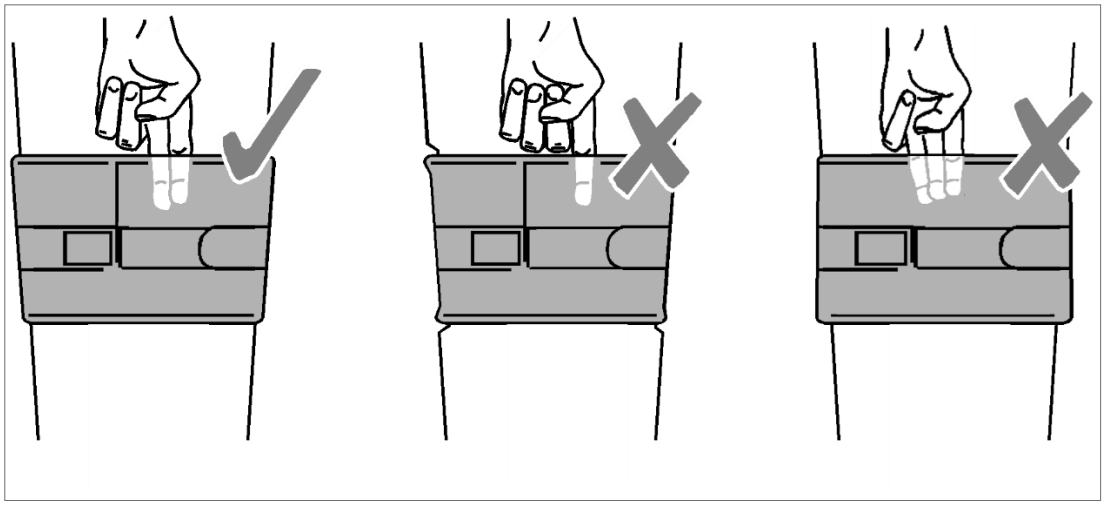
High temperatures under surgical lights can cause heat accumulation!

Your patient can be injured.

- Consider reducing the duration of blood flow occlusion at high temperatures. Do not actively warm children while blood flow is occluded.

Cuff

1. Preselect the pressure on the tourniquet. Observe the tourniquet's Instructions for Use.
2. Inflate the cuff. Adapt the pressure to the individual patient to prevent nerve/muscle damage due to excess pressure. Select the lowest pressure necessary.
3. Grip under the cuff with two fingers to check whether you can clearly feel the counterpressure.
   - Check on the proximal side.



4. Monitor the cuff and tourniquet.
5. Monitor the time on the tourniquet regularly.

4.6 Ending the occlusion of blood flow

4.6.1 Reducing the pressure in the cuff

- Deflate the cuff in several stages using the tourniquet. Observe the tourniquet's Instructions for Use.
- Reduce the pressure in the cuff slowly, if necessary in stages, to prevent metabolites from being washed in quickly when blood flow is restored.

4.6.2 Removing the cuff

1. End the occlusion of blood using the tourniquet. Observe the tourniquet's Instructions for Use.
2. Disconnect the cuff hose from the connection hose or tourniquet.
3. Open the cuff fasteners.
4. Remove the cuff from the extremity.
5. Reprocess the cuff; see chapter '5 Reprocessing' on page 24.

5 Reprocessing

5.1 Safety instructions for reprocessing

5.1.1 General safety instructions

We recommend that you always document any maintenance work and part replacements in writing.

It is the responsibility of the user to ensure that the required cleaning and disinfection results are achieved. Validation and routine monitoring of the procedure will generally be necessary.

Reprocessing may be carried out only by persons who have the appropriate expertise. The person in question must possess the equipment required to carry out these measures.

5.2 Reprocessing the cuffs

5.2.1 Overview

Surface	After each application	Pre-cleaning	Wipe cleaning	Wipe disinfection	Automated cleaning and disinfection	Comment
Fabric sleeve	X	X			X	
Foil	X	X			X	
Bladder including cuff hose and connector with protection cap	X	X	X	X		

5.2.2 Material compatibility

NOTICE

Unsuitable cleaning agents and disinfectants!

The product may become damaged.

Do not use any:

- cleaning agents containing solvent-based components.
- cleaning agents with a pH value >10.5.
- disinfectants that contain hydrogen peroxide.
- disinfectants containing organic or inorganic acids or bases, as these may cause corrosion damage.
- disinfectants containing chloramines or phenol derivatives, as these may cause stress cracks in the plastic materials used.

☞ Follow the manufacturers' instructions for cleaning agents and disinfectants regarding material compatibility, concentration, and contact time.

NOTICE

Unsuitable disinfectants!

The product may become damaged.

Only disinfectants from the following active substance groups may be used for manual disinfection of the bladder, including the cuff hose and connector with protection cap:

- Quaternary ammonium compounds
- Alcohols
- Glycol derivatives

Use only cleaning agents and disinfectants that are suitable for the reprocessing of medical devices. Use disinfectants whose effectiveness has been confirmed by recognised test procedures (e.g., according to VAH, DGHM, or RKI listing).

5.3 Procedure

	Instructions
Warnings	
⚠ WARNING	**Danger to users, patients and third parties** • Reprocess the brand new product clinically after removing the transport packaging and before using it for the first time (the bladder, including the cuff hose and connector with protection cap, is reprocessed by means of wipe disinfection; the fabric sleeve and the foil are reprocessed by means of automated cleaning and disinfection). • Use only clinically reprocessed cuffs. • Ensure that a validated reprocessing procedure is in place.
⚠ WARNING	**Risk of infection due to unsuitable aids** Pathogens can be transmitted. • Wear disposable gloves during all cleaning and disinfection procedures. • Use only aids that can be suitably reprocessed or disposable products.
⚠ WARNING	**Risk of infection due to unsuitable reprocessing** Pathogens can be transmitted. • Make sure all areas of the product are easy to access. • Use only suitable load carriers for automated reprocessing. • Always use demineralised water for the final rinse.
NOTICE	**Avoiding product damage** • Frequent cleaning, disinfection, sterilisation, and prolonged storage times reduce the ageing resistance of the cuff. • Unsuitable aids: Use only lint-free, soft cloths and soft brushes.

	Instructions
Preparations prior to cleaning **⚠ WARNING**	Prevent coarse dirt from drying onto the cuff. Clean the cuffs directly after use to ensure effective reprocessing. 1. Remove the cuff from the tourniquet. 2. Disassemble the product for reprocessing into the following components: • Fabric sleeve • Foil • Bladder including cuff hose and connector with protection cap 3. Close the protection cap on the hose connection to prevent liquid from entering the bladder. 4. Remove any coarse dirt from the individual parts of the cuff. For manual precleaning, hold the individual parts of the cuff under running water or place them in suitable cleaning solution. Use only a soft brush or a clean, soft cloth to remove any coarse dirt.
	Instructions
Manual cleaning ***NOTICE*** Accessories: • Lint-free disposable cloths • Soft brush (brush head ≤ 1mm) • Cleaning agent: mikrozid® AF wipes	Manual cleaning and disinfection is intended only for the bladder, including the cuff hose and the connector with protection cap. 1. Clean the surfaces of the bladder and cuff hose, including the closed connectors, evenly with a clean, lint-free cloth that is slightly damp (not wet) and moistened with cleaning agent (mikrozid® AF wipes). 2. Wrap the cloth moistened with cleaning agent around the connector and clean it using circular movements to thoroughly remove any dirt from gaps and grooves. For stubborn residue, use a soft brush in addition. 3. If visible contamination remains, repeat the cleaning process to avoid impairing the effectiveness of disinfection.

	Instructions
Manual disinfection Accessories: • Lint-free disposable cloths • Soft brush (brush head ≤ 1mm) • Disinfectant: mikrozid® AF wipes	1. Wipe evenly over the surfaces of the bladder, including the cuff hose and the connector with protection cap, with a damp (never wet), clean and lint-free cloth moistened with disinfectant (mikrozid® AF wipes). 2. Wrap a fresh cloth moistened with cleaning agent around the connector and clean it using circular motions to thoroughly remove any dirt from gaps and grooves. 3. Additional step for hard-to-reach areas (e.g., the recess of the connector): Place a fresh cloth moistened with disinfectant over a soft, non-abrasive brush (brush head ≤ 1 mm). Insert the brush covered with the cloth into the recess. Wipe gently in circles at least three times, then wipe gently back and forth three times, ensuring that the surface of the recess is fully wetted. 4. Use a fresh cloth moistened with disinfectant and wipe all surfaces one last time in circular motions to remove any residues and ensure even wetting. Allow the disinfectant to act for the required contact time (1 minute).
	Instructions
Automated cleaning and disinfection	Automated reprocessing is intended only for the fabric sleeve and foil, using a washer-disinfector compliant with DIN EN ISO 15883. The following parameters for automated cleaning and disinfection have been validated: • Secure the product on a suitable load carrier and position the fabric sleeve and foil so that the cleaning agent reaches all surfaces. Ensure that the fabric sleeve is fully wetted on both the inside and the outside. During validation, a load carrier for laboratory glassware was used (width 55 cm, height 19 cm, depth 27.5 cm). Distance between spikes: 5 cm. • Clean and disinfect using a suitable programme:
	Automated cleaning: • Pre-rinse: 1 min with cold water • Cleaning: 5 min, 55 °C with demineralised water and the cleaning agent neodisher® MediClean forte (concentration: 0.5% (5 ml/l)) • Intermediate rinse: 1 min with cold, demineralised water **Automated disinfection:** • Disinfection: 5 min, 93 °C with demineralised water
NOTICE	Make sure no visible dirt is present any more. Repeat reprocessing if necessary.

	Instructions
Drying	Allow the individual components of the cuff to dry in the air or wipe it with a clean, soft, lint-free (disposable) cloth.
	Instructions
Maintenance, check and inspection	1. Check the success of reprocessing by means of visual inspection. 2. If reprocessing was not successful, reprocess the product again. 3. Assemble the cuff (‘4.2 Disassembly’ on page 16). 4. Conduct a visual and functional inspection before application (‘4.1 Visual and functional inspection before application’ on page 15).
	Instructions
Storage	The cuff must be stored in dry condition, protected from dust and sunlight, and at room temperature. It should be stored in protective packaging for contamination-free storage.
	Instructions
Service life	The cuffs have a service life of 50 reprocessing cycles. After exceeding this number of cycles, the operator will assume the responsibility and liability for its functionality and condition.

6 Maintenance and repairs

Damaged foil, bladder or fabric sleeve

- Replace the cuff and dispose of the damaged cuff.

Repairs

The product contains no parts that the user could repair themself.

- Dispose of the defective cuff.

7 Detecting and rectifying errors

Fault	Cause	Solution
No pressure build-up in the cuff.	Connector not plugged in or defective. Tourniquet defective. Bladder defective.	• Check the connection to the tourniquet. • Replace the cuff. • Check the tourniquet.
Cuff cannot be deflated.	Cuff hose kinked or jammed. Tourniquet defective.	• Check the routing of the cuff hose. • Disconnect the cuff connection. • Check the tourniquet.
Cuff loses pressure when blood flow is occluded.	Bladder defective. Connection hose defective. Hose or connector defective. Tourniquet defective.	• Adjust the pressure. • With standard connectors: Check the connector sealing after finishing surgery. • Replace the defective bladder or hose with a new cuff after finishing surgery. • Check the tourniquet.
Cuff fastener opens.	Cuff fastener dirty with foreign objects.	• Clean the hook-and-loop strip with a hook-and-loop cleaning comb (300.001).
Cuff fastener worn.	Frequent use and reprocessing.	• Replace the cuff.
Cuff slips distally.	Cuff overlapping is insufficient. Strongly conical extremity.	• Check the necessary cuff overlapping (‘4.4 Applying the cuffs’ on page 18) and select a larger cuff if necessary. • Use a conical cuff (UT 1332-XL/UT 1330-XL).
Cuff does not have a round fit anymore.	Foil deformed.	• Replace the cuff.
Cuff does not fit around the extremity.	Incorrect cuff size selected.	• Select a suitable cuff size. • Determine the size using the cuff size tape.

8 Accessories

Connection hoses to the cuff

REF number	Description
UT 1276-300	Connection hose-D (orange-orange), 3 m
UT 1276-500	Connection hose-D (orange-orange), 5 m
UT 1277-300	Connection hose-A (orange-orange), 3 m
UT 1277-500	Connection hose-A (orange-orange), 5 m
UT 1187-500	Connection hose-D (orange-standard), 5 m
UT 1188-500	Connection hose-A (standard-orange), 5 m
UT 1321-300	Connection hose-D (standard-standard), 3 m
UT 1321-500	Connection hose-D (standard-standard), 5 m

Accessories for the cuff

REF number	Description
UT 1315	Cuff size tape
300.001	Hook-and-loop cleaning comb

9 Using the device in combination with other devices

9.1 ATMOS Tourniquets

Feature	Value
Type designation	UT 1380-E, elsa, mein Tourniquet 1 channel
	UT 1380-EP, elsa, mein Tourniquet 1 channel with printer
	UT 1380-H, heidi, mein Tourniquet 2 channel
	UT 1380-HP, heidi, mein Tourniquet with printer
	UT 1380-S, sophie, mein Tourniquet 2 channel (CGS)
	UT 1380-SP, sophie, mein Tourniquet 2 channel with printer (CGS)
Maximum pressure	600 mmHg
Compatibility Connector	Orange connector (Rectus connection)

9.2 Tourniquets from third-party suppliers

Feature	Value
Type designation	Tourniquets from third-party suppliers
Maximum pressure	600 mmHg
Compatibility Connector	Standard CPC connector

9.3 ATMOS Connection Hoses

Feature	Value
Type designation	UT 118X-XXX Connection hose
	UT 127X-XXX Connection hose
	UT 1321-XXX Connection hose
Compatibility Connector	Orange connector (Rectus connection) or Standard CPC connector

9.4 Size tape

Feature	Value
Type designation	UT 1315 Cuff size tape
Compatibility Cuff	Suitable for ATMOS Cuffs

10 Disposal and environmental specification

10.1 Disposal

Packaging

Please recycle the product packaging.

Cuffs and connection hoses

1. Clean and disinfect the product.
2. In Germany: Send the product back to ATMOS or your specialist dealer. They will dispose of the product properly.
3. In other countries: Dispose of the product properly and in accordance with country-specific laws and regulations.

10.2 Expected service life

The ATMOS Cuffs have an expected service life of 50 reprocessing cycles. Regular, thorough cleaning and disinfection of the cuffs and their applied parts as well as operation of the products in line with the Instructions for Use are assumed.

10.3 Environmental specification

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

The basis for the disposal of medical waste in the European Union is the European Waste Directory. If necessary, countries down to the municipal level may issue their own waste management regulations, which must be observed.

Outside the European Union, the respective national regulations on the disposal of medical waste must be observed.

Type of disposal	Includes	Waste code*
Packaging	Separation of cardboard, paper and plastic	15 01 01 15 01 02 15 01 06
Article with patient contact	Cuff Components of the cuff	18 01 04 20 01 11
Articles without patient contact	Cuff Components of the cuff	20 01 11

* Waste code in accordance with the currently valid European Waste Catalogue Ordinance (AVV)

11 Technical Data

Material	Cuff hose: EPDM Fabric sleeve: polyester, viscose, polyamide
Maximum pressure	650 mmHg
Colour	Dark blue with black velcro tape and colored label
Dimensions	See table (Page 5)
Weight	See table (Page 5)
Packaging unit	1 pc.
Reuse	Reusable
Reprocessing	See chapter ‘5 Reprocessing’ on page 24.
Risk classification	Class I according to Rule 1
CE marking	CE
Environmental conditions Transport/storage • Temperature range • Humidity without condensation • Air pressure	 -30...+60 5...95 % 700...1060 hPa
Environmental conditions Operation • Temperature range • Humidity without condensation • Air pressure	 +5...+40 °C 5...95 % 700...1060 hPa
Reference number (REF)	See table (Page 5)

12 Notes



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