



INSTRUCTIONS FOR USE

Reusable convective warming blankets and warming mats

MOECK & MOECK

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Subject to technical modifications

Due to the constant development of the product, the figures and technical details included in these instructions for use may differ slightly from the current status.

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1 GENERAL INFORMATION

1.1 Intended purpose

Reusable warming blankets and warming mats for patient temperature control with a convective warming device.

1.2 Indications

For the treatment of patients in medical facilities where temperature management is required.

1.3 Contraindications

- ► Warming of ischaemic limbs
- ► Warming of body parts distal to an arterial clamp
- Any application where influencing the patient's body temperature is medically contraindicated
- It should be noted that heat therapy can increase the effectiveness or supply of medicines to patients, which may cause harm to patients

1.4 Target patient group

- ► Adult patients
- ► Paediatric patients (premature infants from 700 g)

1.5 Intended users

▶ Personnel with medical training

1.6 General features

▶ Professional medical devices

Reusable convective warming blankets for optimal patient temperature control.

Variety of options

A wide range of products with various cutting guides and models for different applications and patient groups.

• Flexibility for patient positioning One or more hose Connections and practical snap-fasteners for ease of use.

Versatility

Can be used before, during and after surgery, whenever temperature management is required.

Flexible application in terms of time Suitable for short-term or long-term use.

Flexible application in terms of control

Models for temperature control from above, models for temperature control from below, models for temperature control from above and below simultaneously.

Material properties

Radiolucent and latex-free: All textiles used.

▶ Patient-facing side (GREEN)

Breathable, antistatic polyester with soft feel and pleasant sensation on the skin.

► Non-patient-facing side (WHITE)

Polyester with polyurethane coating that acts as a barrier to air and fluids, and transfers the heat to the patient.

1.7 Product combination

All MOECK WARMING SYSTEM® warming blankets and warming mats are compatible with the TWINWARM series of air warming devices.



There is also a wide range of medical air warming devices whose function has been tested in combination with MOECK WARMING SYSTEM® warming blankets and warming mats (in accordance with IEC 60601-2-35). However, their use is the sole responsibility of the user.

More information is available on request

1.8 Symbol definitions

Symbols	Name/Definition/Reference number
	Manufacturer Indicates the manufacturer of the medical device Source: ISO 15223 [5.1.1]
CH REP	Representative in CH Indicates the authorised representative in Switzerland Source: Art. 4 para. 1 let. g MedDO
<u>~~</u>	Date of manufacture Indicates the date on which the medical device was manufactured Source: ISO 15223 [5.1.3]
LOT	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified Source: ISO 15223 [5.1.5]
REF	Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified Source: ISO 15223 [5.1.6]
SN	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified Source: ISO 15223 [5.1.7]
#	Model number Indicates the product's model or type number Source: ISO 15223 [5.1.10]
[]i	Consult the instructions for use or consult the electronic instructions for use Indicates the need for the user to consult the instructions for use Source: ISO 15223 [5.4.3]
A	Caution Indicates that caution is necessary when handling the device or controller close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences Source: ISO 15223 [5.4.4]
	Contains no natural rubber latex Indicates that there is no natural rubber latex or dry natural rubber latex as a material of construction within the medical device or the medical device's packaging Source: ISO 15223 [5.4.5] and Appendix B

Symbols	Name/Definition/Reference number
MD	Medical device Indicates that the item concerned is a medical device Source: ISO 15223 [5.7.7]
UDI	Unique Device Identifier Indicates a carrier that contains Unique Device Identifier (UDI) information Source: ISO 15223 [5.7.10]
C€	CE marking Demonstrates compliance with all applicable guidelines and regulations of the European Union
₽MAX ♣	Observe the maximum temperature of 40 °C when warming babies
<u> </u>	Wash at a maximum temperature of 70 °C Application of ISO 7000 – 3096
\otimes	Do not bleach Application of ISO 7000 — 124
0	Drying in the tumble dryer possible Low temperature; maximum output temperature 60 °C Application of ISO 7000 – 3107
×	Do not iron Application of ISO 7000 – 3113
<u>®</u>	Mild cleaning process Professional dry cleaning with tetrachloroethene and all solvents listed under symbol F Application of ISO 7000 – 3118

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2 WARNINGS AND SAFETY PRECAUTIONS



2.1 Warnings

WARNING! A signal word to indicate a potentially hazardous situation, which, if not avoided, may result in serious injury or death.

WARNING!

Measures to reduce the risk of thermal damage:

- ► The hose nozzle of the air warming device must be connected to a hose connection of the warming blanket or warming mat.
- Do not use any foils or similar materials between the patient's skin and the warming blanket or warming mat.
- The temperature for premature infants, newborns, babies and children must not exceed 40 °C. The vital signs of young patients must be continuously monitored during temperature control, and children must never be left unattended

WARNING!

Measures to reduce the risk of injury from impaired ventilation:

The warming blanket must not block the patient's airway due to the risk of suffocation.

WARNING!

Measures to reduce the risk of patient injuries from falls:

► To prevent the patient from sliding around or slipping off, the patient must be secured, especially when the operating table is tilted and warming mats are used.

WARNING!

Measures to reduce the risk of exposure to biological or chemical hazards:

 Cover unhealed wound surfaces — Only contact with intact skin is permitted.

2.2 Cautions

CAUTION! A signal word to indicate a potentially hazardous situation, which, if not avoided, may result in a minor or moderate injury

CAUTION!

The warming blankets and warming mats must be reprocessed before first use and after each use.

CAUTION!

MOECK WARMING SYSTEM® warming blankets should only be placed with the green side facing the patient.

CAUTION!

Warming blankets and warming mats may only be used with air warming devices for which the safety of the combination has been tested.

CAUTION!

The use and operation of warming blankets and warming mats is reserved exclusively for trained medical personnel.

CAUTION!

The operator should monitor the patient's body temperature at regular intervals.

CAUTION!

Do not place any heavy drapes or objects on the warming mat.

CAUTION!

To avoid the risk of capacitive current flow, please fold the push-button strip with stainless steel buttons outwards or cover the button with surgical tape.



2.3 Instructions for use

NOTICE! Read these instructions for use and those of the air warming device carefully before use.

NOTICE!

Reprocessing and repair of warming blankets and warming mats must only be carried out in accordance with the method prescribed by MOECK & MOECK.

NOTICE!

Before using the warming blankets or warming mats, make sure that they are undamaged:

- Do not use any warming blankets or warming mats with holes, tears or thermal damage.
- Do not use any mats with damaged or deformed 3D spacer fabrics.
- Do not use any warming blankets or warming mats that show signs of the polyurethane coating peeling off on the white side.

NOTICE!

Es muss ein Ersatzprodukt zur Verfügung stehen.

NOTICE!

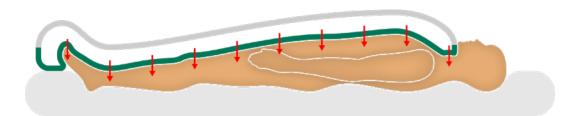
If an incident occurs that is directly or indirectly related to a MOECK WARMING SYSTEM® product, please immediately inform the manufacturer and the competent authority in your country and that of the patient (if different).

3 POSITIONING INFORMATION

3.1 Warming blankets — For use over the patient

Use a warming blanket over the patient:

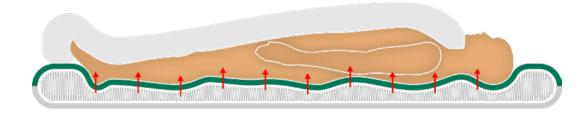
- ► Carefully lay the patient on the operating table.
- ► Spread out the warming blanket with the GREEN side (patient side) on the patient.
- ► Ensure that the patient is comfortable and in a stable position.
- Carefully fasten all straps or fixing devices to ensure that the patient is securely positioned during surgery.
- Ensure that the patient is sufficiently supported to prevent movement during the procedure.
- Connect the air warming device according to Section 5 "CONNECTION WITH AIR WARMING DEVICES" (Page 18).



3.2 Warming mats — For use under the patient

Use a warming mat under the patient:

- ► The warming mat is placed on the operating table with the GREEN side (patient side) facing up.
- ► Carefully lay the patient on the warming mat.
- Ensure that the patient is comfortable and in a stable position.
- Carefully fasten all straps or fixing devices to ensure that the patient is securely positioned during surgery.
- ► Ensure that the patient is sufficiently supported to prevent movement during the procedure.
- ► Connect the air warming device according to Section 5 "CONNECTION WITH AIR WARMING DEVICES" (Page 18).



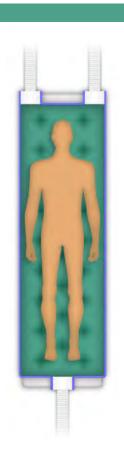
4 USAGE SPECIFICATIONS

The following pages show the individual warming blankets and warming mats and explain their proper use.

4.1 UNIVERSAL II (UNI II)

Тор	Bottom	Type No.	Dimensions¹ and weight	Hose connections	Features
		906	204×64 cm (L×W) ca. 1,960 g	•••	 Placement under the patient Full, unrestricted access to the patient The integrated layer reduces contact pressure and minimises fluid accumulation on the surface



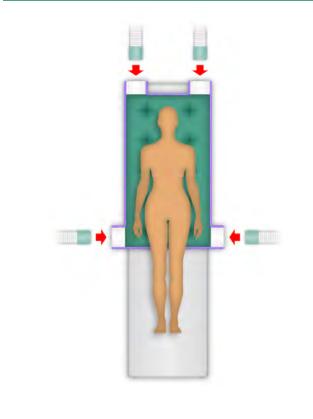


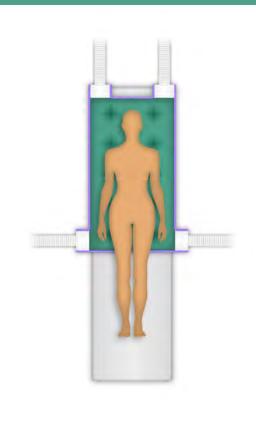
Recommendations for use ³											
↓	0>	(O)							***************************************		
Pre-OP	Post-OP	Intra-OP	Supine Position	Prone Position	Lateral Position	Lithotomy Position	Beachchair Position	Transfer	Paediatrics		

General surgery	✓	Neurosurgery	✓
Vascular surgery	\checkmark	Orthopaedics and Trauma surgery	\checkmark
Obstetrics and Gynaecology	\checkmark	Paediatrics	
Cardiac surgery	✓	Plastic surgery	✓
Head surgery	✓	Abdominal surgery	\checkmark
Maxillofacial surgery	✓	Thoracic surgery	\checkmark

4.2 UNIVERSAL III (UNI III)

Тор	Bottom	Type No.	Dimensions ¹ and weight	Hose connections	Features
		910	115×64 cm (L×W) approx. 1,200 g	•••	 Placement under the patient Full, unrestricted access to the patient The integrated layer reduces contact pressure and minimises fluid accumulation on the surface



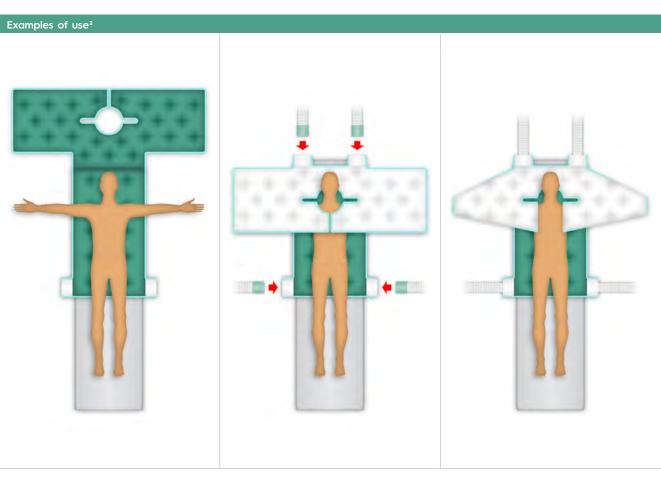


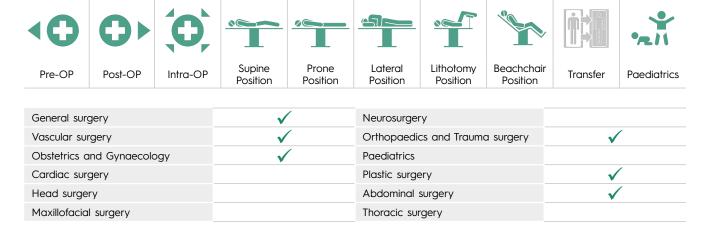
Recommendations for use ³										
4○	0>	(O)							***************************************	
Pre-OP	Post-OP	Intra-OP	Supine Position	Prone Position	Lateral Position	Lithotomy Position	Beachchair Position	Transfer	Paediatrics	

General surgery	√	Neurosurgery	✓
Vascular surgery	\checkmark	Orthopaedics and Trauma surgery	\checkmark
Obstetrics and Gynaecology	\checkmark	Paediatrics	\checkmark
Cardiac surgery	\checkmark	Plastic surgery	\checkmark
Head surgery	√	Abdominal surgery	√
Maxillofacial surgery	✓	Thoracic surgery	√

4.3 ADULT II / ERWACHSENE II (EW II)

Тор	Bottom	Type No.	Dimensions ¹ and weight	Hose connections	Features
		904	Upper section 70×170 cm (L×W) Lower section 115×64 cm (L×W) approx. 1,540 g	•••	 Placement under the patient The integrated layer reduces contact pressure and minimises fluid accumulation on the surface With upper body covering Separable using snap-fasteners in the breast area or at the head opening

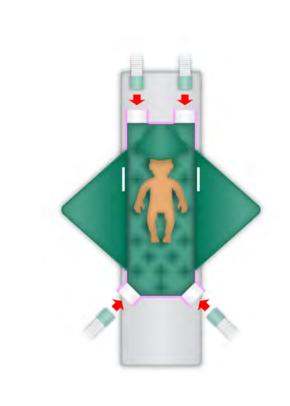


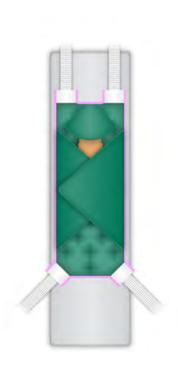


Recommendations for use³

4.4 BABY INFANT / BABY KLEINKIND (BKK)

Тор	Bottom		Dimensions ¹ and weight	Hose connections	Features
		902	130×52 cm (L×W) Wings 96×49 cm (L×W) approx. 890 g	•••	 Placement under the patient Full, unrestricted access to the patient The integrated layer reduces contact pressure and minimises fluid accumulation on the surface With head and body covering



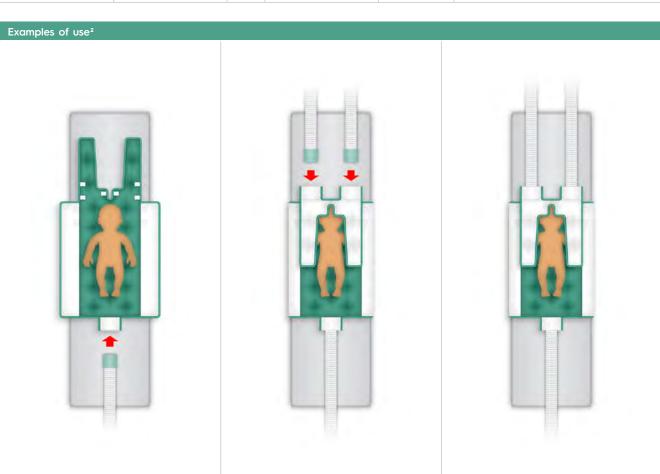


Recommendations for use ³										
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Pre-OP	Post-OP	Intra-OP	Supine Position	Prone Position	Lateral Position	Lithotomy Position	Beachchair Position	Transfer	Paediatrics	

General surgery		Neurosurgery	
Vascular surgery	\checkmark	Orthopaedics and Trauma surgery	
Obstetrics and Gynaecology		Paediatrics	\checkmark
Cardiac surgery	√	Plastic surgery	
Head surgery	√	Abdominal surgery	
Maxillofacial surgery	√	Thoracic surgery	

4.5 INFANT CARDIO / KLEINKIND CARDIO (KKC)

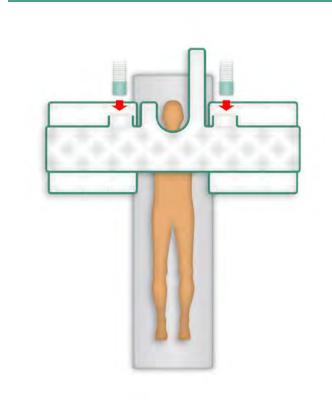
Тор	Bottom	Type No.	Dimensions¹ and weight	Hose connections	Features
		909	Thorax hoses 48×19 cm (L×W) Lower section 86×74 cm (L×W) approx. 590 g	•••	 Placement under the patient The integrated layer reduces contact pressure and minimises fluid accumulation on the surface Suitable for cardiac catheterisation tables Perforated lying area for fluid drainage

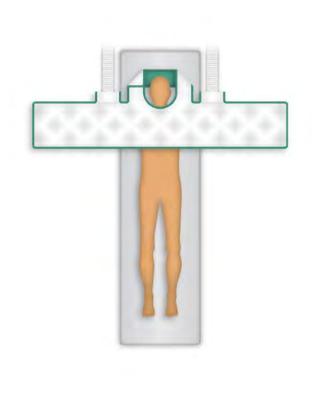




4.6 UPPER BODY / OBERKÖRPER (OKD)

Тор	Bottom	Type No.	Dimensions ¹ and weight	Hose connections	Features
		894	193×70 cm (L×W) Head section 57×16 cm (L×W) approx. 440 g	• •	 Placement over the patient For temperature control of the head and upper body Complete coverage of the arms

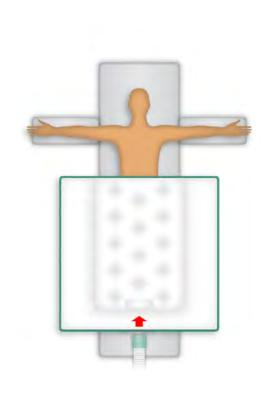


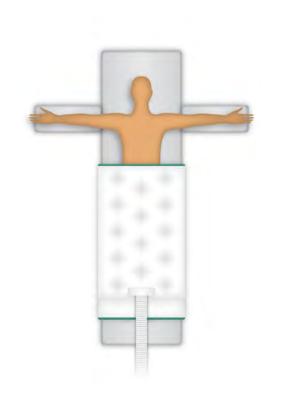


Recommend	Recommendations for use								
4⊕	0>	(O)							211
Pre-OP	Post-OP	Intra-OP	Supine Position	Prone Position	Lateral Position	Lithotomy Position	Beachchair Position	Transfer	Paediatrics
General surg	gery		\checkmark		Neurosurgery				
Vascular sur	gery		√		Orthopaedics and Trauma surgery			\checkmark	
Obstetrics a	ınd Gynaecolo	ogy	✓	✓ Paediatrics					
Cardiac surgery				Plastic surgery			✓		
Head surge	Head surgery		Abdominal surgery			✓			
Maxillofacial surgery				Thoracic surgery					

4.7 LOWER BODY / UNTERKÖRPER (UKD)

Тор	Bottom	Type No.	Dimensions ¹ and weight	Hose connections	Features
		897	115×118 cm (L×W) approx. 400 g	•	 Placement over the patient For tempering the lower body Suitable for temperature control as a full-body blanket for children





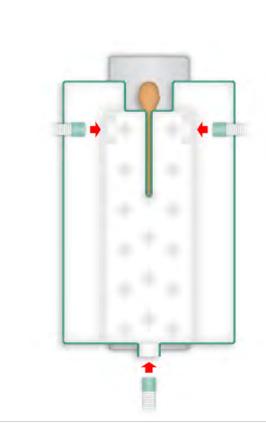
Recommendations for use ³									
↓	0>	(O)			<u> </u>				***************************************
Pre-OP	Post-OP	Intra-OP	Supine Position	Prone Position	Lateral Position	Lithotomy Position	Beachchair Position	Transfer	Paediatrics

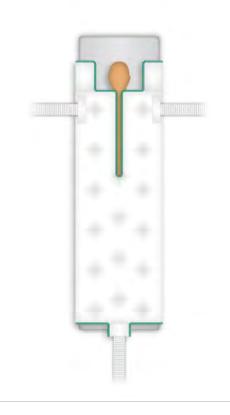
General surgery	✓	Neurosurgery	
Vascular surgery	\checkmark	Orthopaedics and Trauma surgery	\checkmark
Obstetrics and Gynaecology	\checkmark	Paediatrics	✓
Cardiac surgery	✓	Plastic surgery	√
Head surgery	\checkmark	Abdominal surgery	✓
Maxillofacial surgery	\checkmark	Thoracic surgery	√

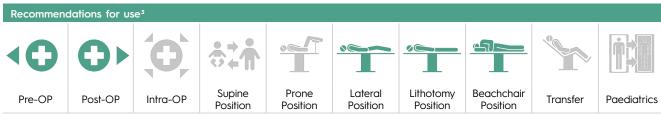
4.8 FULL BODY / GANZKÖRPER (GKD)

Тор	Bottom	Type No.	Dimensions ¹ and weight	Hose connections	Features
		895	196×128 cm (L×W) approx. 710 g	•••	 Placement over the patient For full-body temperature control Complete coverage of the patient Snap-fasteners allow separation of top third





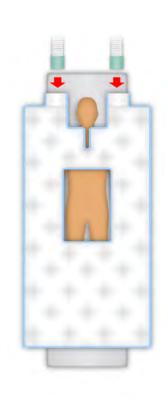


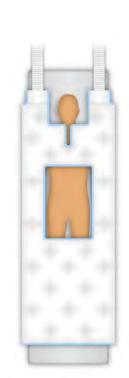


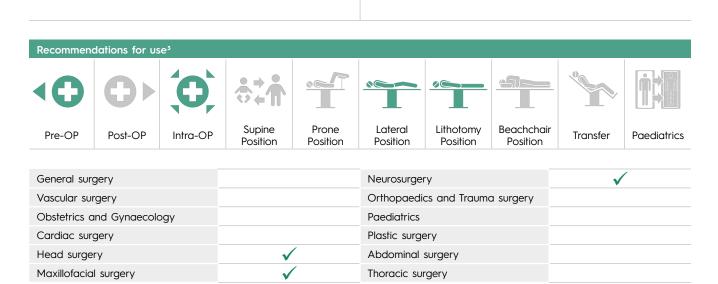
General surgery		Neurosurgery	✓
Vascular surgery		Orthopaedics and Trauma surgery	
Obstetrics and Gynaecology		Paediatrics	
Cardiac surgery		Plastic surgery	
Head surgery	✓	Abdominal surgery	
Maxillofacial surgery	\checkmark	Thoracic surgery	

4.9 MULTI I

Тор	Bottom	Type No.	Dimensions¹ and weight	Hose connections	Features
		908	180×94 cm (L×W) Cutout 55×36 cm (L×W) approx. 520 g	• •	 Placement over the patient For full-body temperature control With operating window and opening in the neck area



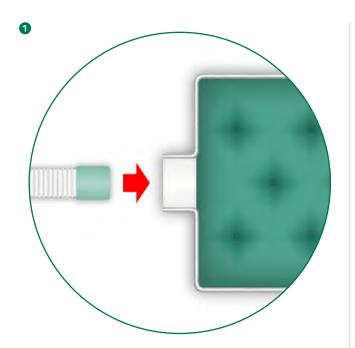


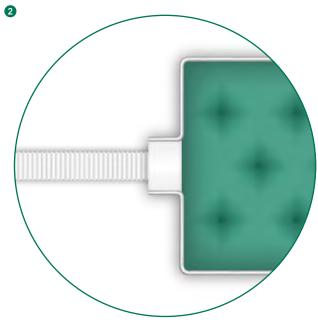


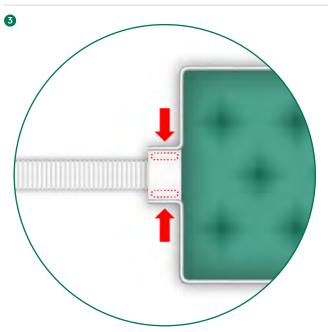
5 CONNECTION WITH THE AIR WARMING DEVICE

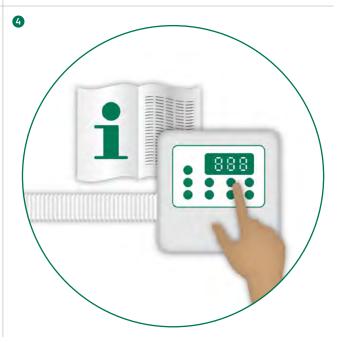
Instructions on connecting warming blankets and warming mats to the air warming device:

- Insert the hose nozzle into one of the hose connection openings on the warming mat (see Fig. 1)
- ► Push the end of the hose until it is behind the Velcro fastening (see Fig. 2)
- ▶ Press the Velcro on the blanket inlet together around the end of the hose so that the rest of the opening is closed. This must fix the hose in place so it cannot slip back out! (see Fig. 3)
- Make sure that airflow is not obstructed by a kinked hose!
- ► Switch the air warming device on according to its instructions for use and operate it (see Fig. ④)
- ► TIP: For best results, use in combination with our TWINWARM BB air warming device (see Section 1.7 "Product combination" Page 4)









REPROCESSING

- ► MOECK WARMING SYSTEM® warming blankets and warming mats are reusable. To protect patients and users, warming blankets and warming mats must be hygienically reprocessed before first use and after use.
- ▶ Please note the current national regulatory and legal requirements as well as the guidelines for hospital hygiene and infection prevention for the reprocessing of medical devices.
- ► The operator is generally responsible for hygienic reprocessing. MOECK & MOECK GmbH provides support with recommendations for carrying out hygienic reprocessing.
- ▶ Please see the manufacturer's document "Reprocessing Instructions for Reusable Convective Warming Blankets and Warming Mats".

PROPER USE

The manufacturer assumes no responsibility for defects, inadequate performance or insufficient safety of the warming blankets/mats if:

- ▶ They are used outside of their intended use
- ▶ Damage occurs due to non-compliance with the safety instructions and warnings
- ▶ The reprocessing of warming blankets/mats is not carried out correctly
- ▶ The recycling of warming blankets and warming mats is not carried out professionally.

WARRANTY

- ► Warranty claims shall only apply to defects for which the manufacturer is responsible.
- ► MOECK WARMING SYSTEM® warming blankets and warming mats are designed to be used at least 50 times and be reprocessed.

This warranty does not apply:

- ▶ To damage caused by improper reprocessing, e.g. deformation of the 3D spacer fabric, delamination of the polyurethane coating of the white textile, etc.
- ▶ To obvious mechanical damage, for example from sharp/ pointed objects, a water extraction press, etc.

DISPOSAL

Disposal of used warming blankets and warming mats is carried out by your reprocessing partner and/or their partner companies. They will carry out professional, documented disposal if reprocessing or maintenance are not possible.

REFERENCES

¹ Fabric products shrink by 3-5% during the first reprocessing cycle. A tolerance of ±2 cm also applies to the stated dimensions.

DISTRIBUTORS

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