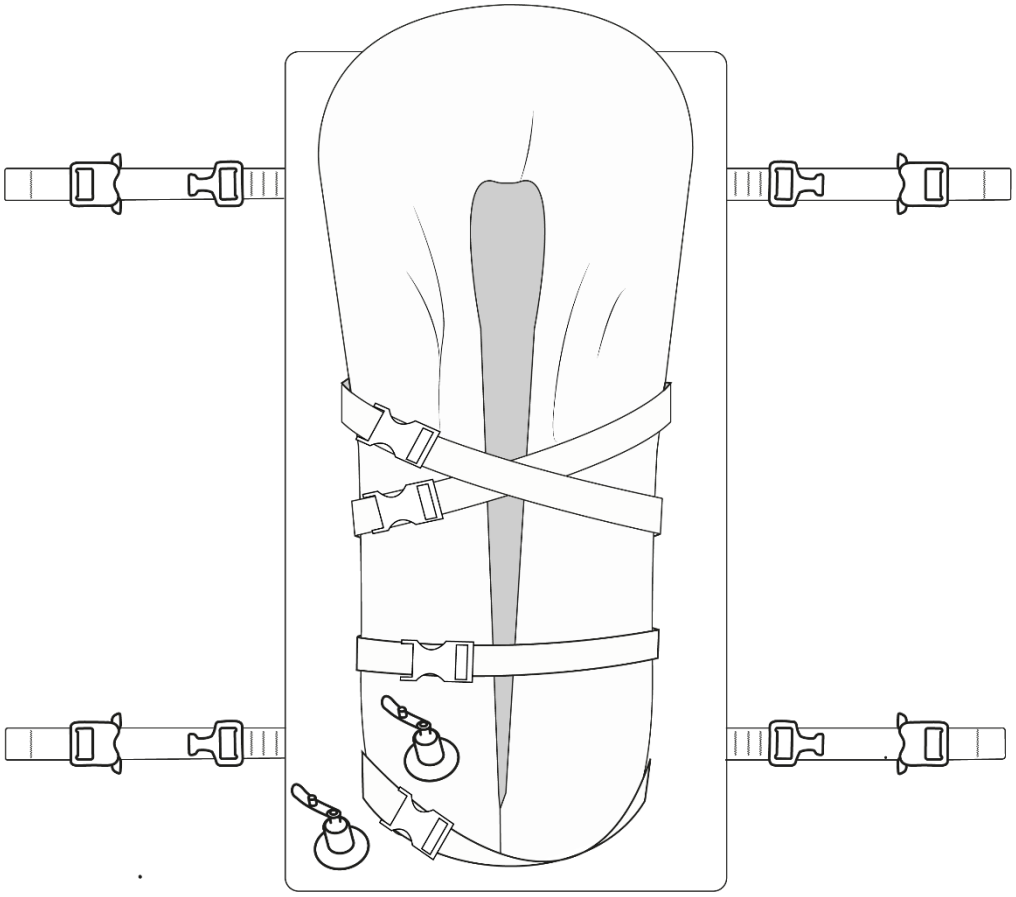
Instructions for Use (IFU)
RedVac Infant Transport System

REF VKF09CHX02 UDI 9010710138482

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MD

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IMPORTANT SAFETY NOTICE

This product may only be used by qualified medical professionals who have been trained in the use of the Infant Transport System.

Improper use may result in the following risks:

- injury to the patient
- compromise or obstruction of the airway
- incorrect securing of the patient or malfunction of the device

Before use:

- read these Instructions for Use completely and carefully
- ensure that you are familiar with the use of the device
- check the device for completeness and proper function before each use
- do not use the device if any parts are missing, damaged, or contaminated

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1. Intended Purpose, Intended Users, and Patient Population

1.1 Intended Purpose

The RedVac Infant Transport System is intended for the positioning, stabilisation and restraint of preterm infants, newborns and infants during pre-hospital, intra-hospital and inter-hospital transport.

The device is intended to secure preterm infants, newborns and infants during pre-hospital, intra-hospital and inter-hospital transport, including newborns already packaged for thermoregulation, while maintaining access for emergency clinical interventions.

It therefore supports the safe positioning of the patient during transport-related movement such as acceleration, braking, or changes in direction.

This device is **not** intended for:

- diagnosis or patient monitoring
- performing or supporting life-sustaining measures
- airway management or airway protection
- use outside the specified weight range

1.2 Intended User

This device is intended for use by trained medical professionals experienced in the transport and securement of infants.

This includes in particular:

- emergency medical services (EMS) personnel
- neonatal and paediatric transport teams
- clinical personnel with appropriate training in the safe transport of infants

1.3 Intended Patient Population

The RedVac Infant Transport System is intended for preterm infants, newborns and infants.

No minimum patient weight, minimum body length or minimum body size is specified by the manufacturer.

The adaptable dual-section vacuum design allows the system to conform to different patient sizes and body shapes, including very small preterm and newborn infants.

Suitability for an individual patient is determined by the ability to correctly position and safely stabilise the patient in accordance with these Instructions for Use.

The product must not be used for patients weighing more than 9 kg.

1.4 Use Environment and Compatibility

The device is intended for use on compatible stretcher systems in:

- road ambulances
- hospital transport areas, including intra-hospital and inter-hospital transport (for example transfer between departments)

The device may only be used with stretchers that:

- are approved for patient transport, and
- have suitable load-bearing frame elements that allow secure attachment of the stretcher attachment straps

The Infant Transport System is attached to the existing frame structure of the stretcher. The supplied stretcher attachment straps are removable and do not require permanent attachment to the trolley bed or stretcher.

	**Before each use, verify that the device is securely attached to the stretcher.**

1.5 Compatibility with Infant Warming Systems

The RedVac Infant Transport System is compatible with the following infant warming and thermoregulation products:

- Dräger TransWarmer® Mattress
- Reliance Medical Infant Warming Mattress
- Rapid Relief Infant Transport Mattress Warmer
- functionally comparable passive or active infant warming products

When correctly positioned, the warming product remains independent of the patient restraint and stretcher attachment systems and must not form part of the load-bearing fixation path.

The warming product may only be used if:

- it is positioned within the patient support area and does not interfere with the attachment of the Infant Transport System to the stretcher;
- all patient restraint straps, stretcher attachment straps, buckles and attachment points remain unobstructed;
- both vacuum sections remain fully functional;
- cables, sensors and other components do not interfere with the patient restraint or stretcher attachment systems; and
- correct positioning and stabilisation of the infant remain possible.

WARNING: Do not use a warming product if it interferes with patient restraint, stretcher attachment, vacuum stabilisation, airway access or required clinical access.

All warming and thermoregulation products must be used in accordance with their respective manufacturers' Instructions for Use.

2. Contraindications

The RedVac Infant Transport System **must not be used** in the following situations:

- for infants with a body weight of more than **9 kg**
- for infants who cannot be safely positioned or secured due to their clinical condition
- if the device or any of its components is damaged, visibly contaminated, or not functioning properly
- if suitable attachment to the stretcher is not possible

Note regarding airway access

The design of the device allows access to the airway and supports necessary medical interventions during transport.

Clinical assessment

Use of the device always requires clinical assessment by qualified personnel.

If safe use cannot be ensured, an appropriate alternative transport method must be selected.

3. Crash Safety Performance

The RedVac Infant Transport System has been tested for dynamic crash safety performance in accordance with the following standards:

- EN 1865-5:2012
- EN 1789:2020+A

Crash safety performance is valid only under the following conditions:

- the device has been installed exactly in accordance with these Instructions for Use.
- only the stretcher attachment straps supplied with the device are used
- the lower and upper vacuum sections are sufficiently rigid, that is, vacuum has been correctly applied
- all patient restraint straps have been correctly applied and secured
- the device shows no visible damage
- no third-party adapters, holders, or other modifications are used

Any deviation from these requirements results in loss of the verified crash safety performance.

4. Safety Information

4.1 Warnings – Risk of Serious Harm

Failure to observe the following warnings may result in serious injury or death.

- The device may only be used by trained medical professionals.
- The maximum patient weight of **9 kg** must not be exceeded.
- Never leave the infant unattended while secured in the product.
- Ensure that straps do not run across the face, airway, medical access sites, or tubing.
- Before moving the patient or the vehicle, check that vacuum stability is sufficient.
- Do not use the product if any components, for example straps, seams, buckles, valves, tubing, or material, are damaged or excessively worn.
- Use only original components and manufacturer-approved accessories.
- Use the device only on suitable and approved stretcher systems.
- Do not make any changes or modifications to the device.
- Discontinue use immediately if safe securing or stabilisation cannot be ensured.

4.2 Precautions

The following measures help prevent injury and malfunction:

- Before each use, inspect the straps, seams, and both evacuation valves (vacuum ports) for damage, leakage, and contamination.
- Ensure that all straps lie flat and are not twisted or folded.
- Apply vacuum gradually to avoid excessive compression of the thorax.
- Keep the infant´s airway and all medical devices, lines, and access points freely accessible at all times.
- Check strap tension after every movement of the stretcher, especially after lifting or exposure to vibration.
- Replace damaged components only with original parts approved by the manufacturer.
- Do not use abrasive cleaning agents, solvents, steam cleaners, or high-pressure cleaners.

4.3 Residual Risks

The RedVac Infant Transport System does not replace clinical monitoring or continuous supervision.

Even when correctly installed and used, the following residual risks may remain in particular:

- unforeseen changes in the infant´s clinical condition
- compromise of the airway due to body position, secretions, or displacement of medical devices
- loss of vacuum stability due to leakage or external influences, for example vibration
- loosening of the straps due to movement or patient activity

5. Quick Reference Guide

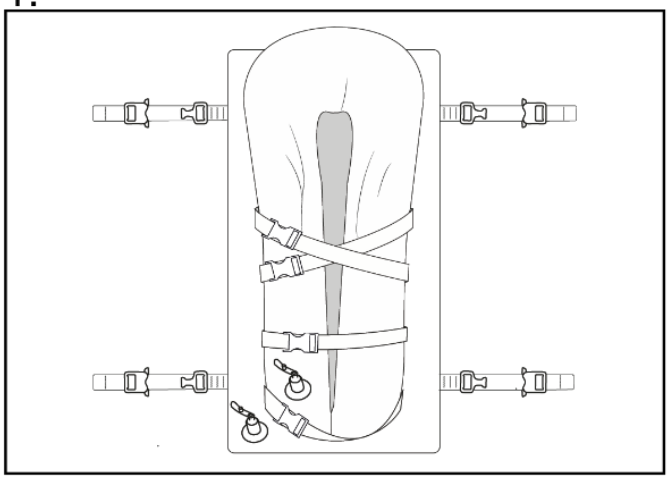
A separate illustrated quick reference guide is provided as part of these Instructions for Use. It shows:

- correct attachment to the stretcher
- positioning of the infant
- application of the restraint straps
- vacuum stabilisation

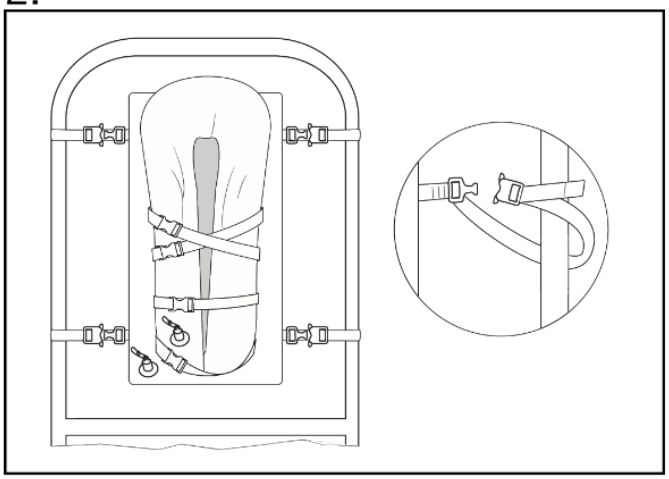
Refer to the illustrations before first use and whenever uncertainty exists.

5.1 Quick Reference Guide (illustrated)

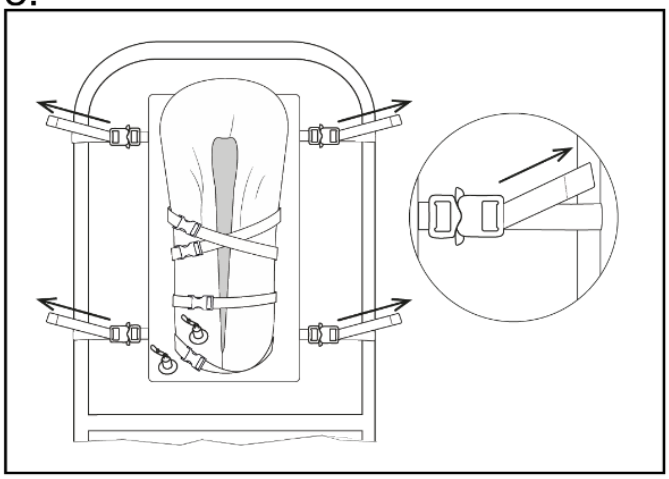
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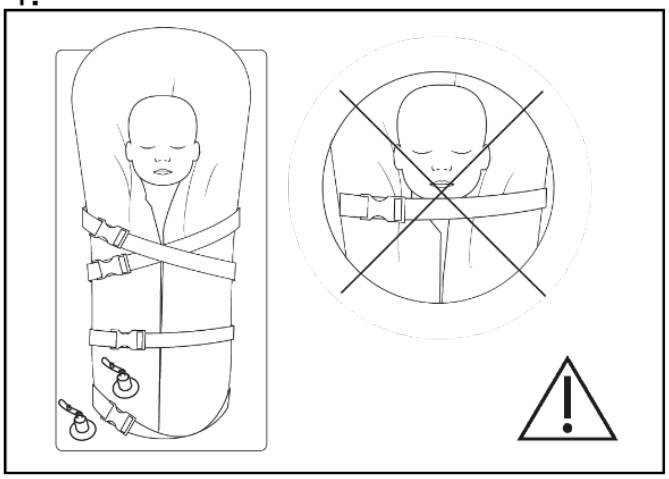
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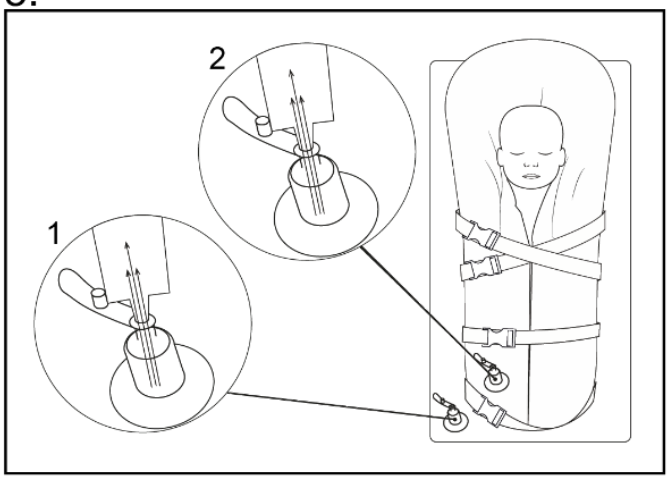
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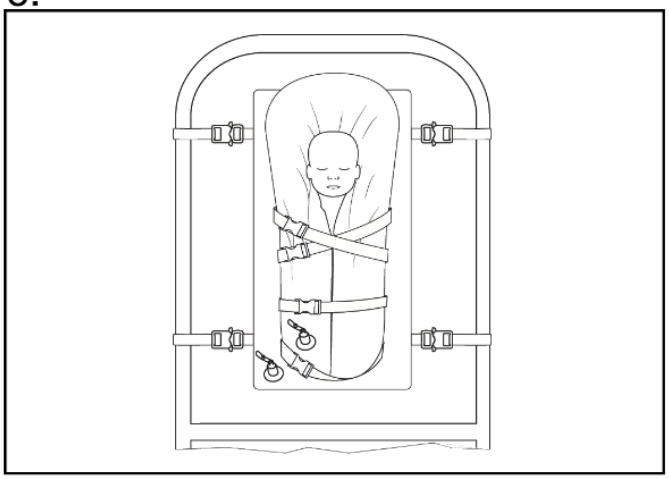
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6. Device Description

The device stabilises the infant during transport by limiting movement and providing secure positioning while maintaining access to the airway and to medical care.

The device is not intended for monitoring, diagnosis, or life-sustaining therapy.

The RedVac Infant Transport System uses two independently functioning vacuum sections for patient positioning and stabilisation.

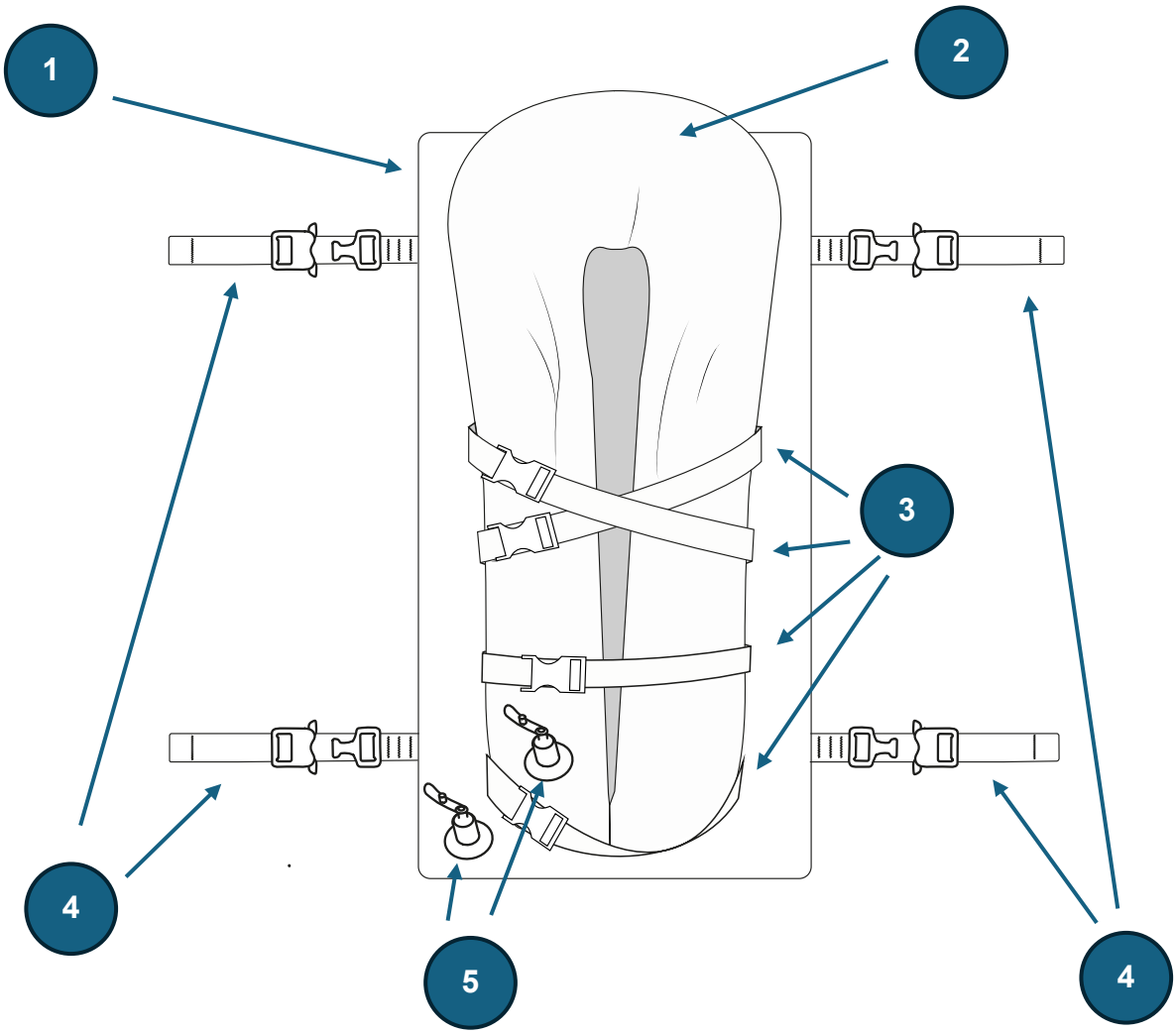
The lower vacuum stabilisation mattress forms a firm, form-stable supporting surface beneath the patient when evacuated.

The upper vacuum moulding chamber conforms individually around the patient’s body and provides additional lateral and close-fitting stabilisation.

This dual-section vacuum design allows the system to adapt to different patient sizes and body shapes, including very small preterm and newborn infants, without relying solely on a predefined restraint strap geometry.

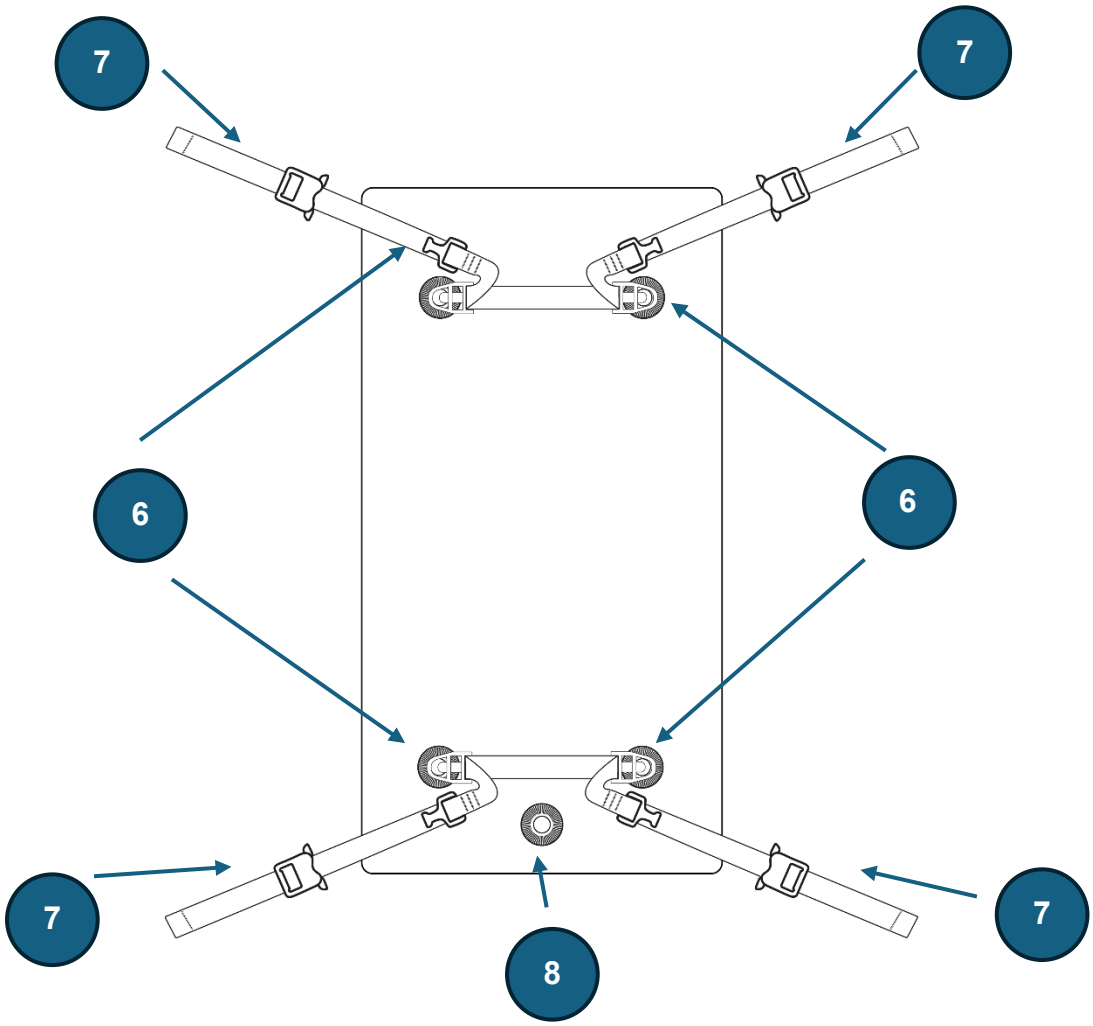
6.1 Components

6.1.1 Top View



1	Lower vacuum stabilisation mattress
2	Upper vacuum moulding chamber
3	Patient restraint straps (upper body strap, lower body strap, and foot strap)
4	Stretcher attachment straps with quick-release buckles
5	Evacuation valves (vacuum ports)

6.1.2 Bottom View



6	Adapter elements (mushroom-head receptacles for click system)
7	Stretcher attachment straps with quick-release buckles
8	Mushroom-head adapter for cover element (wipe-clean cover)

7. Parts and Components Checklist – Before Each Use

Do not use the device if any components are missing, damaged, or not functioning properly.

Before each use, check that all components are present and in proper working condition.

8. Installation on the Stretcher

8.1 Compatibility

The RedVac Infant Transport System is designed for use with a wide range of patient transport devices used in pre-hospital, hospital and rescue operations.

The system has been evaluated for compatibility with appropriate transport equipment, including:

- Stryker Power-PRO TL
- Stryker Power-PRO XT
- Ambulance stretchers
- Hospital patient trolleys
- Spine Boards
- Basket Stretchers (Rescue Stretchers)
- Other transport devices providing suitable attachment points for safe patient restraint

The supplied removable stretcher attachment straps allow secure installation without requiring permanently mounted fixation straps on the transport device.

Before use, the operator shall ensure that the selected transport device provides suitable attachment points and that the Infant Transport System is correctly installed in accordance with these Instructions for Use.

Compatibility Documentation

Compatibility statements or compatibility assessment documents for specific transport devices are available from Kohlbrat & Bunz GmbH upon request.

Where required, compatibility evaluations can be provided for individual stretcher or transport systems to support local validation, procurement or regulatory requirements.

8.2 Requirements for the Stretcher

Use the device only with stretcher systems that are suitable and approved for patient transport.

The stretcher must meet the following requirements:

- It is designed for the combined weight of the infant and the device.
- It has stable, load-bearing frame elements for secure attachment of the fixing straps.
- It allows secure strap attachment without slipping, loosening, or deformation.

The Infant Transport System is attached to the existing frame structure of the stretcher.

Before each use, verify that the device is securely attached to the stretcher.

8.3 Approved Method of Attachment to the Stretcher

- Use only the stretcher attachment straps supplied with the device.
- Do not use third-party adapters, hooks, clips, or attachment systems.
- The device must be attached to the stretcher only as described in these Instructions for Use.
- Any deviation from the approved method of attachment may impair crash performance and may compromise the safe use of the device.
- The stretcher attachment straps are removable and are not intended to remain permanently affixed to the trolley or stretcher.

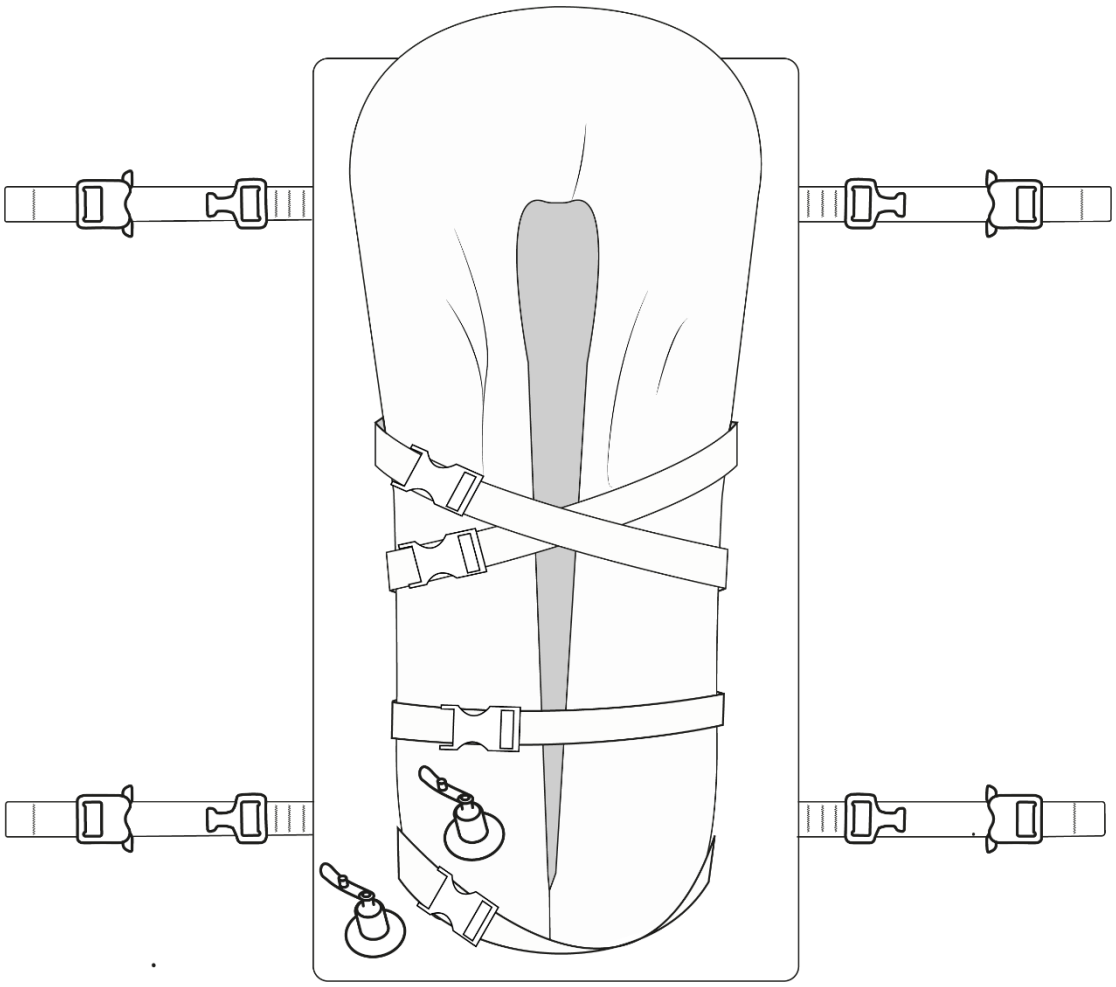
8.4 Installation Procedure (illustrated step-by-step instructions)

STEP 1

Open all four stretcher attachment strap buckles.

Ensure that:

- all straps are fully opened;
- the buckles are accessible; and
- the straps are not twisted or entangled



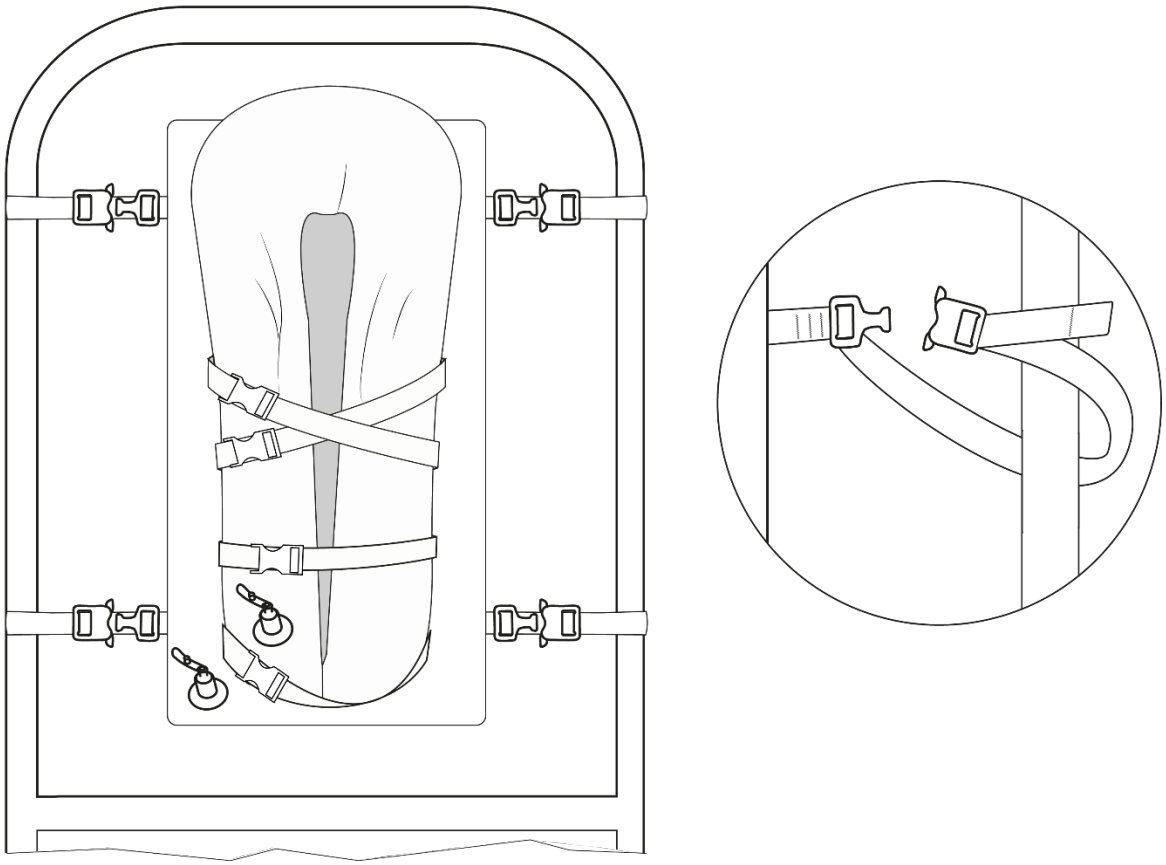
STEP 2

Place the device centrally on the stretcher.

Route each attachment strap around the stretcher frame and close the buckle.

Ensure that:

- each strap is correctly routed around the stretcher frame;
- the straps are not twisted or trapped; and
- all buckles are correctly aligned and fully engaged.

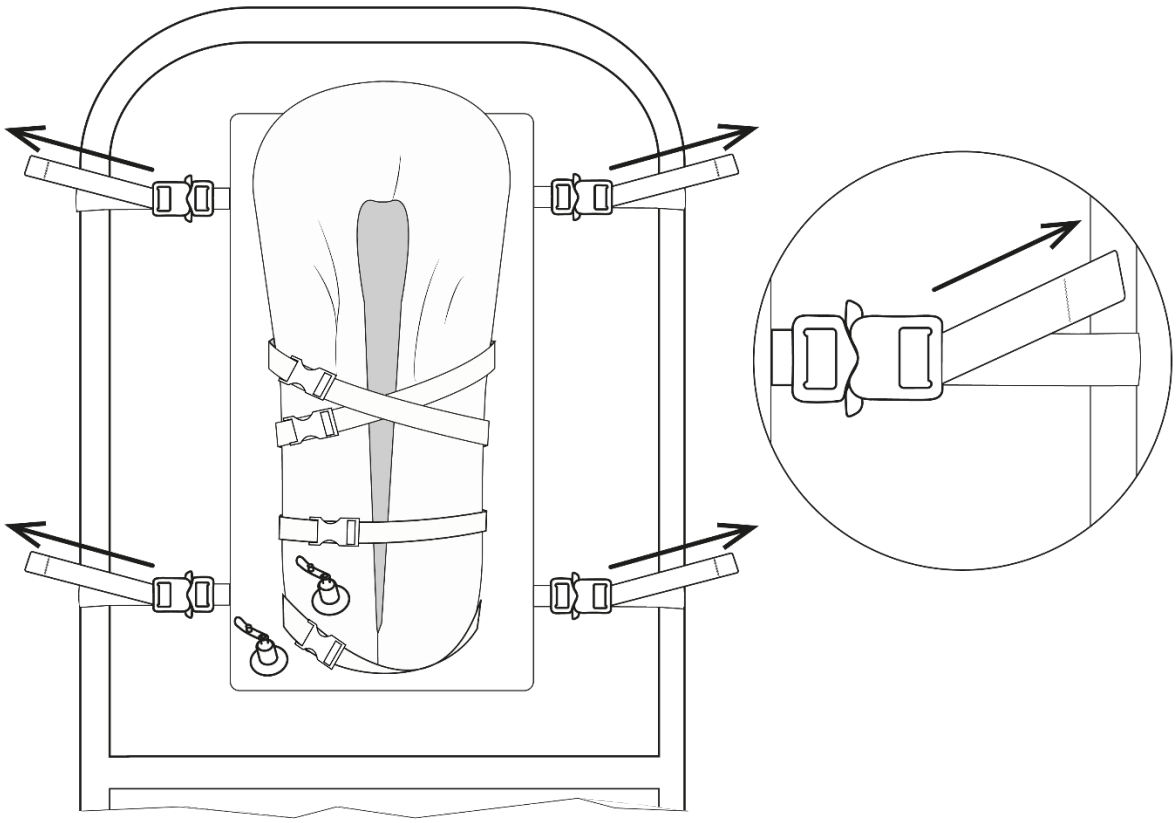


STEP 3

Tighten all four straps evenly until the device is securely fixed to the stretcher and has no free play.

Ensure that:

- the device lies flat and centrally on the stretcher;
- all four straps are correctly routed and securely fastened;
- all buckles are fully engaged;
- the device cannot move on the stretcher; and
- no straps are twisted, trapped, damaged, or loose.



8.5 Inspection Checklist

Before placing the infant in the device, check that:

- the device is positioned centrally and correctly on the stretcher frame;
- all four stretcher attachment straps on the device are correctly routed around the stretcher frame and securely fastened;
- all four stretcher attachment buckles are fully engaged and secure;
- the device cannot be moved by pushing or pulling it; and
- the straps and components do not interfere with oxygen lines, infusion lines, monitors or other medical devices.

9. Positioning the Infant (illustrated step-by-step instructions)

Step 1 – Preparation before placing the infant in the device

Before placing the infant in the device, check:

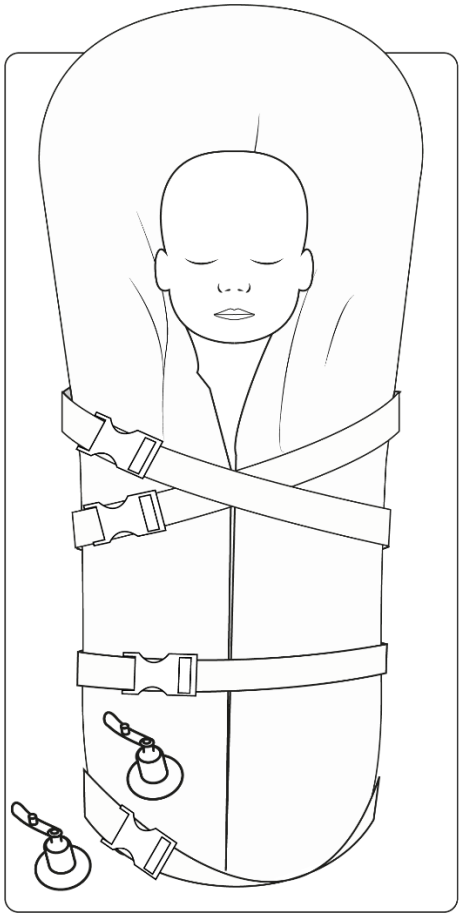
- that the restraint straps are correctly positioned and functioning properly
- that the evacuation valves (vacuum ports) are accessible and functioning properly
- that the attachment points and connecting elements are securely in place

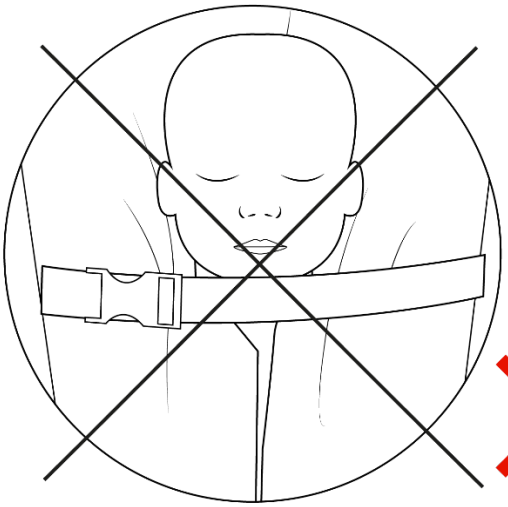
Step 2 – Positioning and initial securing

Carefully place the infant centrally in the device.

- Ensure straight alignment of the head, spine, and pelvis (neutral position).
- Ensure that the airway remains freely accessible.
- Apply the patient restraint straps (upper body strap, lower body strap, and foot strap) without fully tightening them.

	Ensure that no strap restricts breathing.



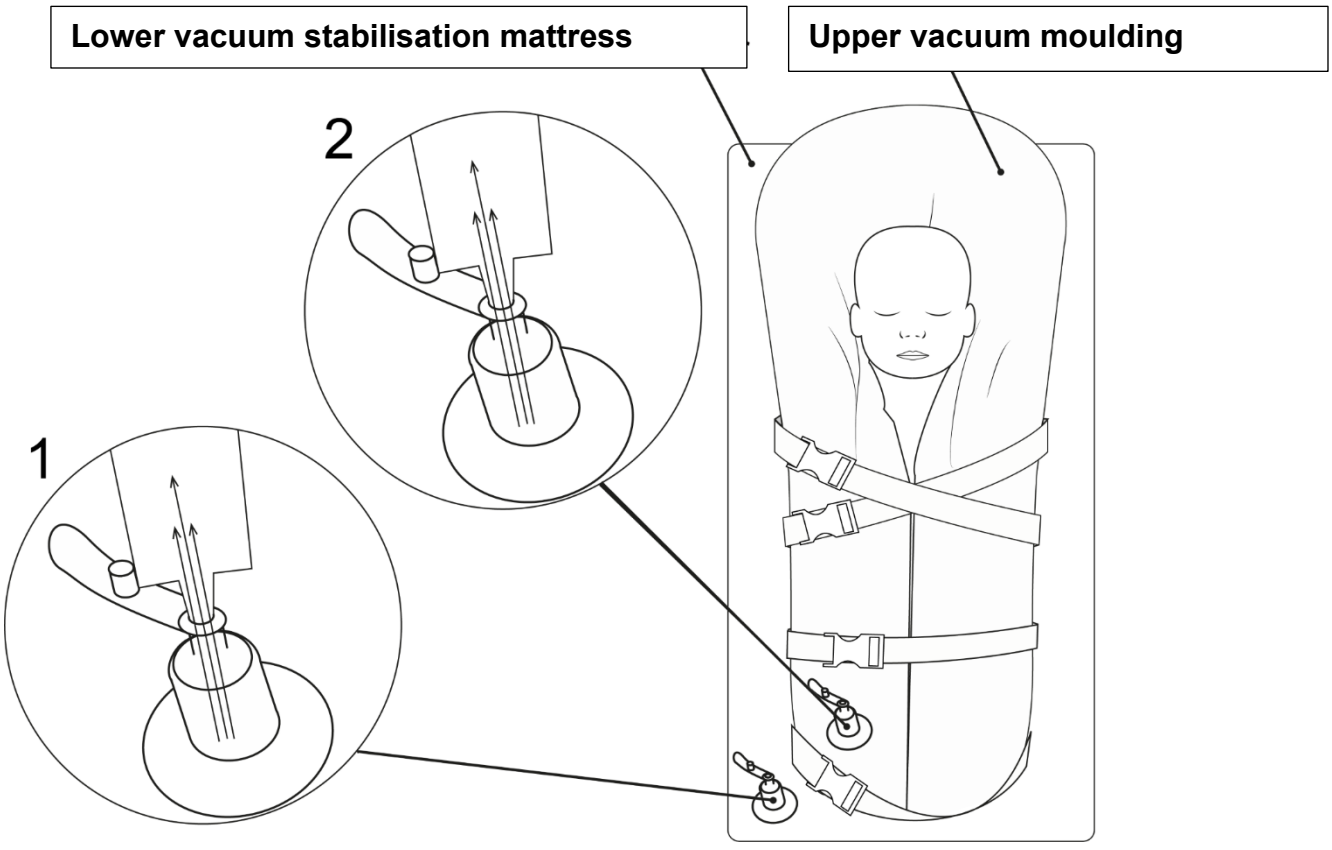


9.1 Vacuum Stabilisation

The RedVac Infant Transport System has two independent vacuum sections:

- **Lower vacuum stabilisation mattress**
  This section provides a stable base and supports secure positioning on the stretcher.
- **Upper vacuum moulding chamber**
  This section conforms to the infant´s body and supports stabilisation by limiting movement without unnecessarily restricting breathing.

Vacuum must only be applied after the infant has been correctly positioned and the restraint straps have been applied.



9.1.1 Lower Mattress (Base Stabilisation)

- Connect a suitable vacuum source, for example a medical suction device or an approved pump, to the lower vacuum port (1).
- Use only suitable devices or devices approved by the manufacturer for vacuum generation.
- Apply vacuum until the lower mattress is uniformly rigid
- Check that the base remains level and that the infant´s position does not change.
- The rigid lower mattress provides a stable support surface and helps maintain safe handling and positioning of the infant during transport.

9.1.2 Upper Mattress (Adaptation to the Infant´s Upper Body)

- Connect the vacuum source to the upper vacuum port (2).
- Apply vacuum gradually until the mattress conforms to the infant´s body.
- Ensure that the infant’s breathing is not restricted, as indicated by visible chest movement.
- Recheck stabilisation after every movement, after lifting, or after exposure to vibration.

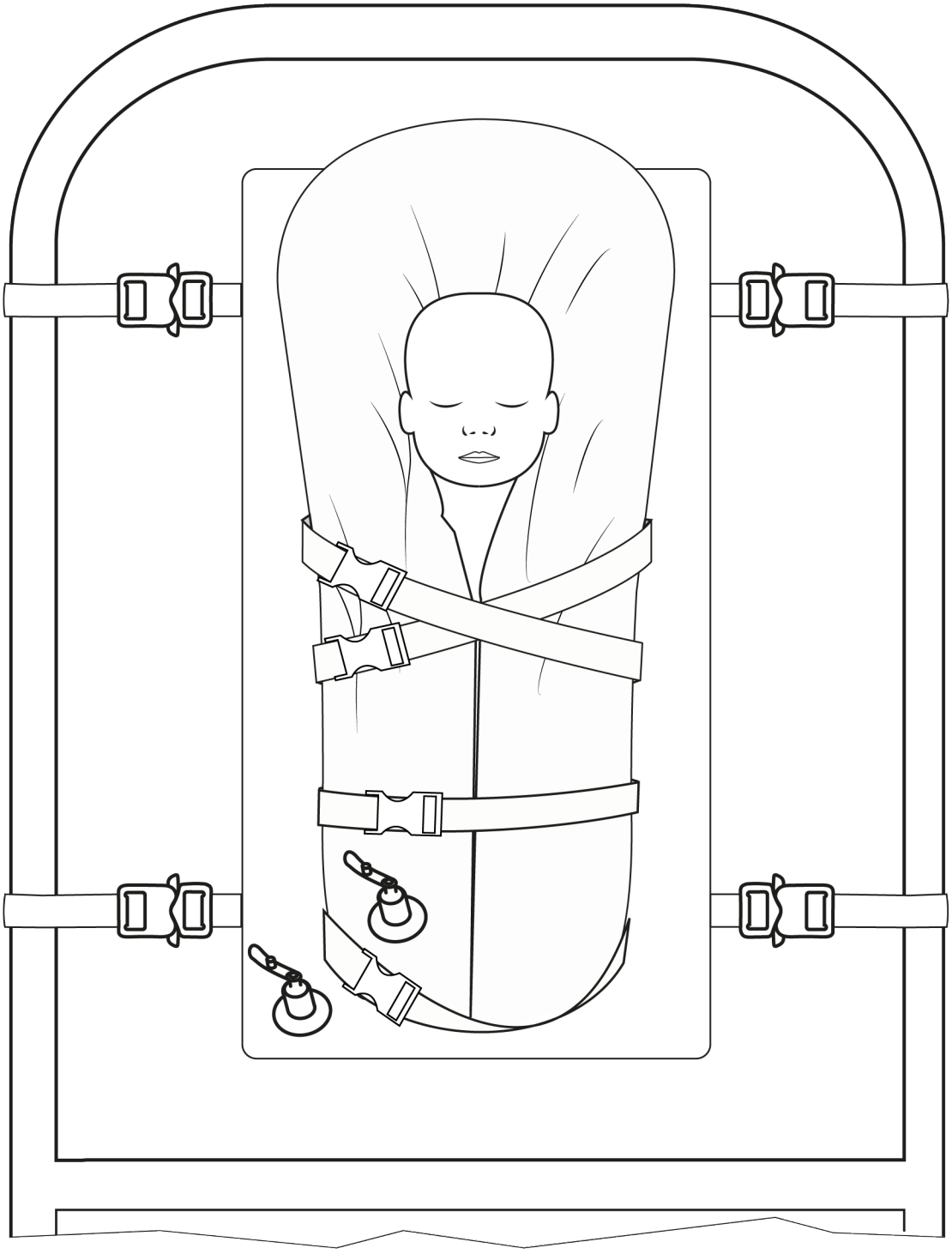


- **WARNING – Thorax Compression**

Excessive vacuum application may impair the infant’s breathing.

- Apply only the minimum vacuum required for stabilization.
- If breathing appears restricted or shallow, reduce the vacuum immediately.
- Continuously monitor the infant´s breathing throughout the transport.

10. Final Safety Checks (before transport)



Before moving the stretcher or vehicle, check the following:

Device

- The lower and upper vacuum sections are sufficiently rigid and stable.
- There is no visible damage, for example tears, leaks, or material damage.
- All attachment elements and straps are correctly applied and secured.

Infant

- All restraint straps are correctly applied, evenly tensioned, and not twisted.
- No strap exerts pressure on the thorax or impairs breathing.
- The airway is freely accessible and visible at all times.
- Monitoring lines, oxygen tubing, infusion lines, and other medical devices are not restricted or kinked.

If the infant can move significantly:

STOP TRANSPORT IMMEDIATELY

- Reposition and correctly adjust the restraint straps.
- Check the vacuum stabilisation and adjust it if necessary.
- Recheck the infant's position.

Continue only when safe stabilization has been ensured.

11. Procedure After Transport

1. Release the vacuum from the lower and upper mattress sections.
2. Before storage, inspect the device for visible contamination or damage.

12. Cleaning and Disinfection

12.1 Preparation

- Close all evacuation valves (vacuum ports) before cleaning.

12.2 Cleaning and Disinfection

The device must be cleaned and disinfected after each use.

- After each use, remove any visible contamination using a soft cloth or sponge with warm water and a mild neutral detergent.
- Do not use abrasive cleaning agents, wire brushes or high-pressure cleaning equipment.

Disinfection

After cleaning, the device may be disinfected using commonly accepted hospital-grade surface disinfectants that are compatible with the device materials.

The device has been designed with smooth, wipe-clean surfaces to facilitate effective cleaning and minimise contamination retention.

The materials are compatible with commonly used healthcare disinfectants, including:

- Quaternary ammonium compound (QAC) disinfectants
- Peracetic acid-based disinfectants
- Sodium dichloroisocyanurate (NaDCC) chlorine disinfectants, including concentrations up to 10,000 ppm available chlorine

Always follow the disinfectant manufacturer's instructions regarding concentration, contact time and application method.

After disinfection, allow the device to dry completely before storage or reuse.

Do not sterilise the device by autoclave, dry heat or any other thermal sterilisation process unless explicitly stated by the manufacturer.

Drying

- Dry the device completely after cleaning and disinfection before reuse.

Approved agents and products

Application	*Product/agent*	*Supplier*	*Active substance / class*	*Suitability*
Surface disinfection	Descogen liquid	Antiseptica	Peroxide compound	According to manufacturer´s instructions
Surface disinfection	Incidin Pro	Ecolab	QAC + phenoxyethanol	According to manufacturer´s instructions
Surface disinfection	Incidin liquid	Ecolab	Alcohols	According to manufacturer´s instructions
Surface disinfection	Incidin Active	Ecolab	Peroxide compound	According to manufacturer´s instructions
Surface disinfection	TPH protect	Schülke	QAC + amines	According to manufacturer´s instructions
Surface disinfection	Mikrozid AF liquid	Schülke	Alcohols	According to manufacturer´s instructions
Surface disinfection	Acryl Des	Schülke	QAC – alcohol-free	According to manufacturer´s instructions
Surface disinfection	Perform	Schülke	Peroxide compound	According to manufacturer´s instructions
Routine cleaning / disinfection	Quaternary ammonium detergent / disinfectant	Various	QAC – based formulation	According to manufacturer´s instructions
High-level wipe disinfection	Clinell Peracetic Acid Wipes (formerly Clinell Sporicidal Wipes)	GAMA Healthcare	Peracetic acid / peroxide system	According to manufacturer´s instructions
High-level surface disinfection	NaDCC solution	Various	Sodium dichloroisocyanurate; up to 10,000 ppm available chlorine	According to manufacturer´s instructions

13. Storage

Store the device under the following conditions:

- in a dry and clean environment
- protected from direct sunlight and heat sources
- at a temperature between **–30 °C and +50 °C**

14. Maintenance and Inspection

The device must be inspected regularly to ensure safe function and reusability.
Use of the device is permitted only if it is in a technically and hygienically sound condition.

Visual and functional inspection

Before each use and at regular intervals, perform the following checks:

- all straps, seams, and fasteners are undamaged and show no signs of wear
- buckles can be opened and closed properly
- straps show no fraying, cuts, or thermal damage
- vacuum ports and valves are leak-tight and functioning properly
- tubes are correctly connected and undamaged
- the material shows no cracks, punctures, deformation, or delamination
- the granulate in both vacuum sections moves freely
- all components are complete and present

Reusability

The device is reusable provided that no damage is present and full functionality is ensured.
A complete visual and functional inspection must be carried out before each reuse.

14.1 Removal from Service

Do not use the device if:

- damage or functional defects are identified
- vacuum stability cannot be reliably achieved
- components are missing or not functioning properly

In such cases, remove the device from service and replace it with suitable substitute equipment.

14.2 Replacement of Components

- Damaged or functionally impaired components, for example straps, valves, or buckles, must be replaced immediately.
- Use only original spare parts approved by the manufacturer.
- The use of non-approved components may impair the function and safety of the device.
- The use of third-party components may invalidate verified crash performance and may affect warranty claims.

15. Disposal

15.1 Disposal of the Device

Dispose of the device and its components in accordance with applicable local regulations for medical waste.

- Contaminated components must not be disposed of with general household waste.

16. Technical Specifications

Parameter	VKF09Cxxx
Maximum patient weight	9 kg
Minimum patient weight	No manufacturer-defined minimum
Minimum patient body size	No manufacturer-defined minimum
Device weight	approx. 2.5 kg
Dimension (L × W)	approx. 70 × 40 cm
System design	Dual-vacuum system with two separate chambers
Material	Biocompatible medical-grade TPU
Vacuum range (system design)	up to approx. –0.6 bar
Crash performance assessment	Dynamically tested (10g / 20g)
Standards and specifications	DIN EN 1789, DIN EN 1865-5
Medical device classification	Class I according to Regulation (EU) 2017/745 (MDR)
Intended use environment	Pre-hospital and clinical transport of infants
Compatibility	Suitable for approved stretcher systems with frame structure
Cleaning	Suitable for wipe disinfection
Reusability	Reusable when in proper condition
Service life	up to 12 years (when used and maintained properly)

Note:

- Vacuum performance depends on ambient temperature and on distribution of the granulate.

17. Performance and Testing

The RedVac Infant Transport System has been evaluated against established performance criteria.

Testing includes, among other things:

- dynamic crash testing in accordance with the applicable standards EN 1865-5:2012 and EN 1789:2020+A
- material resistance and tensile testing of straps, seams, and buckles
- testing of vacuum retention capability to assess leakage, valve function, and long-term stability
- biocompatibility testing of patient-contacting surfaces, where required by applicable regulatory requirements

18. Troubleshooting

Problem	Possible cause	Corrective action
Strap does not engage	Contamination in the buckle or misalignment	Clean the buckle, remove contamination, and reconnect
Strap loosens	Incorrect strap routing or buckle not fully engaged	Re-route the strap and check that the buckle is fully locked
Vacuum not stable	Valve not leak-tight or tubing not connected	Check the tubing, connect it correctly, and check for leaks
Mattress is uneven or lumpy	Granulate unevenly distributed	Release the vacuum, distribute the filling evenly, and reapply the vacuum
Infant remains mobile	Insufficient strap tension or insufficient vacuum	Readjust the straps and increase the vacuum gradually

	**DISCONTINUE USE IMMEDIATELY** if structural damage is detected

19. Manufacturer and Regulatory Information

19.1 Manufacturer

Kohlbrat & Bunz GmbH
Loretostrasse 6–8
5550 Radstadt, Austria
Website: www.kohlbratbunz.com

For technical support, spare parts, or service, contact the manufacturer or an authorised distributor.

19.2 EU Declaration of Conformity

This device complies with the applicable European legislation for medical devices. A copy of the EU Declaration of Conformity is available on request.

19.3 Regulatory Information

- Product classification: medical device, Class I, according to Regulation (EU) 2017/745 (MDR)
- National or institutional requirements may require additional measures for emergency transport
- The device may be placed on the market only by the manufacturer or its authorised representative

19.4 Reporting of Serious Incidents

In the event of malfunction of the device or a serious incident that has led, or may lead, to injury or risk of injury:

- discontinue use of the device immediately
- inform the manufacturer and the competent national authority in accordance with applicable local requirements

20. Warranty

Extended warranty

In addition, the manufacturer provides an extended warranty for the entire service life of the device, up to 12 years, against defects in materials and workmanship, provided that:

- the device is used in accordance with these Instructions for Use
- maintenance and inspection requirements are observed
- only approved components are used

The warranty does not cover:

- damage resulting from improper use or incorrect installation
- improper cleaning or use of non-approved chemicals
- mechanical impact, crushing, or transport damage
- unauthorised modifications or repairs
- use of non-approved accessories or spare parts

Exclusion of warranty

Warranty claims may be rejected if the device shows signs of improper use, unauthorised modification, or insufficient maintenance.

21. Spare Parts and Accessories

Use only original components supplied or expressly approved by the manufacturer. The use of non-approved components may impair the function and safety of the device and may affect warranty claims.

Reference to component overview

Further information on individual components can be found in the following sections:

- section “Device Description / Components“
- section “ Parts and Components Checklist

Example of replaceble components

- restraint straps (upper body strap, lower body strap, and foot strap)
- stretcher attachment straps with attachment elements

	**The use of third-party spare parts or accessories invalidates verified crash performance and may affect warranty claims.**

22. Repairs

Repairs may only be carried out by:

- the manufacturer
- authorised service personnel

Repairs, modifications, or other interventions by the user are not permitted.

Note on unauthorised interventions

Unauthorized actions may:

- compromise patient safety
- affect function and structural integrity of the device
- affect warranty claims
- invalidate verified crash performance

Procedure in case of damage

If the device is damaged or malfunctions:

- discontinue use immediately
- remove the device from service
- contact the manufacturer or authorised service personnel

	**The use of third-party spare parts or accessories invalidates verified crash performance and may affect warranty claims.**

23. Document Control

Version: Issue 03
Date of issue: September 2026
Approved by: PRRC / Ing. Michael Graf

Summary of changes

- 02 Initial issue
- 03 Changes stretcher strap attachment