

Safety Instructions

Changes to the performance characteristics must be reported to the manufacturer and the distributor.

Life Span - The Medical Devices Directive stipulates that the manufacturer of a medical device must specify a period of time that describes the so-called safe use. We are thus fulfilling a legal requirement and, for formal reasons, are specifying a period of three years from the date of purchase. The period mentioned has no relation to the actual possible use or maximum period of use by the user.

Usage - Never sit on the cushion without its cover. Based on the structure of the cushion, the cover is needed to keep the cushion in shape.

Seating cushion - Upper side & bottom plate - When placing the cushion on the wheelchair, ensure that the flat bottom plate is on the seating surface of the wheelchair. The user sits on the upper side (cells).

Control, if there is air inside the cushion - Once a day, the cushion needs to be checked if there is still air in the cushion. Refilling is necessary within 8 – 21 days.

Procedure of filling air in the cushion - Please fill the air with the pump that is enclosed in the delivery. Electrical pumps might lead to too much inner pressure and could cause bursting. Please open the valve with the hand and not with pliers. When using a tool, the valve can be damaged, bent or jammed.

Storage - The product is made of natural rubber and it should not be exposed to sunlight (UV-light), which could cause a premature ageing of the material. If the cushion is not in use, we recommend to store it inside the delivery box.

Maximum user weight - No restrictions

Cleaning - The washing temperature (60° C) should not be exceeded. If the temperature is higher, the cells could stick together. Please consider that UV-light sterilization is impossible because it damages the material.

Cleaning fluids - The fluid used may not contain silicon oil because this will damage the material of the cushion.

Fluid for preserving the cushion - Not necessary

Smouldering and hot ash - The cushion cover is flame retardant. In case of contact with glow, it can still be damaged.

Reuse / Change of cushion to other person - Should the cushion be forwarded to another person, it must be disinfected and cleaned even when there is no obvious dirt. A new cover must be taken.

Optimal adaptation to the seat - The seat width and depth should be adapted to the wheelchair. A cushion too big could lead to a leak because it might chafe on parts of the wheelchair. If it is too small, the cushion doesn't offer an optimal pressure relief.

Air loss - In case of air loss the cushion should be refilled in order to check the valve. If the valve is closed correctly, please contact your health care specialist or medical supply retailer.

Hole in the cushion - If there is a hole in the cushion, contact your health care specialist or medical supply retailer.

Pets - If there are any pets at your place, please consider that they might damage the cushion.



User Manual

CONFORM® Med. Air Cushion System

CE The manufacturer declares, that CONFORM® Med. Air Cushion Systems are in accordance with all requirements for medical products class 1 as set out in the guideline 2017/745/EU (Appendix VIII, Chapter III, Paragraph 4.1 - Regulation 1).

CONFORM® Medical Air Cushion Systems are Medical Products Class I (DE/CA /23/051/603NA01.01)



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Certified according to ISO 9001 and ISO 13485



HIGH QUALITY
MADE IN GERMANY

Scope of delivery

CONFORM[®] Medical Air Cushion with cover, manual pump and carrying box.

Intended use

CONFORM[®] Med. Air Cushions are made for prevention of pressure ulcer. It can also be used to support the therapy of existing wounds on the bottom.

This cushion is made for people with limited mobility or who have to sit permanently (due to paraplegia, spina bifida, stroke, ALS [amyotrophic lateral sclerosis], MS [multiple sclerosis]) or due to other reasons not mentioned.

This product is to be used as seating surface in a wheelchair. The application is intended for human use.

CONFORM[®] Med. Air Cushion, made by Wolff Kunststoffe GmbH is available

- in 3 various seat heights (5; 7.5; 10 cm)
- 1-, 2- and 4-chamber version
- 4-chamber version with central valve
- all standard sizes of seating surface from a wheel chair (Measurement width x depth)

Functional principle

The cushion has a valve to fill in air. Since the air cells of the cushion are connected with each other by a channel system they create a communicating system, spreading pressure evenly and provide a pressure relief when sitting on the cushion. Due to the star-shape of each cell, they stabilize each other once inflated. The cushion corners are designed with integrated metal eyelets for straps in order to fix the cushion on the wheelchair.

Instruction on handling

The instruction needs to be done by nursing staff, medical device consultant, nurse, occupational therapist or other qualified person. If the cushion is handed over in hospital and taken home, it is necessary that the person using it and/or other people involved (family, home care) are instructed to the handling of the cushion properly.

Duration of application – no limitation

Reuse – please read safety instructions on the last page

Cleaning

After removing the cover the cushion can be cleaned and disinfected by using a common disinfection spray or tissue (recommendations www.rki.de). The cushion as well as the cover are washable at 60°C by using hygienic detergent. We recommend a gentle machine wash cycle at 40°C without spinning after closing the valves.

For elderly people's home and hospitals a special washing powder is available called "Eltra 40 Plus", please check the manufacturer site for respective country (<https://de-de.ecolab.com>).

How to inflate the cushion



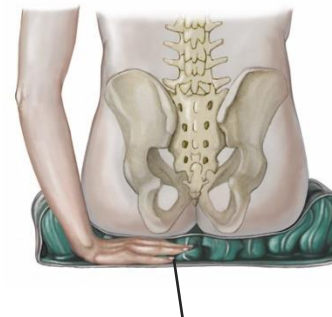
Inflate the CONFORM[®] Air Cushion with the enclosed pump until it begins to arch. Attach the pump tubing to the cushion valve. Open the valve by turning it anticlockwise and inflate the cushion. Close the valve by turning it clockwise.

If necessary, the person can also sit on the cushion while inflating it.



Seat the patient and deflate the cushion. The patient sinks comfortably but consider not letting the patient's bottom touch the base of the cushion.

The distance between the sitting person (usually the ischial tuberosities or coccyx) and the base of the cushion should be approximately ¾ of an inch or 1.5 - 2 cm.



If it is possible to insert your hand between the person's deepest point of the bone bottom and the base of the cushion, it has been set correctly.

If there is still too much air inside, you can open the valve and deflate.

about 1,5 – 2 cm – or 0,5 – 0,8 inch distance