




User Manual CONFORM[®] C4 cushion

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

 CE-Declaration: 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).



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GLN (Global Location Number): 42 518157 0000
SRN : DE-MF-0000178949

Scope of delivery

CONFORM® Medical Air Cushion in carrying box with cover, user manual and pump.

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. The CONFORM® C4 cushion offers in addition the possibility for stabilisation of seating and positioning. 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)
- as well as custom-made size on demand

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 C4 cushion can be used as a 1-chamber and/or 4-chamber cushion. This is depending on the position of the central valve in the front of the cushion (detailed explanation see next page). 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 limit

Reuse – please read safety instructions on the last page

Cleaning

In the private environment - The cushion is disinfected by cleaning the surface with common disinfectant sprays or disinfectant wipes (disinfectant wipes (<https://edoc.rki.de/handle/176904/224> - Hygiene requirements for cleaning and disinfecting surfaces as well as <https://www.rki.de> - List for surface disinfection). The CONFORM® C4 (central valve front) cushion cannot be washed in the washing machine. The cushion cover should be washed in the washing machine at 40°- 60°C. This ensures sufficient cleaning with today's disinfectant detergents (Sagrotan or similar).

In public facilities/hospitals - The disinfection of the pillow is done by surface cleaning with common disinfectant sprays or disinfectant wipes Disinfectant wipes (<https://edoc.rki.de/handle/176904/224> - Hygiene requirements for cleaning and disinfection of surfaces as well as <https://www.rki.de> - List for surface disinfection). The pillowcase can then be washed in the washing machine from 40°- 60°C. We recommend the detergent Eltra 40 plus (manufacturer: Ecolab). The CONFORM® C4 pillow should not be washed in the washing machine. Chemo-thermal disinfection at 60° with Ecolab Ozonit and Turbo Emulsion is possible. The pad can also be cleaned in disinfectant immersion baths.

User Manual

Open the adjuster and the valve (the cushion can only be inflated, when both are open)



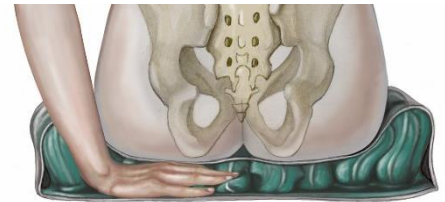
ADJUSTER IS CLOSED



ADJUSTER IS OPEN

Attach the pump tube onto the cushion valve. Open the adjuster and the valve by turning. Inflate the cushion. Close the valve by turning it clockwise. Now, the adjuster is still open and the air can float between all cells and chamber.

Now the person is placed onto the CONFORM® cushion, unless you have performed the inflation process under the seated person anyway. Now you have to release air again, so that the user can sink as deep as possible into the cushion. To do this, the valve must be opened again. If air is deflated from the cushion, be careful not to let the user touch the bottom plate with the coccyx bone or ischial tuberosities. The distance between the lowest points of the person seated to the bottom plate should be about 2 cm. If you can just put a hand between, the cushion is adjusted individually for the user.



Depending on the need, the cushion can be filled with more or less air in the chambers, to optimize the seating position. To let the air flow in all 4 cells of the cushion, the controller must be opened (but keep the valve closed). Please wait while positioning (approx. 10 sec.) until the air has. Then close the adjuster in this setting to have the 4-chamber seat. Thanks to the central valve control, the dispersed cushion can fulfill both - the function of a 1- or 4-chamber cushion. For a 1-chamber option, the adjuster remains to be open.

Detailed description regarding the difference from 1- and 4-chamber version

Remark: For visual demonstration of the air flow, the cushion has no cover. Always use the cushion cover, when the cushion is in use.



When the adjuster is open – the air can float all over inside seating surface. The cushion has now the function of a **1-chamber cushion**.



When the adjuster is closed, the airflow is kept in each of the **4-chambers**.

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.

Central valve - Make sure that the valve does not rub against the back of the user's knee.

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 C4 cushion with central valve can't be washed in the washing machine. The washing temperature (60° C) of the cushion cover should not be exceeded. Please consider that the 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

