



O2-TopiCare® Wound Cuff for the O2-TopiCare® Adaption System for use on the leg, foot and arm

Scope of delivery:

- 1 O2-TopiCare® wound cuff including hose system,
- 1 loose velcro tape for additional fixation,
- 1 heel fixation (velcro tape included)

Product description:

The O2-TopiCare® wound cuff is a system for the treatment of chronic wounds with the help of topical wound oxygenation. This procedure uses an oxygen source, such as an oxygen concentrator, and generates a system overpressure of oxygen of approximately 50mbar. This causes a multiple increase in the oxygen partial pressure in the wound tissue – whereby a faster wound healing is ensured. The filling of the O2-TopiCare® wound cuff starts with a flow setting of 4-5 l/ min. at the oxygen concentrator. In order to stimulate the venous return flow of the blood, it's possible to connect an AV impulse generator which sends an impulse to the foot vein plexus and thus simulates the natural walking movement.

The O2-TopiCare® wound cuff system is designed for single patient use and may not be used universally.

Indications:

- Diabetic foot
- Decubitus ulcers
- Venous and arterial ulcers
- Ulcer cruris
- Burns
- Post-surgical wounds
- Skin transplantations

Contraindications:

- Fistulas or deep wound cavities which can't be sufficiently examined in depth

Side effects:

With proper use, there are no side effects known so far.

Interactions:

There are no interactions with other medical devices known so far. Before and during the application of the system, it's not allowed to use greasy/ oily salves, creams or similar because a chemical reaction of the substances with the oxygen can't be ruled out. Attention: While using oxygen, all rules for the avoidance of fire hazard have to be considered. That means a strict ban of open flames, such as smoking, candles, lighters and more.

Information on sterility:

The products have not been sterilized. The application does not require this.

Risks of reprocessing:

In a reprocessing, the material properties can change or the materials can be destroyed when there is a heat exposure above 75°C. There is a danger of a cross-infection. Furthermore, it's possible that tissue parts or exogenous proteins remain in the materials. Due to their toxic effect, a tissue- or rejection-reaction can be caused.

Storage:

The medical device must be stored dry and at room temperature.

Product Disposal:

The disposal of the products may only be carried out in accordance with the valid national provisions for waste products.

Safety instructions:

If the packaging is damaged, do not use the product. In case of known intolerance or allergy against one or more of the components or substances, do not use the product.

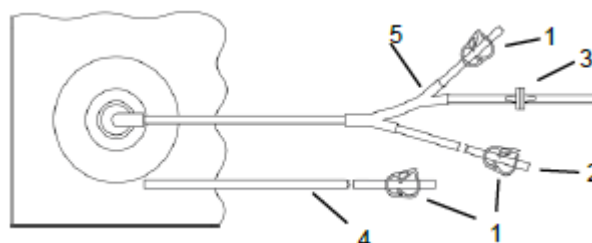
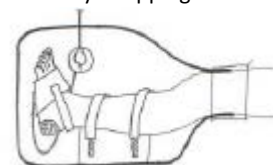
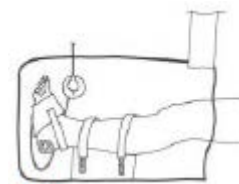
General information:

The topical wound oxygenation or secretion aspiration is not intended as an exclusive therapy method for wound healing. The application must be monitored and the indication must be checked regularly by suitable personnel. Appearance, colour of the wound and the patient's state of health must be checked at regular intervals. The application time depends on the estimation of the responsible medical expert. A daily application time of at least 60-90 minutes is recommended.

Instructions for use:

Before using O2-TopiCare® please ensure a hygienic hand disinfection.

1. Feed leg or arm of the patient into the O2-TopiCare® cuff and take place the best position. When you intend to use the cuff for application on the leg please use the attached heel cushion.
2. By additional use of A-V Impulse System please attach the ImPad cuff (arm or foot) to the patient and connect the hose with the hose of O2-TopiCare® from the inside of the cuff. Please also refer to the operating instructions of A-V Impulse System. By use of O2-TopiCare® cuff without A-V Impulse System please close the clip (1) at the connection hose (4). Attention! It is important to ensure a sufficient distance of the O2-TopiCare® cuff foil to the wound. This is important for the prevention of skin irritations.
3. Please fix the O2-TopiCare® cuff with the flexible yellow sealing tape so that the O2-TopiCare® foil will be tightly applied to the skin of the patient.
4. Then you have to stretch the overlapping foil smooth and fold it to the left side.
5. The yellow sealing tape has to be wrapped tightly around the edge of the O2-TopiCare® cuff so that the cuff and the patient's leg are covered equally by the sealing tape.
6. Fix the sealing tape with the attached Velcro by wrapping around of the leg.
7. Afterwards fix the second Velcro for more stability.
8. Connect the hose (4) of the ImPad cuff with the hose of the A-V Impulse System.
9. Connect the oxygen concentrator with the hose (2) and turn on the device.
10. The controlling of cuff pressure can be measured by a pressure gauge. An adapter for pressure measuring is included at the O2-TopiCare® cuff (5). In case of excess pressure an excess pressure valve (3) will open.



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| 1. Clip | 2. O ₂ -hose | 3. Excess pressure valve |
| 4. A-V Impulse connecting hose | 5. Connection for pressure measuring | |