

Instructions for use

B-Care Oral Care

24-hour oral hygiene kit

Ver. 1/10.03.2025

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1. Introduction

These instructions apply to the B-Care Oral Care medical device. Before use the device, please read all the information in these instructions, on the packaging, and on the device itself.

Intended use

B-Care Oral Care is designed to assist in maintaining oral cleanliness in intubated patients. Maintaining adequate oral cleanliness in intubated patients helps to prevent the occurrence of life-threatening complications such as ventilator-associated pneumonia (VAP).

Intended user, working environment, service life

The device, after training, can be used by medical personnel (doctors, nurses, etc.).

The shelf life of the product is 2 years from the date of manufacture, provided that the product is stored in the original packaging under the environmental conditions specified in section 6.

The expiry date of the product is indicated on the product label next to the symbol:



⚠ Do not use the product beyond its shelf life.

B-Care Oral Care is a non-sterile, single-use product. After use, the product must be disposed of in accordance with the regulations in force in this area.

Indications/ Contraindications

⚠ Warning: The device is intended for use in adults only.

Products compatible with B-Care Oral Care

To effectively carry out cleaning and moisturizing of the oral cavity, it is necessary to use, along with the components of the B-Care Oral Care, appropriate products designed for these purposes.

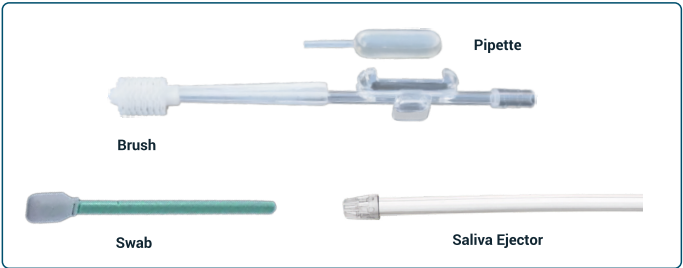
2. Product description

B-Care Oral Care is supplied as a three-pack blister with devices in each pack, providing 24 hours of patient oral hygiene. It is recommended that the patient's cleaning and moisturizing procedure be carried out every 8 hours according to the instructions in Section 3. The device can also be used as part of other patient care procedures in effect at individual healthcare facilities.

Each three-pack blister, in its upper part, is equipped with a hole with which it can be hung, for example, on an IV hanger or on a bed arm. Starting from the bottom of the blister, the individual pack can be efficiently detached from the rest of the blister thanks to the perforations that are located between the packs.

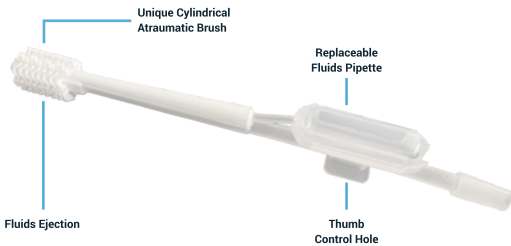
One pack of the product B-Care Oral Care contains the following components:

- B-Care Oral Care Toothbrush,
- Two pipettes (4 ml),
- Swab,
- Saliva ejector.



B-Care Oral Care Toothbrush

The toothbrush of the B-Care Oral Care product ends with a cylindrical cleaning part. In the middle part of the toothbrush, there is a pipette holder.



Pipettes

The product B-Care Oral Care includes two pipettes (4 ml) which, when filled with mouthwash and placed in the centre of the toothbrush, are used to dispense the fluid during the patient's oral cleaning activity.

Swab

Once soaked in moisturizing gel, the swab is used to moisturize the patient's mouth after a previously performed cleaning.

Saliva ejector

A saliva ejector is used to remove secretions, excess mouthwash, and other fluids from the patient's mouth both before and after a cleaning or moistening procedure.

3. Use of the B-Care Oral Care product

The following describes how to use the B-Care Oral Care device.

1. Open the collection box containing three-pack blisters.
2. Take out one blister and hang it in an easily accessible place, e.g. on an IV hanger or bed arm.
3. Check that the expiration date of the product (indicated next to the symbol ⚠) has not passed, and check that the packaging of each product is intact.

⚠ Do not use the products if the expiry date has passed or the packaging of the product is damaged.

⚠ Do not use for patients with injured oral mucous membrane.

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4.Tear the first pack from the bottom of the blister pack.

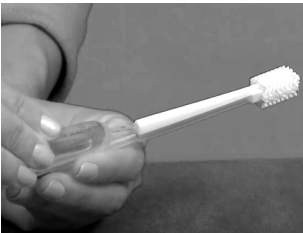
5.Open the pack.



6. Connect the saliva ejector to the tip of the medical suction unit. With the suction source switched on, use the saliva ejector to clean the patient's mouth of lingering secretions and other fluids.



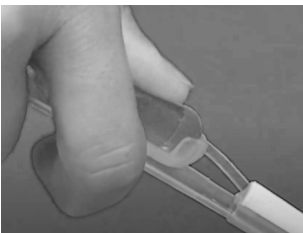
7. Remove the toothbrush and pipette from the pack and fill the pipette with mouthwash



8. Place the filled pipette in the pipette holder of the toothbrush. Ensure that the tip of the pipette is in the liquid hole of the toothbrush head.



9. Start the cleaning procedure



10.Dispensing the liquid into the brush head, gently clean the accessible parts of the patient's mouth. The cleaning fluid is dispensed into the brush head by pressing the pipette in the handle with the thumb.



11. Moisten the patient's mouth with a swab and using a moisturising gel suitable for this purpose.Start the cleaning procedure

12. When all operations have been completed, dispose of all product components in accordance with the relevant regulations.

4. Safety warnings and cautions

-  Do not use the products if the expiry date has passed or the packaging of the product is damaged.
-  Warning: The device is intended for use in adults only.

5. Symbols associated with the use of the product

Symbol	Description
	The symbol indicates information which has an impact on the safety of the user, the patient or third parties in relation to the device, and with which it is mandatory to be acquainted before using the device.



The symbol indicates that the device is a medical device.



The symbol indicates the compliance of the product with the requirements of Regulation 2017/745 EU (MDR) and other European Union regulations.



The symbol refers to a medical device that should be protected from direct heat sources (e.g.: sunlight).



The symbol indicates the need to protect the product from moisture.



The symbol indicates the range of temperature values to which the product can be safely exposed.



The symbol indicates the manufacturer of the medical device to which this Instruction applies.



The symbol indicates the need to read the Instructions for Use.



The symbol indicates the date of expiry until which the product can be safely used.



The symbol indicates the batch number of the manufactured product.



The symbol indicates the catalogue number of the medical device.



The symbol indicates the UDI number of the medical device.



The symbol refers to a medical device that is intended for single use.



A medical device bearing this symbol should not be used if its packaging is damaged. In this case, the user should refer to the Instructions for Use for information on further handling of the device.

5. Storage and transport

Temperature: +5 to +30°C

Protect the product from moisture and excessive exposure to sunlight during transport and storage.

7. Disposal

Disposal of the product and its packaging must be carried out in accordance with local regulations.

8. Contact with a healthcare professional

If you are not a medical professional and are in doubt about the performance of the device or do not know how to operate it, contact a healthcare professional familiar with the device or contact the manufacturer directly.

9. Manufacturer contact details

Manufacturer's contact details for technical support or to report unexpected actions or events related to the medical device:

Airway Medix S.A.
Szara 10 Street
00-420 Warsaw, Poland
e-mail: info@airway-medix.com
www.airway-medix.com

10. Reporting of serious product-related incidents

In case of serious incidents related to the device, they should be reported immediately to the manufacturer and to the Office for Registration of Medicinal Products for Medical Devices and Biocidal Products.
www.urpl.gov.pl