

Pur-Zellin Box

General description of the device/Intended purpose

Pur-Zellin Box is a reusable non-sterile dispenser box for Pur-Zellin sterile made of ABS non-active device and an accessory to Pur Zellin sterile to minimize contamination on sterile Pur-Zellin swabs after the removal from its sterile packaging used by healthcare professionals and by lay persons.

The Pur-Zellin Box comprises a unit with a flap, a lid with a blue shield, a roll holder spindle and instructions for use.

Indication

The indication of this product is to be used as an accessory for Pur-Zellin sterile.

Reference Numbers

REF	Name	Dimensions
996857/5	Pur-Zellin Box	Ca. 20 cm x 25 cm x 14 cm

Handling

Disinfection

① The Pur-Zellin Box must be disinfected from the inside and the outside before the first use and each time the roll is replaced. First, disinfect hands. Then disassemble the box completely (only the flap may remain attached to the unit). The area directly around the flap must be disinfected in its open and closed position.

② The blue shield can be detached from the lid by pulling the ring and can be easily snapped back in place.

Installation of swab roll

③ With the flap open, remove the Pur-Zellin roll from its sterile packaging and push it onto the spindle. Place the spindle on the holders inside the box so that the swabs can be pulled out from below the roll. Pull the roll until the first row of swabs lie on the flap.

④ Now put the lid on the box. The blue shield prevents access to the inside of the box through the opened flap. The swabs should protrude only slightly below the shield.

⑤ Finally, close the flap.

Removal of swabs

⑤ To remove swabs, open the flap and disinfect hands.

⑥ Now pull out the swabs from under the shield until the next perforation becomes visible (do not pull the swabs any further than the printed line on the flap). Press down the blue shield with one finger and tear off the swab at the perforation. Swabs that have been pulled out too far must be disposed of. Do not push them back into the box through the opening underneath the shield or let them get stuck between the shield and the flap.

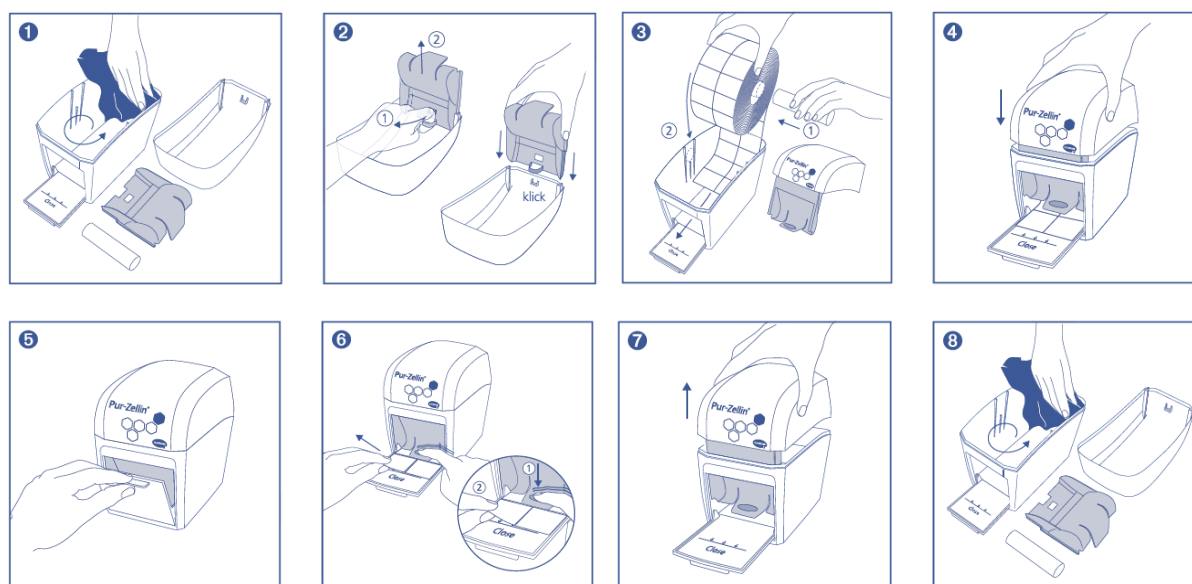
⑤ Close the flap immediately after you have removed the swabs.

Replacement of swab roll

⑦ When the Pur-Zellin roll is empty, open the lid of the box, remove any remaining swabs inside and dispose of them.

⑧ Before inserting a new swab roll, disinfect hands and carry out a wipe-down disinfection of the box as described above.

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Application Notes

- For cleansing and disinfection HARTMANN recommends Bode products. For wipe disinfection, use an alcoholic (30 %) surface disinfectant, for example Bacillol 30. Alternatively the Pur-Zellin Box can be placed in a cleaning and disinfection device. For this, disassemble the Pur-Zellin Box into its individual parts (top part, roll, blue shield, lower part and flap); machine: washer-disinfector; cleansing and disinfecting agent: liquid, alkaline disinfectant detergent, for example Dismoclean 28 alka med, concentration: 0.5 %; process water total hardness: 0.18 -1.25 mmol/l; program sequence: pre-rinse with cold water for 3 min., thermally disinfect with Dismoclean 28 alka med at 70°C for 5 min., rinse with process water at 7 °C for 3 min., dry at 90°C for 10 min.
- You should also observe the on-site hygiene procedures for personal hygiene and disinfection of surroundings.
- After disinfection and before reassembly, the Pur-Zellin Box must only be handled with disinfected hands.
- If the box is stored, ensure that all parts are stored inside the box itself. Before re-using the box, the box must be disinfected as described above.

Contraindications

Not known.

Special notes

- The word 'Close' on the flap of the box indicates to the user that the flap must be closed after removing a swab.
- The Pur-Zellin Box must be replaced if the unit or flap becomes damaged.
- If these instructions for use are followed correctly, the Pur-Zellin Box will last for 10 years. After this time the box should be disposed of.

Product disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Pur-Zellin Box should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

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Incident reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.


Labelling

Lot-No. with 9-digit code


e.g.:

	9	001	01	17	1
explanation definition	[9 = 2019] year	[999-000] serial production order	for internal purposes only		

Date of Manufacture

e.g.:  **2019** **04** **01**
year month day

Use-by date

e.g.:  **2024** **04** **01**
year month day

Shelf life: 10 years

Medical Device



Unique Device Identifier



Latest Date of Revision: 2020-05-26