



# Pur-Zellin® Box non-sterile

## EN Instruction for processing of medical devices

### Product

Pur-Zellin® Box

### Product description

Reusable non-sterile dispenser box for Pur-Zellin germ-reduced made of Acrylnitril-Butadien-Styrol (ABS).

### Intended purpose

Pur-Zellin Box is a reusable, non-sterile dispenser box for long-term use, which is used as an accessory to Pur-Zellin germ-reduced. It is used to minimize contamination on the swabs after the removal from their packaging and can be used by instructed lay persons and healthcare professionals.

### Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 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 authorized representative and to your national authority.

### 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.

### Cleaning/Disinfecting Instructions

<b>Preparation at place before cleaning/disinfecting</b>	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. The blue shield can be detached from the lid by pulling the ring and can be easily snapped back in place.
<b>Degree of degradation</b>	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.
<b>Cleaning/Disinfection</b>	HARTMANN recommends an alcoholic surface disinfectant for routine wipe-down disinfection of the Pur-Zellin Box. Alternatively the Pur-Zellin Box can be placed in a cleaning and disinfection device.
<b>Additional information</b>	<p>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. Before re-using the box, the box must be disinfected as described above.</p> <p><b>Installation of swab roll</b> With the flap open, remove the Pur-Zellin roll from its 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. 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. Finally, close the flap.</p> <p><b>Removal of swabs</b> To remove swabs, open the flap and disinfect hands. 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. Close the flap immediately after you have removed the swabs.</p>


<b>Additional information</b>	<p><b>Replacement of swab roll</b> When the Pur-Zellin roll is empty, open the lid of the box, remove any remaining swabs inside and dispose of them. Before inserting a new swab roll, disinfect hands and carry out a wipe-down disinfection of the box as described above.</p> <p>If the box is stored, ensure that all parts are stored inside the box itself.</p>
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The instructions provided above have been validated by the manufacturer of the Device as being capable of preparing a Device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

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