

# Histofix®-Safe: New biopsy fixation device ensuring zero exposure to formaldehyde at all stages of manipulation



The formaldehyde solution carries certain health risks for the user, according to Regulation (EU) No. 605/2014 as it has been classified as carcinogenic and mutagenic substance.



Histofix®-Safe is a closed-loop safety device, specially designed and patented by ITW Reagents for the fixation and transfer of small histological specimens, which prevents user exposure to formaldehyde solution.



The grid is fitted with a safety plug that guarantees the absence of vapors and must be removed before using the device.

The bi-directional valve under the grid, prevents the formaldehyde solution and the biopsy from flowing back into the original container unless pressure is applied.



The device meets the requirements of the Regulation (EU) 2017/746 on In Vitro Diagnostic Devices (IVDR).



Minimal exposure to formaldehyde



Intuitive and easy to use



Easy to store and transport



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## How to use Histofix®-Safe

Histofix®-Safe consists of two transparent polypropylene containers, connected by a magenta polypropylene lid, with a built-in bi-directional valve that allows the transfer of formalin between the two containers in both directions.

One of the containers is empty for sample reception and the other container is pre-filled with neutral 3.7-4.0% formaldehyde solution, buffered to pH 7 with sodium phosphate and stabilized with methanol.

### Main advantages

- No exposure to formaldehyde.
- The bi-directional valve avoids formaldehyde backflow and prevents sample/biopsy transfer to the formaldehyde reservoir container.
- The sample grid enables easy biopsy recovery.
- The burr next to the sample grid facilitates easy biopsy deposition.
- Tested tightness.
- Stability during pneumatic tube transportation.

| Product code | Product name   | CAS number | Amount of formaldehyde |
|--------------|--|------------|------------------------|
| 258462.0955  | Histofix®-Safe<br>Preservative ready to use for clinical diagnosis | 50-00-0    | 50 x 20 mL             |
| 258462.0961  |  |            | 50 x 40 mL             |
| 258462.0962  |  |            | 50 x 30 mL             |

50 devices per box



A227,EN;202411



Keep the empty container at the top and the container with the formaldehyde at the bottom.



Unscrew the empty container and remove the sealing plug by pressing the tab towards the burr.

**IMPORTANT:** when unscrewing, hold the device at the magenta thread and never at the lower container.



Place the sample on the grid of the stopper, using tweezers and the central burr of the stopper. Screw the empty container back on, making sure that it is tightly closed.



Turn the assembly to have the container with the formaldehyde liquid on top.

The tissue sample falls down and remains in the empty container.



Press the upper container until all the liquid flows into the lower container through the bidirectional valve. The sample will be immersed in the formaldehyde, starting the fixation process.



Hold the assembly in this position.

The sample is ready to be transported in formaldehyde to the laboratory.



Turn the Histofix®-Safe, leaving the sample container and the formaldehyde on top.



Press the upper vessel to pass all the formaldehyde through the two-way valve into the lower vessel.



Unscrew the upper empty container to recover the sample.

**IMPORTANT:** when unscrewing, hold the device at the magenta thread and never at the lower container.



Collect the sample retained on the grid with the help of tweezers. The sample is ready to be processed.