

# Instructions for use of HistoFor BFS fixative solution

## HistoFor BFS: 10% buffered formalin solution



In vitro diagnostic  
medical device

### Intended use:

HistoFor BFS is designed for fixation and transport of biological material.  
The product is an *in vitro* diagnostic medical device and is intended for professional use.  
The product is designed for single use.

### Method principle:

The aim of biological material fixation is to preserve cells and tissues in their natural form and to allow their further processing. The fixation of a sample serves to protect it from degradation while preserving the natural shape and arrangement of macromolecules within and around the cell to the greatest possible extent. Fixation terminates all ongoing biological processes and increases the mechanical stability of the sample.

### Solution composition:

HCHO 36-40%	100 ml/l
H <sub>2</sub> O	900 ml/l
KH <sub>2</sub> PO <sub>4</sub>	4.0 g/l
Na <sub>2</sub> HPO <sub>4</sub>	6.5 g/l
pH 6.8-7.2 at 20°C	

### Content of possible packages:

Sampling containers:		Canisters:	
Container volume / fixative solution prefill	Name:	Weight of fixative solution in the canister	Name:
20 ml / 10 ml	HistoFor BFS-20	1 kg	HistoFor BFS-L1
40 ml / 20 ml	HistoFor BFS-40	5 kg	HistoFor BFS-L5
60 ml / 30 ml	HistoFor BFS-60	10 kg	HistoFor BFS-L10
125 ml / 60 ml	HistoFor BFS-125	20 kg	HistoFor BFS-L20
180 ml / 90 ml	HistoFor BFS-180		
250 ml / 125 ml	HistoFor BFS-250		
500 ml / 250 ml	HistoFor BFS-500		
1,000 ml / 500 ml	HistoFor BFS-1000		
2,500 ml / 1,250 ml	HistoFor BFS-2500		
5,000 ml / 2,500 ml	HistoFor BFS-5000		

### Procedure for the use of HistoFor BFS in sampling containers:

1. Before handling HistoFor BFS solution, use personal protective equipment, see 'Instructions for Safe Handling'.
2. Before use, visually inspect the solution for any physical defects and for damage to the HistoFor BFS packaging. If there is a defect or damage, do not use the product.
3. When unscrewing the cap, hold the container vertically or place the container on a stable surface to prevent accidental spill of HistoFor BFS. Carefully unscrew the cap anticlockwise.
4. Immediately immerse the taken tissues in the container with HistoFor BFS fixative solution. The tissues must be freely inserted into the container and completely immersed in the solution, which must be 10-20 times the volume of the fixed tissue.
5. Immediately screw the cap on in a clockwise direction. Be careful, the cap must not jam or become twisted. The cap must seal the container tightly to prevent leakage of HistoFor BFS. If stained with HistoFor BFS, the label may become completely illegible.
6. Record the patient details on the label.
7. Prepare the sample container according to the regulations for the transport you have chosen. In addition, keep the safe treatment instructions.

### Procedure for using HistoFor BFS in canisters:

1. Before handling HistoFor BFS solution, use personal protective equipment, see 'Instructions for Safe Handling'.
2. Before use, visually inspect the solution for any physical defects and for damage to the HistoFor BFS packaging. If there is a defect or damage, do not use the product.
3. When unscrewing the cap, hold the canister vertically or place the canister on a stable surface to prevent accidental spill of HistoFor BFS. Carefully unscrew the cap anticlockwise.
4. Use the HistoFor BFS solution for your laboratory needs (e.g. to fix and transport biological material in volumes other than those supplied in the sampling containers). Immediately immerse the taken tissues in HistoFor BFS fixation solution. The tissues must be freely inserted into the container and completely immersed in the solution, which must be 10-20 times the volume of the fixed tissue.
5. Immediately screw the cap on in a clockwise direction. Be careful, the cap must not jam or become twisted. The cap must seal the container tightly to prevent leakage of HistoFor BFS. If stained with HistoFor BFS, the label may become completely illegible.

## Instructions for use of HistoFor BFS fixative solution

### **Storage conditions:**

Store at 4-25°C. Protect from direct sunlight.

**After tissue sampling, the sample medium must be stored at 10-25°C.**

Store in a closed container. Leaving the container open for a longer period of time may reduce the concentration of formaldehyde (HCHO).

### **Safety measures:**

Only for professional use.

The product must not be used after the specified expiry date.

If spilled, prevent the contents from entering drains and sewage. Dust the contents with absorbent material, e.g., sand or dry soil, put it in covered containers and dispose of them as hazardous waste. Clean contaminated objects and the floor thoroughly.

Do not use when the appearance (colour of the solution) changes.

### **Disposal method:**

Dispose of unused or otherwise unsuitable product as organic waste containing hazardous substances, code 16 03 05\*, according to applicable legislation and regulations. Empty packaging containing residues of hazardous substances or packaging contaminated with hazardous substances, code 15 01 10\*, shall be disposed of as hazardous waste in accordance with applicable waste legislation.

Dispose of used product containing residual biological material in accordance with applicable waste legislation as hazardous waste (infectious waste) code 18 01 03 02\*.

**Expiry:** 18 months from the production date.



### **Note:**

The occurrence of any serious adverse event related to this device must be reported to the manufacturer and to the competent authority (for the Czech Republic, the State Institute for Drug Control) where the user or patient is established.