DIAPATH

PATENTED PRODUCT CE IVD

SafeCapsule

Disposable pre-filled containers with formalin in safety capsule, for transport and histological specimen fixation

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Intended use

Transport, fixation and storage of histological specimens

Code	Description	Packaging	Pre-filled volume
SC021	Container with blue screw cap, pre-filled with buffer solution	35 pcs	33 ml
SC022E	Safety red capsule pre-filled with formalin + marker	35 pcs	7 ml

Description

- Closed-circuit safety device for the fixation and the transport of small histological specimens
- User-friendly device that assures **complete safety** of fixative use, eliminating the risk of formalin exposure for the operator
- **Perfect seal** of the device in accordance with **UNI EN 14254:2004 standard** " Requirements and test methods for single-use evacuated and non-evacuated receptacles, intended by their manufacturers, for the primary containment and preservation of specimens, other than blood specimens, derived from the human body, for the purpose of in vitro diagnostic examination"
- Device compliant with all dispositions of **EU regulation 605/2014** regarding the toxicity of solutions containing formaldehyde, Legislative Decree 81/2008 regarding workers' safety measures and **Guidelines of SIAPEC-IAP** Italian Division (February 2016) on formalin use
- The assembly of the red safety-capsule within the blue cap assures specimen fixation inside one solution of neutral buffer solution 10% (formaldehyde 4%)
- After device assembly, red capsule with **formalin and marker** allows an **immediate visual identification of active device**, respect the device containing only the buffer solution
- Constant immersion of biopsy inside the formalin, even in case of accidental overturning of the device
- The red Capsule -containing concentrated formalin sealed by an aluminium layer- is enclosed in a plastic sachet that further protects against accidental contact with the formalin in the event of damage and breakage of the aluminium film.
- Latex free
- Phthalates free
- **Patented product**

Capsule containing formalin, individually packed to avoid possible overturning

Blue cap with removable aluminum (High tight)

Container pre-filled with neutral buffered solution for an easy release of the specimen

Transparent label for a clear specimen visibility

Composition

• Formaldehyde	CAS No. 50-00-0	EC No. 200-001-8
• Methanol	CAS No. 67-56-1	EC No. 200-659-6
• Sodium phosphate monobasic	CAS No. 10049-21-5	EC No. 231-449-2
• Disodium phosphate dodecahydrate	CAS No. 10039-32-4	EC No. 231-448-7

Instruction of use

SafeCapsule device is intended for the sampling and the management of histological specimen in total safety. Neutral buffered 10% formalin, inside the assembled containers, assures a primary fixation of the specimen compatible with diagnostic techniques in use.

Step 1: Loosen the blue cap, a few turn without removing it completely, then remove the aluminum film from the blue cap

Pleaase note: *this operation is necessary due to the possible amount of buffer solution trapped in the blue cap. Loosening the cap facilitates the release of the solution into the vial.*

Step 2: Remove completely the blue cap and immerse the sample into the vial filled with the buffer solution

Step 3: Remove the red capsule from its protection package and screw it into the blue cap. Make sure you screw the capsule all the way in and tilt the device for a few seconds in order to facilitate the flow of formalin from the capsule to the vial.

Step 1

Step 2 Step 3

NOTE:

- To take the biological sample from the activated SafeCapsule device, we suggest to tilt the device to allow to the possible volume of fixative returned into the cap to go back to the vial and after unscrew the **complex blue cap – red cap under the hood.**
- The neutral buffered solution is not dangerous for the operator, as indicated by the label on the removable high-strength aluminum film
- After assembling the safety capsule, the transparent label placed on the pre-filled container will show the warning symbols of the device

GUIDELINES

- Make sure that the "Sample Volume / Fixing Volume" ratio is suitable for a correct fixation of the sample. *"The volume of the ratio between fixative and tissue must be included in the collection / handling and presentation procedures i.e. the volume of neutral buffered formalin at 10% should be 15-20 times the sample volume"* (1)

- The plastic sachet containing the red capsule enables immediate visual confirmation of the good condition of the capsule. If "droplets" can be seen inside the plastic sachet, it is recommended to dispose of it so as to exclude any contact with the formalin.

- In order to minimize the morphological and structural alterations of the tissues deriving from cold ischemia, it is necessary to immerse the sample in the neutral buffered solution and screw the safety capsule in the shortest time interval from the sampling. "*The time that elapses between excision and fixation of the tissue is referred to as "cold ischemia time", it is reported for the deleterious effects on the preservation of antigens and nucleic acids. The American CAP/NSH guidelines list the cold ischemia time as a mandatory field in the checklist of the histological examination request as the ASCO/CAP guidelines for performing immunocytochemical analyzes for predictive purposes in breast cancer . Recent European guidelines for molecular tissue investigations underline the importance of cold ischemia time on the outcome of the analysis*" (2)

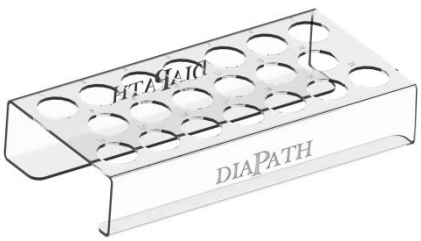
(1) College of American Pathologist Practical Guide to Specimen Handling in Surgical Pathology
(2) Ministry of Health Superior Health Council Superior Health Council Section I Traceability Guidelines, Collection, Transport, Filing and Storage of cells and tissues for diagnostic investigations of ANATOMIC PATHOLOGY

To avoid mistakes, only qualified, trained staff should use the product. Professional use product. The guidelines concerning safety on the workplace must be applied according to current regulations. The tools used for diagnosis must be suitable for diagnostic use in laboratory. Only authorized, trained, competent staff should perform the diagnosis.

Features of containers

Code	Kind of container	Pre-filled volume	Dimensions (H x Ø sup.)
SC021	Polypropylene transparent container of 60ml with double screw blue cap: - External (for pre-filled container) - Inner (for SafeCapsule) Label reporting formalin and biohazard risk icons are intended only after SafeCapsule activation	32 ml	8.3 cm X 4 cm
SC022	Polypropylene safety red capsule with pierceable sealing. Label with formalin icons	8 ml	4 cm X 3.8 cm

To guarantee the right transport of specimens, available a tray for the safe transport of pre-filled containers (code SC0015).



Physic-Chemical features of SafeCapsule solutions

Neutral buffered solution inside the pre-filled container with blue cap

- pH between 7.4 and 7.5
- Molarity of phosphate buffer: 0.07 M

Formalin solution inside SafeCapsule

- Formalin solution at 24%
- The solution contains methanol as stabilizer

Formalin solution after SafeCapsule activation

- Neutral buffered solution 10% (formaldehyde at 4%)
- pH between 7.0 and 7.4
- Molarity of phosphate buffer: 0.05 M

Suggested volume range specimen/fixative:	1:10
Suggested fixation time	6/48 hours, depending on specimen dimension

Note: We declare that the final concentration of the product is 4%. We hereby ensure that during the evaluation of risk analysis, the parameter (4% concentration) is guaranteed by Diapath's internal processes and internal quality controls, in which is considered the variation in percentage of raw materials, transport variables and packaging.

Labeling

Labelling allows a correct detection of the risk during the different step of the use of the device as shown in the chart.

Device in compliance with all regulations regarding the new classification about toxicity of solution containing formaldehyde:

- Regulation (EU) No 605/2014 of 05/06/2014 and s.m.i. for dispositions contained into Chapter IX, Annex II of Legislative decree 9th of April 2008, No.81 – PROTECTION FROM CARCINOGENS AND MUTAGENS AGENTS.

Blue cap	NO GHS SYMBOLS	• Label printed on resistant aluminum film, it concerns the neutral buffered solution contained into the pre-filled container • Any risk icon • **No meaning after assembling safety red capsule inside the blue cap**
Safety red capsule		• Label printed over the pierceable seal of SafeCapsule, it concerns the formalin 24% solution • Pictograms regarding formalin 24% • **No meaning after assembling safety red capsule inside the blue cap**
Pre-filled container		• Transparent label over the pre-filled container, it concerns the neutral buffered 10% formalin (formaldehyde 4%) solution • Pictograms regarding formalin and biohazard risk icon • **Acquires meaning only after assembling safety red capsule inside blue cap**

Quality control

All batches are under analytical controls useful to define their conformity.
The products and the raw materials are entered and constantly monitored by computer systems that allow traceability between batch number of each single product and batches of their raw materials.

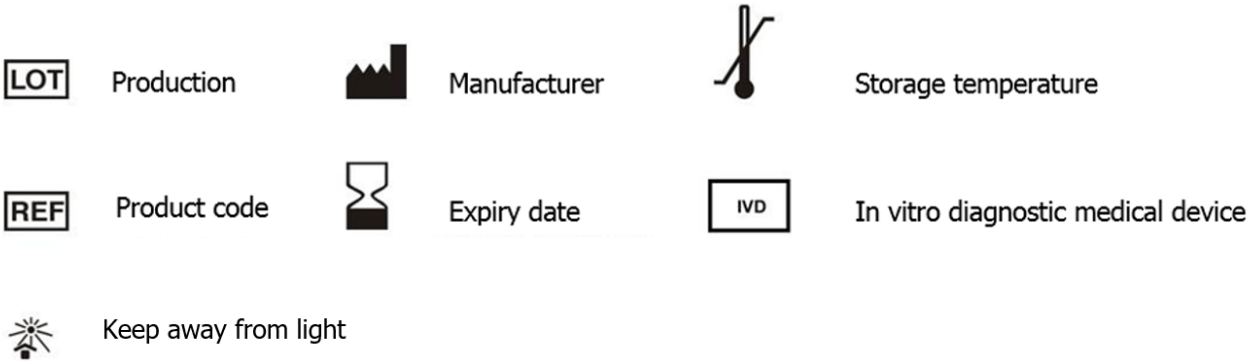
Storage

Store the product at room temperature according to the specifications listed on the label. The product, if properly stored and integrally packed, is stable up to the expiry date reported on the label. Do not use after the expiry date.
If the reagent is not stored as recommended, its performance may change and must be validated by the user. After opening, the reagent is stable up to the expiry date but only if stored in its container and in accordance with the specifications listed on the label. It is recommended to close the container tightly after use.

Disposal instruction

The expired and/or unused product must be disposed of according to local waste regulations, based on danger classification on the label and after the evaluation of possible contamination. In some cases, an analytical evaluation to determine the correct waste classification and the risks may be necessary.

Labeling legend



For more information, see MSDS.