

# DIAPATH

## SafeCapsule Prostate Biopsy Kit

*Kit for the collection, fixation and transport of prostate biopsies*



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### Inteded use

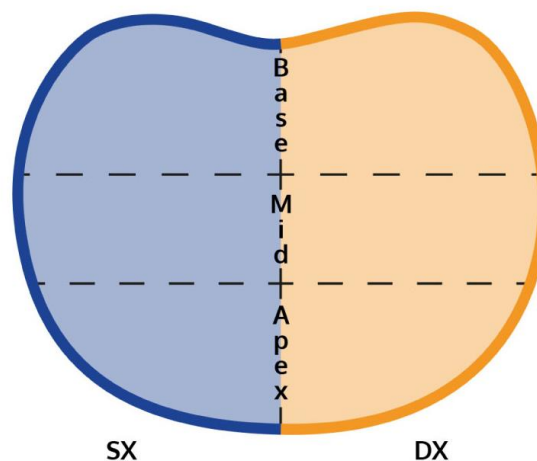
Collection, fixation and transport of prostate biopsies



	Components	Code	Pieces
SC100	SafeCapsule – container with Buffer Solution	SC041/A	2x91 ml
	SafeCapsule – safety capsule with Formalin 24%	SC042/A	2x19 ml
	Cassette holder rack		2 pcs
	Diaprint Biopsy Cassette Light Blue pre-marked SX	GP07003/A	8 pcs
	Diaprint Biopsy Cassette Orange pre-marked DX	GP07004/A	8 pcs
	Bags for transport of biological specimens	S4751/A	2 pcs
	Biopsy filters	070158/A	40 pcs

### Basics of method

**SafeCapsule Prostate Biopsy Kit** provides all the material necessary for the collection, fixation and transport of prostate biopsies. Prostate mapping involves coded sampling in various areas of the prostate gland at high risk of developing neoplastic disease, including particularly suspicious areas (focal areas). The product is a valid support for the correct identification of the samples thanks to the presence of differently colored pre-marked cassettes that identify the laterality, to the layout of the prostate that allows to define, also graphically, the sampling sites, the two racks for the insertion of the cassettes containing the samples and the presence of SafeCapsule 250mL for collection, fixation and transport in **total safety** for the sample and for the operator.



Diapath contributes to Prostate Cancer Foundation against prostate cancer

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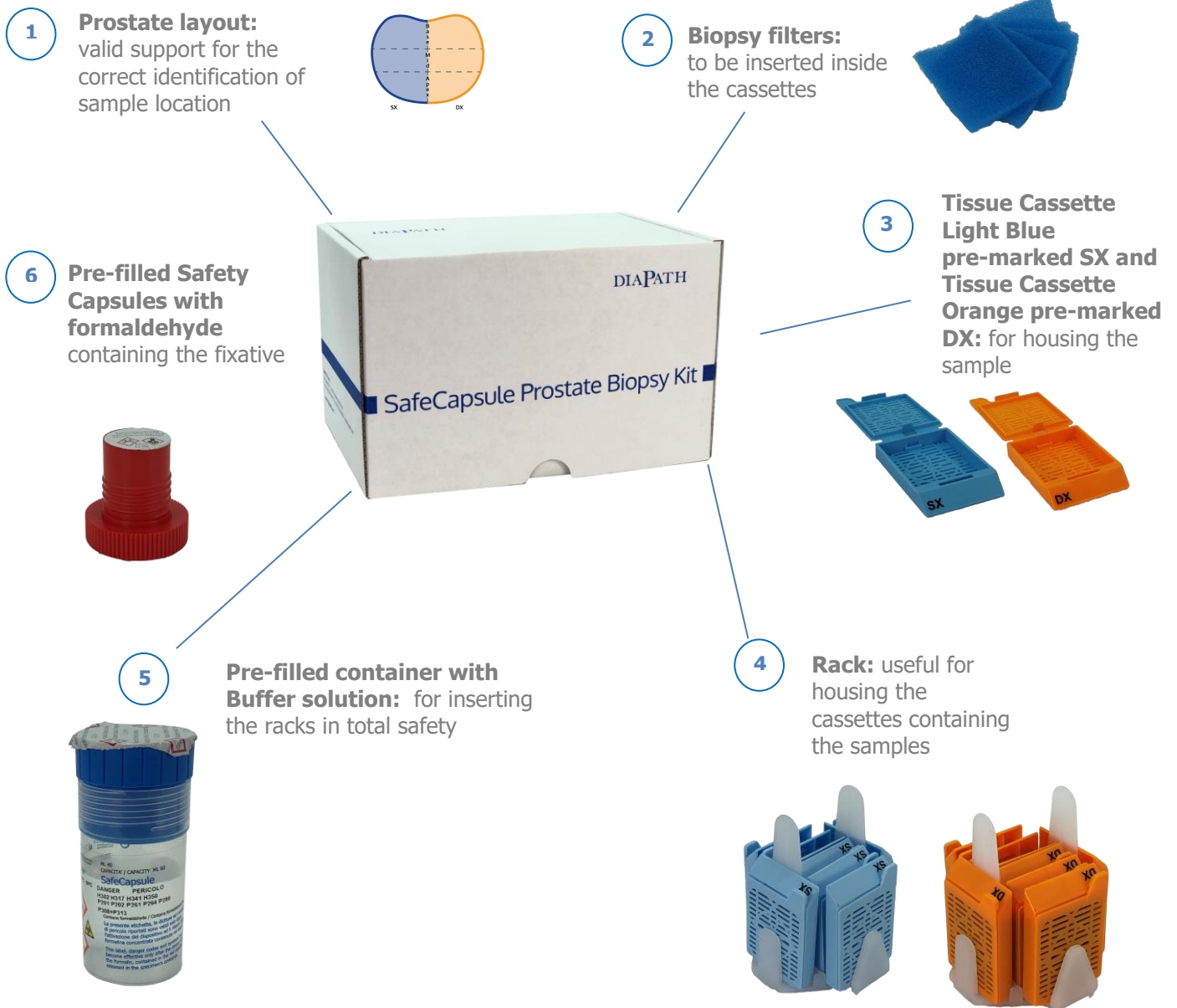
## Composition

Formaldehyde	CAS No. 50-00-0	EC No. 200-001-8
Methanol	CAS No. 67-56-1	EC No. 200-659-6
Monobasic sodium phosphate	CAS No. 10049-21-5	EC No. 231-449-2
Dibasic sodium phosphate	CAS No. 10039-32-4	EC No. 231-448-7

## Instructions for use

The SafeCapsule device responds to the need for sampling and management of the histological sample in complete safety. The 10% neutral buffered formalin, present inside the assembled containers, guarantees a primary fixation of the sample perfectly compatible with the diagnostic techniques in use.

### SafeCapsule Prostate Biopsy Kit contains:



## How to use SafeCapsule Prostate Biopsy Kit:

### 1 Workflow configuration

Remove all the content from the box and place it on the working table according to the following configuration

**NOTE:** make sure you have soaked the sponges in a water-based solution before inserting them inside the cassettes



### 2 Method

#### Left (SX)



#### Right (DX)



**NOTE:** extract/remove the rack from the activated SafeCapsule unscrewing the complex red-cap blue-cap under the ventilated hood

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## 3 Sending specimens to Anatomic Pathology



SafeCapsule Prostate Biopsy Kit includes all the necessary for sending specimens to Anatomic Pathology. Insert activated SafeCapsule inside the bags for the transport of biological specimens and send the box to the lab.

### NOTE:

- The neutral buffered solution is not dangerous for the operator, as shown 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 describe the danger of the device
- Make sure you have soaked the sponges before inserting them into the cassettes
- To remove the biological sample from the activated SafeCapsule device, unscrew the complex **red-cap blue-cap** under the ventilated hood.

### GUIDELINES

- Make sure that the "Sample volume/Volume of fixative" ratio is suitable for correct fixing of the sample. *"The volume of the ratio between fixative and tissue must be included in the collection / handling and presentation procedures ie 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 possible time interval from the collection. *"The time between tissue excision and fixation is referred to as" cold ischemia time ", it is reported for 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 analysis outcome "(2)*

(1) College of American Pathologist Practical Guide to Specimen Handling in Surgical Pathology

(2) Ministero della Salute Consiglio Superiore di Sanità Sezione I Linee Guida Tracciabilità, Raccolta, Trasporto, Conservazione e Archiviazione di cellule e tessuti per indagini diagnostiche di ANATOMIA PATOLOGICA

To avoid mistakes, qualified and 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. The diagnosis should be performed only by authorized, trained and competent staff.

### 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 reagent according to the specifications on the label. The product, if opportunely stored and integrally packed, is stable up to the expiry date reported on the label. Do not use after expiration 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 expiration 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 the use.

### Disposal instructions

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

### Warning and precautions

Please refer both to the instructions of use and information concerning hazardous substances classification on the label.

Consult the Safety Data Sheet (MSDS) for the information concerning substances mixing risks, precautions of use and first aid procedures in case of accidental loss.

### Label legend



Production



Manufacturer



Storage temperature



Product code



Expiry date



In vitro diagnostic medical device



Keep away from light