USER INSTRUCTIONS
CYTOFOAM DISK

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Manufactured by **Exmoor Plastics Ltd**
Lisieux Way, Taunton, Somerset, TA1 2LB, UK for:

Exmoor Innovations Ltd.
Lisieux Way, Taunton, Somerset, TA1 2LB UK
Tel: +44 (0)1823 354307 Fax: +44 (0)1823 354035
sales@exmoorinnovations.com

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CytoFoam Disk

Pending Patent Application Number 1203348.6

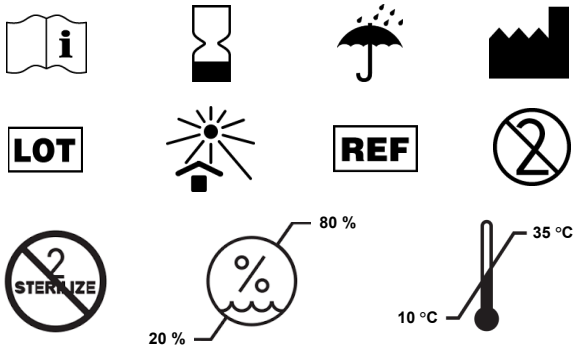
USER INSTRUCTIONS

REF **CFD1**

STERILE R

IVD

In vitro diagnostic medical device
De diagnostic *in vitro* dispositif médical
Diagnóstico *in vitro* de dispositivos médicos
In-vitro-Diagnostikum
Nel dispositivo diagnostico *in vitro*



Do Not Use if Package is Damaged
Ne pas utiliser si l'emballage est abîmé
No utilizar si el paquete está dañado
Nicht verwenden, wenn Verpackung beschädigt ist
Non usare se la confezione é danneggiata

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GENERAL

CytoFoam is supplied in two forms, CytoFoam Core and CytoFoam Disk. The CytoFoam Core is intended for the collection of cells when performing fine needle aspiration (FNA) cytology and the CytoFoam Disk is intended for the collection of cells from serous fluid samples.

INDICATIONS FOR USE

The device is intended to assist in the diagnosis and characterisation of tumours, typically cancers and other abnormal growths.

INTENDED PURPOSE

To enable the cells in a fluid specimen to be incorporated into a cellblock, allowing paraffin processing, histological sectioning and additional molecular investigations to be undertaken, e.g. immunohistochemistry or in situ hybridisation, to allow accurate diagnosis and characterisation of tumours.

Important

Only to be used by, or on the order of, a competent biomedical scientist.

This device has been sterilised by gamma irradiation and is for single use only.

CONTRA INDICATIONS

None

PREPARATION AND ASSEMBLY

Handle with surgical gloves.

· *Environment and safety*

Procedures utilising this device must be undertaken in an appropriate laboratory environment.

· *Familiarisation*

It is essential that users familiarise themselves with the procedure and techniques prior to use.

· *General*

The competent biomedical scientist with the responsibility of the procedure shall direct the procedure and sub activities.

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TECHNIQUE

CytoFoam Disks allow cell blocks for histology to be made from fluid cytology specimens, such as serous fluids and needle washings. First, the fluid is centrifuged and the supernatant is removed by a pipette to leave a deposit of cells at the base of the universal container. The CytoFoam Disk is dropped into the universal container so as to absorb the deposit of cells at its base. If there is a lot of deposit to absorb then two CytoFoam Disks should be used. Absorption should be encouraged by prodding the foam with the tip of a plastic pipette, or similar. The foam is then left for 10 minutes to fully absorb the fluid and suspended cells.

Industrial methylated spirits is then poured into the universal container. This seals in the cells. The CytoFoam Disk should be left in the industrial methylated spirits for only a short time, for no more than 30 seconds, as prolonged alcohol fixation causes artifactually negative immunohistochemistry results. Firm shaking at this point usually causes the CytoFoam Disk to break away from the bottom of the universal container and float within the industrial methylated spirits. The industrial methylated spirits is then removed by pipette and replaced with formalin. It is recommended that the disk is fixed in formalin for at least 6 hours and preferably 12 hours. Fixation requirements vary from one laboratory to another, according to variations in laboratory practice and users should evaluate their own fixation protocols to determine an optimal result. In some situations the result may be required urgently and it may be possible to validate a shorter fixation protocol. Inadequate fixation can sometimes make sectioning difficult and adversely effect the quality of immunohistochemistry.

For more information on CytoFoam and processing, please see www.exmoorinnovations.com

UNEXPECTED PERFORMANCE

In the event that one CytoFoam Disk is not sufficient to absorb the deposit of cells, a second disk should be added to increase the amount absorbed.

RISKS/SIDE EFFECTS

Clinical

Local laboratory protocols should be followed.

Inadequate formalin fixation can lead to artefactually negative immunohisto-chemistry and thus lead to inaccurate interpretation. Formalin fixation should be for at least 6 hours and preferably 12 hours or alternatively utilise a validated local protocol.

General

Follow local protocols for laboratory safety.

CytoFoam Disks are intended to be used with fresh specimens that could bear infectious pathogens.

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HANDLING

Pack contents sterile if packaging unbreached.

Do not use if packaging breached.

Do not resterilise.

Handle in a clear environment with surgical gloves.

Do not exceed use by date.

STORAGE

Store in a clean, dry environment, at room temperature.

Do not use if packaging wetted or breached.

Avoid extremes of temperature and humidity. Optimal storage conditions are between 10 - 35°C and 20 - 80% relative humidity.

Keep out of direct sunlight.

DISPOSAL

Follow local laboratory protocol.