



CytoFoam Disk

Patent Granted GB250557

USER INSTRUCTIONS

REF CFD1



CE

STERILE R

IVD

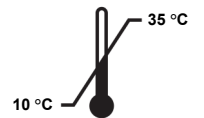
In vitro diagnostic medical device
De diagnostic *in vitro* dispositif médical
Diagnóstico *in vitro* de dispositivos médicos
In-vitro-Diagnostikum
Nel dispositivo diagnostico *in vitro*



LOT



REF



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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CE



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USER INSTRUCTIONS CYTOFOAM DISK

GENERAL

CytoFoam is supplied in two forms, CytoFoam Core and CytoFoam Disk. 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 and also the collection of material from endoscopic FNA samples when the endoscopic needle cannot be fitted to a CytoFoam Core device.

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.

CytoFoam is not intended for use with a clotted specimen or solid specimen as the specimen will not be absorbed by the foam. Clotted or solid material should be submitted directly for histopathological examination in the same way as a biopsy.

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.

USER INSTRUCTIONS CYTOFOAM DISK

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. In each pack of CytoFoam there are two Disks, one 6mm in diameter and the other 12mm. If there is a lot of deposit to absorb then the larger 12mm CytoFoam Disk or two CytoFoam Disks should be used. If the serous fluid specimen is partly clotted then the clot should also be processed separately for histology as it may contain tumour cells. Absorption by the CytoFoam Disk 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. 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. The use of alcohol based fixatives, e.g. ThinPrep, is not recommended with CytoFoam as these will stop the cells from sticking to the foam. Subsequently cells are lost during processing.

CytoFoam Disk is also used to collect specimens from endoscopic FNAs when the endoscopic needle cannot be fitted to a CytoFoam Core device. In this situation the tip of the endoscopic FNA needle is placed on the centre of a 12mm CytoFoam Disk and the contents of the needle are ejected directly onto the CytoFoam Disk. The Disk is then left for a minute for the specimen to start to clot and then it is placed in formalin. The specimen must not be allowed to dry out.

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. As with any histology specimen, inadequate fixation can sometimes make sectioning difficult and adversely affect 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.

As with any histology specimen inadequate fixation can sometimes make sectioning difficult and adversely affect the quality of immunohistochemistry.

General

Follow local protocols for laboratory safety.

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

USER INSTRUCTIONS CYTOFOAM DISK

HANDLING

Pack contents sterile if packaging unbreached.

Do not use if packaging breached.

Do not resterilise.

Handle in a clean 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.