USER INSTRUCTIONS
CYTOFOAM CORE

RISKS/SIDE EFFECTS Cont'd

General

Clinician to avoid distractions when handling needle as this may lead to harm.

If the patient is anti-coagulated, has liver disease or has a clotting disorder then check the patient's coagulation performance prior to the procedure.

Avoid needle stick injury. In the event of needle stick injury follow local protocols.

HANDLING

Pack contents sterile if packaging unbreached.

Do not use if packaging breached.

Do not resterilise.

Handle the device aseptically.

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

Discard into a sharps container per local protocols. Dispose of any biohazard waste by incineration following local protocols.

PATIENT BRIEFING

The patient's identity should be checked and confirmed.

The patient's medical history should be reviewed.

The patient should have the nature of the procedure explained to them.

The patient should be asked if they are taking any medication, particularly any anticoagulants.

The patient should be asked if they have a history of fainting during needle puncture procedures.

The patient should be made aware of the possible complications.

After the procedure it may be appropriate to ask the patient to stay for observation. This depends on the site of the procedure and the clinical context.

The patient should be advised that after the procedure, mild analgesics may be used to control post-operative pain. Aspirin or aspirin substitutes should not be taken for 48 hours after the procedure (unless aspirin is prescribed for a cardiac or neurological condition).

The patient should be asked to report to their doctor any continued bleeding, pyrexia, severe pain or severe swelling following the procedure.

It may be appropriate to give the patient an information sheet, to accompany the verbal information given to them.

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Exmoor Innovations

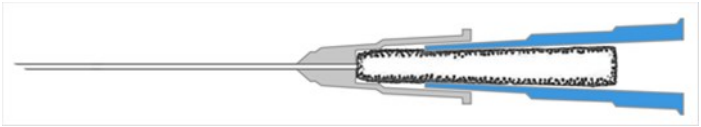
CytoFoam Core

Pending Patent Application Number 1203348.6

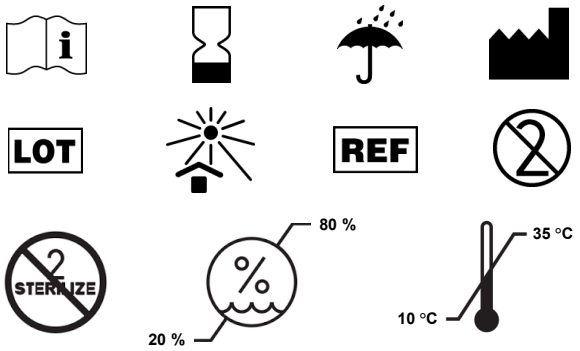
USER INSTRUCTIONS

REF CFC1

Avoid needle stick injury!
Read instructions for use



CE 0120 STERILE R



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

USER INSTRUCTIONS
CYTOFOAM CORE

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 medical practitioner and in conjunction with a competent cellular pathology laboratory.

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

CONTRA INDICATIONS

To be used with caution in anti-coagulated patients or patients with a clotting disorder.

To be used with caution in proximity to large blood vessels, nerves and major organs.

To be used with caution if the patient has a potentially infectious disease.

PREPARATION AND ASSEMBLY

Handle aseptically with surgical gloved hands only.

Immediately prior to use, visually inspect the assembly to confirm that the foam core is abutting the proximal end of the needle within the hub to ensure that any sample gathered will be absorbed into the foam and not be lost into the needle hub.

· *Environment and safety*

FNA procedures utilising this device must be undertaken in an appropriate environment having all emergency materials for safety to hand.

· *Familiarisation*

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

· *General*

The competent medical practitioner with the responsibility of the procedure shall direct the timing of the procedure and sub activities.

USER INSTRUCTIONS
CYTOFOAM CORE

TECHNIQUE

Pre Laboratory Handling Instructions

Prepare the patient.

Take care to avoid needle stick injury. Leave the needle sheath in place until ready to perform the procedure. In the event of needle stick injury follow local protocols. The skin at the puncture site should be cleaned prior to the procedure in the same way that it would for a routine venepuncture. After the procedure pressure should be applied to the puncture site to reduce bruising and bleeding, as would be the procedure for routine venepuncture.

To avoid inadvertent disconnection of needle hub from the blue Luer connector (which houses the foam core), ensure the needle sheath is removed whilst holding the hub of the needle and hold both components with thumb and forefinger of the preferred hand whilst collecting the cell sample.

Once the sample has been collected then it should be expelled on to a glass slide in the usual way for an FNA specimen by air pressure from a syringe attached to the end of the blue Luer connector away from the needle. Some of the sample in the foam will be ejected but some will remain. If collecting a large amount of sample into the foam is a priority then one can separate the needle from the blue Luer connector once the sample has been collected, and then just expel the sample from the needle on to the slide.

In the event that the sample is so small that the foam fails to harvest cells, attach a syringe to the blue Luer connector and expel the contents onto a slide. Then using the tip of the foam core uplift some of the sample from the slide and process as originally intended.

After harvesting sufficient sample into the foam core, separate the needle from the blue Luer connector that contains the foam and **place the plastic transit cap over the tip of the foam core**. This is important as without the transit cap some of the sample may be washed from the foam by the formalin. Place immediately into formalin and **allow 6 hours and preferably 12 hours for formalin fixation** prior to processing or alternatively utilise a validated local protocol. Insufficient fixation can cause artifactually weak or negative immunohistochemistry, especially for some nuclear markers. If DNA preservation is critical then part of the foam can be cut off and frozen or preserved in methanol or another suitable preservative for DNA. **Do not allow the sample to dry out**.

Place the transit label, which includes processing information, on the formalin transit pot. Follow local protocols for sample protection and delivery to laboratory.

Laboratory Handling Instructions - Supplied as an adhesive label to be placed on the specimen pot

1. It is recommended that the specimen 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.
2. Using forceps pull the foam core from its blue plastic housing by gripping close to the blue Luer plastic housing and pulling.
3. Wrap the core with tissue processing paper.
4. Paraffin process as for a normal biopsy specimen. If there is only scanty specimen at the tip then embed so as to cut the tip in cross section and so maximise the number of cells in the sections.

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

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UNEXPECTED PERFORMANCE

In the event that the sample is so small that the foam fails to harvest cells, connect a syringe to the blue Luer housing and expel the contents onto a slide. Then, using the tip of the foam core, uplift some of the sample from the slide and process as originally intended.

In the event that the needle hub is separated from the blue Luer housing prior to procedure completion, ensure that the device is relocated using a forward twisting motion. Visually confirm that the foam core is abutting the proximal end of the needle to avoid sample wastage. Alternatively, replace the components and restart the procedure.

RISKS/SIDE EFFECTS

Clinical

Some discomfort will be experienced, usually similar to that of a venepuncture, but occasionally so severe as to require the procedure to be terminated. This can be reduced by using local anaesthetic.

Some bleeding and bruising during and after the procedure, usually similar to that of a routine venepuncture, but occasionally more severe, particularly in patients that are anti-coagulated or have a clotting disorder. Bruising in an exposed area, for example the neck, can lead to an unsightly mark.

As with phlebotomy needles, there is the potential to damage important anatomical structures such as nerves, large blood vessels and major organs if used without due skill or care.

As with routine fine needle aspiration cytology sampling, there is a small risk of pneumothorax when samples are taken from around the chest, axilla and lower neck.

After the procedure, mild analgesics are used to control post-operative pain. Aspirin or aspirin substitutes should not be taken for 48 hours after the procedure (unless aspirin is prescribed for a cardiac or neurological condition). When sterility is maintained throughout the procedure, infection is rare. Should an infection occur, it may require treatment with antibiotics.

If a lung or kidney biopsy has been performed, it is common to see a small amount of blood in sputum or urine after the procedure.

About one-quarter to one-half of patients having lung FNAs will develop pneumothorax. Usually, the degree of collapse is small and resolves on its own without treatment. A small number of patients will develop a pneumothorax serious enough to require hospitalisation and placement of a chest tube for treatment.

For biopsies of the liver, bile leakages may occur, but these are rare.

Pancreatitis may occur after biopsies in the area around the pancreas.

Deaths have resulted from fine needle aspiration procedures, but are extremely rare.

When a major organ such as a lung, the liver or a kidney has been sampled then the patient should be retained for observation after the procedure according to local protocols.