



FORMALIN-FREE

TissueSAFE

High vacuum biospecimens transfer system

TissueSAFE: High Vacuum Biospecimens Transfer System

Elimination of formalin from the surgery suite to the histology lab.

The International Agency for Research on Cancer (IARC¹) has classified formaldehyde as a class 1 carcinogen. This new classification is encouraging health authorities, surgical staff, pathologists and histotechnicians to look for ways to eliminate the substance from work environments.

A critical exposure point for facility personnel is in the transfer of tissue from the surgical suite to the pathology lab.

Current drawbacks

- Mounting concerns from surgical and pathology staff regarding the health effects of formalin exposure.
- Facilities can incur significant costs and downtime as a result of a formalin spill.
- Use of formalin can inhibit proper molecular testing.
- Inconsistent documentation of fixation start times from surgery and remote sites.
- Ergonomic issues can result from the use of bulk formalin containers (5 gallon cubes, large twist-on caps, ...).

TissueSAFE: taking control of the fixation process

● No formalin fumes

- Immediately after excision, specimens are transferred to an adjacent room where the TissueSAFE^{2,3} is installed. Tissue is placed into sterilized specimen bags and seal under vacuum. Users can add important case information by writing directly on the printed note field, including information into the sealable document pouch, or using an option label.
- The sealed specimen bag is then placed into a carryable "coolbag" for short distances or refrigerated transfer box for remote sites.
- A Radio Frequency Identification Device (RFID) smart card (optional), is placed into the transfer box to continuously monitor and document tissues temperature from the surgery suite to the histology lab.
- Fixation can now start under controlled conditions in the laboratory.

● No drying of tissues

● No spilling

Benefits

- Specimens are held in "as fresh" conditions.
- Specimens original colors are preserved.
- Drying of tissues is eliminated.
- Autolytic process is slowed down.
- Faster cooling of tissues due to lack of insulating air.

EUROPEAN PATENT
NO. EP 2 070 410 B1



¹ International Agency for Research on Cancer (2006) Monographs on the evaluation of Carcinogenic Risk to humans, vol 88. IARC, Lyon, France

² Tissue transfer to pathology labs: under vacuum is the safe alternative to formalin. G. Bussolati, L. Chiusa, A. Cimino, G. D'Armento. Virchows Arch. (2008) 452:229-231

³ Vacuum-based preservation of surgical specimens: An environmentally-safe step towards a formalin-free hospital Di Novi C, Minniti D, Barbaro S, Zampirolo MG, Cimino A, Bussolati G. Sci Total Environ. 2010 Jul 15; 408(16):3092-5.



How to control fixation. Start with fresh tissues in your lab!

Innovative TissueSAFE technology for high vacuum sealing/transfer of biospecimens to the histology lab.



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Your choice of fixation protocols



Formalin fixation? **Yes**

Selected blocks are inserted in cassettes for fixation in formalin under controlled conditions (eg. FixMATE).

Molecular studies? **Yes**

Specimen can be fixed in an ethanol based molecular fixative (eg. FineFIX).

Tissue banking? **Yes**

Selected blocks can be frozen for tissue banking.

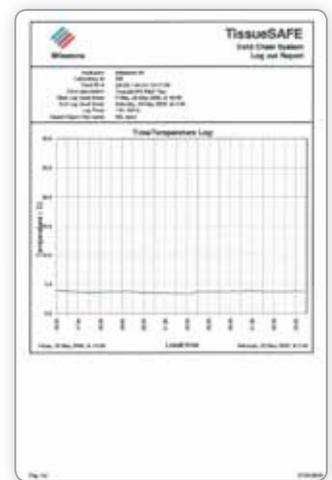
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Improved work conditions in grossing area

Upon arrival bags are opened. Tissues arrive life-like, allowing better visualization. They can first be documented through a macro digital imaging system (MacroPATH D). After grossing, excess tissue can be retained in the specimen bag or placed in a closed formalin container.

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Complete time and temperature documentation

The smart card data are retrieved by a standard PC. Time and temperature information is displayed and a report can be printed.



1 Activation of the smart card

At the beginning of the shift activate the RFID smart card to continuously monitor time and temperature. Place card in the transfer cart. Set temperature at 2-4 °C.



2 Documenting time of sealing

At the push of the button a label is printed with name of hospital, date and time. The label is affixed through the sealed bag.



3 Sealing the specimen

Specimens are placed in single use special vacuum bags and sealed by closing the cover of the TissueSAFE. Use the pre-printed note field or sealable document pouch to include additional important information.



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From the surgery suite to the histopathology lab

Three transfer modules are available:
1. Basic - 2. Large volume with UPS power supply - 3. For car transfer

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Collecting specimens in the transfer cart



During the surgery hours, vacuum sealed specimens are collected

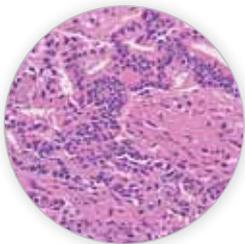
Optimal morphological preservation for up to 64 hours

All tissues specimens.

All types of tissues⁴ have been preserved under vacuum (colon, gall bladder, spleen, kidney, thyroid, breast etc...) for up to 48-64 hours with optimal histological preservation⁵.

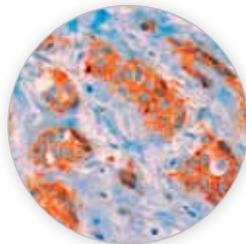
Excellent H&E, HC, IHC, FISH staining properties.

Over a thousand cases, using vacuum preservation, were tracked at the Molinette University Hospital in Turin, Italy. Morphological preservation and immunohistochemical reactivity were excellent and no adverse effects from the process were noted.



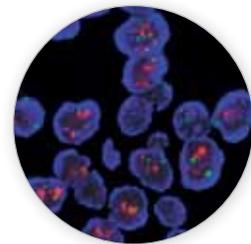
H&E

Adenocarcinoma of the colon. The specimen was kept under vacuum at 4°C for 48h, then routinely processed with formalin fixation and paraffin embedding. The structure is preserved and diagnosis is feasible. H&E x 150



IHC

Infiltrating ductal carcinoma of the breast. The tissuespecimen, removed on Friday afternoon, was kept under vacuum at 4°C till monday morning (64h), then routinely grossed, fixed and processed. The histological structure is well preserved. Staining for HER2 antigen (Herceptest™ by DAKO) shows a continuous membrane staining in >30% of cells (3+score).



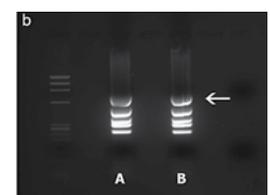
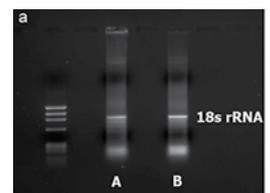
FISH

Infiltrating ductal carcinoma of the breast. Tissue specimen kept (at the surgical theatre) for 64h under vacuum, at 4°C. Dual-color FISH demonstrates amplification of HER 2 gene (red signal).

Molecular studies. Biobanking.

The quality of RNA preservation is of course related to the time of processing, but even tissues kept under vacuum at 4°C for 48 hours provided nucleic acids of acceptable quality³. This finding is in agreement with reports on the stability of RNA in non-fixed surgical specimens kept on ice⁴.

Colon mucosa either (A) frozen immediately after removal or (B) preserved under vacuum at 4°C for 48 h. (a) shows 1% denaturing agarose gel of total RNA running: the 18s band is visible and no degradation is appreciable. (b) represents RT-PCR products of cytokeratine 20mRNA of different bp number. The upper band (arrow) is related to a 716-bp product.



⁴Micke P, Ohshima M, Tahmasebpour S, Ren ZP, Ostman A, Ponten F, Botling J (2006) Biobanking of fresh frozen tissue: RNA is stable in non-fixed surgical specimens. *Lab Invest* 86:202-211.

⁵Evaluation of tissue preservation using a vacuum-based refrigeration system for specimen transfer from theatre to laboratory D Boyle, R Carson, P Kelly, M Catherwood, S Carroll, L Venkatraman, S McQuaid, H McBride, J James, MB Loughrey, Department of Pathology, Royal Group of Hospitals Trust, Belfast, Northern Ireland.

Images courtesy of Prof. G. Bussolati Turin University (Italy).

Benefits for all

Histopathology laboratory staff

- Starting time and length of fixation controlled by the laboratory.
- No toxic fumes. No handling of heavy containers.
- Colors of biospecimens preserved. "Fresh-like" conditions.
- Optimization of antigen retrieval protocols based on laboratory controlled fixation data.
- Possibility for tissue banking.
- Processing with molecular fixatives.
- Retaining of specimens post gross.

Surgical theatre staff

- No more exposure to toxic formalin fumes.
- Reduced handling of bulk chemicals.

Safety officer

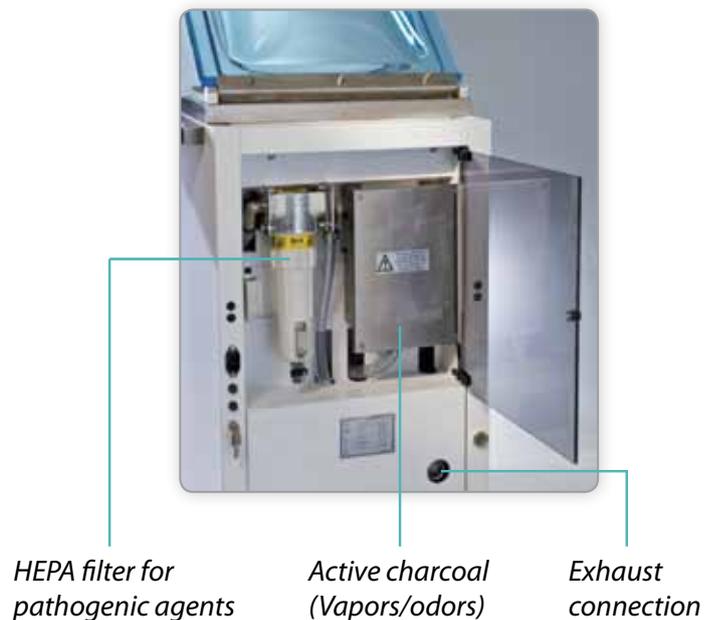
- Compliance with regulatory safety guidelines.
- Reduction of workplace spills and associated costs and downtime.

Hospital administrator

- Elimination of environmental concerns.
- Dramatic reduction in formalin use and lower recycling costs.



The safety features of TissueSAFE



MILESTONE



HELPING PATIENTS

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