

CellSafe+™ Biopsy Capsule

Instructions for Use



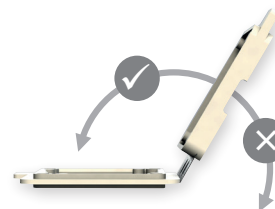
1 INTENDED USE

The CellSafe+™ Biopsy Capsule is designed to contain small tissue fragments and biopsies during specimen collection and tissue processing. These specimens are used to facilitate the diagnosis of the pathological state, and intended *for in-vitro examination of cellular deformity*.

2 PRINCIPLE OF THE METHOD

The CellSafe+™ comprises 2 interlocking plastic frames - one slightly smaller than the other - which are linked by a mesh hinge. The frames surround a polyester mesh membrane with a pore size of 200 x 200 microns which will contain the majority of small specimens received for tissue processing.

The CellSafe+™ can only be closed in one way to produce a 3.5mm cavity



Tissue specimens collected during clinics and operations are placed into the CellSafe+™ for safety, and then placed into a CellStor™ specimen pot containing neutral buffered formalin 10% to preserve the specimen. The CellSafe+™ ensures that it is easy to locate small specimens, eliminating the risk of specimens being damaged or lost. The fine 200 micron pore mesh of the CellSafe + retains exceptionally small biopsy specimens but allows formalin to freely enter the biopsy capsule for fixation of the specimen.

The mesh used in manufacture of the CellSafe+™ Biopsy Capsule is x-ray transparent and therefore calcium content of fine needle biopsies of breast tissue (FNB Breast Cores) can be analysed without removing the biopsy from the CellSafe+™

Once received at the laboratory the CellSafe+™ containing the biopsy can be removed from the specimen pot during cut-up/grossing, and transferred directly to a cassette for processing. This eliminates the risk of the biopsy being lost or damaged during transfer of the biopsy from the specimen pot to the processing cassette. The fine mesh of the CellSafe+™ allows processing chemicals to freely enter the biopsy capsule to process the specimen, without risk of loss of the specimen.

3 INSTRUCTIONS FOR USE

SAFETY INSTRUCTIONS:

We recommend that a maximum of two biopsies are placed in a CellSafe+™ at any one time. Only specimens greater than 200 micron (0.2mm) in size should be used with the CellSafe+™.

THE CELLSAFE+™ IS DESIGNED FOR SINGLE USE ONLY.

STORAGE INSTRUCTIONS:



Keep dry.



Keep away from sunlight.

TYPE OF SPECIMEN TO BE USED WITH:

Any fresh tissue specimen from the human body, required for histological examination. Particularly designed for use with fine needle core biopsies, punch biopsies, fragments of skin. Only specimens greater than 200 micron (0.2mm) in size should be used with the CellSafe+™.

HANDLING AND TREATMENT BEFORE USE:

No special requirements.

PERFORMANCE CHARACTERISTICS & METHOD LIMITATIONS:

The plastic frame and mesh used in the manufacture of CellSafe+™ are suitable for use in common tissue processing reagents including Formaldehyde solutions, Bouin's Fluid, Alcohol solutions, Xylene, Chloroform, Citrus based cleaning agents and Paraffin wax (melting point up to 65°C).

If you are using any unusual reagents we suggest that you carry out preliminary chemical compatibility tests before using the CellSafe+™.

CellSafe+™ can be used in Microwave Tissue Processors.

Important: When closing the CellSafe+™, apply pressure evenly at all four corners, using forefinger and thumb. Do not apply pressure directly to the mesh area; this may result in a lattice/ grid effect being embossed on the tissue sample.

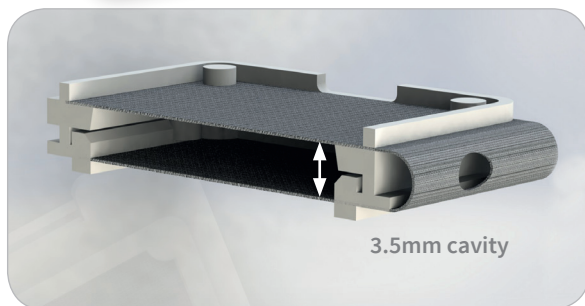
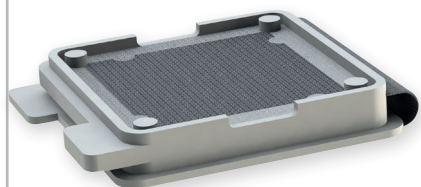
3 INSTRUCTIONS FOR USE *Cont.*

When closed the CellSafe+™ is 5mm thick and will fit into most standard size tissue processing cassettes. However, due to the large number of manufacturers and designs of such cassettes, it is impossible to guarantee that the CellSafe+™ is compatible with all cassettes. Before processing any tissue in a CellSafe+™ you should ensure that the cassette lid can be securely closed with the CellSafe+™ in position.

The CellSafe+™ can be placed in the cassette either before or after the tissue has been placed inside.

Many users issue the CellSafe+™ to the clinic so that the biopsy can be placed inside immediately and returned to the laboratory in a pre filled fixative container. This greatly reduces risk of damage to the biopsy - or even loss of material. It also saves time in the laboratory.

4 INSTRUCTIONS



4 INSTRUCTIONS *Cont.*

BIOPSIES PLACED DIRECTLY IN CELLSAFE+™ IN A CLINIC

1. Place the biopsy into the CellSafe+
2. When closing the CellSafe+™, apply pressure evenly at all four corners, using forefinger and thumb. Do not apply pressure directly to the mesh area; this may result in a lattice/ grid effect being embossed on the tissue sample.
3. Place the CellSafe+™ into a pre-filled CellStor™ Neutral Buffered Formalin 10% specimen pot as quickly as possible to ensure that the specimen begins fixation.

SYSTEM II CASSETTES

(Cassettes With Stainless Steel Lids)

1. Insert the CellSafe+™ capsule into the cassettes with the larger plastic frame positioned in the base of the cassette well.
2. Place the tissue specimen onto the mesh.
3. Close the CellSafe+™ by pushing the smaller frame into position ensuring it is completely closed. When closing the CellSafe+™, apply pressure evenly at all four corners, using forefinger and thumb. Do not apply pressure directly to the mesh area; this may result in a lattice/ grid effect being embossed on the tissue sample.
4. Fit the stainless steel lid.
5. WARNING: do not use cassettes with stainless steel lids in microwave processors.

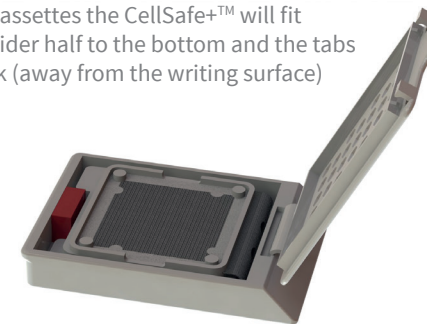
SYSTEM II+/ SYSTEM III CASSETTES

(Cassettes With Plastic Lids)

1. Insert the larger plastic frame into the cassette with the hinge adjacent to the label end of the cassette.
2. Place the tissue onto the mesh.
3. Close the CellSafe+™ by pushing the smaller frame into position ensuring it is completely closed. There should be a 1mm gap between the frame and the cassette wall which will accommodate the plastic edge and the locating tabs on the cassette lid.

4 INSTRUCTIONS *Cont.*

4. Please be aware that for some cassettes the CellSafe+™ may only fit in one orientation. For most cassettes the CellSafe+™ will fit with the wider half to the bottom and the tabs to the back (away from the writing surface)



TISSUE FRAGMENTS AND WASHINGS

1. In some instances tissue fragments or washings may need to be processed. The CellSafe+™ can be used as a filter using the following procedure.
2. Insert the larger PLASTIC frame into the cassette.
3. Hold or support the cassette horizontally and slowly pour the suspension through the CellSafe+™.
4. The tissue fragments will be retained in the CellSafe+™ and when all the suspension has been filtered the CellSafe+™ and the cassette can be closed.

5 AFTER PROCESSING

After processing in the normal manner the cassette can be opened and the CellSafe+™ removed. The CellSafe+™ can be opened by pulling the 2 tabs away from each other. The tissue can then be removed and embedded following your standard procedure.

THE CELLSAFE+™ MUST NOW BE DISCARDED - IT IS NOT DESIGNED TO BE RE-USED.