BiopSafe® Biopsy Container

4% formaldehyde neutral buffered solution

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CH REP

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CH-6300 Zug

INSTRUCTION FOR USE (20 ml & 60 ml)

The BiopSafe® Biopsy Container is a closed formalin system which consists of a container, a lid, a matrix, a filter, and a formalin liquid. The formalin is encapsulated in the lid. After the tissue has been added to the container, the lid is put on and closed, whereafter the formalin is released. The BiopSafe® Biopsy Container is manually operated.

INTENDED USE

The BiopSafe® Biopsy Container is intended to preserve tissue in a closed formalin system.

INTENDED USER

The BiopSafe® Biopsy Container is intended to be used by nurses, laboratory technicians, or other staff trained in using biopsy containers.

CONTENTS

BiopSafe® Biopsy Container containing 4% formaldehyde in a neutral buffered solution (pH 7.0) with <0,2% methanol (a 10% formalin solution).

STORAGE

The BiopSafe® Biopsy Container should be stored upright between +10°C and +25°C, protected from direct sunlight, and adequately ventilated. Should be used before the expiry date.

EXPIRY DATE

Refer to the BiopSafe® Biopsy Container label.
The BiopSafe® Biopsy Container is produced with a 2-year shelf life.

SIZE OF TISSUE/BIOPSY

For the 20 ml BiopSafe® Biopsy Container, tissues in the range 1 mm^3 to 1 cm^3 is recommended.
For the 60 ml BiopSafe® Biopsy Container, tissues in the range 2 mm^3 to 3 cm^3 is recommended.

WARNING AND PRECAUTIONS

- May cause an allergic skin reaction.
- Suspected of causing genetic defects.
- May cause cancer.
- Obtain special instructions before use.
- Avoid breathing vapours/spray.
- Wear protective gloves/eye protection/face protection.
- If skin irritation or rash occurs, Get medical advice/attention.
- If exposed or concerned: Get medical advice/attention.
- Dispose of contents/container to local waste disposal facility.
- Restricted to professional use.
- Avoid direct contact with the formaldehyde solution in the lid.

DISPOSAL

Formaldehyde is to be considered as hazardous waste. Dispose of content/container in accordance with local regulations.

PROCEDURE FOR SAMPLING

Wear protective medical gloves (Butyl or Nitrile) and eye protection.

INCIDENTS

In case the BiopSafe® Biopsy Container has been unintentionally activated or broken, secure the BiopSafe® Biopsy Container in a closed container and discard it according to local regulations.

Should a serious incident occur, it must be reported to BiopSafe® at info@biopsafe.com as well as the country's competent authority where the user is established.

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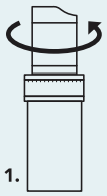
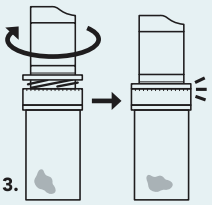
BiopSafe® Biopsy Container

PROCEDURE

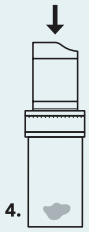


1. *Twist the lid containing formalin counterclockwise and open the BiopSafe® Biopsy Container.*

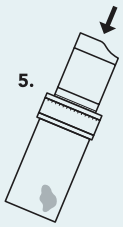
2. *Place the tissue in the empty container.*



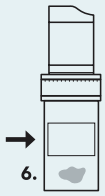
3. *Twist the lid clockwise until it is completely closed.* *NOTE: LEAVE NO GAP BETWEEN THE LID AND THE CONTAINER.*



4. *Release the formalin by pressing the top of the lid firmly.*



5. *Tilt the BiopSafe® Biopsy Container at approximately a 45-degree angle and shake 3-5 times until all the formalin has been released from the lid. Make sure that the tissue is fully submerged in the formalin.*



6. *According to local procedures, add a label with patient data and other relevant information on the BiopSafe® Biopsy Container.*

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