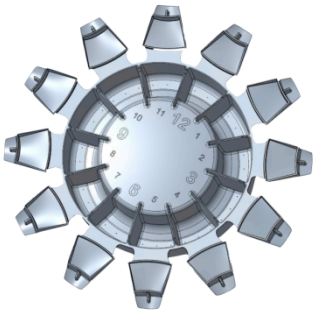
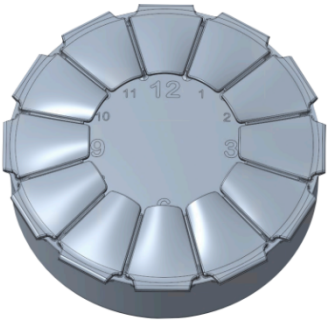
INSTRUCTIONS FOR USE: BIOPSY CYLINDER HOLDER





LOC-CORE® BIOPSY CYLINDER HOLDER

IVD CE

INTRODUCTION.

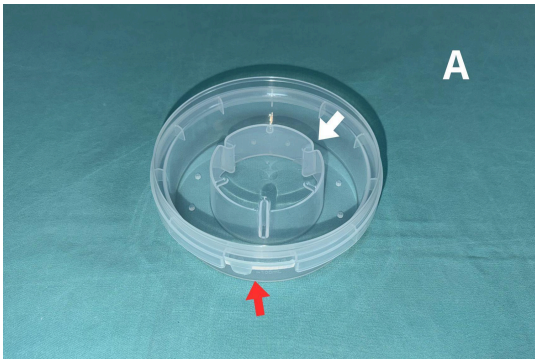
Nowadays, multiple biopsies are performed, and numerous containers are required for their identification. Furthermore, contact between healthcare professionals and formaldehyde must be avoided. **This new device prevents contact with formaldehyde and features 12 compartments**. It is essential for facilitating the handling of biopsies, as well as their precise and secure identification.

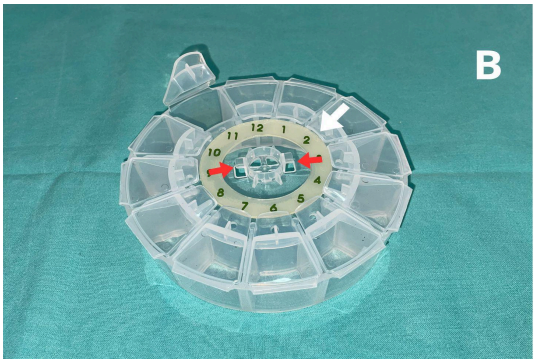
COMPONENTS

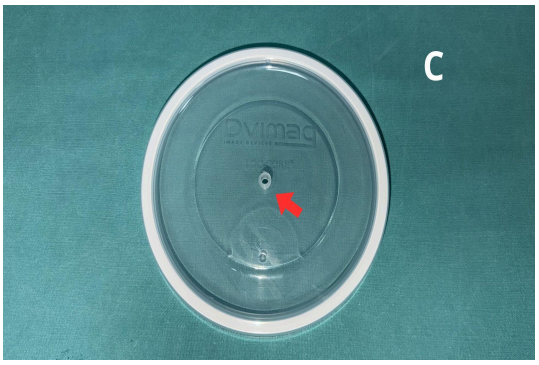
This biopsy handling *in* vitro medical device consists of 3 components:

1. **Container (Fig. A):** This is the base of the device where pre-filling with Buffer solution takes place. It has slots (thin arrows) in the center for coupling the cylinder holder, and a safety seal (thick arrow) to prevent opening prior to use.
2. **Cylinder Holder (Fig. B):** This is the piece that has 12 numerated compartments for depositing the biopsy cylinders. It also contains a connector tube (thick arrow) for the passage of liquid into the container, and two tabs for handling (thin arrows).
3. **Lid / Cap (Fig. C):** Allows for the hermetic sealing of the device and features a Luer Lock connector for the introduction of formalin (arrow).
4. **Accessories:** 12 histology sponges (26 mm × 30 mm); 12 securing clips; 1 pair of tweezers.

*A biopsy needle, fine hypodermic needle and sterile gauze are also required for use and are not included with the components of this product.



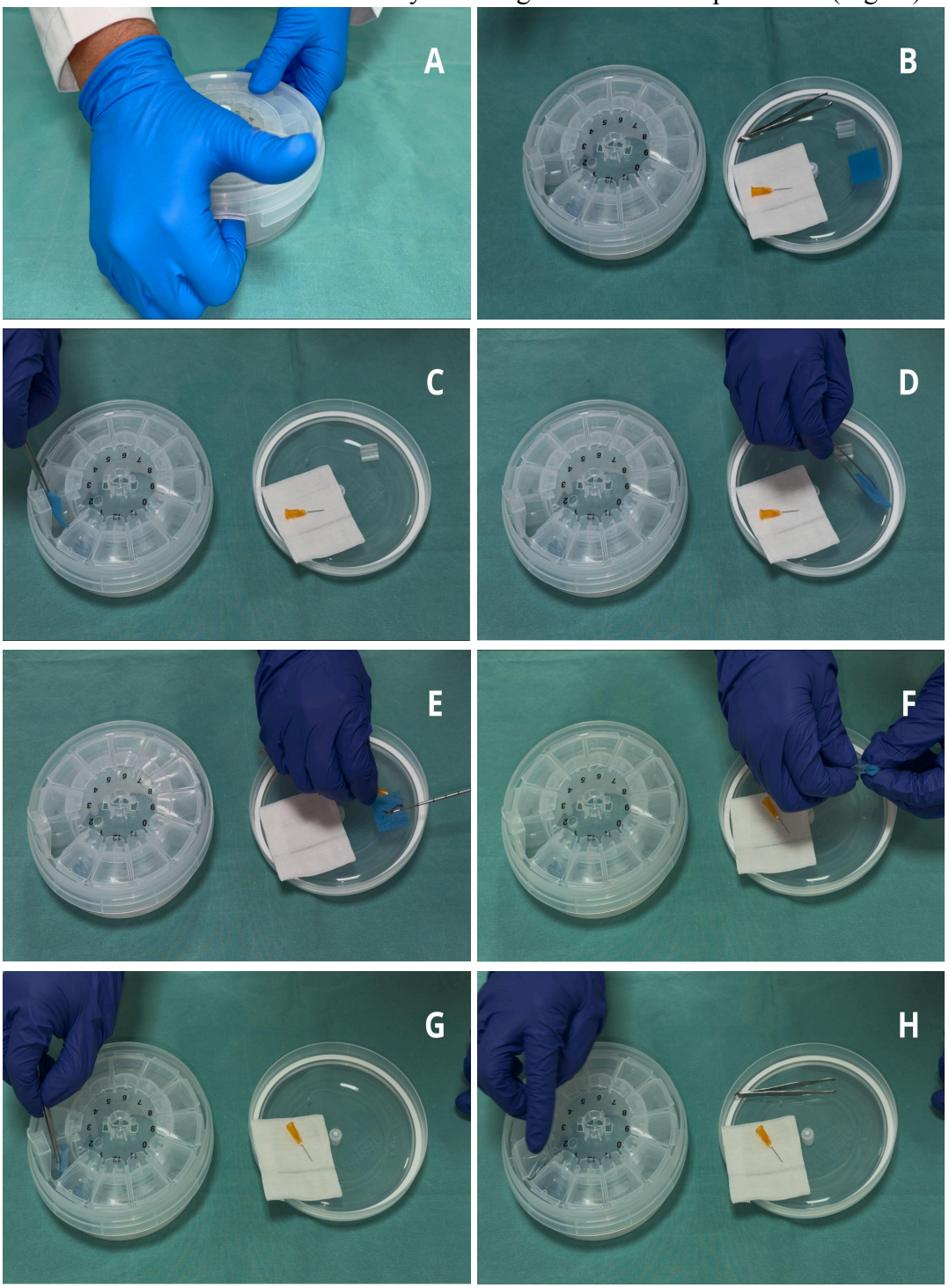


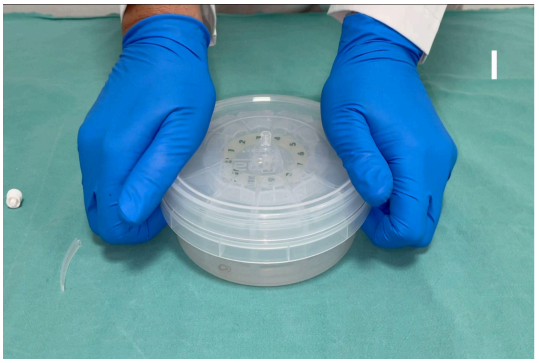


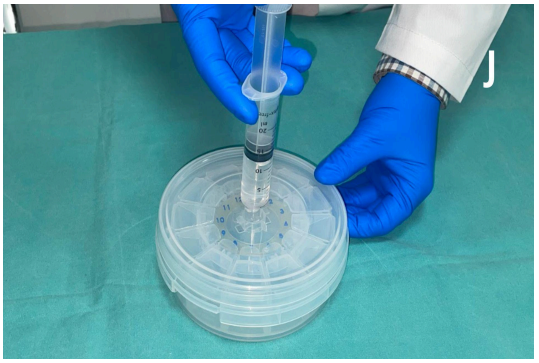
STEPS TO FOLLOW

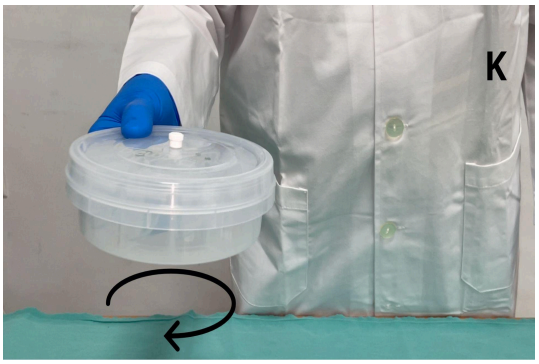
1. Remove the safety seal by pressing with the fingers (Fig. A). Remove the connector plug by twisting slightly and remove the lid. Extract the plastic film and discard it.
2. Prepare the materials: Prepare the sponge, securing clip, fine hypodermic needle, sterile gauze, and tweezers, which are placed on the underside of the lid (Fig. B).
3. Moisten the sponge to prevent the tissue core from sticking: Grasp the sponge with tweezers and submerge it into the compartment (Fig. C). Once moistened, place it back on the lid (Fig. D).
4. Place the core specimen on the sponge: Using the sterile needle, remove the tissue core from the biopsy needle and place it in the center of the sponge (Fig. E).
5. Secure the ends of the sponge: Fold the sponge in half and attach the securing clip (Fig. F).
6. Place the sponge in the compartment: Using tweezers, grasp the clip attached to the sponge and submerge it into the compartment (Fig. G).
7. Close the lid: Close the lid and continue placing the remaining core specimens into the compartments (Fig. H).
8. To secure the lid, first apply downward pressure with the heel of the hand onto the proximal edge of the lid ring, then press down along the remainder of the ring using the rest of the hand. Whenever possible, this procedure should be performed on a firm, stable surface. (Fig. I).
9. Connect the pre-filled syringe by twisting slowly and inject its content (Fig. J).

10. Remove the syringe and place the connector plug. Next, perform circular movements of the device for about 15 seconds to achieve an adequate distribution of the formaldehyde throughout all the compartments (Fig. K).





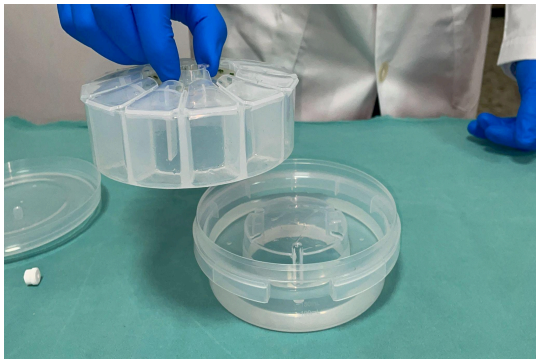


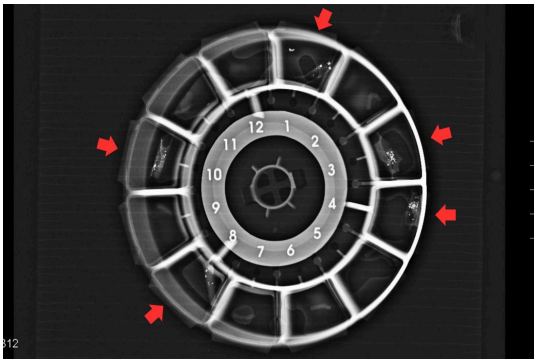


Figures for the steps to follow: A, B, C, D, E, H, I, J, K.

NOTE

- The device must be handled by well-informed and trained healthcare personnel.
- It is mandatory to keep the device in a secure place to prevent drops to the floor.
- In cases of breast biopsies the radiopaque numbers allow for the identification of cylinders with microcalcifications.
- To perform the mammographic examination, slowly extract the cylinder holder by holding the tabs to empty the liquid from the compartments. With the cylinder holder extracted, cylinders must be placed in the center of the compartment with a needle.
- Once the mammographic study is performed, couple the components by slowly twisting the cylinder holder onto the container.
- For handling the cylinders in the pathology department, the cylinder holder can also be extracted to empty the liquid from the compartments (Image). **IMPORTANT:** Handle slowly and controlled to prevent dropping the device, which could cause the involuntary opening of the compartments.





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