

Protocol of use



OPERATING THEATRE

A) OPENING PACKAGING

When tissues a/o biomaterials are explanted, open sterily the **MicroDTTect®** device in the operating room, the device is presented in a double envelope (Figure 1). Placing the envelope upright on a plane and grab the flaps of the same with both hands.

Pull the flaps simultaneously in the direction shown by the arrows (Figure 2) until the medical paper_PE envelope is opened for half the overall length. Following this opening, a sterile operator will open the transparent PEHDS envelope (Figure 3) and pick up the contents (Figure 4).



Figure 1



Figure 2



Figure 3



Figure 4

B) OPENING MINIGRIP

To open the minigrip you need to grab the flaps with both hands and perform a longitudinal movement equal and contrary to the closing axis of the minigrip (Figure 5).

If you perform the wrong movement as indicated (Figure 6) the minigrip, in addition to not opening up, could go against breaking!



Figure 5



Figura 6

C) INSERTION OF REMOVED SAMPLES

When tissues a/o biomaterials are explanted, open sterily the device MicroDTTect® on the operating field using the minigrip and place the explanted samples inside the device (Figure 7). It's possible to do the analysis of single sample or all the explanted samples of biomaterials or tissues pooling, inserting them into a single device.

WARNING: It is important to use clean surgical instruments to pick up the explanted material and to change the gloves every time you insert the samples inside the MicroDTTect®, to avoid cross contamination and to dirty the external surface of the device.

If the samples to be analysed accidentally touch other surfaces, before insertion into the MicroDTTect®, they cannot be used for subsequent microbiology investigations.

D) CLOSURE OF THE DEVICE

Take out the air from the chamber and close the device tightly with the minigrip (a) and then use the blue clamp for the second safety closure (b) (Figure 8).



Figure 7: Open the bag and place the explanted sample inside the device microDTTect



Figure 8: Remove inside air, close the device hermetically

E) DELIVERY OF THE EXPLANTED MATERIAL TO THE LABORATORY

After sample collection is done in MicroDTTect® send to the microbiology laboratory for specific laboratory investigations.

LABORATORY

F) OPENING OF THE STORAGE POCKET

To activate the easy opening of the storage pocket you need to start pulling the PVC from the top tip of the diamond seal (at the point indicated by the red arrow) in the direction of the blue arrow (Figure 9)



Figure 9

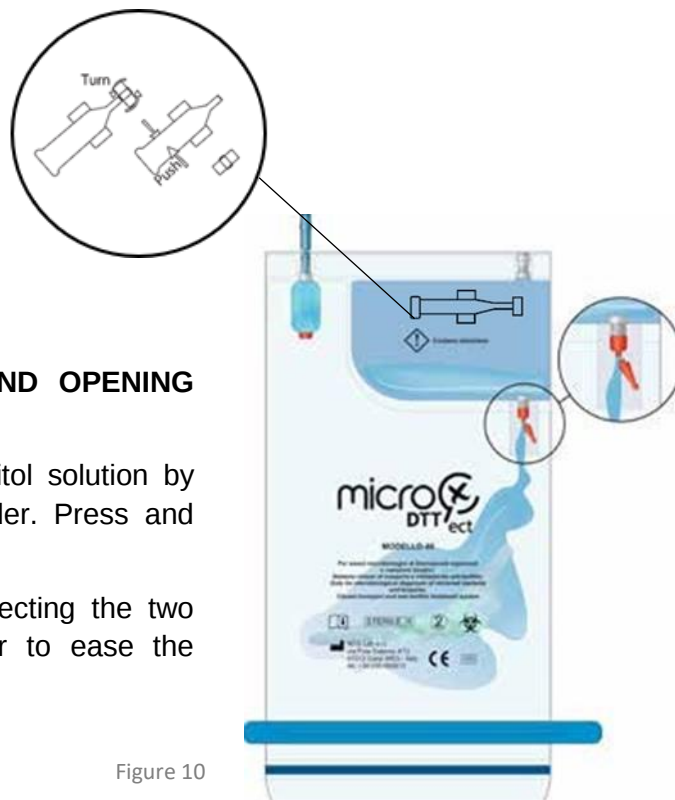


Figure 10

G) PREPARATION OF DTT SOLUTION AND OPENING RED VALVE

Before any transfer, prepare the dithiothreitol solution by breaking the strip/vial containing the powder. Press and release it until its complete dissolution.

Then break the red breakable valve connecting the two chambers, pressing on the DTT chamber to ease the complete exit of the liquid (Figure 10).

NOTE:

If the processing of the sample is carried out during the day: Snap off the stem of the frangible valve to wet the explanted samples directly in laboratory.

If the processing of the sample is carried out on the next day or by 48h from the explant: Snap off the stem the frangible valve to wet the explanted samples directly in laboratory and conserve the device horizontally in refrigerator at 4°C. Before processing it, leave the device for few minutes at room temperature.

If the processing of the sample is carried out between 48h and within 72 h: Preserve the device horizontally into freezer at -20°C and don't snap off the stem of the red frangible valve. Before processing it, defrost the device at room temperature, snap off the stem of the red frangible valve and then it is possible to begin with the analysis.

H) PLACE THE DEVICE ON THE MECHANICAL SHAKER

Place the device on the mechanical shaker (80 rpm) for 15 minutes: the DTT dissolves the biofilm on the sample (Figure 11). The sample can be manipulated manually to facilitate the action of the solvent.



Figure 11

I) EXTRACT THE ELUTE

After the necessary time, place the device under the laminar flow hood, snap off the stem of the blue valve (Figure 12) to connect the sample to the extraction system.

Then, extract the elute from the chamber with the syringe (figure 13), open blue clamp and transfer the elute in the dedicated test tubes (Figure 14) filling them to the top level. At the end, close the blue clips for each tube.



Figure 12

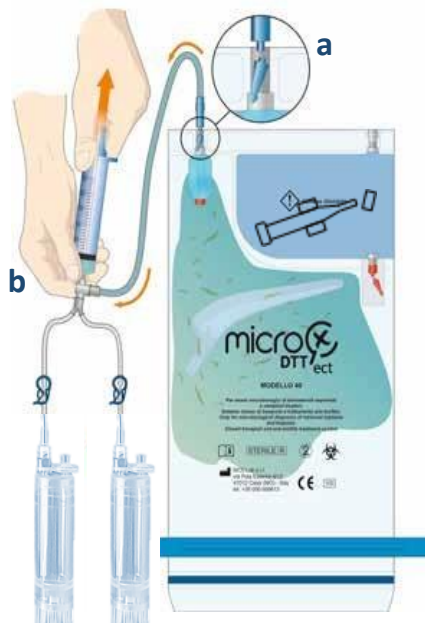


Figure 13



Figure 14

J) HEMOCULTURE (Optional)

Unscrew the protective cap (a) from the luer-lock port (2) located on the lower part of the tube and use the vacuette (J), supplied, by inoculation into blood culture bottles for aerobic and anaerobic microorganisms (Figure15).

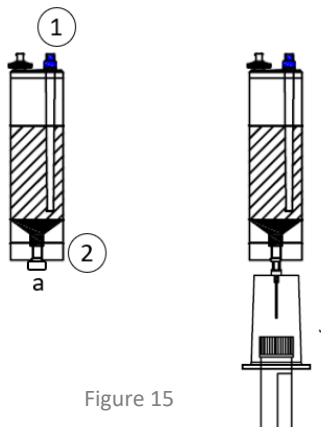


Figure 15

Screw the cap (a) back on for the next steps.

K) CENTRIFUGATION

Disconnect the test tubes from the device and place them in the centrifuge on 3200 rpm for 10 minutes (Figure 16).



Figure 16

L) COLLECTION OF PELLETS AND SUPERNATANT

At the end of the cycle use the port (1) located in the upper part of the tube, to connect a luer lock syringe on tube access, under laminar flow hood, and withdraw the supernatant liquid (Figure 17).

Shake the tube to allow the sphere contained inside to facilitate the detachment of the pellet from the walls.

By using the port (2) located on the lower part of the tube, connect a luer lock syringe and extract 100µl of pellet (Figure 18) and inoculate in solid culture and in enrichment broth according to the laboratory procedure (Figure 19).

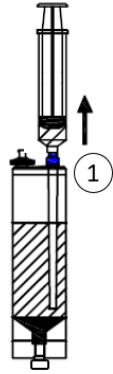


Figure 17

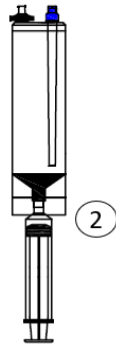


Figure 18

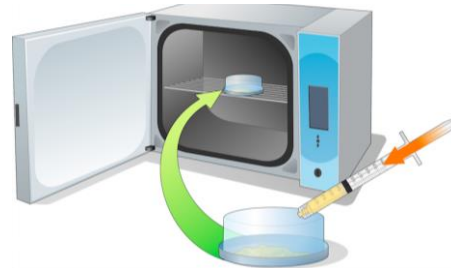


Figure 19