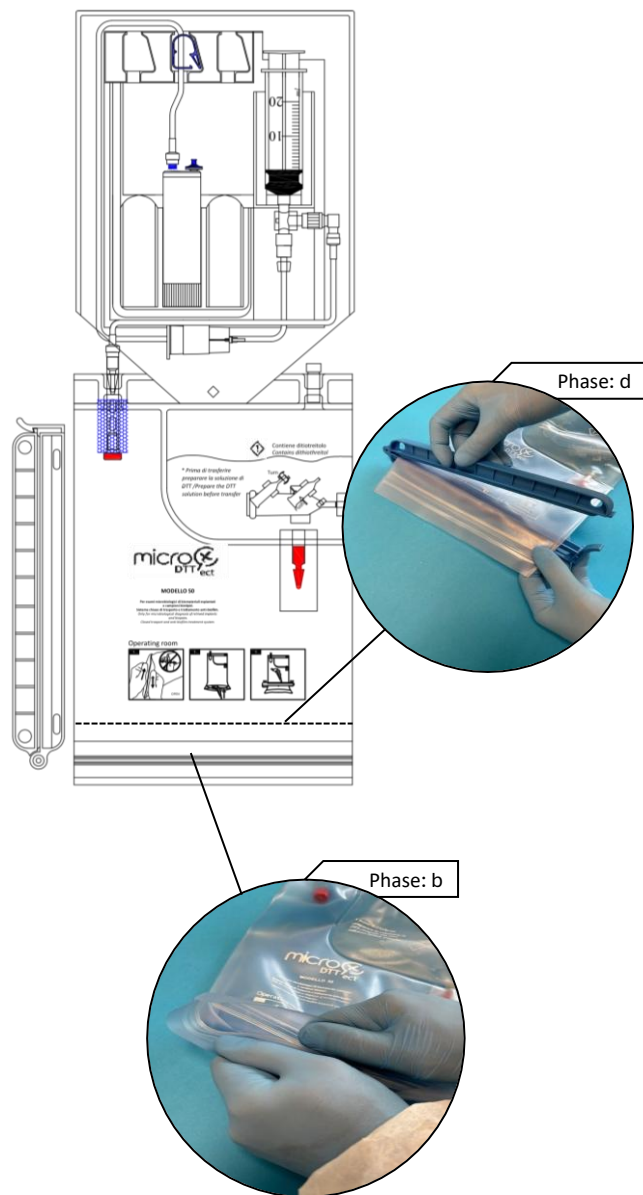


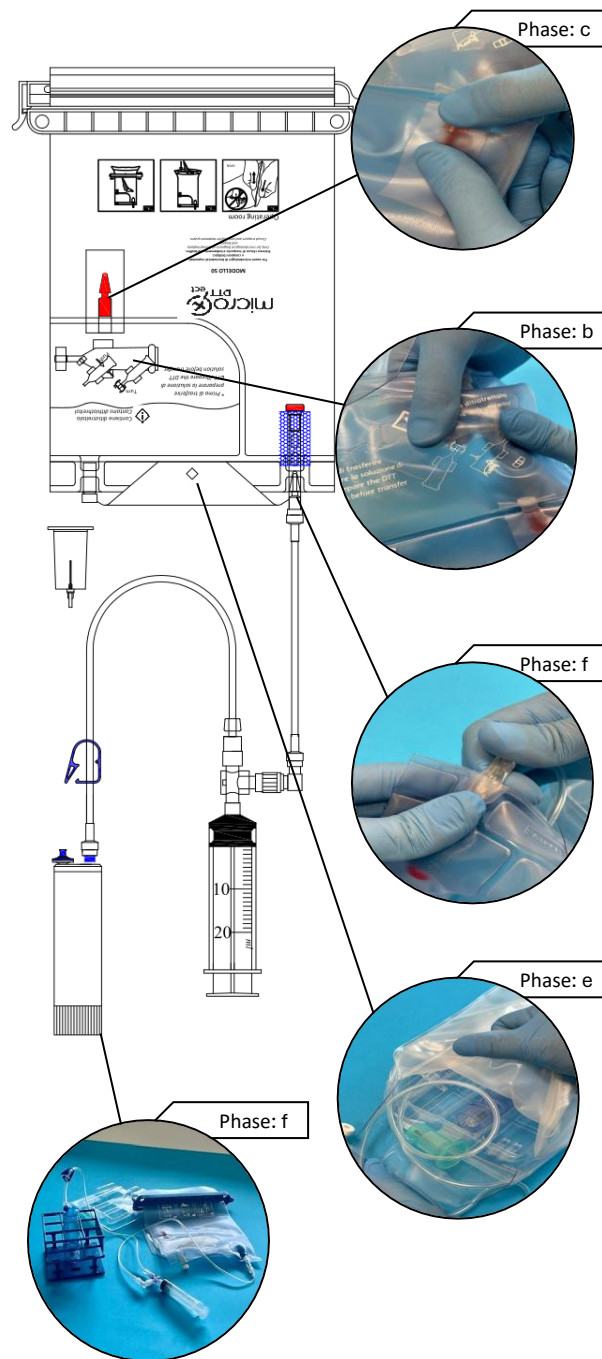
Instructions for use

Phases: b; d; graphical representation
Instructions for use (operating room)



Instructions for use

Phases: b; c; e; f; graphical representation
Instructions for use (Laboratory)



MICRODTTect

In vitro test tube closed-loop disposable diagnostic medical device for the collection and transport of harvested material.

DESCRIPTION:

MicroDTT is a closed-loop device consisting of: main collection bag Ref.(2), sealed on the bottom with a minigrip Ref.(1) which is internally parted from a secondary chamber Ref.(6) containing – according to the purchased product code, 50, 100 o 150 mls of isotonic solution and a strip/vial Ref.(5) containing 5,10 o 15 mgs of dithiothreitol. The main bag is connected to the internal chamber via a unidirectional valve equipped with a transparent red frangible Ref.(4), conversely its output is connected to the parting system via a die cut tube with a sponge filter and a transparent frangible Ref.(7). This parting system organized inside a rigid blister and contained in the blister bag Ref.(8), is connected to the main bag via a diamond-shaped weld joint and it consists of: a piece of tube that connects the bag to the stopcock connector, core connector of the suction and parting systems of the device, which is connected to the syringe Ref.(11) and according to the code, one, two, three piece/s of tube funneling through, up to one, two or three vial/s Ref.(10).

OPERATING INSTRUCTIONS (Operating room) phase:

**Before using the device verify the wholeness of the packages and the shelf life of the products; the latter cannot be used if the package is open, damaged or wet.*

**** Each reference to components in the following text is connected to its own graphical representation included in the document.**

- Open the device in a sterile environment;
- Open the collection bag Ref.(2) via designated minigrip REF.(1), in order to open the device properly, grab the two flaps of the bag and slightly pull them in opposite directions;
- Place the harvested sample inside the collection bag Ref.(2), remove any air from the bag and close the minigrip Ref.(1);
- Rotate the collection bag Ref.(2) so that the ziplock of the bag is face up, then fasten the ziplock of the collection bag Ref.(2) with the safety clamp Ref.(3) by placing it under the minigrip Ref.(1);
- Apply on the collection bag Ref.(1), the designated traceability label provided with the device;
- Send it to the designated laboratory after placing the device in the provided bag.

OPERATING INSTRUCTIONS (Laboratory) phase:

** Before using the device verify that the collection bag is closed with no obvious leaks.*

**** Each reference to components in the following text is connected to its own graphical representation included in the document.**

- Remove the device from the bag for the transport of biological material;
- Prepare the dithiothreitol solution by breaking the vial/strip Ref.(5) which contains the DTT powder, then press and release until its total dissolution;
- Break the red frangible Ref.(4) and drain the solution from the chamber Ref.(6) to the bag Ref.(2);
- Place the device on the tilting shaker for 15mins at a speed of 80rpm;
- Open the blister bag Ref.(8), from the satinized side, by breaking the diamond-shaped weld joint in order to extract the blister;
- In order to distribute the solution into the vial/s proceed by breaking the frangible Ref.(7), rotate the device so that the safety clamp Ref.(3) is face up, then keep the direction of the device and **after verifying that the vial/s is upright for the entire time of the phase**, Simulate several sampling and perfusions with the syringe Ref.(11) until the vial is full Ref.(10), then close the clamp Ref.(12);
- Disconnect the vial/s Ref.(10) from the system, place the same vial/s in the centrifuge, then proceed with the separation for 10mins at a speed of 3200rpm;
- At the end of the cycle remove the vial/s supernatant Ref.(10) by connecting a male luer lock syringe [not provided] to the needle-free connector Ref(10a);
- Shake the vial/s Ref.(10), so that the sphere in the vial/s can ease the detachment of the pellet from the walls; remove both the base of the vial /s Ref.(10b) and the cap Ref.(10c); connect a male luer lock syringe or alternatively a Vacutainer Ref.(9), to the needle-free valve Ref.(10d), placed on the lower side of the vial/s and remove the pellet.

INTENDED USE:
Disposable closed loop in vitro diagnostic medical device (IVD) for the collection and transport of the harvested material (implantable or prosthetic materials, such as articular prosthesis or any of their parts or components, metal plates, screws, nails, cardiac valves, vascular prosthesis etc.) which must undergo further microbiological tests.

Target Population: The manufacturer declines to the specialist physician any liability related to the use of the device and the choice of patients in terms of age, gender, nationality, and the assessment of any current or preexisting condition.

Please give notice to the manufacturer and to the competent local Authority of any serious adverse event related to the device.

Link:
https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

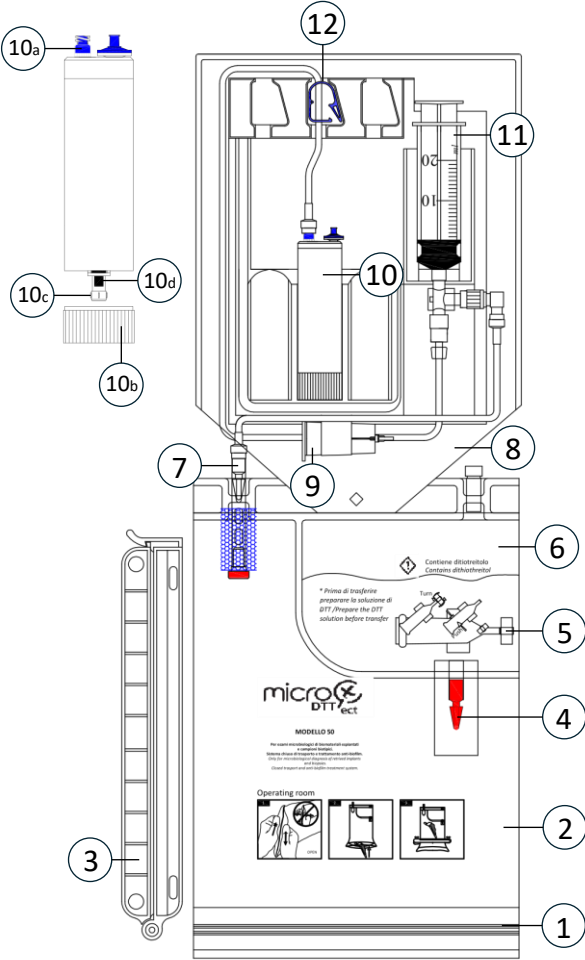
Before using the device, please verify the integrity of the package and the shelf life of the product; the product cannot be used if the package is open, damaged or wet. Please store the product in a fresh and dry place, away from sunlight or heat sources.

Shelf life:
3 years from the manufacturing date. Codes: DTT05010, DTT10020 e DTT15030
Please use the products in the order of reception (based on first-in, first-out principle) and note down the expiration date present on the label. Any unused device or any waste deriving from the product must be disposed of in accordance to the local rules and regulations

DESCRIZIONE DEL SIMBOLO / DESCRIPTION OF SYMBOLS	SIMBOLO /SYMBOL
Data di scadenza / Expiry date	
Marchio CE / CE marking	
Numero di lotto di fabbricazione / Batch Code - Lot Number	
Codice del prodotto / Product Code	
Data di fabbricazione / Date of manufacture	
Fabbricante / Legal Manufacturer	
Monouso: Non riutilizzare anche sullo stesso paziente / Disposable: do not re-use even on the same patient	
Non risterilizzare: Il dispositivo non può essere risterilizzato dopo l'uso / Do not re-sterilize: The device cannot be re-sterilized	
Sterile: con metodo di sterilizzazione per irraggiamento / Sterile - method of sterilization by irradiation	
Attenzione: consultare i documenti di accompagnamento / Attention: see attached document	
Attenzione: consultare le istruzioni per l'uso / Attention: see instructions for use	
NON utilizzare nel caso la confezione sia danneggiata / DO NOT use if the package is damaged	
Condizioni di stoccaggio: evitare di esporre i cartoni o le singole confezioni alla luce diretta del sole / Storage conditions: avoid exposing the individual packages or cartons to direct sunlight	
Condizioni di stoccaggio: evitare di esporre i cartoni o le singole confezioni alla all'umidità o alla pioggia / Storage conditions: avoid exposing cartons or individual packages to humidity or rain	
Apirogeno / Pyrogen-free	
Irritante e Nocivo / Irritat and harmful	
Privo di lattice / Latex free	
Barriera sterile doppia / Double sterile barrier	
Dispositivo medico diagnostico in vitro / In vitro diagnostic medical device	
Identificazione unica dei dispositivi / Unique device identification	



MICRODTTect
DTT05010 – DTT10020 – DTT15030



REFERENCES:

- 1. Minigrip Ziplock
- 2. Collection bag
- 3. Safety Clamp
- 4. Red Frangible
- 5. Strip/Vial
- 6. Chamber
- 7. Frangible
- 8. Blister bag
- 9. Vacutainer
- 10.Vial:
 - a. Needle-free junction
 - b. Base of the vial
 - c. Cap of the vial
 - d. Needle-free valve
- 11.Syringe
- 12.Clamp