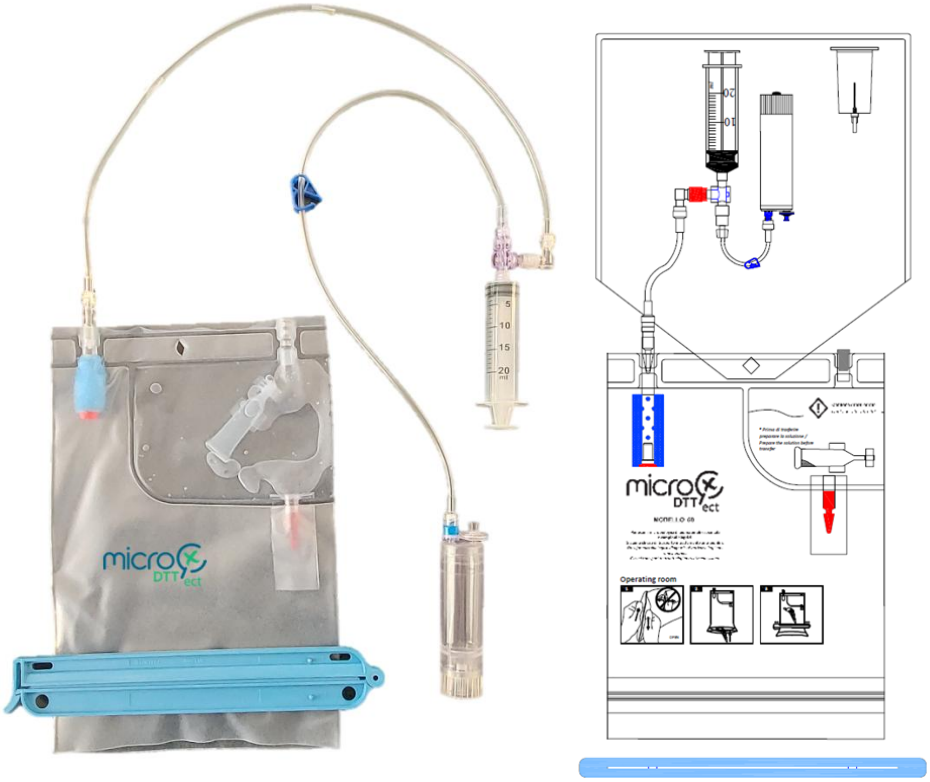
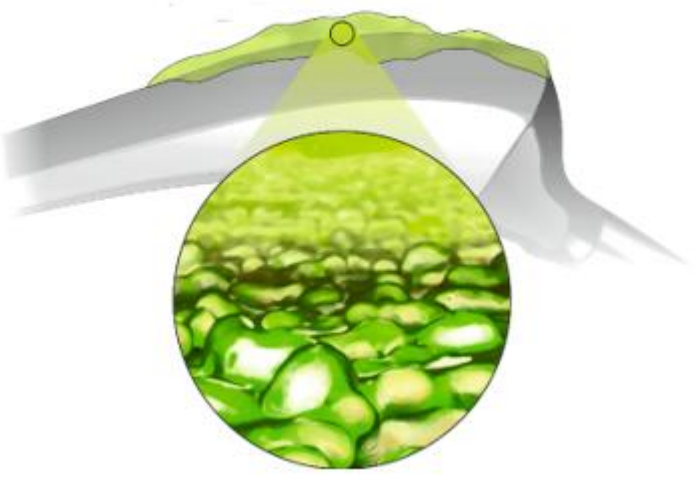
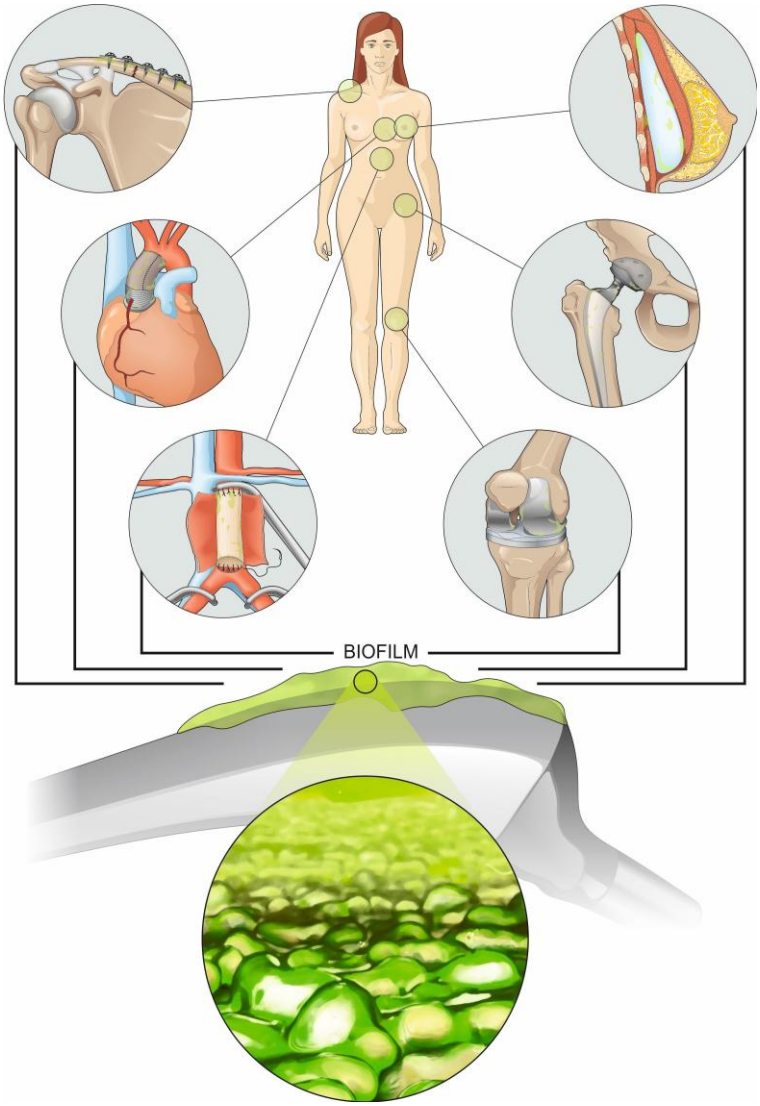
microX DTTect



# AT THE HEART OF INFECTION CONTROL



NOVA HEALTH




IMPROVE SENSIBILITY AND SPECIFICITY OF BIOFILM-RELATED INFECTIONS WITH MICRODTTECT BASIC METHODOLOGY[1], WITH COMPLETELY CLOSED DEVICE FOR HARVESTING, TRANSPORTING AND PROCESSING EXPLANTED SAMPLES TO DETECT BACTERIA

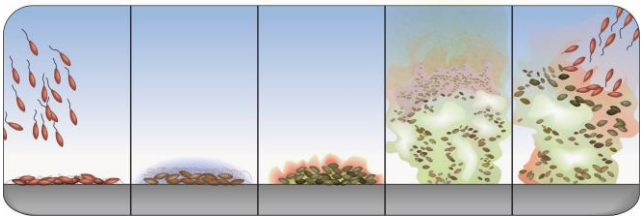
# IMPLANT AND TISSUE INFECTIONS

Implant and tissue infections are a major threat and represent a significant burden in terms of a patient's chances of recovery after a surgery of trauma.

Surgical site infections are related to significant complications and an increase in mortality and hospitalization time. They are also a remarkable expense to health care systems around the world.

DETERMINING THE STRAIN OF BACTERIA ACTUALLY RESPONSIBLE FOR AN INFECTION IS ESSENTIAL TO DIAGNOSE AND TREAT THE INFECTION AND ANY RESISTANCE PRESENT.

Diagnosis implant and tissue infections is challenging: this is predominantly due to the nature of biofilm associated with the progress of an infection. Biofilm plays a particularly important role in implant and non-implant related infections.



**Bacteria biofilm formation process**

Biofilm is a complex bacterial community protected by a self-produces that adheres to a living or inert surface. Bacteria settle on surfaces, adhere to them, actively multiply, forming colonies and create a highly viscoelastic matrix.

Biofilm makes the bacteria difficult to access for both the body's own defense as well for antibiotics, and difficult to detect in diagnostic when using traditional microbiological methods.

Biofilm formation on medical devices is associated with hospital-acquired infections. Its high tolerance to antibiotics causes classical treatments lack efficacy, and the removal of the biofilm-contaminated device is often the only therapeutic option.

It is also fundamentally important to avoid risks of contamination by other bacteria which are not directly responsible for the infection. Cross-contaminations play also a role in infection diagnosing.

An undiagnosed or incorrectly diagnosed infection has far-reaching consequences for the patient, who will do not receive optimal treatment, possibly leading to further complications and hospitalization, impairing their quality of life.

Moreover, every missed diagnosis has a cost. Expenses related to misdiagnosis of PJI can be high and include direct costs, like the resulting wrong treatment and indirect costs, as for example the need for further treatments, the occurrence of further complications, the need for more prolonged hospitalization and the resulting work loss compensations and medico-legal claims, etc.…

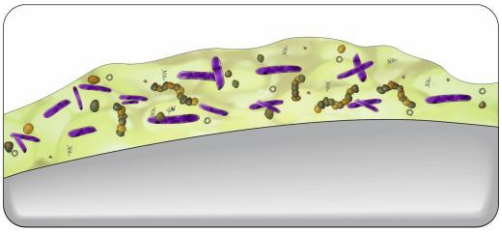
DIAGNOSIS AND PATHOGEN IDENTIFICATION ARE CURRENTLY CONSIDERED THE BENCHMARK OF DIAGNOSIS OF PJI, BUT BOTH FALSE NEGATIVE (FN) AND FALSE POSITIVE (FP) RESULTS OF INTRA-OPERATIVE IDENTIFICATION OF THE PATHOGEN MAY TRIGGER EXTRA-COSTS.

# IMPLANT AND TISSUE INFECTIONS

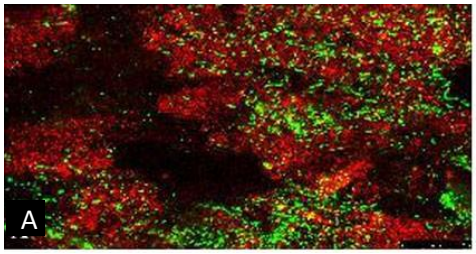
Some study groups tried to find new diagnostic methods to detect bacteria responsible for implant-related and non-implanted-related infections:

**DITHIOTHREITOL (DTT)**
**can dissolve the polysaccharide**
**matrix of the biofilm and detach the bacteria,**
**helping identify bacteria strain,**
**reducing false negative cultures.**

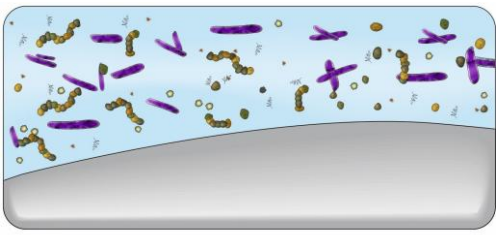
Residual biofilm (red) an bacteria (green) on implant before (A) and aEer (B) treatment with DTT



**Bacterial biofilm on a biomaterial surface**




**Bacterial biofilm on a PE disc (confocal laser scanning microscopy)**



**Bacterial biofilm dissolved in the DTT solution**


**PE disc surface aGer treatment with DTT (confocal last scanning microscopy)**

| | SENSITIVITY | SPCIFICITY | POSITIVE PREDICTIVE VALUE | NEGATIVE PREDICTIVE VALUE | ACCURACY |
|---|---|---|---|---|---|
| DTT | 85.7% | 94.1% | 94.7% | 84.2% | 89.5% |
| Sonication | 71.4% | 94.1% | 93.7% | 72.7% | 81.6% |
| Tissue Culture | 71.4% | 76.5% | 78.9% | 68.4% | 73.7% |

Drago et al., Clin Orthop Relat Rec, 2012

**IT IS ALSO NECESSARY THAT THE DIAGNOSTIC METHODS ALLOW TO AVOID CROSS-CONTAMINATIONS: TO PRESERVE SAMPLES FROM ANY CONTAMINATION IN EVERY SINGLE STEP (HARVESTING, TRANSPORTING, PROCESSING AND CULTURE) TO AVOID FALSE POSITIVE CULTURES AND DETECT BACTERIA ACTUALLY RESPONSIBLE FOR SURGICAL-SITE INFECTIONS**

# THE SOLUTION FOR IMPLANT RELATED INFECTIONS

**microDTTect** is a completely closed device from the operating theatre **t**o the microbiology laboratory, based on a new method of extracting bacteria and detaching bacterial biofilms[1]

- Highly resistant and non-drillable, heat-sealable PVC structure, equipped with minigrip
- 0.9% physiological solution and vial containing DTT powder, in quantities equal to 50mg - 100mg and 150mg depending on the model, designed to dissolve the polysaccharide matrix of the biofilm and allow to detect bacteria
- Extraction system to collect fluid into the test tubes
- Dedicated test tubes to collect fluid and withdraw supernatant and pellet through a completely closed circuit to avoid contamination

microDTTect guarantees a successful result in all the key steps that lead to the diagnosis of explanted samples:

HARVEST the explanted samples to be analyzed under sterile and safe conditions

Place the explanted material inside the container and seal it closed (using the mini-grip and the additional clamp)

TRANSPORT the samples to be analyzed under sterile and safe conditions

Transport the device under safety conditions to the laboratory: the system is completely sealed closed and it can be transported minimizing the risk of contamination for the sample or the operator

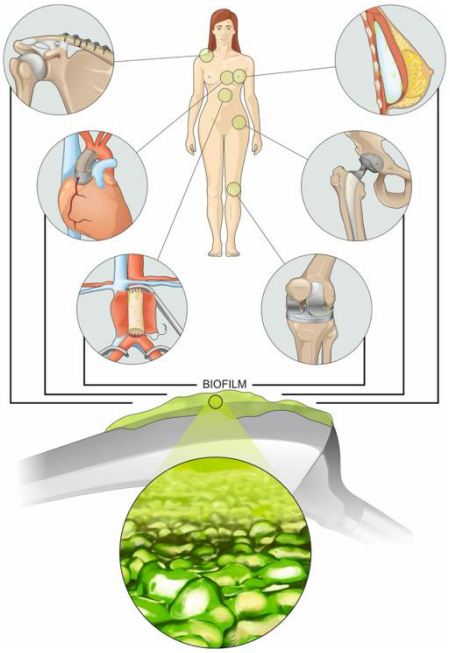
PROCESS the samples quickly under sterile conditions

The device remains closed throughout the process in the laboratory:

- Place the samples inside the device
- Remove the air from the chamber and close tight the device through the minigrip and the clamp for the second security closing
- Before transferring prepare the DTT solution in the containment chamber, breaking the strip/vial containing the powder, press and release it until completely dissolved
- Open the frangible red valve that connect the two chambers (the containment chamber and the DTT solution chamber) and press to let the DTT solution overflowing
- Place the device on the mechanical shaker for 15 minutes at 80rpm
- Open the frangible blue valve to connect the device containment chamber to the extraction system
- Withdraw the elute through the syringe and transfer it in the dedicated test tubes filling to the allowed maximum level
- Close the blue clamp for each tube, disconnect the tubes from the device and put them in the centrifuge for 10 minutes at 3200rpm
- At the end of the cycle, use the port located on the top of the tube, remove the supernatant from the tube by connecting a luer lock syringe
- Shake the vial to allow the sphere contained inside to facilitate the detachment of the pellet from the walls. By using the port located on the lower part of the tube, connect a luer lock syringe or alternatively use a vacuette to collect the pellet to be put on the culture plates

# PROTOCOL OF USE --- OPERATING THEATRE

1. Explant the biomaterials/ biopsies to be analyzed at the laboratory




2. Open the bag and place the explanted sample inside the device

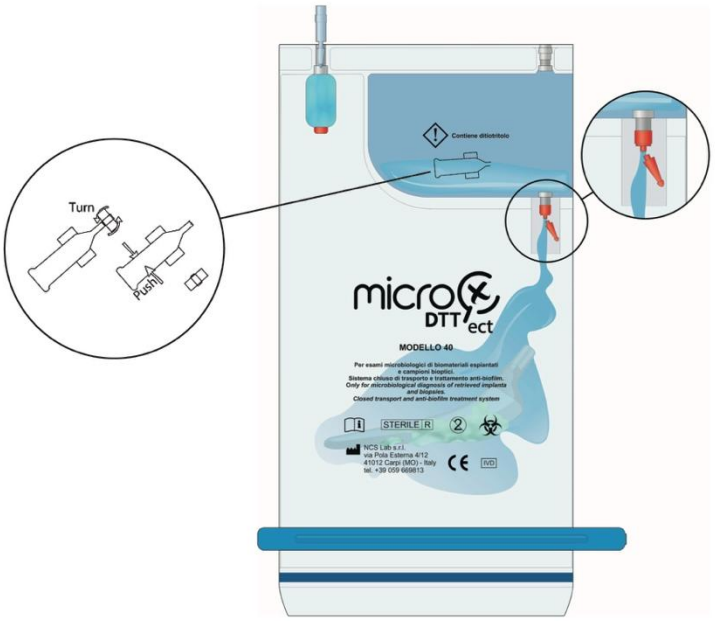

3. Remove the air in the bag, close the device hermetically, by closing the mini-grip (a) and then the clamp (b)


b

# PROTOCOL OF USE --- LABORATORY

Before the start of the analytical phase, the sample is transported to the laboratory within the closed system, without activation of the DTT. DTT activation is performed exclusively in the laboratory, at the start of the analytical phase.

4. At the start of the analytical phase, in the laboratory, prepare the DTT solution in the dedicated containment chamber by breaking the strip/vial containing the powder and pressing and releasing it until the powder is completely dissolved.



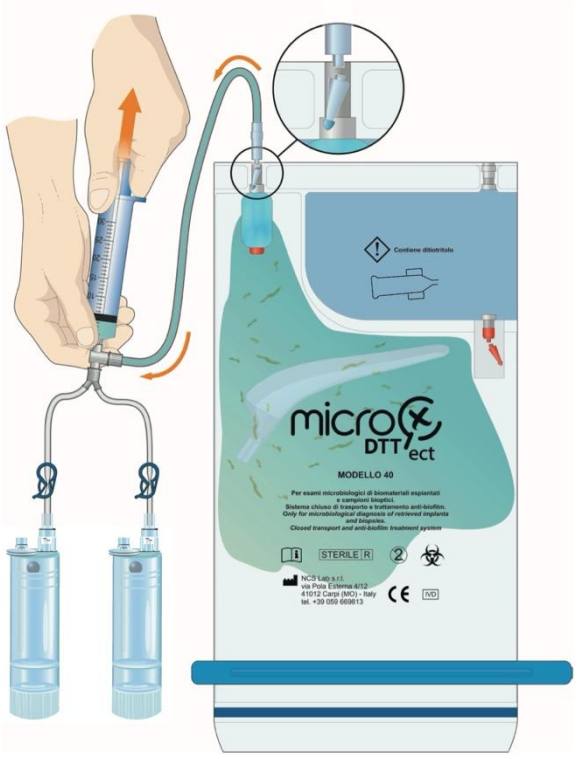

5. Open the red valve connecting the sample containment chamber to the chamber containing the DTT solution, thereby initiating contact between the sample and the DTT.

6. Place the device on the mechanical shaker for 15 minutes at 80rpm

7.

(a) snap off the stem of the blue valve to connect the chamber to the extraction system

(b) withdraw the elute through the syringe



# PROTOCOL OF USE --- LABORATORY

8. Transfer the elute in the dedicated test tubes

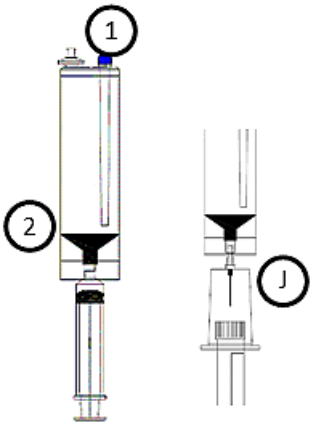
9. Centrifuge the test tubes for 10 minutes at 3200rpm

10.

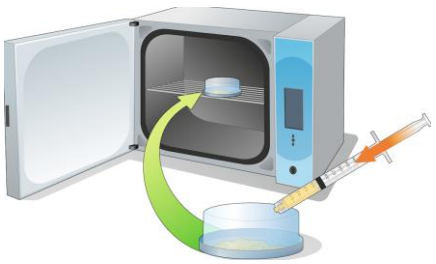
(a) At the end of the cycle use the port (1) located in the upper part of the vial to remove the supernatant from the vial connecting a luer lock syringe.

(b) Shake the vial to allow the sphere contained inside to facilitate the detachment of the pellet from the walls.

(c) By using the port (2) located on the lower part of the vial, connect a luer lock syringe or alternatively use a vacuette (J) to collect the pellet to be put on the culture plates.




11. Perform microbiological culture in accordance with laboratory protocol



# DIFFERENT DEVICES SIZE FOR VARIOUS EXPLANTED SAMPLES DIMENSIONS

Use the correct size of microDTTect according to samples dimension

microDTTect 50

microDTTect 100

microDTTect 150


The MicroDTTect equipped with additional access via needle, to connect directly, in total sterility and safety, the device to the bottles for blood culture is available only on request.

The vacuette (A) inside the devices DTT05010, DTT10020 and DTT15030 performs the same function for inoculation in blood culture bottles.

## AREAS OF USE

In all **surgical procedures with a known or suspected infection**, in particular:

ORTHOPAEDICS:

- Osteoarticular infection
- Prosthetic revisions:
  - Septic mobilization
  - Aseptic mobilization
- Revision of fixation devices
- Arthroscopy

VERTEBRAL SURGERY

NEUROSURGERY

PLASTIC SURGERY

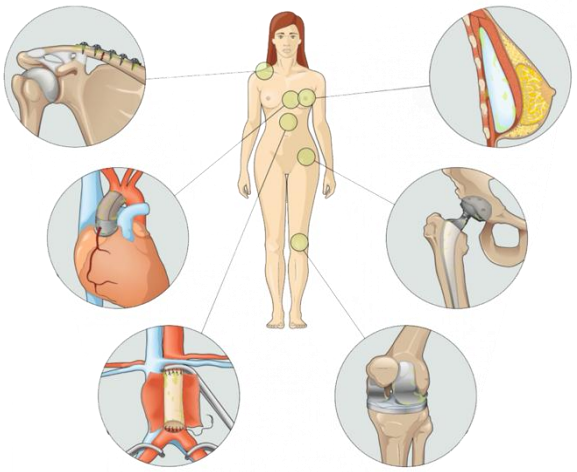
HEART SURGERY

MAXILLOFACIAL SURGERY

VASCULAR

SURGERY

BIOPSIES



In all l**aboratory tests for isolating bacteria and/or detaching bacterial biofilms.**

## ORDERING INFORMATIONS

**microDTTect**

| ARTICLE CODES | DESCRIPTION |
|---|---|
| **DTT05010** | microDTTect 50 with 1 test tube |
| **DTT10020** | microDTTect 100 with 2 test tubes |
| **DTT15030** | microDTTect 150 with 3 test tubes |

**microDTTect with needle (only on request)**

| ARTICLE CODES | DESCRIPTION |
|---|---|
| **DTT05011** | microDTTect 50 with 1 test tube and blood colture needle |
| **DTT10021** | microDTTect 100 with 2 test tubes and blood colture needle |
| **DTT15031** | microDTTect 150 with 3 test tubes and blood colture needle |

## REFERENCES

**BIBLIOGRAFIA**

# Notes

Manufacturer:

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