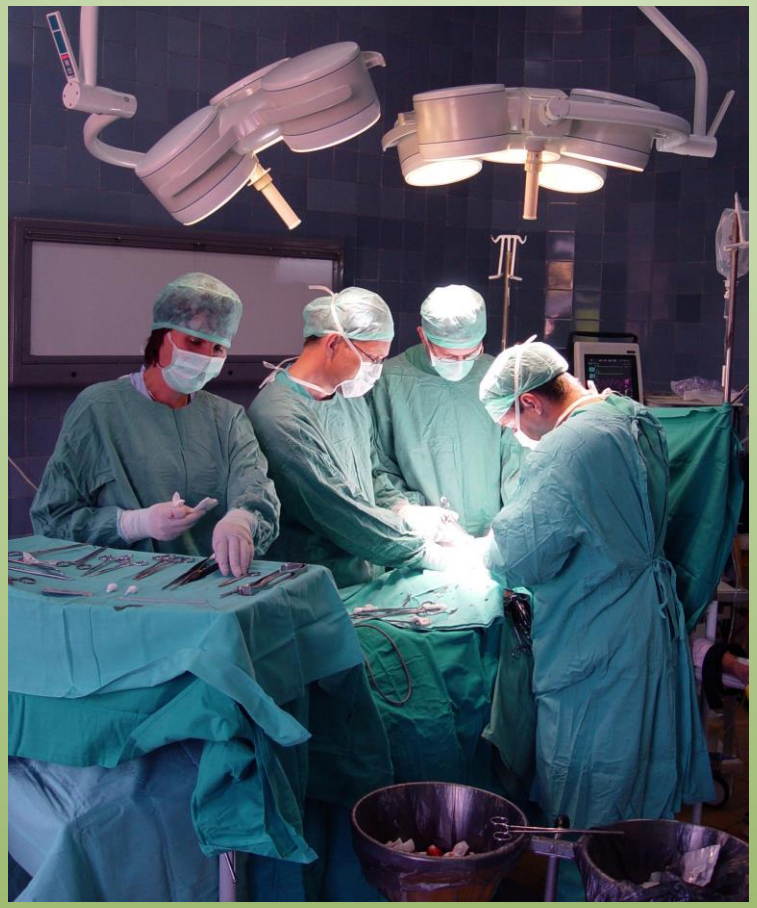
Tissue in the operating room
- Gowns and drapes -



Since the early 50s it is known that, during surgery, the cotton does not constitute an effective barrier to the passage of microorganisms, especially in the presence of liquids.
The drapes made of cotton fluff forgiveness and filaments, dangerous because they can penetrate into the wound and cause infection as foreign bodies and microorganisms of vehicle

An analysis of 1992 showed that each SSI (Surgical Site Infection) determined additional 7.3 days of hospitalization after surgery, with social costs, economic and health relevant.

For many SSI, the source of pathogens is the endogenous flora present on the patient's skin, mucous membranes or inside the organs
The mucous membranes or skin, when they are recorded, are exposed to risk of contamination with the endogenous flora.

The exogenous sources of infection include the responsible personnel of surgery, the operating room environment, principals indicated and the flora is represented by gram-positive bacteria (staphylococci and streptococci).

Among the measures to prevent intraoperative fall "clothing and surgical drapes" which must comply with the rules 93/42/EEC on

- Medical devices -

In support of the European legislation C.E.N. (European Committee for Standardization), he has worked and continues to work in the drafting of the European Standard EN 13795 identified by the initials

Technical standards EN 13795 together with other standards:

EN ISO 22610 and EN ISO 22612
on how to measure the resistance to bacterial penetration from wet and dry

EN ISO 9073-10 (linting)

EN 20811 (penetration of liquids)

represent the gold standard for barrier materials to use surgery.

The EN 13795 provides requirements that gowns and drapes must have to be classified as "standard performance" or "high performance “

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	I_B	≥ 2,8 [b]	Not required	6,0 [b c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 20	Not required	≥ 20	Not required

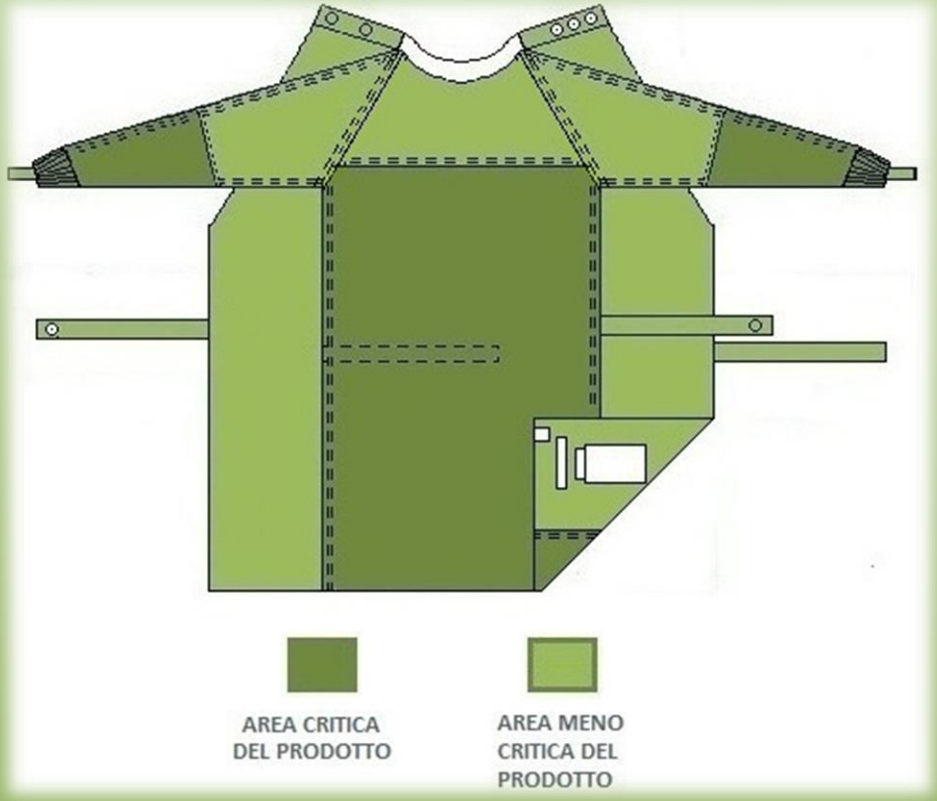
Table 2 — Characteristics to be evaluated and performance requirements for surgical drapes

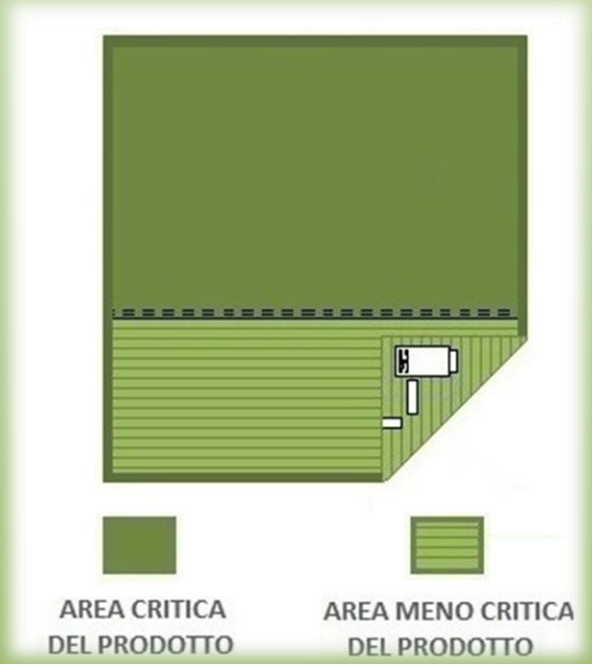
Characteristic	Test method (for references, see Clause 2)	Unit	Requirement			
			Standard performance		High performance	
			Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	I_B	≥ 2,8[b]	Not required	6,0 [b c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	N	≥ 15	Not required	≥ 20	Not required

For each product identified two areas:

Critical product area: For coats front and forearm
For the curtains close the wound

Less critical product area: All other parts of the product





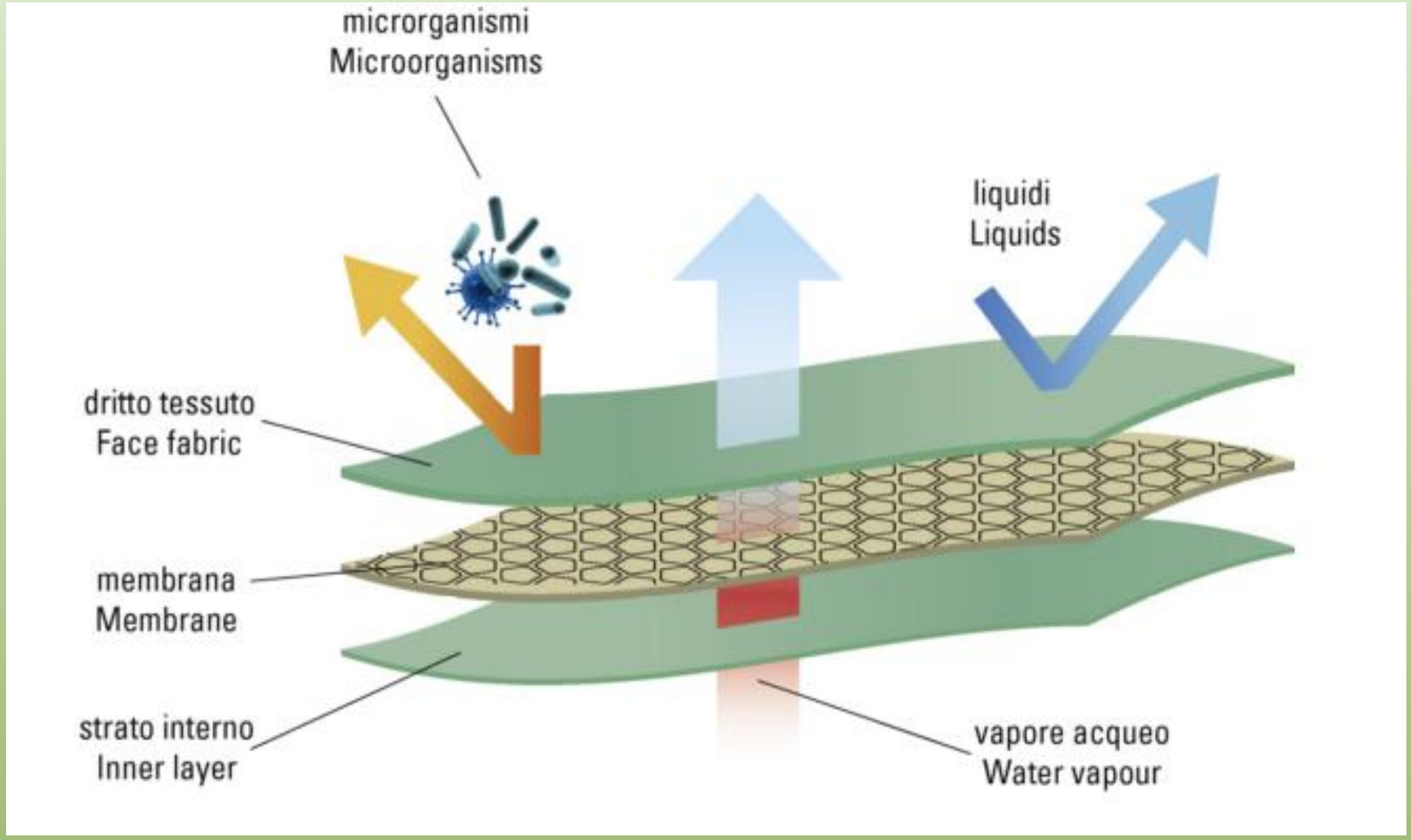
The fabrics used for gowns and drapes from the operating room are:

the critical area of product: 100% PES with tri-laminated membrane polytetrafluoroethylene (PTFE)
tri-laminated in 100% PES membrane with polyurethane (PU)

for less critical area of product: 99% PES microfibers 1% CARBON FIBER

The laminate textile in three layers, trilaminate, is equipped with a special membrane inserted between two outer layers of polyester threads, suitably twisted, a microporous structure, which gives:

- A protective function;
- An absolute barrier to the passage of liquids and microorganisms (18/20 nm; 1 nanometer = 1 millionth of a millimeter);
- Breathable effect;
- Unalterable for the transition from hot to cold (stable up to 250 ° C);
- To make comfortable the fabric, which are coupled to different fabrics or knits.


microrganismi
Microorganisms
liquidi
Liquids
dritto tessuto
Face fabric
membrana
Membrane
strato interno
Inner layer
vapore acqueo
Water vapour

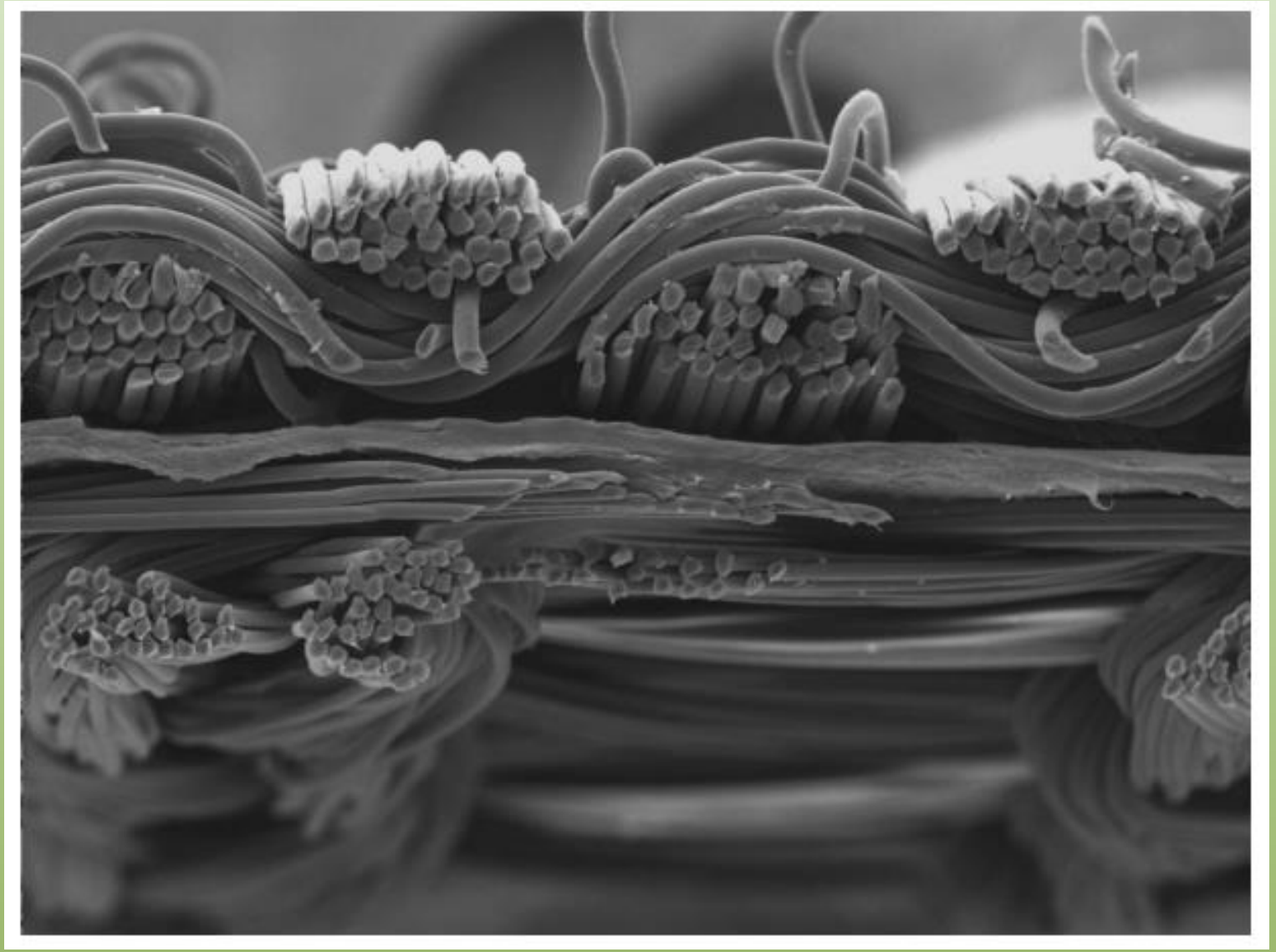
Tri-laminated for protection
In the operative field

- Security
- Hygiene
- Comfort
- Duration of textiles
- ➢ High Performance PLUS

Tri-laminated for protection in the operative field

- Breathability
- Lightness and draping
- Optimal level of absorbency

Photograph showing technically the composition of a 3-layer laminate, followed by scanning electron microscope

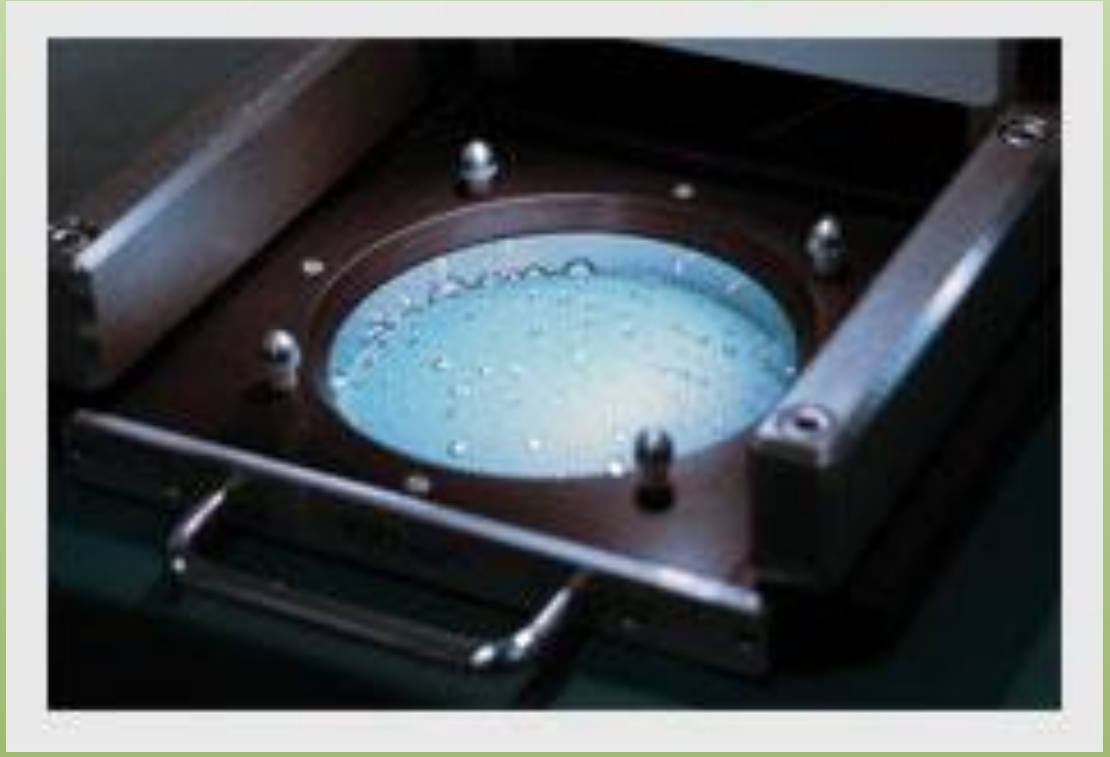


The structure of the expanded PTFE membrane is rich in micropores whose average diameter is about 0.02 uM not sufficient for the passage of a molecule of liquid, the main vehicle for the transport of pathogens (micro holes are smaller than about 20,000 times of the water molecule; while they are larger than about 700 times of the molecule of water vapor).

Pathogens of infection	size (µm)
Polio-, Hepatitis-A-Virus	0,024 - 0,030
Hepatitis-C-Virus	0,027 - 0,30
HIV	0,08 - 0,11
Hepatitis-B-Virus	0,042 - 0,047
Staphylococcus aureus	0,8 - 1,0

Therefore, the waterproof membrane allows the passage of molecules of steam but does not pass through the water molecules.
This means ensuring thermoregulation of the human body that allows the patient to keep you warm, while the right offers to the surgical team breathability

The water resistance is the ability of a product, to control the dispersion of the liquid in the areas in contact with the area of intervention.
The EN 13795 provides for the test by the method EN 20811 of the penetration of liquids, ie the water column.
The water column is measured by placing the fabric under a column of water and adding liquid until appear 3 drops of water on the fabric.
The measure is in millimeters, so if it says "2000 mm", the fabric resists the pressure of a water column of two meters. In addition, the water penetrates.



E 'a primary objective to ensure the best barrier to liquids, since the capillarity of tissues enables transfer of microorganisms

The use of the polyester filament yarn 100% in the inner and outer layers of the laminate textile, implies an absence of linting EN ISO 9073-10

The linting is the name of the process that allows the material to release particles into the air. This phenomenon can be observed in operating rooms where often form balls of colored particles that in the absence of moving people tend to fall to the ground

he special membrane present in the tri-laminated, may be subjected to multiple sterilization processes, such as gas steam, without altering their structure and characteristics.
The fabrics into TTR, generally, when properly used, are guaranteed for 70/80 sterilization cycles

The fabric used for the less critical area of the product is composed of 99% polyester and 1% carbon, has excellent characteristics of water repellency (microfiber).

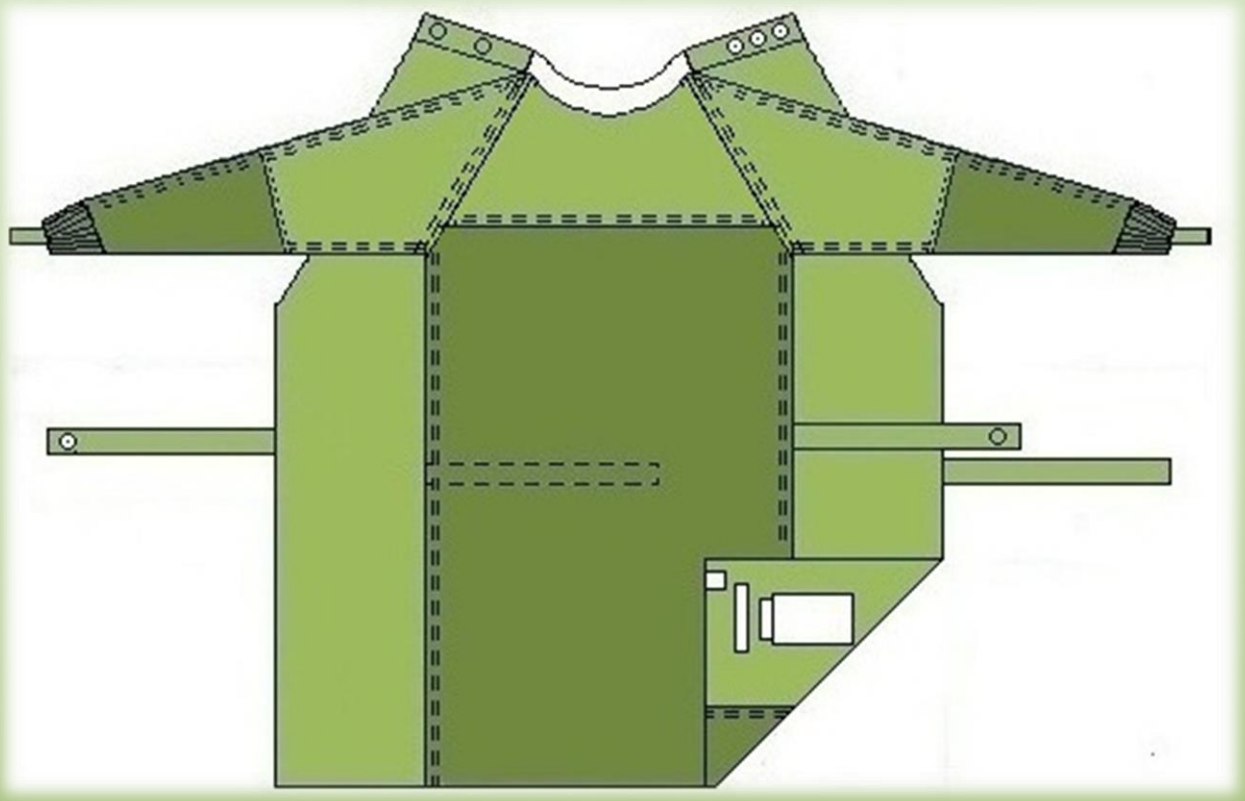
COATS AND TOWELS FOR THE OPERATING ROOM

Overalls: according to the type of intervention with more or less shedding of liquid, there are two types of clothing

STANDARD PERFORMACE

Where is the critical area that is less critical are made of the same fabric (microfiber)

HIGH PERFORMANCE



Where the critical area of the product (front and forearm) are made of tri-laminate fabric

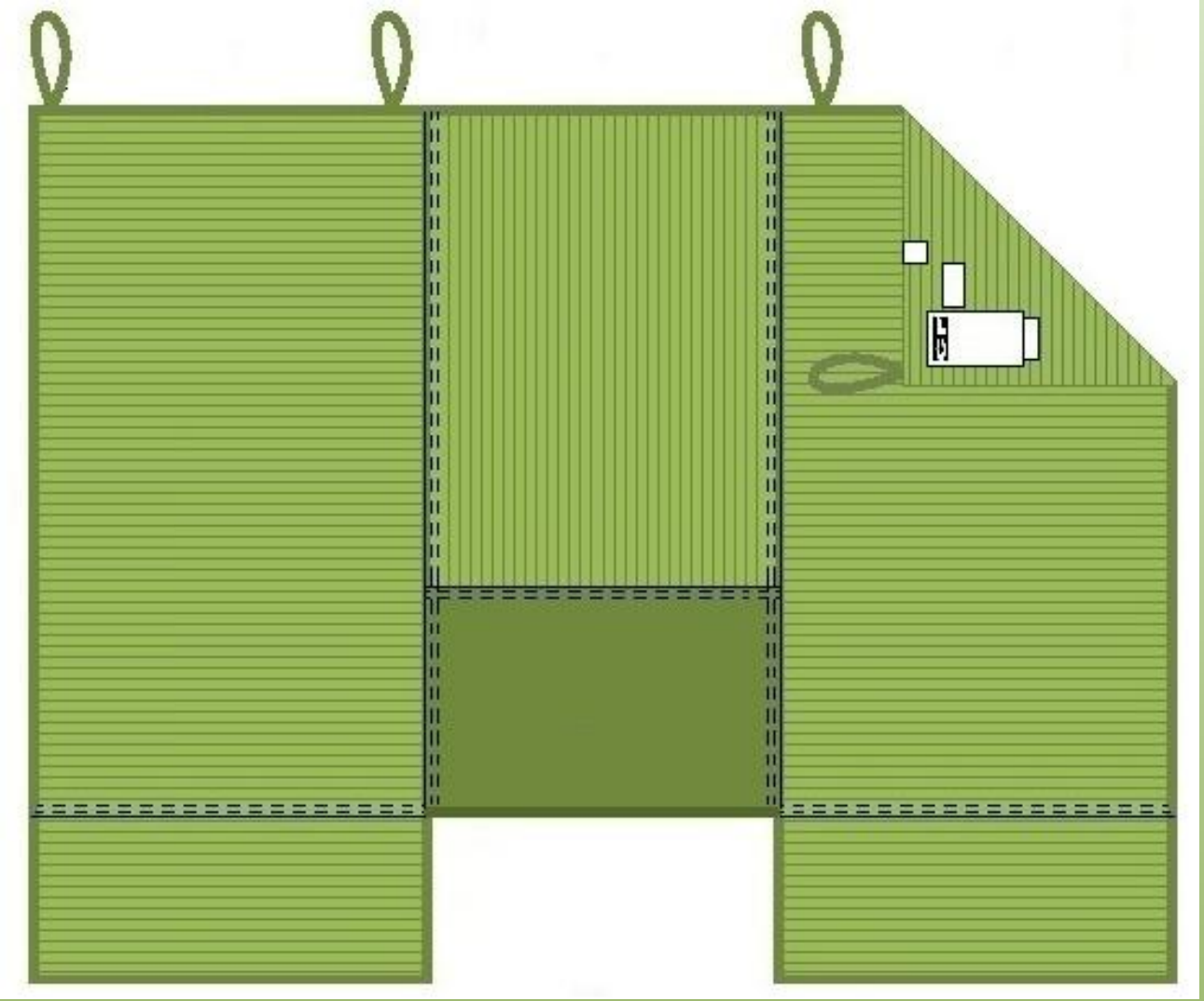
While the area is made less critical in microfibre fabric.

Rolls: also in this case, according to the type of intervention we have two categories.

STANDARD PERFORMACE

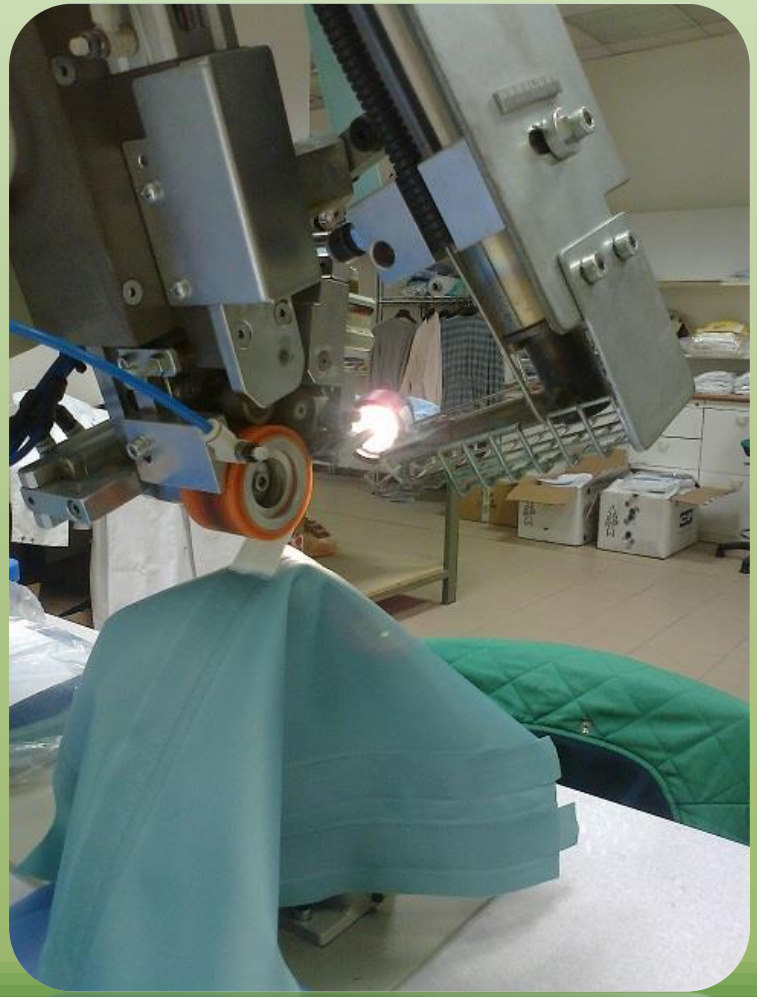
Where the entire cloth is composed of microfibre fabric

HIGH PERFORMACE



Where the critical area (in contact with the patient) is made of fabric trilaminate, while the remaining parts are in microfibre fabric.

The pack overalls involves the application of a tape welded on the seam of the forearm, this to make it impermeable to the passage of liquids.
This operation is performed by a machine (termonastratrice) which works at high temperatures (between 450 ° and 550 ° depending on the type of material used)



For checking the impermeability of the seam, the sleeve is subjected to a water pressure of 0.1 bar for a time of 120 seconds, using a device known 'Suter test'

he seams of the sheets are not heat sealed as they are not subjected to pressure as in the case of the sleeve of the coat. The union of the critical area with the least criticism is mainly carried out with machine double needle stitching to English.

For verification of the presence or absence of holes in the critical part of the product, both gowns that sheets are subject to control by means of dummy and / or light table.


Mod. CX-T