Surgical drapes and gowns

Examining the relevant standards and directives

Nosocomial infections, that is infections acquired in the hospital or in a healthcare facility, constitute a major problem in public health. These infections are among the ten leading causes of death in industrialised countries.

> "a healthy individual can disperse to the air approximately 5,000 bacteria-carrying skin scales per minute during walking"

The majority of postoperative surgical site infections are acquired at the time of surgical procedure, when the microorganisms can reach the open wound.

The skin of the staff and/or patient constitutes the most important source of microorganisms. A healthy individual can disperse to the air approximately 5,000 bacteria-carrying skin scales1 per minute during walking. The particles are 5 μm to 60 μm in size and the average number of aerobic and anaerobic bacteria carried is estimated to be about five per skin scale.

The airborne particles can contaminate the wound directly by sedimentation or indirectly by first settling on instruments or other items that are then brought into contact with the wound.

Gowns, drapes and clean air suits are used to minimise the risk of contamination. Their role is to improve patient safety but also to minimise the spread of infectious agents such as MRSA (Methicillin-resistant Staphylococcus aureus) and other antibiotic resistant bacterial strains, human immunodeficiency virus (HIV), and many others, and thereby decrease the risk for staff as well as other patients to be contaminated by these infectious agents.

They have to be an excellent barrier to microorganisms in addition to possessing other important qualities which are also necessary.

Surgical drapes and gowns

A surgical drape is defined as a drape covering the patient or equipment during a surgical procedure to prevent the transfer of infective agents.

A surgical gown is defined as a cloth that has to be worn by a member of the surgical team during a surgical procedure to prevent the transfer of infective agents.

Clearly the barrier property to microorganisms is one of the most important characteristics needed, but other properties like resistance to liquids, abrasion and tearing, plus a fabric's linting and a garment's comfort must be considered when selecting products for a healthcare facility.

Nowadays two categories of materials are used to manufacture surgical gowns and drapes[2]:

- *Reusable material*
- *Single-use material*

The choice of using single-use or reusable gowns or drapes will be sometimes difficult, each category of products having its own advantages and disadvantages. The barrier properties, the physical properties as well as the comfort, the cost and also the environmental impact have to be taken into consideration for the final decision. There is no rule at this point in time, and each country and each hospital have to work out their own policy their own way.

Reusable materials

In the past cotton fabrics were the fabrics of choice but now they have almost completely disappeared from the operating room due to their low resistance to liquid penetration, their high porosity and their high tendency to generate lint. Tightly woven textiles of a blend of polyester and cotton have since appeared on the market. With a good water repellent chemical finish they exhibit relatively good performance, but repeated wash cycles could alter the final resistance to liquid penetration.

Over the last 15 years there has been increasing usage of reusable drapes and gowns produced from a new generation of microfilament materials.

The yarn in microfilament[3] fabrics is made of fine, continuous polyester filaments. Very often antistatic properties of the fabric are obtained by using together with polyester filaments conductive carbon fibres during weaving.

Those fabrics release practically no particles and have a strong resistance to tear and abrasion for a long, useful life. By using a suitable fluid-repellent finish the fabric can be reprocessed quite frequently.

Another group of materials that are also frequently used are composite materials, a combination of woven or knitted fabrics engineered to obtain enhanced performance characteristics by laminating or coating them with various types of films that provide increased protection against strike-through of liquids and microorganisms.

Trilaminates (three-layer construction) that are comprised of a membrane sandwiched between an upper and a lower layer are now highly developed. By choosing suitable materials for the different layers the final properties of the composite are really optimised. The membrane used is generally a total barrier for bacteria and viruses, but not for water vapour molecules, rendering the escape of human perspiration possible.

Reinforced areas of reusable gowns or drapes are often based on multilayer constructions because high levels of performance are required. Those reinforcement areas are ▸

principally located around the patient wound, for drapes, and on the front and sleeves of the gown.

Single-use materials

Nonwoven materials are the essential component of single-use surgical gowns and drapes.

They are based on various forms of natural and synthetic fibres; that is, components such as wood pulp and cotton, or polyester, polyolefin respectively[4].

Based on the way the links between the fibres take place in the nonwoven - chemically, physically, mechanically, thermally - nonwovens are segmented in different categories.

For surgical gowns a nonwoven should be soft and breathable while a high level of barrier protection is also required. Several types of nonwovens can meet these requirements. Spunlaced materials, SMS (Spunbond/Meltblown/Spunbond – consisting of three thermally bonded layers, generally based on polypropylene) or SMMS (Spunbond/Meltblown/Meltblown/Spunbond) can be used.

Owing to the firm bonding of the fibres these materials are particularly low-linting and abrasion-resistant, yet extremely soft and breathable, providing excellent wearing comfort.

For drapes either coated wet, dry laid or multilayer, SMS are used.

Like reusable, single-use gowns and drapes can be reinforced for specific applications and in some areas. When necessary they are reinforced with other material such as a plastic film, or are used in double or triple layers in order to achieve the requirements of the operating room.

Medical Devices Directive

As a medical device, textiles used in operating theatres have to be conform with the requirements of the European Medical Devices Directive MDD 93/42/EEC[5] (last technical revision being brought about by the Directive 2007/47/EC).

> “surgical drapes, gowns and clean air suits are classified as Class I (Non Invasive) Medical Devices, and must conform to chemical, physical and microbiological properties as well as meet specified safety parameters”

According to the MDD medical devices should provide patients, users and third parties with a high level of protection and attain the performance levels attributed to them by the manufacturer.

Devices are divided into four risk classes: Class I, Class IIa, Class IIb and Class III. Classification is carried out in accordance with Annex IX of the MDD.

Surgical drapes, gowns and clean air suits are classified as Class I (Non Invasive) Medical Devices. Those medical devices have to conform to chemical, physical and microbiological properties as well as meet specified safety parameters of use, storage, transport and labelling.

For medical devices belonging to Class I the responsibility of safety for putting the medical device on the market is taken by the manufacturer.

For other medical devices (Classes II and III) manufacturer and independent assessment centres such as notified bodies, national agencies, and the European commission have to work together.

European standardization EN 13795

The EN 13795 European Standard for surgical gowns and drapes specifies the performance requirements, manufacturing standards and testing methods for both reusable and single-use products.

This standard has been written in the spirit of the European directive and aims at preventing the transfer of infections between medical staff and patients during surgical operations and other invasive interventions. It provides the technical link to comply with the European MDD directive.

Moreover, the standard wants to guarantee the same safety and performance levels for all products, disposable or reusable articles alike, and this during the entire product life.

During March 2011 a new version of the standard was published. Whereas the previous version (dated 2009) was divided in three parts - EN 13795-1:2002+A1 :2009, EN 13795-2 :2004+A1:2009, and EN 13795-3:2006+A1:2009 - the recent version of 2011 is a unique document merging the three previous parts.

EN 13795 - 2011: Title

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performances levels.

EN 13795 - 2011: Content

The standard is structured as follows:

1. Scope
2. Normative references
3. Terms and definitions
4. Performance requirements
5. Testing
6. Manufacturing and processing requirements
7. Information to be supplied by the manufacturer or processor

The annex A explains the significant changes that have been made between this new standard and the previous edition.

The annex B defines the test methods.

The annex C gives information concerning the prevention of infection in the operating room.

The annex D gives information concerning further characteristics like comfort, adhesion and liquid control.

What are the test methods used?

The testing for the evaluation of the performance of products has to be done according to the test methods specified in annex B.

All the tests have to be performed on the finished products and if the product is used after sterilisation, testing has to be performed on products after sterilisation with the exception of the microbial cleanliness test. Testing includes potential weak spots.

Besides physical tests which are well known like:

- *Tensile strength in dry and wet states - EN 29073-3*
- *Burst strength in dry and wet states - EN 13938-1*
- *Resistance to fluid penetration - EN 20811*

Other more specific characteristics have to be measured. These include:

- *Cleanliness - microbial - EN ISO 11737-1*

  Microbial cleanliness determines the bioburden or the total content of viable microorganisms on the product. It has to be done on the finished product before sterilisation. The test results are expressed as a number of CFU (colony forming unit)/100 cm²

- *Cleanliness - particulate matter - ISO 9073-10 and Linting - ISO 9073-10*

  The ISO standard specifies a test method for measuring the linting in the dry state.

  The EN13795 brings the following amendments to the standard.

  Only particles whose size range is between 3 µm and 25 µm have to be considered as linting, due to the fact that only particles of this size range are considered to be capable of carrying microorganisms.

  The cleanliness particulate matter (PM) corresponds to the particle counts from steps 30 s, 60 s and 90 s of the linting measurement that are added together.

  The results of the test are expressed as follows:

  - *Linting = $\log_{10}$ (lint count ≥ 3µ)*
  - *Cleanliness - Particulate matter: IPM (index for particulate matter) = $\log_{10}$ (PM ≥ 3µ)*

- *Resistance to microbial penetration - dry - ISO 22612*

  This test method provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles.

  A talc powder is used as a carrier of germs. The method establishes the quantity of bacteria that can penetrate through the test material being carried on talcum powder. Test results are expressed in the CFU (colony forming units) that were observed on the agar plate.

- *Resistance to microbial penetration - wet - ISO 22610*

  This International Standard specifies a test method, with associated test apparatus (see photo), which is used to determine the resistance of a material to the penetration of bacteria, carried by a liquid, when subjected to mechanical rubbing.

  Test results are expressed as I_B 'Barrier Index'. A total barrier material gives the maximum achievable value of 6.0.

  When the values are below 6.0 it means that a penetration of bacteria is possible: 2.8 as I_B is the limit which has been accepted for some products.

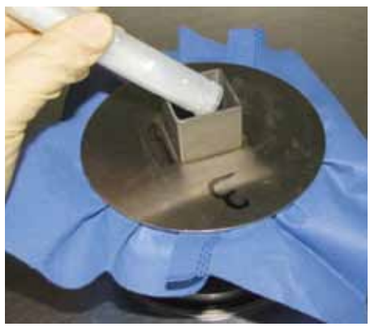
Performance and requirements

To comply with EN 13795 products should meet all the requirements specified in either tables 1, 2 or 3 of the standard, as appropriate to the product.

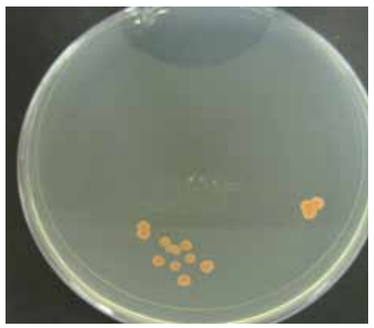
These minimum values account for the circumstances of the surgical operation, therefore they distinguish between products for standard performances and products for higher performances on the one hand, and between the critical and less critical zones of the product on the other hand.

The critical zone of a product has a greater chance of being involved in the transfer of infection carriers on the operation site, or on the invasive zone, or vice versa. For example, the front piece and the sleeves of surgical gowns are in the immediate proximity of the operation site.

A product for standard performances or high performances is defined in function by its exposure to biological or other fluids, to mechanical pressure or by the duration of a surgical operation.



Introduction of the contaminated talc powder - ISO 22612 test



Bacteria that have passed through the material Requirement: ≤ 300 CFU

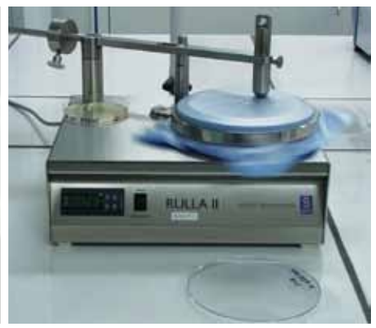


Illustration of the test system ISO 22610

> “standard EN13795 is aimed principally at the protection of the patient; this determines the direction in which the sample is brought into contact with the contaminating agent during the test”

As an example, Table 1 gives the general requirements of the EN13795 for gowns.

a. Test conditions: challenge concentration 10^8 CFU/g talc and 30 min vibration time.

b. The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610, was found to be 0.98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0.98 I_B are probably not different; materials varying by more than 0.98 I_B probably are different. (The 95% confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives).

c. I_B = 6.0 for the purpose of this European Standard means: no penetration. I_B = 6.0 is the maximum achievable value.

Action for manufacturers or processors

According to their performance, surgical drapes and gowns must be further categorised and defined as standard or high performance devices.

The manufacturer and processor should document that the requirements set down in the EN13795 standard are met.

Validated manufacturing and procedures should be used including validation of the product itself, validation of each step of manufacture and processing, and recording of each important key variable.

If the manufacturer or processor differentiates between critical and less critical areas, he has to supply information to clearly identify them.

Further characteristics

Standard EN13795 also mentions some interesting additional properties such as ‘liquid control’, adhesion properties or comfort.

Table 1. Characteristics and use requirements to be assessed with surgical gowns

Characteristic	Unit	EN 13795 requirements			
		Standard performance		*High performance*	
		Critical product area	*Less critical product area*	*Critical product area*	*Less critical product area*
Resistance to microbial penetration - dry	CFU	Not required	≤ 300[a]	Not required	≤ 300[a]
Resistance to microbial penetration - wet	I_B	≥ 2.8[b]	Not required	6.0[b c]	Not required
Cleanliness - microbial	CFU/100 cm²	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness - particulate matter	IPM	≤ 3.5	≤ 3.5	≤ 3.5	≤ 3.5
Linting	$Log_{(10)}$ (lint count)	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0
Resistance to liquid penetration	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength - dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength - wet	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength - dry	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength - wet	N	≥ 20	Not required	≥ 20	Not required

The following test methods to measure the comfort properties of gowns and drapes can be used.

- *Air permeability - ISO 9237*
- *Skin model - ISO 11092 - EN31092*
- *Thermal manikin - EN ISO 15831 - ASTM F2370*

Image: Manikin of Centexbel

Besides tests that have to prove the conformity of the product, the European directive introduces the notion of risk analysis by proposing the following tests:

- *Non-toxicity of the medical device - ISO 10993-5*

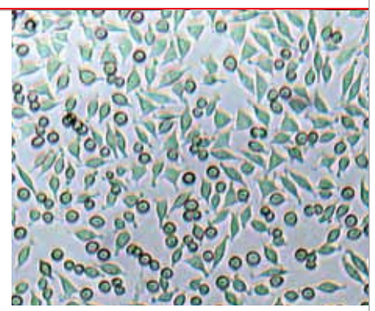


Image: Cytotoxicity test on fibroblasts cells

- *Measurement of the electrical risk - ISO 2878 (BS2050) and EN 1149*

- *Protection against laser beams*
  - *ISO 11810-1: primary ignition and penetration*
  - *ISO 11810-2: secondary ignition*

Image: Apparatus developed by Centexbel for the evaluation of the laser protection

Who is protected?

Standard EN13795 is aimed principally at the protection of the patient; this determines the direction in which the sample is brought into contact with the contaminating agent during the test.

If the manufacturer also claims the protection of the medical staff, the surgical gown will no longer be considered as a medical device but as PPE (personal protection equipment).

In this case, the product has to comply with the corresponding directive 89/686/EEC (protective clothing) and standard EN14126: Protective Clothing. Performance requirements and tests methods for protective clothing against infective agents. ■

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3. *Univ Prof Dr Ojan Assadian, Gerhard Fluch, Administrative Director Norbert Grass, Dr Milo Halabi, Dr Markus Hell, Prim. Univ Prof Dr Harald Hertz, Prim Dr Peter Zenz, 2011, Reusable surgical fabrics - Consensus statement- State of the art 2011, CliniCum special edition October 2011.*
4. *William A Rutala, PhD, MPH and David J Weber, MD, MPH, 2001, A review od single-use and reusable gowns and drapes in health care, Infection Control and Hospital epidemiology, 22, (4), p248-257.*
5. *European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.*

Authors

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Yvette Rogister joined Centexbel 23 years ago after one year of teaching at the University of Louvain-La-Neuve. As an engineer in chemistry she started her career as a researcher and followed a lot of projects concerning textiles and surface modifications by different processes. Later she contributed largely to the development of the laboratory of microbiology and hygiene in relation to textiles. By participating in different standardisation committees and developing testing methods she now has extensive experience in numerous different fields including antimicrobial treatments, barrier textiles, medical textiles and medical devices.

Ing Mark Croes

After a career of almost 15 years in technical service and product development servicing the European pharmaceutical, paper and textile markets with an American specialty chemicals’ manufacturer, Croes joined Centexbel ten years ago as a Technological and Innovation Consultant, supporting the activities in the field of Health and Safety in the laboratory.

Centexbel, Belgian Textile Research Centre

The Belgium based laboratory offers highly specialised technological services including customised advice, measuring and testing, certification, process innovation and product development to the manufacturers of medical and hygiene oriented textile products. The laboratory specialises in the evaluation of cleanliness and barrier properties - both particle and microbial - of medical and hygiene products.