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.

The majority of postoperative surgical site infections are acquired at the time of surgical procedure, when the microorganism 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 scales per minute during walking. 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 clear 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 lustre 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:

- 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 on 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.

Some 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.

Telinates (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...
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 wool, gip, and cotton, or polyester, polyethylene respectively.

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

For surgical gowns and nonwoven should be soft and breathable while a high level of barrier protection is also required. Several types of nonwovens can meet these requirements.

Spunbonded materials, SMS (Spunbond/ Meltblown/Spunbond) - consisting of three thermally bonded layers, generally based on polypropylene or SMM (Spunbond/ 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. The standard EN 13795 brings the following amendments to the standard.

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 applicable to the product.

Mouse micron counts - ISO 16889-3

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

Linting = log10 (lint count – background) ≥ 3µ

The results of the test are expressed as follows:

Resistance to microbial penetration - dry - EN 13795-2

This test method provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles. A test result is used as a criterion of 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 22612

This test method provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles. A test result is used as a criterion of 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 22600

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.

Medical Devices Directive

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

This 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.

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.

The test results are expressed as 1, 2, 3, 4, 5, or 6. The ISO standard specifies a test method for measuring the linting in the dry state.

The EN13795 brings the following amendments to the standard.

EN 13795 - 2011: Content

The standard is structured as follows:

Scopes

Normative references

Terms and definitions

Performance requirements

Testing

Manufacturing and processing requirements

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.

Medical Workwear and Textiles

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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.

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

a. Test conditions: challenge concentration

b. The Least Significant Difference (LSD) for

c. The Least Significant Difference (LSD) for

d. This is the minimum difference needed to

e. The minimum difference needed to

**Action for manufacturers or processors**

According to their performance, surgical drapes and gowns must be further classified 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.

**Further characteristics**

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

**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 protective equipment).

In this case, the product has to comply with the corresponding directives 89/686/ECC (protective clothing) and standard EN4126.

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Unit</th>
<th>EN 13795 requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance to microbial penetration - dry</td>
<td>CFU</td>
<td>Not required</td>
</tr>
<tr>
<td>Resistance to microbial penetration - wet</td>
<td>I</td>
<td>≥ 2.8 I</td>
</tr>
<tr>
<td>Cleanness - microbial</td>
<td>CFU/100 m²</td>
<td>&lt; 300</td>
</tr>
<tr>
<td>Cleanness - particulate matter</td>
<td>IPM</td>
<td>≤ 3.5</td>
</tr>
<tr>
<td>Linting</td>
<td>Log₈ (lint count)</td>
<td>≤ 4.0</td>
</tr>
<tr>
<td>Resistance to liquid penetration</td>
<td>cm H₂O</td>
<td>≥ 20</td>
</tr>
<tr>
<td>Bursting strength - dry</td>
<td>kPa</td>
<td>≥ 40</td>
</tr>
<tr>
<td>Bursting strength - wet</td>
<td>kPa</td>
<td>≥ 40</td>
</tr>
<tr>
<td>Tensile strength - dry</td>
<td>N</td>
<td>≥ 30</td>
</tr>
<tr>
<td>Tensile strength - wet</td>
<td>N</td>
<td>≥ 30</td>
</tr>
</tbody>
</table>

**enda References:**


**Authors**

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Tine Reynaert joined Centexbel 23 years ago after one year of teaching at the University of Leuven-Les-Neves. As an engineer in chemistry she started her career as a consultant 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 standardization committees and developing testing methods she now has extensive experience in numerous areas including antimicrobial treatments, barrier textiles and medical devices.

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Offer a service of about 15 years in technical service and product development serving the European pharmaceutical, paper and textile market with an American specialty chemical’s manufacturer, Croes joined Centexbel two years ago as a Technologist and Innovation Coordinator but became the Head of Microbiological Laboratory on 1 January 2011. He has followed a lot of projects concerning textiles and surface modifications by different processes. Later he contributed largely to the development of the laboratory of microbiology and hygiene in relation to textiles. By participating in different standardization committees and developing testing methods she now has extensive experience in numerous areas including antimicrobial treatments, barrier textiles and medical devices.

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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 consultant 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 standardization committees and developing testing methods she now has extensive experience in numerous areas including antimicrobial treatments, barrier textiles and medical devices.

**References**

1. European Standard EN13795, 2011, Surgical drapes, gowns and drapes on sites, such as medical device for patient, clinical staff and equipment – General requirements for manufacturers, processors and products; test methods; performance requirements and performance levels.