Reusable Surgical Fabrics

Consensus statement
State of the art 2011

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Chair: Prim. Univ.-Doz. Dr. Petra Apfalter
For years many different high-quality fabrics have been used in operations. They are mainly used as drapes for operations and as protective clothing.

When choosing suitable materials it is not only fundamental requirements of the material itself but also the requirements of the users and patients and economic and ecological aspects as well which play a decisive role.

Surgical fabrics are medical products and are subject to the Medical Devices Act. This means there are high requirements for the fabrics and also for the manufacturers and processors. The requirements and also test methods for these products are regulated in EN 13795.

Surgical fabrics play an important role to ensure optimum care is provided during operations. For example, using surgical fabrics can prevent a patient’s wound becoming contaminated as a result of germs or skin particles from the patient or surgical staff. The use of modern, innovative fabrics can be seen as making a key contribution to the protection of patients and staff.

With this in mind, yours
Reusable Surgical Fabrics

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1. Introduction
Sterile surgical gowns and patient drapes which are resistant to the penetration of germs help prevent the transfer of pathogens from medical staff to patients and vice versa. For more than two decades high-quality fabrics which can be reused several times have been available for use in operating theatres. Reusable surgical fabrics have to protect patients against intraoperative, nosocomial infections and postoperative complications and protect medical staff against contact with infectious material.

Reusable surgical gowns and drapes have proven practical especially during dynamic operations where there are a lot of fluids involved. To date this has been proven in two consensus statements (cf., for example, Mittermayer et al. 2008, von Eiff et al. 2004) and two expert opinions (cf., for example, Mittermayer et al. 2007, Diab-Elschahawi/Grass/Hermann/Mannsberger/Meusburger 2010). Reusable surgical gowns and drapes are highly functional. If nothing else, time and money can also be saved with practically composed and easy-to-handle reusable sets.

Surgical fabrics have to fulfill the following requirements:
• maximum protection for patients, users and third parties
• high microbiological and hygiene standards to prevent the risk of infection
• good wearing comfort of the clothing to maintain the high performance
• sweat-absorbing
• easy handling of the drapes

Surgical drapes and materials are a key element when preventing postoperative wound infections. Only when these are used can a sterile operating environment be guaranteed to ensure aseptic work. For secure and effective barrier protection, surgical drapes need to have certain essential characteristics, however.

As well as the clear need for sterility, the most important properties of this medical device group are described and stipulated in the European standard for surgical drapes and gowns, EN 13795, part 1 (2002), part 2 (2004) and part 3 (2006). Attention has to be paid here to requirements in terms of resistance against germ and liquid penetration, linting, fire resistance, cleanliness and tensile strength. Currently available surgical fabrics therefore have to be extremely durable and resistant and also fulfill high requirements in terms of impermeability to fluids and fluid control.

Apart from the quality requirements which surgical fabrics must generally fulfill and which are regulated in European standards (e.g. in EN 13795), in the last few years environmental aspects have also increasingly become an area of focus in discussions about disposable versus reusable fabrics in operations.

A recent study at the University of Minnesota was able to show that the use of high-grade reusable fabrics in surgery is not only more cost-effective but also causes much less environmental pollution than the use of disposable fabrics (cf. van den Berge 2010). You can read more on this in the chapter “Environmental compatibility”.

2. European Standard EN 13795
The European Standard EN 13795 regulates the requirements for manufacturers and processors of surgical gowns, drapes and cleanroom clothing in operating theatres. This concerns disposable and also reusable equipment. It also stipulates the necessary test methods for such products. Here it is clarified that the distributor, i.e. either the
• manufacturer of single-use products,
• provider of leased textiles (reusable fabrics),
• manufacturer of reusable fabrics with CE marking or
• hospitals with in-house production is responsible for fulfilling EN 13795.

In 2011 the previous three-part EN 13795 was revised and brought together in one document. The revised version of EN 13795:2011 is intended to “assist the communication between users, manufacturers and third parties with regard to material or product characteristics and performance requirements” (OENORM EN 13795).

2.1. Applicability of EN 13795
The objective of the standard and its context are comprehensively and clearly defined. The area of application is also clearly defined by indicating what is handled in the standard and what is not. The information to be provided by the manufacturer is clearly defined and can be checked objectively. The characteristics which are to be assessed are clearly set out. The standard takes into consideration the central importance of the requirements for manufacture and processing and the requirements for testing.

Another key aspect of EN 13795 is the precise stipulation of the test methods. The standard specifies that validated procedures for manufacture and processing have to be used for testing the fabrics. All manufacturing and processing steps have to be included in this validation. All data concerning the manufacture and processing of surgical gowns, drapes and cleanroom clothing also has to be documented and the documents must be stored. No technical changes have been made in this European standard. The general requirements, requirements for use and test methods are the same as those in EN 13795-1, EN 13795-2 and EN 13795-3.

3. General conditions and standards
Nowadays the following materials are used to manufacture reusable fabrics for surgical environments:

3.1. Microfilament fabrics
The yarn in microfilament fabrics is made of fine, continuous polyester filaments. Conductive carbon fibres are generally also woven into the material to guarantee permanent antistatic qualities. These fabrics are highly resistant to tearing and rubbing and release practically no particles when used. Thanks to the fluorocarbon component, the materials are fluid-repellent, which means that high-quality materials can be reprocessed up to 80 times.

3.2. Laminates
A trilaminate (three-layer construction) is a membrane sandwiched between an upper and lower layer. Selecting suitable surface materials produces liquid-absorbing or repellent effects as desired. The membranes can be designed to prevent bacteria or viruses from penetrating together with liquids. The membrane is not a barrier for water vapour molecules. Human perspiration can therefore escape in the form of moisture vapour, thus maintaining natural thermoregulation. Furthermore, trilaminates are impervious to liquids even under high pressure and absorb high volumes of fluid on the surface and are therefore used in surgical areas (high performance).
4. Studies on reusable fabrics

Now there are four studies overall on the use of disposable and reusable fabrics in surgery. The latest work by the University of Minnesota from July 2010 compares disposable and reusable fabrics with regard to their environmental effects:

1. Comparative Life Cycle Assessment of Disposable andReusable Surgical Gowns. (Van den Bergh A.J, Zimmer C., American Reusable Fabrics Association Green Summit, Quebec, QC, July 2010)

2. SAFEC (Safety/Ecology/Economy in the O.R.) study (Feltgen M., Werner H.F, Hygiene und Medizin [Hygiene and Medicine], Suppl. 2, November 2000, p. 60 ff.)


4. Life Cycle Assessment Comparing Laundered Surgical Gowns with Polypropylene Based Disposable Gowns. (Carre A. Report for the Australian Industry Group and the Fabric Rental and Laundry Association (Victoria) by the Centre for Design at RMIT. 27 November 2008)

Only the SAFEC study contains Austrian results. This study proved that the requirements can be met if reusable medical devices are processed professionally and suitable material and quality management systems are on board. In addition, it showed that reusable textiles have satisfactory characteristics in terms of barrier properties, particulate release and mechanical strength when exposed to wet conditions and exceed the standard requirements. The reusable surgical gowns and drapes consist of robust and high-performance materials. Innovative textiles (trilaminates and microfilament fabrics) clearly satisfy all normative requirements and are the reason for the high safety demonstrated by processable surgical fabrics.

The EDANA study conducted in England, France and Wales arrives at different results in parts, but it must be said that the EDANA and SAFEC studies cannot be compared directly because of the different conditions (type and number of parameters examined, scope, materials and processes used). In individual cases the products being considered for selection would have to be examined objectively and then compared.

5. Cost effectiveness

In a study by Prof. DDrlf von Eiff from the Centre for Hospital Management in Münster from 2007, the costs of surgical drapes - reusable fabrics and disposable fabrics - were compared with each other as well as the costs per operation and the costs at the hospital level (cf. von Eiff 2007). At first glance the reusable providers are clearly above the costs of disposable products. But several differences have to be considered here, there is no direct comparability. The reason: in the von Eiff study it was discovered that reusable drapes are bigger than disposable drapes on average. Reusable fabrics are also better than the disposable products in terms of their tear and bursting strength.

In the area of set composition there is also no direct comparability because the contents and quality of the sets vary from provider to provider. The set prices for single-use products cannot be used for total costing because generally there are additional costs for logistics, daily delivery, distribution in the hospital, storage and disposal of the surgical sets.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Test method (see section 2 for dated references)</th>
<th>Unit</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance to microbial penetration – dry</td>
<td>EN ISO 22612</td>
<td>CFU</td>
<td>Critical product area: not required; Less critical product area: ≤ 300&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Resistance to microbial penetration – wet</td>
<td>EN ISO 22610</td>
<td>I&lt;sub&gt;p&lt;/sub&gt;</td>
<td>Critical product area: ≥ 2.8&lt;sup&gt;b&lt;/sup&gt;; Less critical product area: not required</td>
</tr>
<tr>
<td>Cleanliness – microbial</td>
<td>EN ISO 11737-1</td>
<td>CFU/100 cm²</td>
<td>Critical product area: ≤ 300; Less critical product area: ≤ 300</td>
</tr>
<tr>
<td>Cleanliness – particulate matter</td>
<td>ISO 9073-10</td>
<td>IPM</td>
<td>Critical product area: ≤ 3.5; Less critical product area: ≤ 3.5</td>
</tr>
<tr>
<td>Linting</td>
<td>ISO 9073-10</td>
<td>log&lt;sub&gt;10&lt;/sub&gt; (lint count)</td>
<td>Critical product area: ≤ 4.0; Less critical product area: ≤ 4.0</td>
</tr>
<tr>
<td>Resistance to liquid penetration</td>
<td>EN 20811</td>
<td>cm H₂O</td>
<td>Critical product area: ≥ 20; Less critical product area: ≥ 10</td>
</tr>
<tr>
<td>Bursting strength – dry</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>Critical product area: ≥ 40; Less critical product area: ≥ 40</td>
</tr>
<tr>
<td>Bursting strength – wet</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>Critical product area: ≥ 40; Less critical product area: not required</td>
</tr>
<tr>
<td>Tensile strength – dry</td>
<td>EN 29073-3</td>
<td>N</td>
<td>Critical product area: ≥ 20; Less critical product area: ≥ 20</td>
</tr>
<tr>
<td>Tensile strength – wet</td>
<td>EN 29073-3</td>
<td>N</td>
<td>Critical product area: ≥ 20; Less critical product area: not required</td>
</tr>
</tbody>
</table>

Source: OENORM EN 13795, Austrian Standards Institute, 2011

<sup>a</sup> Test conditions: Challenge concentration 10⁷ CFU/g talcum and 30 min. vibration time.

<sup>b</sup> The Least Significant Difference (LSD) for the barrier index I<sub>p</sub> 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 (in their barrier effect). Thus materials varying by up to 0.98 I<sub>p</sub> are probably not different (in their barrier effect), materials varying by more than 0.98 I<sub>p</sub> are probably different (in their barrier effect). (The 95% confidence level means that an observer would be correct 19 times out of 20.)

<sup>c</sup> I<sub>p</sub> = 6.0 for the purpose of this standard means: no penetration, I<sub>p</sub> = 6.0 is the maximum achievable value.
If all covering materials needed in an operation are taken into consideration in costing, reusable fabrics tend to be more attractive economically. The following reasons support this finding:

- Disposable coverings are often applied in several layers.
- Disposable products do not cling to the patients so well because of their lower material weight.
- Disposable products are usually smaller than reusable fabrics.
- Additional drapes are often needed to weigh down the edges.
- The poor thermal insulation of disposable products often leads to the use of additional materials.
- Defective disposable drapes (tensile strength!) have to be covered with additional drapes or replaced.

It is understandable that costs are a decisive criterion for the hospital’s economy. The actual costs do not only depend on the purchase price, however – they also depend on the hospital in question, the operation frequency, the patients and the individually available processing options. The choice of either disposable or reusable fabrics has to be made in each hospital individually.

A decision to obtain surgical gowns and drapes based entirely on the price argument ignores risks such as the risk of infection for the patient. As an example von Eiff indicates total hip endoprosthesis in his study. This is an operation with a heavy mechanical load. If the bond does not stick, the use of additional materials.

• Defective disposable drapes (tensile strength!) have to be covered with additional drapes or replaced.

So if we compare disposable products with reusable fabrics, these additional costs have to be included. In practice this does not usually happen though – here von Eiff speaks of a cost gap. But it is a fact that surgical fabrics are usually not purchased by those who are aware of these risks, such as the surgical staff. Instead it tends to be the hospital management which is responsible for purchasing. And here - in Germany this can already be seen very clearly - it is only price-based arguments which play a role.

In Austria the situation is different. At a round table meeting in 2008 it could be seen, for example, that Austrian hospital managers and doctors mainly choose reusable fabrics. It is not only the price card that is played here. Instead quality is considered more important. Economising is also given a lot of consideration in Austria but this is usually done with a complete examination of the cost effectiveness of the surgical drape system and not only using the individual price of a (usually not comparable) surgical set. This is because surgical gowns and drapes play a comparatively minor role in the overall costs of a hospital.

6. Wearing comfort

6.1. Thermophysiological function

Clothing which is permeable to water vapour (“breathable”) improves thermal comfort for the wearer because of its ability to exchange moisture between the inner and outer layers, especially when working and exercising. Even with an ambient temperature of 25 °C, the wearer’s core temperature still remains within ranges that are felt to be acceptable – as long as the clothing is breathable.

Non-breathable fabrics, however, lead to a rapid rise in temperature, and after a tolerance period of 133 minutes, the critical limit of 38.2 °C is reached. Temperatures above this level mean a great

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<td></td>
<td></td>
<td></td>
<td>Less critical product area</td>
</tr>
<tr>
<td>Resistance to microbial penetration – wet</td>
<td>EN ISO 22610</td>
<td>I₀</td>
<td>≥ 2.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>not required</td>
</tr>
<tr>
<td>Cleanliness – microbial</td>
<td>EN ISO 11737-1</td>
<td>CFU/100 cm&lt;sup&gt;2&lt;/sup&gt;</td>
<td>≤ 300</td>
</tr>
<tr>
<td>Cleanliness – particulate matter</td>
<td>ISO 9073-10</td>
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<td>Resistance to liquid penetration</td>
<td>EN 20811</td>
<td>cm H&lt;sub&gt;2&lt;/sub&gt;O</td>
<td>≥ 30</td>
</tr>
<tr>
<td>Bursting strength – dry</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>≥ 40</td>
</tr>
<tr>
<td>Bursting strength – wet</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>≥ 40</td>
</tr>
<tr>
<td>Tensile strength – dry</td>
<td>EN 29073-3</td>
<td>N</td>
<td>≥ 15</td>
</tr>
<tr>
<td>Tensile strength – wet</td>
<td>EN 29073-3</td>
<td>N</td>
<td>not required</td>
</tr>
</tbody>
</table>

a) The Least Significant Difference (LSD) for the barrier index I₀ 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 (in their barrier effect). Thus materials varying by up to 0.98 I₀ are probably not different (in their barrier effect); materials varying by more than 0.98 I₀ are probably different (in their barrier effect). (The 95% confidence level means that an observer would be correct 19 times out of 20.)

b) The Least Significant Difference (LSD) for the barrier index I₀ 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 (in their barrier effect). Thus materials varying by up to 0.98 I₀ are probably not different (in their barrier effect); materials varying by more than 0.98 I₀ are probably different (in their barrier effect). (The 95% confidence level means that an observer would be correct 19 times out of 20.)

c) I₀ = 6.0 for the purpose of this standard means: no penetration, I₀ = 6.0 is the maximum achievable value.

Source: OENORM EN 13795, Austrian Standards Institute, 2011
physiological strain, leading to queasiness, heat stress and reduced powers of concentration.

In addition, the body’s perspiration cover rate should not exceed 45 percent. Here 61 percent is regarded as the upper limit. A single drop of sweat falling into a wound contains more germs than enter from the ambient air or textiles!

6.1.1. Microclimate of the clothing
Experts from the German Hohenstein Institute regularly carry out series of tests with surgical clothing from hospitals. The management usually wants blended fabrics because they are easier to look after, and cost reasons also come into consideration here. The staff, however, expect higher wearing comfort from pure cotton. The general rejection of synthetic fibres is usually based on bad experiences with low quality products, which are considered stiff and itchy and absorb sweat badly.

Wearing trials with people as test subjects show that blended fabrics provide a better microclimate than cotton, and – as soon as they are worn – they are also considered more pleasant to wear than conventional cotton clothing.

6.1.2. Measurable comfort
The wearing comfort of clothing is definitely not just a subjective matter – it can also be measured and assessed objectively. At the research centre in Hohenstein the so-called wear comfort rating for textiles has been developed for this purpose. This goes from “very good” (1) to “unsatisfactory” (6), and is calculated using a series of measurements determined in a clothing physiology laboratory.

As well as the thermophysiological characteristics of a fabric such as heat insulation, breathability and moisture management, skin sensory aspects of wearing comfort are also measured: for the wearers it makes a difference if the fabrics are pleasantly soft and smooth or unpleasantly itchy or stick to skin which is damp with sweat. All these – objectively measurable – characteristics of fabrics are incorporated in the calculation of the wear comfort rating. Additional help for orientation is provided by the Hohenstein quality label which indicates the determined wear comfort ratings, for instance, in standardised form on a product. This quality label with the wear comfort rating is awarded on the basis of standardised tests for all kinds of work and protective clothing.

6.1.3. Thermophysiological effects
The moisture vapour transmission rate Ret for textiles is the measure of their breathability: the lower the resistance, the greater the breathability. This applies for surgical gowns and also drapes. The materials provide good oxygen permeability and higher water vapour permeability at the same time.

In the binding standards for surgical gowns and drapes (EN 13795) there are currently no regulations regarding the thermophysiological requirements or moisture vapour transmission rate, but compliance with wearing comfort requirements is recommended, however.

6.1.4. Skin sensory effects
Like the thermophysiological properties, skin sensory effects, such as sticking to the skin and hairiness, can be examined using suitable test methods. These properties play a significant role in evaluating the wearing comfort of the fabrics as does the also quantifiable sweat absorption rate.

6.2. Resilience
6.2.1. Importance of surgical fabrics in infection control
While surgical gowns and drapes play a negligible role as sources of infection per se, they may well act as carriers: infectious pathogens can adhere to fabrics and from there be released to the environment again. There is a certain balance between germ uptake and release (cleaning cloth effect), although excessive amounts of

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**Table 3**

**Requirements for surgical gowns and drapes**

<table>
<thead>
<tr>
<th>General requirements</th>
<th>General requirements from the perspective of users</th>
<th>Requirements from the perspective of surgeons</th>
<th>Requirements from the perspective of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Barrier function (against the penetration of germs)</td>
<td>• Protective function</td>
<td>• Germ barrier</td>
<td>• Protective function</td>
</tr>
<tr>
<td>• Prevention of germ transmission</td>
<td>• Liquid tightness (resistance to liquid penetration)</td>
<td>• Prevention against injuries to the patient</td>
<td>• High cut resistance</td>
</tr>
<tr>
<td>• Protection of the patient</td>
<td>• High cut resistance, tensile strength and tear propagation resistance</td>
<td>• Prevention of cooling of the patient</td>
<td>• Liquid tightness</td>
</tr>
<tr>
<td>• Protection of the user</td>
<td>• Well sealed seams</td>
<td>• High tensile strength</td>
<td>• High tensile strength and tear propagation resistance</td>
</tr>
<tr>
<td>• Can be processed without losing quality</td>
<td>• High product safety</td>
<td>• Good adhesiveness of the tapes</td>
<td>• Good stretchability when dry and wet</td>
</tr>
<tr>
<td>• Sets can be composed individually</td>
<td>• Low flammability limit (when working with electricity, especially in HF surgery)</td>
<td>• Liquid tightness including in operations with large quantities of blood</td>
<td>• Good adhesiveness of the tapes including when drenched</td>
</tr>
<tr>
<td>• Good drapability</td>
<td>• Easy handling</td>
<td>• Absorbency/high liquid absorption with the drapes</td>
<td>• Easy to remove the tapes</td>
</tr>
<tr>
<td>• Antistatic properties</td>
<td>• Practical composition/correct sequence of the sets</td>
<td></td>
<td>• Prevention of cooling</td>
</tr>
<tr>
<td>• Low flammability</td>
<td>• Easy storage</td>
<td></td>
<td>• Delay of heat loss</td>
</tr>
<tr>
<td>• No unpleasant odours</td>
<td>• Easy to remove the protective adhesive strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Skin compatibility of the tapes</td>
<td>• Easy to remove packaging</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Labelled with barcodes for documentation (comprehensibility)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
fluids can easily rinse the germs and contaminants out again. A certain amount of germs and contamination can also accumulate in textiles. Here the presence of proteins also helps germs survive.

6.2.2. Fabric as a germ barrier

When walking, a healthy person can release a million bacteria-carrying skin particles into the air every minute – the way the germs migrate depends on contact, movement and also the cut of the clothing. Resistance to bacterial penetration describes the ability of a material or combination of materials to prevent microorganisms from getting from one side to the other.

Safe barriers against microorganisms are required to put a stop to nosocomial infections (staff to patient) and occupational diseases (patient to staff).

The resistance of surgical gowns and drapes is tested (EN 13795) both in a dry and wet state (see Table 1). Dry fabrics are generally a good germ barrier. As soon as they become moist, however, germs can penetrate more easily. Sources of moisture in the operating theatre are primarily irrigation fluids and blood.

Pursuant to the German RKI guidelines “Prevention of postoperative infections in operations” (2007 Recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute), impervious surgical gowns are therefore to be worn and impervious drapes (Category IA) to be used for operations where large amounts of fluids occur. Furthermore, it has to be ensured that surgical fabrics are free of contamination and damage.

Regarding the new variant Creutzfeld-Jakob disease (vCJD), the statement made by Prof. Dr. med. et MS Andreas F. Widmer (Symposium “Safety in the operating theatre takes priority”, 27 June 2003, Lucerne) is also worth mentioning: “The use of reusable laundry in the operating theatre does not involve any risk of transmitting vCJD. Reusable laundry is therefore used at the Canton Hospital of Basel without restriction.”

With the exception of actual suspected cases of vCJD, reusable fabrics can be considered safe regarding possible transmission of vCJD because of the special processing method.

6.2.3. Abrasion (linting)

Even if they lint, sterile textiles do not release any germs to the environment. Fabric lint may however impair wound healing because of reactions to foreign bodies. Low-linting fabrics should therefore be preferred. Compared with properly processed reusable materials, disposable fabrics may release up to ten times more lint (SAFEC study).

7. Processing

Reusable surgical fabrics have to be processed in accordance with the Medical Devices Act and meet the criteria of the EN 13795 series of standards. According to the recommendation of the German Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI), manufacturers “must prove the required properties with recognised validated methods and document them” (2007 Recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute). The products and their packaging must therefore be manufactured to the applicable standards and the sterilisation method indicated. Validation must cover all the steps in the process and also specify the method and intervals for routine monitoring. It is up to the supplier or external processor of reusable textiles for healthcare facilities to choose a suitable process.

7.1. The processing method

The process actually starts in the operating theatre with the proper collection of surgical fabrics in specially provided containers. Foreign bodies in the surgical fabrics can put the staff at risk and also damage the fabrics and processing machines. Hospitals should therefore ensure that foreign bodies (e.g. disposable fabrics or surgical instruments) are removed from the surgical fabrics.

7.1.1. Sorting/incoming inspection

The processors in Austria sort the used surgical fabrics on the unclean side of the laundry. This sorting process conforms to the hygiene, occupational health, safety and legal requirements. It also leads to a substantial improvement in quality assurance, as the surgical fabrics can be treated using a specially designed process.

7.1.2. Washing/disinfecting/drying

All surgical fabrics must be washed including thermal or chemical-thermal disinfection and subsequently sterilised. Listed washing and disinfecting processes are used here, including of the Austrian Society for Hygiene, Microbiology and Preventive Medicine (cf. standard methods of the German Society for Hygiene and Microbiology DGHM for testing chemical disinfection processes). After the cleaning process the surgical fabrics are dried, folded in a special way, made into sets and sterilised. The way they are folded means the fabrics can be quickly and simply unfolded while maintaining sterility.

The processes are monitored according to the hygiene guidelines for laundries processing hospital textiles issued by the Austrian Society for Hygiene, Microbiology and Preventive Medicine (Österreichische Krankenhaus-Zeitung 22 (1981) 493) and/or to RAL-GZ 992-2 (quality label concerning the proper care for hospital laundry) and/or the RABC (Risk Analysis and Biocontamination Control) system published as European Standard EN 14065.
All the sterilisation data is stored and can be accessed at any time. The textiles are either tumble dried or go through a tunnel finisher, depending on the material used. A function check must be performed between drying and sterilisation!

7.1.3. Function check
After processing and before reuse, the fabrics have to be checked for defects. These can be holes in the material or errors at the seams. Liquid tightness must also be checked. At special illuminated checking points there is a 100% visual inspection of every fabric under cleanroom conditions. Fabrics with damage which could endanger their operational safety are rejected. Special patches are attached where there is smaller damage to ensure tightness as stipulated in EN 13795 (cf. Hloch/Bohnen 2005).

7.1.4. Quality assurance
All Austrian processors monitor their handling of medical devices by using certified quality management systems according to the current European standards. All surgical fabrics undergo state-of-the-art treatment using validated processing and sterilisation methods to guarantee the greatest possible safety for patients and operating theatre staff. This means that the validation process involves quantitative physical, chemical and biological analyses. The key physical data obtained form the basis for continuous quality assurance of the observed processes. These quality assurance measures ensure that every step in the process (collecting, cleaning, disinfecting, drying, 100% function checks, taping, functional folding, packing, sterilising and picking) meets the validated process specifications. An integral part of quality assurance is a computer-aided system that enables complete traceability of each individual part of the sterile operation set. Another benefit of these systems is supervised packing of the operation sets; this ensures that the right article is in the right position in the set. A validated process is used to determine when reusable textiles have to be withdrawn from use.

7.1.5. Function check
The textiles are either tumble dried or go through a tunnel finisher, depending on the material used. A function check must be performed between drying and sterilisation.

8. Environmental compatibility
Factors such as environmental pollution and climate change have become issues which also have to be taken increasingly into consideration in hospitals. In particular in the discussions about the pros and cons of using reusable fabrics or disposable fabrics, these points also need to be included in the decision for or against certain surgical fabrics. In a project report published in November 2008 in Australia by Andrew Carre, programme director of the Life Cycle Assessment Program at the Royal Melbourne Institute of Technology, it was shown that the use of reusable fabrics in surgery causes much less environmental pollution than the use of disposable fabrics (cf. Carre 2008).

In particular the more expensive manufacturing process and the associated environmental impact with the production of disposable fabrics and also the necessary disposal of such fabrics after a single use cause a high amount of environmental pollution.

A study published in July 2010 by the American Reusable Fabrics Association Green Summit confirms the findings from 2008 (cf. van de Berghe 2010). Researchers from the University of Minnesota examined the life cycle assessment of reusable surgical fabrics - in this case in particular the use of surgical gowns which can be reused numerous times.

The life cycle assessment of a product comprises all processes from manufacture, use, reprocessing up to disposal. This also includes the use of resources such as gas and electricity and also fuel for transporting the product. The required infrastructure and the pollution potential (air, water) of the respective product are also included in the assessment.

The study findings show there is a clear advantage of reusable fabrics over disposable ones. This applies in all areas such as manufacture, transport, cleaning and disposal.

Reusable fabrics are significantly superior to disposable ones in terms of carcinogenicity, effects on people’s respiratory tracts, environmental pollution, acid formation, microbial contamination and global warming. This also applies to the environmental effects caused by ozone as well as photochemical oxidation. For the exact results see figure 1 on page 10.

There are admittedly some limitations in how much can be read into the data collected for the study cited in the diagram. These include geographical differences, the software used and data quality, for example. But ultimately the study authors still come to the conclusion that the best results for the life cycle assessment can be achieved as follows:

- reduction
- reuse
- maintenance
- recycling

9. Summary
A series of international studies, consensus statements and expert opinions show that reusable surgical fabrics are better than disposable fabrics. This applies both to safety and the ability to withstand stress and also the wearing comfort and breathability. In terms of costs, reusable fabrics are also better than disposable ones. Not least, recent study data show that reusable fabrics have a clearly better ecological assessment than disposable fabrics.
Superiority of reusable fabrics to disposable fabrics in terms of life cycle assessment (standard influences)

Health
- Carcinogenic
- Non-carcinogenic
- Effects on the respiratory tract (average)

Environmental burden
- Acid formation
- Ecotoxicity
- Eutrophication (nutrient intake)
- Global warming
- Ozone depletion
- Photochemical oxidation

Disposable fabrics
Reusable fabrics

Source: Minnesota Technical Assistance Program; www.mntap.umn.edu; University of Minnesota; Driven to Discover
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