

# HIGH-TECH SURGICAL GOWNS AND DRAPES - SAFETY, COMFORT, SUSTAINABILITY AND COST- EFFECTIVENESS

# OVERALL COMPARISON BETWEEN REUSABLES AND DISPOSABLES

|                              | High-tech reusable | Cotton reusable | Disposable |
|------------------------------|--------------------|-----------------|------------|
| <b>Barrier effect</b>        | +                  | -               | +          |
| <b>Cleanliness</b>           | +                  | +               | ?          |
| <b>Particle emission</b>     | +                  | -               | -          |
| <b>Strength</b>              | +                  | +               | -          |
| <b>Thermal management</b>    | +                  | -               | -          |
| <b>Comfort/breathability</b> | +                  | +               | -          |
| <b>Environmental impact</b>  | +                  | +/-             | -          |
| <b>Functionality</b>         | +                  | -               | +          |
| <b>Cost effectiveness</b>    | +/-                | +/-             | +/-        |
| <b>Value for money</b>       | +                  | -               | +/-        |
| <b>Balance</b>               | <b>9</b>           | <b>3</b>        | <b>2</b>   |

# SURGICAL GOWNS AND DRAPES ARE MEDICAL DEVICES, REGULATED BY STANDARDS TO PROTECT PATIENTS AND HOSPITAL STAFF

- Surgical textiles, such as surgical gowns, surgical drapes and clean air suits, are used to protect patients and hospital staff from infections
- Surgical textiles are regulated by EN 13795 series of standards
- EN 13795 specifies requirements and excludes non-conforming products from the market – e.g. fabrics without sufficient barrier function, whether disposables or reusables (cotton)
- Modern reusable products (like micro fibres or laminates) provide not only safety but also more comfort, sustainability and cost-effective solutions compared with disposables

# SURGICAL GOWNS AND DRAPES ARE MEDICAL DEVICES

- Surgical gowns and drapes serve
  - + to reduce post-operative wound infections, thereby **protecting hospital staff** and
  - + **protect patients** against hospital-acquired infections (HAIs)
- Surgical gowns and drapes are medical devices which are subject to legal requirements in terms of infection control

|              |                |                   |            |             |            |
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| Legal        | Implementation | EN 13795          | Properties |             |            |

# LEGAL REQUIREMENTS FOR SURGICAL TEXTILES ARE SPECIFIED IN EN 13795 SERIES

- Due to their intended use surgical textiles are usually considered to be medical devices and have to meet given essential requirements
- Essential requirements in the Medical Device Directive are specified by the EN 13795 series of European Standards
- EN 13795 brings together current infection control knowledge
- EN 13795 sets minimum requirements for barrier performance, cleanliness and strength

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## “STATE OF THE ART,, IN SCIENCE AND TECHNOLOGY BECOMES APPLICABLE LAW

- Scientific publications show the correlation between hospital-acquired infections (HAIs) on the one hand and between transmission of infective agents and the barrier effect of surgical textiles on the other hand
- New state-of-the-art knowledge for determining clinical action
- The latest developments in know-how are becoming legally binding requirements under the legislation governing medical devices

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## EUROPEAN DIRECTIVES BECOMING NATIONAL LAW

- The basic health and safety requirements for medical devices are stipulated in Directive 93/42/EEC governing medical devices
- Implementation into national law makes the provisions of the Directive legally binding at national level
- The Directive's provisions are detailed in technical standards

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## COMPLIANCE WITH STANDARDS IS RECOMMENDED FOR TWO REASONS

- Standards document latest developments in science and technology – if problems occur, not complying with standards means having acted contrary to better knowledge (also see product liability)
- Compliance with harmonised standards automatically gives a presumption of conformity with the basic health and safety requirements in the European Directive



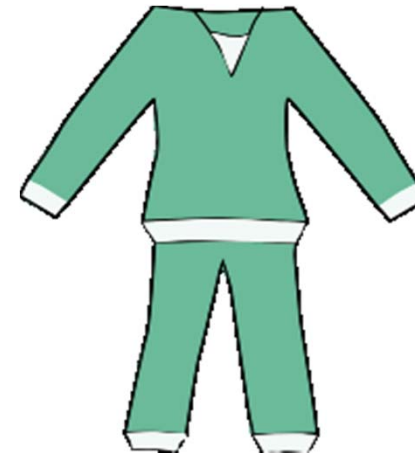
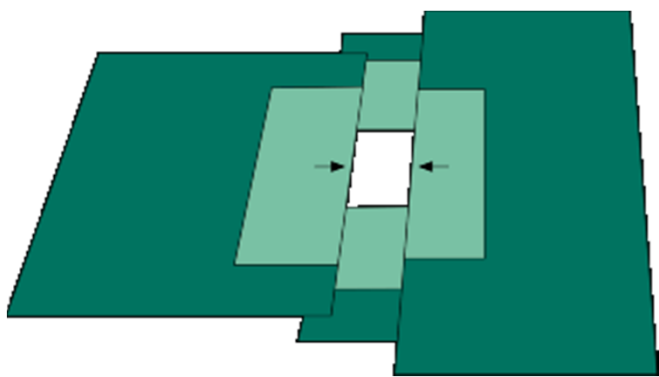
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## WHAT IF A MEDICAL PRODUCT IS NOT STRICTLY “PLACED ON THE MARKET”?

- Although the Directive on medical devices only address at those “placed on the market” ...
  - National regulations and good manufacturing practices also govern the *putting into service* of medical devices
  - In 1999, the European Court of Justice upheld a patients claim, rejecting a Danish hospital’s argument that device which caused the damage had not been “placed on the market” – and was limited to in-house processing and did not go beyond the hospital.

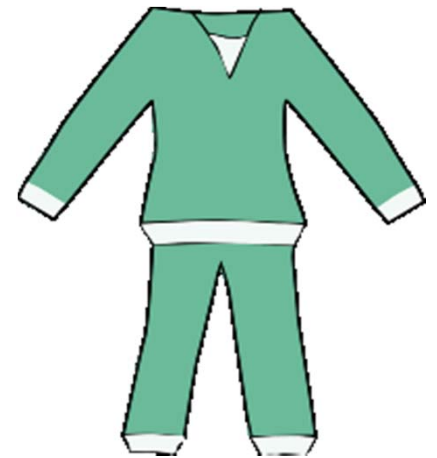
# REQUIREMENTS OF SURGICAL GOWNS AND DRAPES SPECIFIED IN EN 13795

- Surgical drapes, surgical gowns and “clean air suits” are covered



## WHAT ARE “CLEAN AIR SUITS”?

- Clean air suits describe a special form of OR clothing which *can be demonstrated* to reduce the particles emitted by the wearer
- This is achieved through materials (with filter effect) and design (e.g. neck/sleeve bands)
- Clean air suits are worn instead of normal working clothes, i.e. also under the OP gown where applicable



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# REQUIREMENTS FOR THE USE OF REUSABLE AND DISPOSABLE PRODUCTS

- The EN 13795 set of standards specifies performance *requirements for ready-for-use products*
- applying to *reusable and disposable products* and
- which have to be complied with by reusable products *during their “life cycle”* (i.e. not merely when they are new)
- objective: whatever is used in the OR has to meet the requirements

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## THREE-PART STRUCTURE ENABLES SIMPLE NAVIGATION THROUGH THE STANDARD

- EN 13795 – Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment
- Part 1: General requirements for manufacturers, processors and products
- Part 2: Test methods
- Part 3: Performance requirements and performance levels

|                     |                     |                          |                |                    |                   |
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## EN 13795 COMPLETED

- EN 13795 parts 1 and 2 were approved respectively in November 2002 and November 2004 and are now in force
- EN 13795 part 3 was approved in March 2006 and is now also in force

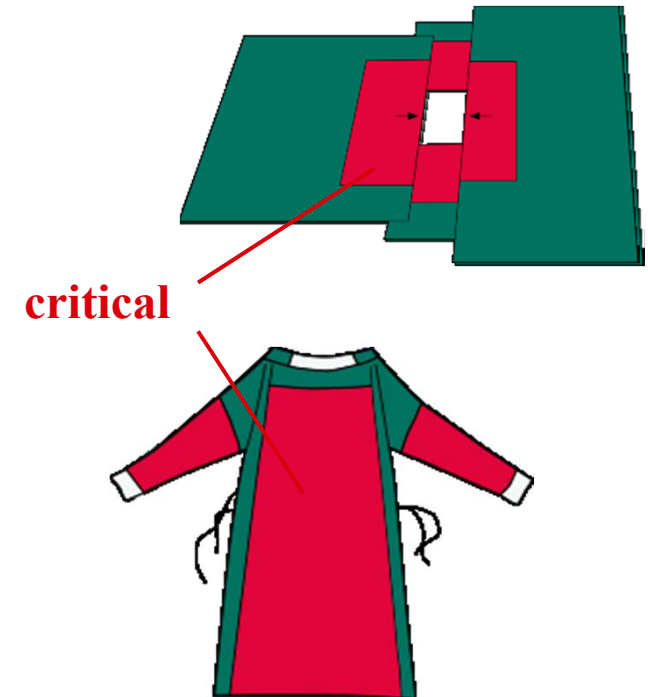
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## WHAT EN 13795 ACHIEVES

- EN 13795 Part 1
  - + Specifies manufacturing and processing requirements
  - + Specifies the relevant characteristics to be evaluated
  - + Defines information to be supplied by manufacturers/processors about their products (instructions on how operators/users are to handle the products; critical and less critical product areas; test results) and
- thus enables meaningful comparison of products

## 2 PERFORMANCE LEVELS 2 PRODUCT AREAS

- In recognition of different practical requirements (e.g. dry and wet surgical procedures) EN 13795 distinguishes between two performance levels : “standard” and “high”
- The manufacturer shall also define “critical” and “less critical” product areas





# RELEVANT PROPERTIES

| Charateristics to be evaluated for                       | Surgical drapes | Surgical gowns | Clean air suits |
|----------------------------------------------------------|-----------------|----------------|-----------------|
| Resistance to microbial penetration - dry                | X               | X              | X               |
| Resistance to microbial penetration - wet                | X               | X              | -               |
| Cleanliness – Microbial                                  | X               | X              | X               |
| Cleanliness - Particulate matter                         | X               | X              | X               |
| Linting                                                  | X               | X              | X               |
| Resistance to liquid penetration                         | X               | X              | -               |
| Liquid control                                           | (X)*            | -              | -               |
| Bursting strength                                        | - dry           | X              | X               |
|                                                          | - wet           | X              | -               |
| Resistance to tearing                                    | - dry           | X              | X               |
|                                                          | - wet           | X              | -               |
| Adhesion for fixation for the purpose of wound isolation | Info. annex     | -              | -               |
| Comfort                                                  | Info. annex     | Info. annex    | Info. annex     |

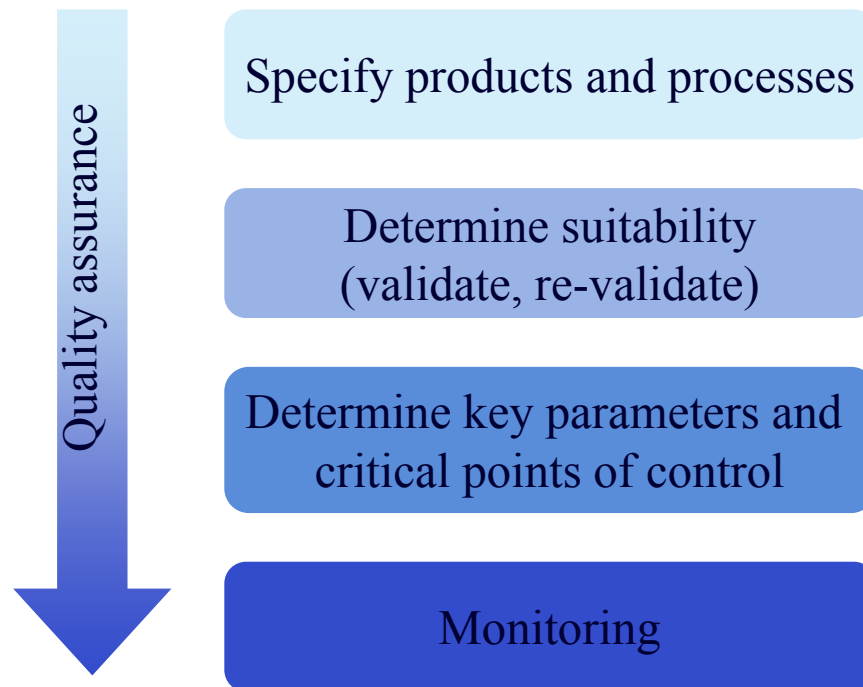
# BETTER REUSABLE QUALITY AND QUALITY ASSURANCE

- EN 13795 requires validated processes for manufacturing and processing to ensure compliance of surgical textiles
- Reusables offer additional performance on top of a guaranteed performance
- Studies revealed inconsistency of disposable products and hence the superior quality (= lower variations) of reusables

|                     |                           |                          |             |             |            |
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| Validated processes | Reusable - more efficient |                          | Homogeneity | Slippage    |            |

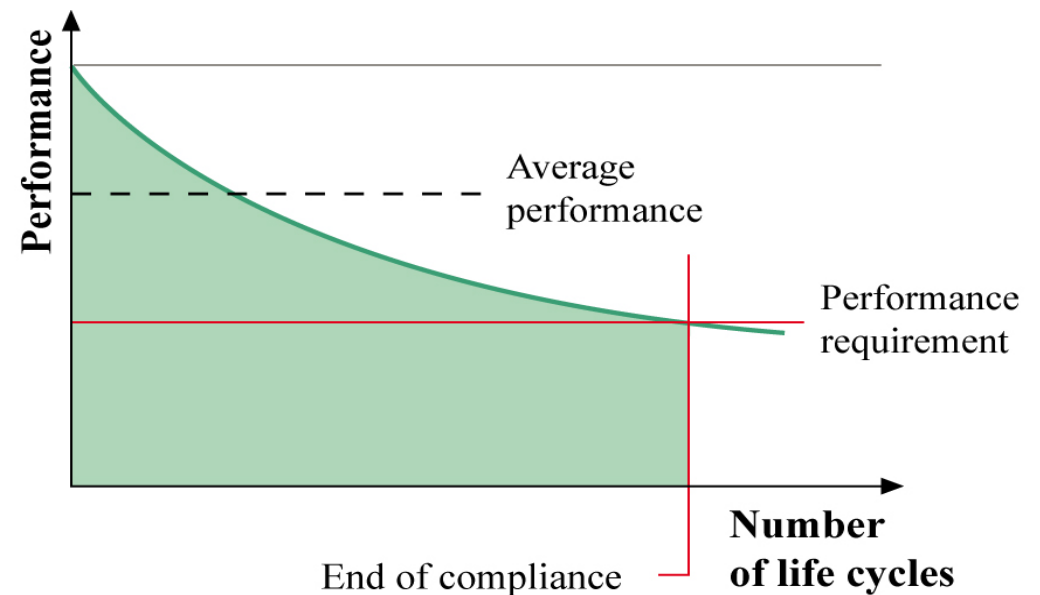
# QUALITY ASSURANCE REQUIRED BY EN 13795

- The standard requires validated procedures for manufacturing and processing as well as a quality assurance system and routine monitoring



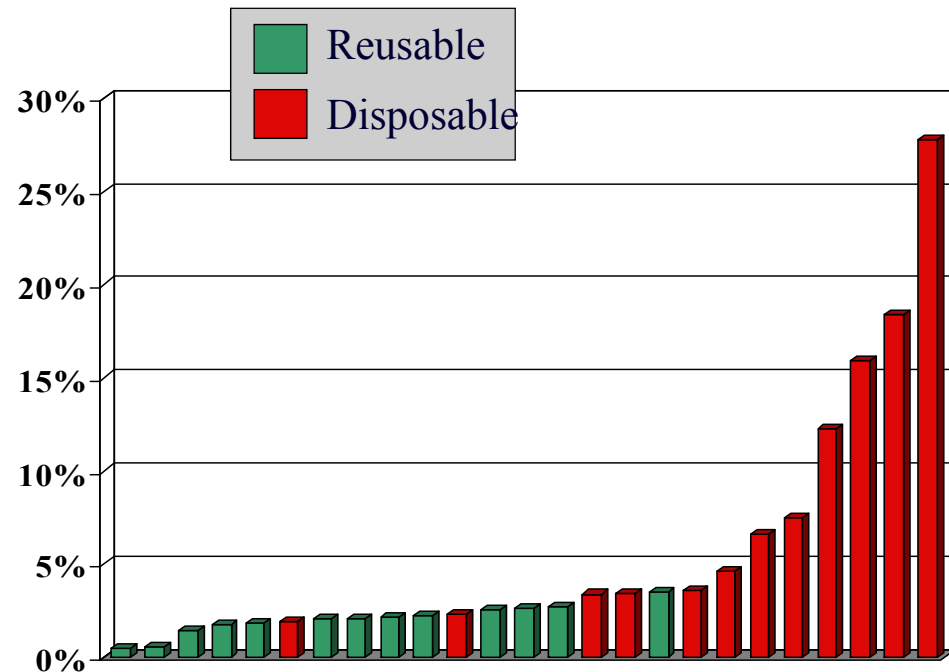
# REUSABLES OFFER AVERAGE PERFORMANCE BEYOND THE ASSURED PERFORMANCE

- Validation of reusable products includes service life tests for each property
- Withdrawn from circulation if only one property falls below its limit value
- The average performance of reusables is inevitably much higher than the assured performance



# REUSABLE OR TEXTILES PROVIDE MORE CONSISTENT QUALITY

- Measurements of the liquid barrier (according EN 20811) show that reusables vary considerably less (lower coefficient of variation) - their quality is more consistent!



|                     |                           |                   |         |             |            |
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| Validated processes | Reusable - more efficient | Homogeneity       |         | Slippage    |            |

## EXPERTS GIVE A CRITICAL ASSESSMENT OF THE QUALITY OF DISPOSABLE PRODUCTS

- “The results indicate that the resistance to liquid penetration performance – sometimes even within the same product – strongly varies, which leads us to expect equally varying degrees of performance in other legally required tests, such as the resistance in the wet microbial penetration test.”
- “As a consequence, the widely held opinion that single-use materials are of homogenous quality and inherently “safe” may no longer be sustained.”

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Validated processes

Reusable - more efficient

Homogeneity

Slippage

# ERRORS AND INCIDENTS IN DISPOSABLES

- A database search at the FDA (US Food and Drug Administration) produced the following results:
- In 10 years (1992-2001), more than 1000 incidents involving drapes.
- More than 1000 incidents involving gowns.

U.S. Food and Drug Administration - Center for Devices and Radiological Health

CDRH MAUDE Database

Other 510(K) Listing MAUDE PMA Classification Registration

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More than 500 records met your criteria.  
 Note: The set of records retrieved by your search is greater than the system capacity and is incomplete. It is not possible to retrieve the missing records.  
 Please narrow your search.  
 Manufacturer: Johnson & Johnson

| #  | Manufacturer         | Brand Name           | Date Report Received |
|----|----------------------|----------------------|----------------------|
| 31 | JOHNSON & JOHNSON ME | MICRO-TOUCH LATEX ME | 04/26/2001           |
| 32 | JOHNSON & JOHNSON ME | MICRO-TOUCH LATEX ME | 04/26/2001           |
| 33 | JOHNSON & JOHNSON ME | MICRO-TOUCH LATEX ME | 04/26/2001           |
| 34 | JOHNSON & JOHNSON    | MAYFIELD PINION      | 04/25/2001           |
| 35 | JOHNSON & JOHNSON    | HARMONIC SCALPEL     | 04/24/2001           |
| 36 | JOHNSON & JOHNSON ME | PROTECTIV ACUVANCE I | 04/17/2001           |
| 37 | JOHNSON & JOHNSON ME | MICRO-TOUCH LATEX ME | 04/16/2001           |
| 38 | JOHNSON & JOHNSON ME | MICRO-TOUCH LATEX ME | 04/16/2001           |
| 39 | JOHNSON & JOHNSON ME | BARRIER ULTRA PROTEC | 04/12/2001           |
| 40 | JOHNSON & JOHNSON ME | BARRIER ULTRA PROTEC | 04/12/2001           |

(Database contains data received through June 28, 2001)  
 Accessibility



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| Validated processes | Reusable - more efficient |                          | Homogeneity    | Slippage           |                   |

## E.g. FLUID PENETRATION ...

- Product description: Barrier Ultra Protec. Gown
- Supplier: Johnson & Johnson Medical, Inc.
- Report type: Initial
- Account: The surgeon reported penetration of this gown in the area of the sleeves and front during a “bloody” operation. No account of germs contained in the blood or other negative influences.  
The inside of the gown displayed two large blood stains in the hip area, with further traces on the inside of the right sleeve.



# SCIENTIFIC STUDIES REVEAL STRENGTHS AND WEAKNESSES OF SURGICAL TEXTILES

- Surgical textiles available on the market were tested for characteristics using test methods listed in EN 13795 (already during its development)
- No single study was able to give a representative picture of surgical textiles available on the market
- Reusable surgical textiles showed impressive performance
- Disposables showed unexpected weaknesses - The myth of disposables was uncovered

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# INFORMATIVE STUDIES ON THE QUALITY OF SURGICAL TEXTILES

- In addition to a large number of individual reports, three wider-ranging studies provide information concerning the quality of OP textiles available on the market
  - 1996 HygCen for Johnson & Johnson (D)
  - 1999/2000 HygCen for Safec (A, CH, D, I, NL, UK)
  - 2001 HygCen for EDANA (F, UK)
- These studies have in common that they do not claim to be representative in terms of sample size and/or procedure

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# SCOPE OF THE STUDIES IS DIFFERENT

- While the 1996 and 2001 studies are limited both in regional terms and in their scope, the 1999 study shows a good cross-section throughout Europe.

| Study        | Reusable     |      |       | Disposable   |      |       |
|--------------|--------------|------|-------|--------------|------|-------|
|              | Manufacturer | Sets | Items | Manufacturer | Sets | Items |
| 1996 (J & J) | 7            | 67   |       | 5            | 14   |       |
| 1999 (Safec) | 19           | 264  | 1.191 | 12           | 101  | 359   |
| 2001 (EDANA) |              | 68   | 199   |              | 50   | 125   |

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## DIFFERING OBJECTIVES ALLOW LIMITED CONCLUSIONS

- As the random sampling was arranged by the commissioning party in all cases, the studies can hardly be expected to be representative, regardless of the numbers of samples
- Only the SAFEC study gives a relevant overview
- The results already give some facts about the respective quality placed on the market
- The studies show how good or bad reusable and disposable products *can be*

# SCIENTIFICALLY DEMONSTRATED PERFORMANCE OF SURGICAL TEXTILES IN MAIN PERFORMANCE CATEGORIES

- Barrier effect (resistance to microbial and liquid penetration)
- Cleanliness
- Linting
- Strength
- Comfort
- Environmental
- Functionality
- Cost efficiency

|                     |                     |                          |                 |                    |                    |                      |                |
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| <b>Barrier</b>      | <b>Cleanliness</b>  | <b>Linting</b>           | <b>Strength</b> | <b>Comfort</b>     | <b>Environment</b> | <b>Functionality</b> | <b>Economy</b> |

## BARRIER EFFECT

- The barrier effect is a central function of OR textiles. This is tested in three ways:
  - + microbial barrier in a dry state
  - + microbial barrier in a wet state
  - + liquid barrier
- Reusable and disposable products are more or less comparable in this respect. The quality does not therefore depend on whether a product is simply reusable or disposable.

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# MICROBIAL BARRIER IN DRY STATE

- Test procedure standardised as per EN ISO 22612
- Development on the basis of EDANA 190
- Identifies the dry filter effect to a certain extent (which is not otherwise tested)
- Costly, destructive test method, not suitable for monitoring
- No substantial results available as yet (not considered in published studies)

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Cleanliness

Linting

Strength

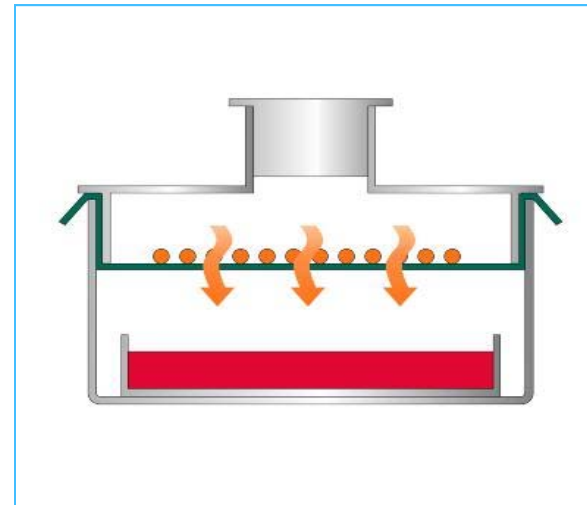
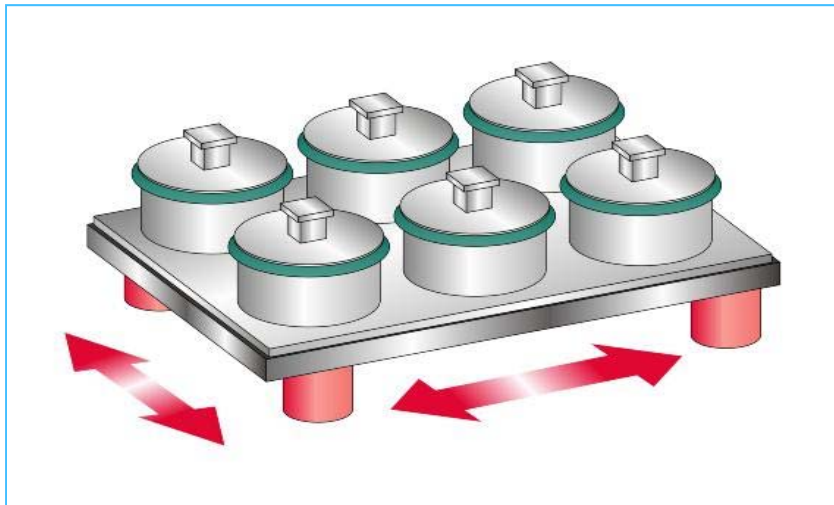
Comfort

Environment

Functionality

Economy

# EDANA 190 / EN ISO 22612





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| <b>Barrier</b>      | <b>Cleanliness</b>  | <b>Linting</b>           | <b>Strength</b> | <b>Comfort</b>     | <b>Environment</b> | <b>Functionality</b> | <b>Economy</b> |

# MICROBIAL BARRIER IN WET STATE

- Test procedure standardised as per EN ISO 22610:2005
- Development on the basis of Swedish Standard SS 8760019
- Practical method, takes account of wet conditions, mechanical action and time
- Destructive method, not suitable for monitoring
- Problems with comparing results over different years
- Test method could still be improved – immediate revision likely

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Linting

Strength

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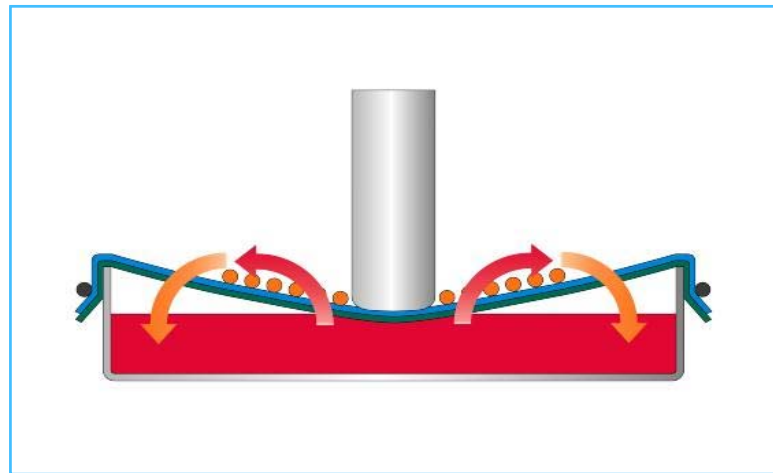
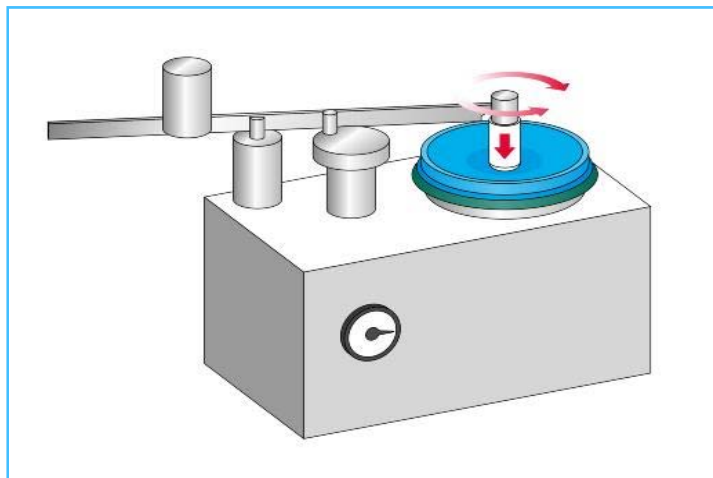
Environment

Functionality

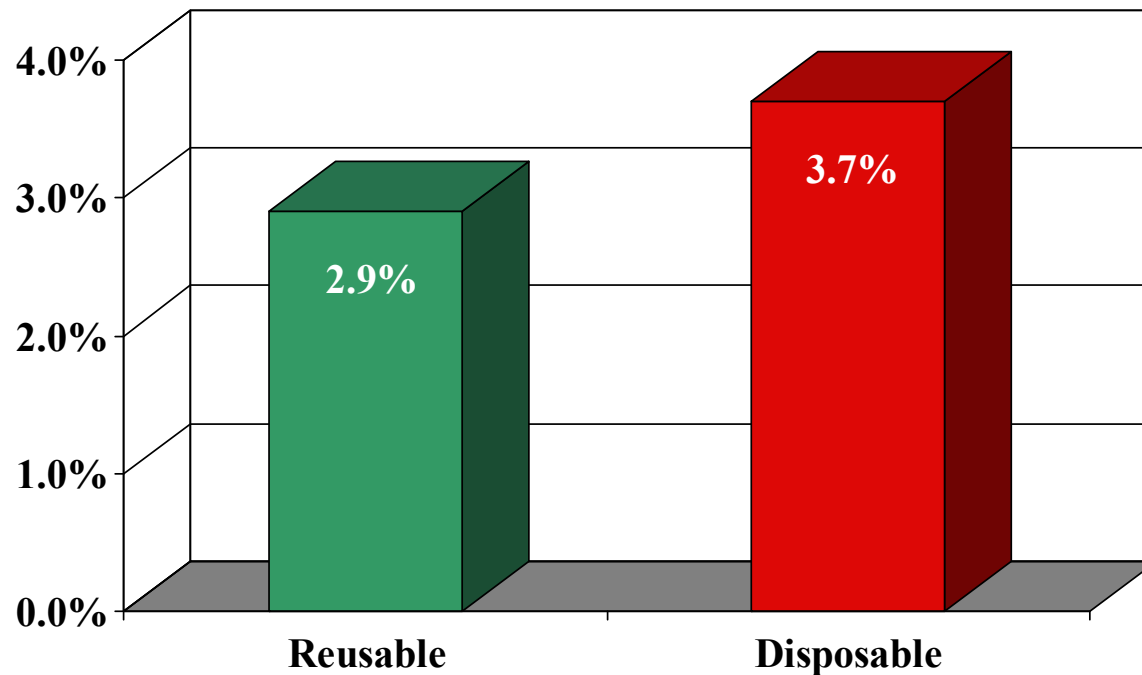
Economy

## SS 8760019 / EN ISO 22610

- The method simulates bacterial penetration in practice: agar and bacteria are on different sides of the material

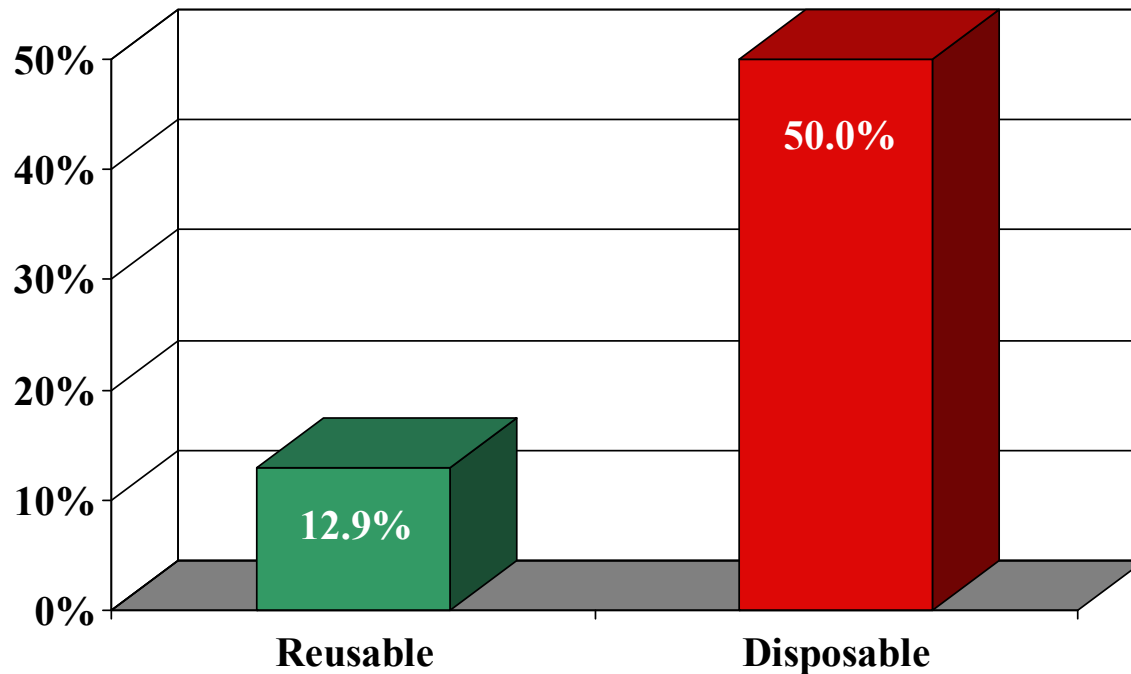


# REUSABLE ITEMS BETTER FOR OR DRAPES



Percentage of surgical drapes with bacterial penetrations in the area close to the wound: reusable items display less penetration

# REUSABLE ITEMS FAR BETTER FOR OR GOWNS



Percentage of “high” performance surgical gowns (front and sleeves) with bacterial penetration: reusable items show considerably less penetration

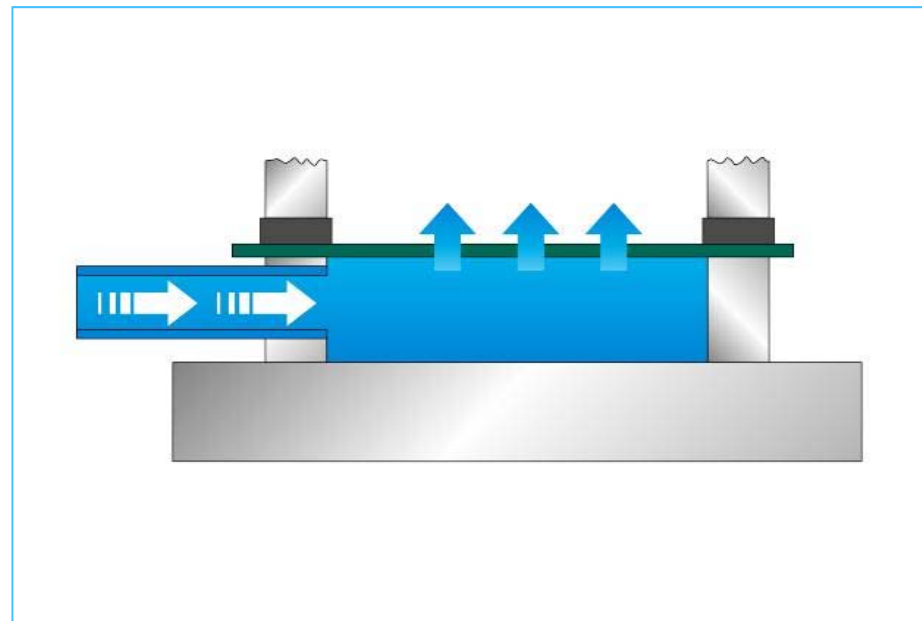
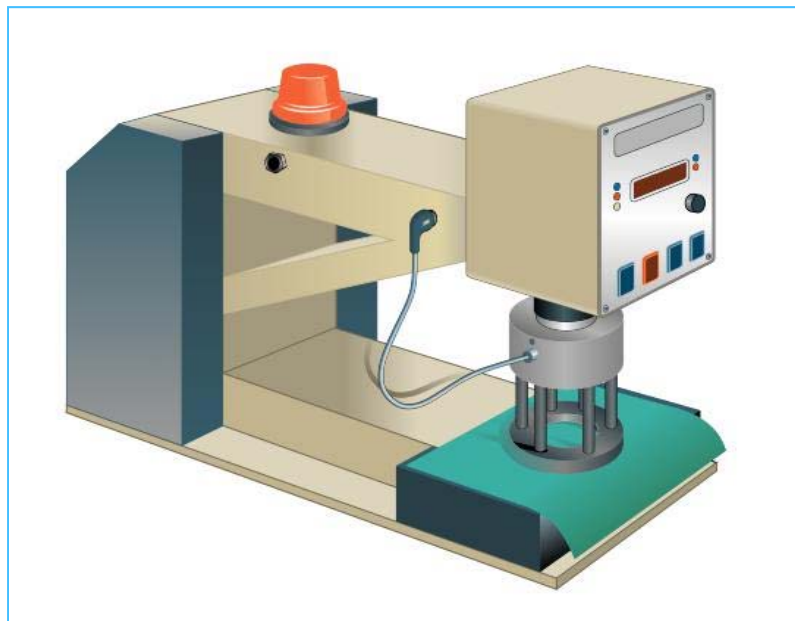
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| <b>Barrier</b>      | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

# LIQUID BARRIER

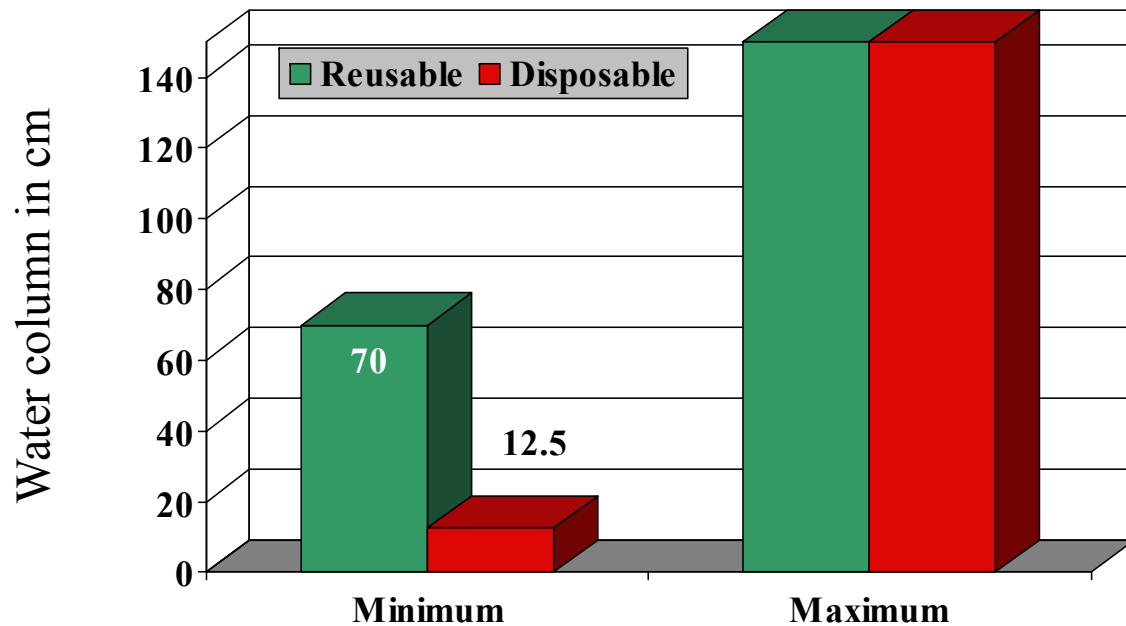
- EN 20811 – Resistance to water penetration
- Also known as hydrostatic head test
- Proven test method with high level of reproducibility and comparability with “old” results
- The method is non-destructive and easy to manage: ideal test procedure for monitoring

|              |              |                   |          |             |             |               |         |
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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

# EN 20811 - LIQUID BARRIER

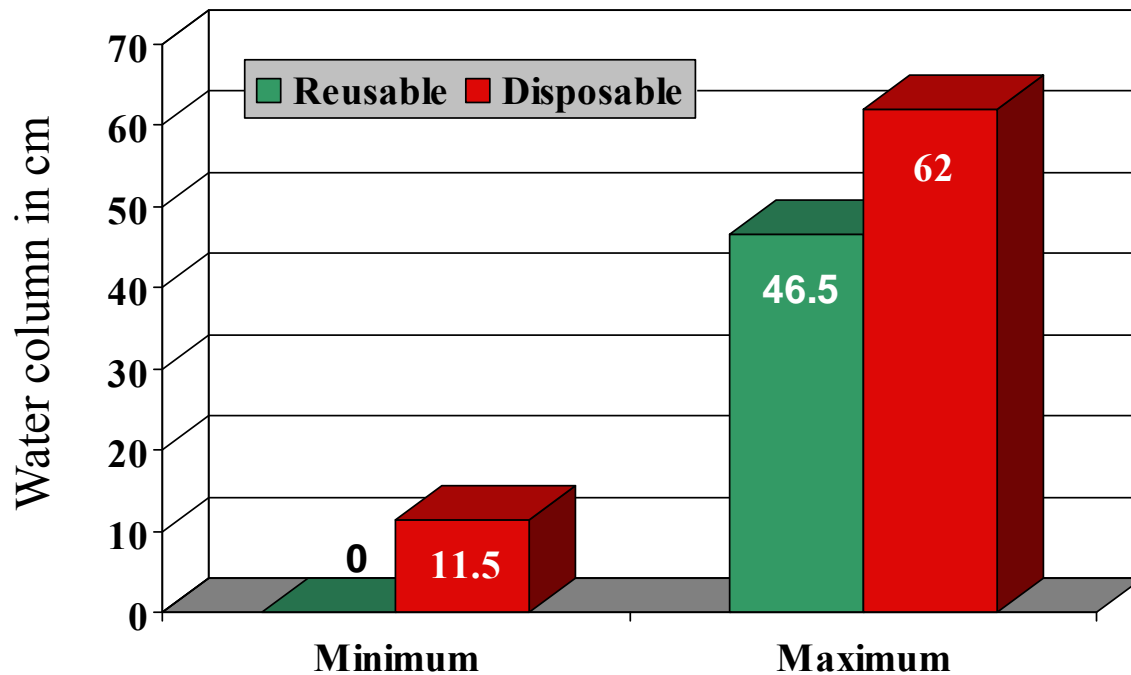


# REUSABLE ITEMS BETTER IN THE CRITICAL AREA OF SURGICAL DRAPES



Significantly higher minimum level for the liquid barrier measured on reusable surgical drapes in the critical area (close to the wound)

# REUSABLE ITEMS WEAKER IN AREA OF SURGICAL DRAPES FAR FROM THE WOUND



Lower minimum and maximum level for reusables for the liquid barrier, measured on surgical drapes in the less critical area (far from the wound), including the seam with the area close to the wound



|              |              |                   |          |             |             |               |         |
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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

## MICROBIAL CLEANLINESS (BIOBURDEN)

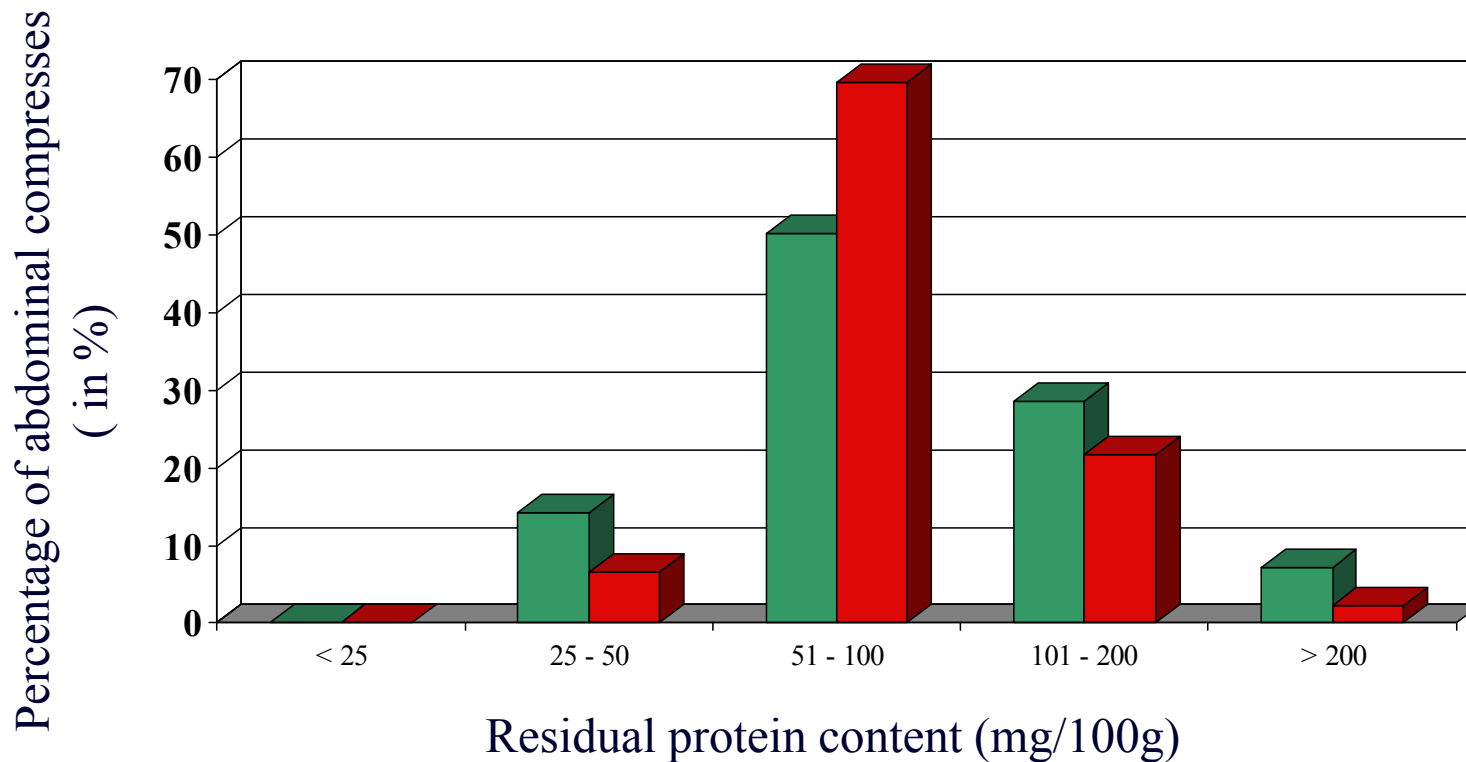
- “Bioburden” is the microbial cleanliness (population of micro-organisms) of a product *before sterilisation*
- This test must be carried out in association with the validation of sterilisation
- Bioburden is an indicator of cleanliness and decontamination in manufacturing and reprocessing
- Testing is conducted in accordance with EN 1174 (Part 2, clause 5.2.4.2)

|                     |                     |                          |                |                    |                   |               |         |
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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

## COMPARATIVE TEST RESULTS NOT PUBLISHED SO FAR

- Clause 5.2.4.2 specifies a stomachal procedure, contact plating is not permissible...
- EN 1174 does not stipulate any specific parameters for the test method, rather only basic principles (measuring principle and validation)
- The procedure can be applied non-destructively and is therefore also suitable for monitoring
- There is no published data available for single-use products

# COMPARABLE LEVELS OF RESIDUAL PROTEIN FOR REUSABLE AND DISPOSABLE ABDOMINAL SWABS



|              |              |                   |          |             |             |               |         |
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# NO MAJOR RISK THROUGH REUSABLE ITEMS IN RELATION TO CJD

- Experts consider it practically impossible in clinically unrecognisable suspected cases of CJD (Creutzfeld-Jacob Disease) for the disease to be transmitted via reusable OR textiles
- “The use of reusable laundry in the operating theatre is not associated with any danger of the transmission of CJD”
- The prerequisite for this is reprocessing using standardised cleaning and sterilisation methods

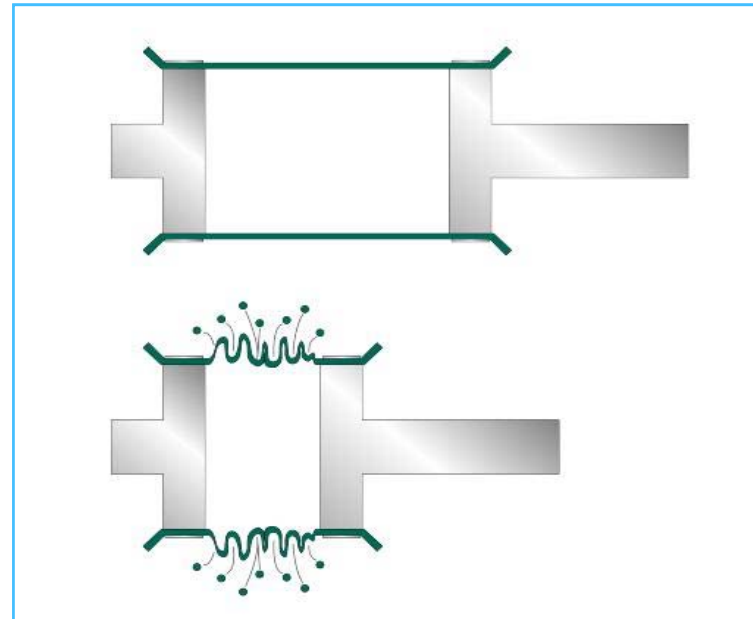
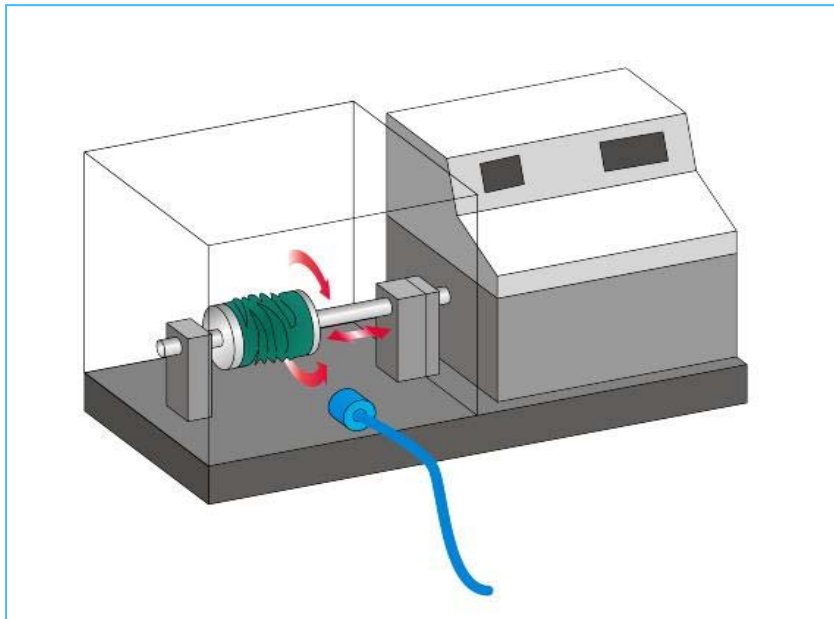
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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

## PARTICLE EMISSION

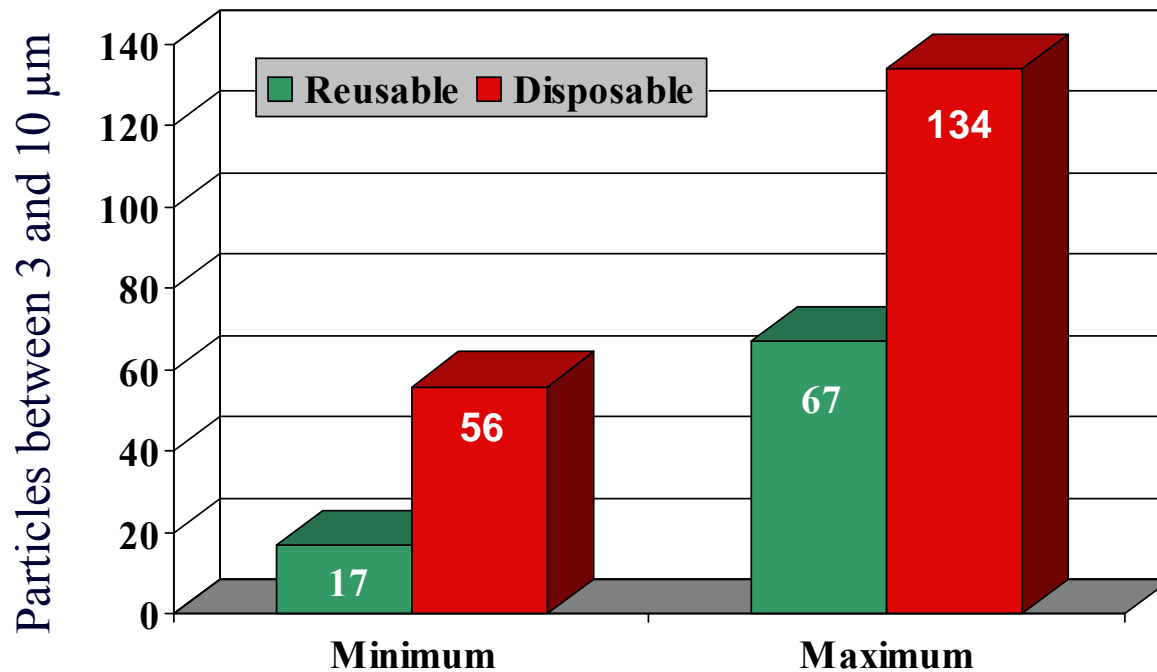
- Distinction is made between fabric (“linting”) and foreign particles (“particulate matter”)
- Both types of particle emission are considered to be equal with regard to their medical relevance, i.e. as potential carriers of micro-organisms and causes of foreign-body reactions
- Particulate matter is calculated from the particle counts during the first 90 seconds

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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

# EDANA 220 / ISO 9073-10



# REUSABLE ITEMS EMIT FEWER PARTICLES



Reusable items emit substantially lower minimum and maximum levels of particles

|                     |                     |                          |                |                    |                   |               |         |
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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

# STRENGTH

- The strength of surgical textiles is especially important because they are subjected to high mechanical stress levels when used
- Even the best possible barrier properties are of little use if the material tears or bursts during use
- In the standard, strength is measured in two ways :
  - + bursting strength
  - + tensile strength
- Reusable products perform better in both categories

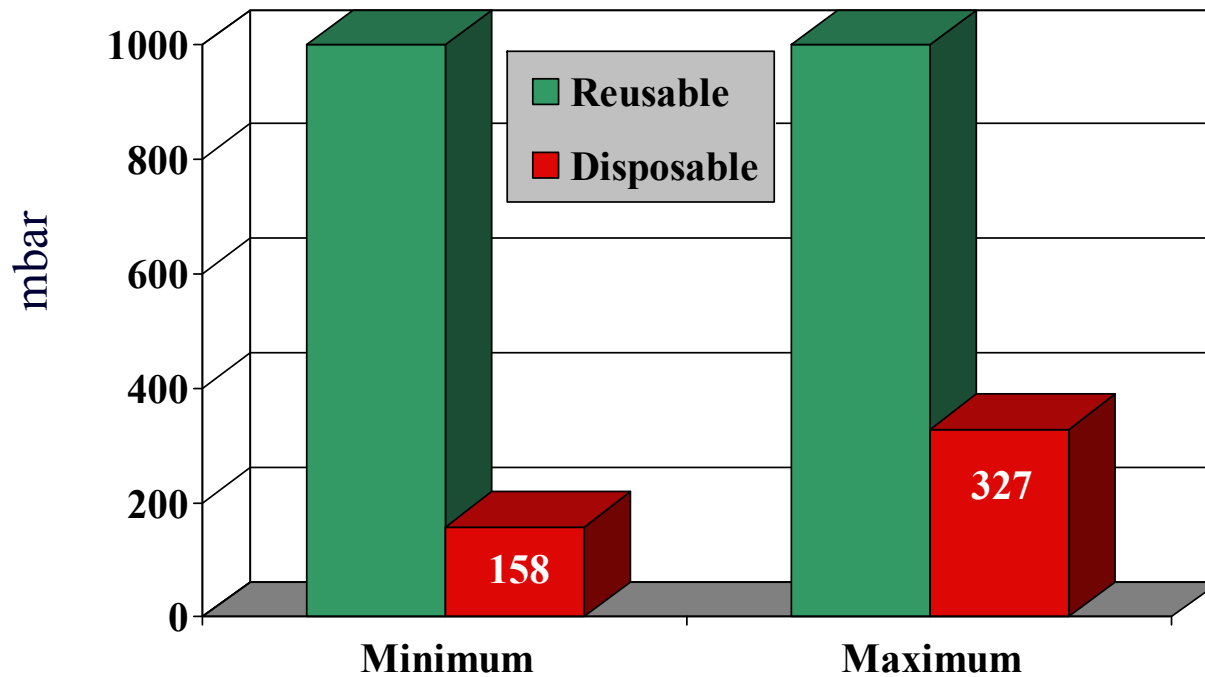


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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

## BURSTING STRENGTH

- Bursting strength describes the strength of the product in all directions of the material
- Heavy mechanical action, e.g. bent arm at elbow
- It is measured in a dry and a wet state in accordance with EN 13938-1

# REUSABLES BEYOND THE MEASURING LIMIT IN ALL CASES



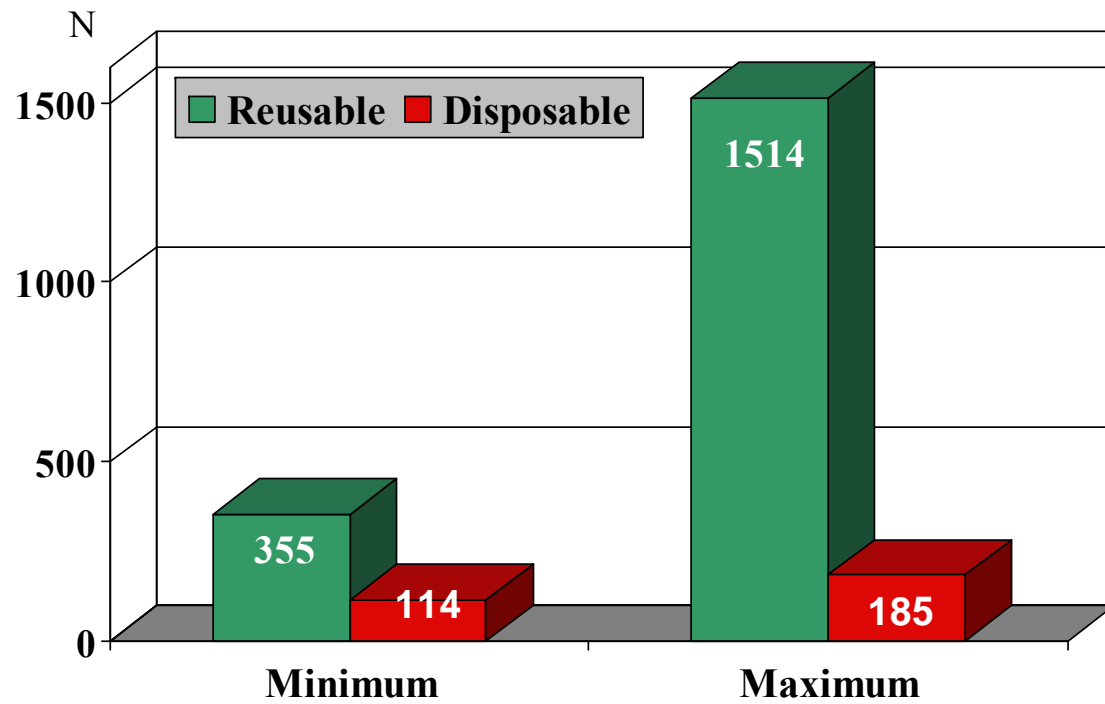
Reusable products offer substantially higher bursting strength than disposable products both for minimum and maximum performance levels

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## TENSILE STRENGTH

- Resistance to tearing describes the strength of the product in the longitudinal (machine or warp) and horizontal direction (weft)
- For example, as surgeon bends forward, the gown can be stretched in different directions at shoulder and back
- It is measured in a dry and a wet state in accordance with EN 29073-3

# WEAKEST REUSABLES CONSIDERABLY BETTER THAN DISPOSABLES



Even weak reusable products offer considerably higher resistance to tearing than disposable products

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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

# COMFORT

- Wear comfort is not just a convenience; it is a physiological requirement
- It is of particular concern to the OR team, whose efficiency needs to be supported rather than impaired
- However, the drape should also offer adequate physiological comfort in order to benefit the patient (EN 13795-1)
- If this is not the case, additional help is often given in the form of increased medication or blankets
- Wear comfort is measured in accordance with EN 31092 (skin model) by calculating water vapour transfer resistance  $R_{et}$

|                     |                     |                          |                |                    |                                         |
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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment    Functionality    Economy |

# PHYSIOLOGICAL REQUIREMENT PROFILE FAVOURS REUSABLES

| Rating         | Requirement value in m <sup>2</sup> Pa/W | Properties                                     | Products                           |
|----------------|------------------------------------------|------------------------------------------------|------------------------------------|
| Very good      | $R_{et B} \leq 8$                        | Can be used in burn-related ORs (approx. 32°C) | Microfibres, non-wovens, laminates |
| Good           | $8 < R_{et B} < 17$                      | Adequate comfort in normal ORs                 | Laminates                          |
| Satisfactory   | $17 < R_{et B} < 40$ or $R_{et R} < 4$   | Acceptable discomfort in normal ORs            | Laminates                          |
| Unsatisfactory | $R_{et B} > 40$ and $R_{et R} > 4$       | Excessive heat stress                          | Foil laminates                     |

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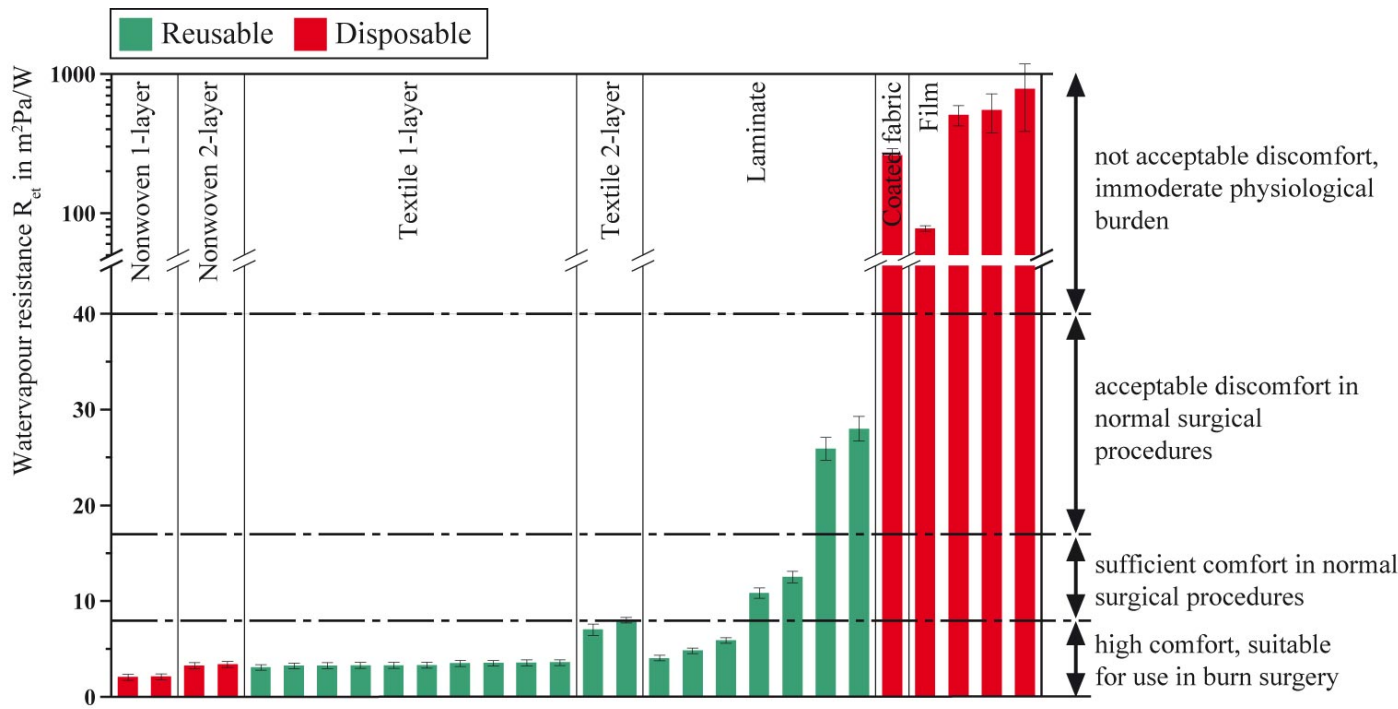
Comfort

Environment

Functionality

Economy

# REUSABLE PRODUCTS PROVIDE MORE COMFORT



Comfort (or discomfort respectively) of various surgical textiles from nonwovens without significant barrier to laminates and films with high barrier performance

|              |              |                   |          |             |             |               |         |
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# ENVIRONMENTAL IMPACT IS MEASURED IN A LIFE-CYCLE ANALYSIS

- The environmental impact of products and their resource consumption are taken very seriously and assessed extensively at both national and international level
- In order to obtain rigorous data, environmental impacts are now determined in accordance with standardised procedures
- Yesterday's "ecobalance" has become today's "life-cycle analysis"



|                     |                     |                          |                |                    |                   |               |         |
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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

## BASICS OF LIFE-CYCLE ANALYSES

- Carried out in accordance with the ISO 14040 series of standards
- Extensive ecological examination: products as systems with defined system limits
- Comparison of functionally equivalent products
- Determination of data (dependability and relevance)
- Differentiated overall assessment

|              |              |                   |          |             |             |               |         |
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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

## METHODOLOGY AND ANALYSIS

- **Inventory**
  - Consumption of energy resources in MJ
  - Consumption of raw material resources in g
  - Emissions into the air in g
  - Emissions into the water in g
  - Waste quantities in g
- **Impact categories**
  - Consumption of renewable and non-renewable energy in MJ
  - Global warming (greenhouse effect) in kg of CO<sub>2</sub> equivalent
  - Acid rain in g of SO<sub>2</sub> equivalent
  - Eutrophication (nutrient pollution) in g of phosphate equivalent

|              |              |                   |          |             |             |               |         |
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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

# TESTING THE ENVIRONMENTAL IMPACT OF SURGICAL GOWNS

- Test conducted by dk-TEKNIK Energy & Environment, Denmark for E.T.S.A., Brussels
- Life-cycle analysis of surgical gowns in accordance with the ISO 14040 series of standards
- Data sources:
  - for reusable products: literature and member information (practically relevant)
  - for disposable products: literature

|              |              |                   |          |             |             |               |         |
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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

## 3 REUSABLE AND 2 DISPOSABLE SURGICAL GOWNS TESTED

- Types of gown examined:
  - 50/50% CO/PES/FC (blended fabric, reusable)
  - 100% PES/FC (microfibre, reusable)
  - PES/laminate (Gore<sup>®</sup> and PU, reusable)
  - Pulp/PES/FC (disposable)
  - Pulp/PES/PE (film, disposable)
- All gowns comply with the relevant directives and standards

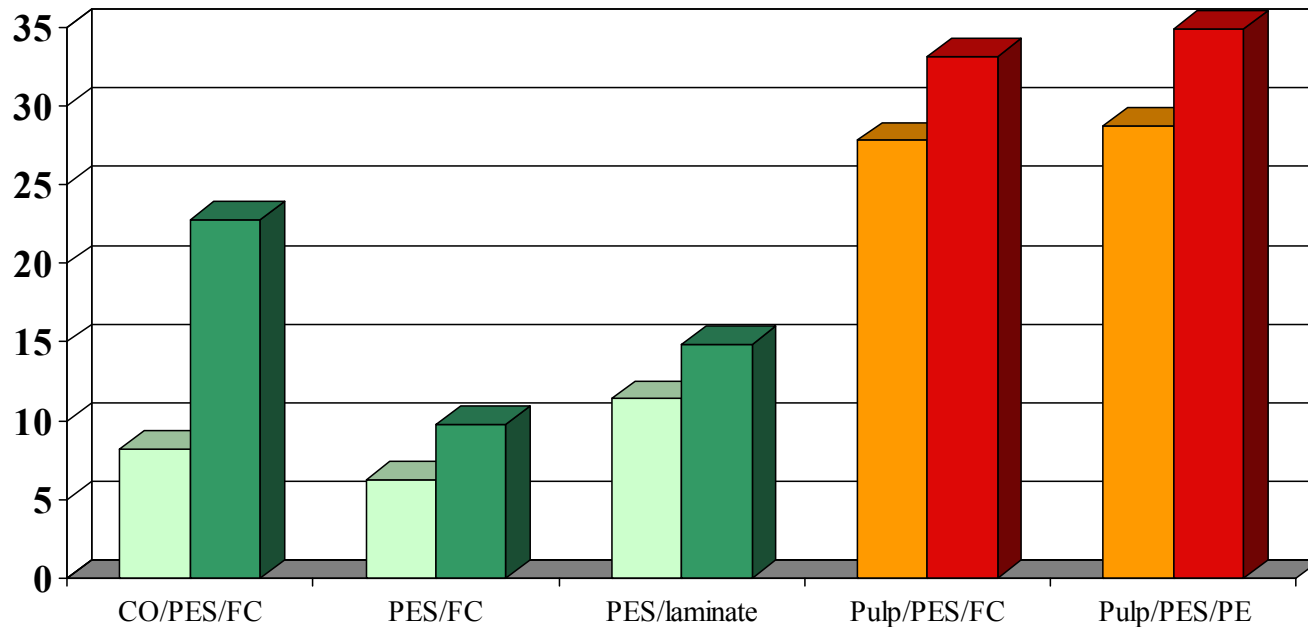
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| Barrier      | Cleanliness  | Linting           | Strength | Comfort     | Environment | Functionality | Economy |

# “BEST CASE” AND “WORST CASE” SCENARIOS

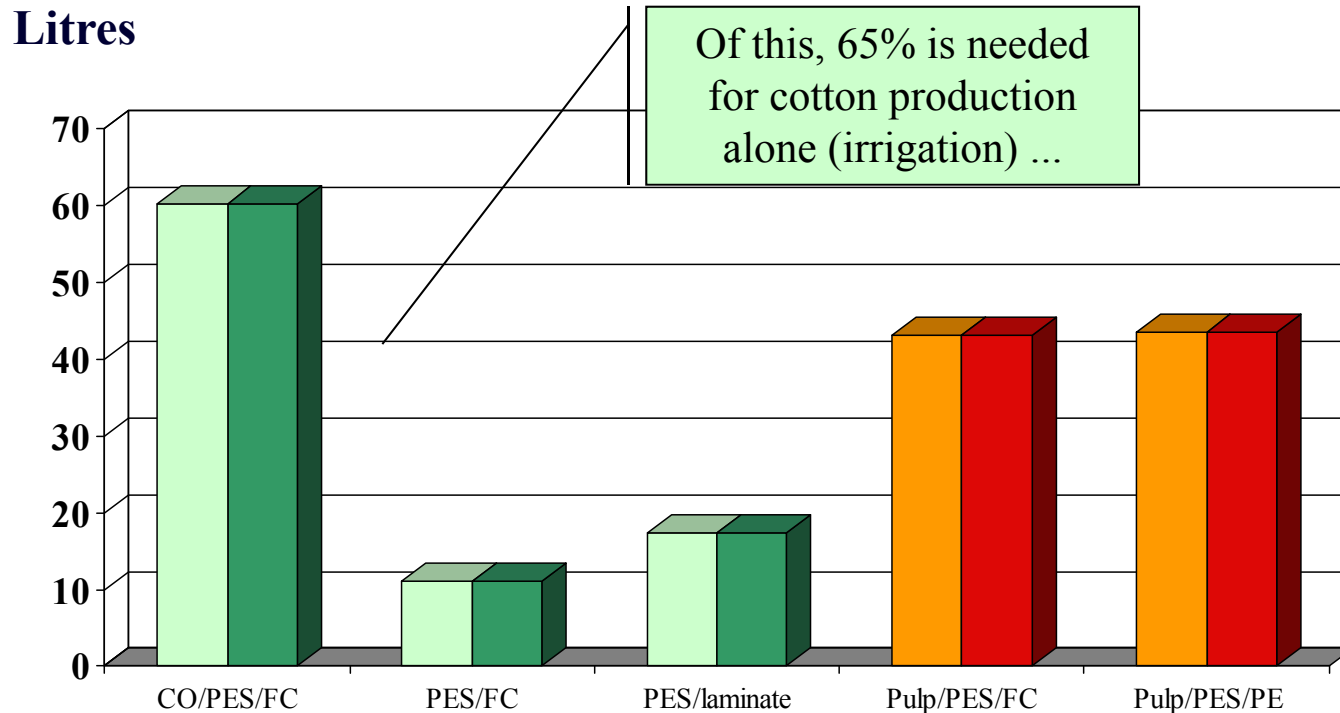
| Products          | Best case                                                                             | Worst case                                                                                |
|-------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| <b>Disposable</b> | Waste incineration with heat recovery<br>Sterilisation with lowest energy consumption | Waste incineration without heat recovery<br>Sterilisation with highest energy consumption |
| <b>Reusable</b>   | Waste incineration with heat recovery<br>Processing with lowest energy consumption    | Waste incineration without heat recovery<br>Processing with highest energy consumption    |

# REUSABLES USE LESS ENERGY

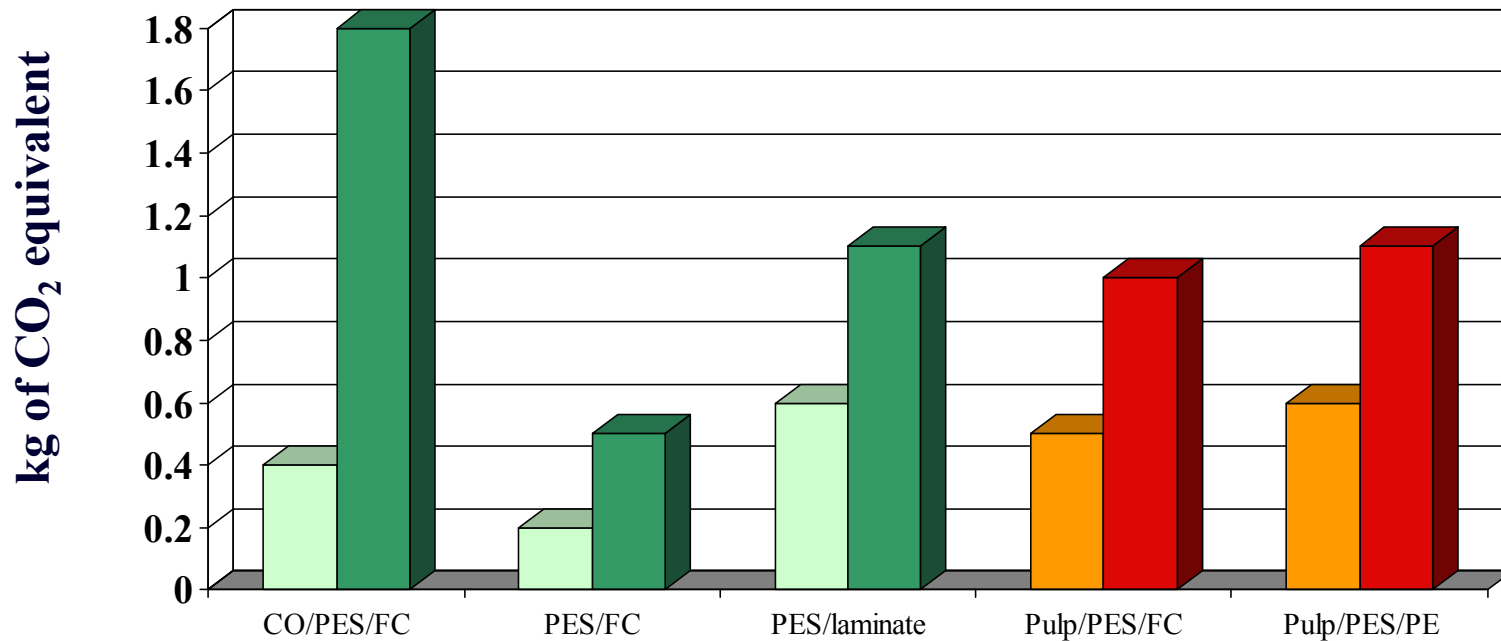
MJ



# MODERN REUSABLES USE LESS WATER



# MODERN REUSABLES DO WELL ON GREENHOUSE EFFECT





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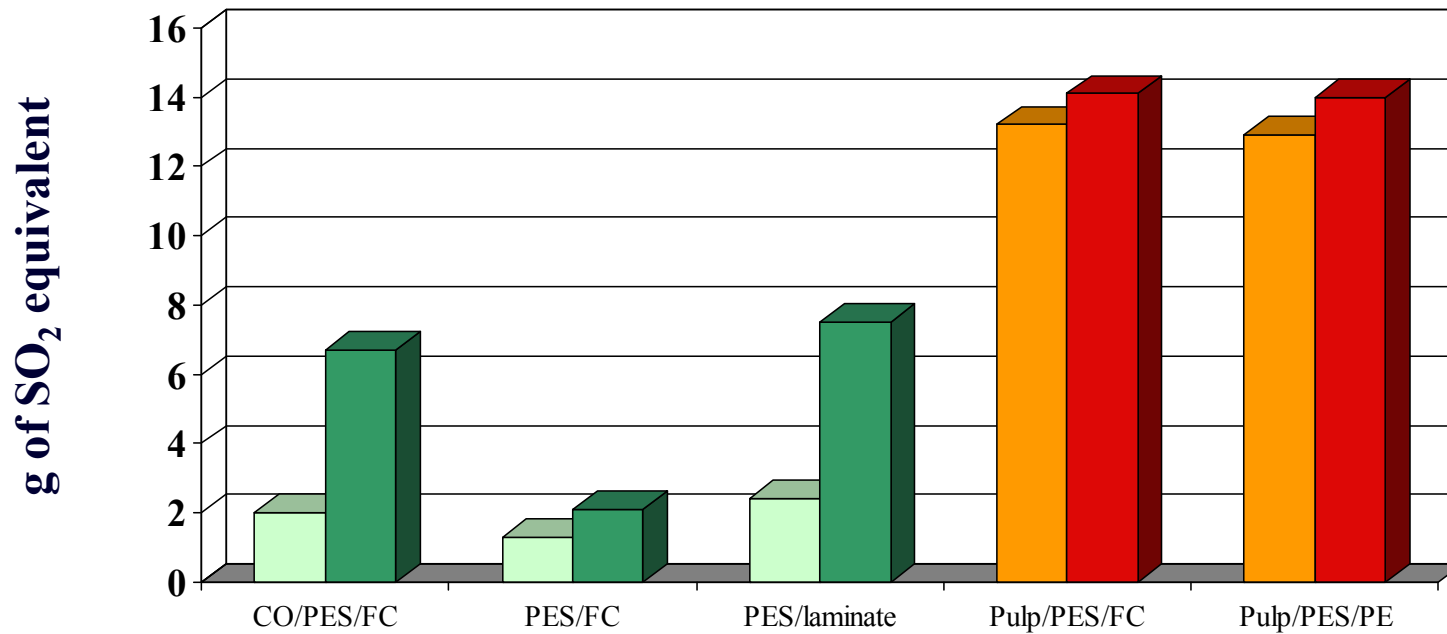
Comfort

Environment

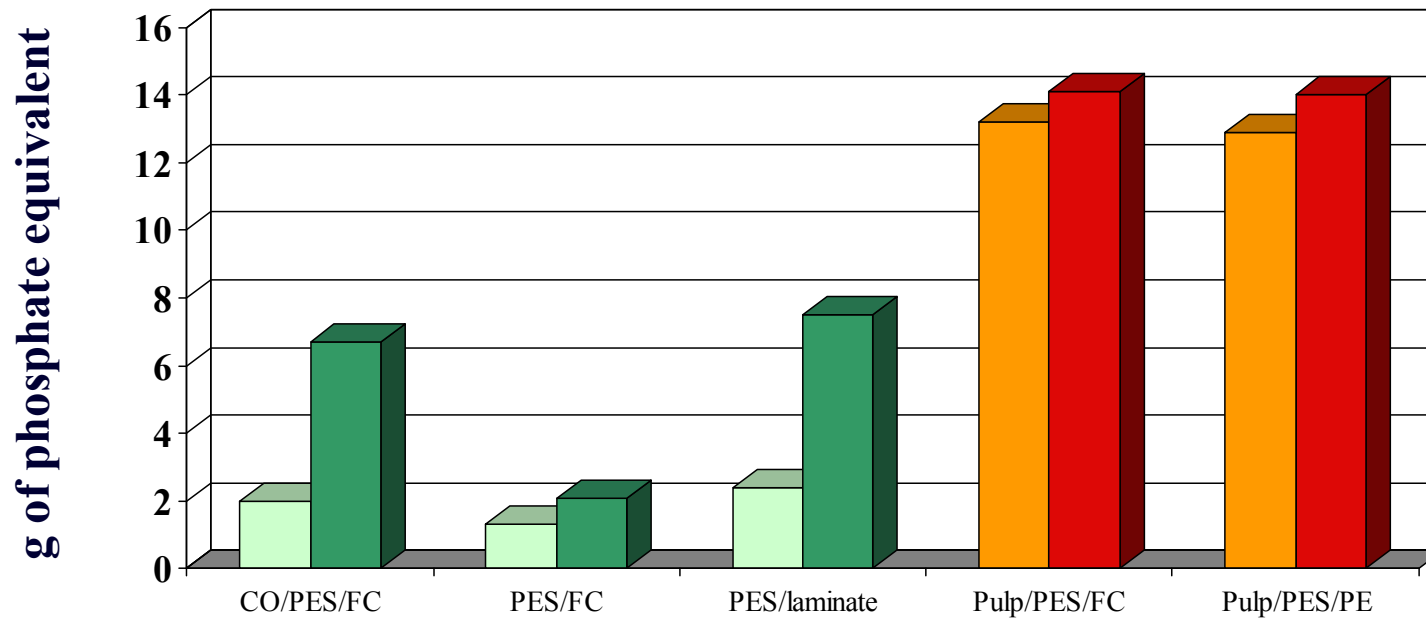
Functionality

Economy

# REUSABLES CAUSE LESS ACID RAIN



# LOWER IMPACT OF REUSABLES ON EUTROPHICATION (NUTRIENT POLLUTION IN WATER)

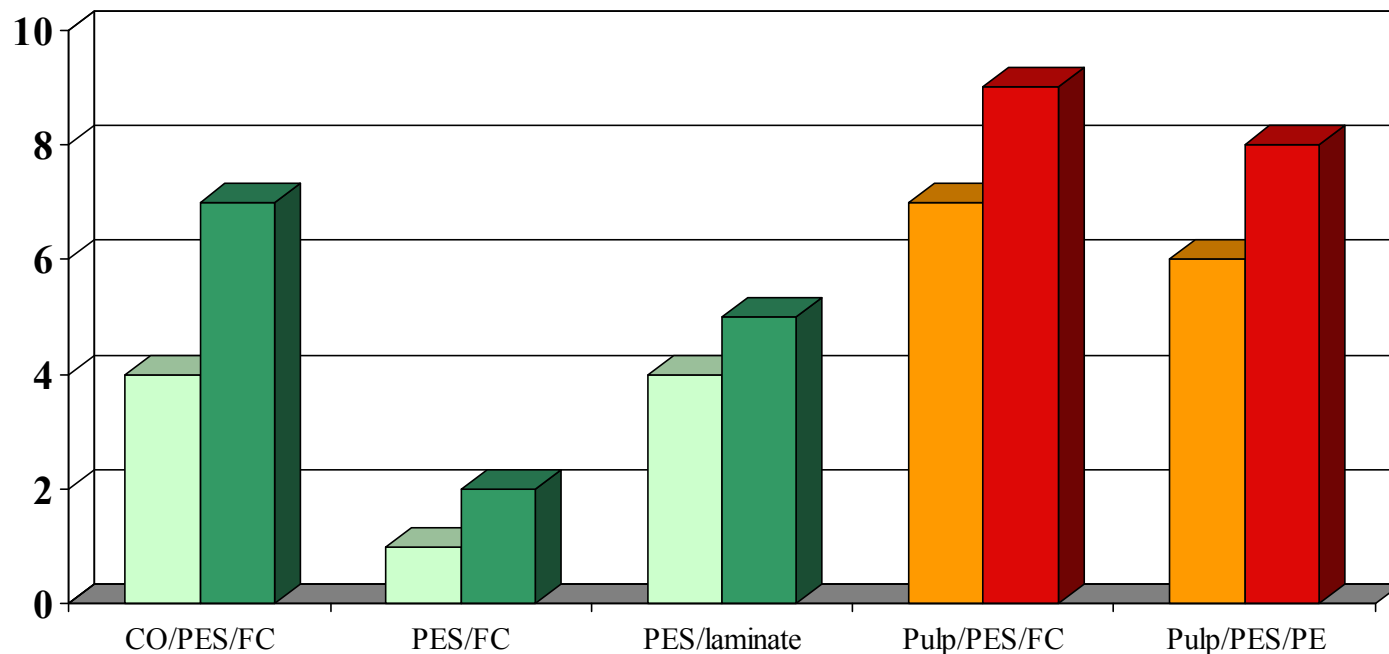


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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | Functionality | Economy |

## ADDITIONAL FINDINGS

- Packaging materials have a considerable impact
- Service lifetime of a surgical gown has a moderate to major influence
- Detergents and washing chemicals have only a moderate influence
- Rewashing and the distance from customers has only a minor influence
- Disposal methods are less relevant for reusables than for disposables

# OVERALL, REUSABLES ARE FAR KINDER TO THE ENVIRONMENT



|                     |                     |                          |                |                    |                   |                      |         |
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| Barrier             | Cleanliness         | Linting                  | Strength       | Comfort            | Environment       | <b>Functionality</b> | Economy |

# FUNCTIONALITY OF SURGICAL TEXTILES

- Modern surgical textiles not only offer safety; they also have high functionality
- Application-specific materials, compresses and sets, application-oriented packing sequence and folding are now standard for reusable and disposable systems
- Both types of product are easy to handle

|              |              |                   |          |             |             |               |         |
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# COMPREHENSIVE INTEGRATION OF LOGISTICS CHAIN THROUGH REUSABLES

- Process costs are often considerable, especially in large, complex organisations – like hospitals – and can be many times higher than production costs
- Providers of disposables sometimes offer combinations of their products as complete surgical sets (CPT) in order to optimise logistics
- Some providers of reusable products also offer to take over the entire logistics process

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## COST EFFECTIVENESS ON A CASE-BY-CASE BASIS

- Difficult to generalise conclusions of sporadic publications claiming greater economic efficiency on the part of respective product and service suppliers
- Individual cases seeking the most economical solution need individual assessment
- At the national economic level, providers of reusables make a substantially higher contribution to the value added in their country

# OVERALL COMPARISON BETWEEN REUSABLES AND DISPOSABLES

|                              | High-tech reusable | Cotton reusable | Disposable |
|------------------------------|--------------------|-----------------|------------|
| <b>Barrier effect</b>        | +                  | -               | +          |
| <b>Cleanliness</b>           | +                  | +               | ?          |
| <b>Particle emission</b>     | +                  | -               | -          |
| <b>Strength</b>              | +                  | +               | -          |
| <b>Thermal management</b>    | +                  | -               | -          |
| <b>Comfort/breathability</b> | +                  | +               | -          |
| <b>Environmental impact</b>  | +                  | +/-             | -          |
| <b>Functionality</b>         | +                  | -               | +          |
| <b>Cost effectiveness</b>    | +/-                | +/-             | +/-        |
| <b>Value for money</b>       | +                  | -               | +/-        |
| <b>Balance</b>               | <b>9</b>           | <b>3</b>        | <b>2</b>   |