Evaluating the Quality of Surgical Drapes Reprocessing Services

Yaffa Raz, RN, MA, CSSD Manager
Lady Davis Carmel Medical Center, Haifa, Israel
Content

- Introduction to surgical drapes and gowns
- CSSD and laundry partnership/cooperation
- Reprocessing standards
- Quality systems
- Quality assurance and control
CSSD vs. Laundry

Mutual
- Important role in infection control (IC)
- Spatial design: segregated areas
- IC principles

Difference
- Materials
- Machines
- Detergents
- Process
- Standards
Surgical Drapes and Gowns

- Made of various materials
- Designed to protect healthcare professionals and patients from the transfer of microorganisms
- Designed to isolate surgical site from contamination
- May be disposable or reusable
Reusable vs. Disposables

- The debate about reusable vs. disposable goes on
- Current situation: both materials are used
Classification

Surgical drapes and gowns are considered medical devices in the United States and Europe.
Standards

- **EN 13795-1** - Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – General Requirements

- **EN 13795-2** – Surgical drapes and gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test Methods

- **EN 13795-3** - Surgical drapes and gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Performance Requirements

- **EN 13795-6** Surgical drapes and gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Manufacturing and processing requirements

Properties

- Barrier to penetration
- Abrasion resistance
- Strength
- Lint-less
- Fire resistance
- Electrostatic properties
- Comfort
- Functionality
- Environmental
- Cost efficiency
Surgical Drapes Reprocessing Cycle

- Use
- Transport
- Sterilization
- Prepare and Pack
- Washing
- Sort
- Quality control
Management Options

Laundry location
- In-house service
- Outsourcing
- Combined service

Linen ownership
- **Hospital owned goods** - Hospital contracts with independent operator to wash the hospital’s linens
- **Rental Service** - Hospital contracts with outside service to provide linen service
In House Service

- A laundry is located in the hospital
  - Surgical drapes preparation room
  - Sterilization
Outsourcing

- Dirty laundry is shipped out
- Sterile surgical drapes are shipped in
Combined Service

- Dirty laundry is shipped out
- Washed surgical drapes are shipped in
- Packing & sterilization

In the hospital
Combined Service

- Dirty laundry is shipped out
- Clean/packed surgical drapes shipped in
- Sterilization in the hospital
CSSD & Laundry Partnership
CSSD & Laundry Partnership

Laundry services

Laundry & Packaging

Laundry, Packaging & sterilization

Laundry: washing
Laundry: Packaging
Laundry: Sterilization
Reprocessing Standards


- **ANSI/AAMI ST79:2010.** "Comprehensive guide to steam sterilization and sterility assurance in health care facilities"

- **HALC** - *Accreditation Standards for Processing Reusable Textiles for use in Healthcare Facilities, 2011*

- **RAL** - *GZ 992/2 “Hospital linen” Quality Certification Mark for Professional Textile Services*
Accreditation Programs

- RAL Quality Certification Mark - RAL-GZ 992/2 for Hospital Linen

- The Healthcare Laundry Accreditation Council (HLAC)
Vendor Evaluation

- A part of quality management
- Intended to assure patient safety
Evaluation Methods

- A facility tour
- Documents review
- Employees qualifications
- Processes and practices
- Tests to examine the quality of the drapes
Facility Tour

- Facility design
  - Workflow
  - Area separation
- Hygiene
  - Facility
  - Hands
  - Dress code
  - Water quality
- Reprocessing methods
- Quality control
- Safety
Facility Design

- **Separated areas:**
  - Sorting area – contaminated
  - Washing - “wet” area
  - Preparation - “dry” area
Sorting

- Physical separation
- Safety
- Infection control
- Sorting methods
- Trolley decontamination
Wet Area Inspection

- Water quality
  - Water reprocessing
- Validated washing programs
  - Program changes
  - Contingency programs
- Detergents
  - Validated
  - Single dose
  - Quantities
- Washer maintenance
  - According to instructions
  - Documentation
Preparation Area

- Conveyors, pressers
- Lighted tables
- Quality control activities
- Re-contamination prevention
- Area restriction and attire
- Packing methods
- Sterilization methods
- Storing
- Transport
Hygiene

- Dress code
- Hands hygiene
- Hygiene program
  - Surface disinfection
  - Machines routine cleaning
  - Carts & vehicles disinfection
- Lint control
- Water quality
Reprocessing Methods

- Standards of practice
- Validated washing programs
- Disinfection
- Drying
- Quality control
Document Review

- Standards of practice
- Quality program
- Compliance to laws and regulations
- Certifications
- Logbooks
Employees Qualifications

- Training program
- Interview employees
Quality Tests

- Bio-burden and other residuals
- Physical properties
## EN 13795 Requirements

### Table 5 - Characteristics to be evaluated and Performance Requirements for Surgical Drapes

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Test method</th>
<th>Unit</th>
<th>Standard Performance</th>
<th>High Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Critical product area</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Less critical product area</td>
<td></td>
</tr>
<tr>
<td>Resistance to microbial penetration – dry</td>
<td>EN ISO 22612</td>
<td>CFU</td>
<td>N/A</td>
<td>≤ 300 a</td>
</tr>
<tr>
<td>Resistance to microbial penetration – wet</td>
<td>EN ISO 22610</td>
<td>$I_B$</td>
<td>≥ 2.8 b</td>
<td>N/A</td>
</tr>
<tr>
<td>Cleanliness – microbial</td>
<td>EN ISO 11737-1</td>
<td>CFU/100 cm²</td>
<td>≤ 300</td>
<td>≤ 300</td>
</tr>
<tr>
<td>Cleanliness – particulate matter</td>
<td>EN ISO 9073-10</td>
<td>IPM</td>
<td>≤ 3.5</td>
<td>≤ 3.5</td>
</tr>
<tr>
<td>Linting</td>
<td>EN ISO 9073-10</td>
<td>log$_{10}$ (lint count)</td>
<td>≤ 4.0</td>
<td>≤ 4.0</td>
</tr>
<tr>
<td>Resistance to liquid penetration</td>
<td>EN 20811</td>
<td>cm H₂O</td>
<td>≥ 30</td>
<td>≥ 10</td>
</tr>
<tr>
<td>Bursting strength – dry</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>≥ 40</td>
<td>≥ 40</td>
</tr>
<tr>
<td>Bursting strength – wet</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>≥ 40</td>
<td>N/A</td>
</tr>
<tr>
<td>Tensile strength – dry</td>
<td>EN 29073-3</td>
<td>N</td>
<td>≥ 15</td>
<td>≥ 15</td>
</tr>
<tr>
<td>Tensile strength – wet</td>
<td>EN 29073-3</td>
<td>N</td>
<td>≥ 15</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Sampling
Bio-burden

- Water
- Wet washed materials
- Dry washed materials
- Surfaces

DIN EN 14065 - Textiles - Laundry processed textiles - Biocontamination control system
ISO 11737-1:2006 - Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
Sampling
Physical Properties

- Each item is examined on an illuminated table
- A sample is taken from each load and examined by QC
  - Appearance - cleanness
  - Smell
  - Softness
- A piece of fabric is reprocessed 15 times and then examined in the laboratory
  - Tear test
  - Linting
  - Whiteness/color stability – colorimetric testing
Laboratory Tests

Part 2 of EN 13795 describes the following tests:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Test method</th>
<th>Unit</th>
<th>Standard Performance</th>
<th>High Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistance to microbial penetration – dry</td>
<td>EN ISO 22612</td>
<td>CFU</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Resistance to microbial penetration – wet</td>
<td>EN ISO 22610</td>
<td>$I_b$</td>
<td>$\geq 2.8 \ a$</td>
<td>$6.0 \ b^c$</td>
</tr>
<tr>
<td>Cleanliness – microbial</td>
<td>EN ISO 11737-1</td>
<td>CFU/100 cm²</td>
<td>$\leq 300$</td>
<td>$\leq 300$</td>
</tr>
<tr>
<td>Cleanliness – particulate matter</td>
<td>EN ISO 9073-10</td>
<td>IPM</td>
<td>$\leq 3.5$</td>
<td>$\leq 3.5$</td>
</tr>
<tr>
<td>Linting</td>
<td>EN ISO 9073-10</td>
<td>$\log_{10}$ (lint count)</td>
<td>$\leq 4.0$</td>
<td>$\leq 4.0$</td>
</tr>
<tr>
<td>Resistance to liquid penetration</td>
<td>EN 20811</td>
<td>cm H₂O</td>
<td>$\geq 30$</td>
<td>$\geq 10$</td>
</tr>
<tr>
<td>Bursting strength – dry</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>$\geq 40$</td>
<td>$\geq 40$</td>
</tr>
<tr>
<td>Bursting strength – wet</td>
<td>EN ISO 13938-1</td>
<td>kPa</td>
<td>$\geq 40$</td>
<td>N/A</td>
</tr>
<tr>
<td>Tensile strength – dry</td>
<td>EN 29073-3</td>
<td>N</td>
<td>$\geq 15$</td>
<td>$\geq 15$</td>
</tr>
<tr>
<td>Tensile strength – wet</td>
<td>EN 29073-3</td>
<td>N</td>
<td>$\geq 15$</td>
<td>N/A</td>
</tr>
</tbody>
</table>
ISO 22612:2005
Clothing for protection against infectious agents -- Test method for resistance to dry microbial penetration
Other Properties

- EN13795 mentions some interesting additional properties:
  - Skin model – ISO 11092 - EN31092
  - Thermal manikin - EN ISO 15831 – ASTM F2370
  - Air permeability - ISO 9237
  - WP resistance to water - ISO 811
  - non-toxicity of the medical device – ISO 10993
  - 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
Transportation Systems

- Inspect the transportation conditions
  - Appearance
  - Carts
  - Smell
  - Temperature loggers
  - Driver’s knowledge
Summary

- Laundry services continue to be the most outsourced hospital department contract
- There is a partnership between CSSD and the laundry
- Hospital’s oversight of contracted laundry services and in house service is an important task
- A comprehensive understanding of processes and quality systems is required
Final Thoughts

- Surgical drapes and gowns reprocessing require a comprehensive quality assurance program.
- Standards and accreditation programs promote safety and infection control
- Effective communication is essential
- Knowledge of reprocessing standards, performance characteristics and requirements
- A commitment to quality assurance to ensure consistency in the performance of the products and services offered.
Thanks!