standardtextile

Reusable Barrier Fabrics: Design, Function and Use

Workshop: Medical Textiles Network and Biocomplexity
University of California, Davis
Sponsored by National Science Foundation

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Speaker Background Information

Positions

Vice President – Standard Textile Co., Inc.
Past President – American Reusable Textile Association

Education

Bachelors Degree – Chemistry, Oberlin College
Masters Degree – MBA, Xavier University

Standards Involvement Includes:

US Delegate to European Committee for Standardization (CEN)

Committee Member - Canadian Standards Association (CSA)

Committee Member - US Association for the Advancement of Medical Instrumentation (AAMI)

•and participating writer/contributor to the following US standards:

Performance standard for surgical gowns and drapes PB70 2003
Processing standard for surgical gowns and drapes ST65:2000
Industrial steam sterilization
Hospital steam sterilization
Biological Indicators
Table top sterilizers

Outline

- Reusable Surgical Fabrics: The Technology Revolution of the 1980”s.
  - Improving the “State-of-the-Art”
  - Global Growth and Presence
- Technology Overview - Microfibers
- International Standards
- Keys to Successful Reusable Programs
- Benefits vs. Single Use Products
- Questions

Improving the State-of-the-Art

- Historically reusable surgical fabrics were traditional fabrics that found application in the clinical setting…

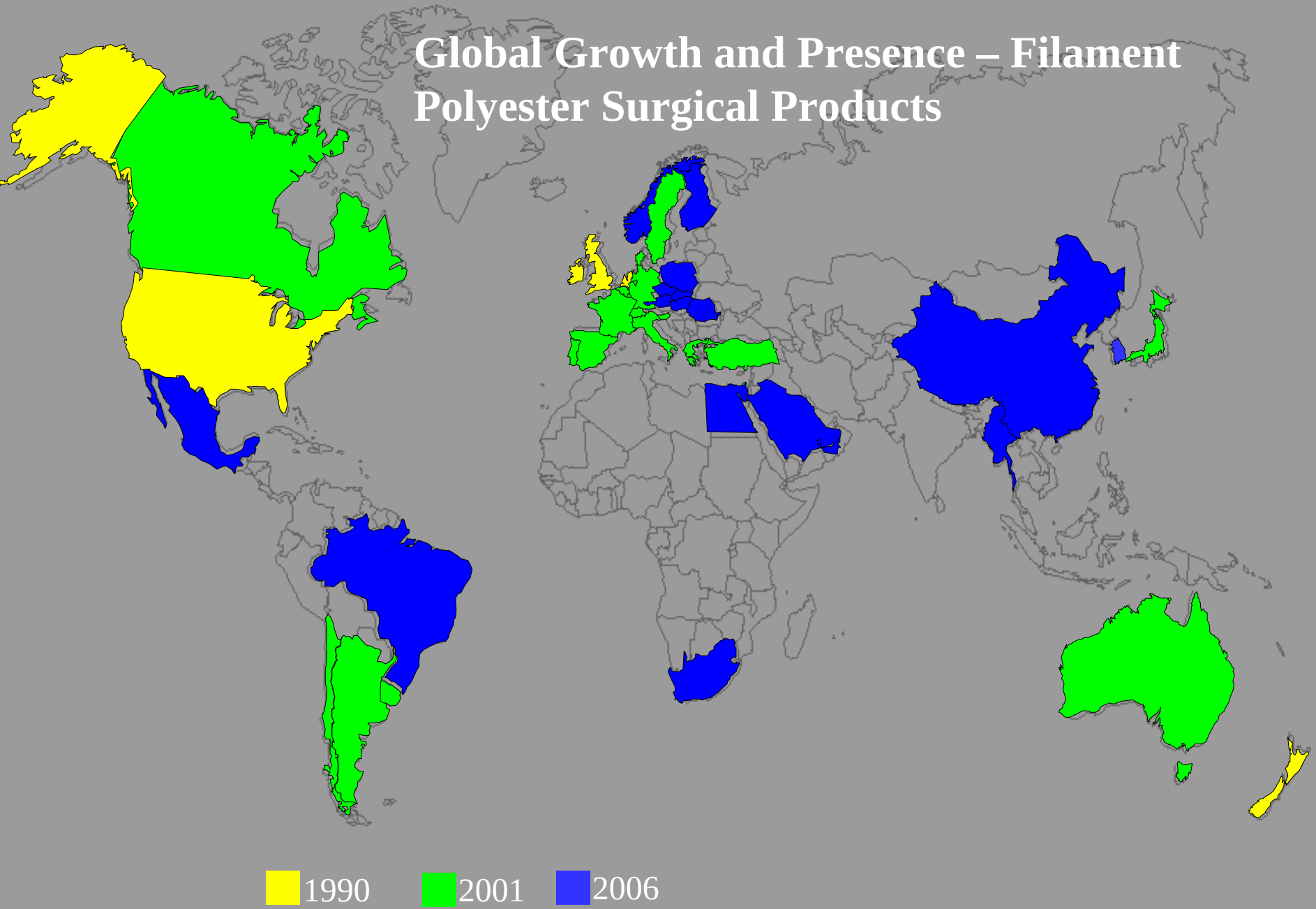
  Muslin was turned into surgical wrappers

  Bed sheets became surgical drapes

  Cotton apparel items became surgical gowns

- In the 1980's, the reusable industry specifically set out to develop and market a new generation of reusable surgical fabrics. The end result is a growing family of barrier fabrics based on extruded filaments, fibers and yarns.

Global Growth and Presence – Filament Polyester Surgical Products



Technology Overview:

Survey of the industry indicated that two characteristics of traditional surgical fabrics needed to be improved upon – linting and barrier performance.

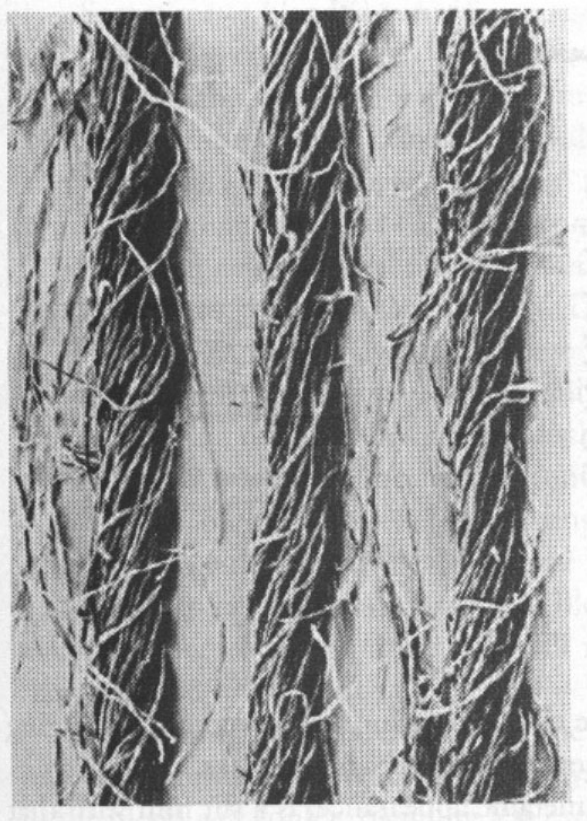
1. Linting: Particles including lint are a safety related concern in the OR and have been identified as the source of contamination that cause potential infections and pyrogenic affects.

2. Barrier: Not only protection of the patient from infection was a concern but protection of the healthcare worker due to infectious diseases like AIDS also focus attention on the need for improved barrier properties for surgical fabrics.

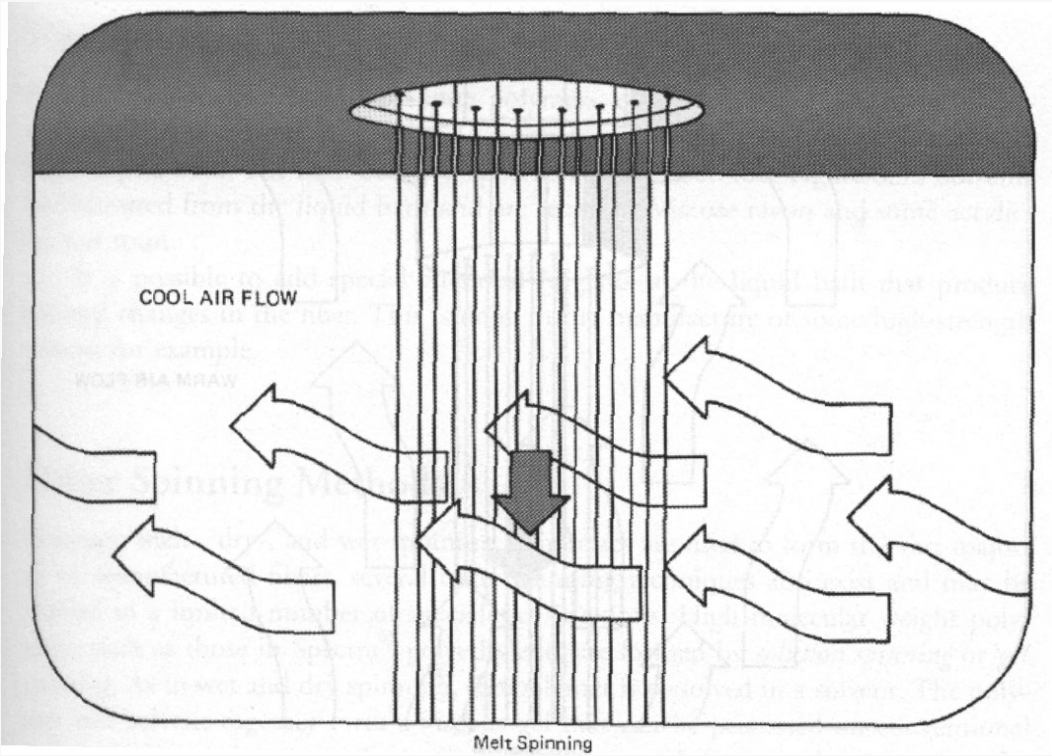
Engineering Fabrics with Low Lint Properties

- Traditional spun yarns used in cotton fabrics and spun laced disposables are both constructed with “staple fibers”. The ends of each fiber is a potential source of lint.

- Filament barrier fabrics use continuous filaments that do not have fiber ends.



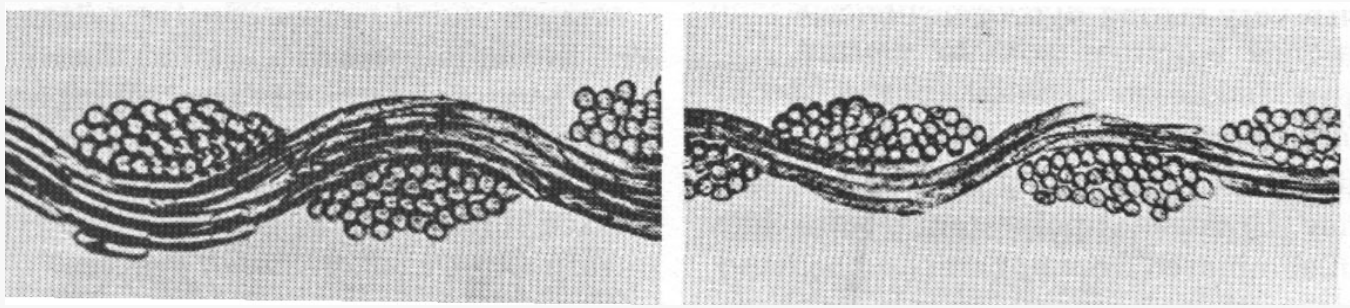
Extruding Filaments/Yarns



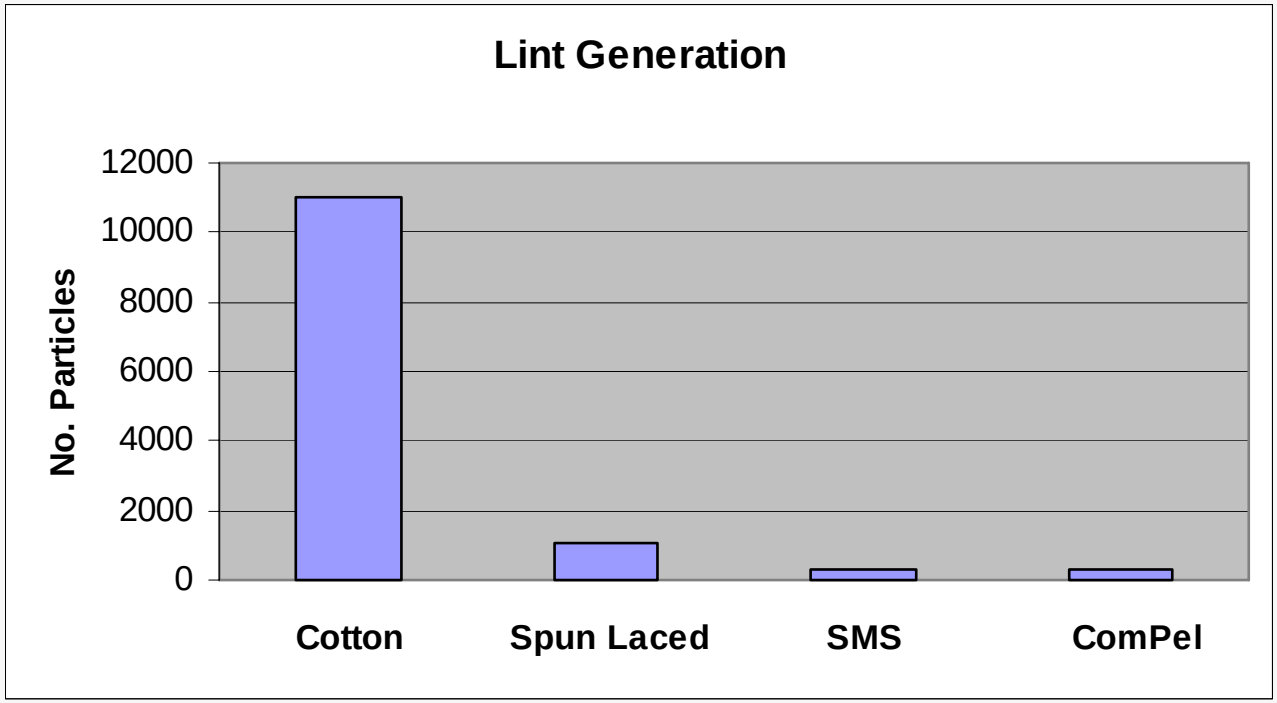
Melt Spinning

Linting

- Cross sectional photos show that the surface of the fabric has no protruding fibers and therefore has very little propensity to lint.



Lint Comparison



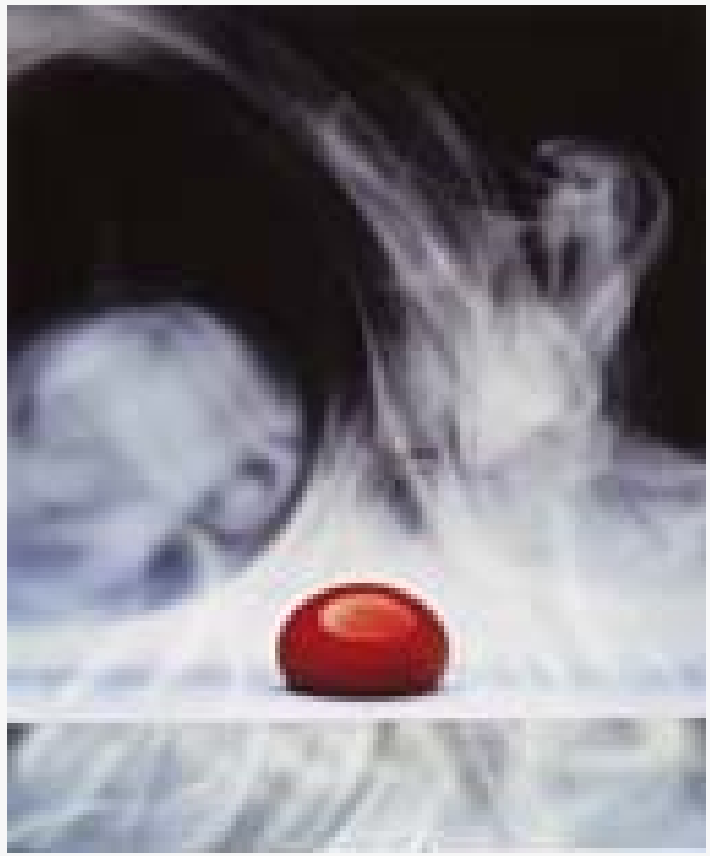
Engineering Fabrics with Barrier Properties

In order to engineer a barrier fabric to meet the changing needs, three areas were addressed:

1. Selection of a hydrophobic fiber.

2. Construction of a fabric with a small pore size.

3. Use of chemical finishes to enhance barrier performance.

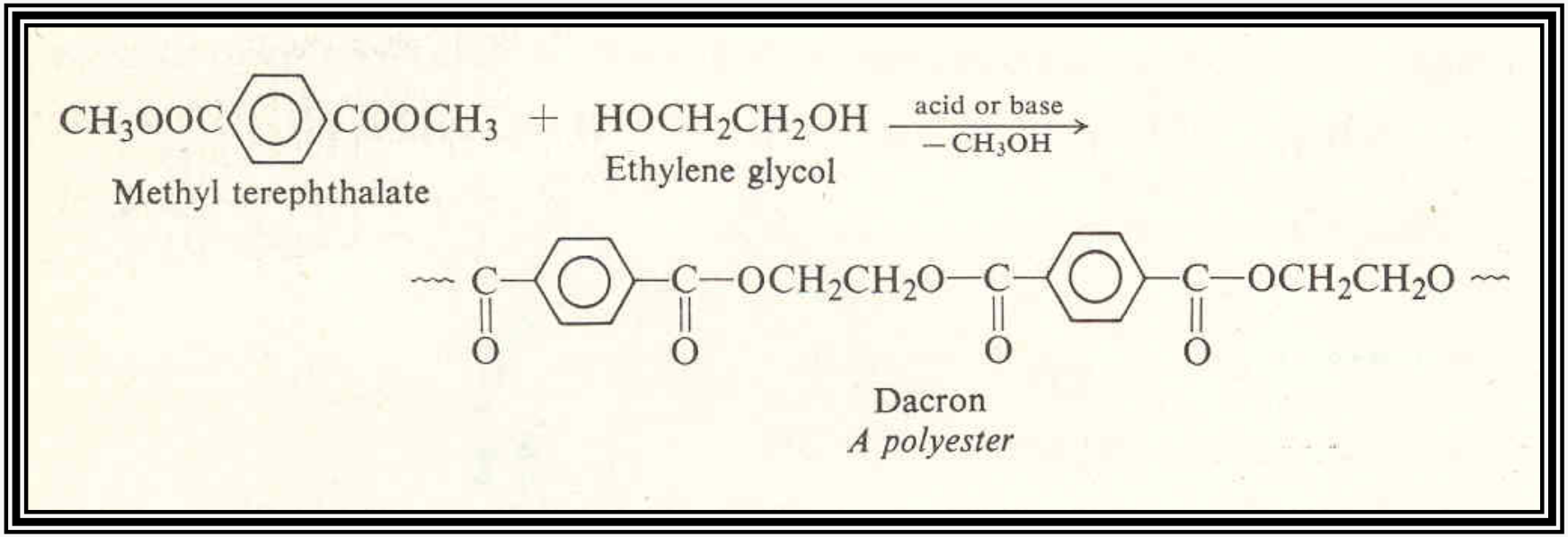


Selection of a Hydrophobic Polymer: Polyester

Moisture Regain…

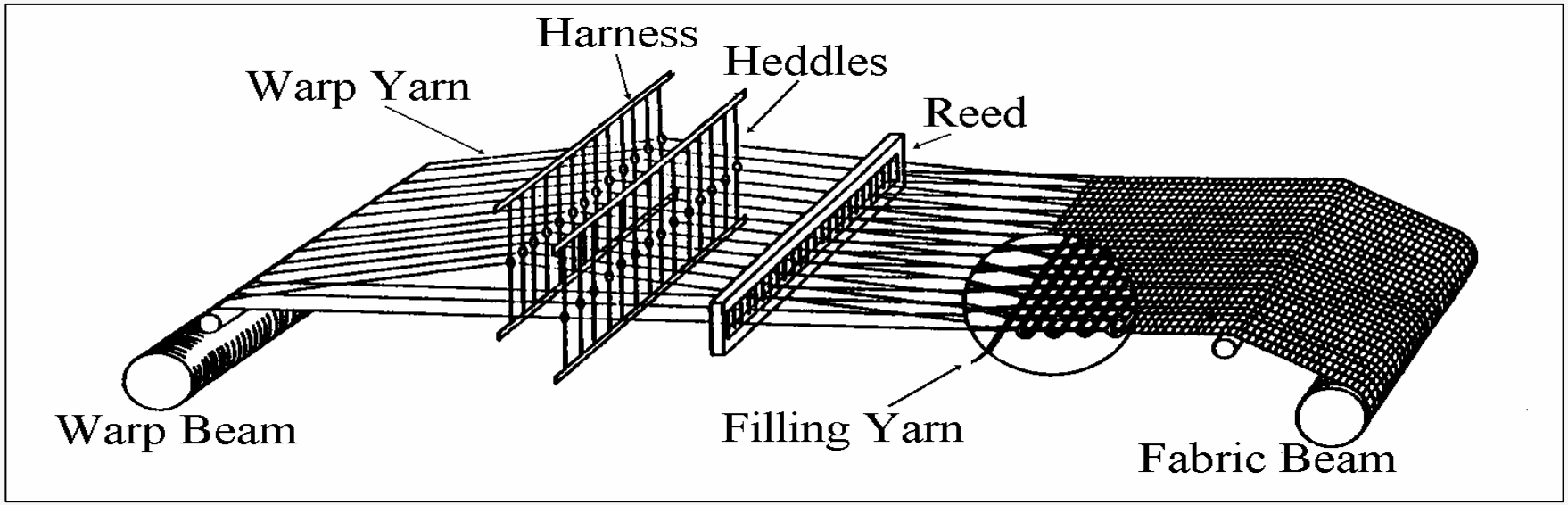
Polyester = 0.3%

Cotton = 7-8%



Weaving and Compaction of Yarns:

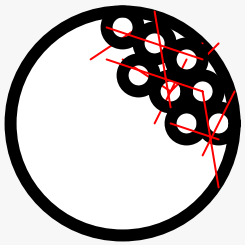
Pore size can be as low as 2 microns



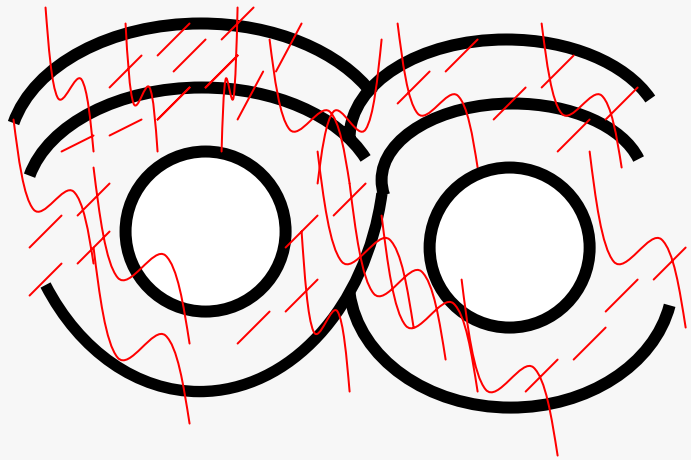
Finishing

Fluorocarbon treatments are used on all "Standard" performance barrier fabrics – microfibers, spun laced, and spun bonded.

These finishes are responsible for providing up to ¾ of the barrier properties of these fabrics.



Entrapment



Cross-Linking

How the Liquid "Barrier" Works

- Question: If the pore size of the fabric is 2 microns but blood cells, water molecules, and other potential contaminates are smaller than 2 microns, how can the fabric act as a barrier?

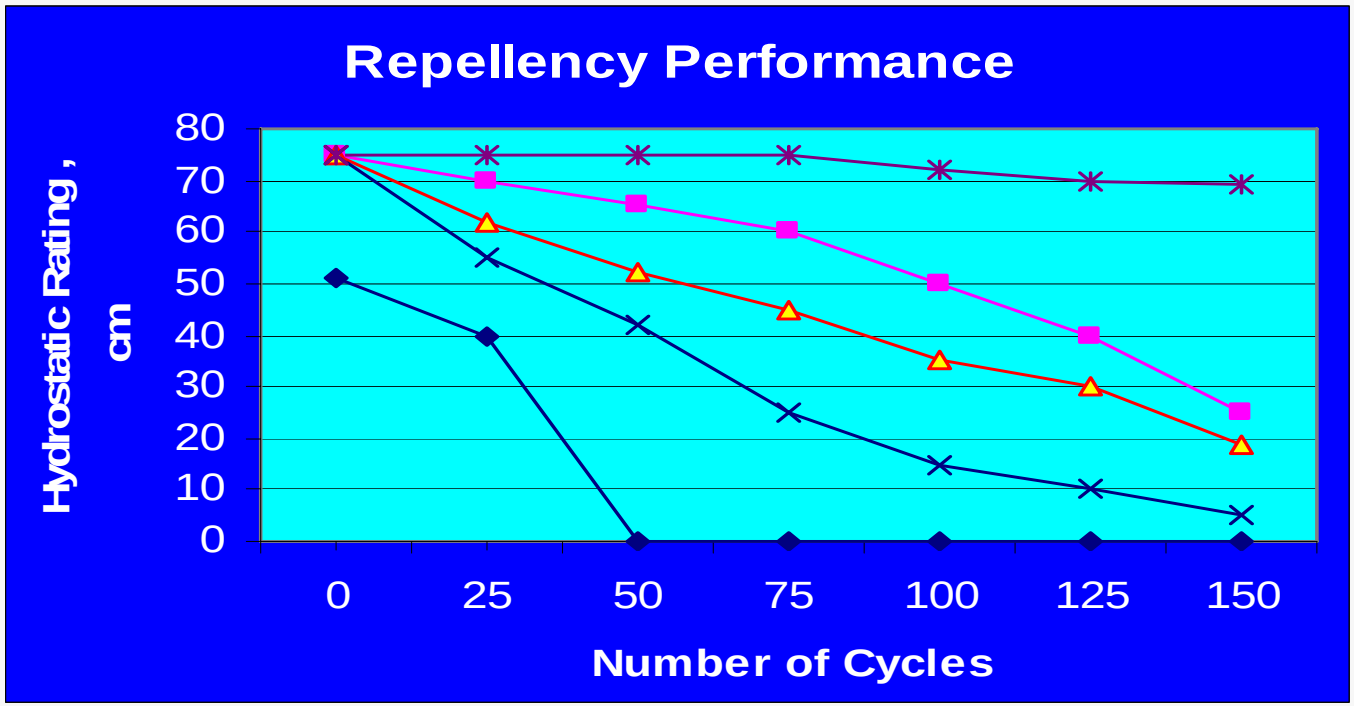
- **Answer: The single most important attribute that allows microfibers to work is the "surface tension" of the liquids it comes in contact with.**

Barrier Performance & Surface Tension

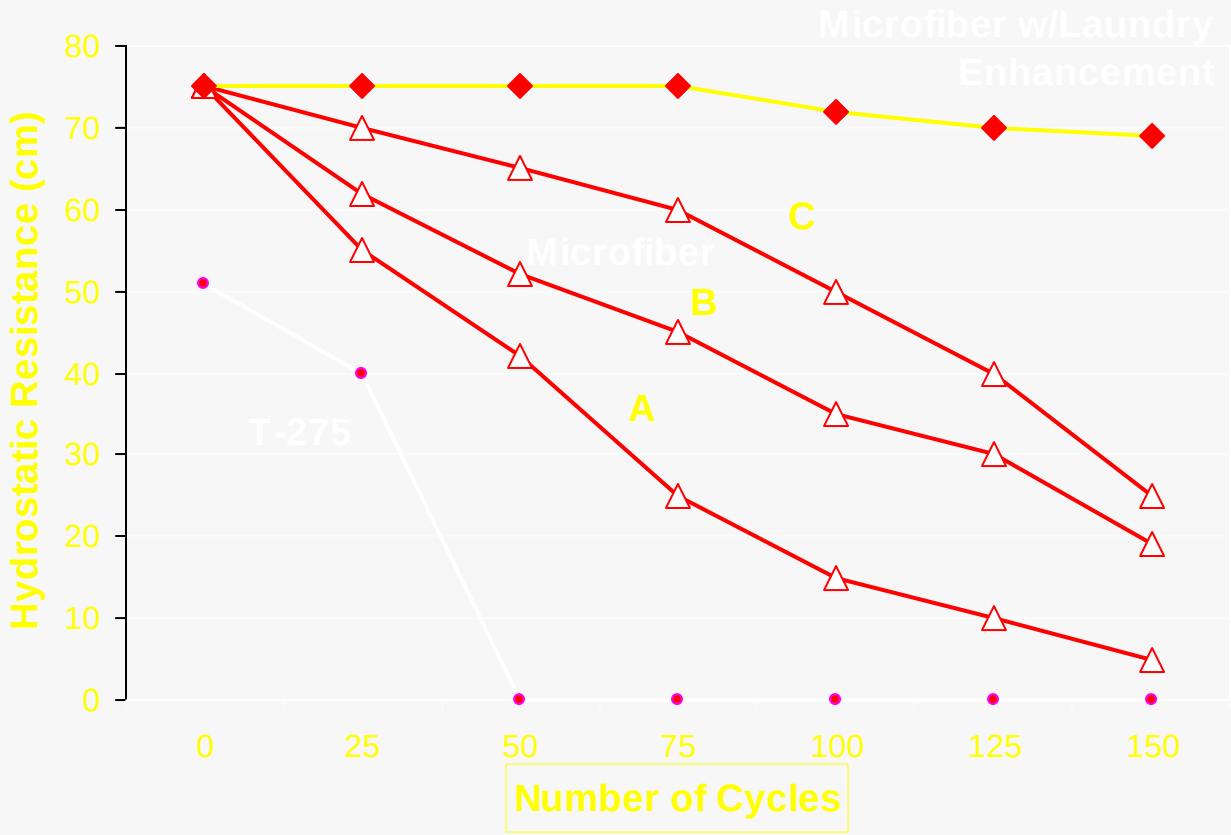
- Several conclusions can be drawn from understanding the role surface tension and its affects on the barrier properties of the fabric. They are:

1. The higher the surface tension of liquids that come in contact with these fabrics, the higher the barrier performance (hydrostatic resistance) will be.
2. For liquids like alcohols that have low surface tensions, these fabrics will only have fair barrier resistance as compared with blood and water. Water has a surface tension around 70 dynes, blood approximately 50 dynes, and alcohols 20 dynes or less.
3. In order to maximize the barrier performance of these fabrics, residual detergents from the laundering process and/or ineffective rinsing of hand scrubs should be avoided.

Performance Expectations – Barrier Performance

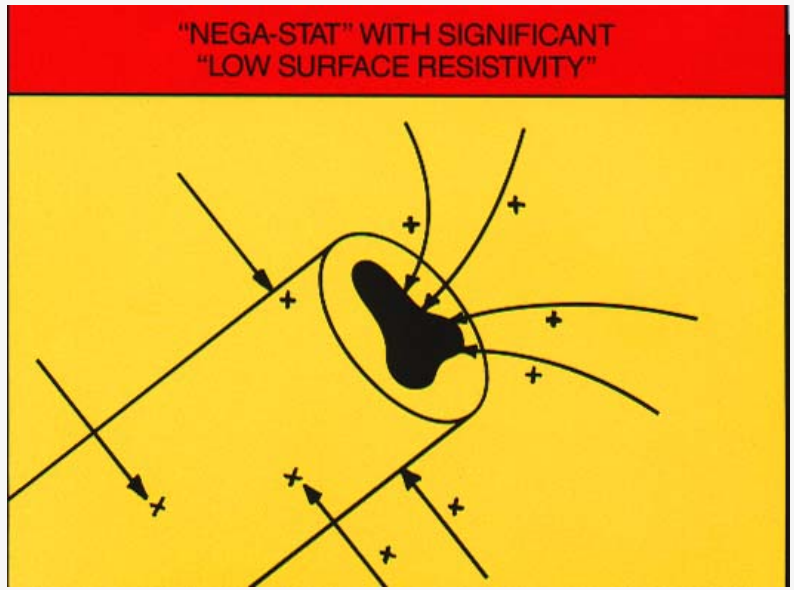


Reusable Protection



Variation: Antistatic Filaments

- Due to the low moisture content of polyesters, they are known to have static issues (water is one of the best antistats). Specialized filament have been developed that utilize a carbon core to control static.



Antistatic Filaments (cont.)

- Two important characteristics of static and these filaments are:

  1. Static is a surface phenomena and is characterized as a probability of the static existing at any one point on a product.

  2. Products with carbon core yarns have a “finite” and not an “infinite” capability to dissipate static. Once the carbon is fully charged, static will again start to travel on the products surface and if it reaches discharge levels, static can exist.

  In designing these fabrics, it is therefore not necessary to have carbon core yarns throughout the product as long as it is in the product in sufficient quantities. Use of carbon core yarns only in the back panel of surgical gowns is recommended.

Direction and Focus of International Standards

- The following international standards have been developed with a primary focus on barrier protection offered by surgical gowns and drapes. In addition, many of the standards include other performance requirements such as being low linting, durable and strong.

  Europe TC 205 WG 14 “Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment”

  US ANSI/AAMI PB70:2003 “Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities”

  Canada CSA Z314.10 “Selection, Use, Maintenance, and Laundering of Reusable Textile Wrappers, Surgical Gowns, and Drapes for Health Facilities”

Levels of Performance (PB-2003)

Level	Test Method	Result
1	AATCC 42	≤ 4.5g
2	AATCC 42	≤ 1.0g
	AATCC 127	≥ 20 cm
3	AATCC 42	≤ 1.0g
	AATCC 127	≥ 50 cm
4	ASTM F 1670	Pass
	ASTM F 1671	Pass

Keyes for a Successful Laundry Operations – A Focus on Quality and Customer Service

- Each step in the process from receipt of goods, laundering, inspection, folding, pack making and sterilization are controlled by documented procedures, product testing, employee training and interface with the customer to ensure their ongoing satisfaction.

US Standards Relating to Laundering Surgical Products

- **AAMI/ANSI ST65:2000 “Processing of Reusable Surgical Textiles for Use in Health Care Facilities”.**

Laundry

Quality Programs
Microprocessor controlled/automated processing equipment

Laundry Formula Cycle Verifications

Laundry Formula Chemical Titrations

Periodic Product Testing

Environmental Stewardship
Use of:
Biodegradable Detergents
Water Reuse Systems
Heat Reclamation Systems

Pack Room

<u>Quality Programs</u>

Visual Inspection over Light Tables

Established Folding Procedures/Methods

Device Master List for each pack produced including contents, configuration, wrapping technique and labeling

Established policy for patching, mending and staining, i.e., what is and is not acceptable with the end user

Sterilization

Quality Programs

- Automated/microprocessor controlled sterilization equipment
- Use of a dedicated steam generator to ensure the highest quality of steam
- Establishment of cart loading procedures
- Utilization of an “overkill” saturated steam sterilization process that is validated, i.e., prevacuum cycle with 132°C set point and a 4 minute exposure
- Daily pre-production testing including chamber warm up and leak tests
- Periodic cycle validation, bowie-dick testing, unit calibration and an established preventative maintenance program
- Production/lot controls including both chemical and biological indicators

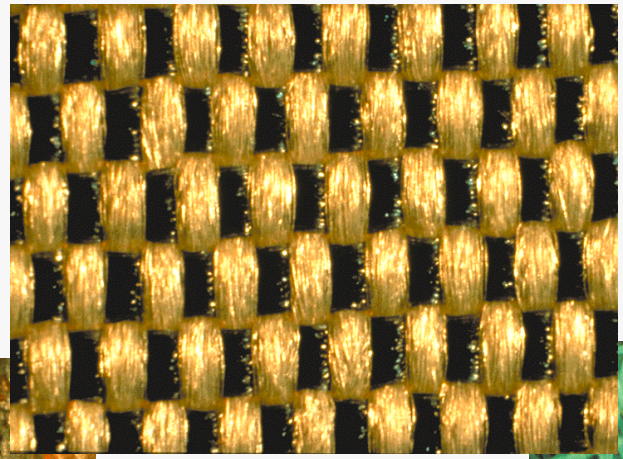
Advantages vs. Single Use Products

- More Homogeneous Fabric – Less Variability in Protection/Highest Level of Protection
- Elimination of “Hazardous” Waste
- Reduced Environmental Impact – Life Cycle
- Lower Cost per Use
- Employment Opportunities for the Community
- Retrieval of Surgical Instruments

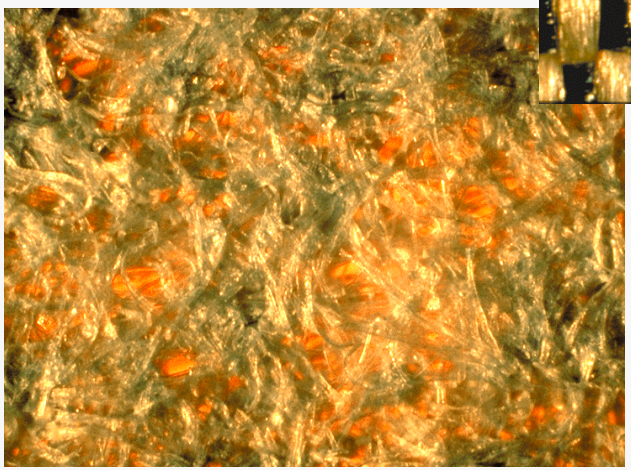
Comparison vs. Single Use Products

A picture is worth a thousand words.....

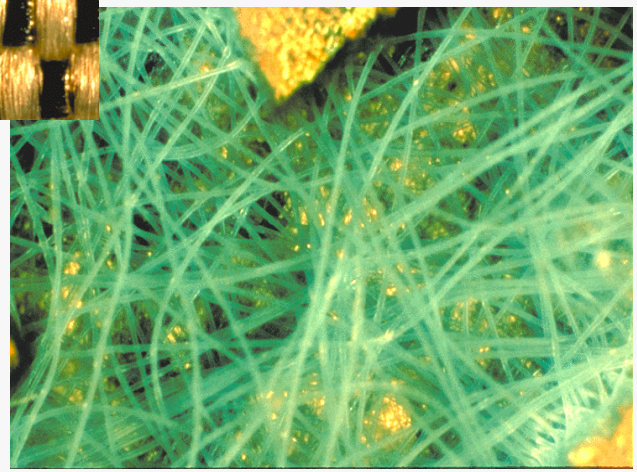
ComPel



Spun-Laced



Spun-Bonded



“Environmental Benefits”

The amount of waste generated is dramatically less than when a disposable system is used. In addition, this usually eliminates the “hazardous” waste category as the eventual retirement of reusable items are not “hazardous” but “general” waste. There will also be less waste than older cotton systems because not only are they lighter in weight, they will also last longer in the system due to the better durability of the fabric. The result is significantly less poundage being discard on an annual basis.

A European life cycle assessment of barrier microfibers versus both cotton and single use items,

clearly demonstrate that filament polyester is by far the most environmental sound choice during a cradle to grave assessment.

Financial Evaluation

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FINANCIAL REVIEW

PrePaK — PARTNERS IN SURGICAL PACK REPROCESSING

WINTER HAVEN HOSPITAL, WINTER HAVEN, FLORIDA

	BASE FOR PROPOSAL		FY 2001 ACTUAL YEAR END RESULTS		FY 2002 ACTUAL YEAR END RESULTS		FY 2003 ACTUAL YEAR END RESULTS		FY 2004 ACTUAL YEAR END RESULTS		FY 2005 ACTUAL YEAR END RESULTS	
	OLD SYSTEM	NEW SYSTEM	OLD SYSTEM	ACTUAL	OLD SYSTEM	ACTUAL	OLD SYSTEM	ACTUAL	OLD SYSTEM	ACTUAL	OLD SYSTEM	ACTUAL
PROCEDURES ANNUALLY	7,045		11,112		10,605		10,900		9,271		10,300	
DISPOSABLE COSTS												
DISPOSABLE ACQUISITIONS	83,999	0	132,491	0	126,446	0	129,963	0	110,540	0	122,809	0
WASTE DISPOSAL ($0.17/lb)	3,390	0	5,347	0	5,103	0	5,245	0	4,461	0	4,956	0
INSTRUMENT REPLACEMENT	420	0	662	0	632	0	650	0	553	0	614	0
SUBTOTAL	87,809	0	138,500	0	132,181	0	135,858	0	115,554	0	128,379	0
REUSABLE COSTS												
LAUNDRY COST	43,010	29,066	67,839	54,752	64,744	54,433	66,545	65,240	56,600	62,899	62,882	65,146
PACKROOM LABOR	83,200	62,400	131,230	81,443	125,243	71,263	128,727	71,263	109,489	71,263	121,641	85,000
STERILIZATION COST	28,050	16,112	44,243	35,708	42,224	35,712	43,399	32,236	36,913	31,603	41,010	35,200
PACKROOM SUPPLIES	3,278	4,663	5,170	12,482	4,934	11,250	5,072	7,596	4,314	7,131	4,793	6,900
DRAPE TAPE	0	3,750	0	1,846	0	2,000	0	1,891	0	1,982	0	2,500
LINEN REPLACEMENT	16,830	65,381	26,546	70,908	25,335	99,254	26,039	90,542	22,148	75,165	24,606	72,213
SUBTOTAL	174,368	181,372	275,029	257,139	262,480	273,912	269,782	268,768	229,463	250,043	254,931	266,959
ADMINISTRATIVE COSTS												
QUARTERLY AUDITS	0	5,000	0		0		0		0		0	
SUBTOTAL	0	5,000	0	0	0	0	0	0	0	0	0	0
START-UP COSTS												
IMPLEMENTATION FEE	0	0	0	0	0	0	0	0	0	0	0	0
FACILITY CONVERSION	0	0	0	0	0	0	0	0	0	0	0	0
INVENTORY INVESTMENT	0	0	0	0	0	0	0	0	0	0	0	0
SUBTOTAL	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL COSTS	262,177	186,372	413,529	257,139	394,661	273,912	405,639	268,768	345,017	250,043	383,311	266,959
NET SAVINGS		75,805		156,390		120,749		136,871		94,974		116,352
COST PER PROCEDURE	$37.21	$26.45	$37.21	$23.14	$37.21	$25.83	$37.21	$24.66	$37.21	$26.97	$37.21	$25.92

Acceptance and Use – Open Heart Case

- Everyday end users around the globe rely on reusable systems to deliver the right product, in the right quantity to ensure not only an effective outcome to the surgical intervention but also protection of their staff from potentially infectious situations. Couple this with the cost and environmental advantages of reusables, it should be the first choice for today's professional healthcare providers.

Questions….