



2015



Comprehensive Comparative
Analysis between Reusable
and Disposable Surgical
Gowns and Drapes

EXECUTIVE SUMMARY

This analysis is an overview of the benefits a reusable gown and drape program provides and how it can help a healthcare facility achieve cost savings and meet environmental goals within the operating room.

Lac-Mac will demonstrate our products:

1. Meet ORNAC, OSHA and AORN recommended practices, CSA and AAMI Standards
2. Validate performance measurements
3. Reduce medical waste
4. Effectively demonstrate cost benefits

Evaluation Criteria	Reusable Drapes	Reusable Gowns
Barrier Effectiveness	Meets ASTM F1670	Meets ASTM F1671
Performance, Quality and Safety	Validated to 80 WDAs ISO 9001 Registered facility Regulated by Health Canada and the FDA	Validated to 75 WDAs ISO 9001 Registered facility Regulated by Health Canada and the FDA
Environmental Impact	Can reduce environmental waste by more than 73% by weight and 93% by volume compared with single-use	Can reduce environmental waste by more than 73% by weight and 93% by volume compared with single-use
Cost Benefits	While reusables demonstrate proven cost savings over single-use, total cost savings will vary based on regulated medical waste costs differing by region	While reusables demonstrate proven cost savings over single-use, total cost savings will vary based on regulated medical waste costs differing by region

WHY REUSABLES IN THE OPERATING ROOM

The operating room is critical to a hospital's success, and to its business model, responsible for generating between 40-60% of the facilities' revenue. The operating room is also a significant cost centre. It has been estimated that the OR can account for approximately 33% of the hospital's supply costs. Additionally, the OR is also a major source for producing medical waste, most notably by the use of disposable surgical products¹.

When considering how to reduce the volume of waste in the operating room, it makes sense to first revisit the old adage of Reduce-Reuse-Recycle.

When conducting a comparative analysis, surgical services managers need to consider the lifecycle costs of disposable items beyond the acquisition cost.

Disposable surgical gowns, towels, back table, mayo and basin stand covers are routinely used for most surgical procedures and disposed of as regulated medical waste after a single use. Studies have shown that using a 'common sense' approach to replacing these products with reusable textile items, which can typically be reused 75 times or more, can reduce surgical waste by an average of 65%.



Look for our Smart Start symbol to identify 'common sense' products which can easily be converted from disposable to reusable.

DECISION CRITERIA

When considering Reusables, protecting patient and surgical team is paramount.

Additionally, consider how Lac-Mac reusable surgical products contribute to:

- ◆ Protection and comfort for surgical team
- ◆ Protection and comfort for patient
- ◆ Driving cost reductions through efficiencies
- ◆ Managing continuing budgetary constraints
- ◆ Environmental responsibility
- ◆ Managing labour costs
- ◆ Positive patient outcomes
- ◆ Ease of use
- ◆ Reducing the need for supplementary products
- ◆ Reducing costs associated with lost/discarded instruments

Single-use surgical products:

- ◆ Offer poor thermal comfort
- ◆ Demonstrate inferior breathability
- ◆ Increase overall cost
- ◆ Are environmentally detrimental
- ◆ Demonstrate poor bursting strength, not resistant to tearing
- ◆ Increase the need for supplementary products
- ◆ Feature poor drapability
- ◆ Often manufactured with questionable 'quality of labour' and 'good manufacturing practices'
- ◆ Responsible for direct relationship to an increase in discarded instruments

The Steps to a Successful Reusable Conversion³:

Step 1: Identify your Allies

A change in product and practice often means changing minds. In getting started, think about what the arguments against reusables might be. Consult with Infection Prevention department and demonstrate that reusable surgical linens meet both CSA and AAMI PB70 liquid barrier performance standards for protective gowns and drapes. Identify and address their concerns. If the healthcare facility has an organized Green Team, contact them and let them know you are making a case for reusables. Green Teams are often very supportive of this type of initiative.

Step 2: Develop a Baseline for Use of Disposables

Before being able to make a case for implementing a reusable program, it is important to be able to quantify how disposables are impacting the operating room and the environment.

Understanding the following will be important:

- ◆ What is the volume of custom packs the OR uses monthly?

Materials Management or Operating Room Managers should be able to provide you with data concerning the number and kinds of OR packs being utilized.

- ◆ What single-use textile products are contained in each type of pack?

An audit of different packs may be required in order to correctly identify disposable textile components within each pack. It will be important to quantify disposable surgical gowns by performance level, towels, size of back table and mayo stand covers, sheets and basin covers in each type of pack.

- ◆ How are disposables being disposed of?

Also relevant to the baseline is determining whether all disposable textiles are currently being disposed of as regulated medical waste. If the facility has a strong RMW segregation program and is segregating disposable textiles as solid rather than medical waste, it will impact your baseline cost assessment. Contact Environmental Services to try and determine what the hospital is spending per pound (a Green Team may be able to assist here) on RMW and/or solid waste. Multiply your total monthly weight by the cost per pound for disposal. This cost will represent a savings when implementing reusables.

- ◆ What are the weights of the disposable textiles products?

Once you have itemized the contents of each pack, gather a sample set of the disposable textile products, weigh the disposable textile items. Multiply these weights times the number of that kind of pack utilized monthly by the OR. This data should provide you with a fairly accurate assessment of the volume of disposable textiles leaving the hospital monthly.

- ◆ What are the item costs for the disposable textiles?

In order to do a cost comparison, you will need to understand how much the disposable textile products are costing the healthcare facility. Because there are additional items within the pack which will not be eliminated, it is important to try and identify costing for just those disposable textile products being replaced rather than the entire pack. Be sure to include handling, packaging and sterilization costs. Multiply the cost in each pack by the number of packs of that type used monthly. Also recognize the common practices which would add to the supply cost, e.g. staff double draping or lining the back table with towels. These are additional supply costs which should be included in the total.

- ◆ Determine total cost for use of disposable textiles monthly

Add the total waste management costs for disposable textiles to the total supply cost for disposable textiles to get the total current baseline cost.

Step 3: Work with your Reusable Supplier, Lac-Mac

The next step is to understand the alternative products which are available to replace the disposable textiles within the packs. Once comparable products have been determined, price quotes based on volume expectations can be provided.

Step 4: Compare Disposable vs. Reusable Pricing

Chart the baseline supply costs for the disposables against the projected costs for the replacement reusables including waste disposal costs. Although waste disposal costs are usually not assigned to the OR budget, it is a cost to the bottom line of the facility.

Disposable Surgical Textiles and Supplies	Reusable Surgical Textiles and Supplies
Total Supply Cost for Disposable Surgical Textiles and Supplies in existing OR custom packs monthly	Potential Supply Costs for Reusable Surgical Textiles and Supplies to replace Disposables
Any additional supply costs for “a la carte” disposable textiles, basins, pitchers for OR monthly	Any additional supply costs for “a la carte” reusable textiles and supplies for the OR monthly
Total pounds of waste generated by disposable surgical textiles and supplies from OR monthly	Savings from recovered instruments—estimated for a typical hospital to be well in excess of \$20,000 per year*
Total costs for managing disposables as RMW, Hazardous waste or solid waste each month	In most cases, Reusables can be downgraded for alternate use at end of life
Total Costs of Using Disposable Surgical Textiles and Supplies, including hidden costs	Cost of Using Reusable Surgical Textiles, including Laundry and Sterilization

- ◆ A thorough understanding of cost considers all expenses associated with product acquisition, distribution, warehousing, and cost of disposal including hidden costs such as instrument loss. Also consider the need for additional supplementary products such as warming aids and absorbent towels.
- ◆ ORs routinely dispose of items included in single-use packs which are never used during the procedure.
- ◆ The overall goal is to source the most *clinically acceptable* products which offer the *lowest total cost*.
- ◆ Individual cases seeking the most economical solution require individual assessment.

**Independent studies have identified instrument losses can in fact be in excess of \$150,000 annually.*

Step 5: Pilot Reusable Surgical Product Trial

There may be times when all concerns have not been alleviated for transitioning out of disposables and into reusables. In this case, it makes sense to pilot the new products. Based on the cost-comparison numbers provided, the healthcare facility will likely agree. Determine a reasonable pilot period for the trial.

Lac-Mac's experienced team of experts can assist you with fielding questions which may be asked by the OR staff before, during and after using the reusable products.

Other pilot projects and studies have resulted in increased clinician satisfaction and positive feedback. This, in addition to the cost-benefits, should result in moving the organization to a reusable surgical textile program.

Additional Considerations

While reusables typically have a higher acquisition cost but a lower cost-per-use than disposables, perioperative services should evaluate all the steps within the supply chain as well as the waste disposal costs in order to accurately assess a one-on-one comparison. When all the data has been gathered and considered, the cost-benefit for reusables will be clear.

In most cases, touch points between a single-use program and a reusable program have been found to be identical with no benefit observed for either program.

Single-Use Systems:

- ◆ Increase waste disposal costs.
- ◆ Add warehousing costs.
- ◆ Have costs associated with additional purchasing transactions.
- ◆ Contain hidden costs (instrument loss, requirement for supplement products such as warming aids, unused pack components, double draping to resist tearing).
- ◆ Often multiple-layering required with single-use drapes due to inferior tensile strength which poses risk for tearing.
- ◆ Require a high volume of product to support consistent supply.

Today's High-Performance Level 4 Reusable Surgical Gowns and Drapes provide an impervious barrier with one layer. The durability of reusable products result in labour savings associated with the reduction of time required to drape patients, by eliminating additional products associated with single-use double draping.

SURGICAL GOWN AND DRAPE CONSIDERATIONS:

- ◆ Barrier protection
- ◆ Compatibility with Infection Control mandates and practices
- ◆ Product quality and workmanship
- ◆ Comfort, breathability
- ◆ Product fit
- ◆ Quality control measures during product production
- ◆ Environmental impact
- ◆ Adherence to standards and guidelines
- ◆ Aseptic presentation and handling
- ◆ Drapability
- ◆ Durability
- ◆ Convenience and ease of use
- ◆ Design features
- ◆ Customization/substitution
- ◆ Flammability/risk for blue flame fires

Barrier Effectiveness for Reusables

The barrier materials used in Lac-Mac reusable surgical gowns and drapes are the key to providing an effective protection against liquids and microorganisms during a surgical procedure. Surgical gowns and drapes are considered Class II medical devices by the *Food and Drug Administration (FDA)*. Under the Medical Devices Act, these products must meet stringent standards.

The barrier effectiveness of Lac-Mac reusable gowns and drapes remain effective throughout the life of the product.

Claims regarding the number of times a product can be effectively reprocessed and reused are authenticated and validated by independent third party lab testing.

CSA and AAMI PB70 Standards for Barrier Protection^(7,8)

The Canadian Standards Association (CSA) and the Association for the Advancement of Medical Instrumentation (AAMI) standard helps take the guesswork out of choosing the right barrier protection associated with risk for exposure to fluid, fluid spray and applied pressure, expected during a procedure. The AAMI standard requires manufacturers to classify and label their surgical gowns, drapes and certain other protective products with the level of barrier protection they provide.

As an example, the surgical team can don a gown identified as Level 4, and be assured it has been tested to meet the anticipated high risk levels for exposure to fluid, fluid spray and applied pressure.

The Standard has established the following as guidelines:

- ◆ A classification system using Levels 1-4 to identify class of barrier protection
- ◆ Liquid barrier performance is based on industry-accepted test methods and to guide manufacturers in appropriate labeling of their medical devices
- ◆ Surgical gowns and drapes shall be prominently labeled with its class of barrier performance
- ◆ No classification identified shall be considered non-protective
- ◆ Levels of classification are in accordance to the barrier performance properties specific to the critical zone(s), including seams and components
- ◆ Must meet flammability standard as defined in CFR16:Part 1610

Lac-Mac Reusable Advantage: Quality

- ◆ Lac-Mac surgical products are manufactured in our modern efficient North American factory using state-of-the-art equipment
- ◆ ISO 9001 registered facility
- ◆ Implemented the latest manufacturing technologies observing Lean Manufacturing philosophies, eliminating waste
- ◆ Products meet or exceed industry standards

Excerpts from Disposable vs Reusable Studies give Critical Assessment on the Quality of Disposables⁵

“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.”

“Both high and standard performance gowns were tested. Considerable differences were identified. They revealed that 50% of all the high performance disposable gowns had defects.”

Reusable Advantage: Safety

- ◆ Surgical gowns are intended to be worn by operating room personnel during surgical procedures, to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, particulate matter, and other potentially infectious materials (OPIM) and associated microorganisms.
- ◆ Surgical drapes are also intended to inhibit the transfer of microorganisms, body fluids, and OPIM, and are used as a protective patient covering to isolate a site of surgical incision from microbial and other cross-contamination.
- ◆ The safety of patients and staff depend on selecting the correct level of protection best suited for the procedure.
- ◆ Proper use, care and adherence to manufacturers' recommended processing guidelines, will ensure continuous, safe, barrier integrity.
- ◆ Understanding the defined levels associated with performance will allow informed and consistent choices about the type of protective products best suited for the procedure at hand.
- ◆ Choose products which are latex-free.
- ◆ Experts consider it practically impossible, in clinically unrecognizable suspected cases of CJD (Creutzfeld-Jacob Disease) for the disease to be transmitted via reusable OR textiles. The use of reusable textile products in the OR is not associated with any danger of transmission of CJD.
- ◆ Reusable surgical products are performance validated to end of life.

Disposable Errors and Incidents - Safety

- ◆ A database search at the FDA produced the following results for one single-use supplier:
“In 10 years, there have been more than 1000 reported incidents involving disposable drapes, and more than 1000 reported incidents involving disposable gowns.”
- ◆ Modification of Single-use drapes within the operating room theatre runs risk for generation of particulate, which is associated with granulomas and surgical site infection.

CSA and AAMI PB70 Standards /ORNAC and AORN Best Practice Recommendations for Reusable Surgical Linen

- ◆ Selection and use of barrier materials should be consistent with their intended purpose. Choosing the appropriate level of barrier protection for surgical gowns and drapes will provide the best opportunity to meet fiscal requirements, staff and patient safety and comfort.
- ◆ Manufacturers' written instructions for Product Care, Processing, Sterilization and Maintenance should be followed.
- ◆ Seams within the critical zone should be constructed to prevent the penetration and passage of potential contaminants. Seams are expected to meet the same level of protection in accordance with the performance claim. Microbial passage is not unidirectional. If liquids wick or transfer through pressure between sterile and non- sterile surfaces, one or both sides may become contaminated.
- ◆ Barrier materials should be as lint-free as possible.
- ◆ The sterility of items shall be measured by event-related rather than time-related practices.

Environmental Impact

“Medical waste is a necessary by-product of any hospital environment; however, the majority of regulated medical waste is produced in the OR from the use of disposable surgical supplies (i.e., surgical drapes, gowns and more).”

According to *Health Care Without Harm*, 4 million tons of general waste is produced by health care facilities in the United States each year. Using reusable surgical products provides a means to decrease regulated medical waste in the OR by an average total of 65% as well as reducing the cost of waste disposal. Disposing of waste, accounts for approximately 20% of a hospital’s environmental services budget².

Waste issues begin with the purchasing department when materials are purchased that eventually become waste requiring disposal. Reducing the amount of disposable surgical materials purchased is an important step towards reducing the amount of regulated medical waste generated.

Statement made by a major Disposable Supplier:

“Decisions on which product to use should be based on other criteria such as clinical performance, patient and staff safety, and cost-effectiveness.”

We agree that these are very important considerations; however, environmental respect is also of utmost importance and one which we cannot afford to overlook. Not only is it possible to quantify environmental benefits, but many lifecycle and product studies have successfully demonstrated that reusables **are** environmentally superior to disposables.

Additionally they are clinically preferred, offer equal or better patient and staff safety, and are more cost-effective.

Additional Environmental Considerations for a Single-Use Program

- ◆ Off-shore manufactured products generate a far greater carbon footprint.

“In one hour, a single container ship entering port generates air pollution equivalent to that of 350,000 cars.”

<http://factsanddetails.com/china.php?itemid=391&catid=10&subcatid=66>

“One giant container ship can emit almost the same amount of cancer and asthma-causing chemicals as 50 million cars”

http://www.greencarreports.com/news/1020063_pollution-perspective-one-giant-cargo-ship-emits-as-much-as-50-million-cars

- ◆ Excessive, environmentally unfriendly packaging.
- ◆ Single-use products generate in excess of 75% more environmental waste.
- ◆ Single-use products are manufactured in China and other off-shore locations which contribute to massive global pollution due to lack of regulatory bodies and good manufacturing practices.

Statistics: “About one third of the industrial waste water and more than 90% of household sewage in China is released into rivers and lakes without being treated. Water shortages and water pollution in China are such a problem that the World Bank warns of “catastrophic consequences for future generations.” Water pollution is especially bad along the coastal manufacturing belt. In many cases factories fouling critical water sources are making goods consumed in the U.S. and Europe.”

<http://factsanddetails.com/china.php?itemid=391>

Hidden Costs

Instrument Loss:

With the rise in use of disposable surgical drapes came the rise in lost instruments which were inadvertently discarded with the linen. The annual costs to healthcare associated with these losses are staggering. Some valuations have been cited to be in excess of \$150,000 annually.

The relationship of these costs are directly associated to the use of single use surgical drapes.

In an attempt to remedy these costly occurrences, hospitals have had to resort to implementing Instrument Detection Devices, geared to identifying metal objects within trash disposal sites. This equipment is being acquired to try and recover some of these costly instruments.

The cost of this detection equipment, as well as the cost of instruments which may still end up in our landfills needs to be recognized as costs directly associated with the use of disposable surgical products.

Advantages of Lac-Mac Reusable Products and Services

- ◆ Latex-free products and manufacturing
- ◆ Low cost-per-use
- ◆ Highly breathable for comfort, a physiological requirement
- ◆ Maintains thermal core temperature for both Surgical Team and Patient
- ◆ Industry-standard colour coding
- ◆ Bar Coding, Use Grid and/or RFID Chip for product traceability
- ◆ Less inventory and storage space required
- ◆ Product customization available
- ◆ Minimal packaging utilizing 100% recycled cardboard cartons
- ◆ Full size selection of gowns available
- ◆ Low-linting
- ◆ Unlimited pack configurations possible
- ◆ Levels of protection permanently identified on products
- ◆ Less time required to drape patient – no layering
- ◆ Education on draping techniques for standardization
- ◆ Waste management, gowns can be downgraded at end of use
- ◆ Support from our team of product experts
- ◆ Additional Reusable Drape Features:
 - ◆ universal draping system allows for adaptable fenestration
 - ◆ barrier section offers superior fluid management
 - ◆ directional arrows and lettering can be added to any drape product
 - ◆ tube/cord holders
 - ◆ bias indicators easily identify bottom of drape
 - ◆ fluid control pouches available



AAMI PB70 and CSA Z314.10.1-10 Levels of Protection

LEVEL 1: Minimal Risk for exposure to Fluid, Fluid Spray and Applied Pressure

When tested for water resistance in accordance with AATCC 42 (impact penetration), all critical zone components shall have a blotter weight gain of no more than 4.5 grams (g), with an AQL of 4%. The test results shall be reported in the manufacturer's product technical information.

AATCC 42:2 < 4.5 g (AATCC: American Association of Textile Chemists and Colorists)
(AQL - Acceptable Quality Level)

LEVEL 2: Low Risk for exposure to Fluid, Fluid Spray and Applied Pressure

When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure), all critical zone components shall have a blotter weight gain of no more than 1.0 (g), and a hydrostatic resistance of at least 20cm, with an AQL of 4%. The test results shall be reported in the manufacturer's product technical information.

AATCC 42:2 < 1.0 g AATCC:127:1998 > 20 cm

LEVEL 3: Moderate Risk for exposure to Fluid, Fluid Spray and Applied Pressure

When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure), all critical zone components shall have a blotter weight gain of no more than 1.0 (g), and a hydrostatic resistance of at least 50cm, with an AQL of 4%. The test results shall be reported in the manufacturer's product technical information.

AATCC 42:2 < 1.0 g

AATCC:127:1998 > 50 cm

LEVEL 4: High Risk for exposure to Fluid, Fluid Spray and Applied Pressure

When a surgical gown or other item of protective apparel is tested for resistance to bacteriophage Phi-X 174 in accordance with ASTM F1671, all critical zone components shall demonstrate passing results with an AQL of 4%. The test results shall be reported in the manufacturer's product technical information.

ASTM F 1671:2003 **Gowns**

(Standard test method for resistance of materials to the penetration of blood-borne pathogens)

ASTM F 1670:2003 **Drapes**

(Standard test method for resistance of materials to penetration by synthetic blood)

Both single-use and reusable surgical gowns and drapes are governed by the same regulatory standards covering performance claims, care & handling, labelling and overall safety practices. There are not more stringent regulations for one or the other.

*Association for the Advancement of Medical Instrumentation – (2003) Liquid
Barrier Performance and Classification of Protective Apparel
and Drapes Intended for Use in Health Care Facilities*

LINEN PROCESSING GUIDELINES:

CSA Standards for Laundry Facilities:

- ◆ Manufacturers shall supply a comprehensive maintenance and laundering instruction guide in support of all types of reusable surgical products provided.
- ◆ Instruction for efficacy protocol for validated barrier integrity of reusable surgical textiles including inspection and repair methods.
- ◆ A tracking mechanism from the manufacturer must provide recommendations for the number of times a product can be used. Bar Code labels, Use Grids and/or RFID chips should be marked each time products are laundered.
- ◆ Refer to CSA standard (*Table 2*) for Sample list of inspection criteria for stains.
- ◆ Chemicals perform essential functions in laundering processes including loosening soil, dissolving oily stains, and preventing redistribution of soil onto the textiles being washed. If chemicals are improperly used, they can damage textiles.
- ◆ Properly processed reusable surgical products pose no health risk to patient, surgical team or to our environment.
- ◆ All textiles shall be laundered before initial use.
- ◆ Care and maintenance procedures shall be designed and implemented to preserve the functional characteristics for reusable gowns and drapes.

Refer to the Lac-Mac “Manufacturer’s Instruction for Use Binder”, which is supplied to our customers, detailing instruction for maintenance, cleaning, sterilization, packaging and storage in support of our surgical products.

Reference: CSA Standards Association: Selection, Use, Maintenance, and Laundering of Reusable Textile Wrappers, Surgical Gowns, and Drapes for Health Care Facilities – Z314.10-03

“Gortex and Cotton Drapes/Gowns/Wrappers” – Published by a Disposable Supplier - Refuted by Lac-Mac

- ◆ Gortex deteriorates over time with washing and handling.

FALSE: *The barrier properties of our GORE[®] Surgical Barrier Fabric used in our Level 4 and Level 3 Surgical products is third party tested and validated to end of life.*

- ◆ Gortex has very specific washing requirements. Washing machines must be adjusted to accommodate special detergents, chemicals and timing.

FALSE: *There are no special machine adjustments required for processing products made with GORE[®] Surgical Barrier.*

- ◆ Gortex must be sterilized at a lower temperature than poly-cotton (gortex is an oil-based product; if the sterilizer is too hot the fibres expand and shrink to weaken and shrink the garment).

MISLEADING: *Surgical products made using GORE[®] are made using Polyester which is in fact a derivative of oil, like single-use products are, however sterilizing any product at too high a temperature may result in damage to the product.*

- ◆ Very dependent on quality of labour to “guarantee” barrier and sterility.

MISLEADING: *Are they suggesting that single-use products are NOT dependent upon quality of labour for barrier and sterility assurances? That is alarming.*

- ◆ Light table/light wand inspection is only as good as the training level of staff and the time this staff invests for the use of the light table – quotas of drapes per day.

TRUE: *Reusable products are light table/light wand inspected by trained employees providing jobs within the community for family, friends and neighbours.*

- ◆ No adhesives on drapes.

TRUE: *Our reusable drapes are not manufactured with adhesives, although adhesives and wash soluble tapes are available to complement our products.*

- ◆ No fluid collection pouches to support Occupational Health and Safety initiatives.

FALSE: *Lac-Mac manufactures various types of reusable drapes featuring fluid collection pouches.*

- ◆ It is difficult to launder Gortex to fully remove petroleum jelly, cement, mineral oil and body fat tissue: all of which are encountered every day in Operating Rooms. If these products cannot be removed then the drape must be disposed of according to CSA standards.

MISLEADING: *Surgical products made using GORE[®] Barrier Fabrics are easy to launder and most stains are readily removed during laundry processing. However, like any textile product, the composition of some stains renders them difficult or at times impossible to remove. CSA standard and AAMI ST65:2008 both include a list of “acceptable stains” which*

should be referred to if acceptability is in question. Only in the most extreme cases is disposal required.

- ◆ Linen gowns, drapes and bundles are larger and heavier than their single-use equivalents.
MISLEADING: *Reusable linen packs can be larger than single-use depending upon the composition and contents. It is difficult to make a blanket statement regarding pack size.*

- ◆ Touching a damp linen bundle contaminates it.
MISLEADING: *Following Best Practices Recommendations and Standards will ensure safe handling of sterile products.*

- ◆ Areas of linen in bundles may become overheated. Steam does not penetrate all linen materials the same, therefore the temperature is not the same throughout the bundle. This is why standards have size and weight restrictions for bundles.

MISLEADING: *Following standards and best practice, sterilization protocols will ensure complete, thorough and validated sterile bundles. Packs and bundles would not be released for use if sterility was in question.*

- ◆ Prions (known and unknown: i.e., CJD) do not respond to sterilization.
TRUE: *Adherence to recommended best practices is crucial and especially so when dealing with any case where Prions may be present.*

- ◆ Patches often fail the ASTM 1670 & 1671 standards for barrier.
FALSE: *Following our recommended patching guidelines will provide a secure non-fail patch. Patches made from the same Level of barrier material will perform to the same result as the barrier fabric to which they are applied.*

- ◆ Quality of steam may be an issue. Sometimes salts and residue become absorbed.
FALSE: *Steam sterilization is a validated and proven effective method for sterilization of reusable textile products. Facilities have controls in place and follow regulated protocols.*

- ◆ Cotton drapes have no barrier qualities.
TRUE/MISLEADING: *Most healthcare facilities have not used cotton as a barrier in more than 20 years. Lac-Mac does not manufacture any surgical products using cotton.*

Note: 'Goretex' as indicated within the sited competitive document, is a brand associated with outerwear products, and should not be confused with GORE® Surgical Barrier fabric which is used within the Medical Products Division.

Gore and Designs are trademarks of W.L. Gore & Associates, Inc.

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