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Sterile Barrier Association

STERILISATION BARRIER SYSTEMS – SINGLE USE OR RE-USEABLES

Sterility and its Maintenance

Sterility and its maintenance, together with the prevention of cross-infection, are at the top of any list of critical factors in patient care. The barrier materials and systems used for instruments, dressings, medical devices, etc., play a vital role in ensuring that sterility is not only efficiently accomplished, but also effectively maintained to the point of use. Making the correct choice is therefore vitally important.

Sterility maintenance is an event related, rather than a time related function. Retention of sterility of the device etc. is dependent, not only on the barrier material and method of sterilization, but also on the challenges it meets after packing and sterilization. These include, but are not limited to, exposure to humidity, airborne micro-organisms and to organisms on the hands of personnel. It can occur during transportation to the clinic, ward or operating theatre, during storage and when opened. Obviously, the degree of contamination is proportional to the handling activity or conditions and other adverse events which may take place. Maintenance of sterility is therefore directly related to the ability of the barrier material to prevent organisms from reaching sterile contents, to resisting physical damage and to the handling techniques employed during storage, transportation and subsequent use. Inappropriate barrier materials or systems can lead to a loss of sterility, which may increase cross-infection levels, whatever their source.

Sterilization Barriers – the Alternatives

Commonly available barrier materials fall into two categories: Single use and Re-usable. Single use materials consist of papers, non-woven and plastic materials used singularly and in various combinations. Textiles (commonly known as linen) and rigid containers represent the re-usable category. The major factors which should be considered when deciding on the most appropriate method for a particular application are performance, integrity, storage, transportation and handling, environmental considerations and last, but by no means least, cost.

Sterilization Performance and Integrity

In order to achieve the initial requirement of “sterility”, the barrier material must allow complete penetration of the sterilant to all component parts. When using a gaseous sterilant, the barrier system must allow for its easy entrance and

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removal during the process. A distinct advantage for single use barrier materials over containers is that, even when double layering is used, as recommended, their high surface area and permeability compared to small filter ports, facilitates efficient sterilization of full and bulky loads. The high surface area and permeability of single use barrier materials is also an advantage when seeking to ensure the removal of condensate generated when steam sterilizing heavy metals objects, aluminium containers, and large instruments. Containers are much more likely to require an absorbent flexible inner wrap to limit the effects of excess moisture. In addition, single use barrier materials, being of light weight, require much less energy during the heating cycle of the sterilization process.

Single use materials, particularly those conforming to national and international standards, offer proven microbial barrier properties. Provided that the manufacturer's instructions are followed, these materials ensure a very high degree of protection during storage, handling, transportation and aseptic opening. Conventional textiles, whilst allowing for sterilization processing, provide a very poor microbial barrier. Repetitive uses may result in minor damage and reduced barrier properties which are not always obvious.

Rigid containers offer good barrier characteristics, especially when new. They are however, susceptible to damage and need frequent and thorough cleaning and inspection of filters, valves, lid clips, gasket seals and assembly during their life cycle.

Storage, Transportation and Handling

Storage begins before any product is actually used. Single use barrier materials require minimal storage space and are supplied in a wide range of quantities and sizes. Similar comments can be made about textiles, but both containers and textiles need a larger inventory and large areas of multiple storage spaces.The limited size range of containers restricts their loading capability in the sterilizer. Additionally, single use barrier materials add virtually no extra weight to a procedure pack or theatre tray.

The wide range of sizes and types of single use sterilization materials allow for convenient and more economic solutions to barrier problems. Another benefit is that peeling open or unwrapping sterilization materials allow aseptic presentation at the point of use and may also provide a sterile field at no extra expense.

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Environmental Considerations

Calculating the environmental burden of different types of materials is difficult. Whether comparing the impact of energy required to produce aluminium, or the fossil fuel to produce plastics, or a managed renewable resource, such as trees for paper, the analyses are not straightforward. Re-usable containers may appear to offer a more environmentally acceptable option. However, these systems require replacement of the inner wraps, filters, indicators, labels and closures.
In addition, containers and textiles need large quantities of water, detergents, disinfectants and energy on a daily basis. Single use materials, on the other hand, may be difficult to recycle because they have been contaminated by infectious materials, or they are made of composite materials. They may however be incinerated, using approved combustion techniques. The energy recovered from that process makes them an environmentally acceptable option. To provide a complete answer to these questions a life cycle assessment for each system is required. This is an extremely complex and costly study which may be subject to interpretation.

Cost

The introduction of single use products into hospitals in the early 1960s lead to a large reduction in nosocomial infections. A significant factor for this improvement was the replacement of textiles by single use materials.

Single use material costs are limited to the initial purchase price and disposal costs. Costs associated with re-usable products include their initial purchase price, storage, capital costs component replacement costs, labour, energy, inspection, repairs (material and equipment), losses, rejection rates, chemicals, maintenance, water treatment, and eventually replacement costs.

The cost of the various systems will vary from user to user and from application to application. Completion of the following table using the costs for your particular application should help you to define this more clearly

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COST COMPARISON

Single Use			Container		Textile	
Disposable Items						
	[	Outer Material (One bag, pouch or wrapping paper)				
	[	Inner Material (One bag, pouch or wrapping paper)			[	
		Filters	[			
		Labels	[		[	
		Closure or seal	[			
		Absorption pad	[			
	[	Autoclave tape or indicator strip	[		[	
Process Costs						
	[	Barrier Material/Container/Textile Sterilization Energy(Mass x Kcal x Cost per Kcal or Kjoules)	[		[	
		Washer Energy Cost (KW x Unit Cost divided by Packs)	[		[	
		Drying Cost (KW x Unit Cost divided by Packs)	[		[	
		Water (Usage per hour x Cost divided by Packs per hour)	[		[	
		Chemical Cost per Pack	[		[	
	[	Waste Disposal Cost including water and treatment	[		[	
		Pressing/ Folding/ Transportation (Labour and Energy)	[		[	
		Inspection Cost per unit per occasional use	[		[	
		Pilferage rate	[		[	
		Repair and maintenace labour and materials	[		[	
		Rejection cost	[		[	
	[	Collection recovery and disposal	[		[	
Capital Costs						
		Initial Cost of Container or Textile + interest divided by life span	[		[	
		Washer/Disinfection Unit (Capital + interest divided by estimated throughput)	[		[	
	[	Heat Sealer (Capital + interest divided by estimated throughput)				
	[	Storage space and racking	[		[	
		Total Cost per Pack				

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