Much research has been conducted to devise suitable packaging materials for in hospital sterilization. Currently, a wide variety of packaging materials and methods are available to the health care market including pouches, flat wraps and rigid containers - all available in varying sizes and configurations. Each type of material has one or more specific properties and characteristics that will support the principles of packaging. Each type is appropriate for specific sterilization processes.

Manufacturers of each type of packaging material must demonstrate by appropriate scientific evidence that (a) the material is suitable for the specific sterilization methods and cycles for which it is designed and recommended and (b) that the material provides an effective barrier to contamination when used or reused according to the manufacturer’s written instructions.

Additionally, the manufacturer should provide the user with adequate inservice education, including complete instructions for one-time use and/or reprocessing procedures essential for effective use.

NOTE: The present standards of performance for steam sterilizers manufactured in the United States (steam gravity, pre vacuum, and pulsing vacuum sterilizers) include testing of the temperature profiles of the sterilization and drying phases of the cycle. A standardized challenge test pack containing gowns, drapes, gauze swabs and wrappers made of standard 140-thread-count muslin (100% cotton) has been used. The test does not address the sterility maintenance or barrier qualities of the materials used.

Because it is used as the packaging material in this challenge pack, and also because it was a common packaging material years ago, 140-thread-count cotton muslin is considered a “standard” material against which to judge other materials for steam penetration. Manufacturers of packaging materials must be able to demonstrate, by appropriate testing, that the material is equivalent to or better than 140-thread muslin for steam penetration.

Most U.S. manufacturers have established their own specifications for the weight, strength, sterilant permeability and water repellency treatments for packaging materials. To date, performance standards for packaging materials have not been established in the United States. There are however, comprehensive British and ISO standards for the manufacture of kraft-type paper, crepe paper, heat sealable pouches and reels constructed from paper and transparent plastic films.

Standards for single-use and reusable packaging materials that are currently being formulated by the member nations of the European Common Market (Euromart) and the International Standards Organization (ISO), will undoubtedly affect the future of manufacture and use of medical grade papers, non woven wraps, as well as other materials used by health care facilities world wide.

WOVEN TEXTILES
Woven textile fabrics to be used as sterilization wrappers are made of natural fibres of cotton, linen...
Alison J.F. Martin, Clinical Education Coordinator, International Healthcare Division of the STERIS Corporation, recently visited South Africa to deliver a series of lectures. While she was here, Steriview interviewed her and asked her the following questions:

Q: You mention Standards and Recommended Practices for Sterilization Monitoring that have been defined by organizations such as JCAHO, AAMI, AORN and CDC in the USA in your presentation. What was it like before CSSD managers had these guidelines to work with?

A: I would think that there was little consistency in practice and procedures within CSSD departments. Each department manager probably considered what they had put in place to be appropriate, efficient and sufficient.

Q: We do not have similar Practice Standards in South Africa, would you recommend that CSSD managers here follow the USA standards and if so, why?

A: The AAMI guidelines, AORN recommended practices and JCAHO standards would provide some direction for CSSD managers in monitoring sterilization practices. They have been utilized in the United States for many years and could provide a model from which to develop South African practice standards and guidelines.

Q: You mention that Biological Indicators should form an important part of sterilization monitoring but that you do not believe that Rapid Readout technology utilizing enzymes to speed up the test results is a good thing. Would you like to tell us why?

A: It is not a good thing to believe you have a true biological indicator in the Rapid Readout. A biological indicator is defined by AAMI as, “a standardized (known population and resistance and stability), viable population of microorganisms known to be resistant to the mode of sterilization being monitored”. No enzymes are utilized. Utilizing a biological indicator provides indication that the conditions were or were not met for sterilization to have occurred. Remember, biological monitoring through the use of chemical or biological indicators does not verify sterility. Biological monitoring is a process of which the purpose is to determine the efficiency of a particular sterilization cycle.

Q: You cite effective Pre-Cleaning as being absolutely essential in order to achieve sterilization. Can you elaborate on this?

A: Pre-cleaning of instruments and devices prepares them for the sterilization process. It removes bioburden from the surfaces so the surfaces can be contacted by whatever form of sterilization method is chosen. For example, for steam sterilization to be effective the steam needs to be able to reach the surfaces of the device. If bioburden is present, the heat from the process just cooks the bioburden onto the surface of the device and the device is not sterilized completely since its surfaces cannot be contacted directly.

As I said in my presentation, it is stated by W. Rutala, PhD, MPH, CIC, when commenting on the effects of cleaning, “studies have been done and shown a 4 log reduction in microbial contaminants with cleaning alone.”

Pre-cleaning is one step that assists to assure the sterilization process can be complete and effective.

Q: Event Related Shelf Life provoked plenty of discussion at all your presentations. What steps should a facility follow if it wants to implement this system?

A: First, the hospital needs to evaluate its current system... how is shelf life currently defined, what materials are being used for wrapping and packaging of instruments, how are items being processed, how are processed items stored, what are the storage conditions, how are items handled and transported.

An event related system requires that storage conditions are maintained and the handling and transport of processed items is appropriate. All individuals who handle, transport and utilize processed items need to be aware of how to identify when a processed item is considered unacceptable for use and respond accordingly.

If a decision is made by all those involved along with the Infection Control practitioner to move to an even related system then, define how the process will work. Communicate, provide policy and education to those involved prior to implementation. Periodic evaluation of the system following implementation is also key.

Q: Glutaraldehyde is still used extensively in South Africa as a high level disinfectant for instruments. You mentioned that STERIS SYSTEM 1 has largely replaced glutaraldehyde in the USA, can you tell us more about this product?

A: Disinfecting of instruments with glutaraldehyde does not kill all forms of microbial life. Sterilization is the only process which kills all microbes including spores. STERIS SYSTEM 1 is a tabletop processor which provides rapid, low temperature, chemical sterilization of immersible instruments and devices. Just In Time for use. It was developed over ten years ago and provides a standardized cycle for sterilizing both rigid and flexible endoscopes which is safe for the user, the environment and the devices.

Q: What materials are being used for wrapping and packaging of instruments? How are processed items stored, what are the storage conditions, how are items handled and transported?

A: An event related system requires that storage conditions are maintained and the handling and transport of processed items is appropriate. All individuals who handle, transport and utilize processed items need to be aware of how to identify when a processed item is considered unacceptable for use and respond accordingly.

If a decision is made by all those involved along with the Infection Control practitioner to move to an even related system then, define how the process will work. Communicate, provide policy and education to those involved prior to implementation. Periodic evaluation of the system following implementation is also key.
and/or blends of cotton and synthetic materials such as polyester and chemically treated fibres (Quarpe®) in various thread counts (number of threads per square inch) and thread weights. They are readily available to the health care market from many manufacturers. Cotton fabrics are extremely penetrable by steam, ethylene oxide and low-temperature steam/formaldehyde. They are not generally recommended to be used as packaging materials for ethylene oxide sterilization. Because they are highly absorbent, cotton wrappers may absorb the moisture themselves, preventing adequate moisture penetration to all surfaces of the packaged contents. Due to potential for charring and deterioration at high temperatures, their use is also questionable for dry-heat sterilization.

According to documented studies, the bacterial barrier efficiency (resistance to dust and moisture penetration) afforded by woven textile wraps is considered to be the least effective of all the various wrapping materials available to the health care market.

Application of plastic, wraps (called dust covers or sterility maintenance covers) to textile sterilized packages adds protection from potential dust and moisture penetration.

All wrappers made of woven textiles are reusable. Any barrier qualities that new textile wraps may possess are diminished by repeated laundering and sterilization cycles.

Prior to each use, they require laundering, delinting and inspection (over illuminated tables) for holes, worn spots, breaks in the fabrics and stains.

Stitching should never be used as a method of repair or mending of holes in wrappers. Small holes and worn spots can be patched with vulcanized or thermoseal patches. Patching of fabrics should be dependent on the extent of wear of the fabric, location and size of holes and tears, effectiveness of the wrap following patching and security of the patching following sterilization.

**Non woven fabrics** are made by methods other than weaving, allowing fibres to be pressure-bonded together to form sheets of fabric.

One nonwoven, SMS, (Spunbond-meltblown-spunbond) is made by a process whereby polyolefin plastics are melted under high heat, extruded into fibres and pressure-layered together to form the sheets of fabric.

**Flat wrapping products constructed of nonwoven SMS fabrics for sterilization wrapping are designed as single-use disposable products; they must not be reused.**

They are available in a range of weights and a wide variety of sizes. Prior to use, individual wrappers should be inspected for pinholes and either thinness or thickness of localized areas of the fabric sufficient to impair its intended functioning.

Although these fabrics generally have the flexibility and handling qualities of muslin for wrapping procedures by conforming to large packs and odd shapes they also can be torn or punctured by sharp edges of devices and/or instrument pans.

Non wovens are suitable for steam, steam formaldehyde and low temperature sterilization processes such as ethylene oxide and gas plasma and provide excellent bacterial barrier properties. They are virtually lint free and are generally resistant to dust penetration due to the very small spaces between the fibres. Plastic polymers, such as polyolefins resist liquid penetration although they do provide excellent water vapour (steam) transmission.

Nonwovens may retain water caused by steam condensation on surfaces of instruments and metal utensils because the fabric itself does not absorb moisture

**PAPERS**

Due to its method of manufacture, paper is essentially a nonwoven material intended for single use. Flat paper wrappers used for packaging procedures differ in many characteristics to the fabrics that are more commonly designated as “non-woven materials”; in particular, they generally lack the flexibility of other types of nonwoven wraps.

**Kraft type papers** are generally smooth-surfaced. They are available in a variety of sizes to accommodate many medical devices and porous or soft-good items. Pouches of medical grade papers specially formulated for sterilization are also available.

**Crepe-type paper** has a surface that is two-way creped to allow stretching and adaptability to the types and sizes of items to be packaged. Both kraft and crepe papers must be of high-grade stock designated as medical grade with known specifications and consistent quality of manufacture. Prior to use, they must be inspected for pinholes, tears, creases or other flaws that would compromise the integrity of packaged items. Papers are easily penetrated by steam, ethylene oxide, low-temperature steam/formaldehyde and dry-heat sterilants.

**Crepe papers have the disadvantage that they are not as drapable as woven or nonwoven materials which means that more care needs to be taken when laying out flat to form a sterile field. This disadvantage is countered to a great extent by the fact that paper generally provides a better bacterial barrier than woven and nonwoven wraps, and that it is more cost-effective to use.**
Reliance 300 Sterilization Wrap Composition

<table>
<thead>
<tr>
<th>Cellulosic bleached ECF virgin pulp</th>
<th>Reliance 310 100%</th>
<th>Reliance 320 100%</th>
<th>Reliance 340 65%</th>
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<tbody>
<tr>
<td>Synthetic fibres</td>
<td></td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Acrylic binder</td>
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<td>25%</td>
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Reliance 300 benefits from the scientific progress made in the Ahlstrom Paper Group Research and Competence Centre and from the Group’s advanced production technology, which results in the following benefits for the user:

**Safety** - it is an excellent bacteriological barrier

Reliance 300’s homogeneous texture facilitates the penetration of steam in sterilizers and provides an extremely effective microbiological barrier.

**Strength** - long lasting sterility

Reliance 300 is strong whether dry or wet, and it maintains sterility through time as well as providing perfect pack integrity.

**Softness** - highly comfortable to use

Reliance 300 is pleasant to the touch and easy to use.