The new European standard EN 868-2 has been approved in order to harmonise the various existing standards in Europe such as BS 6254, DIN 58953-5 and the French Pharmacopoeia 134 and for the first time to create a standard that covers all materials and systems used as a means of maintaining sterility. The standard encompasses 8 parts as can be seen from the accompanying diagram. The first part EN 868-1 which was mandated on 27 January 1997 is a general requirement and is known as the horizontal standard. Parts 2-8 which are known as the vertical standards have recently been approved by the European Committee for Standardization (CEN) on the 13 May 1999.

The purpose of this review is to give readers a better understanding of the European Standard EN 868-2 Packaging materials and systems for medical devices which are to be sterilized - Part 2: Sterilization wrap - Requirements and test methods. It must be borne in mind when studying the provisions of this standard that they supplement the general requirements of the standard EN 868-1. Parts 1 and 2 therefore need to be read together when comparing this new standard to other existing standards such as BS 6254.

The General Requirements for Part 1 are :-
- Compatibility with the medical device
- Compatibility with the method of sterilization
- Compatibility with the labelling system
- Toxicity
- Microbial Barrier
- Shelf Life

It states that it is the manufacturer’s responsibility to provide documentation, to confirm the compatibility of the packaging system, with the medical device, method of sterilization and labelling system. The manufacturer must also provide information on toxicity and also most importantly, supply certification for a recognised international barrier test such as DIN 58953 Part 6, BS 6256 :1989 or ASTM F 1608 Bacterial Filtration Efficiency Test. Proof must also be provided on shelf life, as such, manufacturers must give a period of time that the pack will remain sterile, given specific circumstances. The EN also points out that the maintenance of sterility is event related rather than time related and many factors may affect this, such as the level of micro-organisms in the environment and the size of particles on which they occur. The first part of the standard very much relies on information supplied by the manufacturer, the second part assures the physical characteristics of the product.

**EN 868-2 General requirements for Sterilization wrap**

This standard is as specific as the BS 6254 and 6255. The difference being that this standard covers all wrapping materials, including linen, barrier fabrics, papers, paper/synthetic blends or wholly synthetic non-wovens. The standard states that the product must first comply with EN868-1, and then with the specific parameters detailed in Part 2, which include :-
- Raw Materials (What can and cannot be used)
- Grammage (A controlled tolerance level of +/- 5%)
- pH, chloride and sulphate levels
- Alcohol Repellency to measure the suitability of a material in terms of low density liquids with respect to its application as a sterile field and or drape.
- Skin Irritation to ensure that the material does not cause an allergenic response during wrapping / handling or as a patient drape.
- Surface Resistivity to ensure that the material does not create a static build up which could create problems in the Operating Theatre.

**Continued on page 3**
Dry Heat sterilization is widely used in the pharmaceutical industry as steam, ETO, radiation, gas plasmas, or liquid sterilants cannot effectively sterilize IV solutions, parenterals, and powdered medicaments. Although dry heat is not well suited for terminal sterilization of packaged pharmaceutical products or medical devices, it is widely used to sterilize components and equipment used in aseptic manufacturing operations. High speed continuous sterilization of glass containers for pharmaceutical dosage forms, is one example of the efficient use of this sterilization method. 

According to Perkins, dry heat should only be used where direct contact with saturated steam is impractical or unattainable and although dry heat is the preferred method for sterilizing orthodontic and delicate ophthalmic instruments, it is not widely used in hospitals. This begs the question of whether there are other applications as well that would warrant the purchase of another piece of sterilization equipment? To answer that question one needs to understand the dynamics of dry heat sterilization.

**Advantages**

The principle advantage of dry heat sterilization is its penetrating power. It is not as corrosive as steam for metals and sharps and it does not erode ground glass surfaces. This makes it suitable for delicate sharp surgical instruments, reusable needles, and glass syringes. (Instruments must be thoroughly dried after cleaning in order to reduce any tendency for corrosion during the dry heat cycle.)

In addition, it is suitable for materials that could be damaged by moisture or that would be impermeable to steam such as petroleum jelly, oils, and powders. Another advantage is its relatively low cost and availability wherever there is an electrical outlet. These features have made it the method of choice in dentist’s offices, small clinics (particularly in underdeveloped countries), and for such procedures as electrolysis. AIDS and the increased awareness of the various forms of Hepatitis have created a market for sterilizers wherever skin is penetrated, for whatever reason. Items to be sterilized by dry heat can be packaged in solid metal trays with lids, closed glass jars, all-paper pouches, aluminium foil, and Nylon™ film.

**Disadvantages**

It is only possible to use gravity and convection dry heat sterilization for materials that will withstand high temperatures (up to 170 degrees C) for long periods of time. The newer rapid heat transfer units will sterilize in as little as six minutes but at a very high temperature of 190 degrees C. Long exposure periods and the need to overcome stratification of temperatures within the chamber are additional disadvantages. Overloading dry heat sterilizers delays heat convection either by circulation or by heat absorption, therefore it is best used with relatively small loads in relatively small chambers. Packaging materials are limited to those that can withstand the chosen times and temperature.

**Time at Temperature**

Heat in the absence of moisture, is a much less efficient process than moist heat, therefore a much higher temperature for longer periods of time must be used. Exact time and temperature models are difficult to establish because the method for destroying micro-organisms by dry heat is largely unknown. What is known is that death occurs primarily as on oxidation process. Studies done by Phiel et.al., in 1967 indicated that other possibilities should also be considered: an effect on DNA is one such possibility. Dry heat sensitivity of spores could result from the genetically determined differences in the water content, or in the water retaining capacity of the spores.

Published information on the exposures necessary to kill pathogens by dry heat shows that while 1 1/2 hours at 100°C will destroy all vegetative bacteria, 3 hours at 140°C is necessary for most resistant spores.

**Sterilizers**

The three mechanisms of heat transfer in dry heat sterilization are conduction, convection, and infrared radiation (IR). Heat penetration of materials by way of conduction is dependent in part by heat availability in the surrounding medium. Air is the chief heat transfer medium used in dry heat sterilization, but it has low specific heat and poor thermal conductivity properties. It takes about six times as much air to transfer a given amount of heat to an object as is required for steam at the same temperature. Due to this low heat transfer rate of air, gravity convection sterilizers require long sterilization times at high temperatures. In addition uniform heating and reproducible cycles are difficult. Heat transfer can be made more efficient by forced convection utilizing blowers and perforated baffles.

*Static-air Gravity Convection sterilizers* operate much the same as an oven at home. Air circulates in

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**Pharmacopoeia Recommendations for Dry Heat Sterilization**

<table>
<thead>
<tr>
<th>Temperature °C</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>160</td>
<td>120</td>
</tr>
<tr>
<td>170</td>
<td>68</td>
</tr>
<tr>
<td>180</td>
<td>35</td>
</tr>
</tbody>
</table>

*Figure 1*
ments can be categorised as follows:- 

- Synthetic materials. These require paper/synthetic blends or wholly synthetic materials. (which include linen, barrier fabrics, paper, Crepe paper, and Non-wovens) 

The standard then details the physical properties of a material, in terms of fluid resistance, with respect to its application as a sterile field or drape. 

- Stretch to ensure the elongation of the material and thereby differentiate it from other papers. 

BROWNE STERILIZER CONTROL TUBES offer an effective and immediate check for Dry Heat Sterilization

Browne Sterilizer Control Tubes allow you to easily and economically monitor your dry heat and fluid sterilization processes. The design of the tube is perfectly suited for use not only in dry heat but also in fluid sterilization where the tube can actually be placed in a control sample of the solution being sterilized. Browne Tubes have always been, and still are the most effective chemical indicators for routine monitoring of dry heat and fluid sterilization, particularly as they offer significant time and cost savings over thermocouple and micro biological test methods.

**BROWNE STERILIZER CONTROL TUBES**

**Properties**

- Tear Strength in order to avoid ripping on the sharp corners of trays. 
- Wet and Dry Burst Strength in order to prevent the pack from bursting during the autoclave cycle. 
- Wet and Dry tensile strength to avoid tearing during wrapping and handling. 
- Stretch to ensure the elongation of the material and thereby differentiate it from other papers.

EN 868-2 Specific Requirements for Sterilization wrap

The standard then details the physical characteristics necessary for Plain paper, Crepe paper, and Non-wovens (which include linen, barrier fabrics, paper/synthetic blends or wholly synthetic materials). These requirements can be categorised as follows:-

- Water repellency to prevent the ingress of water-borne bacteria. 
- Mason Jar to measure the suitability of a material, with respect to its application as a sterile field or drape. 
- Pore size in order to control the ingress of air-borne bacteria.

Browne Sterilizer Control Tubes

Easy To Use

Select the Control Tube suited to your sterilization parameters (time/temperature) and distribute them throughout the load. For dry heat place the tubes throughout the load closely beside or inside the most inaccessible articles to be sterilized. (Instructions for use and colour guides are included with each box). The

Browne Control Tubes will show you immediately if the time at temperature was achieved.

**Conclusion**

These criteria have been designed to safeguard and provide the end user with a suitable system for packaging materials that require sterilization. There is a perception in the South African market that the requirements of EN 868 Parts 1 and 2 are less onerous than the long standing BS 6254 and BS 6255 standards. This is not the case and the dictum caveat emptor (let the buyer beware), very much applies to the purchasing of Sterilization wrap by your particular hospital.
DRY HEAT STERILIZATION

This type of dry heat sterilizer has more moving parts and is consequently more expensive to buy and maintain.

The third and newest type of dry heat sterilizer is the Rapid Heat Transfer Sterilizer. It utilizes heated air that moves at a rate of 750 metres/minute at a very high 190 degrees C temperature. This high temperature, high velocity air transfers heat in such an efficient manner that the manufacturer claims that sterilization can take place anywhere from 6 to 12 minutes, depending upon the items being sterilized and whether or not they are packaged. As is the case with all methods of sterilization, the higher the temperature, the greater the concentration of sterilant and a faster process.

Monitoring

As part of its review criteria for pre-market 510(k) notification submissions for sterilizers, the FDA requires manufacturers to use biological indicator challenge test packs in the performance validation of their products and to recommend challenge test packs to users for routine monitoring of sterilization cycles. There must be a test pack for each type of cycle indicated in the labelling\(^1\). The 510(k) submission must also include a description of how the test pack(s) present a rigorous challenge to the sterilization process, the rational for the composition of the test pack, and a description of how the test pack itself was validated. The Association for the Advancement of Medical Instrumentation (AAMI) committees have proposed an example of how a challenge biological test pack could be assembled by any facility intending to use something other than that which is recommended by the sterilizer manufacturer. (See AAMI's Recommended Practice ST50.)

A number of chemical indicators suitable for dry heat sterilization are available on the market although it is important to verify their accuracy in measuring temperature and time at these very high temperatures. There is also no substitute for mechanical monitoring with well-maintained and calibrated temperature gauges.

Conclusion

Dry heat sterilization can be used for many things besides the rare case of sterilizing talc. The ability to just “plug-it-in” has a great deal of appeal in many different environments. It is quicker and safer than ETO in sterilizing delicate ophthalmic instruments and it’s ideal where low cost and portability are the key criteria. It is appropriate of use in dental offices where quick easy sterilization of dental equipment is required.

As Perkins wrote so succinctly: Most people responsible for the purchase, operation, and maintenance of sterilizers are unaware that speed is the militant force working against sterilization. It reduces the overall factor of safety; it becomes the accomplice of trapped air, and it demands a high degree of reliability in functional and mechanical controls. It is important to remember that sterilization is an event. It requires the maximum control of all variables so as to effect a minimum margin of doubt in the end result\(^8\).

References

6. Perkins, op.cit
8. Perkins, op.cit