

INFORMATION SHEET 47

27 October 2016

Safety Aspect of Gauze and Swabs



Introduction

Whilst the treatment of chronic wounds developed rapidly in the latter part of the twentieth century and continues to do so today, there is and will be a continuing need for the apparently simple gauze based dressings for use as absorbents and packing in operative procedures, wound cleansing and general patient care. In comparison to the complex wound management products used for the treatment of difficult to heal wounds, these 'traditional' dressings have become regarded as commodities and the properties cited in standards and monographs given little or no regard. These properties or requirements were developed over many years and were included in the standards to try to ensure adequate performance or to reduce risk to patients, requirements which are just as pertinent today as they ever were.

Original standards were simple construction standards, often scoffed at and considered restrictive but they evolved in the absence of adequate performance test methods simply because they demonstrated how to make a product that did the job. We are told that the very first recorded specification for a medical gauze appeared five thousand years ago in the Egyptian book of the dead as a specification for bandages used in the mummification process. Examination of mummies and their wrappings currently on display in many museums shows them to be in remarkably good condition given their vintage.

The traditional raw material used for these 'simple' dressings has been cotton and, as it is a renewable source, it is the material of choice today.

A brief description of the Cotton Gauze Production Process

Cotton 'bolls' that are harvested from plants annually are contaminated with residues of leaf debris, seeds and seed shells. Much of this plant debris is removed at the plantation prior to the cotton being baled for shipment to the textile producers. The first stage of the process is then to card the fibres into parallel slivers, which also helps to dislodge a high proportion of the remaining leaf and shell. Next these slivers are twisted or spun into yarns.

Yarns are set onto looms to be woven into the raw gauze fabric but prior to this the lengthways warp threads must be sized or stiffened to facilitate the passage of the loom shuttle carrying the widthways weft threads. This process provides us with the basic fabric known as 'grey' cloth.

Raw cotton fibres contain a natural wax which renders them completely non absorbent and this, together with the size applied to the warp threads must be removed in order to impart the absorbent properties essential for the finished dressings to function properly. This is achieved by a bleaching process that uses a solution of alkaline peroxide and detergents to clean and bleach the fabric to a good absorbent white colour. The bleaching liquors are subsequently washed off and the dried fabric is now ready for conversion into the finished products.

Standard Requirements for Gauze Based Dressings.

BS EN 14079:2003 is the European standard covering performance requirements and test methods for cotton gauze and absorbent cotton and viscose gauze fabrics. Earlier, but no less authoritative standards are the monographs set out in the 1988 edition of the British Pharmacopoeia. These monographs cover the x-ray detectable components as well as the gauze fabrics. At first glance these standards and monographs appear to be very prescriptive – but there are good reasons for them and it is worthwhile examining them more closely. Even if a medical gauze does not claim compliance with BS EN 14079 or the BP monographs, the properties described are still relevant.

Construction

Whilst when properly cleaned, cotton is absorbent, the volume which the fibres themselves can hold is relatively small. For this reason, a swab is made from a large area of fabric which is folded several times to provide a bulky pad which consists of layers of gauze but mainly air spaces within the body of the pad. It is these air spaces which retain the bulk of any fluid absorbed. Hence an eight-ply pad will have eight layers of fabric, a twelve-ply twelve layers etc.

There are other aspects in the construction of swabs which must be taken into account if risks to patients are to be minimised. Because of the open nature of the fabric it is impossible to cut it without generating some threads which could detach from the pad. Hence all cut edges should be folded inside. In the event of a loose thread becoming detached from the body of the cloth, this will prevent it from being deposited onto or into the patient. Similarly, BP monographs require that all x-ray detectable components are securely fixed to the fabric. When a detectable thread is used this is best achieved by fixing it to the gauze so that it is folded into the body of the pad thus ensuring that if the fixation method fails, the thread should remain trapped within the swab. When large abdominal swabs are produced, strips or patches of detectable material are often used. These can be secured by stitching them into one corner of the pad. Abdominal swabs are usually supplied with a tape attached to one corner. This is draped outside the body to facilitate removal at the end of the procedure. It is vital that such tapes are securely attached to the body of the swab otherwise it may become detached when pulled, leaving the swab itself in the body cavity.

The BS EN 14079 standard and monographs list a series of criteria and test methods for gauze and related products, all of which are related to either performance or safety. Each is worth a brief examination.

Absorbency

This is a rather crude test but provides a very simple means of assessing the prime function of the product. Compare a sample of grey gauze with a fully prepared swab to see how effective a very simple test can be.

Acidity or Alkalinity

This test will demonstrate if all the alkaline caustic soda used in the scouring and bleaching process has been removed. Sometimes the cloth is rinsed with a mild acid solution to neutralise the alkali. It is important to ensure that there are no traces of this left behind, as it may have the potential to risk harming patients.

Colouring Matter

Some swabs are required to be supplied dyed either green or blue. In these cases it is essential to use a non-toxic dyestuff and to ensure that all soluble residues are removed at the end of the dyeing process. These tests will demonstrate if this has been achieved.

Minimum Breaking Load, Threads per 10 cm and Weight per Unit Area

These parameters examine the basic structure of the gauze and determine if the fabric is adequate for its intended purpose.

Ether Soluble Substances

Waxes and oils are soluble in ether. This test will show how well the cotton wax and any weaving lubricants have been removed.

Fluorescence

Cotton fibres display a very slight brownish fluorescence when viewed under ultra-violet light. However, the writer has recently spoken with some suppliers enquiring about the suitability of gauze which exhibits a very bright blue fluorescence indicating that it has been treated with an optical whitening agent. The question is, what benefit to the performance of the product does such a treatment impart? No one yet has provided any sort of answer. The truth is that these materials are complex chemical compounds, some of which are thought to be potential carcinogens. They provide no benefit to the performance of the product yet must involve an additional expense to the processor so why are they present? The BP monographs make it quite clear that gauze treated in this manner is not acceptable.

Foreign Fibres

The presence of more than an occasional foreign fibre may detract from the performance of the product. Some products are made from a mixture of cotton and viscose fibres but these will be clearly labelled and microscopic examination will identify both fibres. The cotton appearing as flatish oval tubes whilst viscose appears as long threads with numerous striations along the length. Viscose fibres can be supplied either bright or matt / delustred. These can be differentiated by mounting the sample on the microscope slide in methyl salicylate. This has the effect of rendering the naturally bright viscose almost invisible thus allowing you to observe the very small particles of titanium dioxide used to delustre the basic material.

Starch and Dextrin

Starch was for many years the traditional sizing used on warp yarns prior to weaving. The reason for this test is to demonstrate that it has been removed and therefore will not be deposited in a patient's body with a consequent risk of harm.

Surface Active Substances.

This test is to check that any wetting agents (detergents) used to assist the bleaching process have been removed. It will also detect if a processor has deliberately added some such substance to assist absorbency, completely unaware that it would also be released into the patient thus causing risk of harm.

Water Soluble Substances

This is another test to ensure that the gauze contains nothing that can leach out into the patient when the product is used.

Loss on Drying

Both cotton and viscose fibres have natural moisture content. This test will ensure that no additional moisture is present which would affect other properties.

Sulphated Ash

This is a test that will show if the gauze has been treated in any way to artificially increase the weight, thus giving a false impression of suitability for purpose.

X-ray detectable Component

These tests will ensure that swabs which incorporate an X-ray detectable component can be detected inside the patient by the use of X-ray equipment. The purpose of this was to avoid the patient being subjected to an unnecessary additional exploratory operative procedure in the unlikely event of a swab being unaccounted for after closure. Whilst the X-ray component must contain sufficient material to render it X-ray opaque, it must retain flexibility. A hard material might cause injury and, if brittle, could break up inside the patient with the potential to cause injury.

There is a growing practice to use devices other than X-ray equipment to search a patient for swabs prior to closure. Whilst this is an immanently sensible procedure it must be pointed out that X-ray detectable products have not necessarily been tested against other detection systems. In these circumstances it is the responsibility of the user to ensure that the products used are capable of detection by the system they use. If in doubt they should discuss it with the suppliers of both the swabs and the detection equipment to be used.

Tied-5s

In theatre it is essential that all items used can be identified and accounted for. This is particularly important in the case of X-ray detectable swabs, some of which need to be left in place for an entire surgical procedure (e.g. abdominal swabs).

For this reason, X-ray detectable swabs used in theatre are usually supplied in bundles of five. They are tied together with a suitable coloured cotton thread that has been dyed to a distinctive colour (usually red) using a non-toxic dye. It is the practice in some establishments to use green swabs in theatre and blue swabs for immediate post-operative applications. A red tying thread will thus stand out in both cases. It is expected that the colour must be fast to avoid any transfer of dye onto the swabs themselves. Such colour leaching is most likely to occur when steam is the chosen method of sterilisation. A simple qualitative method of assessing the colour fastness of tying thread is to place a sample of thread between two white swabs and subject this 'sandwich' to a steam sterilisation cycle. Then examine the two surfaces of swab in contact with the thread for any colour transfer. They should both be completely free of colour.

They are tied in fives as this is the number of convention in the tally system used in operating theatres. The common practice is to keep a tally of the swabs when they are issued and again when they are retrieved from the patient ('counting them out and counting them back'), thus ensuring that all are accounted for. The use of a highly coloured tying thread for each 5 swab bundle thus enables

swabs to be tracked and accounted for, e.g. if five tied-5s units are issued, then at the end of the procedure they will need to account for twenty five swabs and five pieces of tying thread.

Manufacturers must adopt a strict regimen when manufacturing tied-5s to ensure that each bundle contains five swabs and not four or six. An incorrect number of swabs in the bundle would disrupt the tally system and risk a swab being left in a patient, or a patient 'left open' and put at greater risk whilst a search is carried out for a swab that does not exist. Unfortunately, a gauze swab left behind undetected in a patient after an operation can and has resulted in their death. This is a sobering thought for those who consider X-ray detectable swabs and tied-5s to be simple commodity items.

Any swab manufacturer and any company distributing swabs are well-advised to make sure they have adequate quality procedures in place and follow them diligently.

Conclusion

The objective of this paper is to show that apparently simple gauze products are not so simple after all. It will also help to prove that no medical devices should be regarded as simple commodities. All these standards and tests were introduced for one simple reason – to protect the patient from injury. They are just as important today as they ever were.

Note

BS EN 14079:2003 (Non-active medical devices. Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze) relates to gauze fabrics. In addition, a comprehensive list of monographs relating to gauze, gauze swabs and dressings containing gauze can be found in Volume II of the 1988 edition of the British Pharmacopoeia. Appropriate test methods for the requirements placed upon them are set out in Appendix XX of the same volume.

Revision 3

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