Direction for use (DFU Sterilization rolls 06.2013 version C)

This direction for use is applicable for the following Sterintech™ products:

Sterilization rolls , Flat :

301.xxx.0001	xxx mm x 200 m

Sterilization rolls, Gusseted :

302.xxx.0001	xxx mm x 100 m

Sterilization rolls , Tyvek :

303.xxx.0001	xxx mm x 70 m

Sterilization Rolls

Note: upon receipt of goods please check whether the package was undamaged and ensure you about the expiry date of the materials.

Introduction:

The Sterilization rolls are intended to pack Medical Devices (surgical instruments etc.) before sterilization in order to protect them and to provide them with a sterile barrier.

The Sterilization rolls are having 3 chemical indicators for the sterilization processes for which they are intended i.e. Steam, Formaldehyde and Ethylene-Oxide. Color change after sterilization is mentioned on the Sterilization rolls for each chemical indicator. Sterilization rolls are compliant to standard EN 868 - 5, ISO 11607- 1 and ISO 11140 - 1 as well as MDD 93/42/EEC Class 1. The products carry a CE mark.

How to use the Sterilization rolls

I. Select the instruments or items you want to pack.
II. Measure the length and select the proper width of the sterilization roll.
III. Cut the Sterilization roll to a length. Take into consideration that the standards recommend that the degree of filling is not exceeding 75% and that the distance from the Medical Device to the top seal should not be less then 3 centimeters. In general a 6-8 cm extra length will be sufficient to comply with these requirements.

Note: The sealing machine used should be validated on a regular basis to ensure that the pre-set temperature is the actual sealing temperature. It is recommended by standards that the sealing machine and it capability of making a proper seal is tested once a day before using the machine. A handy tool to do so is the use of a Seal Checker ™.

IV. Seal the bottom end. Temperature (170-180 degrees Celsius, for Tyvek 120 - 125 degrees Celsius)
V. Insert the Medical Device in the single end open pouch
VI. Seal the top end.
VII. Place the ready pack into a basket or in the way your working instructions are describing it.
VIII. Sterilize the pouch.
IX. When unloading the sterilizer check the proper chemical indicator to have changed into the right color.
X. Packs should be completely dry otherwise the sterility integrity is not present.
XI. Store the item in sterile storage for later usage

Note: The pouch should be marked by a printed expiry date, sterilization date and machine and cycle number in order to be able to trace back in case of any need to do so. This can be done by the sealing machines printer (if available) of alternatively label gun label.

Warnings

International standards are recommending the use of rotary heat sealers only for sealing Medical Device. However when only impuls / bar sealer is available a special attention should be given to the sealing of gusseted materials as the risk that the seal is not complete around the gusseted part is very high.

Storage conditions.

Please take into consideration the storage conditions provided for at the box of the sterilization rolls. Only in case the storage conditions were met, SP Medikal guarantee products compliance to standard within the expiry date.

Technical Data Sheet.

For these products technical data sheets are available in which reference to standards, packaging, certificates etc. are enclosed.

This Direction for use may be changed in the future. Check on our website regularly for updated Directions for use.

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