Name : Sterilisation Reels and Pouches

Product Code: CLFRxxxx, CLGRxxx, CLFPxxxXxxx, CLGPxxxXxxx, CLSSxxxXxxx

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Intended Use

The intended use of Sterilisation Reels and Pouches is as a sterile barrier packaging material for medical devices being sterilised by steam or ethylene oxide gas

Sterilisation Reels and Pouches are intended to be used by professional healthcare personnel working in sterile services (or similar) departments.

Single Use

Sterilisation Reels and Pouches are single use only.

Storage Conditions

It is recommended that Sterilisation Reels and Pouches are stored under the conditions stated on the label of the box. If this is not possible, it should be prevented from getting wet or from being exposed to high temperatures (>40degC).

Precautions

Sterilisation Reels and Pouches should be stored away from any sources of ignition.
Like any paper sheet, Sterilisation Reels and Pouches should be handled in such a way as to prevent cuts.

Disposal

If the paper side is separated from the film side, unused Sterilisation Reels and Pouches may be disposed of by disposing of the paper in waste paper stream and the film in the plastics stream. If the film is not

separated from the paper, the whole item should be disposed of in general the general waste stream and may be incinerated.

Used Sterilisation Reels and Pouches should be disposed of by taking into account possible microbial contamination. The user should reference their own procedures in this matter.

Selection of the correct reel or pouch size.

1) The size of pouch, or length of reel to use will be dependent upon the size of the item to be sterilised. Use a size of pouch or length of reel that easily accommodates the item without putting any stress on the side seals. Ensure to allow extra space for the sealing operation.

2) If double packing is deemed necessary, wherever possible ensure that the inner pack is smaller in volume than the outer pack. Also ensure that you position paper side against paper side and film side against film side.

3) Gussetted Pouches or reels should be used for deep items.

Filling the Package

1) When using reels, cut off a length to the required dimensions and seal at one end (see later for sealing conditions.

2) When placing the medical device in the package, orient it such that it allows aseptic presentation when the sterilised package is opened.

Heat-Sealing Packages

1) Heat sealing should be carried out using a heat-sealing machine designed for medical packaging.

2) The following guidelines apply to Clinipak heat-seal flat and gusseted sterilisation reels and pouches:

<u>Seal Strengths and integrity</u>

The final strength and the integrity of the seal depend on three parameters:-

a) Temperature
b) Pressure
c) Time

If any one of these is varied the final seal strength can be significantly altered, therefore the type of sealing machine should be carefully chosen.

Recommended Sealing Machines

Type: Rotary
Jaw width: 12mm minimum
Jaw type: Grooved wheels
Temperature range: 0 - 200°c (controlled to +/-2%)

The use of a grooved wheel can give up to 15% more seal area than a flat jaw, with a corresponding increase in seal strength.

Effect of Altering The Sealing Conditions.

A) Use of high pressure forces the molten polymer into the Paper giving a stronger seal with increased fibre tear.
B) Increasing the temperature softens the polymer allowing it to flow more easily, also giving a stronger seal with increased fibre tear.
C) Reducing the speed allows better thermal transfer allowing the polymer to flow more easily.

Recommended Machines Settings Clinipak CLFP, CLGP, CLFR and CLGR reels and pouches

Speed: 6 - 10 metres/minute.
Temperature: 160 - 180°C, depending on dwell time and pressure.
Pressure: Adjust to give good a good even indentation.

Heat Sealer Performance checks (Recommendation)

Once the sealing conditions have been established it is recommended that at the start of each shift sample pouches/reels are sealed and then peeled apart to confirm the performance of the heat sealer and the integrity of the seal. The seal should peel in a firm uniform manner with minimum fibre lift when opened in the direction of the indicator arrows.

Sealing Self-Seal Pouches

1) Remove the backing paper from the self-adhesive strip at the end of the pouch.

2) Fold over the end of the pouch along the pre-creased line so that the adhesive strip overlaps the end of the film and contacts both the film side and the paper side, thereby sealing the open end of the pouch.

3) Press across the whole length of the adhesive strip to ensure complete contact between the adhesive strip and the paper and film.

Adding additional information to a reel or sealed pouch

1) Any writing of information should be carried out on the film side only. Do not write on the paper side.

2) Ensure that the writing implement does not damage the film in any way – ball-point pens are not suitable writing implements.

3) Only markers which are compatible with the sterilisation process should be used.

4) Ensure that any writing does not cover the indicators.

5) If labels are to be placed on package, they must be placed on the film side only. They must not be placed on the paper side.

Positioning Packages in an autoclave

Packages should be placed upright in a wire basket in the steriliser. If it is not possible to place the packages upright, they can be placed flat with porous material facing down. The packages should not be folded and they must not touch the chamber walls. The basket should not be packed too full, as the packages expand during the sterilization process and they must also be allowed to breathe freely.

Post-sterilisation Inspection

1) Packages should be allowed to cool before handling

2) Packages should be inspected to ensure they are undamaged. A

3) Packages should be inspected to ensure that the process indicator has changed colour correctly. The change of process indicator colour indicates that the package has undergone the process indicated. It does not provide evidence of sterilisation.

4) Packages should be inspected to ensure they are not wet.

Storage

Post-sterilised and inspected packages should be stored in a clean environment away from direct sunlight. Ideally, the storage area should be climate-controlled but if this is not a requirement.
The storage area or shelf should be free of anything that could cause the packaging to be punctured.

Opening the Package

The film should be peeled away from the paper starting at the corners. Pulling should be done slowly and carefully to avoid fibres from breaking away and contaminating the medical device/instrument.