



安庆康明纳包装有限公司

"A Trusted Name in Medical Packaging" Anqing Kangmingna Packaging Co. , Ltd

Business is not for the best profits, but for the best partners!

HEAT SEALING GUSSET REEL AND FLAT POUCH

MATERIALS&COMPOSITION

Heat Sealing Gusset Reels /Pouches are made by a medical use plastic material called laminated transparent film produced in green or light blue colours which comes from a special film of PET and CPP together with medical 60gsm Arjo Paper and only on special request by customers we can produce with 70gsm. This paper is produced by an high technological system in white color and has been studied to assure an highanti-bacterial protection; The printing is with indicators, one for steam sterilization ,one for ethylene oxide sterilization (EO). On special request by customer, Formaldehyde (FORM)indicator can also be printed. The inks used are water basis and non-toxic.

SPECIFICATION

Heat-sealing Gusset Roll

KMNHG-075100	Heat-Sealing Sterilisation Gusset 75 X100	8
KMNHG-100100	Heat-Sealing Sterilisation Gusset 100x100	6
KMNHG-150100	Heat-Sealing Sterilisation Gusset 150x100	4
KMNHG-200100	Heat-Sealing Sterilisation Gusset 200x100	2
KMNHG-250100	Heat-Sealing Sterilisation Gusset 250x100	2
KMNHG-300100	Heat-Sealing Sterilisation Gusset 300x100	2
KMNHG-350100	Heat-Sealing Sterilisation Gusset 350x100	2

NOTE: There is no specified size for Heat-sealing Gusset Pouch and they are made according to customer's requirements.

FUNCTION& DESCRIPTIVE INFORMATION

Heat Sealing Gusset Reels and Pouches are used for steam,EO or FORM process sterilization of single items; Reels assure a packaging with an high technological quality content in order to satisfy the different needs of packaging in hospital, dental and industrial fields. the correct sterilization is certified, at correct temperatures, by the change of indicators colours: for ethylene oxide sterilization temperature is 30℃-54℃ and the color changes from pink to yellow/brown; for steam sterilization, temperature is 121℃-132℃ and the color changes from light blue to dark grey/black; For FORM

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sterilization, temperature is 60°C-80°C and the color changes from red to green. The reel or pouch can be sterilized only once because it is a Disposable medical device packaging. So they should be thrown away because it can not be used for a second sterilization cycle.

INSTRUCTION& USES

- 1) Complex instruments (e.g. air-powered instruments, endoscopes and instruments with lumen or channels) should be prepared and sterilized according to the manufacturer's instructions. Gusset reel/pouch allow "bulky" items to be packed.
- 2) Sterilization Rolls need to be cut to required length.
- 3) Do not use if the pack is damaged. Do not reuse. Single use only.
- 4) One of the open ends of the roll should be closed with a calibrated medical sealing device and validated sealing process to form a pouch. The recommended sealing temperature is between 170 – 190 °C With 1-6 second dwell time.
- 5) Cover sharp ends of instruments with an instrument protector, to prevent puncturing and tearing.
- 6) Place the item to be sterilized into the pouch. Do not fill pouches to more than 75% of their capacity. Always leave minimum 1.5 cm gap between the material and each seal edge of the pouch for a smooth airflow.
- 7) Manually remove as much air as possible from the pouch before closing.
- 8) Close the open end of the pouch with a calibrated medical sealing device and validated sealing process.
- 9) Avoid stress on the seals during handling. For example, fill the pouch horizontally while working on a flat surface.
- 10) When loading into the sterilizer place the pouches into the basket in a way that film faces film and paper faces paper.
- 11) Gusset Sterilization Rolls should be put upright in the basket or container and not too tight together; such that a hand can slide in between them.
- 12) Allow dry time for pre-vacuum steam sterilization process
- 13) After a cycle of sterilization, check the color change: If sterilization is really implemented, it will turn dark grey/ black from initial light blue under steam sterilization. For EO sterilization, the color turns yellow/ brown from initial pink.

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◆ **Standards:**

KMNPack heat-seal sterilization reels and pouches comply to FDA, EN868, ISO11607 and ISO11140-1 standards.

Turn to Black from Blue under steam sterilization:

Steam Indicator before Sterilization: Blue



Steam Indicator after Sterilization: Black



Turn to Yellow from Pink under EO sterilization:

EO Indicator before Sterilization: Pink



EO Indicator after Sterilization: Yellow



Handle pouches with care when removing from the sterilizer to prevent tearing.

Store pouches in an area protected from sunlight, water and other liquids.

14) Do not use wet pouch. Repeat the sterilization process after changing the pouch.

15) To open the pouch, use a thumb and index finger to hold the paper side and a thumb and index finger to pull back the film side of the pouch.

Always open the pouch from the direction of the arrow.

For a clean peel, open the pouch slowly.

WARNINGS

1) Before starting sterilization process, please check that the reel/pouch is filled for maximum 3/4 of its volume so that sealings are not obstructed at the edges.

2) Cover the end and the cutting surfaces of instruments with appropriate protection.

3) Put the instruments with the handle at the opening of reel/pouch.

4) Do not use solvent substances on reel/pouch.

5) Do not use a stationary Permanent marker to write on the reel/pouch

Use a Medi Marker – a medical marker, a non-gassing waterproof pen

Medi Marker pen is a permanent marker for use on medical packaging without compromising the microbial integrity of a sterile pack.

The permanent non-gassing waterproof ink is bleed and fade resistant

Important to use a **Medi Marker** to write on paper side of the reel/pouch, this way maximum care are taken to avoid the pack to be

compromised/contamination during packing and ensure a safe and compliant

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pack, to ensure Patient safety.

6) Please carefully check the weight of the instruments to be sterilized in order to avoid risks of breaking.

PRECAUTIONS AND CONTRAINDICATIONS

- 1) It is forbidden using the reel/pouch if it is damaged.
- 2) The reels/ pouches have to avoid the sunlight and stored in a dry place. The packaging must also be managed less as possible and has to be kept closed.
- 3) The reel/pouch has to be used only after having checked that no dust is on its packing and if it is partially used, it must be hermetically closed in its plastic protection.