

TECHNICAL DATA SHEET

NuMedical Sterilization Pouches

Intend Use

Intended to be used to enclose medical devices that are to be sterilized. It is designed to allow sterilization of the enclosed medical device and also to maintain sterility of the device until the packaging is opened for use of the device, or until a predetermined shelf date is expired. This device is disposable and single use only.

Product Overview

Built-in multi-parameter internal/external process indicators that change color when all three criteria for sterilization have been met – time, temperature and pressure (steam).

Manufactured from medical grade paper with extra-wide chevron to protect against instrument breaching, thumb-notch for easy opening, 6 corner tack seals to prevent curling and other potential contaminants from entering pouch upon opening and a perforated fold to help ensure the adhesive strip forms an airtight seal.

Once sterilized contents will remain sterile for up to 3 years provided the integrity of the pouch has not been compromised. For use with steam and EtO sterilization processes only.

Materials

69 gsm medical grade paper

50 gsm PET/CPP lamination film

Instruction for Use

Loading: Carefully place items into pouches and remove excess air before sealing. Where possible, use a pouch rack to stand pouches on edge in the sterilizer to facilitate sterilization and drying. When loading multiple pouches, be sure that the plastic side faces the paper side of each adjacent pouch.

Sterilization: Steam chemical indicator ink printed on the inside of each pouch is certified as a multi-variable (parameter) indicator. Internal multi-variable (parameter) chemical indicators are designed to react to the 3 variables required for sterilization - temperature, specified time, presence of steam - and provide a more reliable indication that the conditions for sterilization have been met. Blue indicators will turn black when processed by steam. Pink indicators will turn yellow when EtO processed. Multi-variable (parameter) indicators meet the ISO 11140-1 Guidelines for sterilization. NuMedical pouches are only available for use in steam sterilizers (autoclaves) and EtO.

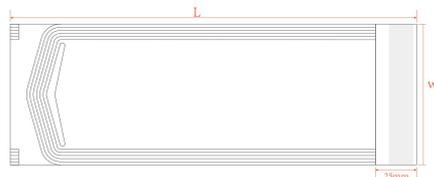
Shelf Life: When properly sealed, sterility is maintained up to three (3) years provided the integrity of the pouch has not been compromised, i.e. pouch becomes wet, damaged or is opened during storage.

Caution - wet pouches may not preserve sterility of contents.

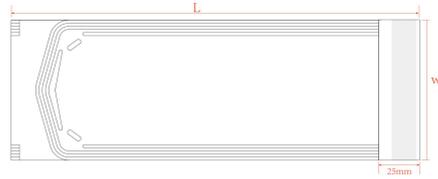
| Property | Unit | | | Method |
|----------------------|---------|--|----------|-------------|
| Steam - 121°C (±3°C) | minutes | | 10(±5s) | ISO 11140-1 |
| Steam - 134°C (±3°C) | minutes | | 2(±5s) | ISO 11140-1 |
| EO Gas - 37°C (±1°C) | minutes | | 25(±15s) | ISO 11140-1 |
| Steam - 54°C (±1°C) | minutes | | 20(±15s) | ISO 11140-1 |

Size Measurement Diagram

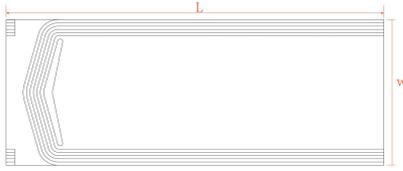
self-sealing steam



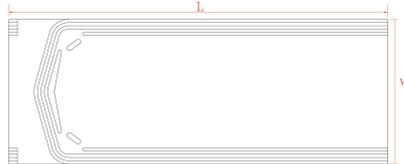
self-sealing steam & EO gas



heat sealing steam



heat sealing steam & EO gas



Visual



| Item Code | Description | Package | Specific Attributes |
|-----------|---------------------------------|------------|---------------------|
| 990611 | 250mm W x 380mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990612 | 300mm W x 380mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990613 | 110mm W x 300mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990614 | 50mm W x 230mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990615 | 300mm W x 460mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990616 | 90mm W x 230mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990617 | 135mm W x 260mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990618 | 190mm W x 330mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990619 | 70mm W x 230mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990620 | 90mm W x 145mm L, self-sealing | 200pcs/box | Non-Sterile, steam |

| | | | |
|--------|-----------------------------------|------------|-----------------------------|
| 990621 | 57mm W x 130mm L, self-sealing | 200pcs/box | Non-Sterile, steam |
| 990600 | 50mm W x 230mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990601 | 57mm W x 100mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990602 | 70mm W x 230mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990603 | 90mm W x 145mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990604 | 90mm W x 230mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990605 | 110mm W x 300mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990606 | 135mm W x 260mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990607 | 190mm W x 330mm L, steam & EO Gas | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990608 | 250mm W x 380mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990609 | 300mm W x 380mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |
| 990610 | 300mm W x 460mm L, self-sealing | 200pcs/box | Non-Sterile, steam & EO Gas |

*Self-sealing or heat sealing can be choiced depend on requirements.

Regulatory

TGA Class 1, ARTG #291157

Storage Conditions

Store all sterilization pouches in a cool, dry place

Country of Origin

China