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INTRODUCTION



• *What is the sterilization packing for medical instrument?*

Defined as EN-868 & ISO-11607, it is the primary packaging for medical instruments with microorganism Barrier, Sterilizable, and sustained and Shelf-life performances.

• *How to design for sterilization packing of disposable medical instruments?*

When choosing sterilization packing for medical instruments, you should consider the following factors:

- **Methods of sterilization**
- **Volume and weight of the loading instrument**
- **Validated date**
- **Convenience of use**



QUALITY CONTROL SYSTEM

SPSM complies with internationally recognized quality, and maintains a strict quality control system for controlling all aspects of the manufacturing process. Beginning from sourcing raw materials, testing, packing, inventory and deliveries.

Quality Certifications and Registrations

SPSM acts in accordance with Global Standards for the medical packaging products ISO 9001:2015, ISO 13485 & CE.

Quality Assurance Section

01.Raw material Sourcing

High quality and efficient suppliers, strict process of incoming inspection by IQC.

02.Production

Class 100,000 grade clean workshop. The production process is continuous with a customized process chart made by the company.

03.Testing

First Article Inspection: The product consistency is ensured and sample drafts are manufactured and tests as per standards and requirements.

04.Quality Inspection

The quality of the product is checked and analyzed during the various stages of the manufacturing of the final product by The QC department. This helps in maintaining the quality of the finished product.

05.Storage and Packing

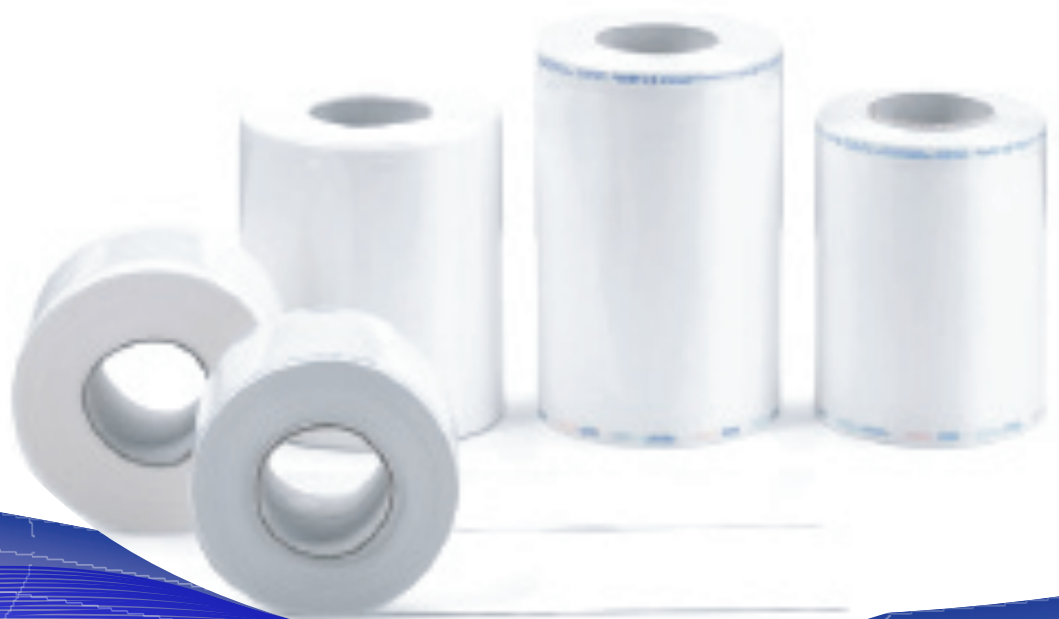
The segregation of unqualified goods are done at the beginning and are separated and then discarded. The final finished goods are safely packed as per the packing standards.

STERILE BARRIER SYSTEM

The term “sterile barrier system” refers to the minimum packaging that prevents proliferation of microorganisms and sterilizing the product to prepare it when it’s time for use. This is where medical pouch sealers play an important role in ensuring that a medical device is safe and sterilized while it’s not being used.

No matter how strict your process of sterilization and disinfection is, you can still have the risk of contaminating your product. This can happen when your packaging and seal closure system is compromised during shipment and storage and could cause serious danger to the user.

The product may be considered a complete sterile barrier system only when it has passed a complete testing protocol and the manufacturer has applied the final seal. This is the only time that the entire packaging system can be considered compliant as per ISO 11607.



HEAT SEALING STERILIZATION REEL

Flat and Gusseted – Paper/Film

FINEFIT® heat-sealing sterilization reels and pouches are universal packing solution for sterilization applications. They ensure reliable and effective protection of the medical equipment against contamination with bacteria from the time of sterilization until the use of the sterile medical equipment.

The Flat and Gusseted type of reels have a wide range of standard sizes which is generally suitable for all the packaging demands of light and medium weight medical devices and instruments.

FINEFIT® heat-sealing sterilization reels and pouches are manufactured from medical grade paper and transparent CPP/PET multi-layer copolymer film. There are two water based non-toxic process indicators for steam and ethylene oxide sterilization which are imprinted on the paper surface which prevents the instrument from getting coloured and helps to differentiate between processed and unprocessed packaging. Formaldehyde indicator is also available if requested.

Brief advantages of FINEFIT® Heat-Sealing Sterilization Reels.

1. Medical grade paper with technic 60gsm or 70gsm is an effective barrier against germs and bacteria. Despite of this, it permits the transmission of air, steam or sterilization gas.
2. It has a reinforced film to avoid tear during opening.
3. The Peel-Easy film permits film separation from paper without any shattering.
4. It has a clean and accurate indicator colour change.
5. It has tear, fiber-free opening and aseptic presentation.
6. It has a triple band seal for higher package integrity which effectively avoids cracking.

Standards

FINEFIT® heat-sealing sterilization reels comply with EN868 and ISO11140-1 standards.

SPECIFICATION

FINEFIT® heat-seal sterilization reels flat-paper/film

SIZE	PACKING/CTN
50 MM(2") X 200 METERS	12
55 MM(2.2") X 200 METERS	12
75MM(3") X 200 METERS	8
100 MM(4") X 200 METERS	6
150 MM(6") X 200 METERS	4
200MM(8") X 200 METERS	2
250MM(10") X 200 METERS	2
300MM(12") X 200 METERS	2
350 MM(14") X 200 METERS	2
400MM(16") X 200 METERS	2
450 MM(18") X 200 METERS	2
500MM(20") X 200 METERS	2
600MM(24") X 200 METERS	2

SPECIFICATION

FINEFIT® GUSSETED Reel/Paper Film

SIZE	PACKING/CTN
75MM(3") X 100 METERS	8
100 MM(4") X 100 METERS	6
150 MM(6") X 100 METERS	4
200MM(8") X 100 METERS	2
250MM(10") X 100 METERS	2
300MM(12") X 100 METERS	2
350 MM(14") X 100 METERS	2
400MM(16") X 100 METERS	2

SELF SEALING STERILIZATION POUCHES

FINEFIT® self-seal sterilization pouches are pre-folded and they assure quick and secure closing without a heat sealer. They are especially suited for use in small general practice, dental surgeries and by users who do not want to pay additional costs of sealing devices.

FINEFIT® self-seal sterilization pouches are constructed from medical grade paper and transparent CPP/PET multi-layer copolymer film and adhesive strip. The two water based, non-toxic process indicators for steam and ethylene oxide sterilization are imprinted on the paper surface which prevents the instrument from getting coloured and helps to differentiate between processed and unprocessed packages

Brief advantages of FINEFIT® SELF-SEAL Pouches

1. Medical grade paper with technic 60gsm or 70gsm is an effective barrier against germs and bacteria despite of that it permits the transmission of air, steam or sterilization gas.
2. It has a reinforced film to avoid tear during opening.
3. The Peel-Easy film permits the film separation from paper with no shatters.
4. It has a clean and accurate indicator colour change.
5. It has tear, fiber-free opening and aseptic presentation.
6. It has a triple band seal for higher package integrity which effectively avoids cracking.

Standards

FINEFIT® self-seal sterilization pouches comply with EN868, ISO11607 and ISO11140-1.

SPECIFICATION

FINEFIT® SELF-SEAL STERILIZATION POUCH

SIZE	PIECES/BOX
57MM X (100+30)MM	200
70MM X (230+30)MM	200
90MM X (135+30)MM	200
90MM X (230+30)MM	200
135MM X (250+30)MM	200
190MM X (330+30)MM	200
200MM X (290+30)MM	200
200MM X (330+30)MM	200
230MM X (365+30)MM	200
305MM X (400+30)MM	200
400MM X (505+30)MM	200
500MM X (600+30)MM	200



ISO 9001:2015

ISO 13485



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