Advanced Engineering Days

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Sterilization packaging with appropriate materials and sterility assurance level

Ebru Öner Usta *[1], **Furkan Ayaz** [2]

[1]*Mersin University, Biotechnology Department, Türkiye, oner_ebru@hotmail.com*
[2]*Mersin University, Biotechnology Research and Application Center, Türkiye, furkanayaz@mersin.edu.tr*

Cite this study: Usta, E. Ö., & Ayaz, F. (2022). Sterilization packaging with appropriate materials and sterility assurance level. 4th Advanced Engineering Days, 1-3

Keywords
Sterilization
Sterilization Packaging
ISO 11607-1 Standard

Abstract

all disinfected materials should be packed with appropriate materials to ensure sterilization safety. The most important step of the sterilization cycle is considered to be packaging. The function of sterile material packaging is to prevent the deterioration of the sterilization integrity of the material by creating a defense against unwanted microorganisms and viruses after sterilization. There are many packaging materials with different properties produced for this purpose. ISO, Standards Institution attaches importance to the packaging of medical devices at an international level. ISO 11607-1 Part-1,-2 standardizes the technical standards that must be followed in medical device packaging. This standard is a guide that is valid in all areas where medical devices are packaged, especially in hospitals. For the sterilization of steam, ethylene oxide, formaldehyde, and hydrogen peroxide gas plasma sterilization methods, sterilization bags, transparent multi-layer copolymer PET/PP film, and medical paper combinations are used. Liquid and steam and C2H4O EO processing indicators by the ISO 11140-1 standard are applied to the paper surface, and these indicators distinguish between treated and untreated packages. Advantages of Sterilization Packaging materials can be summarized as Product protection, Microbial barrier, Physical protection from damage, Compatibility with the sterilization method, Maintenance of sterility and integrity until use, Easy opening, and aseptic presentation, Identification of the Product (printing, labeling). As a result, the probability of a single viable microorganism remaining at the end of the selected sterilization process should be ≤10-6.

Introduction

Sterilization means the complete removal or destruction of all forms of microbial life including bacterial spores. No absolute assurance that there is 0 microorganism.

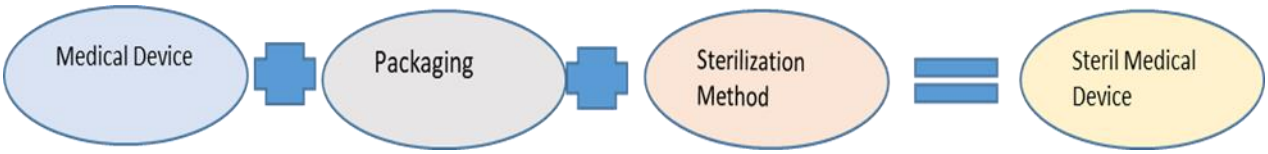

Figure 1. Steril Medical Device Definition

There is no 100% guarantee that there are no microorganisms. The packaging concept is divided into three phases; 1) Primary packaging protects the items from contamination following sterilization. 2) Secondary packaging is used to aid in correct storage and interior conveyance to the consumer. 3) Packing for Transportation External transport of sterile commodities in both primary and secondary packing [1]. The primary packaging protects the product from becoming recontaminated following sterilization. It should offer an effective

microbiological barrier while also allowing air and the sterilizing agent, such as steam, to flow through. Primary packaging is sufficient when there is no risk of dust being deposited on the pack. In dust-free storing or if the goods are to be used immediately. The principal packaging keeps the environment sterile while being stored and transported. The medical paper, two layers of non-woven sheets, a single or double laminated PET/PP, or a box with a sufficient filter are examples of primary packaging (s) [2].

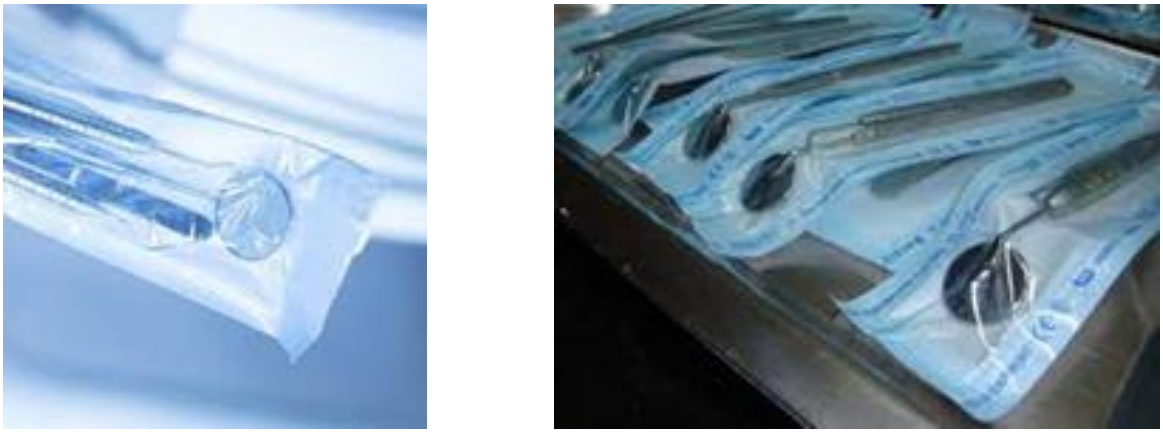

Figure 2. Before Sterilization Samples

Products for sterilization packing reliably and securely guard medical equipment against bacterial and chemical contaminates. The sterilization packaging offers a strong microbiological barrier from the moment of sterilization until the sterile equipment is utilized. The usage instructions and suggested storage conditions must be followed to guarantee high-performance qualities and sterility (3). Sterilization packaging consists of three components. These components are the indicators that show successful results, different weights of medical paper and PET/PP. During sterilized pack storage, permit sterilization while retaining a strong bacterial barrier performance. Bacterial barrier against airborne contamination (airborne, microparticles, dust), Fluids (drops, aerosols). Bacterial barriers work on the principle that bacteria die or burn their energy before crossing the barrier material (Tortuous path). Non-compliant materials include those that are not sufficiently barrier to prevent bacteria from entering. Poor quality medical paper 1) POST-sterilization characteristics 2) Poorly manufactured film-to-paper pouches (no sealing in some areas) 3) Materials with holes or a narrow tortuous path [3].

Figure 3. DUPONT website [4]

The requirements that must be met by medical packaging used during sterilizing procedures; Internationally Recognized as ISO 11607-1 Medical Device Packaging, Part 1 Packaging for a medical device that has undergone terminal sterilization must comply with the ISO 11607-1 requirement for materials, sterile barrier systems, and packaging systems. Process requirements have been noted for forming, sealing, and installation. When sterilization is complete, the SAL value, also known as the Sterility Assurance Level, should be 106 (1/1,000,000). In other terms, it refers to the likelihood that 1x106 sterilized materials contain no more than one live bacterium.

Results

Each medical device used for OR must run through following processes before usage cleaning, disinfection, preparation, packaging, sterilization, storage.

Figure 4. Belimed Infection Control [5]

The Central Sterile Supply Department (CSSD) is critical to sterilization safety. Again, Sterilization Packaging is an important step in the successful conclusion of the sterilization process. As a result, sterilization packages should create a high bacterial barrier by allowing the sterilization agents to penetrate the materials to be sterilized. Its performance should be measured by its SAL value. The performance evaluation criteria of 60gr medical paper, which is widely used in sterilization packaging, are generally listed in Table 1.

Table 1. Sterilization Packaging Evaluation Criteria [5]

Medical Paper Technical Specifications		Unit	60 gr
Tensile Strength (Dry)	MD	N/15mm	110
	CD	N/15mm	50
Tensile Strength (Wet)	MD	N/15mm	18
	CD	N/15mm	9
Burst strength	Dry	kPa	250
	Wet	kPa	50
Water Repeliency	-	sn	25

Discussion

Sterilization packages are evaluated by ISO 11607 -1.2 standards and meet the requirements of the standard. They also prove the reliability of the sterilization method by complying with the internationally accepted SAL (1/1000000) value [6].

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