MDS-G021

Guidance for Surgical Sutures

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Contents

Introduction

Purpose

The purpose of this document is to assist the manufacturers and authorized representatives of surgical sutures with/without needles to comply with the SFDA Requirements for Medical Devices Marketing Authorization (MDS-REQ 1).

Scope

This guidance applies to manufacturers and authorized representatives of surgical sutures with/without needles used for general soft tissue approximation and wound closure/ support.

The applicant of the surgical sutures marketing authorization shall submit the necessary documents to prove that the surgical sutures to be marketed complies with the essential principles of safety and performance which specified in the Requirements for Medical Device Marketing Authorization (MDS-REQ 1), including proof of compliance with relevant Standards.

All requirements and test methods indicated in the applicable standards that referred to in the marketing authorization application shall be met, and if that is not possible, the SFDA shall be provided with justifications.

This document does not add any requirements related to compliance with the essential principles of safety and performance, which specified in the Requirements for Medical Device Marketing Authorization (MDS-REQ 1). Rather it just indicates some information and guidance of surgical sutures related characteristics.

Background

The SFDA has issued this guidance document in accordance to the following:

- Article 8 of the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 06/07/1442 H.

- Articles (8/1), (10/3) item (7) and (10/28) of the "Implementing Regulations of the Medical Devices Law" issued by Board Resolution No. (3-29-1443) dated 19/02/1443 H.

- Requirements for Medical Device Marketing Authorization (MDS-REQ 1)".

- SFDA CEO decision dated (26/06/1444) approving the issuance of medical devices standards including surgical sutures related standards.

Composition

Sterile catgut	Consists of sutures prepared from collagen taken from the intestinal membranes of mammals. After cleaning, the membranes are split longitudinally into strips of varying width, which, when assembled in small numbers, according to the diameter required, are twisted under tension, dried, polished, selected and sterilized. The sutures may be treated with chemical substances such as chromium salts to prolong absorption and glycerol to make them supple, provided such substances do not reduce tissue acceptability.
Sterile non-absorbable sutures	Sutures that, when introduced into a living organism, are not metabolized by that organism. Sterile non-absorbable sutures vary in origin, which may be animal, vegetable, metallic or synthetic. They occur as cylindrical monofilaments or as multifilament sutures consisting of elementary fibres that are assembled by twisting, cabling or braiding; they may be sheathed; they may be treated to render them non-capillary; they may be colored.

Materials

Silk (Filum bombycis)	Sterile braided silk suture is obtained by braiding a number of threads, according to the diameter required, of degummed silk obtained from the cocoons of the silkworm Bombyx mori L.
Linen (Filum lini)	Sterile linen thread consists of the pericyclic fibres of the stem of Linum usitatissimum L.
Poly (ethylene terephthalate) (Filum ethylene polyterephthalici)	Sterile poly (ethylene terephthalate) suture is obtained by drawing poly (ethylene terephthalate) through a suitable die. The suture is prepared by braiding very fine filaments in suitable numbers, depending on the gauge required.
Polyamide 6 (Filum polyamidicum-6)	Sterile polyamide 6 suture is obtained by drawing through a suitable die a synthetic plastic material formed by the polymerization of ε-caprolactam. It consists of smooth, cylindrical monofilaments or braided filaments, or lightly twisted sutures sheathed with the same material.
Polyamide 6/6 (Filum polyamidicum-6/6)	Sterile polyamide 6/6 suture is obtained by drawing through a suitable die a synthetic plastic material formed by the polycondensation of hexamethylenediamine and adipic acid. It consists of smooth, cylindrical monofilaments or braided filaments, or lightly twisted sutures sheathed with the same material.
Polypropylene (Filum polypropylenicum)	Polypropylene suture is obtained by drawing polypropylene through a suitable die. It consists of smooth cylindrical mono-filaments.

Monofilament and multifilament stainless steel (Filum aciei irrubiginibilis monofilamentum/multifilamentum)	Sterile stainless steel sutures have a chemical composition as specified in ISO 5832-1 - Metallic Materials for surgical implants - Part 1: Specification for wrought stainless steel, and comply with ISO 10334 - Implants for surgery - Malleable wires for use as sutures and other surgical applications. Stainless steel sutures consist of smooth, cylindrical monofilaments or twisted filaments or braided filaments.
Poly (vinylidene difluoride) (PVDF) (Filum poly (vinylideni difluoridum))	Sterile PVDF suture is obtained by drawing through a suitable die a synthetic plastic material formed by polymerization of 1.1-difluoroethylene. It consists of smooth, cylindrical monofilaments.
Sterile synthetic absorbable braided sutures	Consist of sutures prepared from a synthetic polymer, polymers or copolymers which, when introduced into a living organism, are absorbed by that organism and cause no undue tissue irritation. They consist of completely polymerized material. They occur as multifilament sutures consisting of elementary fibres which are assembled by braiding. The sutures may be treated to facilitate handling and they may be colored.
Sterile synthetic absorbable monofilament sutures	Consist of sutures prepared from a synthetic polymer, polymers or copolymers which, when introduced into a living organism, are absorbed by that organism and cause no undue tissue irritation. They consist of completely polymerized material. They occur as monofilament sutures. The sutures may be treated to facilitate handling and they may be colored.

Performance Specifications

Suture - Related Specifications		
#	**Specification**	**Testing Methods and Acceptance Criteria**
1	**Diameter** Thickness of surgical sutures. The diameter of sutures affects their tensile strength, knot security, and tissue reaction.	• The results are compared with the limits given in the USP monographs for different types of sutures. • Methodology specified in "USP 43-NF38 <861> Sutures – Diameter". • Acceptance criteria according to USP 43-NF38 (2020).
2	**Tensile Strength** Maximum amount of force that a material can withstand before breaking. It is an important indicator of the quality and performance of sutures, as it reflects their ability to resist breaking under tension during surgery or healing.	• Methodology specified in "USP 43-NF38 <881> Sutures – Tensile Strength". • Acceptance criteria according to USP 43-NF38 (2020).
3	**Needle Attachment** Point of connection where the needle is affixed to the sutures. Several methods can be used including swaged-on attachments which is a process where the suture materials are attached to the needle permanently by placing the suture into the needle end and crimping it. Or using an eyed needle in which the suture materials are threaded in the needle hole.	• Methodology specified in "USP 43-NF38 <871> Sutures – Needle Attachment". • Acceptance criteria according to USP 43-NF38 (2020).
4	**Resorption Profile** Rate at which the materials of the sutures break down and are absorbed by the body over time.	There are several methods used to determine the resorption profile and these include: ○ In Vitro testing where the suture materials are immersed in solutions or enzymes that mimic the body's natural reaction of breaking down the materials and monitor the changes over time. ○ In Vivo testing where the suture materials are placed into living organisms to observe the resorption process under normal physiological conditions.

5	**Minimum breaking load** Minimum amount of force or tension required by the sutures materials to break or fail. In other terms, maximum amount of force that the materials can withstand during its normal use before it fails.	Acceptance criteria according to European pharmacopoeia 11th edition.
6	**Extractable color** Color bleeding or leaching from the suture materials when it comes into contact with the body tissues since colors can migrate from the sutures and stain surrounding tissues leading to complications.	Acceptance criteria according to USP 43-NF38 (2020).
7	**Soluble chromium compounds** Chromium compounds used in surgical sutures as pigments to give colors to the suture materials as they aid in visibility and differentiation during surgeries. Note: due to toxicity of chromium compounds, its uses in sutures significantly decreased over the years and shift have been made towards biocompatible materials when it comes to coloration.	Acceptance criteria according to USP 43-NF38 (2020).
8	**Monomer and oligomers** • Molecular components of the suture materials. • Monomers are synthetic materials, such as polymers or copolymers, which are processed into a suture. • Oligomers are larger molecular structures consisting of a small number of monomer units and they can arise during the manufacturing of surgical sutures when the monomers partially polymerize but do not fully form long polymer chains.	It is important for manufacturers to ensure a proper processing and polymerization of the sutures to minimize the presence of monomers and oligomers.
9	**Length** Length of Suture without stretching.	Length of each strand not less than 95.0% of the length stated on the label.

Needle - Related Specifications		
#	Specification	Test and Acceptance Criteria
1	**Smoothness of needle surface (freedom from dents)** The surface of the suture needle shall be smooth and shall be free from dents.	Visual test.
2	**Cleanliness of needle surface** The surface of the suture needle shall be free from grinding marks and polishing dirt.	Visual test.
3	**Sharpness of needle point** The suture needle should have sharpened tip.	Visual test.
4	**Cleanliness and smoothness of needle eye (swage)** The eye (swage) of the needle shall be clean and properly formed and shall be smooth from inside and outside.	Visual test.
5	**Chemical composition of needle**	• ASTM A751
6	**Hardness of needle (Vickers Hardness)** The measurement of resistance of needle material to indentation.	• ISO 6507-1 • ISO 4545-1
7	**Corrosion resistance of needle** The ability to protect the needle substrate from corrosion.	• ISO 13402 • ASTM F1089
8	**Resistance to breakage and deformation of needle (Bend Test)** • The straight suture needle shall deem to have failed as being too hard, if it breaks before the initial bend of 90° is achieved. • There shall not be any permanent set in the curved suture needles after the test.	ASTM F1874
9	**Needle penetration** • Penetration force of a surgical needle. • Piercing resistance required to be less than 25g.	GSO ASTM F3014

General requirements

Biocompatibility Evaluation

The biocompatibility evaluation of the finished product should be conducted as per the international standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process". This standard describes the test selection necessary to evaluate biocompatibility. The evaluation report should include the following:

- The basis and methods used for the biocompatibility evaluation.
- Description of the materials used in the product.
- The nature and duration of contact with the human body.
- The addressed endpoints in the biological risk assessment.
- The relevant scientific data demonstrating the biocompatibility of materials, or test results.

In the evaluation report, the following endpoints should be addressed, taking into account the suture type, needle type, contact duration, and the nature of body contact:

Cytotoxicity	Tests employing cell culture techniques used to determine the cell death (e.g. cell lysis), the inhibition of cell growth, colony formation, and other effects on cells caused by medical devices, materials and/or their extracts. • Testing should be conducted in accordance with ISO 10993-5.
Sensitization	Tests used to estimate the potential for contact sensitization by medical devices, materials and/or their extracts, using an appropriate model. • Testing should be conducted in accordance with ISO 10993-10.
Irritation or intracutaneous activity	Tests used to estimate the irritation potential of medical devices, materials and/or their extracts, using an appropriate site for application such as skin, eye and mucous membrane in a suitable model. The test(s) performed shall be appropriate for the route (skin, eye and mucosa) and duration of exposure or contact. • Testing should be conducted in accordance with ISO 10993-10.

Pyrogenicity	Pyrogenicity tests as part of a biological evaluation are intended to detect material-mediated pyrogenic reactions of extracts of medical devices or materials. No single test can differentiate pyrogenic reactions that are material-mediated from those due to endotoxin contamination (see ISO 10993-11:2017, Annex G). Material-mediated pyrogenicity is rare. It has been observed in medical devices containing biologically-derived materials.
Acute systemic Toxicity	Tests used where contact allows potential absorption of toxic leachables and degradation products, to estimate the potential harmful effects of either single or multiple exposures, during a period of less than 24 h, to medical devices, materials and/or their extracts in an animal model. These tests shall be appropriate for the route of exposure. • Any testing performed should be conducted in accordance with ISO 10993-11.
Sub-acute/ sub-chronic toxicity	Acute systemic toxicity tests used where contact allows potential absorption of toxic leachables and degradation products, to estimate the potential harmful effects of either single or multiple exposures, during a period of less than 24 h, to medical devices, materials and/or their extracts in an animal model. These tests shall be appropriate for the route of exposure. • Any testing performed should be conducted in accordance with ISO 10993-11.
Chronic Toxicity	Tests used to determine the effects of either single or multiple exposures to medical devices, materials and/or their extracts during a major period of the life-span of the test animal (e.g. usually 6 months in rats). These tests shall be appropriate for the route and duration of exposure or contact. • Testing should be conducted in accordance with ISO 10993-11.

Hemocompatibility	Tests used to evaluate, using an appropriate model or system, the effects of blood-contacting medical devices or materials on blood or blood components. One haemocompatibility test, haemolysis, determines the degree of red cell lysis and the release of haemoglobin caused by medical devices, materials, and/or their extracts in vitro. • Testing should be conducted in accordance with ISO 10993-4.
Genotoxicity	Genotoxicity tests used to assess the potential for gene mutations, changes in chromosome structure and number, and other DNA or gene toxicities caused by medical devices, materials and/or their extracts. A battery of in vitro tests is initially used. • Testing should be conducted in accordance with ISO 10993-3.
Implantation effects	Implantation tests can be used to assess the local pathological effects on living tissue, at both the gross level and microscopic level, of a sample of a material or final product that is surgically implanted or placed in an implant site or tissue appropriate to the intended application (e.g. special dental usage tests). These tests shall be appropriate for the route and duration of contact. • Testing should be conducted accordance with ISO 10993-6.
Carcinogenicity	Test to determine the carcinogenic potential of medical devices, materials, and/or extracts using multiple exposures for a major portion of the life span of the test animal. • Testing should be conducted in accordance with ISO 10993-3.

When the biocompatibility evaluation determines that biological tests are required, the complete test reports should be submitted to the SFDA. The test reports should be issued by ISO/IEC 17025 accredited laboratory. The reports should be provided in English. The test report should include the following information:

- Any referenced standards.
- Test article preparation
- Test method
- Test parameters and acceptance criteria

- Analysis of results
- Conclusions

Shelf life

Shelf life is the duration of time when the finished product remains safe and effective. Manufacturers of surgical sutures should determine the product's shelf life through real-time ageing testing and/or accelerated ageing testing. If accelerated ageing testing needs to be conducted, it is recommended to refer to the ASTM F1980 standard titled "Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices." Guidance on conducting accelerated ageing tests for medical devices and sterile barrier systems is provided by this standard. The real-time ageing testing should be conducted in parallel with the accelerating ageing to validate the obtained results.

Sterilization

The finished product must be supplied in a sterile state, which is achieved when it is free from viable microorganisms. The sterility assurance level (SAL) should reach 1x10-6, which means a ≤1/1 million chance that a single viable microorganism is present on a sterilized item. The surgical sutures can be sterilized by Ethylene Oxide, Gamma radiation or any other suitable sterilization method. The selection of the sterilization method should at least consider the following factors: the compatibility between the product and the sterilization method; the compatibility of the packaging material and the sterilization method, and the impact of sterilization on the safety and effectiveness of the product. In cases where the sterilization method employed is susceptible to leaving behind residues, such as in ethylene oxide sterilization, it is imperative that the pertinent information regarding residue and treatment methods be documented and made unequivocally clear. For ethylene oxide sterilization, the acceptable limits are specified in ISO 10993-7.

Several standards have been established to ensure their effective sterilization. The following standards, though not exhaustive, are designed to guarantee that surgical sutures are safe for use in clinical settings:

- ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
- ISO 11135-1 *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
- ISO 11137-1 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*

- ISO 20857 *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*
- ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

Labeling

The product labeling shall comply with the following:

- Requirements for labeling and information provided by the manufacturer specified in the Requirements for Medical Device Marketing Authorization (MDS-REQ1).
- Requirements for labeling specified in the applicable standards.

The details strictly necessary for the user to identify the product properly are indicated on or in each primary packaging and on the protective cover (box) and may include:

- Gauge number
- Length in centimeters or meters,
- Suture type and structure (e.g. absorbable, no absorbable, braided, monofilament, sheathed)
- An indication if the suture is colored.
- Material from which the suture is made.
- Shape of the needle, If applicable;
- Needle length, If applicable;
- Quantity of sutures needles, If applicable;
- Curvature, If applicable;
- Point configurations, If applicable;
- Type of eye (either eyed or eyeless), If applicable;
- Statement to the effect that the needle is detachable, if applicable.

Annex (1) Abbreviations and Definitions

SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
Medical device	Any instrument, apparatus, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in return it may be assisted in its intended function by such means.
Medical Device Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Authorized Representative	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulations.
Intended Use	The purpose specified by the manufacturer for the use of a medical device.
Labeling	Any written statement, information, or illustration printed on a medical device, including identifying information, technical description, method of use, and manner of storage and transportation.
Standards	Non-mandatory documents approved by the SFDA, including rules, guidelines, specifications of medical devices and supplies, or production processes and methods related thereto as well as terms and symbols, and packaging and labelling requirements.