General Standard for Surgical Sutures

1. Scope

This Standard provides definitions, relevant international standards, classification requirements, and test methods for surgical sutures.

This present Standard is applicable to all single use surgical sutures, inclusive of non-absorbable and absorbable sutures. Examples of their use include general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures (only if applicable).

2. Normative references

The following standard contains provisions which, through reference in this text, constitute provisions of this present standard. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below:

2.1 Nonabsorbable Surgical Suture

The following references are specific to Nonabsorbable Surgical Suture.

United States Pharmacopeia, *Monographs for Nonabsorbable Surgical Suture*
European Pharmacopeia, *Monographs for Sutures, Sterile*
European Pharmacopeia, *Monograph for Beeswax*

ASTM F138-13a, *F138-13 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)*

ISO 5832-1, *Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel*

ISO 10334, *Implants for Surgery - Malleable Wires for Use as Sutures and Other Surgical Applications*

EN 62570, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

2.2 Absorbable Surgical Suture

The following references are specific to Absorbable Surgical Suture.

United States Pharmacopeia, *Monographs for Absorbable Surgical Suture*
United States Pharmacopeia, *USP Monograph Triclosan*
European Pharmacopeia, *Monographs for Sutures, Sterile Absorbable*

2.3 Common References

The following references are common to both Nonabsorbable Surgical Suture and Absorbable Surgical Suture.

ISO 13485*, Medical devices - Quality management systems - Requirements for regulatory purposes*

ISO 14971, *Medical Devices – Application of Risk Management*

ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements*

EN 1041: 2008, *Information supplied by the manufacturer of medical devices*

ISO 16061, *Instrumentation for use in association with non-active surgical implants -- General requirements*

ISO 14630*, Non-active surgical implants -- General requirements*

EN 62366-1:2015 / A1, *Medical Devices – Application of Usability Engineering to Medical Devices*

ISO 10993-1, *Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process*

ISO 10993-2, *Biological evaluation of Medical Devices – Part 2: Animal welfare requirements*

ISO 10993-3, *Biological evaluation of Medical Devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-4, *Biological evaluation of Medical Devices – Part 4: Selection of tests for interactions with blood*

ISO 10993-5, *Biological evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of Medical Devices – Part 6: Tests for local effects after implantation*

ISO 10993-7, *Biological evaluation of Medical Devices – Part 7: Ethylene oxide sterilization residuals*

ISO 10993-9, *Biological evaluation of Medical Devices – Part 9: Framework for identification and quantification of potential degradation products*

ISO 10993-10, *Biological evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization*

ISO 10993-11, *Biological evaluation of Medical Devices – Part 11: Tests for systemic toxicity*

ISO 10993-12, *Biological evaluation of Medical Devices – Part 12: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

ISO 10993-13, *Biological evaluation of Medical Devices – Part 13: Identification and quantification of degradation products from polymeric medical devices*

ISO 10993-14, *Biological evaluation of Medical Devices – Part 14: Identification and*

quantification of degradation products from ceramics

ISO 10993-15, *Biological evaluation of Medical Devices – Part 15: Identification and quantification of degradation products from metals and alloys*

ISO 10993-16, *Biological evaluation of Medical Devices – Part 16: Toxicokinetic study design for degradation products and leachables*

ISO 10993-17, *Biological evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances*

ISO 10993-18, *Biological evaluation of Medical Devices – Part 18: Chemical characterization of medical device materials within a risk management process*

ISO 10993-19, *Biological evaluation of Medical Devices – Part 19: Physico-Chemical, Morphological And Topographical Characterization Of Materials*

ISO 10993-20, *Biological evaluation of Medical Devices – Part 20: Principles and Methods For Immunotoxicology Testing Of Medical Devices*

EN 556-1:2001 AC, *Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices*

ISO 11737-1, *Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

ISO 11135, *Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11138-2, *Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes*

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 11137-2, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*

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*

ISO 14644-1, *Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness*

ISO 14644-2, *Cleanrooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

ISO 14644-5, *Cleanrooms and associated controlled environments - Part 5: Operations*
MEDDEV 2.7.1 Rev. 4, *Guidelines on Medical Devices/Clinical Evaluation: A guide for manufacturers and Notified Bodies*
Regulation (EC) No 1272/2008, *Classification, labelling and packaging of substances and mixtures (CLP)*

3. Classifiaction of Sutures

Form:

Sutures are available in both forms (with and without needles) and are provided sterile

Structure:
Sutures have both single-strand and multi-strand (stranded and woven) structures

Material:

Nonabsorbable Surgical Suture: a flexible strand of material that is not absorbed in living mammalian tissue.

It may be in either monofilament or multifillament form. If it is a multifilament strand, the individual filaments may be combined by twisting, braiding, or any combination thereof. It may be either sterile or nonsterile. Its diameter and tensile strength correspond to the size designation indicated on the label, within the limits prescribed herein. It may be modified with respect to body or texture, or to reduce capillarity, and may be suitably bleached. It may be impregnated or treated with a suitable coating, softening, or antimicrobial agent. It may be colored by a color additive approved by the local regulatory body.

Category				
Material	Natural fiber (silk) Synthetic fiber		Natural fiber (silk) Synthetic fiber	Metal
Dyeing	Dyed or undyed		Dyed or undyed	—
Structure	Multi-strand	Single-strand	Single-strand or multi-strand	—
Coating	With coating	Without/with coating	Natural fiber (silk), synthetic fiber, with the effect of its coating on the suture diameter	—

Absorbable Surgical Suture: a sterile, flexible strand prepared from collagen derived from healthy mammals or from a synthetic polymer. Suture prepared from synthetic polymer may be in either monofilament or multifilament form. It is capable of being

absorbed by living mammalian tissue, but may be treated to modify its resistance to absorption. Its diameter and tensile strength correspond to the size designation indicated on the label, within the limits prescribed herein. It may be modified with respect to body or texture. It may be impregnated or treated with a suitable coating, softening, or antimicrobial agent. It may be colored by a color additive approved by the local regulatory. The collagen suture is designated as either Plain Suture or Chromic Suture . Both types consist of processed strands of collagen, but Chromic Suture is processed by physical or chemical means so as to provide greater resistance to absorption in living mammalian tissue.

Category			
Materials	**Animal collagen**	**Artificially synthetic polymer**	
System	Plain/chromic	—	
Dyed	Dyed/undyed	Dyed/undyed	
Structure	—	Multi-strand	Single-strand
Coating	—	With coating	Without/with coating

4. Requirements

4.1 General

a. Surgical Suture manufacturer shall have quality systems assuring compliance with ISO 13485, ISO 14971, ISO 14630, and ISO 16061.
b. The design of the Surgical Suture will include usability engineering requirements of IEC 62366.

4.2 Appearance

a) The suture shall have smooth surface, uniform color and yarn evenness, and shall be free from stains or knots. The surface of multi-strand suture shall be coated.

b) If the suture is provided with a needle, the needle-suture connection shall be smooth and burr-free.

4.2 Performance

Surgical Sutures utilize common design features with performance requirements of:

a. Common Design Features (as measured in accordance with the applicable Phamacopeial monograph)

I. **Length**

- The length of each strand is NLT 95.0% of the length stated on the label.

II. **Diameter**

- The average diameter should be within the limits ofthe applicable monograph for the size stated on the label. None of the observed individual measurements should be less than or greater than the limits on individual diameter in the applicable monograph.

III. **Tensile Strength**

- The average tensile strength is NLT that set forth in the applicable monograph for the class and size stated on the label.
- Breaking strength of suture

IV. **Needle Attachment Strength**

- The average and individual needle attachment strength is NLT that set forth in the applicable monograph for the size stated on the label.

V. **Extractable Color (if suture is dyed)**

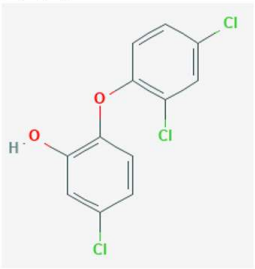
- Extracted color solution (prepared per the applicable monograph) is not more intense than that of the appropriate Matching solution.

b. Needle Specific

I. **Refer to General specification for Surgical Needles**

a. Triclosan (specific to antimicrobial sutures)

I. **Composition**

Material Composition	Entry
Chemical Name	Triclosan, 2,4,4'-trichloro-2'-hydroxy-diphenyl ether
Chemical Formula	$C_{12}H_7Cl_3O_2$ 
Molecular Weight (g/mol)	289.54
Chemical Family	Ether
CAS Number	CAS 3380-34-5
Chemical Grade	USP

II. **Material Requirements**

Characteristics	Requirements
Appearance	A fine white powder as compared to the standard maintained at each location.
Identification	An infrared spectrum prepared using a representative sample of this material will compare with a standard reference. Standard references are cataloged at each location. Note: The Triclosan USP Monograph Identification requirement (the retention time of the major peak in the chromatogram of the Assay preparation must correspond to that of the Standard preparation) is tested by the supplier within the test for Active Substance.
Active Substance	97.0% - 103.0%
Melting Point	56 – 58 °C
Sum Heavy Metals	≤20 mg/kg
TCDD Tox Equivalents	<0.001 µg/kg
2,4 dichlorophenol	≤10 mg/kg
Monochlorophenols (Reported as the Sum of 3- and 4-chlorophenol)	≤10 mg/kg
2,3,7,8 tetrachlorodibenzo-*p*-dioxin (Reported as 2, 3, 7, 8tetrachldibenzo-p-dioxin)	<0.001 µg/kg
2,3,7,8-tetrachlorodibenzofuran (Reported as 2, 3, 7, 8-tetracldibenzo-furan)	<0.001 µg/kg

Characteristics	Requirements
2,8-dichlorodibenzo-*p*-dioxin (Reported as 2, 8-dicldibenzo-p-dioxin)	≤0.5 mg/kg
1,3,7-trichlorodibenzo-*p*-dioxin (Reported as 1, 3, 7-tricldibenzo-p-dioxin)	≤0.25 mg/kg
2,8-dichlorodibenzofuran (Reported as 2, 8-dicldibenzo-furan)	≤0.25 mg/kg
2,4,8-trichlorodibenzofuran (Reported as 2, 4, 8-tricldibenzo-furan)	≤0.5 mg/kg
Water Content	≤0.1%
Completeness of Solution	Solution is clear
Individual Related Compound	≤0.10%
Total Related Compounds	≤0.5%

Triclosan used on finished product meets USP material requirements and has 97%-103% active substances.

4.3 Biological Evaluation

Materials used in the construction of the Surgical Suture shall be evaluated for biological compatibility in accordance with ISO 10993-1, ISO 10993-2, ISO 10993-3, ISO 10993-4, and ISO 10993-5.

4.4 Labeling – marking

- **a.** Surgical Suture shall be labeled in accordance with ISO 15223-1 and EN 1041:2008.
- **b.** Surgical Suture shall come with instructions for use or provide contact information to request said instructions.

4.5 Packaging – sterile barriers

- **a.** When the Surgical Suture is provided sterile by the manufacturer, the design shall be compliant with ISO 11607-1, and its sterile barrier sealing and forming process compliant with ISO 11607-2.
- **b.** ~~Average package seal strength shall be in the range of 0.1N/mm (0.57lbs/in) to 0.7N/mm (3.99lbs./in). Alternatively, an acceptable sterile barrier seal strength may be defined by rationale provided by the manufacturer as necessary for the given package design and device~~.
- **c.** Average seal strength should be based on validated materials and processes for the packaging materials in question and provide sufficient sterile barrier.

4.6 Sterilization

- **a.** When the Surgical Suture is delivered sterile by irradiation from the manufacturer, it will be compliant with ISO 11137-1, and ISO 11137-2
- **b.** When the Surgical Suture is delivered sterile by Ethylene Oxide (EtO) from the manufacturer, it will be compliant with ISO 11135 and ISO 10993-7

5. Testing [reference to associated requirement]

5.1 Labeling – marking

Visually confirm:

a. Product code and description shall be correct, present, legible, and undamaged on either the primary packaging or the Device **[Labeling-Marking]**

b. Batch number or serial number shall be correct, present, legible, and undamaged on either the primary packaging or the Device **[Labeling-Marking]**

c. The manufacturer's information (name and contact information) shall be correct, present, legible, and undamaged on the packaging **[Labeling-Marking]**

d. Shelf life (expiry date) shall be present on the primary packaging or Device, legible, undamaged, and must be after the date of inspection **[Labeling-Marking]**

5.2 Packaging

Visually confirm, without optical magnification:

a. The interior of any sealed package shall be free of foreign matter (excludes materials intended to be part of the product such as a sodium stearate lubricant), surface flash, burrs, loose, trapped, or imbedded particles **[Clean]**
b. Sterile barrier packaging material should not have embedded particulate or imperfections per validated ranges or materials specifications ~~greater than 0.6 sq.mm~~ **[Packaging-Sterile Barrier]**
c. Sterile barrier packaging seal should not have bubbles, channels, suture material, gels entrapped air or un-melted material (e.g. spotty seals or voids) and should meet minimum seal requirements **[Packaging-Sterile Barrier]**
d. Sterile barrier packaging should not have holes, cracks, or cuts **[Packaging-Sterile Barrier]**
e. Dents, or creases in seal region may lead to channels; Waves or curles can make it difficult to seal materials together **[Packaging- Sterile Barrier]**
f. Lack of uniform or skips in adhesive coating on materials may lead to open channels in the seal **[Packaging- Sterile Barrier]**
g. Instructions for Use are included with each device, or labeling identifies contact information necessary to request a copy **[Labeling-Marking]**
h. Printed inks on packaging components should be evaluated to ensure durability post manfacuting processing is maintained, remains durable post during transit, and [**Labeling-Marking]**
i. Printing inks shall not be of a type which can be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system, nor change colour to an extent which renders the label illegible **[Labeling-Performance]**

Sterile barrier seal shall be confirmed by:

j. The seal region should be evaluated per recognized test methods (such as ASTM F88). The seal strength range specified in Section 4.5 shall be used to determine acceptability of sterile barrier seal strength as calculated from the average of the maximum peel force values taken from individual side seals of sealed package. The peeled surfaces should be smooth and uniform, without phenomenon such as delamination or tearing **[Packaging-Sterile Barrier]**

k. Package Sterile barrier integrity of the seals and closures (used to establish the capability of the sterile barrier system to maintain sterility) should be evaluated per recognized test method (such as standard test methods referenced per ISO11607:2019, Annex B) or as per validated integrity test methods **[Packaging-Sterile Barrier]**

Biocompatibility and toxicological attributes of the Packaging Materials and/or components (including printing inks) should be evaluated. Guidance on biocompatibility is given in ISO 10993-1. **[Packaging-Materials]**

5.3 Performance

Testing and evaluation of the following properties shall be performed per the

applicable Pharmacopeial monograph (e.g., USP or EP)

a. Length
b. Diameter
c. Tensile Strength
d. Needle Attachment Strength
e. Extractable Color (if suture is dyed)