Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2020
Document Type: USP Monographs
DocId: GUID-874E1C1B-F5A7-4B58-8D6E-460BAFF5005A_4_en-US
DOI: https://doi.org/10.31003/USPNF_M80200_04_01
DOI Ref: sst6l

Nonabsorbable Surgical Suture

DEFINITION

Nonabsorbable Surgical Suture is a flexible strand of material that is not absorbed in living mammalian tissue. It may be in either monofilament or multifilament 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 FDA.

Nonabsorbable Surgical Suture is classed and typed as follows. Class I Suture is composed of silk or synthetic fibers of monofilament, twisted, or braided construction where the coating, if any, does not significantly affect thickness (e.g., braided silk, polyester, or nylon; monofilament nylon or polypropylene). Class II Suture is composed of cotton or linen fibers or coated natural or synthetic fibers where the coating significantly affects thickness but does not contribute significantly to strength (e.g., virgin silk sutures). Class III Suture is composed of monofilament or multifilament metal wire.

SPECIFIC TESTS

[Note—If the Suture is packaged with a fluid, make the required measurements for the first four of the following tests within 2 min after removing it from the fluid.]

- **Length**

Sample: A length of Suture

Analysis: Lay the *Sample* out smooth and without tension on a plane surface and determine the length of the *Sample*.

Acceptance criteria: The length of each strand is NLT 95.0% of the length stated on the label.

Change to read:

- **Sutures—Diameter** ⟨861⟩

Sample: 10 strands of Suture

Analysis: Determine the diameter as directed in the chapter.

Acceptance criteria: The average diameter on the 10-strand *Sample* is within the limits on average diameter (for all 30 measurements) in *Table 1* 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 *Table 1*.

Table 1. Average Knot-Pull Limits of Various Sizes and Diameters of Sutures

		Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Limits on Average Knot-Pull (except where otherwise specified)[a], Tensile Strength (in N)[b,c]		
USP Size[d]	Metric Size (Gauge No.)	Min.	Max.	Min.	Max.	Class I Min.	Class II Min.	Class III Min.
12-0	0.01	0.001	0.009	—	0.015	0.01[a]	—	0.02[a]
11-0	0.1	0.010	0.019	0.005	0.025	0.06[a]	0.05[a]	0.20[a]

		Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Limits on Average Knot-Pull (except where otherwise specified)[a], Tensile Strength (in N)[b,c]		
USP Size[d]	Metric Size (Gauge No.)	Min.	Max.	Min.	Max.	Class I Min.	Class II Min.	Class III Min.
10-0	0.2	0.020	0.029	0.015	0.035	0.186[a]	0.14[a]	0.59[a]
9-0	0.3	0.030	0.039	0.025	0.045	0.422[a]	0.28[a]	0.68[a]
8-0	0.4	0.040	0.049	0.035	0.060	0.59	0.39	1.08
7-0	0.5	0.050	0.069	0.045	0.085	1.08	0.59	1.57
6-0	0.7	0.070	0.099	0.060	0.125	1.96	1.08	2.65
5-0	1	0.10	0.149	0.085	0.175	3.92	2.26	5.30
4-0	1.5	0.15	0.199	0.125	▲0.225 ▲ (USP 1-Dec-2020)	5.88	4.51	8.04
3-0	2	0.20	0.249	0.175	0.275	9.41	6.47	13.3
2.5-0	2.5	0.25	0.299	0.225	0.325	13.6	7.28	15.2
2-0	3	0.30	0.349	▲0.275 ▲ (USP 1-Dec-2020)	0.375	14.1	10.0	17.7
0	3.5	0.35	0.399	0.325	0.450	21.2	14.2	33.3[a]
1	4	0.40	0.499	0.375	0.550	26.7	17.7	46.7[a]
2	5	0.50	0.599	0.450	0.650	34.5	24.9	57.9[a]
3 and 4	6	0.60	0.699	0.550	0.750	47.9	36.1	89.3[a]
5	7	0.70	0.799	0.650	0.850	60.4	—	112.0[a]
6	8	0.80	0.899	0.750	0.950	71.4	—	133.0[a]
7	9	0.90	0.999	0.850	1.050	88.6	—	156.0[a]
8	10	1.00	1.099	0.950	1.150	—	—	178.0[a]
9	11	1.100	1.199	1.050	1.250	—	—	201.0[a]

		Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Limits on Average Knot-Pull (except where otherwise specified)[a], Tensile Strength (in N)[b,c]		
USP Size[d]	Metric Size (Gauge No.)	Min.	Max.	Min.	Max.	Class I Min.	Class II Min.	Class III Min.
10	12	1.200	1.299	1.150	—	—	—	224.0[a]

[a] The tensile strength of sizes smaller than USP size 8-0 (metric size 0.4) is measured by straight pull. The tensile strength of sizes larger than USP size 2-0 (metric size 3) of monofilament Class III (metallic) Nonabsorbable Surgical Suture is measured by straight pull. Silver wire (silver-coated fabric) meets the tensile strength values of Class I Sutures but is tested in the same manner as Class III Sutures.

[b] The limits on knot-pull tensile strength apply to Nonabsorbable Surgical Suture that has been sterilized. For nonsterile Sutures of Class I and Class II, the limits are 25% higher.

[c] To convert from N to kg, divide N by 1.0197 and round to one significant figure.

[d] USP sizes may not represent all sizes commercially available. For sizes other than those listed in the table, suture manufacturers must generate appropriate diameters and tensile strength data to support use.

- **Tensile Strength ⟨881⟩,** *Surgical Suture*

  Sample: NLT 10 strands of Suture

  Analysis: Determine the tensile strength of the *Sample* as directed in the chapter. Average all observations obtained.

  Acceptance criteria: The average tensile strength is NLT that set forth in *Table 1* for the class and the size stated on the label.

- **Sutures—Needle Attachment ⟨871⟩:** Suture on which eyeless needles are swaged meets the requirements.

- **Sterility Tests ⟨71⟩:** Suture that is claimed to be sterile meets the requirements.

Change to read:

- **Extractable Color** (if Suture is dyed)

  Matching solutions: Prepare by combining the colorimetric solutions (CS) in the proportions indicated in *Table 2*, and adding water, if necessary, to make 10.0 parts. [See *Reagents, Indicators, and Solutions—Solutions, Colorimetric Solutions (CS)* for composition.]

Table 2. Matching Solutions

	Parts of Each CS per 10 Parts of Total Volume		
Color of Suture (Extractable Color)	Cobaltous Chloride CS	Ferric Chloride CS	Cupric Sulfate CS
Yellow-brown	0.2	1.2	—
Pink-red	1.0	—	—
Green-blue	—	—	2.0
Violet	1.6	—	8.4

Sample: NLT 250 mg of Suture

Analysis: Place the *Sample* in a conical flask containing 1.0 mL of water for each 10 mg of the *Sample*. ▲For microsutures use 2.5 mL of water for each 25 mg of the *Sample*.▲ (USP 1-Dec-2020) Cover the flask with a short-stemmed funnel, heat the contents of the flask at the boiling point for 15 min, cool, and restore the volume by the addition of water, if necessary, to replace that lost by evaporation. Decant the water from the Suture, and compare it with the *Matching solution*.▲ Where fibrous extraneous material may affect the color, filter the solution before performing the color determination.▲ (USP 1-Dec-2020)

Acceptance criteria: Any color present is not more intense than that of the appropriate *Matching solution*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve nonsterilized Suture in well-closed containers. Preserve sterile Suture dry or in fluid, in containers (packets) so designed that sterility is maintained until the container is opened. A number of such containers may be placed in a box.

• **Labeling:** The label of each individual container (packet) of Suture indicates the material from which the Suture is made, the size, construction, and length of the Suture, whether it is sterile or nonsterile, kind of needle (if a needle is included), number of sutures (if multiple), lot number, and name of the manufacturer or distributor. If removable needles are used, the labeling so indicates. Suture size is designated by the metric size (gauge number) and the corresponding USP size. The label of the box indicates also the address of the manufacturer, packer or distributor, and the composition of any packaging fluids used.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
NONABSORBABLE SURGICAL SUTURE	Leslie Furr Associate Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	GCDF2020 General Chapters - Dosage Forms 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(5)

Current DocID: GUID-874E1C1B-F5A7-4B58-8D6E-460BAFF5005A_4_en-US
DOI: https://doi.org/10.31003/USPNF_M80200_04_01
DOI ref: sst6l