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Absorbable Surgical Suture

DEFINITION

Absorbable Surgical Suture is 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 FDA. 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.

IMPURITIES

• **Soluble Chromium Compounds**

Standard solution: 2.83 µg/mL of potassium dichromate in water

Sample solution: 5 mL of the fluid prepared as directed in the *Extractable Color* test

Analysis: To 5 mL each of the *Standard solution* and *Sample solution* add 2 mL of a solution (1 in 100) of diphenylcarbazide in alcohol and 2 mL of 2 N sulfuric acid.

Acceptance criteria: Any color that develops in the *Sample solution* is not more intense than that in the *Standard solution* [1 ppm of chromium (Cr)].

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: Determine the length of the *Sample* without stretching.

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

Collagen suture: The average diameter, and NLT 20, of the 30 measurements on the 10-strand *Sample* are within the limits on average diameter in *Table 1* for the size stated on the label. None of the individual observed measurements should be less than or greater than the limits on individual diameter in *Table 1*.

Table 1. Collagen Suture

USP Size[a]	Metric Size (Gauge No.)	Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Knot-Pull Tensile Strength (in N)[b]	
		Min.	Max.	Min.	Max.	Limit on Average Min.	Limit on Individual Strand Min.
9-0	0.4	0.040	0.049	—	0.060	—	—

USP Size[a]	Metric Size (Gauge No.)	Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Knot-Pull Tensile Strength (in N)[b]	
		Min.	Max.	Min.	Max.	Limit on Average Min.	Limit on Individual Strand Min.
8-0	0.5	0.050	0.069	0.045	0.085	0.44	0.24
7-0	0.7	0.070	0.099	0.060	0.125	0.69	0.54
6-0	1	0.10	0.149	0.085	0.175	1.77	0.98
5-0	1.5	0.15	0.199	0.125	0.250	3.73	1.96
4-0	2	0.20	0.249	0.175	0.325	7.55	3.92
3-0	3	0.30	0.349	0.250	0.375	12.3	6.67
2-0	3.5	0.35	▲0.339▲ (USP 1-Dec-2020)	0.250	0.450	19.6	10.2
0	4	0.40	0.499	0.375	0.550	27.2	14.2
1	5	0.50	0.599	0.450	0.650	37.3	19.1
2	6	0.60	0.699	0.550	0.750	44.2	25.5
3	7	0.70	0.799	0.650	0.850	57.9	29.3
4	8	0.80	0.899	0.750	—	68.6	34.2

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

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

Synthetic suture: The average diameter of the strands being measured is within the tolerances prescribed in *Table 2* for the size stated on the label. None of the individual observed measurements should be less than or greater than the limits on individual diameter in *Table 2*.

Table 2. Synthetic Suture

USP Size[a]	Metric Size (Gauge No.)	Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Knot-Pull Tensile Strength (in N)[b] (except where otherwise specified)
		Min.	Max.	Min.	Max.	
12-0	0.01	0.001	0.009	—	0.015	—
11-0	0.1	0.010	0.019	0.005	0.025	—
10-0	0.2	0.020	0.029	0.015	0.035	0.25[c]
9-0	0.3	0.030	0.039	0.025	0.045	0.49[c]

USP Size[a]	Metric Size (Gauge No.)	Limits on Average Diameter (mm)		Limits on Individual Diameter (mm)		Knot-Pull Tensile Strength (in N)[b] (except where otherwise specified)
		Min.	Max.	Min.	Max.	
8-0	0.4	0.040	0.049	0.035	0.060	0.69
7-0	0.5	0.050	0.069	0.045	0.085	1.37
6-0	0.7	0.070	0.099	0.060	0.125	2.45
5-0	1	0.10	0.149	0.085	0.175	6.67
4-0	1.5	0.15	0.199	0.125	0.250	9.32
3-0	2	0.20	0.249	0.175	0.325	17.4
2-0	3	0.30	▲0.349▲ (USP 1-Dec-2020)	0.250	0.375	26.3
0	3.5	0.35	0.399	0.325	0.450	38.2
1	4	0.40	0.499	0.375	0.550	49.8
2	5	0.50	0.599	0.450	0.650	62.3
3 and 4	6	0.60	0.699	0.550	0.750	71.5
5	7	0.70	0.799	0.650	—	—

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

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

[c] The tensile strength of the specified USP size is measured by straight pull.

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

Sample: NLT 10 strands of Suture

Analysis: Determine the tensile strength of the *Sample* as directed in the chapter.

Acceptance criteria

Collagen suture: The tensile strength, determined as the minimum strength for each individual strand tested and calculated as the average strength from any one lot, is as set forth in *Table 1*. If NMT 1 strand fails to meet the limit on individual strands, repeat the test with NLT 20 additional strands; the requirements of the test are met if none of the additional strands fall below the limit on individual strands, and if the average strength of all the strands tested does not fall below the stated limit in *Table 1*.

Synthetic suture: The minimum tensile strength of each size of synthetic suture, calculated as the average strength from any one lot, is as set forth in *Table 2*.

- **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 3*, and adding water, if necessary, to make 10.0 parts. [See *Reagents, Indicators, and Solutions—Solutions, Colorimetric Solutions (CS)* for composition.]

Table 3. Matching Solutions

Color of Suture (Extractable Color)	Parts of Each CS per 10 Parts of Total Volume		
	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*. Close the flask, and allow it to stand at 37 ± 0.5° for 24 h. Cool. 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.

Acceptance criteria: Any color present is not more intense than that of the appropriate *Matching solution*. ▲▲ (USP 1-Dec-2020)

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve 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 size, length, type of Suture, including the material composition as well as the physical configuration (e.g., monofilament/multifilament, twisted/braided), 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
ABSORBABLE 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

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