

# 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 <sup>a</sup> | Metric Size<br>(Gauge No.) | Limits on Average<br>Diameter (mm) |       | Limits on Individual<br>Diameter (mm) |       | Knot-Pull Tensile<br>Strength<br>(in N) <sup>b</sup> |                                                                                       |
|-----------------------|----------------------------|------------------------------------|-------|---------------------------------------|-------|------------------------------------------------------|---------------------------------------------------------------------------------------|
|                       |                            | Min.                               | Max.  | Min.                                  | Max.  | Limit on<br>Average<br>Min.                          | Limit on<br>Individual<br>Strand Min.                                                 |
| 9-0                   | 0.4                        | 0.040                              | 0.049 | —                                     | 0.060 | —                                                    |  |

| USP Size <sup>a</sup> | Metric Size<br>(Gauge No.) | Limits on Average<br>Diameter (mm) |                                 | Limits on Individual<br>Diameter (mm) |       | Knot-Pull Tensile<br>Strength<br>(in N) <sup>b</sup> |                                       |
|-----------------------|----------------------------|------------------------------------|---------------------------------|---------------------------------------|-------|------------------------------------------------------|---------------------------------------|
|                       |                            | Min.                               | Max.                            | Min.                                  | Max.  | Limit on<br>Average<br>Min.                          | Limit on<br>Individual<br>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▲<br>(USP 1-Dec-<br>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                                  |

<sup>a</sup> 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.

<sup>b</sup> 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 <sup>a</sup> | Metric Size<br>(Gauge No.) | Limits on<br>Average Diameter (mm) |       | Limits on Individual Diameter (mm) |       | Knot-Pull Tensile<br>Strength (in N) <sup>b</sup><br>(except where<br>otherwise<br>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 <sup>c</sup>                                                                             |
| 9-0                   | 0.3                        | 0.030                              | 0.039 | 0.025                              | 0.045 | 0.49 <sup>c</sup>                                                                             |