

# DRAFT UGANDA STANDARD

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## Surgical sutures — Specification — Part 1: Absorbable

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## Foreword

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The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 14, Medical devices.

DUS 1958 consists of the following parts, under the Surgical sutures — Specification

- — *Part 1: Surgical sutures — Specification — Part 1: Absorbable*
- — *Part 2: Surgical sutures — Specification — Part 2: Non Absorbable*

## Introduction

Surgical sutures are used in a variety of different surgical procedures to close wounds and aid in tissue healing. These sutures may be a single filament or multifilament or braided or twisted with or without a coating

Surgical sutures are classified into two types:

- a) Absorbable surgical sutures
- b) Non-absorbable surgical sutures

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# Surgical sutures — Specification — Part 1: Absorbable

## 1 Scope

This Draft Uganda Standard specifies the requirements, sampling and test methods for absorbable surgical sutures

## 2 Normative references

The following referenced documents referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

US ISO 24153 — *Random sampling and randomisation procedures*.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <http://www.iso.org/obp>

### 3.1

#### **absorbable sutures**

sutures capable of being absorbed by living animal tissues.

### 3.2

#### **monofilament**

suture made of a single strand

### 3.3

#### **multifilament**

suture composed of several filaments twisted or braided together

### 3.4

#### **surgical sutures**

medical devices that are used to hold body tissues together after a surgery or injury.

## 4 Types of absorbable sutures

### 4.1 Natural absorbable sutures

Sutures prepared from collagen derived from healthy mammals. Natural absorbable sutures are categorized into two: plain and chromic gut.

## 4.2 Synthetic absorbable sutures

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.

## 5 General description

5.1 The suture shall either be monofilament or multifilament. If multifilament, the individual filament may be combined by spinning, twisting, braiding or any combination.

5.2 It may be coloured, coated or both.

## 6 Quality requirements

### 6.1 Length

The length of the suture without stretching shall be not less than 95 per cent of the length stated on the label and shall not exceed 400 cm.

### 6.2 Diameter

6.2.1 Collagen suture — When determined in accordance with Annex A, the average diameter, and not fewer than 20, of the 30 measurements on the 10-strand sample are within the limits on average diameter prescribed in Table 1. None of the individual measurements is less than the midpoint of the range for the next smaller size or more than the midpoint of the range for the next larger size.

6.2.2 Synthetic suture — When determined in accordance with Annex A, the average diameter of the strands being measured is within the tolerances prescribed in Table 2. None of the observed measurements is less than the midpoint of the range for the next smaller size or more than the midpoint of the range for the next larger size.

Table 1 — Diameter and tensile strength of natural (collagen) sutures

Gauge number (Metric size)	Limits on average diameter (mm)		Knot pull tensile strength (kgf)		Knot pull tensile strength (N)	
	Min	max	Limit on average min.	Limit on individual strand ,min	Limit on average min.	Limit on individual strand ,min
0.4	0.040	0.049	-	-	-	-
0.5	0.050	0.069	0.045	0.025	0.44	0.24
0.7	0.070	0.099	0.07	0.055	0.69	0.54
1	0.10	0.149	0.18	0.10	1.76	0.98
1.5	0.15	0.199	0.38	0.20	3.73	1.96
2	0.20	0.249	0.77	0.40	7.55	3.92
3	0.30	0.339	1.25	0.68	12.2	6.67
3.5	0.35	0.399	2.00	1.04	19.6	10.2
4	0.40	0.499	2.77	1.45	27.2	14.2
5	0.50	0.599	3.80	1.95	37.3	19.1
6	0.60	0.699	4.51	2.40	44.2	25.5
7	0.70	0.799	5.90	2.99	57.8	29.3
8	0.80	0.899	7.00	3.49	68.6	34.2

Table 2 — Diameter and tensile strength of Synthetic Sutures

Gauge number (Metric Size)	Limits on Average Diameter (mm)		Knot-Pull Tensile (in kgf) (except where Strength otherwise specified)* Limit on Average Min.	Knot-Pull Tensile Strength (in N) (except where otherwise specified)
	Min	Max		
0.01	0.001	0.009	—	—
0.1	0.010	0.019	—	—
0.2	0.020	0.029 *	0.025	0.24*
0.3	0.030	0.039	0.050*	0.49*
0.4	0.040	0.049	0.07	0.69
0.5	0.050	0.069	0.14	1.37
0.7	0.070	0.099	0.25	2.45
1	0.10	0.149	0.68	6.67
1.5	0.15	0.199	0.95	9.32
2	0.20	0.249	1.77	17.4
3	0.30	0.339	2.68	26.3
3.5	0.35	0.399	3.90	38.2
4	0.40	0.499	5.08	49.8
5	0.50	0.599	6.35	62.3
6	0.60	0.699	7.29	71.5
7	0.70	0.799	—	—

### 6.3 Minimum breaking load (tensile strength)

#### 6.3.1 Collagen suture

When determine on not fewer than 10 strands of Suture as prescribed in Annex B, 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 not more than one strand fails to meet the limit on individual strands, repeat the test with not fewer than 20 additional strands: the requirements of the test are met if none of the additional strands falls 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.

#### 6.3.2 Synthetic suture

When determine on not fewer than 10 strands of Suture as per Annex B, 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.

### 6.4 Needle attachment

6.4.1 If the sutures are supplied with an eyeless needle attached that is not stated to be detachable, they shall comply with the requirements given in table 3 when tested for needle attachment as prescribed in annex C.

6.4.2 If sutures are supplied with removable needle, they shall comply with the requirements given in table 4 when tested in accordance with annex C.

**Table 3 — Needle Attachment for Absorbable sutures**

Gauge Number		Limits on Needle Attachment			
Natural(collagen) Absorbable Suture	Synthetic Absorbable Sutures	Average (in kgf) (Min.)	Individual (in kgf) (Min.)	Average (in N) (Min.)	Individual (in N) (Min.)
-	0.1	0.007	0.005	0.069	0.049
-	0.2	0.014	0.010	0.137	0.098
0.4	0.3	0.021	0.015	0.206	0.147
0.5	0.4	0.050	0.025	0.490	0.245
0.7	0.5	0.080	0.040	0.784	0.392
1	0.7	0.17	0.08	1.67	0.784
1.5	1	0.23	0.11	2.25	1.08
2	1.5	0.45	0.23	4.41	2.25
3	2	0.68	0.34	6.67	3.33
3.5	3	1.10	0.45	10.8	4.41
4	3.5	1.50	0.45	14.7	4.41
5	4	1.80	0.60	17.6	5.88
6 and larger	5 and larger	1.80	0.70	17.6	6.86



Table 4 — Removable Needle Attachment for Absorbable sutures

Gauge Number		Limits on Needle Attachment			
Natural(collagen) Absorbable Suture	Synthetic Absorbable Sutures	minimum (in kgf)	Maximum (in kgf)	Minimum (in N)	Maximum (in N)
1.5	1	0.028	1.59	0.274	15.6
2	1.5	0.028	1.59	0.274	15.6
3	2	0.028	1.59	0.274	15.6
3.5	3	0.028	1.59	0.274	15.6
4	3.5	0.028	1.59	0.274	15.6
5	4	0.028	1.59	0.274	15.6
6	5	0.028	1.59	0.274	15.6

### 6.5 Extractable colour

Dyed sutures shall be colour fast when tested in accordance with Annex D.

### 6.6 sterility

It shall be sterile when tested in accordance with annex E

## 7 Packaging

7.1 The sterile sutures (dry or in fluid) shall be packed in sachets or packets or containers that maintain sterility until the container is opened and allows the withdrawal and use of the suture in aseptic conditions.

7.2 A number of sachets (packets or containers) may be packaged in a box.

## 8 Labelling

8.1 The primary package of the suture shall be legibly and indelibly marked with the following information:

- a) Name and address of manufacturer;
- b) name of the product,
- c) size of the suture;(gauge number)
- d) material and composition,
- e) type of suture( absorbable);
- f) structure (monofilament, or multifilament);
- g) length of suture, in centimetres;
- h) if appropriate, that the suture is coloured,
- i) batch number;

- j) absorption time,
- k) sterile;
- l) kind of needle if included;
- m) Warnings, like “**DO NOT RESTERILIZE. DISCARD OPEN UNUSED SUTURES. STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES**”; and
- n) date of manufacture and expiry.

8.2 If the sachets (packets or containers) are packaged in boxes, the boxes shall be labelled with the following

- i) name and address of the manufacturer/ packer/distributor;
- ii) name of product;
- iii) type of suture( absorbable);
- iv) structure (monofilament or multifilament);
- v) composition of any packaging fluid if used;
- vi) batch number;
- vii) name of product; and
- viii) sterile

Note — if the suture is packaged with a fluid, make sure that testing is done within 2 minutes after removing it from the fluid.

## 9 Sampling

Sampling shall be done in accordance with US ISO 24153

## **Annex A** **(normative)**

### **Diameter of sutures**

#### **A.1 Introduction**

The gauge for determining the diameter of the suture is of the dead-weight type, mechanical or electrical, and equipped with a direct-reading dial, a digital readout, or a printed readout. Use a gauge graduated to 0.002 mm or smaller. The anvil of the gauge is about 50 mm in diameter, and the presser foot is  $12.70 \pm 0.02$  mm in diameter. The presser foot and moving parts connected therewith are weighted so as to apply a total load of  $210 \pm 3$  g to the specimen. The presser foot and anvil surfaces are plane to within 0.005 mm and parallel to each other to within 0.005 mm. For measuring the diameter of metric size 0.4 and smaller, remove the additional weight from the presser foot so that the total load on the suture does not exceed 60 g.

#### **A.2 Natural (Collagen) absorbable sutures.**

A.2.1 Carry out the test on 10 sutures. Determine the diameter immediately after removal from the container or packet and without stretching.

A.2.2 Lay the strand across the centre of the anvil and the pressor foot, and gently lower the foot until its entire weight rests upon the suture

A.2.3 Lower the pressor foot slowly to avoid crushing the suture. Measure the diameter at at three points along the suture strand at intervals of 30 cm over the whole length of the suture.

A.2.5 For a suture less than 90 cm in length, measure at 3 points approximately evenly spaced along the suture. The suture is not subjected to more tension than is necessary to keep it straight during measurement.

#### **A.3 Synthetic absorbable sutures**

A.3.1 Lay the strand across the center of the anvil and presser foot, and gently lower the foot until its entire weight rests upon the suture.

A.3.2 Measure the diameter of the suture at three points corresponding roughly to one-fourth, one-half, and three-fourths of its length. In the case of braided suture of sizes larger than 3-0 (metric size 2), make two measurements at each point at right angles to each other, and use the average as the observed diameter at that point.

A.3.3 In measuring multifilament, attach a portion of the designated section of the strand in a fixed clamp in such a way that the strand lies across the center of the anvil. While holding the strand in the same plane as the surface of the anvil, place the strand under tension by suitable means, taking care not to permit the strand, if twisted, to untwist. Measure the diameter at the designated points on the strand, and calculate the average diameter.

## Annex B (normative)

### Minimum breaking load

#### B.1 Introduction

Carry out test on five sutures. The minimum breaking load is determined over a simple knot formed by placing one end of a suture held in the right hand over the other end held in the left hand, passing one end over the suture and through the loop so formed (see Figure B1) and pulling the knot tight.

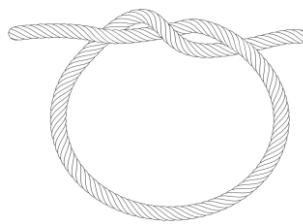


Figure B1 — Simple knot

#### B.2 Collagen absorbable sutures

Refer to Table 1 for breaking load.

#### B.3 Synthetic absorbable sutures

Refer to Table 2 for breaking load.

#### B.4 Procedure

B.4.1 Determine the tensile strength of surgical suture on a motor-driven tensile strength testing machine having suitable clamps for holding the specimen firmly and using either the principle of constant rate of load on specimen or the principle of constant rate of elongation of specimen, as described below.

B.4.2 Gauge length is defined as the interior distance between the two clamps. For gauge lengths of 125 to 200 mm, the mobile clamp is driven at a constant rate of elongation of  $30 \pm 5$  cm per minute. For gauge lengths of less than 125 mm, the rate of elongation per minute is adjusted to equal 2 times the gauge length per minute. For example, a 5-cm gauge length has a rate of elongation of 10 cm per minute.

B.4.3 Determine the tensile strength of the suture, whether packaged in dry form or in fluid, promptly after removal from the container, without prior drying or conditioning.

B.4.4 Attach one end of the suture to the clamp at the load end of the machine, pass the other end through the opposite clamp, applying sufficient tension so that the specimen is taut between the clamps, and engage the second clamp. Perform as many breaks as are specified in the individual monograph. If the break occurs at the clamp, discard the reading on the specimen.

## **Annex C** (normative)

### **Needle attachment**

C.1 If the sutures are supplied with an eyeless needle attached that is not stated to be detachable, they shall comply with the requirements given in table 3 for needle attachment and for removable needle attachment, they shall comply with the table 4

C.2 Carry out the test on 5 sutures. Use a suitable tensiometer, such as that described for the determination of the minimum breaking load.

C.3 Fix the needle and suture (without knot) in the clamps of the apparatus in such a way that the swaged part of the needle is completely free of the clamp and in line with the direction of pull on the suture.

C.4 Set the mobile clamp in motion and note the force required to break the suture or to detach it from the needle.

C.5 The average of the 5 determinations and all individual values are not less than the respective values given in Table 3 and table 4

C.6 If not more than 1 individual value fails to meet the individual requirement, repeat the test on an additional 10 sutures. The attachment complies with the test if none of these 10 values is less than the individual value in Table 3 and Table 4 for the gauge number concerned.

## Annex D (normative)

### Extractable colours

D.1 Prepare the matching solution that corresponds to the extractable colour of the suture by combining the colorimetric solutions in the proportions indicated in table D1 and adding water, if necessary to make 10.0 parts.

D.2 Place 0.25 g of suture in a conical flask containing 1.0 ml of water for each 10 mg of the sample. Close the flask, and allow it to stand at  $37 \pm 0.5^\circ$  for 24 hours.

D.3 Cool, decant the water from the Suture, and compare it with the Matching Solution: any color present is not more intense than that of the appropriate Matching Solution

**Table D1 – Colour referencing solution.**

<b>Colour of strand</b>	<b>Composition of reference solution (parts by volume)</b>			
	<b>Red primary solution</b>	<b>Yellow primary solution</b>	<b>Blue primary solution</b>	<b>Water R</b>
Yellow-brown	0.2	1.2	-	8.6
Pink-red	1.0	-	-	9.0
Green-blue	-	-	2.0	8.0
Violet	1.6	-	8.4	-

## Annex E (normative )

### Sterility test

#### E.1 Introduction

The following culture media have been found to be suitable for the test for sterility. Fluid thioglycollate medium is primarily intended for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria. Soya-bean casein digest medium is suitable for the culture of both fungi and aerobic bacteria.

#### E.2 Fluid thioglycollate medium

L-Cystine	0.5 g
Agar	0.75 g
Sodium chloride	2.5 g
Glucose monohydrate/anhydrous	5.5 g/5.0 g
Yeast extract (water-soluble)	5.0 g
Pancreatic digest of casein	15.0 g
Sodium thioglycollate or	0.5 g
Thioglycollic acid	0.3 mL
Resazurin sodium solution (1g/L of resazurin sodium), freshly prepared	1.0 mL
Water R	1000 mL
pH after sterilisation $7.1 \pm 0.2$	

E.2.1 Mix the L-cystine, agar, sodium chloride, glucose, water-soluble yeast extract and pancreatic digest of casein with the water R and heat until solution is effected.

E.2.2 Dissolve the sodium thioglycollate or thioglycollic acid in the solution and, if necessary, add 1 M sodium hydroxide so that, after sterilisation, the solution will have a pH of  $7.1 \pm 0.2$ . If filtration is necessary, heat the solution again without boiling and filter while hot through moistened filter paper.

E.2.3 Add the resazurin sodium solution, mix and place the medium in suitable vessels which provide a ratio of surface to depth of medium such that not more than the upper half of the medium has undergone a colour change indicative of oxygen uptake at the end of the incubation period. Sterilise using a validated process. If the medium is stored, store at a temperature between 2 °C and 25 °C in a sterile, airtight container.

E.2.4 If more than the upper one-third of the medium has acquired a pink colour, the medium may be restored once by heating the containers in a water-bath or in free-flowing steam until the pink colour disappears and cooling quickly, taking care to prevent the introduction of non-sterile air into the container. Do not use the medium for a longer storage period than has been validated. Fluid thioglycollate medium is to be incubated at 30-35 °C.

E.2.5 For products containing a mercurial preservative that cannot be tested by the membrane-filtration method, fluid thioglycollate medium incubated at 20-25 °C may be used instead of soya-bean casein digest medium provided that it has been validated as described in growth promotion test.

### E.3 Alternative thioglycollate medium

Where prescribed or justified and authorised, the following alternative thioglycollate medium may be used. Prepare a mixture having the same composition as that of the fluid thioglycollate medium, but omitting the agar and the resazurin sodium solution, sterilise as directed above. The pH after sterilisation is  $7.1 \pm 0.2$ . Heat in a water-bath prior to use and incubate at 30-35 °C under anaerobic conditions.

### E.4 Soya-bean casein digest medium

Pancreatic digest of casein	17.0 g
Papaic digest of soya-bean meal	3.0 g
Sodium chloride	5.0 g
Dipotassium hydrogen phosphate	2.5 g
Glucose monohydrate/anhydrous	2.5 g/2.3 g
Water R	1000 mL
pH after sterilization	$7.3 \pm 0.2$

E.4.1 Dissolve the solids in water R, warming slightly to effect solution. Cool the solution to room temperature. Add 1 M sodium hydroxide, if necessary, so that after sterilisation the solution will have a pH of  $7.3 \pm 0.2$ .

E.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilise using a validated process. Store at a temperature between 2 °C and 25 °C in a sterile well-closed container, unless it is intended for immediate use. Do not use the medium for a longer storage period than has been validated. Soya-bean casein digest medium is to be incubated at 20-25 °C.

The media used comply with the following tests, carried out before or in parallel with the test on the product to be examined.

### E.5 Sterility

Incubate portions of the media for 14 days. No growth of micro-organisms occurs.



## Bibliography

- [1] British Pharmacopoeia, 2017
- [2] ISO 11135 (both parts), Sterilization of health care products — Ethylene oxide
- [3] ISO 11137 (all parts), Sterilization of health care products — Radiation
- [4] ISO 17665 (all parts), Sterilization of health care products — Moist heat
- [5] US Pharmacopoeia 40, 2017

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