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Surgical sutures — Specification — Part 1: Absorbable

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This African Standard was prepared by ARSO/TC 78, Medical devices and equipment's

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Introduction

Surgical sutures are used in a variety of different surgical procedures for tissue approximation and aid inn tissue healing. These sutures may be a single filament/multifilament or braided/twisted with/without a coating and with/without needle(s).

Surgical sutures are classified into two types:
a) absorbable surgical sutures; and
b) non-absorbable surgical sutures.

Surgical sutures — Specification — Part 1: Absorbable

1 Scope

This Draft African Standard specifies the requirements, sampling and test methods for absorbable surgical sutures. This standard does not cover antimicrobio-impregnated sutures.

2 Normative references

The following documents are 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.

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 24153, *Random sampling and randomization procedures*

ISO 2859-1, *Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

3 Terms and definitions

For the purpose of this standard the following definitions apply.

3.1
absorbable suture
suture capable of being absorbed by living animal tissues during the healing process

3.2
monofilament suture
suture made of a single strand

3.3
multifilament suture
suture composed of several filaments twisted or braided together

3.4
surgical suture
medical device that is used to hold/appose body tissues together after a surgery or injury

4 Types

Absorbable surgical sutures shall include the following types:

a) Natural absorbable sutures prepared from collagen derived from healthy mammals. Absorbable sutures are categorized into two:
- plain; and
- chromic gut.

b) synthetic absorbable 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 Requirements

5.1 General requirements

5.1.1 Absorbable surgical sutures shall either be monofilament or multifilament. If multifilament, the individual filament may be combined by spinning, twisting, braiding or any combination.

5.1.2 They may be coloured, coated or both.

5.2 Specific requirements

5.2.1 Biocompatibility

When tested in accordance with the relevant parts of ISO 10993, absorbable surgical sutures shall be biocompatible if the test is conducted appropriately to the body contact with indicated contact duration.

5.2.2 Length

The length of the absorbable surgical sutures without stretching shall be not less than 95 % of the length stated on the label and shall not exceed 400 cm.

5.2.3 Diameter

5.2.3.1 Collagen absorbable surgical sutures

When determined in accordance with Annex A, the average diameter, and not fewer than 20, of the 30 measurements on the 10-strand sample shall be within the limits on the average diameter specified in Table 1. None of the individual measurements shall be 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) absorbable surgical sutures

USP size	**Gauge number (metric size)**	**Limits on average diameter** mm		**Knot pull tensile strength** kgf, min.		**Knot pull tensile strength** N, min.	
		Minimum	**Maximum**	**Limit on average**	**Limit on individual strand**	**Limit on average**	**Limit on individual strand**
9-0	0.4	0.040	0.049	-	-	-	-
8-0	0.5	0.050	0.069	0.045	0.025	0.44	0.24
7-0	0.7	0.070	0.099	0.07	0.055	0.69	0.54
6-0	1	0.10	0.149	0.18	0.10	1.76	0.98
5-0	1.5	0.15	0.199	0.38	0.20	3.73	1.96
4-0	2	0.20	0.249	0.77	0.40	7.55	3.92
3-0	3	0.30	0.339	1.25	0.68	12.2	6.67
2-0	3.5	0.35	0.399	2.00	1.04	19.6	10.2
0	4	0.40	0.499	2.77	1.45	27.2	14.2
1	5	0.50	0.599	3.80	1.95	37.3	19.1
2	6	0.60	0.699	4.51	2.40	44.2	25.5

3	7	0.70	0.799	5.90	2.99	57.8	29.3
4	8	0.80	0.899	7.00	3.49	68.6	34.2

5.2.3.2 Synthetic absorbable surgical sutures

When determined in accordance with Annex A, the average diameter of the strands being measured shall be within the tolerances specified in Table 2. None of the observed measurements shall be 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 2 — Diameter and tensile strength of synthetic absorbable surgical sutures

USP size	**Gauge number (metric size)**	**Limits on average diameter** mm		**Knot-pull tensile strength limit on average** kgf, min.	**Knot-pull tensile strength** N
		Minimum	**Maximum**		
12-0	0.01	0.001	0.009	-	-
11-0	0.1	0.010	0.019	-	-
10-0	0.2	0.020	0.029 a	0.025	0.24 a
9-0	0.3	0.030	0.039	0.050 a	0.49 a
8-0	0.4	0.040	0.049	0.07	0.69
7-0	0.5	0.050	0.069	0.14	1.37
6-0	0.7	0.070	0.099	0.25	2.45
5-0	1	0.10	0.149	0.68	6.67
4-0	1.5	0.15	0.199	0.95	9.32
3-0	2	0.20	0.249	1.77	17.4
2-0	3	0.30	0.339	2.68	26.3
0	3.5	0.35	0.399	3.90	38.2
1	4	0.40	0.499	5.08	49.8
2	5	0.50	0.599	6.35	62.3
3 and 4	6	0.60	0.699	7.29	71.5
5	7	0.70	0.799	-	-
a Knot pull tensile strength has been specified					

5.3 Minimum breaking load (tensile strength)

5.3.1 Collagen absorbable surgical suture

When determined on not fewer than 10 strands of sutures 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, shall be as given 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.

5.3.2 Synthetic absorbable surgical suture

When determined on not fewer than 10 strands of sutures in accordance with Annex B, the minimum tensile strength of each size of synthetic suture, calculated as the average strength from any one lot, shall be as given in Table 2.

5.4 Needle attachment

5.4.1 If the absorbable surgical 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.

Table 3 — Needle attachment for absorbable surgical sutures

Gauge number		**Limits on needle attachment** min.			
Natural (collagen) absorbable suture	**Synthetic absorbable sutures**	**Average** kgf	**Individual** kgf	**Average** N	**Individual** N
-	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

5.4.2 If absorbable surgical sutures are supplied with removable needle, they shall comply with the requirements given in Table 4 when tested in accordance with Annex C.

Table 4 — Removable needle attachment for absorbable surgical sutures

Gauge number		**Limit on needle attachment**			
Natural (collagen) absorbable suture	**Synthetic absorbable suture**	**Minimum** kgf	**Maximum** kgf	**Minimum** N	**Maximum** 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

5.5 Extractable colour

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

5.6 Sterility

Absorbable surgical sutures shall be sterile when tested in accordance with Annex E.

6 Packaging

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

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

7 Labelling

7.1 The primary package of the absorbable surgical suture shall be legibly and indelibly labelled in the official language of member state with the following information:

a) name and physical address of manufacturer;

b) name of the product as “Surgical suture (Absorbable)”;

c) size and gauge number;

d) material and composition;

e) type of suture in accordance with Clause 4;

f) structure (monofilament, or multifilament);

g) length in centimetres;

h) type of needle in accordance with ARS surgical suture needle;

i) indication of needle attachment as detachable or non-detachable;

j) batch number;

k) absorption time;

l) sterile;

m) warnings, like “DO NOT RE-STERILIZE”, “DISCARD OPEN UNUSED SUTURES”, “STORE AT ROOM TEMPERATURE”, and “AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES”;

n) manufacturing date; and

o) expiry date.

7.2 If the absorbable surgical sutures are coloured, the colour of the suture shall be indicated on the label.

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

a) name and physical address of the manufacturer;

b) name of product as ““Surgical suture (Absorbable)”;

c) type in accordance with Clause 4;

d) **structure (monofilament or multifilament)**
e) composition of any packaging fluid, if used;

f) batch number; and

g) sterile.

NOTE If the suture is packaged with a fluid, make sure that testing is done within 2 min after removing it from the fluid.

8 Sampling

Sampling shall be done in accordance with ISO 24153 and ISO 2859-1.

Annex A
(normative)

Determination of diameter

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 mm ± 0.02 mm in diameter. The presser foot and moving parts connected therewith are weighted so as to apply a total load of 210 g ± 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 Procedure

A.2.1 Natural (collagen) absorbable surgical sutures

A.2.1.1 Carry out the test on 10 sutures. Determine the diameter immediately after removal from the container or packet and without stretching.

A.2.1.2 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.2.1.3 Lower the pressor foot slowly to avoid crushing the suture. Measure the diameter at three points along the suture strand at intervals of 30 cm over the whole length of the suture.

A.2.1.4 For a suture less than 90 cm in length, measure at three 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.2.2 Synthetic absorbable surgical sutures

A.2.2.1 Lay the strand across the centre of the anvil and presser foot, and gently lower the foot until its entire weight rests upon the suture.

A.2.2.2 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.2.2.3 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 centre 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)

Determination of tensile strength

B.1 Introduction

Carry out the test on ten 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 B.1) and pulling the knot tight.

Figure B.1 — Simple knot

B.1 Collagen absorbable surgical sutures

Refer to Table 1 for breaking load**.**

B.2 Synthetic absorbable surgical sutures

Refer to Table 2 for breaking load**.**

B.3 Procedure

B.3.1 Determine the tensile strength of a 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.3.2 Gauge length is defined as the interior distance between the two clamps. For gauge lengths of 125 mm to 200 mm, the mobile clamp is driven at a constant rate of elongation of 30 cm/min ± 5 cm/min. For gauge lengths of less than 125 mm, the rate of elongation per minute is adjusted to equal two times the gauge length per minute. For example, a 5-cm gauge length has a rate of elongation of 10 cm/min.

B.3.3 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.

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)

Determination of 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 Table 4.

C.2 Carry out the test on ten sutures. Use a suitable tensilometer, 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 ten 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 one individual value fails to meet the individual requirement, repeat the test on an additional ten 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)

Determination of extractable colours

D.1 Prepare the matching solution that corresponds to the extractable colour of the suture by combing the colorimetric solutions in the proportions as specified in Table D.1 and adding water, if necessary to make 10.0 parts.

Table D.1 – Colour referencing solution

Colour of strand	**Composition of reference solution (parts by volume)**			
	Red primary solution	**Yellow primary solution**	**Blue primary solution**	**Water *R*a**
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	-
a *R* implies water, Reagent grade or distilled water.				

D.1 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 °C ± 0.5 °C for 24 h.

D.2 Cool, decant the water from the suture and compare it with the matching solution; any colour present is not more intense than that of the appropriate matching solution.

Annex E
(normative)

Determination of sterility

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	**0.5g**
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	**1 000 ml**
pH after sterilization	**7.1 ± 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 sterilization, the solution will have a pH of 7.1 ± 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. Sterilize 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 °C to 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 °C to 25 °C may be used instead of

soya-bean casein digest medium provided that it has been validated as described in the growth promotion test.

E.3 Alternative thioglycollate medium

Where prescribed, justified and authorized, 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, sterilize as directed above. The pH after sterilization is 7.1 ± 0.2. Heat in a water-bath prior to use and incubate at 30 °C to 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*	**1 000 ml**
pH after sterilization	**7.3 ± 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 sterilization the solution will have a pH of 7.3 ± 0.2.

E.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilize 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 °C to 25 °C.

The media used comply with the following tests given in E.6, 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.

E.6 Growth promotion test of aerobes, anaerobes and fungi

E.6.1 Test each lot of ready-prepared medium and each batch of medium prepared either from dehydrated medium or from ingredients. Suitable strains of microorganisms are indicated in Table E.1.

Table E.1 — Strains of the test microorganisms suitable for use in the growth promotion test

Test microorganisms	
Aerobic bacteria	Fungi
Staphylococcus aureus ATCC 6538, CIP 4.83,NCTC 10788, NCIMB 9518, NBRC 13276	*Candida albicans* ATCC 10231, IP 48.72, NCPF 3179, NBRC 1594

E.6.2 Inoculate portions of Fluid Thioglycollate Medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism: *Clostridium sporogenes, Pseudomonas aeruginosa,* and *Staphylococcus aureus.* Inoculate portions of alternative thioglycollate medium with a small number (not more than 100 cfu) of *Clostridium sporogenes* F. Inoculate portions of soybean-casein.

E.6.3 Digest Medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism: *Aspergillus brasiliensis, Bacillus subtilis,* and *Candida albicans.* Incubate for not more than three days in the case of bacteria and not more than five days in the case of fungi.

E.6.4 Seed lot culture maintenance techniques (seed-lot systems) are used so that the viable microorganisms used for inoculation are not more than five passages removed from the original master seed- lot. The media are suitable if a clearly visible growth of the microorganisms occurs.

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