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DRAFT EAST AFRICAN STANDARD

Surgical sutures — Specification — Part 1: Absorbable

EAST AFRICAN COMMUNITY

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

The Community has established an East African Standards Committee (EASC) mandated to develop and issue East African Standards (EAS). The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the public and private sector organizations in the community.

East African Standards are developed through Technical Committees that are representative of key stakeholders including government, academia, consumer groups, private sector and other interested parties. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the Principles and procedures for development of East African Standards.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

The committee responsible for this document is Technical Committee EASC/TC *078*, *Healthcare and medical devices*.

Attention is drawn to the possibility that some of the elements of this document may be subject of patent rights. EAC shall not be held responsible for identifying any or all such patent rights..

DEAS 1019: 2019 consists of the following parts, under the general title *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; and

b) non-absorbable surgical sutures.

Surgical sutures — Specification — Part 1: Absorbable

1 Scope

This Draft East African Standard specifies the requirements, sampling and test methods for absorbable surgical 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 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 during the healing process

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/appose body tissues together after a surgery or injury

4 Types

Absorbable sutures shall include the following types:

a) natural absorbable sutures, prepared from collagen derived from healthy mammals. Natural 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 The suture shall either be monofilament or multifilament. If multifilament, the individual filament may be combined by spinning, twisting, braiding or any combination.

5.1.2 It 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, the suture 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 suture 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 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 shall be within the limits on the average diameter prescribed 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.

5.2.3.2 Synthetic suture

When determined in accordance with Annex A, the average diameter of the strands being measured shall be within the tolerances prescribed 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 1 — Diameter and tensile strength of natural (collagen) sutures

USP size	Gauge number (Metric size)	Limits on average diameter Mm		Knot pull tensile strength, min. kgf		Knot pull tensile strength, min. N	
		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

Table 2 — Diameter and tensile strength of synthetic sutures

USP size, Min.	Gauge number (Metric size)	Limits on average diameter Mm		Knot-pull tensile (except where strength otherwise specified)* Limit on average, min. kgf	Knot-pull tensile strength (except where otherwise specified) 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*	0.025	0.24*
9-0	0.3	0.030	0.039	0.050*	0.49*
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	-	-

5.3 Minimum breaking load (tensile strength)

5.3.1 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, 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 suture

When determined on not fewer than 10 strands of suture 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 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.

5.4.2 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, 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

Table 4 — Removable needle attachment for absorbable sutures

Gauge number		Limits on needle attachment			
Natural (collagen) absorbable suture	Synthetic absorbable sutures	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 sutures shall be colour fast when tested in accordance with Annex D.

5.6 Sterility

It shall be sterile when tested in accordance with Annex E.

6 Packaging

6.1 The sterile sutures (dry or in fluid) shall be packed 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 suture shall be legibly and indelibly marked with the following information:

a) name and physical 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 RE-STERILIZE. DISCARD OPEN UNUSED SUTURES. STORE AT ROOM TEMPERATURE. AVOID PROLONGED EXPOSURE TO ELEVATED TEMPERATURES”; and

n) date of manufacture and

o) date of expiry.

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

i) name and physical address of the manufacturer;

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; and

vii) 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.

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 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 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 sutures

A.2.2.1 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.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 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 the 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 B.1) and pulling the knot tight.

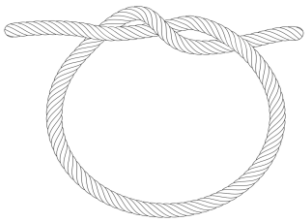

Figure B.1 — Simple knot

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 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.4.2 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.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 five 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 five 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 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 combing the colorimetric solutions in the proportions indicated in Table D.1 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 ° ± 0.5° for 24 h.

D.3 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.

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				

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	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 - 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 - 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 - 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 -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 E1.

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. FInoculate 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 3 days in the case of bacteria and not more than 5 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

Table E1—. 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

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[9] US Pharmacopoeia 40, 2019

[10] US 1958-1:2019, *Surgical sutures — Specification — Part 1: Absorbable*

