



DRAFT EAST AFRICAN STANDARD

Surgical suture needles — Specification

EAST AFRICAN COMMUNITY

DRAFT EAST AFRICAN STANDARD FOR PUBLIC REVIEW

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East African Community
P.O. Box 1096,
Arusha
Tanzania
Tel: + 255 27 2162100
Fax: + 255 27 2162190
E-mail: eac@eachq.org
Web: www.eac-quality.net

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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*.

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Surgical suture needles — Specification

1 Scope

This Draft East African Standard specifies the requirements, sampling and test methods for surgical suture needles.

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.

ASTM A751-01, *Standard Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products*

ASTM F1089-02, *Standard Test Method for Corrosion of Surgical Instruments*

ASTM F1840-10, *Standard Terminology for Surgical Suture Needles*

ISO 6507-1, *Metallic materials — Vicker hardness test — Part 1: Test method*

ISO 24153, *Random sampling and randomisation procedures*

ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

ASTM F3014 – 14, *Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures*

ASTM F1874 - 98, *Standard Test Method for Bend Testing of Needles Used in Surgical Sutures*

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>

33.1 attachment area

portion of the needle where the attachment of the suture takes place, for example, eyed, drilled and channel (see Annex A)

3.2 curvature

shape of the needle viewed in profile. Some common shapes include, but are not limited to: straight, 1/2 curve or “ski,” 1/8 circle, 1/4 circle, 3/8 circle, 1/2 circle, 5/8 circle, and compound curvature (see Annex A).

3.3

strand

fibre/suture used to hold body tissues together after a surgery or injury

3.4

surgical suture needle

surgical needle necessary for the placement of sutures in tissues

3.5

swage

any attachment method that uses mechanical force to crimp the end of the needle and firmly hold the suture in place.

4 Types

4.1 Eyed suture needles

Surgical suture needles that have a hole at the suture side of the needle. Eyed suture needles are categorized into closed eye or French (split/spring) eye.

4.2 Swaged or eyeless needles

Surgical suture needles that have a suture crimped within the needle. The suture strand is permanently attached needle by the manufacturer.

5 Requirements

5.1 General requirements

5.1.1 The surface of the suture needle shall be smooth and free from dents.

5.1.2 The suture needles shall be free from grinding marks, polishing dirt or the other material which could necessitate cleaning prior to sterilization.

5.1.3 The point of the needle shall be sharp except where otherwise specified.

5.1.4 The eye (swage) of the needle shall be clean and properly formed and shall be smooth from inside and outside.

5.2 Chemical composition

When tested in accordance with ASTM A751-01, the suture needles shall be made of stainless steel wires of either of the composition given in Table 1 or Table 2.

Table 1 — Chemical composition for surgical suture needles

Element	Percentage %
Carbon	0.30 – 0.40
Manganese	1.00 max.
Phosphorous	0.045 max.
Sulphur	0.045 max.
Silicon	1.00 max.
Chromium	12.00 – 14.00
Nickel	1.00 max.

Table 2 — Chemical composition for surgical suture needles

Element	Percentage %
Carbon	0.60 – 0.75
Manganese	1.00 max.
Phosphorous	0.040 max.
Sulphur	0.030 max.
Silicon	1.00 max.
Chromium	16.00 – 18.00
Nickel	0.75 max.

5.3 Quality requirements

5.3.1 Hardness

When tested in accordance with ISO 6507-1, the hardness of the surgical suture needle shall be 525 HV to 625 HV (*Vicker hardness*).

5.3.2 Corrosion resistant

The surgical suture needle shall comply with the requirements for corrosion resistance given in F1089-02 when tested in accordance with ISO 13402.

5.3.3 Bend test

The surgical suture needles shall be tested in accordance with ASTM F1874 - 98. The straight suture needle shall be deemed to have failed as being too hard, if it breaks before the initial bend of 90° is achieved. There shall not be any permanent set in the curved suture needles after the test.

5.3.4 Penetration test

The penetration test of surgical needles shall be done in accordance with ASTM F3014 – 14. The piercing resistance shall be less than 25 g.

This test is applicable to all needles, except blunt point needles.

6 Packaging

The surgical suture needle shall be packed in suitable packets or containers that protect the needle from contamination and deterioration.

7 Labelling

The package shall be legibly and indelibly marked with the following information:

- a) manufacturer's name and physical address;
- b) product name;
- c) batch number;
- d) shape of the needle ;
- e) needle length;
- f) curvature;
- g) point configurations;
- h) type of eye (either eyed or eyeless);
- i) quantity of suture needles;
- j) warning/ precautions;
- k) instruction for use; and
- l) month and year of manufacture and expiry.

8 Sampling

Random samples of the product for test shall be drawn in accordance with ISO 24153. (Acceptance criteria - none shall fail).

Annex A (normative)

Sizes shapes and dimensions

A.1 Schematic of a surgical suture needle

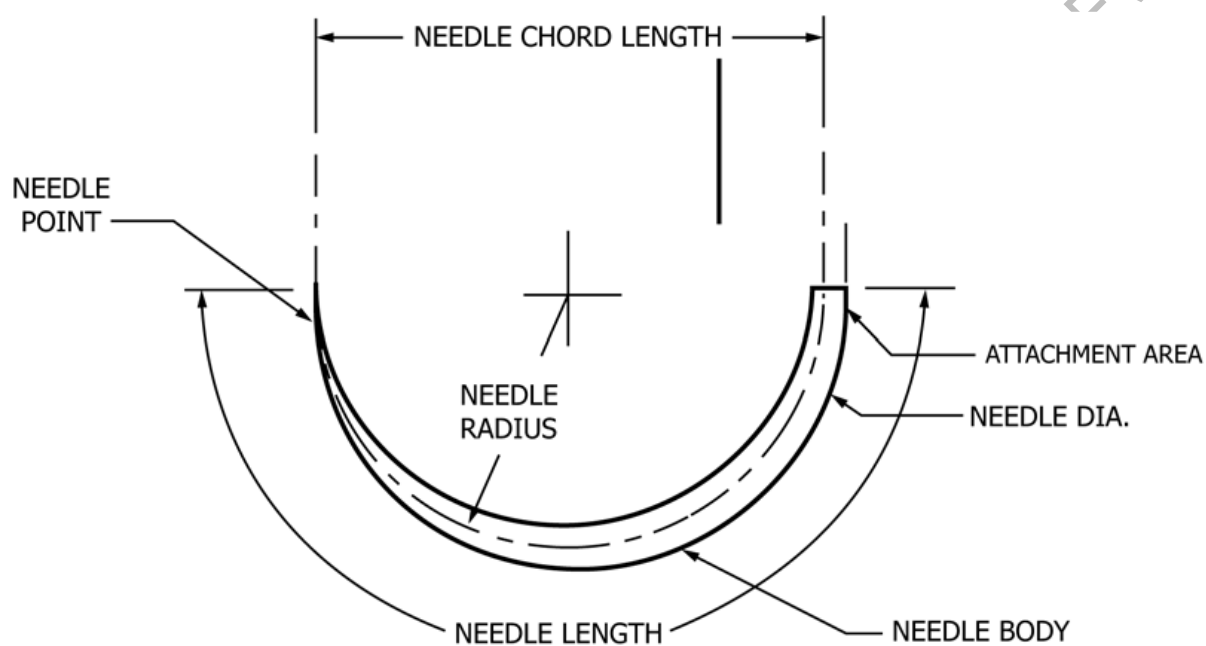


Figure A.1 — Schematic of a surgical needle

A.2 Curvatures

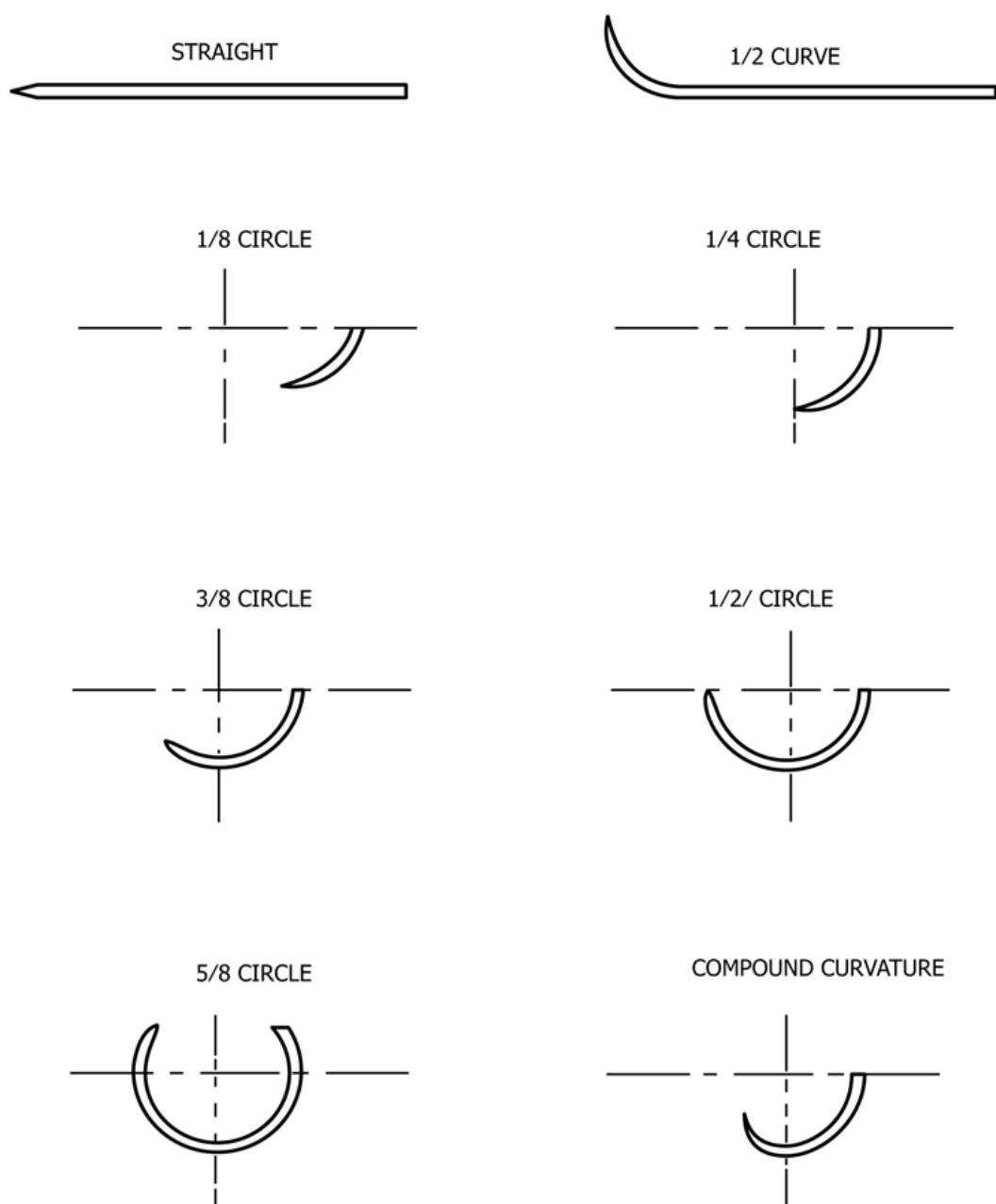


Figure A.2 — Typical curvatures

A.3 Point configurations

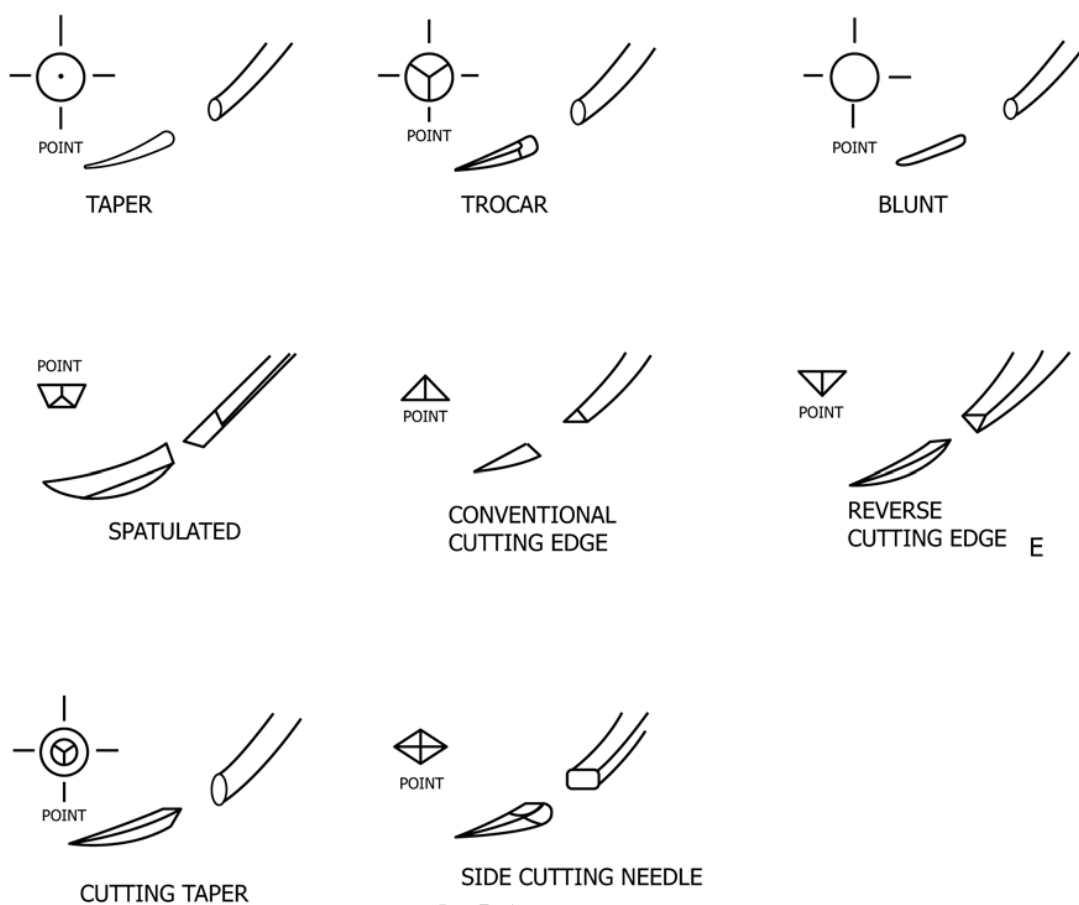


Figure A.3 — Typical point configurations

A.4 Attachment end of surgical suture needles

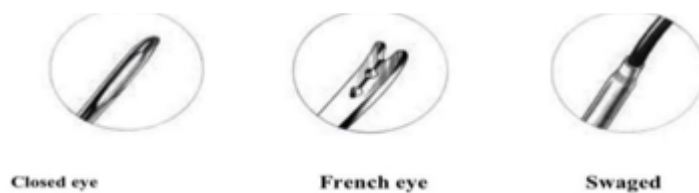


Figure A.4 — Needle eye

Bibliography

- [1] IS 1501:2002, *Method for Vickers hardness test for metallic materials (Third Revision)*.
- [2] IS 7531 (1990): *Surgical Instruments — Corrosion Resistance of Stainless Steel Surgical Instruments — Methods of Tests*.
- [3] IS 9165 (Part 1): 1992, *Surgical instruments — Needles, suture Part 1 — Specification*.
- [4] ISO 6507-2:2018, *Metallic materials — Vickers hardness test — Part 2: Verification and calibration of testing machines*.

