
Surgical suture needles — Specification



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Introduction

<Text indicating rationale for the development/harmonization of the standard>

Draft African Standard for comments only — Not to be cited as African Standard

Surgical suture needles — Specification

1 Scope

This Draft 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

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

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

ISO 7438, Metallic materials — Bend test

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

attachment area

portion of the needle where the attachment of the suture takes place, for example, eyed, drilled and channel (See Figure A.1)

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

These are 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

These are surgical suture needles that have a suture crimped within the needle. The suture strand is permanently attached to the 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.

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

5.2 Chemical composition

5.2.1 The stainless steel wire used in manufacturing of surgical suture needles shall be based on either Formulation I or Formulation II.

5.2.2 When tested in accordance with ASTM A751-01, Formulation I shall comply with the requirements given in Table 1 and Formulation II with the requirements given in Table 2.

Table 1 — Chemical composition for surgical suture needles based on Formulation I

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.
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Table 2 — Chemical composition for surgical suture needles based on Formulation II

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
Molybdenum	0.75 max.

5.3 Specific 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 resistance

5.3.2.1 Boil test

When tested in accordance ASTM F1089-02, surfaces for surgical suture needles shall show no signs of corrosion (without magnification) with the following exceptions: rust (ferrous oxide) on serrations, teeth, locks, ratchets, inserts, brazed junctions, soldered junctions, etched areas, engravings, or laser marks shall not be cause for rejection.

5.3.2.2 Copper sulfate test

When tested in in accordance ASTM F1089-02, surfaces for surgical suture needles shall show no signs of copper plating (without magnification) with the following exceptions: copper plating on serrations, teeth, locks, ratchets, brazed junctions, soldered junctions, etched areas, engravings, laser marks, or dulling of polished surfaces shall not be cause for rejection.

5.3.3 Bend test

When tested in accordance with ISO 7438, the straight surgical suture needle shall be deemed to have failed, 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

When tested in accordance with the penetration test given in ASTM F3014-14, the piercing resistance of the surgical suture needle shall be less than 25 g. This test is applicable to all needles, except blunt point needles.

6 Packaging

Surgical suture needles shall be packed in suitable packets or containers that protects the needle from contamination and deterioration.

7 Labelling

The package shall be legibly and indelibly labelled in the official language of the member state with the following information:

- a) name and physical address of manufacturer;
- b) name product as "Surgical suture needle";
- 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

8.1 Random samples of the product for test shall be drawn in accordance with ISO 24153 and ISO 2859-1.

Annex A
(normative)

Sizes, shapes and dimensions

A.1 Schematic of a surgical suture needle

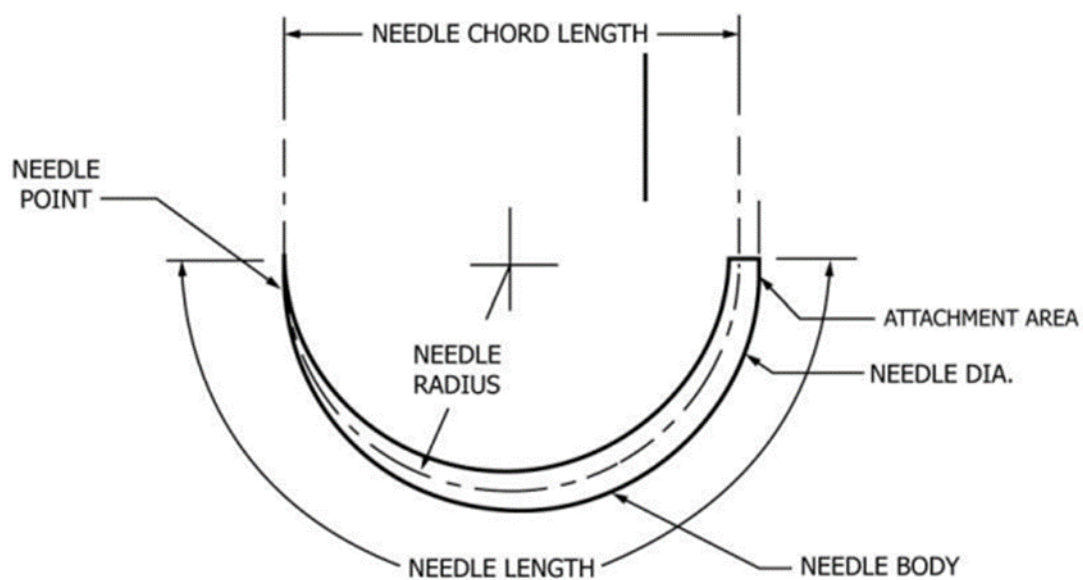


Figure A.1-Schematic of a surgical needle

A.2 Curvatures

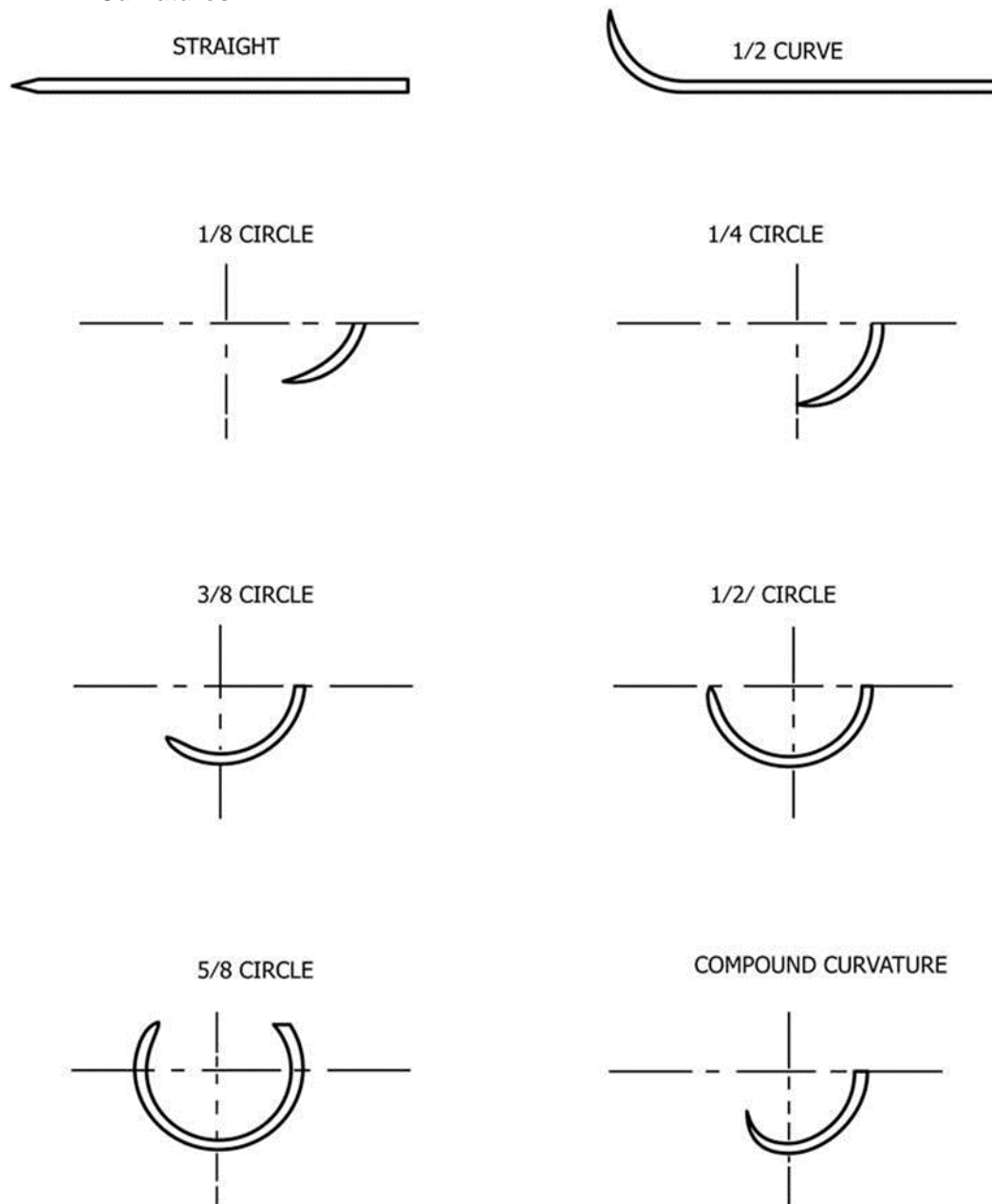


Figure A.2 — Typical curvatures

A.3 Point configurations

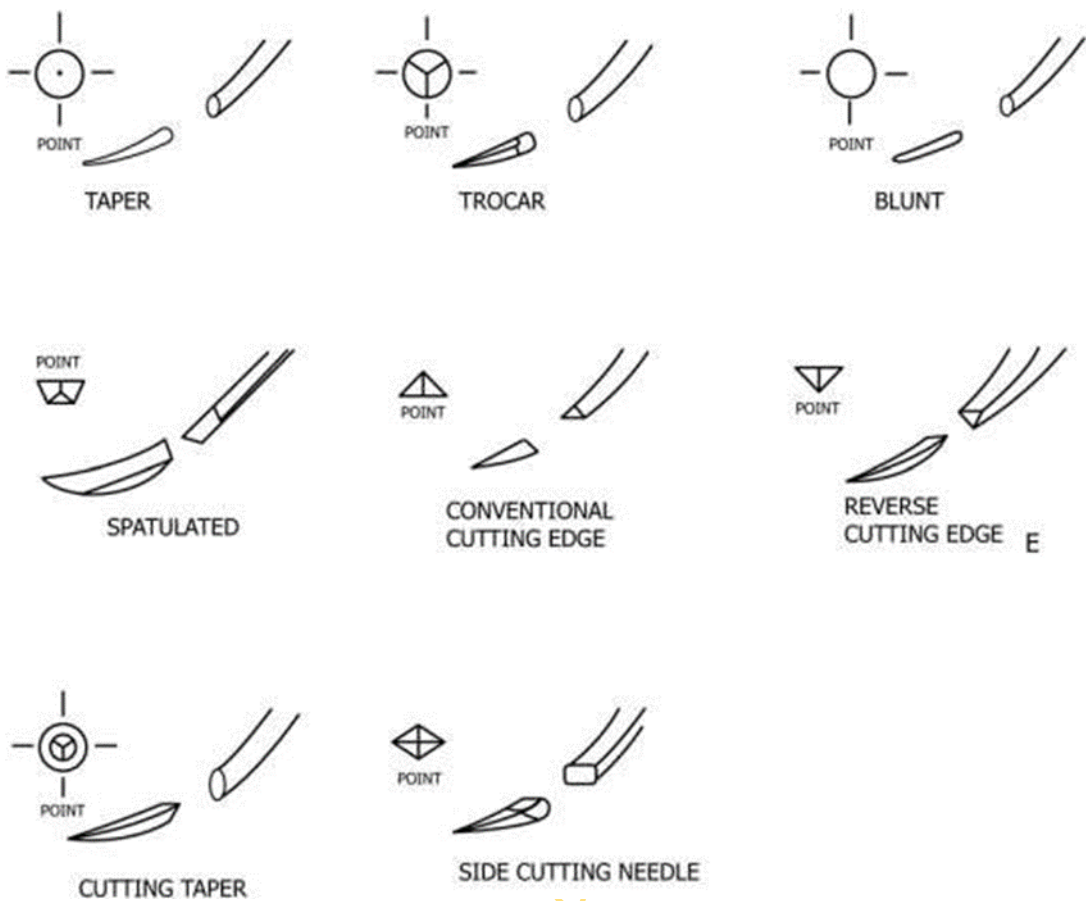


Figure A.3 — Typical point configurations

A.4 Attachment end of surgical suture needles

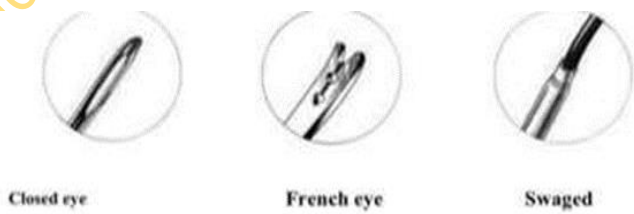


Figure A.4 — Needle eye

Annex B
(informative)

Needles type according to the body and point

The following are typical needle types according to the body design and point of needle

1. **Taper-point needles:** these needles designed to provide good penetration to soft tissue, after needle passes through the tissue the tissue closes tightly around suture material which forming leak-proof suture line. Needle holder position is between needle point and attachment area this position confers more stability to needle held. Its available with wide range of diameter the finer diameters good for softer tissue like gastrointestinal and vascular, High diameters is good for tougher tissue such as muscle.
2. **Blunt taper point:** This type is not as sharp as standard needle whereas the blunt needle has been designed to reduce the risk of needle stick injury, used in all surgery which contain vary friable tissue such as the liver and any specialty that includes surgery of the muscle or fascia.
3. **Taper-cut needle:** This needle like two needles in one with round body to reduce the trauma to wound and with cutting tip to improve the penetration and the cutting tip is limited to the point of needle, they are not recommended for suturing skin.
4. **Revers cutting needle:** This needle has a triangle shape body, the triangle apex in outer side of the curve concave, with sharp edge on the outside curvature help to cut the wound with three edge on sides, utilize specifically for tough and default penetration tissue such as skin, tendon sheath, or oral mucosa and ligament.
5. **Conventional cutting needle:** This needle Has a triangle shape like reverse cutting but the triangle apex in inner side of the curve concave, its suitable for most purposes atypically applied on skin, ligament, nasal cavity, tendon and oral.
6. **Spatula needle:** These fine needles are designed with sharp cutting edge, square, flat body from the top to bottom to reduce tissue injury whereas has easy penetration and high control passage through and between soft tissue layer and they are designed specific to ophthalmitis and oculoplastic surgical procedure.

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*.
- [5] US EAS 1018:2021 *Surgical instruments — Needles, suture — Specification*.
- [6] <https://gmdgroup.com.tr/en/surgical-needles/>

