

# DRAFT UGANDA STANDARD

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## Surgical suture needles — Specification

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## Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to coordinate the elaboration of standards and is

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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.



# Surgical suture needles — Specification

## 1 Scope

This Draft Uganda standard specifies the requirements, sampling and test methods for surgical suture needles.

## 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.

ASTM A 751 – 01, *Standard Test Methods, Practices, and Terminology for Chemical Analysis of Steel Products*

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

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

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

DUS 1961, *Standard Test Method for Penetration Testing of Needles Used in Surgical Sutures*

DUS 1962, *Standard Test Method for Bend Testing of Needles Used in Surgical Sutures*

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

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in F1840 – 10 and the following 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 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 needles 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 categorised 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 Chemical composition**

When tested in accordance with ASTM A 751 – 01, the suture needles shall be made of stainless steel wires of either of the following Composition;

**Table 1 — Chemical composition for surgical suture needles**

Element	Percentage
Carbon	0.30 - 0.40
Manganese	1.00 Max
Phosphorus	0.045 Max
Sulphur	0.045 Max
Silicon	1.00 Max
Chromium	12.00 - 14.00
Nickel	1.00 Max

OR

**Table 2 — Chemical composition for surgical suture needles**

Element	Percentage
Carbon	0.60 - 0.75
Manganese	1.00 Max
Phosphorus	0.040 Max
Sulphur	0.030 Max
Silicon	1.00 Max
Chromium	16.00 - 18.00
Molybdenum	0.75 Max

## 5.2 General requirements

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

## 5.3 Quality requirements

### 5.3.1 Hardness

When tested in accordance with US 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 WDUS ISO 13402.

### 5.3.3 Bend test

The surgical suture needles shall be tested in accordance with WDUS 1962. 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 (for all Needles, except blunt point needle)

The penetration test of surgical needles shall be done in accordance with DUS 1961. The piercing resistance shall be less than 25 g.

## 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

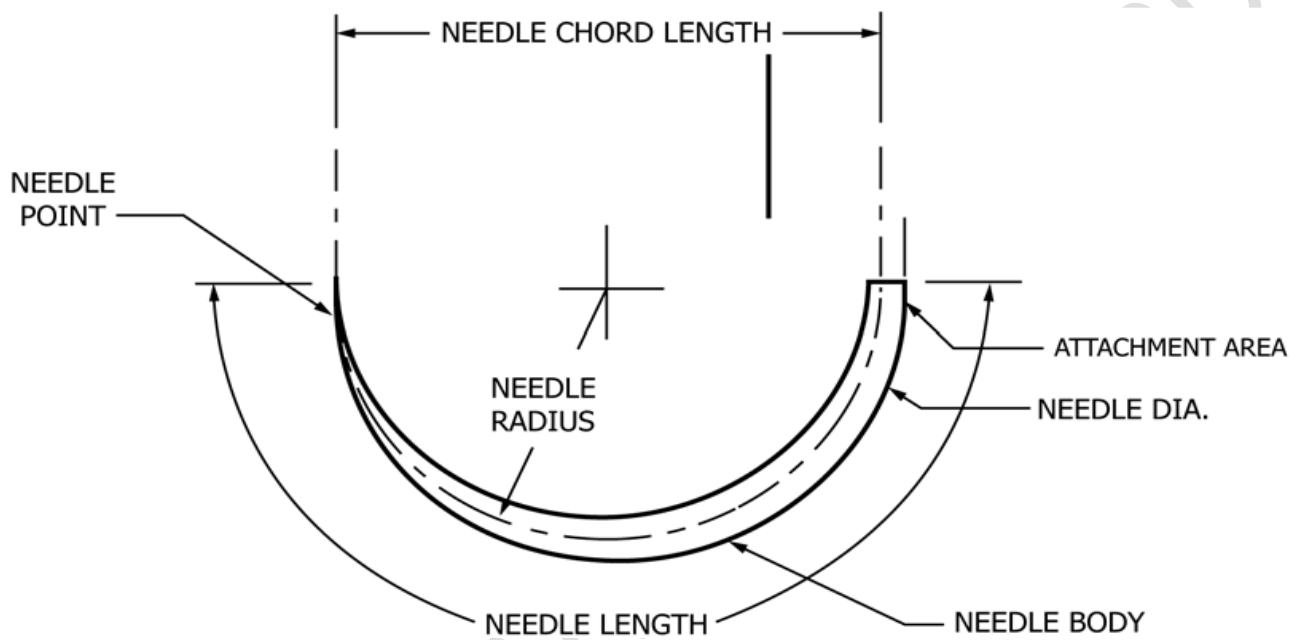
Random samples of the product for test shall be drawn in accordance with US ISO 24153. Acceptance criteria none shall fail.



**Annex A**  
(informative)

**Sizes shapes and dimensions**

**A.1 Schematic of a surgical suture needle**



**Figure A1 — Schematic of a Surgical Needle**

A.2 Curvatures

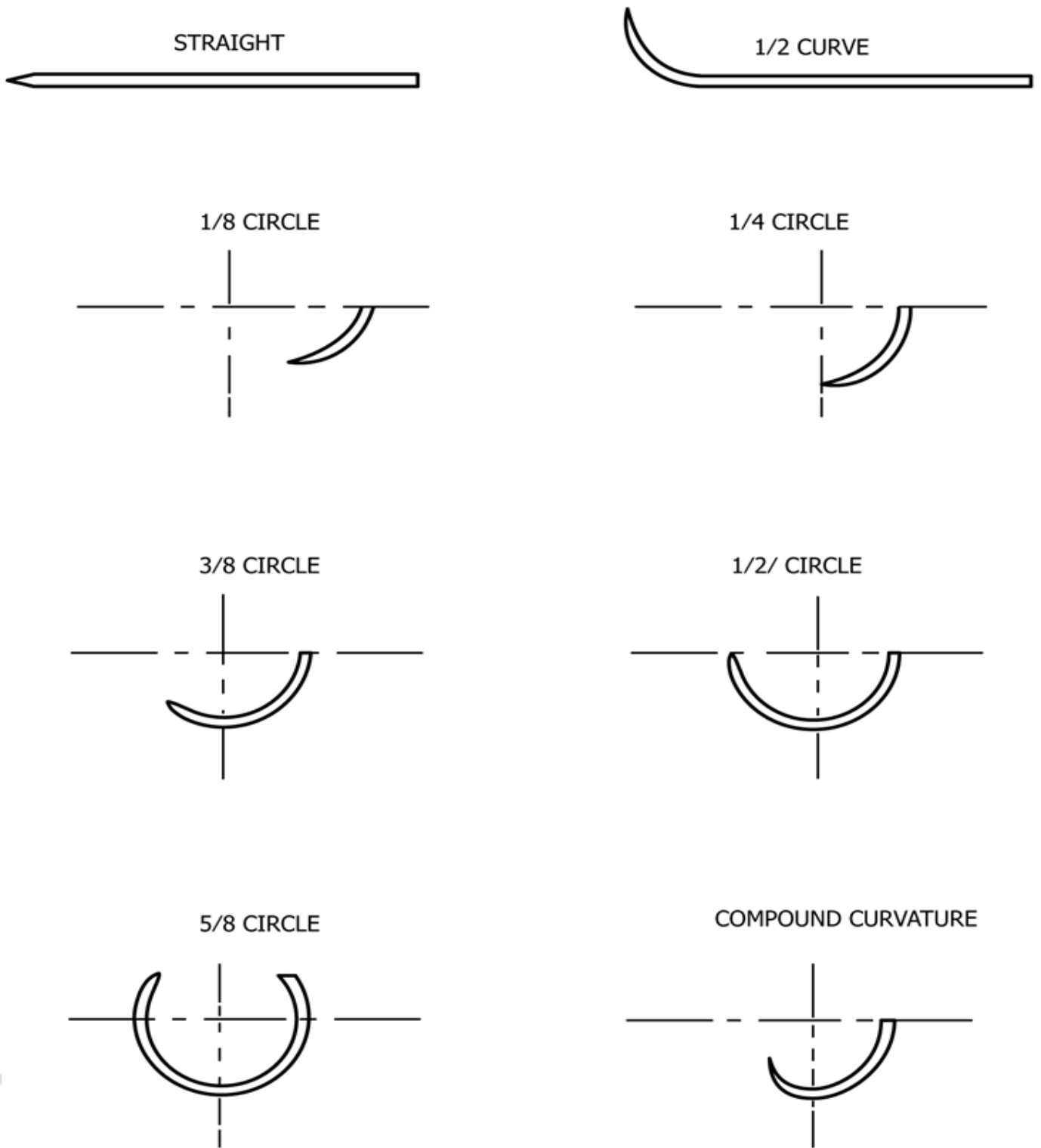


Figure A.2 — Typical Curvatures

### A.3 Point Configurations

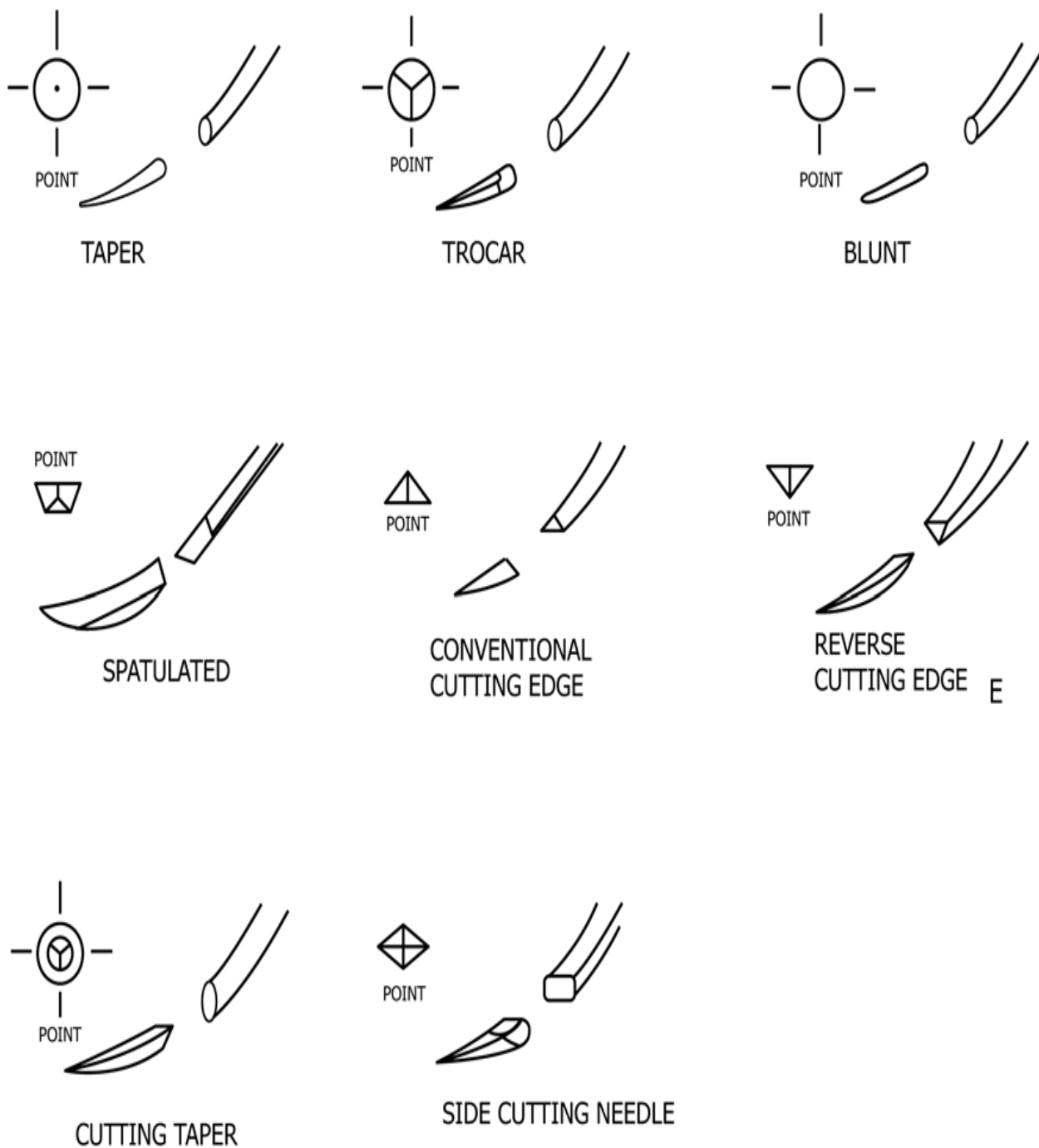


Figure A.3 — Typical point configurations

**A.4 Attachment end of surgical suture needles**



**Figure 4 — Needle eye**

## Bibliography

- [1] ASTM F1840 — 10:2016, *Standard Terminology for Surgical Suture Needles*
- [2] Is 1501:2002, *method for Vickers hardness test for metallic materials (Third Revision)*
- [3] IS 7531 (1990): *Surgical Instruments — Corrosion Resistance of Stainless Steel Surgical Instruments — Methods of Tests*
- [4] IS 9165 (Part 1): 1992, *Surgical instruments — needles, suture Part 1 — Specification*
- [5] ISO 6507-2:2018, *Metallic materials — Vickers hardness test — Part 2: Verification and calibration of testing machines*



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