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Traditional Chinese medicine — Sterile three-edge needle for single use

Médecine traditionnelle chinoise — Aiguille stérile à trois bords à usage unique

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Foreword

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This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Originating in ancient China, the three-edge needle is one of major types of acupuncture needles. The three-edge needle was originally called "Feng Zhen", which literally means “sharp-edge needle”. Its clinical application for the specific indications was earliest recorded in *Huangdi's Canon of Medicine*, which is the earliest writing about traditional Chinese medicine. The therapy which applies the three-edge needle is called three-edge needle therapy.

The three-edge needle has a special needle body structure like an arrow head with three sharp edges. This structure was designed in order to meet specific clinical requirements, such as bloodletting and draining abscesses mainly by the manipulation methods including shallow pricking, deep pricking, multi-point shallow pricking, pricking in and edge cutting out, and needle scratching. Of the manipulation methods, pricking in and edge cutting out (mainly for breaking the fibrous tissue) and needle scratching (leaving marks on skin) can only be practiced by the three-edge needle, which cannot be replaced by other bloodletting medical instruments such as the blood point lancet and the syringe.

It is due to the special structure of the three-edge needle that the practitioner can bleed the clinically required blood amount by controlling the depth instead of repeated pricking which induces pain in patients. This structural advantage of the three-edge needle outweighs the blood point lancet and the syringe both in clinical function, such as draining an abscess, and in obtaining a clinically required amount of blood.

Since the three-edge needle is an invasive medical instrument, it is important to use the sterile needle only once. The quality of the three-edge needle has a direct impact on the safety of patients and the quality of the therapy. Therefore, this document specifies the technical parameters of the sterile three-edge needle for single use to ensure its quality and safety.

Traditional Chinese medicine — Sterile three-edge needle for single use

1 Scope

This document specifies the configuration, dimensions, parameters, requirements and test methods of a sterile three-edge needle for single use. It also specifies requirements for packaging, labelling, transit and storage.

This document excludes requirements for the handle of a three-edge needle, which is structurally different from the body of a three-edge needle.

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-10, *Biological evaluation of medical devices — Part 10: Tests for skin sensitization*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

ISO/TS 10993-19, *Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 15510, *Stainless steels — Chemical composition*

ISO 21920-3, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 3: Specification operators*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
three-edge needle
needle with a head in a triangular pyramid shape, of which the three side faces form three edges extending up to a sharp tip

3.2
head of the three-edge needle
part of the *three-edge needle* (3.1) with three edges

3.3
tip of the three-edge needle
sharp apex of the *head of the three-edge needle* (3.2)

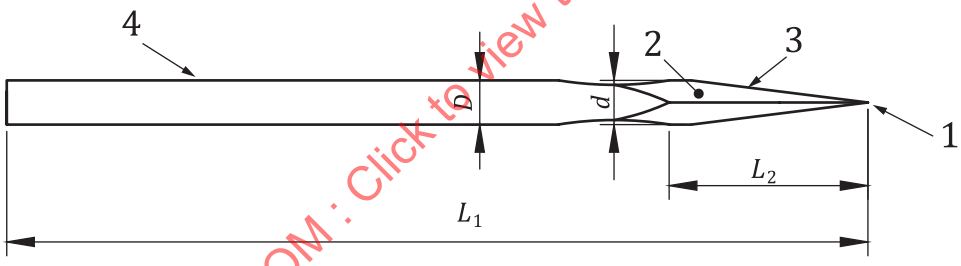
3.4
body of the three-edge needle
part of the *three-edge needle* (3.1) excluding the *head of the three-edge needle* (3.2)

3.5
edge of the three-edge needle
lateral edge of the triangular pyramid which forms the *head of the three-edge needle* (3.2)

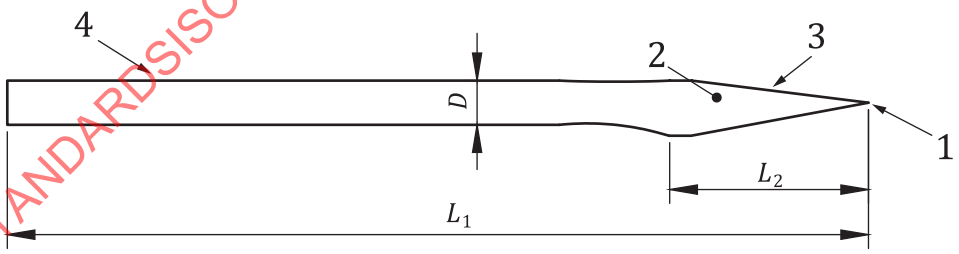
4 Specifications

4.1 Configuration

The configuration, the basic parts and the parameters of the three-edge needle are shown in Figure 1. The head of the three-edge needle may vary according to the dimensions and parameters specified in 4.2.



a) Top view



b) Side view

Key

1 tip of the three-edge needle
2 head of the three-edge needle
3 edges of the three-edge needle
4 body of the three-edge needle
d external diameter of the widest part of the head of the three-edge needle

D external diameter of the body of the three-edge needle
L_1 whole length of the three-edge needle
L_2 length of the head of the three-edge needle

Figure 1 — Example of a typical structure of a three-edge needle

4.2 Dimensions and parameters

4.2.1 Whole length of the three-edge needle

The whole length of the three-edge needle shall be as shown in Table 1.

Table 1 — Whole length of the three-edge needle

Dimensions in millimetres

Length L_1	Tolerance
$50 \leq L_1 \leq 80$	±2,0

4.2.2 Length of the head of the three-edge needle

The length of the head of the three-edge needle shall be as shown in Table 2.

Table 2 — Length of the head of the three-edge needle

Dimensions in millimetres

Length L_2
$1{,}5 \leq L_2 \leq 20$

4.2.3 External diameter of the widest part of the head of the three-edge needle

The external diameter of the widest part of the head of the three-edge needle shall be as shown in Table 3.

Table 3 — External diameter of the widest part of the head of the three-edge needle

Dimensions in millimetres

Diameter d
$1 \leq d \leq 4{,}5$

4.2.4 External diameter of the body of the three-edge needle

The external diameter of the body of the three-edge needle shall be as shown in Table 4.

Table 4 — External diameter of the body of the three-edge needle

Dimensions in millimetres

Diameter D	Tolerance
$1 \leq D \leq 3{,}5$	±0,30

4.3 Material

The three-edge needle shall be made from stainless steel that conforms to ISO 15510.

5 Requirements

5.1 Hardness

The hardness degree of the head of the three-edge needle shall be no less than $200HV_{0,2kg}$.

The test method of hardness shall conform to ISO 6507-1.

5.2 Roughness

The maximum value of roughness average of the head of the three-edge needle shall be as specified in Table 5.

Table 5 — Roughness average of the head of the three-edge needle

Dimensions in micrometres

Roughness average
≤ 0,8

The test method of roughness shall conform to ISO 21920-3.

5.3 Puncture force

The tip of the three-edge needle shall be sharp. If the puncture force is low, this indicates that the tip is sharp. See the test method of the puncture force in Annex A.

5.4 Corrosion resistance

The three-edge needle shall have good resistance to corrosion. If the conditions of storage have been met, there shall be no corrosion of the head and the body of the needle before the expiry date. See the test method of the corrosion resistance in ISO 17218:2014, Annex C.

5.5 Sterility assurance

The three-edge needle shall be validated through a sterilization process.

NOTE The appropriate sterilization methods and the requirements for validation and routine control of a sterilization process for medical devices are provided in ISO 11135, ISO 11137-1 and ISO 17665.

5.6 Biological compatibility

The three-edge needle shall be evaluated and documented in accordance with the guidance and principles given in ISO 10993-1, ISO 10993-4, ISO 10993-10, ISO 10993-18 and ISO/TS 10993-19.

5.7 Appearance quality

5.7.1 The tip of the three-edge needle shall be sharp-edged, burr free and have no deficiencies such as scars fringes, spikes or hooks.

5.7.2 The three sides of the head of the three-edge needle shall be smooth and even. The section of the head of the three-edge needle shall be an equilateral triangle or an isosceles triangle.

5.7.3 The edge of the three-edge needle shall be sharp and free from defects (e.g. burrs).

5.7.4 The body of the three-edge needle shall be straight and its surface shall be smooth and free of burrs, edges, holes, marks and cracks.

6 Packaging

6.1 Primary package

6.1.1 The sterile three-edge needle for single use shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

6.1.2 The material and design of this primary package shall not have detrimental effects on the contents. The material and design of this primary package shall be such as to ensure:

a) the maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

b) the minimum risk of contamination of the contents during removal from the package;

c) adequate protection of the contents during normal handling, transit and storage;

d) that once opened, the package cannot be easily resealed, and it shall be obvious that the package has been opened.

NOTE The requirements of materials, sterile barrier systems and packaging systems for terminally sterilized medical devices are provided in ISO 11607-1.

6.2 Secondary package

One or more primary packages shall be packaged in a secondary package.

The secondary package shall be sufficiently robust to protect the contents during handling, transit and storage.

One or more secondary packages may be packaged in a storage or transit package.

7 Labelling

7.1 General

The symbols to be used with medical device labels, labelling and information to be supplied on the package shall conform to ISO 15223-1.

7.2 Primary package

The primary package shall be marked with at least the following information:

a) the name, trademark or logo of the manufacturer;

b) a description of the contents, including the designated metric size in accordance with 4.2;

c) the lot number, prefixed by the word “LOT” and/or the date of manufacture;

d) the expiry date;

e) the method of sterilization, the word “STERILE” or a symbol;

f) the words “For single use” or “Do not reuse” or a symbol.

7.3 Secondary package

The secondary package shall be marked with at least the following information:

a) the name, address and trademark of the manufacturer;

b) a description of the contents, including the designated metric size in accordance with 4.2, the quantity and the type;

c) the lot number, prefixed by the word “LOT” and/or the date of manufacture;

d) the expiry date;

e) the method of sterilization, the word “STERILE” or a symbol;

f) the words “For single use” or “Do not reuse” or a symbol;

g) if appropriate, the license certificate number;

h) information for handling, storage and transportation;

i) a warning to check the integrity of each primary package before use, such as “Do not use if package is damaged” or a symbol;

j) if used, the names or composition of additives (such as lubricant) used as a coating on the surface of the head or the body of the three-edge needle.

8 Transit and storage

8.1 The three-edge needle shall have sufficient protection from damage during transit and storage.

8.2 Once the three-edge needle is packaged, it shall be stored and transported in a clean, well-ventilated and non-contaminated environment.

8.3 The storage and transportation environment shall have controls in place for humidity, temperature and exposure to direct sunlight.