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Traditional Chinese medicine — Thread-embedding acupuncture needle for single use

Médecine traditionnelle chinoise — Aiguille d'acupuncture à usage unique incorporant un fil

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

Thread-embedding acupuncture therapy is an innovative treatment method within the scope of traditional Chinese medicine. This method of treatment is also known as “long-term” acupuncture. Following the same principles of acupuncture and channel meridians, thread-embedding therapy is the method for preventing and treating disease by the continuous stimulating effect of the thread in the acupoints.

In recent years, the sustainability and effectiveness of acupuncture have been demonstrated by the publication of numerous clinical research studies. Alternative acupuncture treatment methods, such as thread-embedding acupuncture, have seen an increase in popularity and demand.

The purpose of this document is to ensure the safety of the thread-embedding acupuncture needle through standardization of this device. It is also intended to promote the international trade of thread-embedding acupuncture needle devices.

Traditional Chinese medicine — Thread-embedding acupuncture needle for single use

1 Scope

This document specifies the safety requirements for the thread-embedding acupuncture needle.

It is applicable to only the needle part of thread-embedding acupuncture needles and excludes medical thread.

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 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

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

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 15510, *Stainless steels — Chemical composition*

ANSI/ASQ Z1.4-2003 (R2013) *Sampling Procedures and Tables for Inspection by Attributes*

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 https://www.iso.org/obp

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

3.1
thread-embedding therapy
treatment method using a sterile hypodermic needle to implant medical thread into specific acupoints

3.2
thread-embedding acupuncture needle
specially modified sterile hypodermic needle designed for implantation of medical thread

3.3
handle of the needle
part of the acupuncture needle that is not inserted into the human body

[SOURCE: ISO 17218:2014, 3.2, modified — Note 1 to entry removed.]

3.4
tip of the needle
sharp apex at the end of the acupuncture needle body that is inserted into the human body

[SOURCE: ISO 17218:2014, 3.3, modified — Note 1 to entry removed.]

3.5
needle tube
assistant tool in the shape of a long, slender tube into which the needle is placed and used for easy insertion

[SOURCE: ISO 17218:2014, 3.7, modified — term has been replaced.]

3.6
medical thread
surgical thread or similar medical material to be implanted in the acupoints

4 Classification and configuration

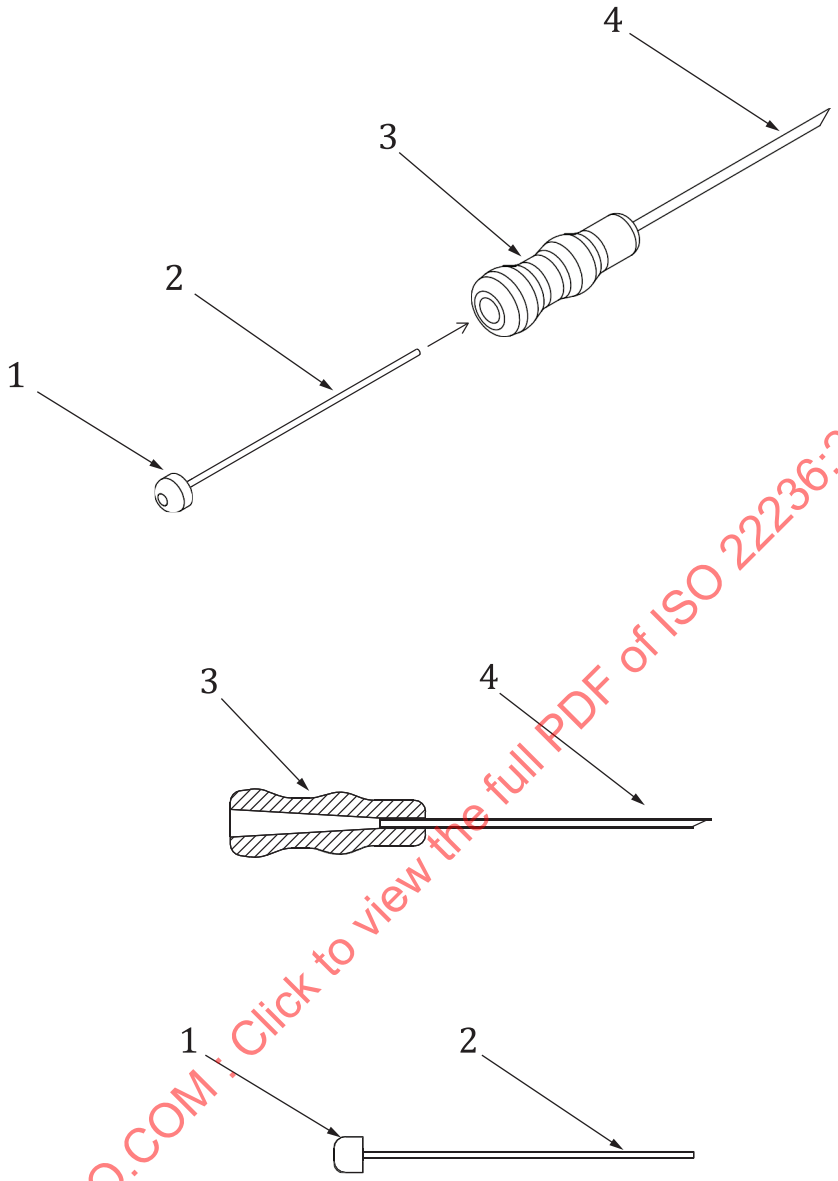
4.1 Configuration

The classification and configuration of the thread-embedding acupuncture needle and the name of its parts are shown in Figure 1 and Figure 2.

There are two types of thread-embedding acupuncture needle:

a) Plunger type thread-embedding needle

   This needle is separate from thread (see Figure 1);



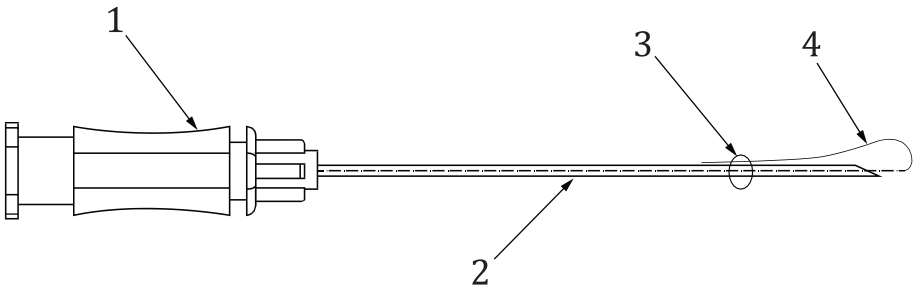
Key

1 thread plunger handle
2 thread plunger body
3 handle of the needle
4 needle tube

Figure 1 — Plunger type thread-embedding needle

b) Pre-installed type thread-embedding needle

This is composed of a needle and thread (see Figure 2).



Key

1 handle of the needle
2 needle tube
3 thread holder
4 thread

Figure 2 — Pre-installed type thread-embedding needle

4.2 Classification

The thread-embedding acupuncture needle shall be classified based on the inclusion of thread in accordance with 4.1.

5 Material

5.1 Plunger type thread-embedding needle

The needle tube and thread plunger body shall be made of stainless steel according to ISO 9626. The stainless steel parts intended to penetrate the body shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

5.1.1 Thread plunger handle

The thread plunger handle shall be made of polypropylene or other material with similar mouldability, strength and biological stability.

5.1.2 Thread plunger body

The thread plunger body shall be made from one of the stainless steels listed in ISO 15510.

5.1.3 Handle of the needle

The handle of the needle shall be made of polypropylene or other material with similar mouldability, strength and biological stability.

5.1.4 Needle tube

The needle tube shall be made from one of the stainless steels listed in ISO 15510. The stainless steel parts intended to penetrate the body shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

5.2 Pre-installed type thread-embedding needle

5.2.1 Handle of the needle

The handle of the needle shall be made of polypropylene or other material with similar mouldability, strength and biological stability.

5.2.2 Needle tube

The needle tube shall be made from one of the stainless steels listed in ISO 15510. The stainless steel parts intended to penetrate the body shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

5.2.3 Thread holder

The thread holder shall be made of polyethylene, or other material with similar mouldability.

5.2.4 Thread

The thread shall be made of polydioxanone, polycaprolactone, poly-L-lactic acid or other material with similar mouldability, strength and biological stability.

6 Requirements

6.1 Surface finish and visual appearance

6.1.1 The needle tube shall be clean and appear free of debris, particulates and other impurities.

6.1.2 The needle tube shall appear straight with a regular cross-section and wall thickness.

6.1.3 The needle tube shall display no visible evidence of corrosion when tested in accordance with ISO 9626:2016, Annex D.

6.1.4 The thread plunger body and handle of the needle shall appear to be free of injection moulding defects such as rough selvedge, burrs, plastic flow and bubbles.

6.1.5 The connection between the needle tube and the handle of the needle, and between the thread plunger body and the thread plunger handle, shall be straight and exhibit no obvious deflection.

6.1.6 When examined at 10 times magnification, the needle tube tip shall be free of burrs, hooks or other defects, and the tip of the needle shall appear sharp and be smooth roundhead.

6.2 Needle tube construction

6.2.1 The size of the needle tube shall be designated by:

a) the designated metric size of the needle tube in millimetres; and

b) the nominal length of the needle tube expressed in millimetres.

6.2.2 The needle tube shall conform to the requirements of ISO 9626:2016, Clause 5.

6.2.3 The actual length of the needle tube shall equal the nominal length within the tolerances given in ISO 7864:2016, Table 1.

6.2.4 The needle tube and thread plunger body shall be reasonably inflexible. The maximum deflection shall be less than 0,55 mm when measured according to ISO 9626:2016, Annex B.

6.2.5 The needle tube and thread plunger body shall resist breaking when tested according to the method in ISO 9626:2016, Annex C.

6.2.6 The needle tube shall be sufficiently sharp such that the maximum piercing force shall not exceed 1,7 N when measured using the penetration force test in ISO 7864:2016, Annex D.

6.2.7 The thread plunger body shall pass smoothly through the lumen of the needle tube.

6.3 Handle of the needle and thread plunger

6.3.1 The union between the handle of the needle and the needle tube shall not separate or become flexible when a force of 40 N is applied as tension in the direction of the needle axis in accordance with ISO 7864:2016, Table 2.

6.3.2 The union between the thread plunger body and the thread plunger handle shall not separate or become flexible when a force of 10 N is applied as tension in the direction of the axis of the thread plunger body.

NOTE See ISO 7864 for a method to test bonding strength.

7 Sterility and biocompatibility

7.1 Sterility assurance

Sterile thread-embedding needles shall be sterilized using a validated sterilization process in order to ensure that the products are sterile.

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

7.2 Biocompatibility

7.2.1 The body of the needle intended to penetrate the human body shall be assessed and documented according to the guidance principles given in ISO 10993-1.

7.2.2 Any toxic side effects associated with material used for the thread plunger body and handle of the needle shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

7.2.3 When a thread-embedding acupuncture needle is sterilized using ethylene oxide (EO), the level of EO residuals, when measured using the procedure specified in ISO 10993-7, shall not exceed 10 µg/g. The EO residuals may be extracted using the method specified in ISO 9626:2016, Annex A.

8 Package

8.1 Primary packaging

8.1.1 The sterile thread-embedding needle shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

8.1.2 The material and design of this primary package shall not have a detrimental effect 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 given in ISO 11607-1.

8.2 Secondary packaging

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

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

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

8.3 Storage packaging

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

9 Inspection

9.1 Production batch

9.1.1 Each production batch shall be made from the same batches of raw materials (see Clause 5).

9.1.2 Each production batch shall be sterilized using the same sterilization process.

9.2 Factory inspection

9.2.1 Each production batch shall be inspected according to ANSI/ASQ Z1.4.

9.2.2 The factory inspection requirements, inspection level and qualified level shall conform to Table 1.

Table 1 — Factory inspection

Clause	Inspection level	Qualified level
6.1	S-2	2,5
6.2, 7.1, 7.2	S-3	4,0

9.2.3 After sterilization, the EO residuals shall be monitored to ensure that the production batch is not released until residual testing is complete.

10 Information supplied by the manufacturer

10.1 General

The thread-embedding acupuncture needle shall be accompanied by the information that is needed for its safe use, taking account of the training and knowledge of potential users.

10.2 Primary package

The primary package shall be marked with the following:

a) the name and address of the manufacturer and supplier, if applicable;

b) a description of the contents, including the metric size in accordance with 6.2.1;

c) the batch code, proceeded by an appropriate identification;

EXAMPLE "LOT" or the lot symbol ISO 7000-2492. See ISO 15223-1:2016, 5.1.5.

d) an indication that the contents of the package are sterile and the method of sterilization (see 7.1);

EXAMPLE The word "STERILE", the sterile symbol ISO 7000-2499 or one of the "sterilized using..." symbols ISO 7000-2500, ISO 7000-2501, ISO 7000-2502 or ISO 7000-2503. See ISO 15223-1:2016, 5.2.1 to 5.2.5.

e) the "use by date", expressed as year and month;

EXAMPLE The "use by date" symbol ISO 7000-2607. See ISO 15223-1:2016, 5.1.4.

f) an appropriate indication that the thread-embedding acupuncture needle is for single use;

EXAMPLE The "do not re-use" symbol ISO 7000-1051. See ISO 15223-1:2016, 5.4.2.

g) a warning to check the integrity of each primary package before use.

10.3 Secondary package

The secondary package shall be marked with the following:

a) name and address of the manufacturer and supplier, if applicable;

b) a description of the contents, including the metric size in accordance with 6.2.1;

c) the batch code proceeded by an appropriate identification;

d) an indication that the contents of the package are sterile and the method of sterilization (see 7.1);

e) the "use by date", expressed as year and month;

f) an appropriate indication that the thread-embedding acupuncture needle is for single use.

10.4 Storage container

10.4.1 If one or more secondary packages is packed in a storage container, the storage container shall be marked with the same information required on the secondary package (see 10.3).

10.4.2 If a storage container is not used but the secondary package(s) are wrapped for transport, the information required in 10.3 shall either be marked on the wrapping or be visible through the wrapping.