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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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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

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 has 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.

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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*

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

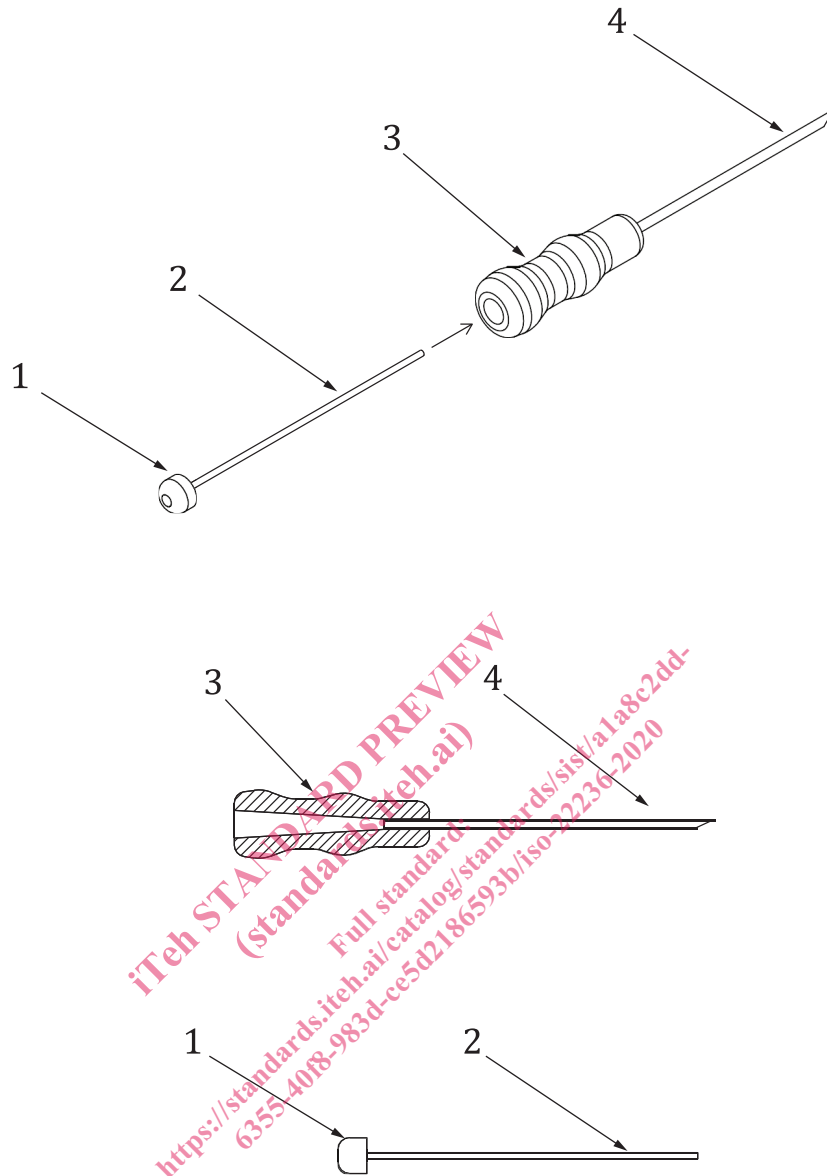
The classification and configuration of the thread-embedding acupuncture needle and the name of its parts are shown in [Figure 1](#) and [Figure 2](#).

There are two types of thread-embedding acupuncture needle:

- a) Plunger type thread-embedding needle

This needle is separate from thread (see [Figure 1](#)).

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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](#)).