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Traditional Chinese medicine — Gua Sha instruments

Médecine traditionnelle chinoise — Instruments Gua Sha

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

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

Introduction

Gua Sha, also known as Gua Sha therapy, is a traditional treatment based on the meridian-acupoint theory of traditional Chinese medicine (TCM). The specific Gua Sha instruments which have different shapes and materials are adopted to perform scraping action to the skin during the Gua Sha treatment so as to prevent or treat diseases.

Gua Sha has been used for more than two thousand years and has demonstrated medical benefits. In recent years, Gua Sha has proved, according to many clinical research projects, to be effective in treating more than 400 types of diseases. Now, it is widely accepted in many countries including China, United States of America, Europe, Australia, Japan, Korea and other Southeast Asian countries.

The purpose of this document is to guarantee the safety and performance of Gua Sha instruments, so as to promote the international trade of Gua Sha instruments and generalize the clinical application of Gua Sha therapy.

Traditional Chinese medicine — Gua Sha instruments

1 Scope

This document specifies appearance, material, requirements of visual inspection, cleaning and disinfection, hardness, roughness, resistance to abrasion, exposure index of radionuclide activity, biocompatibility of Gua Sha instruments, as well as related information on package, transport and storage, labelling and instructions for use.

Electro-devices and other forms are outside the scope of this document.

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 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

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

ISO/IEC Guide 37, *Instructions for use of products of consumer interest*

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:

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

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

3.1
Gua Sha
therapy consisting of scraping or applying friction to the skin surface without causing abrasion or injury to the skin

3.2
Gua Sha instrument
instrument made of hard material with different sizes and shapes for single or repeated usage during Gua Sha therapy

4 Appearance

4.1 Shape

A variety of shapes can be applicable as follows:

a) oval-shaped;

b) rectangle-shaped;

c) notch-shaped;

d) triangle-shaped;

e) comb-shaped;

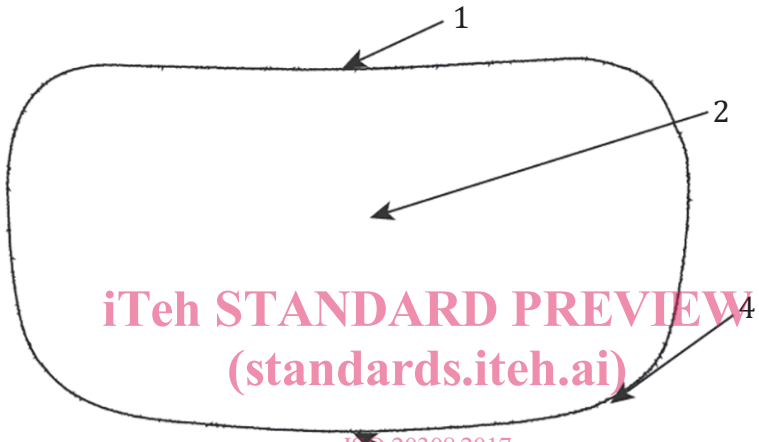
f) fish-shaped;

g) other shapes.

NOTE Dimensions and configurations of Gua Sha instruments are given in Annex B.

4.2 Appearance

The general configuration of a Gua Sha instrument and the term for each part is shown in Figure 1.



Key

1 handle for practitioner
2 body of Gua Sha instrument
3 side of scraping on skin
4 angle of scraping on skin

Figure 1 — Example of the typical structure of a Gua Sha instrument

5 Material

A variety of materials can be applicable as below:

a) buffalo-horn;

b) bian-stone;

c) jade;

d) other materials.

6 Requirements

6.1 Visual inspection

When inspected with the naked eye:

a) the surface of the Gua Sha instrument shall appear flat, smooth, free from particles and extraneous matters, and

b) any part of the Gua Sha instrument shall have no acute angle, crack or obvious deformation or damage.

6.2 Cleaning and disinfection

Gua Sha instruments for single or repeated use shall be in accordance with ISO 17664 in order to avoid skin irritation and infection

6.3 Hardness

According to Moh's hardness scale, the hardness of any type of Gua Sha instrument shall be no less than 3.

6.4 Roughness

After polishing, the surface roughness of the Gua Sha instrument shall be no more than 6,3 μm.

NOTE For appropriate method to measure the roughness, see Annex A.

6.5 Resistance to abrasion

6.5.1 The Gua Sha instrument shall have sufficient resistance to abrasion induced by 150 times of repeated disinfection.

6.5.2 If the requirements for storage specified in this document have been met, there shall be no abrasion of the Gua Sha instrument before the expiry date.

6.6 Exposure index of radionuclide activity

6.6.1 The internal exposure index is the quotient of specific activity of the radionuclide Ra-226 divided by the limits of the specific activity of the radionuclide Ra-226 specified in this document.

$$I_{\mathrm{Ra}} = \frac{C_{\mathrm{Ra}}}{200} \tag{1}$$

where

I_{Ra} is the internal exposure index;

C_{Ra} is the specific activity of the radionuclide Ra-226, measured as "Bq•kg^{-1}";

200 is the limit of the specific activity of the radionuclide Ra-226, measured as "Bq•kg^{-1}".

6.6.2 The external exposure index is the quotient of the specific activity of the radionuclide Ra-226, Th-232 and K-40 divided by the limits of the specific activity of the radionuclide Ra-226, Th-232 and K-40 specified in this document.

$$I_r = \frac{C_{Ra}}{370} + \frac{C_{Th}}{260} + \frac{C_K}{4200} \quad (2)$$

where

I_r is the external exposure index;

C_{Ra} is the specific activity of the radionuclide Ra-226, measured as "Bq•kg^{-1}";

C_{Th} is the specific activity of the radionuclide Th-232, measured as "Bq•kg^{-1}";

C_K is the specific activity of the radionuclide K-40, measured as "Bq•kg^{-1}";

370 is the limit of the specific activity of the radionuclide Ra-226, measured as "Bq•kg^{-1}";

260 is the limit of the specific activity of the radionuclide Th-232, measured as "Bq•kg^{-1}";

4200 is the limit of the specific activity of the radionuclide K-40, measured as "Bq•kg^{-1}".

6.6.3 The internal exposure index of the Gua Sha instrument shall be no more than 0,5 and the external exposure index shall be no more than 0,65.

6.7 Biocompatibility

The biocompatibility of the Gua Sha instrument shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Compliance is demonstrated by:

a) analogy with published data; or

b) the selection of materials already shown to be biocompatible by proven clinical use in a similar application; or

c) experience with similar devices already on the market together with evidence of traceability to the materials used in the Gua Sha instrument; or

d) compliance with published procedures for biological evaluation of medical devices.

7 Packaging

7.1 Primary packaging

The Gua Sha instrument shall be sealed in primary packaging. There shall be no foreign matter within the primary package under visual inspection.

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

a) the maintenance 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.

7.2 Secondary packaging

One or more items of primary packaging shall be packaged in secondary packaging.

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

One or more items of secondary packaging may be packaged in storage and/or a transit package.

8 Transport and storage

Once the Gua Sha instruments are packaged, they shall be kept in a clean, dry, well-ventilated and non-corrosive environment. The storage environment shall protect the Gua Sha instruments from exposure to high humidity, high temperatures and direct sunlight.

9 Labelling and instructions for use

9.1 Labelling

9.1.1 Primary packaging

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

a) the name or trademark or logo of the manufacturer and/or supplier;

b) a description of the contents, including the designated metric size;

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

d) the expiry date;

e) for a Gua Sha instrument intended for single use, the words “For single use” or “Do not reuse” or symbol;

f) material;

g) dimension.

9.1.2 Secondary packaging

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

a) the name, address and trademark of the manufacturer and/or supplier;

b) description of the contents, including the designated metric size, the quantity and the classification;

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

d) expiry date;

e) for a Gua Sha instrument intended for single use, the words “For single use” or “Do not reuse” or symbol;

f) information for handling, storage and transportation;

g) a warning to check the integrity of each item of primary packaging before use, such as “Do not use if packaging is damaged” or symbol.