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Copper-bearing contraceptive intrauterine devices — Requirements and tests

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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~~www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document might be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see ~~www.iso.org/patents~~www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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~~www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7439:2015), which has been technically revised.

The main changes are as follows:

~~1 The section~~— the subclause on clinical performance has been revised (see 5.2~~)~~);

— the movable collar has been added in the ~~section~~subclause on insertion instrument (see 6.3~~.~~.4);

— requirements for packaging integrity have been added;

~~4~~ — the instructions for health care providers have been amended in accordance with ~~‘~~the "Family planning: ~~a~~A global handbook for ~~providers’~~providers"[4];

~~5~~ — the requirement for stability in situ has been removed since there is no practical way of controlling it.

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~~www.iso.org/members.html.

Introduction

Although every foreign object in the uterus exhibits a certain contraceptive effect, the method by which copper-bearing contraceptive intrauterine devices (IUDs) function is by the continuous release of copper ions. This interferes with some enzymatic functions, immobilizes sperm cells and inhibits fertilization.

The IUD is a highly effective contraceptive device with a long history of safe use. It can be used for many years, with a prompt return of fertility upon removal.

IUDs do not prevent sexually transmitted infections and condom use is recommended for those at risk.

IUDs containing copper are regarded as single use sterile medical devices implanted in the uterus. These medical devices are inserted and removed by trained and competent ~~Health Care Providers~~health care providers.

Copper-bearing contraceptive intrauterine devices — Requirements and tests

1 Scope

This document specifies requirements and tests for single-use, copper-bearing contraceptive intrauterine devices (IUDs) and their insertion instruments.

It is not applicable to IUDs consisting only of a plastics body or whose primary purpose is to release progestogens or other medicinal products.

NOTE Some aspects of this document can be applicable to medicated intrauterine devices and IUDs not containing copper.

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

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirementsGood clinical practice*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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

European Pharmacopoeia (Ph. Eur.)[1]

ASTM D 3078-standard, Standard *test method for determination of leaks in flexible packaging by bubble emission*

ASTM F 1929 *standard test method for detecting seal leaks in porous medical packaging by dye penetration*

European Pharmacopoeia (Ph. Eur.) [2] ISO 13485 *Medical devices — Quality management systems — Requirements for regulatory purposes*

[1] European Directorate for the Quality of Medicines (EDQM) of the Council of Europe.

[2] European Directorate for the Quality of Medicines (EDQM) of the Council of Europe.

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~~https://www.iso.org/obp

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

3.1
contraceptive intrauterine device
IUD
copper-bearing device placed in the uterine cavity for the purpose of preventing pregnancy

3.2
insertion instrument
instrument designed to place an IUD in the uterine cavity

3.3
thread
retrieval string attached to an IUD for the purposes of verifying the presence and facilitating the removal by a professional health care provider

Note 1 to entry: The thread is intended to lie in the cervical canal and the vagina when the body of the device is placed correctly in the uterine cavity.

3.4
viscoelastic property
property of an IUD enabling an approximate return to its initial configuration after deformation

3.5
active surface area
surface area of copper in the IUD that is intended to come into contact with uterine fluids

3.6
lot
quantity of IUDs produced during essentially the same time using the same process, same lots of raw materials, common equipment and which are sterilized at the same time

3.7
client
recipient or patient receiving a contraceptive product

3.8
unique device identifier
series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard

Note 1 to entry: The unique identifier might include information on the lot or serial number and be able to be applied anywhere in the world. It allows the unambiguous identification of a specific medical device.

4 Quality verification

Copper bearing IUDs should be manufactured within an integrated quality management system conforming to ISO 13485.

NOTE For most countries and regions, this is a regulatory requirement.

For quality verification purposes, the sample size requirements and acceptance criteria specified in Annex A shall be used. These requirements are based on ISO 2859-1.

The sampling plans have been simplified to take into account typical industry lot sizes, the specific characteristics of IUDs and the nature of the manufacturing processes used to produce them. The sample sizes and acceptance criteria have been selected to provide an acceptable level of consumer protection taking into account the costs of sampling and testing. In addition to verification testing, it is strongly recommended that manufacturers conduct process validation and capability studies, and adopt statistical process control procedures such as the use of control charts to ensure acceptable product quality.

The sampling and acceptance criteria given in Annex A are intended to cover the following situations:

a) continuing production of lots within a stable manufacturing environment;

b) the assessment of isolated lots (e.g. fewer than 5), for example when purchasers wish to conduct confirmatory testing on a limited number of lots, when production is interrupted or intermittent, or for surveillance testing.

In addition, the rules for switching between normal and tightened inspection in ISO 2859-1 have been adopted to provide greater level of consumer protection should the quality of a manufacturing process deteriorate. These rules are applied as follows:

— Normal inspection – the specified sample sizes for normal inspection apply at the start of production. Normal inspection continues to apply unless two nonconforming lots are found in any sequence of 5 or fewer lots tested. If this occurs the number of samples used to assess the conformity for future lots shall be increased to those specified for tightened inspection.

— Tightened inspection – the specified sample sizes for tightened inspection shall apply until a sequence of 5 lots have been accepted. –Following the acceptance of 5 sequential lots, the manufacturer may return to the sample sizes for normal inspection.

The switch to reduced inspection has not been adopted for the testing of copper bearing IUDs. Switching to smaller sample sizes is not considered acceptable given the potential for increased consumer risk because of the small sample sizes specified under normal inspection for many of the tests.

5 Intended clinical performance

5.1 General

ISO 14630:2012, Clause 4, shall apply.

ISO 14155 shall apply.

5.2 Clinical performance

5.2.1 General

An IUD shall meet the requirements specified in 5.2.2.to 5.2.~~10~~9, based on a single-arm clinical study over a period of five years of user wear-time (the minimum intended lifetime of use). -The manufacturer shall present these data in a final report of the clinical evaluation before releasing a modified or newly designed IUD onto the market.