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Fallopian rings — Requirements and test methods

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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

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.

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 157, *Non-systemic contraceptives and STI barrier prophylactics*.

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.

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Introduction

Fallopian rings are devices which provide permanent contraception. These devices are elastic bands made from medical grade silicone. They are implanted bilaterally using a laparoscopic surgical procedure. After the rings are applied to each fallopian tube, they cut off the blood supply and occlude the tubal lumen. This stops the ova from travelling to the uterus, thereby preventing fertilisation. Fallopian rings are provided sterile and packaged as a set of two.

This document has been necessitated as a result of the product marketing experience gained by manufacturers and procurement agencies.

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Fallopian rings — Requirements and test methods

1 Scope

This document specifies the minimum requirements and test methods for fallopian rings used for tubal occlusion in women for permanent contraception. This document does not address the applicator or other accessories used to place the fallopian rings.

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 10993-3, *Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

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

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ASTM F640, *Standard test methods for determining radiopacity for medical use*

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/

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3.1
fallopian rings
elastic band made of medical grade silicone placed around a loop of fallopian tube bilaterally using a laparoscopic surgical procedure or open surgery, cutting off the blood supply to occlude the tubal lumen and prevent fertilization

3.2
lot
collection of *fallopian rings* (3.1) manufactured at essentially the same time, using raw materials of the same specifications, the same process and common equipment, packed in the same type of individual container

Note 1 to entry: The recommended maximum individual lot size for production is 10 000 pairs, but it is possible for a purchaser to specify the lot size as part of the purchasing contract and quality management system of the manufacturer.

3.3
lot number
number or combination of numerals, symbols or letters used by the manufacturer to identify a *lot* (3.2) or individually packaged product, and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.4
lot test
test to assess the conformity of a *lot* (3.2)

Note 1 to entry: A lot test may be limited to include only those parameters which may change from lot to lot.

3.5
inspection level
relationship between lot size and sample size

Note 1 to entry: Inspection level designates the relative amount of inspection.

3.6
sampling plan
specific plan which indicates the number of units of products from each *lot* (3.2) which are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and of manufacture to the use before date)

3.7
shelf life
period of time from the date of manufacture during which the *fallopian rings* (3.1) are required to confirm to the requirements specified in this document

3.8
radio-opacity
quality or state of being radio-opaque

Note 1 to entry: It is the property of the material in obstructing the passage of radiation energy such as X-rays and will produce a white image on the exposed X-ray film, which confirms that the implanted device is in position.

3.9
visible defects
defects which are visible to unaided eye during inspection, such as discolouration, any fibres or protrusions on the fallopian ring

3.10
laparoscope
instrument inserted through an incision in the abdominal wall and used to visualize the surgical field, where it has working channels with the applicator to insert the *fallopian rings* (3.1)

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