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Fallopian rings — Requirements and test methods

Anneaux de fallope — Exigences et méthodes d'essai

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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 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.

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.

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/

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)

4 Requirements

4.1 Quality verification

Fallopian rings are mass produced articles manufactured in very large quantities. Inevitably, there will be some variation between individual rings, and a small proportion of rings in each production run might not meet the requirements of this document. Further, the majority of the test methods described in this document are destructive. For these reasons, the only practicable method of assessing conformity with this document is by testing a representative sample from a lot or series of lots. Basic sampling plans are given in ISO 2859-1. Reference should be made to ISO/TR 8550 (all parts) for guidance on the use of acceptance sampling system, scheme or plan for the inspection of discrete items in lots. When on-going verification is required of the quality of fallopian rings, it is suggested that, instead of concentrating solely on evaluation of the final product, attention is also directed at the manufacturer's quality system. It should be noted that ISO 13485 covers the provision of an integrated quality system for the manufacture of medical devices. Sampling plans shall be selected to provide an acceptable level of consumer protection. Suitable sampling plans are given in Annexes A and B.

a) Annex A describes sampling plans based on ISO 2859-1 and is most applicable to manufacturers or purchasers assessing the conformity of a continuing series of lots. The full level of consumer protection available depends upon the switch to tightened inspection if deterioration in quality is detected. The switching rules, described in ISO 2859-1:1999, Clause 9, cannot offer their full protection for the first two lots tested but become progressively more effective as the number of lots in a series increases. Use the sampling plans in Annex A when five or more lots are being tested.

b) Annex B describes sampling plans, based on ISO 2859-1, that are recommended for the assessment of isolated lots. The sampling plans in Annex B provide approximately the same level of consumer protection as those given in Annex A when used with the switching rules. It is recommended that these sampling plans are used for the assessment of fewer than five lots, for example in cases of dispute, for referee purposes, for type testing, for qualification purposes or for short runs of continuing lots.

It is necessary to know the lot size in order to derive the number of fallopian rings to be tested from ISO 2859-1. The lot size will vary between manufacturers and is regarded as part of the process and quality controls used by the manufacturer. If the lot size is not known or cannot be confirmed by the manufacturer, then a lot size of 10,000 fallopian rings shall be assumed for determining the sample sizes for testing.

4.2 Physical requirements

4.2.1 Dimensions

Fallopian rings are tested for the inner diameter and outer diameter in accordance with Annex C and shall conform to the requirements given in Figure 1.

Cut rings shall be free from fibrous protrusions at the outer and inner surface. Angle of cut shall be at 90° (≤5° angulations is allowed).

Dimensions in millimetres

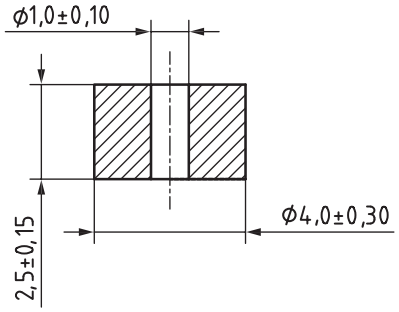

Figure 1 — Fallopian ring

4.2.2 Tensile properties

Fallopian rings tested in accordance with Annex D for the tensile properties shall conform to the requirements stated below.

a) The force at break shall be ≥20,50 N.

b) Elongation at force at break shall be ≥560 %.

4.2.3 Loading force on ring applicator

Fallopian rings tested in accordance with Annex E for the force of loading on ring applicator shall conform to the requirement stated below.

The force required to load fallopian rings on the ring applicator shall be ≤35 N.

4.2.4 Elastic memory

Fallopian rings tested in accordance with Annex F for the elastic memory shall conform to the requirement stated below.

The recovery of the inner diameter shall be such that the increase in the inner diameter ≤25 % of the original diameter.

4.2.5 Repeat loading strength

Fallopian rings tested in accordance with Annex G for the repeat loading strength shall neither break nor develop any cracks when viewed using ×20 magnification.

4.2.6 Visible defects

Fallopian rings tested for the visible defects shall not have defects such as discolouration, any fibres or protrusions on the ring.

4.3 Packaging

4.3.1 Packing mode

One pair of fallopian rings shall be packaged in peel open pouch/blister pack with seal width ≥2 mm.

4.3.2 Primary pouch

Each pouch/blister pack shall ensure:

a) adequate protection of the contents during normal handling, transit and storage for a period of 4 years;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions at a temperature(s) ranging from 0 °C to 50 °C; and

c) minimal risk for contamination of the contents during removal from the pouch/blister pack.

4.3.3 Instruction for use

Every dispenser box shall be provided with at least one instruction for use describing the method to be adopted for:

a) loading of rings on the ring applicator; and

b) storage and handling requirements in clean and dry place.

4.3.4 Package seal strength

Fallopian rings packs shall be tested for package seal integrity and seal strength in accordance with Annex J and peel force shall be 4,4 N to 19,0 N.

4.3.5 Package seal integrity

Fallopian rings packs shall be tested for package seal integrity and seal strength in accordance with Annex J and there shall be no evidence of leakage of the package.

4.3.6 Sterility

Fallopian rings supplied as sterile shall meet the requirements of sterility test as specified in the latest version of national/international pharmacopoeia.

The manufacturer shall establish procedures and systems to validate the type of sterilization used for the fallopian rings as sterility testing alone cannot be deemed as the criteria for confirming the sterility of the product. Validation of ethylene oxide sterilization process shall be done according to ISO 11135 and gamma sterilization shall be done according to ISO 11137-1 and ISO 11137-2.

4.4 Biological requirements

The biological safety of fallopian rings shall be evaluated in accordance with the principles given in ISO 10993-1, according to which fallopian rings are classified as a permanent contact implant device, and the following tests shall be complied with:

a) cytotoxicity as per ISO 10993-5;

b) sensitization as per ISO 10993-10;

c) irritation or intracutaneous reactivity as per ISO 10993-10;

d) subchronic (Subacute) toxicity as per ISO 10993-11;

e) genotoxicity as per ISO 10993-3;

f) acute systemic toxicity as per ISO 10993-11;

g) implantation as per ISO 10993-6.

These tests shall be repeated only in the case of a significant change such as change in formulation or grade of silicone tubing material, change in sterilization method, change in manufacturing process, etc.

The results of the test shall be reviewed and interpreted by a qualified toxicologist.

4.5 Radio-opacity

Fallopian rings shall be radiopaque. This test shall be a type test used for the initial evaluation of the silicone elastomeric tubing material. ASTM F640 shall be referred for determining radio-opacity of the elastomeric material.

4.6 Clinical evaluation

4.6.1 General

Fallopian rings made of silicone-based elastomer have been used to effect female sterilization for nearly 50 years. They have been studied extensively, and clinical reports from the published literature[8] show a long history of safety and effectiveness. Rings manufactured in accordance with the requirements of this document are expected to have comparable clinical performance. This means the manufacturers' fallopian rings are similar to the fallopian rings used in the cited published clinical studies and comply with this document with respect to the following characteristics:

— peak load;

— elongation at peak load;

— strain capacity;

— loading force on ring applicator;

— elastic memory;

— repeat loading strength.

To establish conformance with this document for a new design of fallopian rings, the manufacturer shall demonstrate, using a one-sided test, that the upper limit of the 95 % confidence interval for a one-year pregnancy rate is ≤2,0 %. To establish this, the manufacturer shall sponsor a clinical study of its new design and demonstrate clinical safety and effectiveness. Completion of the one-year phase of the study is sufficient to begin marketing. However, the women in the study should be followed for an additional four years to record any additional pregnancies and serious adverse events.

4.6.2 New clinical study of manufacturer's fallopian rings

A manufacturer may make significant changes to the fallopian ring with respect to design, materials or manufacturing procedures. In this case, the manufacturer shall sponsor a clinical study of its fallopian ring and demonstrate clinical safety and effectiveness. To this end, the sponsor shall conduct a single-arm clinical study, enrolling sexually-active women of reproductive age, following these women for a total of five years. Biostatistical analysis of the study shall show, using a one-sided test, that the upper limit on the 95 % confidence interval for the one-year failure rate (pregnancy) is less than 2,0 %. Completion of the one-year phase of the study is sufficient to begin marketing. However, the women in the study should be followed for an additional four years (a total of five years) to record any additional pregnancies and serious adverse events. Any unusual findings shall be included in updated labelling.

5 Storage condition

The fallopian rings shall be stored at a temperature ranging from 0 °C to 50 °C.