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Female condoms — Requirements and test methods

Préservatifs féminins — 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*.

This third edition cancels and replaces the second edition (ISO 25841:2014) which has been technically revised.

The modifications are as follows:

— clinical failure mode definitions have been harmonized with ISO 29943-2;

— tolerances have been specified for the amount of lubricant applied to the female condom and the length, width and sheath thickness of the female condom. These tolerances are to be applied to the nominal values specified by the manufacturers for these design features;

— manufacturers are required to specify female condom width and thickness at three locations along the length of the female condom sheath;

— manufacturers are required to identify specifications and test methods as appropriate to verify the design and to ensure the quality and consistency of components and materials used for the retention features and any insertion feature used with the female condom;

— manufacturers are recommended to establish procedures for the periodic monitoring of microbial contamination (bioburden) as part of their quality management system including requirements for the absence of specific pathogens and limits for total viable counts on finished female condoms; methods of determining bioburden levels on female condoms are given in Annex I;

— detailed changes have been made to the test methods for determining freedom from holes and airburst properties to improve the reproducibility of female condom testing between laboratories and accommodate female condoms made from a wider range of sheath materials including sheaths made from natural rubber latex;

— a greater degree of harmonization with ISO 4074 has been achieved for common requirements and definitions;

— for female condoms with sheaths made from natural rubber latex, reference is included in the procedures for estimating provisional shelf lives from accelerated stability studies given in ISO 4074;

— the maximum lot size for female condoms has been limited to 500 000;

— labelling requirements have been revised and updated.

Introduction

A female condom is a sheath that completely lines the vaginal canal and is designed to be retained in the vagina during sexual intercourse and after withdrawal of the penis to prevent pregnancy and transmission of sexually transmitted infections (STIs).

A female condom is distinguished from a male condom in that it is retained in the vagina after withdrawal of the penis. The external component of the device can provide some coverage to the external female genitalia. Nonporous, intact, polymer films can be effective barriers to human immunodeficiency virus (HIV), other infectious agents responsible for the transmission of STIs and spermatozoa. Female condoms made from polymer films that are free from holes and defects, have adequate physical properties so as not to break during use, are correctly packaged to protect them during storage and are correctly labelled to facilitate their correct use, can be effective for contraceptive purposes and in the prevention of sexually transmitted infections (STIs).

To be safe, it is essential that the female condom and any lubricant, additive, dressing, individual packaging material or powder applied to it neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage or use.

Female condoms are non-sterile medical devices but manufacturers are advised to take appropriate precautions to minimize microbiological contamination of the product during manufacture and packaging. To ensure high quality products, it is essential that female condoms be designed and produced under a good quality management system. Reference can be made, for example, to ISO 9000, ISO 9004, ISO 9001, ISO 13485 and ISO 14971. To estimate the shelf life of any new or modified female condom, the manufacturer conducts stability tests before the product is placed on the market. This ensures that manufacturers have adequate data to support shelf-life claims and that these data are available for review by regulatory authorities, test laboratories and purchasers. They are also intended to limit the need for third parties to conduct long-term stability studies. Real-time shelf-life studies are also initiated, but not necessarily completed, prior to placing the product on the market.

Because female condoms are a relatively new class of device and designs of female condoms vary considerably, clinical investigations in humans are necessary to continue to build evidence of safety and efficacy. These investigations enable an assessment of the overall performance of internal and external retention features, failure modes, safety and effectiveness of female condoms. This document represents minimal requirements and test methods and acknowledges that new designs can require further due rigour of retention and other features as well as additional definition of specifications and test methods by the manufacturer.

All of these issues are addressed in this document.

Female condoms — Requirements and test methods

1 Scope

This document specifies the minimum requirements and test methods for female condoms that are supplied to consumers for contraceptive purposes and for assisting in the prevention of sexually transmitted infections (STIs).

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 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 4074, *Natural rubber latex male condoms — Requirements and test methods*

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

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

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

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 15223 (all parts), *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 29943-2, *Female condoms — Guidance on the design, execution, analysis and interpretation of clinical failure mode studies*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1 and the following 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 General terms

3.1.1
acceptable quality limit
AQL
quality level that is the worst tolerable process average when a continuing series of *lots* (3.1.9) is submitted for acceptance sampling

[SOURCE: ISO 2859-1:1999, 3.1.26]

3.1.2
consumer package
package intended for distribution to a consumer, containing one or more *individual container(s)* (3.1.7) of *female condom* (3.1.5)

3.1.3
date of manufacture
date of formation of the *female condom* (3.1.5) sheath or the date the female condoms are packed in their *individual containers* (3.1.7) provided, in the latter case, a maximum period of bulk storage is specified and shelf-life studies have been conducted on female condoms that have been subjected to the maximum bulk storage period

3.1.4
expiry date
date after which the *female condom* (3.1.5) should not be used

3.1.5
female condom
sheath that completely lines the vaginal canal and is designed to be retained in the vagina during sexual intercourse and after withdrawal of the penis to prevent pregnancy and transmission of sexually transmitted infections

3.1.6
identification number
number, or combination of numbers, symbols or letters used by a manufacturer on *consumer packages* (3.1.2) to uniquely identify the *lot numbers* (3.1.10) of individual female condoms contained in that package and from which it is possible to trace those *lots* (3.1.9) through all stages of manufacturing, packaging and distribution

Note 1 to entry: When the consumer package contains only one kind of female condom, then the identification number can be the same as the lot number. However, if the consumer package contains several different types of female condoms, for instance, female condoms of different shapes or colours, then the identification number will be different from the lot number.

3.1.7
individual container
primary package containing a single *female condom* (3.1.5)

3.1.8
inspection level
index of the relative amount of inspection of an acceptance sampling scheme, chosen in advance and relating the sample size to the lot size

[SOURCE: ISO 3534-2:2006, 4.3.5]

3.1.9
lot
collection of *female condoms* (3.1.5) of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed with the same lubricant and any other additive or dressing in the same type of *individual container* (3.1.7)

3.1.10
lot number
number or combination of numerals, symbols or letters used by the manufacturer to identify a *lot* (3.1.9) of individually packaged *female condoms* (3.1.5) and from which it is possible to trace that lot through all stages of manufacture up to packaging

3.1.11
non-visible hole
hole in a *female condom* (3.1.5) that is not visible under normal or corrected vision but is detected by a suitable water leakage test

Note 1 to entry: Leakage during testing can be detected, for instance, by rolling a female condom on absorbent paper.

Note 2 to entry: Suitable tests are specified in this document.

3.1.12
sampling plan
specific plan which indicates the number of units of product from each *lot* (3.1.9) that are to be inspected (sample size or series of sample sizes) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers)

3.1.13
shelf life
period from *date of manufacture* (3.1.3) to the claimed *expiry date* (3.1.4) during which *female condoms* (3.1.5) are required to conform to the requirements for bursting pressure, bursting volume, freedom from holes and package integrity specified in this document

3.1.14
visible hole
hole or tear in the *female condom* (3.1.5) that is visible under normal or corrected vision before the condom is filled with water during the test for freedom from holes

3.1.15
visible defects
<condom, other than visible holes> broken, missing or severely distorted retention features, permanent crease with adhesion of the film or unintentional adhesion of the film to retention features including defect particles from *female condoms* (3.1.5) or other materials embedded in the female condom wall

3.1.16
visible defects
<individual containers> empty, leaking, damaged or dirty containers, illegible or missing information or absence of a notch or other device to facilitate opening the container without damaging the *female condom* (3.1.5) or rendering illegible any important information printed on the container

Note 1 to entry: Important information includes *lot number* (3.1.10), *expiry date* (3.1.4) and any instructions for use printed on the container.

3.2 Terms related to female condom failure modes

3.2.1
acute failure event
female condom (3.1.5) failure identified by the risk analysis conducted in accordance with ISO 14971

3.2.2
clinical breakage
female condom (3.1.5) breaks or tears during intercourse or withdrawal of the female condom from the vagina

Note 1 to entry: This might not be noticed until after inspection of the female condom following intercourse.

3.2.3
clinical breakage rate
number of *female condom* (3.1.5) broken or torn during sexual intercourse or withdrawal divided by the number of female condoms used during sexual intercourse

Note 1 to entry: Typically reported as a percentage.

3.2.4
non-clinical breakage
female condom (3.1.5) breakage that does not potentially expose the vagina to semen or other penile discharge

Note 1 to entry: An example of a non-clinical breakage is tearing a female condom while opening the package.

3.2.5
non-clinical breakage rate
number of *female condom* (3.1.5) broken that do not potentially expose the vagina to semen or other penile discharge divided by the number of female condom packages opened

Note 1 to entry: Typically reported as a percentage.

3.2.6
total breakage
sum of female condom *clinical* (3.2.2) and *non-clinical breakages* (3.2.4)

3.2.7
total breakage rate
number of *clinical* (3.2.2) and *non-clinical breakages* (3.2.4) divided by the number of female condom packages opened

Note 1 to entry: Typically reported as a percentage.

Note 2 to entry: The total breakage rate will not be the sum of the *clinical breakage rate* (3.2.3) and the *non-clinical breakage rate* (3.2.5). The clinical breakage rate has a different denominator than the other two rates.

3.2.8
clinical slippage
situation where the condom slips completely out of the vagina during sexual intercourse

3.2.9
clinical slippage rate
number of *female condoms* (3.1.5) that slipped divided by the number of female condoms used during sexual intercourse

Note 1 to entry: Typically reported as a percentage.

3.2.10
clinical misdirection
situation where the penis is inserted between the *female condom* (3.1.5) and the vaginal wall

3.2.11
clinical misdirection rate
number of *female condoms* (3.1.5) that misdirect divided by the number of female condoms used during sexual intercourse

Note 1 to entry: Typically reported as a percentage.

3.2.12
clinical invagination
external retention feature of the *female condom* (3.1.5) is partially or fully pushed into the vagina during sexual intercourse

3.2.13
clinical invagination rate
number of *female condoms* (3.1.5) that invaginate divided by the number of female condoms used during sexual intercourse

Note 1 to entry: Typically reported as a percentage.

3.2.14
total clinical failure
number of *female condoms* (3.1.5) with at least one *acute failure event* (3.2.1) that results in potential vaginal exposure to semen and other penile discharge

Note 1 to entry: Any female condom which experiences multiple clinical failure events only counts as a single clinical failure

Note 2 to entry: Includes female condoms with the following failures: *clinical breakage* (3.2.2), *slippage* (3.2.8), *misdirection* (3.2.10), *invagination* (3.2.12) or any failure event(s) in the risk assessment as described in 6.6.

3.2.15
total clinical failure rate
number of *female condoms* (3.1.5) with clinical failure divided by the number of female condoms used during sexual intercourse

Note 1 to entry: Typically reported as a percentage.

3.2.16
total female condom failure
female condom (3.1.5) with any type of clinical failure event or non-clinical failure event

3.2.17
total female condom failure rate
number of *female condoms* (3.1.5) with a clinical failure event or a non-clinical failure event divided by the number of female condom packages opened

Note 1 to entry: Typically reported as a percentage.

4 Quality verification

Female condoms are mass-produced articles manufactured in large quantities. Inevitably, there will be some variation between individual female condoms, and a small proportion of female condoms in each production run might not meet the requirements in 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 8550-1 and ISO/TR 8550-2 for guidance on the use of acceptance sampling system, scheme or plan for the inspection of discrete items in lots. For testing purposes, sampling shall be conducted by lot number, not by identification number.

When ongoing verification is required of the quality of female condoms, it is suggested that, instead of concentrating solely on evaluation of the final product, attention is also directed at the manufacturer's quality system. In this connection, 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 Annex A and Annex B.

— 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. The sampling plans in Annex A are recommended when five or more lots are being tested.

— 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 from ISO 2859-1 the number of condoms to be tested. 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 500 000 condoms shall be assumed for determining the sample sizes for testing.

5 Lot size

The maximum individual lot size for production shall be 500 000 condoms.

This document does not specify the size of a lot, but it is possible for a purchaser to do so as part of the purchasing contract. Purchasers are encouraged to specify a lot size compatible with the manufacturer's quality management system.

6 Design

6.1 General

Female condoms shall be designed to prevent pregnancy and STIs during vaginal intercourse. A female condom is distinguished from a male condom in that it has an internal retention feature to prevent slippage and retain the female condom in the vagina after insertion and after withdrawal of the penis. A female condom also shall have an external retention feature to prevent invagination. A female condom may be made from natural rubber latex or synthetic materials.

The design of a female condom shall take into consideration the following:

a) product insertion into the vagina;

b) product retention and prevention of slippage during sexual intercourse or penile removal;

c) penile misdirection during sexual intercourse;

d) invagination of the female condom during sexual intercourse;

e) safe product removal after sexual intercourse;

f) the safety of all materials used in the construction of the female condom including the risk of any interaction between the materials;

g) the impermeability of the of the film to microorganisms;

h) the risk of breakage of the female condom during insertion, use and withdrawal.

6.2 Product insertion feature

Designs for female condoms shall include either a feature or tool to aid in the proper insertion and deployment of the female condom or methods for insertion of the female condom without such additional aids.

The insertion feature design, materials and/or method shall be evaluated for function as part of design validation and clinical evaluation of the finished female condom device described in Clause 9.

The insertion feature materials shall be evaluated for biocompatibility (irritation, sensitization, cytotoxicity and acute systemic toxicity) as an integrated feature of the finished female condom device in accordance with Clause 8.

Specifications and test methods as appropriate to verify the design and to ensure the quality and consistency of components and materials used for each insertion feature consistent with those used in the clinical trial described in Clause 9 shall be identified.

Examples of specifications the manufacturer should consider include critical dimensions, durometer (hardness), stiffness (modulus) and density.

6.3 Retention features

Designs for female condoms shall incorporate intra-vaginal retention features to retain the female condom within the vagina during sexual intercourse and permit safe withdrawal after use. Intra-vaginal retention features might be affixed on or placed within the sheath. Examples of intra-vaginal retention mechanisms include, but are not limited to, elastomeric rings and open or closed cell foam components.

Designs for female condoms shall incorporate external retention features to keep the open end of the female condom open during sexual intercourse, prevent misdirection of the penis and prevent female condom invagination. External retention features include but are not limited to annular, triangular or other-shaped components affixed to the open end of the female condom.

Retention feature designs, materials and/or methods shall be evaluated for function as part of design validation and clinical evaluation of the finished female condom device described in Clause 9 of this document. They shall also be evaluated in this manner to ensure the features stay affixed to the sheath or are retained within the sheath so that they remain intact during sexual intercourse and during product withdrawal, so that the features are completely removed from the vagina when the female condom is removed from the vagina.

Retention feature materials shall be evaluated for biocompatibility (irritation, sensitization, cytotoxicity and acute systemic toxicity) as an integrated feature of the finished female condom device in accordance with Clause 8.

The specifications and test methods required to verify the design and to ensure the quality and consistency of components and materials used for each retention feature shall be specified.

Examples of specifications that should be considered include critical dimensions, durometer (hardness), stiffness (modulus), bonding between the retention features and the sheath (if appropriate) and density.

Any of the critical requirements for the retention features that can change between lots shall be specified and appropriate test methods shall be described. The conformity level shall be an AQL of 2,5. The sampling plan shall be S-2.

6.4 Lubrication

The design of a female condom may include lubrication in any of the following manners:

a) lubricant pre-applied directly on the packaged female condom as supplied;

b) lubricant supplied in a separate container to be applied to the female condom by the user;

c) both pre-applied and as a separate container.

The type and amount of lubricant is unique to each female condom design. The nominal amount of lubricant consistent with amount of lubricant used in the clinical trial described in Clause 9 shall be specified. The specified amount of lubricant shall be based on the amount recovered using the test method specified in Annex C. This amount can differ significantly from the amount of lubricant added during manufacture, particularly if the internal retention feature is a sponge. The tolerance for the amount of lubricant shall be within ±15 % of the specified nominal amount.

When tested in accordance with the method given in Annex C, taking 13 female condoms from each lot, no female condom lubricant mass measurement shall be outside the specified range.