
Condoms — Guidance on clinical studies —

Part 2: Female condoms, clinical function studies based on self-reports

Préservatifs — Lignes directrices relatives aux études cliniques —

Partie 2: Préservatifs féminins, analyse fonctionnelle des défaillances graves sur la base d'auto-déclarations



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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).

Attention is drawn to the possibility that some of the elements of this document may 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).

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

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*.

A list of all the parts of ISO 29943 can be found on the ISO website.

Introduction

There is limited information on the safety and effectiveness of female condoms. Therefore, clinical validation of any new female condom is necessary to ensure that its performance during actual use is not inferior to the performance of female condoms of existing designs.

This clinical study guidance is intended to help in the design, execution, analysis, and interpretation of clinical function studies conducted in accordance with requirements of ISO 25841 for female condoms. In addition to information regarding the clinical validation study, this document provides recommendations on risk assessment, pilot studies, and statistical analysis plans. Annexes include previously used case report forms (CRF) and protocols that can be modified or adapted.

To date, there has been considerable variation in female condom designs and materials. Many female condoms are held in place with external rings and are often anchored within the vagina using rings, sponges or other unique designs. From the published literature, the most common acute failure events associated with female condom use are breakage, slippage, invagination and misdirection. However, the definitions for these acute failure events have been inconsistent from one published study to another. A sponsor planning to conduct a female condom study should review the definitions in this document to determine their applicability for the product.

For further information regarding definitions of female condom failures, refer to Reference [12] and Reference [16]. Also, note that the definitions used in this document are based on existing designs and might need to be expanded or adapted according to the female condom under investigation. Other types of acute failure events (unique to a particular design) can be identified as part of the risk assessment per ISO 14971 or during the pilot study.

NOTE Based on the normative clinical requirement of relevant standards, these studies are designed to recruit participating couples who agree to use the test and control condoms for vaginal intercourse. Such studies can also collect incidental data on condom use during anal sex; however, that is not the primary objective. To satisfy study power requirements, it is critical that sufficient reports are collected on condom use during vaginal intercourse. Study sponsors typically take preventive measures, such as initial screening and consenting of study couples, and obtain agreement that study couples will use condoms this way.

It should also be noted that these clinical function studies are not typically designed to directly evaluate condom protection against pregnancy or sexually transmitted infections (STIs).

Finally, it is important to recognize that clinical function studies of condoms are human research studies. Therefore, all persons designing, conducting, and analysing clinical studies of new female condoms should be familiar with all relevant requirements for research involving human subjects, including ethical considerations. For additional information, refer to ISO 14155.

Condoms — Guidance on clinical studies —

Part 2:

Female condoms, clinical function studies based on self-reports

1 Scope

This document is intended to help in the design, execution, analysis, and interpretation of clinical function studies conducted in accordance with the requirements of ISO 25841 for female condoms.

These clinical studies compare the performance of a new female condom to an established female condom during vaginal intercourse (not anal intercourse). In particular, these studies are designed to assess acute failure events during use.

This document also provides direction on the analysis of data when the study is completed, as well as interpretation of these results by manufacturers and regulatory bodies.

Certain clinical trial elements are not addressed in this document, including compensation, confidentiality of individuals and their records, use of local ethics committees, etc. These and many other clinical trial design issues are covered in greater detail in ISO 14155.

2 Normative references

There are no normative references in this document.

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 <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE All of the clinical failure events defined below represents potential vaginal exposure to semen and other penile discharge. Non-clinical failure events do not risk exposure.

3.1

clinical breakage

breakage or tearing of the condom during intercourse or withdrawal from the vagina

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

Note 2 to entry: Any breakages that do not meet the definition of clinical breakage are considered “non-clinical breakage” (e.g. tearing the condom when opening the package).

3.2

clinical breakage rate

number of female condoms broken or torn during intercourse or withdrawal divided by the number of female condoms used during intercourse

Note 1 to entry: The clinical breakage rate is typically reported as a percentage.