INTERNATIONAL STANDARD

ISO 29943-1

First edition
2017-07

Condoms — Guidance on clinical studies —

Part 1: Male condoms, clinical function studies based on self-reports

Préservatifs — Directives relatives aux études cliniques —

Partie 1: Préservatifs masculins — Études fonctionnelles cliniques basées sur des auto-déclarations

Reference number
ISO 29943-1:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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

Male condoms made from natural rubber latex (NRL) have a long history of safety and effectiveness and their performance during use is well established. However, male condoms made from new materials require clinical validation to ensure that their performance during actual use is not inferior to that of NRL condoms. Such clinical validation studies, called clinical function studies, are designed to compare the rates of acute failure event, i.e. breakage or complete slippage. Statistical analysis based on a non-inferiority comparison is employed to help ensure that the difference is not excessive.

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 the ISO 23409 for synthetic male condoms. However, it can also be used with appropriate modifications to evaluate other male condoms with additional claims for improved efficacy or safety (see ISO 4074:2015, Clause 8). In addition to information regarding the clinical validation study, this document provides recommendations on pilot studies and statistical analysis plans. Annexes include previously used case report forms and protocols that can be modified or adapted.

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.

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, running and analysing clinical studies of new condoms should be familiar with all relevant standards for research involving human subjects, including ethical considerations. For additional information, refer to ISO 14155.

Condoms — Guidance on clinical studies —

Part 1: Male 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 23409 for male synthetic condoms.

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

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).