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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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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

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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.*

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.

