Second edition
2014-01-15

Female condoms — Requirements and test methods

Préservatifs féminins — Exigences et méthodes d'essai

Reference number
ISO 25841:2014(E)

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Published in Switzerland

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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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition (ISO 25841:2011), which has been technically revised.

Introduction

A female condom is a sheath that completely lines the vaginal canal and is designated 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. Non-porous, intact, polymer films can be effective barriers to human immunodeficiency virus (HIV), to other infectious agents responsible for the transmission of STls, and to spermatozoa. Female condoms made from polymer films can be effective for contraceptive purposes and in the prevention of STI transmission. To be effective, it is essential that female condoms completely line the vaginal canal, be 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 use.

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 manufacturing 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 9001, ISO 9004, ISO 13485, and ISO 14971. To estimate the shelf-life of any new or modified female condom, manufacturers conduct 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 in the market.

Because female condoms are a relatively new class of devices 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 International Standard 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 these issues are addressed in this International Standard.