Third edition
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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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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.