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

避孕套 临床研究指南 第2部分：女用避孕套基于自我报告的临床功能研究  
**(English Translation)**

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## Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 2 of GB/T 42168, "Guidelines for Clinical Studies of Condoms". GB/T 42168 has already published the following parts.

---Part 1: Self-reported clinical functional studies of male condoms;

---Part 2: Self-reported clinical functional studies of female condoms.

This document is modified to adopt ISO 29943-2:2017 "Condoms - Clinical investigation guidelines - Part 2: Female condoms - Self-reported" Clinical functional studies.

This document has undergone the following structural adjustments compared to ISO 29943-2:2017.

---Appendix A corresponds to Appendix B of ISO 29943-2:2017;

---Appendix B corresponds to Appendix C of ISO 29943-2:2017;

---Appendix C corresponds to Appendix D of ISO 29943-2:2017;

---Appendix D corresponds to Appendix F of ISO 29943-2:2017;

---Appendix F corresponds to Appendix H of ISO 29943-2:2017;

---Appendix G corresponds to Appendix A of ISO 29943-2:2017;

---Appendix H corresponds to Appendix G of ISO 29943-2:2017.

The technical differences between this document and ISO 29943-2:2017, and the reasons therefor, are as follows.

---The normative reference GB/T 42062 (see Chapter 4) has been added to adapt to my country's national conditions.

The following editorial changes have been made to this document.

---ISO 15841 and ISO 14155 have been replaced by YY/T 1567 and YY/T 0297, respectively (see Chapter 1);

---Informative reference to GB/T 42061 has been added (see 6.12).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Contraceptive and Obstetric Devices (SAC/TC169).

## Introduction

GB/T 42168, "Guidelines for Clinical Research on Condoms," consists of two parts.

---Part 1: Self-reported clinical functional studies of male condoms. The aim is to aid in the design, implementation, analysis, and interpretation of these studies.

Clinical functional studies conducted in accordance with the requirements of YY/T 1777.

---Part 2: Self-reported clinical functional studies of female condoms. The aim is to aid in the design, implementation, analysis, and interpretation of these studies.

Clinical functional studies conducted in accordance with the requirements of YY/T 1567.

Information regarding the safety and effectiveness of female condoms is limited. Therefore, clinical trials are necessary for any new type of female condom.

This is to ensure that its performance in actual use is no less than that of existing female condoms.

This document aims to assist in the design, execution, analysis, and interpretation of clinical functional studies conducted in accordance with the requirements of YY/T 1567 for female condoms.

In addition to information on clinical validation studies, this document provides recommendations on risk assessment, pilot experiments, and statistical analysis planning.

Appendix this includes previously used case report forms (CRFs) and protocols that can be modified or adapted.

To date, the design and materials of female condoms have changed significantly. Many female condoms are secured with an outer ring, typically using a ring...

A sponge or other unique design secures the condom inside the vagina. Based on published literature, the most common acute complications associated with female condom use are...

Acute failure events include breakage, slippage, indentation, and dislocation. However, the definitions of these acute failure events are inconsistent across different studies. (Plan) Initiators of research into female condoms should review the definitions in this document to determine their suitability for the product.

For further information on the definition of female condom failure, please refer to the references. Also, please note that the definitions used in this document are based on for existing designs, expansion or adjustment may be necessary based on the female condoms investigated. Other types of acute failure events (specific to the design) (Specific to the design) can be used as part of the risk assessment in GB/T 42062 or identified in pre-testing.

**Note:** In accordance with relevant clinical guidelines, these studies aim to select candidates who consent to vaginal intercourse using the test and control condoms.

The partner. Such studies can also incidentally collect data on condom use during anal sex; however, this is not the primary objective. To meet the research needs...

The requirement for sufficient condom use during vaginal intercourse is crucial. Study initiators typically take precautions.

Measures include, for example, initial screening and obtaining informed consent from research subjects, and obtaining their consent to use condoms in this manner.

It should also be noted that these clinical functional studies are not typically intended to directly assess the protection of condoms against pregnancy or sexually transmitted infections (STIs).

Protective effect.

Finally, it is important to recognize that clinical functional studies of condoms are human studies. Therefore, the design, implementation, and analysis of novel female condoms are crucial.

All personnel involved in the contraceptive clinical study should be familiar with all relevant research standards involving the study population, including ethical considerations. For further information, see [link to relevant documentation].