INTERNATIONAL STANDARD

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Rubber condoms for clinical trials — Measurement of physical properties

Préservatifs masculins en caoutchouc destinés aux essais cliniques — Mesurage des propriétés physiques

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16037 was prepared by Technical Committee ISO/TC 157, *Mechanical contraceptives*.

Introduction

Clinical investigations of condoms involve many aspects, notably condom acceptability and failure. Useful studies require many condoms and subjects, which are expensive. Clinical studies often underestimate the potential influence of condom physical properties, whose laboratory testing is far less expensive. As physical properties may vary over time and from product to product, a lack of brand- and lot-specific data may well reduce the usefulness of a clinical investigation for improving condom quality and efficacy.

While some investigations may best be conducted using condoms of the participants' choice, it is usually appropriate to ensure that all participants use condoms having the same physical characteristics. In most cases, each clinical investigation will evaluate condoms of one or more types. Study condoms of each type should generally be from the same lot, in order to ensure that they are characterized by the same physical properties. If special properties are desired, independent test laboratories may be able to advise as to which laboratories or manufacturers should be contacted for assistance.

In most situations determination of these characteristics should be part of the study design. Assistance in this regard is available from a number of independent testing laboratories, and from some condom manufacturers. Laboratories should be experienced in, and accredited for, condom testing, in accordance with recognized standards.

It is believed that gathering as much physical information as possible about the condoms used is a sensible precaution. In principle, tests on physical properties should all be done at the beginning of the investigation, and some should be repeated at the end. In investigations running over more than six months, additional tests may be considered during the investigation to give a profile of the change in physical properties over the duration of the study.

While there have been several clinical investigations on condom failure, relatively few of these fully identify the physical characteristics of the condoms used. Thus, it is difficult to compare meaningfully the results of different investigations, or to build hypotheses about design or manufacturing factors that may affect condom efficacy.

Having developed an International Standard on the requirements and test methods for natural latex rubber condoms, (ISO 4074), ISO/TC 157 remains interested in further clinical validation of the physical requirements given, and in any data that may suggest a need for amendments to them. This document offers guidance on the measurement of physical properties characterizing condoms used in clinical investigations. Recommended sample sizes for laboratory testing in this document are in some cases intentionally larger than those in ISO 4074.

This document is written primarily for investigations on natural rubber condoms, but the principles apply to condoms of other materials also. It should not be expected that elongation properties of synthetic materials will be similar to those of natural rubber.

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1 Scope

This International Standard is intended as a guideline for clinical researchers working with condoms. It suggests a series of laboratory tests to be conducted on the products to be used in any clinical investigation, so that it will be easier to relate the clinical results to the design and quality of the condoms used.

This International Standard is not applicable to the design of clinical investigations.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 4074, *Natural latex rubber condoms — Requirements and test methods*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 4074 apply.

4 Length

4.1 Measure and record the length of 13 condoms per lot, as described in ISO 4074. Calculate lot mean length and standard deviation (or confidence interval).

4.2 The length and width of any teat (reservoir) should also be measured (see also 5.2 below).

5 Width

5.1 Measure and record the flat width of 13 condoms per lot, as described in ISO 4074, at sections every 10 mm between 30 mm from the closed end and 30 mm from the open end (rim). For each section, calculate the lot mean width and standard deviation (or confidence interval).

5.2 Alternatively, a profile of the condom may be constructed by photocopying cleaned, dusted and flattened specimens alongside a transparent ruler.