

National foreword

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**Condoms — Guidance on clinical
studies —**

Part 1:

**Male condoms, clinical function
studies based on self-reports**

Préservatifs — Directives relatives aux études cliniques —

*Partie 1: Préservatifs masculins — Études fonctionnelles cliniques
basées sur des auto-déclarations*



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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.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

Male condoms made from natural rubber latex (NRL) have a long history of safety and effectiveness and their performance during use is well established. However, male condoms made from new materials require clinical validation to ensure that their performance during actual use is not inferior to that of NRL condoms. Such clinical validation studies, called clinical function studies, are designed to compare the rates of acute failure event, i.e. breakage or complete slippage. Statistical analysis based on a non-inferiority comparison is employed to help ensure that the difference is not excessive.

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 the ISO 23409 for synthetic male condoms. However, it can also be used with appropriate modifications to evaluate other male condoms with additional claims for improved efficacy or safety (see ISO 4074:2015, Clause 8). In addition to information regarding the clinical validation study, this document provides recommendations on pilot studies and statistical analysis plans. Annexes include previously used case report forms and protocols that can be modified or adapted.

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.

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, running and analysing clinical studies of new condoms should be familiar with all relevant standards for research involving human subjects, including ethical considerations. For additional information, refer to ISO 14155.

Condoms — Guidance on clinical studies —

Part 1:

Male condoms, clinical function studies based on self-reports

1 Scope

This document is intended to help in the design, execution, analysis and interpretation of clinical function studies conducted in accordance with the requirements of ISO 23409 for male synthetic condoms.

These clinical studies compare the performance of a new male condom to an established male condom during vaginal intercourse (not anal intercourse). In particular, these studies are designed to assess acute failure events during use (i.e. clinical slippage and clinical breakage).

This document also provides direction on the analysis of data when the study is completed, as well as interpretation of these results by manufacturers and regulatory bodies.

Certain clinical trial elements are not addressed in this document, including compensation, confidentiality of individuals and their records, use of local ethics committees, etc. These and many other clinical trial design issues are covered in greater detail in ISO 14155.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <http://www.iso.org/obp>

— IEC Electropedia: available at <http://www.electropedia.org/>

NOTE All of the clinical failure events defined below represents potential vaginal exposure to semen and other penile discharge. Non-clinical failure events do not risk exposure.

3.1

clinical breakage

breakage or tearing of the condom during intercourse or withdrawal from the vagina

Note 1 to entry: This might not be noticed until after inspection of the condom following intercourse.

Note 2 to entry: Any breakages that do not meet the definition of clinical breakage are considered “non-clinical breakage” (e.g. tearing the condom when opening the package).

3.2

clinical breakage rate

number of condoms broken or torn during intercourse or withdrawal divided by the number of condoms used during intercourse

Note 1 to entry: The clinical breakage rate is typically reported as a percentage.

3.3

clinical slippage

condom slipping off completely during intercourse or during withdrawal from the vagina

Note 1 to entry: Sometimes slippage occurs because the user failed to hold onto the condom at the base of the penis during withdrawal and/or because the user delayed withdrawal after sex. These events are considered user failures; record such events as "non-clinical slippage." Do not count such user failures as clinical slippage events.

Note 2 to entry: If a condom slips off primarily as a result of breakage, do not count that as a slippage event.

3.4

clinical slippage rate

number of condoms that slipped completely off the penis during intercourse or withdrawal divided by the number of condoms used during intercourse

Note 1 to entry: The clinical slippage rate is typically reported as a percentage.

3.5

clinical failure event

clinical breakage (3.1) or *clinical slippage* (3.3)

3.6

non-inferiority margin

δ

statistical term used to identify clinically meaningful differences between products

Note 1 to entry: Differences between product means which are less than δ are interpreted as noise inherent in the study while differences between product means which are greater than δ are attributed to a meaningful difference between products.

3.7

bias

systematic error caused by a variable not considered in the calculation of results

Note 1 to entry: Three common causes of bias in this type of clinical study are 1) selection bias, where certain types of study subjects are not representative for the outcome being assessed, 2) recall bias, where poor questionnaire design or lengthy time between when condom is used and when the use events are recorded and 3) misclassification, where the outcome of interest (e.g. breakage or slippage) is recorded or assigned erroneously.

Note 2 to entry: The term bias is used in statistics to refer to how far the expected value of a statistic lies from the parameter it is estimating.

4 Pilot clinical studies

Validation of a new condom to generally accepted standards requires considerable time, effort and money. Therefore, pilot studies should be done to characterize and quantify the risk in undertaking the necessary larger scale investigation of clinical breakage and slippage. Typically, these pilot studies enrol 35 to 50 couples who use three to five condoms of each type (test and control). Pilot studies are intended to help determine whether the larger clinical validation study is warranted (i.e. are study results promising). Pilot studies can also be used to test questionnaires and other study instruments. Such studies also provide information for assumptions on clinical failure rates in the intended study population as these will influence the calculations of study power and sample size of the larger study. [Annex B](#) contains a sample outline for a pilot clinical study.

3.2

clinical breakage rate

number of condoms broken or torn during intercourse or withdrawal divided by the number of condoms used during intercourse

Note 1 to entry: The clinical breakage rate is typically reported as a percentage.

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Note 1 to entry: The clinical slippage rate is typically reported as a percentage.

3.5

clinical failure event

clinical breakage (3.1) or *clinical slippage* (3.3)

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5.3.2.1 Inclusion criteria

The following is a list of recommended criteria for selection of study couples.

- a) mutually monogamous, current relationship \geq 3 months;
- b) already protected from pregnancy, e.g. oral contraceptive, intrauterine device, injectable, patch, male or female sterilization;
- c) 18 years to 45 years of age;
- d) sexually active, sufficient to meet protocol requirements; agree to have penile-vaginal intercourse with frequency sufficient to meet protocol requirements;
- e) agree to use only study condoms during time of participation;
- f) agree not to use drugs or non-study devices that can affect sexual performance;
- g) able to understand instructions for correct use of condoms;
- h) no known sexually transmitted infections including HIV/AIDS;
- i) agree to use only lubricant(s) provided by the study;
- j) agree not to wear any genital piercing jewellery while using study condoms;
- k) willing and capable of following requirements of protocol, including willingness to respond to questions about reproductive and contraceptive history and use of condoms during interviews and on self-administered questionnaires;
- l) available for follow-up.

If self-administered questionnaires are used in the study, the study subjects should have an adequate level of literacy commensurate with the questionnaires.

5.3.2.2 Exclusion criteria

The following is a list of recommended criteria for excluding a couple from the study at the time of entry or at any time during the study.

If either partner is (or becomes) aware that

- a) he/she is allergic or sensitive to the material(s) of the test or control condoms,
- b) female partner is pregnant or desires to become so while participating in study,
- c) subject knowingly has a sexually transmitted infection,
- d) commercial sex workers,
- e) itinerant persons who cannot be able to complete the study, e.g. migrant farm workers,
- f) male partner has known erectile or ejaculatory dysfunction,
- g) either partner is using any medications or preparation applied topically or intravaginally to the genitalia other than that supplied for the study,
- h) either partner is an employee of study sponsor or affiliated with clinical research centre,

it is possible to conduct a condom breakage and slippage study in a population at risk of pregnancy, i.e. not using a back-up contraceptive. In fact, this can be more representative of the target population in the commercial market. However, the risk of pregnancy during the study should be considered, as well as any measures in the protocol to manage that risk. Such a study can be subject to additional requirements from the local regulatory body.

5.4 Informed consent

The purpose and requirements of the study should be explained before prospective couples are presented with informed consent forms. Subjects should also be advised that more detailed information about sexual activity will be collected than is typical of most family planning visits. Subjects should be given an opportunity to ask questions about the study and/or the content of the informed consent. Couples should be informed that both partners should agree to participate in the study in order for them to join. If both members of the couple agree to participate, they should each be given a separate informed consent form to sign. All volunteers should provide written informed consent before they are enrolled in the study. All participants should receive a copy of their signed informed consent forms.

Subjects should be informed about the potential for condom failure and the availability of emergency contraception in the event of condom failure (if not otherwise using a highly effective alternate method of contraception).

NOTE Useful information regarding informed consent is available in Reference [11]. Also see Reference [12].

5.5 Test and control condoms

5.5.1 General

Both control and test condoms should be evaluated according to ISO 16037. This is important because these results are used to establish the specifications of the new condom and to verify that the control condom represents a typical condom already approved for market. When the test condom is synthetic, then sufficient sample sizes should be used to establish baseline properties as specified in ISO 23409.

NOTE ISO 16037 is a test method and not restricted to rubber products.

The protocol for the clinical function study should provide physical description of both test and control condoms, including material, length, lay-flat width, thickness, lubricant formulation and appearance.

5.5.2 Test condom

The test condom should meet performance specifications throughout the study.

- a) Test condoms used in the clinical study should be manufactured using the same manufacturing process(es), equipment, specifications and quality assurance procedures as the product to be commercially marketed. Test condoms for the clinical study should be selected from a normal production run.
- b) Test condoms should be selected from a single lot. As stated above, when the test condom is synthetic, the compliance of the lot with the specification should be assessed using the sample plans specified in ISO 23409:2011, Annex B.

If test condoms for the clinical study are selected from more than one lot, then precautions should be taken to ensure that the individual lots comply with the specification and are of a similar age and from a similar period of production, e.g. within 3 months. It is not acceptable to mix samples from lots produced using significantly different processes or equipment.

- c) As specified in ISO 23409:2011, Clause 11, when the test condom is synthetic the airburst properties of test condoms from all lots (preferably only a single lot) should be determined using a sample size of at least 2 000 condoms. Other properties of the condom should be determined and recorded using the principles underlying ISO 16037.
- d) For the purposes of the trial, the test condoms can be packed in non-standard packaging, i.e. showing sequence and randomization allocation without typical brand. However, the packaging should provide the same level of protection to the condom as normal production packaging. If non-standard packaging is used, the manufacturer or the organization responsible for the trial should ensure that the proper labelling information (such as that specified in ISO 23409:2011, 16.2 for synthetic condoms) is made available to the study participants.

NOTE Local regulations can require additional labelling.

5.5.3 Control condom made from natural rubber latex

The control condom selected for the breakage and slippage study should meet the following conditions.

- a) Normal production condoms should be used, subject to any special packaging required to mask the product for the trial.
- b) The condom should be selected from a standard commercial design that is representative of condoms typically found in the market. Unusual designs should not be selected unless specifically justified by the trial design, in which case the scope of any claims supported by the trial can be subject to limitations.
- c) A standard type and quantity of lubricant should be used, preferably a 100 cSt to 350 cSt polydimethylsiloxane fluid. The quantity of lubricant should be 400 mg to 600 mg, as measured in ISO 4074:2015, Annex C. Equivalent lubricants based on aqueous and glycol formulations are acceptable provided they have no deleterious effect on the properties of the condoms. The selection of an unusual lubricant can result in any claims supported by the trial being subject to limitations.
- d) Selection of appropriate control condom should be justified with respect to study population of market and condom design and quality.

5.5.4 Expiration date of control condom

Condoms should be selected from expiration date as specified in ISO 4074 or ISO 23409, from a single manufacturing lot (if possible) that is at least 2 years before expiration date at the commencement of the trial. Where possible, full manufacturing records should be available for the lot and the lot should be identified for full traceability. The lot should be thoroughly mixed and homogenized before the trial or any testing commences.

5.5.5 Storage conditions

Condoms should be distributed and stored under such conditions that they are protected from prolonged exposure to temperatures in excess of 32 °C and any other environmental factors that could affect their quality. Storage conditions should be recorded and fully traceable.

5.5.6 Trial duration exceeds 1 year

If the duration of the trial exceeds 1 year, the study sponsor should retain samples of both the test and control condoms (per initial sampling plan) and store them under the same conditions as the trial condoms. The retained samples should be retested at the end of the trial to confirm ongoing compliance with the airburst and freedom from holes requirements of ISO 4074 or ISO 23409, as appropriate, and characterize the properties of the condom. The results of any retests should be included in the trial report.

Manufacturers can retest the condoms at regular intervals (e.g. every 6 months) during the trial. If, at any stage, the retained samples fail to meet the airburst and freedom from holes requirements of ISO 4074 or ISO 23409, then consideration should be given to terminating the trial.

5.5.7 Sampling of control condoms for bench testing

Sampling plans based on ISO 4074:2015, Annex B should be used to confirm compliance with the requirements of ISO 4074. Sampling plans based on ISO 23409:2011, Annex B should be used to confirm compliance with the requirements of ISO 23409.

5.6 Randomization

Typically, the most efficient design for a condom functionality study, in terms of couple and condom numbers, is a randomized, crossover study. With the crossover study design, study subjects are first

given a set of one condom type to use and then return for a set of the other condom type. The protocol should contain a provision for the randomization scheme designating the sequence, e.g. test condoms first and control condoms second or the other way around.

5.7 Allocation concealment and study masking

To the degree possible, product assignment should be masked from study couples, investigators and data analysts after randomization. The study protocol should describe such masking procedures.

5.8 Use of additional lubricant

Lubricant is normally applied to the test and control condom before packaging. However, some test condoms can require users to apply lubricant. In addition, some users can desire additional lubricant.

The study protocol should address whether additional lubricants can be used with the condoms. The protocol should also specify the type and amount of lubricant available for the user. In addition, the case report forms should capture the use of any lubricants, including the type, amount (to the degrees possible) and location applied.

If the lubricant supplied to the study subjects is different from the lubricant applied prior to packaging, then material screening and testing should be conducted to ensure that any additional lubrication does not have any deleterious effects on either the test or control condoms.

NOTE It might be possible to adapt the testing principles of ASTM D7661 for testing the effects of lubricant on condom properties. ASTM D7661 is a test method to assess the compatibility of unlubricated natural rubber latex male condoms with lubricants.

5.9 Instructions and interactions with study couples

Detailed verbal and written instructions, as well as training, on correct condom use should be documented in the protocol and provided to all study participants.

The training and instructions should carefully address the following:

- a) purpose of study and duration of participation;
- b) clear definitions (with illustrations) of key outcome measures (clinical slippage, clinical breakage and safety);
- c) correct condom use;
- d) time frames for using test and control condoms and recording data;
- e) careful review of the “Individual Condom Use” case report form (CRF) and any other CRFs with instructions on how to properly complete them;
- f) telephone and/or other contact information for study coordinator.

In addition, couples should be instructed to contact research staff immediately if they encounter any problems related to the study. Serious adverse reactions should be reported immediately to the study sponsor and the ethics committee.

5.10 Interviews and data collection

5.10.1 Schedule for interviews and condom distribution

The protocol should have a schedule for CRF distribution.

- a) enrolment interview:
 - questionnaire, enrolment, provide condoms and condom use CRFs.For crossover studies, only the first set of condoms should be distributed at the enrolment interview.
- b) mid-study interview, if crossover design:
 - collect individual condom use CRFs from first set and any unused condoms;
 - provide second set of condoms and individual condom use CRFs.
- c) exit interview:
 - collect individual condom use CRFs from the second set and any unused condoms.

For the purpose of this document, CRFs can be paper-based or electronic. Examples of CRFs are provided in the annexes.

5.10.2 Enrolment interview

The protocol should have provisions for an initial interview for obtaining informed consent from both partners, ensuring that inclusion/exclusion criteria are met and to provide study participants with instructions and initial set of condoms.

There should be an Enrolment CRF to collect the following data on the study participant:

- a) age, condom experience, reproductive history and other demographic information;
- b) risk of STI and pregnancy;
- c) method of contraception used during study;
- d) ability to comply with the study protocol (e.g. length of relationship, frequency of intercourse, problems with erection/ejaculation, use of genital jewellery, etc.);
- e) other, e.g. data on circumcision, genital mutilation (modification), as appropriate.

If desired, the protocol might contain provisions for a penis measurement kit. The kit should allow for a consistent means of measuring erect penis length and circumference. This information should be provided to the investigator at a later visit.

[Annex D](#) is a sample form for initial entry into the study (study entry CRF).

5.10.3 Individual condom use CRF

Per the randomization scheme, the protocol should contain a provision for providing the designated number of condoms (test or control) to the participating couples together with appropriate CRFs. The Condom Use CRF should provide for entries to collect the following event information for each condom.

Condom breakage and slippage studies are heavily reliant on user reports and memory recall. To minimize the impact of recall bias, a limited number of condoms (e.g. five) of each type should be used over no more than a 2-week to 3-week time period. Study instructions should direct participating

couples to complete the CRF for individual condom use as soon as possible after each sex act. The time frame should be no more than a few hours, not days, to reduce memory recall errors.

- a) package opened (yes/no);
- b) type of intercourse: vaginal, oral, anal;
- c) condom broken prior to intercourse while opening package or putting condom on;
- d) condom broken during intercourse;
- e) condom broken during withdrawal;
- f) location of break, if any;
- g) condom slipped completely off penis during intercourse;
- h) condom slipped completely off penis during withdrawal;
- i) semen leakage from condom, noticed by user;
- j) use of additional lubricant;
- k) safety-related events: burning, itching, irritation, etc.

The study sponsor can collect information on user acceptability.

Study couples should be instructed to examine the condom carefully after the penis is withdrawn but before the condom is removed from the penis. Breaks which are known to have occurred during removal of condom from penis should not be included in the calculation of clinical failure.

[Annex F](#) includes several CRFs from earlier studies that were used for recording the events of a single condom use. Study sponsors are encouraged to adopt one of these sample Condom Use CRFs for their own use.

5.10.4 Mid-study CRF, crossover trial

If a crossover trial is conducted, then the protocol should have a provision for a mid-study interview at which the initial set of individual condom use CRFs is collected from the participating couples and a second set of condoms and CRFs is given to the couple. A mid-study interview CRF could collect additional data on

- a) problems with condom use,
- b) acceptability,
- c) safety, and
- d) other.

[Annex E](#) is a sample mid-study CRF that might be adopted.

5.10.5 Compiling data from CRFs

The protocol should also explain how data will be collected from the Condom Use CRFs from each study arm and compiled on the following:

- a) number of packages opened;
- b) number of condoms used for vaginal intercourse;
- c) number of condoms broken prior to intercourse while opening package or putting condom on;

- d) number of condoms broken during intercourse or withdrawal (clinical breakage);
- e) number of condoms that slipped completely off penis during intercourse or withdrawal (clinical slippage);
- f) number of condoms used for oral sex or anal sex.

5.11 Data integrity

5.11.1 General

A condom breakage and slippage study is dependent upon user self-reports of clinical failures from each coital act. Considering the limits of human memory, the timeframe for recording these data by the user should be as immediate to each coital act as possible. Therefore, to ensure accuracy, reliability and traceability of all data, the study protocol should thoroughly address selection of study couples, instructions for study participants, timeframes for reporting events, design of coital diaries and other case report forms (CRFs), study schedules, as well as distribution of study condoms (test and control) and overall collection of study data.

5.11.2 Interactive voice response systems (IVRS)

If using the telephone to collect daily coital information, sponsors are advised to implement interactive voice response systems (IVRS) that pose pre-recorded questions and enabling participants to respond using the keypad of their telephone. The advantage of this approach is that resources are “time stamped” and can potentially uncover participant fraud.

5.11.3 Mail-in and web-based data reporting

Because a condom breakage and slippage study relies on patient-reported outcomes, it is possible to conduct such a study and allow study couples to submit their reports by mail or Internet.

This does not substitute for face-to-face interviews at study entry and completion. In this situation, procedures should be in place to minimize the potential for participant fraud.

The following are examples of procedures that should allow a third-party audit to validate the study and its underlying data.

- a) Clinical investigators should keep the envelopes when couples return information by mail. If no CRFs will be returned via mail, couples should be asked to send a personal identifier by mail (e.g. name of pet, oldest sibling, name of high school, etc.) which can be used to verify the participants' identity in future contacts. The investigator should keep the envelope and information in the letter for verification of enrolment.
- b) To verify the couple's participation, the informed consent document could request that, in addition to the collection of electronic data or data collected via the postal service, the clinical investigator might contact the study couple via telephone when either the sponsor monitors or the government agency conducts inspections of the clinical investigator's facility. Or, if the couple cannot be reached by telephone that day, a letter will be sent with a post card (pre-addressed to the investigator) that will verify the couple is a participant in the study. The telephone contact might ask for personal information that could verify the individual's participation. The post card should have the postal stamp and date of the couple's post office which could be compared with the couple's known address and the post card could require additional information that would help verify the couple's participation.

Study sponsors also need to be mindful of computerized systems used to create, modify, maintain, archive or transmit clinical data (e.g. e-Patient Reported Outcomes). The primary focus should be on computerized systems used at clinical sites to collect data in order to ensure the quality and integrity of electronic data, but same principles might be applied to computerized systems belonging to contract research organizations, data management centres and sponsors. Regulatory bodies that review such

studies and other persons using the data from computerized systems should have confidence that the data are no less reliable than data in paper form.

5.11.4 Web-based data collection systems and additional suggestions

Given the self-report nature of these condom studies, use of web-based data collection systems can be possible in certain regions with selected user populations. Conducting studies by web, email and postal communication can assist recruitment and facilitate the execution of the study. Loss to follow-up can be reduced since couples do not have to visit the study centre.

When conducting such studies, manufacturers and/or organizations responsible for the study should take steps to ensure the following:

- a) that full details of the proposed study are provided to potential couples to enable them to make an informed assessment of the risks prior to entering the study;
- b) that contact details are provided to allow potential couples to ask questions prior to entering the study;
- c) that written informed consent is obtained from both partners prior to enrolment and the provision of any samples;
- d) that adequate questions are asked to identify any participants that do not meet the inclusion criteria that should be excluded on the basis of one or more of the exclusion criteria or for whom the trial can pose a special risk;
- e) that adequate advice is provided to the couples about what actions to take if the condom should tear, break or slip off or if there is any adverse reaction to the condom. The couples should be provided with relevant contact details including telephone numbers and addresses to facilitate seeking advice from the study centre or other nominated sources of help and information;
- f) that adequate records are kept about the provision and return of samples and documentation including any questionnaires, record sheets, report forms, etc.

The manufacture or organizations concerned should take steps to verify that participants are genuine, meet the inclusion criteria and do not conflict with any of the exclusion criteria. Verification of addresses using appropriate databases and follow-up interviews, in person or by telephone, with a randomly selected proportion of the study population are ways of achieving this.

5.12 Control of distribution chain

The principles of ISO 13485 should be followed in the production of both test and control condoms. In general, all condoms used in a clinical trial, both test and control condoms, should have been produced, tested and foiled to production specifications for manufacturing, testing, lubrication and packaging. Documentation to this effect should be as complete as possible. At a minimum, each condom foil/individual container should be labelled with the batch number and the expiry date. The individual foil/container, the consumer package or both should protect the condoms from environmental damage as is appropriate for the product for at least the duration of the clinical trial period.

The manufacturer should take steps to ensure that the batch records are fully completed and approved by QC/QA prior to dispatch along with the necessary shipping documents to the clinical study centre. The manufacturer should also ensure that an adequate number of samples are retained for any follow-up investigations that can become necessary.

The clinical study centre should take steps to complete their receiving and inventory records and make checks on the sample packs to ensure they are free from any damage during transit.

The clinical study centre should store the samples according to the manufacturer's directions until they are ready to be given out to the study participants. The clinical study centre should follow the procedures for coding and any further labelling required as defined in the study protocol. The centre

should also ensure that, for traceability purposes, the individual foil/container with the manufacturer's batch number and expiry date remain visible to the user.

5.13 Analysis of returned condoms

It can be useful to analyse condoms that broke or slipped during the clinical trial. This kind of evaluation is a significant element in a general quality systems approach to device manufacture. It can also help explain some of the study findings when the trial is complete. [Annex H](#) contains a sample protocol for treating returned condoms. [Annex H](#) also includes diagrams illustrating a number of examples of condom break types.

WARNING — The study described in [Annex H](#) requires direct contact with contaminated devices. It is strongly recommended that operators should wear gloves during the operation to reduce risks of any infectious accidents.

5.14 Other methodological details

The study protocol can be needed to address the following concerns:

- a) language of instructions and case report forms and availability for review;
- b) regional differences in condom usage that could affect applicability of results to worldwide;
- c) social, cultural and economic setting of the study population, particularly literacy, access to medical care, community and family values, etc.;
- d) it is possible that naive condom users experience higher clinical failure rates until they become familiar with the products^[8]; a brief, pre-planned condom use run-in period can be appropriate prior to enrolling study couples;
- e) if the study calls for run-in periods (learning period before use of test condom “counts” towards clinical failure rates) or wash-out periods (time period between use of test and control condoms), the protocol should provide the methodological details for these, including how such data will be managed;
- f) Monitoring Clinical Studies: Some regulatory bodies require clinical function studies for the approval of certain condoms. When this is the case, the study protocol or standard operating procedures should include a comprehensive monitoring plan
 - 1) to ensure the data are in compliance with Good Clinical Practice (GCP), Institutional Review Board (IRB) policies, as well as local regulatory regulations,
 - 2) to standardize the clinical data monitoring, and
 - 3) to ensure the validity, accuracy and integrity of the data.

A suitably qualified external trial monitor should be appointed to monitor the trial throughout its course from initiation to study close-out.

5.15 Statistical analysis plan

5.15.1 General

The statistical analysis plan (SAP) should be developed and written with details on how the clinical study data will be analysed and interpreted. The SAP should be written and finalized prior to study implementation.

The following subclauses give examples of the components that should be considered when writing the SAP.

The design, analysis and interpretation of condom breakage and slippage studies should not be done without the help of an experienced statistician, familiar with non-inferiority testing and methods for making valid statistical inferences.

5.15.2 Primary study hypothesis

The primary end point in a clinical validation study of a new condom is total clinical failure. The primary research objective is to determine whether the expected total clinical failure rate of a new test condom is comparable with the expected total clinical failure rate of a legally marketed NRL male condom when used during vaginal intercourse. The clinical research question should be rephrased in statistical terms as a non-inferiority hypothesis. (For example, for synthetic condoms, the expected difference in total clinical failure rates, between the test and control condoms, is less than the amount, δ , specified in ISO 23409.)

Therefore, the statistical plan should present a precise statement of the prospective study hypothesis in statistical terms, i.e. null (H_0) and alternative (H_A) hypotheses. For a condom non-inferiority study, this would typically look something like:

- H_0 : Expected test condom total clinical failure rate – expected control condom total clinical failure rate $\geq \delta$;
- H_A : Expected test condom total clinical failure rate – expected control condom total clinical failure rate $< \delta$.

If the null hypothesis of inferiority is rejected using an appropriate test statistic, then the alternate hypothesis of non-inferiority is accepted.

The failure rates observed in the clinical study based on a small number of condom uses per couple are only estimates of the expected rates that would be observed if an infinite number of condoms had been used. It is not sufficient for the observed difference in failure rates to be $< \delta$ to conclude non-inferiority. Rather, the study results should provide a high degree of confidence that the difference in expected rates is $< \delta$.

5.15.3 Secondary study hypotheses

Based on the results from pilot studies and other factors (e.g. design or market feedback), it can be reasonable to test whether the new condom performs better than the control condom. As part of the SAP, study sponsors might prospectively specify a secondary hypothesis for superiority. If the study results support a conclusion of non-inferiority, then the secondary hypothesis might be tested.

Study sponsors should also develop secondary hypotheses to address the study end points of clinical slippage and breakage as individual variables, again comparing the test condom with the control condom. These should be done as non-inferiority analyses using a δ for each individual variable that is a little smaller than that specified in the normative standard for total failure rate. For example, ISO 23409 specifies a δ of 2,5 % for testing the total failure rates. Based on currently available data, it would be appropriate to use a δ of 2,0 % to test breakage rates and slippage rates individually.

5.15.4 Study design

Typically, the most efficient study design for a condom functionality study is a two-period crossover trial.

The study should enrol a sufficient number of couples so a minimum of 200 couples complete the study. Because of attrition, it is prudent to enrol extra participants to ensure sufficient numbers at end of study. For example, if one expects a 15 % loss to follow-up, then the study should enrol at least 235 couples.

The study should ensure a minimum 1 000 uses of each condom type.

The study population and investigational sites should be heterogeneous and represent the target population. Therefore, the study should include multiple investigational sites and the number of study couples enrolled should be evenly distributed across sites.

Couples should be asked to use a specified number of condoms of each type during consecutive acts of vaginal intercourse in the first condom use period, followed by the same number of uses of the alternate condom type in a second and subsequent use period. Instances of condom use for anal intercourse should be excluded from the primary analysis. The number of each type of condom used (e.g. five if there are 200 participating couples) should be chosen to ensure that at least 1 000 uses of each condom type are available for the primary analysis.

Because some couples might not use their allocated number of condoms, it might be useful to provide all participating couples with extra condoms to help ensure the target number of 1 000 condom uses. Alternatively, the study design could specify a larger number of participating couples.

5.15.5 Statistical analysis

It is recommended that the statistical analysis plan be specified prior to implementation of the study. This includes plans for primary analyses, as well as all key subgroup and secondary analyses.

Primary analyses should be performed using all available condom use data. Data from all study sites should be pooled unless statistically significant and clinically meaningful interactions between centre and condom type are detected. If such interactions are observed, comparisons should be made separately for each centre. Any missing data (e.g. due to non-use or data errors) should be ignored in the primary analyses unless patterns are identified which suggest condom type comparisons can be biased. If such patterns are observed, efforts should be made to identify their causes and effects on analyses.

Analyses should be based on a confidence interval approach to non-inferiority testing^[3] based on the null and alternative hypotheses specified in [5.15.2](#).

The outcomes of each condom use by a particular couple are expected to be more alike than the outcomes of condom use by another couple. This will result in correlated data that should be accounted for in the statistical analysis. One approach would be to use generalized estimating equations (GEE) with an identity link function and an independent working correlation structure^[5]. This method is described in further detail for condom studies in Reference [\[8\]](#).

The proportion of test and control condoms experiencing clinical failure will be calculated. The difference in proportions, and an upper one-sided 95 % confidence limit for the difference, will be reported. An upper limit that is less than δ will be interpreted as statistical evidence that the test condom is non-inferior to the control condom with respect to clinical failure.

An upper one-sided 97,5 % confidence limit for the difference that is less than 0 % could be further interpreted as statistical evidence that the test condom is superior to the control condom.

Study power is the probability of concluding non-inferiority. In addition to the number of enrolled couples and condom uses, the power of the study will depend on the degree of correlation and the true clinical breakage and slippage rates. Although these quantities are unknown, sample size calculations can typically be made assuming a correlation of no more than 0,2. Also, to be conservative, one should assume failure rates corresponding to the upper range of expected rates in the target population (e.g. 3 %). This need for an estimate of expected failure rates underscores the importance of pilot studies.

NOTE [Annex A](#) provides an example formula for the power calculation.

5.15.6 Additional statistical comments and concerns

Low total clinical failure proportions (<0,5 %) in the control arm can make implementing a functionality study challenging; careful choice of the study population to minimize this possibility is essential.

Strongly consider a pilot study if there is no objective data on the anticipated clinical failure rates of the test condom in the study population.

5.16 Clinical study results: Review and interpretation

5.16.1 General

When the clinical validation study and statistical analysis are completed, it is important to critically evaluate the results to determine whether the test condom performs acceptably well in comparison with the control condom. Principles for such an evaluation include careful consideration of the control condom characteristics, characteristics of the couples participating in the study, reliability of self-reporting and the rates for slippage and breakage.

5.16.2 Total clinical failure rates for control condom

The total clinical failure rates during actual use should be in the range of 0,5 % to 4,0 % for condoms made from natural rubber latex. If the total clinical failure rates for the control condom fall outside of this range, then a rationale should be provided to justify the validity of the trial. One should carefully investigate the design and conduct of the study to determine if there are any unusual factors that could have contributed to the unusually high or low rates (e.g. study population factors, study bias, breaches in data integrity, participant fraud, etc.).

5.16.3 Non-inferiority

The primary hypothesis for the clinical validation study is that the performance of the test condom is not inferior to that of a selected control condom with respect to total clinical failure.

The study should be sufficiently documented to allow an evaluator to independently reproduce the statistical results.

If the upper one-sided 95 % confidence limit for the difference in the total clinical failure rates (test minus control) is less than δ , then this can be interpreted as statistical evidence that the test condom is non-inferior to the standard control condom. One can then conclude that the test condom is comparable in performance with the control condom used in the study.

If the upper bound on the confidence interval around the difference in rates exceeds δ , then the evaluator should systematically explore the underlying reasons. One reason can be that the test condom is inferior to the control condom. However, other factors, including the user population and methodological problems, might explain such study findings.

5.16.4 Superiority

If the upper one-sided 97,5 % confidence limit of the difference in total clinical failure rates is less than 0 %, this might be interpreted as statistical evidence that the test condom is superior to the NRL control condom with respect to total clinical failure.

5.16.5 Safety (adverse events)

Any reports of adverse events or complaints should be thoroughly investigated to determine whether the test condom poses an unacceptable safety risk in comparison with the control condom. Individual complaints of irritation, burning, itching, bleeding, etc., should be followed up with clinical evaluation. The study report should fully address these events. For each event, provide information on severity, duration and relatedness and how each event was clinically resolved.

5.16.6 What happens if one is unable to conclude non-inferiority?

If the study data do not allow one to conclude that the total clinical failure rate of the test condom is less than δ higher than the corresponding control condom rate, then one cannot make a statistical conclusion of non-inferiority.

Upon request, an evaluator could critically review the study design and data to determine whether the test condom might still be considered suitable for marketing. Under this circumstance (no statistically-based conclusion of non-inferiority), a regulatory body can consider other factors, such as:

- a) the individual clinical slippage and breakage rate differences between condom types;

NOTE Under these circumstances, there can be a role for a follow-up study and/or a meta-analysis of this and previous studies.

- b) beneficial qualities of the test condom that can increase condom use;
- c) labelling mitigation (e.g. to be used only by persons who are latex sensitive, place test results in labelling, etc.).

Annex A (informative)

Formula for power calculation

Denote the true (unknown) test and control condom failure probabilities as F_T and F_C , respectively, and let $\Delta = F_T - F_C$. Also, define the correlation between condom uses by ρ and assume that each couple uses Z condoms of each type. Then the number of couples required to have $P \times 100$ % power (e.g. $P = 0,9$ corresponds to 90 % power) to conclude non-inferiority is given by [Formula \(A.1\)](#):

$$N = \{G(P) + 1,645\}^2 \times \text{Var}(\Delta) / \{(\delta - \Delta)^2\} \tag{A.1}$$

where

$$\text{Var}(\Delta) = F_T(1 - F_T) \times \{1 + (Z - 1)\rho\} / Z + F_C(1 - F_C) \times \{1 + (Z - 1)\rho\} / Z - 2\rho \times \{F_T(1 - F_T) \times F_C(1 - F_C)\}^{1/2}$$

is a measure of the variance of the difference in failure rates and where $G(\cdot)$ is the inverse cumulative normal probability function.

For example, if $F_T = F_C = 0,03$, $\rho = 0,2$ and each couple uses $Z = 5$ condoms per type, then $\text{Var}(\Delta) = 0,0093$. In order to have 90 % power, $G(0,9) = 1,282$ and $N = 128$ couples should be enrolled for $\delta = 0,025$.

If one does not perform a crossover trial, then [Formula \(A.1\)](#) provides the number of couples that should use each type (i.e. there should be $2N$ total enrolled couples) where $\text{Var}(\Delta) = F_T(1 - F_T) \times \{1 + (Z - 1)\rho\} / Z + F_C(1 - F_C) \times \{1 + (Z - 1)\rho\} / Z$.

For the above example (alternate to the crossover design), $N = 287$ couples using five condoms of one type plus 287 different couples using five condoms of the other type to achieve 90 % power, i.e. 574 total couples, 287 in each arm.

Annex B (informative)

Pilot clinical investigation (sample outline)

B.1 General

The following is an outline for conducting a clinical feasibility study of a new condom to obtain a preliminary estimate of slippage and breakage during use. As with the pivotal breakage and slippage study, such feasibility studies should also comply with ISO 14155.

B.2 Study design

- $n = 35$ couples, typically need to recruit 40 to 45 couples to finish with 35.
- Each couple to use three condoms of the test product and natural rubber latex control.
- Double-masked randomized crossover design.
- Each couple should be given two consecutive weeks to complete each evaluation (one type of condom).
- Each couple should complete a diary of each coital event when one of the samples is used, including the sexual position used.
- At the end of the use of each product, the couple should be interviewed either by telephone, Internet or by clinic visit, the latter being preferred.
- Clinical end points should be condom slippage and breakage during use, as well as any genito-urinary adverse events.
- Socio-economic data should be collected and recorded (e.g. age, race, level of education).
- Financial payment to panellists should be made at the end of the study.

B.3 Inclusion criteria

- Couples not at risk of pregnancy (using alternate contraception).
- No known sexually transmitted infections, including HIV/AIDS.
- Couples should be experienced condom users, minimum 10 male condoms used in the last 12 months.
- Subjects between 18 to 45 years of age.
- Monogamous heterosexual couples who agree to practice vaginal sex only during the study.

B.4 Exclusion criteria

- Couples who work for the clinical testing laboratory or who are relatives of staff of the clinical test laboratory or a sponsor of the study.
- Participants with known allergy to natural rubber latex or material(s) of test condom.

- Participants with known sensitivity to the residual chemicals used in the manufacture of natural rubber latex condoms or the test condom materials.
- Couples where one knowingly has a sexually transmitted infection.

B.5 Informed consent

Participating study subjects should be given appropriate informed consent. See [5.4](#).

B.6 Adverse event report form

A draft template is attached (see [Annex G](#)).

B.7 Statistical analysis

- To be determined, 95 % confidence interval.
- Confounding factors to be noted are couples who cluster break on either the test or control product and if more than 20 % of the recruited fail to complete the study.

Annex D (informative)

CRF — Study entry (sample)

CALIFORNIA FAMILY HEALTH COUNCIL - INITIAL HISTORY

ID -

Date

<p>1. What is your birthdate (month/day/year) ? <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p>2. What is the highest level of education you have completed?</p> <p>1 <input type="checkbox"/> 8th grade or less 2 <input type="checkbox"/> Some high school 3 <input type="checkbox"/> High school diploma or equivalent (GED) 4 <input type="checkbox"/> Some college 5 <input type="checkbox"/> BA (Bachelor's degree) 6 <input type="checkbox"/> Post-graduate degree</p> <p>3. What is your race/ethnicity?</p> <p>1 <input type="checkbox"/> White 2 <input type="checkbox"/> Hispanic/Latino 3 <input type="checkbox"/> African American 4 <input type="checkbox"/> Asian or Pacific Islander 5 <input type="checkbox"/> Native American 6 <input type="checkbox"/> More than one, Describe: _____</p> <p>4. Including your study partner, how many sexual partners have you had in the last 6 months? _____</p> <p>5. Are you allergic to latex or polyurethane?</p> <p>0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p> <p>6. In the last year have you used injection drug needles?</p> <p>0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p> <p>7. In your lifetime, how many times have you had each of the following?</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Never</th> <th style="text-align: center;">1-2x</th> <th style="text-align: center;">3+x</th> <th></th> </tr> </thead> <tbody> <tr> <td>Trichomonas</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">2 <input type="checkbox"/></td> <td style="text-align: center;">→</td> </tr> <tr> <td>Chlamydia</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">2 <input type="checkbox"/></td> <td style="text-align: center;">→</td> </tr> <tr> <td>Gonorrhea</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">2 <input type="checkbox"/></td> <td style="text-align: center;">→</td> </tr> <tr> <td>Syphilis</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">2 <input type="checkbox"/></td> <td style="text-align: center;">→</td> </tr> <tr> <td>Genital herpes</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">2 <input type="checkbox"/></td> <td style="text-align: center;">→</td> </tr> </tbody> </table> <p>8. Have you ever been diagnosed with any of the following?</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Never</th> <th style="text-align: center;">Yes</th> <th></th> </tr> </thead> <tbody> <tr> <td>HIV</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">→</td> </tr> <tr> <td>Hepatitis</td> <td style="text-align: center;">0 <input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td style="text-align: center;">→ If yes, What type? _____</td> </tr> <tr> <td>HPV/Genital warts (condylomata) 0</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">1 <input type="checkbox"/></td> <td></td> </tr> </tbody> </table>		Never	1-2x	3+x		Trichomonas	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	→	Chlamydia	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	→	Gonorrhea	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	→	Syphilis	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	→	Genital herpes	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	→		Never	Yes		HIV	0 <input type="checkbox"/>	1 <input type="checkbox"/>	→	Hepatitis	0 <input type="checkbox"/>	1 <input type="checkbox"/>	→ If yes, What type? _____	HPV/Genital warts (condylomata) 0	<input type="checkbox"/>	1 <input type="checkbox"/>		<p>MALE ONLY:</p> <p>9. On average, how often do you and your current partner have vaginal intercourse?</p> <p>1 <input type="checkbox"/> Less than 4 times per month 3 <input type="checkbox"/> 7 - 10 times per month 2 <input type="checkbox"/> 4 - 6 times per month 4 <input type="checkbox"/> More than 10 times per month</p> <p>10. In the last year have you had sex with a man?</p> <p>0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p> <p>FEMALE ONLY:</p> <p>11. How would you describe your living arrangement?</p> <p>1 <input type="checkbox"/> Married to study partner 2 <input type="checkbox"/> Not married to but living with study partner 3 <input type="checkbox"/> Not married to or living with study partner</p> <p>12. When did you begin a sexual relationship with your current partner? (Month/Year) _____ / _____</p> <p>13. What is your current method of birth control?</p> <p>1 <input type="checkbox"/> Birth control pills 2 <input type="checkbox"/> Depo Provera shot 3 <input type="checkbox"/> Contraceptive patch 4 <input type="checkbox"/> IUD 5 <input type="checkbox"/> Sterilization (tubal ligation or vasectomy) 6 <input type="checkbox"/> Other, Describe: _____</p>
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RA Init-#: _____ - _____ Date: ____ / ____ / ____ Edited by: _____ Date: ____ / ____ / ____ Batch-Record #: _____ - _____

INITIAL HISTORY

ID -

Date

1. What is your birthdate (month/day/year) ?

2. What is your employment status? (Check one only.)

- | | |
|--------------------------------------|---------------------------------------|
| 1 <input type="checkbox"/> Full-time | 4 <input type="checkbox"/> Unemployed |
| 2 <input type="checkbox"/> Part-time | 5 <input type="checkbox"/> Homemaker |
| 3 <input type="checkbox"/> Student | 6 <input type="checkbox"/> Disabled |

3. What is the highest level of education you have completed?

- | | |
|--|---|
| 1 <input type="checkbox"/> 8th grade or less | 4 <input type="checkbox"/> Some college |
| 2 <input type="checkbox"/> Some high school | 5 <input type="checkbox"/> BA (Bachelor's degree) |
| 3 <input type="checkbox"/> High school diploma or equivalent (GED) | 6 <input type="checkbox"/> Post-graduate degree |

4. What is your race/ethnicity?

- | | |
|--|--|
| 1 <input type="checkbox"/> White | 5 <input type="checkbox"/> Native American |
| 2 <input type="checkbox"/> Hispanic/Latino | 6 <input type="checkbox"/> More than one |
| 3 <input type="checkbox"/> African American | <i>Please describe:</i> _____ |
| 4 <input type="checkbox"/> Asian or Pacific Islander | _____ |

5. What is your total combined household annual income?

- | | |
|--|---|
| 1 <input type="checkbox"/> \$0 - 5,000 | 5 <input type="checkbox"/> \$30,001 - 40,000 |
| 2 <input type="checkbox"/> \$5,001 - 10,000 | 6 <input type="checkbox"/> \$40,001 - 50,000 |
| 3 <input type="checkbox"/> \$10,001 - 20,000 | 7 <input type="checkbox"/> \$50,001 - 60,000 |
| 4 <input type="checkbox"/> \$20,001 - 30,000 | 8 <input type="checkbox"/> More than \$60,000 |

6. Do you smoke? (cigarettes, pipes, cigars)

- 0 No, Never
 1 No, I quit
 2 Yes

7. How often do you drink alcoholic beverages?

- 0 Never
 1 Less than monthly
 2 Monthly \Rightarrow Number of drinks/beers per month _____
 3 Weekly \Rightarrow Number of drinks/beers per week _____
 4 Daily \Rightarrow Number of drinks/beers per day _____

8. How many sexual partners have you had during your lifetime? _____

9. Including your study partner, how many sexual partners have you had in the last 6 months? _____

10. How many times have you been pregnant (female) or responsible for a pregnancy (male) ? _____

11. How many times have you used male condoms with all partners, including your current partner?

- 0 Never \Rightarrow If Never, skip to Q15
 1 1 - 2 times
 2 3 - 10 times
 3 11 - 50 times
 4 51 or more times

12. When did you last use a male condom with any partner, including your current partner?

- 1 Less than 6 months ago
 2 Between 6 months and 1 year ago
 3 Between 1 and 5 years ago
 4 More than 5 years ago

13. How many times have you experienced a male condom break during vaginal intercourse with other partners (not including your current partner)?

- N Not applicable (no other partners/ no condom use w/other partners)
 0 0 (Never)
 1 1 - 2 times
 2 3 - 5 times
 3 6 - 10 times
 4 More than 10 times

14. Have you ever used a polyurethane (non-latex) condom?

- 0 No \Rightarrow If No, skip to Q#15
 1 Yes
 2 Unsure \Rightarrow If Unsure, skip to Q#15

14a. If Yes, what was your impression of the condom?

- 0 Negative
 1 Positive
 2 Neutral

15. Are you allergic to latex or polyurethane, or have you had problems when you used latex or polyurethane products?

- 0 No
 1 Yes, Describe: _____

16. Do you have any genital piercings?

- 0 No 1 Yes, Describe: _____

17. Are you currently participating in any other clinical studies?

- 0 No
 1 Yes, Describe: _____

Annex E (informative)

CRF — Mid-study (sample)

ACCEPTABILITY SURVEY		MALE FEMALE																																																																																																																																
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COMPLETE THIS FORM SEPARATELY FROM YOUR PARTNER. PLEASE RECORD YOUR HONEST OPINIONS.																																																																																																																																		
<p>1. Using the 1 to 7 scale, please circle the number that best describes your experience with the study condom you just used:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 10%; text-align: center;">1</th> <th style="width: 10%; text-align: center;">2</th> <th style="width: 10%; text-align: center;">3</th> <th style="width: 10%; text-align: center;">4</th> <th style="width: 10%; text-align: center;">5</th> <th style="width: 10%; text-align: center;">6</th> <th style="width: 10%; text-align: center;">7</th> </tr> </thead> <tbody> <tr> <td>a. The study condom was easy to put on.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>b. The study condom had a pleasant smell or no smell.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>c. The study condom made little or no noise.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>d. The study condom felt soft.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>e. The study condom was comfortable.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>f. The study condom increased sensitivity and stimulation.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>g. The study condom transmitted body heat.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>h. I liked the <u>amount</u> of lubricant on the <u>outside</u> of the study condom.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>i. I liked the <u>amount</u> of lubricant on the <u>inside</u> of the study condom.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>j. I liked the way the lubricant <u>felt</u>.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>k. The lubricant on the study condom <u>lasted</u> long enough.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>l. The study condom was not messy.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>m. My overall sexual experience was good while using the study condom.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>n. I liked the study condom as much as other condoms I have used.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>o. MALES ONLY: The study condom fit well.</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </tbody> </table> <p>2. Would you purchase a condom like the study condom you just used? 0 <input type="checkbox"/> No: skip to Q4 1 <input type="checkbox"/> Maybe 2 <input type="checkbox"/> Yes</p> <p>3. Would you be willing to pay more for this condom than condoms you've used in the past? Based on a box of 6 condoms, how much more would you pay? 0 <input type="checkbox"/> No more 1 <input type="checkbox"/> Up to 50¢ more 2 <input type="checkbox"/> Up to \$1.00 more 3 <input type="checkbox"/> Up to \$2.00 more</p> <p>4. What was the <u>ONE</u> thing you liked best about the study condom? _____ _ _ </p> <p>5. What was the <u>ONE</u> thing you liked least about the study condom? _____ _ _ </p> <p>6. How highly would you recommend the study condom you just used? 1 <input type="checkbox"/> Highly recommend 2 <input type="checkbox"/> Recommend 3 <input type="checkbox"/> Recommend with reservations 4 <input type="checkbox"/> Not recommend</p>				1	2	3	4	5	6	7	a. The study condom was easy to put on.								b. The study condom had a pleasant smell or no smell.								c. The study condom made little or no noise.								d. The study condom felt soft.								e. The study condom was comfortable.								f. The study condom increased sensitivity and stimulation.								g. The study condom transmitted body heat.								h. I liked the <u>amount</u> of lubricant on the <u>outside</u> of the study condom.								i. I liked the <u>amount</u> of lubricant on the <u>inside</u> of the study condom.								j. I liked the way the lubricant <u>felt</u> .								k. The lubricant on the study condom <u>lasted</u> long enough.								l. The study condom was not messy.								m. My overall sexual experience was good while using the study condom.								n. I liked the study condom as much as other condoms I have used.								o. MALES ONLY: The study condom fit well.							
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NOTE CFHC granted permission for its CRFs to be used in condom function studies.

Annex F (informative)

CRF — Individual condom use (sample)

The following are three separate paper-based examples of CRFs used to capture the key event information after condom use, i.e. slippage events and breakage events. It is critical that study participants enter this information into the CRF as soon after each coital act as practicable. They should not wait several days or a week and then try to recall events from multiple coital acts over that period.

It is not unusual for study sponsors to attempt to collect additional use information from the study participants. Keep in mind that the CRF for an individual condom use should be clear and easy to follow. Any attempt to collect non-primary outcome data should be weighed against the potential for making the CRF more confusing.

California Family Health Council (CFHC), Family Health International (FHI) and Sagami-France provided the three CRF examples and all three granted permissions for these CRFs to be reproduced or adapted by any interested study sponsor.

11. Did you experience any of the following while using this condom? (Check Yes or No for every item.)

	No	Yes
We started intercourse without the condom	<input type="checkbox"/>	<input type="checkbox"/>
The condom slipped <u>along the shaft</u> of the penis <u>during</u> intercourse (see Diagram D)	<input type="checkbox"/>	<input type="checkbox"/>
The condom bunched up during intercourse (see Diagram C)	<input type="checkbox"/>	<input type="checkbox"/>
The condom stretched out of shape (see Diagram D)	<input type="checkbox"/>	<input type="checkbox"/>
The condom fit was too tight	<input type="checkbox"/>	<input type="checkbox"/>
Not enough lubrication/too dry during intercourse	<input type="checkbox"/>	<input type="checkbox"/>
The condom caught the male's pubic hair	<input type="checkbox"/>	<input type="checkbox"/>
The condom made noise during intercourse	<input type="checkbox"/>	<input type="checkbox"/>
The male lost his erection during intercourse	<input type="checkbox"/>	<input type="checkbox"/>
We used the condom for anal intercourse	<input type="checkbox"/>	<input type="checkbox"/>

12. Did ejaculation occur while wearing this study condom?

Yes

No. Ejaculated without a study condom

No. Ejaculation did not occur with this act of intercourse

13. Did you do the following during withdrawal? (Check Yes or No for each.)

	Yes	No
I held on to the ring of condom	<input type="checkbox"/>	<input type="checkbox"/>
Withdraw while penis was still erect	<input type="checkbox"/>	<input type="checkbox"/>

14. Do you think that semen may have leaked from the condom?

No

Yes, When the condom broke

Yes, When the condom slipped off the penis

Yes, When the condom slipped along the penis

Yes, At another time, describe.

Yes, I don't know when

15. How long did vaginal intercourse last while wearing this condom? _____ minutes

16. Please rate the following. (Check one box per line.)

	MALE ANSWERS				FEMALE ANSWERS			
	Excellent	Good	Fair	Poor	Excellent	Good	Fair	Poor
Stimulation during intercourse	<input type="checkbox"/>							
Condom lubricant	<input type="checkbox"/>							
Overall lubrication during intercourse	<input type="checkbox"/>							

17. Did you experience any discomfort that started while using this condom?

No: Skip to Q#18 Yes

17a. What ONE discomfort best describes the type? (Check ONLY most severe)

MALE ANSWERS	FEMALE ANSWERS
<input type="checkbox"/> Burning	<input type="checkbox"/> Burning
<input type="checkbox"/> Irritation	<input type="checkbox"/> Irritation
<input type="checkbox"/> Constriction	<input type="checkbox"/> Diminished sensitivity
<input type="checkbox"/> Dryness	<input type="checkbox"/> Dryness
<input type="checkbox"/> Other, describe: _____	<input type="checkbox"/> Other, describe: _____
<input type="checkbox"/> Genital itching	<input type="checkbox"/> Genital itching
<input type="checkbox"/> Genital rash	<input type="checkbox"/> Genital rash
<input type="checkbox"/> Diminished sensitivity	<input type="checkbox"/> Dryness

17b. How severe was the discomfort?

MALE ANSWERS	FEMALE ANSWERS
<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe

17c. How long did the discomfort last?

MALE ANSWERS	FEMALE ANSWERS
<input type="checkbox"/> Only while wearing the condom	<input type="checkbox"/> Only while in contact with the condom
<input type="checkbox"/> 1 - 10 minutes after the condom was removed	<input type="checkbox"/> 1 - 10 minutes after the condom was removed
<input type="checkbox"/> More than 10 minutes but less than 1 hour after	<input type="checkbox"/> More than 10 minutes but less than 1 hour after
<input type="checkbox"/> One hour or more after condom was removed	<input type="checkbox"/> One hour or more after condom was removed

17d. Do you know what might have caused the discomfort?

No

Yes, describe: _____

17e. Did you do anything medically to treat the discomfort?

No

Yes, describe: _____

18. Who filled out this Condom Report? Man Woman Both partners together

19. Additional comments:

EXAMPLE 2 Three-page CRF for individual condom use, submitted by FHI.

BSCUQ1

FAMILY HEALTH INTERNATIONAL
 A Comparative Assessment of Synthetic Condom and Natural Rubber Latex Condom:
 Failure Modes
CONDOM USE QUESTIONNAIRE

1. Centre number: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	2. Study number: <input style="width: 20px; height: 20px;" type="text"/> 9 <input style="width: 20px; height: 20px;" type="text"/> 6 <input style="width: 20px; height: 20px;" type="text"/> 0 <input style="width: 20px; height: 20px;" type="text"/> 9	3. Couple number: <input style="width: 20px; height: 20px;" type="text"/>
4. Condom type: <input style="width: 20px; height: 20px;" type="text"/> 1 = Natural Rubber Latex 2 = Synthetic		
CONDOM USE DATA Please complete one of these questionnaires for each condom package opened. For the following items, please circle the response which best answers the question in some cases, you might be instructed to select more than one answer. Please notice that some questions instruct you to "skip to" other questions based on your response. In these cases, do not answer any of the questions between the original one and the one to which you were instructed to skip.		
5. Condom number. Circle one. Do not use more than 4 condoms for intercourse. <div style="display: flex; justify-content: space-around; width: 100%;"> 1 2 3 4 5 6 </div> 6. Date condom opened <div style="display: flex; justify-content: space-around; width: 100%;"> <div style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> Month</div> <div style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> Day</div> <div style="text-align: center;"><input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> Year</div> </div> 7. Was the condom stored in a cool, dry place? Circle one, 0 = No 1 = Yes	8. Did the condom break or tear <u>before putting it on the penis</u> ? Circle one. 0 = No 1 = Yes, while opening the package 2 = Yes, after opening, at the condom tip 3 = Yes, after opening, along the condom shaft 4 = Yes, after opening, at the condom opening 5 = Yes, after opening, at other location	
<u>If the condom broke before putting it on, do not answer any more questions.</u> If the condom did not break and you tried to put it on, answer the following questions.		
9. Did you use the provided lubricant <u>before putting on the condom</u> ? <i>Circle all that apply.</i> 0 = No 1 = Yes, on the inside of the condom 2 = Yes, on the outside of the condom 3 = Yes, inside the vagina 4 = Yes, inside the anus 10. Did you use another type of lubricant before putting on the condom? <i>Circle all that apply.</i> 0 = No 1 = Yes, on the inside of the condom 2 = Yes, on the outside of the condom 3 = Yes, inside the vagina 4 = Yes, inside the anus <i>If yes, specify lubricant type _____</i> 11. Was there any genital contact before putting on the condom? <i>Circle one.</i> 0 = No 1 = Yes, but no vaginal or anal penetration 2 = Yes, with vaginal or anal penetration	12. Who tried to put on the condom? <i>Circle one.</i> 1 = female 2 = male 3 = both 13. Was the penis erect before putting on or trying to put on the condom? <i>Circle one.</i> 0 = No 1 = Yes 14. Was the condom unrolled before putting on or trying to put the condom on the penis? <i>Circle one.</i> 0 = No 1 = Yes 15. Were you able to put the condom on the penis? <i>Circle one.</i> 0 = No 1 = Yes, the condom went on easily 2 = Yes, but the condom did not go easily. 16. Did the condom break <u>while putting it on or trying to put it on</u> , but before intercourse? <i>Circle one.</i> 0 = No 1 = Yes, at the condom tip 2 = Yes, along the condom shaft 3 = Yes, at the condom opening 4 = Yes, other	
<u>IF THE CONDOM BROKE WHILE PUTTING IT ON OR TRYING TO PUT IT ON, SKIP TO QUESTION 33.</u>		

FAMILY HEALTH INTERNATIONAL
 A Company Assessment of a Plastic Condom and a Latex Condom:
 Failure Modes
CONDOM USE QUESTIONNAIRE

STUDY IDENTIFICATION

Centre number: Study number: Couple number:

Condom type:

1 = Latex
 2 = Plastic

Answer the following questions ONLY IF the condom was used for vaginal intercourse.
 If the condom was NOT used for vaginal intercourse, skip to Question 33.

<p>28. Did the male partner ejaculate while wearing the condom? <i>Circle one.</i></p> <p>0 = No 2 = Yes, during vaginal sex</p> <p>1 = Yes, during anal sex 3 = Yes, during other sex</p> <p>29. Did the condom ring slip from the base of the penis during vaginal intercourse? <i>Circle one.</i></p> <p>0 = No 1 = Yes, it slipped completely off the penis 2 = Yes, it slipped but not completely off the penis 3 = don't know not sure</p>	<p>30. Was the penis still hard when it was pulled out of the vagina? <i>Circle one.</i></p> <p>0 = No 1 = Yes</p> <p>31. Did you hold on to the base of the condom during withdrawal from the vagina? <i>Circle one.</i></p> <p>0 = No 1 = Yes</p> <p>32. Did the condom ring slip from the base of the penis during withdrawal from the vagina? <i>Circle one.</i></p> <p>0 = No 1 = Yes, it slipped completely off the penis 2 = Yes, it slipped but not completely off the penis 3 = don't know not sure</p>
---	---

33. Did one or both partners drink alcohol within one hour of using the condom?

0 = No
 1 = Yes, only male partner
 2 = Yes, only female partner
 3 = Yes, both partner

34. Did either of you experience genital burning, irritations, rash, itching, pain or other medical event that began while using this condom? *Circle one.*

0 = No
 1 = Yes, only male partner
 2 = Yes, only female partner
 3 = Yes, both partner

} If 1, 2, or 3, complete *Medical Event form*

Initials of person reviewing form: _____ Date form reviewed: _____

EXAMPLE 3 One-page CRF for individual condom use, submitted by Sagami-France.

Ref number: _____

SHORT QUESTIONNAIRE

1. Description ("A" or "B") 2002 1945 1988 Please use this area for notes

If any of the condoms used, please indicate the type:

Type of intercourse: (Please mark the main reason, eg. oral intercourse by vaginal, please mark 1 for oral and 2 for vaginal, if any other type, please tick below)

Oral	Vaginal	Anal
------	---------	------

Does it require lubrication during intercourse (eg. you do not use any other lubricant)?

1 How long was the condom when using this condom? (min)

No length	0-5 min	5-10 min	10-20 min	20-30 min	Longer
No length	0-5 min	5-10 min	10-20 min	20-30 min	Longer

2 How long was the insertion when using this condom? (min)

0-5 min	5-10 min	10-20 min	20-30 min	Longer
0-5 min	5-10 min	10-20 min	20-30 min	Longer

3 Were you ready when using the condom if woman is dry this can lead to breakage? (Please tick below)

YES	NO
YES	NO

4 Did condom break? (Please tick below)

YES	NO
-----	----

If YES, go to question 5, if NO, go to 8

5 Where did it break? (Please tick below)

Test roll	Leak	Rip
-----------	------	-----

6 When did it break? (Please tick below)

Taking out of package	During foreplay	During intercourse	Neutral after intercourse
-----------------------	-----------------	--------------------	---------------------------

7 Which type of break? (Please tick below)

Small hole	Split	Tear
------------	-------	------

8 Could you explain why the condom broke?

9 Did the condom slip? (Please tick below)

YES	NO
-----	----

If YES, go to question 10, if NO, go to 14

10 When did the condom slip? (Please tick below)

During foreplay	On the withdrawal
-----------------	-------------------

11 How far on the penis did the condom slip? (Please tick below)

Right off the penis	1/3 down the shaft of the penis	1/2 down the shaft of the penis	3/4 down the shaft of the penis
---------------------	---------------------------------	---------------------------------	---------------------------------

12 Did you hold the condom when withdrawing? (Please tick below)

YES	NO
-----	----

13 Did any semen enter the vagina or urethra? (Please tick below)

YES	NO
-----	----

14 It is normal to have various sensations on and around the penis and vagina, especially when using gelic lubricating but did you feel something different (and you do not feel with your hand on your own)? (Please tick below, multiple answers are accepted)

Nothing different	Itch	Reduced sensation	Painful
Nothing different	Itch	Reduced sensation	Painful

15 What did you most notice about this condom? (Please tick below, multiple answers are accepted)

Soft to touch	Natural feeling	Thinness	On the loss	Comfort	Sensation
Soft to touch	Natural feeling	Thinness	On the loss	Comfort	Sensation

Annex G (informative)

CRF — Adverse event (sample)

Time Began: _____ Time Ended: _____ Interview Length: _____

Interviewer's Initials: _____ Date: _____

• **If an individual reaches you directly:** "What is your name? _____ (Name). I would like to ask you some questions about your experience with the test products. It will take around 5 minutes. Is this a good time for you to discuss it now?" (If not, reschedule day _____ time _____ - is there a number where I may reach you? _____)

• **If an individual left you a message:** "May I speak to _____ (Name)? This is _____ from _____. You are participating in a study with the Group. You had called and left a message about a reaction to one of our test products. I would like to ask you some questions about your experience with the test products. It will take around 5 minutes. Is this a good time for you to discuss it now?" (If not, reschedule day _____ time _____ - is there a number where I may reach you? _____)

1. "What is the product that you were using when you experienced your reaction?"

2. "Would you describe what happened?" (Circle symptoms from no. 3 as they are mentioned.)

3. "Would you say that your _____ (symptom) was mild, moderate or severe?"	Subject's Assessment		
	Mild	Moderate	Severe
Itching			
Burning/stinging			
Redness			
Bumps			
Other: _____			
Other: _____			

4. "How soon after you put the product on did you first experience this reaction?"

5. "How long did your reaction last?" _____

6. "Have you seen a doctor?" _____ yes _____ no (skip to 10)

7. "May we contact your doctor?" _____ yes _____ no (skip to 10)

8. "What is your doctor's name?" _____

9. "What is your doctor's telephone number?" (_____) _____ - _____

10. "Have you experienced similar reactions with similar products?" _____ yes _____ no

"Which products?"

Example interviewer response:

"I recommend that you stop using the product if you have not already done so and do not use any additional test products we gave you. If you wish to see a physician and have not already done so, and your physician determines that your reaction is product-related, please provide us with a copy of your doctor's note with his name and office number so that we may review it for reimbursement. Call me back if you have any problems. Thank you for your time and patience."

Annex H (informative)

Protocol for evaluation of returned used condoms

H.1 General

The following is a suggested protocol for in-house evaluation of condoms returned by study subjects after a tear or break during use. [Figure H.2](#) and [Figure H.3](#) give detailed step-by-step procedures.

H.2 Disinfection of returned used condoms

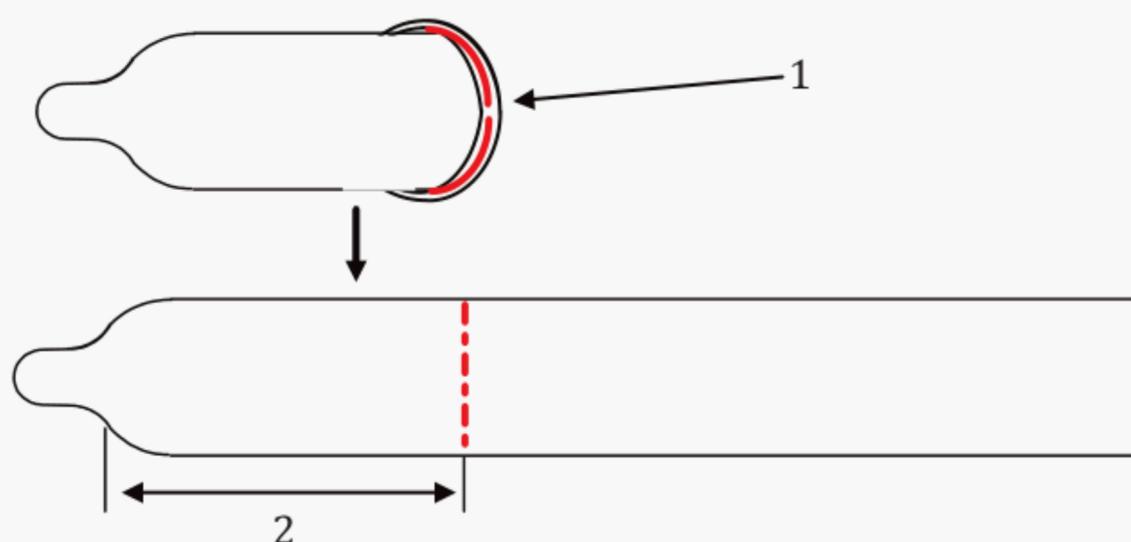
WARNING — This study requires direct contact with condoms that might be contaminated with infectious microbes. To reduce the risk of an infectious accident, it is strongly recommended that the operator wear surgical or exam gloves, safety glasses and a laboratory coat whenever handling the used condom.

H.2.1 Remove the returned used condom (“the sample”) from its plastic shipping bag.

H.2.2 Examine the sample and record observations, if any.

H.2.3 If the sample is not fully unrolled, mark its unrolled part within oil-based marker. If the sample is wet and not possible to mark, then photograph it. Then, unroll the sample to the rim (see Note).

NOTE In [Figure H.1](#), the mark illustrates the length of the sample unrolled onto the user’s penis. If the length is extremely short, the user might not have unrolled the condom to the base of the penis before use. In that case, the risk of slippage might increase.



Key

- 1 marking
- 2 length of the sample unrolled onto the penis

Figure H.1 — Marking the returned condom

H.2.4 Prepare a disinfection solution (see [Figure H.2](#)).

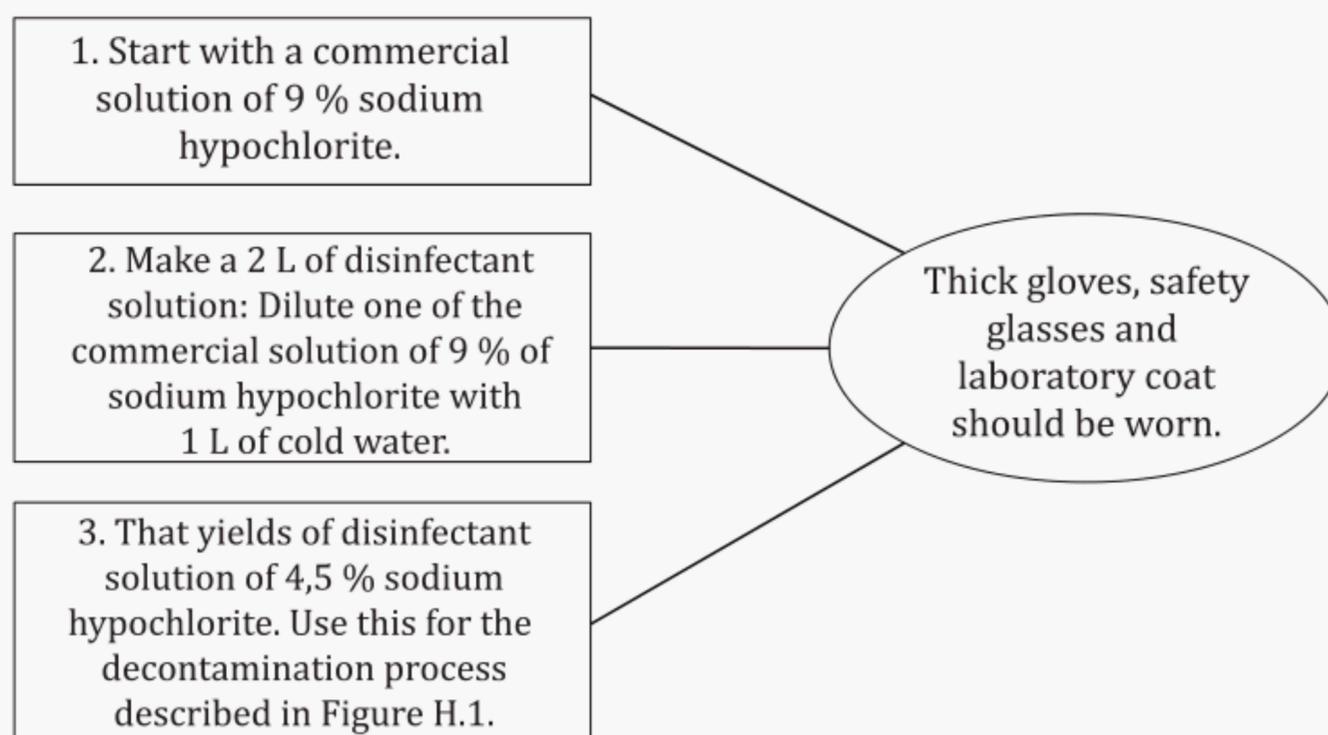


Figure H.2 — Preparation of the disinfectant solution (4,5 % sodium hypochlorite)

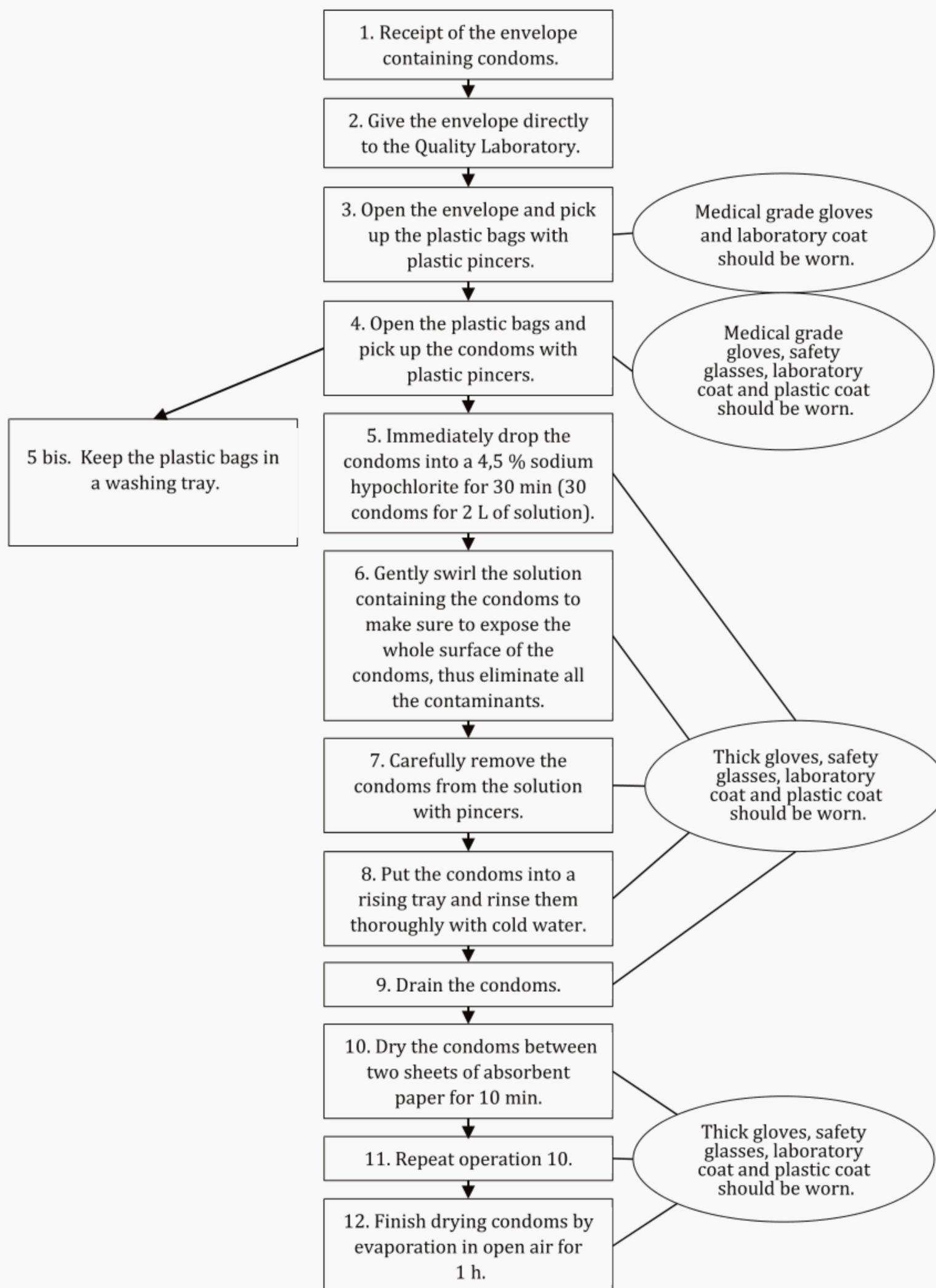
Instructions:

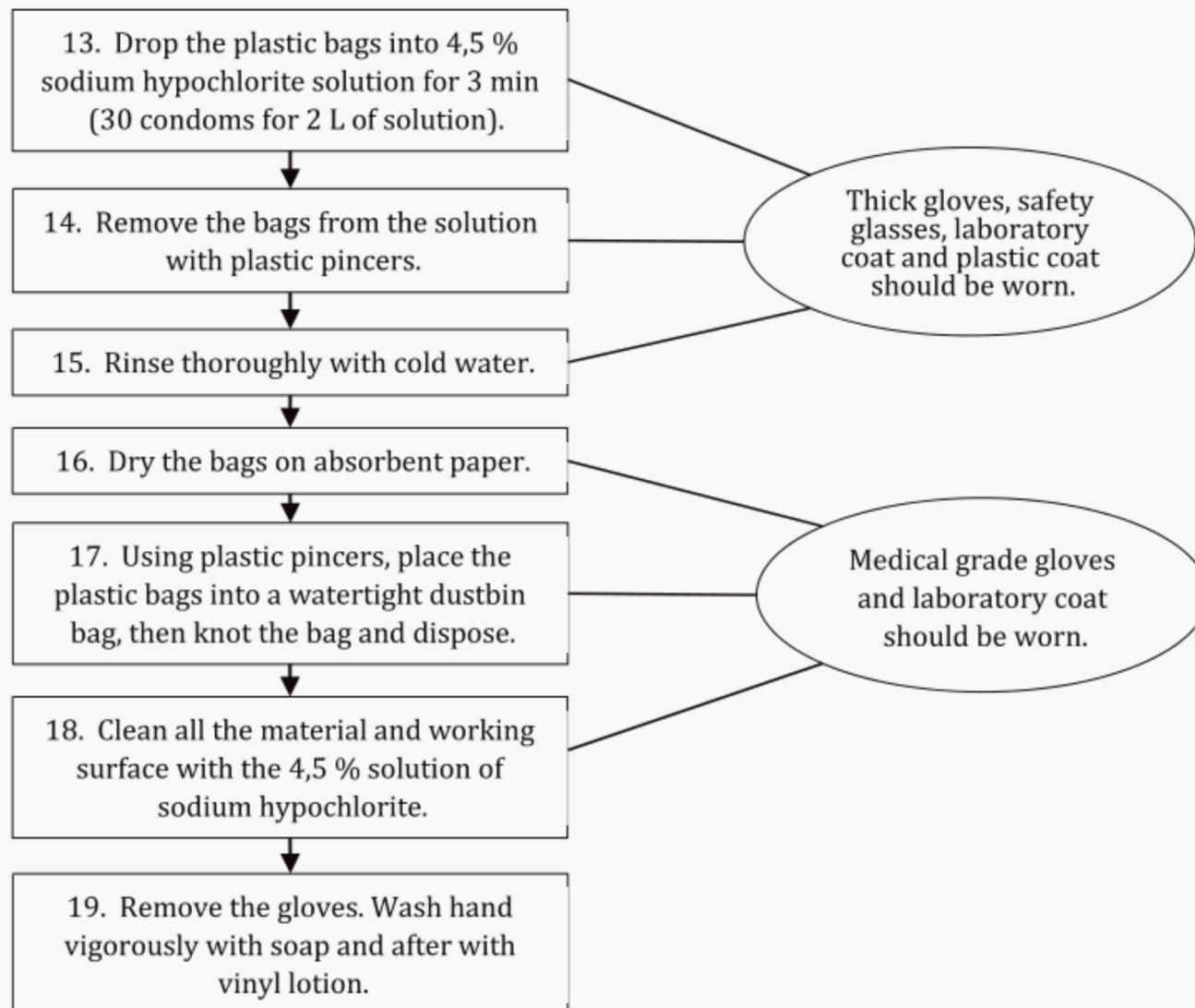
- a) The commercial solution can be stored for 6 months, keeping away from the heat and direct light.
- b) The dilutes 4,5 % solution, if free from protein, can be stored for 1 week at room temperature.
- c) Properly disposed of diluted solution after its use to disinfect a condom sample.

Make freshly prepared diluted solution for the next set of used condoms.

H.2.5 Following the step-wise procedures given in [Figure H.3](#), prepare the condom for evaluation.

NOTE There are alternate methods for disinfecting the condom samples. To disinfect by boiling, about 15 min might be required. For chemical disinfection, be sure to use a chemical agent that does not adversely affect the physical properties of the condoms. In any case, continue to use exam or surgical gloves.





NOTE Steps 1 and 2: Administrative Department. Step 3 to 19: Quality Laboratory.

Figure H.3 — Returned condoms, procedure for condom decontamination

H.2.6 Rinse the disinfected sample with water and apply a suitable powder, e.g. silica, to absorb moisture.

H.3 Observation

H.3.1 Place the sample on a mandrel of similar diameter.

NOTE If a condom manufacturer does the observations, then it is best done using one of the condom mandrels from the dipping process.

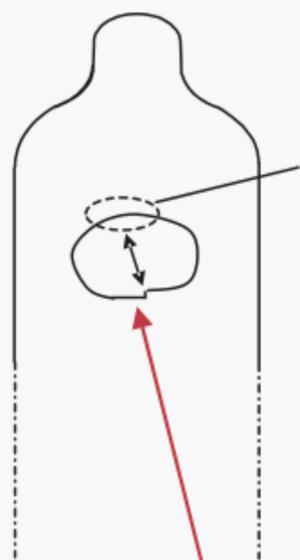
H.3.2 Make sketches or take photos of the sample especially the torn parts.

H.3.3 Record observations (see Note).

NOTE It is helpful to observe the torn parts and find the starting point of the tear.

H.3.3.1 Examples of observations, how to find the starting point.

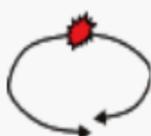
In the image below,  and  indicate the starting point of the tear. The red arrow indicates a gap.



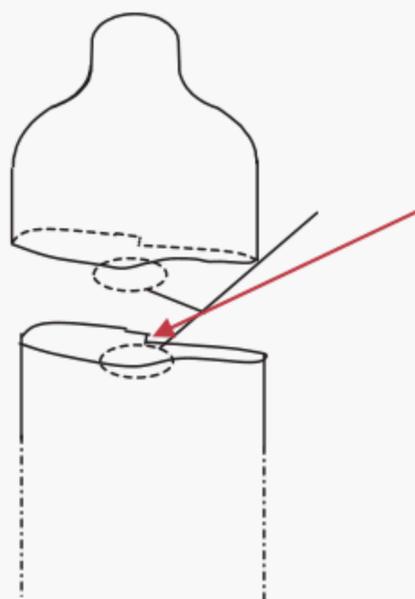
Circular tear

The starting point of the circular tear is often determined at the

diagonal line , in the highlighted area.

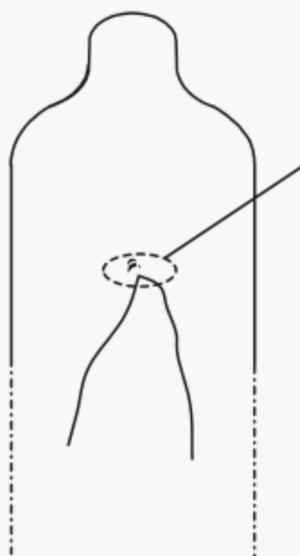
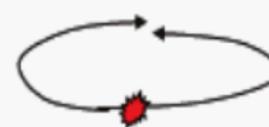


If a gap is observed on the circular tear portion, the starting point of the tear is often determined at the opposite side of the gap.



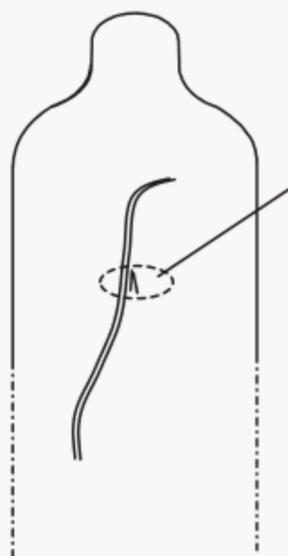
Split tear

The starting point of the tear is often determined at the opposite side (to that of a circular tear) in the highlighted area.



V shape tear

The starting point is often found at the close end of V.

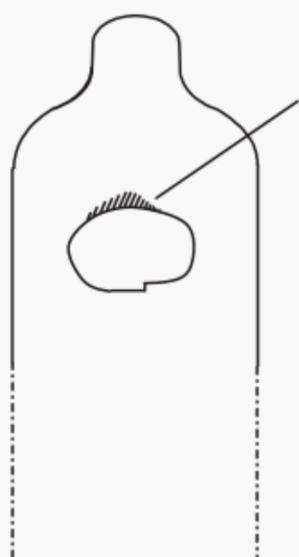


Crack tear

The starting point is often found at the part where condition of the film is not normal.



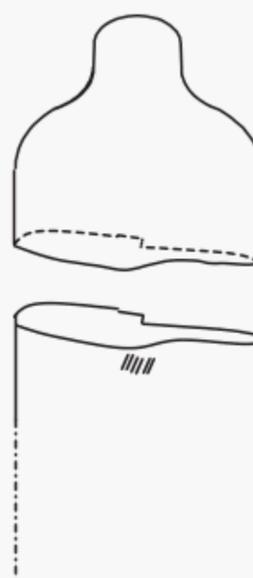
H.3.3.2 Examples of the starting point/tear:



Transformation

The film elongated and tore due to the load exceeding the strength limit. Possible reasons are as follows.

- a) The strength of the film itself was poor.
- b) The condom did not fit the penis well and adhered too tightly to the side of the penis.
- c) Air was present between the condom and the penis and the condom burst during the sexual intercourse.
- d) When taking out the condom, film was damaged by the pouch.



Scratch

The hard item scratches the film. During the sexual intercourse, the condom was torn at the scratched part. Possible reasons are as follows.

- a) The condom is already scratched during the production process.
- b) The user scratches the condom with her/his nails or rings.

H.4 Tensile measurements

After making the visual observations described above, the Quality Laboratory should conduct tensile testing of the sample to determine whether it has acceptable strength. Using a test specimen taken from the sample, either ring or dumbbell, the Quality Laboratory should follow appropriate standards or published procedures for tensile testing. For example, for dumbbell specimens, you could use the method described in Reference [22]. However, if the country where the sample was used already has a standard for tensile testing of condoms, then typically one would apply that national standard.

WARNING — Some methods for disinfection might adversely affect the physical properties of a condom and lead to unexpectedly poor results from tensile testing. Consider this when developing your in-house protocol.

H.5 Records

Record the following items:

- a) sketches and/or photos of the sample;
- b) any observations reported by the study couple;
- c) results of tensile testing, if possible;
- d) any conclusions on presumed causes of the tear based on evidence from the above three items, a) to c).

NOTE See Reference [23] for the description of “blunt puncture”.

H.6 Conclusion

It is often difficult to determine the underlying cause of a condom tear based only on a single sample of a torn condom. Therefore, the Quality Laboratory should re-evaluate all torn samples after the study is complete and determine if there are any trends.

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