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Copper-bearing contraceptive intrauterine devices — Requirements and tests

Dispositifs contraceptifs intra-utérins contenant du cuivre — Exigences et essais

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7439:2015), which has been technically revised.

The main changes are as follows:

— the subclause on clinical performance has been revised (see 5.2);

— the movable collar has been added in the subclause on insertion instrument (see 6.3.4);

— requirements for packaging integrity have been added;

— the instructions for health care providers have been amended in accordance with the "Family planning: A global handbook for providers"[4];

— the requirement for stability in situ has been removed since there is no practical way of controlling it.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Although every foreign object in the uterus exhibits a certain contraceptive effect, the method by which copper-bearing contraceptive intrauterine devices (IUDs) function is by the continuous release of copper ions. This interferes with some enzymatic functions, immobilizes sperm cells and inhibits fertilization.

The IUD is a highly effective contraceptive device with a long history of safe use. It can be used for many years, with a prompt return of fertility upon removal.

IUDs do not prevent sexually transmitted infections and condom use is recommended for those at risk.

IUDs containing copper are regarded as single use sterile medical devices implanted in the uterus. These medical devices are inserted and removed by trained and competent health care providers.

Copper-bearing contraceptive intrauterine devices — Requirements and tests

1 Scope

This document specifies requirements and tests for single-use, copper-bearing contraceptive intrauterine devices (IUDs) and their insertion instruments.

It is not applicable to IUDs consisting only of a plastics body or whose primary purpose is to release progestogens or other medicinal products.

NOTE Some aspects of this document can be applicable to medicated intrauterine devices and IUDs not containing copper.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ASTM D 3078, *Standard test method for determination of leaks in flexible packaging by bubble emission*

ASTM F 1929*standard test method for detecting seal leaks in porous medical packaging by dye penetration*

European Pharmacopoeia, (Ph. Eur.)[1)]

3 Terms and definitions

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

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
contraceptive intrauterine device
IUD
copper-bearing device placed in the uterine cavity for the purpose of preventing pregnancy

1) European Directorate for the Quality of Medicines (EDQM) of the Council of Europe.

3.2
insertion instrument
instrument designed to place an IUD in the uterine cavity

3.3
thread
retrieval string attached to an IUD for the purposes of verifying the presence and facilitating the removal by a trained health care provider

Note 1 to entry: The thread is intended to lie in the cervical canal and the vagina when the body of the device is placed correctly in the uterine cavity.

3.4
viscoelastic property
property of an IUD enabling an approximate return to its initial configuration after deformation

3.5
active surface area
surface area of copper in the IUD that is intended to come into contact with uterine fluids

3.6
lot
quantity of IUDs produced during essentially the same time using the same process, same lots of raw materials, common equipment and which are sterilized at the same time

3.7
client
recipient or patient receiving a contraceptive product

3.8
unique device identifier
series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard

Note 1 to entry: The unique identifier might include information on the lot or serial number and be able to be applied anywhere in the world. It allows the unambiguous identification of a specific medical device.

4 Quality verification

Copper bearing IUDs should be manufactured within an integrated quality management system conforming to ISO 13485.

NOTE For most countries and regions, this is a regulatory requirement.

For quality verification purposes, the sample size requirements and acceptance criteria specified in Annex A shall be used. These requirements are based on ISO 2859-1.

The sampling plans have been simplified to take into account typical industry lot sizes, the specific characteristics of IUDs and the nature of the manufacturing processes used to produce them. The sample sizes and acceptance criteria have been selected to provide an acceptable level of consumer protection taking into account the costs of sampling and testing. In addition to verification testing, it is strongly recommended that manufacturers conduct process validation and capability studies, and adopt statistical process control procedures such as the use of control charts to ensure acceptable product quality.

The sampling and acceptance criteria given in Annex A are intended to cover the following situations:

a) continuing production of lots within a stable manufacturing environment;

b) the assessment of isolated lots (e.g. fewer than 5), for example when purchasers wish to conduct confirmatory testing on a limited number of lots, when production is interrupted or intermittent, or for surveillance testing.

In addition, the rules for switching between normal and tightened inspection in ISO 2859-1 have been adopted to provide greater level of consumer protection should the quality of a manufacturing process deteriorate. These rules are applied as follows:

— Normal inspection – the specified sample sizes for normal inspection apply at the start of production. Normal inspection continues to apply unless two nonconforming lots are found in any sequence of 5 or fewer lots tested. If this occurs the number of samples used to assess the conformity for future lots shall be increased to those specified for tightened inspection.

— Tightened inspection – the specified sample sizes for tightened inspection shall apply until a sequence of 5 lots have been accepted. Following the acceptance of 5 sequential lots, the manufacturer may return to the sample sizes for normal inspection.

The switch to reduced inspection has not been adopted for the testing of copper bearing IUDs. Switching to smaller sample sizes is not considered acceptable given the potential for increased consumer risk because of the small sample sizes specified under normal inspection for many of the tests.

5 Intended clinical performance

5.1 General

ISO 14630:2012, Clause 4, shall apply.

ISO 14155 shall apply.

5.2 Clinical performance

5.2.1 General

An IUD shall meet the requirements specified in 5.2.2.to 5.2.9, based on a single-arm clinical study over a period of five years of user wear-time (the minimum intended lifetime of use). The manufacturer shall present these data in a final report of the clinical evaluation before releasing a modified or newly designed IUD onto the market.

NOTE 1 Guidance conducting a clinical study of Cu-IUDs is provided in ISO 11249[2].

The IUD and IUD insertion instrument shall be carefully designed to work together. The clinical study design shall ensure that the insertion instrument used in the study is the same (or very similar) instrument that is marketed either with or for the IUD.

NOTE 2 Clinical validation for minor changes that do not affect the safety and effectiveness of the insertion device might not be necessary. Significant changes that might affect the safety and effectiveness can require a new clinical validation according to ISO 11249.

5.2.2 Study duration

The clinical study duration shall be a minimum of five years, i.e. follow study subjects for a minimum of five years of user wear-time. The duration shall be as long as the proposed duration of use for the IUD labelling.

5.2.3 Study population

The clinical study population shall comprise women who are at risk for pregnancy, i.e. women who have regular unprotected heterosexual vaginal intercourse.

5.2.4 Sample size

5.2.3.1 The study sample size shall be sufficient to yield 10 000 woman-months of use in the first year of the clinical study.

5.2.3.2 The study sample size shall be sufficient to yield 200 women who fully complete a minimum of five years of wear-time. Longer follow-up is required if a longer wear-time is specified.

5.2.3.3 For IUDs with innovative designs, i.e. different shapes, surface features or metallic composition, that have not previously been subjected to a full clinical investigation, the study sample size shall be sufficient to yield 20 000 woman-months of use in the first year of the clinical study.

NOTE 1 This requirement applies to IUDs that are not equivalent to designs that have been subjected to clinical validation.

NOTE 2 The developer of a new IUD is responsible for checking whether the new IUD represents an innovative design that will be subject to the more stringent clinical study design requirements.

5.2.3.4 For IUDs with innovative designs, the study sample size shall be sufficient to yield 400 women who fully complete five years of wear-time.

To account for IUD expulsions and IUD discontinuation in a single-arm, 5-year clinical study, approximately 900 to 1 000 women should be enrolled. A statistical analysis should be undertaken to establish the study sample size and the total number of women to be enrolled.

5.2.5 Contraceptive performance

For the first year of the clinical study, the upper limit of the 95 % confidence level, two-sided confidence interval, for the one-year pregnancy rate computed using life table methods[3] shall be <2 %. A one-year pregnancy rate shall be calculated by the same methodology for each subsequent year of the study and shall meet the same performance target of <2 %.

NOTE For clinical contraceptive studies, pregnancy is the obvious outcome of interest, but there are other ways to analyse and present study results on effectiveness. Besides life-table analysis, some regulatory bodies require alternate analyses, e.g. the Pearl Index. Before initiating a clinical study, a study sponsor is expected to consult with the relevant regulatory body that will review the study results.

5.2.6 Expulsion rate

For the first year of the clinical study, the one-year expulsion rate computed by life table methods shall be <10 %. A one-year expulsion rate shall be calculated by the same methodology for each subsequent year of the study and meet the same performance target of upper limit of <10 %.

5.2.7 Discontinuation rate

For the first year of the clinical study, the one-year discontinuation rate computed by life table methods shall be <35 %. A one-year discontinuation rate shall be calculated by the same methodology for each subsequent year of the study and meet the same performance target of upper limit of <35 %.

5.2.8 Investigation report

A clinical investigation report on the clinical study shall be generated that provides all relevant clinical information from the study. See ISO 14155:2020, 8.4 and Annex D. At a minimum, the report shall present the following results:

a) Rates on the following:

— unintended pregnancies, specifying ectopic pregnancies;

— IUD expulsions;

— IUD removals due to bleeding;

— IUD removals due to pain;

— IUD removals due to pelvic inflammatory disease;

— IUD removals for other medical reasons;

— IUD removals for planned pregnancy;

— IUD removals for other personal reasons;

— IUD removals at the clinical investigator's choice; and

— loss to follow up.

b) Data on the following:

— discontinuation rate, including time between insertion and removal;

— effects on bleeding pattern;

— occurrence of uterine cervical perforation;

— return of fertility after IUD removal;

— outcome in the event of pregnancy with the IUD still in situ;

— other side effects;

— complications during IUD removal, e.g. severe pain, bleeding, broken IUD, broken retrieval thread.

For collecting data on pain, bleeding and other patient reported outcomes (PROs), it is recommended that study sponsors employ a validated PRO instrument, such as an eDiary, to improve ease-of-use, patient compliance and data accuracy. See also ISO 11249.

c) Information on each study subject:

— age, gravidity and parity of each study subject;

— timing of IUD insertion relative to the menstrual cycle, e.g. interval, postpartum, post-abortion;

— frequency of clinical visits during the follow-up period;

— training, experience and skill of the clinical investigator(s).

5.2.9 Labelling

All information and labelling relating to clinical performance data, shall be reviewed annually and updated as necessary. See Clause 12.

6 Design attributes

6.1 General

ISO 14630:2012, Clause 5, shall apply.

Thread and copper shall be integral parts of the IUD.

6.2 Shape

When tested by visual and tactile inspection, an IUD shall have a form fitting the uterine cavity and designed in such a way as to minimize the risk of perforation and subsequent bowel obstruction. The IUD and insertion instruments shall not exhibit sharp edges.

The design of the IUD shall be such that no excessive forces are required for insertion and removal.

6.3 Dimensions

6.3.1 IUD

The maximum length of an IUD shall be ≤38 mm; the maximum width of an IUD shall be ≤34 mm.

When tested as specified in 8.2.1 using the sampling requirements specified in Annex A, the dimensions of the IUD shall be within a tolerance of ±5 % of the manufacture's nominal specifications, and shall not exceed the maximum dimensions specified in this subclause.

6.3.2 Copper components

The nominal active surface area of copper shall be greater than 200 mm^2 and less than 380 mm^2. If copper wire is used, the nominal diameter of the copper wire shall be at least 0,25 mm. The sampling and acceptance requirements specified in Annex A shall apply.

The measured diameters shall be within a tolerance of ±5 % of the specifications given by the manufacturer. The copper surface area of the IUDs shall be within a tolerance of ±10 % of the active surface area specified by the manufacturer.

6.3.3 Thread

When determined in accordance with 8.2.2 using the sampling and acceptance requirements specified in Annex A, the length of the thread shall be not less than 100 mm.

6.3.4 Insertion instrument

The maximum nominal outer width of that part of an insertion instrument intended to come into contact with the cervical canal shall not be greater than 5 mm. The sampling and acceptance requirements specified in Annex A shall apply.

The dimensions shall be consistent with the specifications given by the manufacturer within tolerances of ±5 %.

The insertion tube shall be equipped with a movable collar (flange) to assist locating the IUD in the correct position in the uterus based on the measurement obtained using the uterine sound.

IUD insertion devices, designed for postpartum use only, can require the insertion tube to be greater than 5 mm in diameter. For such products, the 5 mm limit may be exceeded.

NOTE IUD insertion devices designed for postpartum use, of a greater width, can also be used after abortion or miscarriage.

6.4 Tensile force

When tested in accordance with 8.3 using the sampling requirements specified in Annex A, the IUD, including the thread, shall withstand a tensile force as given in Table 1.

Table 1 — Tensile force of IUDs

IUD type	Tensile force N
T-shaped devices	9,5
All other devices	12

6.5 Stability

6.5.1 Shelf-life stability

The IUD shall meet any performance specification given by the manufacturer based on in vitro studies for the complete duration of the declared shelf life.

6.6 Viscoelastic property

When tested in accordance with 8.4 using the sampling requirements specified in Annex A, the residual deformation of any part of the IUD from its original design position shall not exceed 5 mm. For T shaped IUDs the maximum residual deformation usually occurs at the ends of the horizontal arms.

Manufacturers of IUDs that need to be folded or distorted before final placement in the insertion instrument shall verify using the procedure in 8.4 that the IUDs recover as specified in this clause after the maximum period of time in the folded or distorted position stated in the instructions for use (see 12.4).

NOTE Plastics often exhibit viscoelastic behaviour and take time to recover from a deformation. Many plastics will not completely recover their original shape. The viscoelastic (memory) test specified in 8.4 ensures the plastic body has sufficient elastic recovery to function correctly after insertion. All IUDs will be subject to some degree of deformation during insertion, even those that do not require to be deformed for final placement in the insertion instrument.

6.7 Detection by X-ray

All parts of the IUD frame shall be detectable by X-ray examination. If barium sulfate is used in the plastics components as the opaque material, its content shall range from 15 % (mass fraction) to 25 % (mass fraction), when tested in accordance with 8.5.

7 Materials

ISO 14630:2012, Clause 6, shall apply.

The plastics body, including the substance conferring radio-opacity, shall be elastic, biocompatible and non-absorbable.

NOTE Plastics often exhibit viscoelastic behaviour and take time to recover from a deformation. Many plastics will not completely recover their original shape. The elastic (memory) test specified in 8.4 ensures the plastic body has sufficient elastic recovery to function correctly after insertion.

The thread shall be monofilament, biocompatible and non-absorbable.

The purity of the copper shall be at least 99,99 %, which shall be certified.

8 Design evaluation

8.1 General

ISO 14630:2012, 7.1, shall apply.

8.2 Determination of dimensions

8.2.1 For determining the dimensions of the IUD and the outer diameter of the insertion instrument, a method that does not alter the shape, such as a contour analyser or any other instrument providing similar accurate results, shall be used.

8.2.2 For determining the length of the thread, a ruler or any other instrument providing similar accurate results shall be used.

8.2.3 The active surface area shall be computed using the appropriate mathematical formulae for the specific type of IUD.

8.3 Determination of tensile force

8.3.1 Principle

The IUD, including the thread, is stretched until breakage of the IUD or detachment or breakage of the thread occurs. The force required to cause breakage is measured.

8.3.2 Apparatus

8.3.2.1 Tensile testing machine, capable of a substantially constant rate of traverse and in accordance with the following:

a) a force range of 0 N to 100 N;

b) a separation speed of (3,3 ± 0,3) mm/s or (200 ± 20) mm/min;

c) automatic recording of force applied during testing; a chart recorder may be used.

8.3.3 Procedure

The test method shall be designed in such a way that the potentially weakest part of the IUD is exposed to the tensile force.

Condition the IUD at a temperature of (23 ± 2) °C for at least 24 h. Place each IUD into the tensile testing machine according to the IUD manufacturer's instructions. If no instructions are supplied by the manufacturer, place the upper part of the IUD in the upper clamp with one of the threads placed in the lower clamp at a distance of 5 cm from its point of attachment to the IUD. Then apply force to stretch the IUD at a speed of 200 mm/min ± 20 mm/min until either it or the thread breaks or detaches. Measure and record the force at break or detachment.

8.3.4 Test report

The test report shall include the following:

a) identification of the sample;

b) number of IUDs tested;

c) breaking force, in newtons, of each IUD;

d) position of the break;

e) date of testing.

8.4 Test of elastic recovery (memory test)

8.4.1 Principle

The elastic recovery of the IUD is tested by determining the recovery after acute flexion.

8.4.2 Procedure

The IUD shall be conditioned at a temperature of (23 ± 2) °C for at least 24 h before the test.

Depending on whether or not the IUD is to be deformed prior to insertion, the test shall be performed as follows.

a) IUD to be deformed for final placement in the insertion instrument

The arms (or parts) of the IUD shall be folded according to the manufacturer's instructions for placing the IUD into the insertion instrument. They shall remain in this folded position for 5 min to 6 min and then be allowed to recover their shape under zero load for 60 s ± 5 s.

b) IUD not to be deformed for final placement in the insertion instrument

The entire IUD shall be inserted into a tube with an inner diameter of (10 ± 0,1) mm for a period of 5 to 6 min and then removed and allowed to recover its shape under zero load for 60 s ± 5 s.

Determine the positions of the arms or parts of the IUD that were subjected to folding.

8.4.3 Test report

The test report shall include the following:

a) identification of the sample;

b) number of IUDs tested;

c) for each IUD, the displacement of any parts from their original position;

d) date of testing.

8.5 Determination of barium sulfate content and identification of barium and sulfate

8.5.1 Ash content test

Ash content shall be determined using the European Pharmacopoeia sulphated ash method, but omitting the use of sulphuric acid.

8.5.2 Identity test

Identification tests shall be performed in accordance with the monograph for barium sulfate (sulfate and barium) on the ash (from the ash content test) as given in the current European Pharmacopoeia method.

8.6 Pre-clinical evaluation

A risk analysis shall be performed according to ISO 14971.

The biological safety shall be evaluated in accordance with the principles given in ISO 10993-1, according to which an IUD is classified as a medical implant device in contact with tissue/bone, the following supplementary test shall be considered:

— carcinogenic studies;

NOTE In accordance with ISO 10993-1, the evaluation does not necessarily require that toxicological testing has to be carried out. A review of existing published information can be sufficient.

9 Manufacturing and inspection

ISO 14630:2012, Clause 8, shall apply.

10 Sterilization

An IUD shall be supplied sterile. A sterility assurance level of 10^{-6} shall apply.

NOTE Local regulatory requirements can have a different sterility assurance level.

ISO 14630:2012, Clause 9 shall apply.

11 Packaging

ISO 14630:2012, Clause 10 shall apply.

Preferably the primary container shall be made from continuous film materials if the method of sterilization permits impermeable packaging to be used.

A card shall be included in the packaging that has a scale measured in cm to allow the correct placement of the movable collar based on the measurement obtained using the uterine sound.

The integrity of the primary container shall be tested according to ASTM D 3078 using a vacuum level of (18,4 ± 1,7) kPa absolute.

NOTE Expansion of the primary container due to distortion when subjected to vacuum can reduce the sensitivity of the test (see Clause 9.3 of ASTM D 3078) and/or cause the container seals to fail. It can be necessary to constrain the primary container, for example in a frame, to prevent excessive expansion of the container causing failure of the holes to be detected.

If the method of sterilization (e.g. ethylene oxide sterilization) requires permeable packaging material to be used, primary container integrity shall be tested according to ASTM F 1929 using Method B (edge dip method). This method shall only be used for permeable packing materials.

The sample sizes and accept/reject requirements specified in Annex A shall apply.

Verification that the primary container integrity test method is capable of detecting nonconforming units shall be demonstrated by puncturing a sample of 20 primary containers with a new 0,31 mm diameter (30 gauge) hypodermic needle, replacing the needle as necessary if it becomes blunt. To confirm the test procedure is acceptable, the punctures in all 20 primary containers shall be detected.

If any punctured primary containers are not detected, the sensitivity of the test method shall be increased, for example by using a lower absolute pressure for the vacuum, constraining the primary container to limit any expansion when under vacuum or extending the period of the test. Consult ASTM D 3078 for further information.

12 Information to be supplied by the manufacturer

12.1 General

ISO 14630:2012, 11.1 and 11.2 shall apply.

These requirements may be met by the use of appropriate symbols as given in ISO 15223-1.

12.2 Labelling of the primary container

The following information shall be given on the primary container:

a) name or trade name and address of the manufacturer;

b) specific identification marks as required by country and regional regulatory bodies, such as unique device identifier;

c) the word “STERILE”;

d) method of sterilization;

e) lot number;

f) “insert before” date;

g) the words “Sterile Medical Device for single use only”, or equivalent, or the appropriate graphical symbol in accordance with ISO 15223-1;

h) details of any special precautions for storage;

i) any additional information required by local regulatory bodies.

12.3 Labelling of the secondary container

The same information on the primary container (see 12.2) and content of the container shall be given on the secondary container.

12.4 Instructions for the health care providers

The following information shall be included in the instructions for use for the health care provider. These requirements are based on the guidelines for IUD use from the Family planning global handbook for providers published by the World Health Organisation[6]. Health care providers should be advised in the instructions for use to refer to the most recent edition of the global handbook for up-to-date information about these requirements and any national or regional guidelines on IUD use.

a) a statement that the device shall be inserted and removed by a trained health care provider;

b) device trade name;

c) name and address of the manufacturer;

d) description of design, dimensions and compositions of IUD;

e) a statement that the device is a sterile medical contraceptive device for single use only;

f) a statement not to use the device if:

   1) insert before date has passed;

   2) seal of individual packing is broken;

g) a statement directing the health care provider to discuss the contraceptive effectiveness, side effects, health benefits, health risks, and complications associated with copper bearing IUDs with the client;

Contraceptive effectiveness of the IUD shall be calculated by an accepted biostatistical methodology (e.g. life-table analysis or Pearl Index). The statement shall not imply or infer effectiveness beyond the time-point the IUD has been studied to date.

NOTE Different regulatory bodies can require specific or additional analyses.

h) a statement directing the health care provider to discuss suitability for use by most women and common misunderstandings about IUDs;

i) a statement instructing the health care provider to assess the client for suitability to receive a copper bearing IUD by:

   1) undertaking an assessment of medical eligibility criteria to rule out contraindications;

   2) rule out pregnancy using the pregnancy checklist; and,

   3) assessment of STI Risk including HIV;

j) a statement that giving antibiotics routinely is not recommended for clients at low risk of STIs;

k) the maximum time the IUD is allowed to be in the insertion instrument;

l) the maximum time device can be in situ within the uterus;

m) description of possible interactions with medication and other forms of treatment such as therapeutic radiation or diagnostic procedure;

n) description on how to undertake a pelvic examination prior to insertion of the IUD to exclude contra-indications and measure the depth and position of the uterus using a uterine sound;

o) description of how to undertake the sterile procedure to insert the IUD including how to load the IUD in the insertion device. If necessary, include a description of how to position the collar correctly on the tube;

p) date of revision of information provided.

12.5 Information intended for the client after insertion of the IUD

The following information shall be provided by the manufacturer as a reminder of the information that the health care provider should communicate to the client after IUD insertion:

a) a statement on contraceptive effectiveness of the IUD. The statement shall not imply or infer effectiveness beyond the time-point the IUD has been studied to date;

b) a statement that the device does not prevent sexually transmitted infections;

c) information about the design, dimensions and composition of the IUD;

d) the mode of action and possible effects on the menstrual cycle;

   NOTE The mode of action works by causing a chemical change that damages sperm and egg before they can meet.

e) warning of minor side effects including some bleeding or spotting immediately after insertion;

f) warning about the risk of heavy or irregular bleeding, cramps and pain and advice on managing these side effects;

g) description of signs of severe complications requiring immediate medical attention including PID, perforations and miscarriage;

h) the procedure for periodically checking the presence of the IUD;

i) risk of partial and complete expulsion of the IUD;

j) recommended maximum in situ time;

12.6 Written information intended for the client

The information specified in 12.5 shall be provided to the client in writing following insertion of the device. The manufacturer shall include an IUD Reminder Card to be completed by the health care provider with each IUD to facilitate the provision of this information.

The IUD Reminder Card shall include the following information (see Figure 1):

a) client name;

b) type of IUD;

c) insertion date;

d) remove or replace by date;

e) where to go if the user has any problems or questions.

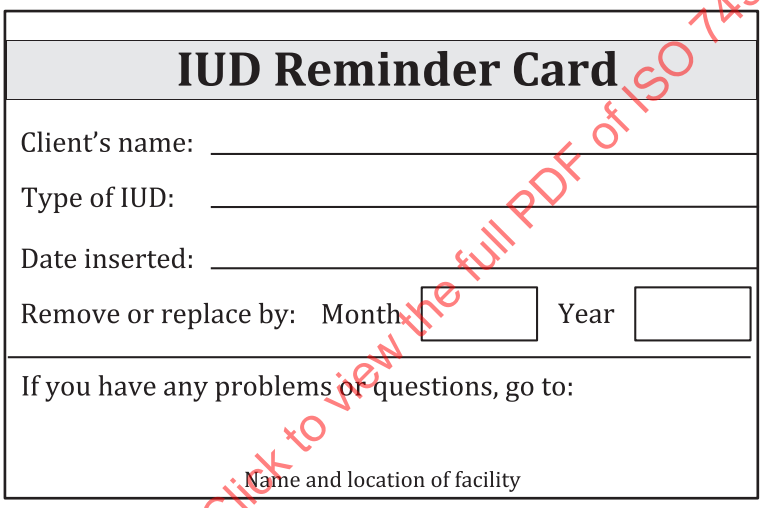

Figure 1 — Example of IUD Reminder Card