TECHNICAL REPORT 7439

Published 1981-10-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Mechanical contraceptives — Intra-uterine devices

Contraceptifs mécaniques — Dispositifs intra-utérins

Technical Report 7439 was drawn up by Technical Committee ISO/TC 157, *Mechanical contraceptives*, and approved by ISO/TC 157 at a meeting in Chicago in May 1978. The main reason which led to the decision to publish this document in the form of a Technical Report and not in the form of an International Standard is the lack of objective means of assessing the product. Also many factors beyond the scope of standardization are important in making the IUD function satisfactory as a contraceptive (for example the patient's confidence and ready acceptance of the device together with the method and skill employed for its introduction).

In the opinion of ISO/TC 157 it is, however, considered useful to issue this Technical Report in an attempt to give the result achieved so far a formal status within ISO while ISO/TC 157 continues its efforts to reach an agreement on an International Standard.

0 Introduction

Intra-uterine devices (IUDs) present certain unique difficulties for standardization. An International Standard normally defines characteristics of a product essential to its proper function. It describes quantitative physical values, the method of measuring them and the tolerances.

In the case of IUDs, the very wide variety of shapes, sizes and other properties allow only a general description of its features. The physical dimensions and characteristics can, therefore, only be standardized to a limited extent.

1 Scope and field of application

This Technical Report describes basic requirements for intra-uterine devices (IUDs), associated insertion instruments, and for packaging, labelling and storage of such devices.

The more important performance criteria have to be assessed by clinical experience and consequently remain outside the scope of this Technical Report.

2 Definitions

2.1 intra-uterine device (IUD) : A device for the purpose of preventing pregnancy.

The device, which may or may not have a tail or thread, is intended to be placed and left entirely in the uterine cavity except for any tail or thread which may extend through the cervical canal into the vagina.

NOTE — There are two types of IUDs, sometimes called "Active IUD" and "Inert IUD", depending on whether or not they are intended to liberate pharmacologically active substances within the uterus.

UDC 615.477.87 **Ref. No. ISO/TR 7439-1981 (E)**

Descriptors : contraceptives, specifications, packages, labelling, storage.

Printed in Switzerland

Price based on 4 pages

2.2 visco-elastic memory : Property of certain IUDs which enables them to return approximately to their initial configuration after deformation.

2.3 insertion instrument : Instrument intended to place an IUD in the uterine cavity.

2.4 tail or thread : Attachment to an IUD for the purpose of verifying the presence of and enabling the removal of the device which is intended to lie in the cervical canal and the vagina when the body of the IUD is placed correctly in the uterine cavity.

3 General requirements for type approval

The manufacturer shall supply to the responsible national authorities detailed specifications and drawings of his product, and whatever information be requested.

3.1 Clinical experience

In general, an IUD shall be designed to permit easy insertion into the uterus, resistance to expulsion from the uterine cavity and easy removal from the uterus.

When inserted according to the manufacturer's instructions, which shall be clearly given (see 6.3), the device shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

Ideally acceptable levels of efficacy and of adverse reactions will have to be established internationally. However, clinical acceptability may vary between countries.

This Technical Report presupposes that the IUD complies with official national clinical regulations or requirements.

3.2 Dimensions of IUD and insertion instrument

The dimensions and tolerances shall be consistent with the currently licensed article.

3.3 Composition of IUD and insertion instrument

The materials of which the IUD, including any tail or thread, and the insertion instrument are made shall be sufficiently resistant to unintended influence by the body fluids and tissues and must be biologically compatible.

3.4 Visco-elastic memory

Those devices which are, by necessity, deformed by the prescribed method of insertion shall have the necessary visco-elastic properties to allow them to take up that form in the uterine cavity which is intended by the manufacturer.

3.5 Visualization by X-rays

The basic material of the whole IUD shall be opaque to X-rays.

3.6 Tail or thread

The tail or thread, if any, must be monofilament.

The tail or thread and its attachment shall be able to withstand a uniform pull of 12 N for at least 10 s.

3.7 Effect of sterilization on entire IUD and insertion instrument materials

The sterilization procedure (for example, ethylene oxide, ionizing radiation) shall not have a significant detrimental effect on the properties of the material. Any sterilization should not form toxic substances or detectable impairments of its physical properties (memory, solidity).

3.8 Sterility

Where a product is distributed as sterile it shall be capable of meeting the requirements of the sterility test methods described in the current *International Pharmacopoeia* (published by WHO).

4 Batch inspection

All tests shall be carried out on the final product prior to distribution for use.

4.1 Dimensions of IUD and insertion instrument

The dimensions of the IUD (including any tail or thread) and its insertion instruments shall be within the tolerances specified by the manufacturer as detailed in 3.2.

4.2 Composition of an entire IUD and its insertion instrument

The material of which an IUD, its tail or thread, and its insertion instrument are made shall comply with the specification submitted for license. When identifying plastic materials, IR-spectrophotometry or Differential Scanning Calorimetry (DSC) or any other appropriate method may be used.

4.3 Test for visco-elastic memory

Place the IUD in the insertion system for the maximum time stated in the manufacturers' instructions for insertion. After release it shall rest for 1 min and then be compared with its original shape. The deviation shall be within the limits stated by the manufacturer. The test temperature shall be 23 ± 2 °C.

4.4 Visualization by X-rays

The quantity and distribution of material opaque to X-rays (for example barium sulphate) shall conform to the specifications submitted for license.

4.5 Breaking strength of any tail or thread

The breaking strength shall be in accordance with the requirements in 3.6. The test temperature shall be 23 ± 2 °C.

5 Sampling

ISO procedure to be used will be added later.

6 Packaging and labelling

6.1 Individual package

The sterile IUD shall be individually packaged with its insertion instrument.

The individual package shall ensure :

a) adequate protection of the contents during normal handling, transit and storage;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions;

c) minimal risk for contamination of the contents during removal from the package;

d) that the package, once opened, cannot easily be resealed.

6.2 Outer container(s)

A convenient number of individual packages (for example 1, 10, 50, etc.) shall be packaged in one or more outer containers which shall be sufficiently robust to protect the contents during transit and storage.

6.3 Labelling

Each individual package and outer container shall carry the following information :

a) brand name of the IUD;

b) IUD size, when appropriate;

c) manufacturer's name and address;

d) batch number;

e) month and year of sterilization;

f) expiration date, if any;

g) storage directives (outer container only);

h) each individual package shall carry the following text :

**"Warning — Sterile unless package is opened or damaged.
Insertion instrument should not be re-used."**

Additionally clear directions for insertion of the IUD shall accompany each package, together with information concerning adverse reactions, contra-indications, precautions and other warnings and information for the consumer, if required by the licensee body.

7 Storage recommendations

Packages should be stored under cool, dry conditions away from light. Extremes of temperature and humidity should be avoided. Packages will remain sterile unless opened or damaged. Poor storage may damage packaging and extremes of temperature can cause plastic to deform or become brittle.