
International Standard



7857/1

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

**Intra-uterine devices —
Part 1 : Determination of breaking force**

Dispositifs intra-utérins — Partie 1 : Détermination de la force à la rupture

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Descriptors : IUD, contraceptive devices, tests, determination, breaking load.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been authorized 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 7857/1 was developed by Technical Committee ISO/TC 157, *Mechanical contraceptives*, and was circulated to the member bodies in October 1982.

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It has been approved by the member bodies of the following countries :

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China	India	South Africa, Rep. of
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France	Poland	

The member bodies of the following countries expressed disapproval of the document on technical grounds :

Australia
USA

Intra-uterine devices — Part 1 : Determination of breaking force

1 Scope and field of application

This part of ISO 7857 specifies a method for the determination of the breaking force of intra-uterine devices (IUDs) with or without a thread, provided that the type of IUD permits the use of the method specified in this part of ISO 7857.

2 References

ISO 291, *Plastics — Standard atmospheres for conditioning and testing*.

ISO 7857/2, *Intra-uterine devices — Part 2 : Recommendations for disinfection*.

3 Principle

Stretching the IUD including the thread where provided, until breakage of the IUD or thread occurs. Measuring of the force required to cause breakage.

4 Apparatus

4.1 Tensile testing machine capable of a substantially constant rate of traverse and complying with the following requirements :

- a) a force range of 0 to 100 N;
- b) a separation speed of $3,3 \pm 0,3$ mm/s (200 ± 20 mm/min);
- c) automatic recording of force applied during test (a chart recorder may be used).

5 Procedure

5.1 Tests shall be made on sterilized IUDs. Multiple packaged IUDs shall be disinfected according to ISO 7857/2 before conditioning.

5.2 Condition the requisite number of IUDs according to ISO 291.

5.3 IUD with thread : Place the IUD in the tensile testing machine according to the manufacturers instructions. If the manufacturer does not supply instructions, place the upper part of the IUD in the upper clamp and place the thread, at a distance of 5 cm from the attachment in the lower clamp. Apply the force and stretch the IUD until it or the thread breaks.

Further samples of the device shall also be tested according to 5.4.

5.4 IUD without thread : Place the IUD in the tensile testing machine according to the manufacturers instructions. If the manufacturer does not supply instructions, place the upper part of the IUD in the upper clamp and the lower part of the IUD in the lower clamp. Apply the force and stretch the IUD until it breaks.

5.5 If the break occurs at either clamp, select a further sample and repeat the test. Measure the force at break, in newtons.

6 Test report

The test report shall include the following particulars.

- a) identification of the sample including whether or not it is provided with a thread;
- b) number of IUDs tested;
- c) force at break, in newtons, of each IUD, determined in accordance with 5.3 and/or 5.4;
- d) position of the break;
- e) date of testing.

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