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 7857/3 was developed by Technical Committee ISO/TC 157, *Mechanical contraceptives*, and was circulated to the member bodies in October 1982.

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

China
Czechoslovakia
Denmark
Egypt, Arab Rep. of
France
India
Korea, Rep. of
Netherlands
Poland
South Africa, Rep. of
Sri Lanka
Sweden
Thailand
USSR

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

Australia
USA

Printed in Switzerland

INTERNATIONAL STANDARD

ISO 7857/3-1983 (E)

Intra-uterine devices — Part 3 : Packaging and labelling

1 Scope and field of application

This part of ISO 7857 specifies requirements for the packaging and labelling of intra-uterine devices (IUDs).

2 Reference

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

3 Packaging

3.1 General requirements

The IUD and insertion instruments shall be either packaged individually or in multiple packages containing up to 100 IUDs and which may also contain an appropriate number of insertion instruments.

The package shall ensure adequate protection of the contents during normal handling, transit and storage.

3.2 Individual package

The IUD shall be individually packaged with its insertion instruments, if required by the national authorities. The contents of the individual package shall be sterile.

The individual package shall ensure

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

b) that when opened, it cannot be easily resealed;

3.3 Multiple package

The contents of the unopened multiple package shall be sterile. The insertion instruments intended for reuse and the IUDs packaged in a multiple package shall be disinfected before use. Recommendations for disinfection are given in ISO 7857/2.

3.4 Outer container(s)

A convenient number of individual or multiple packages shall be packaged in one or more outer containers, which shall be sufficiently robust to protect the contents during transit and storage.

4 Labelling

4.1 Individual package

Each individual package shall be marked with the following information :

a) brand name of the IUD;

b) name and address of the manufacturer;

c) IUD size, if appropriate;

d) batch number;

e) expiration date, if required by national authorities;

f) month and year of sterilization;

4.2 Multiple packages

Each multiple package shall be marked with the following information :

a) the requirements of 4.1 a) to 4.1 f);

b) the manufacturers instructions for disinfection.

4.3 Outer containers

Each outer container shall be marked with the following information :

a) the requirements of 4.1 a) to 4.1 f);

b) if appropriate, the requirements of 4.2 b);

c) directions for storage.

5 Directions for use

Directions for use of the IUD shall accompany each package and shall comprise the following :

a) directions for the insertion of the IUD;

b) details of contra-indications and adverse reactions, as required by the licensee-body;

c) precautions and warnings regarding the use of the IUD, as required by the licensee-body;

d) other information required by the licensee-body;

e) if appropriate, the recommended method of disinfection.