

Australian Standard[®]

**CONTRACEPTIVE DEVICES—
DIAPHRAGMS**

This Australian standard was prepared by Committee CS/9, Contraceptive Devices. It was approved on behalf of the Council of the Standards Association of Australia on 15 May 1984 and published on 3 August 1984.

The following interests are represented on Committee CS/9:

Australian Federation of Consumer Organizations
Canberra Consumers Inc.
Confederation of Australian Industry
Department of Health (Commonwealth)
National Biological Standards Laboratory
Royal Australian College of General Practitioners
Royal Australian College of Obstetricians and Gynaecologists
State Departments of Health
The Australian Federation of Family Planning Associations

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DIAPHRAGMS**

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PREFACE

This edition of this standard was prepared by the Association's Committee on Contraceptive Devices to supersede AS 1808—1980. The first edition of the standard was published in 1975, following submissions from Canberra Consumers Inc., The Australian Federation of Family Planning Associations, and other organizations. A revision was undertaken in 1980 at the request of the Australian Department of Health and this edition was prepared at the request of the National Biological Standards Laboratory.

The principal change in this edition is the deletion of the specification that the spring be made of stainless steel.

Amendments have also been made to the labelling requirements so that manufacturers can dispense with the information leaflet, provided that the information required on use, storage and the way to inspect the diaphragm before use is given on the primary pack.

As there have been rare instances of Toxic Shock Syndrome (TSS) associated with the use of diaphragms during menstruation, the committee felt that advice similar to that required to be supplied with tampons, should be given to the user. This has resulted in the inclusion of additional care and use instructions which may be given on a separate leaflet in the primary pack.

It is strongly recommended that in view of the nature of this standard, manufacturers and purchasers should make use of the scheme operated by the Standards Association of Australia (see Note to Clause 8) whereby the product may bear the certification mark of the Standards Association of Australia.

In developing this standard, the committee considered the draft documents prepared by ISO/TC 157, Mechanical Contraceptives.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard

for

CONTRACEPTIVE DEVICES—DIAPHRAGMS

1 SCOPE. This standard specifies requirements for natural and synthetic rubber vaginal diaphragms for contraceptive use.

NOTE: The efficacy of spermicidal preparations and lubricants used with diaphragms is not within the scope of this standard.

2 REFERENCED DOCUMENT. The following standard is referred to in this standard:

AS CK15 Code of Recommended Practice for the Storage of Vulcanized Elastomers.

3 DEFINITIONS. For the purpose of this standard, the following definitions apply:

3.1 Diaphragm—a natural or synthetic rubber vaginal diaphragm for contraceptive use, including any lubricant or dressing applied by the manufacturer.

3.2 Rim, dome and spring—parts of the diaphragm as indicated in Fig. 1.

3.3 Nominal size—the nominal external diameter of the rim of a diaphragm, as indicated in Fig. 1, expressed in millimetres.

3.4 Expiry date—the date (month and year), being not more than three years after the date of manufacture, after which the goods should not be supplied.

3.5 Unit pack—the pack enclosing a single diaphragm.

3.6 Primary pack—the complete pack in which a diaphragm is to be supplied to the consumer, excluding any wrapping, bag, box, carton or similar article in which any complete pack is placed at the time of sale or despatch.

3.7 Batch—a limited quantity of product which is made in one cycle of manufacture and being uniform with respect to starting material, composition, method of manufacture and probability of exposure to chemicals and/or microbial contamination.

3.8 Batch number—a number, or combination of numerals, symbols, or letters, which is given by a manufacturer to a batch of goods, to identify uniquely that batch, and from which it is possible to trace that batch through all stages of manufacture and distribution.

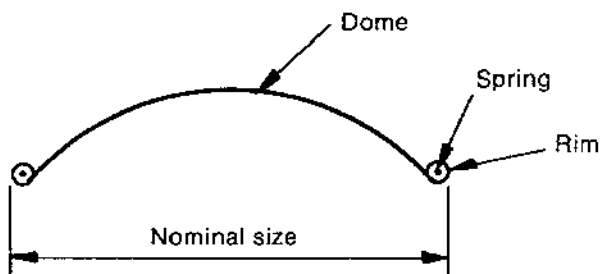


Fig. 1. COMPONENTS OF A DIAPHRAGM

4 MATERIALS.

4.1 General. The various components of diaphragms and any dressing materials used shall be manufactured from materials which are known to comply with the requirements of Clauses 4.2 to 4.4.

4.2 Dome and rim. The dome and rim shall be manufactured from filled or unfilled natural or synthetic rubber which contains no compound ingredient or pigment that might have a deleterious effect on the rubber used or liberate substances which are toxic or otherwise harmful under normal conditions of use.

4.3 Spring. The spring shall be made of a material which does not adversely affect the rubber or corrode when the diaphragm is stored and used under normal conditions throughout its useful life.

4.4 Dressing materials. Dressing materials applied to the diaphragm shall not liberate substances which are either toxic or otherwise harmful under normal conditions of use or have a deleterious effect on the rubber.

NOTE: Facilities are available at the Department of Health (Commonwealth) for the assessment of data relating to the non-toxicity of the materials used in the formulation of the dressings.

5 DESIGN AND CONSTRUCTION.

5.1 Size. The external diameter of the diaphragm shall be measured at three positions at 6° degree angles to one another and none of the measurements shall deviate from its nominal size by more than 2 mm.

NOTE: The preferred range of sizes is from 45 mm increasing by 5 mm intervals up to a maximum of 100 mm.

5.2 Dome thickness. When measured in accordance with Appendix A, the thickness of the rubber of the dome shall not be less than 0.2 mm at any of the three places measured.

5.3 Rim and spring. The rim of the diaphragm shall be reinforced with a spring which shall be completely covered by rubber.

6 TESTS.

6.1 Spring test.

6.1.1 Test requirements. When the diaphragm is tested in accordance with the procedure described in Clause 6.1.2

- (a) the spring shall not project through the surface of the rim;
- (b) there shall be no deformation of the spring; and
- (c) there shall be no visible evidence of any other defects.

6.1.2 Procedure. The test procedure shall be as follows:

Compress the rim of the diaphragm so that opposite positions of the rim make contact. Release the pressure. Repeat these two steps a further 99 times over a period of 10 min.