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Australian Standard 1808—1980

DIAPHRAGMS FOR CONTRACEPTIVE USE

STANDARDS ASSOCIATION OF AUSTRALIA
Incorporated by Royal Charter

THE FOLLOWING SCIENTIFIC, INDUSTRIAL, CONSUMER AND GOVERNMENTAL organizations and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Department of Health

Australian Federation of Consumer Organizations

Canberra Consumers Inc.

Confederation of Australian Industry

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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AUSTRALIAN STANDARD

DIAPHRAGMS FOR CONTRACEPTIVE USE

AS 1808—1980

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PREFACE

This standard was prepared by the Association's Committee on Contraceptive Devices and first published in 1975, following submissions from Canberra Consumers Inc., The Australian Federation of Family Planning Associations, and other organizations. The revision was undertaken at the request of the Australian Department of Health.

Vaginal diaphragms are packaged in a way which normally will protect them during storage. Nevertheless, some simple precautions are necessary to maintain quality after the products have left the manufacturer's control, and information in this regard is given in Appendix D.

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 9) whereby the product may bear the certification mark of the Standards Association of Australia.

This standard is largely based on BS 4028—1966, Diaphragms for Contraceptive Use.

This standard may require reference to the following standard:

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

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
DIAPHRAGMS FOR CONTRACEPTIVE USE

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

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

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

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

Useful life—the period of time between the completion of manufacture of the diaphragm and the first appearance of any deterioration of the diaphragm.

Unit pack—the pack enclosing a single diaphragm.

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.

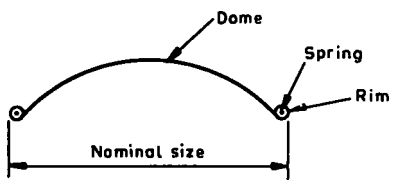

Fig. 1. COMPONENTS OF A DIAPHRAGM

3 MATERIALS.

3.1 General. The various components of diaphragms and any dressing materials used shall be manufactured from materials which are known to meet the requirements of Clauses 3.2 to 3.4.

3.2 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.

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

3.4 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.

4 DESIGN AND CONSTRUCTION.

4.1 Size. The external diameter of the diaphragm shall be measured at two positions at right angles to one another and neither measurement 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.

4.2 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.

4.3 Rim and Spring. The rim of the diaphragm shall be reinforced with a stainless steel spring in the form of a ring which shall be of the helical wound type or of flat leaf or clock spring construction. The spring shall be completely covered by rubber.

5 TESTS.

5.1 Spring Test.

5.1.1 *Test requirements.* When the diaphragm is tested in accordance with the procedure described in Clause 5.1.2—

(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.

5.1.2 *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.

5.2 Inflation Test for Freedom from Defects. When the diaphragm is tested in accordance with Appendix B, there shall be no pin-holes, thin spots, uncovered or protruding spring or any other defects of a visual or obvious nature likely to affect the safety of the user or the reliabilty of the diaphragm as a contraceptive.

5.3 Accelerated Ageing Test. When tested in accordance with Appendix C, the diaphragm shall not exhibit tackiness or significant change in the hardness of the rubber. After passing the accelerated ageing test, the diaphragm shall also pass the inflation test for freedom from defects described in Appendix B and the spring test described in Clause 5.1.