INTERNATIONAL STANDARD

ISO 14607

Second edition
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Non-active surgical implants — Mammary implants — Particular requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established 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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14607 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in collaboration with Technical Committee ISO/TC 150, *Implants for surgery*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14607:2002), which has been technically revised.

Introduction

In addition to the requirements given in the level 1 standard, this International Standard provides a method for addressing the fundamental principles outlined in ISO/TR 14283, as they apply to non-active surgical implants. It also provides a method to demonstrate compliance with the relevant Essential Requirements as outlined in general terms in Annex I of the Directive 93/42/EEC of 14 June 1993 concerning medical devices (amended by the Commission Directive 2003/12/CE), as they apply to mammary implants for use in clinical practice.

Further specific information on mammary implants indicating how to comply with the Directive 93/42/EEC is given by the Communication from the European Commission on community and national measures in relation to mammary implants.

There are three levels of European Standards dealing with non-active surgical implants. These are as follows (with level 1 being highest):

— Level 1: General requirements for non-active surgical implants;

— Level 2: Particular requirements for families of non-active surgical implants;

— Level 3: Specific requirements for types of non-active surgical implants.

This is a level 2 standard and contains particular requirements for a family of mammary implants.

The level 1 standard, ISO 14630, contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.

To address all requirements, it is necessary to start with a standard of the lowest available level.

Non-active surgical implants — Mammary implants — Particular requirements

1 Scope

This International Standard specifies particular requirements for mammary implants for clinical practice.

With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies

ISO 34-1:2004, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 37, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14630:—[1)], *Non-active surgical implants — General requirements*

NF S 99-401:1994, *Medical devices — Silicone elastomer of medical grade*

NOTE The Bibliography gives informative references to other useful standards.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 14155-1, ISO 14155-2 and ISO 14630 and the following apply.

3.1
anterior projection
maximum height of the implant when placed with its base on a flat horizontal surface at its nominal volume

1) To be published. (Revision of ISO 14630:2005)

3.2
base dimensions
length of the major axis and the length of the minor axis when the implant is placed with its base on a flat horizontal surface at its nominal volume

3.3
diffusion
movement of material in and/or out of an implant through an intact shell

3.4
injection site
component designed to be penetrated by a needle to alter the volume of the implant

3.5
mammary implant
implant with a shell which is filled by the manufacturer or the surgeon and is designed to add to or replace volume of the breast

3.6
orientation means
mark in or on the implant to assist the surgeon in positioning the implant

3.7
release
movement out of an implant of material originating from the filling material or the shell, or products resulting from the interaction of the two

3.8
shell
envelope of the implant

3.9
seam
seal junction of materials fused or adhered together

3.10
valve
component of the shell into which an accessory is inserted to inflate variable volume implants

4 Intended performance

The requirements of ISO 14630:—, Clause 4, apply.

Specific attention shall be paid to ensure that the clinical condition and safety of the patient are not compromised during the expected lifetime of the device under conditions of normal use.

NOTE 1 Information on expected duration of intended performances is given in 11.6.

NOTE 2 Information on the nature of the benefit expected from a mammary implant is given in 7.2.

NOTE 3 Information on specific risks related to the mammary implant is given in Clauses 5, 6 and 7.

5 Design attributes

The requirements of ISO 14630:—, Clause 5, apply.

In order to meet the intended performance requirements, the design attributes shall take into account the ability to detect rupture.

The effect of ageing of materials shall be investigated.

6 Materials

The requirements of ISO 14630:—, Clause 6, apply.

In addition, if silicone elastomer is used, NF S 99-401:1994 applies.

Special attention shall be given to

— biological evaluation of the device and its components following implant failure;

— stability of the material (particularly filling material).

7 Design evaluation

7.1 General

The requirements of ISO 14630:—, 7.1, apply.

Mammary implants shall be designed and manufactured in such a way that, when used under the conditions and for the purpose intended, they will not compromise the clinical condition, the safety or the health of the patient. Any residual risks or undesirable side-effects that might be associated with their use shall constitute acceptable risks when weighted against the benefits to the patient, taking into account the fact that their benefit is deemed to be primarily aesthetic and psychological in nature, whether the application is for reconstructive and/or cosmetic purposes.

Risk analysis and conformity evaluation shall be performed on the filler material, shell and mammary implant.

7.2 Pre-clinical evaluation

7.2.1 General

The pre-clinical evaluation of mammary implants shall conform to ISO 14630:—, 7.2.

Where no test is described in this International Standard, or when the test described is not applicable, description for the alternative validated test method and sample preparation used shall be documented by the manufacturer. The adequacy of the pass/fail criteria adopted for the evaluation shall be verified prior to testing.

All testing shall be performed on finished sterilised devices or components.

The sample size selected shall be based on a statistical rationale, which shall be justified and documented.

NOTE With regard to validated test methods available for the pre-clinical evaluation, this International Standard reflects the present state of the art.

Where appropriate, for materials other than silicone, the manufacturer should consider and develop tests as indicated in 7.2.2.

7.2.2 Mechanical tests

7.2.2.1 General

Mechanical tests shall be conducted in accordance with Annexes A, B, C, D and E and shall comply with the stated requirements.

The goal of mechanical tests is to ensure a low rupture rate of the device under normal conditions of use.

7.2.2.2 Shell integrity

7.2.2.2.1 General

The integrity of the shell shall be evaluated.

The following properties of the silicone elastomer shell shall be tested in accordance with Annex B and shall comply with the stated requirements. A worst-case assumption should be considered.

For materials other than silicone elastomer, relevant tests shall be developed.

7.2.2.2.2 Elongation

The elongation of the silicone elastomer shell shall be tested in accordance with B.1 and shall comply with the stated requirements.

7.2.2.2.3 Tear resistance

The tear resistance shall be tested in accordance with B.1.

7.2.2.2.4 Strength of joints, seams or seals

The resistance to failure of joints, seams and seals shall be tested in accordance with B.2 and shall comply with the stated requirements.

7.2.2.2.5 Design of shell

Care shall be taken when selecting materials to be used in the manufacture of the shell. Surfaces both inside and outside the shell shall be suitable to minimize or prevent frictional abrasion both between shell-to-shell surface and between shell surface and the implantation site. If such frictional abrasion is likely to be a significant problem, the manufacturer shall indicate any relevant tests carried out to ensure the suitability of the shell when implanted.

7.2.2.3 Valve or injection site competence

The competence of the valve or injection site shall be tested in accordance with Annex C and shall comply with the stated requirements.

7.2.2.4 Filling material

7.2.2.4.1 General

The physical compatibility between the filling material and the shell shall be demonstrated by providing long-term data on shell performance and integrity.

7.2.2.4.2 Test for silicone gel cohesion

If silicone gel is used as filling material, cohesivity testing shall be performed to measure both the rheological properties and the integrity of the gel in accordance with Annex D and shall comply with the stated requirements in order to optimize clinical performance and safety.

For filling materials other than silicone gel, an appropriate and validated test for cohesivity shall be used.

7.2.2.5 Implant resistance

7.2.2.5.1 General

Static rupture resistance testing, fatigue resistance testing and impact resistance testing shall be conducted in accordance with Annex E and shall comply with the stated requirements.

7.2.2.5.2 Fatigue resistance test

The fatigue resistance test shall be conducted in accordance with E.1. After testing, the shell of the implant shall not present any tears, cracks or cuts when examined under $\times$ 10 magnification.

7.2.2.5.3 Impact resistance test

The impact resistance test shall be conducted in accordance with E.2 and shall comply with the stated requirements.

7.2.2.5.4 Static rupture resistance test

The static rupture resistance test shall be performed in accordance with E.3 and the test results shall be recorded.

7.2.2.6 Volume

The volume of prefilled implants shall be within $\pm$ 2,5 % of the volume stated on the packaging (see 11.3). Volume shall be expressed in SI units.

7.2.2.7 Dimensions

The intended design base dimensions and anterior projection and their tolerances shall be recorded.

7.2.2.8 Surface

If the surface is specially treated or processed in order to form a specific texture, the surface characteristics shall be tested in accordance with Annex A and the test results shall be recorded.

7.2.3 Chemical evaluation

7.2.3.1 General

Shell and filler materials shall be chemically evaluated.

7.2.3.2 Shell material, silicone elastomer or coated materials

An analysis of the extractable or releasable chemicals (especially the characterization and quantification of materials of low molecular mass) is necessary to assess the safety of the device.

7.2.3.3 Filler materials

A detailed chemical characterization of the filler material shall be established.

Long-term stability data, established under physiological conditions, and accelerated ageing studies shall be provided to demonstrate the effects of time and temperature on the physical and chemical characteristics of the device.

7.2.3.4 Release test

Release from the whole implant shall be evaluated.

NOTE 1 No validated test method is currently available. For implants with a silicone shell and silicone filling, it is not clear which proportion of the release comes from the shell or the filler material respectively. The test methods and requirements for this clause are under consideration.

NOTE 2 There are currently two test methods available that might provide some valuable information concerning the release: the ASTM F 703-96 and the release test described in Annex H.

7.2.4 Biological evaluation

The implant shall be evaluated for biological safety in accordance with the requirements of ISO 10993-1.

The local and systemic toxicity of any substance introduced into the body by mammary implants shall be assessed. The toxicological evaluation shall be based on the chemical characterization and toxicokinetics of the materials, available scientific data addressing toxicological hazards and risks and, where necessary, specific testing.

The evaluation shall address the potential for short-term and long-term effects, including cytotoxicity, irritation, haemocompatibility, genotoxicity, implantation, immunotoxicity and other forms of systemic toxicity, reproductive toxicity and carcinogenicity. Moreover, the effects of shell surface texture on surrounding tissues shall be evaluated. This evaluation shall be taken into account in the risk analysis. Knowledge of the toxicokinetics of potentially toxic or reactive ingredients or degradation products is necessary when these could be released into the body in substantial quantities following implantation. Information on distribution, transformation and elimination, applicable to the route of exposure, is therefore necessary.

The manufacturer shall determine and justify if in vivo tests are necessary or not.

NOTE Evaluation might include a study of relevant experience and/or actual testing. This kind of evaluation might conclude that no testing is needed if the implant material, manufactured in the same way, has a demonstrable history of use in a specified role that is equivalent to that of the device under design (ISO 10993-1:2003, Clause 6).

7.3 Clinical evaluation

The requirements of ISO 14630:—, 7.3, apply.

In the case of clinical investigation, the requirements of ISO 14155-1 and ISO 14155-2 apply.

NOTE Additional information on literature review is provided in ISO 14155-1:2003, Annex A.

The purpose of the clinical evaluation is to estimate the frequency and rate at which local complications occur, in particular capsular contracture and ruptures/deflation of implants, after a correct implantation of a mammary implant.

The criteria for acceptance (i.e. safety and effectiveness) of clinical evaluation shall be clearly identified in order to allow a risk/benefit assessment and to provide evidence of the safety and the performance of the implant.

The clinical data shall be based upon an appropriate duration of patient follow-up and a sufficient number of representative patients to allow for an accurate analysis of the results.

The clinical data provided by the manufacturer shall originate either

a) from prospective clinical investigations performed with the mammary implant in question, in compliance with an appropriate program, or

b) from literature, from previously performed clinical investigations or from data based on experience from the use of implants having the same design parameters and performance characteristics as the mammary implant to be evaluated.

When using data from the literature, or obtained using other products, a number of criteria shall be fulfilled, namely:

— the equivalence between the device being evaluated and the devices that are the subject of the reports shall be demonstrated in terms of critical design parameters and performance characteristics;

— all data used shall be generated from well-controlled clinical trials, from properly designed and conducted cohort or case/control studies, or from well-documented case histories. Clinical data shall be generated, reported and critically assessed by appropriately experienced and knowledgeable experts. Ideally, data should be published in peer review journals. Evidence put together from isolated case reports to permit scientific evaluation, or from unsubstantial opinions is inadequate for this purpose.

7.4 Post-market surveillance

The requirements of ISO 14630:—, 7.4, apply.

As part of the pre-market requirements, the manufacturer shall also make arrangements for prospective clinical evaluation of long-term performance and complication rates. These arrangements shall foresee the analysis of capsular contracture rate, rupture/deflation rate and systemic effects after pre-established periods of time.

8 Manufacturing

The requirements of ISO 14630:—, Clause 8, apply.

9 Sterilization

Implants shall be supplied sterile.

The requirements of ISO 14630:—, 9.1, 9.2 and 9.4, apply.

10 Packaging

The requirements of ISO 14630:—, Clause 10 apply.

11 Information supplied by the manufacturer

11.1 General

The requirements of ISO 14630:—, Clause 11, apply. The information below shall be supplied by the manufacturer on the label, or as data in the package of information supplied by the manufacturer.

NOTE With regard to aspects of traceability, see ISO 16054 and CR 14060.

11.2 Resterilization

If resterilization is not allowed, this shall be stated in the information provided by the manufacturer.

If resterilization is allowed, the requirements of ISO 14630:—, 9.3, apply.

NOTE A device to be resterilized is considered a non-sterile device.

11.3 Base dimensions

Base dimensions, anterior projection and nominal volume shall be indicated on the label.

11.4 Effects on diagnostic techniques

The effect of the implant on diagnostic techniques, such as mammography or magnetic resonance imaging (MRI), shall be stated.

11.5 Filling materials

For inflatable implants, the manufacturer shall indicate the recommended filling material and the filling instructions.

11.6 Information on expected lifetime

The manufacturer shall provide information on the expected duration of performance of the device as intended, preferably expressed as percentage implant durability at ten years (or earlier if ten-year information is not yet available), in accordance with the Kaplan Meier method or an alternative statistical method. Such relevant information includes the indication of factors that could have a significant influence on the actual lifetime of an individual implant.

NOTE 1 In practice, it is not possible to predict accurately the actual lifetime of an individual implant. It is well understood that several factors are beyond the control of the manufacturer. These factors might have a significant effect on the lifetime of an individual device. The factors include the actual implantation procedure, the anatomy and state of health of the patient, the behaviour and activities (e.g. sporting activities), as well as predictable and unpredictable external mechanical influences.

NOTE 2 The manufacturer may select his preferred method of indicating information relating to expected lifetime under defined conditions. This includes information based on statistics.

Examples of possible methods include:

— indicating a probability of lifetime reaching an expected value;

— indicating a range of anticipated lifetime;

— by indicating statistical information derived from data obtained by means of similar devices already implanted.

NOTE 3 The results of tests indicated within this International Standard provide useful data for the manufacturer in his assessment process to provide information on the anticipated lifetime.

11.7 Information for the patient

The manufacturer shall provide the user with the information destined for the patient, as specified in Annex F. The information support for the patient shall contain an informed consent sheet. This consent sheet is intended to be signed and dated by the patient.

NOTE The manufacturer is not responsible for the transfer of information from the user to the patient, nor for having the patient sign the consent sheet.

11.8 Labels

The package shall include at least two labels for use on the patient record and/or the patient card.

The labels shall list the following:

a) the name or trade name and the address of the manufacturer;

b) the details necessary for identification of the implant;

NOTE These can include

— commercial reference of the implant,

— prosthesis description,

— filling volume,

— patient name,

— left or right (tick as appropriate).

c) the serial number or batch code.

11.9 Information for the user

The manufacturer shall provide the user with the information, as specified in Annex G.

11.10 Marking on implants

In addition to the requirements of ISO 14630:—, 11.3, the nominal volume or size shall be indicated on the implant.

11.11 Manufacturer’s device card

A manufacturer's device card shall be completed by the physician and then given to the patient for the purposes of device traceability. This card/sticker shall include at least the following:

— the brand of the implant;

— the size of the implant;

— the manufacturer's serial or batch number.

NOTE The manufacturer is not responsible for handing over the device card with the information to the patient.

Annex A
(normative)

Test for surface characteristics

A.1 Principle

This test determines the average surface characteristics of mammary implants.

A.2 Materials

Mammary implant.

A.3 Procedure

The characteristics of the surface shall be examined by scanning electron microscopy (SEM) and documented in order to present the average surface characteristics (standard deviation).The surface characteristics (e.g. pore size, peaks and valleys) shall be measured over an area of approximately 4 mm^2.

The samples shall include at least three samples taken from the base, the radius and the apex of the implant (a total of nine). They shall be representative of the surface as a whole.

NOTE For manufacturing control (QA), other methods (stylus, laser, etc.) calibrated against the SEM are allowed.

A.4 Expression of results

The average measurements and standard deviation of the characteristics shall be recorded.

The data are meant to generate information to improve knowledge on the correlation of texture and performance.

NOTE The data resulting from the test at this point in time cannot be related to the performance or safety of the device.

Annex B
(normative)

Tests for shell integrity

B.1 Shell material

B.1.1 Sample preparation

Unless otherwise indicated below, all test samples shall be prepared using die H2, as detailed in ISO 37. Where the implant is prefilled, the silicone gel or other material shall be removed. The tests shall include mandrel marks or orientation means if these are present on the shell. If required, propan-2-ol is recommended to aid sample cleaning.

The tests are most conveniently carried out using a commercially available tensile testing frame. In all cases, the samples shall be securely clamped at either end and then extended at a constant rate of 500 mm/min.

B.1.2 Elongation

Elongation shall be determined in accordance with the requirements of ISO 37.

Elongation shall be 450 % minimum.

B.1.3 Tensile set

The test shall be carried out in accordance with the requirements of ISO 37.

The sample shall be elongated to 300 %, maintained at this elongation for 3 min, and then relaxed to the starting position. After this, the tensile set shall be a maximum of 10 %.

B.1.4 Tear resistance

Tear resistance shall be determined in accordance with ISO 34-1:2004, Method C. The results shall be recorded.

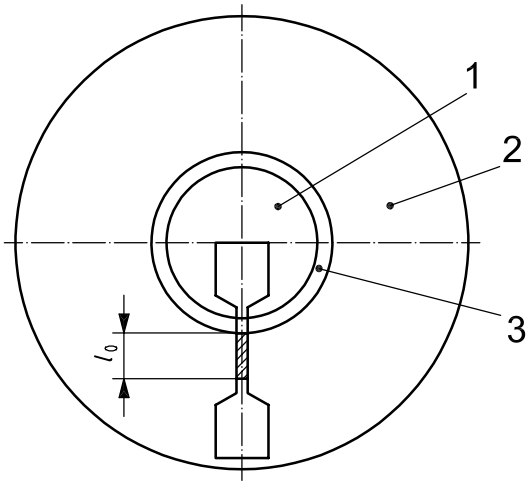
B.2 Strength of joints, seams and seals

B.2.1 Principle

This test determines the strength of joints, seams and seals.

B.2.2 Procedure

B.2.2.1 Joints, seams and seals, which are critical to shell integrity, shall be tested as follows. Samples shall be prepared and tested as outlined in B.1.1. The test specimen shall be taken from a finished, sterilized product, as indicated in Figure B.1, such that the junction is within the reference portion of the sample.



Key

1 patch
2 shell
3 junction

Figure B.1 — Sample

The area of the shell adjacent to the bonded area, designated l_0 in Figure B.1, shall not fail when elongated to 300 % and held at this value for a period of 10 s.

B.2.2.2 Bond, seams, seals and surface attachments, which are not critical to shell integrity, shall be tested as follows. Samples shall be prepared according to B.1.1. The area of the shell adjacent to the bonded area shall not fail when elongated to 100 % and held at this value for a period of 10 s.

Annex C
(normative)

Test method for valve competence and injection site competence

C.1 Valve competence

C.1.1 Principle

This test method determines valve competence.

C.1.2 Materials

Assembled implant.

C.1.3 Procedure

The valve shall be tested on an assembled implant as follows.

Prior to testing, manipulate valve to simulate its use for filling an implant, as described in the instructions for use.

Apply a retrograde pressure (pressure to the inner or lumen side of the valve) equivalent to 3 kPa (approximately 300 mm of water) using air, water or a test medium with demonstrated equivalence. Maintain this pressure for 5 min.

Examine the valve for leakage. When the test medium is air, immerse the valve in water to check for leaks (bubbles). If liquid test media are used, check for droplets which might emerge at the outer surface of the valve.

Reduce the pressure to the equivalent of 0,3 kPa (approximately 30 mm water). Hold at this pressure for 5 min and check for leaks.

C.1.4 Requirement

No leakage shall occur during the test period.

C.2 Injection site competence

C.2.1 Principle

This test method determines injection site competence.

C.2.2 Materials

Needles recommended by the manufacturer for normal use.

Water or a test medium with demonstrated equivalence.

C.2.3 Procedure

The injection site of the assembled device shall be tested with needles recommended by the manufacturer for normal use.

Using water or a test medium with demonstrated equivalence, apply an intraluminal pressure of 3 kPa (approximately 300 mm of water).

Puncture the injection site for a total of five times at 1 min intervals within a 1 mm^2 area near the centre of the site.

Examine the injection site for leakage. When the test medium is air, immerse the site in water to check for leaks (bubbles). If liquid test media are used, check for droplets which might emerge at the outer surface of the site.

C.2.4 Requirements

The injection site is considered to leak and not to meet the requirements of the test if droplets of fluid or bubbles, which might appear on the punctured surface, are not static after 30 s.

Annex D
(normative)

Test for silicone gel cohesion (silicone filling materials only)

D.1 Principle

This test method determines the cohesion of the silicone gel.

D.2 Materials

Silicone gel.

D.3 Apparatus

Test apparatus as shown in Figure D.1, internal volume 100 ml ± 5,0 ml.

D.4 Procedure

The test shall be performed at a temperature of 23 °C ± 2 °C, as follows.

a) Use test apparatus as shown in Figure D.1.

b) Fill the apparatus with the gel.

   A representative test sample of the gel should be collected from a single implant of sufficient size to allow gel to be removed as one cohesive mass.

   Care should be exercised when removing the gel and transferring it to the test fixture. Severe mixing, handling, air entrapment, etc. will produce erroneous results.

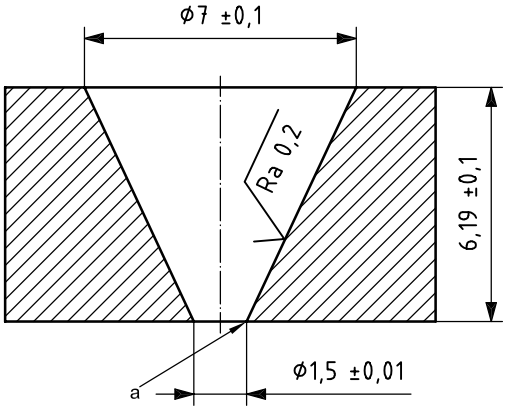
c) At the beginning of the test, the gel shall be flush with the lower surface of the apparatus and shall be flush with, or above, the top surface.

d) Allow the gel to flow unrestricted through the lower opening for 30 min.

e) Note if any gel separates from the test volume.

f) Measure the projecting length of the gel.

Dimensions in centimetres,
value of surface roughness in micrometres



NOTE The value of surface roughness, Ra, is the mean height of the profile below and above the line, as defined in ISO 4287.

a Sharp angle.

Figure D.1 — Test for gel cohesion

D.5 Requirements

The specimen shall meet the requirements of the test if there is no separation and the projecting length of the gel is less than or equal to 30 mm.

Annex E
(normative)

Mechanical tests on a mammary implant in its implantable state

E.1 Fatigue test

E.1.1 Principle

This test method determines the resistance of the implant to fatigue.

E.1.2 Materials

Mammary implant.

E.1.3 Apparatus

The apparatus is shown schematically in Figure E.1. It consists of a fixed plate and a mobile plate, the latter being attached to a motor via a connecting arm, which generates alternating motion in the mobile plate. The mobile plate also includes an adjustment mechanism such that its distance from the fixed plate can be varied. Thus the implant can be compressed as required.

The total length of travel of the mobile plate shall be 40 mm, corresponding to 20 mm travel in each direction from the central starting position. The motor shall be geared so as to produce 200 cycles per minute, which corresponds to a frequency of 3,3 Hz.

E.1.4 Procedure

The implant shall be held by compression force between two opposing vertically positioned support plates. Deformations shall be introduced into the implant by the alternating movement of one of the plates. The compression force ensures the prosthesis remains in position between the plates, thus allowing the implant to be subjected to shear forces.

Inflatable implants shall be filled according to the manufacturer's instructions prior to the test. The test shall be performed at a temperature of 23 °C $\pm$ 2 °C, as follows.

a) Determine the projection of the mammary implant.

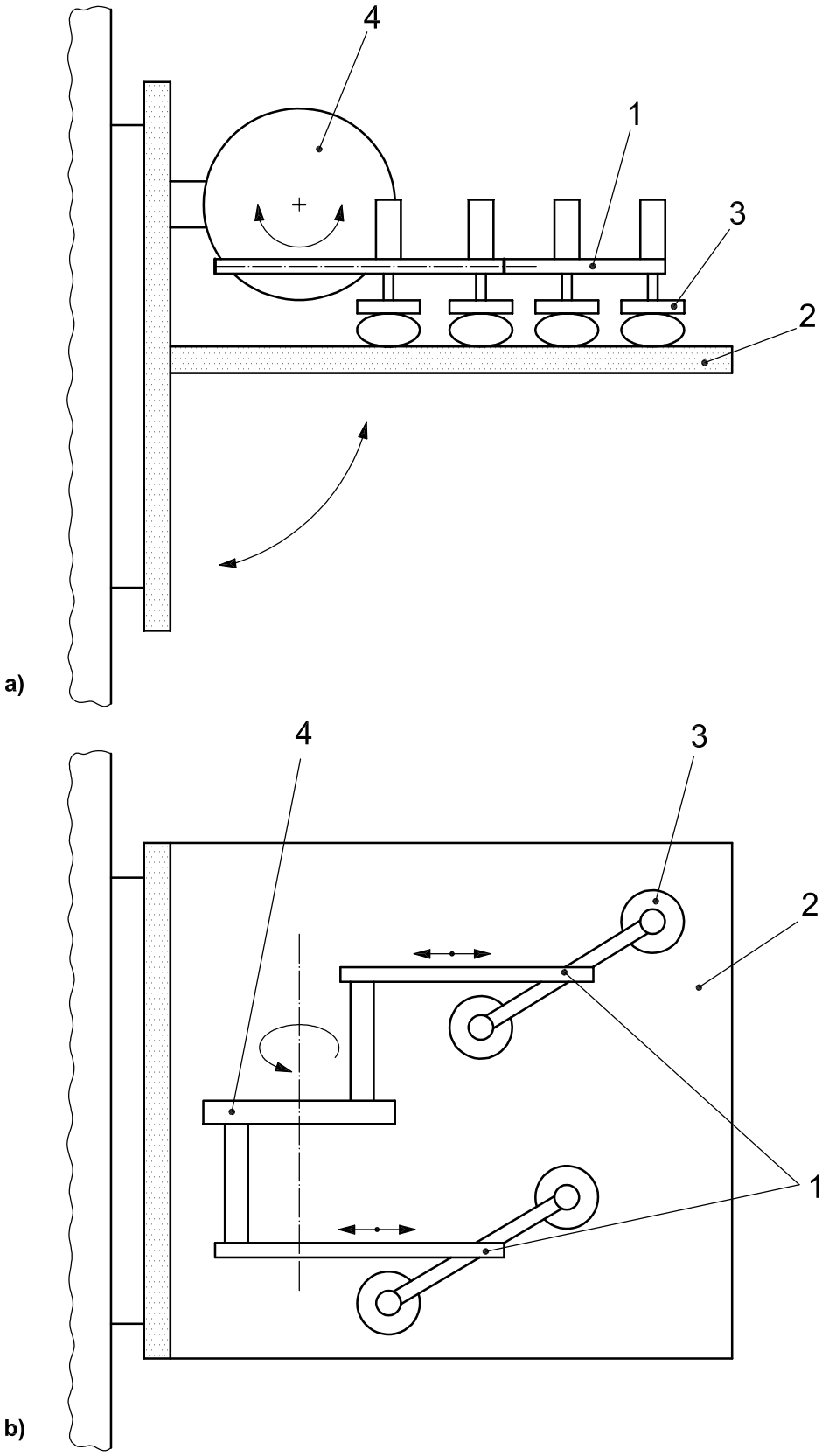
b) Place the implant between the two plates and adjust the distance between the plates to correspond to 80 % of the projection.

c) The test shall proceed for 2×10^6 cycles.

d) Inspect the implant in accordance with E.1.5.

E.1.5 Requirement

Following this test, no tears, cracks, or cuts shall be present on the mammary implant when observed visually at a $\times$ 10 magnification.



Key

1 connecting arm
2 fixed plate
3 mobile plate
4 motor

Figure E.1 — Fatigue test apparatus

E.2 Impact resistance test

E.2.1 Principle

This test method determines the impact resistance of mammary implants. The test is based on the vertical drop of a specified mass on the implant. The implant is subjected to an impact force proportional to the mass of the implant. The implant force is varied by adjusting the vertical distance from which the mass of 4,4 kg is allowed to fall.

The drop height is given by the following equation:

$$H = 0{,}95m + 144$$

where

H is the drop height in millimetres (mm);

m is the implant mass in grams (g).

E.2.2 Apparatus

The apparatus is shown schematically in Figure E.2. It consists of a frame equipped with a mobile gantry to which a total mass of 4,4 kg is attached. When disconnected from the gantry, the mass runs freely on two guide runners, which ensures a regular and reproducible drop to the base of the frame. A metal plate of 250 mm diameter comes into contact with the implant.

The gantry contains a fixing mechanism such that it can be positioned on the frame at a variable height from the base. The frame may conveniently include a height gauge and manual winch for positioning, and the gantry may conveniently include an electronically controlled release mechanism for the mass.

When the mass holding mechanism is released, the mass falls on the implant. The force generated is proportional to the starting height.

E.2.3 Procedure

Inflatable implants shall be filled according to the manufacturer's instructions prior to the test.

The test shall be performed as follows.

a) Weigh the implant.

b) Calculate the drop height (in millimetres) according to the implant mass and the equation given in E.2.1.

c) Note the implant projection and position the gantry such that the total distance between the impact weight and the frame base consists of the calculated drop height and implant projection.

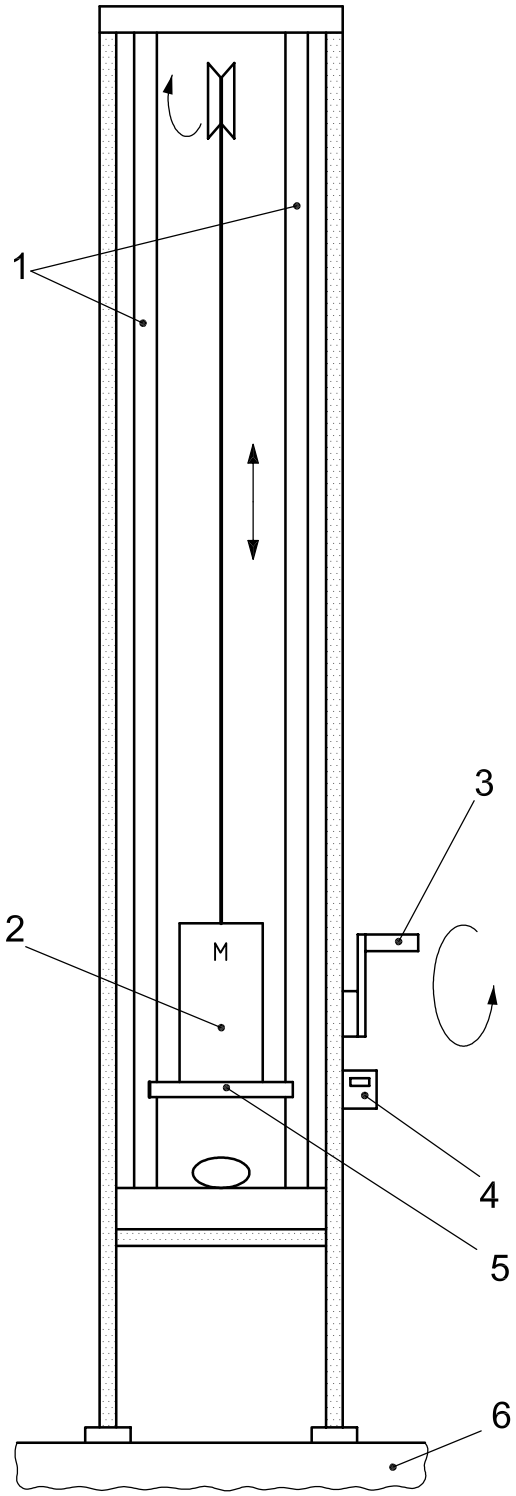
d) Position the implant on the frame base, centred directly beneath the impact plate.

e) Release the mass retaining mechanism.

f) Inspect the implant in accordance with E.2.1.

E.2.4 Requirement

The implant shall not rupture.



Key

1	guide runners	4	height gauge
2	mobile gantry	5	impact plate
3	manual winch	6	frame base

Figure E.2 — Impact resistance test apparatus

E.3 Static rupture resistance test

E.3.1 Principle

This test determines the static rupture resistance of mammary implants.

E.3.2 Materials

Mammary implants.

E.3.3 Apparatus

Compression device machine with a horizontal fixed plate and a mobile plate.

E.3.4 Procedure

Inflatable implants shall be filled according to the manufacturer's instructions prior to the test.

Position the mammary implant in the centre of the bottom plate. At the moment the test starts, no pressurizing force will be present on the mammary implant. This means that the zero force point is not influenced by any mass of the top plate. Start recording the force signal and the motion signal simultaneously. Pressurize the implant slowly (quasi-static) at a speed of 5 mm/min or slower until it ruptures. During this sequence, the signals of distance and force shall be recorded continuously.

During the test, the implant shall not extend to the area outside plates. If the size of the implant is too large, larger diameter plates shall be used.

Inspect the implant for damage and note the place of the rupture and the force and projection height at the moment of rupture.

Annex F
(normative)

Information for the patient

This information is intended to be given to the patient by the user well before the surgery. With regard to item c), the information shall be provided after surgery on an adequate support such as a patient card.

NOTE 1 The patient card can also include the localization of the implant (left or right) and the name of the surgeon.

The information shall be written in a way that is easy to read and understand, on a suitable support or supports, such as a patient handbook, informed consent sheet or patient card.

NOTE 2 The manufacturer can use the support(s) he thinks the most appropriate for the product, but a paper support including all the following information is strongly recommended.

The information to the patient shall include:

a) name or trade name, and address of the manufacturer;

b) description of the implant, including type, materials and principles (e.g. prefilled or inflatable implant), chemical components in general terms (e.g. silicone), characteristics (e.g. textured or smooth);

c) the manufacturer's identifying reference for traceability (e.g. batch number), size (filling volume), shape and commercial reference;

d) expected lifetime, expressed in accordance with 11.6;

e) the following warning: “Mammary implants have a limited lifetime”, and the following statement: “This implant may have to be removed or replaced, which may imply revision surgery”;

f) anticipated benefits;

g) anticipated risks: the information includes all the potential local complications, such as capsular contracture, rupture (mentioning the possibility of “silent” rupture), leakage, deflation, and wrinkling; the potential general effects on health shall also be indicated;

h) undesirable effects, e.g. pain, infections, aesthetic consequences (asymmetry, displacement, hypertrophic scarring), changes in the nipples and breast sensation;

i) possible effects of the implant on breast feeding;

j) the need to consult a surgeon for medical follow-up;

k) the need to consult a physician or a pharmacist before the use of topical medicines (e.g. steroids) in the breast area;

l) the need to continue to consult a physician to carry out normal checks in order to detect breast cancer;

m) the need to inform a physician or a surgeon of the presence of an implant if any surgery of the breast area is scheduled;

n) effects of the implant on diagnostic techniques such as mammography;

o) the need to inform the radiologist if a mammography is carried out in order to adapt the mammographic compression;

p) possible effects of the implant on autopalpation;

q) an indication that the patient should consult a physician if the patient suspects any complications, in particular in the case of trauma or compression caused, for example, by extreme massaging of the breast region, by some sport activities or by using seat belts;

r) the recommendation to carry the patient card to facilitate medical care in case of emergency (e.g. in case of a road accident).

Annex G
(normative)

Information for the user

As a minimum, the following information shall be provided:

a) indications for surgery;

b) description of the implant;

c) instructions for use;

d) counter indications;

e) potential complications and their possible resolution;

f) precautions for the surgery;

g) instructions and precautions for removal;

h) recommendations for medical follow-up;

i) expected lifetime, expressed in accordance with 11.6;

j) a statement requiring the surgeon to ensure that the patient will receive the minimum information described in 11.7, provided by the manufacturer;

k) at least all the information available to fulfil 11.7.

Annex H
(informative)

Silicone release assessment from mammary implants by an in vitro method

H.1 Principle

The test consists of submerging of the implants (37 °C ± 2 °C) while stirring in a simulated body fluid (SBF). This in vitro procedure is supposed to simulate the pH and ion concentrations found in human plasma (the composition of the SBF is given in H.2.2.) and to evaluate the amount of silicone released during 60 d (+ 10 d if necessary).

Determination of the silicone amount released by the implant is based upon the measurement of elemental silicon in the samples of SBF taken regularly from the solution. The analyses are performed by inductively coupled plasma optical emission spectrometry (ICP-OES).

At the end of the study, the results are treated in order to express the total amount of silicone released by the implant as a function of the following elements:

— the exact amount of SBF surrounding the implant;

— the exact volume taken from the solution for the measurement of silicon;

— the theoretical ratio silicon/silicone.

H.2 Material and apparatus

— Orbital shaker; the rotation shall be efficient enough to allow the implants to be stirred properly with the least contact possible with the wall of the container;

— ICP optical emission spectrometer;

— standard silicon solution;

— SBF;

— plastic leak-proof containers; the containers used to perform the analysis shall not interact with SBF and shall have a shape allowing a proper submergence of the implant with the least contact possible with the wall of the container (volume between 7 to 9 × volume of breast implant)

H.2.1 Sample preparation

To ensure that all the implants occupy the same volume and are properly submerged in the SBF solution, the inflatable implants shall be saline filled to their nominal volumes.

H.2.2 Simulated body fluid (SBF)

Composition of simulated body fluid in mmol/l shall be as indicated in Table H.1.

Table H.1 — Composition of simulated body fluid

Na^+	142,0
K^+	5,0
Mg^{2+}	1,5
Ca^{2+}	2,5
Cl^-	147,8
HCO_3^-	4,2
HPO_4^{2-}	1,0
SO_4^{2-}	0,5

H.2.3 SBF preparation

Dissolve each salt separately in 100 ml of water. Mix all the solutions together except the calcium chloride solution, which shall be added last.

H.2.4 Material preparation

Plastic containers used to perform the study shall be cleaned prior to use to ensure the removal of any silicone mould release agents used in their manufacture, or other contaminants. They shall be filled with a solution of detergent, closed tightly and stirred on the orbital shaker, then rinsed out thoroughly with water and dried with a tissue.

H.3 Procedure

Perform eight samples at T = 0 d, 10 d, 20 d, 30 d, 40 d, 50 d, 60 d and 70 d ($\pm$ 2 d).

If one of them seems out of range, another one shall be performed the day after (so T can be $+$ 3 d).

H.3.1 Condition of release determination and Si measurements

The test shall be performed on three implants having a volume of 220 ml $\pm$ 20 ml.

The implant (silicone gel-filled or saline-filled), having a volume V (ml), shall be placed in a plastic container. A volume of $6V \pm 0{,}03V$ of SBF shall be added.

The container shall be closed tightly and stirred for 1 h on an orbital shaker. 10 ml of SBF shall be taken for analysis and the same volume of fresh SBF shall be added. This initial sampling constitutes the T = 0 data for each implant tested.

The container shall then be placed in an oven at a constant temperature of 37 °C $\pm$ 2 °C and stirred for 10 min every day on the orbital shaker.

10 ml of SBF shall be removed every 10 days for analysis by ICP-OES, and the same volume of fresh SBF shall be added.

It is also possible to weigh the container with the SBF and the implant each time 10 ml has been taken for analysis, and to add SBF until the initial mass is obtained. This operation compensates for the amount of SBF lost when handling the device.

10 ml of SBF shall be removed every 10 days for analysis by ICP-OES, and the same volume of fresh SBF shall be added. Six samplings are thus performed at 10 d, 20 d, 30 d, 40 d, 50 d, 60 d (± 2 d). If one of them seems out of range, another one shall be performed the day after (i.e. T can be + 3 d).

The silicon shall be analysed within one hour after being taken from the reaction medium.

Before every set of measurements, the spectrograph shall be calibrated with silicon standards prepared in SBF from a 1 000 µg/ml standard solution in water. The concentration of these standards depends on the results of the previous analysis.

The silicon standard chosen shall be certified by an accredited laboratory.

H.3.2 Expression of the results

Each sample shall be analysed several times to obtain a mean concentration of silicon and a standard deviation for each time period.

For each type of implant, the results shall be expressed in mass of silicon and mass of silicone released by the implant as a function of the time.

If

V is the volume of SBF added at $T = 0$,

x_0 is the concentration of silicon measured at $T = 0$ (µg/ml),

V_{P1} is the volume removed at $T = 10$ d,

x_1 is the concentration of silicon measured at $T = 10$ d (µg/ml),

V_{P2} is the volume removed at $T = 20$ d,

x_2 is the concentration of silicon measured at $T = 20$ d (µg/ml),

the amount of silicon X (mg) in the solution shall be determined as follows:

at day 0 $X \text{ mg} = (x_0 \times V)/1\,000$;

at day 10 $X \text{ mg} = (x_1 \times V)/1\,000 + (x_0 \times V_{P1})/1\,000$;

at day 20 $X \text{ mg} = (x_2 \times V)/1\,000 + (x_1 \times V_{P2})/1\,000$;

etc.

The slope of the curve corresponds to the mean amount of silicon released in a day as a function of the time.

The elemental silicon given by ICP-OES shall be converted into the total amount of silicone. This conversion is done to determine the total amount of polydimethylsiloxane released from individual implants. The concentration, expressed mole to mole, is calculated from the silicon concentration (parts per million) to the mass (mg) of silicone.

The value of the silicone/silicon ratio is calculated from the theoretical ratio given by the 12th edition of the Merck Index (part dimethicone) with the pattern [-$(CH_3)_2$Si-O-]: silicon × 2,64 = silicone.

NOTE It is common knowledge that silicone is not the only source for silicon within an implant. Therefore this calculation does not reflect the real release of silicone.

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