INTERNATIONAL STANDARD

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Implants for surgery — Specific requirements for mammary implants

Implants chirurgicaux — Exigences spécifiques relatives aux implants mammaires

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14607 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Annexes A, B, C, D and E form a normative part of this International Standard.

Implants for surgery — Specific requirements for mammary implants

1 Scope

This International Standard provides specific requirements for mammary implants for clinical practice.

With regard to safety, it specifies intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

NOTE At the time of publication, several test methods specified in the annexes were being validated. For the time being, where appropriate, disclosure statements are included in these annexes.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14630:1997, *Non-active surgical implants — General requirements*

NF T46-002:1988, *Vulcanized or thermoplastic rubber — Tensile test*

NF T46-007:1978, *Vulcanized rubbers — Determination of tear strength (angle tear test piece with or without nick and crescent test piece)*

NF S99-401:1994, *Medical devices — Silicone elastometer of medical grade*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 14630 and the following apply.

3.1
mammary implant
implant designed to add to or replace volume of the breast

3.2
shell
envelope of the implant

3.3
seam
seal
junction of materials fused or adhered together

3.4
valve
component into which an accessory is inserted to inflate variable-volume implants

3.5
injection site
component designed to be penetrated by a needle to alter the volume of the implant

3.6
diffusion
movement of material in the single direction out of an implant through an intact shell

3.7
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

3.8
anterior projection
maximum height of the implant when placed with its base on a flat horizontal surface at its nominal volume

3.9
orientation means
mark in or on the implant to assist the surgeon in positioning the implant

4 Intended performance

The requirements of ISO 14630:1997, clause 4, apply.

5 Design attributes

The requirements of ISO 14630:1997, clause 5, apply.

6 Materials

The requirements of ISO 14630:1997, clause 6, apply.

In addition, if silicone elastomer is used, NF S99-401 applies.

With regard to device failure, special attention shall be given to the biological evaluation of the device and any components that may be exposed to tissue as a result of implant rupture. Biological evaluation should be in accordance with the principles set out in ISO 10993-1.

7 Design evaluation

7.1 General

The requirements of ISO 14630:1997, clause 7, apply.

7.2 Pre-clinical evaluation

7.2.1 General

The pre-clinical evaluation of mammary implants shall conform to ISO 14630:1997, 7.2.

NOTE With regard to validated test methods available for pre-clinical evaluation, this International Standard reflects the present state of the art. Tests for the evaluation of abrasion of mammary implants and for the evaluation of gel bleeding of mammary

implants *in vitro* are currently under development. As soon as acceptable and validated test methods are available, these will be considered for inclusion in this International Standard by amendment or revision.

The sample size selected shall be based on a statistical rationale which shall be justified and documented. In addition the items of 7.2.2 to 7.2.9 shall be addressed (where applicable).

Where appropriate for materials other than silicone, the manufacturer should consider and develop tests as indicated in 7.2.

7.2.2 Shell integrity

The integrity of the shell shall be evaluated.

The integrity of the silicone elastomer shall be tested in accordance with annex B and shall comply with the stated requirements.

For other materials, it is recommended that tests with similar conditions be developed.

7.2.3 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.

7.2.4 Filling material

If silicone is used as filling material, the cohesion of silicone gel shall be tested in accordance with annex D and shall comply with the stated requirements.

A similar test for filling materials other than silicone gel shall be validated.

7.2.5 Mechanical tests

7.2.5.1 General

Mechanical tests shall be conducted in accordance with annex E and shall comply with the stated requirements.

7.2.5.2 Fatigue test

The fatigue 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.

7.2.5.3 Impact resistance test

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

7.2.5.4 Diffusion test

Gel diffusion shall be evaluated.

NOTE No validated test method is currently available. The test method and requirements for this clause are under consideration.

Where no test method is described in this International Standard, description of the validated test method and sample preparation used should be documented by the manufacturer.

7.2.5.5 Abrasion test

The abrasion properties shall be evaluated.

NOTE No validated test method is currently available.

The methodology outlined in ASTM D 3389 is recommended as a guide. This method applies to all implants with the exclusion of implants with a silicone elastomer shell filled with silicone gel.

7.2.6 Volume

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

7.2.7 Dimensions

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

7.2.8 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 test results shall be recorded.

7.2.9 Biological evaluation, toxicokinetics and degradation studies

The implant shall be evaluated for biological safety, including reproductive toxicity and mutagenicity and immunogenicity.

NOTE Evaluation may include a study of relevant experience and/or actual testing. Such an evaluation can result in the conclusion that no testing is needed if the material has a demonstrable history of use in a specified role that is equivalent to that of the device under design (ISO 10993-1:1997, clause 6).

7.3 Clinical evaluation

The requirements of ISO 14630:1997, 7.3, apply.

8 Manufacturing

The requirements of ISO 14630:1997, clause 8, apply.

9 Sterilization

Implants shall be supplied sterile.

The requirements of ISO 14630:1997, 9.1 and 9.3, apply.

10 Packaging

The requirements of ISO 14630:1997, clause 10, apply.

11 Information supplied by the manufacturer

11.1 General

The requirements of ISO 14630:1997, clause 11, apply, together with the following.

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 14630:1997, 9.2, shall apply.

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

11.3 Dimensions

Base dimensions, anterior projection or 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 shall be stated.

11.5 Filling materials

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

11.6 Marking on implants

The nominal volume or size shall be indicated.

11.7 Information on expected lifetime

The manufacturer shall provide relevant information on the expected duration of performance of the device as intended. Such relevant information includes the indication of factors which 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 out of the control of the manufacturer. These factors may 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.

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 are

— by indicating a probability of lifetime reaching an expected value,

— by indicating a range within which such a lifetime is anticipated to lie, or

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

NOTE 2 The results of tests indicated within this International Standard provide useful data for the manufacturer in his assessment process to provide information on anticipated lifetime.

11.8 Labelling: additional labels

The package shall include at least two additional labels.

Each label shall list the following:

a) name or trade name of the manufacturer;

b) details necessary for identification;

c) the serial number or batch code.

NOTE Details of identification could include:

— commercial reference of the prosthesis;

— prosthesis description;

— filling volume;

— patient name;

— left or right (tick as appropriate).

Annex A
(normative)

Surface characteristics

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 from each sampling area. The samples shall include at least three samples taken from the base, the radius and the apex of the implant (total of nine). They shall be representative of the surface as a whole. The average measurements and standard deviation of the characteristics shall be recorded.

NOTE 1 The data resulting from the test at this point in time cannot be related to the performance or safety of the device. The data are meant to generate information to improve knowledge on the correlation of texture and performance.

NOTE 2 For manufacturing control (QA), other methods (stylus, laser, etc.) calibrated against the SEM, are allowed.