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Non-active surgical implants — Mammary implants — Particular requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

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Contents

Page

iTeh STANDARD PREVIEW
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ISO 14607:2007
https://standards.iteh.ai/catalog/standards/sist/0d80c7c6-c022-426a-82d9-c56846530c32a/iso-14607-2007

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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).

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

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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.

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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.

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

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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.

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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 14607:2007
https://standards.iteh.ai/catalog/standards/sist/0d80c7e6-c022-426a-82d9-
standards/sist/0d80c7e6-c022-426a-82d9-14607-2007

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)

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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

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3.8
shell
envelope of the implant

ISO 14607:2007
https://standards.iteh.ai/catalog/standards/sist/0d80c7e6-c022-426a-82d9-c5684653c32a/iso-14607-2007

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.

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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.

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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.

ISO 14607:2007
https://standards.iteh.ai/catalog/standards/sist/0d80e7c0-c022-426a-82d9-e5684653c32a/iso-14607-2007

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.

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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.

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7.2.2.2.3 Tear resistance

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

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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.

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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 × 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.

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7.2.2.5.4 Static rupture resistance test

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

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7.2.2.6 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.

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.

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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.

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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.

ISO 14607:2007
https://standards.iteh.ai/catalog/standards/sist/0ab9c760-c022-42ba-82e0-c568462c3c32/iso-14607-2007

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.

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