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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*,

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This third edition cancels and replaces the second edition (ISO 14607:2007), which has been technically revised.

The main changes compared to the previous edition are as follows:

— limit values for trace elements have been added (6.4);

— determination of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in silicone gels (new Annex A) has been included;

— mechanical test on a mammary implant in its implantable state (new Annex C, previously Annex E), specifically the fatigue test (C.1), has undergone major revision;

— test for silicone gel penetration (silicone filling materials only) (new Annex F) has been included;

— silicone diffusion assessment from mammary implants by an *in vitro* method (new Annex G, previously Annex H) has undergone major revision;

— test for surface characteristics (new Annex H, previously Annex A) has undergone major revision.

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This corrected version of ISO 14607:2018 incorporates the following corrections:

— In B.2.2, second paragraph, "shell adjacent to the bonded area," has been changed to "test specimen", "," after " Figure B.2" has been deleted , and "held" has been changed to "maintained".

— In B.2.3, first paragraph, "shell adjacent to the bonded area" has been changed to "test specimen designated l_0 in Figure B.1 and Figure B.2" and "held" has been changed to "maintained".

— “prostheses projection” has been replaced by “anterior projection” in two instances, in C.1.6 a) and C.2.5 a).

— “implant projection” has been replaced by “anterior projection” in two instances, in C.2.3 c).

— In G.2.4, first paragraph, “for meeting” has been deleted.

— In G.3.2, third paragraph, “6 Vi ± 0,03Vi” has been replaced by “6,00 Vi ± 0,03Vi”.

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Introduction

There are three levels of International Standards dealing with non-active surgical implants. These are as follows (with level 1 being the 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 document 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, the lowest available level is the level to start with.

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Non-active surgical implants — Mammary implants — Particular requirements

1 Scope

This document specifies particular requirements for mammary implants.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 34-1:2015, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

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ISO 37:2017, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 4287, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

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ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of materials*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ASTM D412−16, *Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension*

ASTM D624−00 (2012), *Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications*

ASTM D792−13, *Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement*

ASTM D2240−15, *Standard Test Method for Rubber Property — Durometer Hardness*

3 Terms and definitions

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

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ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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

Note 1 to entry: For inflatable and adjustable implants, this applies to the implant's nominal volume.

3.2
base dimension
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

Note 1 to entry: For inflatable and adjustable implants, this applies to the implant's nominal volume.

3.3
cure
process of transforming uncured polymer into an elastic material through a covalent crosslinking reaction

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3.4
diffusion
movement of material in and/or out of an implant through an intact shell

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3.5
filling volume
volume of the material contained within the shell or volume of the solution necessary to fill an inflatable or adjustable mammary implant

3.6
implant volume
volume of the shell and filler material together

3.7
injection site
component designed to be penetrated by a needle to alter the volume of the implant

3.8
mammary implant
implant with a shell which has been filled by the *manufacturer* (3.9) or is designed to be filled by the surgeon, and is intended to add or replace volume of the breast

3.9
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

[SOURCE: ISO 10993-18:2005, 3.2]

3.10
orientation means
mark in or on the implant to assist the surgeon in positioning the implant

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3.11
shell
envelope of the *mammary implant* (3.8)

3.12
seam
seal junction of implant materials fused or adhered together

3.13
silicone elastomer
synthetic rubber obtained by the crosslinking of silica reinforced silicone polymer chains essentially made of repeat diorganosiloxane units

3.14
silicone gel
partially crosslinked silicone polymer, featuring a semisolid material consisting of crosslinked silicone polymer and liquid silicone polymer [silicone oil or polydimethylsiloxane (PDMS)])

3.15
silicone polymer
polymer chains essentially made of repeat diorganosiloxane units

3.16
supplier
company who manufactures and/or supplies the raw materials and components used for the production of mammary implants

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3.17
tensile set
tensile elongation remaining after a specimen has been stretched and allowed to relax in a controlled manner

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3.18
valve
shell component allowing inflation of mammary implant with variable volumes of liquids when needed and providing a tight closure the rest of the time

4 Intended performance

The requirements of ISO 14630:2012, Clause 4, shall apply.

5 Design attributes

The requirements of ISO 14630:2012, Clause 5, shall apply.

6 Materials

6.1 General

The requirements of ISO 14630:2012, Clause 6, shall apply.

Materials shall be manufactured and tested under a quality management system.

The information stated within Clause 6 shall be available from the manufacturer.

NOTE This information can typically be obtained from the raw material supplier.

When other materials than silicone are used, the manufacturer shall establish suitable test methods and acceptance criteria to demonstrate the appropriate performance and safety of the implant.

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6.2 Cytotoxicity

The components of each production raw material lot shall be cured and tested for cytotoxicity in accordance with ISO 10993-5. No cytotoxic effects, as defined in ISO 10993-5, shall be induced by the material tested, or throughout the culture.

6.3 Residual low molecular weight oligomers

The combined residual oligomers, cyclotetrasiloxane (D4) and cyclopentasiloxane (D5), in uncured or cured gel shall be tested in accordance with Annex A.

6.4 Trace elements

The components of each production raw material lot shall be in accordance with the Table 1 specifications on metal impurities.

Table 1 — Metals impurities limit content

Element	Content limit per element (mg/kg)
As, Pb, Cd, Hg, V, Mo, Se, Co, Sb, Ba, Cr, Cu, Sn, Ni	**≤10**

If one of these metals comprises part of the formulation component (for example $BaSO_4$), it is not considered an impurity, and shall be considered for the biological evaluation of the implant.

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6.5 Physico-mechanical properties and characterization

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The following mechanical characteristics of silicone elastomers, after cure, shall be available for every raw material lot:

— elongation at break (%), according to ISO 37:2017 or ASTM D412-16

— tensile strength at break (MPa) according to ISO 37:2017 or ASTM D412-16

— modulus at 100 % elongation (MPa), according to ISO 37; 2017 or ASTM D412-16

— hardness (IRHD), according to ASTM D2240-15 or ISO 7619-1

— relative density, or specific gravity, according to ASTM D792-13

— tear strength (kN/m), according to ISO 34-1:2015, Method C, or ASTM D624-00 (2012), Die B.

The penetration or bulk gel hardness of silicone gel, after cure, shall be available for every raw material lot.

6.6 Documentation of materials

The manufacturer shall require from the supplier for each type of material, a certificate of analysis including at least the following information:

a) supplier's name, address and telephone number;

b) material reference;

c) for silicone material the range of properties (as defined in 6.5), with defined specification limits and test methods, including cure conditions. For other materials, same type of information shall be required, if applicable.

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7 Design evaluation

7.1 General

The requirements of ISO 14630:2012, 7.1, shall apply.

The design of mammary implants shall be based on a risk assessment 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.

7.2 Pre-clinical evaluation

7.2.1 General

The pre-clinical evaluation of mammary implants shall conform to ISO 14630:2012, 7.2, and fulfil the requirements of ISO 10993-1.

The texture of the breast implant shell is to be taken into account when demonstrating biocompatibility.

Extrapolation of biocompatibility data for smooth breast implants is not sufficient for demonstrating the biocompatibility of textured breast implants.

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

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All testing samples shall be representative of finished sterilized devices.

A worst-case assumption shall be considered.

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The sample size selected shall be based on a statistical rationale, which shall be justified and documented. Where appropriate, for materials other than silicone, the manufacturer shall consider and develop tests as indicated in 7.2.2 to 7.2.5.

7.2.2 Mechanical tests

7.2.2.1 Shell integrity

7.2.2.1.1 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.

7.2.2.1.2 Elongation

The elongation of the silicone elastomer shell shall be tested in accordance with B.1.2.

7.2.2.1.3 Tensile set

The tensile set of the silicone elastomer shell shall be tested in accordance with B.1.3.

7.2.2.1.4 Strength of joints, seams or seals

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

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7.2.2.2 Implant resistance

7.2.2.2.1 Fatigue resistance test

The fatigue resistance test shall be conducted in accordance with C.1.

7.2.2.2.2 Impact resistance test

The impact resistance test shall be conducted in accordance with C.2.

7.2.3 Physical evaluation

7.2.3.1 Design of shell

Surfaces both inside and outside of the shell shall be suitable to minimize 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.

7.2.3.2 Valve or injection site competence

The competence of the valve or injection site shall be tested in accordance with Annex D.

7.2.3.3 Filling material

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7.2.3.3.1 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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7.2.3.3.2 Silicone gel cohesion

If silicone gel is used as filling material, cohesivity testing shall be performed in accordance with Annex E.

7.2.3.3.3 Silicone gel penetration

Penetration of silicone gel shall be evaluated. Testing to verify if specifications are met shall be performed in accordance with Annex F.

NOTE It is not possible to perform this test on a finished device. Therefore, it is usually performed as a process control (see F.1).

7.2.3.4 Diffusion test

Diffusion from the whole implant shall be evaluated.

NOTE There are currently two test methods described in Annex G and ASTM F703-18 that might provide some valuable information concerning the diffusion. These two methods are given as examples but are not mandatory.

7.2.3.5 Volume

The volume of the implants filled by the manufacturer shall be within ±2,5 % of the implant volume stated on the labelling.

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7.2.3.6 Dimensions

The actual device base dimensions and anterior projection shall be measured and recorded.

7.2.3.7 Surface

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

Annex H can be used as a guide.

7.2.3.8 Surface contamination

The manufacturer shall conduct a risk assessment to define appropriate limits for particulate contamination of the surface of the finished mammary implant.

7.2.4 Chemical evaluation

Each shell, filler material and, if applicable, coating material shall be chemically evaluated in accordance with ISO 10993-18.

7.2.5 Biological evaluation

The implant shall be evaluated in accordance with the requirements of ISO 10993-1, within a risk management process.

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7.3 Clinical evaluation

The requirements of ISO 14630:2012, 7.3, shall apply.

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

7.4 Post-market surveillance

The requirements of ISO 14630:2012, 7.4, shall apply.

8 Manufacturing

The requirements of ISO 14630:2012, Clause 8, shall apply.

9 Sterilization

The requirements of ISO 14630:2012, 9.1, 9.2 and 9.4, shall apply.

Implants shall be supplied sterile.

10 Packaging

The requirements of ISO 14630:2012, Clause 10, apply.

Packaging design shall be validated according to ISO 11607-1.

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