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Non-active surgical implants — Mammary implants — Specific requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

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Foreword

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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 document 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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This fourth edition cancels and replaces the third edition (ISO 14607:2018), which has been technically revised.

The main changes are as follows:

— trace elements subclause (6.4) was revised;

— language regarding biological evaluation and risk management was revised and expanded in the general part of the pre-clinical evaluation subclause (7.2.1);

— contamination subclause was re-named to particulate contamination (7.2.3.8) and completely revised;

— requirements regarding implantation studies were added (7.2.5);

— clinical evaluation requirements were expanded (7.3);

— surface category was added to the label requirements (11.3);

— Annex C “Mechanical tests on a mammary implant in its implantable state” was expanded and revised;

— the fatigue resistance testing method (Clauses C.1 and C.3) was revised and expanded;

— Annex F “Test for silicone gel penetration (silicone filling materials only)” was re-structured and the language clarified;

— Annex G “Assessment of silicone diffusion from mammary implants using an in vitro method” was deleted because it was agreed that the test method given in the Annex did not accomplish its purpose;

— Annex H "Test for surface characteristics" was re-numbered to Annex G, re-named to "Surface classification" and changed to normative, completely revised and an expanded surface classification was added;

— Annex J "Tests for surface particulate contamination" was newly added;

— the language of test report subclauses in all Annexes was harmonized as much as possible.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 3 standard and contains specific requirements for 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.

Non-active surgical implants — Mammary implants — Specific requirements

1 Scope

This document specifies specific 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 34-1:2022, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 37:2024, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by 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 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

ISO/TS 10993-20, *Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices*

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 14630:2024, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 21920-2, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters*

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

ASTM D624-00 (2020), *Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications*

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

ASTM D2240, *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.

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

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

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

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 cross-linking *silicone polymers* (3.17)

3.4
diffusion
movement of material in and/or out of an implant through an intact *shell* (3.13)

3.5
filling volume
volume of the material contained within the *shell* (3.13) or volume of the solution necessary to fill an inflatable or adjustable *mammary implant* (3.8)

3.6
implant volume
volume of the *shell* (3.13) 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* (3.13) 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 the volume of the breast

3.9
manufacturer
natural or legal person who manufactures or fully refurbishes a medical device, or has a device designed, manufactured, or fully refurbished, and markets that medical device under its name or trademark

[SOURCE: ISO 10993-18:2020, 3.23]

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

3.11
particle-free water
purified water that has been passed through a suitable filter of 0,22 µm pore size

[SOURCE: USP 43-NF 38 – Reagent Specifications[8]]

3.12
particulate contamination
extraneous particles that are unintentionally present on the surface of an implant

Note 1 to entry: Particulate contamination can come from many sources during the manufacturing process.

3.13
shell
envelope of the *mammary implant* (3.8)

3.14
seam
seal junction of implant materials fused or adhered together

3.15
silicone elastomer
synthetic rubber obtained by the cross-linking of silica-reinforced *silicone polymer* (3.17) chains essentially made of repeated diorganosiloxane units

3.16
silicone gel
semi-solid material consisting of cross-linked *silicone polymer* (3.17) and liquid silicone polymer [silicone oil or polydimethylsiloxane (PDMS)]

3.17
silicone polymer
polymer chains essentially made of repeated organosiloxane units

Note 1 to entry: The silicone polymers can be presented in many levels of viscosity.

3.18
supplier
company which manufactures and/or supplies the raw materials and components used for the production of *mammary implants* (3.8)

3.19
tensile set
tensile elongation remaining after a specimen has been stretched and allowed to relax in a controlled manner

3.20
valve
shell (3.13) component allowing inflation of *mammary implant* (3.8) with variable volumes of liquids when needed and providing a tight closure the rest of the time

4 Intended performance

The requirements of ISO 14630:2024, Clause 4, shall apply.

5 Design attributes

The requirements of ISO 14630:2024, Clause 5, shall apply.

6 Materials

6.1 General

The requirements of ISO 14630:2024, Clause 6, shall apply.

Materials should be manufactured and tested under an appropriate quality management system.

NOTE ISO 13485 is an example of quality management standard, which can be appropriate depending on local or regional regulation.

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

6.2 Cytotoxicity

Each raw material lot shall be tested for cytoxicity in accordance with ISO 10993-5. The test specimens shall be representative of the materials used in the manufacture of mammary implants and should be cured as appropriate in advance of testing. No cytotoxic effects, as defined in ISO 10993-5, shall occur.

6.3 Silicone gel residual low molecular weight oligomers

The combined residual oligomers, octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6), in uncured or cured silicone gel shall be tested in accordance with Annex A. These shall be reported in mg/kg and the total concentration of D4, D5, D6 combined shall not exceed 150 mg/kg (see also Clause A.9).

6.4 Trace elements

6.4.1 General

The presence of trace elements in raw materials can have two distinct sources.

— The first source is unintentional: they generally are residual substances entrapped into the ingredients used to formulate the raw materials. As such, they can be considered as impurities and shall not be present above a defined content limit, as reported in Table 1.

— The second source is intentional, that is, they are part of the product formulation. Typical examples of such intentional elements are some metals, like Platinum (Pt), used under the form of a complex to catalyse the curing reaction of some silicones. In this case, they shall not be considered as impurities and shall rather be taken into account in the larger context of the toxicological evaluation of the implant.

6.4.2 Limits on trace elements present as impurities

Table 1 — Unintentional trace elements impurities limit content

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

6.4.3 Intentionally added trace elements

If one of these trace elements is part of the formulation component, it is not considered an impurity.

Two trace elements which are commonly added are Platinum (Pt) and Tin (Sn).

If the cross-linking reaction of some silicones used for breast implants is catalysed by a platinum complex, the concentration of platinum in the final silicone component after the cross-linking reaction should not exceed 30 mg/kg.

If the cross-linking reaction of some silicones used for breast implants is catalysed by a tin complex, the concentration of tin in the final silicone component after the cross-linking reaction should not exceed 450 mg/kg.

6.5 Physico-mechanical properties and characterization

The following mechanical characteristics of the shell material (e.g. silicone elastomers, after cure) shall be available for every raw material lot:

— elongation at break, in percentage (%), in accordance with ISO 37 or ASTM D412;

— tensile strength at break, in megapascals (MPa), in accordance with to ISO 37 or ASTM D412;

— modulus at 100 % elongation, in megapascals (MPa), in accordance with ISO 37 or ASTM D412;

— hardness, in accordance with ASTM D2240 or ISO 48-4;

— relative density or specific gravity, in accordance with ASTM D792;

— tear strength, in kilonewtons per meter (kN/m), in accordance with ISO 34-1:2022, Method C, or ASTM D624-00 (2020), Die B.

Every raw material lot of silicone gel shall be tested in accordance with Annex F and shall comply with the specifications of the raw material manufacturer.

6.6 Documentation of materials

For each type of material, the manufacturer shall have available a certificate of analysis including at least the following information:

a) supplier's name, address and contact details;

b) material reference;

c) test result including test methods applied for 6.2;

d) for silicone gels test results including sample preparation (e.g. cure condition) for 6.3;

e) test results including the test methods and sample preparation applied for 6.4;

f) test results including defined acceptance criteria, test methods applied and sample preparation (e.g. cure condition) for 6.5.

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

7 Design evaluation

7.1 General

The requirements of ISO 14630:2024, 7.1, shall apply.

An appropriate risk management process in accordance with ISO 14971 shall be established for all stages in the life cycle of the implant.

7.2 Pre-clinical evaluation

7.2.1 General

The pre-clinical evaluation of mammary implants shall conform to ISO 14630:2024, 7.2, and fulfil the requirements of ISO 10993-1.

Under ISO 10993-1, the biological evaluation of any material or medical device intended for use in humans shall form part of a structured biological evaluation programme within a risk management process in accordance with ISO 14971. Part of this risk management process involves the identification of clinical safety signals attributed to the device, biological hazards, estimation of the associated biological risks, and the determination of their acceptability.

The texturing technique, surface roughness, surface complexity, and pore size (as described in Annex G), of the breast implant outer surface, shall be taken into account when performing biological evaluation.

The use of extrapolated data from other breast implants can be sufficient to demonstrate biological safety only if these data are from implants with the same surface texturing technique and surface roughness grade as the implant under assessment. See Annex G for details regarding surface texturing technique. More requirements on biological evaluation are described in 7.2.5. When evaluating products with new surface texturing technique all new data shall be generated, unless otherwise justified.

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.

All testing samples shall be representative of finished sterilized devices.

A worst-case assumption shall be considered.

If the sample size is not specified in the applicable test method, 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.2.1.

7.2.2.1.3 Tensile set

The tensile set of the silicone elastomer shell shall be tested in accordance with B.2.2.

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 Clause B.3.