International Standard

ISO 14607

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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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) has been revised;

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

— contamination subclause has been renamed to particulate contamination (7.2.3.8) and completely revised;

— requirements regarding implantation studies have been added (7.2.5);

— clinical evaluation requirements have been expanded (7.3);

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

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

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

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

— Annex G “Assessment of silicone diffusion from mammary implants using an in vitro method” has been deleted as the test method given in the annex did not accomplish its purpose;

— Annex H “Test for surface characteristics” has been re-numbered as Annex G and has been renamed “Surface classification”, its status has been changed to normative, it has completely revised and an expanded surface classification has been added;

— Annex J “Tests for surface particulate contamination” has been newly added;

— the language of test report subclauses in all annexes has been 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 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

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]