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Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants

Implants chirurgicaux — Essais non destructifs — Contrôle radiographique des implants chirurgicaux métalliques moulés

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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*, Subcommittee SC 1, *Materials*.

This second edition cancels and replaces the first edition (ISO 9584:1993) which has been technically revised.

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

— normative references, and terms and definitions have been updated;

— applicable radiographic approach for components based on Co, Fe and Ti alloys have been added;

— applicable requirements for image quality indicator, acceptance limits and personal certification have been added.

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.

Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants

1 Scope

This document establishes a method for detecting and evaluating internal imperfections of cast metallic surgical implants and related weldments.

The procedures established in this document apply to film-based methods.

The recommendations on the acceptance limits for internal imperfections in cast metallic surgical implants are given in Annex A.

NOTE In this document, when not otherwise specified, the term "manufacturer" refers to the "implant manufacturer", and the term "product" refers to the "metallic cast implant for surgery" or to the "component of metallic cast implant for surgery".

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 5576, *Non-destructive testing — Industrial X-ray and gamma-ray radiology — Vocabulary*

ISO 5579, *Non-destructive testing — Radiographic testing of metallic materials using film and X- or gamma rays — Basic rules*

ISO 5580, *Non-destructive testing — Industrial radiographic illuminators — Minimum requirements*

ISO 9712, *Non-destructive testing — Qualification and certification of NDT personnel*

ISO 19232-1, *Non-destructive testing — Image quality of radiographs — Part 1: Determination of the image quality value using wire-type image quality indicators*

ISO 19232-2, *Non-destructive testing — Image quality of radiographs — Part 2: Determination of the image quality value using step/hole-type image quality indicators*

ISO 19232-3, *Non-destructive testing — Image quality of radiographs — Part 3: Image quality classes*

ASTM F629, *Standard Practice for Radiography of Cast Metallic Surgical Implants*[1)]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 5576 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/

1) Where indicated in the text, content has been modified and reprinted, with permission from ASTM F629, copyright ASTM International. A copy of the complete standard may be obtained from www.astm.org.

3.1
image quality
characteristic of a radiographic image which determines the degree of detail it shows

[SOURCE: ISO 19232-1:2013, 3.1]

3.2
image quality indicator
IQI
device comprising a series of elements of graded dimensions which enable a measure of the image quality to be obtained

Note 1 to entry: The elements of IQI are commonly wires or steps with holes.

[SOURCE: ISO 19232-1:2013, 3.2]

3.3
image quality value
measure of the image quality required or achieved and is equal to the thinnest element which can be detected on the radiograph

[SOURCE: ISO 19232-1:2013, 3.3, modified — Note 1 to entry has been deleted.]

3.4
lot
total number of products manufactured from the material of the same metal pouring, processed under the same conditions and essentially at the same time

3.5
test object
material, component or assembly that is the subject of the radiographic examination

[SOURCE: ASTM F2895:2020, 3.2.27]

4 Inspection procedure

4.1 General

Radiographic examination of metallic surgical implant castings can create spurious indications resulting from grain diffraction patterns and actual imperfections.

Radiographic techniques shall be used which ensure that differences between such diffraction patterns and actual imperfections are distinguished.

4.2 Radiographic method

The radiographic method shall be in accordance with ISO 5579 or ASTM F629.

NOTE 1 Irradiation energy for radiographs of test objects with a 12,7 mm material thickness can be found in ASTM F629 (information in this note has been modified and reprinted from ASTM F629).

Radiographic method parameters, such as orientation of the irradiation beam and the number of exposures, shall be established by the manufacturer or purchaser based on the characteristics and applicable requirements of the product.

NOTE 2 Applicable approaches for radiographies of cobalt-, iron- and titanium-based products can be found in ASTM F629.

For the product provided by a third party or for radiographic service provided by a third party, the radiographic method shall be previously established by the manufacturer or purchaser.