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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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Contents

Page

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*

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/

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.[1)]

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.

1) Information in the NOTE has been extracted from ASTM F629, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken PA 19428. A copy of the complete standard can be obtained from ASTM.

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.

4.3 Image quality indicator

Each image quality indicator shall represent an area of interest of the object test.

An image quality indicator shall be included in all radiographic images for test object acceptance.

Image quality indicator material selection shall be based on ISO 19232-1 and ISO 19232-2, and be appropriate to the test specimen dimensions. Image quality indicators should be from the same or similar material as the test object. In the image quality indicator selection, the following can be considered (see ASTM F2895[8]):

a) replacement of high-density image quality indicators by less dense material image quality indicators;

b) replacement of thicker image quality indicators by thinner image quality indicators.

4.4 Image quality

The image quality shall be in accordance with ISO 19232-3.

The required image quality level of the radiographic image, unless otherwise established by the manufacturer or purchaser, shall be as follows:

a) at least an image quality level 2, for X-ray energies less than 500 kV;

b) at least an image quality level 4, for X-ray energies equal or greater than 500 kV.

NOTE 1 Image quality level N is a designation for expressing the quality image, where a hole corresponding to N times the thickness of the image quality indicator is visible in a radiographic image, which is obtained when using an image quality indicator whose thickness is no more than 2 % of the test object thickness.

NOTE 2 Image quality of radiographs can be found in ISO 19232-1 for wire-type image quality indicators and ISO 19232-2 for step/hole-type image quality indicators.

4.5 Radiographic examination

Radiographic films shall be examined under illumination in accordance with ISO 5580.

NOTE Guidance for radiographic examination can be found at ASTM E1742/E1742M[4].

5 Inspection levels

Unless otherwise established and justified by the manufacturer or purchaser, the inspection shall be 100 % of the lot.

6 Acceptance limits

The product acceptance and rejection criteria for internal imperfections shall be established by the manufacturer or purchaser in written specifications.

These criteria shall consider acceptance limits for size, number, separation and density (image) for single imperfections and for group of imperfections.

Unless otherwise established and justified by the manufacturer or purchaser, imperfections of linear nature (ratio length to width greater than 3 to 1) shall not be accepted.

NOTE 1 Useful radiographic images to be used as reference in product inspection can be found in ASTM E192[2], ASTM E1320[3], ASTM E2660[6] and ASTM E2669[7].

NOTE 2 Recommended acceptance limits are given in Annex A.

7 Personnel certification

7.1 Radiographic imaging

Personnel taking the radiographic image shall be certified to level I as specified in ISO 9712.

7.2 Radiographic examination

Personnel examining the radiographic image shall be certified to level II or III as specified in ISO 9712 and shall be specifically trained for the product range of medical implants.

8 Report

A record of radiographic examination results shall be maintained, including any rejected pieces.

The radiographs and their evaluations shall be documented so that they are traceable to the examined product.

The manufacturer or purchaser shall establish the storage format in order to ensure the image quality level of the implant evaluation.

Reports and radiographs shall be maintained in accordance with applicable requirements for the product good manufacturing practice.

For radiographic services supplied by third party, unless otherwise requested by the manufacturer or purchaser, the radiographs shall be supplied together with the test object.

NOTE Useful information concerning different types of inspection documents supplied to the purchaser for the delivery of metallic products, including the validation and transmission of inspection documents, can be found in EN 10204[1].

Annex A
(informative)

Radiographic examination of cast metallic surgical implants — Acceptance limits for internal imperfections

A.1 Recommended acceptance limits

The manufacturer's or purchaser's acceptance and rejection criteria should describe type, size and separation of acceptable imperfections in relation to the inspection area.

For this, the manufacturer or purchaser should indicate on drawings the different inspection areas of the products (see Clause A.2). According to the stress level in the inspection areas, the acceptance limits as given in Table A.1, for single imperfections, and Table A.2, for group of imperfections, are recommended.

A.2 Inspection areas

The stress level in the inspection areas, as function of the imperfection acceptance limits, should be indicated as A, B, C, D or E, both for single imperfections and for group of imperfections.

Table A.1 — Recommended limits for size, number, separation and (image) density for single imperfections (voids, inclusions, less density)

Maximum length[a] d mm	Minimum separation mm	Maximum image density		Maximum numbers[b] per inspection area[c]				
		shallow	medium	A	B	C	D	E
0,25 ≥ d ≥ 0,50	1	X	—	0	2	2	3	4
		—	X	0	1	1	1	2
0,5 > d ≥ 1,0	2	X	—	0	1	2	2	2
		—	X	0	0	1	1	2
1,0 > d ≥ 1,5	3	X	—	0	0	1	1	2
		—	X	0	0	0	0	1
1,5 > d ≥ 2,0	4	X	—	0	0	0	1	2
		—	X	0	0	0	0	1

[a] Length imperfection lower than 0,25 mm should be disregarded.

[b] If larger imperfections are not present, smaller imperfections should be accepted up to the maximum number allowed for all imperfection's sizes of the inspection areas.

[c] 25 mm length at any 25 mm by 25 mm surface area that exists in the designated zone.

Table A.2 — Recommended limits for size, number, separation and (image) density for group of imperfections (porosity shrinkage)

Maximum length[a] *d* mm	Minimum separation mm	Maximum image density		Maximum numbers[b] per inspection area[c]				
		shallow	medium	A	B	C	D	E
≤ 1,5	3	X	—	0	0	2	3	4
		—	X	0	0	1	1	2
1,5 > d ≥ 3,0	6	X	—	0	0	1	1	2
		—	X	0	0	0	0	1
3,0 > d ≥ 5,0	10	X	—	0	0	0	1	2
		—	X	0	0	0	0	1

[a] The maximum length should be the diameter in which all single imperfections of the group are contained. Single imperfections with lengths lower than 0,25 mm should be disregarded.

[b] If larger imperfections are not present, smaller imperfections should be accepted up to the maximum number allowed for all imperfection's sizes of the inspection areas.

[c] Any 25 mm by 25 mm surface area that exists in the designated zone.