INTERNATIONAL STANDARD

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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

Reference number
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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9584 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee SC 1, *Materials*.

Annex A of this International Standard is for information only.

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

1 Scope

This International Standard establishes a method for detecting and evaluating internal imperfections of cast metallic surgical implants.

Guidance on the acceptance limits for internal imperfections in cast metallic surgical implants is given in annex A.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1027:1983, *Radiographic image quality indicators for non-destructive testing — Principles and identification.*

ISO 5579:1985, *Non-destructive testing — Radiographic examination of metallic materials by X- and gamma rays — Basic rules.*

ISO 5580:1985, *Non-destructive testing — Industrial radiographic illuminators — Minimum requirements.*

ASNT-SNT-TC-1A,[1] *Personnel qualification and certification in non-destructive testing.*

1) American Society for Non-destructive Testing

3 Definitions

The terms used in this International Standard are defined in ISO 5576.

4 Procedure

4.1 Radiographic method

The radiographic method shall be in accordance with the requirements in ISO 1027 and ISO 5579.

4.2 Illumination of radiographs

Radiographs shall be examined under illumination complying with the requirements of ISO 5580.

Radiographic examination of metallic surgical implant castings may 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.

4.3 Image quality

For X-ray energies less than 500 kV, the quality level for radiography shall be either:

— at least 2 % (2-2T) in accordance with the method in ASTM E 142, or

— an equivalent image quality number (IQN) in accordance with ISO 1027.

For high energy X-rays (greater than 500 kV), a (2-4T) image quality or an equivalent IQN in accordance with ISO 1027 shall be satisfactory.

5 Inspection levels

Unless otherwise requested by the manufacturer or purchaser of the implant, the inspection shall be 100 % of the lot.

6 Acceptance limits

The product acceptance and rejection criteria for internal imperfections shall be established by written specifications. Recommended acceptance limits are given in annex A.

7 Documentation

7.1 Radiographs

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

Unless otherwise requested by the purchaser, the radiographs shall be supplied together with the implants.

7.2 Report

A record of radiographic examination results shall be maintained.

8 Personnel certification

The personnel performing radiographic examination in accordance with this International Standard shall be certified to level 2 as specified in ASNT-SNT-TC-1A or recognized national equivalents and shall be specifically trained for the product range of medical implants.

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 metallic surgical implants (see A.2). According to the stress level in the inspection areas, the acceptance limits as given in table A.1 are recommended.

A.2 Inspection areas

A
B
C
D
E

} To be indicated by the manufacturer or purchaser

Table A.1 — Recommended limits for size, number, separation and (image) density for single imperfections and group of imperfections

Type of imperfection[1]	Maximum length[2] mm	Minimum separation mm	Maximum image density		Maximum number[3] per 25 mm inspection area length[4]				
			shallow	medium	A	B	C	D	E
Single imperfection (voids, inclusions, less density)	0,25 to 0,5	1	×	–	0	2	2	3	4
			–	×	0	1	1	1	2
	> 0,5 to 1	2	×	–	0	1	2	2	2
			–	×	0	0	1	1	2
	> 1 to 1,5	3	×	–	0	0	1	1	2
			–	×	0	0	0	0	1
	> 1,5 to 2	4	×	–	0	0	0	1	2
			–	×	0	0	0	0	1
					Maximum number per inspection area				
Group[5] of imperfections (porosity shrinkage)	⩽ 1,5	3	×	–	0	0	2	3	4
			–	×	0	0	1	1	2
	> 1,5 to 3	6	×	–	0	0	1	1	2
			–	×	0	0	0	0	1
	> 3 to 5	10	×	–	0	0	0	1	2
			–	×	0	0	0	0	1

1) Linear imperfections (length:breadth > 3:1) should not be accepted.

2) Imperfections < 0,25 mm should be disregarded.

3) If larger imperfections are not present, smaller imperfections should be accepted up to the maximum number allowed for all sizes of the inspection areas.

In areas which are to be machined, the number of imperfections, imperfection size, intensity and separation are unlimited provided they are completely removed by the subsequent machining operation.

4) Any 25 mm by 25 mm surface area that exists in the zone designated.

5) For groups of imperfections, that is, single imperfections separated by less than twice the longest dimension of the longest imperfection, the maximum dimension should be the diameter in which all the single imperfections of the group are contained.

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