INTERNATIONAL STANDARD

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Implants for surgery — Non-destructive testing — Liquid penetrant inspection of metallic surgical implants

Implants chirurgicaux — Essais non destructifs — Contrôle par ressuage des implants chirurgicaux métalliques

Reference number
ISO 9583:1993(E)

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 9583 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 — Liquid penetrant inspection of metallic surgical implants

1 Scope

This International Standard establishes a method for detecting and evaluating imperfections revealed by liquid penetrant on the surfaces of metallic surgical implants.

Guidance on the acceptance limits for imperfections on metallic surgical implants in the raw and finally treated and finished conditions 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 3059:1974, *Non-destructive testing — Method for indirect assessment of black light sources.*

ISO 3452:1984, *Non-destructive testing — Penetrant inspection — General principles.*

ISO 3453:1984, *Non-destructive testing — Liquid penetrant inspection — Means of verification.*

ASTM D 95:1983, *Test method for Water in Petroleum Products and Bituminous Materials by Distillation.*

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

1) American Society for Non-destructive Testing

3 Inspection method

3.1 Inspection condition

The surfaces shall be cleaned in accordance with ISO 3452:1984, subclauses 6.2, 6.3 and 10.2 so that they are free of any material which would interfere with the penetration of the inspection fluid or would in itself retain the penetrant and result in false indications.

3.2 Procedure

The liquid penetrant inspection of metallic surgical implants shall be performed in accordance with ISO 3452 using the penetrant systems classified therein.

3.3 Penetrant materials

3.3.1 Sensitivity

According to type, stress category, material and manufacturing stage of the implant, penetrant material systems of normal, high or very high sensitivity shall be used. The sensitivity level shall be established by the manufacturer or purchaser.

3.3.2 Compatibility

In accordance with ISO 3452:1984, clause 6, all penetrant materials shall be compatible with each other.

4 Inspection level

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

5 Acceptance limits

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

6 Inspection documentation

The inspection results shall be documented so that they are traceable to the examined implants.

7 Penetrant materials control

NOTE 1 The efficiency of penetrant materials deteriorates due to contamination and ageing.

The following tests shall be conducted to evaluate usefulness of the materials.

7.1 Penetrants

The density, visible dye intensity and fluorescent dye intensity shall be checked in accordance with ISO 3453.

7.2 Emulsifiers

7.2.1 Water content

The water content of oil-base emulsifiers shall be determined by ASTM D 95 and shall not exceed 10 %. The frequency of testing shall be 30 days for open containers and 3 months for closed containers.

7.2.2 Penetrant contamination

The contamination of the emulsifier (oil-base and water-base) by the penetrant shall not exceed 10 %. The concentration of the penetrant shall be checked by a refractometer. For each emulsifier and/or emulsifier concentration used, a calibration for determining the refractometer correction shall be conducted.

The frequency of testing shall be weekly or before use, whichever of the two alternatives is the more frequent.

7.3 Developer

Dry and liquid developers shall be checked in accordance with ISO 3453.

7.4 Ultraviolet radiation lamp

Ultraviolet radiation lamps used for fluorescent penetrant inspection shall be checked for ultraviolet radiation output in accordance with ISO 3059. The frequency of testing shall be weekly.

8 Personnel certification

The personnel performing liquid penetrant inspection 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)

Liquid penetrant inspection of metallic surgical implants — Acceptance limits for surface 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 and separation for single and group of imperfections

Type of imperfection[1]	Maximum length[2] mm	Minimum separation mm	Maximum number[3] per 25 mm inspection area length[4]				
			A	B	C	D	E
Single imperfections[5] (voids, inclusions)	0,25 to 0,5	1	0	2	3	4	6
	> 0,5 to 1	2	0	1	2	3	4
	> 1 to 1,5	3	0	0	1	2	3
	> 1,5 to 2	4	0	0	0	1	2
	> 2 to 3	6	0	0	0	0	1
			Maximum number per inspection area				
Group[6] of imperfections (porosity)	≤ 2	3	0	0	2	3	6
	> 2 to 4	6	0	0	1	2	3
	> 4 to 6	10	0	0	0	1	2

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 and separation are unlimited provided they are completely removed by the subsequent machining operation.

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

5) The imperfections which should be evaluated may be larger than the defect size on the surface depending on the depth of the imperfections.

In order clearly to identify the imperfections size the wipe-off technique using a volatile remover liquid may be adopted.

6) 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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