

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*



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Foreword

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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.