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**Liquid penetrant inspection of
metallic surgical implants**

(ISO 9583:1993, NEQ)

外科金属植入物液体渗透检验

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Foreword

This Standard non-equivalently uses the international standard ISO 9583:1993 *Implants for surgery - Non-destructive testing - Liquid penetrant inspection of metallic surgical implants (English version)*.

This Standard lists the content of ISO 3452:1984 *Non-destructive testing - Penetrant inspection - General principles* which is in normative references of the international standard; see adoption explanation.

Due to the use of porous material made in China, therefore, control of the infiltration material in Clause 7 (except 7.4) quotes the corresponding provisions of HB/Z 61-1998 *Penetrant Inspection*, an aviation standard of People's Republic of China Ministry.

7.4 of this Standard identically uses 5.1.4 of ASTM F601-1992 *Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants*.

Annex A, Annex B of this Standard are normative.

Annex A provides the acceptable threshold level of discontinuities on the surface of surgical metal implants.

Annex B provides penetration testing procedures.

This Standard was proposed by and approved by China Drug Administration.

This Standard shall be under the jurisdiction of National Technical Committee on Surgical implants and Orthopedic Instruments of Standardization Administration of China (CSBTS/TC 110).

The drafting organization of this Standard: Tianjin Medical Device Quality Supervision and Inspection Center of China Drug Administration.

Main drafters of this Standard: Zhang Wenhui, Song Duo, Xing Jiaqiang.

Liquid penetrant inspection of metallic surgical implants

1 Scope

This Standard specifies the inspection methods, inspection level, acceptable limits, inspection records, penetrant material control, qualification examination of penetrant inspection personnel of liquid penetrant inspection of metallic surgical implants.

This Standard is applicable to inspect the discontinuities or defects on the surface of metallic surgical implants.

NOTE See GB/T 12604.3-1990 *Terminology for nondestructive testing - Penetrant testing* for terminology for nondestructive testing involved in this Standard.

2 Normative references

The following standards contain the provisions which, through reference in this Standard, constitute the provisions of this Standard. At the time of publication of this Standard, all editions indicated are effective. All standards shall be revised; the parties who enter into agreement based on this Standard are encouraged to investigate whether the latest versions of these documents are applicable.

HB/Z 61-1998 *Penetrant Inspection*

3 Inspection methods

3.1 Inspection conditions

The surface of test specimen shall be clean without any substance to impede liquid penetrant inspection or generate false penetrant indication.

3.1.1 Surface pre-cleaning¹

- 1) choose suitable cleaning material and process to remove the grease on the specimen surface;

¹ 6.2 in ISO 3452.

sensitivity, high sensitivity and super sensitivity. The sensitivity level is agreed by the manufacturer and the buyer of penetrant material via negotiation.

3.3.2 Applicability⁶

The penetrant material used shall be applicable to the material of test specimen. It shall consider the effect of long corrosion.

3.3.3 Cleaning after inspection⁷

After inspection, remove penetrant and developer. The residual of inspection material shall make specimen react with other factor to generate corrosive effect during use. In order not to interfere with subsequent processes or use requirements, in-time cleaning must be conducted after inspection.

4 Inspection level

Unless there are special requirements from the manufacturer or buyer of metallic surgical implants, 100% inspection shall be carried out for each batch of products.

5 Acceptable limit

The reference for product being accepted or rejected shall be specified in the given norm. See Annex A of this Standard for recommended acceptable limit.

6 Inspection record⁸

The inspection results shall be recorded so as to trace the metallic surgical implants for the inspection.

- a) determined inspection method and operation procedure;
- b) inspection data;
- c) determined personal qualification and signature;
- d) penetration techniques, ambient temperature, used penetrant material as well as manufacturer;
- e) suitable used sketch or description to determine all displayed locations and influential factors;

⁶ 6.1.1 in ISO 3452.

⁷ 11.1 in ISO 3452.

⁸ 13 in ISO 3452.

Annex A (Normative)

Liquid penetrant inspection of metallic surgical implants- Acceptable limit level of surface Discontinuous defects

A.1 Recommended acceptable limit level

The acceptable and rejection limit level of manufacturer or buyer is related to the shape, size and space of discontinuous defects in the inspection area.

The manufacturer and buyer shall indicate different inspection areas for metallic surgical implants (see A.2).

Table A.1 Limit levels of size, space and amount of recommended single or group surface discontinuous defects

Defect type	Maximum length mm	Minimum space mm	Maximum defect amount of each 25 mm × 25 mm of inspection area				
			A	B	C	D	E
Single defect (pore inclusion)	0.25 ~ 0.5	1	0	2	3	4	6
	> 0.5 ~ 1	2	0	1	2	3	4
	> 1 ~ 1.5	3	0	0	1	2	3
	> 1.5 ~ 2	4	0	0	0	1	2
	> 2 ~ 3	6	0	0	0	0	1
			Maximum defect amount of each area				
Group defect (loosening)	≥ 2	3	0	0	2	3	6
	> 2 ~ 4	6	0	0	1	2	3
	> 4 ~ 6	10	0	0	0	1	2

- 1) Linear defect size (length : width > 3:1) is not acceptable.
- 2) Size < 0.25 mm can be neglected.
- 3) In the inspection area, if there is no big defect, the sum of small defect size shall be accessed according to the maximum amount of acceptable limit level. There are several defects in the inspection area can be used for mechanical cutting. The size and space of defects cannot be limited because they can be dealt with by the later mechanical cutting.
- 4) Indicate any surface area of 25 mm × 25 mm.
- 5) According to the size and depth of discontinuous defect, access the surface discontinuous defect. It shall use the cleaning method for volatile solvent for clear recognizable defect size.
- 6) Group-shaped defect, i.e., single defect space is less than twice the maximum length of the maximum defect; group defect size includes the sum of all single defect size.

Annex B (Normative)

Penetrant inspection procedure

B.1 Inspection procedure

B.1.1 Penetration

B.1.1.1 Applied temperature

The temperature of test specimen surface and penetrant material must be within the range provided by the instruction on use of penetrant material manufacturer.

B.1.1.2 Penetrant application

The inspection surface shall be totally wetted and covered by penetrant. The penetrant can be applied by dipping, spraying (electrostatic spraying) and brushing.

B.1.1.3 Penetration time

Penetration time shall be in accordance with penetrant's characteristics, temperature for use, material for inspection and defect type. The penetrant must not be dried within the penetration time. In the penetration time, the complete wetting time for test specimen surface shall not be less than the time recommended by manufacturer. Longer penetration time shall display more obvious discontinuous defect.

B.1.2 Application of emulsifier

B.1.2.1 According to the penetrant type, after penetration, use dipping or spraying to apply the emulsifier on the surface for inspection.

B.1.2.2 Emulsification time is critical. It shall determine according to the structure of inspection surface and discontinuous defect type. Emulsification time shall be sufficient for water washing of inspection surface. However, it must not filter out the penetrant through over emulsification in discontinuous defect.

B.1.3 Removal of excess penetrant materials

B.1.3.1 General requirements

B.1.5 Application of photographic developer

B.1.5.1 Dry powder photographic developer

After the surface to be inspected is dried, apply the dry, loosening photographic developer which suits penetrant on the surface to be inspected, e.g., spraying, manual spreading, etc.

B.1.5.2 Liquid photographic developer

After the surface to be inspected is dried, it shall evenly apply the photographic developer which suits penetrant on the surface to be inspected. The application of photographic developer shall be performed in spraying, electrostatic spraying, dipping. Before applying, it shall make solid particle in the suspension uniformly distributed. Over thick liquid photographic developer layer may cause display blurred. After drying, the photographic developer shall display a thin, rough layer on the surface to be inspected.

B.1.6 Development time

After the photographic developer is applied, the surface to be inspected shall maintain sufficient development time. The development time shall be in accordance with used inspection material, material to be inspected and exist defect type. Generally, it should be 50% of penetration time. For small discontinuous defect, it can reach to penetration time. The maximum development time is usually twice the penetration time. If the penetration time is too long, it may cause reverse penetration of a great amount of penetrant in wide and deep discontinuous defect, which shall produce false indication caused by excess stain.

B.2 Inspection

B.2.1 Fluorescent penetrant inspection

During fluorescent penetrant inspection, the inspection room and area should be dark. It can use dark amber light to illuminate. The inspection should be performed under black light. The wavelength of black light is within 320 nm ~ 400 nm. The wavelength at the peak is 365nm. Before inspection, dark field adaptation time for inspection personnel should not be less than 5 min.

B.2.2 Dye penetration inspection

During dye penetration inspection, it should use day light or artificial light to illuminate in inspection area. The light intensity must not be less than 500 lx so as to make the surface to be inspected have an appropriate defect display. It shall prevent inspection under dazzling light.

B.2.3 Auxiliary observation

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