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AMERICAN SOCIETY FOR TESTING AND MATERIALS
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Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[1]

This standard is issued under the fixed designation F 601; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice is intended as a guide for fluorescent penetrant inspection of metallic surgical implants.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 95 Test Method for Water in Petroleum Products and Bituminous Materials by Distillation[2]

E 165 Test Method for Liquid Penetrant Examination[3]

E 433 Reference Photographs for Liquid Penetrant Inspection[3]

2.2 *ASNT Recommended Practice:*[4]

Recommended Practice No. SNT-TC-1A

2.3 *Military Standard:*[5]

MIL-I-25135 Inspection Material, Penetrant

3. Significance and Use

3.1 This practice is intended to confirm the method of obtaining and evaluating the fluorescent penetrant indications on metallic surgical implants.

3.2 The product acceptance and rejection criteria will be as agreed upon between the purchaser and the supplier.

4. Fluorescent Penetrant Method

4.1 Perform fluorescent penetrant inspection of metallic surgical implants in accordance with Practice E 165, Method A.

4.2 The penetrant system used shall conform to a minimum of Sensitivity Level 3, in accordance with the latest revision of MIL-I-25135.

4.3 All penetrant materials shall be compatible with each other.

5. Penetrant Method Materials Control

5.1 The penetrant method materials deteriorate in usefulness through contamination and age. The following controls should be used to evaluate the materials' usefulness unless the supplier's requirements are more stringent:

5.1.1 *Penetrants*:

5.1.1.1 *Water Content*—Where there is a possibility of water contamination to penetrant materials, the water content should be determined by Test Method D 95. The water content shall not exceed 10 %. The frequency of testing shall be at least once every 30 days for open containers.

5.1.1.2 *Fluorescent Brightness*—Fluorescent brightness should be determined at least once every 30 days or before use by comparison of samples of the working penetrant to a sample of new penetrant under black light. No visible difference shall be allowed.

5.1.2 *Developer*:

5.1.2.1 *Dry*—The developer should be dry and fluffy. Developers showing evidence of fluorescence when compared to new developer shall not be used.

5.1.2.2 *Wet*—A method should be employed to assure adequate suspension of the wet developer prior to use. The specific gravity of the developer should be from 1.018 to 1.034. This method does not apply to nonaqueous solvent developer due to the volatile nature of the product.

5.1.3 *Black Lights*—Black lights used for fluorescent penetrant inspection should be checked for black light output (with a filter) for a minimum of 800 μW/cm^2 at a distance of 381 mm (15 in.) from the lamp face. This measurement could be determined by using a calibrated black light meter. The

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[1] This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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[2] *Annual Book of ASTM Standards*, Vol 05.01.

[3] *Annual Book of ASTM Standards*, Vol 03.03.

[4] Available from American Society for Non-Destructive Testing, 3200 Riverside Dr., Columbus, OH 43221.

[5] Available form Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111–5094, Attn: NPODS.

frequency of testing shall be at least once every 7 days or before use.

6. Evaluation

6.1 A general method of evaluating fluorescent penetrant indications is encompassed in reference photographs E 433.

7. Personnel Certification

7.1 The personnel performing fluorescent penetrant inspection under this practice shall be certified in accordance with ASNT Recommended Practice No. SNT-TC-1A or recognized national equivalent.

8. Keywords

8.1 fluorescent; penetrant inspection; testing methods; surgical implants

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 A method of nondestructive inspection, known as fluorescent penetrant inspection, is employed as a quality control tool for surgical devices. This method of inspection is not only used by the manufacturers, but by their suppliers and also independent testing laboratories. This method has been used for over twenty years for the nondestructive examination of surgical implants and devices. Fluorescent penetrant inspection provides a sensitive method of detecting surface imperfections such as scratches, cracks, surface porosity, and welding joint imperfections.

X1.2 Fluorescent penetrant inspection uses a specially formulated penetrating oil, manufactured by many sources, which also has a fluorescent dye as part of its formula. The method of inspection allows for the fluorescent penetrating oil to enter surface discontinuities; a subsequent process removes all other surface remnants of the penetrating oil, thus leaving the fluorescent material only in surface discontinuities. A final "developer" is applied to bring out the penetrating oil from the discontinuities. Then an ultra violet light (black light) is used to inspect the part for the presence of the fluorescent material. This method allows for highly sensitive examination of small discontinuities that normally would not be visible by unaided visual inspection.

X1.3 Due to a variety of specifications being applied to the inspection of surgical implants and devices, a task force was formed under Committee F-4 to standardize methods for fluorescent penetrant inspection of metallic surgical implants; the result was Practice F 601. The task force, comprised of a large cross section of manufacturers, testing experts, government representatives, and other interested parties, developed a universally accepted practice for surgical implants and devices.

X1.4 This is a *standard practice* and is only intended to confirm the standardized method of obtaining and evaluating the fluorescent penetrant indications, as well as the evaluation of the materials used in the testing method. This practice is not intended to set acceptance standards; this type of specification would be extremely difficult due to such variables as surface finish (that is, mechanically polished, vapor blasted, electro polished, etc.); manufacturing method (that is, wrought, forged, cast, etc.); as well as other variables in surface texture.