

Designation: F601 - 13

Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants¹

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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:²

D95 Test Method for Water in Petroleum Products and Bituminous Materials by Distillation

E165 Practice for Liquid Penetrant Examination for General Industry

E1135 Test Method for Comparing the Brightness of Fluorescent Penetrants

E1417 Practice for Liquid Penetrant Testing

2.2 ASNT Recommended Practice:³

Recommended Practice No. SNT-TC-1A

2.3 SAE Standard:⁴

AMS 2644 Inspection Material, Penetrant ds/sist/9e1a11

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 E165, Method A.
- 4.2 The penetrant system used shall conform to a minimum of Sensitivity Level 3, in accordance with the latest revision of AMS 2644.
- 4.3 All penetrant materials shall be compatible with each other.

5. Preparation for Testing

5.1 Pre- and post-cleaning requirements are to be agreed upon between the purchaser and supplier.

6. Penetrant Method Materials Control

- 6.1 The penetrant method materials deteriorate in usefulness through contamination and age. The following controls shall be used to evaluate the materials' usefulness unless the supplier's requirements are more stringent:
 - 6.1.1 Penetrants:
- 6.1.1.1 Water Content of Non-Water-Based Water-Washable Penetrants—Water content of non-water-based Method A penetrants shall be checked monthly in accordance with Test Method D95. If the water content of the in-use penetrant exceeds 5 %, the penetrant shall either be discarded or sufficient unused penetrant added to reduce the water content to below 5 %.
- 6.1.1.2 *Penetrant Brightness*—Brightness tests of in-use fluorescent penetrants shall be conducted quarterly. Tests shall be in accordance with Test Method E1135 with a representative sample of the unused penetrant serving as the reference. Brightness values less than 90 % of the unused penetrant brightness are unsatisfactory and the in-use penetrants shall be discarded or otherwise corrected, as appropriate.
 - 6.1.2 *Developer:*
- 6.1.2.1 The following forms of developers are allowed for use with Type 1 Method A penetrants:

Form A: Dry developers.

Form C: Water suspendable developers.

Form D: Nonaqueous developers for Type 1 penetrants.

6.1.2.2 The parameters for controlling the application and required tests frequencies of developers are located in Practice E1417 and Practice E1417, Table 1.

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

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from American Society for Nondestructive Testing (ASNT), P.O. Box 28518, 1711 Arlingate Ln., Columbus, OH 43228-0518, http://www.asnt.org.

⁴ Available from Society of Automotive Engineers (SAE), 400 Commonwealth Dr., Warrendale, PA 15096-0001, http://www.sae.org.