Designation: ~~F601 – 18~~ F601 – 23

Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants[1]

This standard is issued under the fixed designation F601; 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~~standard 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

~~D95 Test Method for Water in Petroleum Products and Bituminous Materials by Distillation~~
~~E165/E165M Practice for Liquid Penetrant Testing for General Industry~~
~~E1135 Test Method for Comparing the Brightness of Fluorescent Penetrants~~
E1417/E1417M Practice for Liquid Penetrant Testing
~~2.2 *ASNT Documents:*[3]~~
~~Recommended Practice No. SNT-TC-1A~~
~~CP-189 Standard for Qualification and Certification of Nondestructive Testing Personnel~~
~~2.3 *SAE Standard:*[4]~~
~~AMS 2644 Inspection Material, Penetrant~~
~~2.4 *ISO Document:*[5]~~
~~ISO 9712 Non-destructive Testing – Qualification and Certification of NDT Personnel~~
~~2.5 *NAS Document:*[6]~~
~~NAS-410 Certification and Qualification of Nondestructive Test Personnel~~

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.

[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.

***A Summary of Changes section appears at the end of this standard**

~~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/E165M~~E1417/E1417M~~, Method A.~~.

4.2 The penetrant system used shall ~~conform to a minimum of Sensitivity Level 3,~~ be Type I, Method A, minimum of Level 3 sensitivity, in accordance with ~~the~~Practice E1417/E1417M~~latest revision of AMS-2644.~~.

4.3 All penetrant materials shall be compatible with each ~~other, and approved~~ other in accordance with ~~AMS-2644.~~Practice E1417/E1417M.

5. Preparation for Testing

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

5.2 If sand/grit blasting is used for pre-cleaning, ~~take care~~ care shall be taken to ensure that defects are not masked or peened over.

6. Penetrant Method Materials ~~Control~~ and Equipment Controls

6.1 The penetrant method materials deteriorate in usefulness through contamination and age. ~~The following controls shall be used to evaluate the materials~~System performance and process control checks shall be performed in accordance with Practice E1417/E1417M~~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/E1417M and Practice E1417/E1417M, Table 1.~~

~~6.1.3 *Black Lights*—Portable, hand-held, permanently mounted or fixed black lights used to inspect parts shall be checked for intensity daily or prior to use, and after bulb replacement, using a calibrated UV-A radiometer. The minimum acceptable intensity is 1000 μW/cm^2 (10 W/m^2) at 15 in. (38.1 cm) from the front of the filter to the face of the sensor. Black lights shall be checked weekly for cleanliness and integrity and shall be cleaned, repaired, or replaced as appropriate.~~

~~6.1.4 *Ambient Light Intensity*—Ambient visible light background shall not exceed 2 fc (21.5 lx) at the examination surface and shall be checked using a calibrated light meter quarterly or when any changes or construction, or both, are made in the inspection area.~~

~~6.1.5 *Penetrant System Performance*—The penetrant system's overall performance shall be checked daily as specified in Practice E1417/E1417M, paragraph 7.8.3.~~

~~6.1.6 *Additional Required Tests*—The following tests shall be performed in accordance with Practice E1417/E1417M:~~

~~6.1.6.1 Wash water temperature and temperature check at the start of every working shift, and~~

~~6.1.6.2 Daily checks for penetrant contamination and inspection area cleanliness.~~

7. Evaluation

7.1 The product acceptance and rejection criteria shall be as agreed upon between the purchaser and supplier.

7.2 Indication ~~verifications are allowed, as~~verification per Practice E1417/E1417M ~~agreed between purchaser and supplier.~~is permitted. If the purchaser has unique requirements, these shall take precedence.

8. Personnel Certification

8.1 ~~Personnel performing examinations to this standard~~If specified in the contractual agreement, personnel performing examination to this practice shall be qualified in accordance with a nationally or internationally recognized ~~NDT~~ nondestructive testing (NDT) personnel qualification practice or standard ~~such as ANSI/ASNT-CP-189, SNT-TC-1A, NAS-410, ISO 9712 or a similar document~~ and certified by the employer or certifying agency, as applicable. ~~The practice or standard used and its applicable revision shall be identified in the contractual agreement between the using parties.~~

9. Keywords

9.1 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~~ decades 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 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~~ ultraviolet light (UV-A) 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 F04 to standardize methods for fluorescent penetrant inspection of metallic surgical implants; the result was Practice F601. 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.