Designation: 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 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]

E1417/E1417M Practice for Liquid Penetrant Testing

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.

4. Fluorescent Penetrant Method

4.1 Perform fluorescent penetrant inspection of metallic surgical implants in accordance with Practice E1417/E1417M.

4.2 The penetrant system used shall be Type I, Method A, minimum of Level 3 sensitivity, in accordance with Practice E1417/E1417M.

4.3 All penetrant materials shall be compatible with each other in accordance with 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, care shall be taken to ensure that defects are not masked or peened over.

6. Penetrant Method Materials and Equipment Controls

6.1 The penetrant method materials deteriorate in usefulness through contamination and age. System performance and process control checks shall be performed in accordance with Practice E1417/E1417M.

7. Evaluation

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

7.2 Indication verification per Practice E1417/E1417M is permitted. If the purchaser has unique requirements, these shall take precedence.

8. Personnel Certification

8.1 If specified in the contractual agreement, personnel performing examination to this practice shall be qualified in accordance with a nationally or internationally recognized nondestructive testing (NDT) personnel qualification practice or standard and certified by the employer or certifying agency, as applicable.

9. Keywords

9.1 fluorescent; penetrant inspection; testing methods; 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**

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 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 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.

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, grit or vapor blasted, electro polished, and so forth); manufacturing method (that is, wrought, forged, cast, and so forth); as well as other variables in surface texture.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F601 – 18) that may impact the use of this standard. (Approved Sept. 1, 2023.)

(1) Five year review.
(2) Changed 'guide' to 'standard' in 1.1.
(3) Removed non-applicable standards from Section 2.
(4) Deleted paragraph 3.2 as it is duplicated in 7.1.
(5) Replaced references to E165/E165M and AMS 2644 with E1417/E1417M, as E1417/E1417M is all inclusive of industry requirements.
(6) Added 'and equipment' to title of Section 6.
(7) Removed individual process checks and referenced E1417/E1417M in 6.1.
(8) Revised 7.2 to direct the user to E1417/E1417M for indication verification.
(9) Added 'nondestructive testing' to 8.1.
(10) Changed 'over twenty years' to 'decades' in X1.1.