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Standard Practice for Radiography of Cast Metallic Surgical Implants[1]

This standard is issued under the fixed designation F629; 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.

ε[1] NOTE—Subsections 4.1, 5.1, and 5.3 were editorially corrected in March 2008.

1. Scope

1.1 This practice covers the procedure for radiographic testing of cast metallic surgical implants and related weldments.

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]

E94 Guide for Radiographic Examination

E192 Reference Radiographs of Investment Steel Castings for Aerospace Applications

E1030 Test Method for Radiographic Examination of Metallic Castings

2.2 *ASNT Standard:*

SNT-TC-1A Recommended Practice for Personnel Qualification and Certification in Nondestructive Testing[3]

3. Terminology

3.1 For definitions used in this practice, refer to the terms in Test Method E1030 and Reference Radiographs E192.

4. Significance and Use

4.1 The requirements in this practice are intended to control the quality of the radiographic image of cast metallic surgical implants and related weldments.

5. Radiographic Methods

5.1 The radiographic method shall be agreed upon between the purchaser and supplier but should be in accordance with Test Method E1030 and Guide E94.

5.1.1 Acceptance criteria should be derived from the reference radiographs presented in Reference Radiographs E192.

5.2 Radiography of cobalt- or iron-base surgical implant castings may create film images resulting from grain diffraction. Radiographic techniques shall be utilized to ensure differentiation between these images and actual indications.

5.2.1 Generally, cobalt- or iron-base surgical implant castings require radiation intensities higher than normal, facilitating reduced exposure times.

5.2.1.1 Energies between 250 and 400 kV may be required to radiograph surgical implants with a ½-in. (12.7-mm) material thickness.

5.2.2 In some instances, filters, at the tube head, and relatively thick lead intensifying screens may reduce grain diffraction while sustaining adequate radiographic sensitivity.

5.2.3 Multiple radiographic exposures in which the implant is rotated between 5 and 180°, relative to the film, may help reduce grain diffraction. Additionally, multiple radiographic exposures in which the radiographic film is moved relative to the central ray of radiation also helps to change the diffraction pattern.

5.3 Radiography of titanium-base surgical implant castings may create a general mottled image. However, standard low-energy radiation should produce acceptable sensitivity.

6. Sensitivity Requirements

6.1 Sensitivity of surgical implant castings shall be 2-2T, with the 2T hole clearly discernible, in the area of interest.

7. Metallurgical Requirements

7.1 In the absence of cast metallic implant standards at this time, the following requirements are suggested:

7.1.1 The product acceptance and rejection criteria shall be as agreed upon between the purchaser and supplier; however, indications which are linear in nature, generally, are unacceptable.

[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.