Designation: F629 – 15

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.

1. Scope*

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

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

1.3 *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 Practice for Radiographic Examination of Metallic Castings

E1320 Reference Radiographs for Titanium Castings

E2660 Digital Reference Images for Investment Steel Castings for Aerospace Applications

E2669 Digital Reference Images for Titanium Castings

F2895 Practice for Digital Radiography of Cast Metallic Implants

2.2 *ASNT Standard:*[3]

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

2.3 *AIA/NAS Standard:*[4]

NAS410 Certification and Qualification of Nondestructive Test Personnel

2.4 *CEN Standard:*[5]

EN 4179 Aerospace series – Qualification and approval of personnel for non-destructive testing

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, E1320, or digital reference images E2660 and E2669.

5.1.2 Digital radiography when agreed upon between purchaser and supplier shall be performed in accordance with Practice F2895.

5.2 Radiography of cobalt- or iron-base surgical implant castings may create radiographic 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.

[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 Aerospace Industries Association (AIA), 1000 Wilson Blvd., Suite 1700, Arlington, VA 22209, http://www.aia-aerospace.org.

[5] Available from European Committee for Standardization (CEN), Avenue Marnix 17, B-1000, Brussels, Belgium, http://www.cen.eu.

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

5.2.3 Multiple radiographic exposures in which the implant is rotated between 5 and 180°, relative to the film or detector, may help reduce grain diffraction. Additionally, multiple radiographic exposures in which the radiographic film or detector 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.

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.

7.1.2 The mutually agreed upon acceptance or rejection limits shall employ ASTM reference radiographic images or other radiographic images, and where feasible, shall identify discontinuity of size and type levels.

8. Personnel Certification

8.1 The personnel performing radiography under this practice shall be certified in accordance with SNT-TC-1A, NAS410, EN 4179, or other internationally recognized equivalent society or organization.

8.1.1 The personnel performing radiographic interpretation shall be certified Level II or Level III individuals, or equivalent, in accordance with SNT-TC-1A, NAS410, EN 4179, or other internationally recognized equivalent society or organization.

9. Report

9.1 A certified report shall be maintained showing radiographic test results including any rejected pieces.

9.1.1 Reports and radiographic images, or an equivalent image of a radiograph shall be maintained by the purchaser for the life of the device.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The acceptance criteria for the radiographic examination of cast metallic surgical implants and related weldments is based on reference radiographs presented in Reference Radiographs E192, E1320, or digital reference images of E2660 or E2669.

X1.2 Specific radiographic techniques have been included to aid radiographic image interpretation and ensure that adequate sensitivity has been maintained.

X1.3 Cobalt-, iron-, and titanium-base surgical implant castings may be radiographically examined according to the procedures referenced in this practice.

SUMMARY OF CHANGES

Committee F04.13 has identified the location of selected changes to this standard since the last issue (F629–11) that may impact the use of this standard. (Approved Dec. 1, 2015.)

(1) Section 6.1: Deleted the phrase “in the area of interest.”
(2) Section 8.1: Changed wording to be consistent with “E” specifications.
(3) Section 8.1.1: Changed wording to be consistent with “E” specifications.