Designation: ~~F749 – 98 (Reapproved 2012)~~ F749 – 13

Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit[1]

This standard is issued under the fixed designation F749; 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 a nonspecific, acute toxicity test used to help determine the biocompatibility of materials used in medical devices.

1.2 The liquids injected into the rabbits are those obtained by Practice F619 where the extraction vehicles are saline, vegetable oil, or other liquids simulating human body fluids.

1.3 This practice is one of several developed for the assessment of the biocompatibility of materials. Practice F748 may provide guidance for the selection of appropriate methods for testing materials for a specific application.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

2. Referenced Documents

2.1 *ASTM Standards*:[2]

F619 Practice for Extraction of Medical Plastics

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

3. Summary of Practice

3.1 The extract liquid is prepared in accordance with Practice F619. The extraction vehicles are saline and vegetable oil, or other extraction vehicles can be used, as described in Practice F619. The extract liquid is injected into rabbits and the animals are observed at regular intervals for 72 h for erythema, edema, or necrosis.

4. Significance and Use

4.1 This practice is to be used to help assess the biocompatibility of materials used in medical devices. It is an acute toxicological test designed to detect the presence of injurious leachable substances.

4.2 This practice may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the method in view of the materials being tested, their potential applications, and the recommendations contained in Practice F748.

4.3 The only applicable limitation is the extract preparation. Refer to Sections 4.3 and 4.4 of Practice F619 for a description of this limitation.

5. Apparatus

5.1 *Cages*—There shall be one cage for each rabbit exposed to one extract liquid. Each rabbit shall be uniquely identified with this identity recorded.

5.2 *Syringes*—Sterile syringes, not greater than 2 mL in volume, with a precision of no less than ±0.10 mL shall be used. Sterile needles of 21 to 26 gauge shall be used.

[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 F04.16 on Biocompatibility Test Methods.

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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.