Designation: F2901 – 12

# StandardGuide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices[1]

This standard is issued under the fixed designation F2901; 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 Medical devices may cause adverse effects on the structure and/or function of the nervous system. In this guide, these adverse effects are defined as neurotoxicity. This guide provides background information and recommendations on methods for neurotoxicity testing. This guide should be used with Practice F748, and may be helpful where neurotoxicity testing is needed to evaluate medical devices that contact nervous system tissue or cerebral spinal fluid (CSF).

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]

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

F1904 Practice for Testing the Biological Responses to Particles ***in vivo***

2.2 *Other Referenced Documents:*

ISO/AAMI/ANSI 10993-3 :2003Biological Evaluation of Medical Devices—Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity[3]

ISO/AAMI/ANSI 10993-5 :2009 Biological Evaluation of Medical Devices—Part 5: Tests for In Vitro Cytotoxicity[3]

ISO/AAMI/ANSI 10993-18 Biological Evaluation of Medical Devices—Part 18: Chemical Characterization of Materials[3]

ANSI/AAMI ST72 :2010 Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing[3]

USP <161> Transfusion and Infusion Assemblies and Similar Medical Devices[4]

## 3. Summary of Guide

3.1 This is an informative guide and should be used with Practice F748.

3.2 The duration of contact between the tissue and medical device should be considered when determining the appropriate panel of testing. This guide may not address neurosurgical instruments or medical devices that have transient incidental contact with the nervous system due to the limited tissue contact duration.

3.3 The evaluation of neurotoxicity should be considered in conjunction with material characterization and other information such as non-clinical tests, clinical studies, post-market experience, and intended use.

## 4. Significance and Use

4.1 The objective of this guide is to recommend a panel of biological tests that can be used in addition to the testing recommended in Practice F748. This guide is designed to detect neurotoxicity caused by medical devices that contact nervous tissue.

4.2 The testing recommendations should be considered for new materials, established materials with different manufacturing methods that could affect nervous tissue response, or materials used in new nervous tissue applications.

4.3 Chemical characterization can be used to evaluate similarity for materials with a history of clinical use in a similar nervous tissue application.

## 5. Tests for Neurotoxicity

5.1 Testing should be performed on the final sterilized device, representative samples from the final sterilized device, or materials processed in the same manner as the final sterilized device. Testing of individual materials may be useful for

[1] This guide 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.

Current edition approved Sept. 1, 2012. Published October 2012. DOI: 10.1520/F2901–12.

[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 National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.