Technical Information Report

AAMI TIR42: 2021

Evaluation of particulate associated with vascular medical devices

AAMI
Advancing Safety in Health Technology

Evaluation of particulate associated with vascular medical devices

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by **AAMI**

Abstract: This document provides information for defining appropriate test methods, determining the source of particulate, assessing the clinical risk of particulate, and establishing product particulate limits. Particulate could arise from many sources including materials, environment, and clinical use. This TIR is intended to offer guidance to the medical device industry when evaluating the tendency for medical devices to release particulate, identifying particulate sources, applying analytical methods for particulate testing, and developing particulate limits based on clinical risk.

Keywords: acute, coating, emboli, hydrophilic, light microscopy, light obscuration, literature review, medical device, particle, particle counting, particulate limits, particulate matter, risk, simulated use, test method, validation

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Association for the Advancement of Medical Instrumentation

Medical Device Particulates Committee

This technical information report (TIR) was developed by the AAMI Medical Device Particulates Committee. Approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Medical Device Particulates Committee** had the following members:

Cochairs:
Terry Irwin, MBA, CMQ/OE
Dinesh Patwardhan, PhD

Project Leader:
Eleni Whatley, PhD

Members:
Susanne Anderson, NAMSA
August Baur, Centurion Sterilization Services
Kendahl Bennis, Boston Scientific
Martin Boehm, Shire/Takeda Pharmaceuticals
Lindsey Borton, MPH, Smiths Medical
Carolyn Braithwaite-Nelson, Spectranetics/Philips
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Amitabh Chopra, Camarillo, CA
James Conti, PhD, Dynatek Labs
Lydia Edgewater, W.L. Gore & Associates
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Dan Floyd, CISS-EO, DuPont Tyvek Medical and Pharmaceutical Protection
Doug Harbrecht, Sterility Assurance Ltd.
Stephanie Hsia, Medtronic Neurovascular
Yin Hu, MD, University Hospitals of Cleveland
Terry Irwin, Edwards Lifesciences
Allan Kimble, DuPuy Synthes USA/Johnson & Johnson
Stan Lam, PhD, Stryker Neurovascular
Rashi Mehta, West Virginia University Hospitals
Rupal Mehta, Rush University Medical Center
Tonya Morris, BS, Nelson Laboratories/Sotera Health
Dinesh Patwardhan, U.S. Food and Drug Administration/CDRH
Christin Pawleski-Hoell, Raumedic Inc.
Sandi Schaible, WuXi Apptec Inc.
Kyle Timme, Cook Research
Craig Weinberg, PhD, Biomedical Device Consultants & Laboratories
Neal Zupec, Baxter Healthcare Corporation

Alternates:
Brian Choules, PhD, Biomedical Device Consultants & Laboratories
Robert John Evjen, Boston Scientific
Siddharth Loganathan, Stryker Neurovascular
Gerald McDonnell, PhD, Johnson & Johnson
Nicholas Packet, DuPont Tyvek Medical and Pharmaceutical Protection
Elaine Strope, PhD, Dynatek Laboratories
Carl Swanson, NAMSA
Eleni Whatley, PhD, U.S. Food and Drug Administration/CDRH
Preston Zook, Nelson Laboratories/Sotera Health

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