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

Approved 31 March 2021
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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Committee representation

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:

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NOTE: Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

Foreword

This technical information report was developed by the AAMI Medical Device Particulates Committee. The objective is to provide technical information that will assist medical device manufacturers in determining acceptable levels of particulate on medical device products used to deliver or implant into the vasculature, or both.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
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- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR42, *Evaluation of acute particulate generation associated with vascular medical devices* (AAMI TIR42:2021), but it does provide important information about the development and intended use of the document.

Introduction

This Technical Information Report (TIR) addresses the particulate matter on limited duration and implantable medical devices, and on accessory devices used in the vascular system during the delivery and implantation or exposure and removal of such devices. Unintentional particulate matter on medical devices can be a quality control issue because of the manufacturing environment or a device design–related issue. Sources of particulate in the manufacturing environment might include glove powders, lint and other fibers, paper particles, packaging materials, paint particles, and many other materials. Release of particulate during use is a characteristic of medical devices that may be addressed in product development. Particulate consisting of device materials can arise because of friction, abrasion or dissolution, and can have significant effects on patient outcome.

Evaluation of particulate associated with vascular medical devices

1 Scope

1.1 General

This document addresses particulate released from intravascular medical devices that have direct contact with circulating blood. It is intended to assist intravascular medical device manufacturers in defining appropriate test methods, determining the source of particulate, assessing the clinical risk of particulate, and establishing product particulate limits.

1.2 Inclusions

This document specifically includes particulate that could be acutely released into the vasculature from intravascular medical devices and accessories used with the devices. This might include particulate as a result of manufacturing, packaging, materials, coatings, and acute device use. This document only addresses particulate that might be released during acute intravascular device use, i.e., from introduction to device and accessory withdrawal.

1.3 Exclusions

This document does not address particulate released after removal of a non-implantable device or after removal of an implant's delivery system and accessories, i.e., chronic particulate release from an implanted device such as due to wear. It excludes intentional therapies in the form of particulate, for example drug coatings on balloons and embolization microspheres or beads, though their delivery systems are included.

This document specifically excludes particulate arising from the operating room or clinical environment in which the device is used.

This document does not address patient-generated particulate, such as those originating from plaque, that might be produced before, during, or following an acute device procedure. Liquids, such as lubricating fluids, are not considered to be particulate in the context of this document.

Routine monitoring of particulate levels on the device due to unintended changes in the manufacturing process or environment are not discussed in this document.

2 Normative references

There are no normative references in this document.

3 Definitions

For the purposes of this technical information report, the following terms and definitions apply.

3.1
acute application
time frame during device delivery, or exposure to the device, up until all accessories have been removed during typical procedures

NOTE Typical acute procedures usually last 2 hours or less. However, for the purposes of this document, acute procedures can last up to 24 hours.