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Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants

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National foreword

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A list of organizations represented on this committee can be obtained on request to its secretary.

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Foreword

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The committees responsible for this document are ISO/TC 194, *Biological evaluation of medical devices* and ISO/TC 150/SC 2, *Cardiovascular implants and extracorporeal systems*.

Cardiovascular biological evaluation of medical devices — Guidance for absorbable implants

1 Scope

The objective of this Technical Report is to provide interim Part-by-Part guidance on potential adjustments to various test methods within the 10993 series to account for the intentional release of soluble components or degradation products from absorbable medical devices. The content is intended to add clarity and present potentially acceptable approaches for reducing the possibility of erroneous or misleading results due to the nature of the absorbable material. All suggestions should be considered as preliminary and subject to change, with final dispositions implemented through direct modification to the respective parts of ISO 10993. Thus, interim adoption of any of the described adjustments requires an accompanying written justification.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
absorb
<biomaterials> action of a non-endogenous (foreign) material or substance passing through or being assimilated by cells and/or tissue over time

2.2
degradation product
<byproduct> any intermediate or final result from the physical, metabolic, and/or chemical decomposition of a material or substance

2.3
degrade
to physically, metabolically, and/or chemically decompose a material or substance

2.4
leachable
substances that can be released from a medical device or material during clinical use

Note 1 to entry: In absorbable devices, leachables can be substances released from the as-manufactured product or substances generated and released as a consequence of its degradation (i.e degradation products).

[SOURCE: ISO 10993-12:2012, 3.10 modified — Note 1 to entry has been added.]

3 General considerations

Biological evaluation is the assessment of the ability of a device, device component, or a material to be present in the body without creating an adverse systemic impact and/or local effect on the surrounding cells and/or tissue. Biological evaluation of an absorbable material should be conducted in accordance with ISO 10993-1:2009 and other relevant parts (see ISO 10993-1:2009, Table A.1).

NOTE 1 General guidance regarding evaluation of devices in accordance with ISO 10993 series can be found in ISO/TR 15499.

By design, polymeric, ceramic, or metallic absorbable materials inherently produce relatively low molar mass degradation products when *in vivo*. The relatively elevated presence of these same products within the culture media can potentially impact the results of some biocompatibility tests. For example, in rare