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Part 4: Application of ISO 17327-1 for coated endovascular devices

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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

A list of all parts in the ISO 25539 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 17327-1 has a broad scope, including all non-active surgical implants, and thus only some of the requirements in ISO 17327-1 are applicable to coated endovascular devices. This document clarifies how ISO 12417-1, ISO/TS 17137, ISO 25539-1, ISO 25539-2, and ISO 25539-3 satisfy the requirements of ISO 17327-1. A device evaluation strategy is needed to identify the appropriate evaluation of specific coated devices.

It is recognized by this ISO committee that many coated endovascular devices have been shown to be safe and effective in clinical use. This document does not intend to require additional evaluation of these devices to comply with this document as the testing does not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of ISO 25539-1, ISO 25539-2, and ISO 25539-3. Similarly, for device modifications or changes in intended clinical use, this document does not intend to require additional evaluation of any aspects of the device that are not expected to change the clinical performance.