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Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices

Implants cardiovasculaires et circuits extra-corporels — Dispositifs de réparation de valves cardiaques

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Foreword

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

Introduction

No heart valve repair device is ideal. Therefore, a group of engineers, scientists, and clinicians, experts well aware of the problems associated with heart valve repair devices and their development, has prepared this document. This document specifies types of tests, test methods, and requirements for test apparatus. It requires documentation of test methods and results. This document deals with those areas that will ensure adequate mitigation of device-associated risks for patients and other users of the device, facilitate quality assurance, aid the heart team in choosing a heart valve repair device, and ensure that the device will be provided in a convenient and usable form. This document emphasizes the need to specify and report types of *in vitro* testing, preclinical *in vivo* and clinical evaluations. It describes the labels and packaging of the device. Such a process involving *in vitro*, preclinical *in vivo* and clinical evaluations is intended to clarify the requirements prior to market release and to enable prompt identification and management of any subsequent problems.

With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical and biocompatibility characteristics, this document also covers important functional and durability characteristics of heart valve repair devices and their accessories. This document does not specify exact test methods for functional and durability testing but it offers guidelines for the test apparatus.

This document should be revised, updated, and amended as knowledge and techniques in heart valve repair device technology improve.