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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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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.