

Implants for surgery — Two-part addition-cure silicone elastomers

ICS 11.040.40

National foreword

This British Standard reproduces verbatim ISO 14949:2001 and implements it as the UK national standard.

The UK participation in its preparation was entrusted to Technical Committee CH/18, Surgical implant materials, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 20 November 2001

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*Implants chirurgicaux — Élastomères de silicone à deux composants à
réticulation par réaction d'addition*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14949 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Annexes A and B form a normative part of this International Standard.

Introduction

Silicones are commercially available in a variety of physical forms and formulations. Silicone-cure products often employ cure mechanisms that utilize metals, free radicals and/or atmospheric moisture. This International Standard was undertaken to describe a subset of silicones with a successful history of use in implant applications; namely, those utilizing two-part addition-cure (platinum-based) chemistry. It was developed in response to a need to standardize the raw materials, formulation, processing, characterization testing and documentation of two-part addition-cure silicone elastomers targeted as implants for surgery.

Two-part addition-cure silicone elastomer is a thermoset elastomer and is commercialized as a two-part (non-crosslinked) product. The two parts should be thoroughly mixed in a fixed ratio before shaping by extrusion, press- or injection-moulding and crosslinking at elevated temperatures.

