International Standard

ISO 5834-1

Implants for surgery — Ultra-high-molecular-weight polyethylene —

Part 1: Powder form

Implants chirurgicaux — Polyéthylène à très haute masse moléculaire —

Partie 1: Produits sous forme de poudre

Fifth edition
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Corrected version
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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

This fifth edition cancels and replaces the fourth edition (ISO 5834-1:2019), which has been technically revised.

The main changes are as follows:

— the normative references have been updated;

— the properties in Table 1 have been updated to harmonize with ASTM F648-21.

A list of all parts in the ISO 5834 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.

This corrected version of ISO 5834-1:2025 incorporates the following correction: in 8.2, the concentration of solution has been changed from 20 mg/kg to 0,02 %.

Introduction

While no known surgical implant material has ever been shown to cause absolutely no adverse reactions in the human body, long-term clinical experience with the material referred to in this document has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications. However, this document covers the raw material and not finished medical devices, where the design and fabrication of the device can impact biological response.