ISO 7198:1998, Cardiovascular Implants -- Tubular Vascular Prostheses

Synopsis

This International Standard specifies requirements relating to testing, packaging, labelling and terminology for sterile tubular vascular prostheses intended to replace, bypass or to form shunts between segments of the vascular system in humans.This International Standard addresses vascular prostheses that are made wholly or partly of: materials of biological origin; synthetic textile materials; and synthetic nontextile materials. In addition, guidance for characterization of compound and composite prostheses is provided. It specifies the designation of materials of manufacture and the construction, and specifies the designation of sizes and dimensions of vascular prostheses. It refers to biological requirements of the materials of construction and of the finished product, taking into account the appropriate part of the horizontal International Standard ISO 10993.This International Standard also specifies the designation of mechanical properties. It describes methods for the measurement and verification of the dimensions and mechanical properties declared by the manufacturer. It refers to sterilization of prostheses and specifies requirements for labelling and packaging. It also provides definitions of terms in common use.This International Standard does not specify all the performance or dimensional characteristics, but it does include methods for verifying that the nominal values disclosed by the manufacturer are within the permitted tolerances. These recommendations do not purport to comprise a complete test program.For the purposes of this International Standard, the disclosure of test methods, results and other information on request shall relate solely to requests from a National Regulatory Authority with responsibility for surgical implants.This International Standard does not apply to human donor tissue devices such as cryopreserved vessels. Also excluded are all patches, pledgets and stents.

Book Information

Paperback: 54 pages

Publisher: Multiple. Distributed through American National Standards Institute (ANSI) (August 23, 2007)

Language: English

ASIN: B000XYSVTA

Product Dimensions: 8.2 x 0.1 x 10.5 inches

Shipping Weight: 6.4 ounces (View shipping rates and policies)

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Best Sellers Rank: #5,858,372 in Books (See Top 100 in Books) #106 inÂ Books > Engineering & Transportation > Engineering > Reference > American National Standards Institute (ANSI)

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