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SYNOPSIS

Doc: MHD 06 (13122) IS/ISO 7198:2016 Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches

Scope:

This Indian Standard specifies requirements for the evaluation of vascular prostheses and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer, based upon current medical knowledge.

NOTE Due to the variations in the design of implants covered by this Indian Standard and, in some cases, due to the relatively recent development of some of these implants (e.g. bio-absorbable vascular prostheses, cell based tissue engineered vascular prostheses), acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this Indian Standard will be necessary.

This Indian Standard is applicable to sterile tubular vascular grafts implanted by direct visualization surgical techniques as opposed to fluoroscopic or other non-direct imaging (e.g. computerized tomography or magnetic resonance imaging), intended to replace, bypass, or form shunts between segments of the vascular system in humans and vascular patches intended for repair and reconstruction of the vascular system.

Salient features of content:

Vascular prostheses that are made of synthetic textile materials and synthetic non-textile materials are within the scope of this Indian Standard. While vascular prostheses that are made wholly or partly of materials of non-viable biological origin, including tissue engineered vascular prostheses are within the scope, this Indian Standard does not address sourcing, harvesting, manufacturing and all testing requirements for biological materials. It is further noted that different regulatory requirements might exist for tissues from human and animal sources.

Compound, coated, composite, and externally reinforced vascular prostheses are within the scope of this standard.

Endovascular prostheses implanted using catheter delivery and non-direct visualization are excluded from the scope of this Indian Standard. This Indian Standard includes information on the development of appropriate test methods for graft materials, referenced in IS/ISO 25539-1:2017 for materials used in the construction of endovascular prostheses (i.e. stent-grafts).

NOTE Requirements for endovascular prostheses are specified in IS/ISO 25539-1:2017.

The valve component of valved conduits constructed with a tubular vascular graft component, and the combination of the valved component and the tubular vascular graft component, are excluded from the scope of this Indian Standard. This Indian Standard can be helpful in identifying the appropriate evaluation of the tubular vascular graft component of a valved conduit but specific requirements and testing are not described for these devices.

Cardiac and pericardial patches, vascular stents, accessory devices such as anastomotic devices, staplers, tunnelers and sutures, and pledgets are excluded from the scope of this Indian Standard.

Requirements regarding cell seeding are excluded from the scope of this Indian Standard. Tissue engineered vascular prostheses that contain or are manufactured using cells present many distinct manufacturing (e.g. aseptic processing, cell seeding, etc.) and testing issues than those produced with synthetic or non-viable biological materials. The *in vitro* testing requirements that are outlined in this Indian Standard can be a useful guide for certain testing requirements for these cell-based products.

Pharmacological aspects of drug-eluting or drug-coated vascular prostheses are not addressed in this Indian Standard.

Degradation, tissue ingrowth and/or tissue replacement, and other time-dependent aspects of absorbable vascular prostheses are not addressed in the standard.

c) Type/grades/classes, if any covered in the standard: Nil.

Chandan Kumar
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