DRAFT INDIAN STANDARD IN WIDE CIRCULATION

Reference : 25000 **Date : 28 March 2024**

TECHNICAL COMMITTEE : Medical and Surgical Cardiology Equipment, MHD 06

To,

All concerned

Dear Madam/Sir,

The following document has been prepared by the Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06. Please click here to view the document.

Document Number : MHD 06 (25000) WC
Title of the document : Cardiovascular implants Transcatheter cardiac occluders
Document Type : New Indian Standard

This document has following salient features which may require specific attention for your valuable comments:

1) This document specifies important in vitro tests including functional and durability characteristics of transcatheter cardiac occluders, and their delivery systems and accessories. This document does not specify exact test methods for functional and durability testing, but it offers requirements and recommendations for performance tests of the cardiac occluder system. Surgical occluders have been omitted from the scope of this document given their significant differences in device geometry, materials, implantation methods, and test methods as compared to transcatheter cardiac occluders. This document is applicable to all intracardiac occluders intended for transcatheter implantation in humans (e.g. atrial septal occluder, ventricular septal occluder, patent foramen ovale occluder, left atrial appendage occluder, and paravalvular leak occluders). This document does not cover non-cardiac occluders, but elements of this document can be applicable to patent ductus arteriosus occluders.
2) The following devices and components are outside the scope of this document: surgical devices, cardiac shunt devices, atrial flow regulators, active components (such as sensors), or degradable or animal tissue components. This document is applicable to both newly developed and modified cardiac occluders, their accessory devices, packaging, and labelling. This document defines operational conditions and performance requirements for cardiac occluders where either adequate scientific or clinical evidence, or both, exists for their justification.

Please examine the document and share your comments regarding further improvement in the document.

Last date for sharing the comments is : 27 April 2024

The comments should be shared in the prescribed template through this portal only; and the comments so received shall be taken up by the Sectional Committee for necessary action. For any other query, please write an email at mhd@bis.gov.in to the undersigned at Bureau of Indian Standard, Manak Bhawan, 9, Bahadur Shah Zafar Marg, New Delhi.

In case no comments are received, we would presume your approval of the documents. However, in case we receive

any comments on the document, the same shall be put up to the Sectional Committee for necessary action.

Thanking You,

Yours faithfully,
(UNNIKRISHNAN A R)
Head (Medical Equipment and Hospital Planning Department)
Email: mhd@bis.gov.in

व्यापक परिचालन में मसौदा(दे)

हमारा सन्दर्भ : 25000 दिनांक : 28-03-2024

तकनीकी समिति : Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

प्राप्तकर्ता : रूचि रखने वाले सभी निकाय

महोदय/या,

निम्नलिखित मसौदा तैयार किया गया है :

प्रलेख संख्या : MHD 06 (25000) WC
शीर्षक :

कृपया इस/इन मानक(को)/संसोधन(नो) के मसौदे(दो) का अवलोकन करें और अपनी सम्मतियाँ यह बताते हुए भेजें कि यदि ये मानक(को) के संशोधन(नो) के रूप में प्रकाशित हो तो इन पर अमल करने में आपके व्यवसाय अथवा कारोबार में क्या कठिनाइयां आ सकती हैं।

सम्मत्तियाँ भेजने की अंतिम तिथि : 27 April 2024

सम्मतियाँ, यदि कोई हों तो, कृपया यहाँ क्लिक करके ऑनलाइन पोर्टल के माध्यम से ऊपर दी गयी अंतिम तिथि तक दर्ज कराएं।

यह/ये प्रलेख भारतीय मानक ब्यूरो की वेबसाइट www.bis.gov.in पर भी उपलब्ध है/हैं।

धन्यवाद।

भवदीय/भवदिया,

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