



DRAFT INDIAN STANDARD IN WIDE CIRCULATION

Reference : 24992

Date : 22 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 (24992) WC

Title of the document : Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2

Document Type : New Indian Standard

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

1) The document is devised to cater the inconsistencies with the labeling and instruction for use associated with sizing procedures for heart valve replacement. For aortic valve replacements, severe mismatch may lead to significant risk of mortality and morbidity. The best approach to avoid prosthesis-patient mismatch is prevention. This requires the surgeon to have clear and accurate information about the sizing parameters and effective orifice area of valve being substituted. The document recommends additional valve sizing parameters to be added on the device labeling. The document also present suitable methods to obtain these parameters and the degree of accuracy required.

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

Last date for sharing the comments is : 21 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 : 24992

दिनांक : 22-03-2024

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 (24992) WC

शीर्षक :

कृपया इस/इन मानक(को)/संशोधन(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।

सम्मतियाँ भेजने की अंतिम तिथि : 21 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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