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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0018-2026

Replacing YY 0018-2016

Implants for osteosynthesis - Metallic bone screws

骨接合植入器械 金属接骨螺钉

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. This document replaces YY 0018-2016 "Metal Screws for Bone Integration Implants". Compared with YY 0018-2016, the main differences are in the structural design. Aside from integration and editorial changes, the main technical changes are as follows:

---The scope has been changed (see Chapter 1, Chapter 1 of the.2016 edition);

---The material requirements have been changed (see 4.1, see

5.1 in the.2016 edition);

---The requirements for maximum torque and fracture torsion angle have been changed (see 4.2.1, see

5.2.1 in the.2016 version);

---The hardness requirements have been changed (see 4.2.2, see

5.2.2 in the.2016 version);

---The surface roughness requirements have been changed (see 4.4.2, see

5.4.2 in the.2016 version);

---The appearance requirements have been changed (see 4.4.3, see

5.4.3 in the.2016 version);

---Size requirements have been changed (see 4.5, see

1 Scope

YY 0018 is the mandatory standard for the metal bone screw, the most-implanted device in orthopaedic trauma. It specifies the requirements, the manufacture, the sterilization, the packaging and the information the manufacturer has to supply for metallic bone screws used in osteosynthesis, and describes the corresponding test methods. The reach beyond the screw itself, into how it is made, sterilized and labelled, is what distinguishes a fundamental requirements standard from a test method, and the YY prefix without /T makes all of it compulsory in China. The 2026 edition takes effect on 1 March 2028, a two-year transition. For a manufacturer or an importer of cortical, cancellous, locking or cannulated screws selling into China, this is the standard the registration dossier is built on.

This document specifies the requirements, manufacturing, sterilization, packaging, and production of metal bone screws (hereinafter referred to as "bone screws") for bone fusion implant devices. The information provided by the vendor describes the corresponding testing methods. This document applies to bone screws used for internal fixation of fractures in orthopedic surgery. This document does not apply to spinal screws, craniofacial screws, and absorbable metal bone screws.

Note. This document can also be used as a reference for absorbable metal bone screws; Appendix A provides relevant information.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 4234.1 Metallic materials for surgical implants - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 screw thread Spiral grooves on the surface of a cylinder or cone.

Note. The prominent spiral ridge is called a thread, which includes the top and bottom.

3.2 buttress thread The asymmetrical thread profile is characterized by a pressure side that is nearly perpendicular to the thread axis.

7 Ethylene oxide sterilization residue

YY 0341.1 Passive Surgical Implants. Osteo-Integration and Spinal Implants - Part