

ICS 11.040.40

CCS C35

YY

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0017-2026

Replacing YY 0017-2016

Implants for osteosynthesis - Metallic bone plates

骨接合植入器械 金属接骨板

Issued on: March 9, 2026

Implemented on: March 1, 2028

Issued by: National Medical Products Administration

Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Requirements
- 5 Test Methods
- 6 Manufacturing
- 7 Ethylene oxide sterilization residue
- 8 Packaging
- 9 References

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 supersedes YY 0017-2016 "Metal Bone Plates for Bone Integration Implants". Compared with YY 0017-2016, the only changes are editorial revisions. Aside from the changes, the main technical changes are as follows:

- The scope of application has been changed (see Chapter 1, Chapter 1 of the.2016 edition);
- The material requirements have been changed (see 4.1,.2016 version 4.1);
- The requirements for static mechanical properties have been changed (see 4.2.2,.2016 version 4.2.2);
- The fatigue performance requirements have been changed (see 4.2.3,.2016 version 4.2.3);
- The surface roughness requirements have been changed (see 4.4.2,.2016 version 4.4.2);
- The appearance requirements have been changed (see 4.4.3,.2016 version 4.4.3);
- Requirements for fit performance have been added (see 4.5);
- Size requirements have been changed (see 4.6, 4.5 in the.2016 version);

---Aseptic requirements have been added (see 4.7);

---The section "Hole and slot in bone plates in ISO 5836 and ISO 9269" has been removed (see Appendix B of the 2016 edition). Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document was prepared by the Orthopedic Implants Subcommittee of the National Technical Committee on Standardization of Surgical Implants and Orthopedic Devices (SAC/TC110/ SC1) is under the jurisdiction of the relevant authorities. The release history of this document and the document it replaces is as follows:

---First released in 1990 as YY 0017-1990, revised for the first time in 2002, revised for the second time in 2008, and revised for the third time in 2016. Revision;

1 Scope

YY 0017 is the mandatory standard for the metal bone plate, the companion to the bone screw standard YY 0018 issued the same day. It specifies the requirements, the manufacture, the sterilization, the packaging and the information the manufacturer has to supply for metallic bone plates used in osteosynthesis, and describes the corresponding test methods. Plates and screws are qualified as a system in practice but standardised separately, because a plate is judged on bending strength and fatigue while a screw is judged on torsion and pull-out. The YY prefix without the /T suffix makes compliance compulsory in China, and the 2026 edition takes effect on 1 March 2028. For a manufacturer or an importer of locking, compression or anatomic plates for the Chinese market, this is the governing document.

This document specifies the requirements, manufacturing, sterilization, packaging, and manufacturers of metal bone plates for bone grafting implants (hereinafter referred to as "bone plates"). The information provided describes the corresponding experimental methods. This document applies to bone plates used in orthopedic surgery to connect and fix fracture ends. This document does not apply to metal spinal plates, craniofacial bone plates, and absorbable metal bone plates.

Note. This document provides information on absorbable metal bone plates; 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/T 4340.1 Metallic materials - Vickers hardness test - Part

3 Terms and Definitions

The terms and definitions defined in YY/T 1503 and YY/T 0856, as well as the following terms and definitions, apply to this document.

3.1 Passive surgical implants designed to provide support for bone, cartilage, tendon, or ligament structures. [Source: YY 0341.1-2020, 3.1]

3.2 Metal bone plate Metal instruments primarily used for connecting and fixing two or more bones after a fracture, having two or more holes and/or slots, with a cross-section It must contain at least two dimensions that can be clearly distinguished (width and thickness). The bone plate is primarily fixed to the bone by screws or ligatures.

Note. Appendix B provides several typical types of metal bone plates.

7 Ethylene oxide sterilization residue

YY 0341.1-2020 Passive Surgical Implants - Osteo-Integration and Spinal Implants - Part