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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1988-2025

Implants for sports medicine - Meniscus repair system

运动医学植入器械 半月板缝合系统

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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. 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 is under the jurisdiction of the National Technical Committee on Standardization of Surgical Implants and Orthopedic Devices (SAC/TC110). This document was drafted by: DaBo Medical Technology Co., Ltd., Tianjin Medical Device Quality Supervision and Inspection Center, and the National Medical Products Administration. The Medical Device Technical Evaluation Center of the Administration Bureau, and the Beijing Medical Device Testing and Research Institute (Beijing Medical Biological Protective Equipment Testing and Research Center). Beijing Deyida Medical Technology Co., Ltd., Beijing Keyibangen Medical Device Technology Co., Ltd., and Shanghai Ligetai Biotechnology Co., Ltd. The company is Hangzhou Ruijian Mustin Medical Equipment Co., Ltd. The main drafters of this document are. Zeng Da, Ye Yanjie, Peng Haiyun, Li Wenjiao, Yao Li, Guo Xiaolei, Aruhan, Han Qizhi, Li Peng, and Kong Qingjun. Wei Ning, Guo Qian, Zhao Zengliang, Wang Yuanqiang, Nie Jiali, Zhang Zhang. Sports medicine implantable device meniscus suture system

1 Scope

YY/T 1988 is the product standard for the implantable systems used to repair a torn meniscus. It specifies the requirements for a meniscus repair system as a sports medicine implant, covering manufacture, sterilization, biological evaluation, packaging and the information the manufacturer has to supply, and it describes the corresponding test

methods. Grouping all of these in one document is the pattern of the Chinese sports medicine implant series, where each device family gets its own particular requirements standard rather than relying on general implant standards alone. It sits beside YY/T 0965 on artificial ligaments, revised in the same period. For a manufacturer of all-inside or inside-out meniscal repair devices, this is the standard a Chinese registration dossier is assessed against, including the labelling and instructions for use.

This document specifies the requirements, manufacturing, sterilization, biological evaluation, packaging, and manufacturer specifications for meniscus suture systems used in sports medicine implants. The information provided describes the corresponding experimental methods. This document applies to the testing and evaluation of meniscus suture systems (hereinafter referred to as meniscus suture systems) used in sports medicine implants. Full suture Refer to parts of this document for information on meniscus suture systems.

Note. The basic principles are explained in Appendix A.

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 following terms and definitions apply to this document.

3.1 meniscus repair system Surgical instruments used for percutaneous or arthroscopic meniscus repair of the knee joint.

Note. It typically consists of an implant and assistive devices. The implant usually includes fixation devices and sutures, while the assistive devices usually include inserters, etc.

3.2 puncture force During the process of fully inserting the inserter with the fixation device into the meniscus simulator, the maximum amount of time required for the inserter needle tip to pierce the meniscus simulator. Force value.

Note. The unit is Newton (N).

3.3 Fixed strength The stitched meniscus simulator was stretched to the maximum force required to fail.