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Implants for sports medicine - Suture anchor

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1. Structure and Drafting Rules for Standardization Documents" drafting. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Standardization Technical Committee on Surgical Implants and Orthopedic Devices (SAC/TC110). This document was drafted by: Tianjin Medical Device Quality Supervision and Inspection Center, State Drug Administration Medical Device Technical Review Center, Beijing Medical Device Evaluation and Inspection Center, Stryker (Beijing) Medical Devices Co., Ltd., Johnson & Johnson (Shanghai) Medical Devices Co., Ltd., Beijing Natong Technology Group Co., Ltd., Beijing Deyidamei Medical Technology Co., Ltd., Beijing Fule Technology Development Co., Ltd. The main drafters of this document. Li Wenjiao, Dong Shuangpeng, Zhang Shu, Ma Chunbao, Yuan Bo, Guo Xiaolei, Zhen Zhen, Guo Xu, Gao Chunyu, Chen Ruikai, Zhao Wenwen, Kong Qingjun and Li Hongyan. Sports Medicine Implantable Anchor with Wire

1 Scope

YY/T 1867 covers the suture anchor, the implant that fixes soft tissue back to bone in shoulder, knee and ankle repair. It sets the requirements such an anchor has to meet and the test methods that verify them, covering the material, the pull-out strength of the anchor in bone, the strength of the suture and of its attachment to the anchor, the dimensions and

the sterility and packaging of the product. The anchor is the weakest link in a rotator cuff or labral repair: if it pulls out or the suture eye fails, the repair fails, and the patient goes back to theatre. Sports medicine implants are one of the fastest-growing device categories in China. For a manufacturer, this is the product-specific text a Chinese registration dossier has to address.

This document specifies the performance requirements of anchors with wires (hereinafter referred to as "anchors with wires") for implantable sports medicine devices, and gives the corresponding test method. The method specifies the content of manufacturing, sterilization, biological safety evaluation, packaging and information provided by the manufacturer.

Note. Appendix A gives the rationale for this document. This document applies to the test and evaluation of anchors with wires for the fixation of soft tissue and bone joints in sports medicine surgery. This document also applies to the test evaluation of non-preset suture anchors and full suture anchors.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 4340.1 Vickers hardness test for metallic materials - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Anchor with wire suture anchor It is a medical device that refixes soft tissues such as tendons and ligaments to human bones through specific surgical techniques. NOTE. Usually consists of implants and accessories. The implant includes anchors, sutures (with or without needles), and auxiliary parts include inserters, thread device etc.

3.2 insertion force insertion force The maximum pressure required to fully insert an anchor implanted into the body by percussion into the test block.

Note. The unit is Newton (N).