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

YY/T 1842.8-2022

**Medical devices - Connectors for reservoir delivery systems for
healthcare applications - Part 8: Citrate-based anticoagulant
solution for apheresis applications**

以下为预期使用本文件中连接件的医疗器械举例：

(English Translation)

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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 of Standardization Documents" drafted.

This document is part 8 of YY/T 1842 "Connectors for Medical Devices and Medical Fluid Storage Container Delivery Systems". YY/T 1842 has the following sections have been

published.

--- Part 1: General requirements and general test methods;

--- Part 8: Application of apheresis citrate anticoagulant.

This document uses the translation method identically to ISO 18250-8:2018 "Connectors for Medical Device Liquid Storage Container Delivery Systems No.

Part 8: Application of apheresis citrate anticoagulants.

Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

During the formulation of the standard series of small aperture connectors for medical liquids and gases (see YY/T 0916), it was found that the wrong connection the risk is not limited to the connection to the patient, but also needs to be considered for the entire reservoir system. In addition, monoclonal antibody was also considered Possible incorrect connection between the coagulant reservoir connector and the trocar. However, the apheresis anticoagulant reservoir connection is not completely full the definition of small-foot-aperture connectors, it was decided to develop a separate standard for such connectors to consider Risk of incorrect connection between other devices that can be used on the same patient.

YY/T 1842 "Connectors for Medical Liquid Storage Container Delivery Systems for Medical Devices" is intended to consist of the following parts.

--- Part 1: General requirements and general test methods;

--- Part 3: Gastrointestinal application;

--- Part 6: Neurological applications;

--- Part 7: Connectors for intravascular infusion;

--- Part 8: Application of apheresis citrate anticoagulant.

This document specifies the geometry, materials, and properties of apheresis anticoagulant reservoir connections to enable analysis (and avoidance) of their He is not apheresis to apply the connection between the connectors.

This document only specifies the connector dimensions of the apheresis anticoagulant reservoir connections for single-use tubing instruments and reservoirs.

This item is not a product standard.

If there is an asterisk (*) at the beginning of a title, paragraph or table title, relevant instructions and guidelines are given in Appendix A.

Medical device medical liquid storage container delivery system Use connectors part
8.apheresis citrate Anticoagulant application

1 Scope

This document specifies the dimensions, design and functional characteristics of the connections for apheresis anticoagulant reservoirs.

This document does not specify dimensional or performance requirements for medical devices or accessories using these connectors. These requirements are used in dedicated medical devices or in the annexed standard.

The following are examples of medical devices intended to use the connectors in this document.

---Apheresis separation pipeline and supporting liquid storage container containing citrate anticoagulant;

---Apheresis separation lines may include, but are not limited to, lines used for blood collection, therapy, and plasma collection.

Some apheresis separation kits are manufactured with pre-connected reservoirs containing citrate anticoagulant. These medical devices do not use this Connectors specified in the documentation.

Note: Although not required in the current medical device product standard, manufacturers are encouraged to use the connectors specified in this document for apheresis devices or accessories. medical instruments Product standards may be revised to increase requirements for apheresis anticoagulant reservoir connections.

2 Normative references

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

1) Synchronization is under development.

YY/T 0916.20-2019 Small aperture connectors for medical liquids and gases-Part 20: General test methods (ISO 80369-20:2015, IDT) YY/T 1842.1-20221) Connectors for medical device medical fluid storage container delivery systems - Part 1: General requirements and general Test method (ISO 18250-1:2018, IDT)

3 Terms and Definitions

The following terms and definitions apply to this document.

accessories accessory Additional components to enable medical devices to.

- achieve the intended use;
- make medical devices suitable for some specific purposes;
- Facilitate the use of medical devices;
- Enhance the performance of medical devices;
- Or enable certain functions to integrate with certain functions of other medical devices.

[Source. ISO 80369-1:2018, 3.1]