YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0778-2018

Radiofrequency ablation catheters

射频消融导管

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1 Scope

YY 0778 is the mandatory Chinese standard for radiofrequency ablation catheters, the catheters advanced into the heart to destroy the tissue responsible for an arrhythmia. It sets the requirements such catheters have to meet and the test methods that verify them, covering the electrode and its energy delivery, the temperature sensing that controls the lesion, the steering and deflection mechanism, the mechanical integrity of the shaft and tip under manipulation, the biocompatibility of the blood-contacting surfaces and the sterility. A tip that detaches or overheats inside a cardiac chamber causes perforation or embolism. Catheter ablation for atrial fibrillation is expanding rapidly in Chinese cardiology. Being a YY standard without the /T suffix, compliance is compulsory in China.

This Standard specifies the terms and definitions, requirements and test methods of radio frequency ablation catheter. This Standard is applicable to surgical accessories used as high-frequency surgical equipment, catheters that can transmit radio frequency energy to target tissues through blood vessels and lumens, and perform cutting and ablation of target tissues, hereinafter referred to as catheters.

2 Normative References

The following documents are indispensable to the application of this document. In terms of

references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 1962.2-2001 Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part 2: Lock Fittings (ISO 594-2:1998, IDT)

GB 9706.1 Medical Electrical Equipment - Part 1: General Requirements for Safety

GB 9706.4-2009 Medical Electrical Equipment - Part 2-2: Particular Requirements for the Safety of High Frequency Surgical Equipment (IEC 60601-2-2:2006, IDT)

GB 9706.19-2000 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment

GB/T 14233.1-2008 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB/T 14233.2-2005 Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use - Part 2: Biological Test Methods

GB/T 16886.1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process

YY 0285.1-2017 Intravascular Catheters - Sterile and Single-use Catheters - Part 1: General Requirements be free from processing and surface defects, and cause minimal damage to blood vessels or lumens during application.

c) If the catheter is lubricated, when examined with normal or corrected vision, the outer surface of the catheter shall have no visible converged lubricant droplets.

4.2.2 Breaking force When carrying out the test in accordance with the specified method, the breaking force of each test section shall comply with the stipulations of Table 1 in YY 0285.1-2017.

4.2.3 Controllability of regulating mechanism If the catheter has an adjustable mechanism, then, it shall satisfy the controllability requirements specified by the manufacturer.

4.2.4 Bending fatigue Put the catheter in the bending model, repeatedly push and pull for 10 times; and rotate 180 then push and pull for 10 times. the appearance of the catheter shall manifest no obvious degumming, cracking, breaking and other adverse phenomena, and shall comply with the requirements of

4.2.3 and 4.5.1.

4.3 Chemical Properties

4.3.1 Corrosion resistance After the corrosion test, there shall be no traces of corrosion on the metal parts of the catheter.

4.3.2 Reducing substances The difference in consumption of potassium permanganate solution [c(KMnO4) =

0.002 mol/L] between the test solution and the same volume of the same batch of blank control solution shall not exceed

4.3.3 Heavy metal The color presented by the test solution shall not exceed the standard control solution with a mass concentration of rho (Pb2+) = 1 g/mL.

4.3.4 pH The difference between the test solution pH and the same batch of blank control solution shall not exceed 1.5.

4.3.5 Evaporation residue In 50 mL test solution, the total mass of non-volatile matter shall not exceed 2 mg.

4.3.6 Ethylene oxide residue If ethylene oxide is used for sterilization, the residual amount shall not be greater than 10 g/g.

4.3.7 UV absorbance The absorbance of the test solution within the wavelength range of 250 nm ~ 320 nm shall not be greater than 0.1.

4.4 Biological Properties

4.4.1 Sterility Sterilized catheters shall be subjected to a validated sterilization process to be sterile.

4.4.2 Biocompatibility The parts expected to come into contact with biological tissues, cells or body fluids shall be assessed and documented in accordance with the guidelines and principles provided in GB/T 16886.1.

4.5 Electrical Properties

4.5.1 DC resistance The DC resistance value of the wire between each electrode and the corresponding core pin in the handle jack shall comply with the manufacturer's regulations.

4.5.2 Insulation resistance of catheter

4.5.2.1 Insulation resistance between electrodes The insulation resistance between any electrode of the multi-core (pole) catheter and the core pins of the corresponding tail wire jacks of other electrodes, and between the core pins of the tail wire jacks corresponding to the temperature sensor shall be greater than 5 M.

4.5.2.2 Insulation resistance between electrode and outer tube The insulation resistance between the outer tube of the catheter and the core pin of the handle jack shall be greater than 5 M.

4.5.3 Temperature sensing accuracy If the catheter has a temperature sensor, then, within the temperature range specified by the manufacturer, the error between the temperature

sensing value of the temperature sensor and

f) Ethylene oxide residue: when inspected in accordance with Chapter 9 in

GB/T 14233.1-2008, they shall comply with the requirements of 4.3.6.

g) UV absorbance: when inspected in accordance with Chapter 7 in

GB/T 14233.1-2008, they shall comply with the requirements of 4.3.7.

5.4.1 Sterility In accordance with the method specified in

GB/T 14233.2-2005, inspect the products in aseptic packaging, which shall comply with the requirements of 4.4.1.

5.4.2 Biocompatibility The biocompatibility test shall be carried out in accordance with the methods and procedures specified in GB/T 16886.1.

5.5 Electrical Properties

5.5.1 DC resistance Use a high-precision multimeter to measure the DC resistance between the corresponding electrode and the handle jack, which shall comply with the requirements of 4.5.1.

5.5.2 Insulation resistance of catheter

5.5.2.1 Insulation resistance between electrodes Use DC resistance measuring equipment, under the condition of 500 V voltage, measure the DC insulation resistance between different electrodes, which shall comply with the requirements of 4.5.2.1.

5.5.2.2 Insulation resistance between electrode and outer tube Use DC resistance measuring equipment, under the condition of 500 V voltage, measure the insulation resistance between the catheter sheath and the core pin of the handle jack, which shall comply with the requirements of 4.5.2.2.

5.5.3 Temperature sensing accuracy Connect the catheter to the equipment specified by the manufacturer, simultaneously put the temperature sensor and the standard thermometer (with an accuracy not lower than 0.1 C) into the constant-temperature water bath device, and the difference between the readings of the equipment shall comply with the requirements of 4.5.3.

5.6 Cardiac Radiofrequency Ablation Catheter

5.6.1 High-frequency continuity Pass a sine wave test current with a frequency of 400 kHz 100 kHz between the head electrode and the corresponding core pin, adjust the test current amplitude to 1 A, then, maintain it for 1 min. During the test, the wire shall remain in continuity and no current interruption shall occur. After 1 min, cut off the test current, and