**Comparison of changes in product technical requirements**

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**Before change:**

**1.1 Specification/model**

Annex A

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Model | Description | Instructions for use | Delivery status | Material of the body-contact part | Dimension | Outer diameter of the inserted portion |
| All-In-One Hand Control Unit and Electrodes | | | | | | |
| 0080 | Electrode (L-Wire Hook with suction function laparoscopic non-stick electrode, 38 cm) | Disposable | Sterile | PTFE coating | 38 cm | 2 mm |

**After change:**

**1.1 Specification/model**

Annex A

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Model | Description | Instructions for use | Delivery status | Material of the body-contact part | Dimension | Outer diameter of the inserted portion |
| All-In-One Hand Control Unit and Electrodes | | | | | | |
| 0080J | Electrode (L-Wire Hook with suction function laparoscopic non-stick electrode, 38 cm) | Disposable | Sterile | PTFE coating | 38 cm | 2 mm |

**No. of Product Technical Requirements for Medical Device**

**This document is provided by the applicant or the registrant**

**Laparoscopic Electrodes**

1. **Model/specification**
   1. Specification/model: See Annex A.
   2. Structural diagram: See Figure 1.
   3. See Annex B for the product diagram.

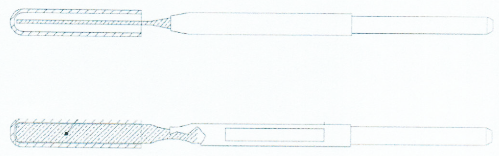


Figure 1: Structural diagram of electrode

1. **Performance indicators**
   1. Requirements for electrode
      1. Appearance: The product surface shall have no such defects as rust or scar.
      2. Dimension: See details in Annex A, with the tolerance of ± 10%.
      3. Connection firmness: The connection between the electrode and the electrosurgical pencil should be firm and able to withstand a force of 15 N without looseness.
      4. Corrosion resistance: After the corrosion resistance test, the corrosion of the electrode should at least meet the requirements of Grade b of the boiling water method specified in YY/T 0149-2006.
      5. Outer diameter of the maximum inserted portion: See details in Annex A; it shall not be bigger than the requirements specified in the table.
   2. Electrical safety
      1. Product safety characteristics

Intensity of protection against electric shock: Type CF applied part.

* + 1. Requirements

The requirements of GB 9706.1-2007, GB 9706.4-2009 and GB 9706.19-2000 shall apply.

* 1. Requirements for flow rate

The suction flow rate shall not be lower than 500 mL/min.

* 1. Electromagnetic compatibility: It shall comply with the requirements of YY 0505-2012 and Clause 36 of GB 9706.4-2009.

1. **Test methods**
   1. Electrode test
      1. Appearance: Verification shall be checked through visual inspection.
      2. Dimension: Use a standard or special measuring tool to make measurement.
      3. Connection firmness: Apply a force of 15 N between the electrode and the electrosurgical pencil for 15 s; the result shall comply with the requirements of 2.1.3.
      4. Corrosion resistance: Conduct the test according to the boiling water method specified in YY/T 0149-2006; the result shall comply with the requirements of 2.1.4.
      5. Test for the outer diameter of the maximum inserted portion: Conduct the test according to the method specified in 5.2 of GB 11244-2005.
   2. Electrical safety

Conduct the test according to the methods specified in GB 9706.1-2007, GB 9706.4-2009 and GB 9706.19-2000.

* 1. Test for flow rate

Operate the machine to run stably. The pressure of the vacuum suction device should not be lower than 0.09 Mpa. The standard measuring cylinder should be used for measurement. The result should comply with the requirements of 2.3.

* 1. Electromagnetic compatibility: Conduct the test according to the method specified in YY 0505-2012 and Clause 36 of GB 9706.4-2009.

**Annex A**

**List of Models/Specifications**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Model** | **Description** | **Instructions for use** | **Delivery status** | **Material of the body-contact part** | **Dimension** | **Outer diameter of the inserted portion** |
| **All-In-One Hand Control Unit and Electrodes** | | | | | | |
| 0055 | All-In-One Hand Piece | Reusable | Non-sterile | N/A | 23.5 cm | N/A |
| 0060 | Electrode (L-Hook with suction function laparoscopic non-stick electrode, 32 cm) | Disposable | Sterile | PTFE coating | 32 cm | 2 mm |
| 0085 | Electrode (J-Wire Hook with suction function laparoscopic non-stick electrode, 38 cm) | Disposable | Sterile | PTFE coating | 38 cm | 2 mm |
| 0062 | Electrode (Curved Blade with suction function laparoscopic non-stick electrode, 32 cm) | Disposable | Sterile | PTFE coating | 32 cm | 2 mm |
| 0063 | Electrode (L-Wire Hook with suction function laparoscopic non-stick electrode, 32 cm) | Disposable | Sterile | PTFE coating | 32 cm | 2 mm |
| 0080 | Electrode (L-Wire Hook with suction function laparoscopic non-stick electrode, 38 cm) | Disposable | Sterile | PTFE coating | 38 cm | 2 mm |
| 0064 | Electrode (Standard Blade with suction function laparoscopic non-stick electrode, 32 cm) | Disposable | Sterile | PTFE coating | 32 cm | 2 mm |
| **Laparoscopic electrodes** | | | | | | |
| 0017 | Electrode (Standard Blade laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0018 | Electrode (Spatula laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0018C | Electrode (Curved Spatula laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0018CS | Electrode (Curved Spatula laparoscopic non-stick electrode/SPLIT STEM, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0019 | Electrode (Curved Blade laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0019L | Electrode (Curved Blade laparoscopic non-stick electrode, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 2 mm |
| 0019S | Electrode (Curved Blade laparoscopic non-stick electrode/SPLIT STEM, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0019LS | Electrode (Curved Blade laparoscopic non-stick electrode/SPLIT STEM, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 3.5 cm |
| 0020 | Electrode (L-Hook laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0020L | Electrode (L-Hook laparoscopic non-stick electrode, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 2 mm |
| 0020S | Electrode (L-Hook laparoscopic non-stick electrode/SPLIT STEM, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0020LS | Electrode (L-Hook laparoscopic non-stick electrode/SPLIT STEM, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 3.5 cm |
| 0021 | Electrode (J-Hook laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0021L | Electrode (J-Hook laparoscopic non-stick electrode, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 2 mm |
| 0021S | Electrode (J-Hook laparoscopic non-stick electrode/SPLIT STEM, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0021LS | Electrode (J-Hook laparoscopic non-stick electrode/SPLIT STEM, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 3.5 cm |
| 0022 | Electrode (Needle laparoscopic non-stick electrode) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0022S | Electrode (Needle laparoscopic non-stick electrode/SPLIT STEM) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0024 | Electrode (Ball laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0026S | Electrode (O-Wire laparoscopic non-stick electrode/SPLIT STEM, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0100 | Electrode (L-Wire laparoscopic non-stick electrode, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 2 mm |
| 0100L | Electrode (L-Wire laparoscopic non-stick electrode, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 2 mm |
| 0100S | Electrode (L-Wire laparoscopic non-stick electrode/SPLIT STEM, 13.5 inch) | Disposable | Sterile | PTFE coating | 33 cm | 3.5 cm |
| 0100LS | Electrode (L-Wire laparoscopic non-stick electrode/SPLIT STEM, 45 cm) | Disposable | Sterile | PTFE coating | 45 cm | 3.5 cm |
| 0105S | Electrode (J-Wire laparoscopic non-stick electrode/SPLIT STEM) | Disposable | Sterile | PTFE coating | 33 cm | 5.0 mm |

**Annex B**

**Product diagrams**

| **Name** | **Model description** | **Product diagram** |
| --- | --- | --- |
| All-In-One Hand Control Unit and Electrodes | L-Hook with suction function laparoscopic non-stick electrode |  |
| J-Wire Hook with suction function laparoscopic non-stick electrode |  |
| Curved Blade with suction function laparoscopic non-stick electrode |  |
| L-Wire Hook with suction function laparoscopic non-stick electrode |  |
| Standard Blade with suction function laparoscopic non-stick electrode |  |
| All-In-One Hand Piece |  |
| Laparoscopic electrodes | Standard Blade laparoscopic non-stick electrode |  |
| Spatula laparoscopic non-stick electrode |  |
| Curved Spatula laparoscopic non-stick electrode |  |
| Curved Blade laparoscopic non-stick electrode |  |
| L-Hook laparoscopic non-stick electrode |  |
| J-Hook laparoscopic non-stick electrode |  |
| Needle laparoscopic non-stick electrode |  |
| Ball laparoscopic non-stick electrode |  |
| O-Wire laparoscopic non-stick electrode |  |
| L-Wire laparoscopic non-stick electrode |  |
| J-Wire laparoscopic non-stick electrode |  |