

**Nutec Global Industria e Comercio Ltda**

(Owner/Operator Number: 10092517)

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786 2667900 EXT, email: [rabreu@unitedregulatory.com](mailto:rabreu@unitedregulatory.com).The Instruction for use is available on the Nutec Global website ([www.nutecglobal.com.br](http://www.nutecglobal.com.br)), if you have any  
questions, please contact us by phone +55 19 3536-3535 or by email [comercial@nutecglobal.tech](mailto:comercial@nutecglobal.tech).**Instructions for Use****Aspiration Cannula**

FDA Regulation Number: 878.4200

Revision 00

**1. Product Features**

Classification Name: Cannula, Injection

Product Code: FGY

Device Class: I



Medical Specialty: General &amp; Plastic Surgery





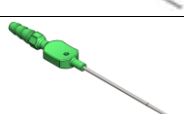

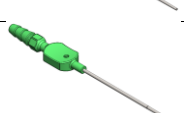
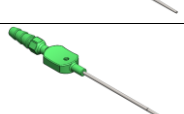
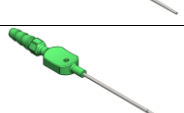







Sterile Product – Sterilized by Ethylene Oxide – ETO



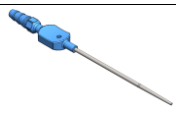
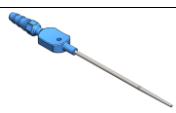

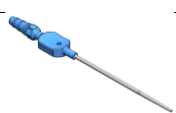
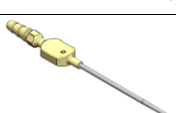
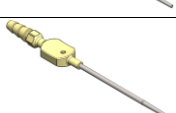
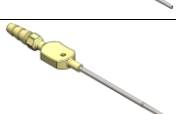
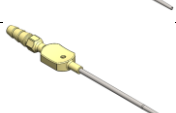
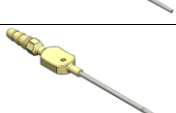
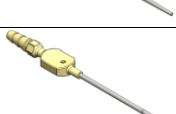
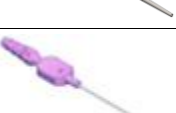
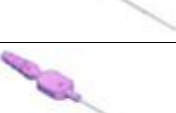


Valid for 2 years from the date of manufacture



Single-use product. Do not reprocess or resterilize.

**2. Technical characteristics**

| Illustrative Image  | Code            | Description                                    | Components  | Function   | Dimension      |
|---|-----------------|--|---|--|----------------|
|  | N001.018.080.US | Rhoton Suction Tips Conic FR 3 - 80mm (3 1/8") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x142mm |
|  | N001.018.100.US | Rhoton Suction Tips Conic FR 3 - 100mm (4")    | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x162mm |






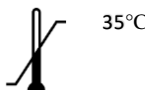
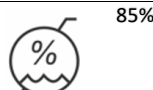




|   |                 |   |   |  |                |
|---|-----------------|---|---|--|----------------|
|    | N001.018.120.US | Rhoton Suction Tips Conic FR 3 - 120mm (4 3/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x182mm |
|    | N001.018.140.US | Rhoton Suction Tips Conic FR 3 - 140mm (5 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x202mm |
|    | N001.018.160.US | Rhoton Suction Tips Conic FR 3 - 160mm (6 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x222mm |
|    | N001.018.180.US | Rhoton Suction Tips Conic FR 3 - 180mm (7 1/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x242mm |
|    | N001.020.080.US | Rhoton Suction Tips Conic FR 4 - 80mm (3 1/8")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x142mm |
|    | N001.020.100.US | Rhoton Suction Tips Conic FR 4 - 100mm (4")     | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x162mm |
|    | N001.020.120.US | Rhoton Suction Tips Conic FR 4 - 120mm (4 3/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x182mm |
|   | N001.020.140.US | Rhoton Suction Tips Conic FR 4 - 140mm (5 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x202mm |
|  | N001.020.160.US | Rhoton Suction Tips Conic FR 4 - 160mm (6 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x222mm |
|  | N001.020.180.US | Rhoton Suction Tips Conic FR 4 - 180mm (7 1/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x242mm |
|  | N001.023.080.US | Rhoton Suction Tips Conic FR 5 - 80mm (3 1/8")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x142mm |
|  | N001.023.100.US | Rhoton Suction Tips Conic FR 5 - 100mm (4")     | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x162mm |
|  | N001.023.120.US | Rhoton Suction Tips Conic FR 5 - 120mm (4 3/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x182mm |
|  | N001.023.140.US | Rhoton Suction Tips Conic FR 5 - 140mm (5 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x202mm |
|  | N001.023.160.US | Rhoton Suction Tips Conic FR 5 - 160mm (6 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x222mm |
|  | N001.023.180.US | Rhoton Suction Tips Conic FR 5 - 180mm (7 1/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x242mm |






|   |                 |  |   |  |                |
|---|-----------------|--|---|--|----------------|
|    | N001.025.080.US | Rhoton Suction Tips Conic FR 6 - 80mm (3 1/8")   | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x142mm |
|    | N001.025.100.US | Rhoton Suction Tips Conic FR 6 - 100mm (4")      | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x162mm |
|    | N001.025.120.US | Rhoton Suction Tips Conic FR 6 - 120mm (4 3/4")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x182mm |
|    | N001.025.140.US | Rhoton Suction Tips Conic FR 6 - 140mm (5 1/2")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x202mm |
|    | N001.025.160.US | Rhoton Suction Tips Conic FR 6 - 160mm (6 1/2")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x222mm |
|    | N001.025.180.US | Rhoton Suction Tips Conic FR 6 - 180mm (7 1/4")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x242mm |
|    | N001.030.080.US | Rhoton Suction Tips Conic FR 7 - 80mm (3 1/8")   | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x142mm |
|   | N001.030.100.US | Rhoton Suction Tips Conic FR 7 - 100mm (4")      | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x162mm |
|  | N001.030.120.US | Rhoton Suction Tips Conic FR 7 - 120mm (4 3/4")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x182mm |
|  | N001.030.140.US | Rhoton Suction Tips Conic FR 7 - 140mm (5 1/2")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x202mm |
|  | N001.030.160.US | Rhoton Suction Tips Conic FR 7 - 160mm (6 1/2")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x222mm |
|  | N001.030.180.US | Rhoton Suction Tips Conic FR 7 - 180mm (7 1/4")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9,0x16,0x242mm |
|  | N001.138.080.US | Frazier Suction Tip Conic FR 10 - 80mm (3 1/8")  | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9.0x16.0x142mm |
|  | N001.138.100.US | Frazier Suction Tip Conic FR 10 - 100mm (4")     | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9.0x16.0x162mm |
|  | N001.138.120.US | Frazier Suction Tip Conic FR 10 - 120mm (4 3/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9.0x16.0x182mm |
|  | N001.138.140.US | Frazier Suction Tip Conic FR 10 - 140mm (5 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9.0x16.0x202mm |

|   |                 |  |   |  |                |
|---|-----------------|--|---|--|----------------|
|  | N001.138.160.US | Frazier Suction Tip Conic FR 10 - 160mm (6 1/2") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9.0x16.0x222mm |
|  | N001.138.180.US | Frazier Suction Tip Conic FR 10 - 180mm (7 1/4") | Stainless Steel 304 / Nitinol / Low Density Polyethylene (LDPE) | Controlled aspiration of tissues and body fluids | 9.0x16.0x242mm |

### 3. Legends of the symbols adopted on the product labeling/packaging (Symbols glossary)

The symbols used are standardized according to technical standard ISO 15223-1 – Medical Devices – Symbols to be used with information to be supplied by the manufacturer, Part 1: General requirements, ISO 7010 – Graphical symbols – Safety colours and safety signs – Registered safety signs and prescription only according to 21 CFR 801.109. The symbology or description may be used.

|   |   |
|---|---|
|    | Do not re-use   |
|    | Do not re-sterilize   |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Refer to instruction manual/booklet                                     |
|  | Sterilized using Ethylene Oxide   |
|  | Temperature limit up to 35°C  |
|  | Humidity limit up to 85%  |
|  | Keep away from sunlight   |
|  | Keep dry  |
|  | Fragile, handle with care   |
|  | Do not use if package is damaged and consult instruction for use.       |

|   |  |
|---|--|
|  | Use by date  |
|  | Date of manufacture  |
|  | Manufacturer   |
|  | Unique device identifier   |
|  | Prescription only<br>Caution: Federal law restricts this device to sale by or on the order of a physician. |

#### 4. Presentation form

Aspiration Cannula are sold individually in sterile condition in Ethylene Oxide (ETO), packaged individually in primary blister packaging, sealed with surgical grade paper and packed in paper cardboard boxes. A label is attached to the cardboard box and the sealed blister, containing the information necessary to identify the product, and patient labels are provided on the packaging.

#### 5. Indications for use

The Aspiration Cannula is a sterile, single-use device intended for the controlled aspiration of fluids and soft tissues from body cavities during various surgical procedures. It is designed to be used with surgical aspirator systems in procedures such as neurosurgery, otorhinolaryngology, oral surgery, maxillofacial surgery, spine surgery, and cardiothoracic surgery. The device consists of a flexible stainless-steel tube that can be molded according to the surgeon's needs, ensuring optimal performance and ease of use. Additionally, it includes a cleaning wire to aid in maintaining patency by removing potential obstructions within the lumen.

This device falls under the Introduction/Drainage Catheter category as defined in 21 CFR 878.4200, as it is intended for fluid aspiration from body cavities in surgical settings.

#### 6. Operating principle / Mechanism of action

Aspiration Cannula are used connected to a surgical aspirator to collect body fluids/fragments through vacuum aspiration. All models operate using vacuum aspiration only and only work when connected to the tubing of a surgical aspirator.

The tapered tips ensure good performance and the molding ensures excellent control during the surgical procedure. There is no passage of electrical current through the product, the product is not indicated for coagulation and should not be used for purposes other than those for which it was designed, other uses are considered contraindicated.

## **7. How to use the product**

Select the Aspiration Cannula model and properly fit it to the surgical aspirator system tubing. Follow the instructions for the surgical aspirator system to be used.

## **8. Sterilization**

Aspiration Cannula are supplied in sterile condition, the sterilization method is by Ethylene Oxide (ETO) and the validity period is 02 (two) years after the date of sterilization.

Sterilization follows the parameters and procedures established in the validation protocol and in the ISO 11135 standard – Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices. The production of the device is carried out with great care, to meet the intended performance of the product. Therefore, the surgical team and other involved parties must handle the devices appropriately to minimize the risk of infection.

## **9. Reprocessing**

Single-use product. Do not reprocess or resterilize.

## **10. Storage conditions**

Products must be stored in a clean, airy place, away from direct sunlight, in their original packaging, at a temperature of up to 35°C and a relative humidity of no more than 85%.

The products cannot be stored on the floor. Therefore, it is recommended to use shelves or pallets, and they should not be stored together with chemical products that may release corrosive vapors. The product must be kept in its original packaging until the moment of use, and the opening of the packaging for surgical use and handling of the product must be carried out by personnel qualified for this procedure.

Before use, check the product's expiration date. Do not use after the expiration date indicated on the product label.

## **11. Conditions for transportation**

Products must be transported in a clean, airy place, away from direct sunlight, in their original packaging, avoiding the effects of vibration, shocks and sudden drops during movement and transportation.

## **12. Handling conditions**

Inspect the packaging and check its integrity. The packaging must be opened by pulling the opening tab at the end of the packaging. The product must then be removed from the packaging. Handling must follow aseptic techniques used in surgical centers.

- Handle with care;
- The product may only be used by technically qualified personnel, such as surgical instrument technicians and surgeons qualified in operating rooms;

- Check the integrity of the primary packaging for any defects or violations;
- The user must be familiar with aseptic handling techniques and the surgical procedure to be performed before using the product;
- When handling the product after use in surgery, follow local legal procedures for handling potentially contaminating products.

### **13. Warnings**

Aspiration Cannula must be used specifically for the intended purposes. Sterile Medical-Hospital Product, exclusive hospital use. The surgery must be performed by medical professionals with adequate experience in the method, in an institutional setting that must have all the appropriate parameters for carrying out the procedure.

- Single-use product. Do not reprocess or resterilize.;
- Do not use if out of date;
- Check the integrity of the packaging before use, do not use if the packaging is damaged, tampered with or past its expiration date;
- The product must be intact for use. If it shows any type of alteration, such as signs of mechanical stress, being bent or any other visible alteration, it must be discarded immediately;
- The product should only be used by qualified surgeons who have the knowledge and experience necessary for the proper use of the product, knowledge of handling sterile products and, above all, the importance of maintaining a completely sterile environment in operating rooms, where care and precaution with every detail are essential to avoid risks of contamination.
- The manufacturing company does not assume responsibility for any damage that may occur to this product and with consequences for the patient, due to improper use;
- Store in a dry place away from humidity and excessive heat, free from particulate contamination (dust and dirt);
- It should not be stored together with chemical products that may release corrosive vapors;
- Transport and keep the product in its original packaging until the moment of use;
- Avoid falls and impacts.

### **14. Precautions**

- Do not use this product after the expiration date indicated on the product label;
- Handle carefully and according to the product manufacturer's instructions;
- Sterile Product - Discard if the packaging that guarantees sterility is damaged or open.

### **15. Contraindications**

Aspiration Cannula should not be used for purposes other than those for which they were designed.

The product described here was developed for use in accordance with the indications described above, so that any other uses are considered contraindicated or without scientific basis.

#### **16. Adverse effects**

Not applicable.

#### **17. Product disposal**

The product was designed to be used in a single surgery and must be discarded immediately after use, in an appropriate place to prevent contamination of people or the environment.

Disposal must follow local legal regulations for the disposal of potentially contaminating products.

#### **18. Consumer assistance**

If the medical product presents a specific unpredictable risk, is outside its specifications or is generating any dissatisfaction, notify Nutec Global's Customer Service (SAC) directly, send the product clean and packed in a plastic bag, duly identified with the description of the non-conformity.

#### **19. Customer complaints**

For more information about the product or to make a complaint, contact Nutec Global through the following service channels: telephone +55 19 3536-3535, email: [sac@nutecglobal.tech](mailto:sac@nutecglobal.tech) or website: [www.nutecglobal.com.br](http://www.nutecglobal.com.br).

To send products for analysis, they must be clean and sterile. Packaging that maintains physical integrity must be used. The packaging and/or product must contain all the information necessary to identify the medical product, related to the handling conditions, cleaning and disinfection methods used, as well as the description and batch number.

#### **20. Manufacturer**



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