

	Sterile & Non-Sterile, Single Patient Use Only		Document #: TFRBI-10-03/01	
	INSTRUCTION FOR USE SUCTION TUBES		Revision #: 01 Doc Date: 10-05-2021	
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INTENDED USE:
A sterile device that is attached to a suction system via the distal end of a suction tube and used for the rapid removal of bulk matter (e.g., vomit, mucus, tissue debris) from a natural or surgical cavity. It is a general-purpose suction tip and will typically be designed with a finger hole in its handle portion which is used by the operator to control the level of suction applied during the procedure or treatment. **GMDN Code: 35917**

DISPOSABLE PRODUCTS:
Check the packing against any damage, pore and tear.
Read carefully expiry date and intended purpose including Sterile Methodology

TESTING AND INSPECTION:
Inspect the device for rust, pits, cracks, pores & dents before use.
CLEANING OF THE PRODUCTS (FOR NON-STERILE PRODUCTS):
Please follow below stated sequence to clean your products before sterile packing in cleanroom:

1. Clean the products by ultrasonic cleaning
 2. Dry the products
 3. Clean the product with 70% IPA solution
 4. Dry the products
- Send product in clean room for sterile packing



WARNING:

- Don't use for second time
- Don't Use if sterile pack is punctured
- Don't use if you observe sharp edges
- Product material is conductive take away from electric source.
- Don't use non-sterile instruments without Sterilization
- Don't use wrong instrument. It can be creating problem in operation
- Our instruments are designed for use by competent surgeons, who have a good knowledge of their features and how they should be used. Any other use can compromise the safety of the user and the patient. It is the responsibility of the surgeon to choose the most suitable instrument for the surgical technique being performed, based on his experience and expertise.

STERILIZATION:
Non-Sterile Instruments can be sterilized using the following methods:-

EO Sterilization:
70% CO₂ / 30% ETO
Concentration ETO: 600mg/L
Temperature: 50°C - 55°C
Exposure time: 6hours
Humidity: 60-85% RH minimum
Pressure: 50-60kpa

Contraindications:

Epi-glottitis or croup are considered absolute contraindications to nasotracheal suctioning. Other situations, while not absolutely contraindicated, that need to be taken into consideration include: head or neck injury, laryngospasm and bronchospasm, occluded nasal passages, and bleeding disorders.

Consequences of reuse the Single Use Product

Reuse of single use instruments can cause cross contamination. It contains the risk of biological and chemical hazards. Re-sterilization of used single use instruments can cause the deterioration of instruments material as well.

SUCTION TUBES ATTACHMENTS ACCORDING TO PATIENT SIZE/AGE

Patient Age	Tube Size (ID mm)	Tube Size (French)
Premature	2.5	5
Newborn	3.0	6
6 months	3.5	6

18 months	4.0	8
3 years	4.5	8
5 years	5.0	10
6 years	5.5	10
8 years	6.0	10
12 years	6.5	12
16 yrs/small adult female	7.0	12
Adult females (average)	8.0	14
Adult males	9.0	14

WARRANTY:

This product is guaranteed to be free from defects in material or workmanship. The warranty is null and void if product damage occurs as a result of mis-handling or mis-use. Care must be taken in the use and reprocessing of this product

SHELF LIFE:

3 years for Non-Sterile Packaging
3 years for Sterile Packaging

OPERATING CONDITIONS:

Follow your operating room SOP's/Laws (These products are not for use in special temperatures

STORAGE & TRANSPORT CONDITIONS:

Store in Dry place and maintain room temperature
During transportation make sure products are packed in appropriate cardboard boxes.

RECYCLE:

When reprocessing medical devices please follow your local government Health & Safety procedures

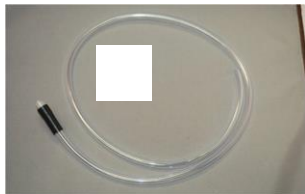
ASSEMBLY INSTRUCTIONS WITH SUCTION MACHINE

As with many suction pumps, the Vacuum Aspirator does not come packaged with the necessary suction tube for suction and clear the operative field. It will be necessary to order a suction tube (for example Frazier suction tube) separately. There is a variety of suction tubes available; from clinical experience, a size 8 French Frazier suction tubes works well for cerumen removal for clear the operative field for doctors.



Short Tubing

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Long tubing

Assembly of the Vacuum Aspirator is relatively straightforward although the packaging contents do not include the best instructions regarding assembly. The most critical step is ensuring that the tubing packaged with the suction pump is attached correctly to the top of the suction canister. Two pieces of tubing (shown above) are packaged with the Vacuum Aspirator:

- 1) A shorter piece of tubing (5') with a pre-attached filter and
- 2) A long piece (40') of tubing.



The longer portion of the tubing with the pre-attached filter connects to the VACUUM/OUT port located on the top of the suction canister while the shorter portion of that same tubing connects to the base of the aspirator. Next, the long piece of tubing with the clear end connects to the PATIENT/IN port located on the top of the suction canister.



Finally, the Frazier suction tube, with the reamer removed connects to the black end of the long piece of tubing. You are now ready to use the Vacuum Aspirator for relevant suction.



Warning:

Please see Suction Machine's manual before connecting it to the suction products. This product is made for only qualified surgeons and trained nursing staff that have good assembly knowledge of the products with suction machines. We are not selling suction machines along with suction tubes so it is a responsibility of relevant doctor or nursing staff to validate suction machine's suction parameters for safety of the patient and user.

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Explanation symbols used on labelling:

	Consult instructions for use		Keep away from sunlight		Catalogue No.
	For single use only		Keep dry		EO Sterilised by ETO (for sterile delivered product only)
	Do not resterilise		Manufacturer		European Union Authorised Representative
	Do not use if packaging is damaged		Batch code		Medical device
	Used by/expiry date				



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