

Instructions for Use

EN

Carefully read the instructions prior to use.

1. PRODUCT DESCRIPTION

VacuSoft is a high-volume aspirator cannula used to remove liquids, solids, and aerosols from the patient's mouth during dental treatments and to keep away tongue and cheeks to allow an unrestricted view of the treatment field.

The VacuSoft aspirator cannula consists of two parts:

- Cannula tube (VacuSoft Base) - reprocessable
- Tip (VacuSoft Tip) – for single use. Non-reprocessable

The tip is available in various degrees of hardness. The following tips are available:

- sensitive comfort (blue tip) – extra soft tip for gentle aspiration of particularly (pressure-) sensitive patients
- comfort (green tip) – soft tip for gentle aspiration in uncomplicated treatment cases
- solid comfort (black tip) – solid tip for aspiration where more resistance is needed for retraction

The funnel-shaped inner construction of the cannula tip prevents the gravity-induced backflow of suctioned media (so-called reflux) into the mouth of the patient.

2. INTENDED USE

VacuSoft universal aspirator cannula is used for large volume evacuation of liquid and solid substances during the dental treatment, e.g. water, aerosol, saliva, blood, filling material. It keeps away tongue and cheeks to allow an unrestricted view of the treatment field.

3. COMPOSITION

VacuSoft tube is made of polypropylene. VacuSoft tips are made of thermoplastic elastomer in different hardness levels.

4. INDICATIONS/CLINICAL BENEFITS

Control of liquid and solid substances through aspiration during dental treatments. Retraction of cheek and tongue during dental treatments.

Liquid control through aspiration which results in relative dryness on the area of treatment. The treatment can be performed undisturbed by saliva, blood and other liquids. The risk of swallowing larger particles by the patient is reduced.

Keeping away cheek and tongue ensures a clear view of the treatment field and enables an undisturbed, more efficient treatment procedure.

5. CONTRAINDICATIONS

N/A

6. SAFETY INSTRUCTIONS

N/A

7. SIDE EFFECTS/INTERACTIONS

No reciprocal or side effects for this device.

8. USER/PATIENT GROUP

The user group are dentists and dental assistants.

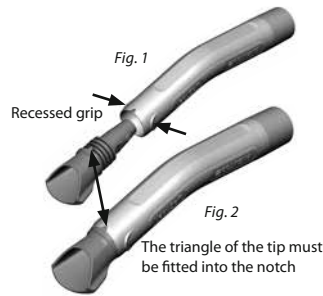
VacuSoft is suitable for all patient groups.

Aspiration with VacuSoft responds to the needs of patients with dementia, cancer patients and children, as low noise and gentle contact with mucosa enables low irritation treatment.

9. PREPARATION

Cannula tube and tip must be connected together as follows:

1. The cannula tube must be reprocessed before the first application and subsequently after each application according to the ISO 17664 processing instructions – see separate reprocessing instructions.
2. Select the tip according to the clinical situation (sensitive comfort, comfort, solid comfort)
3. Attach the tip to the end of the cannula tube on which there is a recessed grip on the left and right (*Fig. 1*)
4. Push the tip into the cannula tube until the tip and tube are flush. The tips must be fitted into the triangular notch in the cannula tube (*Fig. 2*). The grooves in the shaft of the tip ensure a secure fit in the cannula tube.
5. Connect the assembled VacuSoft to the suction machine.



10. PROPER USE

Use VacuSoft universal aspirator cannula in connection with a suction machine for large volume evacuation of liquid and solid substances during the dental treatment.

11. TEST METHOD FOR CORRECT APPLICATION

N/A

12. REPROCESSING, CLEANING, DISINFECTION, MAINTENANCE

The cannula tube must be reprocessed before the first application and subsequently after each application according to ISO 17664 – see separate reprocessing instructions.

The cannula tube must always be reprocessed without the tip. The tips are single use devices.

13. SINGLE USE DEVICE

VacuSoft Tips are single use devices. They are not intended to be reprocessed. After reprocessing the safety, effectiveness and performance of the product cannot be guaranteed any more.

14. SHELF LIFE AND STORAGE

See expiration date and storage symbols on the packaging.

15. DISPOSAL

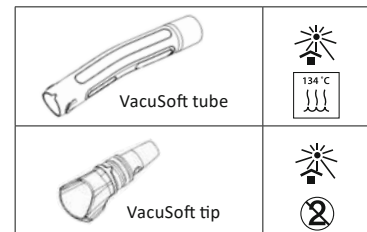
VacuSoft can be disposed with the practice waste unless local requirements define otherwise.

16. TECHNICAL DATA











The cannula tube is designed for connection to aspiration systems with a 16 mm tip connector according to DIN 7494-2.

17. REPORTING OBLIGATION

All serious incidents occurring in conjunction with the product must be reported to the manufacturer and to the competent authority of the member state where the user and/or patient is registered.



Glossary

	Consult instructions for use
	Keep away from sun light
	Do not re-use
	Manufacturer
	Use-by date
	Batch Code
	Rx only – restricted device for professional use only
	Medical Device
	Catalogue number
	Sterilizable in a steam sterilizer (autoclave) at temperature specified