

JET CATHETER

for single use
User Manual



1 Symbols

Standardized symbols according to EN ISO 7000, EN ISO 7010 and IEC 60417

	CE marking European Conformity		Do not reuse
	Warning		Sterilized using ethylene oxide
	Caution		Do not resterilize
	Production date Manufacturer		Do not use if package is damaged
	Medical Device		Does not contain latex
	Number of units		Does not contain phthalates (DEHP)
	Reference or Catalog		Keep away from rain
	Unique device identification		Keep away from sunlight
	Use by date		Temperature limit
	Outer diameter		Humidity limitation
	Single sterile barrier system		Electronic instructions for use
	Single sterile barrier system with protective packaging outside		Refer to instruction manual/booklet

CARL REINER® Symbols

	4 Lumen Catheter mode		Defined Laser resistance
	3 Lumen Catheter mode		Not Laser resistant
	2 Lumen Catheter mode		
	1 Lumen Catheter mode		

2 Product Overview

Ref	Description	Pressure measurement	Gas analysis	Laser resistant	Sterile STERILE EO
CTFS-513-000	1 Lumen Jet Catheter - HF	PP	X	X	✓
CTFS-514-000	1 Lumen Jet Catheter - HF	PP	X	X	✓
CTFS-514-001	1 Lumen Jet Catheter - HF	PP	X	✓	✓
CTFS-515-000	1 Lumen Jet Catheter - HF	PP	X	X	✓
CTFS-516-001	1 Lumen Jet Catheter - HF	PP	X	✓	✓
CTFS-517-000	1 Lumen Jet Catheter - HF	PP	X	X	✓
CTFS-524-011	2 Lumen Jet Catheter - HF	PP	✓	✓	✓
CTFS-526-011	2 Lumen Jet Catheter - HF	PP	✓	✓	✓
CTFS-534-000	3 Lumen Jet Catheter - NF + HF	P _{AW}	X	X	✓
CTFS-544-010	4 Lumen Jet Catheter - NF + HF	P _{AW}	✓	X	✓
CTFS-546-010	4 Lumen Jet Catheter - NF + HF	P _{AW}	✓	X	✓

(PP) Pause Pressure

(P_{AW}) Airway pressure

(HF) High Frequency Ventilation

(NF) Normal Frequency Ventilation

3 Product Description

- Jet Catheters are used for infraglottic ventilation and/or monitoring via the transoral or transnasal route during Jet ventilation by the TwinStream™ Multi Mode Respirator.
- Duration of application is short-term resp. for the duration of the intervention.

-  The listed Jet Catheters are sterile single use products, therefore intended for use on a single patient and must not be reprocessed!
- Reprocessing influences the function of the product. Any reuse involves the potential risk for cross contamination. Damaged products must not be used!

-  The listed Jet Catheters do not contain phthalates (DEHP).

-  The listed Jet Catheters do not contain latex.

4 Intended Use

- Jet Catheters are intended as products to the TwinStream™ Multi Mode Respirator.
- The 1 to 4 Lumen Jet Catheters deliver gases between the TwinStream™ Multi Mode Respirator via transnasal or transoral route for superimposed high or low frequency Jet ventilation (SHFJV® = pulsatile ventilation on two different pressure plateaus) including airway pressure measurement and/or respiratory gas analysis possibility (Jet Catheter dependent).

5 Intended Users

The intended operators are exclusively medical specialists such as anaesthesiologists, surgeons, ENT physicians and pulmonologists/internists who have been trained in the use of the TwinStream™ Multi Mode Respirator and its accessories.

Based on his/her professional training, the user must have knowledge of proper handling and should have been properly instructed by an authorised person (the person responsible for the device).

6 Intended Patient Population

- The TwinStream™ Multi Mode Respirator provides supraglottic ventilation which is suitable for patients from premature to severely obese patients (1 to 200 kg).
- Infraglottic ventilation can be carried out in patients with a minimum tracheal diameter of 5.4 mm as the lower limit and up to a maximum weight of 200 kg.
- The selection of the appropriate instrument size is made by the attending physician according to the anatomical and physiological characteristics of the patient.
- Restrictions regarding patient anatomy or physiology must be made by the attending physician prior to use.
- Only Total IntraVenous Anesthetized (TIVA) patients are treated.

7 Medical Conditions

Jet Catheter for infraglottic ventilation and/or monitoring with TwinStrea™ Multi Mode Respirator.

Areas of application are anaesthesia, surgery (incl. thoracic surgery), ENT, pulmonology, as well as diagnostic and surgical procedures in the lungs and trachea.

8 Indications

8.1 4 Lumen Jet Catheter

- Microlaryngeal surgery for SHFJV® - application in difficult anatomical conditions, with standard laryngoscope.
- Thoracic surgery for SHFJV® or NFJV or HFJV - as well as for unilateral lung ventilation.

8.2 3 Lumen Jet Catheter

Microlaryngeal surgery for SHFJV® - application in difficult anatomical conditions, with standard laryngoscope.

8.3 2 Lumen Jet Catheter

- Microlaryngeal surgery for HFJV - application in difficult anatomical conditions, with standard laryngoscope.
- Thoracic surgery for HFJV - as well as for unilateral lung ventilation.
- Suitable for CO₂ laser application - only valid for 2 Lumen Jet Catheters with defined laser resistance.

8.4 1 Lumen Jet Catheter

- Microlaryngeal surgery for HFJV - application in difficult anatomical conditions, with standard laryngoscope.
- Thoracic surgery for HFJV - as well as for unilateral lung ventilation.
- Suitable for CO₂ laser application - only valid for 1 Lumen Jet Catheters with defined laser resistance.

9 Contraindications

- Severe obstructive/restrictive lung disease and massive laryngeal or tracheal haemorrhage.
- Bleeding in the tracheal and bronchial system (relative contraindication).
- Extreme obesity (body weight > 200 kg).
- Patients at risk of aspiration and non-fasted patients.
- Positional disability and inability to hyperextend the head.
- Limitations for individual Jet Catheters due to anatomical restrictions size selection.
- Expiratory airway cross-sectional reduction of more than 50% due to stenosis, tumor, etc.
- In case of pulmonary edema and pulmonary fibrosis and stiff chest.
- Hepatitis C or HIV.

10 Risk Factors

- Impaired lung function (decreased lung compliance, and or obstructive lung disease).
- Pronounced obesity.
- High grade stenosis.
- Poorly adjustable larynx.
- Combination of multiple risk factors.
- All known risk factors with TIVA.
- In time consuming procedures, in patients with impaired lung function (COPD, smokers) Jet Ventilation may become insufficient.

11 Safety Information

This chapter provides safety information related to the Jet Catheter. Carefully review all sections of this safety chapter before using.

-  Be sure to read the Instructions for Use before using the Jet Catheter and any accessories used with the Jet Catheter.
The instructions for use of the TwinStream™ Multi Mode Respirator must also always be observed!

11.1 Definition of Safety Information

Warning Symbol	Signal Wort	Definition
	Danger	Important information about a potential hazard that could result in death or serious injury to the patient, user or third party if it is not prevented.
	Warning	Important information about a potentially situation that could result in minor or moderate injury to the user, patient or damage to the medical device or other property if it is not prevented.
	Caution	Notes contain special information of important explanations or to avoid difficulties in operating the medical device.

11.2 General Safety Information

Danger:

In case of visible damage and/or contamination, the disposable material must not be used on the patient!

Warning:

- The listed Jet Catheters are sterile single use products, therefore intended for use on a single patient and must not be reprocessed!
- Reprocessing influences the function of the product. Any reuse involves the potential risk for cross contamination. Damaged products must not be used!
- No unauthorised modifications may be made to the Jet Catheter (or other original accessories) or to the TwinStream™ Multi Mode Respirator!
- During the entire ventilation period, care must be taken that the Jet Catheter is not bent and kinked beyond the maximum bending radius and/or squeezed by mechanical influences.
- Inserting additional components such as HME filters, water traps or nebulisers into the ventilation system may result in a loss of system performance
- The Jet Catheters may only be used in combination with the correct Lumen mode of the TwinStream™ Multi Mode Respirator. using the wrong mode could endanger the patient!
- The infraglottic Jet Catheters may only be used with a TwinStream™ Multi Mode Respirator (as original accessories).
- The Jet Catheter can only be applied transnasally if the spatial constriction and the increased vulnerability of the nasal mucosa are not impaired.
- Infraglottic Jet ventilation requires correct placement of the Jet Catheter under visual control. For position control, the markings on the Jet Catheter shaft must be observed. Auscultation: If the infraglottic positioning is correct, Jet sounds are heard equally on both sides. After intubation, fix the Jet Catheter.
- Possible damage to the Jet Catheter during intubation (e.g. by teeth or rough surfaces of intubation instruments) must be avoided.
- Damaged Jet Catheters must not be used/reused.
- After intubation and before connection with adapters (or in the case of 1 Lumen Jet Catheter directly with the Single Use EasyConnect™ Tubing Set) the guide wires of the Jet Catheters must be removed! For intubated Jet Catheters, guide wires must not be moved towards the patient under any circumstances! Avoid possible occlusion of the respiratory cross section due to head and neck movements.
- If the position of the patient or the Jet Catheter changes after intubation, the position of the Jet Catheter must be checked and, if necessary, repositioned.
- Convective heat therapy may be used as hypothermia prophylaxis in case of prolonged non air-conditioned Jet ventilation.

Caution:

- The use of Jet Catheters as accessories to the TwinStream™ Multi Mode Respirator must only be carried out by suitable, trained, healthcare professionals.
- With the 3 and 4 Lumen Jet Catheters, the Lumen for pressure measurement continues on the patient side over the tip of the catheter in a single Lumen and ends with a rounded, centrally closed tip and with two lateral



eyes near the tip.

This sensitive, slender, approximately 6 cm long tip tube

must not be shortened or kinked by the user.

- The ventilation mode selected on the TwinStream™ Multi Mode Respirator must match the selected Jet Catheter. (Mode is described on the packaging of the Jet Catheter) .
- The optimal size of the Jet Catheter should be selected individually for each patient only after clinical assessment.
- Ensure adequate hydration.

11.3 1 Lumen and 2 Lumen Jet Catheters

Warning:

If there is concomitant reduced lung compliance and/or obstructive lung disease, infraglottic ventilation may become insufficient over time.

Caution:

When using 1 or 2 Lumen Jet Catheters, always measure the pause pressure (= pressure in the expiration phase) and monitor it carefully (risk of barotrauma!).

11.4 Laser Risk

Danger:

- The use of a laser (CO₂ or other) with a standard endoscope with the infraglottic technique using a Jet Catheter always involves a residual risk.
- Complications can arise from accidental bombardment even with non-flammable, laser-resistant Jet Catheter materials.
- Effective smoke evacuation is required.
- Always observe warnings on the display of the TwinStream™ Multi Mode Respirator. If the user misinterprets or ignores warnings, the use of Jet Catheters can lead to barotrauma in the event of sudden obstruction of the gas outflow or dislocation of the Jet Catheter (possible consequences): Emphysema, pneumothorax, pneumoperitoneum or mediastinal emphysema, tracheal rupture with tracheoesophageal fistula formation, etc.).
- If a laser or an electrosurgical probe is used during treatment, the Jet Catheter may burn and release toxic, corrosive vapours or gases, especially if high oxygen or nitrous oxide air mixtures are used (ensure adequate extraction of the laser smog!).
- Operate laser application (CO₂ laser) only in Laser Safe Mode (LSM) of the TwinStream™ Multi Mode Respirator (the applied oxygen concentration is then kept below 40%) and exclusively using Jet Catheters with defined laser resistance.
- A Jet Catheter damaged by laser or an electrosurgical probe must be replaced immediately!

12 Undesirable Side Effects

- Barotraumas
 - If Jet Catheters are operated with the wrong Lumen mode (the correct Lumen mode can be read on the packaging of the Jet Catheter), delays in emergency shutdown may occur. Excess pressure in the lungs can lead to barotrauma in this case.
 - Furthermore, when using a 4 Lumen ventilation mode with e.g. a 2 Lumen Jet Catheter, an uncontrollable gas leak can occur, whereby the resulting infraglottic ventilation pressure during active Jet Ventilation can trigger a barotrauma (always check and observe Jet Catheter packaging instructions and mode display!).
 - If a 1 or 2 Lumen Jet Catheter is used, barotrauma may occur if the gas outflow is suddenly blocked (with these Jet Catheters, the pressure is measured in the expiration phase = pause pressure).
- Subcutaneous emphysema
- Pneumomediastinum
- Tracheal rupture with tracheoesophageal fistula formation (with overdistension of the stomach) Hematoma
- Dry mucous membranes
- Hypothermia
- Fluid loss (sufficient fluid supply)
- Risk of aspiration
 - As with all other forms of Jet ventilation, there is no absolute aspiration protection with SHFJV®.
 - Ventilation via the Jet instruments or via Jet catheters is usually performed during elective procedures on fasting patients.
 - Only the use of the SHFJV® generates a positive end expiratory pressure.
 - Therefore, the risk of aspiration can only be considered low with the SHFJV®.
- Dislocation of the tube with possibility of hyperinflation of the gastrointestinal tract, hypercapnia, or hypoxia.

- Risk of injury to the trachea or respiratory tract.
 - The Jet Catheters are positioned with guide wires.
 - With the help of the guide wires, the desired curvature for application is achieved.
 - After intubation, the wires must be removed.
 - Insertion of the Jet Catheter or subsequent insertion of the laryngoscope may result in mechanical deformation (e.g. Jet Catheter kinks before or during intubation, edge of endoscope kinks the Jet Catheter, defective endoscope cuts open Jet Catheter).
 - This can cause injuries in the trachea and in the entire respiratory tract.
- Stridor/laryngospasm
 - Post extubation stridor/laryngospasm can occur as with any intubation anaesthesia. (therefore, postoperative monitoring!)
- Bleeding
 - If massive bleeding occurs in the surgical area during surgery, insert a tube immediately after suctioning and block the cuff to prevent blood from entering the deeper airways.
- Laser risk
 - When using a laser, laser-resistant Jet Catheters must be used for infraglottic Jet ventilation. These are basically non-flammable at clinically usual laser intensities, but can also be damaged and leak under certain conditions by laser bombardment at clinically usual laser intensities:
 - Fire and explosion hazard with increased O₂ concentrations of the inspiratory gas mixture.
 - Formation of laser smog during laser irradiation of tissue or other carbon donors due to thermal effects.
 - Formation of harmful polymer fume due to pyrolysis (always aspirate reaction products, otherwise risk of non-cardiac pulmonary oedema).
 - Potential risk of infection for operating staff due to backflow of laser smog because of the open ventilation system.
 - Release of alveolar damaging pyrolysis derivatives if inhalation anaesthetics are wrongly used (general anaesthesia instead of TIVA = total intravenous anaesthesia).
 - Visual impairment and inhalation trauma due to laser induced smoke and dusts inhalation trauma due to thermal decomposition products of the Teflon Jet catheters at extremely high laser powers, beyond the usual clinical intensity (temperatures beyond 500°C).

13 Functions

13.1 General Description

- In the case of infraglottic Jet ventilation, the Jet Catheter must be placed under visual supervision.
- After checking the position, the Jet Catheter should be fixed immediately to avoid catheter dislocation.
- The laryngoscopic placement of the Jet Catheter should also be carried out under fiberoptic control, especially in unclear anatomical situations, in order to avoid injury to the laryngeal inlet and trachea.
- The Jet Catheters are delivered with guide wires which help to achieve the desired curvature especially in the tube tip area (facilitates intubation). In addition, the guide wires define the predefined Lumen assignments and guarantee the patency of the lumina of the Jet Catheters (safety aspect).
- 2 to 4 Lumen Jet Catheters may be used with the EasyConnect™ adapter, REF CTNI-610-400
- 1 Lumen Jet Catheters may be connected with the EasyConnect™ adapter, REF CTFS-500-400
- The defined LASER resistance of the Jet Catheter is indicated on the packaging.

13.2 4 Lumen Jet Catheter (REF CTFS-546-010 resp. CTFS-544-010) and 3 Lumen Jet Catheter (REF CTFS-534-000)

- For superimposed High Frequency Jet Ventilation (NF+HF)
- NOT laser resistant
- Continuous airway pressure measurement
- Breathing gas analysis (only available with 4 Lumen Jet Catheter)
- Features length markers



13.3 2 Lumen Jet Catheter (REF CTFS-526-011 resp. CTFS-524-011)

- For high-frequency Jet ventilation (HF)
- Defined laser resistance
- Pause pressure measurement
- Breathing gas analysis
- Features a plastic sleeve that can be adjusted by the user



13.4 1 Lumen Jet Catheter (REF CTFS-516-001 resp. CTFS-514-001)

- For high-frequency Jet ventilation (HF)
- Defined laser resistance
- Pause pressure measurement
- NO breathing gas analysis
- Features a plastic sleeve that can be adjusted by the user



13.5 1 Lumen Jet Catheter (REF CTFS-517-000/CTFS-515-000/CTFS-514-000/CTFS-513-000)

- For high frequency Jet ventilation (HF)
- NOT laser resistant
- Pause pressure measurement
- NO breathing gas analysis
- Features length markers



14 Operation

Remove the Jet Catheter from the sterile packaging before using.

14.1 2/3/4 Lumen Jet Catheters

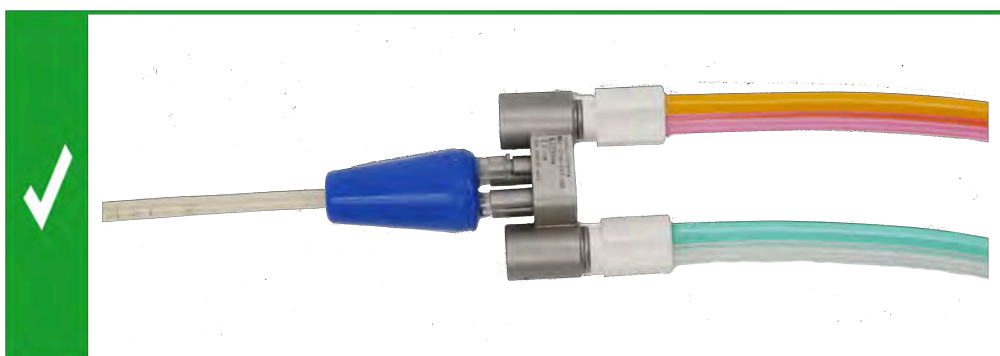
1. Connect the 4 Lumen Jet Catheters to the EasyConnect™ adapter (REF CTNI-610-400)
2. And connect EasyConnect™ adapter (REF CTNI-610-400) to the Single Use EasyConnect™ Tubing Set complete (REF CTFS-220-SU1).



Make sure that the Jet Catheter is correctly connected to the reprocessable EasyConnect™ adapter or to the Single Use EasyConnect™ Tubing Set complete as shown in the above pictures.

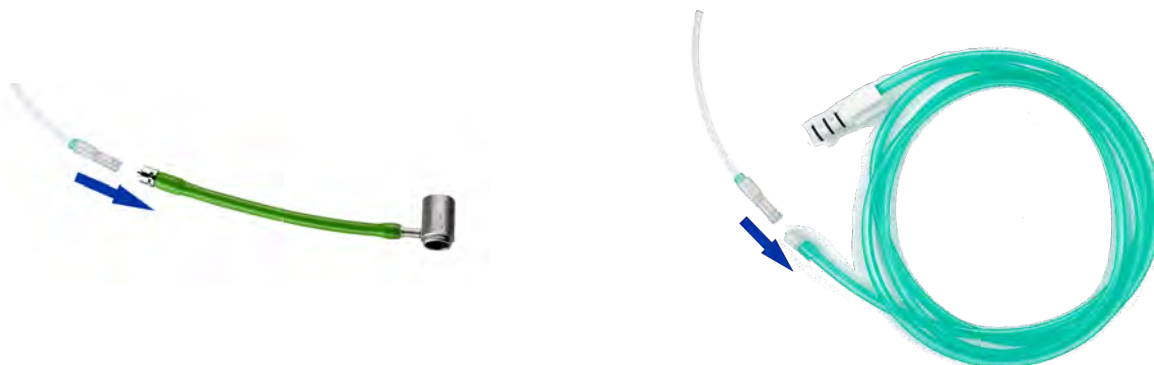
Notice:

Only one correct connection position is possible at a time.



14.2 1 Lumen Jet Catheter

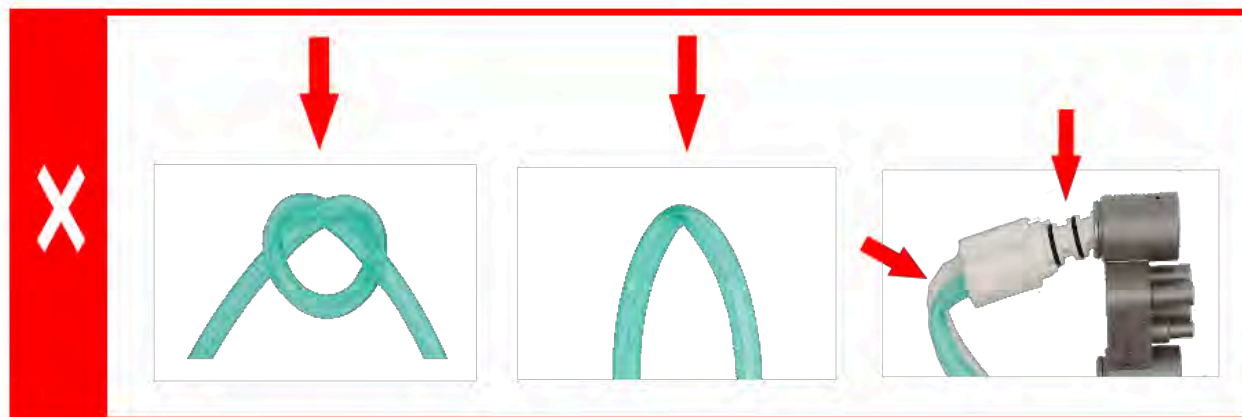
1. Connect the 1 Lumen Jet Catheter to the reprocessable EasyConnect™ adapter (REF CTFS-500-400).
2. Or connect the 1 Lumen Jet Catheter to the Single Use EasyConnect™ Jet Tubing for 1 Lumen mode (REF CTFS-220-1U1).



Caution:

- Reprocessable EasyConnect™ adapters and Single Use EasyConnect™ Tubing Sets must not be knotted, nor kinked.
- Lateral forces on the connector, or forces due to pulling on the tube, during use of the product must be avoided to prevent overstressing of the connector.

- If shear forces are applied to the connector, it is possible that the connector (or EasyConnect™ plug) will be damaged.

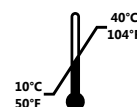


- If there is visible damage and/or contamination, the disposable material must not be used on the patient!
- Jet Catheter size must be selected individually for each patient based on the clinical judgement of a qualified practitioner.
- Intubate the patient according to current medical standards.
- Disposal of the Single Use EasyConnect™ Tubing Sets and Jet Catheters must be in accordance with nationally applicable hospital hygiene and waste disposal guidelines.
- Jet Catheters must not be reused!

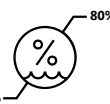
15 Storage and Transport Conditions

- Each set is supplied individually and sterile in a sterile packaging.
- Expiry date: see product label.

- Observe minimum/maximum temperature (+10°C/+40°C) during storage and transport.



- Observe minimum/maximum humidity (0%/80%) during storage and transport.



Warning:

- Keep away from rain/moisture and store in dry place.
- Keep away from sunlight/light sources and protect from heat.
- Store and transport in original packaging.
- The sterility of the set and the components is only guaranteed as long as the packaging is unopened and undamaged, but not longer than indicated on the label.

16 Safe Disposal

Used or damaged products must be disposed according to applicable national and international legal directives.

17 Guarantee and Liability

CARL REINER® GmbH guarantees that the devices it supplies, including the accessories, are validated and without defect in terms of material and workmanship.

CARL REINER® GmbH assumes no liability for product performance and patient safety:

- if the devices aren't used and stored in accordance with the Instruction For Use (IFU)
- the warnings and precautions are not observed
- modifications of any kind are made to the product.
- the use of non-original spare parts
- misuse

In case of a serious incident that has occurred in relation to the device, the user and/or patient has to issue a report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

18 Legal Information



Classification: Class IIa



e-IFU database

<https://qr.carlreiner.eu/jet-catheter-ifu>

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