

Jet Converter and Accessories

Instructions for Use



Be sure to read the instructions for use before using the Jet Endoscopes and all devices/accessories to obtain all the information necessary for the intended use of the device.

1 Product Overview

Jet Converter		
REF	Product Name	Brand Name
CTNS-6B0-AC0	Jet Converter for SHFJV [®] acc. to ALOY, VERES and SLAVEI	JetCON™

Supporting Arm Adaptors		
REF	Product Name	Brand Name
CTNS-860-051	Adaptor for Jet Converter and Bronchoscopes to Universal Supporting Arm REF GE CA 305-07-01	JetCON™ SA ADPT GEO
CTNS-710-112	Adaptor for Jet Converter and Bronchoscopes to Supporting Arm REF CTFI-710-012	JetCON™ SA ADPT SPH
CTNS-710-115	Adaptor for Jet Converter and Bronchoscopes to Supporting Arm REF CTFI-710-010	JetCON™ SA ADPT M8

Cleaning Adaptors		
REF	Product Name	Brand Name
CTFI-811-006	Adaptor (LF) for machine cleaning and disinfection of Jet Lines from Jet Endoscopes	EasyConnect™ CLN JET ENDO LF
CTFI-811-007	Adaptor (LF) for machine cleaning and disinfection of Monitoring Lines from Jet Endoscopes	EasyConnect™ CLN MON ENDO LF
CTFI-811-M06	Adaptor (LM) for machine cleaning and disinfection of Jet Lines from Jet Endoscopes	EasyConnect™ CLN JET ENDO LM
CTFI-811-M07	Adaptor (LM) for machine cleaning and disinfection of Monitoring Lines from Jet Endoscopes	EasyConnect™ CLN MON ENDO LM

2 Intended Use

2.1 Jet Converter

The Jet Converter is intended for Jet Ventilation via third-party endotracheal tubes or laryngeal masks.

2.2 Supporting Arm Adaptors

Adaptors for supporting arms are intended to attach CARL REINER® Jet Instruments to a third-party supporting arm or rail.

2.3 Cleaning Adaptors

Cleaning Adaptors are used to attach CARL REINER® Jet Instruments to a washer – disinfectant.

3 Intended Users

- Jet Instrument and its accessories may only be used by professional users in health care facilities. The user must have knowledge of proper handling and should have been properly instructed by an authorised person (the person responsible for the device).
- Processing is carried out exclusively by trained specialists.

For the training program/instruction, please contact the Sales Representative or office@carlreiner.at.

4 Intended Patient Population

Jet Ventilation can be set for patients with a body weight from 3 kg up to 200 kg.

5 Indication

Jet Ventilation of patients during interventional, diagnostic and surgical procedures.

6 Contra-Indications

- Extreme obesity with a body weight >200 kg
- Patients at risk of aspiration and non-fasted patients
- Increased risk of infection, airborne diseases (e.g. HIV, hepatitis C, HPV, CJK, BSE, TSE)
- Massive laryngeal or tracheal haemorrhage at the surgical site
- Respiratory Anesthesia with volatile anesthetics
- Rigid thorax

7 Residual Risks

- Barotrauma
- Hypothermia
- Risk of aspiration
- Dehydration of mucosa
- Risk of airway fire during laser surgery
- Stridor/laryngeal spasms
- Bradycardia

8 Risk Factors

- Limited lung function (decreased lung compliance and/or obstructive pulmonary disease)
- Pronounced or extreme obesity
- High grade stenosis
- Restrictive and obstructive pulmonary disease
- Expected heavy bleeding risk (coagulopathy)
- Pulmonary edema and pulmonary fibrosis
- Rigid thorax
- Combination of several risk factors

9 Safety Information

Carefully review all sections of this safety chapter before using the device.

Definition of Safety Information

Warning Symbol	Signal Word	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.

Danger:

- The supraglottic as well as infraglottic Jet Ventilation method requires an “open” ventilation system. Therefore, the distal opening of the Jet Instrument must not be closed.
- Do not use too many surgical instruments at the same time or too big instruments, it may cause obstruction of the endoscope's working channel.
- Jet Endoscope are delivered non-sterile and must be sterilized before first use!
- Jet Endoscope must be cleaned and processed immediately after use.

Warning:

- Check the devices for damages prior to use. Damaged devices must not be used until all necessary repairs have been completed. Make sure that the maintenance interval is observed.
- No unauthorized modifications must be made to the devices as they can endanger the health of the patient, the operator as well as third parties.
- The patient must receive only TIVA (Total Intravenous Anaesthesia) because inhalation anaesthetics in the conventional sense (e.g. mixture of nitrous oxide and oxygen, admixture of inhalation anaesthetics) are not compatible with the device or the use of an open ventilation system!
- In all forms of high frequency ventilation, clinical monitoring of the patient by auscultation of the lung and observation of thoracic excursion is critical to avoid endobronchial misalignment or dislocation.
- The instrument may only be used to open or reach the upper airways (trachea, larynx, bronchi). But not for esophagus, rectum, artificial orifice or other body orifices.
- Blocked Jet or Monitoring lines prevent the ventilator from starting and operation must be interrupted.

Caution:

- Always choose the correct ventilation mode when using the Jet Instrument with a jet ventilator.
- Only use with a TwinStream™ or TwinStream™ EVO Jet Ventilator and the specified accessories. When combining medical devices of various manufacturers without a compatibility certificate, the user takes on legal responsibility of a manufacturer according to the EU Medical Devices Regulation.

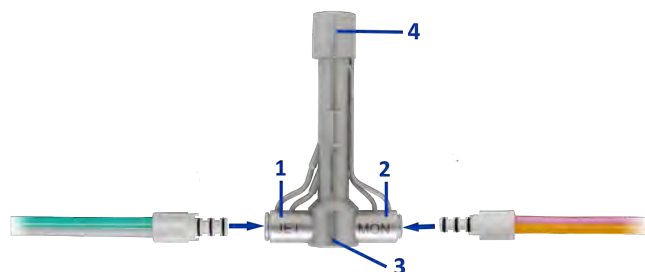
10 Operation

10.1 Jet Converter

10.1.1 Description of Functions

Superimposed high-frequency Jet Ventilation (S-HFJV) with the TwinStream™ or TwinStream™ EVO in conjunction with the Jet Converter can be carried out via any standard endotracheal tube, double-lumen tube or via a laryngeal mask (LMA). The patient is ventilated via the Jet Lines integrated in the Jet Converter. The Jet Converter is also equipped with Measuring Lines that allow continuous monitoring of airway pressure and respiratory gas analysis (EtCO₂ and FiO₂ AW).

10.1.2 Application



1. Connector for Jet Lines
2. Connector for Monitoring Lines
3. Proximal end connector for bacterial filter
4. Distal end connector for standard ET-Tubes/LMA or T-Piece adaptor

Fig.1

10.1.2.1 Jet Converter without Bacterial Filter and Humidifier

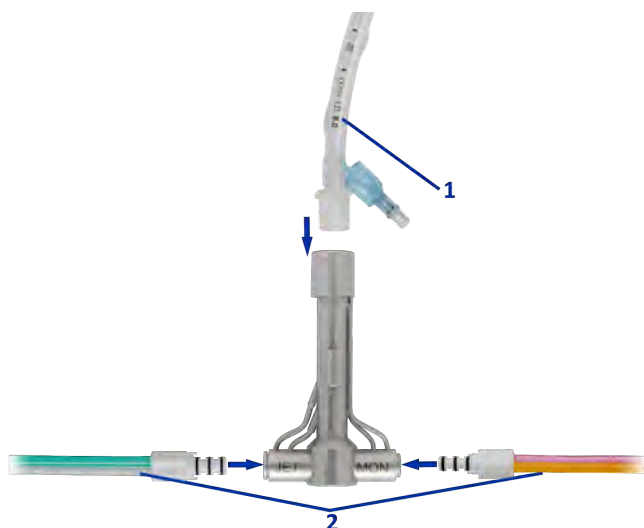
1. Connect Jet Converter with standard ET-Tubes or LMA to distal end connector.
2. Connect Jet Converter with EasyConnect™ Tubings for Jet Ventilation. (green/transparent) and monitoring measurement (yellow/red).
3. Start Jet Ventilation with TwinStream™/TwinStream™ EVO.

Notice:

For the operation of the TwinStream™/TwinStream EVO™ ventilator, please refer to the relevant instructions for use for the devices.

Tip:

To assure maximum patient safety both connectors have a different diameter to guarantee two ventilation lines and the two monitoring lines can not be inadvertently interchanged.



1. Standard ET-Tube or LMA
2. EasyConnect™ Tubings

Fig.2

10.1.2.2 Jet Converter with Bacterial Filter and Humidifier

Jet Converter can also connect with an external humidifier and bacterial filter

1. Connect the T-Piece (dimension 22mm inside) to Jet Converter distal end connector.
2. Connect standard ET-Tube or LMA to T-Piece.
3. Connect the tubing from the external humidifier to the T-piece.
4. Connect the bacterial filter (dimension 22mm outside) to Jet Converter proximal end connector.

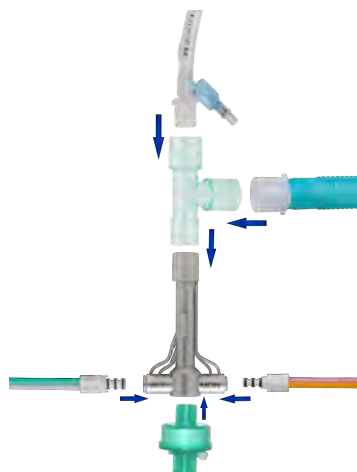


Fig.3



Fig.4 Jet Converter with Humidifier and Bacteria Filter

10.2 Supporting Arm Adaptors

10.2.1 Description of Functions

Supporting Arm Adaptors are used to connect CARL REINER® Jet Instruments to the supporting arms or rails.

10.2.2 Application

Carl Reiner Jet Converter can be fitted onto the cone of the Supporting Arm Adaptor (CTNS-860-051/CTNS-710-112) using a cylinder section and then secured in place using the supporting arm's clamping mechanism

1. Insert the cone of the Supporting Arm Adaptor (CTNS-860-051/CTNS-710-112) into the cylinder block of the Jet Converter.
2. Connect the corresponding supporting arm to CTNS-860-051/CTNS-710-112.



Fig.5



Fig.6

11 Processing

11.1 General Information

Jet Instruments and Accessories are made of surgical stainless steel and are reusable devices. The devices are delivered non-sterile and must be sterilized before first use and then cleaned, disinfected and sterilized after each use to avoid cross-infection via the device surface.

When working with contaminated products, personal protective equipment guidelines must be followed.

There is no limitation on the number of permitted processing cycles, as the devices have appropriate safety precautions and are monitored by annual maintenance.

Warning:

- Do not disconnect the connectors from the Cleaning Adaptors
- The O-rings on the Cleaning Adaptors have to be inspected, faulty or missing rings have to be replaced
- Take care to ensure that the thin tubes of the Jet Instruments are not blocked

11.2 Processing Procedure

Jet Instruments and Accessories should be cleaned and processed within 60 Minutes after use to ensure the effectiveness of the treatment.

11.2.1 Pre-treatment

All Jet Instruments and Accessories that are contaminated with body fluids or grossly contaminated must be flushed with distilled water immediately after use. Attention must be paid to the Jet and Monitoring Lines. These must be flushed with a syringe filled with distilled water to prevent blockades.

11.2.2 Transport to the processing facility

The products must be securely stored in a suitable transport container immediately after pre-treatment and then transported to the processing facility.

11.3 Cleaning and Disinfection

11.3.1 Machine Cleaning and Thermal Disinfection

11.3.1.1 General Information

A cleaning and disinfection device that complies with the requirements of ISO 15883 must be used for cleaning and disinfection. For disinfection the A_0 -Value must be ≥ 3000 .

Caution:

- Please follow the instructions for use of the washer - disinfectant manufacturer
- Use a suitable cart (e.g. MIC cart)
- Keep devices well separated from one another to avoid direct metal to metal contact
- Do not stack devices on the top of one another
- Do not overfill the cart
- Arrange products so that water does not collect and condensation can drain away

11.3.1.2 Cleaning Adaptors

Description of Function

Cleaning Adaptors are used to facilitate the cleaning of the Jet and Monitoring Lines during machine cleaning and disinfection. Therefore, a Cleaning Adaptor always consists of a connection piece to a Jet Instrument and a standard connection to a washer - disinfectant.

REF	Name	Picture
CTFI-811-006	EasyConnect™ CLN JET ENDO LF	
CTFI-811-M06	EasyConnect™ CLN JET ENDO LM	
CTFI-811-007	EasyConnect™ CLN MON ENDO LF	
CTFI-811-M07	EasyConnect™ CLN MON ENDO LM	

11.3.1.3 Loading of the Washer Cart

11.3.1.3.1 Jet Converter

1. Place the Jet Converter on the standard cleaning nozzle of the mobile injector unit.
2. Connect the Cleaning Adaptors (CTFI-811-xxx) to the mobile injector unit, using the Luer-Lock System.
3. Connect the Cleaning Adaptors (CTFI-811-xxx) to the Jet and Monitoring Lines.



Fig.7 Jet Converter on standard cleaning nozzle

11.3.1.3.2 Supporting Arm Adaptors

Place the Supporting Arm Adaptors in appropriate containers based on their shape, or in such a way that any liquids can drain out of any cavities.

11.3.2 Recommended Automated Cleaning/Disinfection Settings

The following cleaning and disinfection parameters have been validated:

Processing Step	Duration [min]	Water Quality	Temperature	Dosage Temperature	Cleaning Agent
Pre-Rinsing	5	Fully demineralized water	-	-	-
Cleaning	10	Fully demineralised water, 50-60°C	50-60°C	35°C	Neodisher® MediClean forte Dosage 6 ml/L*
Rinsing	1	Fully demineralized water	-	-	-
Thermal Disinfection	5	Fully demineralized water	91°C	-	-
Drying	15	-	110°C	-	-

*Automated cleaning should be carried out with (mild) alkaline cleaning agents (pH<11). Dosage should be in accordance with the instructions of the manufacturer.

Notice:

Please note that the on-site cleaning and disinfection process must be validated in accordance with national and international standards and guidelines.

11.4 Visual Inspection and Functional Test

1. Visual inspection of the products for residual contamination and chemical residues:

- Check whether residual contamination or chemical residues are visible on the product
- Perform a patency check on the Jet and Monitoring Lines:
 - Blow through the lines using an air-filled syringe
 - If a blockage occurs: Blow through the lines with a compressed air gun using medical-grade compressed air to clear the blockage
 - If the blockage cannot be cleared, the Jet Endoscopes must no longer be used and must be handed over to the sales representative or manufacturer in a disinfected state

2. If residual contamination is present, the cleaning/disinfection process must be repeated

3. No water residue may remain on or inside the products. To remove it, use an air-filled syringe, a compressed air gun with medical-grade compressed air, or a clean, soft, lint-free cloth

4. Damage and wear:

- Surface intact
- Product itself intact
- Labeling legible
- No sharp ends
- No dents

Damaged products and products whose labeling is no longer legible must be discarded.

11.5 Packaging

Products intended for sterilization must be packaged in suitable packaging material that complies with applicable national and international standards.

11.6 Recommended Sterilization Method

The following fractional vacuum process using a large-capacity steam sterilizer has been validated:

Operating temperature	Sterilization time	Vacuum drying at	Drying time
134°C	5 minutes	40 mBar	10 minutes

Notice:

Please note that the on-site sterilization process must be validated in accordance with national and international standards and guidelines.

12 Accessories

REF	Product Name	Brand Name	Accessory Type
CJVNA113202	Jet-Ventilation tubing set, EvoConnect™ to Easy-Connect™, single use	EvoConnect™ - EasyConnect™	Tubings
CJVNA112202	Jet-Ventilation tubing set, EvoConnect™ to EasyCon-nect™, single use, sterile	EvoConnect™ - EasyConnect™-S	
CTFS-220-SN1	Single Use EasyCon-nect™ Tubing Set for Jet Endoscopes and Jet Converter, length 200 cm	EasyConnect™ - EasyConnect™	
CTFS-220-SU1	Single Use EasyConnect™ Tubing Set for Jet Endo-scopes and Jet Converter, length 200 cm, sterile	EasyConnect™ - EasyConnect™-S	
CTNS-220-0S0	EasyConnect™ Tubing Set for Jet Endoscopes and Jet Converter, length 150 cm	-	
CTNS-220-0S1	EasyConnect™ Tubing Set for Jet Endoscopes and Jet Converter, length 200 cm		
CTNS-220-1S0	EasyConnect™ Jet Tubing Set for Jet Endoscopes / Jet Converter, length 150 cm		
CTNS-220-1S1	EasyConnect™ Jet Tubing Set for Jet Endoscopes / Jet Converter, length 200 cm		
CTNS-220-200	EasyConnect™ Monitoring Tub-ing Set for Jet Endoscopes / Jet Converter, length 150 cm		
CTNS-220-201	EasyConnect™ Monitoring Tub-ing Set for Jet Endoscopes / Jet Converter, length 200 cm		
CTNS-860-000	Universal Support Arm for Jet Endoscopes or Jet Converters	-	Third-party Product
B J892001	Bacterial filter type “Sterivent”	-	Third-party Product
-	Standard endotracheal tubes, double-lumen tube and ventilation masks	-	Third-party Products
-	Bronchoscopy elbow connec-tor or double swivel elbow	-	Third-party Products

13 Storage Conditions

Sterilised devices must be stored in dry and dust-free conditions. The storage period depends on the storage conditions and internal or national regulations.

14 Maintenance and Life Time

14.1 Maintenance

The state of Jet Instrument and Accessories must be evaluated every 12 months (Jet and Monitoring Line inspection, weld seams, sharp edges, cones), and must be carried out by the qualified personnel who is authorised by the manufacturer.

Caution:

Maintenance and repair work on the Jet Instruments and Accessories can only be conducted if these have been cleaned and disinfected prior to their being collected or sent in. We reserve the right to return contaminated devices to the sender.

14.2 Life Time

The longevity and / or reusability of processed products depends very much on the care taken during cleaning and disinfection. It should be pointed out that each preparation accelerates the natural material aging and reduces the life of the product. However, after each reprocessing or before each use, the devices must be carefully checked for damage (sharp edges, burrs, cracks or breakages, etc.).

Caution:

In the case of visible, mechanical damage or blocked lines, the Jet Instrument and Accessories must not be used on the patient but must be returned immediately to the Customer Service Department!

15 Disposal

Jet Instruments and Accessories are made from surgical stainless steel and titan, which should be re-introduced into the production chain through metal waste recycling. Disposable Products should be disposed of via disposal facilities for hazardous garbage.

16 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.

17 Legal Information



0483



e-IFU Database

<https://qr.carlreiner.eu/instrument>

Distributed by

CLS Surgical

customerservice@cls-surgical.com

Call us: 0151 733 1900

www.cls-surgical.com