TSC LIFE

Innovation with purpose

Broncoflex®

User Manual

Single-Use Bronchoscope

REF	Broncoflex® 5.6 /3.0 XFlo	**10040001**
	Broncoflex™ 5.6/2.8 Vortex	**10030001**
	Broncoflex™ 3.9/1.4 Agile	**20030001**

2025 | User Manual | 10030531-B_25/05 | EN

This page is intentionally left blank.

Contents

1. Important information - read before use

"WARNING" indicates a particularly hazardous situation. Failure to observe the instruction may damage the instrument, cause injury, or even death.

"CAUTION" indicates that use or improper use of the instrument may cause a problem, such as product malfunction, failure or damage.

1.1 Foreword

This user manual contains essential information for the optimum and safe use of the Broncoflex. The information in this user manual is subject to change at any time, without notice. Make sure that you are using the latest version by logging onto Axess Vision website https://www.tsc-life.com or contacting the local representative.

This user manual does not contain any explanations of information concerning endoscopic techniques per se.

Carefully read this manual, along with the manuals for all the instruments used, and use them as instructed. Keep all user manuals in a safe and readily accessible place. Should you have any questions or comments concerning this manual, contact us for more information.

This manual describes the recommended inspection and preparation procedures to be followed before using the instrument, along with the precautions to take for product disposal after use.

Carefully follow all the instructions given in this user manual. Poor understanding of these instructions could lead to:

- severe injuries to the patient,
- severe injuries to the user,
- severe injuries to a third party,
- equipment damage.

1.2 Intended use

This video-bronchoscope is intended to provide an optical display of the pulmonary tract using a monitor (Screeni™) and to be used with endotherapy accessories and instruments.

The pulmonary tract include the organs, tissues and subsystems represented by the nasal passages, trachea and bronchial tree beyond the primary bronchi. The video-bronchoscope is inserted via the oral or nasal route.

The Broncoflex should not be used for any purpose other than that described herein.

1.3 Indications for use

This video-bronchoscope is designed for use exclusively in a hospital environment.

1.3.1 Endotherapy accessories and instruments

The effective length of an endoscopic instrument should be at least 30 cm greater than the effective length of the endoscope.

Model	Minimum compatible endotracheal tube size	Minimum compatible dual lumen endo-bronchial tube size	Maximum size of endotherapy instruments
Broncoflex 3.9/1.4 Agile	≥ 5.0 mm	≥ 35 Fr.	≤ 1.2 mm
Broncoflex 5.6/2.8 Vortex	≥ 6.0 mm	≥ 41 Fr.	≤ 2.6 mm
Broncoflex 5.6/3.0 XFlo	≥ 6.0 mm	≥ 41 Fr.	≤ 2.6 mm

1.3.2 Compatibility instrument

Endoscopic accessories:

– Endotherapy instruments compatible with the working channel ID (such as biopsy forceps, cytology brushes, endoscopic needles, Cryoprobes, electrosurgical probes).

– Accessories with standard Luer slip and/or Luer Lock (using the enclosed introducer).

– Easy BAL Clip (ref 41010000)

– High frequency electrosurgical equipment fulfilling EN 60601-2-2 only for Broncoflex 5.6/3.0 XFlo

1.3.3 Patient Population

The Broncoflex can only be used on adult patients.

1.4 Contraindications

The images generated by this device should not be used for diagnostic purposes. The Broncoflex is suitable for qualitative visualization but not for structural sizing. Indeed, quantitative sizing may lead to inaccurate results because the geometric distortion of the device has not been evaluated.

Physicians must interpret and support any findings in other ways, based on the patient's clinical data.

1.5 User qualification

The Broncoflex should only be used by trained medical personnel who are authorised to perform bronchial endoscopy procedures under the responsibility of the physician in charge of the patient's examination.

Where there are official standards and/or regulations relating to user qualification for performing endoscopy, and endoscopic treatment defined by the medical administration or by other official institutions, such as the academic endoscopy society, these must be respected.

Otherwise, this instrument must only be used by a doctor approved by the head of department responsible for accident prevention in the hospital or by the person in charge of the corresponding department (pulmonology department, etc.). The physician must be able to perform the video endoscopy and the planned endoscopic procedure, safely, in accordance with the guidelines set by the academic endoscopy society and considering the risks of complications related to endoscopy and the endoscopic procedure.

Staff should be aware of potential risks and injuries associated with endoscopic procedures that are primarily: perforation, bleeding, and infection.

1.6 Warnings ⚠ and cautions for use ⓘ

Observe all the warnings and precautions described in this manual. Otherwise, Axess Vision cannot be held liable in case of injury to the patient or user or damage to the device.

⚠	Check that the packaging is intact before use. Devices for which the packaging has been damaged must not be used and must not, under any circumstances, be re-sterilised.
⚠	Always check the expiry date indicated on the Broncoflex label before use.
⚠	Inspect each Broncoflex before use to detect any deterioration. If the product is damaged, does not function properly, or has been dropped, do not use it.
⚠	In the event of difficulties inserting the applied part of the Broncoflex into the bronchi or a tube, do not apply force and attempt to determine the cause before continuing.
⚠	Powered and/or active endotherapy instruments (e.g. laser probe or other electrosurgical equipment) must not be used with the Broncoflex Vortex and Agile. Powered and/or active endotherapy instruments (e.g. laser probe or other electrosurgical equipment) are compatible with XFlo.
⚠	Only for XFlo : Do not activate an endotherapy instrument (especially laser or electrosurgical equipment) in the endoscope before the instrument's distal end can be seen in the image on the displaying unit, as this can lead to patient injury or damage the endoscope.
⚠	Only for XFlo : The endoscope and active endotherapy instruments, e.g. HF and laser instruments, are not to be used when highly flammable gases e.g. anaesthetic aerosols are present in the patients airways. This could potentially cause patient injury.
⚠	Only for XFlo : Use of endotherapy instruments including Argon Plasma Coagulation (APC) probe may in rare cases cause gas embolism. Monitor the patient appropriately during and after treatment.
⚠	Before each use, the compatibility of the Broncoflex with all non-powered endotherapy accessories and instruments should be checked.
⚠	Handle cutting or perforating endotherapy instruments with care so as not to damage the flexible tube of the Broncoflex.
⚠	The device is single-use. Do not reuse the Broncoflex, as it may contaminate or cross-contaminate, leading to infection of the patient.
⚠	Before using the Broncoflex, check the parts to be inserted into a patient to ensure that there are no rough surfaces, sharp edges or unwanted projections that could cause damage.
⚠	Do not use the device while administering a highly flammable anaesthetic gas to the patient as this may cause injury to the patient.
⚠	Do not use the device during defibrillation as this may cause injury to the user.
⚠	Risk of injury to the patient or damage to the Broncoflex when inserting or removing an accessory into or from the working channel while the deflection zone is not straight and the deflection lever is not released.
⚠	No Broncoflex modifications or repairs are allowed.
⚠	Using the Broncoflex near medical devices that generate high frequencies can disrupt the image. In order to continue the examination properly, any interfering devices should be removed or disabled.

⚠	Should a malfunction occur while using the Broncoflex, immediately stop the examination in progress and carefully remove the Broncoflex from the patient after having released the deflection lever.
⚠	The light-emitting portion on the distal end of the endoscope may radiate heat. Prolonged contact with the mucous membrane may cause injury (tissue damage or coagulation). Prolonged contact between the tip of the device and the mucous membrane should be avoided.
⚠	The patient's vital signs must be monitored throughout the examination.
❗	The product must be handled and used with extreme care by qualified personnel.
❗	Provide a similar backup system so that the procedure can continue in the event of malfunction.
❗	Do not exceed a suction pressure of -638 mmHg (-850 mbar).
❗	Do not use alcohol on the lens. If necessary, clean the lens with isotonic saline solution and a sterile non-woven compress.
❗	US federal law restricts these devices for sale only by, or on the order of, a physician.
❗	For the use of endotherapy accessories or instruments, follow good endoscopy practice. Please contact Axess Vision or your local representative to verify the compatibility of specific or highly specialised endotherapy accessories or instruments prior to use with the Broncoflex.

2. Description of the Broncoflex

2.1 Product description

The Broncoflex is a single-use video-bronchoscope which is part of a system made up of the endoscope (Broncoflex) and its reusable display monitor (Screeni). For further information concerning the Screeni display monitor, please see the corresponding user manual.

2.1.1 System components

Bronchoscopes				
Item code	**Description**	**External diameter of insertion tube (mm)**	**Working channel inner diameter (mm)**	**Colour code**
10040001	Broncoflex 5.6/3.0 XFlo	Min: 5.4 Max: 5.6	Min: 3.0	Orange 
10030001	Broncoflex 5.6/2.8 Vortex	Min: 5.4 Max: 5.6	Min: 2.8	Orange 
20030001	Broncoflex 3.9/1.4 Agile	Min: 3.6 Max: 3.9	Min: 1.4	Grey 

Display monitor		
Item code	**Description**	**Illustration**
30030001	Screeni	

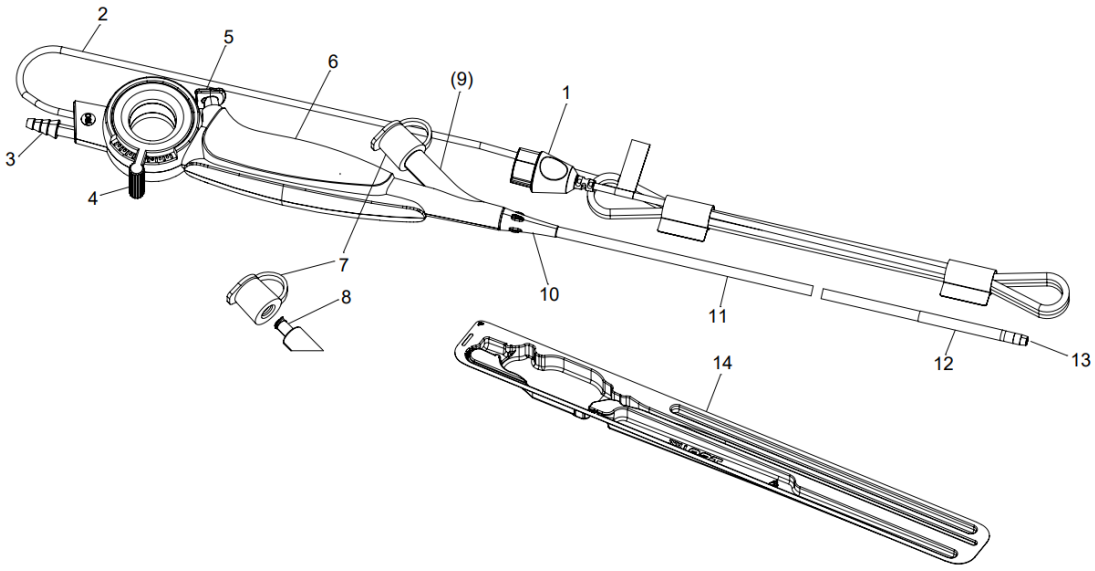
2.2 Checking package contents

The Broncoflex is supplied sterile and ready to be used in a sterile bag (sterilisation method: ethylene oxide ETO).

Broncoflex devices are packaged in boxes of 5.

When opening the box, if you notice that the packaging providing the consumable's sterile barrier has been pierced or opened, do not use the Broncoflex. It should be returned to the local representative and must not, under any circumstances, be re-sterilised.

2.3 Broncoflex details



Number	Component	Position	Material
1	Connector	Connects the endoscope to its Screeni display system.	Grey ABS and black TPE
2	Video cable	Transmits the video signal to the Screeni display monitor.	PVC
3	Suction cone	Connects the endoscope to a suction system.	POM
4	Deflection lever	Controls distal end high/low deflection.	ABS
5	Suction button	Activates suction when pressed.	ABS
6	Handle	Used to hold the system, suitable for left- and right-handed users.	ABS-PC
7	Biopsy valve	Used to hermetically seal the working channel infeed and ensure it remains airtight during instrument insertion through the valve.	Silicone
8	LUER LOCK connector	Used to screw on a device (syringe type) to the working channel.	POM (black) MABS (transparent)
9	Working channel	Used to inject liquid or to pass an instrument.	PU
10	Tube guard	Provides the junction between the handle and the insertion tube.	TPE
11	Insertion tube	Flexible part inserted into the airways.	TPE
12	Articulated section	Articulates in one plane: up and down, when the deflection lever is pressed.	TPE
13	Distal tip	Contains the LEDS, camera and the outfeed of the working channel.	HPP
11-12-13	Applied part	Insertion tube, articulated section and distal end.	See corresponding number
14	Rigid thermoformed tray with Tyvek ® peelable lidstock	Protects the endoscope during transport.	PETG & Tyvek®
-	Packaging items	Box package.	Cardboard

Abbreviations: ABS (acrylonitrile butadiene styrene), TPE (thermoplastic elastomer), PVC (polyvinyl chloride), POM (polyoxymethylene), MABS (Methyl methacrylate acrylonitrile butadiene styrene), PU (polyurethane), PC (polycarbonate), HPP (high performance polymer), HDPE (high density polyethylene), PET (polyethylene terephthalate).

The materials making up the Broncoflex comply with biocompatibility requirements for medical devices.

3. Instructions for using the Broncoflex

3.1 Precautions prior to use

	Check that the packaging is intact before use. Devices for which the packaging has been damaged must not be used and must not, under any circumstances, be re-sterilised.
	Always check the expiry date indicated on the Broncoflex label before use.
	Inspect each Broncoflex before use to detect any deterioration. If the product is damaged, does not function properly, or has been dropped, do not use it.
	Before each use, ensure that the Broncoflex is compatible with all the non-powered endotherapy accessories and instruments used.

Before use and upon receipt of the system, the elements received should be visually inspected in order to detect any potential damage caused during the transport phase. Ensure that all components are present, using the system description in this user manual. If any components are missing or damaged, do not use the system and contact your local local representative.

As long as the sterile barrier (Rigid thermoformed tray with Tyvek ® peelable lidstock) has not been opened, the Bronchoscope remains sterile in its packaging.

Once the Tyvek ® peelable lidstock is open, gently remove the endoscope from its blister pack. It is now ready for use.

Only the distal end and endoscope insertion tube are considered as applied parts and only these parts of the equipment should come into contact with the patient.

3.2 Using the Broncoflex for an examination

	In the event of difficulties inserting the applied part of the Broncoflex into the bronchi or a tube, do not apply force and attempt to determine the cause before continuing.
	Powered and/or active endotherapy instruments (e.g. laser probe or other electrosurgical equipment) must not be used with the Broncoflex Agile & Vortex.
	Do not use the device during defibrillation as there is a risk of user injury.
	Risk of injury to the patient or damage to the Broncoflex when inserting or removing an accessory into or from the working channel while the deflection zone is not straight and/or the deflection lever is not released.
	The product must be handled and used with extreme care by qualified personnel.
	Do not exceed a suction pressure of -638 mmHg (-850 mbar).

1. Connect the endoscope connector to the Screeni port identified by the symbol  , then power on the Screeni (follow the instructions in the Screeni user manual).
2. Check that the illumination LEDs and camera are working correctly by pointing at an object (for example the palm of the hand).
3. Make sure that the deflection functions in the up and down position at the specified angles.
4. Test the working channel seal by connecting a syringe filled with sterile saline-type liquid to the LUER LOCK screw tip. Check for leaks.
5. Connect a hose between the suction cone of the endoscope and the suction system (not supplied). Use a regulator to adjust the suction pressure to a value of no more than -638 mmHg (-850 mbar). Next, check the operation of the piston controlling suction.
6. Ensure that the endotherapy instruments provided for the procedure are compatible with the Broncoflex and are satisfactory.
7. The system is now ready for use. Proceed with the examination.
8. At the end of the examination, remove the Broncoflex gently after releasing the deflection lever.
9. Once removed, ensure that there are no damaged or missing endoscope parts.

To end, switch off the Screeni display monitor, then disconnect and dispose of the Broncoflex.

3.3 Consumable disposal

After use, the Broncoflex is considered to be contaminated. To avoid any contamination, it must be discarded in accordance with local directives concerning the disposal of contaminated medical devices comprising electronic components.

4. Warranty

The Broncoflex is not covered by a warranty. The Broncoflex shelf-life is specified on the product label. If you observe a product defect, please report the information to the local representative, providing as much detail as possible. If necessary, take photos of the defect if it is visible.

5. Troubleshooting and Serious Incidents

Inspection indications and actions are proposed below to resolve most problems encountered.

If the following instructions are insufficient to correct the problem encountered, return the Broncoflex to the local Axess Vision-accredited local representative for analysis.

Problem	Cause(s)	Actions
No image and/or LEDs do not illuminate	The connector is incorrectly attached to the Screeni	Ensure that the connector is pushed firmly into the port on the Screeni and that the Screeni is switched on. See the Screeni user manual.
Poor quality image	Vision impaired by secretions on the camera.	Clean the lens with isotonic saline solution and a sterile non-woven compress.
Defective suction	The biopsy valve is damaged, poorly fitted or incorrectly closed.	Re-fit/close the valve, or replace it.
	Excessive or insufficient suction pressure	Adjust the suction pressure to no more than -638 mmHg (-850 mbar).
Channel obstructed	The working channel is obstructed by secretions	Outside of the patient, clean the channel with a cleaning brush, or rinse it by injecting a sterile isotonic solution with a syringe. If the working channel cannot be cleared, prepare a new endoscope.

Any serious incident that has occurred in relation to the device should be reported to Axess Vision Technology (via local representative) and the competent authority of the Member State which the user is established.

Serious incident means incidents that directly or indirectly led, might have led or might lead to any of the following:

(a) the death of a patient, user or other person,

(b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,

(c) a serious public health threat (= an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time).

6. Transport, storage and use conditions

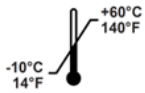
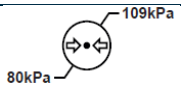
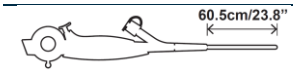
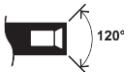
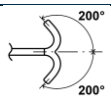
Broncoflex devices must be stored in their original unopened packaging, in a clean, dry and dark place. The storage conditions to ensure optimum product shelf life are normal temperature and pressure conditions, i.e. 20 °C and 1.013 bar.

	Parameters	Minimum	Maximum
Transport and storage conditions	Temperature	-10 °C (14 °F)	+60 °C (140 °F)
	Relative air humidity (no condensation)	10%	90%
	Atmospheric pressure	80kPa	109kPa
Conditions of use	Temperature	+ 10 °C (50 °F)	+ 40 °C (104 °F)
	Relative air humidity (no condensation)	30%	85%
	Altitude and atmospheric pressure	≤ 2000m – 80kPa ~ 109kPa	

7. Broncoflex labels and symbols

The meanings of the various symbols and labels are described in the table below:

Symbol	Meaning
	For single use only, do not re-use.
	Do not re-sterilise.
	Ethylene oxide sterilised with single sterile barrier system.
	Ethylene oxide sterilised with single sterile barrier system and protective packaging outside
	Product manufacturer.
	Date manufactured.
	Do not use if package is damaged.
QTY	Number of elements in the package.
	See the user manual before use.
	Indicates that the instructions for use contain important cautionary information, such as warnings and precautions, that cannot, for various reasons, be displayed on the medical device itself.
	See the user manual for instructions on using this product.
GTIN	GTIN (Global Trade Item Number).
	Product expiry date (Year-Month-Day).

	Part applied to the BF: BF type electronic device, compliant with standard “IEC 60601-1. Protection against electrical discharges”.
LOT	Batch number.
REF	Product catalogue number.
	Keep out of sunlight and away from UV radiation.
CE 1639	Conformity marking as per the European Medical Devices Regulation (MDR) 2017/745, accompanied by the identification number of the notified body SGS.
	Do not expose the box to rain.
	Fragile contents.
	Store in an environment with a relative humidity of between 10 and 90%.
	Store in an environment with a temperature of between -10 and +60 °C.
	Store in an environment with an atmospheric pressure of between 80 and 109 kPa.
	Minimum working channel inner diameter and maximum applied part outer diameter. MAJ
	Effective length of the inserted part.
	Camera field of vision.
	Deflection angle of the distal end.
MD	Medical device
	Latex free
	Phthalate free
Pat. Pending	Patented device.
Rx only	Device to be used on prescription only.
	Consult electronic Instructions for Use QR code - link to Instructions for Use

8. Technical characteristics

Type	Broncoflex 5.6/3.0 (XFlo)	Broncoflex 5.6/2.8 (Vortex)	Broncoflex 3.9/1.4 (Agile)
Product reference	10040001	10030001	20030001
Field of vision direction	0°		
Field of vision	120°		
Field depth	5 ~ 50 mm		
Lighting system	2 LEDs		
Image resolution	400x400		
High/low deflection angle	180°/180°	200° / 200°	220° / 220°
External diameter of insertion tube	5.4 mm	5.4 mm	3.6 mm
Distal end outer diameter	5.6 mm	5.6 mm	3.9 mm
Working channel inner diameter	3.0 mm	2.8 mm	1.4 mm
Working length	605 mm		
Sterilisation	Ethylene oxide ETO		
Device class	Is		

8.1 Essential performance

The essential performance of the Broncoflex single-use bronchoscope is the viewing of the upper airways and of the bronchial tree. It involves other procedures such as performing examinations requiring suction of secretions or the use of endotherapy accessories or instruments designed for use in combination with a bronchoscope and compatible with the Broncoflex.

8.2 Information concerning the electrical safety rating and electromagnetic compatibility

See the Screeni user manual.

9. Applicable standards

Broncoflex operation complies with the following regulatory texts:

- **European Medical Devices Regulation (EU) 2017/745**: Regulation (EU) 2017/745 of the European Parliament and the council of 5 April 2017 on medical devices
- **IEC 60601-1 edition 3.1**: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2 edition 4.1:** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- **IEC 60601-2-18:** Medical electrical equipment - Part 2-18: Particular requirements for the basic safety of endoscopic equipment
- **ISO 8600-1:** Medical endoscopes and endotherapy devices - Part 1: General requirements
- **ISO 10993-1:** Biological evaluation of medical devices - Part 1: Evaluation and tests within a risk management process
- **ISO 80369-7:** Small connectors for liquids and gasses used in the health sector - Part 7: 6% connectors (Luer) for intravascular or hypodermic applications
- **ISO 60601-2-2:** Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Axess Vision certifies the compliance of its equipment, both in terms of design and of manufacturing to normative standards.

10. Manufacturer's contact details

Axess Vision Technology
Zone de la Liodière
6 rue de la Flottière
37300 Joué-lès-Tours – France
https://www.tsc-life.com

TSC LIFE

Innovation with purpose

TSC Life
Axess Vision Technology
Zone de la Liodière
6 rue de la Flottière
37300 Joué-lès-Tours – France

www.tsc-life.com
letsconnect@tsc-life.com

CE 1639