



TSC LIFE

Innovation with purpose

Note: Always consult the latest User Manual of Broncoflex® devices.

1. Broncoflex® User Manual ref. 1003012
2. Screeni® User Manual ref. 30030511
3. Easy BAL Clip™ User Manual ref. 41040406

The use of our medical equipment is solely intended for the use of healthcare professionals. Healthcare professionals have the obligation to exercise their own professional clinical judgment when determining the suitability of a specific product for treating an individual patient. TSC Life does not provide medical advice and strongly advises healthcare professionals to undergo training on the usage of any specific product before using it. Healthcare professionals should consistently refer to the package insert, product label, and/or instructions for use, including guidelines for cleaning and sterilization (if applicable), before utilizing any product supplied by TSC Life. The information presented aims to display specific products and the extensive range of offerings from TSC Life. Availability of products may vary across markets due to regulatory and/or medical practices specific to each region. For inquiries regarding the availability of specific TSC Life products in your area, please reach out to your TSC Life representative.

TSC Life

Zone de La Liodière | 6 rue de la Flotière | 37300 Joué-lès-Tours | France
T +33 2 47343290 | letsconnect@tsc-life.com | www.tsc-life.com

Manufactured by : Axess Vision Technology, S.A.S.

TSC LIFE

Technical Datasheet

BRONCOFLEX®



**The Smart Choice for Single-Use Bronchoscopy.
Everything you need. Nothing you don't.**

tsc-life.com



Description	<p>Broncoflex® is a single-use flexible bronchoscope which is part of a system made up of the endoscope (Broncoflex®) and its reusable high-definition display system (Screeni®).</p> <p>Three different bronchoscopes are available:</p> <ul style="list-style-type: none">• Broncoflex® 5.6/3.0 XFlo• Broncoflex® 5.6/2.8 Vortex• Broncoflex® 3.9/1.4 Agile <p>Combined with:</p> <ul style="list-style-type: none">• Screeni®• Easy BAL Clip™
Intended Use	<p>This 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.</p> <p>The pulmonary tract includes the organs, tissues and subsystems represented by the nasal passages, trachea and bronchial tree beyond the primary bronchi. The bronchoscope is inserted via the oral or nasal route.</p> <p>Broncoflex® should not be used for any purpose other than that described herein.</p>
Indications for Use	<p>This bronchoscope is designed for use exclusively in a hospital environment.</p> <p>Broncoflex® can only be used on adult patients.</p> <p>Endotherapy accessories and instruments</p> <p>The effective length of an endoscopic instrument should be at least 30 cm greater than the effective length of the endoscope.</p>

Name	Minimum compatible endotracheal tube size	Minimum compatible dual lumen endo-bronchial tube size	Maximum size of endotherapy instruments
Broncoflex® 5.6/3.0 XFlo	6,0mm	≥ 41Fr.	2,8mm
Broncoflex® 5.6/2.8 Vortex	6,0mm	≥ 41Fr.	2,6mm
Broncoflex® 3.9/1.4 Agile	5,0mm	≥ 35Fr.	1,2mm

Name, Part Numbers and Dimensions

Name	Part Number/REF	External diameter of insertion tube	Working channel inner diameter
Broncoflex® 5.6/3.0 XFlo	10040001	5,6mm	3,0mm
Broncoflex® 5.6/2.8 Vortex	10030001	5,6mm	2,8mm
Broncoflex® 3.9/1.4 Agile	20030001	3,9mm	1,4mm
Screeni®	30030001	NA	NA
Easy BAL Clip™	41010000	NA	NA

Quick Access to Digital Product Information

Explore More:
Our Bronchoscopy Solutions



Direct Access
to the latest User Manuals



Key Features for Performance and Efficiency



Large Working Channel in a Regular Scope

Optimized design combining a large working channel with a standard-size scope, ensuring both efficient suction performance and efficient ventilation¹.



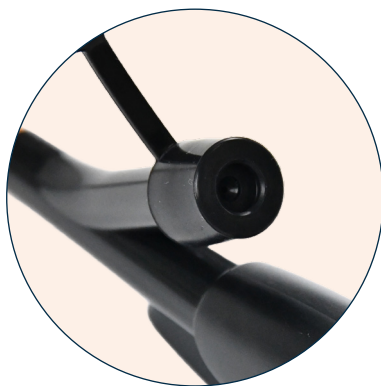
Optimized Tool Passage for Smooth Instrumentation

Seamless insertion and maneuverability, even with instruments in place, allowing precise interventions.



Luer Lock Connection for Maximum Compatibility

Secure and adaptable —compatible with both Luer lock and slip-tip syringes without the need for adapters.



Sealed Biopsy Valve for a Secure System

Ensures a closed system, reducing contamination risks and maintaining procedural efficiency.

Single-Use Broncoflex® Sizes


Broncoflex® 5.6/3.0 XFlo

Description	Specification	
Part Number/REF	10040001	
Tube guard color	Orange	
Weight	127g	
Optics	Field of vision direction	0°
	Field of view	120°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
Insertion tube	High/low deflection angle	180°/180°
	Minimum outer diameter	5,4mm
	Maximum outer diameter	5,6mm
	Working length	605mm
Working channel	Internal diameter	3,0mm
Handle	Printed sizes	
Sterilization Method	Ethylene Oxide (EO)	
Instrument Compatibility	Endotracheal tube (internal diameter)	6,0mm
	Double-lumen tube (internal diameter)	41Fr.
	Argon Plasma Coagulation	Yes
	Cryobiopsy	Yes
	Stent placement catheter	Yes
GMDN Code	60963	
GTIN-14 Code	03664977000110 (x5 devices) 03664977000103 (x1 device)	
Device class	Class Is (EU) MDR 2017/745	




1. Kelebeyev S, Davison W, Ford BL, et al. The Effects of Endotracheal Tube Size During Bronchoscopy in Simulated Models of Intubated Patients. *Laryngoscope*. 2023;133(1):147-153.

Broncoflex® 5.6/2.8 Vortex

Description	Specification	
Part Number/REF	10030001	
Tube guard color	Orange	
Weight	127g	
Optics	Field of vision direction	0°
	Field of view	120°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
Insertion tube	High/low deflection angle	200°/200°
	Minimum OD	5,4mm
	Maximum OD	5,6mm
	Working length	605mm
Working channel	Internal diameter	2,8mm
Sterilization Method	Ethylene Oxide (EO)	
Instrument Compatibility	Endotracheal tube (internal diameter)	6,0mm
	Double-lumen tube (internal diameter)	41Fr.
GMDN Code	60963	
GTIN-14 Code	03664977110031 (x5 devices) 03664977010034 (x1 device)	
Device class	Class IIa (MDD 93/42/EEC) Class Is (EU) MDR 2017/745 	



Broncoflex® 3.9/1.4 Agile

Description	Specification	
Part Number/REF	20030001	
Tube guard color	Grey	
Weight	124g	
Optics	Field of vision direction	0°
	Field of view	120°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
Insertion tube	High/low deflection angle	220°/220°
	Minimum outer diameter	3,6mm
	Maximum outer diameter	3,9mm
	Working length	605mm
Working channel	Internal diameter	1,4mm
Sterilization Method	Ethylene Oxide (EO)	
Instrument Compatibility	Endotracheal tube (internal diameter)	5,0mm
	Double-lumen tube (internal diameter)	35Fr.
GMDN Code	60963	
GTIN-14 Code	03664977120030 (x5 devices) 03664977020033 (x1 device)	
Device class	Class IIa (MDD 93/42/EEC) Class Is (EU) MDR 2017/745 	





Screeni®

Description	Specification	
Part Number/REF	30030001 (no accessories) - 30030000 (with accessories)	
Electrical	Power supply	Power requirement: 100-240V AC / 50-60Hz / 0,6A Power output: 15V DC / 2A
	Protection type against electrocution	Class 2
	Battery type	Lithium-Ion Battery
	Autonomy	3h
Touch screen	Screen size	10,1in
	Maximum resolution	1280x800
Miscellaneous	Protection Rating	IP 30
	Dimensions (L x H x D)	300 x 200 x 110mm
	Weight	1.8kg
	Accessories supplied	Charger, mounting bracket, HDMI cable and medical-grade power supply (including UK-US-AU-EU adaptors)
	Physical memory size	16Gb
	Input connections	USB Type A
	Output connections	Ethernet (SN SCR30), HDMI (SN SCR31)
GMDN Code	56654	
GTIN-14 Code	03664977030032 (x1 device)	
Device class	Class I (EU) MDR 2017/745 <div> <div>CE</div> <div>1639</div> </div>	



Easy BAL Clip™

Description	Specification
Part Number/REF	41010000
Material	ABS-PC
Length	90mm
Width	75mm
Height	30mm
Weight	15.5g
GMDN	62137
GTIN-14 Code	03664977000042
Device class	Class I (EU) MDR 2017/745 <div> <div>CE</div> <div>1639</div> </div>

Safety Properties

- DEHP free.
- Does not contain latex or latex components.
- Biocompatible according to ISO 10993-1 for the intended use.

Packaging

Broncoflex®

Each single-use device is packaged in a sterile Tyvek® pouch, containing either a protective blister or a protective tube.

Broncoflex® devices are packaged in carton boxes of 5 products. Each Broncoflex® carton includes a label indicating sterilization by EO.
Carton packaging box, dimensions 980 x 110 x 130mm.
Weight 1,53kg
User Manual (or QR Code), carton box and unit labelling/carton box labelling are included.

Recommended Storage 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	+60 °C
	Relative air humidity (no condensation)	10%	90%
	Atmospheric pressure	80kPa	109kPa
Conditions of use	Temperature	+ 10 °C	+ 40 °C
	Relative air humidity (no condensation)	30%	85%
	Altitude and atmospheric pressure	2000m – 80kPa ~ 109kPa	

Regulatory Information

FDA 510(k) clearance, Regulatory Class II.
Electrical Safety Certified Body Certificate by UL.
CE mark for Vortex, Agile, Screeni® and Easy BAL Clip™.
For applicable standards please refer to the User Manual.

Cleaning and Disinfecting Screeni

According to the User Manual.

Waste disposal

According to hospital practice and/or local legislation.



Manufacturer

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

We are a global leader in the medical industry, committed to support sustainable and accessible patient care.

Our mission is to drive innovation by creating evidence-based solutions that empower healthcare professionals to improve patient outcomes. With a bold vision of touching the lives of 25 million patients annually, we aim to disrupt the healthcare market through agility, integrity, and reliability. Our commitment to continuous improvement ensures that we not only meet but exceed the expectations of our partners, patients, and stakeholders, fostering a healthier, more sustainable future for all.



Innovation with purpose