TSC LIFE

TSC LIFE

Innovation with purpose

TSC LIFE

Technical Datasheet

BRONCOFLEX®

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

tsc-life.com

BRONCOFLEX®

Description	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®). Three different bronchoscopes are available: • Broncoflex® 5.6/3.0 XFlo • Broncoflex® 5.6/2.8 Vortex • Broncoflex® 3.9/1.4 Agile Combined with: • Screeni® • Easy BAL Clip™
Intended Use	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. 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. Broncoflex® should not be used for any purpose other than that described herein.
Indications for Use	This bronchoscope is designed for use exclusively in a hospital environment. Broncoflex® can only be used on adult patients. **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.

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

Innovation with purpose

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 ventilation[1].
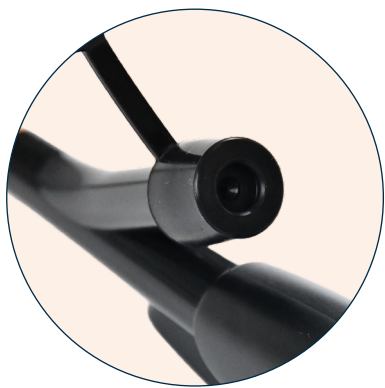
Optimized Tool Passage for Smooth Instrumentation

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 / 500x500
	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 CE 1639	

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 / 500x500
	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 CE 1639	

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 / 500x500
	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 CE 1639	

Innovation with purpose

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)
	DICOM	Yes (MDR)
GMDN Code	56654	
GTIN-14 Code	03664977030032 (x1 device)	
Device class	Class I (EU) MDR 2017/745	

CE

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

CE

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 a protective blister or a rigid thermoformed tray with Tyvek® peelable lidstock .

Broncoflex® devices are packaged in carton boxes of 5 products. Each Broncoflex® carton includes a label indicating sterilization by EO.
XFlo : Carton packaging box, dimensions 980 x 110 x 130mm. Weight 1,50kg
Vortex / Agile : Carton packaging box, dimensions 995 x 120 x 152mm. Weight 2,01kg
User Manual (or QR Code), carton box and unit labelling/carton box labelling are included.

Regulatory Information

FDA 510(k) clearance, Regulatory Class II.
Electrical Safety Certified Body Certificate by UL.
CE mark.
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.

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	

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