

# 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.

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

# TSC LIFE

## Technical Datasheet

# BRONCOFLEX™



**Single-use Bronchoscopy.**  
**Everything you need. Nothing you don't.**

tsc-life.com

<b>Description</b>	<p>Broncoflex™ is a single-use video-bronchoscope which is part of a system made up of the endoscope (Broncoflex) and its reusable high-definition display system (Screeni™).</p> <p>Two different bronchoscopes are available:</p> <ul style="list-style-type: none"> <li>• Broncoflex 5.6/2.8 (Vortex)</li> <li>• Broncoflex 3.9/1.4 (Agile)</li> </ul> <p>Combined with:</p> <ul style="list-style-type: none"> <li>• Screeni™</li> <li>• Easy BAL Clip™</li> </ul>
<b>Intended Use</b>	<p>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.</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 video-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>
<b>Indications for Use</b>	<p>This video-bronchoscope is designed for use exclusively in a hospital environment.</p> <p>Broncoflex can only be used on adult patients.</p> <p><b>Endotherapy accessories and instruments</b> 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 5.6/2.8 (Vortex)	≥ 6,0mm	≥ 41 Fr.	≤ 2,6mm
Broncoflex 3.9/1.4 (Agile)	≥ 5,0mm	≥ 35 Fr.	≤ 1,2mm

## Name, Article Number and Dimensions

Name	Article Number/REF	External diameter of insertion tube	Working channel inner diameter
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

## Single-Use Broncoflex Sizes

### Broncoflex 5.6/2.8 (vortex)

Description	Specification	
<b>Article Number/REF</b>	10030001	
<b>Tube guard color</b>	Orange	
<b>Weight</b>	127g	
<b>Optics</b>	Field of vision direction	0°
	Field of vision	87.5°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
<b>Insertion tube</b>	High/low deflection angle	200°/200°
	Minimum outer diameter	5,4mm
	Maximum outer diameter	5,6mm
	Working length	605mm
<b>Working channel</b>	Internal diameter	2,8mm
<b>Sterilization Method</b>	Ethylene Oxide (EO) Sterilization	
<b>Instrument Compatibility</b>	Endotracheal tube (internal diameter)	6mm
	Double-lumen tube (internal diameter)	41Fr
<b>GMDN Code</b>	60963	
<b>GTIN-14 Code</b>	03664977110031 (x5 devices) 03664977010034 (x1 device)	
<b>Device class</b>	Class IIa (MDD 93/42/EEC)	



## Broncoflex 3.9/1.4 (Agile)

Description	Specification	
Article Number/REF	20030001	
Tube guard color	Grey	
Weight	124g	
Optics	Field of vision direction	0°
	Field of vision	87.5°
	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)	5mm
	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)	



## Screeni

Description	Specification	
Article Number/REF	30030001	
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 IIa (MDD 93/42/EEC)	



## Easy BAL Clip

Description	Specification
Article 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 (MDR 2017/745)

## 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 has a sterile barrier made of a Tyvek® pouch with a protective blister inside.

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, 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.

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

## Cleaning and Disinfecting Screeni

According to the User Manual.

## Waste disposal

According to hospital practice and/or local legislation.

## Manufacturer

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