



# 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®



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

tsc-life.com

**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

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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 ventilation<sup>1</sup>.



### 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)<br>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)<br>03664977010034 (x1 device)   |           |
| Device class             | Class IIa (MDD 93/42/EEC) <br>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)<br>03664977020033 (x1 device)   |           |
| Device class             | Class IIa (MDD 93/42/EEC) <br>Class Is (EU) MDR 2017/745 |           |





## Screeni®

| Description            | Specification  |   |
|------------------------|--|---|
| <b>Part Number/REF</b> | 30030001 (no accessories) - 30030000 (with accessories)  |   |
| <b>Electrical</b>      | Power supply   | Power requirement: 100-240V AC / 50-60Hz / 0,6A<br>Power output: 15V DC / 2A                          |
|                        | Protection type against electrocution  | Class 2   |
|                        | Battery type   | Lithium-Ion Battery   |
|                        | Autonomy   | 3h  |
| <b>Touch screen</b>    | Screen size  | 10,1in  |
|                        | Maximum resolution   | 1280x800  |
| <b>Miscellaneous</b>   | 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   |
| <b>GMDN Code</b>       | 56654  |   |
| <b>GTIN-14 Code</b>    | 03664977030032 (x1 device)   |   |
| <b>Device class</b>    | Class I (EU) MDR 2017/745<br> |   |



## Easy BAL Clip™

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

## 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 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.

### 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                 | +60 °C  |
|   | Relative air humidity (no condensation) | 10%                    | 90%     |
|   | Atmospheric pressure                    | 80kPa                  | 109kPa  |
| <b>Conditions of use</b>                | 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 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  
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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