



# TSC LIFE

## Innovation with purpose

Note: Always consult the latest User Manual of Cystoflex devices.

- 1. Cystoflex User Manual ref. 11010144
- 2. Screeni User Manual ref. 30030511

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

Manufactured by : Axess Vision Technology, S.A.S. | Zone de La Liodière | 6 rue de la Flottière | 37300 Joué-lès-Tours | France  
 T +33 2 47343290 | letsconnect@tsc-life.com | www.tsc-life.com

# TSC LIFE

## Technical Datasheet

# CYSTOFLEX®



**Efficiency Without Compromise.**  
**Smarter Cystoscopy, Seamless Workflow.**

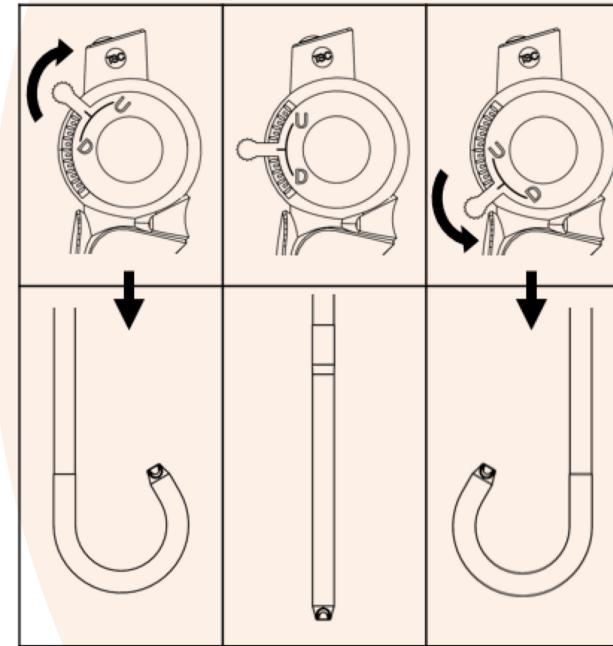
<b>Description</b>	<p>The Cystoflex® is a single-use flexible cystoscope which is part of a system made up of the endoscope (Cystoflex) and its reusable high-definition display system (Screeni™).</p> <p>Two different cystoscopes are available:</p> <ul style="list-style-type: none"> <li>• Cystoflex Standard Deflection</li> <li>• Cystoflex Reverse Deflection</li> </ul> <p>Combined with:</p> <ul style="list-style-type: none"> <li>• Screeni</li> </ul>
<b>Intended Use</b>	The Cystoflex is a sterile, single use, flexible cystoscope intended to be used for endoscopic access to and examination of the lower urinary tract. The Cystoflex is intended to provide visualization via Axxess Vision Technology displaying units and can be used with endoscopic accessories.
<b>Indications for Use</b>	The Cystoflex is designed for use in a hospital environment. The Cystoflex is designed for use in adults.

## Name, Article Number and Dimensions

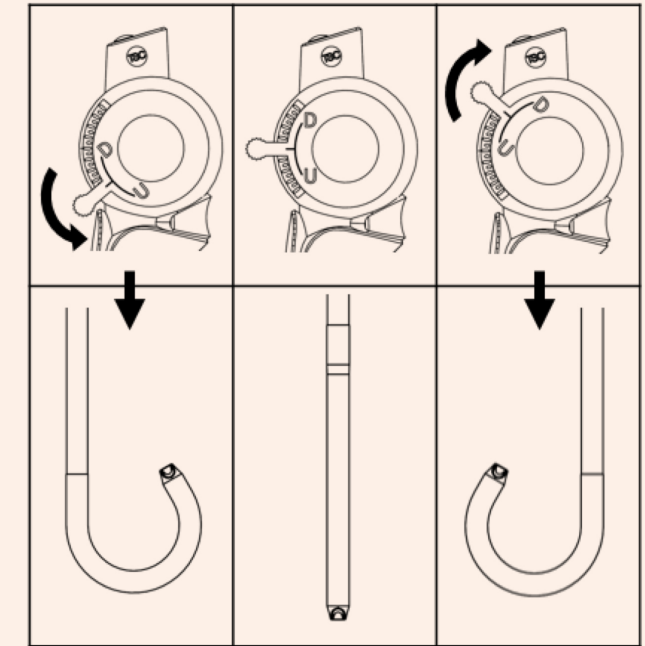
Name	Model	Article Number/REF	Shaft outer diameter (Fr/mm)	Distal tip outer diameter (Fr/mm)	Working channel inner diameter (Fr/mm)
Cystoflex	Standard Deflection	11010011	Max : 17/5,7	12/4	6,6/2,2
	Reverse Deflection	11010012			
Screeni	NA	30030001	NA	NA	NA



**Standard Deflection**



**Reverse Deflection**



## Quick Access to Digital Product Information

Explore More:  
Our Urology Solutions



Direct Access  
to the latest User Manuals



# Single-Use Cystoflex Specifications

## Cystoflex

Description	Specification	
Article Number/REF	11010011 (Standard Deflection) 11010012 (Reverse Deflection)	
Tube guard color	Green	
Weight	108g	
Optics	Direction of view	0°
	Field of view	120°
	Field depth	5-50mm
	Image resolution (pixels)	400x400
	Lighting system	2 LEDs
Insertion tube	Bending angle up/down	210°min/210°min
	Distal end outer diameter	12 Fr / 4 mm
	Maximum outer diameter	17 Fr / 5,7 mm
	Working length	39cm
Working channel	Minimal internal diameter	6,6 Fr /2,2 mm
Sterilization Method	Ethylene Oxide (EO) Sterilization	
Protection Rating	Handle:	IPX1
	Distal end :	IPX7
Accessories compatibility	<p>The Cystoflex standard and reverse deflections are compatible with the following ancillary devices and accessories:</p> <ul style="list-style-type: none"> <li>• Endoscopic accessories labelled for use in a minimum working channel size of (ID) 6,0 Fr/2,0 mm or less</li> <li>• Accessory devices with a minimum working length of 55cm</li> <li>• Irrigation set lines (sterile water or saline bag) with Luer connection</li> <li>• Syringe and other Luer connecting accessories</li> <li>• Holmium YAG laser (2,1 microns wavelength)</li> <li>• High frequency electrosurgical equipment fulfilling EN 60601-2-2. To keep high frequency leakage currents within allowed limits, the maximum sinus peak voltage level of the electrosurgical unit shall not exceed 2,2 kVp</li> <li>• X-RAY</li> </ul>	
GMDN Code	61728	
GTIN-14 Code	<b>Standard Deflection</b>	<b>Reverse Deflection</b>
	03664977000073 (x5 devices) 03664977000059 (x1 device)	03664977000080 (x5 devices) 03664977000066 (x1 device)
Device class	Class Is (EU) 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

### Cystoflex

Each single-use device has a sterile barrier made of a rigid thermoformed tray with Tyvek® peelable lidstock or a sterile Tyvek® pouch, containing a protective tube.

Cystoflex devices are packaged in carton boxes of 5 products. Each Cystoflex carton includes a label indicating sterilization by EO.

Carton packaging box, dimensions 980 x 110 x 130mm.  
Weight 1,53kg  
Carton box and unit labelling/carton box labelling are included.  
User Manual can be found on the website or by scanning the dedicated QR code on the label.

### Regulatory Information

Electrical Safety Certified Body Certificate by UL.  
CE mark.  
For applicable standards please refer to the User Manual.

### Recommended Storage Conditions

Cystoflex 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.

### 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 Flotière  
37300 Joué-lès-Tours – France



## Screeni

Description	Specification	
<b>Article Number/REF</b>	30030001 (no accessories) - 30030000 (with accessories)	
<b>Electrical</b>	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
<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)
<b>GMDN Code</b>	56654	
<b>GTIN-14 Code</b>	03664977030032 (x1 device)	
<b>Device class</b>	Class I (EU) MDR 2017/745	

	Parameters	Minimum	Maximum
<b>Transport and storage conditions</b>	Transportation temperature	-10 °C (14 °F)	+60 °C (140 °F)
	Storage temperature	+5 °C (41 °F)	+35 °C (95 °F)
	Relative air humidity	10%	90%
	Atmospheric pressure	80kPa	109kPa
<b>Conditions of use</b>	Temperature	+ 10 °C (50 °F)	+ 35 °C (95 °F)
	Relative air humidity (no condensation)	30%	85%
	Altitude and atmospheric pressure	≤ 2000m – 80kPa ~ 109kPa	