TSC LIFE

Innovation with purpose

Cystoflex™

User manual

Single-Use Cystoscope

REF

Cystoflex™ Standard Deflection: 11010011

Cystoflex™ Reverse Deflection: 11010012

2024 | User Manual | 11010144-B_24/08 | EN

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Contents

1. Important information - read before use

"WARNING" indicates a particularly hazardous situation. Failure to observe the instruction may damage the instrument, cause injury, or even death.

"CAUTION" indicates that use or improper use of the instrument may cause a problem, such as product malfunction, failure or damage.

1.1 Foreword

This user manual contains essential information for the optimum and safe use of the Cystoflex™. The information in this user manual is subject to change at any time, without notice. Make sure that you are using the latest version by logging onto Axess Vision Technology website https://www.tsc-life.com or contacting the local representative.

This user manual does not contain any explanations of information concerning endoscopic techniques per se.

Carefully read this manual, along with the manuals for all the instruments used, and use them as instructed. Keep all user manuals in a safe and readily accessible place. Should you have any questions or comments concerning this manual, contact us for more information.

This manual describes the recommended inspection and preparation procedures to be followed before using the instrument, along with the precautions to take for product disposal after use.

Carefully follow all the instructions given in this user manual. Poor understanding of these instructions could lead to:

- severe injuries to the patient,
- severe injuries to the user,
- severe injuries to a third party,
- equipment damage.

1.2 Intended use

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 Axess Vision Technology displaying units and can be used with endoscopic accessories.

1.3 Indications for use

The Cystoflex is designed for use in a hospital environment.

The Cystoflex is designed for use in adults.

1.4 Contraindications

The image generated by this device should not be used for diagnostic purposes. The Cystoflex is suitable for qualitative visualization but not for structural sizing. Indeed, quantitative sizing may lead to inaccurate results due to image geometric distortion. Physicians must interpret and support any findings in other ways, based on the patient's clinical examination.

- Febrile patients with urinary tract infections (UTIs), acute urethritis, acute prostatitis, acute epididymitis
- Patients with sever coagulopathy
- Patients with known unpassable urethral stricture

The user must exercise professional judgement when deciding whether a cystoscopy procedure will be beneficial and necessary for high-risk patients.

1.5 Adverse events

Potential adverse events in relation to flexible cystoscopy (not exhaustive):

- Intra-procedural pain or discomfort
- Haematuria
- Abdominal pain
- Dysuria - pain and discomfort on voiding
- Increased voiding frequency
- Urethral narrowing (strictures) due to scar tissue formation
- Urinary tract infections (UTI).

1.6 User qualification

Users of Cystoflex are trained clinicians/physicians.

Before initial use of the Cystoflex, it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings and cautions described in these instructions.

Where there are official standards and/or regulations relating to user qualification for performing endoscopy, and endoscopic treatment defined by the medical administration or by other official institutions, such as the academic endoscopy society, these must be respected.

1.7 Warnings ⚠ and cautions for use

Observe all the warnings and precautions described in this manual. Otherwise, Axess Vision Technology cannot be held liable in case of injury to the patient or user or damage to the device.

	N°	Warning
⚠	1	Check that the packaging is intact before use. Devices for which the packaging has been damaged must not be used and must not, under any circumstances, be re-sterilised.
⚠	2	Always check the expiry date indicated on the Cystoflex label before use; do not use if the product has already expired.

⚠	3	Do not use if labelling is incomplete or illegible.
⚠	4	Inspect the entire surface of the Cystoflex before use to detect any deterioration. If the product is damaged, does not function properly, or has been dropped, do not use it.
⚠	5	Before using the Cystoflex, check the parts to be inserted into a patient to ensure that there are no rough surfaces, sharp edges or unwanted projections that could cause damage.
⚠	6	For the use of endo-therapy accessories, follow the dedicate accessory instruction for use with flexible cystoscopes. Failure to follow these indications may result in patient injury, or accessories and cystoscope damage or malfunction.
⚠	7	Before each use, the compatibility of the Cystoflex with all endotherapy accessories and instruments should be checked. See 3.3. for Accessories compatibility.
⚠	8	Axess Vision Technology is not responsible about the high frequency electrosurgical equipment used. The user needs to check the high frequency electrosurgical equipment IFU.
⚠	9	Patient leakage currents may be additive and too high when using an energised endoscopic instrument in the Cystoflex. Only energised endoscopic instruments classified as "type CF" or "type BF" applied part shall be used with Cystoflex to minimise total patient leakage current.
⚠	10	High frequencies surgical equipment can cause thermal damage to the Cystoflex due to electric discharge or capacitively coupled high frequencies current.
⚠	11	Axess Vision Technology is not responsible about the laser fiber used. When using compatible laser equipment, the user must be familiar with safety precautions, guidelines, and proper use of the laser equipment, including, but not limited to, proper eye and skin protection to avoid laser injuries.
⚠	12	Do not use the device while administering a highly flammable anaesthetic gas to the patient as this may cause injury to the patient.
⚠	13	Do not use the device during defibrillation as this may cause injury to the user.
⚠	14	Should a malfunction occur while using the Cystoflex, immediately stop the examination in progress and carefully remove the Cystoflex from the patient after having released the deflection lever. See chapter 5 for Troubleshooting.
⚠	15	Do not look directly into the light emitted from the cystoscope.
⚠	16	The distal end of the Cystoflex may become hot from the heat from the light emission part. Avoid long periods of contact between the distal end of the Cystoflex and the mucosal membrane, as sustained contact with the mucosal membrane may cause mucosal injury.
⚠	17	Always watch the endoscopic live image on the Screeni™ when advancing or withdrawing the Cystoflex or when operating the articulated part.
⚠	18	In the event of difficulties inserting the applied part of the Cystoflex into the urinary tract, do not apply force and attempt to determine the cause before continuing.
⚠	19	Risk of injury to the patient or damage to the Cystoflex when inserting or removing an accessory into or from the working channel while the deflection zone is not straight, and the deflection lever is not released.

	20	Handle cutting or perforating endotherapy instruments and accessories with care so as not to damage the working channel of the Cystoflex.
	21	When using an energized endoscopic accessory, ensure the tip is always visible on the screen. Failure to see the tip may indicate that the accessory is inside the working channel of the Cystoflex and, if activated, can cause damage to the Cystoflex or injury to the patient.
	22	Using the Cystoflex near medical devices that generate high frequencies (>2.2kVp) can disrupt the image. In order to continue the examination properly, any interfering devices should be relocated, removed or disabled.
	23	Do not withdraw the Cystoflex if an endoscopic instrument is protruding from the distal end of the working channel, as this can damage the urethral mucosa.
	24	The device is single use. Do not re-sterilize, do not reuse the Cystoflex in another patient, as it may contaminate or cross-contaminate, leading to infection of the patient.
	25	No Cystoflex modifications or repairs are allowed
	1	The product must be handled and used with extreme care by qualified personnel.
	2	Provide a similar backup system so that the procedure can continue in the event of malfunction.
	3	Do not use alcohol on the lens. If necessary, clean the lens with isotonic saline solution and a sterile non-woven compress.
	4	Close the second port with a Tuohy Borst or a Female Cap during irrigation without tool.
	5	US federal law restricts these devices for sale only by, or on the order of, a physician.

2. Description of the Cystoflex

2.1 Product description

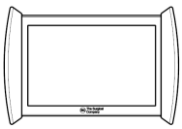
The Cystoflex is a sterile, single-use flexible video-cystoscope which is part of a system made up of the endoscope (Cystoflex) and its reusable display monitor (Screeni). For further information concerning the Screeni display monitor, please see the corresponding user manual.

The Cystoflex consists of two main components: a handle with articulation control, accessory access point, and a flexible shaft portion.

The essential performance of the Cystoflex single use cystoscope is the viewing of the lower urinary tract. It involves other procedures such as performing examinations requiring irrigation, or the use of urology accessories designed for use in combination with a cystoscope and compatible with the Cystoflex.

2.1.1 System components

Cystoflex device and models						
Code	**Model**	**Item Description**	**Illustration**	**Shaft maximal outer diameter (Fr/mm)**	**Distal tip outer diameter (Fr/mm)**	**Working channel inner diameter (Fr/mm)**
11010011	Standard deflection mode	Moving the deflection lever up, moves the distal tip up. Moving the deflection lever down, moves the distal tip down **(Figure 1).**		17/5.7	12/4	6.6/2.2
11010012	Reverse deflection mode	Moving the deflection lever up, moves the distal tip down. Moving the deflection lever down, moves the distal tip up **(Figure 1).**				

Display monitor		
Item code	**Description**	**Illustration**
30030001	Screeni	

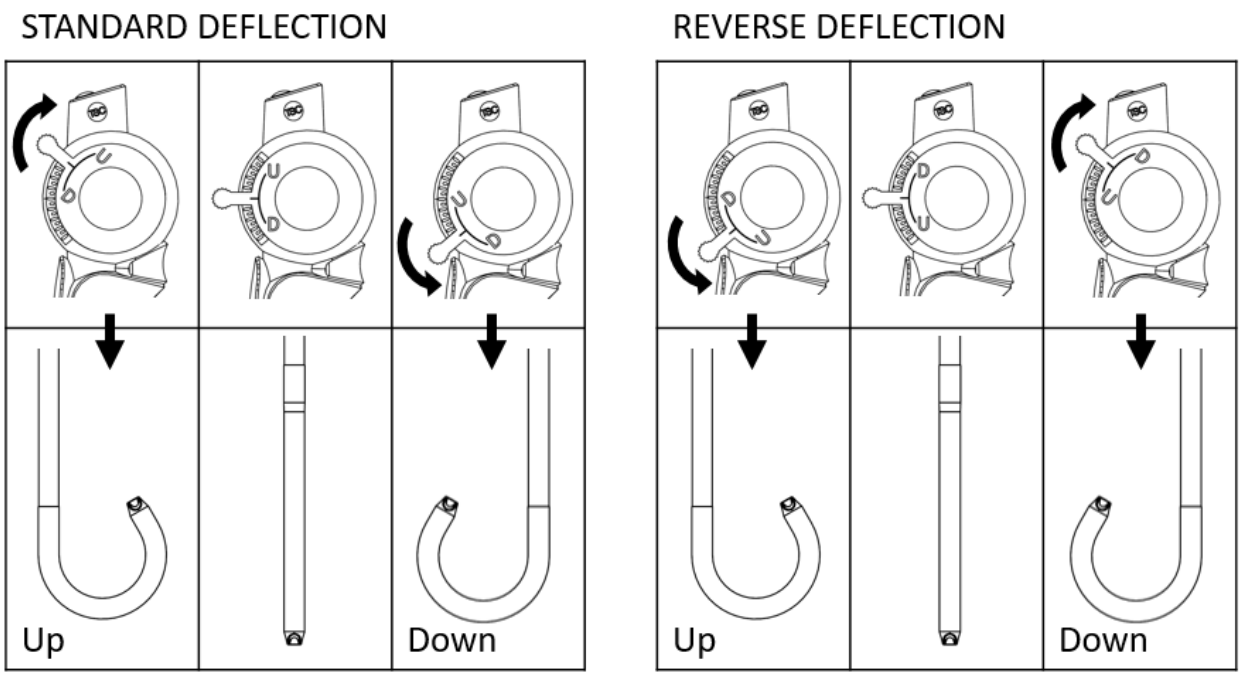


Figure 1. Articulated deflection control movements depend upon the model used

2.2 Cystoflex details

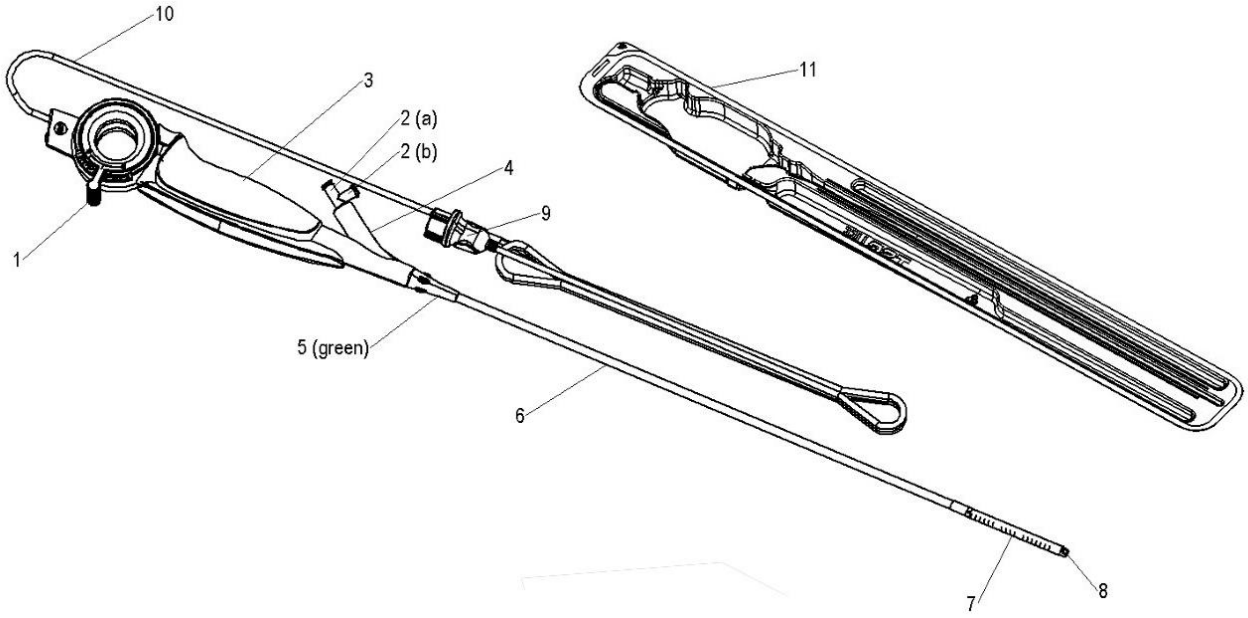
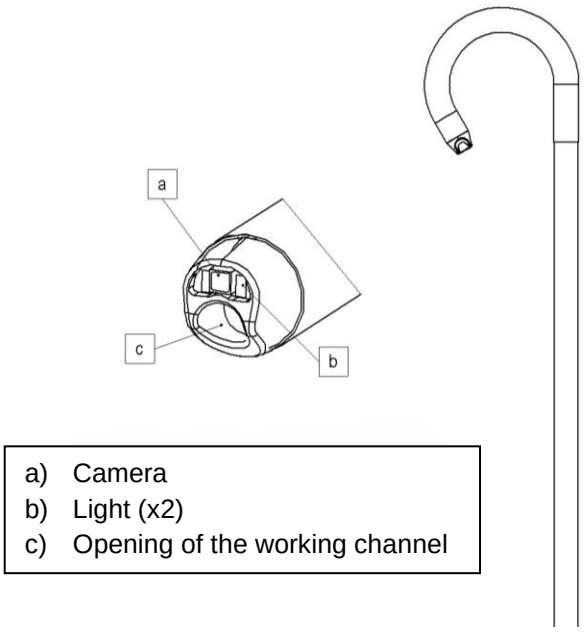


Figure 2. Cystoflex single use flexible cystoscope.

Number	Component	Description
1	Deflection lever	Controls distal end up/down of the articulated section.
2 (a)	Luer-type accessory port	Point of access for delivering accessories into the working channel of the cystoscope.

2 (b)	Luer-type irrigation port	Access to deliver irrigation and solutions to the working channel.
3	Handle	Used to hold the device. Enables users to insert, withdraw rotate the flexible shaft. Suitable for left- and right-handed users.
4	Working channel	Used to inject liquid or to insert instruments.
5	Tube guard (green)	Provides the junction between the handle and insertion tube. Protects the device during the use.
6	Insertion tube	Flexible shaft inserted into the urinary tract.
7	Articulated section **(Fig. 3)**	Articulates up and down when the deflection lever is pressed. Depending on the model, the articulation control can be 'Standard' or 'Reverse' **(Fig.1).**
8	Distal tip **(Fig. 3)**	Contains the camera (a), leds X2 (b), opening of the working channel (c).
6-7-8	Applied part	Insertion tube, articulated section and distal end.
9	Connector	Connects the endoscope to its Screeni display system.
10	Video cable	Transmits the video signal to the Screeni display monitor.
11	Rigid thermoformed tray with Tyvek ® peelable lidstock	Protect the endoscope during transport.
-	Packaging items	Box package.

The materials making up the Cystoflex comply with biocompatibility requirements for medical devices.



a) Camera
b) Light (x2)
c) Opening of the working channel

Figure 3. Articulated section and distal tip

2.3 Checking package contents

The Cystoflex is supplied sterile and ready to be used in a sterile bag (sterilisation method: ethylene oxide ETO).

Cystoflex devices are packed in boxes of 5.

If you notice that the packaging providing the consumable's sterile barrier has been pierced or opened, do not use the Cystoflex It should be returned to the local representative and must not, under any circumstances, be re-sterilised.

3. Instructions for using the Cystoflex

3.1 Precautions prior to use

 Check Warnings 1, 2, 3, 4, 5

Before use and upon receipt of the system, the elements received should be visually inspected to detect any potential damage caused during the transport phase. Ensure that all components are present, using the system description in this user manual. If any components are missing or damaged, do not use the system and contact Axess Vision Technology local representative.

As long as the sterile barrier (Rigid thermoformed tray with Tyvek® peelable lidstock) has not been opened, the Cystoflex remains sterile in its packaging.

Once the Tyvek® peelable lidstock is open, gently remove the endoscope from its blister pack. It is now ready for use.

Only the distal end and endoscope insertion tube are considered as applied parts and only these parts of the equipment should come into contact with the patient.

3.2 Solutions compatibility

 Check Caution 3

Cystoflex is known to withstand exposure to the following fluids: sterile water, saline solution, contrast media, lubricant (water based), iodine solution.

3.3 Accessories compatibility

 Check Warnings 6, 7, 8, 9, 10, 11

The Cystoflex standard and reverse deflections are compatible with the following ancillary devices and accessories:

- Endoscopic accessories labelled for use in a minimum working channel size of (ID) 6.0 Fr/2.0 mm or less
- Accessory devices with a minimum working length of 55cm
- Irrigation set lines (sterile water or saline bag) with Luer connection
- Syringe and other Luer connecting accessories
- Holmium YAG laser (2.1 microns wavelength)
- 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
- X-RAY

Note: There is no guarantee that instruments selected solely using this minimum working channel size will be compatible in combination. Compatibility of selected instruments should be tested before the procedure

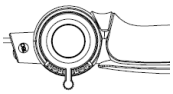
3.4 Using the Cystoflex for an examination

Check Warnings 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24

Check Cautions 1, 2, 3, 4

1. Switch on the Screeni by pressing on/off button, then connect the endoscope connector to the Screeni port identified by the symbol  (follow the instructions in the Screeni User Manual).

   The handle of the Cystoflex can be held in either hand.

2. Check that the illumination and camera are working correctly by pointing at an object (e.g., the palm of the hand). Ensure a clear image is displayed on the Screeni video monitor.
3. Make sure that the articulate part functions smoothly and correctly, by sliding the deflection lever in the up and down position. Confirm the deflection model: the articulation control can be *Standard* (lever up=tip up) or *Reverse* (lever up = tip down) **(Figure 1).**
4. Slide the deflection lever in the middle position  to confirm the articulate part returns to the neutral position.
5. Connect a Tuohy Borst sealing adapter - if needed – or a Female Cap to the access port on the handle to prevent fluid from leaking from the port during the procedure. Refer to Tuohy Borst/Female Cap Instructions for Use.
6. Connect the irrigation supply tube of a compatible irrigation source (syringe, gravity-fed bag) to the irrigation port on the Cystoflex handle **(Figure 2).** Ensure that there is no leakage and that the water is discharging from the distal tip.
7. Ensure that the endotherapy instruments provided for the procedure are compatible with the Cystoflex and are satisfactory. See chapter 3.3 for accessories compatibility.
8. Lubricate the insertion tube with a water-based lubricant before the insertion in the urethra.

9. The system is now ready for use. Proceed with the examination as per standard practise to the desired treatment area.
10. Insert endoscopic accessories into the accessory port and advance them through the working channel until they can be seen on the Screeni monitor.
11. At the end of the examination, remove the Cystoflex gently after releasing the deflection lever.
12. Once removed, ensure that there are no damaged or missing endoscope parts.

To end, switch off the Screeni display monitor, then disconnect and dispose of the Cystoflex.

3.5 Consumable disposal

After use, the Cystoflex is considered contaminated. To avoid any contamination, it must be discarded in accordance with local directives concerning the disposal of contaminated medical devices comprising electronic components.

4. Warranty

The Cystoflex is not covered by a warranty. The Cystoflex shelf-life is specified on the product label. If you observe a product defect, please report the information to the local Axess Vision Technology representative, providing as much detail as possible. If necessary, take photos of the defect if it is visible.

5. Troubleshooting & Serious Incidents

Inspection indications and actions are proposed below to resolve most problems encountered.

If the following instructions are insufficient to correct the problem encountered, return the Cystoflex to the local Axess Vision Technology representative for analysis.

Problem	Cause(s)	Actions
No image and/or no illumination	The connector is incorrectly attached to the Screeni	Ensure that the connector is pushed firmly into the port on the Screeni and that the Screeni is switched on. See the Screeni user manual.
Poor quality image	Vision impaired on the camera.	Clean the lens by passing isotonic saline solution in the working channel or with a sterile non-woven compress.
Absent or reduced flow of fluid (e.g., saline, contrast)	The working channel is blocked	Outside the patient, rinse the channel by injecting a sterile isotonic solution with a syringe. If the working channel cannot be cleared, prepare a new endoscope.

Difficulty in inserting/withdrawing accessories into the working channel.	Accessory is blocked in the working channel	Return the bending lever to the neutral position.
Loss of articulation control. The distal part remains articulated in bending position.	Distal or proximal mechanical break /damage	Return the bending lever to the neutral position.

Any serious incident that has occurred in relation to the device should be reported to Axess Vision Technology (via local representative) and the competent authority of the Member State which the user is established.

Serious incident means incidents that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person,
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
- a serious public health threat (= an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time).

6. Transport, storage and use 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.

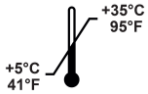
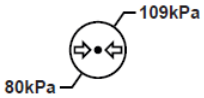
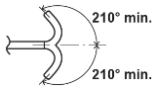
	Parameters	Minimum	Maximum
Transport and storage conditions	Transportation temperature	-10 °C (14 °F)	+60 °C (140 °F)
	Storage temperature (1)	+5 °C (41 °F)	+35 °C (95 °F)
	Relative air humidity (no condensation)	10%	90%
	Atmospheric pressure	80kPa	109kPa
Conditions of use	Temperature	+ 10 °C (50 °F)	+ 35 °C (95 °F)
	Relative air humidity (no condensation)	30%	85%
	Altitude and atmospheric pressure	≤ 2000m – 80kPa ~ 109kPa	

(1) Storage under higher temperatures may impact shelf life.

7. Cystoflex labels and symbols

The meanings of the various symbols and labels are described in the table below:

Symbol	Meaning
	For single use only, do not re-use.
	Do not resterilise.
	Ethylene oxide sterilised with single sterile barrier system.
	Ethylene oxide sterilised with single sterile barrier system and protective packaging outside.
	Product manufacturer.
	Do not use if package is damaged.
QTY	Quantity.
	See the user manual before use.
	Caution. Indicates that the instructions for use contain important cautionary information, such as warnings and precautions, that cannot, for various reasons, be displayed on the medical device itself.
	See the user manual for instructions on using this product.
GTIN	GTIN (Global Trade Item Number).
	Date of manufacture.
	Product expiry date (Year-Month-Day).
	Type BF applied part: BF type electronic device, compliant with standard “IEC 60601-1. Protection against electrical discharges”.
LOT	Batch number.
REF	Product catalogue number.
	Keep away from sunlight and away from UV radiation.
MD	Medical Device.
	Do not expose the box to rain.

	Fragile contents, handle with care.
	Store in an environment with a relative humidity of between 10% and 90%. See 6. Transport, storage and use conditions.
	Store in an environment with a temperature of between +5°C and +35°C. See 6. Transport, storage and use conditions.
	Store in an environment with an atmospheric pressure of between 80 kPa and 109 kPa. See 6. Transport, storage and use conditions.
Pat. Pending	Patented device.
	Minimum working channel inner diameter and maximum applied part outer diameter. See 8. Technical Characteristics.
	Effective length of the inserted part. See 8. Technical Characteristics.
IPX1	Protected against vertical water drops (IEC 60529).
IPX7	Protected against the effects of temporary immersion in water (IEC 60529).
	Camera field of view. See 8. Technical Characteristics.
	Deflection angle of the distal end. See 8. Technical Characteristics.
Rx only	Device to be used on prescription only.
CE 1639	Conformity marking as per the European Medical Devices Regulation (MDR) 2017/745, accompanied by the identification number of the notified body SGS.

A full list of symbol explanations can also be found on :

https://www.tsc-group.com/endovision/symbols-glossary/

8. Technical characteristics

Type	Cystoflex Standard deflection	Cystoflex Reverse deflection
Product reference code	**11010011**	**11010012**
OPTICAL SYSTEM		
Direction of view	0°	
Field of view	120°	
Field depth	5-50 mm	
Lighting system	2 LEDS	
Image resolution	400x400	
INSERTION PORTION		
Bending angle up/down (1)	210°min./210°min.	
Insertion cord diameter	16.2 Fr +/-0.3Fr (5.4mm +/-0.1mm)	
Maximum diameter of insertion portion	Max 17 Fr (5.7mm)	
Distal end outer diameter	12 Fr (4mm)	
Working length	39 cm +/-1cm	
Working channel inner diameter (2)	Min 6.6 Fr (2.2mm)	
Weight	108 g	
Sterilisation	Ethylene oxide ETO	
Degree of protection against ingress of liquids	IPX7 for insertion portion IPX1 for handle	

(1) Please be aware that the bending angle can be affected if the insertion cord is not kept straight or have inserted endoscopic instruments

(2) There is no guarantee that endoscopic instruments selected solely using this minimum working channel width will be compatible in combination

8.1 Information concerning the electrical safety rating and electromagnetic compatibility

See the Screeni User Manual.

9. Applicable standards

Cystoflex operation complies with the following regulatory texts:

- **MDR (EU) 2017/745**: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- **IEC 60601-1 edition 3.2**: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2 edition 4.1:** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- **IEC 60601-2-18:** Medical electrical equipment - Part 2-18: Particular requirements for the basic safety of endoscopic equipment
- **ISO 8600-1:** Medical endoscopes and endotherapy devices - Part 1: General requirements
- **ISO 10993-1:** Biological evaluation of medical devices - Part 1: Evaluation and tests within a risk management process
- **ISO 80369-7:** Small connectors for liquids and gasses used in the health sector - Part 7: 6% connectors (Luer) for intravascular or hypodermic applications

Axess Vision Technology certifies the compliance of its equipment, both in terms of design and of manufacturing to normative standards.

10. Manufacturer's contact details

Axess Vision Technology

Zone de la Liodière

6 rue de la Flottière

37300 Joué-lès-Tours – France

https://www.tsc-life.com

TSC LIFE

Innovation with purpose

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