



PureClear™ Inspection Scopes

Model C2-350, C2-950 and C1-800



Instructions For Use (IFU)

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Contact Information:

Manufacturer:

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 Tel (763) 525-8450



Symbol Descriptions

Read this operating manual for additional warnings and instructions for use.



WARNING



Date of manufacture

**GENERAL WARNINGS**

1. Follow the instructions for cleaning, disinfecting and sterilizing provided in this document.
2. Do not autoclave PureClear Inspection Scopes.
3. Do not attempt to service any part of this product.
4. To ensure operator safety, read and understand this manual before using the PureClear Inspection Scope.
5. The PureClear Inspection Scope emits visible light energy from its distal end when connected to a light source. Avoid looking directly at this emitted light or directing it toward others.
6. Carefully inspect the external surfaces of the PureClear Inspection Scope and any accessories to assure they are smooth and free of any protrusions or sharp edges.
7. Do not bend device below a 0.85" (21.6 mm) radius; this may cause damage to the device.
8. Do not apply excessive force to the PureClear Inspection Scope. If you feel resistance, or an obstruction hinders the path of the PureClear Inspection Scope, you may look through the eyepiece and gently attempt to manipulate or rotate the device to avoid the obstacle. You may also slowly withdraw a short distance and try advancing again. Applying excessive force to the PureClear Inspection Scope can result in damage to the device.
9. Avoid rubbing the PureClear Inspection Scope against sharp edges. This can cause damage to the device.

Intended Use

The PureClear Inspection Scope is used for visual inspection of medical devices.

Indications for Use

Visual Inspection of channels, lumens and inner components during reprocessing of medical devices and endoscopes to visually verify that they are free of damage and debris.

Contraindications for Use

Not for human use.

Product Description

The PureClear Inspection Scope allows for enhanced visual inspection by providing light, vision, magnification and the option for documentation in hard-to-see crevices, channels, and lumens in medical devices – areas as small as 1mm and not visible to the un-aided eye.

The PureClear Inspection Scope can be used with or without a camera attached to the eyepiece.

PureClear Inspection Scope Features and Connections

The user features and connections are shown in the following illustration.

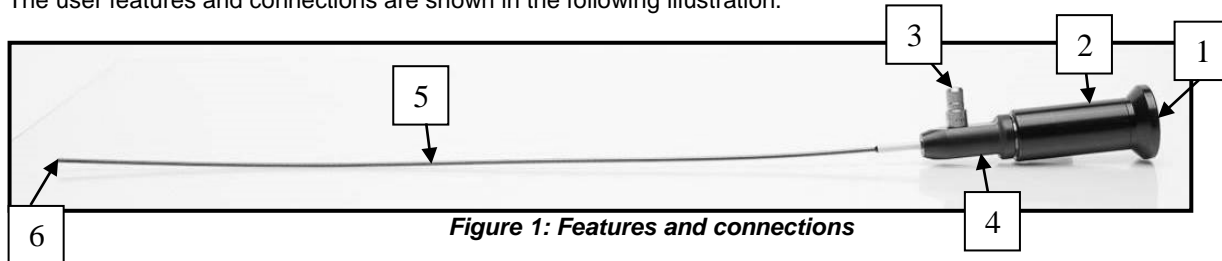


Figure 1: Features and connections

#	Name	Function
1	Eye Cup	DIN 58105:2000-06 standard eyecup for viewing directly or connecting to a B-mount camera.
2	Eyepiece	The eyepiece converts the image from the fiber optic section of the endoscope to an image useable to the eye. The eyepiece can correct for most variations in the vision of the user.
3	ACMI Light Source Connector	Point of entry for light used for illumination utilizing a standard ACMI male light source connector. It is compatible with a light source or light cable utilizing the ACMI connector format.
4	Integral Endoscope Hub	The hub combines the eyepiece, ACMI light connector, and the endoscope shaft into an integrated unit. It is constructed of non-electrical conducting materials providing three-way electrical isolation.
5	Flexible Working Length	The portion of the PureClear Inspection Scope that is inserted into a device during visual inspection.
6	Distal Lens	The objective lens on the distal end of the endoscope.

Accessory Components (sold separately)

The following components are intended for use with the PureClear Inspection Scope:

- Light Cable, ACMI-ACMI, 1 mm, Model 5163-100
- PureClear Inspection LED Light Source, Model 5197-202

The following components are optional:

- Flexible Arm, Manfrotto, 520 mm, Model 237HD
- Nano Clamp, Manfrotto, Model 386BC-1
- Super Clamp, Manfrotto, Model 635
- Digital Camera, Firefly™, Model GT405

Unpacking the Device

The PureClear Inspection Scope has been thoroughly inspected and carefully packaged before shipping. Once the unit is removed from its container, it should be carefully inspected for shipping damage. If there is any damage, contact the shipping carrier and Pure Processing immediately.



WARNING: Do not attempt to use the PureClear Inspection Scope if it appears to be damaged.



WARNING: The PureClear Inspection Scope is **NOT STERILE** as supplied from Pure Processing. The user must follow the protocol for cleaning and disinfecting or sterilizing described in the Instructions for Cleaning and Disinfecting or Sterilizing section.

Inspection

Prior to use, inspect the PureClear Inspection Scope for signs of wear or damage. Operation can be verified by following the steps in the [Verifying Operation](#) section of this manual.



WARNING: Carefully inspect the external surfaces of the PureClear Inspection Scope and any accessories to assure they are smooth and free of any protrusions or sharp edges.

Routine Maintenance

There are no user serviceable parts within the PureClear Inspection Scope. No user maintenance beyond cleaning is required. Refer all service or replacement needs to PureClear Medical, LLC. The contact information is listed at the end of this document.

Verifying Operation

Following the steps listed below will ensure the proper use and performance of the PureClear Inspection Scope. This is necessary to confirm the operation of the scope prior to use, or anytime the scope's operation needs to be checked.



WARNING: The PureClear Inspection Scope requires no external source of electrical power. **DO NOT** connect the PureClear Inspection Scope to a source of electrical power.



WARNING: The minimum bend radius of the PureClear Inspection Scope is 0.85in. Do not bend the PureClear Inspection Scope into a sharper bend or damage to the device could occur.

IMAGE QUALITY

1. The PureClear Inspection Scope can be checked by simply viewing through it with the eye and observing for a visual defect. When viewing with the eye the image should be immediately in focus. The PureClear Inspection Scope does not have a focus adjustment.
2. Make sure enough light is available before verifying an image with the PureClear Inspection Scope. Bright room lighting is usually enough light to produce a good image.
3. Normal operation will produce a focused discernable image to the user. The image should appear round and will include a grid pattern created by the characteristics of the fiber optics of the PureClear Inspection Scope. The grid-like pattern is normal and should not be confused with being out-of-focus or the cause of a cloudy image. The PureClear Inspection Scope cannot clearly focus on an object closer than 5mm but will focus to infinity.
4. Image defects will appear as, no discernable image and complete darkness, no image but uneven light, or a view that is partially obstructed by dark or discolored spots. These defects are a result of damaged fiber optics or eyepiece lenses and cannot be corrected by the user. See the [Troubleshooting and Servicing](#) section of this manual to obtain repair service.

ILLUMINATION

1. The illumination capability of the PureClear Inspection Scope can be verified by attaching it to a PureClear Inspection LED Light Source, or equivalent light source. Once connected, the distal tip of the PureClear Inspection Scope will cast visible light from its tip and can be observed on any surface to which it is directed.
2. Normal illumination will disperse a uniform circular field of light onto the target surface as shown in Figure 2.



Figure 2: Light pattern from distal tip.

3. Optical fibers, after repeated use, can become stressed and eventually damaged. A PureClear Inspection Scope with damaged fibers is not necessarily at the end of its useful life and can still provide useful service. The user must judge when the PureClear Inspection Scope is no longer adequate for use, but as a guide, when 10% of the image or illumination has been degraded or lost it is recommended that a replacement be acquired.

Setup & Performing Inspection

Following the steps listed below will ensure the proper use and best performance of the PureClear Inspection Scope. Follow these steps prior to inspection.

1. Clamp the device into an arm fixture (optional).
2. Attach the 1 mm light cable to the ACMI connector.



WARNING: The use of a non-specified light cable can result in overheating and cause permanent damage to the PureClear Inspection Scope.

3. Attach 'B' mount camera to eye cup (optional).
4. Grasp the PureClear Inspection Scope near its end and gently insert into the intended device as shown in Figure 3.
5. Adjust light source for ideal lighting.
6. Use short advancements while keeping your fingers close to the device's opening. View through the eyepiece or camera monitor while inserting into the device. If an obstruction hinders the path of the PureClear Inspection Scope, gently attempt to manipulate or rotate the device to avoid the obstacle (Figure 4).



Figure 3: Inserting the scope tip into device.



Figure 4: Rotating device to avoid obstacle



WARNING: The minimum bend radius of the PureClear Inspection Scope is 0.85in. Do not bend the PureClear Inspection Scope into a sharper bend or damage to the device could occur.



WARNING: Do not apply excessive force to the PureClear Inspection Scope. If you feel resistance, or an obstruction hinders the path of the PureClear Inspection Scope, you may look through the eyepiece and gently attempt to manipulate or rotate the device to avoid the obstacle. You may also slowly withdraw a short distance and try advancing again. Applying excessive force to the PureClear Inspection Scope past an obstacle could result in damage to the device.

7. Once the device has reached the end of the area you are inspecting, retract the scope slowly while looking for debris or damage.

Instructions for Cleaning and Disinfecting or Sterilizing



WARNING: The PureClear Inspection Scope is provided non-sterile. Before initial use and after each use, the external surfaces of the PureClear Inspection Scope should be cleaned.

PREPARATION FOR CLEANING

To clean, disinfect, or sterilize the PureClear Inspection Scope follow CHART 1 below.

**CHART 1
Compatible Cleaning and Disinfecting or Sterilizing Methods for PureClear Inspection Scope**

Method	PureClear Inspection Scope
Enzymatic cleaning solutions	YES
Neutral pH soap and water	YES
Isopropyl alcohol wipes	YES
Cidex® 2.4% glutaraldehyde solution	YES
Cidex OPA	YES
Tristel Trio Wipe System™	YES
STERIS V-PRO®	YES
Sporox® 0.85% Phosphoric Acid Solution	NO
Ethylene Oxide Gas (EtO)	YES
STERIS SYSTEM 1E®	YES
Sterrad ® 100S, 50, 200, NX, 100NX Systems	YES*
Autoclave, steam or heat	NO

(*Tested up to 20



cycles) **WARNING:** Cleaning does not disinfect or sterilize the PureClear Inspection Scope. Be sure to follow your institution's specific cleaning and disinfecting or sterilizing procedures in consultation with this manual. The user is responsible to ensure that their procedures result in disinfection or sterilization, whichever is required.



WARNING: Use only cold soak disinfecting or sterilizing solutions that are approved for use with endoscopes and endoscopic accessories.



WARNING: Do not use caustic or harsh detergents to clean the PureClear Inspection Scope. The optical surfaces of the PureClear Inspection Scope will be damaged from exposure to aggressive cleaning agents.



WARNING: Do not reprocess the PureClear Inspection Scope using steam sterilization, autoclave, or dry heat. Use of these processes will result in damage to the instrument, and void its warranty.



WARNING: The optics of the PureClear Inspection Scope will be damaged or degraded if left exposed to cleaning or disinfecting solutions for extended periods of time. Do not exceed the disinfectant solution manufacturer's recommended exposure times for cleaning and disinfecting.



WARNING: Do not allow liquids to dry on the lens of the distal tip of the PureClear Inspection Scope. Dried residue is difficult to remove and will leave deposits that obscure the image of the PureClear Inspection Scope.



WARNING: Do not clean, disinfect, or sterilize the PureClear Inspection Scope or its accessories using an ultrasonic cleaner, washer sanitizer, washer pasteurizer, washer sterilizer, steam autoclave, or any method with a processing temperature above 60°C (140°F).

Compatible Cleaning Methods

Enzymatic Cleaning Solutions
Neutral pH soap and water
Isopropyl alcohol wipes

INSTRUCTIONS FOR CLEANING

1. Follow the cleaning agent manufacturer's instructions for use and precautions regarding health hazards, dispensing, measuring, and storage of cleaning agents.
2. If accessories such as a video camera or remote light source are being used, turn them OFF and then disconnect them from the PureClear Inspection Scope prior to cleaning.
3. Place the PureClear Inspection Scope in a bath of enzymatic detergent that has been prepared according to the manufacturer's instructions. Soak the device in detergent for the duration specified by the manufacturer.
4. Use clean cotton gauze pads that are saturated with the detergent solution to wipe down all surfaces of the PureClear Inspection Scope. Use soft brushes with the detergent solution to remove any residues from areas that cannot be reached with the gauze pads.
5. Rinse all components with copious amounts of cool (not cold) flowing utility (tap) water for 45 to 60 seconds.
6. Dry with a soft, lint-free cloth or sponge.

Compatible Disinfecting Methods

Cidex 2.4% Glutaraldehyde Solution
Cidex OPA
Tristel Trio Wipe System™



WARNING: Follow the disinfectant manufacturer's instructions for disinfecting.



WARNING: High level disinfecting does not result in terminal sterilization. Bacterial endospores may still remain viable after high level disinfecting.

HIGH LEVEL DISINFECTING USING COLD SOAKING SOLUTIONS

1. Select only the disinfecting solutions listed above in the Compatible Disinfecting Methods section of this manual.
2. Follow all recommendations regarding health hazards, dispensing, measuring and storage from the manufacturer of the cleaning and disinfecting agents.
3. Complete the previously described INSTRUCTIONS FOR CLEANING section of this manual before proceeding with high level disinfecting.
4. Soak the PureClear Inspection Scope in the selected disinfecting solution per the solution manufacturer's instructions for high level disinfecting.
5. Rinse the PureClear Inspection Scope with critical (sterile) water, again following the instructions of the disinfecting solution manufacturer.
6. Dry with a sterile, soft, lint-free cloth or sponge. Ensure that the distal tip and proximal end of the PureClear Inspection Scope are dried. Air drying could leave deposits on these optical surfaces which could result in a degraded image.

Compatible Sterilizing Methods**STERIS®**

- STERIS SYSTEM 1E®
- STERIS V-PRO®

STERRAD® (Tested up to 20 cycles)

- STERRAD 100S
- STERRAD 50
- STERRAD 200
- STERRAD NX
- STERRAD 100NX

Complete the previously described INSTRUCTIONS FOR CLEANING section of this manual before proceeding with sterilizing.

The PureClear Inspection Scope is compatible with STERIS SYSTEM 1E by STERIS Corporation. Follow the instructions provided with the STERIS equipment for sterilization processing. The PureClear Inspection Scope is also compatible with STERRAD 100S, 50, 200, NX, and 100NX systems for up to 20 cycles. Follow instructions provided with STERRAD equipment for sterilization processing.

Disposal of Waste Products

The PureClear Inspection Scope does not produce any waste materials.

Troubleshooting and Repair Service

No maintenance beyond cleaning is required with the PureClear Inspection Scopes. Again, the thin optical fibers within the scope are fragile and can break when stressed. Broken Fibers are often the cause of full or partial loss of image and unfortunately cannot be repaired, however please contact Pure Processing for a Return Materials Authorization to have the scope evaluated

Condition	Appearance	Cause	Correction
No Light	No image or very dark image looking through scope. No light when scope pointed at surface.	No power to light source	Plug in, power on <i>Light Source</i>
Low Light	No image or very dark image looking through scope. Weak or uneven light pattern when scope pointed at surface.	Dimmer turned down	Turn dimmer knob on the <i>Light Source</i> to increase light output
Low Light	No image or very dark image looking through scope. Weak or uneven light pattern when scope pointed at surface.	Debris on the either distal tip of <i>Light Cable</i>	Wipe ends of light cable. Caution, ensure that the cable has cooled for 5 minutes if in use.
Low Light	No image or very dark image looking through scope. Weak or uneven light pattern when scope pointed at surface.	Broken light fibers in scope	Replace scope. (The user must judge when the <i>PureClear Inspection Scope</i> is no longer adequate for use, but as a guide, when 10% of the image or illumination has been degraded or lost it is recommended that a replacement be acquired).
Low Light	No image or very dark image looking through scope. Light cables not passing adequate amount of light when testing distal ends of cable.	Broken light fibers in <i>Light Cable</i>	Replace <i>Light Cable</i>
No image or distorted image	No image or heavily distorted, cracked appearance.	Broken image fibers	Replace <i>PureClear Inspection Scope</i>
Overly bright image	White-out type reflection	<i>Light Source</i> is too bright	Adjust <i>Light Source</i> dimmer knob
Blurry Image	Image not clear and the outer ring of the image on the monitor is also not clear	Camera out of focus	Focus <i>Firefly Digital Camera</i>
Blurry or overly bright image	Light will often reflect back appear as white-out through scope	Moisture on lens	Wipe off end of <i>PureClear Inspection Scope</i> with soft cloth
Blurry Image or overly bright image	Will often reflect light back and give a bright colored image through scope	Debris or film on lens	Wipe off end of <i>PureClear Inspection Scope</i> with soft cloth

Warranty

The PureClear Inspection Scope is warranted, when new, to be free of defects in material and workmanship and to perform in accordance with the manufacturer's specifications when subject to normal use service for a period of 1 year from the date of purchase. Pure Processing at its option, will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the purchaser. It shall be the purchaser's responsibility to return the device directly to Pure Processing after receiving a Returned Material Authorization Number from Pure Processing's Customer Service Department. Prior to returning the device, it shall be the purchaser's responsibility to clean and disinfect the device and to package it in a manner that minimizes the possibility of shipping damage.

EXCEPT TO THE EXTENT PROVIDED ABOVE, PURE PROCESSING MAKES NO REPRESENTATION OR WARRANTY TO THE PURCHASER OR TO ANY THIRD PARTY, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED, CONCERNING THE DEVICE, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL PURE PROCESSING BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER FOR BREACH OF ANY WARRANTY, FOR BREACH OR REPUDIATION OF ANY OTHER TERM OR CONDITION OF SALE, OR FOR LIABILITY ON THE BASIS OF NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, EVEN IF PURE PROCESSING SHALL HAVE BEEN ADVISED IN ADVANCE OF THE LIKELIHOOD THEREOF.

REPAIR OR REPLACEMENT OF THE DEVICE AS PROVIDED ABOVE SHALL BE THE SOLE AND EXCLUSIVE REMEDY FOR ANY BREACH OF THE WARRANTY GIVEN ABOVE.

Specifications

Power Source

No source of electrical power is required for the PureClear Inspection Scope. Refer to the IFU of any accessories, like Light Sources, for power requirements.

Illumination Source

Light source connected with a light cable.

Physical Properties

Size

	PureClear Inspection Scope, Short, Model C2-350	PureClear Inspection Scope, Long, Model C2-950	PureClear Inspection Scope, Mini, Model C1-800
Working Length	35 cm (13.8")	95 cm (37.3")	80 cm (31.8")
Scope Diameter	1.9 mm (0.075")	1.9 mm (0.075")	0.86 mm (0.034")
Eyecup diameter	31.8 mm (1.25")	31.8 mm (1.25")	31.8 mm (1.25")
Overall Length including Eyepiece	45 cm (17.7")	105 cm (41.3")	90 cm (35.4")

Weight

PureClear Inspection Scope: 18.2 grams (0.64oz)
 PureClear Long Inspection Scope: 20.2 grams (0.71oz)
 PureClear Mini Inspection Scope: 17.8 grams (0.61oz)

Optical

Field of View 72° in air
 Angle of View 0°

Connectors

One ACMI compatible light source connector.
 One DIN 58105:2000-06 compatible eyecup for direct viewing or attachment of external equipment.

Accessories Included

1 Instruction manual

Environmental Conditions

Storage and transport

Humidity: 10 to 100% (condensing)
 Temperature: -20°C to +60°C
 Pressure: 600 hPA to 900 hPA

Normal Operation

Humidity: 0-100% (condensing)
 Temperature: +5°C to +40°C

Manufacturer

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