

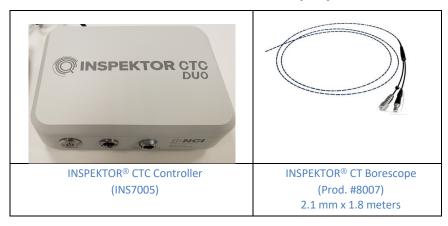
CTC Digital Borescope System

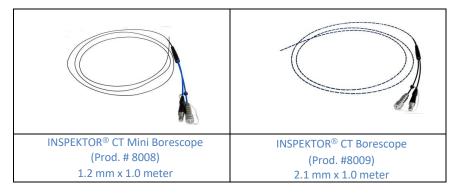
Includes:

Product # INS7005 INSPEKTOR® CTC Box
Product # INS8007 INSPEKTOR® CT Borescope
Product # INS8008 INSPEKTOR® CT Mini Borescope
Product # INS8009 INSPEKTOR® CT Borescope

INSPEKTOR® is a registered trademark of NCI, Inc.

INSPEKTOR® CTC Flexible Borescope System





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	The following instructions for use are applicable to the INSPEKTOR® CTC DUO Flexible Borescope Systems.

Including Models: INS 7002, INS7003 and INS7005

Intended Use

The INSPEKTOR® CTC Digital Borescope Systems are waterproof and are patented and designed to work in wet and dry environments. They are used to provide visualization of working channels and lumens in surgical instruments and endoscopes larger than 1.2 mm. The systems allow the technician to inspect the lumens during and after the cleaning process to visually confirm that they are void of foreign material.

Indications for Use

Visual Inspection of endoscope working channels and surgical instrument lumens to confirm they are cleaned to the technician's expectations.

Contraindications for Use

The INSPEKTOR® Scopes are not intended for use in human patients.

GENERAL WARNINGS

- The INSPEKTOR[®] Borescopes are polymer coated flexible devices. Avoid sharp metal edges when either inserting or retracting the INSPEKTOR[®] CTC Borescope.
- 2. Follow the cleaning, disinfecting, and sterilization instructions provided in this manual.
- 3. Do not autoclave INSPEKTOR® devices.
- 4. Do not attempt to service any part of this product. **
- 5. To ensure operator safety, read and understand this manual before using the INSPEKTOR® Borescope.
- 6. The INSPEKTOR[®] Borescope emits visible light energy from its distal end. Avoid looking directly at this emitted light or directing it toward others.
- 7. Carefully inspect the external surface of the INSPEKTOR® Borescope to assure it is smooth and free of any protrusions or sharp edges.
- 8. Do not bend device below a 20 mm radius or to the point of kinking. Over bending may cause damage to the device and render the INSPEKTOR® Borescope inoperable.

- 9. Applying excessive force to push an INSPEKTOR® Borescope past an obstacle could result in damage to the device. If the INSPEKTOR® Borescope requires significant push force, observe the monitor and attempt to avoid the obstacle by manipulating the flexible scope.
- 10. Avoid rubbing the scope against sharp edges. This can cause damage to the device.
- 11. Store between 60° 90° F. Keep away from magnetic fields while storing.
- 12. Do NOT use the INSPEKTOR® CTC Controller Box in excessively high temperatures above 120º F as the materials of construction are not designed to operate under these conditions.
- 13. Marginal INSPEKTOR[®] CT Borescope light leaks are common and may even be noticeable on new scopes. This does not affect the function of the INSPEKTOR[®] CTC Digital Borescope System.
- 14. Do not submerse the CTC Controller Box in any fluid.
- 15. INSPEKTOR® CT Borescopes should not be exposed to temperatures in excess of 212 degrees F.
- 16. If the INSPEKTOR[®] CTC is used in a manner not specified in the instructions for use, the protection provided by the equipment may be impaired.

Product Description

Both the INSPEKTOR® CTC DUO Controller and INSPEKTOR® CT Digital Borescopes are comprised of two components. The INSPEKTOR® CTC DUO Controller houses an LED light source and camera control board in a waterproof (IP65) compartment. The INSPEKTOR® CT Borescopes plug into the CTC DUO Controller individually.

The INSPEKTOR® CTC Systems are designed to work in wet and dry environments and are used to inspect small lumens and working channels of surgical instruments and endoscopes for foreign matter. This allows the cleaning/sterilization processing technicians to determine whether their surgical equipment is visually free from foreign matter.

INSPEKTOR® CTC Box's waterproof status, as defined by the International Electro Technical Commission is IP65 and INSPEKTOR® CT Borescopes are IP67.

Caution:

Turn off the INSPEKTOR CTC DUO Monitor when unplugging either INSPEKTOR borescope or when plugging in a borescope. Turn the monitor on again after exchanging the borescope.

Warning:

Do not submerse the INSPEKTOR® CTC Box in any fluid.

Inspection of the INSPEKTOR® CT Borescope (Prod. # 8007, 8008 & 8009)

It is important to visually inspect INSPEKTOR CT Borescopes for signs of excessive wear or deterioration. <u>Inspect Borescope Daily</u>. Possible indications of wear that would require replacement would include:

- Unacceptable or poor image quality
- Cracking, tears or degradation of the sheathing or epoxy joints

INSPEKTOR® CT Digital Borescope System Cleaning Instructions

Cleaning and Disinfection of the INSPEKTOR® CTC Controller Box (Prod. # 7005)

Cleaning and Disinfection – To remove debris, wipe the INSPEKTOR® CTC Controller Box with a soft, nonabrasive cloth using a hospital approved cleaning agent such as alcohol (70% Isopropyl). Allow proper contact time.

Caution:

Do not wipe down the INSPEKTOR® CTC Controller Box without the INSPEKTOR® CT Borescope connected and the USB protective cover in place.

Cleaning and Disinfection of the INSPEKTOR® CT Borescope (Prod. # 8007, 8008 & 8009)

The INSPEKTOR® CT Digital Borescope is used to inspect surgical instrument lumens and endoscope channels in the sterile processing department or in endoscopy. The inspection of the inner surface aids in the visualization of foreign debris and bio-burden and further assures their removal before the sterilization of instruments or high-level disinfection of endoscopes. The INSPEKTOR® CT Borescopes may be used on either the dirty side or the clean side of the Sterile Processing Department or in the Endoscopy reprocessing area. The INSPEKTOR® CT Borescope should be cleaned in the manner described below to prevent cross contamination of instruments or endoscopes with foreign debris or bio-burden. Note: It is further recommended that the INSPEKTOR® CT Borescopes should be quickly wiped between each individual instrument inspection with a water moistened fiber-free cloth to remove any adherent foreign debris or bio-burden.

Cleaning – Dirty Side

1. Clean and Disinfection – Begin by cleaning the INSPEKTOR CT Borescope fiber. The INSPEKTOR® CT Borescope may be wiped with a hospital approved cleaning/disinfecting agent such as those used to disinfect the sink after cleaning surgical instruments or endoscopes. (Examples: Oxivir®, OxyCide®, Sani Cloth® Sani-HyPerCide®). Follow the manufacturer's cleaning agent's instructions for use. Rinse the INSPEKTOR® CT Borescope with tap water after cleaning. Wipe with a water moistened a fiber-free cloth. (Connector cap must be securely placed on connector before cleaning or submersion in fluid. See Caution.)

Note: While cleaning - When the INSPEKTOR® CT Borescope is used on the dirty side of the Sterile Processing area it is recommended the INSPEKTOR® CT Borescopes should be quickly wiped between each individual instrument inspection with a tap water moistened <u>fiber-free cloth</u>. This is done to minimize the risk of transferring any foreign debris to the next instrument being inspected that may have been picked up during previous inspection.

Once a complete set of instruments has been cleaned, repeat cleaning of the INSPEKTOR borescope with recommended disinfectant wipe followed by rinsing and or wiping with a water moistened fiber-free cloth.

- 2. High Level Disinfection High level disinfection may be achieved by submersing the INSPEKTOR® Borescope in a Cidex OPA® solution mixed according to the manufacturer's Instructions. (Note: The Connector Cap must be securely snapped into place before submersion.) High level disinfection should be done weekly, or at a regular interval determined by the facility, to prevent microbial growth.
- 3. **Sterilize** The INSPEKTOR® CT Borescope may be sterilized <u>once per month</u>. **Compatible Sterilization Methods for the INSPEKTOR® CT (see below)**.

Note: Low Temperature Sterilization of the INSPEKTOR® borescope is <u>not required</u> if high level disinfection is utilized.

Cleaning – Clean Side

When the INSPEKTOR® CT Borescope is used on the clean side of the Sterile Processing area and the instruments are considered clean, it is recommended the INSPEKTOR® CT Borescopes should be quickly wiped between each individual instrument inspection with a water moistened <u>fiber-free cloth</u> to minimize the risk of transferring any foreign debris to the next instrument being inspected that may have been picked up during previous inspection.

- 1. **Disinfection** If the INSPEKTOR® CT Borescope comes in contact with any visible foreign matter, it should be cleaned and disinfected as noted in **Cleaning Dirty Side**, above.
- 2. **Sterilize** The INSPEKTOR® CT Borescope may be low temperature sterilized once per month. **Compatible Sterilization Methods for the INSPEKTOR® CT Borescopes (see below).**

Note: Sterilization of the INSPEKTOR borescope is <u>not required</u> if high level disinfection is utilized.

High level Disinfection
(See Above under Cleaning – Dirty Side)

Caution:

If the INSPEKTOR® CT Borescope is disconnected from the INSPEKTOR® CTC Controller, the INSPEKTOR® CT Borescope protective cap must be placed securely on the proximal electronic end of the connector prior to wiping or submersing the INSPEKTOR® CT Borescope. This is accomplished by lining up the red dots on the connector and the connector cap and pushing until they click together.

Compatible Sterilization Methods for the INSPEKTOR® CT Borescopes (Prod. # 8007, 8008 & 8009)

- ✓ STERIS V-PRO® Low Temperature Sterilization Systems
 - STERIS SYSTEM 1E
 - V-PRO 1 Standard Cycle
 - V-Pro 1 Plus Lumen & Non-Lumen Cycles
 - V-PRO max Lumen, non-lumen & Flexible Cycles
 - V-PRO 60 Lumen & Non-Lumen Cycle.

Follow the instructions provided with the STERIS equipment for sterilization processing.

- ✓ STERRAD®
- 100S,
- **5**0
- **200**
- NX, and 100NX systems.

Follow instructions provided with $\mathsf{STERRAD}^{\circ}$ equipment for sterilization processing.

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

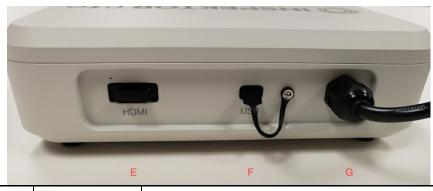
INSPEKTOR® CTC System Set Up

When using the INSPEKTOR CTC System around a wet field, the INSPEKTOR® CTC must be plugged into a Ground Fault Interrupter (GFI electrical outlet)



A B C

А	Camera On/Off Button	Push the button to turn the Camera on or off.
В	Scope Illumination Port	Remove the protective cap from the INSPEKTOR® CT Scope camera connection. Line up the red dots and securely push the connector into this port.
С	Scope Camera Port	Push the INSPEKTOR® CT Scope illumination connection into this port.



Е	HDMI Connection	Remove protective cap, connect supplied HDMI cable
		to a monitor with an HDMI input.

	T	
F	USB micro-B 1.2m port	Allows connection to a computer to capture video and photos if needed. When not in use, always have the USB protective cap installed.
G	Electrical Power Connection	Connect to any 120V and 60Hz AC outlet. If using around a wet field; the INSPEKTOR® CTC Box must be connected to a Ground Fault Interrupter (GFI) electrical outlet.
Н	INSPEKTOR® CT Scope Camera Connector with Cap on.	To connect with the INSPEKTOR® CTC Controller Box, remove the cap and line up the red dots and insert into INSPEKTOR® CT Camera Port (C)
ı	INSPEKTOR® CT Scope Illumination Connector	To connect with the INSPEKTOR® CTC Controller Box, insert into INSPEKTOR® CT Scope illumination Port (B). Do not twist the connector when inserting or removing.



Mounting Instructions

Mounting the INSPEKTOR® Monitor (product 7005) onto the Wall Mount (product 6005):

- Remove the four screws on the posterior of the INSPEKTOR® CTC Box
- ➢ Place the Wall Mount on the back and secure it to the INSPEKTOR[®] CTC Box with the four screws in their respective screw holes (follow the Wall Mount Instructions).
- Confirm that all four of the screws are tight
- Confirm the INSPEKTOR® CTC Box's power adapter is accessible when it is connected and disconnected.

Mounting the INSPEKTOR® Boxes (product 7005) onto the Flex Arm (product #6006)

- If unassembled, screw together flex arm base to flex arm.
- Screw the threaded end of the Flex Arm into the Connection Port located on the bottom of the INSPEKTOR® CTC Box.
- Confirm that the Flex Arm is screwed in tight prior to mounting the Flex Arm to any surface per the Flex Arm instructions for use.
- ➤ Confirm the INSPEKTOR[®] CTC Box power adapter is accessible when it is connected and disconnected.

Software Installation

To capture images or videos, install the software with the following instructions

Go to: www.inspektor.com

- ➤ Open INSPEKTOR® Specifications
- Open Download INSPEKTOR Software
- Open Compressed (zipped) Folder
- Open INSPEKTOR Software
- Open LYD Viewer Ver 1.0.2.0
- Open setup.exe
- > Follow the Wizard
- Return to INSPEKTOR® Software
- Open FIFB-160K-01_x64
- Open FIFB-160K 01) Driver x64.msi
- > Follow the Wizard to install

INSPEKTOR® CT Environmental Condition & Power Requirements:

- Indoor use only
- > Power requirements: 110 Volts and 60 cycles
- Maximum altitude up to 2 000 m
- > Temperature range 5°C to 40°C
- Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C

Warranty

The INSPEKTOR® CTC Digital Borescope System is warranted, when new, to be free of defects in material and workmanship and to perform in accordance with the manufacture's specifications when subject to normal use and service for a period of one year from the date of purchase. NCI, Inc. 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 NCI after receiving a Returned Material Authorization Number from NCI Inc. 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. Repair or preplacement of the device as provided above shall be the sole and exclusive remedy for any breach of the warranty.

**Opening or servicing of the INSPECTOR CT Monitor by anyone other than the manufacturer affects the water-resistant nature of the monitor and will void the warranty. If any component of the CT needs service, obtain a Return Authorization Number by calling: 763-427-2907.

The INSPEKTOR® CTC is manufactured to NCI, Inc's. exclusive specifications by:

Myriad Fiber Imaging Tech, Inc. 56 Southbridge Road Dudley MA 01571



VPRO*- is a registered trademark of Steris plc

Sterrad® and Cidex®- are registered trademarks of Advanced Sterilization Products

Oxivir® is a registered trademark of Diversey, Inc.

OxyCide™ – is a Trademark of Ecolab

Sani Cloth® Sani-HyPerCide® is a registered trademark of PDI, Inc.

NCI, Inc. 7125 Northland Terrace N Suite 100 Brooklyn Park, MN 55428

INSPEKTOR® - is a registered trademark of NCI, Inc.