

CT Digital Borescope Systems

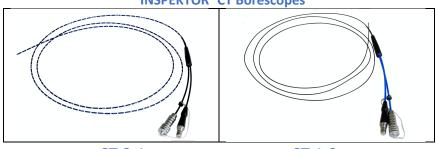
Includes Product #:
INS 7000-10 INSPEKTOR® CT Monitor
INS 7004 INSPEKTOR® CT DUO
INS 8007 INSPEKTOR® CT Digital Borescope
INS 8008 INSPEKTOR® CT Mini Digital Borescope
INS 8009 INSPEKTOR® CT Digital Borescope

INSPEKTOR® is a registered trademark of NCI, Inc.

INSPEKTOR® CT and CT DUO Monitors



INSPEKTOR® CT Borescopes



CT 2.1mm CT 1.2mm

Owner Manual

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The following - Instructions for Use - are applicable to both the INSPEKTOR® CT & INSPEKTOR® CT Mini Digital Borescope Systems. Including Models:

INS7000, INS7000-10 INS7001, INS7004

Intended Use

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

GENERAL WARNINGS

- The INSPEKTOR[®] CT Borescopes are polymer coated flexible devices. Avoid sharp metal edges when either inserting or retracting the INSPEKTOR[®] CT 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 and monitor.
- 6. The INSPEKTOR® Borescopes 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 surfaces of the INSPEKTOR® Borescopes to assure they are 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. Excessive bending may cause damage to the device and render the INSPEKTOR® CT 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 borescope against sharp edges. This can cause damage to the device.
- 11. Store between $60^{\circ} 90^{\circ}$ F. Keep away from magnetic fields while storing.
- 12. Do NOT use the INSPEKTOR® Controller Monitors in excessively high temperatures above 1209 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 exist on new scopes. This does not affect the function of the INSPEKTOR® CT Digital Borescope System.
- 14. Disinfectants may cloud the monitor screen. Wipe any disinfectant fluid from the screen with a damp soft cloth and water.
- 15. INSPEKTOR® CT Borescopes should not be exposed to temperatures in excess of 212 degrees F.
- 16. If the INSPEKTOR® CT 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® CT and INSPEKTOR® CT Mini Digital Borescopes are comprised of two components. The INSPEKTOR® CT Monitor houses an LED light source, camera control board and the monitor, in a waterproof (IP65)* compartment. The INSPEKTOR® CT Scopes plug into their respective monitors. Do not plug the INSPEKTOR® CT Mini Borescope (Prod #8008) into the INSPEKOR® CT Monitor (Prod. #7000-10). The INSPEKTOR® CT Mini Scope (prod. #8008) will only work when plugged into the INSPEKTOR CT DUO Monitor (Prod. #7004).

The INSPEKTOR® CT Systems are patented and 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 °CT Monitor's waterproof status, as defined by the International Electro Technical Commission is IP65 and INSPEKTOR °CT Borescopes are IP67.

Caution:

Turn off the INSPEKTOR CT or CT 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® CT or CTC Controller 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. Inspect Borescope Daily. 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® CT Monitor (Prod. # 7000-10 & 7004)

Cleaning and Disinfection – To remove debris, wipe the INSPEKTOR® CT Controller Monitor with a soft, nonabrasive cloth using 70% isopropyl alcohol. Allow proper contact time. Wipe the screen with an appropriate 70% isopropyl alcohol wipe.

Caution: Do not wipe down the INSPEKTOR® CT Controller Monitor without the INSPEKTOR® CT Borescope connected and the micro 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 these inner surfaces 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 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</u> <u>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, begin with a clean borescope. (See above under Cleaning – Dirty Side. It is also 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.

- Disinfection If the INSPEKTOR® CT Borescope comes in contact with any visible foreign matter, it should be cleaned with a hospital approved disinfectant wipe as noted in Cleaning – Dirty Side.
- Sterilize The INSPEKTOR® CT Borescope may be low temperature sterilized once per month. Compatible Sterilization Methods for the INSPEKTOR® CT (see below).

Note: Sterilization of the INSPEKTOR Borescope is <u>not</u> required 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® CT Monitor, 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.

Rev3 IFU NCI 100120

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 STERRAD® equipment for sterilization processing.

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

Sterilize - The INSPEKTOR® CT Borescope may be sterilized <u>once per</u> month.

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

INSPEKTOR® CT System Set Up

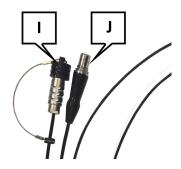
When using the INSPEKTOR® CT Systems around a wet field, the INSPEKTOR® CT Monitor must be plugged into a Ground Fault Interrupter (GFI electrical outlet)



Α	INSPEKTOR [®] CT Scope illumination port	To connect INSPEKTOR® CT light cable.
В	INSPEKTOR® CT Scope Camera 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	Flex Arm connection port	Socket to screw optional Flex Arm distal end into this hole.
D	USB micro-B port	For use when exporting images or video to a computer. Keep protective cap on when not in use to maintain waterproof integrity.
Е	Electrical Connector	Connect to any 120V and 60Hz AC outlet. If using around a wet field, the INSPEKTOR® CT Monitor must be connected to a Ground Fault Interrupter (GFI) electrical outlet.



Power Button on side of monitor.



I	INSPEKTOR® CT Scope Camera Connector	To connect with the INSPEKTOR® CT Monitor, remove the cap and line up the red dots and insert into INSPEKTOR® CT Camera Port (F)
J	INSPEKTOR® CT Scope Illumination Connector	To connect with the INSPEKTOR® CT Monitor, insert into INSPEKTOR® CT Scope illumination Port (G) . Do not twist the connector when receiving or removing

Mounting Instructions

Mounting the INSPEKTOR® Monitors (product 7000-10 & 7004) onto the Wall Mount (product 6005):

Remove the four screws on the posterior of the INSPEKTOR® CT Monitors

- Place the Wall Mount on the back and secure it to the INSPEKTOR® CT Monitor 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® CT Monitor's power adapter is accessible when it is connected and disconnected.)

Mounting the INSPEKTOR® Boxes (product 7000-10 & 7004) 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® CT Monitor.
- 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® CT Monitor 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: 100-240V~, 1.0A, 50/60Hz
- Maximum altitude up to 2000 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® CT 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, Inc. 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 replacement 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® CT 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.
$OxyCide^{TM}$ – 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.