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Description

The NeuroView® endoscope consists of a fiber optic bundle contained in a stainless steel shaft. The proximal end of the device has connections for the irrigation, image, and illumination. The image and illumination connection are contained in a unitized connector body (see figures 1, 2, and 3) for attachment of a video camera and a light source cable. An optical coupler for attachment of a video camera and light cables are available from Integra. Cables are available to connect with other manufacturer's equipment. The proximal end of the irrigation port is fitted with a female Luer lock connector.

Indications

The NeuroView endoscopes are intended for accessing and visualizing nerves, neural tissue and surrounding tissue where cerebrospinal fluid (CSF) may be contacted during neurosurgical procedures (including intracranial).

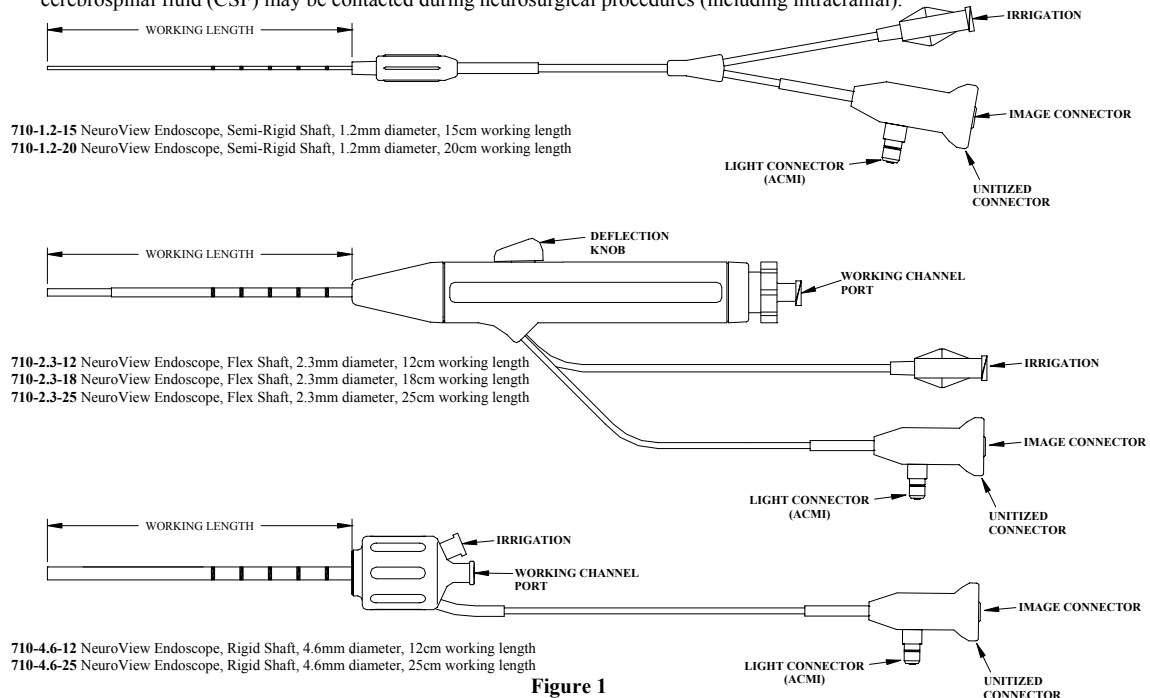


Figure 1

Contraindications

The NeuroView endoscope cannot be used in channels smaller than the tip diameter of the endoscope/cannula.

WARNINGS

- **High flow irrigation, with or without raised intracranial pressure, may cause hypertension, cardiac arrhythmia and arrest.**
- **Electrosurgical instruments, which do not have electrical insulation covering the entire length of their shaft, should not be used through the working channel of the endoscopes.**

PRECAUTIONS

- Monitor the amount of irrigation fluid, using only enough to remove blood from the field of view.
- Do not advance the endoscope forcefully or blindly.
- If visualization becomes obscured during advancement, discontinue advancement of the endoscope to allow irrigation of the field of view, or retract to improve view. Never advance without visualization.
- When using irrigation/aspiration, monitor patient for any elevation in intracranial pressure or presence of bradycardia.
- The endoscope shall be used only by qualified physicians.
- Assure that the tip of any working instrument is clearly viewed in the endoscope's image when performing treatment with the instrument.

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to the following:

- Infection – local and/or systemic which might include brain abscess, meningitis, ventriculitis
- Hemorrhage – intraventricular, intraparenchymal, subdural epidural hemorrhage
- Increased intracranial pressure
- Injury to blood vessels including tearing or perforation
- Other neurological injury including weakness in arms and legs resulting from tissue injury during passage of the endoscope
- Other standard complications associated with neuroendoscopy

Irrigation Fluid Use

Drainage

Drainage through large wound.

The endoscope is inserted into a large wound (e.g. a cavity created following debulking of a tumor). Fluid egresses freely or may be removed by aspiration.

Drainage through a separate cannula or drainage catheter.

The endoscope may be advanced through or along side a separate cannula or drainage catheter that allows an open channel for irrigating fluid egress when working in a restricted access space.

- Ensure that there is adequate space in the cannula for irrigating fluid to freely egress.
- Visually monitor the free egress of irrigation fluid.
- Be on the alert for signs and symptoms of raised intracranial pressure.

While using irrigating fluid, be constantly aware of signs of raised intracranial pressure. Intracranial pressure can be monitored by placing an intraparenchymal or intraventricular monitoring device during the surgery or during the period of irrigation.

Classic systemic signs of increased intracranial pressure include, but are not limited to:

- bradycardia
- hypertension
- respiratory abnormalities

Potential complications of increased intracranial pressure include, but are not limited to:

- decreased cerebral perfusion pressure resulting in ischemic damage
- brain herniation leading to irreversible neurological damage, coma or death

Prevent increased intracranial pressure by:

- verifying that the irrigation fluid can easily leave the surgical sight through wide, unobstructed channels
- simultaneously using nearby suction device
- placing a ventricular catheter to allow unimpeded egress of fluid through the ventricular catheter when working within ventricles

If increased intracranial pressure is suspected:

- immediately cease the flow of irrigation fluid
- immediately provide an egress channel for fluid (suction, ventricular drain)
- obtain an accurate measurement of intracranial pressure from a monitoring device
- if elevated in spite of the above measures, use other methods known to rapidly reduce intracranial pressure (hyperventilation, administration of osmotic diuretics).

Equipment Set-up and Connections

Prior to use of the endoscope, the user should become familiar with the operation of the other equipment required. This equipment includes an endoscopic video camera, a video monitor, a light source, a light cable with ACMI connector and the Integra optical coupler.

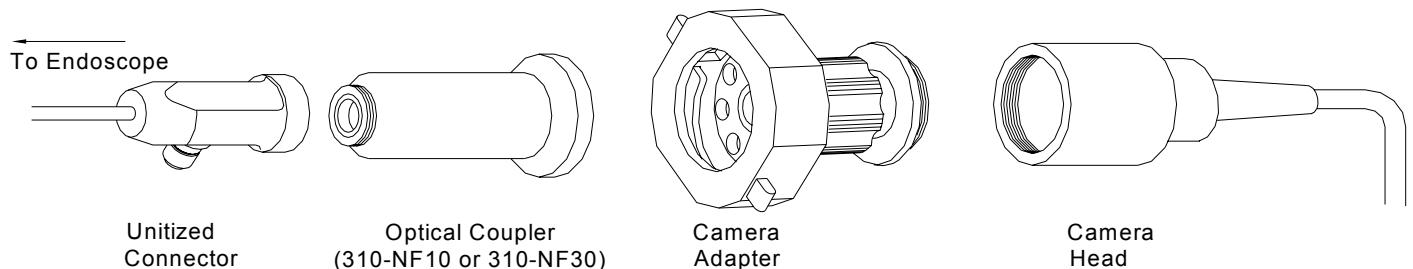


Figure 2

The camera head, light cable, and optical coupler must be sterilized and handled with standard aseptic technique. The user should read the individual instruction manuals provided with each of these pieces of equipment and understand the cleaning and sterilization methods indicated.

Image

Thread the optical coupler onto the unitized connector. Connect the optical coupler, to the camera, and focus.

Irrigation

Locate the irrigation connector extending from the endoscope. Remove and discard the cap from the irrigation connector. Connect a source of fluid. Irrigation may be provided with a syringe or a saline bag with an optional irrigation cuff. Be sure to flush all the air bubbles from the endoscope and the tubing set prior to use.

Illumination

Attach the ACMI light cable to the ACMI fitting located on the unitized connector. Connect the other end to the light source.

CAUTION

The endoscope should only be connected to a 1 or 2 MM light cable. Other light cables could overheat and damage the illumination fibers on the endoscope.

Final set-up

The final assembly should be seen as below.

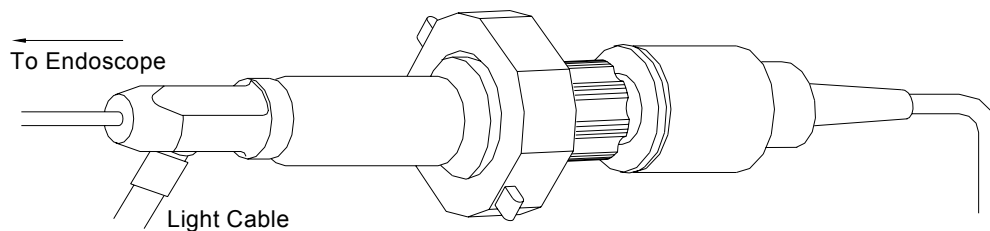


Figure 3

Handling and Storage

The NeuroView endoscope is a delicate instrument, which should be handled with care at all times. The key components of the endoscope portion are a glass fiberoptic bundle and a light guide, both of which can be damaged by improper handling. The following guidelines are recommended:

- Avoid sharp bending of the image and light guides
- Do not place any heavy objects on the endoscope
- Avoid pinching or clamping the image and light guides

Damage to the fiberoptic bundle will result in decreased illumination in the field of visualization, or loss of image or distortion of image.

The tip of the NeuroView Flexible Shaft Endoscope must be in a straight undeflected position when working instruments are inserted into or removed from the working channel. Instruments being used through the endoscope working channel should exceed the overall length of the working channel by at least 2cm. Do not deflect the distal tip of the NeuroView Flexible Shaft Endoscope if an instrument being used in the working channel is not extended beyond the tip and visible in the endoscopes image.

Operation

The endoscope is now ready to be advanced to the area of interest. Carefully plan the intracranial pathway to be followed. Advance the endoscope to the surgical site, monitoring as necessary. When the tip of the endoscope is located near area of interest, the physician may then inspect visually, and then proceed with the desired therapy. The image is observed on the monitor.

Flushing solution is used as necessary to clear the viewing field. Aspiration may be used to remove excessive irrigation fluid.

Sterilization

The endoscope is a sterile, single use device. **Do Not Resterilize or Reuse.**

Disposal

Dispose of the endoscope per normal institutional procedures for medical waste.

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Ordering Information

710-1.2-15 NeuroView Endoscope, Semi-Rigid Shaft, 1.2mm diameter, 15cm length
710-1.2-20 NeuroView Endoscope, Semi-Rigid Shaft, 1.2mm diameter, 20cm length
710-2.3-12 NeuroView Endoscope, Flex Shaft, 2.3mm diameter, 12cm length
710-2.3-18 NeuroView Endoscope, Flex Shaft, 2.3mm diameter, 18cm length
710-2.3-25 NeuroView Endoscope, Flex Shaft, 2.3mm diameter, 25cm length
710-4.6-12 NeuroView Endoscope, Rigid Shaft, 4.6mm diameter, 12cm length
710-4.6-25 NeuroView Endoscope, Rigid Shaft, 4.6mm diameter, 25cm length
310-NF10 Optical coupler, Non-focusing, 10K
310-NF30 Optical coupler, Non-focusing, 30K

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RETURN GOODS POLICY

- Authorization, from customer service, must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Non-sterile product must be returned in unused saleable condition in original package.
- Custom or special order products will not be accepted for credit.

SYMBOLS USED ON LABELING



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician



Sterile unless package is opened or damaged



See instructions for use



Expiration date



Do not reuse after opening



Serial number

U.S. Patent #5,415,158 and #5,951,463

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