



**Natus<sup>®</sup>**  
**Camino<sup>®</sup> Flex Ventricular**  
**Intracranial Pressure Monitoring Kit**

**REF** NTVTUN

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**Natus Medical Incorporated**  
5955 Pacific Center Blvd  
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**MADE IN USA**





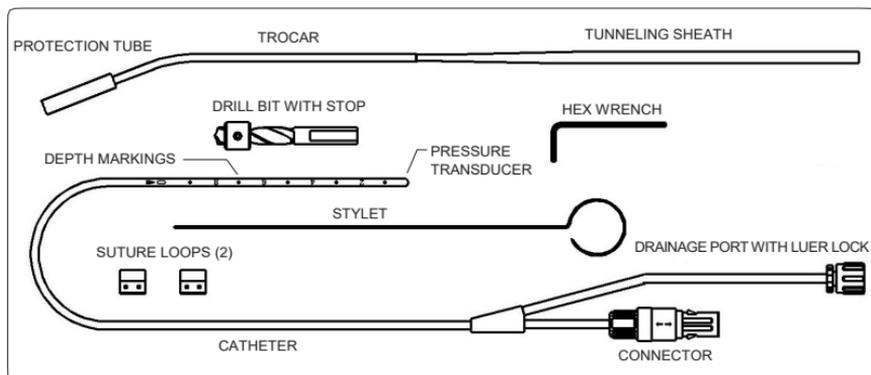
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**Intracranial Pressure Monitoring Kit**

**Instructions for Use**

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## NATUS® CAMINO® FLEX VENTRICULAR INTRACRANIAL PRESSURE MONITORING KIT (VTUN)



**Figure 1:** Contents of the Kit

### INDICATIONS FOR USE

Use of the Natus® Camino® Flex Ventricular Intracranial Pressure Monitoring Kit is indicated when direct and continuous intraventricular intracranial pressure (ICP) monitoring and cerebrospinal fluid (CSF) drainage are required.

### SYSTEM DESCRIPTION

The system is designed for use in a hospital environment, such as intensive care units, by clinicians with experience in neurological/intracranial pressure monitoring. ICP monitoring, using this device, is an invasive method for measuring intracranial pressure.

The Natus Camino Flex Ventricular Intracranial Pressure Monitoring Kit contains a sterile, non-pyrogenic 9/10 French catheter embedded with a micro miniature silicon strain gauge pressure transducer that is used to monitor ICP and drain CSF. In addition to the catheter, the following sterile, non-pyrogenic accessories are included: (**Fig. 1**).

- One (1) 0.125" (3.17 mm) diameter stainless steel trocar with scalp tunneling sheath.
- One (1) 0.029" (0.7 mm) diameter stainless steel catheter introducer stylet.
- Two (2) suture loops.
- One (1) 7 mm diameter drill bit with drill stop.
- One (1) Hex wrench.

This Catheter interfaces with the following Camino ICP Monitoring Systems:

- Camino® Advanced Monitor (CAM01) fitted with the Camino® Flex Adapter (FLEXADR)
- Natus® Camino® ICP and Temperature Monitor (CAM02)

**NOTE:** In addition to the accessories provided in this kit, various surgical instruments and supplies are required to place the Natus Camino Flex Ventricular Catheter (Catheter).

The following surgical instruments and supplies are recommended for preparation of the surgical sites (Not included in Kit):

- Hair clippers
- Sterile drapes, towels or similar
- Antiseptic solution for scalp such as povidone-iodine
- Ruler, used to locate insertion and tunneling exit sites
- Marker, used to mark insertion and tunneling exit sites

The following surgical instruments and supplies are recommended for tunneling and subsequent catheter implantation (Not included in Kit):

- Scalp anesthetic such as 1% Xylocaine® or similar
- Syringe and needle for administration of scalp anesthetic
- Scalpel for scalp incisions at catheter insertion and tunneling exit sites
- Sterile gauze or similar absorbent materials
- Self retaining type retractors or similar to provide bone exposure
- Hand drill
- Syringe and sterile saline for irrigation of twist drill hole to remove bone fragments, blood, etc.
- Sharp instrument to open the dura, such as an 18 gauge spinal needle, 11 blade scalpel, or similar.

- Forceps, sutures and needles, and scissors for suturing scalp incisions after the implantation procedure.

A complete set of surgical instruments and supplies are available from Natus in the Natus Cranial Access Kits.

## CONTRAINDICATIONS

ICP monitoring should not be conducted where components of the monitoring system will come in direct contact with any infected tissue. This includes, but is not limited to: infections of the scalp, bone, meninges, ventricles, and blood stream. Monitoring is also contraindicated in patients who are receiving anti-coagulants or are known to have a bleeding diathesis. ICP monitoring is contraindicated where trained personnel are not available to continuously supervise monitoring.

This device is not designed, sold, or intended for any use except as indicated.

## WARNINGS

- Ensure monitor is plugged into power source prior to patient preparation.
- **DO NOT** use the Natus Camino Flex Ventricular Catheter for more than 5 days. If monitoring is continued for more than 5 days, placement of a new Catheter through a new twist drill hole is recommended. The Catheter is classified as a prolonged exposure device (i.e., less than 30 day exposure). To limit the contact to less than 30 days, **DO NOT** implant more than five Catheters consecutively.
- **DO NOT** use the drainage port with luer lock for the intrathecal administration of medication. The luer lock fitting on the drainage port of the catheter is designed for connection to an external ventricular drainage device for the purpose of draining cerebrospinal fluid from the ventricle.
- The Natus Camino Flex Ventricular Intracranial Pressure Monitoring Kit (Catheter and Accessories) is designed for **SINGLE-USE ONLY. DO NOT RESTERILIZE OR REUSE**. All components are extremely difficult to clean after being exposed to biological materials and adverse patient reactions may result from reuse.
- Use of catheter or cables other than those specified for the Camino Advanced Monitor (Monitor) fitted with a Camino Flex Adapter, or Camino ICP Monitor (Monitor) may result in malfunction of or damage to the monitor.
- Inspect the package for breaches prior to opening and discard if a breach is detected. Inspect the Catheter and accessories for damage prior to use, and again, discard if damage is detected.

The Catheter must be calibrated **IN AIR prior to implantation**. Initialization procedures for specific Camino Monitors are below.

### • Camino Advanced Monitor fitted with Camino Flex Adapter

The Camino Flex Adapter  button must be pressed before catheter implantation. If the button is not pressed before implantation and a "Check Catheter Connection" message is displayed on the monitor, discard and replace the Catheter.

### • Camino ICP and Temperature Monitor

The Camino Flex Extension Cable (FLEXEXT) must be connected to the Monitor prior to connecting the Catheter. If the Catheter reads "Catheter Failure" after initialization is completed, discard and replace the Catheter.

- The sterile Catheter should remain in its sterile packaging until the insertion site has been fully prepared. This will reduce the risks for bacterial contamination of the Catheter body.
- The Camino Advanced Monitor fitted with the Camino Flex Adapter should be connected to a power source and turned on before any patient preparation is started. This is recommended to minimize the total time that the twist drill hole and Catheter remain in communication with the atmosphere while in the sterile field. **DO NOT** immerse the tip of the Catheter or Catheter connectors in any fluid prior to implantation in the patient. Failure to follow these instructions may lead to ICP measurement error.
- Obstruction of ventricular catheters may occur due to the presence of blood in the CSF, collapse of the ventricles and/ or dislocation of the catheter tip from the ventricles, kinking of the catheter drainage lumens/tubing, or clogging of the drain holes by the choroid plexus.
- Punctures of the brain to insert a ventricular catheter can predispose an intracerebral hemorrhage and edema causing a further rise in ICP.
- In patients with small ventricles, the ventricular walls may collapse around the tip of the catheter resulting in obstruction and predisposing to tentorial herniation.
- The Catheter may be used in children, but care must be taken to ensure adequate size of the anterior horn of the lateral ventricle. Ventricular size can vary widely in children due to developmental variations and the presence of disease states such as Traumatic Brain Injury and Hydrocephalus.

- An imaging study should be performed before Catheter insertion to verify the size and location of the anterior horn of the lateral ventricle, which will be cannulated. The size and location of the ventricles may be altered by swelling of the adjacent tissues, for example in Traumatic Brain Injury.
- The tip of the Catheter is implanted within the anterior horn of the left or right lateral cerebral ventricle. A cylindrical volume with a height of at least 11 mm and a diameter of at least 5 mm is required for Catheter implantation.
- Other known complications include, but are not limited to: infection, overdrainage, catheter migration, air leakage into the ventricle, and fluid leakage.

## PRECAUTIONS

- It is essential to maintain strict sterile technique during Catheter placement to avoid infections and complications. All procedures should be performed by a qualified clinician using standard surgical procedures.
- To plug or unplug the Catheter from the Cable, or to plug or unplug the Cable from a Camino Monitor or Adapter, push or pull the connector without turning it. Hold the connector housing and do not pull directly on the Catheter or Cable to prevent damage to the connector, Cable, or Catheter.
- Read all instructions included with the Natus Camino Flex Ventricular Intracranial Pressure Monitoring Kit, Adapter, and Monitor prior to use. Only qualified personnel should assemble or operate these products.
- Avoid any contamination of the Catheter's connector with any fluid during usage.
- The inserted portion of the Catheter is radiopaque.
- **Magnetic Resonance Imaging (MRI) Information:** The Natus Camino Flex Ventricular Catheter is MR Conditional at 1.5 Tesla (T) and 3.0T environments. Please reference the MRI Safety section for information essential to safe use in the MR environment.

## INITIALIZING AND IMPLANTING THE CATHETER

### a. Turning on the Monitor

Please reference the User Manual for the specific Camino Monitor or Adapter for the specific "powering on" procedure.

### b. Extension Cable and Catheter Connection

**CAUTION:** The Natus Camino Flex Extension Cable must be **STERILIZED** prior to each use. Please consult the sterilization instructions in your specific Monitor or Adapter User Manual.

Pass the male connector of the sterile Cable (the end with the black barrel) from the sterile field to non-sterile personnel. (Fig. 2)

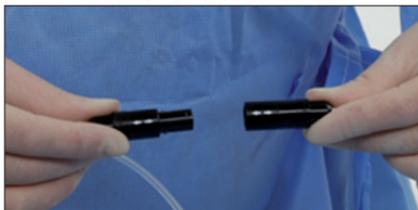


**Figure 2:** Handling the Cable between Sterile and Non-Sterile Personnel

Connect the male fitting of the cable (arrows facing upwards) to the receptacle on the front of the Adapter, or side Monitor until an audible "click" is heard.

Outside of the sterile field, remove the double blister tray containing the Natus Camino Flex Ventricular Catheter (Catheter) and the double blister tray containing the Kit Accessories from the dispenser box. Using aseptic technique, open both outer tray lids by pulling on the tab to expose the inner trays and lids. Transfer the inner trays into the sterile field.

In the sterile field, align the arrows on the end of the Catheter fitting with the female fitting of the Cable. Connect the two fittings; an audible "click" will be heard. Secure the cable in the sterile field and place the Catheter tip on a dry, sterile surface. (Fig. 3)



**Figure 3:** Connecting the Catheter and Cable

### c. Catheter Initialization Process

**Reminder:** Refer to your specific Camino Monitor User Manual for information regarding initializing procedure.

#### Using the Camino Advanced Monitor fitted with a Camino Flex Adapter

Once the Catheter is connected to the Adapter by way of the Extension Cable, the LED on the Adapter will change from flashing yellow to solid yellow, signaling the start of the catheter initialization process. This process will take approximately 30 seconds. During this time, the ICP "mmHg" display will countdown from approximately 30 to 0. After the countdown is completed and the Monitor screen displays "0 mmHg" ( $\pm 1$  mmHg), the Adapter LED will flash green. If this value does not read "0 mmHg" ( $\pm 1$  mmHg), please refer to Section 6 of the Adapter User Manual for troubleshooting information.

**Prior to implantation of the catheter** press  to complete the zeroing process. The flashing green LED light will change to a solid green light and an ICP value will be displayed on the Monitor.

**Notice:** After the  button is pressed, the ICP value displayed on the Monitor may not read "0 mmHg". The ICP sensor is responsive to the fluid environment of the brain. When the button is pressed, an offset is applied to compensate for this small effect. This compensation will not affect the ICP reading.

#### Using the Camino ICP and Temperature Monitor

Connect the Catheter to the monitor by way of the Camino Flex Extension Cable (FLEXEXT). The touch screen will indicate that it is being initialized. A message will appear stating that "The Catheter has been successfully initialized and is ready for implantation". Select "Accept" on the touch screen to complete the initialization process for the Catheter. Note that the ICP reading will self adjust when the Catheter is implanted. This process will take approximately 10 seconds. If the monitor reports a "**Catheter Failure**" message in the status bar, discard the catheter and replace with a new one.

**NOTE:** The Camino Flex Ventricular Catheter can be disconnected from the Camino Flex Extension Cable during tunneling and implantation procedures. This will prevent monitor alarms from being triggered by sudden changes in pressure that may occur.

### d. Catheter Implantation

#### Using the Camino Advanced Monitor fitted with a Camino Flex Adapter:

Refer to your Adapter User Manual for instructions regarding troubleshooting "Check Catheter Connection" messages that may occur during Catheter implantation.

#### Using the Camino ICP and Temperature Monitor:

If "Catheter Failure" message appears in the status bar, discard and replace the catheter.

**NOTE:** To minimize the risk of surgical site infections, it is recommended to prepare the surgical area in accordance with evidence-based guidelines, such as Mangram et al. Guideline for Prevention of Surgical Site Infection, 1999. Infection Control and Hospital Epidemiology, 20(4), pp. 257-258 and Nichols RL. Preventing Surgical Site Infections: A Surgeon's Perspective. Emerging Infectious Diseases. 7(2), Mar-Apr 2001.

- Use an appropriate antiseptic agent available for preoperative preparation of the skin at the incision site. Members of the surgical team who have direct contact with the sterile operating field, sterile instruments, or supplies used in the field, should wash their hands and forearms by surgical scrubbing immediately before the procedure for at least 2-5 minutes. After scrub, keep hands up and away from body. Dry hands with a sterile towel and then put on a sterile gown and gloves.
  - To reduce the risk of infection, the use of depilatory agents or no hair removal is recommended. If shaving or clipping is performed, shave or clip the area immediately before the operation, preferably with electric clippers.
  - The skin should be free of gross contamination.
1. Select a Catheter insertion site for access to the ventricle.
  2. To prepare the entry site, it is recommended to follow evidence based guidelines, such as Mangram et al. Guideline for Prevention of Surgical Site Infection, 1999. Infection Control and Hospital Epidemiology, 20(4), pp. 257-258.
  3. Apply an antiseptic in concentric circles beginning in the area of the proposed incision. The prepared area should be large enough to extend the incision or create new incisions, if necessary. The skin preparation procedure may need to be modified depending on the condition of the skin or location of the incision site.

4. The insertion site incision should be 1-1.5 cm in length and carried to the bone (see **Fig. 4** Step 1, Step 2).
5. Once the incision has been made, expose the bone with a self-retaining type retractor, or similar.
6. Drill a hole through the skull using the drill bit provided in the Accessories Kit included with the Catheter. Ensure that the twist drill hole extends through the inner table of the skull exposing the dura.
7. Open the dura by making a cruciate incision, using an 11-blade scalpel, 18 gauge spinal needle, or similar.
8. Irrigate the skull hole with sterile saline and make sure that the entry site in the dura is of adequate size to allow the catheter to pass through without bending, and that it is cleared of any debris.

### Tunneling the Catheter

To tunnel the Catheter in preparation for inserting into the patient's ventricle, follow one of the two techniques described on this page.

#### Tunneling Anterior to Posterior:

Using the trocar with tunneling sheath provided, and beginning at the drill hole incision, pass the trocar between the scalp and skull toward and out from the scalp exit site.

Puncture the scalp at the exit site and pull the trocar through until approximately 10 cm of the plastic tunneling sheath is exposed at the exit site.

Cut the sheath perpendicular to its length, approximately 1 cm from the scalp.

This will leave a tunnel running about 7 cm from the drill hole site to the scalp exit site. Ensure the sheath is unobstructed and free of debris that may damage the pressure sensor, and that all of the tapered section of the sheath has been removed. Do not force the Catheter through the sheath. Carefully feed the Catheter through the sheath from the scalp exit site to the incision site, ensuring that there is at least 20 cm of Catheter pulled through the sheath toward the insertion site.

Slide the sheath out from under the scalp, over the tip of the Catheter.

#### Tunneling Posterior to Anterior

Position the tip of the catheter within the trocar's plastic sheath, and use the trocar to tunnel the Catheter under the scalp toward the drill hole, starting from the scalp exit site (see **Fig. 4** Step 3).

Continue pulling the trocar and feeding the Catheter through the tunnel until at least 20 cm of the catheter is beyond the scalp. Remove the trocar with sheath from the Catheter (see **Fig. 4** Step 4).

Once the Catheter tunneling procedure is completed, follow the instructions for inserting the Catheter into the ventricle.

### Insertion of the Catheter into the ventricle

1. Insert the stylet into the Catheter. The stylet is placed in a dedicated lumen, designed to prevent communication of CSF from the drainage lumen to the stylet. The stylet insertion point is located at an opening on the Catheter with a black arrow on the white stripe with depth markings at the 10 cm mark. Gently insert the stylet to the bottom of its lumen at the Catheter tip. Do not force the stylet beyond this point (see **Fig. 4**, Step 5).
2. Insert the Catheter by holding the Catheter and stylet together. The depth insertion may be gauged using the centimeter markings on the Catheter (see **Fig. 4**, Step 6).

**NOTE:** If the ventricles of the patient are enlarged, it may be appropriate to advance the Catheter by several millimeters beyond the point where fluid is first obtained; this will assist keeping the Catheter tip in the ventricle as decompression occurs.

3. Remove the protective cap from the luer fitting at the end of the drainage line. Verify ventricular placement by looking for the flow of cerebrospinal fluid along the length of the Catheter and at the drainage port.
4. While holding the Catheter in place at the insertion site, remove the stylet, and then gently pull on the connector end of the Catheter until it makes a right angle bend and lies flat against the skull (**Fig. 4** Step 7)
5. Attach the Catheter to the External Ventricular Drainage system luer lock connector. The Catheter may be connected to a variety of CSF drainage systems. Ensure that flow of CSF continues after pulling the connector end. If the bend created at the twist drill hole is too tight, CSF flow may be restricted.
6. Connect the Catheter to the Camino Flex Extension Cable. At this time, the Camino Monitor should begin displaying mean ICP (mmHg) and a pressure waveform.

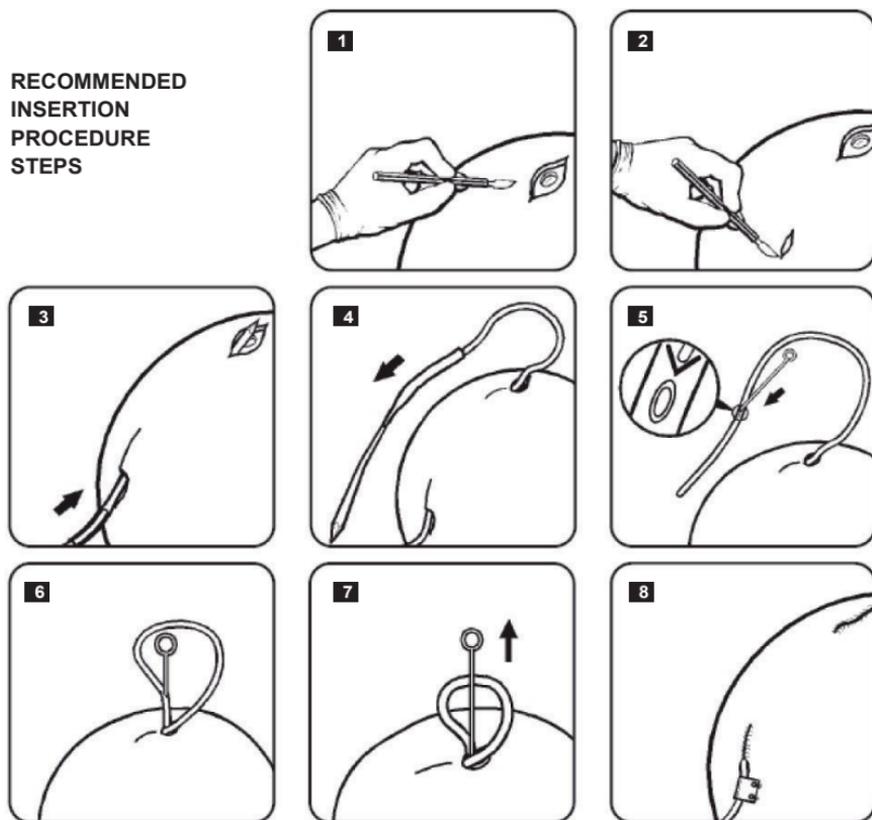
**NOTE:** During routine use, close the drainage system for approximately five minutes before recording the intracranial pressure (ICP). Closing the stopcock prevents the system from reading a lower ICP that may result from actively draining CSF.

7. Temporary closure of the scalp over the insertion site and at the Catheter exit site may be accomplished through a variety of surgical means such as sutures, staples, or by surgical dressing alone. The surgeon is best advised to use the method his/her practice and training dictates to be best for the patient. If the incisions are primarily closed, sterile dressings should be used to cover the wound sites for 24- 48 hours following evidence-based guidelines, such as Mangram et al. Guideline for Prevention of Surgical Site Infection, 1999. Infection Control and Hospital Epidemiology, 20(4), pp. 263.
8. Use the enclosed suture loops and standard suturing technique to secure the catheter to the scalp adjacent to the site where the catheter exits the scalp tunnel (see **Fig. 4**, Step 8).
9. Retain Catheter position and provide strain relief by loosely coiling the Catheter next to the suture loop site and tie the Catheter coil down.
10. Make sure the Camino Flex Extension Cable is properly connected to the Camino Monitor.

### **Disposal**

After patient use, the Kit accessories and the Catheter must be handled as biohazardous material and disposed of in accordance with local, state and Federal environmental requirements following facility protocols.

**RECOMMENDED  
INSERTION  
PROCEDURE  
STEPS**



**Figure 4:** Recommended Insertion Procedure

**SPECIFICATIONS**

Transducer type	Strain gauge micro electro-mechanical system (MEMS) piezoresistive silicon chip
Transducer size	9Fr/10Fr (3.3 mm diameter)
Functional pressure range	-10 to 125 mmHg
Functional over/under pressure range	-200 to 900 mmHg
Accuracy	-10 to 10 mmHg: $\pm 1$ mmHg 11 to 33 mmHg: $\pm 2$ mmHg 34 to 125 mmHg: $\pm 6\%$
Zero drift	$\pm 4$ mmHg from 15 minutes up to 24 hours after insertion $\pm 2$ mmHg from 24 hours up to 120 hours after insertion
Temperature coefficient	$\pm 2$ mmHg maximum change over temperature range of 22°C – 45°C (72°F – 113°F)
Depth markings	Located each 1 cm up to 9 cm from the catheter tip

MR Conditional



Read and understand this document in its entirety before conducting a Magnetic Resonance Imaging procedure on a patient with an implanted Camino Flex Ventricular Catheter (Catheter). Failure to heed these Warnings and adhere to the Conditions For Safe Use may result in serious injury to the patient.

## MRI SAFETY INFORMATION

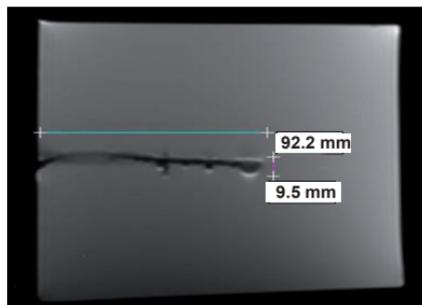
Non-clinical testing has demonstrated the Camino Flex Ventricular Catheter is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static Magnetic Field of 1.5 Tesla (T) and 3.0T.
- Maximum spatial gradient magnetic field of 3500G/cm (35T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2W/kg (Normal Operating Mode).
- Under the scan conditions defined above, the Camino Flex Ventricular Catheter is expected to produce a maximum temperature rise of less than 0.4°C after 15 minutes of continuous scanning.
- Additional instructions or information essential to safe use in the MR environment can be located following the image artifact information below.
- In non-clinical testing, the image artifact caused by the device extends approximately 3.1mm from the catheter when imaged with a spin echo pulse sequence and a 1.5T MRI system, and 1.85mm from the catheter when imaged with a spin echo pulse sequence and a 3.0T MRI system. (See Fig. 5-10)
- In non-clinical testing, the image artifact caused by the device extends approximately 5.4mm from the catheter when imaged with a gradient echo pulse sequence and a 1.5T MRI system and 5.9mm from the catheter when imaged with a gradient echo pulse sequence and a 3.0T MRI system.
- Imaging employing Gradient Echo sequences is not recommended because of the greater image artifact generation as compared to Spin Echo sequences.

## WARNINGS:

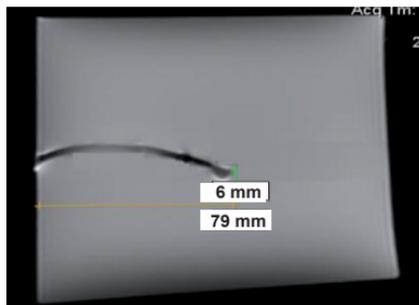
- Patient injury may occur if the Conditions for Safe Use of the Catheter in the MRI Environment are not followed. Heating of greater than 4°C is possible for any other configuration than the recommended coiled configuration.
- Do not use Head Transmit Surface Coils.
- Do not exceed a MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg, Normal Operating Mode only.
- Do not bring any catheter accessories (trocar, stylet, drill bit, drill stop, drill stop or hex wrench) into the MRI environment. This includes MR-equipped operating suites.
- Immediately abort the scan should the recommended configuration (coiled) of the catheter comes loose. If possible, instruct the patient to report a loose coil configuration.

(A) Sagittal Plane



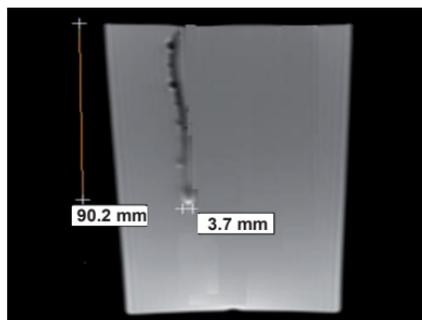
**Figure 5:** Catheter imaged in sagittal plane using 1.5T spin echo imaging sequence

(A) Sagittal Plane



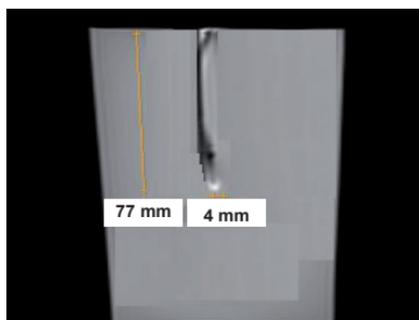
**Figure 8:** Catheter imaged in sagittal plane using 3.0T spin echo imaging sequence

(B) Axial Plane



**Figure 6:** Catheter imaged in axial plane using 1.5T spin echo imaging sequence

(B) Axial Plane



**Figure 9:** Catheter imaged in axial plane using 3.0T spin echo imaging sequence

(C) Coronal Plane



**Figure 7:** Catheter imaged in coronal plane using 1.5T spin echo imaging sequence

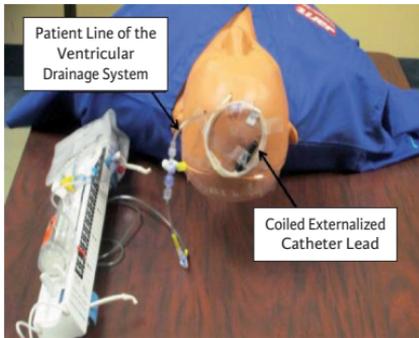
(C) Coronal Plane



**Figure 10:** Catheter imaged in coronal plane using 3.0T spin echo imaging sequence

Preparing the Device for Safe Use in the MR Environment

- Do not take any of the non-implanted accessories such as the stylet, drill bit, drill stop, hex wrench etc., into the MRI environment.
- Ensure that the extension cable and monitor are disconnected from the Catheter prior to entering the MR environment.
- Ensure all components of the External Ventricular Drainage system used with the Catheter are MR Safe or MR Conditional to 1.5T or 3.0T.
- **Coil the externalized lead of the Catheter in a 2.5 inch (6.3 cm) to 3.5 inch (8.8 cm) diameter range and tape to the top of the patient's head using adhesive tape. (See Fig. 11 and 12)**
- **Ensure that the catheter is securely coiled and no portion of the externalized lead or black connector is routed along the side of the patient's head or shoulders.**



**Figure 11:** Recommended Configuration – Catheter coiled on the top of the patient's head; with catheter connected to drainage system



**Figure 12:** Recommended Configuration – Catheter coiled on the top of the patient's head; with catheter not connected to drainage system

MRI Scanning Parameters for Safe Use of Device

- A knowledgeable MRI expert must verify that the MRI Safety Information has been followed prior to performing the MRI procedure.
- For use in 1.5T and 3.0T MRI systems only.
- Do not exceed a maximum head or whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Use only the following coils for MRI Procedures:
  - Transmit / Receive Body Coils,
  - Transmit Body Coils / Body Receive-Coil, and
  - Transmit Body Coils / Head Receive Coil
- Ensure that the proper patient weight is used for the SAR calculations and verify that the MRI system has appropriately calculated and updated the SAR value after all parameter changes have been made.

## **HOW SUPPLIED**

Natus Camino Flex Ventricular Intracranial Pressure Monitoring Kit is supplied sterile and non-pyrogenic in a double-wrap packaging.

## **CUSTOMER SERVICE INFORMATION**

### **Natus Medical Incorporated**

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1-608-829-8500 (International)

[www.natus.com](http://www.natus.com)

## **PRODUCT INFORMATION DISCLOSURE**

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**Rx ONLY**

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

Attention: Selon la législation fédérale (USA) ce dispositif ne peut être vendu que par un médecin ou un praticien, ou sur leur ordonnance.

Attenzione: La legge federale degli Stati Uniti limita la vendita di questo prodotto ai soli medici, direttamente o su prescrizione medica.

Achtung: Laut US-Bundesrecht darf dieses Produkt nur von einem Arzt oder im Auftrag eines Arztes verkauft werden.

Precaución: La ley federal de Estados Unidos restringe la venta de este dispositivo a los médicos y a las personas autorizadas por los mismos.

Voorzicht: De Amerikaanse federale wetgeving beperkt de verkoop van dit hulpmiddel door een arts of geneeskundige of op medisch recept.



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Référence du catalogue  
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Manufacturer  
Fabricant  
Fabbricante  
Hersteller  
Fabricante  
Fabrikant



Lot number  
Numéro de lot  
Numero di lotto  
Lot-Nummer  
Número de lote  
Lot nummer



Date of manufacture  
Date de fabrication  
Data di fabbricazione  
Herstellungsdatum  
Fecha de fabricación  
Fabricagedatum



Use by  
Utiliser jusque  
Utilizzarenoladiscadenza  
Verfallsdatum  
Usese hasta la fecha  
Uiterste gebruiks datum



Do Not Reuse  
Ne pas réutiliser  
Non riutilizzare  
Nicht wiederverwenden  
No volver a utilizar  
Niet hergebruiken



Non-pyrogenic  
Apyrogène  
Non pirogenico  
Nicht pyrogen  
No pirogénico  
Niet pyrogeen



Do Not Resterilize  
Ne pas restériliser  
Non risterilizzare  
Nicht erneut sterilisieren  
No reesterilizar  
Niet hersteriliser



Consult instructions for use  
Consulter le mode d'emploi  
Consultare le istruzioni per l'uso  
Siehe Gebrauchsanweisung  
Consultar instrucciones de uso  
Raadpleeg de gebruiksinstructies



Sterile - Sterilized using Ethylene Oxide  
Stérile - Stérilisé à l'oxyde d'éthylène  
Sterile - Sterilizzato con Ossido di Etilene  
Steril - Mit Ethylenoxid sterilisiert  
Estéril - Esterilizado utilizando óxido de etileno  
Steriel - Gesteriliseerd met ethyleenoxide



Serial Number  
N° de série  
Numero di serie  
Serienummer  
Número de serie  
Lotnummer



MR Conditional (Catheter & Suture Loops)  
Compatible avec l'IRM sous certaines conditions (cathéter et anses de suture)  
Compatibilità RM condizionata (catetere e anelli di sutura)  
Bedingt MR-taughich (Katheter und Nahtschlingen)  
RM condicionada (Catéter y lengüetas de sutura)  
MR-conditioneel (katheter en hechtlossen)



MR Unsafe (other accessories)  
Non compatible avec l'IRM (autres accessoires)  
Non compatibile con RM (altri accessori)  
MR-Unsafe (anderes Zubehör)  
No seguro para RMN (Otros accesorios)  
MR Unsafe (niet veilig bij MR; overige accessoires)



Do not use if package is damaged  
Ne pas utiliser si l'emballage est endommagé  
No utilizar se la confezione è danneggiata  
Nicht verwenden, wenn die Verpackung beschädigt ist  
No utilizar si el embalaje está dañado  
Niet gebruiken indien de verpakking is beschadigd



This product is not manufactured with Dry Natural Rubber or Natural Rubber Latex.  
Ce produit n'est pas fabriqué avec du caoutchouc naturel sec ou Latex de caoutchouc naturel.  
Il prodotto non è fabbricato con gomma natural secca o lattice di gomma naturale.  
Das Produkt wurde weder mit Trockenkautschuk noch Naturgummilatex hergestellt.  
Este producto no está fabricado con caucho natural seco ni con látex de Caucho Natural.  
Dit product werd niet vervaardigd met droog natuurlijk rubber of latex van natuurlijk rubber.