CLEARPOINT®
NEURO

SmartFlow

Neuro Cannula

INSTRUCTIONS FOR USE

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I. Intended Use

The MR Compatible Ventricular Cannula is intended for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."

Warning: This device is intended for "single patient use only". Contents of unopened, undamaged package are sterile and non-pyrogenic. Do not re-sterilize.

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

II. Device Description

Package Contents:

NGS-NC-01	**16 ga SmartFlow Neuro Cannula, .008" ID x 4 ft, 18mm tip**
NGS-NC-02	**16 ga SmartFlow Neuro Cannula, .008" ID x 10 ft, 18mm tip**
NGS-NC-03	**14 ga SmartFlow Neuro Cannula, .021" ID x 4 ft, 18mm tip**
NGS-NC-04	**14 ga SmartFlow Neuro Cannula, .021" ID x 10 ft, 18mm tip**
NGS-NC-05	**16 ga SmartFlow Neuro Cannula, .008" ID x 10 ft, 15mm tip**
NGS-NC-06	**16 ga SmartFlow Neuro Cannula, .008" ID x 10 ft, 13mm tip**
NGS-NC-07	**14 ga SmartFlow Neuro Cannula, .021" ID x 10 ft, 13mm tip**
NGS-NC-08	**14 ga SmartFlow Neuro Cannula, .021" ID x 10 ft, 13mm tip (short cannula)**

The Cannula has a stepped distal tip with a rigid ceramic cannula body protecting the fluid lumen while providing rigidity to the distal portion of the device. Soft tubing protects the lumen in the center portion and at the proximal end where it terminates at a female luer fitting. The Cannula must be used with a supporting structure (e.g. stereotactic guide tube and frame) to provide support and control during insertion. A 16 ga Guide Tube is provided with the 16 ga device for this purpose. The fluid carrying central lumen is manufactured from non-reactive silica.

III. General Warnings and Precautions

Warning: The device is intended for single patient use only and is provided sterile and non-pyrogenic. Do not re-sterilize. All components of the cannula are MR safe.

Warning: Do not apply lateral pressure to the Cannula body or tip as damage may occur.

Warning: Avoid inadvertent lateral pressure to the cannula caused by pulling on the flexible extension of the device.

Warning: The Cannula must be supported at all times during and while inserted into the brain. Failure to do so could cause inadvertent movement of the Cannula. Inadvertent movement could cause harm to the patient and / or damage to the device.

Warning: Handle with care while removing from packaging and preparing for insertion.

Warning: Do not use if any of the parts of the device are damaged.

Warning: All tools, ancillary equipment and devices must be MR compatible when the Cannula is being used in a MR scanner. When labeling is unclear, assume the device is not compatible. Always follow the manufacturer's instructions.

Warning: There are no known and reliable means of cleaning, disinfecting, repairing, and sterilizing these devices that returns them to original specifications and renders them safe and effective for reuse.

Caution: The compatibility of instruments and devices with the Cannula should be evaluated before use.

Caution: The Cannula does not have graduated markings on the Cannula body and should be used with a stereotactic frame to gauge insertion depth.

Caution: The Cannula should be held from the point of insertion into a stereotactic frame until the device contacts the brain to prevent the device from advancing in an uncontrolled manner that could result in injury.

Caution: During set-up of the procedure, route the flexible line in such a manner that it will not be inadvertently moved or disturbed by personnel or equipment during the procedure.

Caution: Do not use the device with a power injector.

General Precautions

Handle all components using standard hospital sterile practices.

Do not bend or kink the Cannula.

Handle the distal portion (last 30 cm and tip) carefully to avoid breaking.

Minimize any forces applied directly to the Cannula.

IV. Use Instructions

A. Preparation

1. Select the appropriate Cannula. Cannula dimensions and flow rates can be found in Section D, Storage and Technical Specifications.
2. Remove the device from the package. The Cannula is packaged in a double sterile barrier; a tray with a sealed Tyvek lid is placed inside a sealed mylar/Tyvek pouch.

   Warning: Do not use the Cannula or any of the contents if the packaging is damaged.
3. The patient's head should be placed in an appropriate head fixation frame to immobilize the patient's head to prevent damage to the device due to unintended movement of the patient during preparation.
4. After creating the entry hole, a small incision shall be made in the dura to allow the Cannula to enter the brain. This will prevent possible damage to the distal tip due to excessive pressure or miss-alignment during entry.

   Warning: The cannula is not intended to pass through intact bone or dura. Damage to the device could occur if the device is passed through either material without creating an appropriate opening.
5. For injection, prime Cannula with Cytarabine solution.

B. Perform the Procedure

1. Carefully insert the Cannula into the brain. The Cannula shall be supported at all times once it has entered the brain.
2. Insert and lock a male locking luer into the proximal connector if not previously connected.
3. Perform injection or aspiration.

C. Procedure Completion

1. Remove the Cannula from the brain.
2. Appropriately dispose of the Cannula.

D. Storage and Technical Specifications

1. **Storage**

   - Store in a cool dry place.

2. **Technical Specifications**

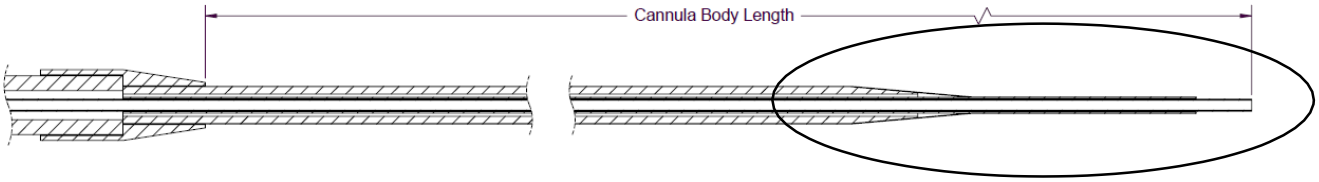
   - **Dimensions and Priming Volume**

     The lumen volume for each device was calculated with a male luer inserted into the female luer on the proximal end.

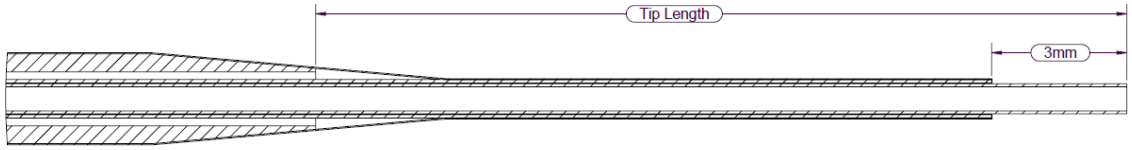
SmartFlow Neuro Cannula Dimensions and Priming Volume

Catalog Number	Outside Dia.			I.D.	I.D.	Length Overall	Priming Volume	Tip Length	Usable Cannula Body Length	Bore Length
	(ga)	(in.)	(mm)	(in.)	(µm)	(ft)	(cc)	(mm)	(cm)	(cm)
NGS-NC-01	16	.065	1.65	.008”	200	4 ft	0.04	18	26.8	30.0
NGS-NC-02	16					10 ft	0.10	18	26.8	30.0
NGS-NC-03	14	.083	2.11	.021”	536	4 ft	0.27	18	26.8	30.0
NGS-NC-04	14					10 ft	0.68	18	26.8	30.0
NGS-NC-05	16	.065	1.65	.008”	200	10 ft	0.10	15	26.5	29.7
NGS-NC-06	16						0.10	13	26.3	29.5
NGS-NC-07	14	.083	2.11	.021”	536	10 ft	0.68	13	26.3	29.5
NGS-NC-08	14						0.68	13	17.9	21.1

CANNULA BODY



TIP LENGTH



<u>Cannula lengths (referring to the rigid distal section)</u>

“**Usable Length”**: The length that can be passed into an introducer or other device.

“Bore Length”: The length used when providing bore collision dimensions required by certain neuro procedure planning software programs.

Note: The bore length is the value that would be entered into the ClearPoint software start-up screen (if necessary).

- **Aspiration Flow Rates**

Note: Due to various Cannula configuration / product codes, there is a range of aspiration flow rates. Select the device that is best suited for the procedure.

Product Code	Configuration	ml/min
NGS-NC-01	.008” ID x 4 ft, 18mm tip	0.2
NGS-NC-02	.008” ID x 10 ft, 18mm tip	0.1
NGS-NC-03	.021” ID x 4 ft, 18mm tip	8.7
NGS-NC-04	.021” ID x 10 ft, 18mm tip	3.2
NGS-NC-05	.008” ID x 10 ft, 15mm tip	0.1
NGS-NC-06	.008” ID x 10 ft, 13mm tip	0.1
NGS-NC-07	.021” ID x 10 ft, 13mm tip	3.2
NGS-NC-08	.021” ID x 10 ft, 13mm tip (short cannula body)	3.2

The above aspiration flow rates were a result of bench testing using normal primate CSF at body temperature (37°C) and a 5 cc BD disposable syringe.

- **Injection Flow Rates**

Note: Due to various Cannula configuration / product codes, there is a range of injection flow rates. Select the device that is best suited for the procedure.

Product Code	Configuration	ml/min
NGS-NC-01	.008” ID x 4 ft, 18mm tip	0.9
NGS-NC-02	.008” ID x 10 ft, 18mm tip	0.6
NGS-NC-03	.021” ID x 4 ft, 18mm tip	24.9
NGS-NC-04	.021” ID x 10 ft, 18mm tip	14.2
NGS-NC-05	.008” ID x 10 ft, 15mm tip	0.6
NGS-NC-06	.008” ID x 10 ft, 13mm tip	0.6
NGS-NC-07	.021” ID x 10 ft, 13mm tip	14.2
NGS-NC-08	.021” ID x 10 ft, 13mm tip (short cannula body)	14.2

The above injection flow rates were a result of bench testing at room temperature, using a 120 mg/ml solution of Cytarabine and a 5 cc BD disposable syringe.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	MR Safe		Sterilized through irradiation
	Consult instructions for use		Manufacturer
	Catalogue number		Prescription Device
	Batch code		Keep dry
	Use by date		Keep away from sunlight
	Non-pyrogenic		Single use
	Double sterile barrier system		Not made with natural rubber latex
	Do not use if the product sterilization barrier or its packaging is compromised		Do not resterilize

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