

CLEARPOINT®
NEURO

SmartFlow

Neuro Cannula

INSTRUCTIONS FOR USE

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I. Indications for Use

The SmartFlow Neuro Cannula, when used with compatible stereotaxic and therapeutic delivery devices, is indicated for intraputaminaal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

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-EE **16 ga SmartFlow Neuro Cannula, .008” ID x 4 ft, 18mm tip**

NGS-NC-02-EE **16 ga SmartFlow Neuro Cannula, .008” ID x 10 ft, 18mm tip**

The SmartFlow Neuro 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 SmartFlow Neuro 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. The SmartFlow Neuro Cannula and guide tube are labeled MR Safe.

III. Contraindications

Do not use in individuals with genetically confirmed AADC deficiency in whom the cranium is not sufficiently developed to allow stable placement of the stereotactic head frame for surgery.

IV. Warnings and Precautions

- Warning:** The device is intended for single patient use only and is provided sterile and non-pyrogenic. Do not re-sterilize.
- 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 used in or near a magnetic resonance (MR) scanner must be MR Safe or MR Conditional. When labeling is unclear, assume the device is MR Unsafe. 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 reusable. Therefore, do not reuse the device.
- Warning:** Do not use the device with a power injector.
- 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.

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.

V. Potential Risks

The following potential risks associated with use of the SmartFlow Neuro Cannula which have been mitigated by pre-clinical testing have been identified:

- Adverse tissue reaction
- Infection
- Improper Device Use/Use Error
- Incompatibility with other devices
- Inaccurate dosage of infusate
- Tissue injury
- Infusate delivered to incorrect target
- Magnetic Resonance Imaging (MRI) Incompatibility

VI. Use Instructions

A. Preparation

1. Select the appropriate cannula.
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.

Warning: The cranium should be sufficiently developed, with sutures closed, to enable surgical placement of the stereotactic frame system on the skull for MRI-guided stereotactic targeting.

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 misalignment 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 eladocagene exuparvovec-tneq suspension.

Note: See the eladocagene exuparvovec-tneq labeling for specific information and complete procedural instructions on intraputaminial administration.

B. Procedure Completion

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

C. Storage and Technical Specifications

1. Storage

- Store in a cool dry place.

2. Technical Specifications

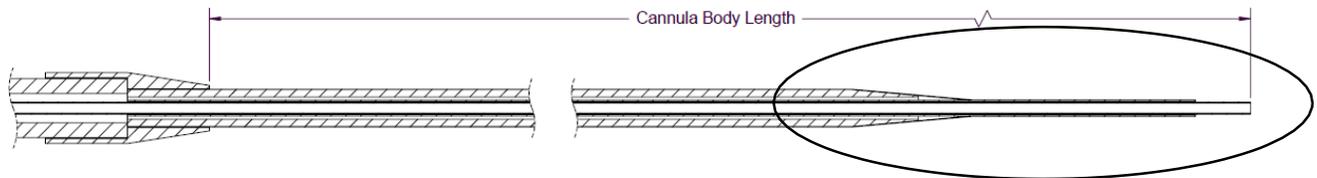
- **Dimensions and Priming Volume**

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

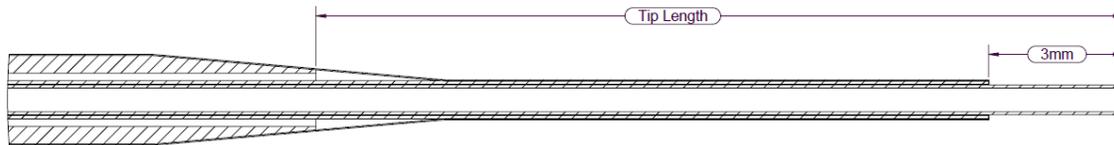
SmartFlow Neuro Cannula Dimensions and Priming Volume

Catalog Number	Outside Diameter			I.D.	I.D.	Length Overall	Priming Volume	Tip Length	Usable Cannula Body Length	Bore Length
	(ga)	(in.)	(mm)	(in.)	(μ m)	(ft)	(cc)	(mm)	(cm)	(cm)
NGS-NC-01-EE	16	.065	1.65	.008"	200	4 ft	0.04	18	26.8	30.0
NGS-NC-02-EE						10 ft	0.10			

CANNULA BODY



TIP LENGTH



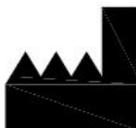
Cannula lengths (referring to the rigid distal section)

“**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).

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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