

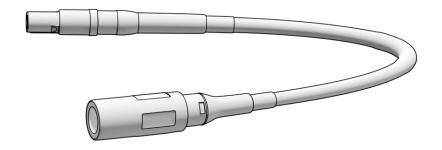
iCONNECT

CARTO SYSTEM CABLE

INSTRUCTIONS FOR USE

REF

001-009075-1



Note: Figure is not drawn to scale.

 $\mathbf{R}_{\scriptscriptstyle\mathsf{ONLY}}$

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

DSP-0303; Rev. C

Effective Date: 08 Jul 2021

SYMBOL LEGEND			
REF	Catalog Number	MD	Medical Device
LOT	Lot Number	C€	Marking for devices entering the European market
Ţi	Consult Operating Instructions	EC REP	Authorized Representative in the European Community
•••	Manufacturer		Do Not Use if Package is Damaged or Opened
~~ /	Date of Manufacture	类	Keep Away from Sunlight
NON STERILE	Device has not been sterilized		Temperature limitation
	Use by date	**	Keep Dry
	Packaging unit	< >	Usable Length
Ronly	Prescription Only		

ENGLISH

CAUTION: Read the instructions carefully before using the product.

DEVICE DESCRIPTION

The CARTO System Cable is a component of the iCONNECT $^{\text{TM}}$ System. The cable offers the ability to use the CARTO® 3 System in conjunction with the *iCONNECT* System.

ADDITIONAL REQUIRED COMPONENTS

- iCONNECT Electronics Hub
- CARTO® 3 System

INDICATIONS

The CARTO System Cable is designed to connect the CARTO 3 System to the appropriate equipment for use with the *iCONNECT* System.

CONTRAINDICATIONS

There CARTO System Cable has no known contraindications.

HOW SLIPPLIED

This cable is provided non-sterile. Inspect the packaging for damage prior to use. Examine the cable prior to use or reuse for any damage or defects (i.e. bent pins, kinks, nicks, crushed or elongated sections). Do not use if any damage or defects are identified.

HANDLING AND STORAGE

The product may only be used in a medical treatment facility that has been set up for the appropriate application and by trained staff. Store the product in its original packaging in a cool, dry place away from light at between 10° C and 25° C. When stored appropriately, the product can be used up to the use before date indicated on the packaging.

CLEANING

The product may be contaminated after use and should be cleaned with a cloth or swab dampened in pH neutral, EPA-approved hospital grade solutions.

DISPOSAL

The CARTO System Cable shall withstand 1000 uses. If damaged or exceeds number of uses, dispose of the product and its residual elements or waste items in accordance with your hospital, administrative and/or local government policy.

WARNINGS

- The CARTO System Cable should only be used by trained physicians.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- No modification of this device is allowed.
- Patient or operator injury can result from improper handling of the cable.
- Failure to abide by the above warnings might result in damage to the product, or result in serious adverse events.

CAUTIONS

- Do not immerse cable connector(s) in fluids.
- If the cable is used in the presence of electrical equipment, noise may be induced into the cable.
- Do not attempt to repair any damage. In case of doubt, discard the cable and do not use or reuse.

INSTRUCTIONS FOR USE

Refer to the *iCONNECT* User Guide for cable connection instructions and operation of the *iCONNECT* System.

TRADEMARKS

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STEREOTAXIS TECHNICAL SUPPORT

For technical support, please contact Stereotaxis TeleRobotic Support Team (TST) at 1-866-269-5268 or 1-314-678-6200 or email tst@stereotaxis.com.

NOTICE TO THE USER AND/OR PATIENT

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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