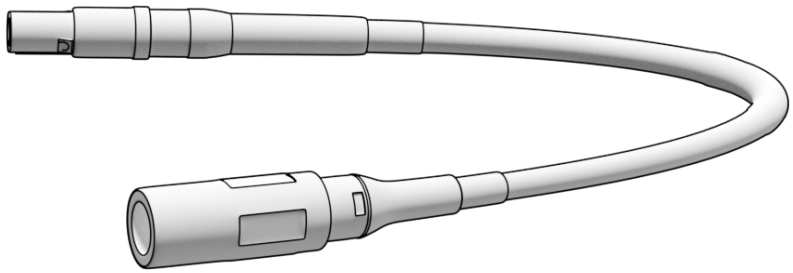
STEREOTAXIS™

iCONNECT

NAVISTAR ADAPTER CABLE

INSTRUCTIONS FOR USE

REF 001-009081-1

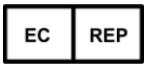


Note: Figure is not drawn to scale.

℞ ONLY

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

DSP-0304; Rev. C
Effective Date: 08 Jul 2021

SYMBOL LEGEND			
	Catalog Number		Medical Device
	Lot Number		Marking for devices entering the European market
	Consult Operating Instructions		Authorized Representative in the European Community
	Manufacturer		Do Not Use if Package is Damaged or Opened
	Date of Manufacture		Keep Away from Sunlight
	Device has not been sterilized		Temperature limitation
	Use by date		Keep Dry
	Packaging unit		Usable Length
	Prescription Only		

ENGLISH

CAUTION: Read the instructions carefully before using the product.

DEVICE DESCRIPTION
The Navistar Adapter System Cable is a component of the iCONNECT™ System. The adapter cable offers the ability to use the NAVISTAR® RMT Catheter or NAVISTAR® THERMOCOOL RMT Catheter in conjunction with the *iCONNECT* System.

ADDITIONAL REQUIRED COMPONENTS
- iCONNECT Electronics Hub
- Biosense Webster Interface Cable C5MHNAVMHS
- NAVISTAR® RMT Catheter *or*
- NAVISTAR® THERMOCOOL RMT CATHETER

INDICATIONS
The Navistar Adapter System Cable is designed to connect a NAVISTAR RMT Catheter or NAVISTAR THERMOCOOL RMT CATHETER to the appropriate equipment for use with the iCONNECT System.

CONTRAINDICATIONS
The Navistar Adapter System Cable has no known contraindications.

HOW SUPPLIED
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 10ºC and 25 ºC. 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 Navistar Adapter 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's regulations regarding disposal.

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.

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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
STEREOTAXIS MAKES NO WARRANTIES, EXPRESS OR IMPLIED, WITH REGARD TO THE DEVICE DESCRIBED IN THIS DOCUMENT. STEREOTAXIS DISCLAIMS ALL REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE, TITLE OR NON-INFRINGEMENT, ARISING BY STATUTE OR IN LAW, OR ARISING FROM A COURSE OF CONDUCT, COURSE OF DEALING OR USAGE OF TRADE.

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STEREOTAXIS IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM REUSE OF THIS DEVICE.

Made in USA

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EC REP

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