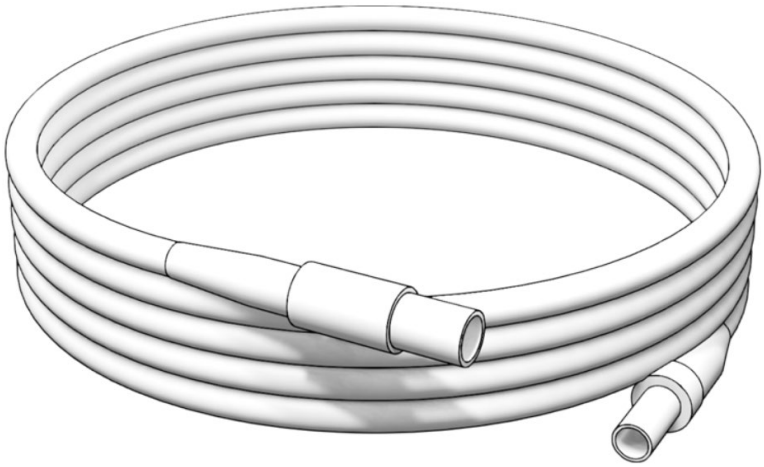
STEREOTAXIS™

iCONNECT

NAVISTAR CABLE

INSTRUCTIONS FOR USE

REF 001-009070-1

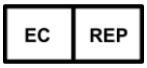


℞ ONLY

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

Made in USA

DSP-0329; Rev. A
Effective date: 16 July 2024

SYMBOL LEGEND			
	Authorized Representative in the European Community		Catalogue Number
	Caution		Consult Operating Instructions
	Date of Manufacture		Do not use if package is damaged and consult instruction for use
	Keep Away from Sunlight		Keep Dry
	Importer		Lot Number
	Manufacturer		Marking for devices entering the European market
	Medical Device		Non-Sterile
	Packaging Unit		Prescription Only
	Serial Number		Temperature Limit
	Usable Length		

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.

INTENDED PATIENT POPULATION
The intended patient population for the *iCONNECT* System Cable is patients undergoing diagnostic and interventional procedures in the following areas: right and left heart, and the coronary, peripheral, and neurovasculature.

INTENDED USERS
The *iCONNECT* System Cable should be used only by qualified medical professionals who have been thoroughly trained in its use.

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.

AUTOCLAVE
For steam sterilization cycles 1 through 9, place the cleaned devices in the autoclave on the bottom shelf. For 10th steam sterilization cycle: Single pouch each cable using an FDA approved pouch. Coil the cable into a loop then place it into the pouch. Do not fold the cable because doing so many break the cable. Use a pouch large enough to prevent stress to the pouch seams and to prevent excessive bending of the cable. A pouch size of 19 cm x 33 cm (7.5” x 13”) or larger is recommended. Place the pouched device in a sterilizer. Do not overlap pouched devices. Sterilize the devices using the following moist heat sterilization cycle parameters:

Cycle Type	Configuration	Exposure Temperature	Pulses	Exposure Time	Minimum Drying Time
Prevacuum	Single-pouch	132°C (270°F)	4	4 minutes	20 minutes

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
If damaged, dispose of the product and its residual elements or waste items in accordance with hospital regulations or local government policy.

WARNINGS
- The *Navistar* Adapter System Cable should only be used by trained physicians.
- Dispose of product packaging in accordance with hospital, administrative and/or local government policy.
- If product damage or defects are identified, dispose of the product 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

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
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.

Stereotaxis, Inc.
710 N. Tucker Blvd. Suite 110
St. Louis, MO 63101
www.stereotaxis.com
1-314-678-6100

EC REP
MDSS (Medical Device Safety Service GmbH)
Schiffgraben 41
30175 Hannover, Germany

MedEnvoy
Prinses Margrietplantsoen
33 – Suite 123,
2595 AM The Hague
Netherlands

UKRP
MDSS-UK RP LIMITED
6 Wilmslow Road, Rusholme
Manchester M14 5TP
United Kingdom
Tel.: 0044 (0)7898 375115

CE 2797