

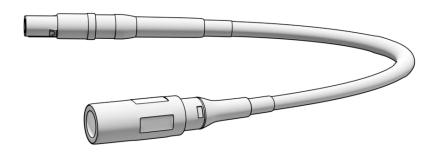
iCONNECT

NAVISTAR ADAPTER CABLE

INSTRUCTIONS FOR USE

REF

001-009081-1



DSP-0304 Rev. B Effective Date: 03/18/2021

Note: Figure is not drawn to scale.

SYMBOL LEGEND			
REF	Catalog Number	**	Keep Away from Sunlight
LOT	Lot Number	Ì	Usable Length
[]i	Consult Operating Instructions	NON STERILE	Device has not been sterilized
	Manufacturer	25°C	Temperature limitation
~~ <u></u>	Date of Manufacture	EC REP	Authorized Representative in the European Community
	To be used before	MD	Medical Device
	Do Not Use if Package is Damaged or Opened	Ronly	Medical prescription
†	Keep Dry	CE	Marking for devices entering the European market

ICONNECT SYSTEM

Navistar Adapter System Cable

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.

INSPECTION BEFORE USE

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

USE AND HANDLING

The product may only be used in a medical treatment facility that has been specifically set up for the appropriate application and by trained staff. The product may only be used if its safe application can be guaranteed. The doctor is responsible for selecting the medically appropriate procedure and method. Refer to the iCONNECT User Guide for cable handling, connection, and instructions for use.

STORAGE

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.

ADDITIONAL REQUIRED COMPONENTS

- iCONNECT Electronics Hub
- Biosense Webster Interface Cable C5MHNAVMHS
- NAVISTAR ® RMT Catheter or NAVISTAR ® THERMOCOOL ® RMT Catheter

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.

CONTRAINDICATIONS

There are no known contraindications to this cable.

CAUTIONS

Do not immerse cable connector(s) in fluids.

Patient or operator injury can result from improper handling of the cable. 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.

INDICATIONS

The cable is designed to connect an electrophysiology catheter to the appropriate equipment for use with the iCONNECT System.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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