

Medtronic

2ACHC

Catheter connecting cable

Technical Manual

! USA

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

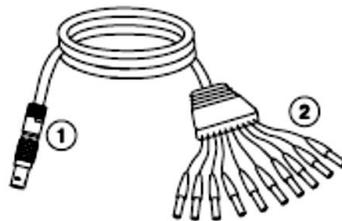
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1 konektorius, kurio distaliniai galai (jungiami prie registracinės sistemos) baigiasi 2 mm diametro kištukais

1 Description

The Medtronic catheter connecting cable, Model 2ACHC, provides conduction from the proximal end of the mapping catheter to standard shielded ECG 2mm pins that connect into standard EP recording and pacing equipment.

The cable is compatible with Achieve mapping catheters, Achieve Advance mapping catheters and standard EP recording systems. The cable is single use only, supplied sterile, and is not intended for reuse or resterilization.



- 1 Proximal connector (Lemo)
- 2 Shrouded leads (x10)

Figure 1. 2ACHC catheter connecting cable

- 1 Proximal connector (Lemo)
- 2 Shrouded leads (x10)

2 Contents of package

The cable is supplied sterile. The package contains the following items:

- 1 model 2ACHC catheter connecting cable
- Product documentation

3 Indications for use

For the indications for use, refer to the technical manual for the compatible Medtronic catheter.

4 Contraindications

For the contraindications, refer to the technical manual for the compatible Medtronic catheter.

5 Intended purpose

The intended purpose of the cable is to enable electrical connection of Achieve family mapping catheters.

6 Intended users

For the intended user, refer to the technical manual for the compatible Medtronic catheter.

7 Intended patient population

For the intended patient population, refer to the technical manual for the compatible Medtronic catheter.

8 Clinical benefit

For the clinical benefit, refer to the technical manual for the compatible Medtronic catheter.

9 Warnings and precautions

Cable integrity – Do not use the cable if it is kinked or damaged. If the cable becomes kinked or damaged while in use, remove it and use a new cable.

7 English

Do not resterilize – Do not resterilize the cable for purpose of reuse. Resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Expiration date – Check to verify the cable is within the expiration date. Do not use if the product date has expired.

For single use only – This cable is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize these devices for purpose of reuse. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device that could result in patient injury, illness, or death.

Serious incident – If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

Sterile package inspection – Visually inspect all sterile-barrier packaging before use. If the device is damaged or the integrity of the sterilization barrier has been compromised, do not use the product. Contact your Medtronic representative for return information.

Technical manual information – If you find information in this manual that is incorrect or illegible, contact your Medtronic representative or your local competent medical authority.

10 Instructions for use

1. Connect the shielded tip jacks from the cable to the ECG interface box.

Note: When connecting to the EP recording system, electrodes 9 and 10 will not be used for models within

the Achieve family that have 8 electrodes.

2. Connect the cable single connector to the mapping catheter electrical connector.

10.1 Cable specifications

Significant physical and performance characteristics are included in the table below.

Length 196 cm \pm 6 cm (77.0 in \pm 2.5 in)

Compatibility

Mapping catheter Medtronic circular mapping catheters with a maximum outer diameter of 1.1 mm (0.043 in)

Operating environmental parameters^a 10 ° C to 40 ° C (50 ° F to 104 ° F)

Sterilization single use, sterile device, irradiation

^a System-level operating temperature

11 Disposal

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See <http://recycling.Medtronic.com> for instructions on proper disposal of this product.

Caution: Discard all used catheters and sterile components in accordance with hospital procedures.

12 Medtronic disclaimer of warranty

For cable disclaimer of warranty, see the disclaimer of warranty packaged with the cable.

13 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and,

upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also

maintains a professional staff to provide technical consultation to product users. For more information, contact

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your local Medtronic representative, or call or write Medtronic at the appropriate telephone number or address

listed on the back cover.

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