

RF MARINR™ MC MULTI-CURVE STEERABLE ABLATION CATHETERS

Product Specifications

The RF Mariner MC and MCXL are sterile, single-use catheters designed to deliver RF energy to cardiac tissue during ablation procedures. Advanced features including curve size adjustment and out-of-plane lateral deflection create a highly versatile catheter.

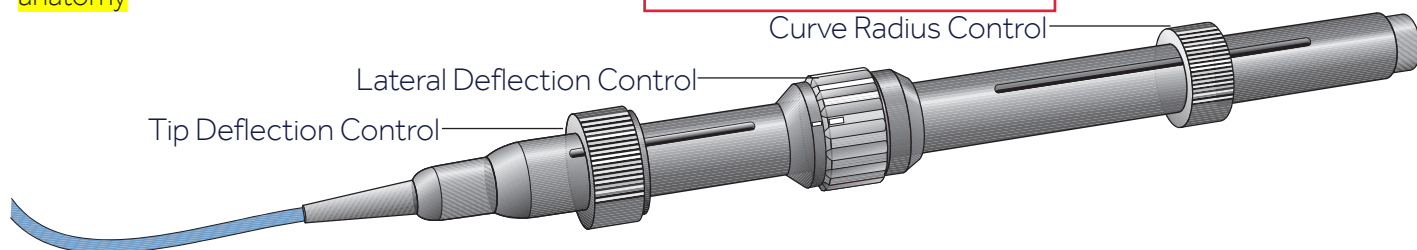
Multi-Curve Technology

- Provides variable curve sizes and reach in one catheter
- Curve adjusts from a small tight curve to a larger reach
- Reduces the need to stock multiple single curve catheters

Incremental Lateral Deflection

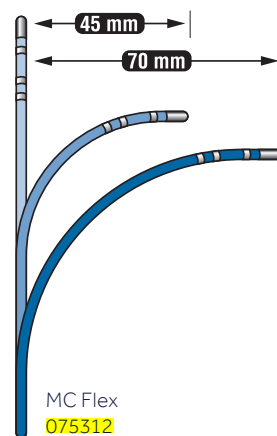
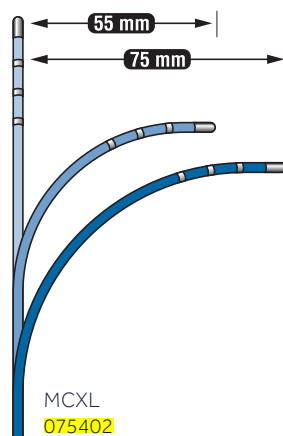
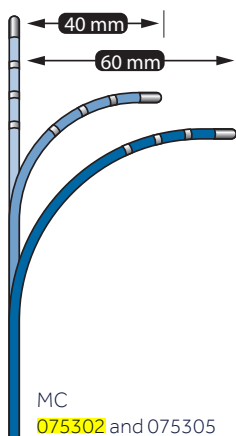
- May increase maneuverability within the heart
- Reduces the need to torque the whole catheter
- Side-to-side tip rotation may aid placement in varied anatomy

Gali padidinti manevringumą širdyje. Sumažina poreikį sukti visą kateterį, gerai perduoda sukamąjį judesį. Antgalio sukimas iš vienos pusės į kitą gali padėti įvairiose anatomijose. Galima valdyti elektrodą lankstant ir sukanant aplink savo ašį (valdymas rankenoje)



Each RF Mariner model is 7 Fr and features a 4 mm tip electrode with embedded thermocouple temperature sensor.

Kiekvienas Mariner modelis yra 7 Fr, 4 mm elektrodai su termoporos temperatūros jutikliu.



Model Number	Model	Curve Reach (mm)	Electrode Spacing (mm)	Length (cm)
075302	MC	40-60	2/5/2	110
075305	MC	40-60	5/5/5	110
075312	Flex	45-70	2/5/2	112
075402	MCXL	55-75	2/5/2	110

Ilgis 110 - 112 cm

Catheter Connecting Cables—366 cm (12 ft)

Model Number	Description
05116	Atakr II™ to RF catheter, sterile

Brief Statement

RF Catheters

Indications

The RF Mariner™ catheter is intended for use with a Medtronic RF power generator to deliver RF energy for intracardiac radiofrequency ablation of accessory atrioventricular (AV) conduction pathways associated with tachycardia for the treatment of AV nodal re-entrant tachycardia and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia.

Contraindications

The use of this device is contraindicated in patients with active systemic infection. The transseptal approach is contraindicated in patients with left atrial thrombus or myxoma, or interatrial baffle or patch. The retrograde transaortic approach is contraindicated in patients with aortic valve replacement.

Warnings/Precautions

General

Related product literature—Do not attempt to operate the Medtronic ablation system or connect the ablation catheter to a Medtronic RF power generator prior to completely reading and understanding the Medtronic ablation system technical manual and the ablation catheter instructions for use.

System compatibility—Use the catheter with only a Medtronic RF power generator and accessories. The safety and use with other RF power generators or accessories has not been tested. Use only Medtronic cables.

Expert users—The catheter should be used only by or under the supervision of physicians well trained in electrophysiology, including the placement and use of intracardiac electrode catheters, and experienced in performing RF catheter ablation procedures.

Necessary environment—Cardiac ablation procedures should be performed only in a fully equipped electrophysiology laboratory.

Ablation therapy hazards

Serious adverse events—A number of serious adverse events have been documented for catheter ablation procedures, including pulmonary embolism; myocardial infarction; cerebrovascular accident; cardiac damage, perforation, and tamponade; perforation of the vasculature; and death. See the "Adverse events" section for additional potential adverse events.

Left-sided ablation procedures—Patients undergoing left-sided ablation procedures should be closely monitored during the postablation period for clinical manifestations of infarction.

Distal pair electrode spacing of > 2 mm—Catheters with distal pair electrode spacing greater than 2 mm should not be used in the ablation of septal accessory pathways or in the treatment of AV nodal re-entrant tachycardia because of the potential for creating inadvertent complete AV block.

Catheter manipulation and placement—Provide adequate fluoroscopic visualization during catheter manipulation and placement. During a transaortic approach, avoid placement of the ablation catheter within the coronary vasculature. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Catheter placement and RF power application within a coronary artery have been associated with myocardial infarction and death.

X-ray and fluoroscopic exposure—Due to the x-ray beam intensity and the duration of the fluoroscopic imaging during ablation procedures, patients and laboratory staff may be subjected to acute radiation injury and increased risk for somatic and genetic effects. The long-term effects of protracted fluoroscopy have not been established. Minimize x-ray exposure. Carefully consider the use of the device in pregnant women and prepubescent children.

AV conduction—Closely monitor AV conduction during RF energy delivery in patients undergoing AV node modification or septal accessory pathway ablation. These patients may be at risk for complete atrioventricular (AV) block. Immediately terminate energy delivery if partial or complete AV block is noted.

Leakage current—Use only isolated amplifiers, pacing equipment, and ECG equipment (IEC 60601-1 Type CF equipment, or equivalent) or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 micro Amps (μA) under any circumstances.

Catheter removal—See your Medtronic ablation system technical manual for information concerning catheter removal following generator shutdown.

Long-term risk—The long-term risks of lesions created by RF ablation have not been established. In particular, any long-term effects of lesions in proximity to the specialized conduction system or coronary vasculature are unknown. Furthermore, the risk/benefit in asymptomatic patients has not been studied.

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