

Transurethral Needle Ablation (TUNA)

CRM Technical Services Standard Letter

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The guidance provided in this letter is for healthcare providers and Medtronic representatives and applies to the following Medtronic device models:

<u>Non-MRI Conditional Device Model Number, Model Name, Description</u>	<u>MRI Conditional Device Model Number, Model Name, Description</u>
C6TR01 VIVA™ CRT-P Digital pacemaker with cardiac resynchronization therapy (OAE-DDDR) P1501DR ENRHYTHM® Dual Chamber Rate Responsive Pacemaker with RapidRead™ Telemetry (OAE-DDDR) C2TR01 SYNCRA® CRT-P Digital pacemaker with cardiac resynchronization therapy (OOE-DDDR) C4TR01 CONSULTA® CRT-P Digital pacemaker with cardiac resynchronization therapy (OAE-DDDR)	RVDR01 REVO MRI® SURESCAN® Dual Chamber Pacemaker with SureScan® Technology (OAE-DDDR)

This Standard Letter addresses Transurethral needle ablation (Medtronic TUNA therapy):

Transurethral needle ablation is a surgical procedure used for benign prostatic hyperplasia (BPH) in which precisely focused, conducted radio frequency energy is used to ablate prostate tissue. Patients with implanted cardiac devices may conditionally undergo procedures that use the Medtronic TUNA system. To avoid affecting cardiac device function when performing the TUNA procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the implanted device and leads.

PATIENT MANAGEMENT GUIDANCE

This document is useful to health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems and who consult with the patients' cardiologists.

Labeling

VIVA™ CRT-P C6TR01 Clinician Manual. Manual Document Number: M956337A001 REV. C, www.medtronic.com/manuals

ENRHYTHM® P1501DR Reference Manual. Manual Document Number: M950679A001 REV. B, www.medtronic.com/manuals

SYNCRA® CRT-P C2TR01 Clinician Manual. Manual Document Number: M950693A001 REV. C, www.medtronic.com/manuals

CONSULTA® CRT-P C4TR01 Clinician Manual. Manual Document Number: M950678A001 REV. C, www.medtronic.com/manuals

REVO MRI® SURESCAN® RVDR01 Implant Manual. Manual Document Number: M954624A001 REV. A, www.medtronic.com/manuals

Additional comments

For further information please contact the following:

Technical questions: Medtronic Technical Services can answer additional questions regarding these device operations.

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Device labeling: For additional device-specific guidance, consult the labeling associated with the device available on the Medtronic Manual Library website at www.medtronic.com/manuals

How to contact U.S. CRM Technical Services: Email: tshelp@medtronic.com

Pacemakers: (800) 505-4636, ICDs: (800) 723-4636, Programmer Support: (800) 638-1991

This information is verified for devices approved in the U.S. and may differ by country. For product-specific information on device operation and indications for use, reference the appropriate product labeling.