Practice Advisory for the Perioperative Management of Patients with Cardiac Rhythm Management Devices: Pacemakers and Implantable Cardioverter-Defibrillators

(Approved by the ASA House of Delegates on October 27, 2004)

A Report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Rhythm Management Devices[*]

PRACTICE advisories are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys. Advisories are not intended as standards, guidelines, or absolute requirements. They may be adopted, modified, or rejected according to clinical needs and constraints.

The use of practice advisories cannot guarantee any specific outcome. Practice advisories summarize the state of the literature and report opinions derived from a synthesis of task force members, expert consultants, open forums and public commentary. Practice advisories are not supported by scientific literature to the same degree as standards or guidelines because of the lack of sufficient numbers of adequately controlled studies. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

Methodology

A. Definition of Cardiac Rhythm Management Devices

For this Advisory, a cardiac rhythm management device (CRMD) refers to any permanently implanted cardiac pacemaker or any implantable cardioverter-defibrillator (ICD). The term CRMD

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[*] Developed by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Rhythm Management Devices: James R. Zaidan, M.D., MBA (Chair), Atlanta, Georgia; John L. Atlee, M.D., Milwaukee, Wisconsin; Peter Belott, M.D., El Cajon, California; Kurt S. Briesacher, M.D., Atlanta, Georgia; Richard T. Connis, Ph.D., Woodinville, Washington; John D. Gallagher, M.D., Lebanon, New Hampshire; David Hayes, M.D., Rochester, Minnesota; Jane E. Hershey, M.D., Highland, Maryland; Neal Kay, M.D., Birmingham, Alabama; David G. Nickinovich, Ph.D., Bellevue, Washington; Marc A. Rozner, Ph.D., M.D., Houston, Texas; and Mark F. Trankina, M.D., Birmingham, Alabama.

Supported by the American Society of Anesthesiologists under the direction of James F. Arens, M.D., Chair, Committee on Practice Parameters. A list of the references used to develop this Advisory is available by writing to the American Society of Anesthesiologists.

Address reprint requests to the American Society of Anesthesiologists: 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573

also refers to any cardiac resynchronization device. The term CRT refers to a CRMD that provides cardiac resynchronization therapy using biventricular pacing techniques. Generic pacemaker and defibrillator codes are provided in appendix 1. Note that every ICD includes both pacing and shock therapies for the management of bradyarrhythmias and tachyarrhythmias.

B. Purposes of the Advisory

The purposes of this Advisory are to: (1) facilitate safe and effective perioperative management of the patient with a CRMD, and (2) reduce the incidence of adverse outcomes. Perioperative management refers to the preoperative, intraoperative, postoperative or recovery period in any setting where an anesthesia provider will be delivering anesthesia care. Adverse outcomes associated with a CRMD include (but are not limited to) damage to the device, inability of the device to deliver pacing or shocks, lead-tissue interface damage, changes in pacing behavior, electrical reset to the backup pacing mode, or inappropriate ICD therapies.[†] Adverse clinical outcomes include (but are not limited to) hypotension, tachyarrhythmia or bradyarrhythmia, myocardial tissue damage, and myocardial ischemia or infarction. Other related outcomes may include extended hospital stay, delay or cancellation of surgery, readmission to manage device malfunction, or additional hospital resource utilization and cost.

C. Focus

This Advisory focuses on the perioperative management of the patient who has a preexisting, permanently implanted CRMD for treatment of bradyarrhythmia, tachyarrhythmia or heart failure. Both inpatient and outpatient procedures are addressed by this Advisory. This Advisory does not address the perioperative management of any patient undergoing CRMD implantation or revision. It is not applicable to any patient: (1) without a permanently implanted pacemaker or ICD, (2) with a

[†] Inappropriate ICD therapy refers to the delivery of antitachycardia therapy (paced or shock) in the absence of a clinically indicated tachyarrhythmia. Inappropriate ICD therapy can harm a patient by inducing ischemia, worsening the arrhythmia, or causing the patient to move during a delicate procedure.

temporary CRMD, (3) with a noncardiac implantable device (e.g., neurological or spinal cord stimulator), or (4) with an implantable mechanical cardiac assist device (e.g., ventricular assist device). This Advisory does not address any procedure where there are no known perioperative CRMD concerns, such as diagnostic radiation (e.g., x-rays, fluoroscopy or mammograms), computed tomography scans, or ultrasound.

D. Application

This Advisory is intended for use by anesthesiologists and all other individuals who deliver or who are responsible for anesthesia care. The Advisory may also serve as a resource for other physicians and health care professionals who manage patients with CRMDs.

E. Task Force Members and Consultants

The American Society of Anesthesiologists (ASA) appointed a Task Force of 12 members to: (1) review and assess currently available scientific literature; and (2) obtain expert consensus and public opinion, and (3) develop a practice advisory. The Task Force members consisted of anesthesiologists and cardiologists in private and academic practices from various geographic areas of the United States, and two methodologists from the ASA Committee on Practice Parameters.

The Task Force used a six-step process. First, they reached consensus on the criteria for evidence of effective perioperative management of cardiac rhythm management devices. Second, original published articles from peer-reviewed journals relevant to these issues were evaluated. Third, consultants who had expertise or interest in CRMDs, and who practiced or worked in various settings (e.g., academic and private practice) were asked to: (1) participate in opinion surveys on the effectiveness of various perioperative management strategies, and (2) review and comment on a draft of the Advisory developed by the Task Force. Fourth, opinions about the Advisory statements were solicited from random samples of active members of both the ASA and the Heart Rhythm Society

(HRS).[‡] Fifth, the Task Force held an open forum at a national anesthesia meeting and at a major cardiology meeting to solicit input on the key concepts of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

The draft document was made available for review on the ASA website, and input was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

F. Availability and Strength of Evidence

Practice advisories are developed by a protocol similar to that of an ASA evidence-based practice guideline, including a systematic search and evaluation of the literature. However, practice advisories lack the support of a sufficient number of adequately controlled studies to permit aggregate analyses of data with rigorous statistical techniques such as meta-analysis. Nonetheless, literature-based evidence from case reports and other descriptive studies is reported. This literature often permits the identification of recurring patterns of clinical practice.

As with a practice guideline, formal survey information was collected from Consultants and members of the ASA. For this Advisory, surveys were also sent to members of the HRS. Additional information was obtained from open forum presentations and other invited and public sources. The advisory statements contained in this document represent a consensus of the current spectrum of clinical opinion and literature-based findings.

Advisories

I. Preoperative Evaluation

Perioperative management of CRMD patients is a common occurrence. It has been reported that more than 500,000 individuals in the United States have permanently implanted pacemakers or ICDs

[‡] Formerly North American Society of Pacing and Electrophysiology (NASPE)-Now called the Heart Rhythm Society (HRS)

with 115,000 new devices implanted each year.[1] Perioperative management of CRMD patients typically begins with a focused preoperative evaluation consisting of: (1) establishing whether a patient has a CRMD, (2) defining the type of device, (3) determining whether a patient is CRMD dependent for antibradycardia pacing function, and (4) determining device function.

Although no controlled trials of the clinical impact of performing a focused preoperative evaluation for CRMD patients were found, case reports suggest that incomplete preoperative examination of patients with CRMDs may lead to adverse outcomes (e.g., inhibited CRMD function, asystole).[2,3,4] The majority of Consultants and random samples from the ASA and HRS memberships agree that the above four preoperative evaluation activities should be conducted.[§]

Advisory. The consensus of the Task Force is that a focused preoperative evaluation should include establishing whether a patient has a CRMD, defining the type of device, determining whether a patient is CRMD dependent for pacemaking function, and determining CRMD function.

Determining whether a patient has a CRMD should be based on: (1) a focused history including but not limited to the patient interview, medical records review, review of available chest x-rays, electrocardiogram [ECG] or any available monitor or rhythm strip information and (2) a focused physical examination (checking for scars, palpating for device).

Defining the type of device is accomplished by: (1) obtaining the manufacturer's ID card from the patient or other source, (2) ordering chest x-rays if no other data are available,[**] or (3) referring to supplemental resources (e.g., manufacturer's databases, pacemaker clinic records, consultation with a cardiologist).

CRMD dependency for pacemaking function may be determined by one or more of the following: (1) a verbal history or an indication in the medical record that the patient has experienced a bradyarrhythmia that has caused syncope or other symptoms requiring CRMD implantation, (2) a

[§] Refer to table 1 for complete results of the Consultant and ASA membership surveys.
[**] Most current CRMDs have an x-ray code that can be used to identify the manufacturer of the device.

history of successful atrioventricular (A-V) nodal ablation that resulted in CRMD placement, or (3) a CRMD evaluation that shows no evidence of spontaneous ventricular activity when the pacemaking function of the CRMD is programmed to VVI pacing mode at the lowest programmable rate.

CRMD function is ideally assessed by a comprehensive evaluation of the device.[5] If a comprehensive evaluation is not possible, then *at a minimum,* confirm whether pacing impulses are present and create a paced beat. Consultation with a cardiologist or CRMD service may be necessary. Contacting the manufacturer for perioperative recommendations may be a consideration.

II. Preoperative Preparation

Preparation for patient safety and proper maintenance of the device during a procedure includes: (1) determining whether electromagnetic interference (EMI) is likely to occur during the planned procedure, (2) determining whether reprogramming the CRMD pacemaking function to an asynchronous pacing mode or disabling any special algorithms, including rate adaptive functions, is needed, (3) suspending anti-tachyarrhythmia functions if present, (4) advising the individual performing the procedure to consider use of a bipolar electrocautery system or ultrasonic (harmonic) scalpel to minimize potential adverse effects of EMI on the pulse generator or leads, (5) assuring the availability of temporary pacing and defibrillation equipment, and (6) evaluating the possible effects of anesthetic techniques on CRMD function and patient-CRMD interactions.

Numerous descriptive studies and case reports suggest that the following procedures are likely to be associated with EMI: (1) electrocautery,[6-11] (2) radio frequency ablation,[12-20] (3) magnetic resonance imaging (MRI),[21-32] and (4) radiation therapy.[33-35] No studies were found that reported EMI during electroconvulsive therapy (ECT). Some descriptive studies report the occurrence of EMI during lithotripsy,[36-37] while other descriptive studies and case reports indicate no apparent EMI effects.[38-40] No controlled trials of the clinical impact of programming the pacemaking function to an asynchronous mode for a procedure were found. Although some case reports suggest that such reprogramming is beneficial during electrocautery,[41-43] other reports indicate that EMI may continue to affect reprogrammed pacemakers.[44-45] The literature lacks sufficient guidance regarding the potential perioperative impact of anesthetic techniques on CRMD function. The majority of Consultants as well as the samples of ASA and HRS members agree that it should be determined whether EMI is likely to occur prior to a planned procedure. The majority of Consultants agree that a CRMD's rate-adaptive therapy should be turned off prior to a procedure, while the ASA and HRS members are equivocal. The majority of Consultants and HRS members disagree that all patients' CRMDs should be programmed to an asynchronous mode prior to surgery, while the ASA members are equivocal. In addition, the majority of Consultants and HRS members agree that pacemaker-dependent patients' CRMDs should be programmed to an asynchronous mode prior to surgery, while the ASA members are again equivocal. The majority of Consultants, ASA and HRS members agree that: (1) suspending anti-tachyarrhythmia functions if present, (2) advising the individual performing the procedure to consider use of a bipolar electrocautery system to minimize potential adverse effects of EMI on the pulse generator or leads, (3) assuring the availability of temporary pacing and defibrillation equipment, and (4) evaluating the possible effects of anesthetic techniques on CRMD function and patient-CRMD interactions are important steps in promoting patient safety and successfully managing patients with CRMDs. The Consultants and ASA members agree, and HRS members are equivocal regarding the consideration of using an ultrasonic scalpel.

Advisory. The Task Force agrees that planned procedures should include a determination as to whether EMI is likely to occur for either conventional pacemakers or ICDs.

If EMI is likely to occur, the conventional pacing function of a CRMD should be altered by changing to an asynchronous pacing mode[††] in pacemaker dependent patients and suspending special

[††] The VVT mode (with attention to the upper rate limit) might also be considered for a patient with ventricular ectopy where concern exists regarding R-on-T pacing during an asynchronous pacing mode. However, the upper pacing rate during VVT mode is manufacturer and possibly generator specific and can approach 200 beats per minute for many

algorithms, including rate-adaptive functions. These alterations may be accomplished by programming or applying a magnet when applicable.[‡‡] However, the Task Force cautions against the use of the magnet over an ICD.[§§] In addition, an ICD's anti-tachyarrhythmia functions should be suspended, if present. For the ICD patient who depends on pacing function for control of bradyarrhythmia, these functions should be altered by programming as noted above. Consultation with a cardiologist or pacemaker-ICD service may be necessary.

For all CRMDs, consider advising the individual performing the procedure to use a bipolar electrocautery system or an ultrasonic scalpel when applicable. Temporary pacing and defibrillation equipment should be immediately available before, during, and after a procedure.

Finally, the Task Force believes that anesthetic techniques do not influence CRMD function. However, anesthetic-induced physiologic changes (i.e., cardiac rate, rhythm or ischemia) in the patient may induce unexpected CRMD responses or adversely affect the CRMD-patient interaction.

III. Intraoperative Management

The primary activities associated with intraoperative management of a CRMD include: (1) monitoring the operation of the device, (2) preventing potential CRMD dysfunction, and (3) performing emergency defibrillation, cardioversion, or heart rate support.

1. Monitoring:

Intraoperative monitoring includes continuous ECG as well as monitoring of the peripheral pulse (e.g., palpation of the pulse, auscultation of heart sounds, monitoring of a tracing of intraarterial

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devices. Generally, VVT mode pacing would not be a consideration except in very rare circumstances. Before using the VVT mode, a cardiologist and the generator manufacturer should be consulted to determine the suitability of the upper pacing rate for any patient.

[‡‡] A magnet correctly applied to a pacemaker often results in asynchronous pacemaker function at a predetermined rate without rate responsiveness. The magnet rate and response varies by manufacturer. Magnet response can be affected by programming and remaining battery life. The magnet rate may be excessive for some patients. Some pacemakers may have no magnet response.

[§§] Magnet application to an ICD rarely alters bradycardia pacing rate and function. A magnet correctly applied to an ICD often results in suspension of tachyarrhythmia therapy. For most ICDs, there is no reliable means to detect appropriate magnet placement. Some ICDs may have no magnet response. Some ICDs can be permanently disabled by magnet application.

pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry).[46] Although no controlled trials were found that examine the clinical impact of ECG or peripheral pulse monitoring for CRMD patients, case reports note the importance of intraoperative ECG monitoring in the detection of pacemaker or cardiac dysfunction for these patients.[4,47-52] The majority of Consultants, ASA and HRS members agree that: (1) continuous ECG monitoring should be done for all CRMD patients, and (2) continuous peripheral pulse monitoring should be conducted.

Advisory. ECG and peripheral pulse monitoring are important components of perioperative management of the patient with a CRMD. The Task Force agrees that a patient's ECG should be continuously displayed, as required by ASA standards, from the beginning of anesthesia until the patient is transferred out of the anesthetizing location, with additional ECG monitoring in the postoperative period as indicated by the patient's medical condition.[46,53] The Task Force believes that these standards should apply to all CRMD patients receiving general or regional anesthesia, sedation or monitored anesthesia care. Continuous peripheral pulse monitoring should be performed for all CRMD patients receiving general or regional anesthesia, sedation or monitored anesthesia care. If unanticipated device interactions are found, consider discontinuation of the procedure until the source of interference can be eliminated or managed.

2. Managing Potential Sources of EMI:

Procedures using electrocautery, radio frequency ablation, lithotripsy, MRI, or radiation therapy may damage CRMDs or interfere with CRMD function, potentially resulting in severe adverse outcomes. Sources of EMI are often unique to specific procedures, and the management of each of these potential EMI sources is reported separately below.

A. Electrocautery. Management of potential sources of EMI associated with electrocautery includes: (1) assuring that the cautery tool and current return pad[***] are positioned so that the current pathway does not pass through or near the CRMD pulse generator and leads, (2) avoiding proximity of the cautery's electrical field to the pulse generator or leads, (3) using short, intermittent and irregular bursts at the lowest feasible energy levels, and (4) using a bipolar electrocautery system or an ultrasonic (harmonic) scalpel, if possible.

Two case reports[54-55] and one observational study[56] suggest that EMI may occur in spite of positioning the current return pad as far as possible away from the generator and leads. However, the majority of Consultants, ASA and HRS members agree that the current return pad should be positioned so that the electrosurgical current pathway does not pass through or near the CRMD pulse generator or leads.

One case report suggested that application of unipolar electrocautery on the sternum resulted in complete pacemaker inhibition.[57] Although some manufacturers suggest substituting bipolar for monopolar electrocautery to minimize CRMD interactions, no clinical literature was found to support this recommendation. The majority of Consultants, ASA and HRS members agree that direct contact between the electrocautery system and the CRMD pulse generator or its leads should be avoided.

Although no recent studies were found examining the benefit of using short intermittent bursts at the lowest feasible energy levels, earlier[†††] literature suggests that short intermittent bursts may be useful in completing procedures without notable EMI interference.[58-62] The majority of Consultants, ASA and HRS members agree that short intermittent bursts should be performed.

Finally, case reports suggest that surgery for pacemaker patients may proceed uneventfully when bipolar electrocautery systems[63-65] or harmonic scalpels[66-67] are used. The majority of Consultants, ASA and HRS members agree that bipolar electrocautery systems should be used when possible.

[***] Although commonly referred to as the "grounding pad," most operating room power supplies in the United States are ungrounded.
[†††] See appendix for an explanation of the term "earlier literature"

The majority of Consultants and ASA members agree that harmonic scalpels should be used when possible, and HRS members are equivocal.

B. Radio frequency (RF) Ablation. Management of potential sources of EMI associated with RF ablation primarily involves keeping the RF current path (electrode tip to current return pad) as far away from the pulse generator and lead system as possible. One observational study reports 3 of 12 cases that resulted in a significant drop in resistance on the pacemaker leads when RF ablation was used in proximity to the leads.[68] One case report suggests that positioning of the RF ablation cluster electrode no closer than 5 cm from the pacer leads allowed the procedure to continue uneventfully.[69] The majority of Consultants, ASA and HRS members agree that the individual performing the procedure should avoid direct contact between the ablation catheter and the CRMD and leads, and should keep the RF ablation current path as far away from the pulse generator and lead system as possible.

C. Lithotripsy. Management of potential sources of EMI associated with lithotripsy includes: (1) avoiding focus of the lithotripsy beam near the pulse generator and (2) disabling atrial pacing if the lithotripsy system triggers on the R-wave. The literature is silent regarding the benefits of focusing the lithotripsy beam away from the pulse generator as well as the benefits of disabling atrial pacing during lithotripsy. The majority of Consultants, ASA and HRS members agree that focusing the lithotripsy beam near the pulse generator should be avoided, and all three groups are equivocal regarding whether atrial pacing should be disabled prior to a procedure if the lithotripsy system triggers on the R-wave.

D. Magnetic Resonance Imaging. The literature is not sufficiently rigorous to examine the effects of specific management activities related to CRMD patients receiving MRI. Some descriptive studies and case reports suggest that MRI may be completed without notable EMI under specific circumstances and with appropriate patient qualification and monitoring.[30-32, 70-77] However, other literature generally suggests that MRI is contraindicated.[21-29] The majority of Consultants, ASA and HRS members generally agree that MRI is contraindicated for all CRMD patients.

E. Radiation Therapy. The literature does not provide sufficient guidance regarding specific management activities related to CRMD patients undergoing radiation therapy. However, none of the Consultants or HRS members, and only 10% of the ASA members agree that radiation therapy is contraindicated for all CRMD patients. Fifty-seven percent of the Consultants, 59% of the HRS members, and 37% of the ASA members agree that radiation therapy is contraindicated for some, but not all CRMD patients; while 43% of the Consultants, 41% of the HRS members, and 53% of the ASA members agree that radiation therapy is not contraindicated for any CRMD patient.

F. Electroconvulsive Therapy. No clinical studies were found that report EMI effects or permanent CRMD malfunction associated with electroconvulsive therapy (ECT). One article reports two cases where patients' ICDs were turned off prior to ECT, but does not report the effect of the therapy on ICD function.[78] However, the author indicates that treatment with ECT might be associated with significant cardiac risks. Transient electrocardiographic changes (e.g., increased P-wave amplitude, altered QRS shape, T-wave and ST-T abnormalities) may result from ECT, and additional cardiac complications (e.g., arrhythmia or ischemia) may occur in patients with preexisting cardiac disease. Finally, physiologic stresses following ECT, such as a period of bradycardia and reduced blood pressure, followed by tachycardia and a rise in blood pressure, may account for cardiac failure in the extended postoperative period (i.e., several hours or days following ECT) among patients with marginal cardiac function.

Advisory. The Task Force believes that EMI could be minimized during certain procedures using a variety of intraoperative management techniques.

The Task Force agrees that the risk of intraoperative interference from electrocautery systems may be minimized by (1) positioning the cautery tool and current return pad so that the current pathway does not pass through or near the CRMD system,[‡‡‡] (2) avoiding proximity of the cautery's electrical field to the pulse generator and leads, including avoidance of waving the activated electrode over the generator,[§§§] (3) using short, intermittent and irregular bursts at the lowest feasible energy levels, and 4) using bipolar electrocautery systems or ultrasonic (harmonic) scalpels if possible. Advising or reminding the individual performing the procedure to implement these management techniques should be considered.

Risk of interference from RF ablation may be reduced by avoiding direct contact between the ablation catheter and the pulse generator and leads, and keeping the RF's current path (electrode tip to current return pad) as far away from the pulse generator and leads as possible. During all RF ablative procedures, consider discussing with the individual performing the procedure any concerns regarding the proximity of the ablation catheter to the CRMD leads.

During lithotripsy, the lithotripsy beam should not be focused near the pulse generator. If the lithotripsy system triggers on the R-wave, atrial pacing might need to be disabled prior to the procedure.

The Task Force believes that MRI is generally contraindicated for CRMD patients. If MRI must be performed, consult with the ordering physician, the patient's pacemaker specialist or cardiologist, the diagnostic radiologist, and the CRMD manufacturer.

The Task Force believes that radiation therapy can be safely performed for CRMD patients.[****] The device must be outside the field of radiation. Therefore, some pulse generators will require surgical relocation prior to commencing radiation. Most manufacturers recommend verification of pulse generator function during and at the completion of radiation. Problems may include

[‡‡‡] For some cases, the electrosurgical receiving plate will need to be placed on a site different from the thigh. For example, in head and neck cases, the receiving plate can be placed on the posterior superior aspect of the shoulder contralateral to the generator position.

[§§§] An inhibitory effect could occur even when the active electrode of the electrocautery is not touching the patient.

[****] Radiation shielding may not be feasible for some patients due to the size and weight of the shield. This may be compensated for by relocating the generator.

pacemaker failure and runaway pacemaker.[††††]

Although transient or long-term myocardial and nervous system effects may be associated with ECT, the Task Force believes that such therapies may be administered to CRMD patients without significant damage to a disabled CRMD. If ECT must be performed, consult with the ordering physician and the patient's cardiologist to plan for the first and subsequent ECT's. All CRMDs should undergo a comprehensive interrogation prior to the procedure(s). ICD functions should be disabled for shock therapy during ECT; however, be prepared to treat ventricular arrhythmias that occur secondary to the hemodynamic effects of ECT. CRMD-dependent patients may require a temporary pacing system to preserve cardiac rate and rhythm during shock therapy. Also, the CRMD may require programming to asynchronous activity to avoid myopotential inhibition of the device in pacemaker dependent patients.

3. Emergency Defibrillation or Cardioversion.

During the perioperative period, emergency defibrillation or cardioversion may become necessary for the CRMD patient. In this case, the primary concern is to minimize the current flowing through the pulse generator and lead system. Recent and earlier case reports suggest that optimal positioning of the defibrillation or cardioversion pads or paddles may be an important factor in the prevention of adverse CRMD-related outcomes.[79-83] The majority of Consultants, ASA and HRS members agree that positioning the defibrillation or cardioversion pads as far as possible from the pulse generator should be done. The majority of Consultants, ASA and HRS members also agree that the anterior-posterior position should be used, and that a clinically appropriate energy output should be used regardless of the type of CRMD.

[††††] Runaway pacemaker is a potentially catastrophic pulse generator malfunction characterized by the sudden onset of rapid, erratic pacing. Runaway pacemaker is the result of multiple internal component failure and it is relatively uncommon in modern devices. Circuitry in modern pacemakers (and ICDs) limits the runaway pacing rate to less than 210 beats per minute.

Advisory. The Task Force believes that before attempting emergency defibrillation or cardioversion of the patient with an ICD and magnet-disabled therapies, all sources of EMI should be terminated and the magnet should be removed to re-enable antitachycardia therapies. The patient should then be observed for appropriate CRMD therapy. For the patient with an ICD and antiarrhythmic therapies that have been disabled by programming, consider re-enabling therapies through programming. If the above activities fail to restore ICD function, proceed with emergency external defibrillation or cardioversion.

Overriding the above discussion is the need to follow existing ACLS and emergency guidelines[84] to provide rapid cardioversion or defibrillation, and attention should be turned to providing this therapy as quickly as possible.

If a life-threatening arrhythmia occurs, follow ACLS guidelines for energy level and for paddle placement. If possible, attempt to minimize the current flowing through the pulse generator and lead system by (1) positioning the defibrillation or cardioversion pads or paddles as far as possible from the pulse generator, and (2) positioning defibrillation or cardioversion pads or paddles perpendicular to the major axis of the CRMD pulse generator and leads to the extent possible by placing them in an anterior-posterior location. A clinically appropriate energy output should always be used regardless of the presence of a CRMD, and the paddles should be positioned as best as can be done in an emergency.

IV. Postoperative Management

Postoperative management of CRMD patients primarily consists of interrogating and restoring CRMD function. Although no recent studies were found examining outcomes associated with interrogating or restoring CRMD function, an earlier case report indicates that a postoperative evaluation resulted in the discovery and correction of a pacemaker problem.[85] The majority of

Consultants, ASA and HRS members agree that postoperative patient management should include interrogating and restoring CRMD function in the postanesthesia care unit (PACU) or intensive care unit (ICU).

Advisory. The Task Force believes that cardiac rate and rhythm should be continuously monitored throughout the immediate postoperative period. Back-up pacing capability and cardioversion-defibrillation equipment should be immediately available at all times.

Postoperative interrogation and restoration of CRMD function are basic elements of postoperative management. The CRMD first should be interrogated to assess postoperative device functions. If interrogation determines that CRMD settings are inappropriate, then the device should be reprogrammed to appropriate settings. For an ICD, all anti-tachyarrhythmic therapies should be restored. Consultation with a cardiologist or pacemaker-ICD service may be necessary.

Appendix 1. Generic Pacemaker and Defibrillator Codes[‡‡‡‡]

The generic pacemaker and defibrillator codes were developed as joint projects by the North American Society of Pacing and Electrophysiology (NASPE)[§§§§] and the British Pacing and Electrophysiology Group (BPEG).[86,87] The five positions refer to the order of the programmed settings on the CRMD.

Generic Pacemaker Code (NBG[*****]): NASPE / BPEG Revised (2002)

Position I	Position II	Position III	Position IV	Position V
Pacing Chamber(s)	Sensing Chamber(s)	Response(s) to Sensing	Programmability	Multisite Pacing
O = None	**O** = None	**O** = None	**O** = None	**O** = None
A = Atrium	**A** = Atrium	**I** = Inhibited	**R** = Rate Modulation	**A** = Atrium
V = Ventricle	**V** = Ventricle	**T** = Triggered		**V** = Ventricle
D = Dual (A+V)	**D** = Dual (A+V)	**D** = Dual (T+I)		**D** = Dual (A+V))

Examples:

AAI = Atrial-only antibradycardia pacing. In the AAI mode, any failure of the atrium to produce an intrinsic event within the appropriate time window (determined by the Lower Rate Limit) will result in an atrial pacing pulse emission. There is no ventricular sensing; thus a premature ventricular event will not likely reset the pacing timer.

AOO = Asynchronous atrial-only pacing. In this mode, the pacing device emits a pacing pulse regardless of the underlying cardiac rhythm.

DDD = Dual chamber antibradycardia pacing function in which every atrial event, within programmed limits, will be followed by a ventricular event. The DDD mode implies dual

‡‡‡‡ The Generic Pacemaker Code (NBG), developed by the North Amercian Society for Pacing and Electrophysiology (now called the Heart Rhythm Society) and the British Pacing and Electrophysiology Group.[86]
§§§§ Now called the Heart Rhythm Society (HRS)
***** NBG refers to NASPE (the "N"), B refers to BPEG (the "B"), and G refers to "generic."

chamber pacing with atrial tracking. In the absence of intrinsic activity in the atrium, it will be paced, and, after any sensed or paced atrial event, an intrinsic ventricular event must appear before the expiration of the A-V timer or the ventricle will be paced.

DDI = Dual chamber behavior in which the atrial activity is tracked into the ventricle only when the atrial event is created by the antibradycardia pacing function of the generator. In the DDI mode, the ventricle is paced only when no intrinsic ventricular activity is present.

DOO = Asynchronous A-V sequential pacing without regard to underlying cardiac rhythm.

VOO = Asynchronous ventricular-only pacing without regard to the underlying cardiac rhythm.

VVI = Ventricular-only antibradycardia pacing. In VVI mode, any failure of the ventricle to produce an intrinsic event within the appropriate time window (determined by the Lower Rate Limit) will result in a ventricular pacing pulse emission. There is no atrial sensing; thus there can be no A-V synchrony in a patient with a VVI pacemaker and any intrinsic atrial activity.

Generic Defibrillator Code (NBD): NASPE / BPEG

Position I	Position II	Position III	Position IV *
Shock Chambers(s)	Antitachycardia Pacing Chamber(s)	Tachycardia Detection	Antibradycardia Pacing Chamber(s)
O = None	**O** = None	**E** = Electrogram	**O** = None
A = Atrium	**A** = Atrium	**H** = Hemodynamic	**A** = Atrium
V = Ventricle	**V** = Ventricle		**V** = Ventricle
D = Dual (A+V)	**D** = Dual (A+V)		**D** = Dual (A+V)

For robust identification, Position IV is expanded into its complete NBG code. For example, a biventricular pacing-defibrillator with ventricular shock and antitachycardia pacing functionality would be identified as VVE-DDDRV, assuming that the pacing section was programmed DDDRV. Currently, no hemodynamic sensors have been approved for tachycardia detection (Position III).

Appendix 2. Literature Review and Consensus-Based Evidence

A. State of the Literature.

For this Advisory, a literature review was used in combination opinions obtained from experts and other sources (e.g., professional society members, open forums, web-based postings) to provide guidance to practitioners regarding the perioperative management of patients with CRMDs. Both the literature review and opinion data were based on *evidence linkages*, consisting of directional statements about relationships between specific perioperative management activities and CRMD function or clinical outcomes.

A study or report that appears in the published literature is included in the development of an advisory if the study: (1) is related to one of the specified linkage statements, (2) reports a finding or set of findings that can be tallied or measured (e.g., articles that contain only opinion are not included), and (3) is the product of an original investigation or report (i.e., review articles or follow-up studies that summarize previous findings are not included). Since CRMDs represent a rapidly changing technology, earlier literature (i.e., literature published before 1990) was rarely included in the evaluation of evidence for this Practice Advisory.

Although evidence linkages are designed to assess causality, few of the reviewed studies exhibited sufficiently acceptable quantitative methods and analyses to provide a clear indication of causality. Therefore, the published literature could not be used as a source of quantitative support (required for the development of practice guidelines). However, many published studies were evaluated that provided the Task Force with important non-causal evidence. For example, descriptive literature (i.e., reports of frequency or incidence) is often useful in providing an indication of the scope of a problem. Information regarding whether a particular adverse outcome is common or rare may have considerable bearing on the practicality of an advisory. Case reports are typically employed as a forum for reporting and recognizing unusual or adverse outcomes, and may suggest caution when devising an advisory.

For the literature review, potentially relevant studies were identified via electronic and manual searches of the literature. The electronic search covered a 39-year period from 1966 through 2004. The manual search covered a 44-year period of time from 1961 through 2004. Over 1500 citations were initially identified, yielding a total of 411 non-overlapping articles that addressed topics related to the evidence linkages. Following review of the articles, 283 studies did not provide direct evidence, and were subsequently eliminated. A total of 128 articles (from 39 journals) contained direct linkage-related evidence. No evidence linkage contained enough studies with well-defined experimental designs and statistical information to conduct a quantitative analysis (i.e., meta-analysis).

Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, $\kappa = 0.72$ to 0.90; (2) type of analysis, $\kappa = 0.80$ to 0.90; (3) evidence linkage assignment, $\kappa = 0.84$ to 1.00; and (4) literature inclusion for database, $\kappa = 0.70$ to 1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.81, Var (Sav) = 0.010; (2) type of analysis, Sav = 0.86, Var (Sav) = 0.009; (3) linkage assignment, Sav = 0.82 Var (Sav) = 0.005; (4) literature database inclusion, Sav = 0.78 Var (Sav) = 0.031. These values represent moderate-to-high levels of agreement.

Future studies should focus on prospective methodologies, when possible, that utilize traditional hypothesis testing techniques. Use of the following methodological procedures for assessing the impact of perioperative management of CRMDs is recommended: (1) comparison studies [i.e., one technique versus another] when clinically feasible, (2) randomization, and (3) full reporting of sample size, effect size estimates, test scores, measures of variability, and p-values.

B. Consensus-Based Evidence.

Consensus was obtained from multiple sources, including: (1) survey opinion from Consultants who were selected based on their knowledge or expertise in perioperative management of CRMDs, (2) survey opinions from randomly selected samples of active members of the American Society of Anesthesiologists and active members of the Heart Rhythm Society, (3) testimony from attendees of two publicly-held open forums at a national anesthesia meeting and at a major cardiology meeting,[†††††] (4) internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 56% (N = 23/41) for Consultants, and 15% (N=89/600) for the ASA membership, and 15% (N=44/300) for the HRS membership (table 1).

The ASA Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the Advisory was instituted. The rate of return was 37% (N = 15/41). The percent of responding Consultants expecting *no change* associated with each linkage were as follows: preoperative evaluation - 71%; preoperative patient preparation- 71; intraoperative Monitoring of CRMDs - 64%; emergency defibrillation or cardioversion - 86%; postoperative monitoring of CRMDs - 79%; postoperative interrogation and restoration of CRMD function - 64%; intraoperative management of EMI during: electrocautery - 79%; radio-frequency ablation - 79%, lithotripsy - 79%, MRI - 79%, radiation therapy - 86%, and electroconvulsive therapy - 79%. Forty-three percent of the respondents indicated that the Advisory would have *no effect* on the amount of time spent on a typical case. Eight respondents (57%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of this Advisory. The amount of increased time anticipated by these respondents ranged from 5-30 minutes.

[†††††] International Anesthesia Research Society; 78th Clinical and Scientific Congress, March 28, 2004 in Tampa, FL, and NASPE Heart Rhythm Society Annual Meeting, May 20, 2004 in San Francisco, CA.

Table 1. Consultant and Membership Survey Responses: Percent Agreement[‡‡‡‡‡]

Survey Item:	Consultants N	Consultants Percent	ASA[§§§§§] Members N	ASA[§§§§§] Members Percent	HRS[******] Members N	HRS[******] Members Percent
1. To perform a preoperative evaluation:						
Establish whether a patient has a CRMD	23	100%	89	100%	44	100%
Define the type of device	23	100%	87	95%	44	100%
Determine whether a patient is CRMD dependent for pacemaking function	23	96%	89	96%	44	96%
Determine CRMD function	23	96%	89	88%	44	71%
2. To prepare a CRMD patient for a procedure:						
Determine if EMI is likely to occur	23	96%	89	91%	44	96%
Turn pacemaking rate-adaptive therapy off	23	52%	89	35%	44	34%
Program pacemaking function to asynchronous mode:						
- All CRMD patients	22	0%	88	21%	43	9%
- Pacemaker dependent patients only	22	73%	83	47%	43	54%
Suspend anti-tachyarrhythmia functions	21	86%	87	54%	43	63%
Consider using a bipolar electrocautery system (when applicable)	22	91%	86	90%	44	77%
Consider using an ultrasonic (harmonic) scalpel (when applicable)	22	68%	88	63%	44	34%
Assure the availability of temporary pacing and defibrillation equipment	22	100%	87	95%	44	89%
Consider the possible effects of anesthetic agents or techniques on CRMD function	22	64%	86	77%	44	66%
3. Intraoperative monitoring should include:						
Continuous ECG	23	100%	88	100%	44	100%
Continuous peripheral pulse	23	96%	88	86%	44	61%
4. For procedures using Electrocautery:						
Position the electrosurgical receiving plate so current pathway does not pass through or near the generator or leads	23	100%	88	97%	44	96%
Avoid proximity of the cautery's electrical field to the pulse generator or leads	23	100%	87	100%	44	96%
Use short, intermittent and irregular bursts						

[‡‡‡‡‡] The percentage of respondents who agreed with each item is presented. The percentages who disagreed or were uncertain are not presented.
[§§§§§] American Society of Anesthesiologists
[******] Heart Rhythm Society

at the lowest feasible energy levels	23	96%	87	83%	44	91%
Use a bipolar electrocautery system (when applicable)	23	91%	88	94%	44	84%
Use an ultrasonic (harmonic) scalpel (when applicable)	23	57%	88	65%	44	41%
5. For Radio frequency Ablation:						
Avoid direct contact between the ablation catheter and the CRMD and leads	23	83%	87	76%	44	91%
Keep the current path (electrode tip to return plate) as far away from the pulse generator and lead system as possible	23	87%	87	78%	44	89%
6. For Lithotripsy:						
Avoid focusing the lithotripsy beam near the pulse generator	23	91%	86	78%	44	86%
If the lithotripsy system triggers on the R-wave, disable atrial pacing prior to procedure	23	39%	86	38%	44	39%
7. For Magnetic Resonance Imaging (MRI):						
MRI contraindicated for all CRMD patients	21	81%	79	80%	44	55%
MRI contraindicated for some, but not all CRMD patients	21	19%	79	18%	44	39%
MRI not contraindicated for any CRMD patient	21	0%	79	2%	44	6%
8. For Radiation Therapy (RT)):						
RT contraindicated for all CRMD patients	21	0%	73	10%	44	0%
RT contraindicated for some, but not all CRMD patients	21	57%	73	37%	44	59%
RT not contraindicated for any CRMD patient	21	43%	73	53%	44	41%
9. For Emergency Defibrillation or Cardioversion:						
Position the defibrillation or cardioversion pads as far as possible from the pulse generator	23	83%	87	69%	44	91%
Use an anterior-posterior position	23	74%	84	61%	44	68%
Use a clinically appropriate energy output regardless of the device	23	100%	87	87%	44	100%
10. To manage CRMD patients postoperatively:						
Interrogate and restore CRMD function in the PACU or ICU	23	96%	88	98%	44	77%

Table 2. Summary of Practice Advisory

Preoperative Evaluation

- Establish whether a patient has a cardiac rhythm management device (CRMD).
  - Conduct a focused history (patient interview, medical records review, review of available chest x-rays, electrocardiogram [ECG] or any available monitor or rhythm strip information).
  - Conduct a focused physical examination (check for scars, palpate for device).
- Define the Type of CRMD.
  - Obtain manufacturer's ID card from patient or other source.
  - Order chest x-ray if no other data are available.
  - Refer to supplemental resources (e.g., manufacturer's databases).
- Determine Dependency on Pacing Function of the CRMD.
  - History of symptomatic bradyarrhythmia resulting in CRMD implantation.
  - History of successful A-V nodal ablation.
  - Inadequate escape rhythm at lowest programmable pacing rate.
- Determine CRMD Function.
  - Interrogate device (consultation with a cardiologist or pacemaker-ICD service may be necessary).
  - Determine whether the device will capture when it paces (i.e., produce a mechanical systole with a pacemaker impulse).
  - Consider contacting the manufacturer for perioperative recommendations.

Preoperative Preparation

- Determine if EMI is likely to occur during the planned procedure.
- Determine whether reprogramming pacing function to asynchronous mode or disabling rate responsive function is advantageous.
- Suspend anti-tachyarrhythmia functions if present.
- Advise individual performing the procedure to consider use of a bipolar electrocautery system or ultrasonic (harmonic) scalpel.
- Temporary pacing and defibrillation equipment should be immediately available.
- Evaluate the possible effects of anesthetic techniques and of the procedure on CRMD function and patient CRMD interactions.

Intraoperative Management

- Monitor operation of the CRMD.
  - Conduct ECG monitoring per ASA standard.
  - Monitor peripheral pulse (e.g., manual pulse palpation, pulse oximeter plethysmogram, arterial line).
- Manage potential CRMD dysfunction due to EMI.
  - Electrocautery.
    - Assure that the electrosurgical receiving plate is positioned so that the current pathway does not pass through or near the CRMD system. For some cases, the receiving plate might need to be placed on a site different from the thigh (e.g., the superior posterior aspect of the shoulder contralateral to the generator position for a head and neck case).

            - Advise individual performing the procedure to avoid proximity of the cautery's electrical field to the pulse generator or leads.
            - Advise individual performing the procedure to use short, intermittent and irregular bursts at the lowest feasible energy levels.
            - Advise individual performing the procedure to reconsider the use of a bipolar electrocautery system or ultrasonic (harmonic) scalpel in place of a monopolar electrocautery system, if possible.
        - Radio-frequency (RF) ablation.
            - Advise individual performing the procedure to avoid direct contact between the ablation catheter and the pulse generator and leads.
            - Advise individual performing the procedure to keep the RF's current path as far away from the pulse generator and lead system as possible.
        - Lithotripsy.
            - Advise individual performing the procedure to avoid focusing the lithotripsy beam near the pulse generator.
            - If the lithotripsy system triggers on the R-wave, consider preoperative disabling of atrial pacing.
        - Magnetic Resonance Imaging.
            - MRI is generally contraindicated in patients with CRMDs.
            - If MRI must be performed, consult with the ordering physician, the patient's cardiologist, the diagnostic radiologist, and the CRMD manufacturer.
        - Radiation Therapy.
            - Radiation therapy can be safely performed in patients who have CRMDs.
            - Surgically relocate the CRMD if the device will be in the field of radiation.
        - Electroconvulsive Therapy.
            - Consult with the ordering physician, the patient's cardiologist, a CRMD service, or the CRMD manufacturer
- Emergency defibrillation or cardioversion.
    - For the patient with an ICD and magnet-disabled therapies:
        - Advise individual performing the procedure to terminate all sources of EMI while magnet is removed.
        - Remove the magnet to re-enable antitachycardia therapies.
        - Observe the patient and the monitors for appropriate CRMD therapy.
        - If the above activities fail to restore ICD function, proceed with emergency external defibrillation or cardioversion.
    - For the patient with an ICD and programming-disabled therapies:
        - Advise individual performing the procedure to terminate all sources of EMI while magnet is removed.
        - Re-enable therapies through programming if the programmer is immediately available and ready to be used
        - Observe the patient and the monitors for appropriate CRMD therapy
        - If the above activities fail to restore ICD function, proceed with emergency external defibrillation or cardioversion
    - For external defibrillation:
        - Position defibrillation/cardioversion pads or paddles as far as possible from the pulse generator
        - Position defibrillation/cardioversion pads or paddles perpendicular to the major axis of the CRMD to the extent possible by placing them in an anterior-posterior location

    - If it is technically impossible to place the pads or paddles in locations that help to protect the CRMD, then defibrillate/cardiovert the patient in the quickest possible way and be prepared to provide pacing through other routes.
    - Use a clinically appropriate energy output

Postoperative Management

- Continuously monitor cardiac rate and rhythm and have back-up pacing and defibrillation equipment immediately available throughout the immediate postoperative period
- Interrogate and restore CRMD function in the immediate postoperative period
    - Interrogate CRMD; consultation with a cardiologist or pacemaker-ICD service may be necessary
    - Restore all anti-tachyarrhythmic therapies in ICDs
    - Assure that all other settings of the CRMD are appropriate

Table 3. Example of a Stepwise Approach to the Perioperative Management of the Patient with a Cardiac Rhythm Management Device

PERIOPERATIVE PERIOD	PATIENT/CRMD CONDITION	INTERVENTION
PREOPERATIVE EVALUATION	***Patient has CRMD***	• Focused history • Focused physical examination
	Determine CRMD type (PM, ICD, CRT)	• Manufacturer's ID card • Chest x-ray (no data available) • Supplemental resources[††††††]
	Determine if patient is CRMD-dependent for pacing function	• Verbal history • Bradyarrhythmia symptoms → CRMD need • AV node ablation → CRMD need • No spontaneous ventricular activity[‡‡‡‡‡‡]
	Determine CRMD function	• Comprehensive CRMD evaluation[§§§§§§] • Determine if pacing pulses are present and create paced beats
PREOPERATIVE PREPARATION	***EMI likely during procedure***	• If EMI unlikely, then special precautions are not needed
	EMI likely; CRMD is PM	• Reprogram to asynchronous mode when indicated • Suspend rate adaptive functions[*******]
	EMI likely: CRMD is ICD	• Suspend anti-tachyarrhythmia functions • If patient is dependent on pacing function, then alter pacing functions as above
	EMI likely: All CRMD	• Use bipolar cautery; ultrasonic scalpel • Temporary pacing and CV/DF available
	Intraoperative physiologic changes likely (e.g. bradycardia, ischemia)	• Plan for possible adverse CRMD-patient interaction
INTRAOPERATIVE MANAGEMENT	***Monitoring***	• ECG monitoring per ASA standard • Peripheral pulse monitoring
	Electrocautery interference	• CT/CRP—no current through PG/leads

[††††††] Manufacturer's databases, PM clinic records, cardiology consultation;
[‡‡‡‡‡‡] With CRMD programmed VVI at lowest programmable rate
[§§§§§§] Ideally CRMD function assessed by interrogation, with function altered by reprogramming if required
[*******] Most times this will be necessary; when in doubt, assume so

INTRAOPERATIVE MANAGEMENT (continued)		• Avoid proximity of CT to PG/leads • Short bursts at lowest possible energy • Use bipolar cautery; ultrasonic scalpel
	RF catheter ablation	• Avoid contact RF catheter with PG/leads • RF current path far away from PG/leads • Discuss these concerns with operator
	Lithotripsy	• Do not focus LIT beam near PG • R-wave triggers LIT? Disable atrial pacing[†††††††]
	MRI	• Generally contraindicated • If required, consult ordering physician, cardiologist, radiologist and manufacturer
	Radiation therapy	• PG/leads must be outside of RT field • Possible surgical relocation of PG • Verify PG function during/after RT course
	ECT	• Consult with ordering physician, patient's cardiologist, a CRMD service, or CRMD manufacturer
EMERGENCY DEFIBRILLATION-CARDIOVERSION	***ICD: magnet-disabled***	• Terminate all EMI sources • Remove magnet to re-enable therapies • Observe for appropriate therapies
	ICD: programming disabled	• Programming to re-enable therapies, • Or proceed directly with external CV/DF
	ICD: either of above	• Minimize current flow through PG/leads • PP as far as possible from PG • PP perpendicular to major axis PG/leads • To extent possible, PP in A/P location
	Regardless of CRMD type	• Use clinically appropriate DC/DF energy
POSTOPERATIVE MANAGEMENT	***Immediate postoperative period***	• Monitor cardiac R&R continuously • Back-up pacing and DC/DF capability
	Postoperative interrogation and restoration of CRMD function	• Interrogation to assess function • Settings Appropriate?[‡‡‡‡‡‡‡] • Is CRMD an ICD?[§§§§§§§]

[†††††††]Atrial pacing spikes may be interpreted by device as R waves, and inhibiting delivery of pacing stimuli or LD could deliver shocks during intrinsic R wave or ventricular vulnerable period.
[‡‡‡‡‡‡‡]If necessary, reprogram appropriate settings

		• Use cardiology/PM-ICD service if needed

Abbreviations:
A/P = anterior/posterior; CRMD = cardiac rhythm management device; CRT = cardiac resynchronization therapy; CT/CRP = cautery tool/current return pad; CV/DF = external cardioversion/defibrillation; ECT = electroconvulsive therapy; ICD = internal cardioverter-defibrillator; ID = CRMD identification card; LIT = lithotripsy; MRI = magnetic resonance imaging; PG = pulse generator; PM = pacemaker; PP = CV/DF pads or paddles; RF = radiofrequency; RT = radiation therapy

[§§§§§§§]Restore all antitachycardia therapies

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