CRHF
REIMBURSEMENT AND HEALTH POLICY

Cardiac Rhythm and Heart Failure Products
CMS HCPCS (C-Code) List for Hospital Outpatient Device Reporting
Updated April 25, 2018

Medtronic

CMS HCPCS (C-CODE)

List for Hospital Outpatient Device Reporting for Cardiac Rhythm and Heart Failure Products

This document is a tool to help determine the appropriate C-Code for CRHF products. It is separated out into sections for device categories (implanted devices, leads, adaptors, catheters, and guidewires). The individual items are in alphabetical order by device name.

The procedure-to-device and device-to-procedure edit files for device-intensive hospital outpatient services were removed as a requirement in 2014. CMS no longer creates a "device code" table that would be used for device intensive Ambulatory Payment Classifications (APCs). CMS expects hospitals to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable.[1]

Determining which C-Code is applicable is the responsibility of the hospital.

Comprehensive APCs:
The CY 2017 Final Hospital Outpatient Prospective Payment System (OPPS) effective January 1, 2017 continues the Comprehensive APC (C-APC) payment methodology that was implemented in CY 2015.

Under C-APCs, the primary service and all adjunctive services provided to support the delivery of the primary service will receive one payment.

Revenue Codes:
The UB Editor recommends using revenue code 275 for pacemaker implants (leads, generators), 278 for other implants (leads, generators, implantable loop recorders), and 272 for non-implantable sterile supplies (catheters).[2]

Disclaimer:
These coding suggestions and coverage guidelines do not replace seeking coding advice from the payer and/or your coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with CMS or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.

All products included in this listing are placed in the appropriate CMS category based on their intended function.

For further information, please contact your Medtronic sales representative or send an email to: RS.healthcareeconomics@medtronic.com.

An electronic version of this document is available at: http://www.medtronic.com/crhfreimbursement

IMPLANTABLE LOOP RECORDER

C1764 – Event Recorder, Cardiac (Implantable)

DEVICE	MODEL NUMBER
Reveal™ DX	9528
Reveal™ XT	9529
Reveal LINQ™	LNQ11

IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

C1721 – Cardioverter Defibrillator, Dual Chamber (Implantable)

DEVICE	MODEL NUMBER
Evera™ XT DR	DDBB1D1, DDBB1D4
Evera™ S DR	DDBC3D1, DDBC3D4
Evera MRI™ XT DR SureScan™	DDMB1D1, DDMB1D4
Evera MRI™ S DR SureScan™	DDMC3D1, DDMC34D

C1722 – Cardioverter Defibrillator, Single Chamber (Implantable)

DEVICE	MODEL NUMBER
Evera™ XT VR	DVBB1D1, DVBB1D4
Evera™ S VR	DVBC3D1, DVBC3D4
Evera MRI™ XT VR SureScan™	DVMB1D1, DVMB1D4
Visia AF MRI™ ICD	DVFB1D1, DVFB1D4

C1882 – Cardioverter Defibrillator, Other than Single or Dual Chamber (Implantable)

DEVICE	MODEL NUMBER
Amplia MRI™ CRT-D SureScan™	DTMB1D1, DTMB1D4
Amplia MRI™ Quad CRT-D SureScan™	DTMB1Q1, DTMB1QQ
Claria MRI™ CRT-D SureScan™	DTMA1D1, DTMA1D4
Claria MRI™ Quad CRT-D SureScan™	DTMA1Q1, DTMA1QQ
Compia MRI™ CRT-D SureScan™	DTMC1D1, DTMC1D4
Compia MRI™ Quad CRT-D SureScan™	DTMC1Q1, DTMC1QQ
Concerto™ CRT-D	D234TRK
Concerto™ II CRT-D	D294TRK
Consulta™ CRT-D	D214TRM
Viva™ Quad S CRT-D	DTBB1Q1, DTBB1QQ
Viva™ Quad XT CRT-D	DTBA1Q1, DTBA1QQ
Viva™ S CRT-D	DTBB1D1, DTBB1D4
Viva™ XT CRT-D	DTBA1D1, DTBA1D4

PACEMAKERS

C1785 – Pacemaker, Dual Chamber, Rate-Responsive (Implantable)

DEVICE	MODEL NUMBER
Adapta™	ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1
Advisa DR MRI™	A2DR01
Azure S DR MR™	W3DR01
Azure XT DR MR™	W1DR01
Revo MRI™	RVDR01
Sensia™	SEDR01
Versa™	VEDR01

C1786 – Pacemaker, Single Chamber, Rate-Responsive (Implantable)

DEVICE	MODEL NUMBER
Adapta™	ADSR01, ADSR03, ADSR06
Advisa SR MRI™	A3SR01
Azure S SR MRI™	W3SR01
Azure XT SR MRI™	W1SR01
Micra™ Transcatheter Pacing System	MC1VR01
Sensia™	SESR01

C2619 – Pacemaker, Dual Chamber, Non-Rate-Responsive (Implantable)

DEVICE	MODEL NUMBER
Adapta™	ADD01, ADVDD01
Sensia™	SED01

C2621 – Pacemaker, Other than Single or Dual Chamber (Implantable)

DEVICE	MODEL NUMBER
Consulta™ CRT-P	C4TR01
Percepta™ CRT-P MRI SureScan™	W1TR01, W4TR01
Serena™ CRT-P MRI SureScan™	W1TR02, W4TR02
Solara™ CRT-P MRI SureScan™	W1TR03, W4TR03
Syncra™ CRT-P	C2TR01
Viva™ CRT-P	C6TR01

LEADS

C1725 – Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)

DEVICE	MODEL NUMBER
Attain™ Venogram Balloon	6215

C1777 – Lead, Cardioverter Defibrillator, Endocardial Single Coil (Implantable)

DEVICE	MODEL NUMBER
Sprint Quattro Secure S™	6935
Sprint Quattro Secure S™ MRI SureScan™	6935M

C1779 – Lead, Pacemaker, Transvenous VDD Single Pass

DEVICE	MODEL NUMBER
CapSure™ VDD	5038, 5038L, 5038S

C1895 – Lead, Cardioverter Defibrillator, Endocardial Dual Coil (Implantable)

DEVICE	MODEL NUMBER
Sprint Quattro™	6944, 6946M
Sprint Quattro Secure™	6947
Sprint Quattro Secure MRI™ SureScan™	6947, 6947M

C1896 – Lead, Cardioverter Defibrillator, Other than Endocardial Single or Dual Coil (Implantable)

DEVICE	MODEL NUMBER
Oval Patch Leads	6721L, 6721M, 6721S, 6939
Subcutaneous Lead System	6996SQ
Transvene™	6881, 6884, 6895, 6933, 6934S, 6937, 6937A, 6939, 6963, 6999

C1898 – Lead, Pacemaker, Other than Transvenous VDD Single Pass

DEVICE	MODEL NUMBER
CapSure™	4003, 4003M, 4004, 4004M, 4503, 4503M, 4504, 4504M, 4965, 5025, 5026, 5525
CapSure™ Epi	4965, 4968
CapSure Sense™	4073, 4074, 4574
CapSure Sense MRI™ SureScan™	4074, 4574
CapSure™ SP	4023, 4024, 4523, 4524, 5023, 5023M, 5024, 5024M, 5523, 5523M, 5524, 5524M, 5525
CapSure™ SP Novus	4092, 4592, 5092, 5592, 5594
CapSure™ Z	4033, 4034, 4533, 4534, 5033, 5034, 5534
CapSure™ Z Novus	5054, 5554
CapSureFix™	4067, 4068, 4568, 5058, 5067, 5068, 5568 (bipolar), 6940
CapSureFix MRI™ SureScan™	5086MRI
CapSureFix™ Novus	4076
CapSureFix Novus MRI™ SureScan™	4076, 5076
Crystalline™	ICM 09, ICM 09B, ICM 09JB
Crystalline™ ActFix	ICF 09, ICQ 09
Epicardial Screw-in	4951M, 5071
Excellence™ +	IMD 49, IMD 49B, IMD 49JB
Excellence™ S+	IME 49, IME 49B, IME 49JB
Excellence™ PS+	IMK 49B, IMK 49JB
Excellence™ SS+	IML 49B, IML 49JB
Impulse™ II	IHP 09B, IHP 09JB
Impulse™	IMG 49, IMG 49B, IMG 49JB
Pirouet™ +	IMU 49, IMU 49B, IMU 49JB
Pirouet™ S+	IMX 49, IMX 49B, IMX 49JB
SelectSecure™	3830
SureFix™	5072

C1900 – Lead, Left Ventricular Coronary Venous System

DEVICE	MODEL NUMBER
Attain Ability™ MRI SureScan™	4196
Attain Ability™ Plus MRI SureScan™	4296
Attain Ability™ Straight MRI SureScan™	4396
Attain™ Bipolar OTW	4194
Attain™ Performa™ MRI SureScan™	4298
Attain™ Performa™ Straight MRI SureScan™	4398
Attain™ Performa™ S MRI SureScan™	4598
Attain™ Stability Quad MRI SureScan™ LV Lead	4798
Attain StarFix™	4195

ADAPTORS, CATHETERS, AND GUIDE WIRES

C1730 – Catheter, Electrophysiology, Diagnostic, Other than 3D Mapping (19 or Fewer Electrodes)

DEVICE	MODEL NUMBER
Achieve Advance™ Mapping Catheter	2ACH15, 2ACH20, 2ACH25
Achieve™ Mapping Catheter	990063-015, 990063-020
Marinr™	072302, 072322M, 072402
Marinr™ CS	043302M, 043325M, 043328M
Torqr™ CS Diagnostic Catheter	041565CS, 041590CS, 041865CS, 041890CS
Torqr™, Soloist™ Diagnostic Catheter	041002JM, 041002UM, 041005DM, 041005JM, 041005UM, 04130DS, 04122JM, 04122UM, 04125JM, 04125UM, 441016JF, 441016U, 44216J, 44216JF, 44216U, 44516J, 44516JF, 44516U

C1731 – Catheter, Electrophysiology, Diagnostic, Other than 3D Mapping (20 or More Electrodes)

DEVICE	MODEL NUMBER
StableMapr™	04401SM, 04402SM

C1733 – Catheter, Electrophysiology, Diagnostic/Ablation, Other than 3D or Vector Mapping, Other than Cool Tip

DEVICE	MODEL NUMBER
5F RF Marinr™	076514, 076515, 076583, 076584, 076585, 076586
Arctic Front Advance™ Cardiac CryoAblation Catheter	2AF234, 2AF284
Arctic Front Advance™ ST Cardiac CryoAblation Catheter	2AFAST23, 2AFAST28
Arctic Front™ Cardiac CryoAblation Catheter	2AF232, 2AF282
Freezor™	307F1, 307F3, 307F5
Freezor™ *MAX* Cardiac CryoAblation Catheter	239F3, 239F5
Freezor™ *Xtra* Cardiac CryoAblation Catheter	227F1, 227F3, 227F5
RF Conductr™ MC	0786022, 0786042, 0787533, 0787544, 07857544, 07856042, 07856044, 0786044
RF Contactr™	70256034, 70257533
RF Enhancr™ II	31744523, 31745523, 31745533, 39745533,
RF Marinr™ MC	075302, 075312, 075402, 075405

C1766 – Introducer/Sheath, Guiding, Intracardiac Electrophysiolgical, Steerable, Other than Peel-away

DEVICE	MODEL NUMBER
FlexCath™ Steerable Sheath	3FC10, 3FC12
FlexCath Advance™	4FC12

C1769 – Guide Wire

DEVICE	MODEL NUMBER
Attain™ Guide Wire	6228GWR
Attain Hybrid™ Guide Wire	GWR419378, GWR419388, GWR419478, GWR419488, GWR419578, GWR419588, GWR419678, GWR419688
Cougar™ LS	LVCLS190J, LVCLS190S
Cougar™ XT	LVCXT190J, LVCXT190S
Thunder™	LVTNDR190S
Zinger™ Light	LVZRLS180J, LVZRLS180S
Zinger™ Medium	LVZRMS180J, LVZRMS180S
Zinger™ Support	LVZRXT180J, LVZRXT180S

C1883 – Adaptor/Extension, Pacing Lead (Implantable)

DEVICE	MODEL NUMBER
Adaptor	2872, 5866-09M, 5866-24M, 5866-37M, 5866-38M, 5866-40M, 6707, 6725, 6726, 6920, 6925, 6981M, 6984M, 6985M 6986M, M/VS-10, LV/IS-10, LV/IS-40, BLV-BIS-10, BLV-BIS-40

ADAPTORS, CATHETERS, AND GUIDE WIRES, *cont'd.*

C1887 – Catheter, Guiding (may include infusion/perfusion capability)

DEVICE	MODEL NUMBER
Attain™	6216A-MB2, 6216A-MP, 6218A-45S, 6218A-50S, 6218A-57S, 6218A-AM, 6218A-EH, 6226DEF
Attain Command™	6250-AM, 6250-EH, 6250-EHXL, 6250-MB2, 6250-MB2X, 6250-MP, 6250-MPR, 6250-MPX, 6250-45S, 6250-50S, 6250-57S, 6250C, 6250S
Attain Command™ + SureValve™	6250V-AM, 6250V-EH, 6250V-EHXL, 6250V-MB2, 6250V-MB2X, 6250V-MP, 6250V-MPR, 6250V-MPX, 6250V-45S, 6250V-50S, 6250V-57S, 6250V-3D, 6250VC, 6250VS
Attain™ Deflectable	6227DEF
Attain Prevail™	6228CTH, 6228CTH80, 6228SYS
Attain Select™	6238TEL
Attain Select™ II	6248DEL
Attain Select™ II + SureValve™	6248V-90S, 6248V-90, 6248V-90L, 6248V-130, 6248V-130L, 6248V-90SP, 6248V-90P, 6248V-130P
C315	C315H2002, C315H4002, C315HIS02, C315J02, C315S1002, C315S402, C315S502
Merit Medical Coronary	1628-017M, 1628-019M, 1628-Y8M
SelectSite™	C304-L69, C304-S59, C304-XL74, C304-XS59

C1892 – Introducer/Sheath, Guiding, Intracardiac Electrophysiological, Fixed Curve, Peel-Away

DEVICE	MODEL NUMBER
OptiSeal™ Valved Peelable Introducer	1000093-001, 1000093-002, 1000093-003, 1000093-004, 1000093-005, 1000093-006, 1000093-007, 1000093-008, 1000093-009, 1000093-010, 1000093-011, 1000093-012, 1000093-013, 1000093-014
SafeSheath™ MultiSite (MSP)	CSG/MSP-00-09, CSG/MSP-00-6.5
SafeSheath™ Ultra	SU5, SU6, SU7, SU8, SU85, SU9, SU95, SU10, SU105, SU11, SU12, SU125, SUL6, SUL7, SUL8, SUL9, SUL10, SUL105, SUL11
SafeSheath™ Worley	CSGWORBC19M, CSGWORBC29M, CSGWORL19M, CSGWORLBC19M, CSGWORLEY109M

C1893 – Introducer/Sheath, Other than Guiding, Other than Intracardiac Electrophysiological, Non-Laser

DEVICE	MODEL NUMBER
Mullins™	008530, 008532, 008552, 008591

C1894 – Introducer/Sheath, Other than Guiding, Other than Intracardiac Electrophysiological, Non-Laser

DEVICE	MODEL NUMBER
FlowGuard™ Introducer	10729, 10730
Introducer	6207BTK, 6207BTKD, 6207BTKL, 6207D, 6207S, 6208BTK, 6208BTKD, 6208BTKL, 6208D, 6208S, 6209BTK, 6209BTKD, 6209BTKL, 6209D, 6209S, 6210BTK, 6210BTKD, 6210BTKL, 6210D, 6210S, 6211BTK, 6211BTKD, 6211D, 6211S, 6212BTK, 6212S, 6214BTK, 6214S, HLS-1007M, HLS 1008M, HLS-1009M, HLS-10095M, HLS 10105M, HLS-1011M, HLS-2507M, HLS-2508M, HLS-2509M, HLS-2511M, HLS-25105M
Micra™ Introducer	M12355A

References

[1] CMS-1656-FC Final Medicare OPPS for CY 2017 released on Tuesday November 1, 2016 and CMS-1656-CN corrected Hospital Outpatient regulation and data files for CY 2017 are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html

[2] ©Copyright American Hospital Association.

Brief Statement

Arctic Front Advance™ Cardiac Cryoablation Catheter Indications: The Arctic Front Advance cardiac cryoablation catheter system is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation.

Contraindications: Use of Arctic Front Advance cryoballoon is contraindicated 1) In the ventricle because of the danger of catheter entrapment in the chordae tendinae, 2) In patients with one or more pulmonary vein stents, 3) In patients with cryoglobulinemia, 4) In patients with active systemic infections and 5) In conditions where the manipulation of the catheter within the heart would be unsafe (e.g., intracardiac mural thrombus).

Warnings/Precautions: Do not re-sterilize this device for purpose of reuse. Use only the 12 Fr FlexCath™ steerable sheath family with the Arctic Front Advance cryoballoon because using another sheath may damage the catheter or balloon segment. Do not inflate the balloon inside the sheath. Always verify with fluoroscopy or by using the proximal shaft visual marker that the balloon is fully outside the sheath before inflation to avoid catheter damage. Do not position the cryoballoon catheter within the tubular portion of the pulmonary vein to minimize phrenic nerve injury and pulmonary vein stenosis. Do not connect the cryoballoon to a radiofrequency (RF) generator or use it to deliver RF energy because this may cause catheter malfunction or patient harm. The catheter contains pressurized refrigerant during operation; release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, this may lead to tissue injury. Do not advance the balloon beyond the guide wire to reduce the risk of tissue damage. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue) to avoid damage to the valve, valvular insufficiency or premature failure of the prosthetic valve. Always inflate the balloon in the atrium then position it at the pulmonary vein ostium to avoid vascular injury. Do not ablate in the tubular portion of the pulmonary vein. Use continuous phrenic nerve pacing throughout each cryoablation application in the right pulmonary veins. To avoid nerve injury, place a hand on the abdomen in the location of the diaphragm to assess for changes in the strength of the diaphragmatic contraction or loss of capture. In case of no phrenic nerve capture, frequently monitor diaphragmatic movement using fluoroscopy. Stop ablation immediately if phrenic nerve impairment is observed. The Arctic Front Advance cryoballoon was not studied for safety of changes in anticoagulation therapy in patients with paroxysmal atrial fibrillation. This equipment should be used only by or under the supervision of physicians trained in left atrial cryoablation procedures. Cryoablation procedures should be performed only in a fully equipped facility.

Potential Complications: Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to the following: Anemia; Anxiety; Atrial flutter; Back pain; Bleeding from puncture sites; Blurred vision; Bradycardia; Bronchitis; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Cold feeling; Cough; Death; Diarrhea; Dizziness; Esophageal damage (including esophageal fistula); Fatigue; Fever; Headache; Hemoptysis Hypotension/hypertension; Lightheadedness; Myocardial infarction; Nausea/vomiting Nerve injury; Pericardial effusion; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Tachycardia; Transient ischemic attack; Urinary infection; Vasovagal reaction; Visual changes.

Freezor™ *MAX*

The Freezor MAX cardiac cryoablation catheter is used as an adjunctive device in the endocardial treatment of paroxysmal atrial fibrillation in conjunction with the Arctic Front cardiac cryoablation catheter for the following uses: 1) Gap cryoablation to complete electrical isolation of the pulmonary veins, 2) Cryoablation of focal trigger sites and 3) Creation of ablation line between the inferior vena cava and the tricuspid valve.

Contraindications: Use of Freezor MAX cryocatheter is contraindicated in patients with active systemic infections, in patients with cryoglobulinemia and other conditions where the manipulation of the catheter would be unsafe (for example, intracardiac mural thrombus).

Warnings/Precautions: Do not re-sterilize this device for purpose of reuse. Do not connect the cryocatheter to a radiofrequency (RF) generator or use it to deliver RF energy because this may cause catheter malfunction or patient harm. Disconnect the catheter's electrical connection prior to defibrillation. The catheter contains pressurized refrigerant during operation; release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue) to avoid damage to the valve, valvular insufficiency or premature failure of the prosthetic valve. Use adequate fluoroscopic visualization during a transaortic approach to avoid placing the ablation catheter within the coronary vasculature. Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. The Freezor MAX catheter was not studied for safety of changes in anticoagulation therapy in patients with paroxysmal atrial fibrillation. This equipment should be used only by or under the supervision of physicians trained in left atrial cryoablation procedures. Cryoablation procedures should be performed only in a fully equipped facility.

Potential Complications: Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to the following: Anemia; Anxiety; Atrial flutter; Back pain; Bleeding from puncture sites; Blurred vision; Bradycardia; Bronchitis; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Cold feeling; Cough; Death; Diarrhea; Dizziness; Esophageal damage; Fatigue; Fever; Headache; Hemoptysis Hypotension/hypertension; Lightheadedness; Myocardial infarction; Nausea/vomiting Nerve injury; Pericardial effusion; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Tachycardia; Transient ischemic attack; Urinary infection; Vasovagal reaction; Visual changes.

Freezor™ Xtra Cardiac Cryoablation Catheter

Indications: The Freezor Xtra cardiac cryoablation catheter, CryoConsole system, and related accessories are indicated for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT). The Freezor Xtra catheter is also intended for minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The Freezor Xtra catheter freezes the target tissue and blocks the electrical conduction by creating an inflammatory response or cryonecrosis.

Contraindications: The Freezor Xtra cardiac cryoablation catheter is contraindicated in patients with the following conditions:

Contraindications: The Freezor *Xtra* cardiac cryoablation catheter is contraindicated in patients with the following conditions:

- Active systemic infections
- Cryoglobulinemia
- Other conditions where the manipulation of the catheter would be unsafe (for example, intracardiac mural thrombus)

Warnings/Precautions: The catheter contains pressurized refrigerant during operation; release of this gas into the body or circulatory system due to equipment failure or misuse could result in gas embolism, pericardial tamponade, tissue emphysema, or other patient injury. Do not pull on the Freezor *Xtra* catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Do not connect the Freezor *Xtra* catheter to a radiofrequency (RF) generator or use it to deliver RF ablation energy. Doing this may cause device malfunction or patient harm. Do not resterilize this catheter for purpose of reuse. This catheter is intended only to be used once for a single patient. Cryoablation involving coronary vessels with liquid nitrous oxide systems has been associated with subsequent clinically significant arterial stenosis. Care should be taken to minimize unnecessary contact with coronary vessels during cryoablation. Avoid positioning the catheter around the chordae tendineae, as this increases the likelihood of catheter entrapment within the heart, which may necessitate surgical intervention or repair of injured tissues. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue). The catheter may become trapped in the valve, damaging the valve and causing valvular insufficiency or premature failure of the prosthetic valve. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing endocardial right-sided procedures. Administer anticoagulation therapy before and after the procedure according to the hospital standards.Introducing any catheter into the circulatory system entails the risk of air or gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Cryoablation procedures should be performed only in a fully equipped facility. This equipment should be used only by or under the supervision of physicians trained in surgical or endocardial cryoablation procedures. Do not attempt to operate the Freezor *Xtra* catheter prior to reading and understanding the Instructions for Use.
Potential Complications: Potential complications/adverse events associated with cardiac catheter cryoablation procedures include, but are not limited to, the following conditions: Access site complications (e.g., hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage), Arrhythmia (including new or worsening existing arrhythmias), Cardiac arrest, Cardiac tamponade/perforation, Catheter entrapment in cardiac structures, requiring surgical intervention, Chest discomfort, pain or pressure, Coronary artery spasm, dissection, thrombosis, Damage to adjacent organs/structures, Death, Endocarditis, Heart block, partial or complete, potentially requiring permanent pacemaker, Hematoma, Hemothorax, Infection/sepsis, Myocardial infarction, Pericardial effusion, Pericarditis, Pleural effusion, Pneumothorax, Pseudoaneurysm, Pulmonary edema, Pulmonary embolism, Stoke/transient ischemic attack/embolism, Thrombosis, Valvular damage, Vascular complication (e.g., stenosis), Vasovagal reaction.

Arctic Front Advance™ Cardiac Cryoablation Catheter, CryoConsole, and Freezor™ *MAX* Cardiac Cryoablation Catheter
Indications: Medtronic CryoCath™ cryoablation system is comprised of cryoablation catheters and a CryoConsole. The Arctic Front Advance cardiac cryoablation catheter system is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation. The Freezor *MAX* cardiac cryoablation catheter is used as an adjunctive device in the endocardial treatment of paroxysmal atrial fibrillation in conjunction with the Arctic Front Advance cryoballoon. Please read the specific product labeling indications for use before using the cryoablation system.
Contraindications: Use of Arctic Front Advance cryoballoon is contraindicated as follows: In the ventricle because of the danger of catheter entrapment in the chordae tendinae, In patients with active systemic infections, In conditions where the manipulation of the catheter within the heart would be unsafe (e.g.,intracardiac mural thrombus), in patients with cryoglobulinemia, in patients with one or more pulmonary vein stents. Use of Freezor *MAX* cryocatheter is contraindicated in patients with the following conditions: Active systemic infections, cryoglobulinemia, other conditions where the manipulation of the catheter would be unsafe (e.g., intracardiac mural thrombus).
Warnings and Precautions: Do not resterilize the cryoablation catheters for purpose of reuse. Use only the appropriate size of the FlexCath™ steerable sheath family with the Arctic Front Advance cryoablation catheters because using another sheath may damage the catheter or balloon segment. Do not connect the cryoablation catheter to a radiofrequency (RF) generator or use it to deliver RF energy because this may cause catheter malfunction or patient harm. The catheter contains pressurized refrigerant during operation; release of this gas into the circulatory system due to equipment failure or misuse could result in gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Do not pull on the catheter, sheath, umbilical cables, or console while the catheter is frozen to the tissue, as this may lead to tissue injury. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue) to avoid damage to the valve, valvular insufficiency, or premature failure of the prosthetic valve. Use continuous phrenic nerve pacing with a hand on the diaphragm throughout each cryoablation procedure in the right pulmonary veins to avoid nerve injury. In case of no phrenic nerve capture, frequently monitor diaphragmatic movement using fluoroscopy. Stop ablation immediately if phrenic nerve impairment is observed.
The Cryoablation (Arctic Front Advance and Freezor *MAX*) catheters were not studied for safety of changes in anticoagulation therapy in patients with atrial fibrillation. This equipment should be used only by or under the supervision of physicians trained in left-atrial cryoablation procedures. Cryoablation procedures should be performed only in a fully equipped facility.
Potential Complications: Potential complications/adverse events that may be associated with cardiac catheterization and ablation listed alphabetically below include but are not limited to: Anemia; Anxiety; Atrial flutter; Back pain; Bleeding from puncture sites; Blurred vision; Bradycardia; Bronchitis; Bruising; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Cold feeling; Cough; Death; Diarrhea; Dizziness; Esophageal damage (including esophageal fistula); Fatigue; Fever; Headache; Hemoptysis; Hypotension/hypertension; Lightheadedness; Myocardial infarction; Nausea/vomiting; Nerve injury; Pericardial effusion; Pulmonary vein stenosis; Shivering; Shortness of breath; Sore throat; Tachycardia; Transient ischemic attack; Urinary infection; Vasovagal reaction; Visual changes.

RF Catheters
Indications: RF catheters are indicated for use with the Medtronic RF generator to deliver RF energy for intracardiac 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: Do not attempt to operate the Medtronic ablation system or connect the ablation catheter to a Medtronic RF generator prior to completely reading and understanding the Medtronic ablation system technical manual and the ablation catheter instructions for use. Use the catheter with only a Medtronic RF generator, accessories, and cables. The safety and use with other RF generators or accessories has not been tested. Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 micro Amps. 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. Cardiac ablation procedures should be performed only in a fully equipped electrophysiology laboratory.

Potential Complications: Potential complications include, but are not limited to, pulmonary embolism; myocardial infarction; cerebrovascular accident; cardiac damage, perforation, and tamponade; perforation of the vasculature; partial or complete AV block; and death. 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. 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. Implanted devices such as pacemakers and implantable cardioverter defibrillators (ICDs) may be adversely affected by RF energy. Catheter materials are not compatible with magnetic resonance imaging (MRI).

IPGs, CRT IPGs, ICDs, and CRT ICDs

Indications: Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm. See device manuals for the accepted patient conditions warranting chronic cardiac pacing. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications. For the MR Conditional IPGs, a complete SureScan™ pacing system, which consists of an approved combination (see mrisurescan.com/) MRI SureScan device with SureScan lead(s), is required for use in the MR environment. Cardiac Resynchronization Therapy (CRT) IPGs are indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications. Implantable cardioverter defibrillators (ICDs) are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Notes on some features in ICDs: The clinical value of the OptiVol™ fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure. Additional notes for DR ICDs: The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied. The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2% in the AF-only patient population studied. CRT ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications: New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration. Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II. NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Some ICDs and CRT ICDs are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The RV Lead Integrity Alert (LIA) feature is intended primarily for patients who have a Medtronic ICD or CRT-D device and a Sprint Fidelis lead (Models 6949, 6948, 6931, and 6930), based on performance data. The RV LIA feature may not perform as well with a St. Jude Medical Riata™/Durata® lead or a Boston Scientific Endotak lead as it does when used with a Medtronic Sprint Fidelis lead. This is because different lead designs may have different failure signatures and conditions that may or may not be detected early by the RV LIA feature.

Contraindications: IPGs and CRT IPGs are contraindicated for concomitant implant with another bradycardia device and concomitant implant with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway. ICDs and CRT ICDs are contraindicated in patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis; patients who have a unipolar pacemaker implanted, patients with incessant ventricular tachycardia (VT) or ventricular fibrillation (VF), and patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

Warnings/Precautions: Changes in a patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Additionally, for CRT ICDs and CRT IPGs, certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and/or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set. Use of the device should not change the application of established anticoagulation protocols. For MR-conditional IPG Systems, before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information, patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete SureScan pacing system consisting of an approved combination MRI SureScan device with SureScan lead(s); patients who have broken, abandoned or intermittent leads; or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω.

Potential Complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate

arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs and CRT ICDs is the acceleration of ventricular tachycardia. SureScan systems have been designed to minimize potential complications in the MRI environment. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

Medtronic Leads

Indications: Medtronic leads are used as part of a cardiac rhythm disease management system. Leads are intended for pacing and sensing and/or defibrillation. Defibrillation leads have application for patients for whom implantable cardioverter defibrillation is indicated. The Attain™ Leads have application as part of a Medtronic biventricular pacing system.

Contraindications: Medtronic leads are contraindicated for the following:

- Ventricular use in patients with tricuspid valvular disease or a tricuspid mechanical heart valve
- Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate or dexamethasone acetate may be contraindicated (includes all leads which contain these steroids)
- Epicardial leads should not be used on patients with a heavily infarcted or fibrotic myocardium.

The SelectSecure™ Model 3830 Lead is also contraindicated for the following:

- Patients for whom a single dose of 40.µg of beclomethasone dipropionate may be contraindicated
- Patients with obstructed or inadequate vasculature for intravenous catheterization

The Attain leads are contraindicated for patients with coronary venous vasculature that is inadequate for lead placement, as indicated by venogram. For the Model 4193 and 4194 leads, do not use steroid-eluting leads in patients for whom a single dose of 1.0 mg dexamethasone sodium phosphate may be contraindicated.

Warnings/Precautions: People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, or the need to reprogram or replace the device. For the SelectSecure Model 3830 lead, total patient exposure to beclomethasone 17,21-dipropionate should be considered when implanting multiple leads. No drug interactions with inhaled beclomethasone 17,21-dipropionate have been described. Drug interactions of beclomethasone 17,21-dipropionate with the Model 3830 lead have not been studied. Attain leads, stylets, and guide wires should be handled with great care at all times. When using a Model 4193 or 4194 lead, only use compatible stylets (stylets with downsized knobs and are 3 cm shorter than the lead length). Output pulses, especially from unipolar leads, may adversely affect device sensing capabilities. Backup pacing should be readily available during implant. Use of leads may cause heart block. For the Model 4193 and 4194 leads, it has not been determined if the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate apply to the use of this highly localized, controlled-release device. For a list of potential adverse effects, refer to the *Physicians' Desk Reference*. Patients should avoid diathermy. Previously implanted pulse generators, implantable cardioverter-defibrillators, and leads should generally be explanted.

Potential Complications: Potential complications related to the use of leads include, but are not limited to the following patient-related conditions: cardiac dissection, cardiac perforation, cardiac tamponade, coronary sinus dissection, death, endocarditis, erosion through the skin, extracardiac muscle or nerve stimulation, fibrillation or other arrhythmias, heart block, heart wall or vein wall rupture, hematoma/seroma, infection, myocardial irritability, myopotential sensing, pericardial effusion, epicardial or pericardial rub, pneumothorax, rejection phenomena, threshold elevation, thrombosis, thrombotic or air embolism, and valve damage. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation or exit block.

Reveal LINQ™ Insertable Cardiac Monitor

Indications: The Reveal LINQ insertable cardiac monitor (ICM) is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia

The device has not been tested specifically for pediatric use.

Contraindications: There are no known contraindications for the implant of the Reveal LINQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions: Patients with the Reveal LINQ ICM should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

Potential Complications: Potential complications of the Reveal LINQ device include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

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

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