REIMBURSEMENT AND HEALTH POLICY FREQUENTLY ASKED REIMBURSEMENT QUESTIONS

Subcutaneous Cardiac Rhythm Monitor

April 2020

Reveal LINQ™

MyCareLink™
Patient Monitor

Medtronic

INTRODUCTION

An insertable loop recorder (ILR) — sometimes also called a subcutaneous cardiac rhythm monitor (SCRM) — is a subcutaneously placed device that continuously records the electrocardiographic rhythm triggered automatically by rapid and slow heart rates or by the patient during a symptomatic episode. Procedures or services related to these devices are reported using the procedure codes for subcutaneous cardiac rhythm monitors. This guide is intended to answer frequently asked questions regarding coverage, coding, and payment for services related to the Reveal LINQ™ device.

TABLE OF CONTENTS

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Please contact Cardiac Rhythm & Heart Failure Reimbursement Services for further information:
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CODING AND PAYMENT

1. What are the correct CPT®* codes to use for the insertion and removal of the Reveal LINQ?

A: Starting in 2019, new codes and descriptors replace the previous codes and language to reflect evolving nomenclature for cardiac monitoring devices (also referred to as implantable loop recorders or ILRs). The table below lists the CPT codes for insertion and removal of the Reveal LINQ.[1]

CPT CODE	DESCRIPTION
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
33286	Removal, subcutaneous cardiac rhythm monitor

2. What CPT code should be reported when the Reveal LINQ requires repositioning?

A: CPT does not have an established code that accurately describes repositioning of Reveal LINQ. The provider may consider using either 17999 (Unlisted procedure, skin, mucous membrane and subcutaneous tissue) or 33999 (Unlisted procedure, cardiac surgery). When reporting either of these codes, a description of the procedure performed must also be included on the claim form. The payer will determine coverage.

3. How is the Reveal LINQ payment for outpatient hospital and physician services affected when more than one procedure is performed during the same episode of care/date of service?

A: **Hospital Outpatient Payment:** Medicare reimburses device-intensive procedures performed in the hospital outpatient setting using Comprehensive Ambulatory Payment Classifications (C-APCs). Under C-APCs, if two procedures designated by Medicare as included in C-APCs are performed concurrently, the procedure with the highest-weighted C-APC will be paid to the hospital. C-APCs package all supplies and services during that episode into one single payment.[2]

Example: If an AF ablation and Reveal LINQ implant are both performed, only one C-APC will be paid to the hospital. In this case, the AF ablation procedure will be paid, as it is the higher-weighted procedure. The cost of inserting the Reveal LINQ is then included in this single payment.

Physician Payment: Medicare physician payment is determined using the multiple procedure reduction rule. For concurrent procedures, the physician will be paid the full amount for the highest-weighted procedure and will be paid at 50% of the fee schedule amount for all additional procedures. For an AF ablation and a Reveal LINQ insertion, for example, the AF ablation will be paid at 100% and the Reveal LINQ insertion will be paid at 50%.[3]

GLOBAL SURGICAL PERIOD

4. What is the global surgical period associated with the Reveal LINQ insertion and removal codes?

A: The insertion and removal codes have a global period of 000 days (minor surgical procedures).[3]

CREDENTIALING

5. Can non-physician practitioners (NPPs), such as nurse practitioners (NPs) and physician assistants (PAs), perform Reveal LINQ insertion & removal procedures?

A: Prior to 2019, Medicare did not cover ILR or subcutaneous cardiac rhythm monitor insertion or removal procedures when performed by an NPP due to their classification as major surgical procedures. The global period for these procedure codes changed to 0 days on January 1, 2019. On or after January 1, 2019, CMS may cover an insertion/removal when performed by an NPP if the following criteria are all fulfilled:

- The procedure is within the scope of practice of the license for the state in which the NPP practices.[4]
- Payer rules must be followed. Payers may or may not allow insertions by NPPs, and the NPP needs to research each payer to obtain policy requirements, supervision rules, and the approval process.
- The NPP must meet the credentialing and supervision requirements at the location where the implant will occur.
- Also consider whether malpractice insurance covers the NPP for performing insertion/removal procedures. Refer to CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 for non-physician practitioner rules.[5]

PLACE OF SERVICE

6. What places of service can receive payment for a Reveal LINQ insertion or removal?

A: Reveal LINQ insertions and removals may receive payment in the following settings.[2,3,6,7] Check with your individual payers for conditions of coverage in each of these places of service.

- Ambulatory surgical center (ASC)
- Hospital inpatient
- Hospital outpatient
- Physician office

7. What place of service (POS) codes are used to identify the implant site on the physician and ASC claim form?

A: Applicable POS service codes and their associated Medicare fee schedules are listed in the table below.[8] Check with individual payers for reimbursement policies regarding these codes and the applicable places of service.

SETTING	POS CODE	MEDICARE FEE SCHEDULE (TECHNICAL COMPONENT)
Office	11	Medicare Physician Fee Schedule (PFS)
Off-campus — Outpatient Hospital	19	Excepted: Outpatient Prospective Payment System (OPPS) Non-excepted: 40% of OPPS
Inpatient Hospital	21	Inpatient Prospective Payment System (IPPS)
On-campus — Outpatient Hospital	22	Outpatient Prospective Payment System
Ambulatory Surgical Center	24	ASC Fee Schedule

Ambulatory Surgical Center (ASC)

8. Do payers allow Reveal LINQ to be inserted or removed in an ASC?

A: Yes. Medicare maintains a list of approved ASC services by CPT code that is reviewed on an annual basis. Most commercial payers also allow Reveal LINQ insertion and removal procedures in an ASC.[6]

9. How is an ASC defined? What makes a facility an ASC?

A: An ASC is a distinct entity that operates exclusively to provide surgical services to patients not requiring hospitalization and has an agreement with CMS to participate in the Medicare program as an ASC.[6,9]

10. How does Medicare physician payment vary when the Reveal LINQ insertion is performed at a hospital or ASC?

A: When a Reveal LINQ insertion or removal procedure is performed in a facility, the physician receives the same payment for their professional service, regardless of the type of facility where the insertion or removal procedure is performed.[3]

11. How do ASC payments for Reveal LINQ procedures compare to hospital outpatient payments?

A: Medicare ASC payments follow rules like those for hospital outpatient payments and include a geographic adjustment. ASC payments are generally less than the Medicare hospital outpatient rates. Rate files are available from the Medicare contractor where the ASC is located.[6]

Hospital

12. In the hospital setting, can the implant be performed somewhere other than an operating room or EP lab?

A: Each hospital must make an individual decision regarding where to insert or remove a Reveal LINQ device, considering patient safety and requirements/processes for tracking revenue and expense. Hospitals have definitive processes to determine these aspects of a procedure, which may include:

- Approval by the hospital's medical administration and finance department
- State credentialing rules
- Compliance with accreditation received by the hospital

Physician Office

13. When an insertion takes place in a office, how is the office reimbursed for the cost of the device?

A: The device cost is included in the global Medicare PFS non-facility amount paid to the office for the insertion procedure.[3]

14. Is there a separate code I need to report for the device when the insertion is performed in the office?

A: There is no additional or separate code reported for the device itself when the insertion procedure is performed in the office. The procedure code is inclusive of the Reveal LINQ device when performed in the office. HCPCS C-codes are only used by the hospital outpatient department.

CODING AND PAYMENT

15. What CPT codes are used to describe monitoring for the Reveal LINQ?

A: CPT codes that describe monitoring for a subcutaneous cardiac rhythm monitor are listed in the table below.[1]

CPT or HCPCS CODE	DESCRIPTION
In-person Programming and Interrogation Evaluation Services	
93285	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified healthcare professional; subcutaneous cardiac rhythm monitor system
93291	Interrogation device evaluation (in-person) with analysis, review, and report by a physician or other qualified healthcare professional, includes connection, recording, and disconnection per patient encounter; subcutaneous cardiac rhythm monitor system, including heart rhythm-derived data analysis
Remote Interrogation Evaluation Services	
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified healthcare professional
G2066[1,3]	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results

16. G2066 is different for reporting the technical component of remote monitoring in 2020. What are the changes?

A: Effective January 1, 2020, CPT® code 93299 (Interrogation device evaluation[s], [remote] up to 30 days; implantable cardiovascular physiologic monitor system or subcutaneous cardiac rhythm monitor system, remote data acquisition[s], receipt of transmissions and technician review, technical support and distribution of results) will be deleted from the CPT code book. CPT code 93299 is reported for the technical services related to long-term monitoring (e.g., Reveal LINQ insertable cardiac monitor [ICM] and OptiVol™ fluid status monitoring).

In place of CPT code 93299, Centers for Medicare & Medicaid Services (CMS) has created a new Healthcare Common Procedure Coding System (HCPCS) code. CMS has specified HCPCS code G2066 (Interrogation device evaluation[s], [remote] up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition[s], receipt of transmissions and technician review, technical support and distribution of results) to replace CPT code 93299 effective January 1, 2020.

CMS published these codes for use in Medicare patients. Some commercial payers may accept this code, but **it will be important to check with your commercial payers before reporting code G2066,** as some commercial payers may have different coding recommendations for this service.

17. What is the minimum number of days that the Reveal LINQ patient needs to be in the remote monitoring program for the services (professional component, technical component) to be billable?

A: The patient must be monitored for a minimum of 10 days of a 30-day monitoring period to meet services.[1]

18. Reveal LINQ has a summary report for a 30-day remote episode. May the summary report be used as a billing document?

A: The summary report is not sufficient as a billing document; however, it may be used as documentation to support that the patient met the required minimum of 10 days of monitoring during the 30-day period. Additional documentation will be needed to demonstrate all aspects of the code were performed. The monitoring procedure includes components of interpretation of the procedure that results in a written report. The interpretation and written report should include findings and relevant clinical issues.

19. How frequently can the 30-day remote monitoring codes be billed?

A: According to CMS (or MLN Matters SE170236), the determination of the date of service is based on the description of the procedure code and the time listed. When the service includes a physician review and/or interpretation and report, the date of service is the date the physician completes that activity. If the service is a technical service, the date of service is the date the monitoring concludes based on the description of the service. Therefore, the professional (93298) and technical (G2066) components of the service may not be billed more than every 31 days.[10]

20. What are the differences between interrogation and programming evaluation?

A: CPT language[1] specifies that both interrogation and programming services require evaluation of all device parameters. In addition, during programming evaluation, iterative adjustments provide information that allows for the selection of the most appropriate final program parameters to provide for consistent delivery of the appropriate therapy and to verify the efficiency and function of the device. The final program parameters may or may not change after evaluation.

For a subcutaneous cardiac rhythm monitor, often but not always, the tachycardia and bradycardia detection criteria will be adjusted during programming evaluation.

21. Why are the remote interrogation services for subcutaneous cardiac rhythm monitors reported once

per 30 days while in-person programming services are reported per patient encounter?

A: Conceptually, programming should only be performed and billed when medically necessary. In a stable patient, this could be as little as once per year. Of course, if the situation demands and the patient is clinically indicated, they could receive programming services more often. In contrast, interrogation services are meant for the clinically stable patient who requires more routine monitoring to demonstrate adequate, continued, and safe device function. The payer will always determine coverage based on documented medical necessity.

22. If the automatic transmission is received and the physician or NPP does not review this information for a few days, what date of service should be submitted on the claim?

A: CMS has published guidance on the appropriate date of service to be used on professional claims when reporting cardiac monitoring. The guidance states that the date of service reported for cardiac monitoring is based on the code description and time listed. In situations where the code describes the professional service, CMS states "the date of service is the date the physician completes that activity." In situations where the code describes the technical service, CMS states " the date of service is the date the monitoring concludes based on the description of the service." CMS recommends for further information to view the Medicare National Coverage Determination Manual, Chapter 1, Section 20.8.1.1.[10,11]

23. For Medicare patients, what is the coinsurance responsibility for Reveal LINQ monitoring?

A: The Medicare beneficiary is responsible for a 20% coinsurance payment for hospital outpatient and physician office device monitoring, for both the technical and professional services. A patient deductible may also apply in addition to the coinsurance amount if the patient's deductible has not been met for the year.[12]

24. Is there a way to bill additionally for each CareLink™ alert during a remote monitoring period?

A: No, remote monitoring codes are time-based and represent all work that occurs over a 30-day period. There is one payment made for the 30-day episode, regardless of the number of times that data is transmitted and/or reviewed.[1]

25. How is billing affected if the patient receives an in-person interrogation evaluation during a 30-day remote monitoring period?

A: In-person interrogation services are not separately reportable during the same period when remote monitoring is being performed. Only the remote monitoring service is billable (CPT code 93298 for the professional service and G2066 for the technical service).[1] If the patient receives in-person interrogation services during the remote monitoring period, this is not separately reportable or payable.

26. How is billing affected if the patient receives an in-person programming evaluation during a 30-day remote monitoring period?

A: When an in-person programming evaluation is performed during the remote 30-day episode, the programming evaluation may be separately billed.[1] The payer will determine coverage based on documented medical necessity.

27. What components of a subcutaneous cardiac rhythm monitor must be evaluated during interrogation evaluation services?

A: The required components are the same for both remote and in-person interrogation[1]:

- All programmed parameters
- Heart rate and rhythm during recorded episodes from both patient-initiated and device algorithm-detected events, when present

SUPERVISION REQUIREMENTS

28. What type of supervision does Medicare require when performing monitoring services for Reveal LINQ?

A: The Medicare PFS defines the type of supervision required for a diagnostic test, which is listed in the table below.[3,13-16]

SERVICE	DESCRIPTION
In-person programming or interrogation	**Direct supervision** by a physician (the physician must be in the suite/office when the test is being performed)
Remote monitoring	**General supervision**, which means there must be physician oversight of the monitoring program

29. Can an NPP serve as a supervisor for in-person Reveal LINQ monitoring?

A: No. Medicare diagnostic testing rules state that the supervisor must be a physician. If an NPP performs the service, the NPP may bill the service with his/her own billing number, provided state licensure allows it. The NPP may NOT supervise a technician, nurse, or other office staff for in-person monitoring services.[16]

30. Should the submitted claim include the billing number of the physician who was the supervisor in the office when the monitoring service was performed?

A: No. Under Medicare diagnostic testing rules, the physician who reads the report bills for the service. The practice should keep a schedule to document the physician supervisor for the date of service when the in-person monitoring was performed. Note the difference between these and alternative incident to billing rules that govern how to report evaluation and management (E/M) services.[17]

PROFESSIONAL AND TECHNICAL COMPONENTS

31. What is the definition of the technical and professional component for device monitoring?

A: See the definitions for each component in the table below.[1]

SERVICE COMPONENT	DESCRIPTION
Technical Component (TC)	▪ All non-physician work, and includes administrative personnel and capital (equipment and facility) costs, and related malpractice expenses. ▪ For remote services, the TC includes remote data acquisition(s), receipt of transmissions and technician review, technical support, and distribution of results.
Professional Component (PC or "26")	Physician's work interpreting a diagnostic test or performing a procedure and includes indirect practice and malpractice expenses related to that work.

32. How does a practice bill when an industry representative provides the technical component of an in-person service?

A: The practice bills only the professional component (93285 or 93291) by appending modifier "-26" on the professional claim form.[18]

33. How does a hospital clinic or a provider-based office bill for device monitoring?

A: The table below outlines how a hospital (inpatient, outpatient, or clinic) or a provider-based department may bill for monitoring.[1]

SERVICE	MODIFIER	DESCRIPTION
In-person programming or interrogation	-26	The physician or non-physician practitioner (NPP) bills the professional component of the service. The professional claim (billing the professional component) includes the appropriate place of service (POS) code on the claim.
	N/A	The hospital or provider-based department bills the technical component (TC) of the service.
Remote monitoring	N/A	The hospital or provider-based department bills the CPT code for the professional component on a professional claim with the appropriate POS.
	N/A	The hospital bills the CPT code for the technical component (TC) of the outpatient service.

34. Who bills the professional component if the technical component is provided by a commercial company such as an Independent Diagnostic Testing Facility (IDTF)?

A: If the technical component of the claim is provided by an IDTF, the physician or NPP bills the professional component of the service only along with the appropriate place of service code.[19]

35. The remote technical component for the Reveal LINQ (HCPCS code G2066) is contractor-priced. How does that affect payment?

A: Codes that are contractor-priced do not have assigned relative value units (RVUs) in the Medicare PFS and therefore payment for these services is determined by the local MAC and varies throughout the country. There is, however, identified national payment (assignment to an Ambulatory Payment Classification or [APC]) for G2066 in the hospital outpatient setting.[3]

36. Why are there no RVUs in the physician fee schedule for the technical component HCPCS code G2066?

A: Medicare (CMS) does not assign RVUs for services that are contractor-priced.[3]

REFERENCES

References

[1] American Medical Association. 2020 CPT Professional Edition. Details may be found in the Cardiovascular monitoring section.

[2] The OPPS 2020 National payment rates based on information published in the OPPS/ASC final rule CMS-1717-FC, correction notice CMS-1717-CN and corresponding Addendum B table which was published on December 30, 2019. Hospital Outpatient Regulations and Notices. cms.gov. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html. Accessed January 6, 2020.

[3] The Medicare Physician Fee Schedule (MPFS) 2020 National payment rates based on information published in the MPFS final rule CMS-1715-F and corresponding tables and which was published on November 1,2019. PFS Federal Regulation Notices. cms.gov. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html. Correction notice CMS-1715-CN published January 2, 2020. Accessed January 30, 2020.

[4] Centers for Medicare and Medicaid Services. Publication 100-04 Medicare Claims Processing Manual, Chapter 12 Physician/NonPhysician Practitioners. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.

[5] Centers for Medicare and Medicaid Services. Publication 100-02: Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673. Accessed March 18, 2020.

[6] The Ambulatory Surgical Center (ASC) ASC 2020 National payment rates based on information published in the OPPS/ASC final rule CMS-1717-FC, correction notice CMS-1717-CN and corresponding Addendum AA table, which was published on December 30, 2019. Hospital Outpatient Regulations and Notices. cms.gov. Available <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index> Accessed January 6, 2020.

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[8] Centers for Medicare and Medicaid Services. Place of Service Code Set. Available at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set. Accessed March 18, 2020.

[9] Centers for Medicare and Medicaid Services. Publication 100-02: Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services. Section 260 - Ambulatory Surgical Center Services. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673. Accessed March 18, 2020.

[10] Centers for Medicare and Medicaid Services. MLN Matters Article SE17023 (Revised) Released February 1, 2019. Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE17023.pdf. Accessed March 18, 2020.

[11] Centers for Medicare and Medicaid Services. Medicare National Coverage Determination Manual, Chapter 1: Coverage Determinations, Section 20.8.1.1: Transtelephonic Monitoring of Cardiac Pacemakers. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part1.pdf. Accessed March 18, 2020.

[12] Centers for Medicare and Medicaid Services. Publication 100-01 Medicare General Information, Eligibility and Entitlement Manual, Chapter 1. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c01.pdf.

[13] Direct supervision definition may be found in the Code of Federal Regulations 42 CFR 410.32(b)(3)(ii), Chapter 42: Public Health, Part 410: SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS, Section 32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions. at, accessed via <https://www.govinfo.gov/app/details/CFR-2011-title42-vol2/CFR-2011-title42-vol2-sec410-32> on March 19, 2020.

[14] Physician Supervision Requirements: Cardiac device monitoring services are defined by Medicare as diagnostic services. As such, Medicare regulations require specific supervision for diagnostic tests. These are applicable to the technical component of the electronic analysis of implanted cardiac devices. These supervision requirements are in addition to any other Medicare coverage requirements. Medicare requires direct supervision of the technical component for all in person cardiac device evaluations. Direct supervision in a hospital (facility) setting means that the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. The physician is not required to be present in the room where the procedure is being performed in this hospital (facility) setting or within any other physical boundary as long as he or she is immediately available.

[15] The Medicare supervision requirements for individual CPT codes are available by accessing the "PFS Relative Value Files" or "Medicare Physician Schedule Look-Up" located at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.

[16] Medicare diagnostic testing rules state that the supervisor must be a Physician. A Non-Physician Practitioner (NPP) such as a nurse practitioner or a physician assistant cannot supervise staff. Centers for Medicare and Medicaid Services. Manual 100-02 Medicare Benefit Policy Manual. Chapter 15: Covered Medical and Other Health Services, Section 80: Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

[17] Centers for Medicare and Medicaid Services. Publication 100-02 Medicare Benefit Policy Manual, Chapter 15, Section 80-Covered Medical and Other Health Services. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

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Brief Statements

Indications

Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant

The Reveal LINQ Insertable Cardiac Monitor 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

This device has not specifically been tested for pediatric use.

Patient Assistant

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal LINQ Insertable Cardiac Monitor to initiate recording of cardiac event data in the implanted device memory.

Contraindications

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

Warnings/Precautions

Reveal LINQ LNQ11 Insertable Cardiac Monitor

Patients with the Reveal LINQ Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external de brillation, 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.

Patient Assistant

Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

Potential Complications

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

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

The Medtronic MyCareLink™ patient monitor and the Medtronic CareLink™ network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to internet connectivity and access, and service availability. The MyCareLink patient monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Network and CareLink™ Mobile Application.

Intended Use

The Medtronic MyCareLink patient monitor and CareLink network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. The CareLink mobile application is intended to provide current CareLink network customers access to CareLink network data via a mobile device for their convenience. The CareLink mobile application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink network availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the internet is required and subject to coverage availability. Standard text message rates apply.

Contraindications

There are no known contraindications.

Warnings and Precautions

The MyCareLink Patient Monitor must only be used for interrogating compatible Medtronic implantable devices.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/ adverse events. For further information, please call Medtronic at 1-800-929-4043 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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