DETECTING ATRIAL FIBRILLATION

WITH ASSERT-IQ™ INSERTABLE CARDIAC MONITOR (ICM)

Abbott

ATRIAL FIBRILLATION (AFIB) STATISTICS

AFIB IS **THE MOST COMMON TYPE** OF CARDIAC ARRHYTHMIA.[1]

33.5 MILLION PEOPLE worldwide have AFib, which is **1.5-2%** of the world's population.[2]

AFIB RELATION TO **STROKE**

Patients with AFib are **5x MORE LIKELY** to have a stroke.[1,2]

30–40%

Approximately **30-40%** of ischemic stroke patients are diagnosed with cryptogenic (unexplained) stroke following diagnostic workup. Commonly referred to as CS.[3-5]

AFIB DETECTION WITHIN CRYPTOGENIC STROKE PATIENTS

Long-term monitoring reveals AFib in **~30%** of cryptogenic stroke (CS) patients.[6]

AFib detection leads to **IMPROVED SECONDARY PREVENTION STRATEGIES**, such as prescription of oral anticoagulants (OACs).[3, 7-11]

LONG-TERM MONITORING WITH AN INSERTABLE CARDIAC MONITOR (ICM)

3X FASTER

ICMs **DETECT AFIB 3X FASTER** than external cardiac monitoring methods for CS patients.[12]

55%

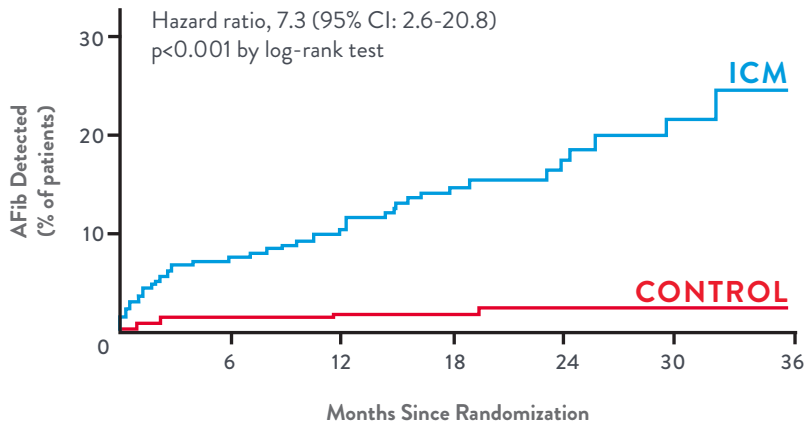
LOWER STROKE RECURRENCE for CS/TIA patients when AFib is detected by an ICM and treated.[13]

ICMs DETECT MORE AFIB THAN CONVENTIONAL METHODS

Cryptogenic Stroke and Underlying Atrial Fibrillation Study (CRYSTAL AF)[14]

The CRYSTAL AF study evaluated the incidence of paroxysmal AFib in patients with cryptogenic stroke and transient ischemic attack (TIA) using an ICM.

Detection of AFib by 36 Months



PATIENT IMPACT

84 DAYS

is the median time to AFib detection in cryptogenic stroke patients.[14]

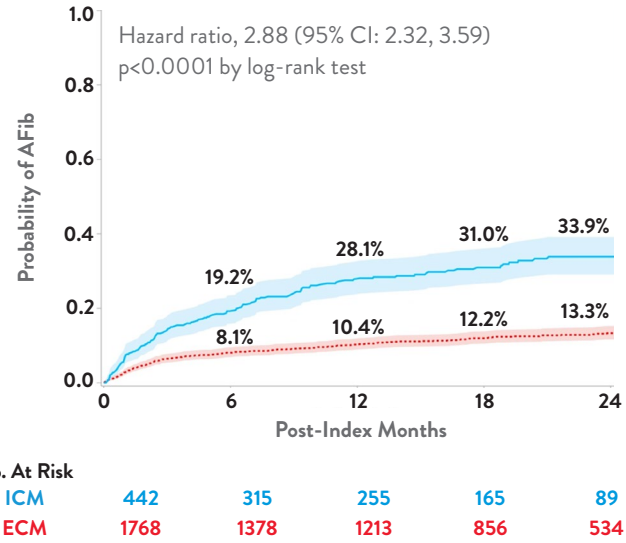
HIGHER **DIAGNOSIS RATES**

Longer monitoring duration leads to higher AFib diagnosis rates.[14]

FASTER AFIB DIAGNOSIS FOUND WITH REAL-WORLD EVIDENCE

A nationwide study of U.S. Medicare beneficiaries with cryptogenic stroke who received an ICM or an external cardiac monitor (ECM) after ischemic stroke demonstrates ICMs provide effective AFib detection and lead to increased oral anticoagulant (OAC) therapy, with almost three times more AFib and OAC rates compared to ECMs.[12]

New AFib Diagnosis in ICM vs ECM Patients



No. At Risk					
ICM	442	315	255	165	89
ECM	1768	1378	1213	856	534

3X FASTER

AFib diagnosis for ischemic stroke patients monitored with an Abbott ICM compared to ECMs.[12]

~3X MORE

ICM patients protected with an OAC at 1.5 years compared to ECM patients.[12]

GUIDELINES RECOMMEND AN **ICM FOR AFIB DETECTION** FOR PATIENTS WITH **CRYPTOGENIC STROKE**

2019 AHA/ACC/HRS Atrial Fibrillation Guidelines

Recommends use of an ICM in patients with cryptogenic stroke (Class IIa, LOE B-R).[15]

RECOMMENDATION	COR	LOE
In patients with cryptogenic stroke (i.e., stroke of unknown cause) in whom external ambulatory monitoring is inconclusive, implantation of a cardiac monitor (loop recorder) is reasonable to optimize detection of silent atrial fibrillation.	**IIa**	**B-R**

2020 European Society Guidelines: Management of Atrial Fibrillation

In patients with stroke and without diagnosed AFib, additional monitoring by non-invasive ECG monitor or injectable recorder should be considered in the long-term.[16]

RECOMMENDATION	CLASS	LEVEL
In stroke patients, additional ECG monitoring by long-term non-invasive ECG monitors or implanted loop recorders should be considered to document silent atrial fibrillation.	**IIa**	**B**

COST EFFECTIVENESS OF CONTINUOUS MONITORING

- ICMs are a cost-effective intervention to prevent recurrent stroke in patients following cryptogenic stroke in U.S., European, and Australian healthcare systems.[17-19]
- Cost-effectiveness models demonstrate ICMs implanted immediately versus delayed (after Holter monitoring) save payers money per quality-adjusted life year (QALY).
    - **$26,342 to $42,967 savings** per QALY by preventing additional strokes.[17-19]
    - Cost savings increase among subgroup analyses with lower CHA2DS2-VASc scores.[17,18]
- In the U.S. model, immediate ICM implant is associated with **60 fewer strokes per 1,000 patients** when compared to standard of care intermittent ECG and Holter monitoring for AFib diagnosis and treatment.[17]

ADVANCED
AFIB ALGORITHM

- With Assert-IQ™ ICM, you can detect arrhythmias more accurately,* with industry-leading advanced algorithms that provide clinically actionable data.
- **5-step AFib detection discriminator** focuses on R-R interval patterns and P-waves in EGMs to verify if a detected AFib event is true or false.

5-STEP SEQUENTIAL AFIB DETECTION DISCRIMINATOR

Interval-Based Steps

1. Pattern Recognition
2. R-Wave Undersensing
3. T-Wave Oversensing

Morphology-Based Steps

4. P-Wave Oversensing
5. P-Wave Detection

*Compared to predicate ICM devices

WHY ASSERT-IQ™ ICM?

SMALL

Slim design; not noticeable after insertion in most patients.

INTELLIGENT

Advanced diagnostic capabilities enable more informed decision making.*

FAST

The transmitter checks in with the device every 20 seconds, so patients are continuously monitored.

LATEST BLUETOOTH®-ENABLED TECHNOLOGY

Automatic, seamless transmission of patient information while they go about their normal day.

LONGEST BATTERY LIFE

Building on a reputation for innovation, Assert-IQ EL+ is the longest lasting Bluetooth®-enabled ICM that operates at full functionality beyond six years with no compromises,[20-28] making it an effective tool to support the expanding patient management needs of your practice.**

** Compared to predicate ICM devices*

*** DM5500*

NO COMPROMISE WITH **MRI SCANS**

Assert-IQ™ ICM is MR Conditional for both 1.5 Tesla (T) and 3T full-body scans. There is no wait limit after insertion, which allows timely patient care.*

Choose between two longevity options to support atrial fibrillation detection and arrhythmia management for your patients.

Assert-IQ™ 3/3+
(DM5000/DM5300)

3 YEAR; May be preferred for traditional cardiac monitoring.

Assert-IQ™ EL+
(DM5500)

6 YEAR; Longer term monitoring; May be preferred for AFib management.

Actual sizes represented.

Assert-IQ™ ICM. **Only from Abbott.**

Powered by SyncUP™ Remote Monitoring Support and myMerlin™ Mobile App, Assert-IQ ICM provides the flexibility to deliver data the way you and your patients need.

** No minimum length of time requirement between implant and MRI scan. For additional information, including warnings, precautions, and potential adverse events, please refer to the Abbott MRI-Ready Systems Manual at* ***https://medical.abbott/manuals*** *or visit* ***cardiovascular.abbott/mriready****.*

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Experience a Faster Diagnosis with **Assert-IQ™ ICM**

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: The Assert-IQ™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses.

The Assert-IQ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Assert-IQ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Assert-IQ ICM has not been specifically tested for pediatric use.

Intended Use: The Assert-IQ ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

Contraindications: There are no known contraindications for the insertion of the Assert-IQ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Potential Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: allergic reaction, bleeding, chronic nerve damage, erosion, excessive fibrotic tissue growth, extrusion, formation of hematomas or cysts, infection, keloid formation and migration.

Refer to the User's Manual for detailed indications for use, contraindications, warnings, precautions and potential adverse events.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

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