Medtronic

Micra™ leadless pacemakers

The leader in leadless.

Micra™ VR2

The world's smallest pacemaker[1]

Micra™ AV2

Available with smarter AV synchrony[2]

Establishing the rhythm.
Pioneering what's possible.

Introducing the next generation of Micra™ leadless pacemakers

Micra AV2 and Micra VR2

Extended longevity

- Micra AV2 has a projected median longevity of 15.6 years – which is 44 percent more than its predecessor, Micra AV.[2]
- Micra VR2 has a projected median longevity of 16.7 years – which is 36 percent more than its predecessor, Micra VR.[2]
- This increased battery life means that more than 80 percent of patients are projected to need one Micra device for life.[2] These innovations required zero change to the device size.

Smarter algorithms

- The enhanced Micra AV2 algorithms boast improvements to performance and efficiency by automatically customizing AV synchrony settings for each patient.[2]
- These automatic adjustments reduce the need for manual programming by more than 50 percent compared to its predecessor, Micra AV.[2]
- The smarter algorithm also improves automatic AV synchrony at faster heart rates between 80–100 bpm,[2] and the upper tracking rate limit is now 135 bpm.

Enhanced delivery system

- The delivery system now has a rounded catheter edge with more surface area to decrease tip pressure during device implant.[3]
- Micra AV2 and Micra VR2 devices are implanted with the same streamlined procedure as previous Micra devices.

93%

smaller than conventional pacemakers[1]

25,000+

patients followed in research activities[4]

Unmatched leadless pacing experience

Redefined patient experience

- No chest scar
- No bump
- No visible or physical reminder of a pacemaker under the skin
- Fewer post-implant activity restrictions

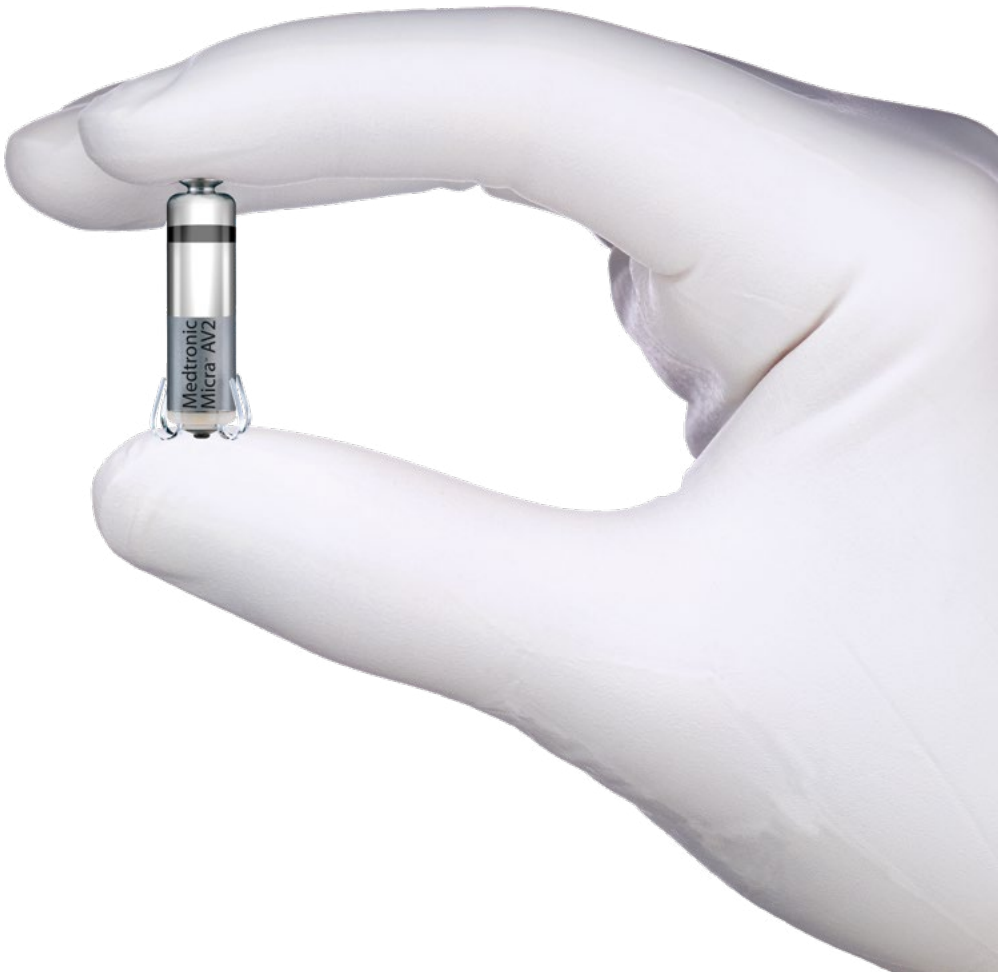
Together,
we can provide new opportunities to redefine the patient experience and reduce complications associated with traditional pacing technology.[6]

Eliminated pocket-related complications[5]

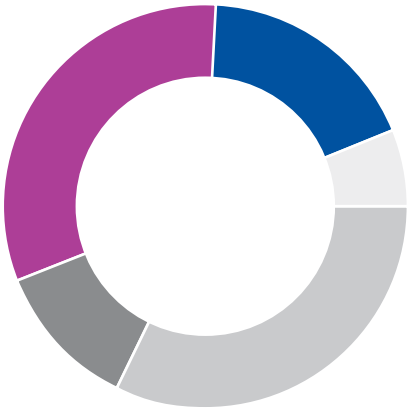
- Infection
- Hematoma
- Erosion

Eliminated lead-related complications[5]

- Fractures
- Insulation breaches
- Venous thrombosis and obstruction
- Tricuspid regurgitation



Unmatched leadless pacing experience



Micra leadless pacemakers are the world's smallest pacemakers for bradyarrhythmia management.[1]

Micra AV2 provides improved automatic AV synchrony,[2] allowing more of your patients to benefit from leadless pacing.

Pacing capsule technical specifications

Parameter	Micra AV2	Micra VR2
Pacing mode	VVI, VVIR, VOO, OVO, VDD, VDI, ODO, OFF	VVI, VVIR, VOO, OVO, OFF
Mass	1.75 g	1.75 g
Volume	0.8 cc	0.8 cc
Electrode spacing	18 mm	18 mm
Battery longevity	15.6 years[2]	16.7 years[2]
Programmer	CareLink SmartSync™ Device Manager	CareLink SmartSync™ Device Manager
Accelerometer-based mechanical atrial sensing	✓	N/A
Accelerometer-based rate response	✓	✓
MRI SureScan™	≤ 3 T	≤ 3 T
Capture Management™	✓	✓
FlexFix nitinol tines	✓	✓
CareLink™ Remote Monitoring	✓	✓

†AVB-only patients who would benefit from leadless pacing per the indications for use.

Anode

- Bipolar pacing

Cathode

- Steroid-eluting electrode
- Separated from FlexFix tines to ensure optimal contact with myocardium

Proximal retrieval feature

- Micra can be snared and retrieved using commercially available tools, if preferred

FlexFix nitinol tines

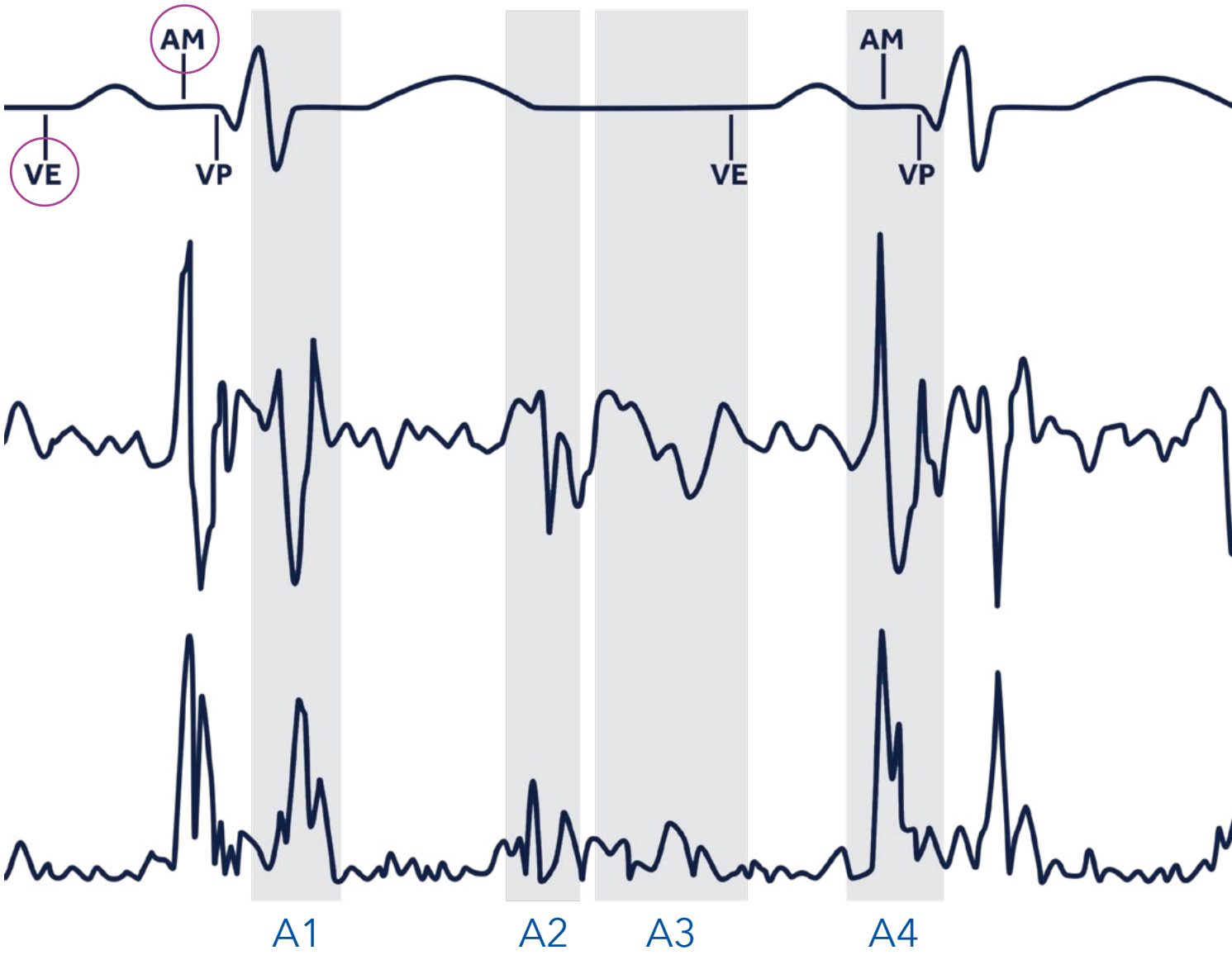
- Multidimensional redundancy: two tines have 15 times the holding force necessary to hold the device in place[8]
- Designed to minimize tissue trauma during deployment, repositioning, and retrieval[9]
- Optimal electrode tissue interface allows for low and stable chronic thresholds[10]

AV synchrony reimagined

The world's smallest pacemaker[1]

Available with smarter AV synchrony[2]

- The Micra AV2 accelerometer detects mechanical atrial activity and uses this information to deliver AV synchronous ventricular pacing
- Delivers an estimated median projected longevity of 15.6 years[2]



Ventricular end (VE) marker

Pacemaker timing indication of A3 window end. Should fall at the end of the A1–A3 ventricular event signals.

Atrial mechanical (AM) marker

Marker that indicates the device detected the atrial mechanical contraction or A4.

Electrocardiogram

Source accelerometer

Rectified accelerometer

A1

Start of ventricular systole, mitral, and tricuspid valves close

A2

End of ventricular systole, aortic, and pulmonic valves close

A3

Diastole, passive blood flow from A to V, corresponds to E-wave on Doppler echo

A4

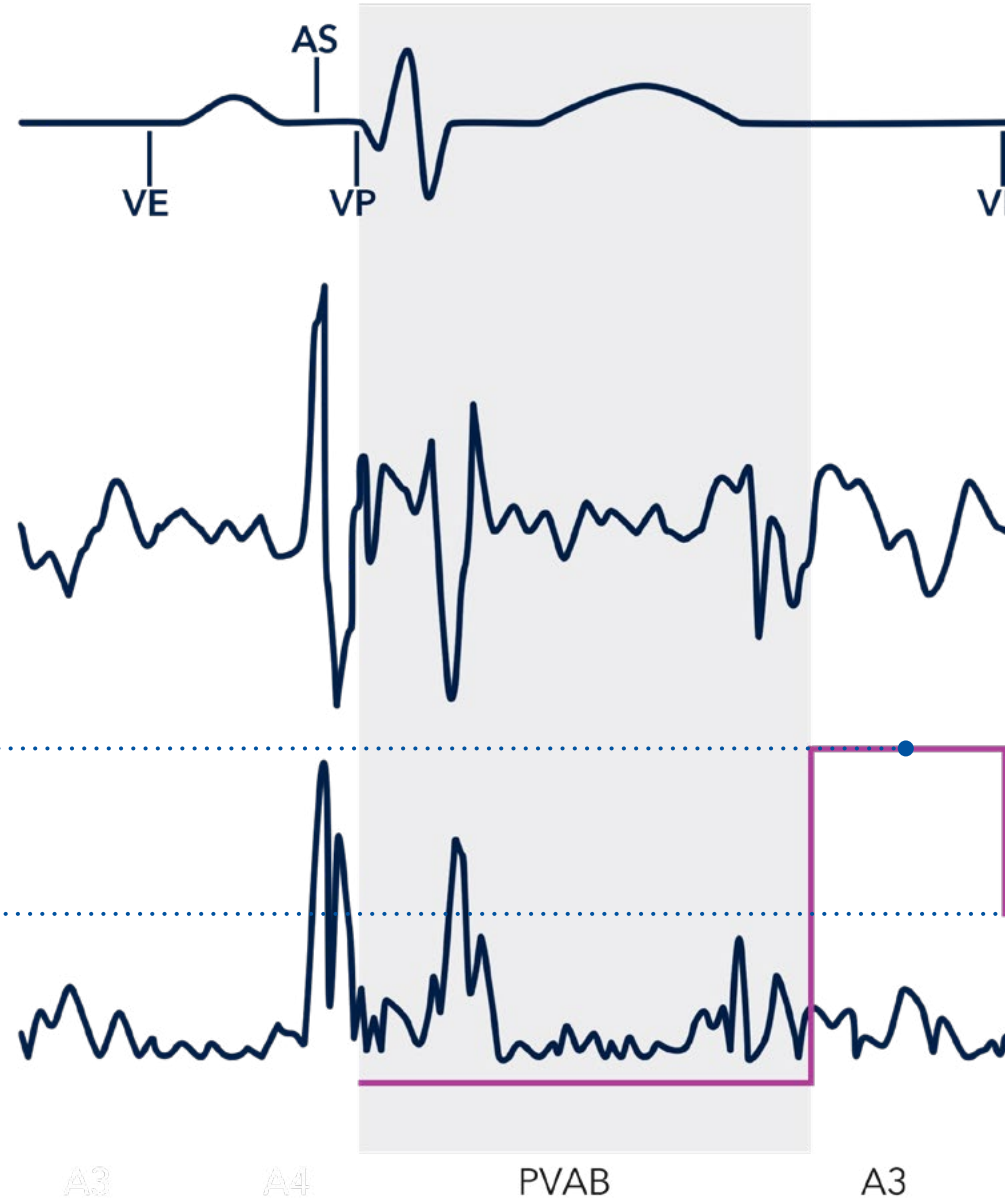
Atrial systole, blood pushed into ventricles, 100 ms electromechanical delay, corresponds to A-wave on Doppler echo

A7

Occurs when the A3 and A4 signals fuse at higher sinus rates: passive and active filling of the ventricles occurs simultaneously, resulting in a larger amplitude signal.

AV synchrony reimagined

Micra AV2 accelerometer signals explained



A3 threshold

Needs to be set higher than the A3 signal, but lower than the A7 signal.

A4 threshold

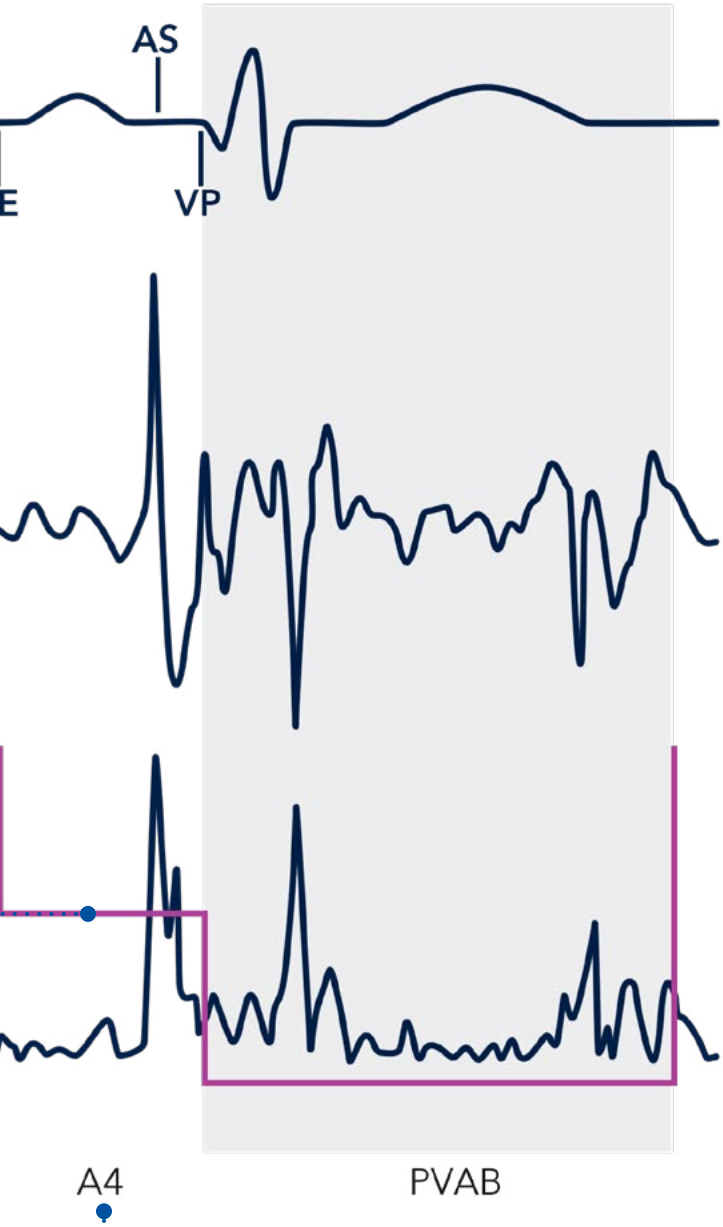
Needs to be set lower than the A4 signal but higher than the noise floor.

Post-ventricular atrial blanking (PVAB) period

The A1 and A2 signals are blanked. No atrial sensing occurs during PVAB.

A3 detection window

A less-sensitive setting where only large accelerometer signals will trigger a detection. It is designed to avoid detecting the A3 signal while still detecting the A7 signal.



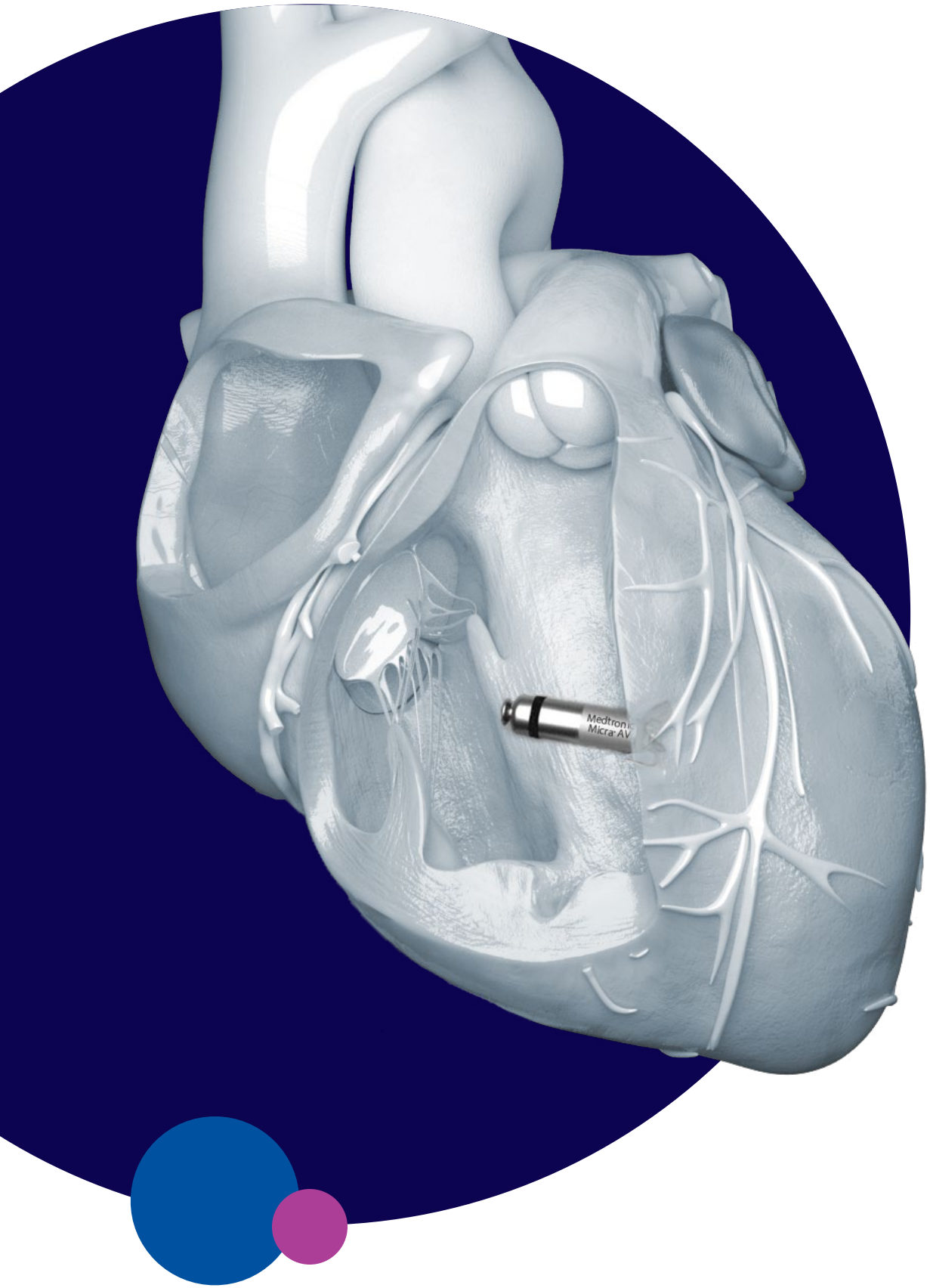
Electrocardiogram

Source accelerometer

Rectified accelerometer

A4 detection window

Used to detect the A4 signal after ventricular diastole has completed.


Medtronic
Micra AV

AV synchrony algorithms

Learn what's new with Micra AV2

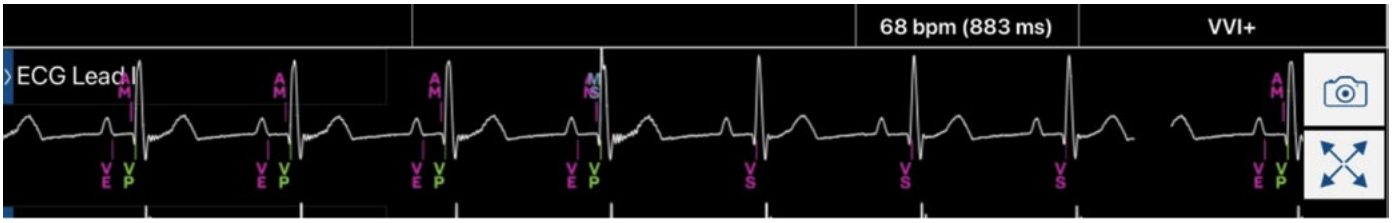
AV Conduction Mode switch

Micra AV2 will mode switch to VVI+ during periods of intact AV conduction to promote intrinsic rhythm in patients with episodic AV block.

- Designed to limit amount of RV pacing and maximize device longevity by disabling atrial sensing during mode switch
- Works by periodically dropping into VVI+ at AV Conduction Mode Switch Lower Rate and switches back to VDD when device paces

Micra AV2 provides a programmable AV Conduction Mode Switch Lower Rate versus fixed 40 bpm in Micra AV.

- Provides more flexibility to leave mode switch on for patients who have idioventricular rates > 40 bpm or high sinus rates with 2:1 block



Atrial Sensing Setup

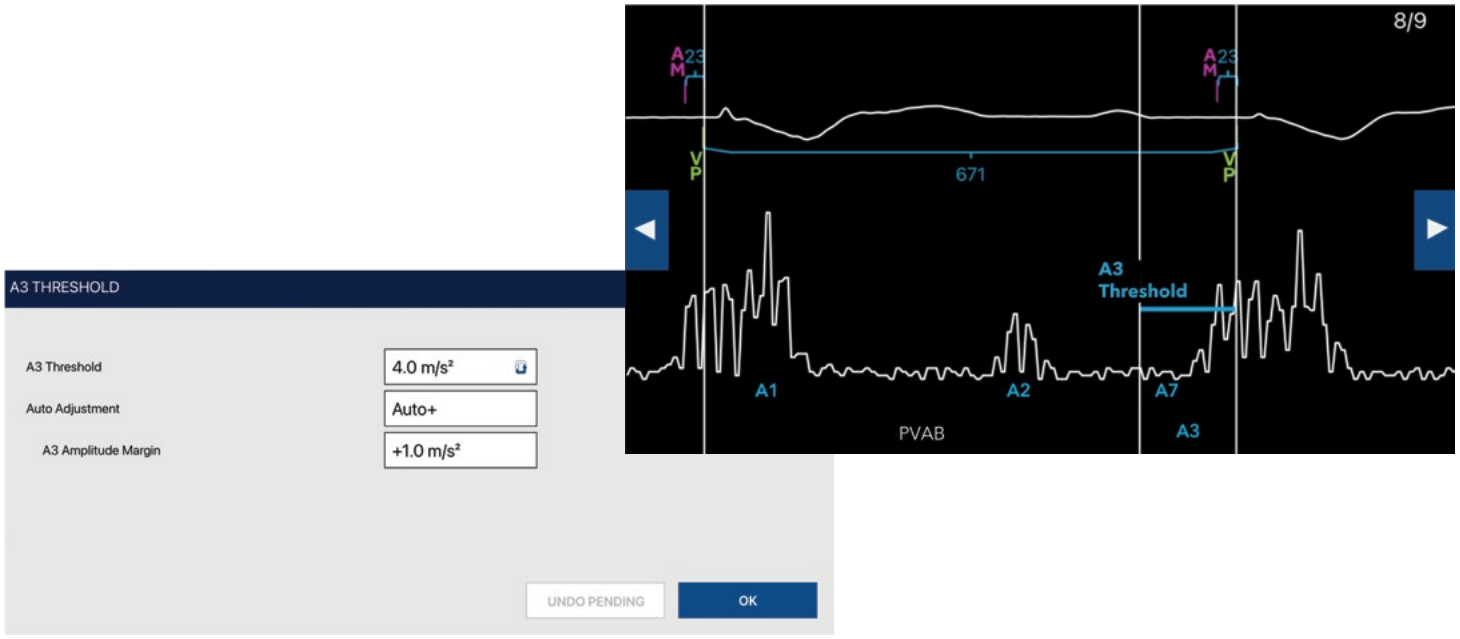
Micra AV2 will automatically set up AV synchrony parameters Atrial Sensing Vector, A3 and A4 Threshold, and A3 Window End related parameters after implant.

- Collects A3 and A4 signal data in VDI mode and then refines settings in VDI and VDD modes. Micra AV2 filters the A3 and A4 signal data for a more accurate method of setting these parameters.[2]
- Reduces need for manual programming by > 50 percent post-Atrial Sensing Setup[2]

Auto+ A3 Threshold

Micra AV2 offers a new algorithm, Auto+, to automatically adjust the A3 Threshold.

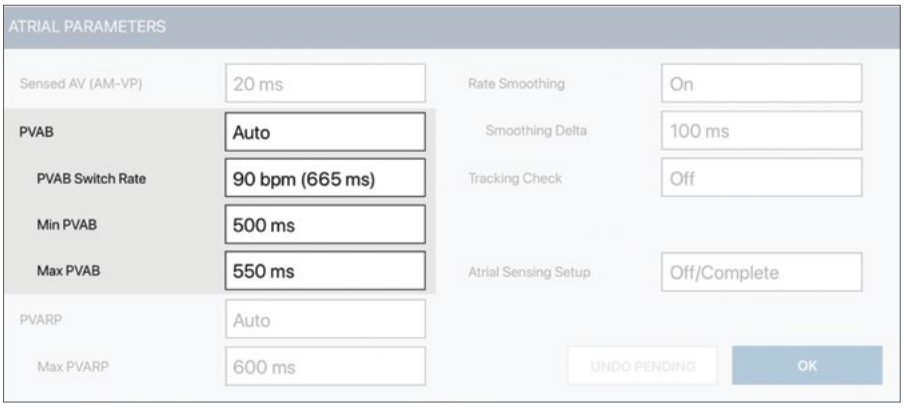
- Auto+ uses filtered, true A3 signal amplitudes to automatically set the A3 Threshold above the A3 signal, but below the A7 signal (summated A3 + A4 signal)
- Sensing of the A7 signal allows tracking at higher heart rates (> 85 bpm)
- Auto+ automatically provides better AV synchrony in the range of 80–100 bpm when directly compared to Auto A3 Threshold[2]



Auto PVAB and Upper Tracking Rate

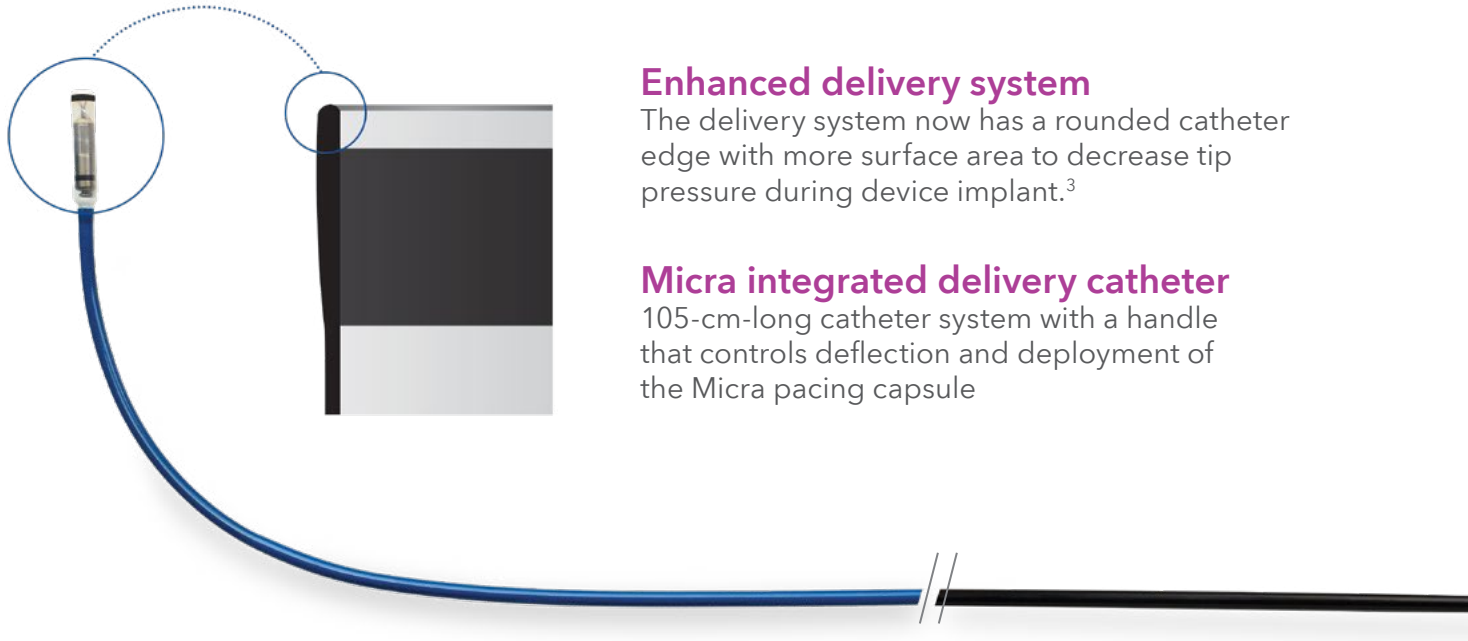
Micra AV2 offers an Auto PVAB algorithm which adjusts PVAB based on ventricular rate.

- When set to Auto, the device switches from the Max PVAB to Min PVAB setting at the PVAB Switch Rate, allowing for a dynamic PVAB
- To benefit patients who are active, Micra AV2 has a higher available tracking capability for faster heart rates.[2] The shortest Min PVAB setting of 425 ms and expanded Upper Tracking Rate settings allow tracking up to 135 bpm, compared to 115 bpm on the previous generation Micra AV.



Same streamlined procedure

with an enhanced delivery system

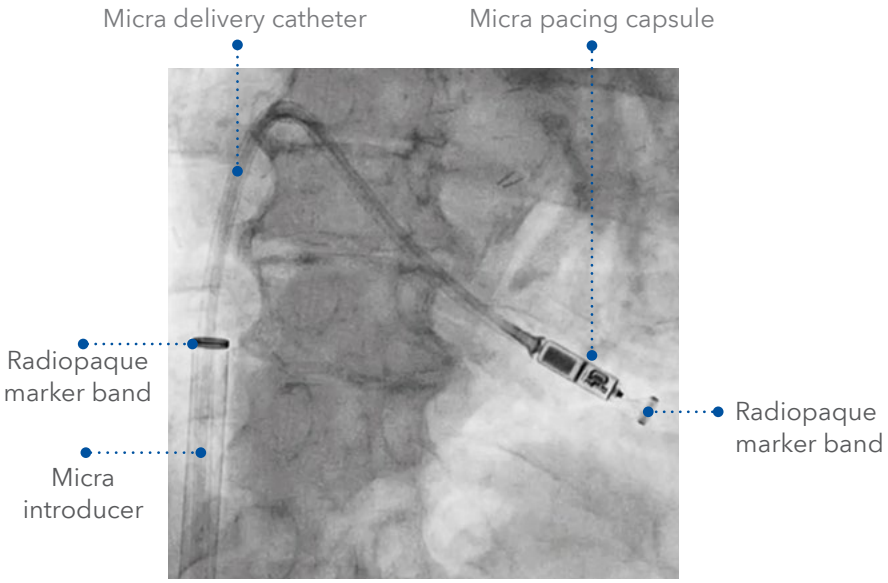


Enhanced delivery system

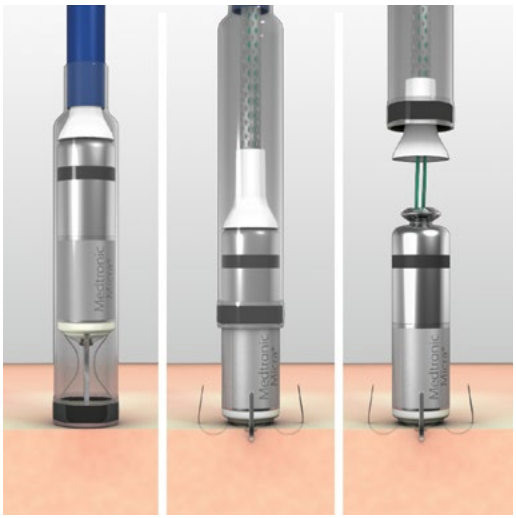
The delivery system now has a rounded catheter edge with more surface area to decrease tip pressure during device implant.[3]

Micra integrated delivery catheter

105-cm-long catheter system with a handle that controls deflection and deployment of the Micra pacing capsule



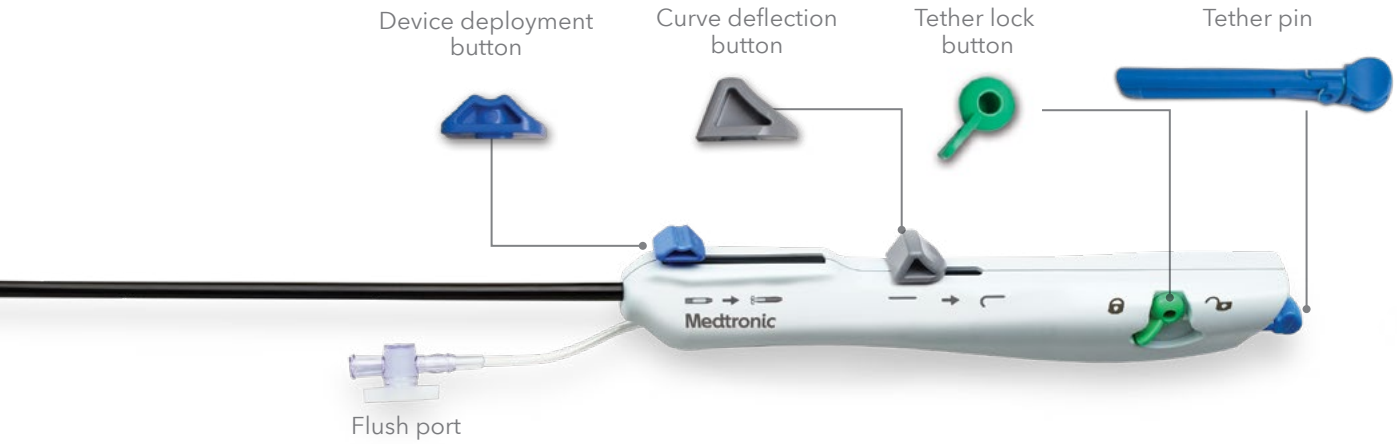
Delivery catheter provides visual feedback when adequate tip pressure has been achieved, and retracts during deployment.



Linear one-step deployment facilitates consistent capsule placement; no torque required.[8]

>99%

implant success in
Micra VR clinical studies[11,12]



Smooth vessel navigation with the Micra introducer

- Lubricious hydrophilic coating
- 23 Fr inner diameter (27 Fr outer diameter)
- Silicone oil-coated dilator tip

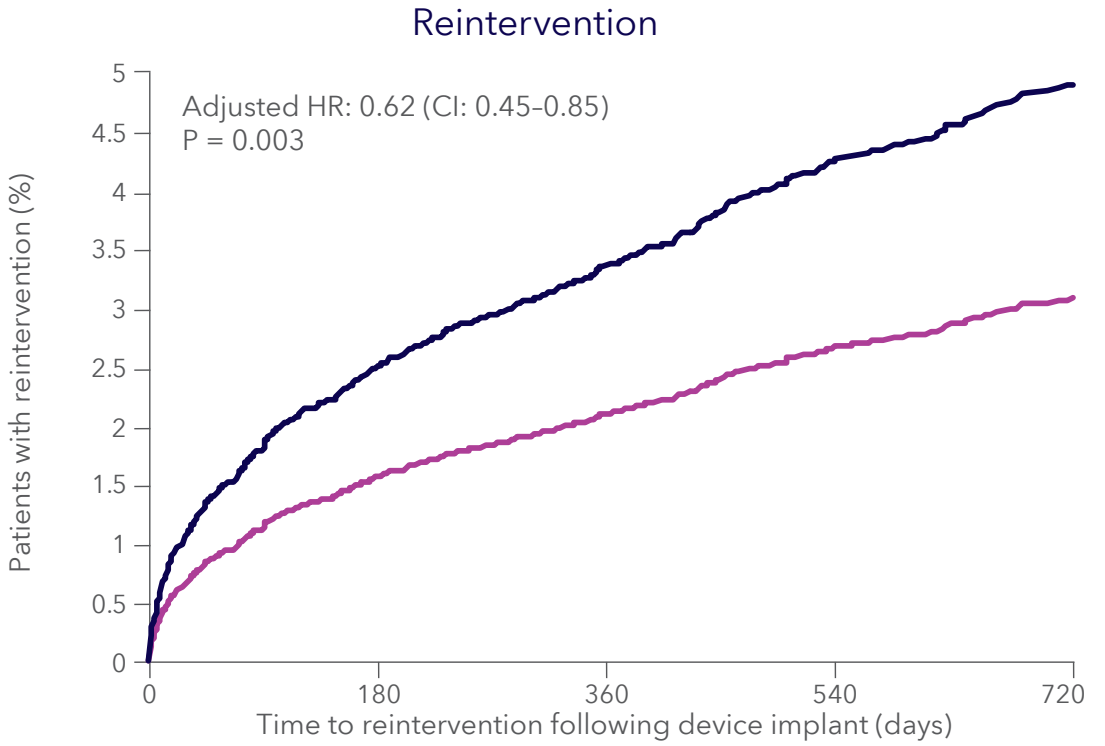
Device life cycle management options

- Micra is designed to offer options at the end of service
  - Micra, designed as the world's smallest pacemaker,[1] can be left in place at end of service because of its small size. When programmed OFF, it can be differentiated from subsequent devices.
  - Micra, also designed with a proximal retrieval feature, can be removed when preferred. Successful retrieval has been demonstrated after four years.[13]

Clinical evidence

The largest claims-based evaluation of leadless pacemakers to date[14]

Micra VR, n = 6,219;
transvenous-VVI, n = 10,212



No. at risk					
Leadless	6,219	5,236	4,742	2,665	1,194
Transvenous	10,212	8,671	7,899	5,353	2,914

38%

reduction in the rate of reintervention through two years for patients receiving Micra VR vs. TV-VVI.

31%

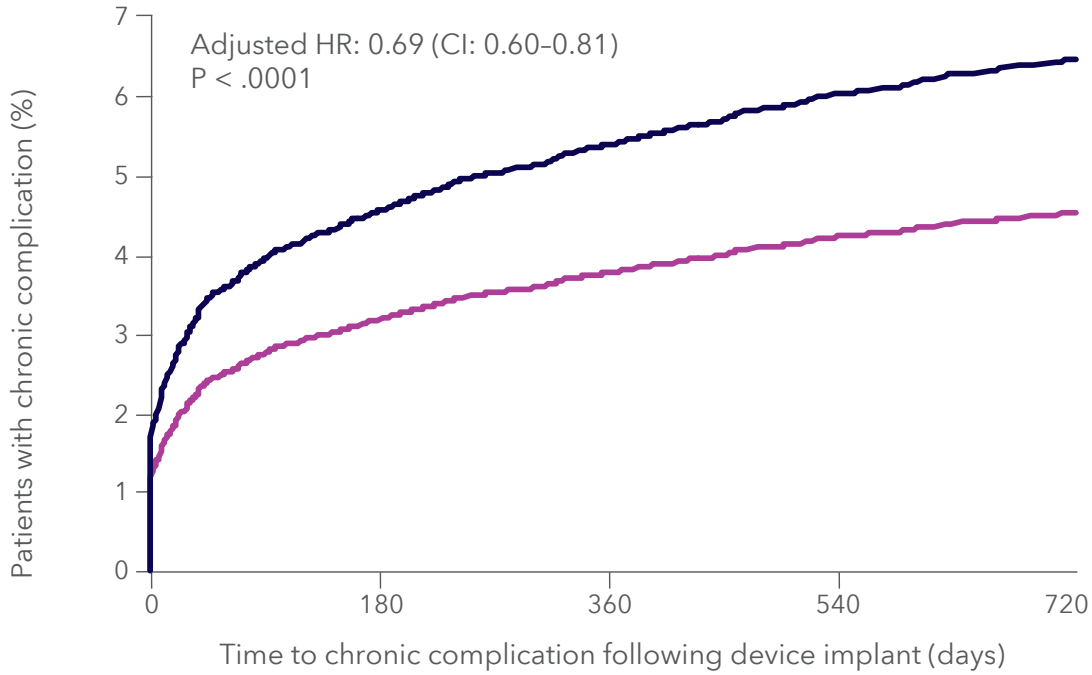
reduction in the rate of chronic complications through two years for patients receiving Micra VR vs. TV-VVI.

No significant difference in all-cause mortality through two years for patients receiving Micra VR vs. TV-VVI

(adjusted HR: 0.97, 95% CI: 0.91–1.04, P = 0.37)

The advantages associated with leadless pacing at two years persist and continue to accrue at three years.[15]

Chronic complication



No. at risk					
Leadless	6,219	5,142	4,659	2,631	1,183
Transvenous	10,212	8,556	7,807	5,300	2,863

Clinical evidence

63%
fewer major complications than traditional pacemakers[†11]

Micra VR procedural performance in clinical study

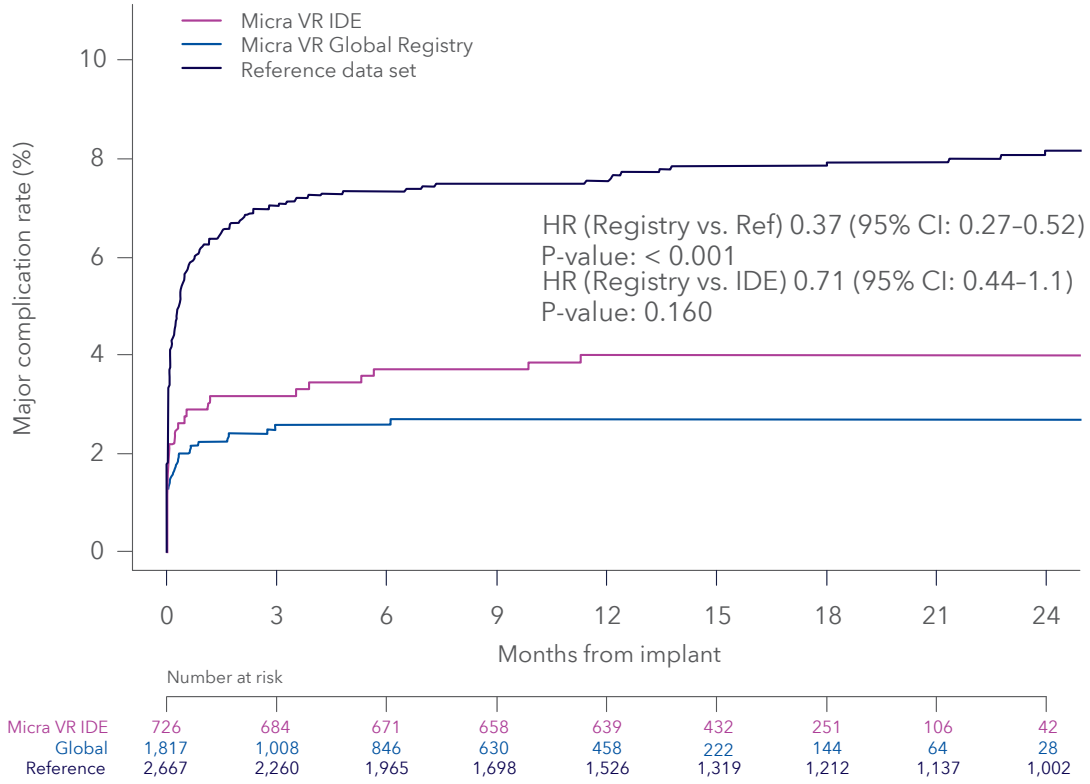
Data from Micra VR IDE and PAR

Primary prespecified safety, effectiveness, and long-term safety objectives were met (n = 726)[12,16]

- 96% of patients experienced no major complications by 12-month follow-up[16]
  - 0 dislodgements or systemic infections
  - Low (0.4%) revision rate
- Pacing thresholds remained low and stable through 12 months[16]

Real-world experience reinforces safety and long-term performance of Micra VR (n = 1,817)[11]

- High implant success rate (99.1%)
- Low major complication rate through 12 months (2.7%)
  - Low dislodgement rate (0.06%)
  - Low procedure-related infection rate (0.17%)



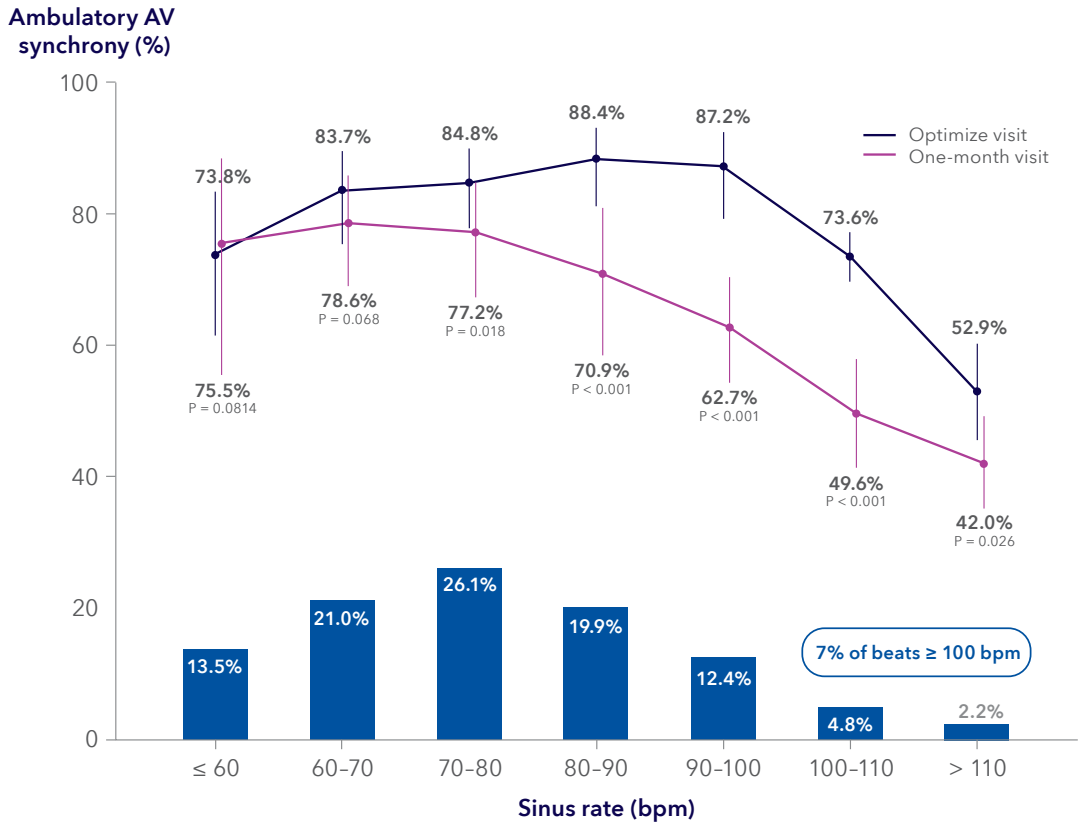
[†]Historical cohort comprised of 2,667 patients from six trials of commercially available technology (HR: 0.46, 95% CI: 0.30–0.72; P-value < 0.001). To adjust for difference in patient populations, propensity matching to a subset of the historical control confirmed a reduction in major complications with Micra VR.

Micra AV algorithm performance

Data from Micra AccelAV study

- The Micra AccelAV study was a prospective, single-arm, multicenter, global study that reported on the performance of the Micra AV leadless pacemaker (n = 152).
- Primary analysis cohort (n = 54) had complete AV block and normal sinus function. The optimized sub-study cohort (n = 20) had complete AV block, normal sinus function, and optimized programming.
- Primary endpoint was to characterize the rate of AV synchrony during a 20-minute resting period at one month post-implant.
- Results showed resting AV synchrony at **85.4%** and stable through three-month follow-up and ambulatory AV synchrony at **82.6%** with optimized programming.[17]
- **No upgrades** through three months and no major complications due to pacemaker syndrome.[17]
- Micra AccelAV study concludes that Micra AV is a proven therapy for patients with complete AV block and normal sinus function.[17]
- Optimized programming recommendations from the Micra AccelAV study have been automated in the Micra AV2 algorithms.[2]

Improved ambulatory AV synchrony with optimized programming



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Brief Statement
Micra™ VR2 and Micra™ AV2
Indications

Micra Model MC1VR01, Micra VR2 Model MC2VR01, and Micra AV Model MC1AVR1, are indicated for use in patients who have experienced one or more of the following conditions:

- Paroxysmal or permanent high-grade AV block in the presence of AF
- Paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy
- Symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when a dual-chamber transvenous pacing system is considered difficult, high risk, or not deemed necessary for effective therapy

Micra AV Model MC1AVR1 is also indicated for VDD pacing in patients with adequate sinus rates who may benefit from maintenance of AV synchrony. The Micra AV device provides AV synchronous ventricular pacing similar to a transvenous VDD system. The implanted device depends on the appropriate sensing of atrial mechanical signals to achieve AV synchrony. The level of AV synchrony may vary in individual patients and may not be predictable prior to implant.
Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.
The device is designed to be used only in the right ventricle.

Micra AV2 Model MC2AVR1 is indicated for VDD pacing in patients when a dual chamber transvenous pacing system is considered a poor option or not deemed necessary for effective therapy, and when a right ventricular transcatheter pacing system promoting AV synchrony at rest is acceptable. Conditions when a patient is considered a poor candidate for transvenous pacing may include, but are not limited to, tortuous anatomy, a need to preserve venous access, or increased risk of infection. The device provides AV synchrony at rest and rate responsive (VVIR) pacing during periods of high patient activity.
Device-mediated AV synchrony can vary depending on patient condition and activity levels, and it can be limited at high sinus rates. During periods of intermittent AV synchrony, the device will provide ventricular pacing support with an increased potential for pacing rate variability. Micra AV2 is indicated for use in patients who have experienced one of the following:

- Paroxysmal or permanent high-grade AV block in the absence of AF
- Paroxysmal or permanent high-grade AV block in the presence of paroxysmal AF
- Paroxysmal or permanent high-grade AV block in the presence of persistent AF when attempts at restoring sinus rhythm are still planned

The device is designed to be used only in the right ventricle.

Contraindications

Micra Model MC1VR01, Micra AV Model MC1AVR1, Micra VR2 Model MC2VR01 and Micra AV2 Model MC2AVR1 are contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device.

The device is contraindicated for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤12.5 cm (4.9 in), or known intolerance to the materials listed in the Instruction for Use, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated, or if the steroid dose from this device cannot be tolerated.

Warnings and Precautions

End of Service (EOS) – When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device, provided the device has not yet become encapsulated. Removal of the Micra device after it has become encapsulated may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.
MRI conditions for use – Before an MRI scan is performed on a patient implanted with the Micra device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks as defined in the device manuals.
Rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate. The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.
Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.
The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explanation of the Micra device, which should be turned off.
For Micra AV Model MC1AVR1 and Micra AV2 Model MC2AVR1, patient activities and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in a loss of AV synchrony.

Potential Adverse Events or Potential Complications

Potential complications include, but are not limited to, toxic/allergic reaction, oversensing, pacemaker syndrome, cardiac arrest, and surgical complications such as cardiac perforation, pericardial effusion, cardiac tamponade, device embolization, hematoma, AV fistula, vessel dissection, infection, cardiac inflammation, and thrombosis.

See the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, MRI conditions for use, and potential complications/adverse events. For further information, please call Medtronic at 800-328-2518 and/or consult Medtronic's 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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