

# CLINICAL **EVIDENCE** GUIDE





# SAFETY & **EFFICACY**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	Duray GZ, et al. Long-term performance of a transcatheter pacing system: 12-Month	To assess the long-term safety of Micra at 12 months	There were 48% fewer major complications with Micra than
MICRA <sup>™</sup> AV	<b>results from the Micra Transcatheter</b> <b>Pacing Study.</b> <i>Heart Rhythm</i> . May 2017;14(5):702-709.	and electrical performance through 24 months (n = 726).	transvenous pacemakers through 12 months. Pacing thresholds remained low and stable at 24 months.
DEVICE TECHNOLOGY	El-Chami MF, et al. Updated Performance of the Micra Transcatheter Pacemaker in the Real-World Setting: A Comparison	To evaluate performance of Micra through 12 months when used in real-world	Implant success rate was 99.1%. The major complication rate was 2.7% through 12 months post-implant,
IMPLANT PROCEDURE & CONSIDERATIONS	to the Investigational Study and a Transvenous Historical Control. Heart Rhythm. December 2018;15(12):1800-1807.	clinical practice (n = 1,817).	representing a 63% reduction in risk relative to transvenous systems.
INFECTION	Piccini JP, et al. Need for System Revision With Leadless Pacemakers in Extended Follow-up: Updated Results from the	To report major complications and system revisions through 3 years	The major complication rate at 36 months was 3.5% and was 58% lower than that for patients with transvenous
DEVICE LIFE CYCLE MANAGEMENT	<b>Micra Transcatheter Pacing System</b> <b>Post-Approval Registry.</b> Heart Rhythm. 2020;17(5S):S229.	from the worldwide Micra post-approval registry (n = 1,815).	pacemakers. All-cause system revision revisions were infrequent and occurred 53% less often compared to
PATIENT CASE STUDIES		<b>–</b>	transvenous systems.
QUALITY OF LIFE	Reynolds D, et al. <b>A Leadless Intracardiac</b> <b>Transcatheter Pacing System.</b> <i>N Engl J</i> <i>Med.</i> June 30, 2016;374(26):2604-2605.	To report major complications and electrical performance through 6 months (n = 725).	Implant success rate was 99.2%. 96.0% of patients experienced no major complications at 6 months, zero dislodgements, and zero systemic infections. 98.3% of patients had
BIBLIOGRAPHY — JULY 2020			adequate pacing thresholds at 6 months.



## **MICRA** AV

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	Chinitz L, et al. Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: Results from the Micra atrioventricular feasibility studies. Heart Rhythm. September 2018;15(9):1363-1371.	To characterize the performance of an AV synchronous algorithm (MARVEL) downloaded into previously implanted Micra VR devices (n = 64).	Average AV synchrony during AV algorithm pacing was 87.0% (n = 64). AV synchrony was significantly greater (P < 0.001) during AV algorithm pacing compared to VVI in high-degree block patients, whereas AVS was maintained in patients with intrinsic conduction.
MICRA <sup>™</sup> AV			
DEVICE TECHNOLOGY	Garweg C, et al. Behavior of leadless AV synchronous pacing during atrial arrhythmias	Prospective, single-center study compared AV synchrony and accelerometer-based atrial sensing signals at two visits ≥ 6 months apart to assess performance over time (n = 9).	Both accelerometer signal amplitude (visit 2– visit 1 = $1.4 \text{ mG}$ ; 95% confidence interval [CI] [-25.8 to 28.4 mG]; P = 0.933) and AVS (visit 1: 90.8%, 95% CI [72.4, 97.4] and visit 2: 91.4%, 95% CI [63.8, 98.5]; P = 0.740) remained stable.
IMPLANT PROCEDURE & CONSIDERATIONS	and stability of the atrial signals over time- Results of the MARVEL Evolve subanalysis. <i>Pacing Clin Electrophysiol</i> . March 2019;42(3):381- 387.		
INFECTION	Garweg C, et al. <b>Predictors of Atrial Mechanical</b> <b>Sensing and Atrioventricular Synchrony with a</b> <b>Leadless Ventricular Pacemaker: Results from</b> <b>the MARVEL 2 Study.</b> <i>Heart Rhythm.</i> Published online July 24, 2020.	To identify predictors of A4 amplitude and high AV synchrony.	CABG history, E/A ratio, atrial contraction excursion, and atrial strain were associated with low A4 amplitude. High AV synchrony was predicted by an E/A ratio < 0.94 and low sinus rate variability at rest.
DEVICE LIFE CYCLE MANAGEMENT			
PATIENT CASE STUDIES	Steinwender C, et al. Atrioventricular synchronous pacing using a leadless ventricular pacemaker: Results from the MARVEL 2 Study. JACC Clin Electrophysiol. January 2020;6(1):94-106.	To report on the performance of an automated, enhanced accelerometer-based algorithm (MARVEL 2) that provides AV synchronous pacing downloaded into Micra VR devices (n = 75).	Median AV synchrony at rest in patients with complete AV block and normal sinus rhythm was $94.3\%$ (n = 40). Stroke volume increased by $1.7 \text{ cm}$ (p = 0.2) or $8.8 + 15.4\%$ during VDD pacing in patients with complete AV block and normal sinus rhythm. There were no pauses or episodes of oversensing-induced tachycardia.
QUALITY OF LIFE			

BIBLIOGRAPHY — **JULY 2020** 

Medtron	ic
Further,Together	

## DEVICE **TECHNOLOGY**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	Bari Z, et al. Physical activity detection in patients with intracardiac leadless pacemaker.	To evaluate the short- and mid- term performance of the Micra activity sensor by testing all three available activity vectors during the exercise tests (n = 51).	The three-axis, accelerometer-based rate adaptive pacing feature proved to be feasible after manual selection of an adequate
MICRA <sup>™</sup> AV	<i>J Cardiovasc Electrophysiol.</i> December 2018;29(12):1690-1696.		activity vector. Vector testing in Micra patients with chronotropic incompetence appears to be beneficial compared with the use of nominal Vector 1.
DEVICE TECHNOLOGY	Blessberger H, et al. Monocenter Investigation Micra MRI Study	To assess the safety and feasibility of cardiac magnetic resonance	Cardiac magnetic resonance imaging at either 1.5 T or 3.0 T proved feasible and safe
IMPLANT PROCEDURE & CONSIDERATIONS	(MIMICRY): Feasibility Study of the Magnetic Resonance Imaging Compatibility of a Leadless Pacemaker System. Europace. January 1, 2019;21(1):137-141. Lloyd M, et al. Rate Adaptive Pacing in an Intracardiac Pacemaker. Heart Rhythm. February 1, 2017;14(2):200-205.	imaging in patients implanted with Micra undergoing either a 1.5 T or 3.0 T cardiac MRI scan (n = 15).	in patients implanted with a Micra, with no relevant changes in device parameters within 3 months of follow-up.
INFECTION		To evaluate the rate adaptive	Accelerometer-based rate-adaptive
DEVICE LIFE CYCLE MANAGEMENT		pacing performance of Micra during treadmill tests to maximum exertion in a subset of patients within the Micra Transcatheter	pacing was proportional to workload, thus confirming rate adaptive pacing commensurate to workload is achievable with an entirely intracardiac pacing system.
PATIENT CASE STUDIES	Soejima K, et al. Safety evaluation of a leadless transcatheter pacemaker for magnetic resonance imaging use. Heart Rhythm. October 31, 2016;13(10): 2056-2063.	Pacing Study (n = 4 2). To characterize interactions of MRI with the Micra transcatheter pacemaker system using bench testing with Monte-Carlo simulations in combination with a	The MRI safety assessment tests conducted for the Micra pacemaker demonstrate that patients with a single device or multiple devices can safely undergo MRI scans in both 1.5T and 3T MRI scanners. No MRI-
QUALITY OF LIFE			
BIBLIOGRAPHY — JULY 2020		clinical case study.	related complications were observed in a patient implanted with a Micra pacemaker undergoing a clinically indicated scan.

# **IMPLANT PROCEDURE & CONSIDERATIONS**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	El-Chami MF, et al. <b>How to Implant a Leadless</b> <b>Pacemaker With a Tine-Based Fixation</b> . <i>J Cardiovasc Electrophysiol</i> . December 1, 2016;27(12):1495-501.	To describe the stages of the implant procedure for the Micra leadless pacemaker.	The critical steps for Micra implant include careful patient selection, careful navigation around the RV to avoid perforation, and careful removal of the tether at the end of the procedure. The procedure can be done in 30–40
MICRA <sup>™</sup> AV			minutes at first and then closer to 20 minutes after 5–10 implantations.
DEVICE TECHNOLOGY	El-Chami M, et al. Impact of operator experience and training strategy on procedural outcomes with leadless pacing: Insights from the Micra Transcatheter Pacing Study. Pacing Clin Electrophysiol. July 2017;40(7):834-842.	To compare the effectiveness of training modalities utilized in the Micra IDE study on procedural outcomes: laboratory- based or locally in-hospital (n = 726).	Among a large group of operators, implantation success was high regardless of experience. While procedure duration and fluoroscopy times decreased with implant number, complications were low and not associated with case number. Procedure and safety outcomes were similar between distinct training methodologies.
IMPLANT PROCEDURE & CONSIDERATIONS	Kiani S, et al. A Predictive Model for Long Term Leadless Pacemaker Performance: Experience with the Micra Transcatheter Pacemaker. <i>Heart Rhythm</i> . 2020;17(5S):235.	To formulate a predictive model for describing long-term electrical performance of Micra (n = 1,843).	75 patients (4.1%) had elevated thresholds at 12 months, of which 13 required system revision. Multivariable regression modeling found male, sex, history of diabetes, implant PCT $\ge$ 2V, and impedance < 800 Ohms were independent predictors of elevated PCT at 12 months (p < 0.05).
INFECTION	Lenarczyk R, et al. Peri-procedural management, implantation feasibility, and short-term outcomes in patients undergoing implantation of leadless pacemakers: European Snapshot Survey. <i>Europace</i> . May 1, 2020;22(5):833-838.	To assess procedural settings, safety measures, and short-term outcomes associated with implantation of leadless pacemakers (LLPM) by surveying a broad range of tertiary European electrophysiology centers (n = 21 centers, n = 69 patients).	Despite a relatively unfavorable clinical profile of patients (including frequent need for anticoagulation), leadless pacemaker implantation remains safe and is associated with a low risk of complications.
DEVICE LIFE CYCLE MANAGEMENT			
PATIENT CASE STUDIES	Piccini JP, et al. Long-term outcomes in leadless Micra transcatheter pacemakers with elevated thresholds at implantation: Results from the Micra Transcatheter Pacing System Global Clinical Trial. <i>Heart Rhythm</i> . May 31, 2017;14(5):685-691.	To characterize acute elevated thresholds for Micra vs traditional transvenous leads (n = 720).	Pacing thresholds in most Micra patients with elevated thresholds decrease after implant. Micra device repositioning may not be necessary if the pacing threshold is ≤ 2 V.
QUALITY OF LIFE			
BIBLIOGRAPHY — JULY 2020	San Antonio R, et al. <b>Management of</b> anticoagulation in patients undergoing leadless pacemaker implantation. <i>Heart</i> <i>Rhythm</i> . December 1, 2019;16(12):1849-1854.	To assess the incidence of bleeding and thromboembolic complications after Micra implantation at a single center with and without therapeutic anticoagulation ( $n = 107$ ).	Bleeding and thromboembolic complications after receiving Micra TPS are infrequent. The use of anticoagulant therapy, regardless of the type (including vitamin K antagonists, new oral anticoagulants, and enoxaparin), does not increase the complications associated with the procedure.

Medtronic
Further,Together

# **INFECTION**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	El-Chami MF, et al. Leadless Pacemaker Implant in Patients with Pre-Existing Infections: Results	To report implant procedure characteristics and outcomes among patients undergoing Micra implant within 30 days of CIED explant for infection (n = 105).	Implant success rate was 99%. Micra was implanted on same day as CIED explant in 37% of patients. There were no recurrent infections requiring Micra device removal.
MICRA <sup>™</sup> AV	from the Micra Post-Approval Registry. <i>J</i> <i>Cardiovasc Electrophysiol</i> . April 2019;30(4):569- 574.		
DEVICE TECHNOLOGY	El-Chami MF, et al. Leadless pacemakers reduce risk of device-related infection: Review of the potential mechanisms. <i>Heart Rhythm</i> .	This publication reviews the current state of evidence regarding the apparent infection resistance of leadless pacemakers.	Several potential design factors, including absence of pocket/lead and parylene coating, were identified that may contribute to apparent bacterial resistance. Positive physiologic effects may also prevent infection including device encapsulation and turbulent blood flow at implant location.
IMPLANT PROCEDURE & CONSIDERATIONS	August 2020;17(8):1393-1397.		
INFECTION	El-Chami MF, et al. Incidence and outcomes of systemic infections in patients with leadless pacemakers: Data from the Micra IDE study. <i>Pacing Clin Electrophysiol</i> . August 2019;42(8):1105-1110.	To analyze the incidence and outcomes of serious infectious events (SIEs; e.g., bacteremia or endocarditis) that developed during follow-up post-Micra implantation (n = 720).	16 patients had documented SIEs during follow-up. SIEs occurred at a mean of 4.8 ± 4.5 months after implant, and all events were adjudicated as unrelated to the Micra device or procedure. No persistent cases of bacteremia after antibiotic cessation were seen over the duration of follow-up. No cases required Micra
DEVICE LIFE CYCLE MANAGEMENT			
PATIENT CASE STUDIES			removal due to device related infection.
QUALITY OF LIFE	Kypta A, et al. Leadless Cardiac Pacemaker Implantation After Lead Extraction in Patients with Severe Device Infection. <i>J Cardiovasc</i> <i>Electrophysiol</i> . September 1, 2016;27(9):1067- 1071.	To assess the safety and feasibility of Micra implant in pacemaker-dependent patients undergoing lead extraction due to severe device infection (n = 6).	Successful lead extraction and implantation of the Micra TPS system was accomplished in all 6 patients, without signs of infection at discharge. All patients remained free of infection during the 12-week follow-up
BIBLIOGRAPHY — JULY 2020			period, with no evidence of infection, including around the Micra device based upon PET scan imaging.



**JULY 2020** 

# **DEVICE LIFE CYCLE** MANAGEMENT

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	Curnis A, et al. First-in-human retrieval of chronically implanted Micra Transcatheter Pacing system. <i>Pacing Clin Electrophysiol.</i> July 2019;42(7): 1063-1065.	To characterize the retrieval of a Micra device 29 months post-implant.	The Micra device was successfully retrieved without complications. Despite 29 months of implant duration, the proximal retrieval feature of the device was free from tissue, allowing the retrieval using a
MICRA <sup>™</sup> AV			snare loop. In the same procedure, a new Micra was implanted in the high right ventricular septum with optimal pacing threshold.
DEVICE TECHNOLOGY	Grubman, et al. <b>To Retrieve, or Not to</b> <b>Retrieve: System Revisions with the</b> <b>Micra Transcatheter Pacemaker</b> . <i>Heart</i> <i>Rhythm</i> . December 2017;14(12):1801- 1806.	To characterize the system revision rate among patients from the Micra IDE and Continued Access trials (N = 989) compared to a historical control group of patients with transvenous pacemakers (N = 2,667).	The overall Micra revision rate was 1.4% at 24 months, 75% lower than that of patients with transvenous pacemakers. Micra was disabled and left in place in 64% of revisions. It was successfully retrieved percutaneously as late as 14 months post-implant.
IMPLANT PROCEDURE & CONSIDERATIONS			
INFECTION	Kiani S, et al. Extraction of a 4-year-old leadless pacemaker with a tine-based fixation. Heart Rhythm Case Rep. August 2019;5(8):424-425. Kypta A, et al. Complete Encapsulation of a Leadless Cardiac Pacemaker. Clin Res Cardiol. January 2016;105(1):94.	To describe the retrieval of a Micra device 4 years post-implant in a patient needing a CRT upgrade due to a myocardial infarction and decreased EF. To describe the histopathological appearance of Micra 1 year post-	Micra was successfully retrieved with relative ease using a steerable sheath and snare with intracardiac echocardiogram guidance. The device did not appear to be encapsulated. Procedure time was 40 minutes with 11 minutes of fluoroscopy. At autopsy, the Micra was found to be located in the right apex, where it was originally implanted, fixed
DEVICE LIFE CYCLE			
MANAGEMENT			
PATIENT CASE STUDIES		implant assessed via autopsy.	by its nitinol tines. The Micra device was completely encapsulated.
QUALITY OF LIFE	Omdahl P, et al. Right Ventricular Anatomy Can Accommodate Multiple Micra Transcatheter Pacemakers. <i>Pacing Clin Electrophysiol</i> . April 1, 2016;39(4):393-397.	To assess the feasibility of implanting multiple Micra devices using cadaver hearts.	Multiple (3) Micra devices could be implanted in clinically acceptable pacing locations within the right ventricle. Micra takes up less than 1% of the volume of a normal right ventricle.
BIBLIOGRAPHY —			



## PATIENT **CASE STUDIES**

	STUDY	ANALYSIS OBJECTIVE	FINDING	
SAFETY & EFFICACY	Feasibility and Safety of Leadless Pacemakers Across Bioprosthetic and Repaired Tricuspid	safety of Micra implant in patients with repaired and bioprosethetic	Implant success was 100% in both groups, with adequate sensing and pacing threshold at implantation. The procedure duration and fluoroscopy time were significantly longer in the operated TV group. Periprocedural complications were similar	
MICRA <sup>™</sup> AV	2019;5(9):1093-1094.	patients without TV replacement (n = 38).	in the 2 groups. Over a mean follow-up of 13 + 9 months, there was no difference in the composite of death, upgrade to CRT, or development of severe tricuspid regurgitation.	
DEVICE TECHNOLOGY	El Amrani A, et al. <b>Performance of the Micra</b> cardiac pacemaker in nonagenarians. <i>Rev Esp</i> <i>Cardiol (Engl Ed)</i> . April 2020;73(4):307-312.	Prospective observational study designed to evaluate the safety and effectiveness of Micra in patients $\ge$ 90 years (n = 41) versus those < 90 years (n = 88).	The device was successfully implanted in 97.6% of patients $\ge$ 90 years and in 98.9% of patients < 90 years. An adequate position was achieved < 2 repositions in 97.5% of patients $\ge$ 90 years . There were 3 major complications (2.3%), all in the group aged < 90 years. There were no device-related deaths reported.	
IMPLANT PROCEDURE & CONSIDERATIONS	Breatnach CR, et al. Leadless Micra Pacemaker Use in the Pediatric Population: Device Implantation and Short-Term Outcomes. <i>Pediatr</i> <i>Cardiol.</i> April 2020;41(4):683-686.	To report the experience of neonatal patients managed with implantation of the Micra pacemaker in a single tertiary	Micra was successfully implanted with satisfactory thresholds in pediatric patients with a median age (IQR) of 13 years old (12–14) and median weight of 37 kg. There were no procedural complications.	
INFECTION	El-Chami MF, et al. Leadless Pacemaker Implantation in Hemodialysis Patients:	outcomes and intermediate-term follow-up of hemodialysis patients undergoing Micra implantation (n = 201).	Micra was successfully implanted in 98.0% of patients. There were 11 major complications in 9 patients (4.5%) adjudicated as related to the Micra device or procedure. No patients had a device-related infection or required device removal because of bacteremia. Micra pacing thresholds and sensing were excellent and remained stable during follow-up.	
DEVICE LIFE CYCLE MANAGEMENT	<b>Experience with the Micra Transcatheter</b> <b>Pacemaker</b> . JACC Clin Electrophysiol. 2019 Feb;5(2):162-170.			
PATIENT CASE STUDIES	Garweg C et al. Leadless cardiac pacemaker as alternative in case of congenital vascular abnormality and pocket infection. <i>EP Europace</i> . February 18, 2016;18(10):1564.	To report the Micra implant experience in a 60-year-old male with congenital venous abnormalities and infection of a previously implanted transvenous pacemaker.	The infected material was first removed using a subclavian approach, and Micra was successfully implanted in the apex of the right ventricle. The implant procedure was uncomplicated and uneventful. Electrical measurements remained stable at the 3-month follow-up.	
QUALITY OF LIFE	Garweg C, et al. Monocentric experience of leadless pacing with focus on challenging cases for conventional pacemaker. <i>Acta Cardiol,</i>	To investigate the safety and efficacy of Micra used in daily	The device was successfully implanted in 65 patients (98.5%). During follow-up of $10.4 \pm 6.1$ months, electrical measurements	
BIBLIOGRAPHY — JULY 2020	October 2018;73(5):459-468.	clinical activity with a focus on challenging cases for conventional pacing (n = 66).	remained stable. One major (loss of function) and 3 minor adverse events occurred. Micra TPS implantation was straightforward for patients with congenital or acquired cardiac and/or vascular abnormalities, previous tricuspid surgery, and after heart transplantation.	



## PATIENT **CASE STUDIES**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	system (Micra) through the same venous access	To describe the experience of a 73-year- old female with persistent atrial fibrillation and symptomatic tachy-brady syndrome implanted with a left atrial appendage	The procedure was well tolerated by the patient and there were no complications. At the end of 1 month, both the devices were found to be working well.
MICRA <sup>™</sup> AV	2018;2018:bcr-2017-222471.	occluder device (WATCHMAN™) and Micra from a single right femoral vein access.	
DEVICE TECHNOLOGY IMPLANT	Karjalainen PP, et al. Transcatheter leadless pacemaker implantation in a patient with a transvenous dual-chamber pacemaker already in place. <i>J Electrocardiol</i> . July-August 2016;49(4):554- 556.	To report the Micra implant experience in an 81-year-old female with an 18-year- old ventricular lead with high pacing threshold.	Micra was successfully implanted in the mid-septum with stable electrical parameters and no in-hospital complications. During the implant procedure, the transvenous pacemaker was in VVI mode at a rate of 40 bpm; after the procedure, it was programmed to a rate of 30 bpm.
PROCEDURE & CONSIDERATIONS INFECTION	Martínez-Sande JL, et al. Acute and long-term outcomes of simultaneous atrioventricular node ablation and leadless pacemaker implantation. <i>Pacing Clin Electrophysiol</i> . November 2018:41(11):1484-1490.	To evaluate the feasibility of atrioventricular nodal ablation (AVNA) performed immediately following leadless pacemaker implantation through the same sheath and long-term outcomes	Immediately following leadless pacemaker implantation (LDP), 27 patients (19.7%) underwent concurrent AVNA. There were 6 (5.5%) complications in patients referred for LDP procedures and 3 (11%) in those who underwent a combined approach. None of these complications
DEVICE LIFE CYCLE	2018;41(11):1484-1490.	vs. those not undergoing AVNA (n = 137).	were solely attributable to the added AVNA component. Pacing and sensing did not differ between the groups.
MANAGEMENT PATIENT CASE STUDIES	Montgomery JA, et al. Feasibility of Defibrillation and Pacing Without Transvenous Leads in a Combined MICRA and S-ICD System Following Lead Extraction. <i>J Cardiovasc Electrophysiol.</i> February 2017;28(2):233-234.	To describe the experience of a 70-year- old female with atrial fibrillation and complete heart block who underwent extraction of her entire ICD system followed by Micra implant and immediate placement of a subcutaneous ICD (S-ICD).	Defibrillation threshold (DFT) testing was successful at 65 J, and post-DFT pacemaker interrogation showed no changes in sensing or pacing, with a paced QRS duration of 125 ms. While the two systems are not in direct communication in the patient, they both appear to be functioning optimally without any indication of adverse device to device interaction.
QUALITY OF LIFE BIBLIOGRAPHY —	Moore SKL, et al. Leadless Pacemaker Implantation: A Feasible and Reasonable Option in Transcatheter Heart Valve Replacement Patients. <i>Pacing Clin Electrophysiol.</i> May 2019;42:542-547.	Retrospective, single-center study designed to determine outcomes of leadless pacemakers compared to transvenous single-chamber pacemakers post transcatheter heart	Leadless pacemakers were associated with decreased tricuspid regurgitation and decreased blood loss during implantation. Frequency of ventricular pacing was similar between the groups.
BIBLIOGRAPHY — JULY 2020			

Medtro	nic
Further,Together	

## PATIENT **CASE STUDIES**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	Okabe T, et al. Leadless Pacemaker Implantation and Concurrent Atrioventricular Junction Ablation in Patients with Atrial Fibrillation. <i>Pacing</i> <i>Clin Electrophysiol.</i> May 2018;41(5):504-510.	To assess the feasibility and safety of concurrent	100% of patients underwent successful Micra implantation followed by concurrent AVJ
MICRA <sup>™</sup> AV		Micra leadless transcatheter pacemaker implantation and atrioventricular junction (AVJ) ablation (n = 21).	ablation. There was no device dislodgements or malfunctions during the 12-month follow-up, as well as no patients with major device-related complications. Pacing thresholds were stable through 12 months.
DEVICE TECHNOLOGY	Piccini JP, et al. Patient Selection, Pacing Indications, and Subsequent Outcomes with	To compare patient characteristics and outcomes	Nearly one-third of patients selected to receive Micra VVI therapy were for indications not
IMPLANT PROCEDURE & CONSIDERATIONS	De Novo Leadless Single-Chamber VVI Pacing. Europace. November 1, 2019;21(11):1686-1693.	of Micra patients with (n = 492) and without (n = 228) a primary pacing indication associated with atrial fibrillation (AF) in the	associated with AF. Non-AF patients required less frequent pacing compared to patients with AF. Risk of cardiac failure, pacemaker syndrome, or syncope were low and did not differ in those
INFECTION	Sideris S, et al. Leadless pacing systems: A valuable alternative for patients with severe access problems. <i>Hellenic J Cardiol</i> . January- February 2018;59(1):36-39.	Micra IDE trial.	with and without AF.
		To report the Micra implant experience in a 72-year old male with restricted access to the superior vena cava (SVC) system,	Micra was successfully implanted in the septal wall of the right ventricle with no peri-procedural complications reported and the patient was discharged 3 days post- implant. Pacing thresholds remained stable
DEVICE LIFE CYCLE MANAGEMENT			
PATIENT CASE STUDIES		immunocompromization, and a high risk of infection.	at the 6-month follow-up; additionally, an improvement in functional status was reported, along with no syncopy or presyncopy events reported.

### **QUALITY OF LIFE**

**BIBLIOGRAPHY**— **JULY 2020** 



# QUALITY **OF LIFE**

	STUDY	ANALYSIS OBJECTIVE	FINDING
SAFETY & EFFICACY	Cabanas-Grandío P, et al. Quality of life of patients undergoing conventional vs leadless pacemaker implantation: A multicenter observational study. J Cardiovasc Electrophysiol. January 2020;31(1):330-336.	To compare quality of life between patients implanted with leadless pacemakers and those implanted with conventional single- chamber pacemakers (n = 106).	At 6-month follow-up, patients in the leadless pacemaker group scored significantly higher on physical function, physical role, and mental health, even after adjusting for covariates. Pacemaker-related discomfort and physical restrictions were significantly lower for the leadless pacemaker group.
MICRA <sup>™</sup> AV			
DEVICE TECHNOLOGY			
IMPLANT PROCEDURE & CONSIDERATIONS	Tjong FVY, et al. Health-related quality of life impact of a transcatheter pacing system. <i>J Cardiovasc Electrophysiol.</i> December 2018;29(12):1697-1704.	To assess health- related quality of life (HRQoL) impact, patient satisfaction, and activity restrictions among Micra patients from the IDE trial (n = 702).	Micra resulted in post-implant HRQoL improvements at 3 and 12 months and high levels of patient satisfaction at 3 months. Micra was also associated with fewer activity restrictions compared with traditional pacemaker systems.
INFECTION			
DEVICE LIFE CYCLE MANAGEMENT		(11 - 702).	

PATIENT CASE STUDIES

### **QUALITY OF LIFE**

**BIBLIOGRAPHY**— **JULY 2020** 

### **SAFETY & EFFICACY**

### MICRA<sup>™</sup> AV

#### DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

### **INFECTION**

#### DEVICE LIFE CYCLE MANAGEMENT

#### PATIENT CASE STUDIES

## **QUALITY OF LIFE**

#### BIBLIOGRAPHY — JULY 2020

# BIBLIOGRAPHY JULY 2020

This bibliography includes the relevant publications on transcatheter pacing categorized by topic for easy reference. Please note that this is not a complete list of all publications on transcatheter pacing, and the document may include publications with views and/or opinions that may not represent those of Medtronic.

#### Safety & Efficacy

Audoubert M, et al. Resistance of the Medtronic Micra Leadless Pacemaker to 60 Hz Electrical Fields. *Can J Cardiol*. October 1, 2017;33(10):S155.

Beurskens NE, et al. Impact of leadless pacemaker therapy on cardiac and atrioventricular valve function through 12 months of follow-up. *Circ Arrhythm Electrophysiol*. May 2019;12(5):e007124.

Bongiorni MG, et al. Feasibility and long-term effectiveness of a non-apical Micra pacemaker implantation in a referral centre for lead extraction. *Europace*. January 1, 2019;21(1):114-120.

Burri H, et al. Leadless pacing using the transcatheter pacing system (Micra TPS) in the real world: initial Swiss experience from the Romandie region-Authors' reply. *Europace*. February 1, 2019;21(2):357.

Da Costa A, et al. Is the new Micra-leadless pacemaker entirely safe? *Int J Cardiol.* March 18, 2016;212:97-99.

Denman R, et al. Very Early Experience with the Micra Transcatheter Leadless Pacemaker System: A Single Centre Experience. *Heart Lung Circ*. August 1, 2016;25:S159-160.

Duray GZ, et al. Long-term Performance of a Transcatheter Pacing System: 12 month results from the Micra Transcatheter Pacing Study. *Heart Rhythm.* February 10, 2017;14(5):702-709.

El-Chami MF, et al. Updated performance of the Micra transcatheter pacemaker in the real-world setting: A comparison to the investigational study and a transvenous historical control. *Heart Rhythm*. December 2018;15(12):1800-1807.

Garweg C, et al. Leadless pacing using the transcatheter pacing system (Micra TPS) in the real world: initial Swiss experience from the Romandie region. *Europace*. February 1, 2019;21(2):356-357.

Garweg C, et al. Monocentric experience of leadless pacing with focus on challenging cases for conventional pacemaker. *Acta Cardiol*. October 2018; 73(5):459-468.

Gifford J, et al. Evaluation of surgical electromagnetic interference in leadless pacemakers. *HeartRhythm Case Rep.* August 28, 2018;4(12):570-571.

Johar S, et al. Initial experience with a leadless pacemaker (Micra<sup>™</sup>) implantation in a low volume center in South East Asia. *Future Cardiol*. September 2018;14(5):389-395.

Lancellotti P, et al. Micra<sup>®</sup> leadless pacemaker. *Rev Med Liege*. 2019;74(S1): S104-S108.

Lau CP, et al. Implantation and Clinical Performance of an Entirely Leadless Cardiac Pacemaker. *Int J Heart Rhythm.* January 1, 2016;1(1):50.

Lee JZ, et al. Leadless pacemaker: Performance and complications. *Trends Cardiovasc Med.* February 2018;28(2):130-141.

Lill ZM, et al. Initial Experience with the Micra Transcatheter Pacing System. *EP Lab Digest*. March 2017;17(3).

Liu B, et al. A Systematic Pooled Analysis of Published Studies Comparing Complication Rates Between Transvenous Pacemakers and Micra Leadless Pacemakers within the Manufacturer adn User Facility Device Experience Database. JAm Coll Cardiol. March 2020;75 (11 Supplement 1):322.

Martínez-Sande JL, et al. The Micra Leadless Transcatheter Pacemaker. Implantation and Mid-term Follow-up Results in a Single Center. *Rev Esp Cardiol (Engl Ed)*. April 2017;70(4):275-281.

Pachón M, et al. Implantation of the Micra Transcatheter Pacing System: Initial Experience in a Single Spanish Center. *Rev Esp Cardiol (Engl Ed)*. March 2016;69(3):346-349.

Piccini JP, et al. Long-term Outcomes in Leadless Micra Transcatheter Pacemakers with Elevated Thresholds at Implantation: Results from the Micra TPS Global Clinical Trial. *Heart Rhythm*. May 2017;14(5):685-691.

Reynolds D, et al. A Leadless Intracardiac Transcatheter Pacing System. *N Engl J Med.* February 11, 2016;374(6):533-541.

Robinson T, et al. 2.5 year Micra TPS implant experience; A comparison with the post approval registry. *Europace*. 2018;20:iv32-iv33.

Soejima K, et al. Performance of Leadless Pacemaker in Japanese Patients vs. Rest of the World—Results From a Global Clinical Trial. *Circ J*. October 25, 2017;

Steinwender C, et al. [Micra<sup>™</sup> leadless pacemaker: Clinical experience and perspectives]. *Herzschrittmacherther Elektrophysiol*. December 2018;29(4): 334-339.

Wang Y, et al. Meta-analysis of the incidence of lead dislodgement with conventional and leadless pacemaker systems. *Pacing Clin Electrophysiol*. October 2018;41(10):1365-1371.



**SAFETY & EFFICACY** 

MICRA<sup>™</sup> AV

TECHNOLOGY

PROCEDURE & CONSIDERATIONS

**DEVICE LIFE CYCLE** 

MANAGEMENT

**PATIENT CASE** 

**QUALITY OF LIFE** 

**BIBLIOGRAPHY**—

**STUDIES** 

**JULY 2020** 

DEVICE

IMPLANT

**INFECTION** 

## BIBLIOGRAPHY JULY 2020

Wiles BM, et al. Design and evaluation of the Micra Transcatheter Pacing System for bradyarrhythmia management. *Future Cardiol.* January 2019;15(1):9-15.

#### Micra AV

Chinitz L, et al. Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: Results from the Micra atrioventricular feasibility studies. *Heart Rhythm.* September 2018;15(9):1363-1371.

Garweg C, et al. Behavior of leadless AV synchronous pacing during atrial arrhythmias and stability of the atrial signals over time-Results of the MARVEL Evolve subanalysis. *Pacing Clin Electrophysiol*. March 2019;42(3):381-387.

Garweg C, et al. Predictors of Atrial Mechanical Sensing and Atrioventricular Synchrony with a Leadless Ventricular Pacemaker: Results from the MARVEL 2 Study. *Heart Rhythm.* Published online July 24, 2020.

Steinwender C, et al. Atrioventricular synchronous pacing using a leadless ventricular pacemaker: Results from the MARVEL 2 study. *JACC: Clinical Electrophysiology*. January 2020;6(1):94-106.

#### Device Technology

Bari Z, et al. Physical activity detection in patients with intracardiac leadless pacemaker. *J Cardiovasc Electrophysiol*. December 2018;29(12):1690-1696.

Blessberger H, et al. Monocenter Investigation Micra® MRI study (MIMICRY): feasibility study of the magnetic resonance imaging compatibility of a leadless pacemaker system. *Europace*. January 1, 2019;21(1):137-141.

Edlinger C, et al. Visualization and appearance of artifacts of leadless pacemaker systems in cardiac MRI: An experimental ex vivo study. *Wien Klin Wochenschr.* July 2018;130(13-14):427-435.

Eggen MD, et al. Design and evaluation of a novel fixation mechanism for a transcatheter pacemaker. *IEEE Trans Biomed Eng.* September 2015;62(9):2316-2323.

Kiblboeck D, et al. Artefacts in 1.5 Tesla and 3 Tesla cardiovascular magnetic resonance imaging in patients with leadless cardiac pacemakers. *J Cardiovasc Magn Reson*. July 5, 2018;20(1):47.

Kypta A, et al. Three Tesla cardiac magnetic resonance imaging in a patient with a leadless cardiac pacemaker system. *Eur Heart J.* September 7, 2017;38(34):2628.

Lloyd M, et al. Rate Adaptive Pacing in an Intracardiac Pacemaker. *Heart Rhythm.* February 2017;14(2):200-205.

Mattson AR, et al. The fixation tines of the Micra<sup>™</sup> leadless pacemaker are atraumatic to the tricuspid valve. *Pacing Clin Electrophysiol*. December 2018;41(12):1606-1610.

Soejima K, et al. Safety evaluation of a leadless transcatheter pacemaker for magnetic resonance imaging use. *Heart Rhythm.* June 29, 2016;13(10):2056-2063.

#### **Implant Procedure & Considerations**

Cheema P, et al. Radiation Exposure During Leadless and Transvenous Pacing System Implantantation. J Am Coll Cardiol. March 2020;75(11 Supplement 1):386.

Cipolletta L, et al. An indissoluble knot: An unexpected troubleshooting during Micra implantation. *Pacing Clin Electrophysiol.* June 2019;42(6):747-748.

Cronin B, et al. Update on Cardiovascular Implantable Electronic Devices for Anesthesiologists. *J Cardiothorac Vasc Anesth*. August 2018;32(4):1871-1884.

El-Chami MF, et al. How to Implant a Leadless Pacemaker With a Tine-Based Fixation. *J Cardiovasc Electrophysiol.* December 1, 2016;27(12):1495-1501.

El-Chami MF, et al. Impact of operator experience and training strategy on procedural outcomes with leadless pacing: Insights from the Micra Transcatheter pacing study. *Pacing Clin Electrophysiol.* April 1, 2017;40(7):834-842.

Essandoh M. Perioperative Management of the Micra Leadless Pacemaker. *J Cardiothorac Vasc Anesth*. December 2017;31(6):e97-e98.

Gabriels J, et al. Balloon Dilation of an Inferior Vena Cava Filter to Implant a Leadless Pacemaker. *JACC: Clin Electrophysiol.* December 26, 2017;3(13):1605-1606.

Gerdes C, et al. Retrieval of Medtronic Micra Transcatheter Pacing System after tether removal. *Europace*. August 2016;18(8):1202.

Hai JJ, et al. Safety and feasibility of a midseptal implantation technique of a leadless pacemaker. *Heart Rhythm*. June 2019;16(6):896-902.

Kiani S, et al. Outcomes of Micra leadless pacemaker implantation with uninterrupted anticoagulation. *JJ Cardiovasc Electrophysiol*. August 2019; 30(8):1313-1318.

Kiani S, et al. The Safety and Feasibility of Same-Day Discharge After Implantation of MICRA Transcatheter Leadless Pacemaker System. *J Atr Fibrillation*. June 30, 2019;12(1):2153.

Kypta A, et al. Subcutaneous Double 'Purse String Suture'–A Safe Method for Femoral Vein Access Site Closure After Leadless Pacemaker Implantation. *Pacing Clin Electrophysiol*. July 2016;39(7):675-679.

Mickus GJ, et al. Perioperative Management of a Leadless Pacemaker: The Paucity of Evidence-Based Guidelines. J *Cardiothorac Vasc Anesth*. December 2016;30(6): 1594-1598.



**SAFETY & EFFICACY** 

### MICRA<sup>™</sup> AV

#### DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

**INFECTION** 

#### DEVICE LIFE CYCLE MANAGEMENT

#### PATIENT CASE STUDIES

## QUALITY OF LIFE

#### BIBLIOGRAPHY — JULY 2020

# BIBLIOGRAPHY JULY 2020

Mohammed M, et al. Outcomes using a single tapered dilator for Micra leadless pacemaker implant. *Indian Pacing Electrophysiol J.* May-June 2020;20(3):105-111.

Morani G, et al. Troubleshooting in PM Leadless: How to manage an indissoluble knot. *J Arrythm.* June 18, 2019;35(4):676-678.

Nayak S, et al. Feasibility of Echocardiogram Guided Leadless Pacemaker Placement on the Ventricular Septum. *J Am Coll Cardiol*. March 2020;75(11 Supplement 1):492.

Okabe T, et al. Leadless pacemaker implantation and concurrent atrioventricular junction ablation in patients with atrial fibrillation. *Pacing Clin Electrophysiol.* May 2018;41(5):504-510.

Roberts PR. Leadless pacemaker implantation: Is it possible to eliminate pericardial effusion as a complication? *Heart Rhythm.* June 2019;16(6):903-904.

San Antonio R, et al. Management of anticoagulation in patients undergoing leadless pacemaker implantation. *Heart Rhythm*. December 2019;16(12):1849-1854.

#### Infection

Beurskens NE, et al. Leadless pacemaker implantation after explantation of infected conventional pacemaker systems: a viable solution?. *Heart Rhythm.* January 2019;16(1):66-71.

El-Chami MF, et al. Leadless pacemakers reduce risk of device-related infection: Review of the potential mechanisms. *Heart Rhythm*. April 2, 2020;S1547-5271(20)30280-0.

El-Chami MF, et al. Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry. *J Cardiovasc Electrophysiol*. April 2019;30(4):569-574.

Garweg C, et al. Leadless cardiac pacemaker as alternative in case of congenital vascular abnormality and pocket infection. *Europace*. 2016 Oct;18(10):1564.

Koay A, et al. Treating an infected transcatheter pacemaker system via percutaneous extraction. *HeartRhythm Case Rep.* May 10, 2016;2(4):360-362.

Kypta A, et al. Temporary leadless pacing in a patient with severe device infection. *BMJ Case Rep.* May 17, 2016;2016:bcr2016215724.

#### **Device Life Cycle Management**

Afzal MR, et al. Techniques for successful early retrieval of the Micra transcatheter pacing system: A worldwide experience. *Heart Rhythm.* June 2018;15(6):841-846.

Borgquist R, et al. Leadless Medtronic Micra pacemaker almost completely endothelialized already after 4 months: first clinical experience from an explanted heart. *Eur Heart J.* April 7, 2016; 37(31):2503.

Breitenstein A, et al. Extraction of a leadless pacemaker 23 months after implantation. *Eur Heart J.* June 1, 2020;41(21):2038.

Chan NY, et al. Successful percutaneous retrieval of a leadless pacemaker due to an acute rise in pacing threshold. *Indian Pacing Electrophysiol J.* November-December 2017;17(6):186-188.

Cheung L, et al. Cremation of Leadless Pacemaker. *Pacing Clin Electrophysiol.* March 11, 2017;40(6):629-631.

Curnis A, et al. First-in-human retrieval of chronically implanted Micra Transcatheter Pacing system. *Pacing Clin Electrophysiol.* July 2019;42(7): 1063-1065.

Fichtner S, et al. Percutaneous extraction of a leadless Micra pacemaker after dislocation: a case report. *Eur Heart J Case Rep.* July 13, 2019;3(3):ytz113.

Grubman E, et al. To Retrieve, or Not to Retrieve: System Revisions with the Micra Transcatheter Pacemaker. *Heart Rhythm.* December 2017;14(12):1801-1806.

Karim S, et al. Extraction of a Micra Transcatheter Pacing System: First-inhuman experience. *HeartRhythm Case Rep.* October 23, 2015;2(1):60-62.

Kiani S, et al. Extraction of a 4-year-old Leadless Pacemaker with a Tine-Based Fixation. *HeartRhythm Case Rep.* May 31, 2019;5(8):424-425.

Kypta A, et al. Complete encapsulation of a leadless cardiac pacemaker. *Clin Res Cardiol.* January 1, 2016;105(1):94.

Kypta A, et al. First autopsy description of changes one year post-implantation of a leadless cardiac pacemaker: Unexpected ingrowth and severe chronic inflammation. *Can J Cardiol.* 2016;32(12):1578.e1-1578.e2.

Li J, et al. Safety and efficacy of leadless pacemaker retrieval. *J Cardiovasc Electrophysiol*. September 2019;30(9):1671-1678.

Morani G, et al. A case of removal of a "dancing" Micra. *EP Europace*. December 1, 2017;19(12):2000.

Morita J, et al. Retrieval of a Micra transcatheter pacing system in a heart with a preexisting lead. *Indian Pacing Electrophysiol J.* 2018;18(5):183-184.



### **SAFETY & EFFICACY**

### MICRA<sup>™</sup> AV

#### DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

**INFECTION** 

#### DEVICE LIFE CYCLE MANAGEMENT

#### PATIENT CASE STUDIES

## **QUALITY OF LIFE**

### BIBLIOGRAPHY — JULY 2020

# BIBLIOGRAPHY JULY 2020

Nozoe M, et al. Successful percutaneous retrieval of a micra transcatheter pacing system at 8 weeks after implantation. *J Arrhythm*. October 13, 2018;34(6):653-655.

Omdahl P, et al. Right Ventricular Anatomy Can Accommodate Multiple Transcatheter Pacemakers. *Pacing Clin Electrophysiol*. December 1, 2015;39(4):393-397.

Ücer E, et al. Close-up of a leadless pacemaker 3 days after implantation. *J Intervent Card Electrophysiol.* September 2017;49(3):289-290.

Vamos M, et al. MICRA Leadless Pacemaker on Autopsy. *JACC: Clin Electrophysiol.* April 6, 2016;2(5):636-637.

Vatterott PJ, et al. Retrieval of a chronically implanted leadless pacemaker within an isolated heart using direct visualization. *HeartRhythm Case Rep.* May 1, 2018;4(5):167-169.

#### **Patient Selection**

Da Costa A, et al. Transcatheter leadless cardiac pacing: the new alternative solution. *Int J Cardiol*. January 15, 2017;227:122-126.

El Amrani A, et al. Performance of the Micra cardiac pacemaker in nonagenarians. *Rev Esp Cardiol (Engl Ed)*. April 2020;73(4):307-312.

Koene RJ, et al. Leadless Pacemaker Technologies: Patient Selection, Approach, and Outcomes. *Curr Cardiovasc Risk Rep.* April 1, 2018;12(4):11.

#### **Patient Case Studies**

Afzal MR, et al. Safety of Implantation of a Leadless Pacemaker via Femoral Approach in the Presence of an Inferior Vena Cava Filter. *Pacing Clin Electrophysiol.* August 2017;40(8):975-976.

Arana-Rueda E, et al. Leadless Pacemaker Implantation in a Patient With a Severe Thoracic Deformity. *Rev Esp Cardiol (Engl Ed)*. June 2018;71(6):497-498.

Arias MA, et al. Thrombus formation at the tip of a leadless pacemaker causing multiple unnecessary repositioning. *Heart Rhythm*. November 2016;13(11):2265.

Beurskens NEG, et al. Percutaneous leadless pacemaker implantation in a patient with bilateral venous thoracic outlet syndrome. *J Vasc Access*. January 2019;20(1):105-106.

Beurskens NE, et al. Successful replacement of the longest worldwide in situ Nanostim leadless cardiac pacemaker for a Micra Transcatheter Pacing System. *J Interv Card Electrophysiol.* March 2018;51(2):161-162.

Boldt L-H, et al. First-in-human: Leadless Micra transcatheter pacing system meets the Nanostim leadless cardiac pacing system. *Europace*. February 1, 2018;20(2):391.

Bongiorni MG, et al. Leadless cardiac pacemaker implant in a patient with two deep brain stimulators: A peaceful cohabitation beyond prejudices. *Int J Cardiol.* November 15, 2016;223:136-138.

Boveda S, et al. Leadless pacemaker surrounded by three valvular prostheses. *Heart Rhythm.* September 2017;14(9):1421.

Conti S, et al. Leadless pacemaker implantation in postpneumonectomy syndrome. *HeartRhythm Case Rep.* December 11, 2019;6(3):124-125.

De Regibus V, et al. Leadless pacing in a young patient with cardioinhibitory vasovagal syncope. *Indian Pacing Electrophysiol J.* May-June 2018;18(3):120-122.

Dunne L, et al. Systemic ventricular implantation of a leadless pacemaker in a patient with a univentricular heart and atrioventricular node calcification. *HeartRhythm Case Rep.* January 28, 2020;6(5):265-267.

El-Chami MF, et al. Leadless pacemaker implantation in hemodialysis patients: experience with the Micra Transcatheter Pacemaker. *JACC: Clin Electrophysiol.* February 18, 2019;5(2):162-170.

Enomoto Y, et al. Leadless Pacemaker and Subcutaneous Implantable Cardioverter Defibrillator Combination in a Hemodialysis Patient. *Circ J.* November 24, 2018;82(12):3108-3109.

Essandoh M, et al. An Echodensity in the Right Ventricle of a Patient with a Leadless Pacemaker: Is it Pathologic? *J Cardiothorac Vasc Anesth*. August 2019;33(8):2358-2359.

Estévez-Loureiro R, et al. Micra Leadless Pacemaker Implantation and Tricuspid Valve Repair with Mitraclip NT in a Patient with End-Stage Right Heart Failure. *Struct Heart*. 2018;2(6):567-568.

Ferrero P, et al. Leadless pacemaker implantation in a patient with complex congenital heart disease and limited vascular access. *Indian Pacing Electrophysiol J.* November-December 2016;16(6):201-204.

Filipovic K, et al. External electrical cardioversion of persistent atrial fibrillation in a patient with a Micra™ Transcatheter Pacing System. *Indian Pacing Electrophysiol J.* January-February 2018;18(1):44-46.

Flores E, et al. Successful implantation of a Micra leadless pacemaker via collateral femoral vein and inferior vena cava filter. *Clinical Case Rep.* March 2018;6(3):502-505.

Fudim M, et al. Transcatheter Leadless Pacemaker Implantation for Complete Heart Block Following CoreValve Transcatheter Aortic Valve Replacement. *J Cardiovasc Electrophysiol.* January 1, 2016;27(1):125-126.



### **SAFETY & EFFICACY**

MICRA<sup>™</sup> AV

#### DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

**INFECTION** 

#### DEVICE LIFE CYCLE MANAGEMENT

PATIENT CASE STUDIES

## QUALITY OF LIFE

#### BIBLIOGRAPHY — JULY 2020

# BIBLIOGRAPHY JULY 2020

Gallotti RG, et al. Leadless pacemaker placement in an 18-kilogram child: Procedural approach and technical considerations. *HeartRhythm Case Rep.* November 1, 2019;5(11):555-558.

Garweg C, et al. Response to atrial arrhythmias in an atrioventricular synchronous ventricular leadless pacemaker: A case report in a paroxysmal atrial fibrillation patient. *HeartRhythm Case Rep.* December 2018;4(12):561-563.

Gattani R, et al. Leadless Pacemaker Implant in a Heart Transplant Patient. *J Am Coll Cardiol.* March 2020;75(11 Supplement 1):2633.

Grabowski M, et al. Implantation of the Micra transcatheter pacing system: Single Polish center experience with the real costs of hospitalization analysis. *Cardiol J.* August 28, 2018;27(1):47-53.

Ho J, et al. Simultaneous atrioventricular node ablation and leadless pacemaker implantation. *HeartRhythm Case Rep.* March 2017;3(3):186.

Holm N, et al. Complications with the MICRA TPS Pacemaker System: Persistent Complete Heart Block and Late Capture Failure. *Pacing Clin Electrophysiol.* April 2017;40(4):455-456.

Johar S, et al. Implant of a left atrial appendage occluder device (Watchman) and leadless pacing system (Micra) through the same venous access in a single sitting. *BMJ Case Rep.* February 16, 2018;2018:bcr2017222471.

Jung W, et al. Successful implant of a leadless pacemaker with tine-based fixation next to an abandoned battery-depleted screw-in helix fixation leadless device. *EP Europace*. March 1, 2018;20(3):500.

Karjalainen PP, et al. Transcatheter leadless pacemaker implantation in a patient with a transvenous dual-chamber pacemaker already in place: Transcatheter leadless pacemaker implantation. *J Electrocardiol*. May 13, 2016;49(4):554-556.

Kerwin SA, et al. Transcatheter pacemaker implantation in a patient with a bioprosthetic tricuspid valve. *J Interv Card Electrophysiol*. October 2015;44(1): 89-90.

Kotschet E, et al. Micra implantation in a patient with transposition of great arteries. *Pacing Clin Electrophysiol.* February 2019;42(2):117-119.

Kypta A, et al. Dawn of a new era: the completely interventionally treated patient. BMJ Case Rep. March 18, 2016;2016:bcr2015214268.

Kypta A, et al. Leadless Cardiac Pacemaker Implantation after Lead Extraction in Patients with Severe Device Infection. *J Cardiovasc Electrophysiol*. June 1, 2016;27(9):1067-1071.

Lau CP, et al. One stage atrioventricular nodal ablation and leadless pacemaker implantation for refractory atrial fibrillation. *J Arrhythm*. February 2019;35(1):139-141.

Lau CP, et al. Transcatheter Leadless Cardiac Pacing with Limited Venous Access. *Pacing Clin Electrophysiol.* May 1, 2016;39(11):1281-1284.

Lau YM, et al. Asystole in focal epilepsy complicating a traumatic subdural hematoma. *J Arrhythm*. August 2017;33(4):330-332.

Ljungström E, et al. Combination of a leadless pacemaker and subcutaneous defibrillator with nine effective shock treatments during follow-up of 18 months. *J Electrocardiol.* September-October 2019;56:1-3.

Marai I, et al. Intraoperative Implantation of Micra Leadless Pacemaker During Valve Surgery. *Ann Thorac Surg*. May 1, 2018;105(5):e211-e212.

Martínez-Sande J.L., et al. Acute and long-term outcomes of simultaneous atrioventricular node ablation and leadless pacemaker implantation. *Pacing Clin Electrophysiol*. November 2018;41(11):1484-1490.

Martínez-Sande JL, et al. Radiotherapy in a leadless pacemaker. *EP Europace*. January 1, 2018;20(1):81.

Martínez-Sande JL, et al. Usefulness of Three-dimensional Transthoracic Echocardiograhy in the Localization of the Micra Leadless Pacemaker. *Rev Esp Cardiol (Engl Ed)*. August 2017;70(8):670-671.

McCanta AC, et al. Implantation of a leadless pacemaker in a pediatric patient with congenital heart disease. *HeartRhythm Case Rep.* August 1, 2018;4(11):506-509.

Morani G, et al. Leadless pacemaker implantation in achondroplastic dwarfism and recurrent cardiac implantable electronic device infections: a case report. *EP Europace*. July 1, 2018;20(7):1160.

Müller GC, et al. Leadless Pacing by Micra Transcatheter Pacing System: First Treatment of a Congenital Heart Disease Patient as the Only Option to Avoid Heart Transplant. *Thorac Cardiovasc Surg.* January 2016;64(S 02):ePP5.

Muraru D, et al. Transthoracic 3D echocardiography imaging of transcatheter pacing system. *Eur Heart J Cardiovasc Imaging*. May 1, 2017;18(8):937.

Ng JB, et al. Simultaneous leadless pacemaker and subcutaneous implantable cardioverter-defibrillator implantation—When vascular options have run out. *J Arrhythm.* February 2019;35(1):136-138.

Nührich JM, et al. Sole transfemoral venous access for cardiac pacemaker implantation. *BMJ Case Rep.* June 22, 2016;2016:bcr2016215938.



### **SAFETY & EFFICACY**

MICRA<sup>™</sup> AV

#### DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

**INFECTION** 

#### DEVICE LIFE CYCLE MANAGEMENT

#### PATIENT CASE STUDIES

## **QUALITY OF LIFE**

#### BIBLIOGRAPHY — JULY 2020

# BIBLIOGRAPHY JULY 2020

Olsen FJ, et al. Malignant ventricular tachycardia and cardiac arrest induced by a Micra<sup>™</sup> leadless pacemaker. *J Electrocardiol*. November-December 2018;51(6):1053-1054.

Opolski MP, et al. Augmented-reality computed tomography-guided transcatheter pacemaker implantation in dextrocardia and congenitally corrected transposition of great arteries. *Cardiol J.* 2018;25(3):412-413.

Pachón M, et al. Leadless Pacemaker After Complicated Hematoma. *Rev Esp Cardiol (Engl Ed)*. June 2016;69(6):607.

Pachón M, et al. Miniaturized Transcatheter Leadless Pacemaker in a Patient with Double Mechanical Prosthesis. *Arg Bras Cardiol.* March 2017;108(3):279-280.

Pachón M, et al. Trascatheter leadless pacemaker in a patient with mitral mechanical prosthesis. *Arch Cardiol Mex.* April-June 2017;87(2):170-171.

Patel S, et al. Leadless Pacemaker Insertion Complicated by Right Ventricular Pseudoaneurysm. *J Am Coll Cardiol.* March 2020;75(11 Supplement 1):3259.

Rao K, et al. Concurrent Implantation of a Leadless Pacemaker Followed by TAVR is a Novel and Feasible Procedure in Patients with Severe Aortic Stenosis and Sick Sinus Syndrome. *J Am Coll Cardiol.* March 2020;75(11 Supplement 1):2780.

Raza A, et al. Novel Application for Leadless Pacemaker in Cervical Spinal Cord Injury. *JAm Coll Cardiol.* March 2020;75(11 Supplement 1):2380.

Razi M, et al. Troubleshooting during pacemaker implant in persistent left superior vena cava with absence of right superior vena cava (isolated persistent left superior vena cava). *Avicenna J Med*. April-June 2016;6(2):47-50.

Regoli F, et al. Combined Left Atrial Appendage Closure and Pace-maker Implant Through a Single Right Femoral Vein Access. *Pacing Clin Electrophysiol*. August 2016;39(8):900-902.

Roberts PR, et al. The use of a single chamber leadless pacemaker for the treatment of cardioinhibitory vasovagal syncope. *Int J Cardiol Heart Vasc*. March 28, 2019;23:100349.

Russell MR, et al. Initial experience with transcatheter pacemaker implantation for adults with congenital heart disease. *J Cardiovasc Electrophysiol*. August 2019;30(8):1362-1366.

Salaun E, et al. Right ventricular and tricuspid valve function in patients chronically implanted with leadless pacemakers. *EP Europace*. May 1, 2018;20(5):823-828.

Sanhoury M, et al. Rescue Leadless Pacemaker Implantation in a Pacemaker Dependent Patient with Congenital Heart Disease and no Alternative Routes for Pacing. *J Atr Fibrillation*. February 28, 2017;9(5):1542.

Shehadeh M, et al. Successful Micra Leadless Pacemaker Implantation through an Iliac Vein Stent. J Am Coll Cardiol. March 2020;75(11 Supplement 1):2685.

Sideris S, et al. Leadless pacing systems: A valuable alternative for patients with severe access problems. *Hellenic J Cardiol*. January-February 2018;59(1):36-39.

Solís LD, et al. Leadless Pacemaker Due to Bilateral Subclavian Stenosis. *Rev Esp Cardiol (Engl Ed)*. April 2017;70(4):294.

Sterliński M, et al. Percutaneous extraction from pulmonary artery in complex congenital heart disease and complete heart block patient. *EuroIntervention*. June 20, 2018;14(2):236-237.

Taborsky M, et al. Extraction of a dislocated leadless pacemaker in a patient with infective endocarditis and repeated endocardial and epicardial pacing system infections. *Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub.* February 2019;163(1):85-89.

Tam TK, et al. Leadless pacemaker tether failure during recapture attempt leading to device embolization. *HeartRhythm Case Rep.* May 1, 2019;5(5):247-250.

Tang GH, et al. First percutaneous Micra leadless pacemaker implantation and tricuspid valve repair with MitraClip NT for lead-associated severe tricuspid regurgitation. *EuroIntervention*. February 2017;12(15):e1845-e1848.

#### Quality of Life

Cabanas-Grandio P, et al. Quality of life of patients undergoing conventional vs leadless pacemaker implantation: A multicenter observational study. *J Cardiovasc Electrophysiol.* January 2020;31(1):330-336.

Tjong FVY, et al. Micra Investigators. Health-related quality of life impact of a transcatheter pacing system. *J Cardiovasc Electrophysiol*.December 2018;29(12): 1697-1704.

#### **Other Transcatheter Technologies**

Ahmed FZ, et al. First Report of Effective Spontaneous Ventricular Tachycardia Defibrillation and Pacemaker Function Using a Totally Leadless Dual-Device Strategy. *Can J Cardiol.* May 2017;33(8).

Ahmed FZ, et al. Totally Leadless Dual-Device Implantation for Combined Spontaneous Ventricular Tachycardia Defibrillation and Pacemaker Function: A First Report. *Can J Cardiol.* August 2017;33(8):1066.e5-1066.e7.

Albatat M, et al. Technological and Clinical Challenges in Lead Placement for Cardiac Rhythm Management Devices. *Ann Biomed Eng.* January 2020;48(1):26-46.



### **SAFETY & EFFICACY**

### MICRA<sup>™</sup> AV

DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

**INFECTION** 

#### DEVICE LIFE CYCLE MANAGEMENT

PATIENT CASE STUDIES

## QUALITY OF LIFE

#### BIBLIOGRAPHY — JULY 2020

# BIBLIOGRAPHY JULY 2020

Asirvatham RS, et al. Nanostim leadless pacemaker retrieval and simultaneous micra leadless pacemaker replacement: a single-center experience. *J Interv Card Electrophysiol.* January 2020;57(1):125-131.

Chew DS, et al. Leadless cardiac pacemakers: present and the future. *Curr Opin Cardiol.* January 1, 2018;33(1):7-13.

Grieco D, et al. The Micra and LEADLESS II trials. *G Ital Cardiol*. 2016;17(10):791-795.

Groner A, et al. The leadless pacemaker: An innovative design to enhance pacemaking capabilities. *JAAPA*. June 2019;32(6):48-50.

Kancharla K, et al. Leadless Pacemakers–Implant, Explant and Long-Term Safety and Efficacy Data. *J Atr Fibrillation*. August 31, 2017;10(2):1581.

Magnusson P, et al. "Leadless Pacemakers." In: Cardiac Pacing and Monitoring -New Methods, Modern Devices. IntechOpen, 2019.

Mondesert B, et al. Technological Advances in Arrhythmia Management Applied to Adults With Congenital Heart Disease. *Can J Cardiology*. December 2019;35(12):1708-1722.

Montgomery JA, et al. Feasibility of Defibrillation and Pacing without Transvenous Leads In A Combined Micra and S-Icd System Following Lead Extraction. *J Cardiovasc Electrophysiol.* February 2017;28(2):233-234.

Piro A, et al. Leadless pacing: Presente e Futuro della stimolazione cardiaca. *G Ital Cardiol*. January 1, 2019;20(1):32-40.

Tjong FVY, et al. Permanent Leadless Cardiac Pacemaker Therapy: A Comprehensive Review. *Circulation*. April 11, 2017;135(15):1458-1470.

Vaidya VR, et al. Real-world experience with leadless cardiac pacing. *Pacing Clin Electrophysiol*. March 2019;42(3):366-373.

Vamos M, et al. Incidence of Cardiac Perforation With Conventional and With Leadless Pacemaker Systems: A Systematic Review and Meta-Analysis. *J Cardiovasc Electrophysiol*. March 2017;28(3):336-346.





**SAFETY & EFFICACY** 

MICRA<sup>™</sup> AV

DEVICE TECHNOLOGY

IMPLANT PROCEDURE & CONSIDERATIONS

**INFECTION** 

#### DEVICE LIFE CYCLE MANAGEMENT

PATIENT CASE STUDIES

## **QUALITY OF LIFE**

BIBLIOGRAPHY — JULY 2020

#### Medtronic 710 Medtronic Parkway Minneapolis, MN 55432-5604

USA

Toll-free in USA: 800.633.8766 Worldwide: +1.763.514.4000

#### medtronic.com

UC201606717b EN ©2020 Medtronic. Minneapolis, MN. All Rights Reserved. 08/2020

