

LEADLESS PACEMAKER

Hangi Hastalarda Kullanılmalı?

Dr. Sabri Demircan

Klasik Pacemaker ile İlişkili Sorunlar

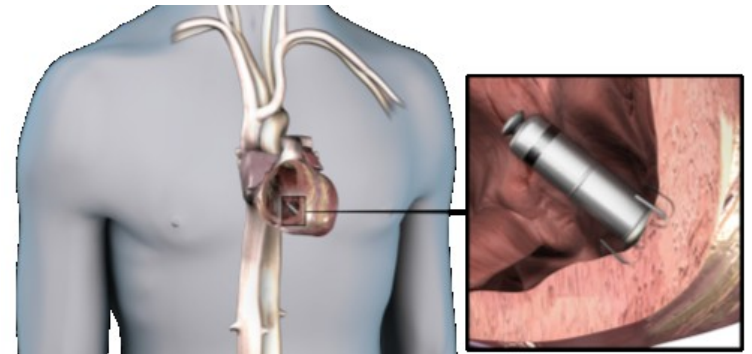
Ceple İlişkili Komplikasyonlar

- Enfeksiyon
- Hematom
- Erozyon



Lead'le İlişkili Komplikasyonlar

- Fraktür
- İnsulasyon defekti
- Venöz tromboz ve obstrüksiyon
- Triküspit yetersizliği



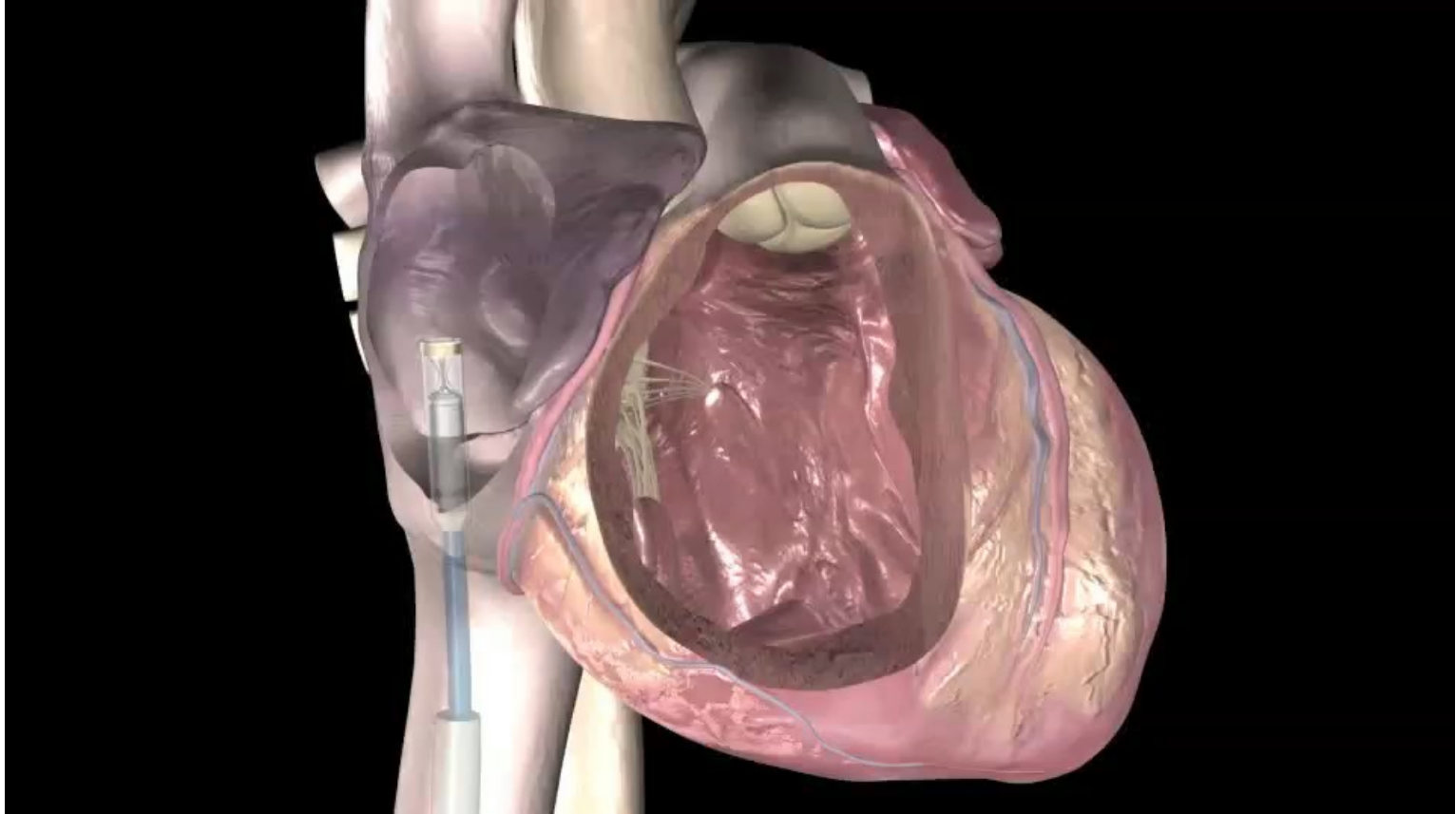
Leadless Pacemaker

Category	Micra™ Transcatheter Pacing System	Nanostim Leadless Pacemaker ¹
Device Size	Length: 26 mm Volume: 0.8 cc	Length: 41 mm Volume: > 1 cc
Fixation	Four self-expanding nitinol tines	Helical screw with angled nylon sutures for counter-rotation
Remote Monitoring Capability	CareLink™ Enabled	None
Rate Response Mechanism	3-axis accelerometer	RV blood temperature
MR Conditional	MR Conditional (at launch)	"Inherently MR Conditional" (no data to support claim)
Longevity	8-10 years	8-10 years
Retrievability Method	Snare + empty Micra delivery catheter	Custom single-loop or tri-loop snare device and Nanostim retrieval catheter
Programming	CareLink 2090 Programmer (same as today)	Nanostim Programmer Link + Merlin programmer + ECG patches
Introducer Sheath	23 Fr	18 Fr

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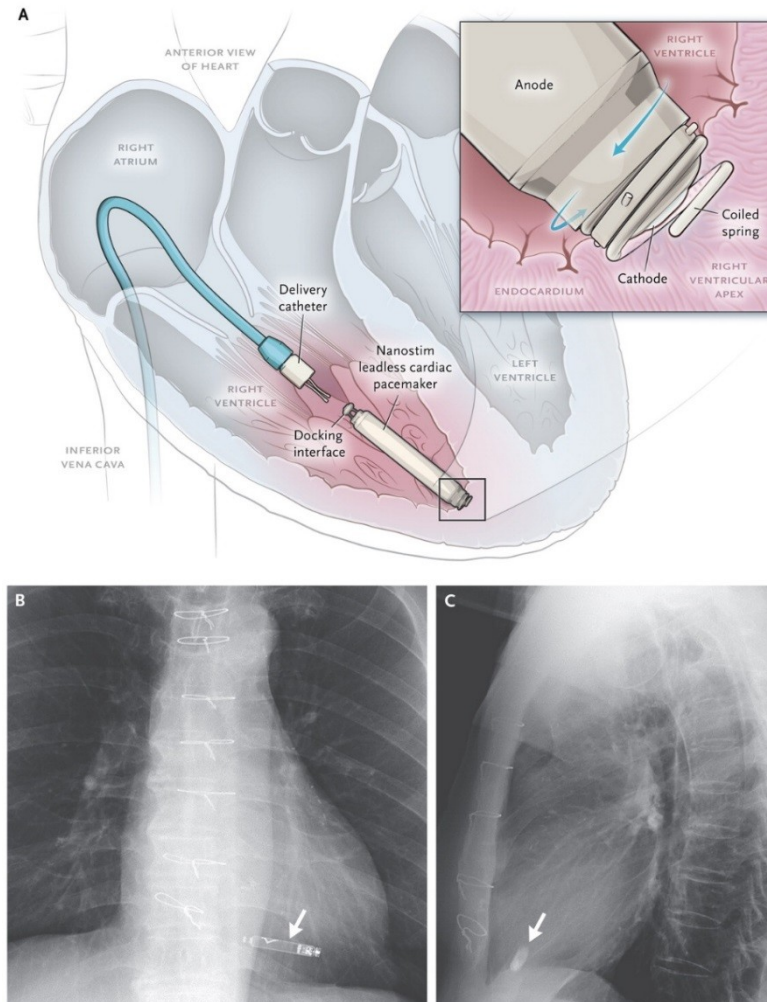


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Nanostim



Reddy VY, et al. Percutaneous Implantation of an Entirely Intracardiac Leadless Pacemaker. *N Engl J Med* 2015; 373:1125-1135

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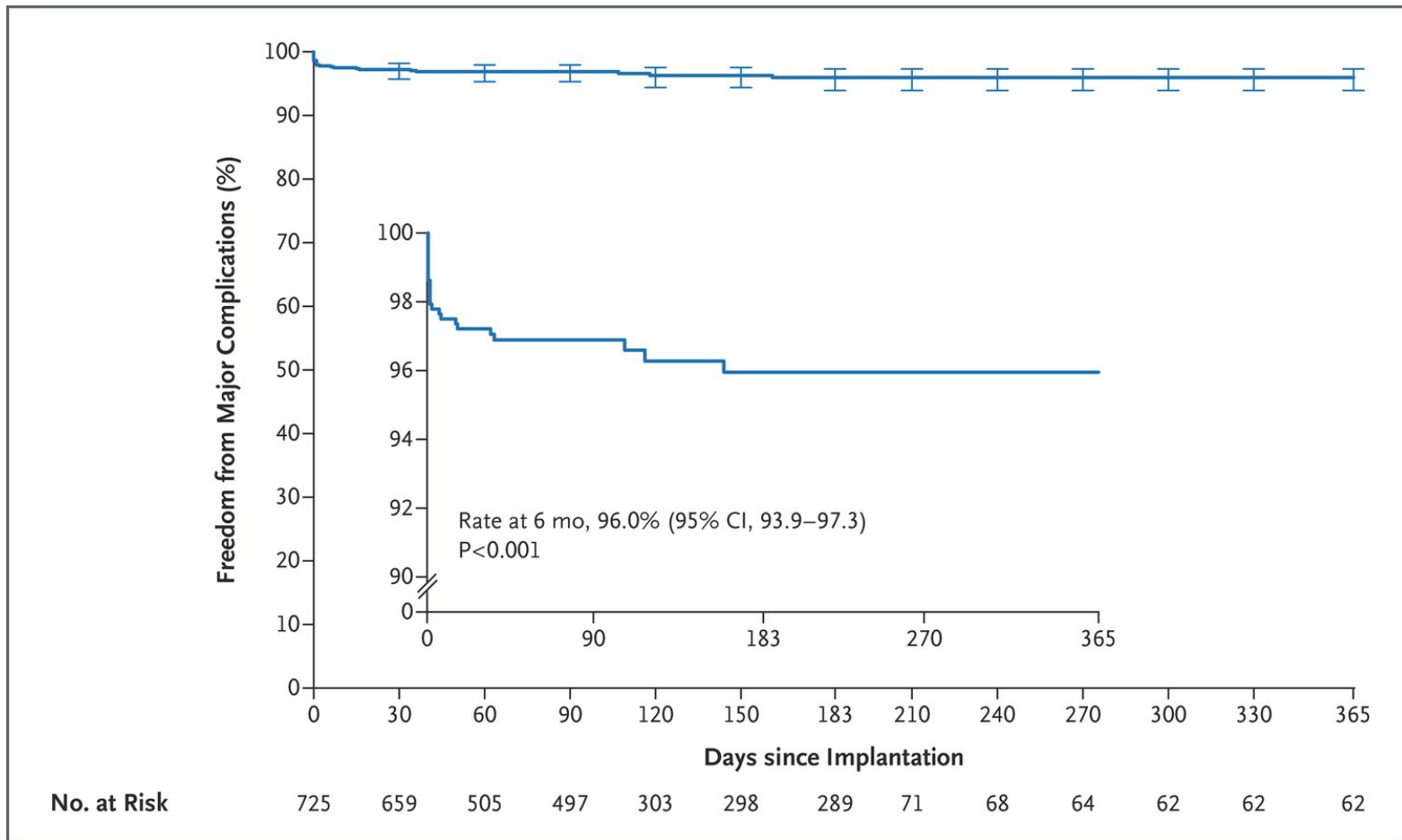
Micra

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Patients Who Underwent Attempted Implantation (N = 725)
Age — yr	
Mean	75.9±10.9
Range	19.0–94.0
Sex — no. (%)	
Male	426 (58.8)
Female	299 (41.2)
Left ventricular ejection fraction — %†	
Mean	58.8±8.8
Range	25.0–91.0
Coexisting conditions — no. (%)	
Diabetes	207 (28.6)
Chronic obstructive pulmonary disease	90 (12.4)
Renal dysfunction	145 (20.0)
Left bundle-branch block	98 (13.5)
Vascular disease	53 (7.3)
Coronary artery disease	203 (28.0)
Atrial fibrillation	526 (72.6)
Congestive heart failure	123 (17.0)
Hypertension	570 (78.6)
Valvular disease	306 (42.2)

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Reynolds D, et al. A Leadless Intracardiac Transcatheter Pacing System. N Engl J Med 2016; 374:533-541

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Table 2. Major Complications in 725 Patients Who Underwent a Transcatheter Pacemaker Implantation Attempt.

Adverse Event	No. of Events Associated with Major Complication Criterion*						Total Events	No. of Patients (%)†
	Death	Loss of Device Function	Hospitalization	Prolonged Hospitalization‡	System Revision	Total Events		
Embolism and thrombosis	0	0	1	1	0	2	2 (0.3)	
Deep vein thrombosis	0	0	0	1	0	1	1 (0.1)	
Pulmonary thromboembolism	0	0	1	0	0	1	1 (0.1)	
Events at groin puncture site: atrioventricular fistula or pseudoaneurysm	0	0	2	3	0	5	5 (0.7)	
Traumatic cardiac injury: cardiac perforation or effusion	0	0	3	9	0	11	11 (1.6)	
Pacing issues: elevated thresholds	0	1	2	1	2	2	2 (0.3)	
Other events	1	0	5	4	1	8	8 (1.7)	
Acute myocardial infarction	0	0	0	1	0	1	1 (0.1)	
Cardiac failure	0	0	3	2	0	3	3 (0.9)	
Metabolic acidosis	1	0	0	0	0	1	1 (0.1)	
Pacemaker syndrome	0	0	1	0	1	1	1 (0.2)	
Presyncope	0	0	0	1	0	1	1 (0.1)	
Syncope	0	0	1	0	0	1	1 (0.1)	
Total	1	1	13	18	3	28	25 (4.0)	

Table 2. Device-Related Serious Adverse Events.*

Event	Primary Cohort (N=300)			Total Cohort (N=526)		
	No. of Events	No. of Patients	Event Rate	No. of Events	No. of Patients	Event Rate
			%			%
Total	22	20	6.7	40	34	6.5
Cardiac perforation						
Cardiac tamponade with intervention	1	1	0.3	5	5	1.0
Cardiac perforation requiring intervention	1	1	0.3	1	1	0.2
Pericardial effusion with no intervention	2	2	0.7	2	2	0.4
Vascular complication						
Bleeding	2	2	0.7	2	2	0.4
Arteriovenous fistula	1	1	0.3	1	1	0.2
Pseudoaneurysm	1	1	0.3	2	2	0.4
Failure of vascular closure device requiring intervention	0	0	0	1	1	0.2
Arrhythmia during device implantation						
Asystole	1	1	0.3	1	1	0.2
Ventricular tachycardia or ventricular fibrillation	1	1	0.3	2	2	0.4
Cardiopulmonary arrest during implantation procedure	0	0	0	1	1	0.2
Device dislodgement	5	5	1.7	6	6	1.1
Device migration during implantation owing to inadequate fixation	0	0	0	2	2	0.4
Pacing threshold elevation with retrieval and implantation of new device	4	4	1.3	4	4	0.8
Other						
Hemothorax	0	0	0	1	1	0.2
Angina pectoris	0	0	0	1	1	0.2
Pericarditis	1	1	0.3	1	1	0.2
Acute confusion and expressive aphasia	0	0	0	1	1	0.2
Dysarthria and lethargy after implantation	0	0	0	1	1	0.2
Contrast-induced nephropathy	0	0	0	1	1	0.2
Orthostatic hypotension with weakness	1	1	0.3	1	1	0.2
Left-leg weakness during implantation	0	0	0	1	1	0.2
Probable pulmonary embolism	1	1	0.3	1	1	0.2
Ischemic stroke	0	0	0	1	1	0.2

Table 3. Non-Device-Related Serious Adverse Events.*

Event	Primary Cohort (N=300)			Total Cohort (N=526)		
	No. of Events	No. of Patients	Event Rate	No. of Events	No. of Patients	Event Rate
			%			%
Total	22	19	6.3	36	29	5.5
Acute renal failure	1	1	0.3	2	2	0.4
Angina pectoris	1	1	0.3	2	2	0.4
Atrial fibrillation with rapid ventricular rates	1	1	0.3	1	1	0.2
Bacteremia	0	0	0	1	1	0.2
Bell's palsy	1	1	0.3	1	1	0.2
Bilateral pulmonary emboli with pulmonary infarction	1	1	0.3	1	1	0.2
Change in mental status	1	1	0.3	1	1	0.2
Dizziness	2	2	0.7	3	2	0.4
Heart failure	0	0	0	4	4	0.8
Heart failure and gout	1	1	0.3	1	1	0.2
Hypertensive emergency	1	1	0.3	1	1	0.2
Lung cancer	1	1	0.3	1	1	0.2
Mechanical fall	0	0	0	1	1	0.2
Methicillin-resistant <i>Staphylococcus aureus</i> infection	1	1	0.3	1	1	0.2
Myocardial infarction	1	1	0.3	1	1	0.2
Palpitations	1	1	0.3	1	1	0.2
Pericardial effusion after placement of epicardial lead	1	1	0.3	1	1	0.2
Reduction in ejection fraction: new onset	0	0	0	1	1	0.2
Seizure: new onset	0	0	0	1	1	0.2
Sepsis	2	2	0.7	2	2	0.4
Shortness of breath	1	1	0.3	1	1	0.2
Stroke	1	1	0.3	1	1	0.2
Syncope: unknown cause	1	1	0.3	1	1	0.2
Syncope: vasovagal	1	1	0.3	1	1	0.2
Urinary retention	1	1	0.3	1	1	0.2
Ventricular tachycardia or ventricular fibrillation	0	0	0	2	2	0.4
Vertigo	0	0	0	1	1	0.2

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Leadless Pacemaker

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Subject Characteristics	No Cardiac Injury (N = 712)	Yes Cardiac Injury (N = 13)	p-value
Age (years)			
Mean ± Standard Deviation	75.8 ± 11.0	81.7 ± 8.6	0.053
Median	78.0	85.0	
25 th Percentile - 75 th Percentile	72.0 - 83.0	77.0 - 88.0	
Minimum - Maximum	19.0 - 94.0	64.0 - 91.0	
Number of Subjects With Measure Available (N,%)	712 (100.0%)	13 (100.0%)	
BMI			
Mean ± Standard Deviation	27.6 ± 5.3	24.5 ± 4.0	0.032
Median	26.8	24.8	
25 th Percentile - 75 th Percentile	24.2 - 30.7	22.1 - 27.9	
Minimum - Maximum	14.2 - 56.9	18.3 - 30.9	
Number of Subjects With Measure Available (N,%)	710 (99.7%)	13 (100.0%)	
Sex			
Male n (%)	422 (59.3%)	4 (30.8%)	0.048
Female n (%)	290 (40.7%)	9 (69.2%)	
Primary Pacing Indication n (%)			
Symptomatic sinus node dysfunction	308 (43.3%)	6 (46.2%)	0.83
AV Blocks	346 (48.6%)	7 (53.8%)	
Other Indications	58 (8.1%)	0 (0.0%)	
Cardiovascular Disease History n (%)			
Cardiomyopathy	76 (10.7%)	1 (7.7%)	1.00
Congestive heart failure	119 (16.7%)	4 (30.8%)	0.25
Coronary artery disease	199 (27.9%)	4 (30.8%)	0.76
Hypertension	561 (78.8%)	9 (69.2%)	0.49
Myocardial infarction	72 (10.1%)	4 (30.8%)	0.038
Pulmonary hypertension	77 (10.8%)	3 (23.1%)	0.16
Tricuspid valve dysfunction	176 (24.7%)	6 (46.2%)	0.10
Coronary artery intervention	108 (15.2%)	4 (30.8%)	0.13
Other Comorbidities n (%)			
COPD	85 (11.9%)	5 (38.5%)	0.015
Chronic lung disease	203 (28.5%)	8 (61.5%)	0.025
Diabetes	203 (28.5%)	4 (30.8%)	1.00
Renal dysfunction	143 (20.1%)	2 (15.4%)	1.00

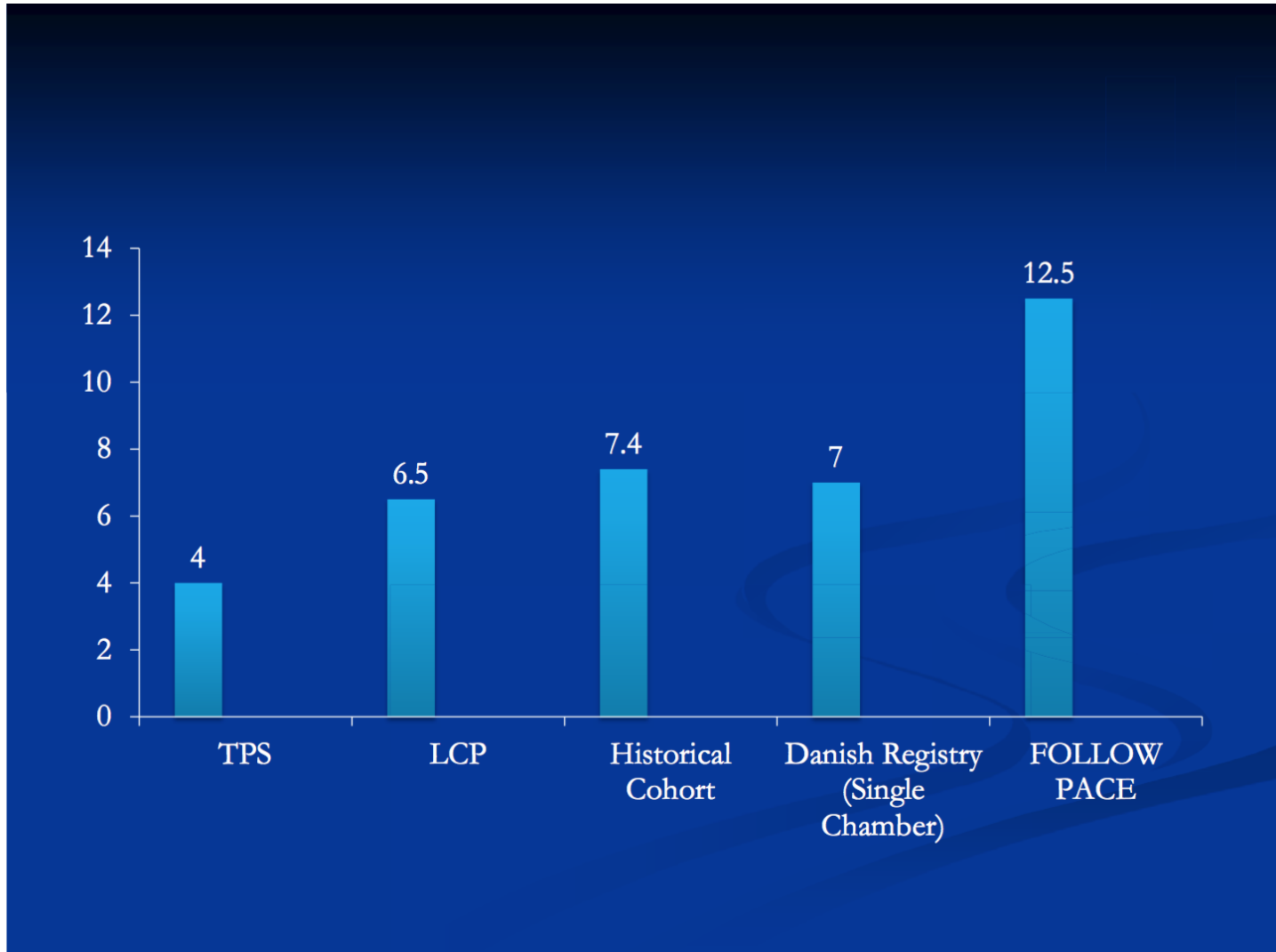
Leadless Pacemaker

Summary of Nanostim leadless cardiac pacemaker (LCP) and Micra Transcatheter pacing system (TPS) investigational device exemption (IDE) trials

Variables	Trials	
	Leadless II-LCP (n=526)	Micra-TPS (n=725)
Implant Success	95.8%	99.2%
Thresholds @ Implant (V@ms)	0.82 @ 0.4	0.63 @ 0.24
Threshold @ 6 Months (V@ms)	0.53 @ 0.4	0.54 V @ 0.24
Complication Rates (6 months)	6.5%	4%
Pericardial Effusion	1.5%	1.6%
Groin Complication	1.2%	0.7%
Device Dislodgement	1.1%	0%

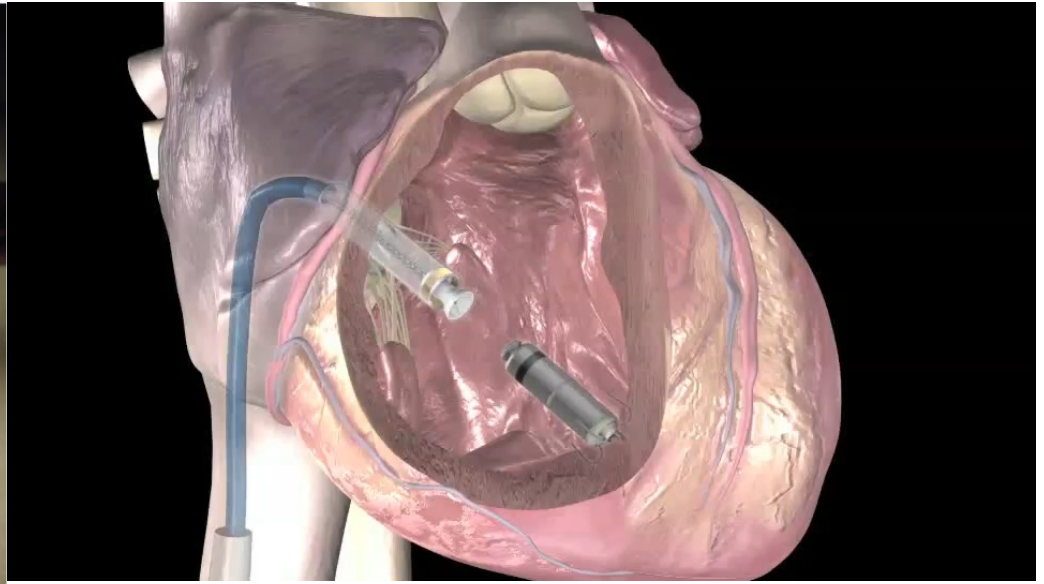
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Komplikasyon



Leadless Pacemaker

Geril Alınma

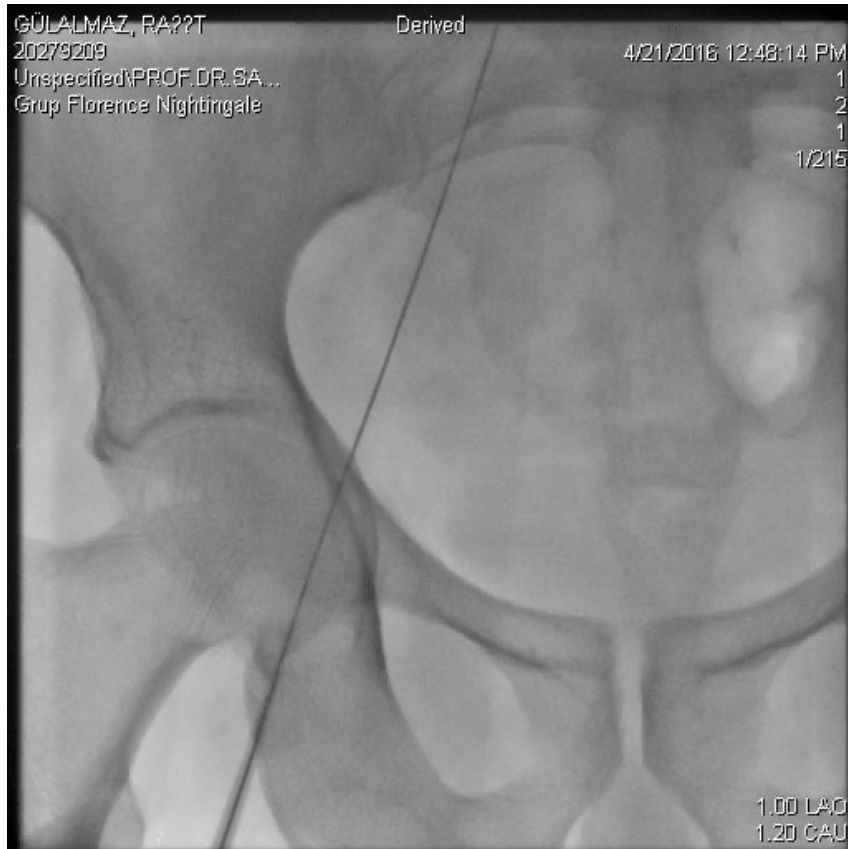


Leadless Pacemaker Olgu

- 56 yaş, erkek hasta
- Fenalık hissi, gece boğulma hissi
- EKG: İnkomplet RBBB
- Holter: Gece saatlerinde 3 sn'den fazla duraklamalara neden olan geçici AV bloklar
- Tekrarlayan Holter incelemelerde benzer bulgular

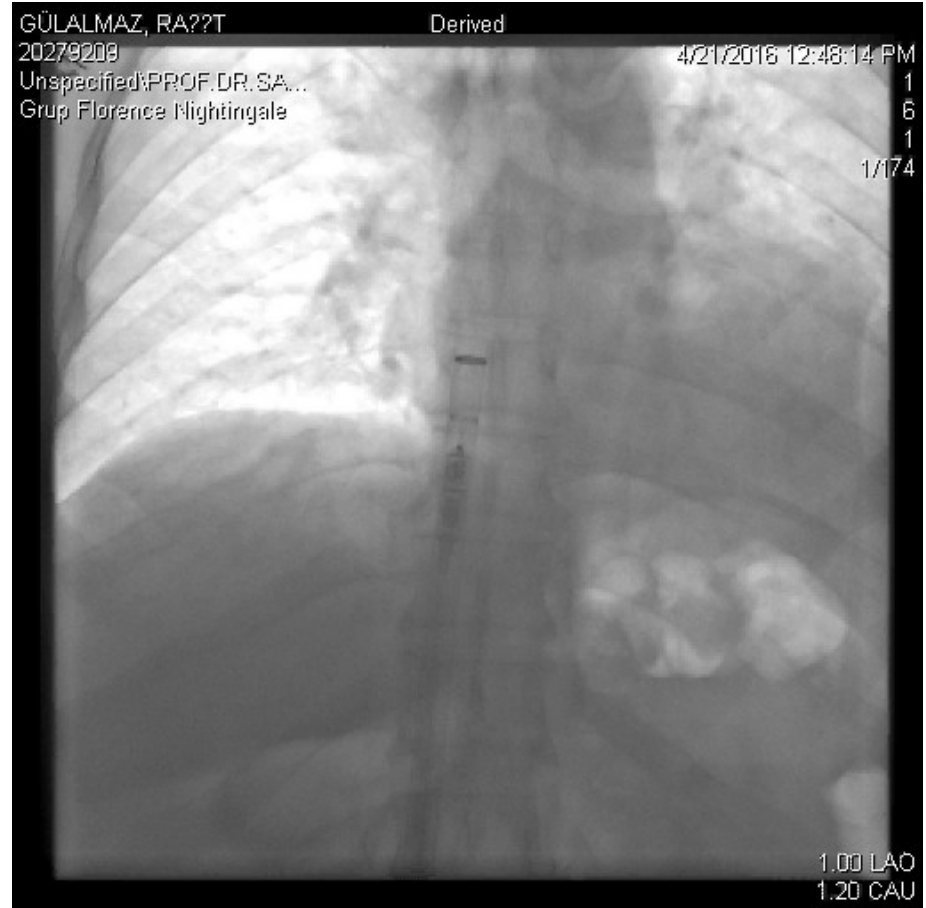
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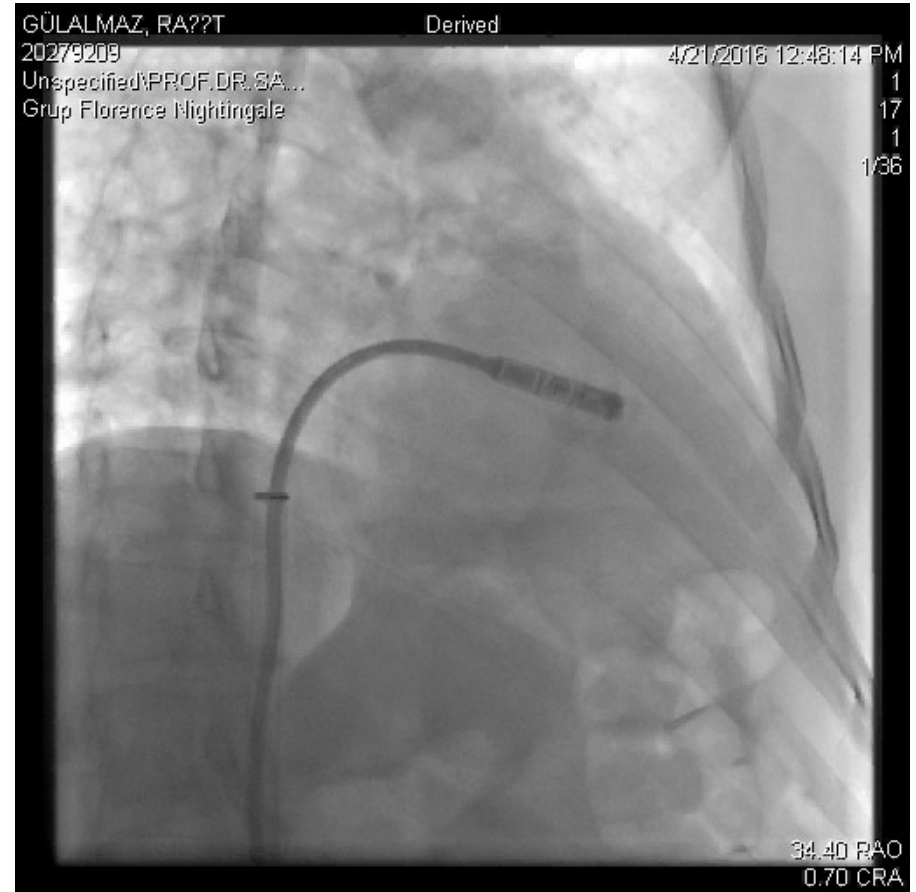
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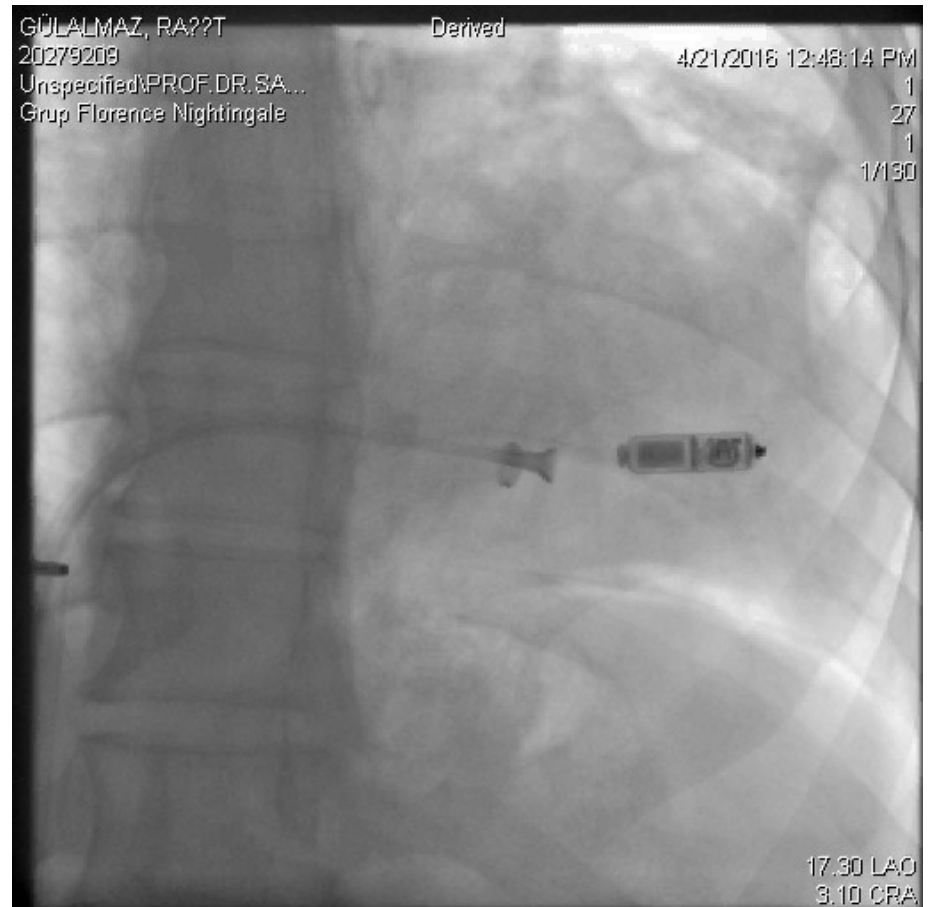
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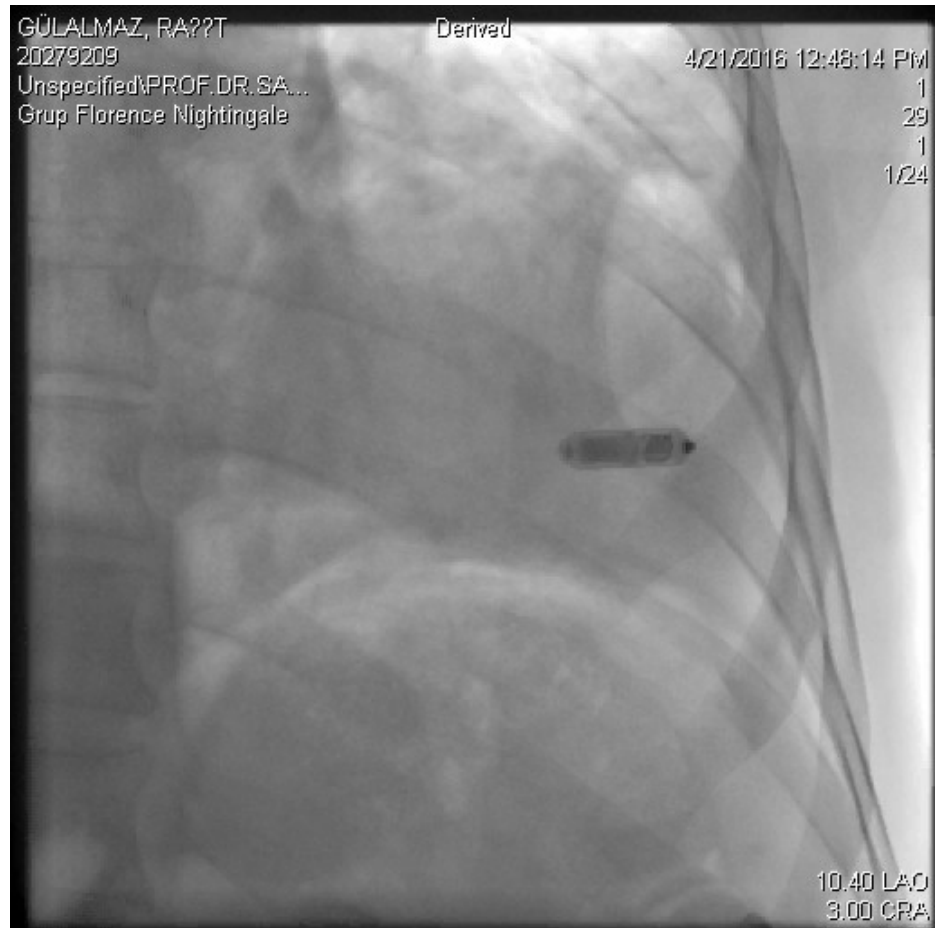
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Leadless Pacemaker

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Leadless Pacemaker

Sorunlar

- Pacing ve sensing sađ ventrikülle sınırlı
- Perkütan geri alınmayı gerektiren yer deđiřtirme
- Pacing eřik artması nedeniyle repozisyon gereksinimi
- Kasık komplikasyonlar

Leadless Pacemaker

Hangi Hastalara?

- Tek odacıklı pace gereksinimi (AF)
- Yaşlı hastalar
- Nadir pacemaker ihtiyacı doğuran özel durumlar
- Vasküler problemi olan olgular
- Pacemaker sistem enfeksiyonu varlığı
- Pacemaker endikasyonu olup konvansiyonel pacemaker'ı reddeden olgular

Pacemaker Teknolojisi

1959



2013



Teşekkürler...