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Micra™

TRANSCATHETER PACING SYSTEM

Objection Handling

Framework

Please click a topic to learn more about it, or click the forward button in the lower right to continue to the next page

Implant Procedure	Device Technology	Long-Term Management	Competitive	Value
Venous Access	Patient Population	Retrieval	Nanostim®	Innovation Pricing
Perforation	Longevity	Chronic Extraction	Fixation Design	10-Pack
Dislodgement	Communication/ Telemetry			Micra™ TPS Academy
Repositionable	CareLink™ Enabled			

Implant Procedure

HOME

IMPLANT PROCEDURE

DEVICE TECHNOLOGY

LONG-TERM MANAGEMENT

COMPETITIVE

VALUE

Please click a topic to learn more about it, or click the forward button in the lower right to continue to the next page

Venous Access

Perforation

Dislodgement

Repositionable

Pivot Question – Venous Access

"I think what you are asking is do we have any clinical experience with the Micra™ Introducer."

"I think what you are asking is do we have experience with other technologies that use similar sized sheaths in the femoral vein."

Micra™ Transcatheter Pacing Study[1]

Key Findings of Late Breaking Clinical Trial

- Met initial safety and performance measures
- 100% implant success in wide range of patients
- No dislodgements, infections, or related deaths observed
- Serious adverse event rate with Micra TPS appears to be in line with traditional systems
- Electrical performance is excellent and remains stable at 3 months, with expected average device longevity of ≥ 10 years
- Long-term safety and benefit will be further evaluated in the ongoing trial

Reference
[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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Venous Access

Clinical Experience with Micra™ Introducer[1]

- 1 serious adverse event (n = 140) related to groin access. Resolved with thrombin injection.

Serious Adverse Events

	Resulting in death, re-operation, or hospitalization	N (pts, %)
DYSRHYTHMIAS		
Transient AV block	No	2 (2, 1.4%)
RBBB	No	1 (1, 0.7%)
VT	No	1 (1, 0.7%)
VF	No	1 (1, 0.7%)
CARDIAC		
Pericardial effusion, no tamponade	1 hospitalization prolonged >48 hrs for both events in same patient*	1 (1, 0.7%)
Acute MI		1 (1, 0.7%)
Pericarditis	No	1 (1, 0.7%)
OTHER		
Arterial pseudoaneurysm	1 hospitalization prolonged >48 hrs†	1 (1, 0.7%)
TOTAL	3 (2, 1.4%)	9 (8, 5.7%)

*Occurred in patient with 18 deployments who had 3 vessel disease
†Resolved after thrombin injection

26

Reference
[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

Venous Access

Clinical Experience with Micra™ Introducer[1]

- Micra Introducer used successfully in a wide variety of patients

Baseline Characteristics

	Patients (n=140)
Male gender	85, 61%
Age (years)	78 (21 – 94)
Height (cm)	170 (144 – 190)
Weight (kg)	76 (41 – 148)
Body Mass Index	26 (20 – 45)
One or more comorbidity	136, 97%
Primary Indication	
Bradycardia with permanent or persistent AT/AF	91, 65.0%
Sinus node dysfunction	22, 15.7%
Atrioventricular block	19, 13.6%
Other reasons	8, 5.7%

Median and ranges reported

22

Reference
[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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Venous Access

Comparably-sized technology

Melody® Transcatheter Pulmonary Valve[1]
Medtronic

- 22 Fr Delivery catheter
- Femoral vein access
- Over 1,500 patients. Ages 5-70.
  - No adverse events related to access or closure
  - No need for closure devices per clinical data
- Commercially available in EU and United States

MitraClip® Percutaneous Mitral Valve Repair System[2]
Abbott

- 24 Fr Delivery catheter
- Femoral vein access
- EVEREST Clinical Trial (n = 248). Median age: 67.
  - Standard venous puncture used without "any special techniques"[1]
  - Closure done with manual or pneumatic compression without any late bleeding
- Commercially available in EU and United States

References
[1] Medtronic Melody Valve U.S. Clinical Trial Report, 2009.
[2] Feldman T, et al. *J Am Coll Cardiol.* 2005;46:2134-2140.

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Pivot Question – Perforation Risk

"I think the question you are asking is do we have data on perforation from the clinical trial."

"I think the question you are asking is what have we done to mitigate the risk of perforation."

Micra™ Transcatheter Pacing Study[1]

Key Findings of Late Breaking Clinical Trial

- Met initial safety and performance measures
- 100% implant success in wide range of patients
- No dislodgements, infections, or related deaths observed
- Serious adverse event rate with Micra TPS appears to be in line with traditional systems
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[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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Perforation Risk

Clinical Experience (n = 140)[1]

- 1 pericardial effusion occurred, without tamponade (n = 140). Occurred in a patient with 18 deployments who had unknown 3 vessel CAD.

Serious Adverse Events

	Resulting in death, re-operation, or hospitalization	N (pts, %)
DYSRHYTHMIAS		
Transient AV block	No	2 (2, 1.4%)
RBBB	No	1 (1, 0.7%)
VT	No	1 (1, 0.7%)
VF	No	1 (1, 0.7%)
CARDIAC		
Pericardial effusion, no tamponade	1 hospitalization prolonged >48 hrs for both events in same patient*	1 (1, 0.7%)
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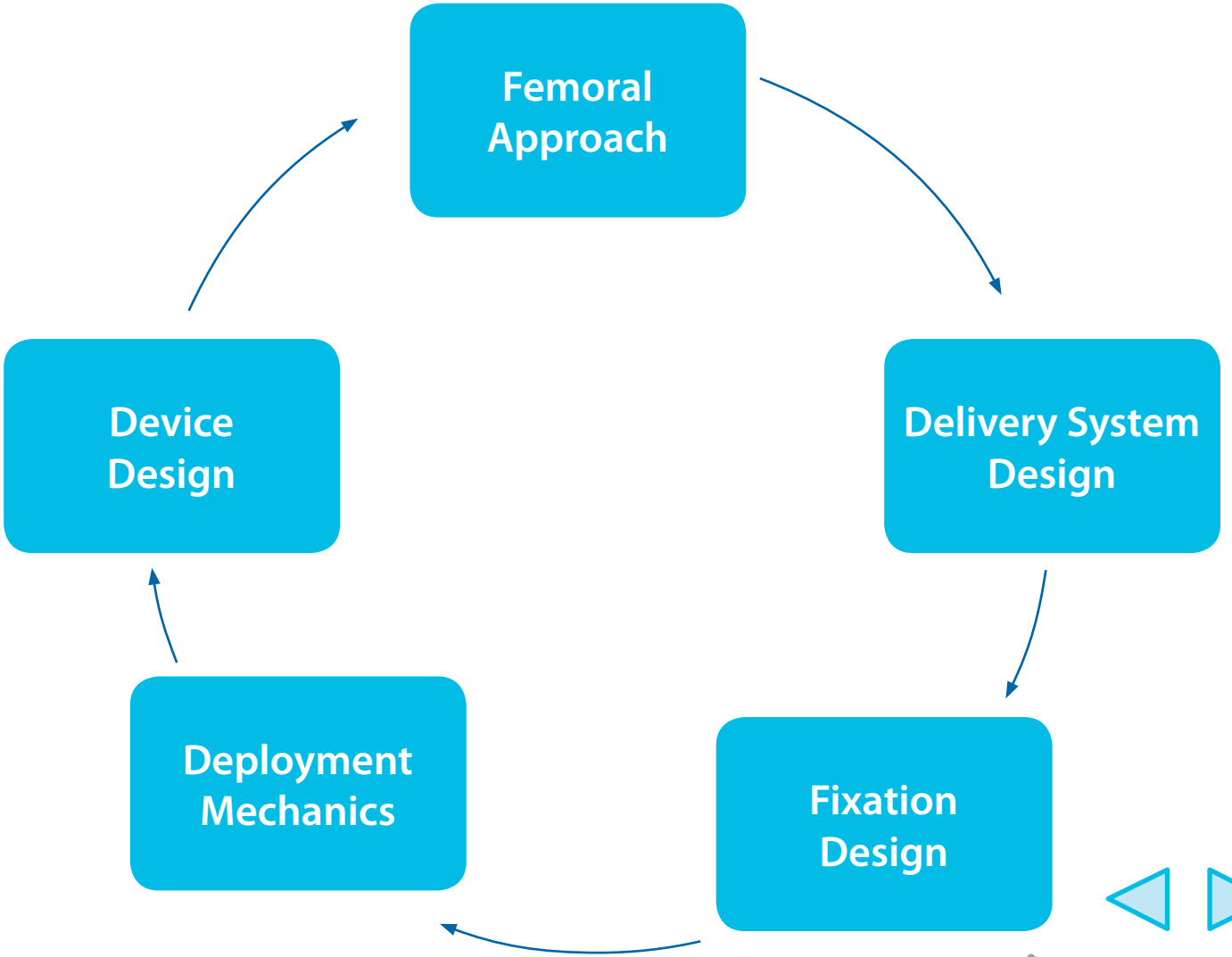
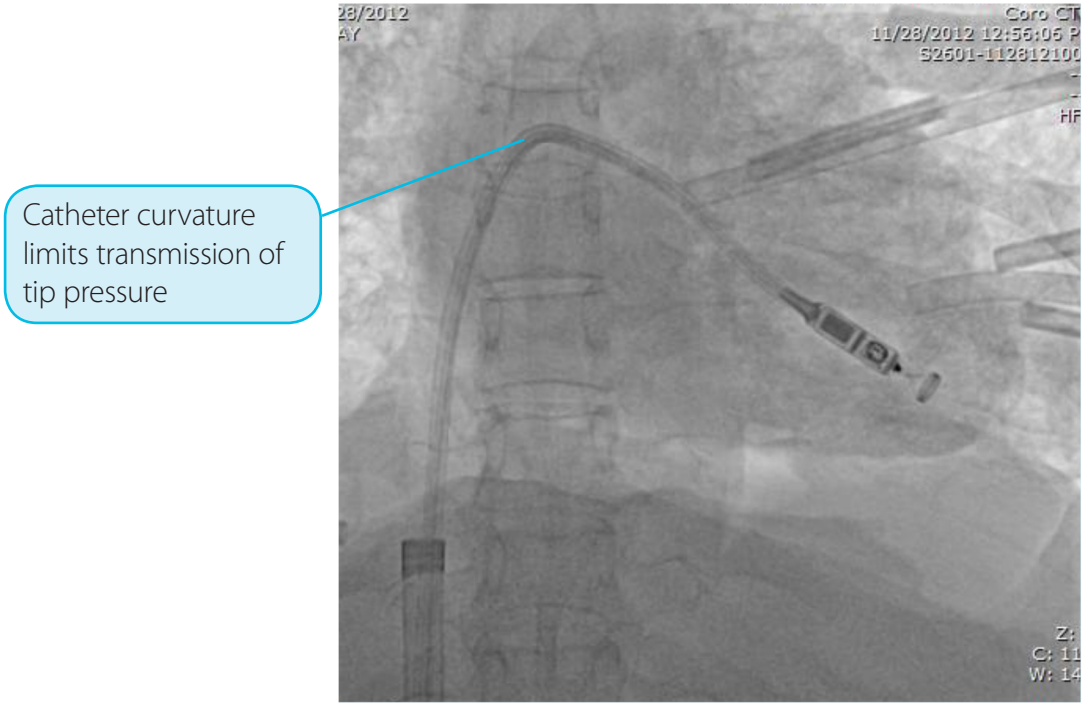
Approach to Mitigate Perforation Risk



Perforation Risk Mitigation

Femoral Approach

- Reduces the transmission of tip force that is achievable at the distal tip of the catheter

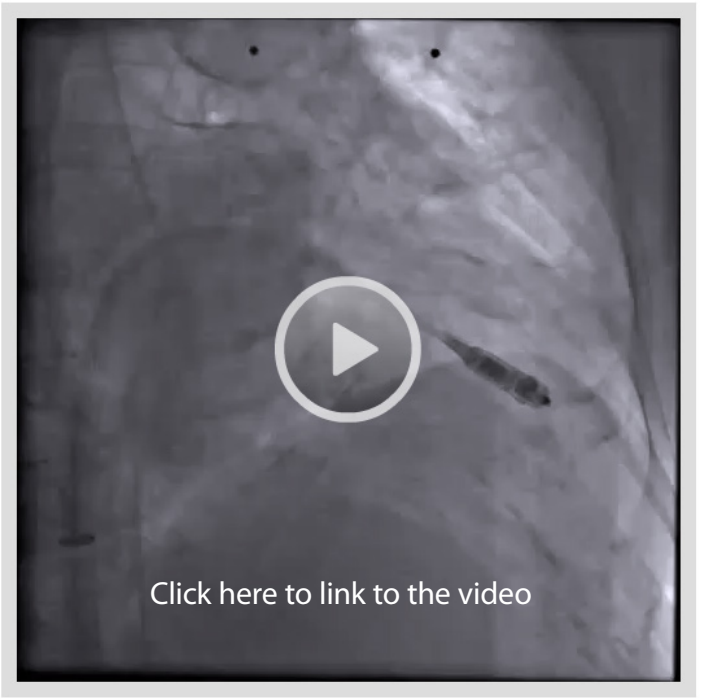


Perforation Risk Mitigation

Delivery System Design

- Provides 11% push efficiency that limits the tip force at the distal tip of the catheter[1]
- Delivery system provides visual feedback when adequate tip pressure is achieved

Catheter provides safety margin between tip force and the force required to perforate the right ventricle.[1]



Reference

[1] Evaluation of Risk of Micra Delivery System Perforation. Medtronic Data on File, 2014.

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Perforation Risk Mitigation

Fixation Design

- Atraumatic, Nitinol FlexFix™ Tines are designed to minimise tissue damage during deployment and repositioning and do not penetrate any further than a traditional active fixation lead

Atraumatic fixation coupled with catheter retraction designed to limit pressure on myocardium during deployment.

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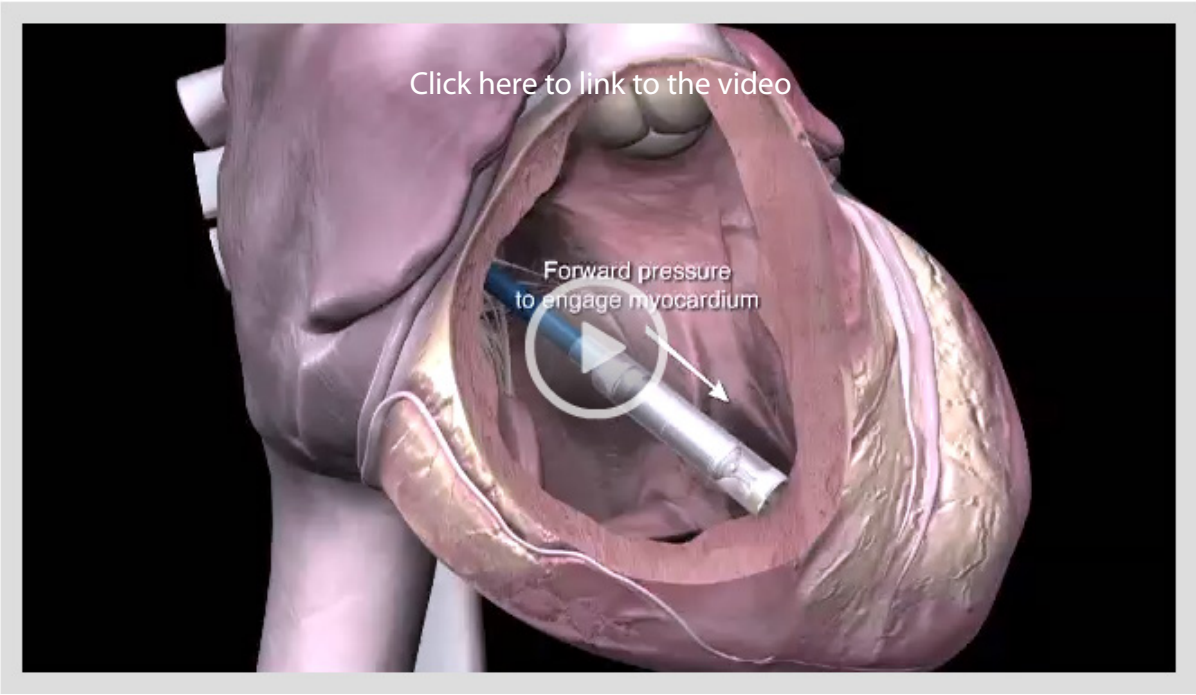
Perforation Risk Mitigation

Deployment Mechanics

- Delivery system retracts when deploying the device into myocardial tissue and does not require any torque to fixate



Catheter retraction limits pressure on myocardium during deployment.

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Perforation Risk Mitigation

Device Design

- Larger catheter/device footprint distributes tip force over a greater surface area[1]

Tip force is distributed over a greater surface area and limits perforation risk.

Reference

[1] Evaluation of Risk of Micra Delivery System Perforation. Medtronic Data on File, 2014.

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Pivot Question – Dislodgement Risk

"I think what you are asking is if we have clinical data to share on fixation performance."

"I think what you are asking is if we have data on tine performance and holding force."

"I think what you are asking is what have we done to mitigate risk of dislodgement."

Micra™ Transcatheter Pacing Study[1]

Key Findings of Late Breaking Clinical Trial

- Met initial safety and performance measures
- 100% implant success in wide range of patients
- No dislodgements, infections, or related deaths observed
- Serious adverse event rate with Micra TPS appears to be in line with traditional systems
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[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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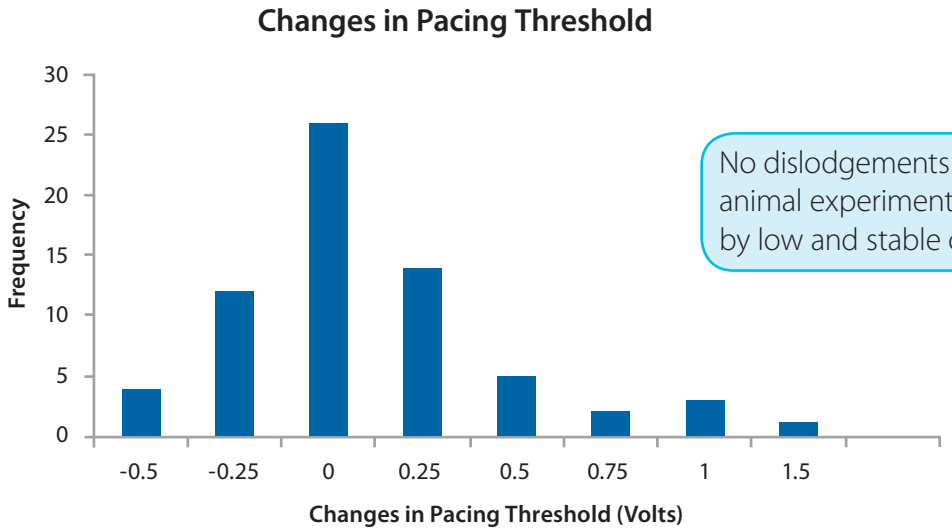
Dislodgement Risk

Pre-Clinical Experience

- Device dislodgement has not been observed in 113 implanted devices in chronic animal experiments[1]



No dislodgements were observed in 113 device implants in animal experiments and fixation stability was characterised by low and stable chronic pacing thresholds.

Reference
[1] Eggen M, Bonner M, Sheldon T, Williams E. Analysis of Micra Fixation Stability via Pacing Threshold Measurement and Fluoroscopy. Presented at EHRA Europace 2014 (Abstract 16-58).

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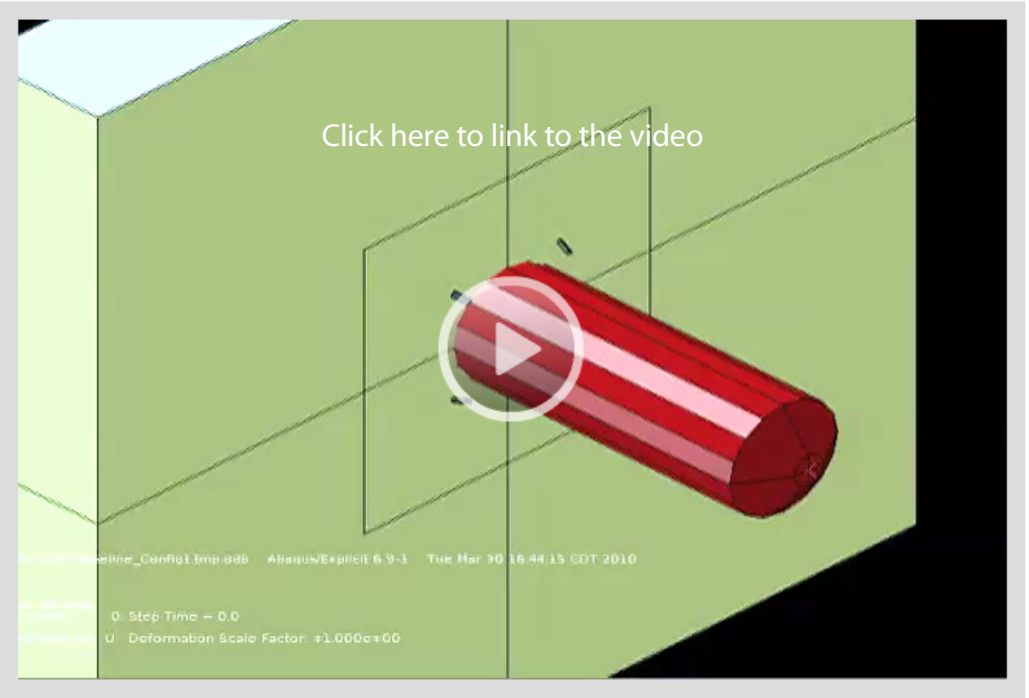
Dislodgement Risk

Design Risk Mitigation

- Multidimensional redundancy – 2 have 15x the holding force necessary to hold the device in place[1]



FlexFix™ Tines provide redundant holding force to secure the device within the myocardium.

Reference

[1] Medtronic Data on File.

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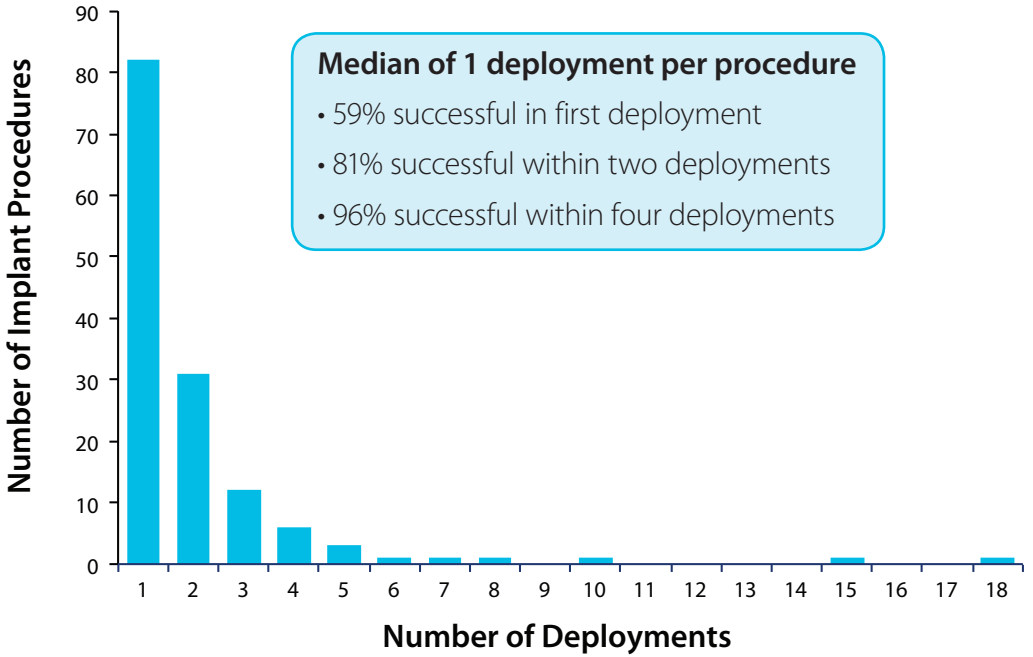
Pivot Question – Repositionable

"I think what you are asking is do we have any clinical experience repositioning the device during implant."

"I think what you are asking is what design elements have we incorporated to make the device repositionable."

Repositionable[1]

Clinical Experience (n = 140)



Reference
[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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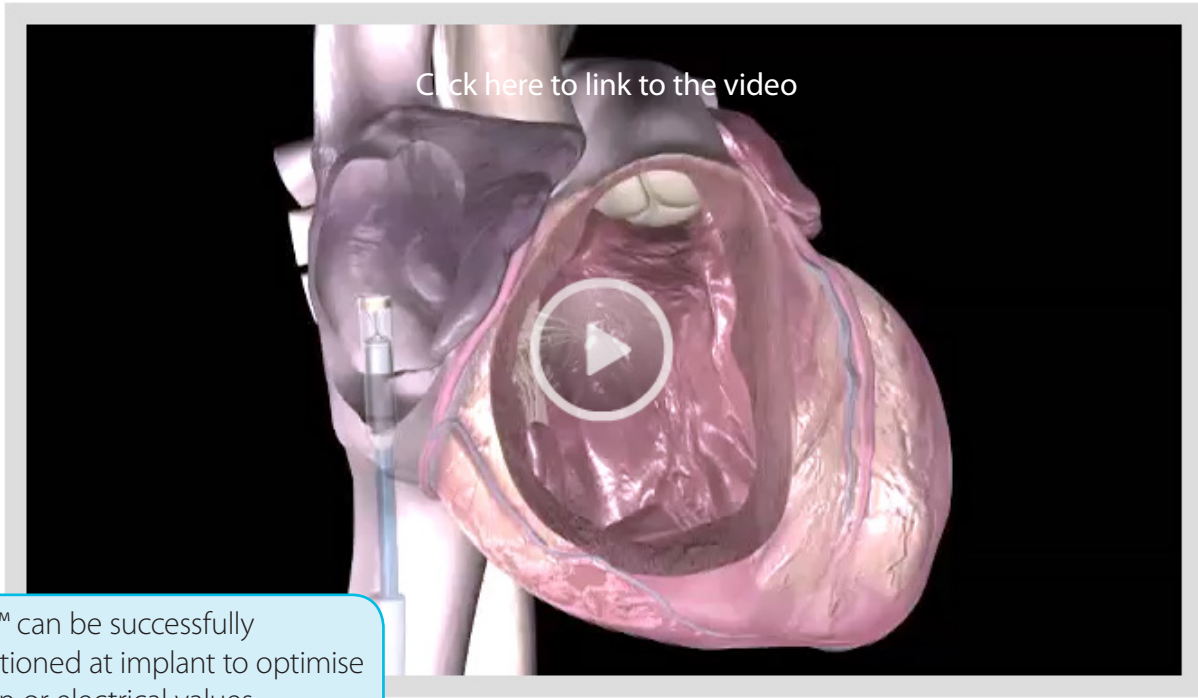
Repositionable

Device and Delivery System Design

- Nitinol FlexFix™ Tines are designed to be atraumatic and minimise tissue damage during deployment and repositioning
- Delivery system incorporates a tether system that provides the operator the ability to re-engage the device and reposition as desired



Micra™ can be successfully repositioned at implant to optimise fixation or electrical values.

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Device Technology

HOME

IMPLANT PROCEDURE

DEVICE TECHNOLOGY

LONG-TERM MANAGEMENT

COMPETITIVE

VALUE

Please click a topic to learn more about it, or click the forward button in the lower right to continue to the next page

Patient Population

Longevity

Communication/ Telemetry

CareLink™ Enabled

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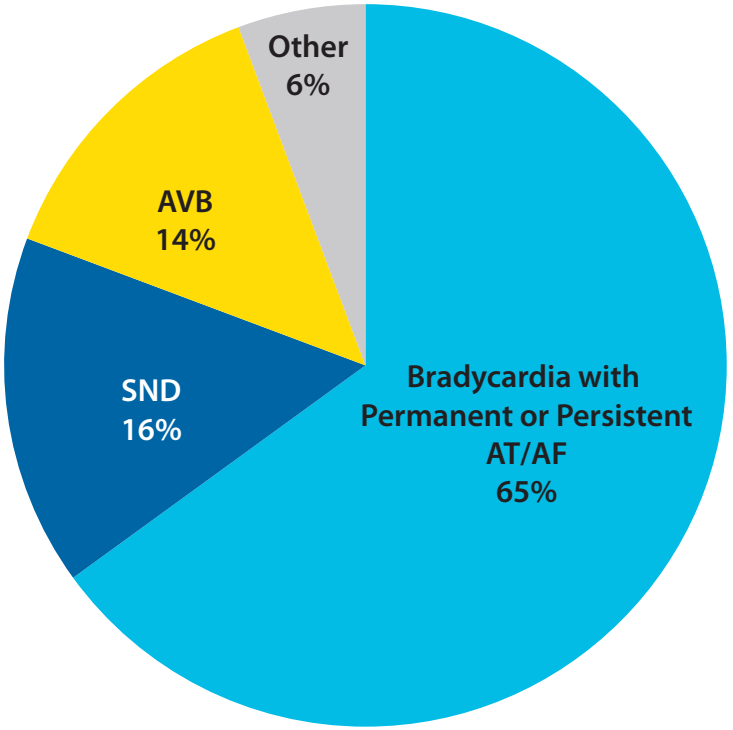
Pivot Question – Patient Population

"I think what you are asking is if there are any new clinical data to recommend different patient populations."

Patient Population

Clinical Experience[1]

Below are the indications for pacing noted in the Micra™ Transcatheter Pacing Study (n = 140).



Reference

[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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Patient Population

Indication for Micra™

Micra is intended for Class I or II indication for a single chamber ventricular pacemaker.

Pivot Question – Longevity

"I think what you are asking is do we have any longevity estimates based on actual pacing conditions from the clinical study."

"I think what you are asking is if there is any compromise in longevity due to Micra's miniaturised size."

Longevity

Clinical Experience with Micra™ Longevity[1]

- Offers comparable longevity to traditional system (10-year battery longevity[2])*

Expected Micra TPS Longevity

Based on use conditions of 60 patients followed to 3 months

- Median pacing = 49% (IQR 10%, 75%)
- Median pacing capture threshold at 0.24 ms = 0.38 V (IQR 0.38 V, 0.57 V)
- Median pacing impedance = 640 Ω (IQR 540 Ω, 725 Ω)

Battery longevity estimated at an average of 12.6 years (range 8.6 – 14.4 years)*

*Estimate does not include pacemaker dependent patients and assumes thresholds remain stable for device lifetime.

* 100% VP, 1.5 V, 60 bpm, 500 ohms, 0.24 ms

References

[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

[2] Medtronic Micra MC1VR01 Clinician Manual, November 2014.

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Longevity

- Micra's device design leverages one of the most reliable pacing leads in the market today and provides therapy in a more efficient way compared to traditional pacing systems
- Optimal electrode tissue interface allows for low and stable chronic thresholds
- The steroid-eluting electrode coupled with Micra's FlexFix™ active tines have been demonstrated in pre-clinical studies to achieve low and stable thresholds[1]

Micra's longevity is comparable to traditional pacing systems.

Reference
[1] Eggen M, Bonner M, Sheldon T, Williams E. Analysis of Micra Fixation Stability via Pacing Threshold Measurement and Fluoroscopy. Presented at EHRA Europace 2014 (Abstract 16-58).

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Pivot Question – Communication/Telemetry

"I think what you are asking is if we have had any issues with telemetry in the clinical study."

"Would it be OK if I shared with you the research and the trade-offs of wireless on the Micra™ device?"

Communication/Telemetry

Clinical Experience[1]

- No telemetry issues occurred in any patients (n = 140)
  - Serious Adverse Event rate 5.7%
    - 7.3% SAE at 1 month in Medtronic reference dataset
    - 12.4% complication at 2 months in FOLLOWPACE
  - 2 patients with prolonged hospitalization (1.4%)
  - No unforeseen events (0%)
  - No device telemetry issues (0%)
  - No dislodgements (0%)
  - No infections (0%)
  - No reoperations (0%)
  - No related deaths (0%)

Reference
[1] Ritter P, Duray G, Steinwender C, et al. Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience. Presented at HRS 2015; (Abstract): LBCT02-01.

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Communication/Telemetry

2090 Programmer Compatible

- Due to energy requirements, longevity impact, and Micra's significantly miniaturised size, wireless communication was not incorporated

- Lower energy-enabled communication mechanisms will continue to be assessed for future iterations of Medtronic pacing technologies

Micra's communication utilises the same instrumentation as today; no accessories required.

Pivot Question – CareLink™ Enabled

"I know remote monitoring is important to you; we are working to get it to you as fast as we can."

CareLink™ Enabled

Remote Monitoring Capability

- Micra™ is CareLink-enabled, and we are currently working to have it added to the CareLink Network
- Our approach is to introduce and offer our next generation remote monitoring platform with the Micra system

As with all new product launches, we are committed to providing remote monitoring functionality in all of our pacing systems.

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Long-Term Management

HOME

IMPLANT PROCEDURE

DEVICE TECHNOLOGY

LONG-TERM MANAGEMENT

COMPETITIVE

VALUE

Please click a topic to learn more about it, or click the forward button in the lower right to continue to the next page

Retrieval

Chronic Extraction

Medtronic

Pivot Question – Retrievability

"I think what you are asking is what data do we have for long-term device management."

"Let me show you the pre-clinical data we have."

"The device is designed to be programmed off; however, we do have some acute retrievability data that I can share."

Retrievability

Pre-Clinical Experience

- The Micra™ device has been successfully retrieved after 28 months in chronic animal models utilising standard percutaneous tools and methods[1]

The ability to successfully extract Micra after 28 months has been demonstrated in chronic animal models.[1]

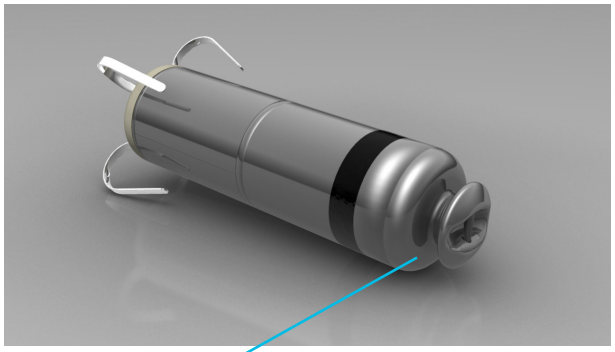
Reference

[1] Bonner M, et al. Extraction of the Micra Transcatheter Pacemaker System. Presented at HRS 2014.

Retrievability

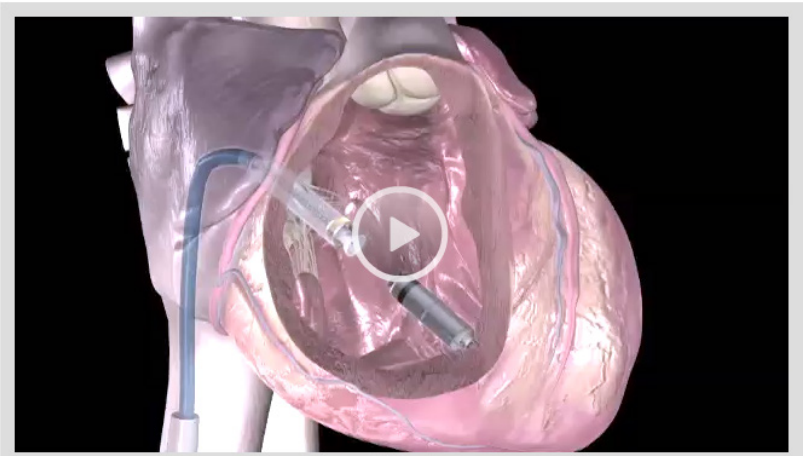
Design Risk Mitigation

- The Micra™ device design incorporates a proximal retrieval feature to enable retrieval via an unloaded Micra delivery catheter and an off-the-shelf interventional snare



Proximal Retrieval Feature

Micra's proximal retrieval feature facilitates acute retrieval.



Click to link to the video

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Chronic Extraction

Design Risk Mitigation

- The Micra™ device has the ability to be programmed off at the end of service and can be differentiated from additional Micra devices, if subsequent devices are implanted

Micra can be deactivated at the end of battery life if extraction is not necessary or possible due to device encapsulation.

Competitive

HOME

IMPLANT PROCEDURE

DEVICE TECHNOLOGY

LONG-TERM MANAGEMENT

COMPETITIVE

VALUE

Please click a topic to learn more about it, or click the forward button in the lower right to continue to the next page

Nanostim®

Fixation Design

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Competitve Comparison – Nanostim®

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

For more information, please reference the Nanostim counter-selling tool.

Reference

[1] http://professional-intl.sjm.com/products/crm/leadless-pacemakers/dual-and-single-chamber/nanostim#tech-specs.

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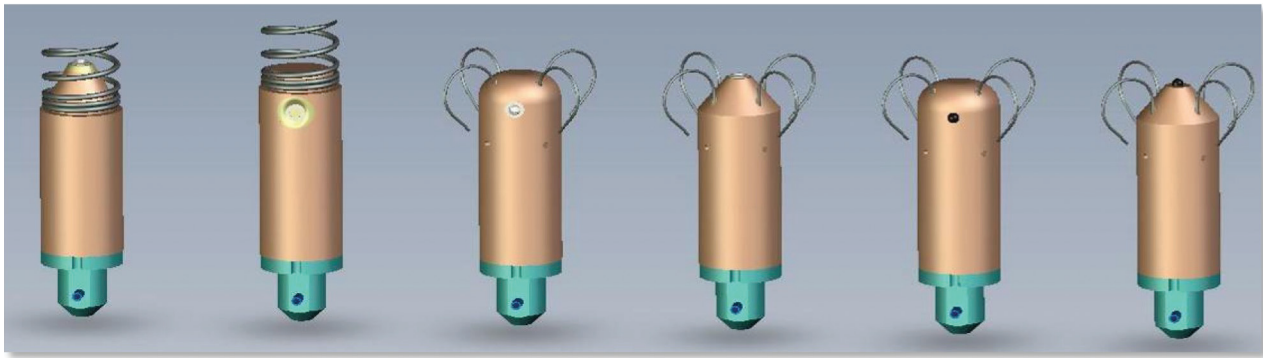
Pivot Question – Fixation Design

"I think what you are asking is why didn't we use a screw-in fixation."

Fixation Design

In our pre-clinical assessment we tested many fixation designs including several screw-in fixation concepts. We moved away from these designs due to the potential for higher thresholds and the risk of device migration.



Atraumatic fixation coupled with catheter retraction limits pressure on myocardium during deployment.

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Value

Please click a topic to learn more about it, or click the forward button in the lower right to continue to the next page

Innovation Pricing

10-Pack

Micra™ TPS Academy

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Pivot Question – Innovation Pricing

"I think what you are asking is the system priced fairly."

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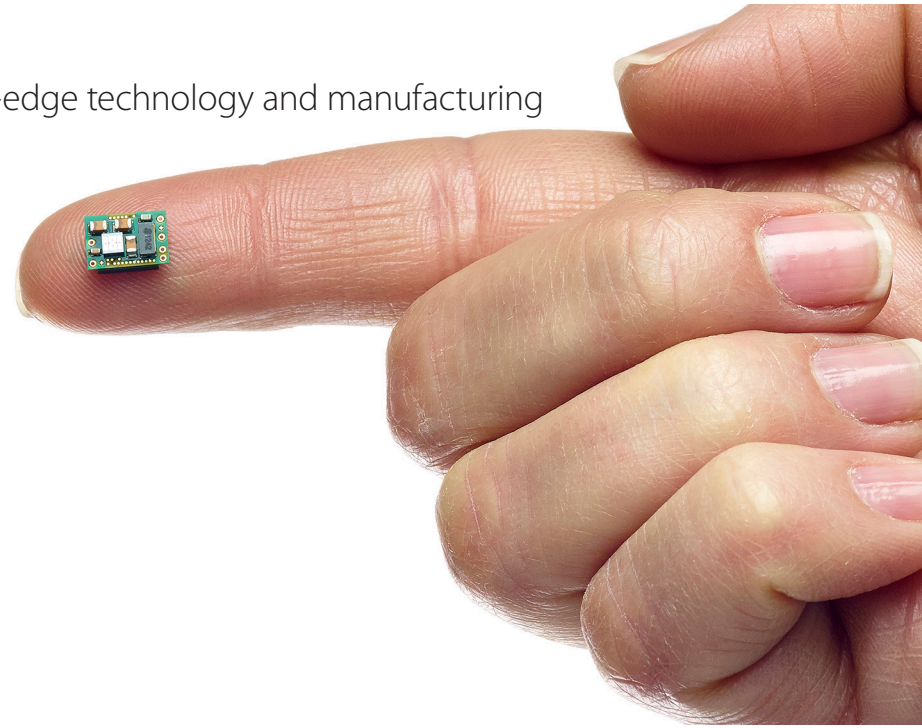
Innovation Pricing

Pricing Rationale

Priced fairly? – Yes

- Novel technology
- Research and development cost: cutting-edge technology and manufacturing
- New testing and quality measure
- Training
- Potential to reduce complications and length of patient stay
- Potential for new reimbursement



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Pivot Question – 10-Pack

"I think what you are asking is why are we asking you to make an initial commitment of 10 devices."

10-Pack

Minimum Order Quantity

- To ensure the safest market introduction and positive patient outcomes, we want to encourage the completion of the learning curve associated with this new procedure and technology
- Additionally, we want to ensure that these skills are retained, once achieved
- Lastly, significant education efforts are required to teach this new procedure and limited educational opportunities. We want to ensure we are educating those who are committed over the long term.

Pivot Question – TPS Academy

"I think what you are asking is why are we asking you to complete a training program in order to access this technology."

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TPS Academy

Micra™ TPS Academy

- Our goal is to prepare you to offer this new therapy to your patients in the safest way possible
- We want to encourage the completion of the learning curve associated with this new procedure and technology
- This robust program has been developed with extensive feedback from physicians with Micra experience

Pre-Training	In-Person Training Program		On-Site Support
Online Modules	**Hands-On Procedure Training**	**Peer-to-Peer Collaboration**	**Access to Expert Support**

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See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

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