



# ELECTRA

5-6 DÉCEMBRE 2024

HOTEL VILLA MASSALIA,  
MARSEILLE | FRANCE

18<sup>èmes</sup> journées françaises  
pratiques de rythmologie  
& de stimulation cardiaque

[WWW.CONGRES-ELECTRA.COM](http://WWW.CONGRES-ELECTRA.COM)

2004 - 2024

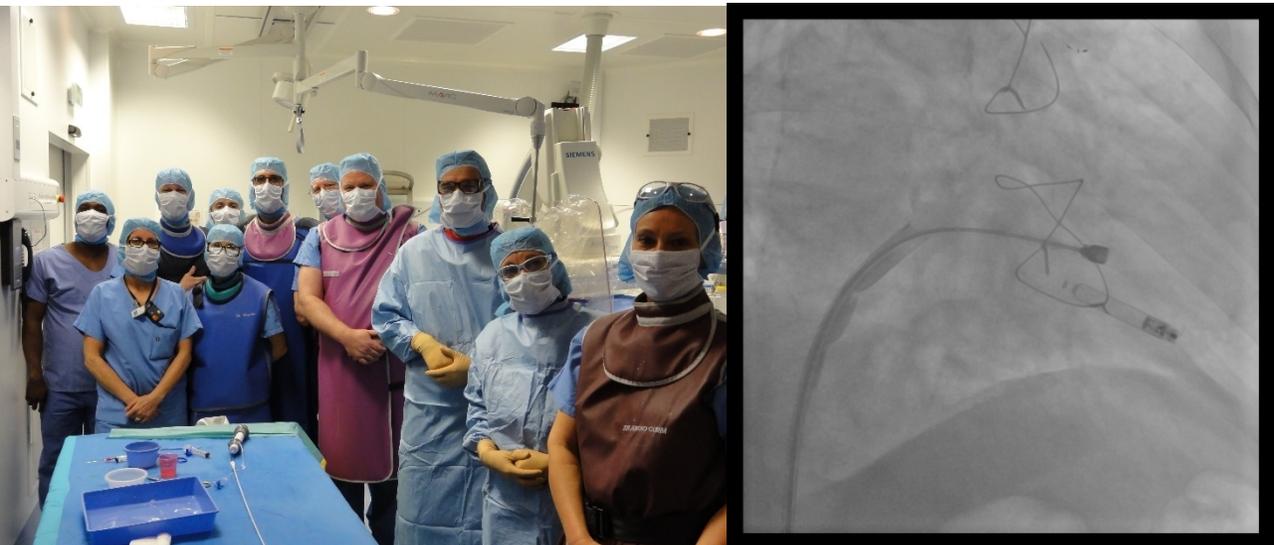
20  
ans  
ELECTRA

## *Stimulation sans sonde AVEIR* *Retour d'expérience*

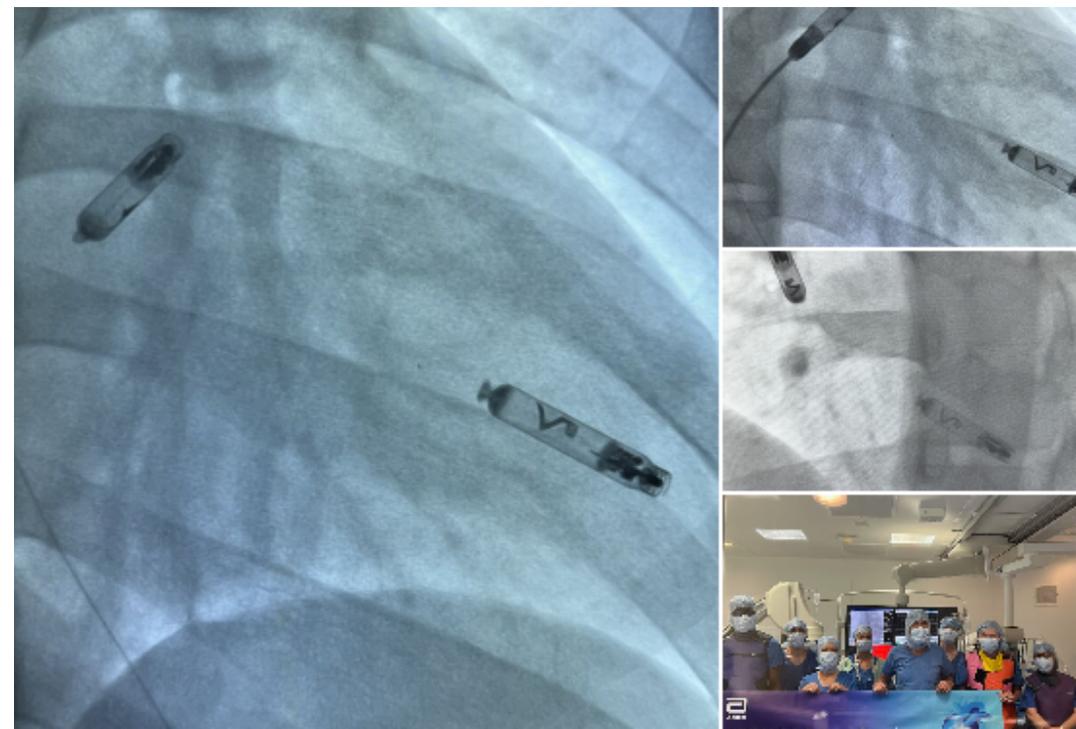


# Le leadless au CHU de Grenoble ... une longue histoire...

*2 premières implantations pm sans sonde (Nanostim) 19/11/2013*



*Nov 2024 2 Premières implantations  
Double leadless Aveir DR*



**2013-2016 Nanostim**

**2022 LEADLESS 2 et Aveir DR i2i**

**2023 Aveir VR**

# Le PM sans sonde : pourquoi??

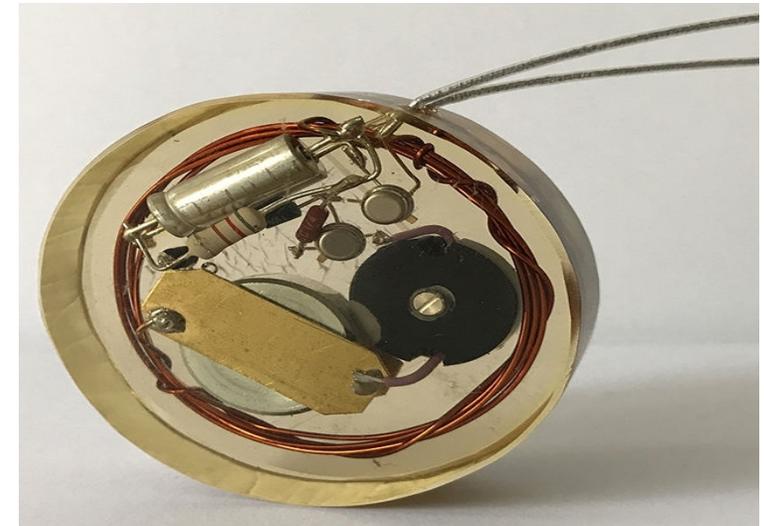
## Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark

Rikke Esberg Kirkfeldt<sup>1,2\*</sup>, Jens Brock Johansen<sup>2,3</sup>, Ellen Aagaard Nohr<sup>4</sup>, Ole Dan Jørgensen<sup>2,5</sup>, and Jens Cosedis Nielsen<sup>1</sup>

*Transvenous pacing : a very long story since 1958/ still imperfect*

- *6000 Danish patients*
- *Cumulative incidence of complications at 6 months*

<b>Any</b>	<b>10%</b>
<b>Major</b>	<b>6%</b>
Lead reintervention	3%
PNO requiring drain	1%
Perforation no drain/drain	0,8%/0,4%
Infection	0,6%
Pocket revision	0,2%
Hematoma requiring reintervention	0,2%



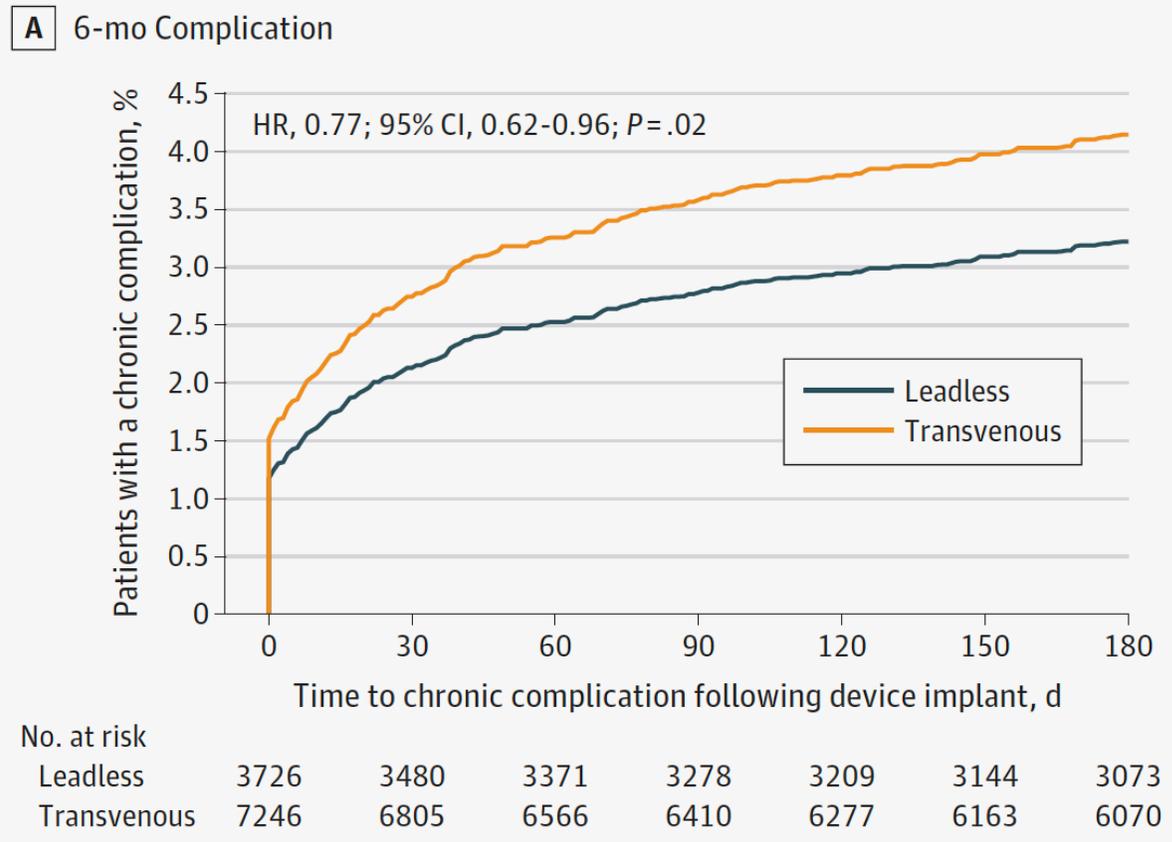
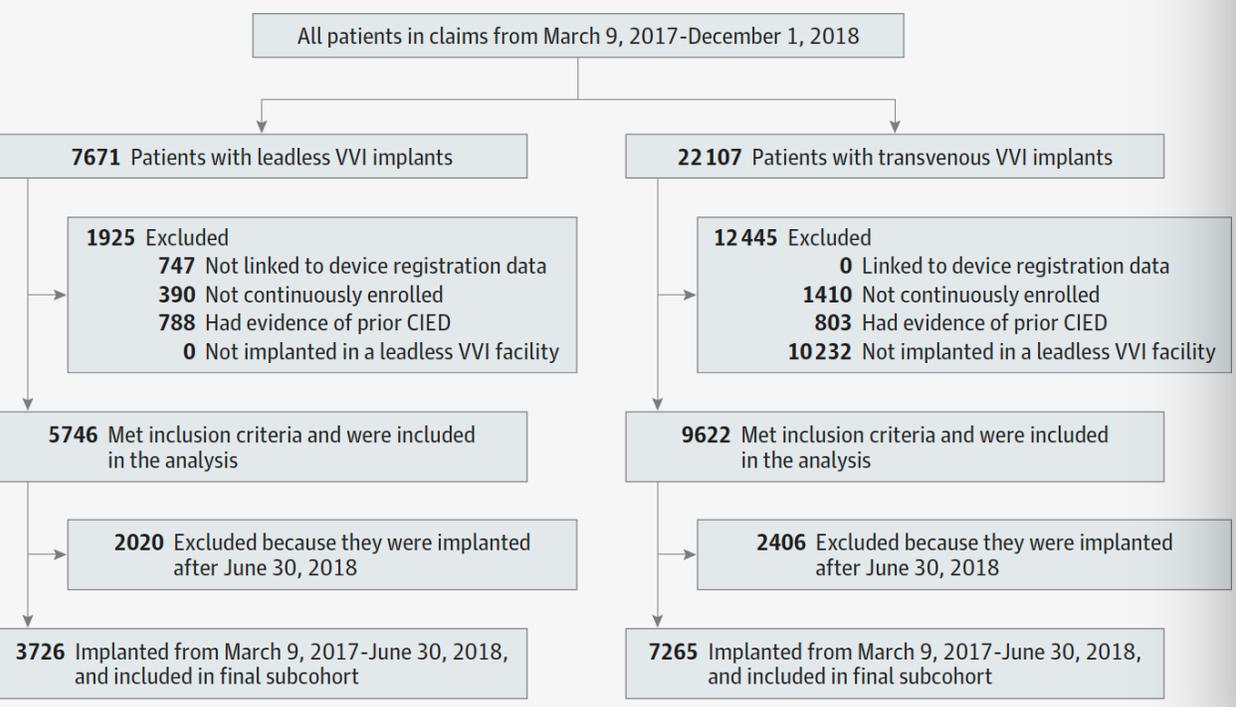
*European Heart Journal 2014; 35, 1186–1194*

# Le PM sans sonde : pourquoi??

JAMA Cardiology | Original Investigation  
**Contemporaneous Comparison of Outcomes Among Patients Implanted With a Leadless vs Transvenous Single-Chamber Ventricular Pacemaker**  
 Jonathan P. Piccini, MD, MHS; Mikhael El-Chami, MD; Kael Wherry, PhD; George H. Crossley, MD; Robert C. Kowal, MD, PhD; Kurt Stromberg, MS; Colleen Longacre, PhD; Jennifer Hinnenthal, MPH; Lindsay Bockstedt, PhD

**33% lower rate of chronic complications / transvenous VVI**

Figure 1. Cohort Formation Flowchart



# Le PM sans sonde : pourquoi??

## Quality of life of patients undergoing conventional vs leadless pacemaker implantation: A multicenter observational study

Variable	1-mo			6-mo		
	C-PM, n = 46	L-PM, n = 22	P	C-PM, n = 58	L-PM, n = 38	P
Chest discomfort	52%	41%	.385	39%	18%	.032
Restriction in physical activities due to chest discomfort	54%	23%	.014	37%	11%	.004
Restriction in daily activities due to chest discomfort	54%	18%	.005	32%	13%	.034
Discomfort in the area of intervention	48%	23%	.048	35%	13%	.017
Restriction in physical activities due to discomfort in the area of the intervention	57%	14%	.001	22%	8%	.067
Restriction in daily activities due to discomfort in the area of the intervention	54%	9%	<.001	20%	8%	.108
Restriction in physical activities due to concern over complications	61%	32%	0.025	27%	13%	.103
Restriction in daily activities due to fear of complications	65%	23%	0.001	29%	3%	.001
Preoccupation about general health	59%	23%	0.005	45%	21%	.017
Feeling of depression	28%	18%	0.369	22%	11%	.136



*Cabanas-Grandío et al, J Cardiovasc Electrophysiol. 2020 Jan;31(1):330-336*

# L'expérience leadless



*Marquage CE 2015 (VR)  
2020 (AV)  
Remboursement 2019 (VR)*



*Marquage CE 2023 (VR)  
Juin 2024(DR)  
Remboursement 2024 (VR)*



EMPOWER



WISE

# L'expérience leadless Aveir



AVEIR VR  
AVEIR A

*Marquage CE Jul 23 (VR)  
Jun 24(DR)*

**Aveir dans le monde :**

**. 20000 à 30000 PM**

- Environ 900 AR seul
- Environ 2100 DR (soit DR de novo, soit upgrade VR vers DR, soit upgrade AR vers DR)

## France leadless

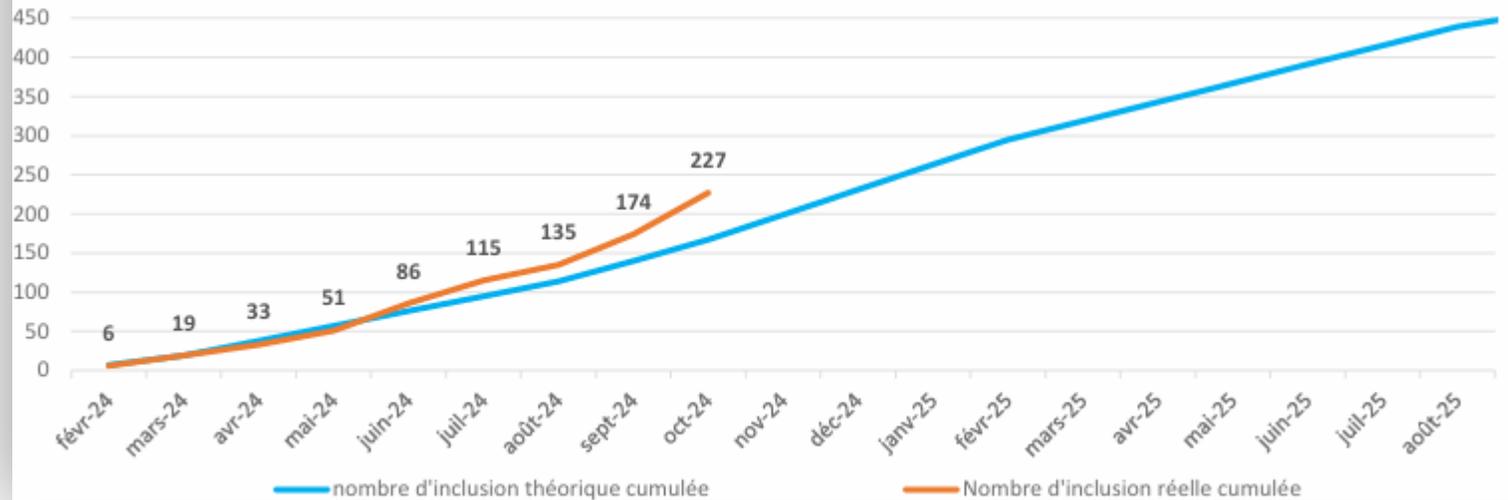
ETAT DES LIEUX DES INCLUSIONS AU 31/10/2024

**Etat des lieux des inclusions au 31/10/2024 :**

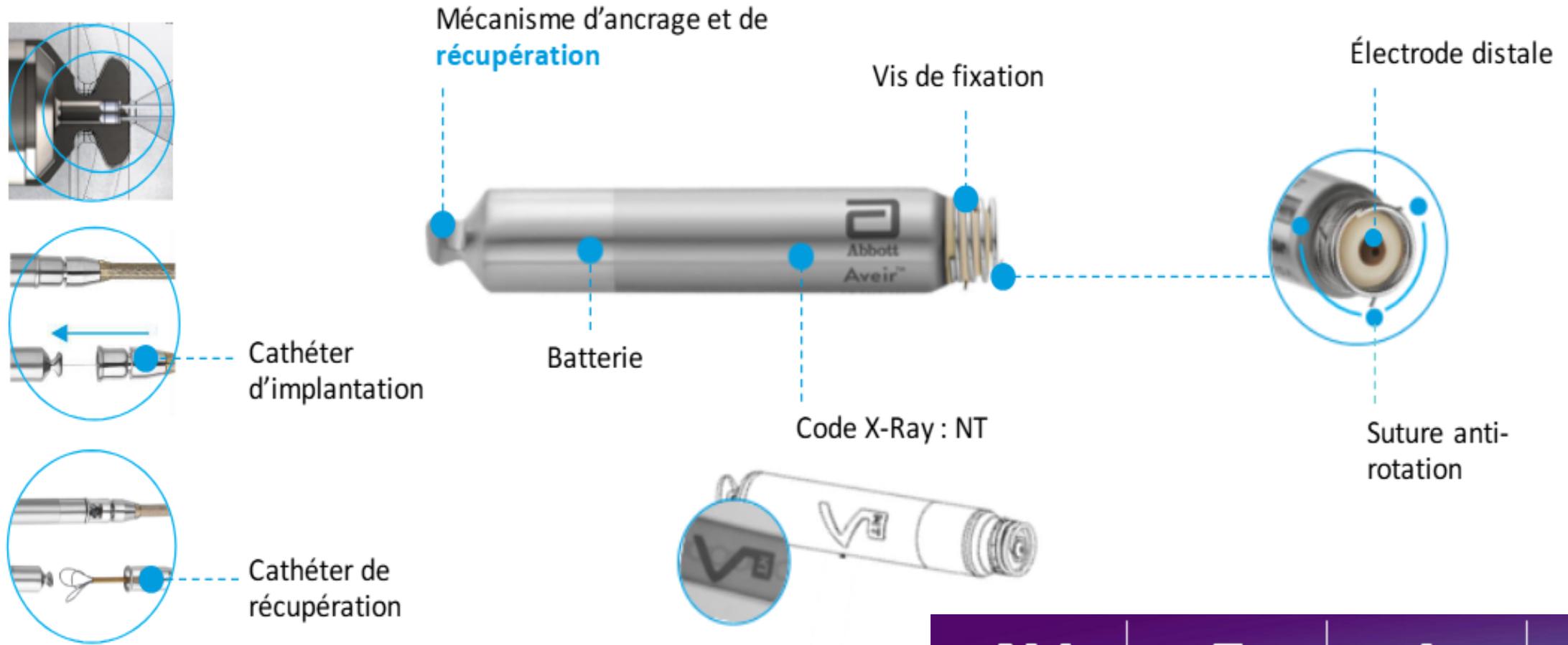
**227** patients inclus par **24** centres (soit 57% de l'objectif).

Pour rappel : l'objectif est d'inclure **400** patients sur une période d'inclusion de **19** mois avec un suivi de 24 mois.

France Leadless: courbe d'inclusion au 31/10/24



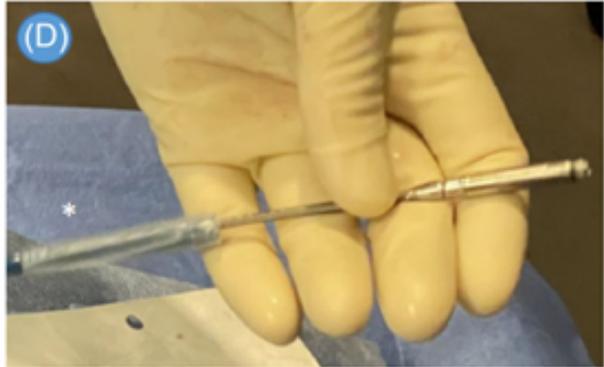
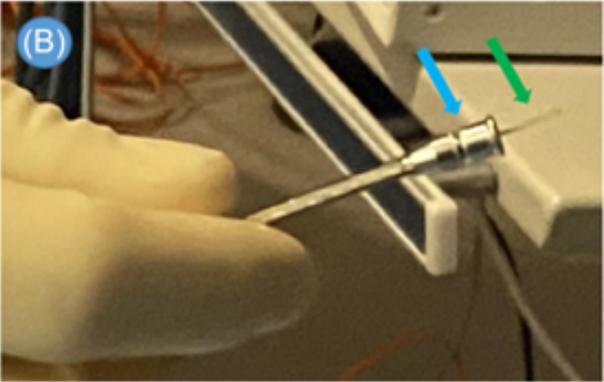
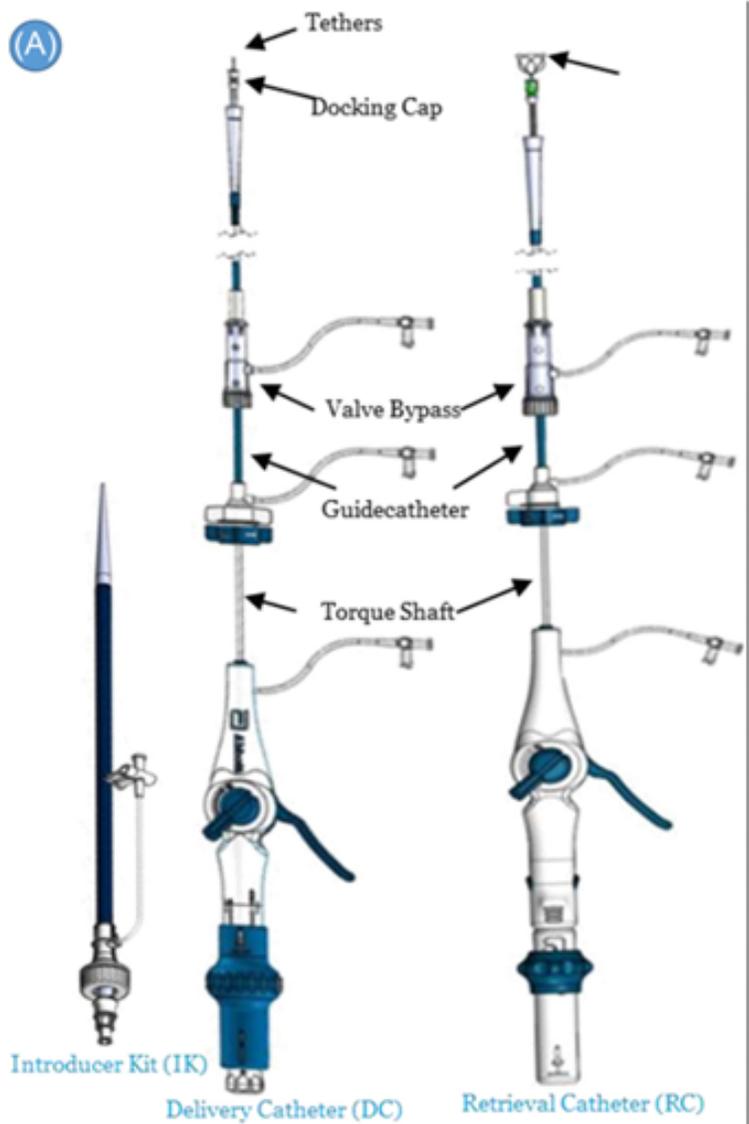
# Le Pacemaker sans sonde AVEIR



**AVEIR™ VR**  
Stimulateur cardiaque sans sonde

<b>AV</b> Atrial & Ventricle Pacing <i>Stimulation atriale et ventriculaire</i>	<b>E</b> Expandable and Extended Longevity <i>Évolutif et longévité étendue</i>	<b>I</b> I2i™ Communication <i>Communication I2i™</i>	<b>R</b> Retrievable <i>Récupérable</i>
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# Le Pacemaker sans sonde AVEIR : cathéter



## RESEARCH CORRESPONDENCE

# Primary Results on Safety and Efficacy From the LEADLESS II-Phase 2 Worldwide Clinical Trial

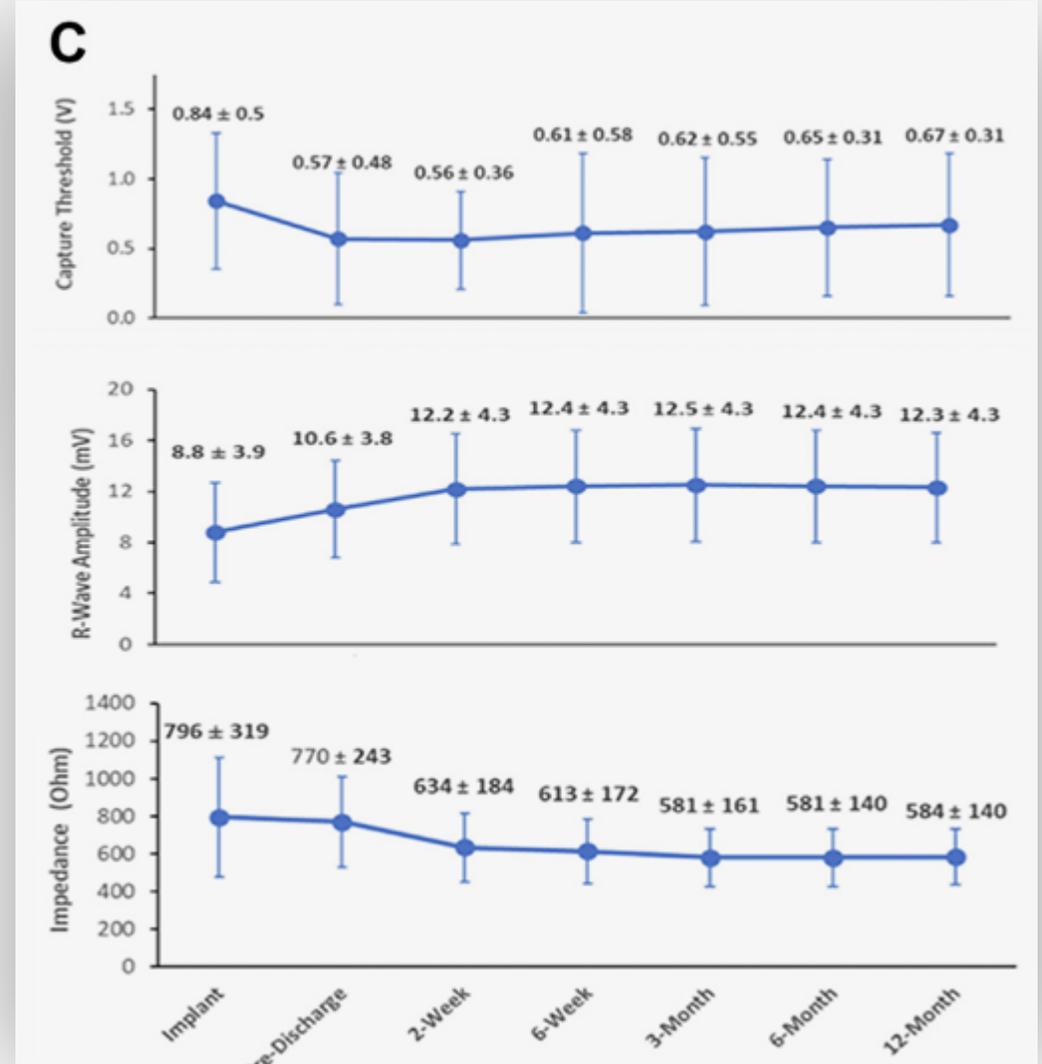


## RESEARCH LETTER

# 1-Year Outcomes of a Leadless Ventricular Pacemaker

The LEADLESS II (Phase 2) Trial

**Succès d'implantation 98%**



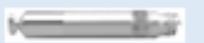
**Reddy et al, JACC Clin Elec trophysiol. 2022;8:115–117.**  
**Reddy et al, JACC Clin Elec trophysiol. 2023;9:1187–1189.**

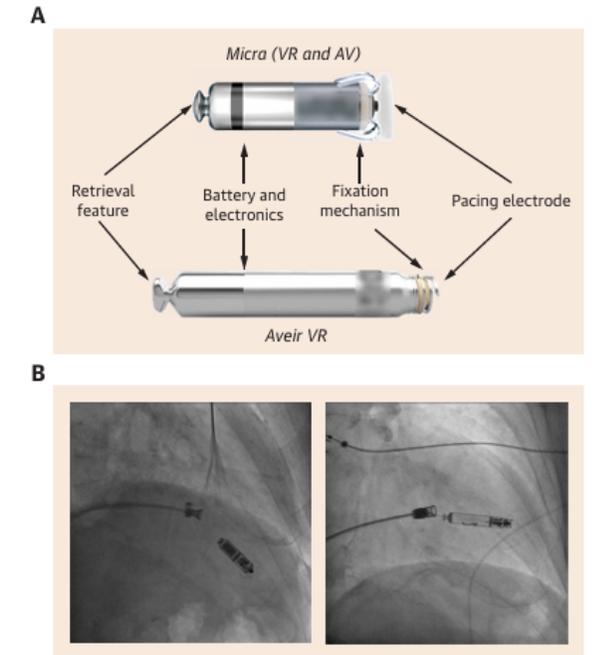
# Quelles différences par rapport aux autres pacemakers sans sondes?

**TABLE 2 Safety of Single-Chamber Leadless Pacemakers in Regulatory Trials and Adjudicated Large Registries (>500 Patients)**

	LEADLESS <sup>6,105</sup>	LEADLESS II <sup>8,10</sup>	Leadless Observational <sup>9</sup>	LEADLESS II phase 2 <sup>13,14</sup>	Micra IDE <sup>15,16</sup>	Micra PAR <sup>17,28</sup>	MAP EMEA <sup>18</sup>	Italian Registry <sup>106</sup>	Total
LP model	Nanostim	Nanostim	Nanostim	Aveir VR	Micra VR	Micra VR	Micra VR	Micra VR	
Short-term complication rate, %	6.1	5.8	5.3	4.8	2.9	2.5	2.6	0.5	3.0
No. of patients	33	718	300	210	726	1,809	928	665	5,389
Follow-up duration, mo	3	1	6 <sup>a</sup>	1.5	1	1	1	1	1.3
Pericardial effusion/cardiac perforation	3.0	1.5	1.3	1.9	1.4	0.4	0.6	0.0	0.8
Dislodgement during procedure	0.0	0.3	0.0	1.4	0.0	0.1	0.0	n/a	0.1
Dislodgement after procedure	0.0	1.0	0.3	0.0	0.0	0.1	0.0	0.2	0.2
Vascular complications	0.0	1.1	1.3	1.0	0.7	0.6	1.1	0.2	0.7
Other	3.0	2.2	3.0	1.0	1.2	1.6	0.9	0.2	1.4
Long-term complication rate, % <sup>b</sup>	3.0	0.6	n/a	1.9	1.1 <sup>c</sup>	1.8	1.0	0.0	1.1
No. of patients	33	718	n/a	210	726	1,809	928	665	5,089
Mean follow-up duration, mo	38 <sup>d</sup>	10.6 <sup>d</sup>	n/a	14.4	16.4	51.1 <sup>d</sup>	9.7	39 <sup>e</sup>	29.7
Dislodgement	0.0	0.0	n/a	0.0	0.0	0.0	0.0	0.0	0.0
Infection	0.0	0.0	n/a	0.0	0.0	0.1	0.1	0.0	0.0
Other	3.0	0.6	n/a	1.9	1.1	1.8	1.1	0.0	1.2

# Quelles différences par rapport aux autres pacemakers sans sondes?

	Nanostim	Aveir VR	Micra VR <sup>a</sup>	Micra AV <sup>b</sup>	Aveir AR <sup>c</sup>	Empower <sup>d</sup>
						
Dimensions, mm	42 × 5.99	38 × 6.5	25.9 × 6.7	25.9 × 6.7	32.2 × 6.5	32.1 × 6.0
Volume, cc	1.0	1.1	0.8	0.8	1.0	0.75
Sheath size, F, ID/OD	18/21	25/27	23/27	23/27	25/27	21/23
Pacing mode	VVI(R)	VVI(R)	VVI(R)	VVI(R) or VDD(R)	AAI(R)	VVI(R) + S-ICD-directed ATP
Can be used as part of a dual-chamber LP	No	Yes	No	No	Yes	No
Fixation	Screw-in helix	Screw-in helix	4 nitinol tines	4 nitinol tines	Screw-in helix	4 nitinol tines
Battery	Lithium carbon monofluoride	Lithium carbon monofluoride	Lithium-hybrid carbon monofluoride silver vanadium oxide	Lithium-hybrid carbon monofluoride silver vanadium oxide	Lithium carbon monofluoride	Lithium carbon monofluoride
Battery longevity, y, at ISO standard setting: 2.5 V at 0.4 ms, 60 beats/min, 100% VP, 600 ohm	N/A	9.9 (VVI(R)); 7.3 (DDDR)	4.7 (VVI(R))	4.8 (VDD)	6.8 (VVI(R)); 5 (DDDR)	N/A
Battery longevity, y, alternative setting <sup>e</sup>	N/A	16.1 (1.25 V at 0.4 ms, 60 beats/min, 100% VP, 500 ohm, single-chamber mode); 9.8 (1.25 V at 0.4 ms, 60 beats/min, 100% VP, 500 ohm, dual-chamber mode)	9.6 (1.5 V at 0.24 ms, 60 beats/min, 100% VP, 500 ohm)	8.6 (1.5 V at 0.24 ms, 60 beats/min, 100% VP, 500 ohm)	11.2 (1.25 V at 0.4 ms, 60 beats/min, 100% VP, 500 ohm, single-chamber mode); 6.8 (1.25 V at 0.4 ms, 60 beats/min, 100% VP, 500 ohm, dual-chamber mode)	N/A
MRI compatible	1.5 T	1.5 T, 3 T	1.5 T, 3 T	1.5 T, 3 T	1.5 T, 3 T	1.5 T, 3 T
Remote monitoring	No	No	CareLink	CareLink	No	No
Magnet mode	Yes, VOO 100/min for 8 cycles, then rate depending on battery status	Yes, VOO 100/min for 5 cycles, then rate depending on battery status	No	No	Yes, AAI (VOO in case of dual-chamber pacing) 100/min for 5 cycles, then rate depending on battery status	N/A



Breeman et al JACC. 2024;84:2131–2147

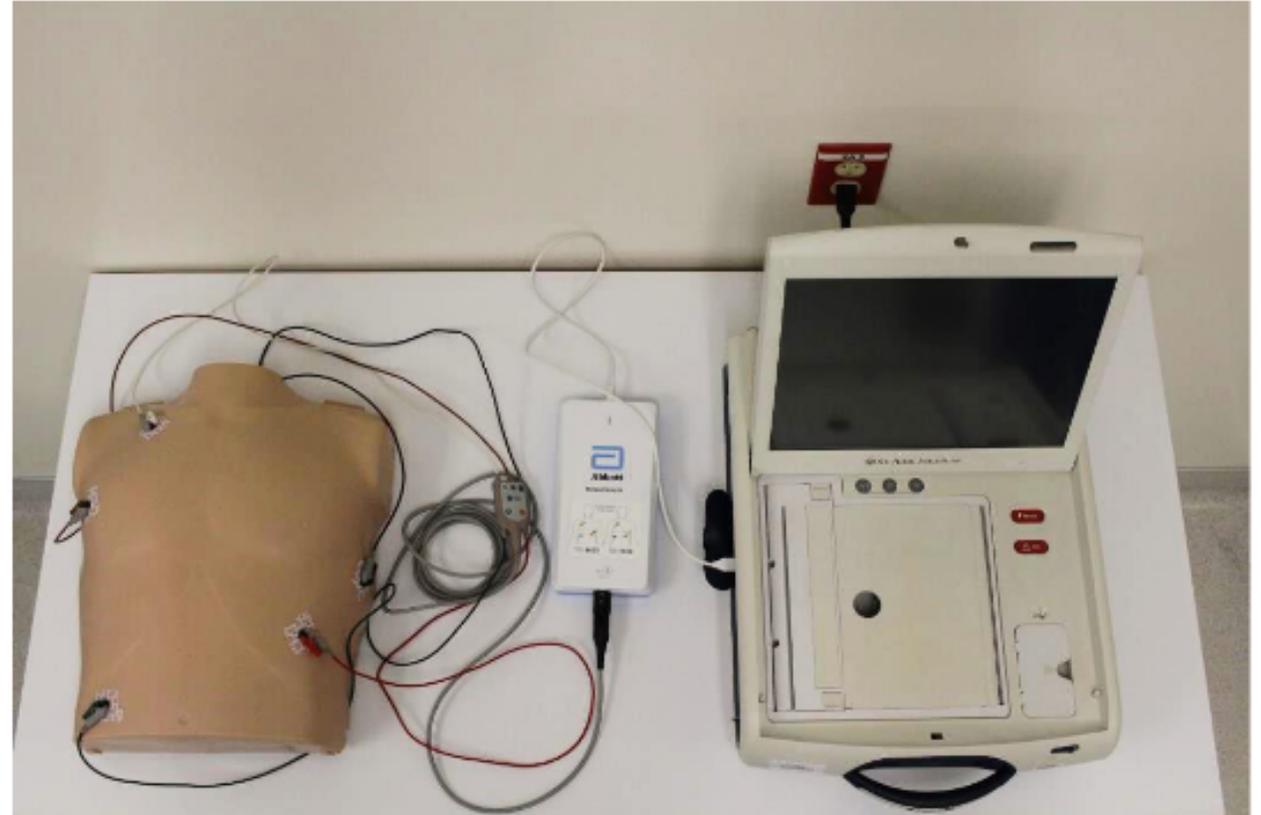
Laczay et al J Cardiovasc Electrophysiol. 2023 Mar;34(3):748-759.

# Quelles différences par rapport aux autres pacemakers sans sondes? Système de communication

## « *télémetrie* » *conductive*

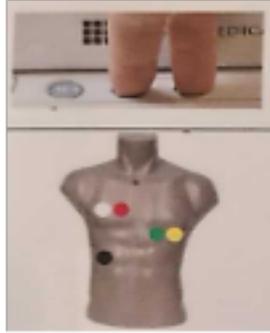
= données encodées dans des impulsions à haute fréquence entre le stimulateur cardiaque sans sonde et les électrodes de surface placées sur le patient

réduction de consommation de la batterie ++++



# Quelles différences par rapport aux autres pacemakers sans sonde? Système de communication

## Module spécifique ++



## Communication sensible

*(penser à supprimer  
Les bruits d'ambiance )*



*Exemple*

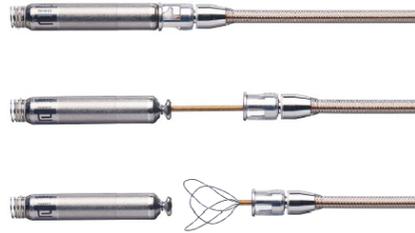
*Application Bistouri  
Electrique (4/40)*

*Leadless réglé en VVI  
Tracé temps réel*

# Quelles différences par rapport aux autres pacemakers sans sonde?

## Récupérabilité

### AVEIR™ VR LP | RETRIEVAL SYSTEM



Tri-loop snare re-docking mechanism

Protective sleeve fully covers the LP's helix during catheter navigation in order to reduce risk of damaging the helix or an injury to cardiovascular structures

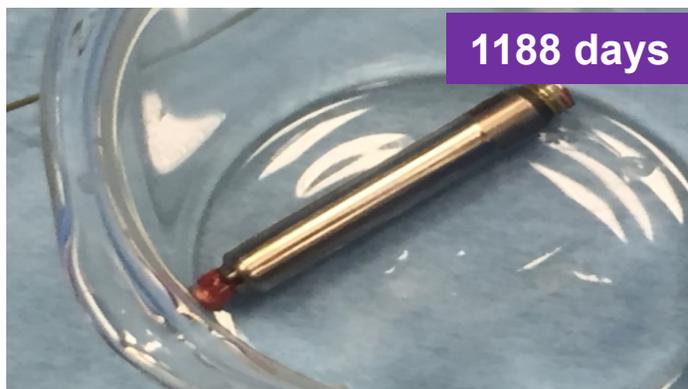


Steerable, deflectable delivery catheter with integrated guiding catheter

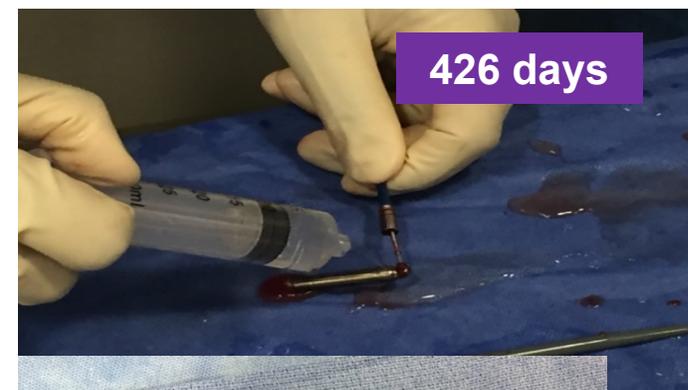
A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker

Dhanunjaya Lakkireddy, MD, FACC, FHRS,\* Reinoud Knops, MD,<sup>†</sup> Brett Atwater, MD,<sup>‡</sup> Petr Neuzil, MD,<sup>§</sup> John Ip, MD,<sup>||</sup> Elkin Gonzalez, MD,<sup>¶</sup> Paul Friedman, MD, FHRS,\*\* Pascal Defaye, MD,<sup>††</sup> Derek Exner, MD,<sup>‡‡</sup> Kazutaka Aonuma, MD,<sup>§§</sup> Rahul Doshi, MD, FHRS,<sup>|||</sup> Johannes Sperzel, MD,<sup>¶¶</sup> Vivek Reddy, MD<sup>\*\*\*</sup>

## Possibility of leadless retrieval (Nanostim™/Aveir™)



### Nanostim Retrieval Gross Pathology



90.4% success retrieval/implant duration range: 0.2–4.0 years

# Quelles différences par rapport aux autres pacemakers sans sonde?

## Evolutivité/possibilité d'upgrade

Implanter un dispositif auriculaire ou ventriculaire seul, ou les deux, pour une stimulation double chambre.

### Commencer par le dispositif auriculaire

Traiter la  
dysfonction  
sinusale  
aujourd'hui



Ajouter  
ultérieurement  
un dispositif  
ventriculaire pour  
bloc cardiaque

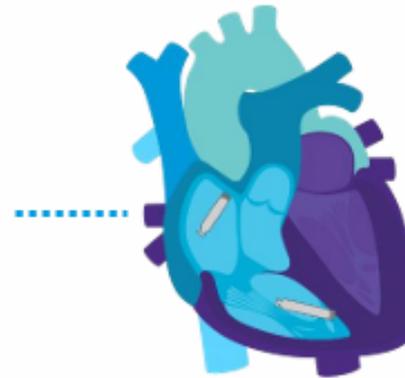


### Ou le dispositif ventriculaire en premier

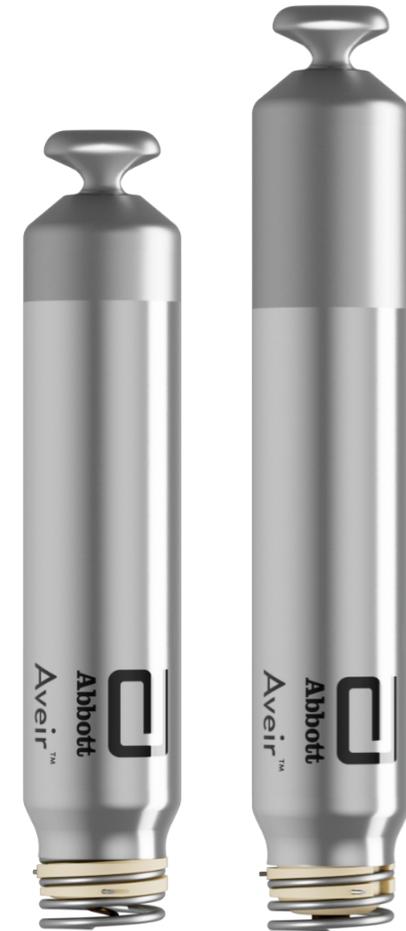
Traiter  
aujourd'hui  
un bloc  
cardiaque  
intermittent  
rare



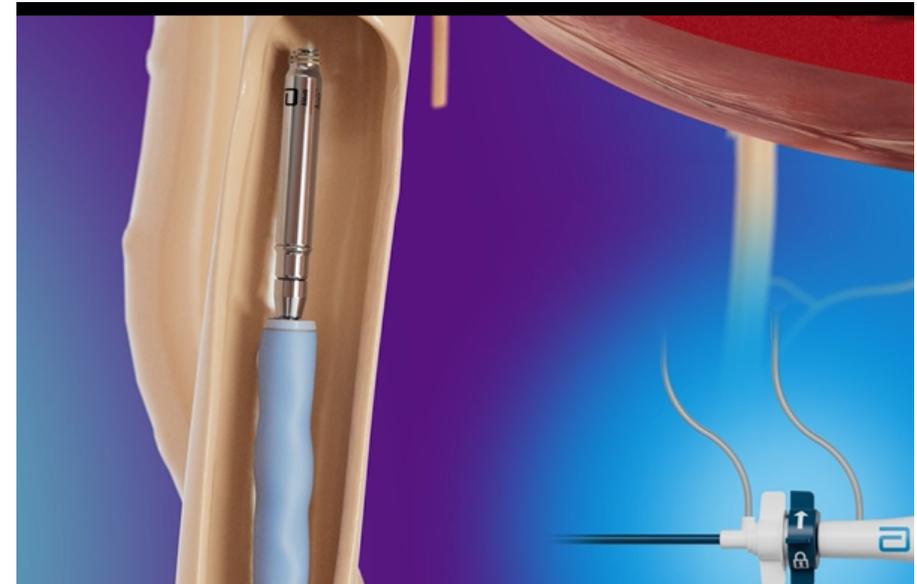
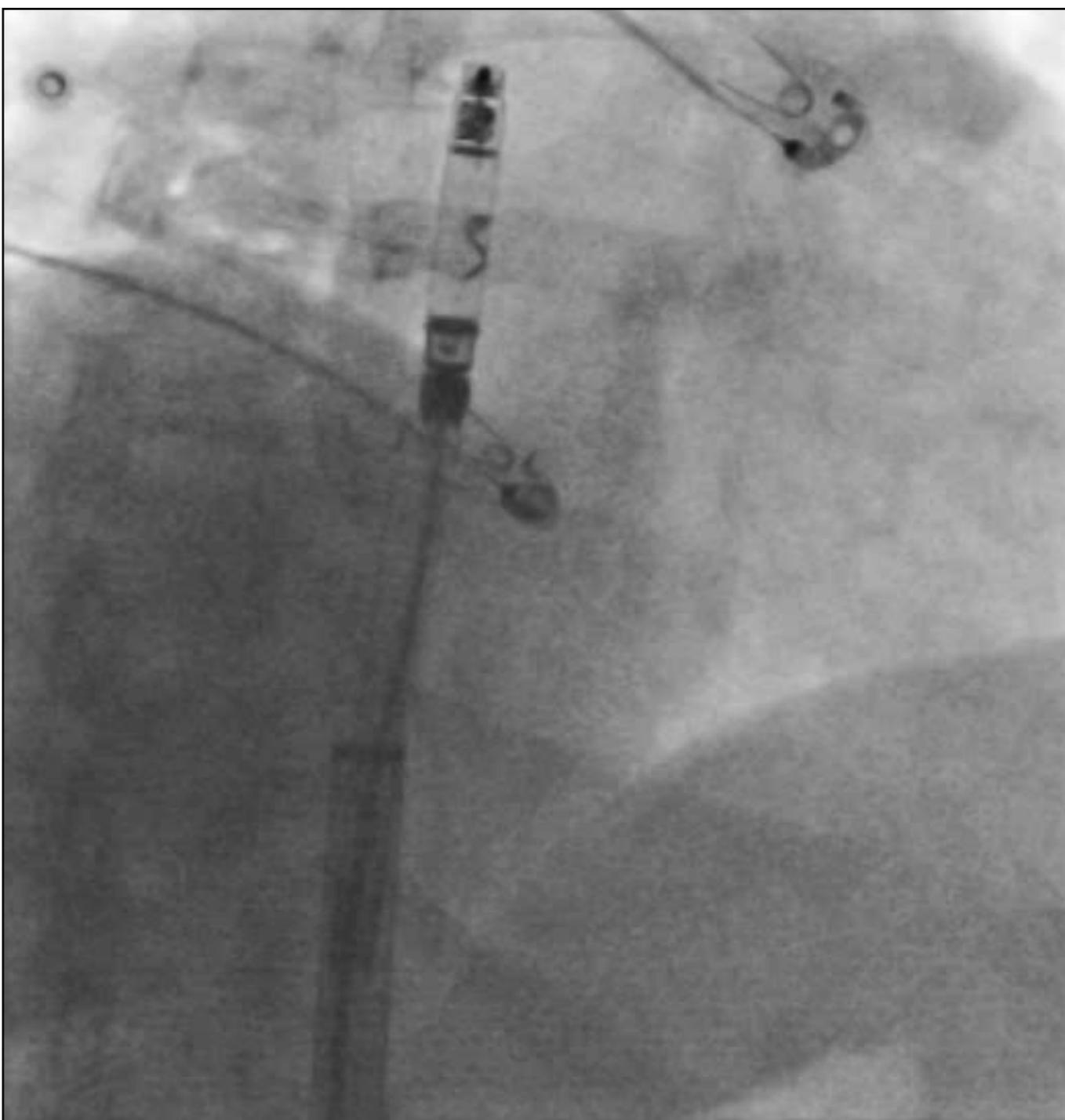
Ajouter  
ultérieurement  
un dispositif  
auriculaire pour  
la maladie  
du nœud sinusal



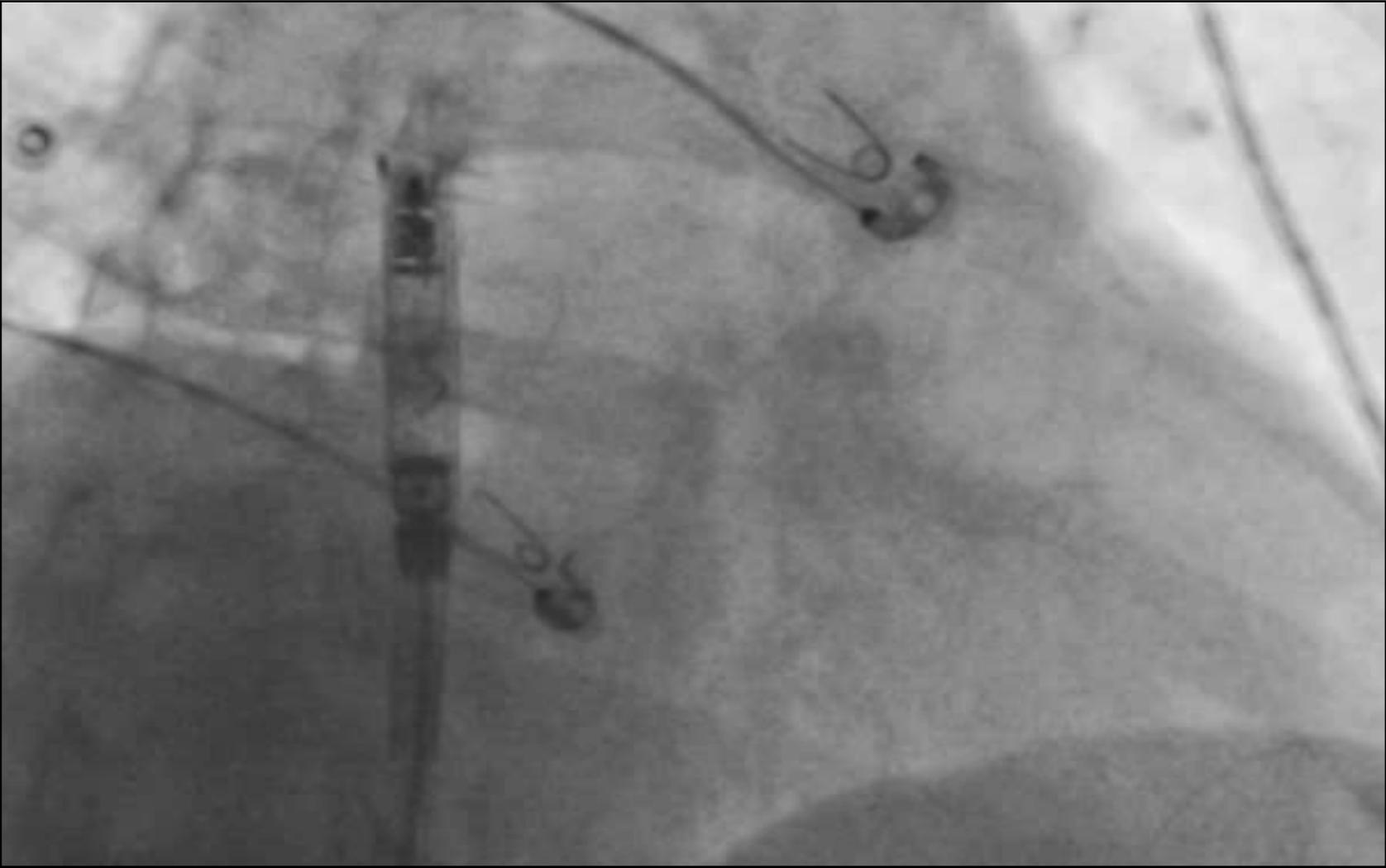
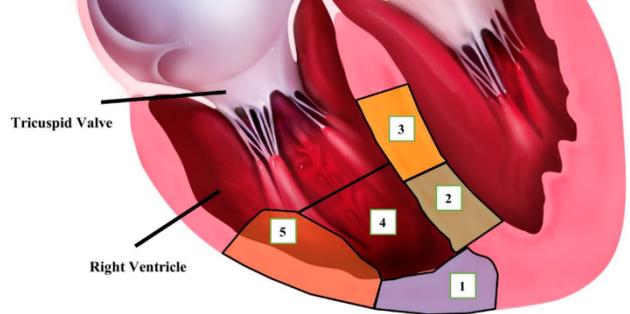
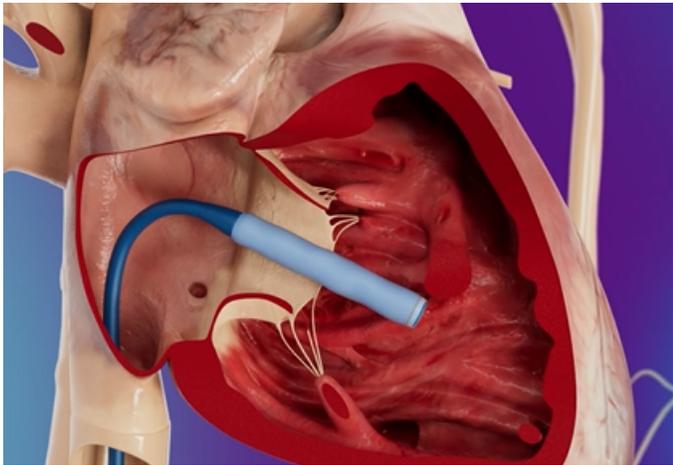
Activer la stimulation à double  
chambre (DDD(R)) via la  
communication i2i™



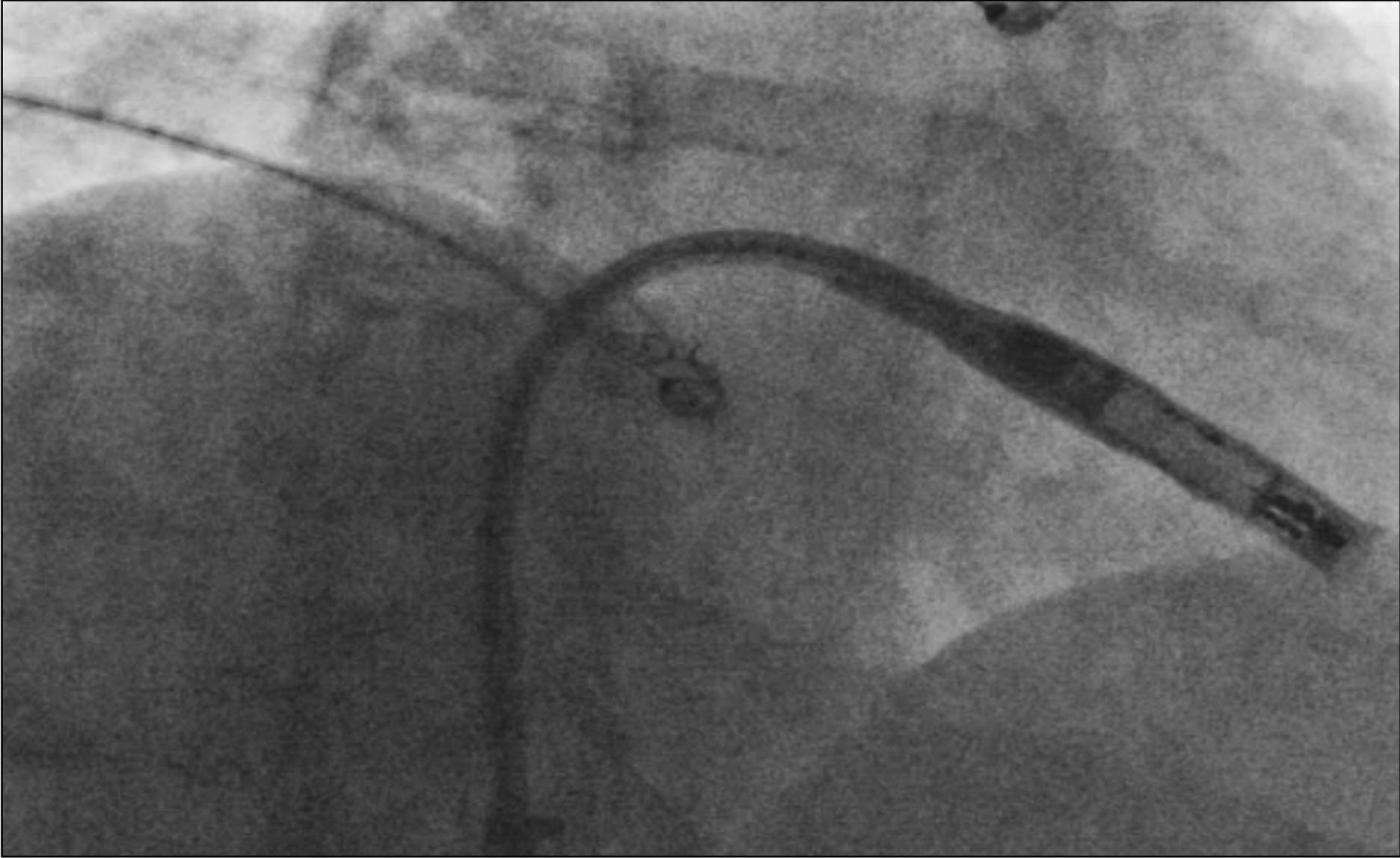
*Exemple implantation Aveir VR*

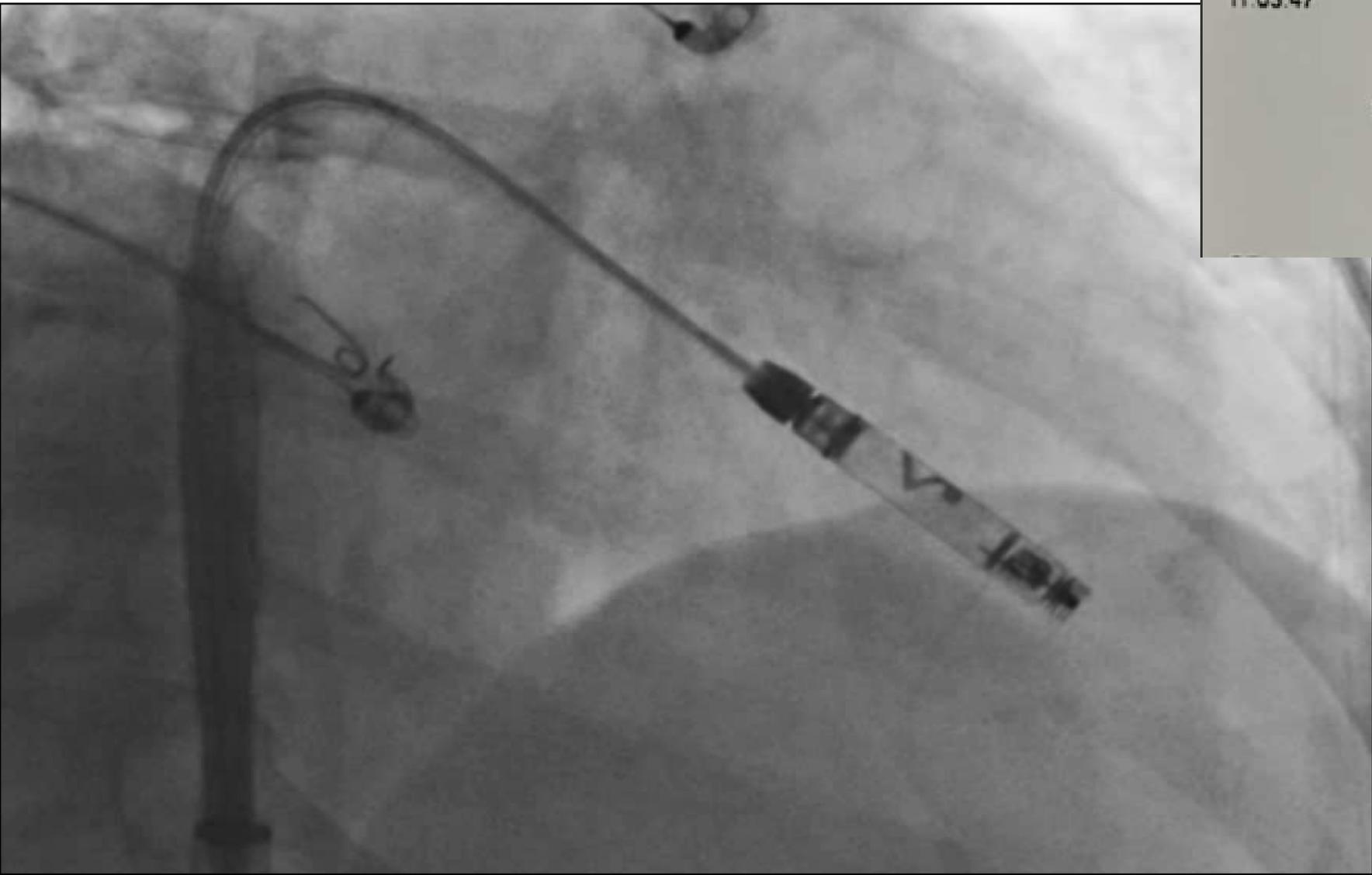


**LAO**

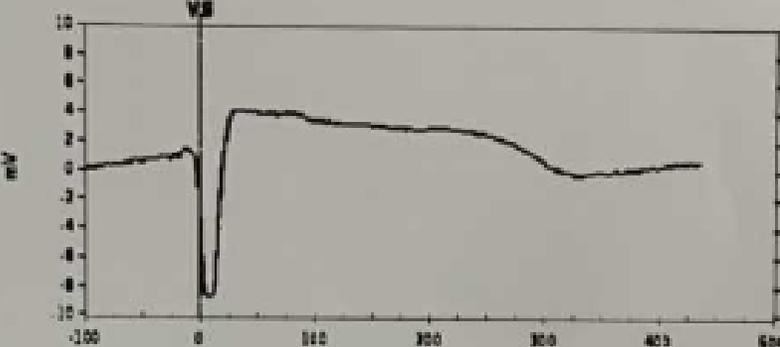


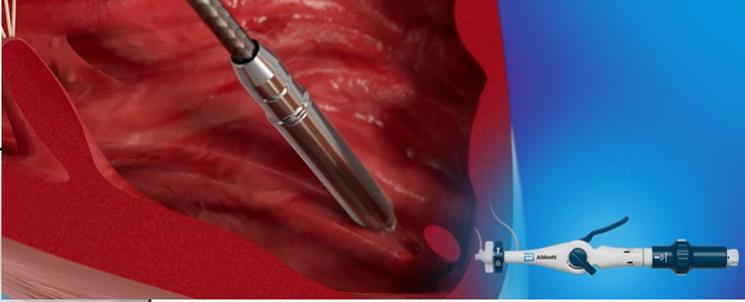
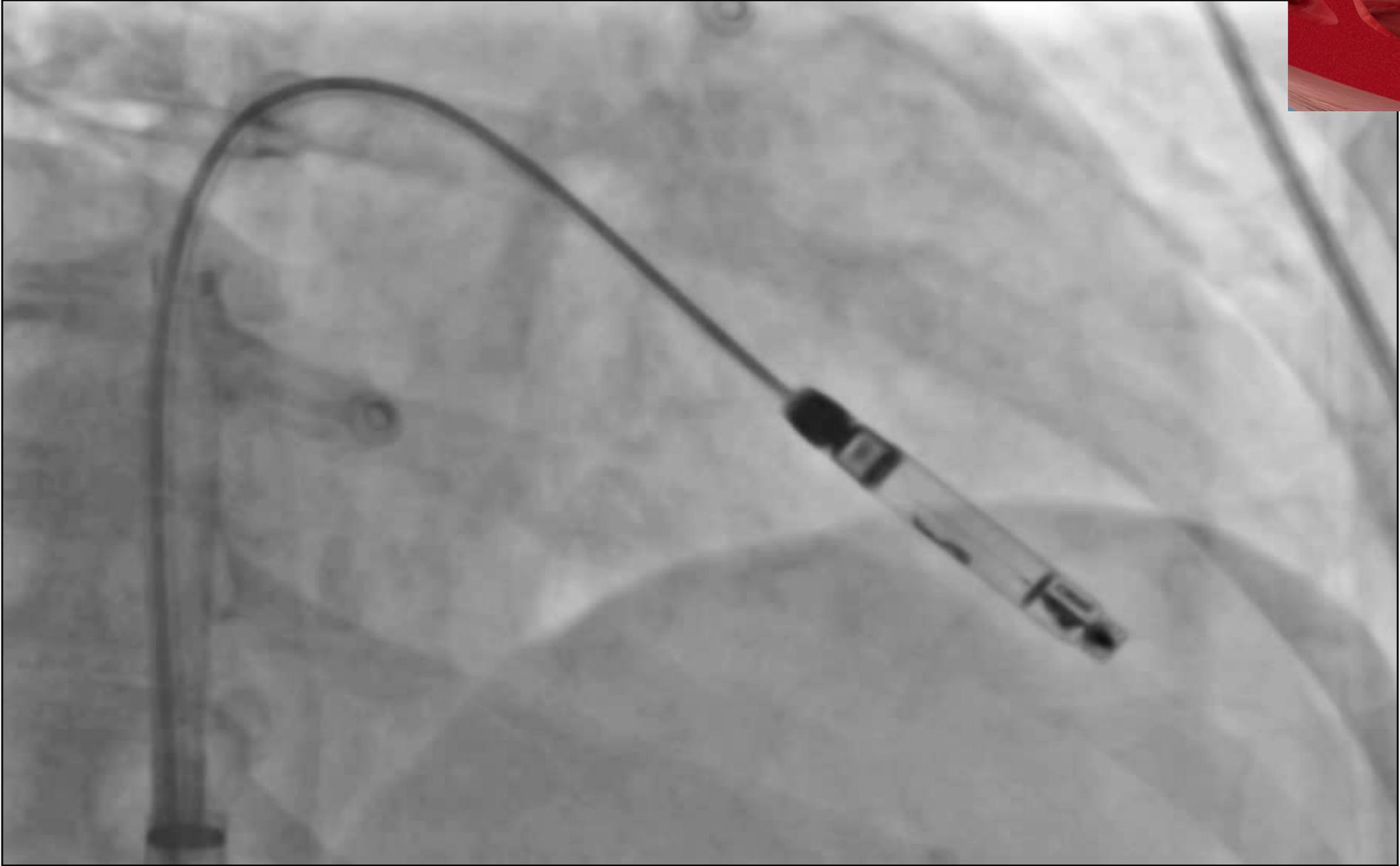


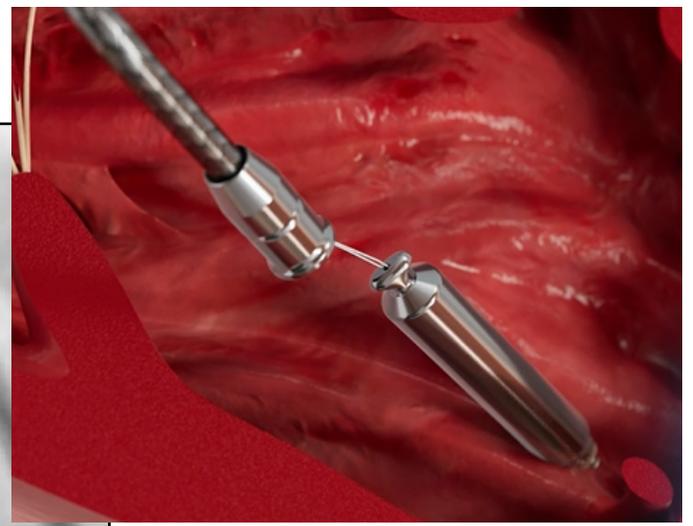


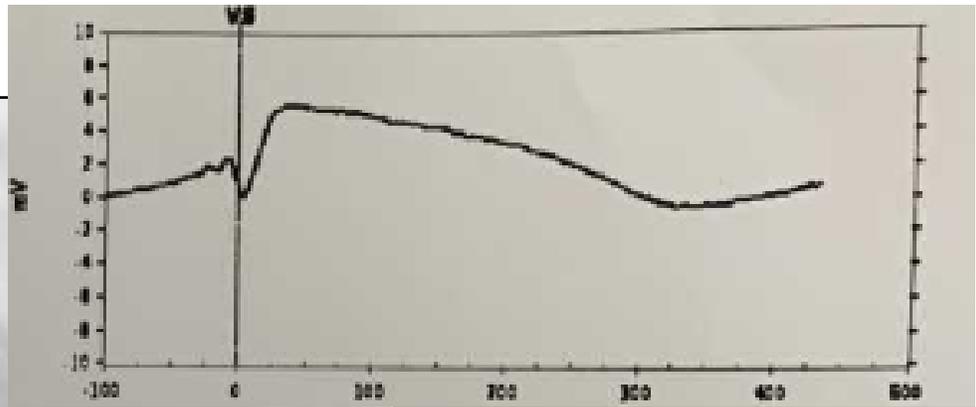
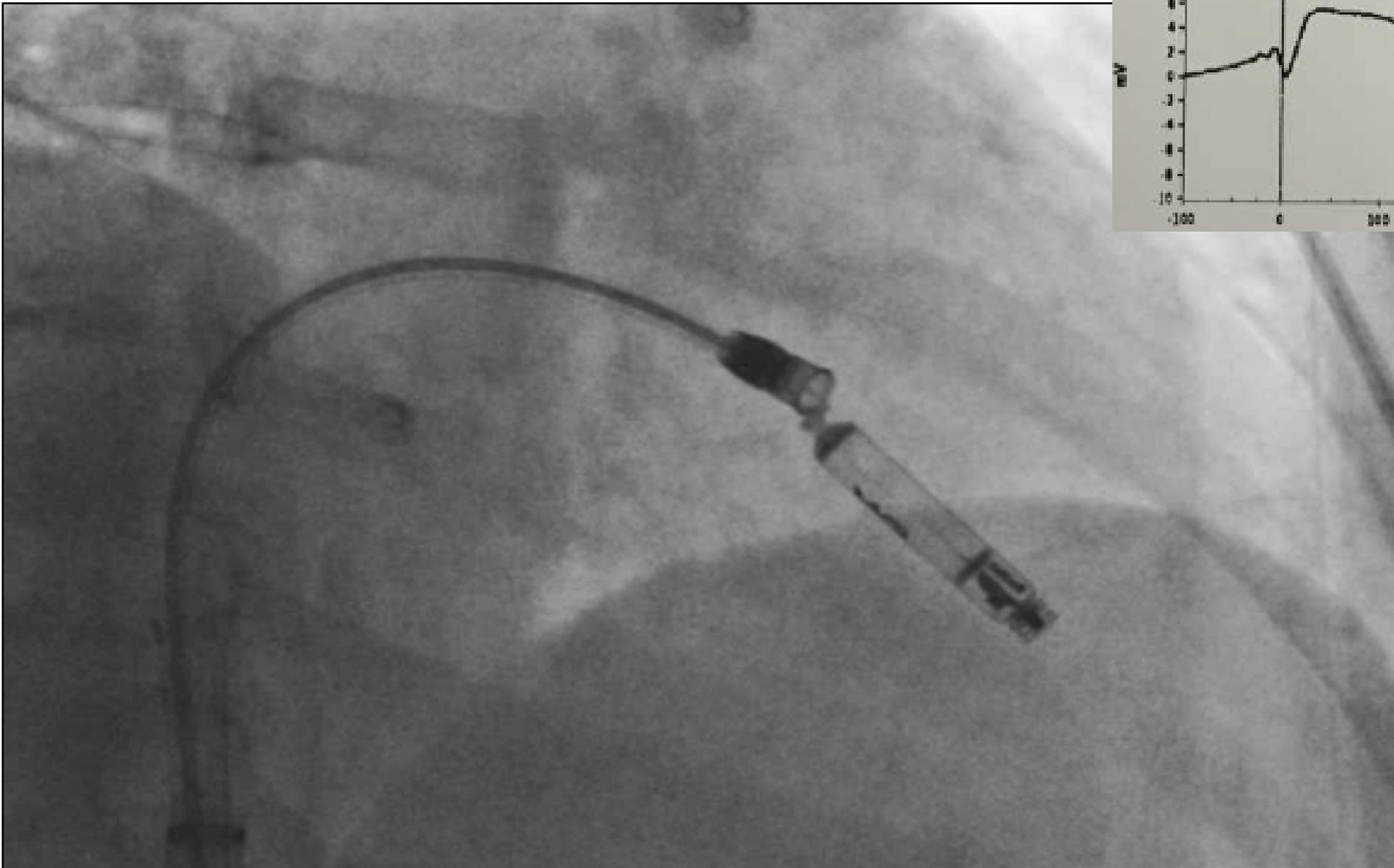


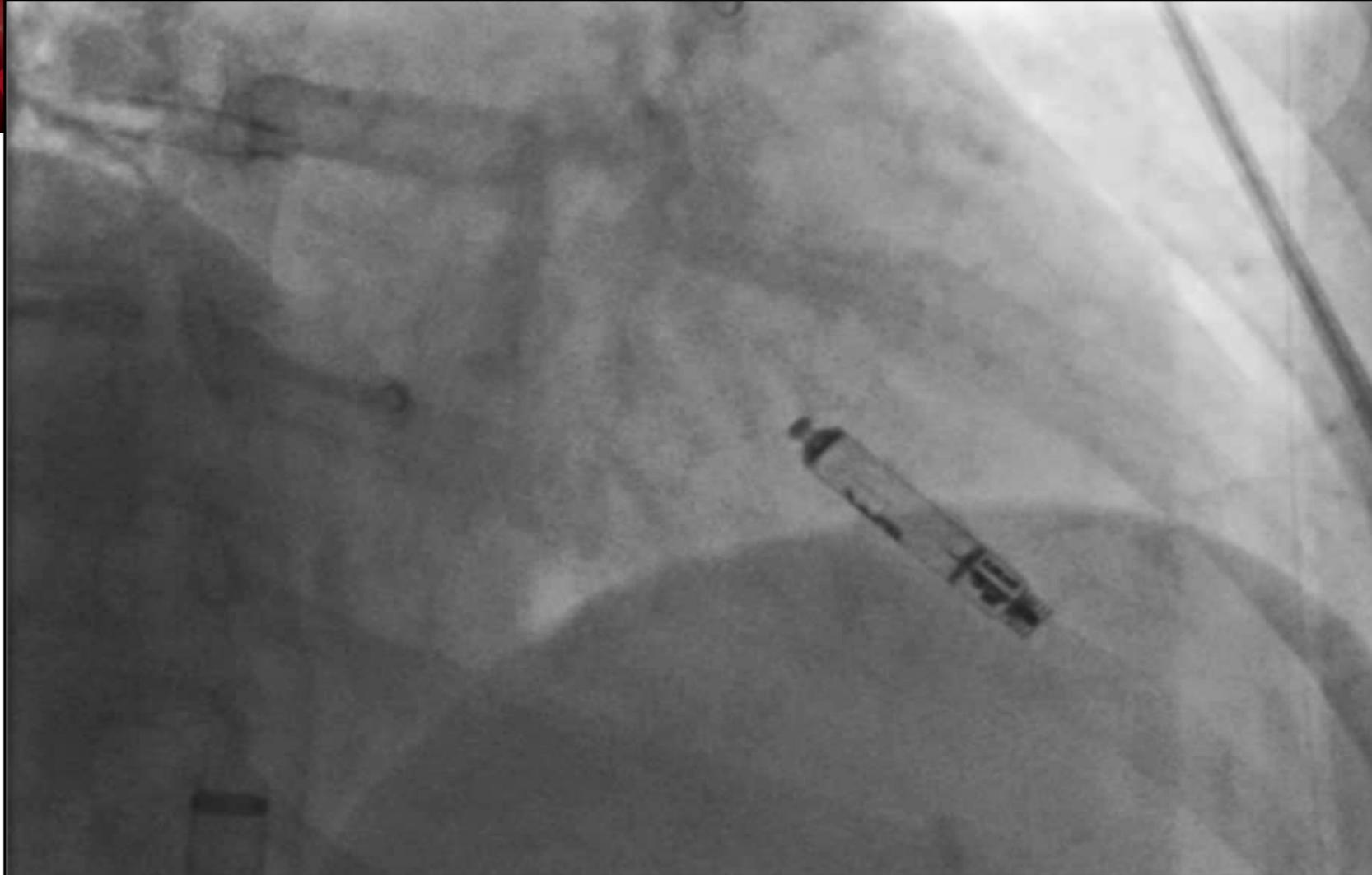
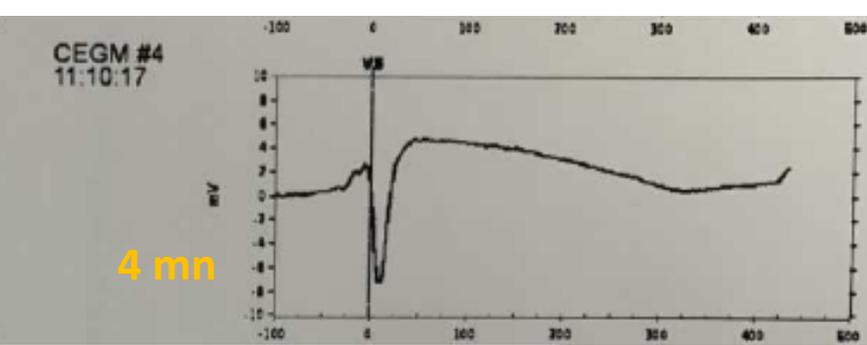
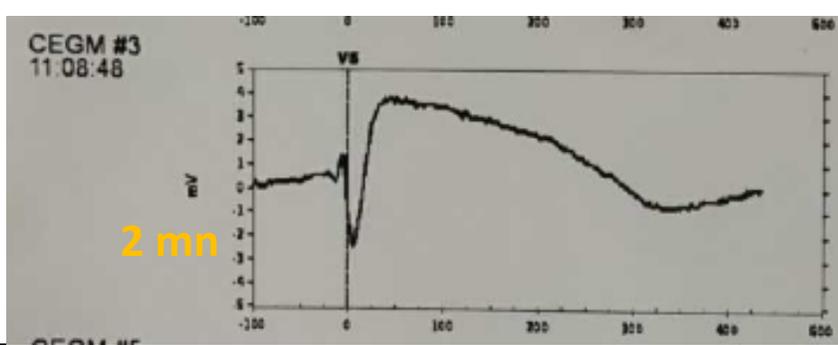
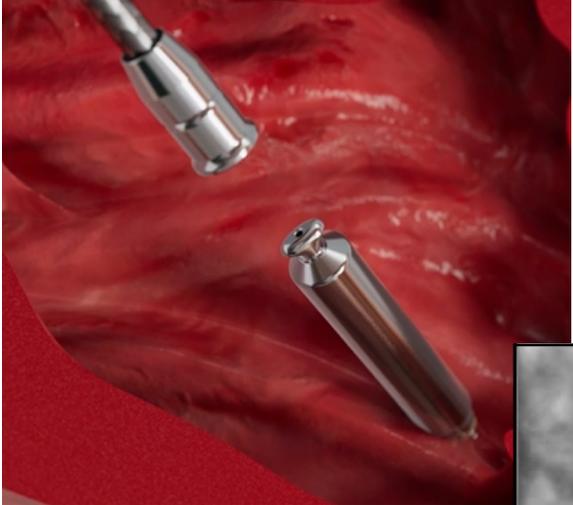
CEGM #1  
11:03:47











*Expérience grenobloise*

*7 pts leadless 2*

*+ 30 patients suivis France LEADLESS*

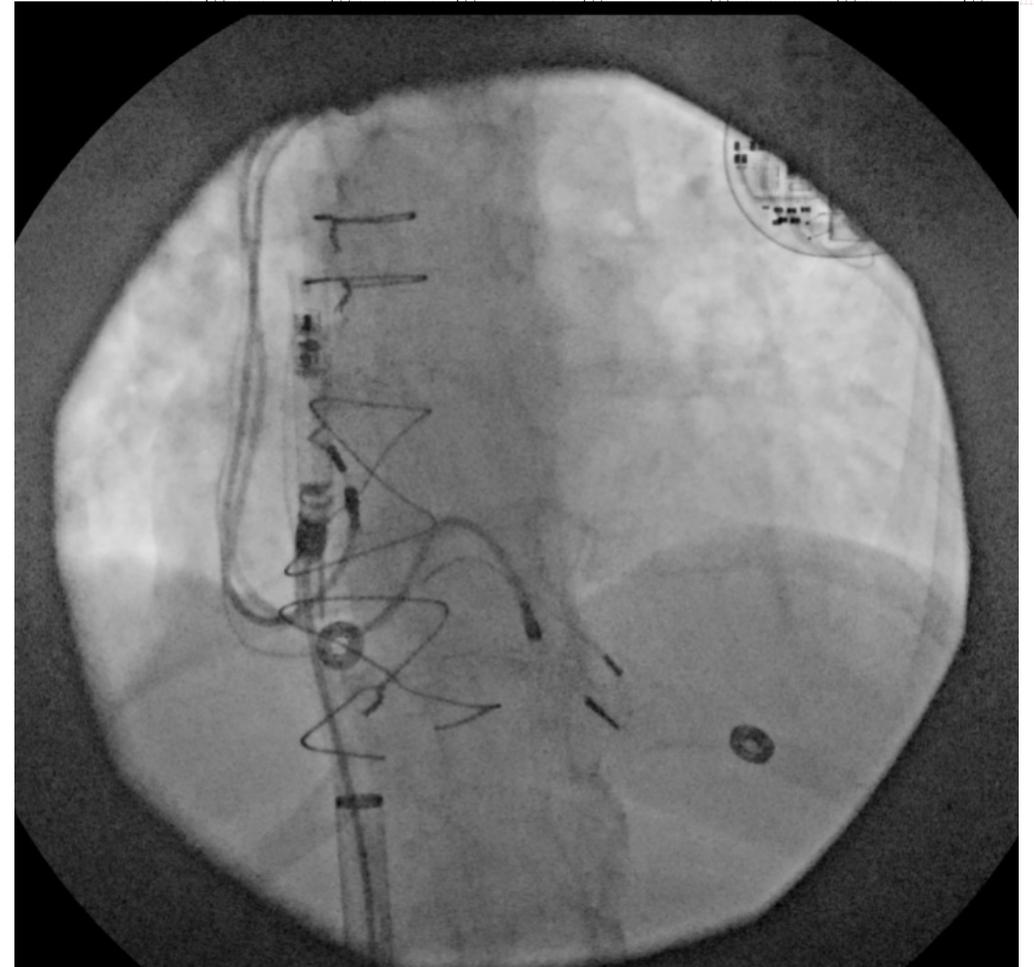
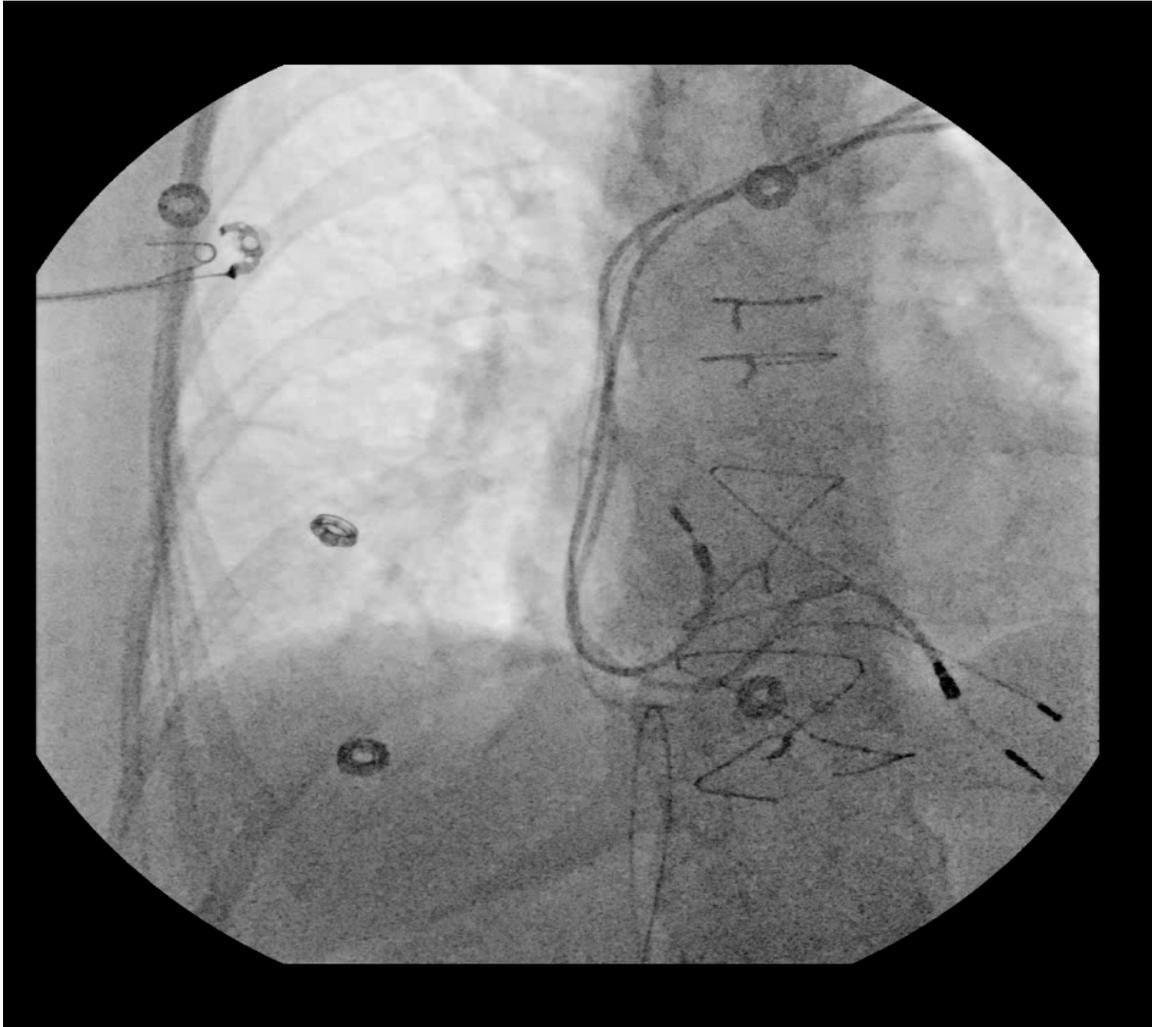


Mme S

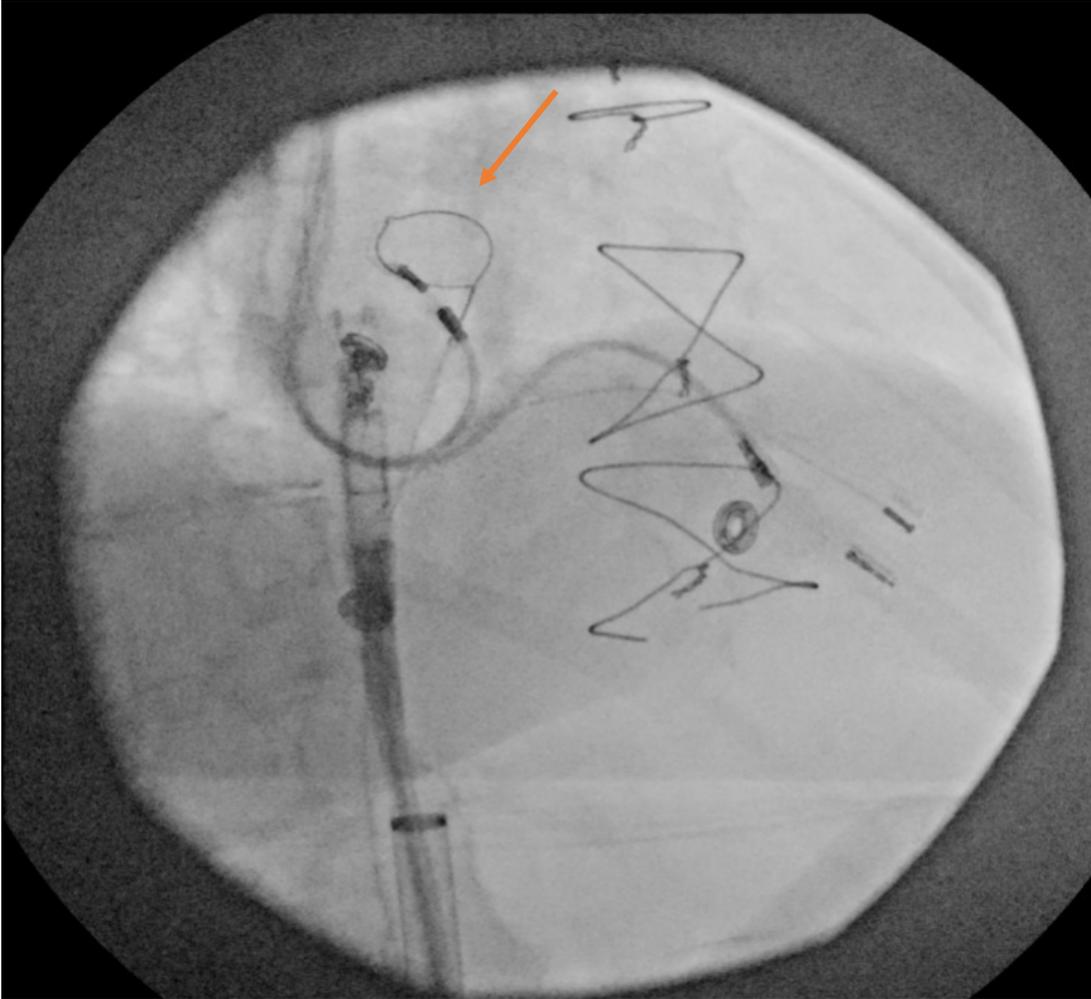
CP congénitale type canal AV, BAVc FA

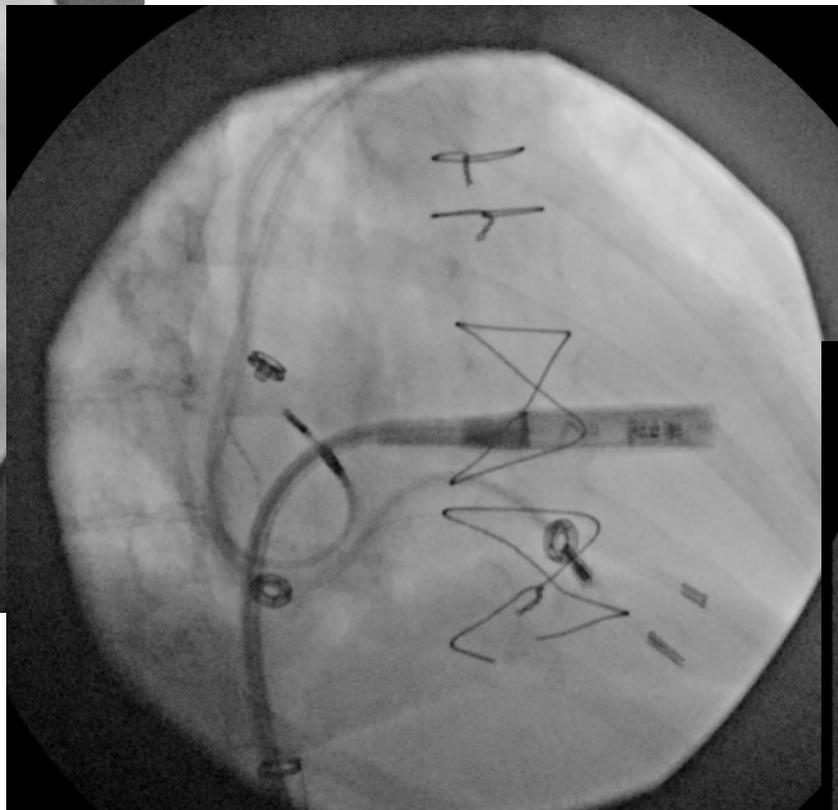
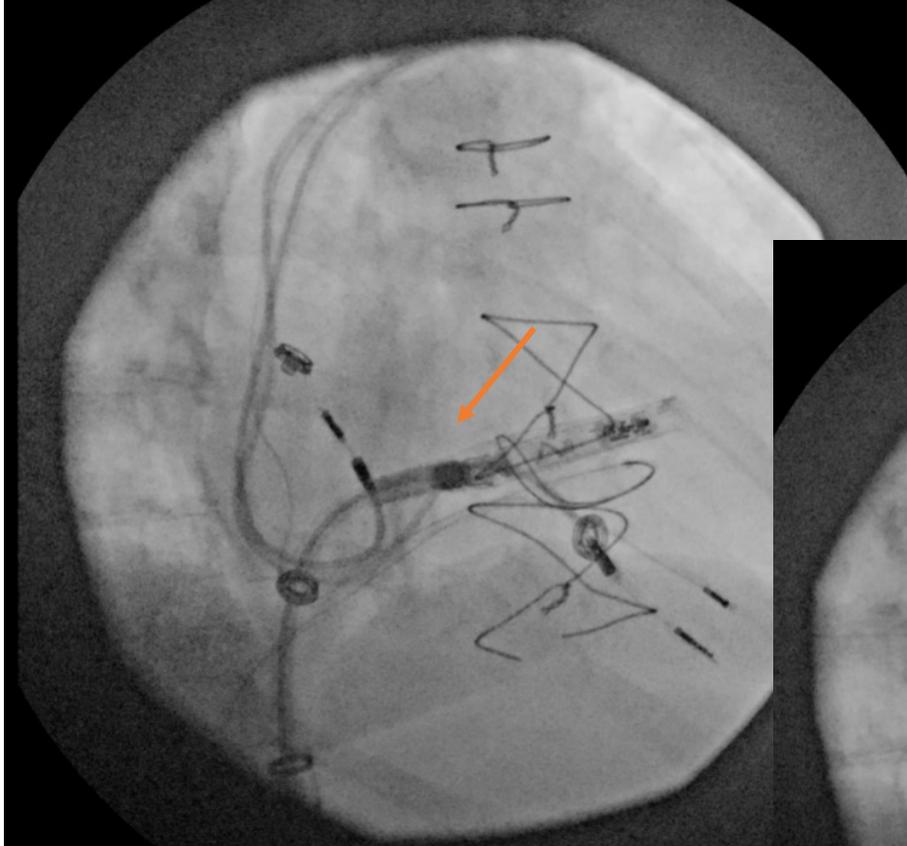
PM post op pour BAV 1997 (2007-2016-2022)

Sonde VD dysfonctionnelle



Lasso Goose Neck 30 mm pour franchir la tricusppe

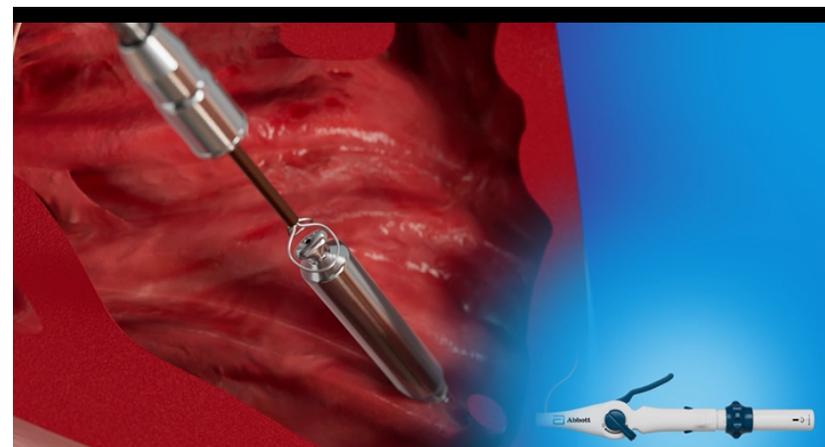
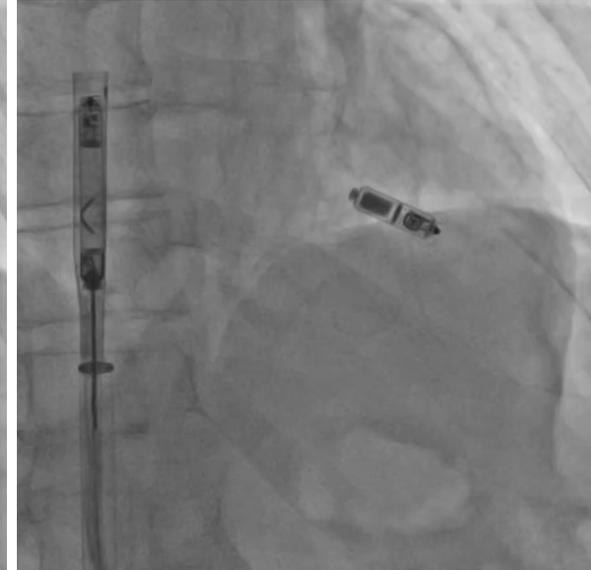
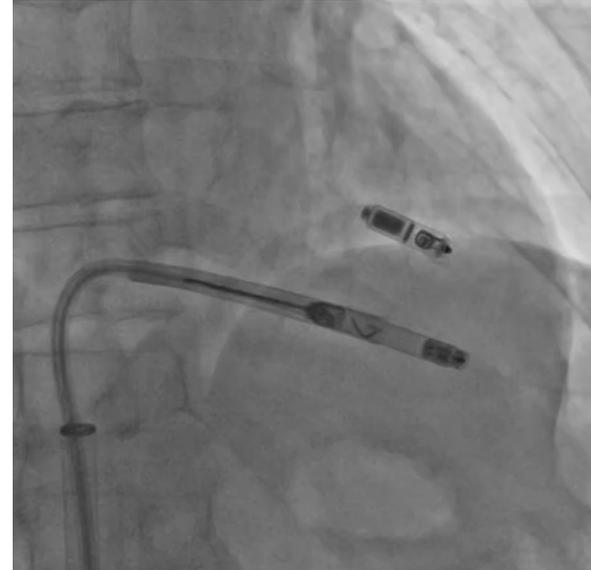
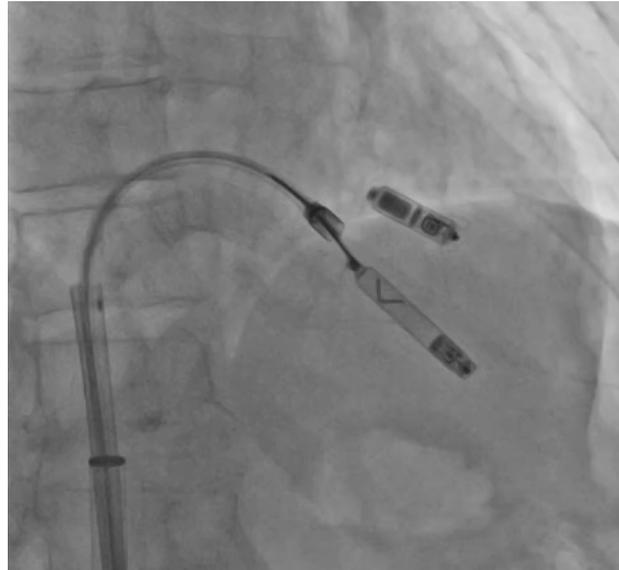
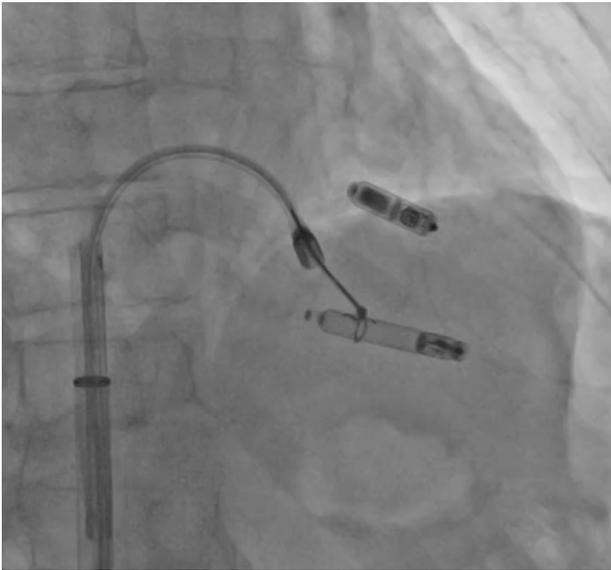




2 positions (unfundibulum bas inefficace, septal moyen OK)  
**Seuil 2,75V** (lesion ++) puis 2,5 imp 960 ohms detection 4 mv  
Seuil sortie hospit inf à 0,5V

*Recall of a Nanostim leadless PM (2016) after reimplantation of a Micra AV*

*Removal of the old Nanostim™, 19/2/2021*



# L'AVEIR AR

## Stimulateur cardiaque sans sonde auriculaire AVEIR™ AR

1. Bouton d'ancrage
2. Vis de fixation externe
3. Électrode hélicoïdale distale interne



Longueur : 32,2 mm Diamètre : 6,5 mm (19,5 F)

## Conception à double vis

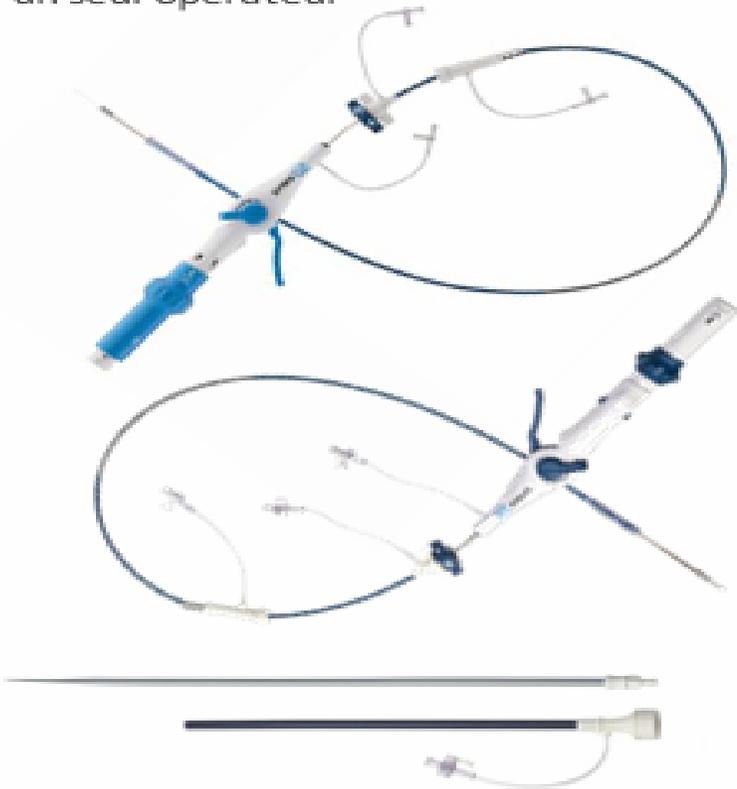
- Une externe inactive de 1,63 mm assure la fixation primaire
- La vis interne fait office d'électrode de stimulation et assure une fixation et une stabilité électrique supplémentaires
- Site d'implantation recommandé : base de l'auricule droit

Model	LSP201A (Right Atrial)	LSP202V (Right Ventricular)
Length	32.2 mm (1.27 in)	38.0 mm (1.50 in)
Diameter	6.5 mm (0.26 in)	6.5 mm (0.26 in)
Volume	0.96 cm <sup>3</sup>	1.1 cm <sup>3</sup>
Mass	2.1 grams	2.4 grams
Electrode Tip	Helical	Semispherical

# L'AVEIR AR

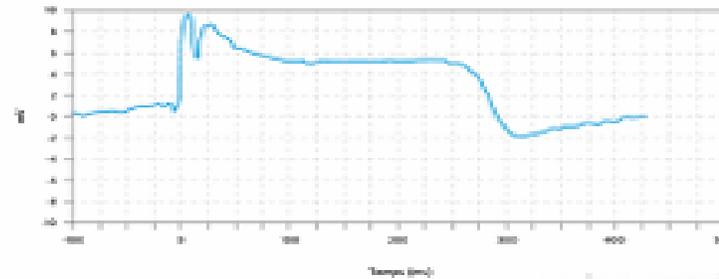
## CATHÉTERS D'IMPLANTATION ET DE RÉCUPÉRATION AVEIR™

Conçu pour une utilisation ergonomique par un seul opérateur



## MODULE AVEIR™ LINK ET PROGRAMMATEUR MERLIN™ (PCS)

Pas de cout additionnel adapté au programmeur actuel

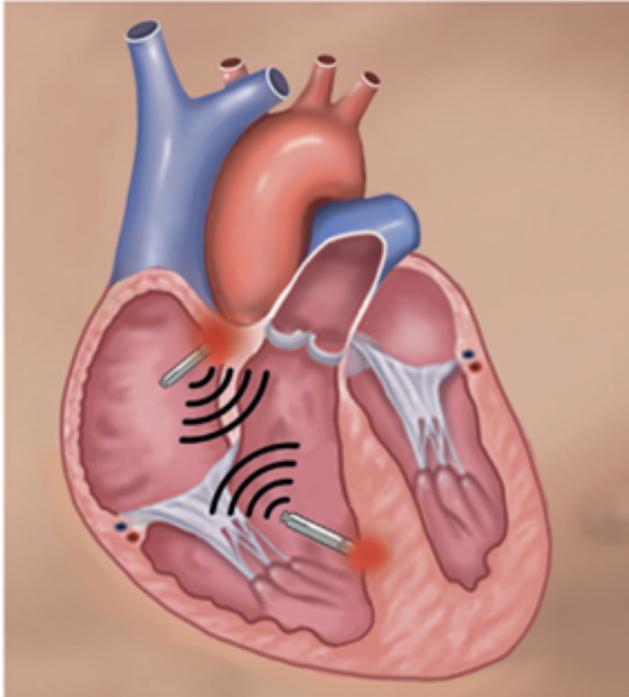


*Même catheter , même programmeur.....*

# L'AVEIR DR : système de communication

A

Communication Between the Leadless Pacemakers

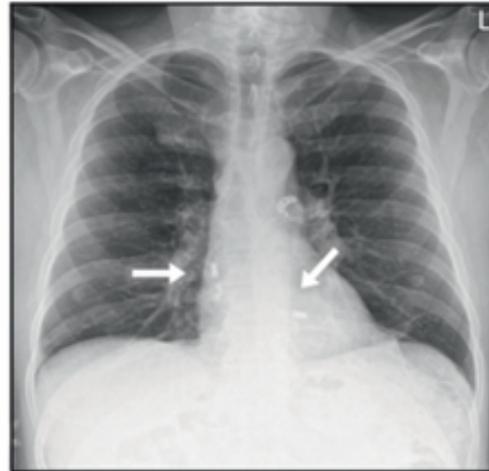


**Communication:**

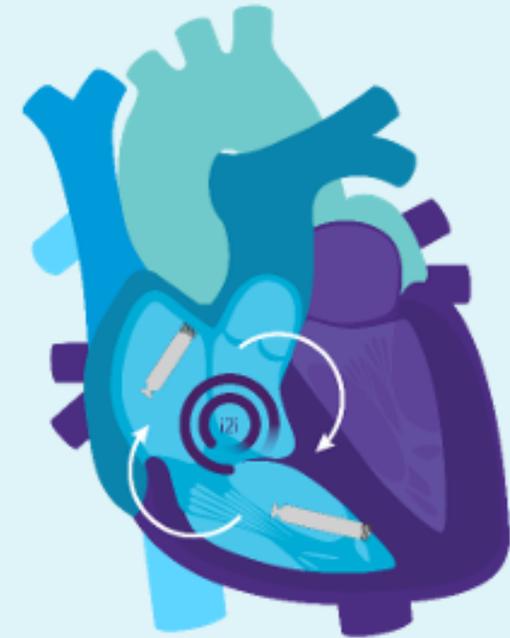
- After each sensed event
- Before each pacing stimulus
- To update target pacing rate
- Automatic mode switch entry/exit
- Upon magnet detection
- When reaching recommended replacement time

B

Position on Chest Radiographs

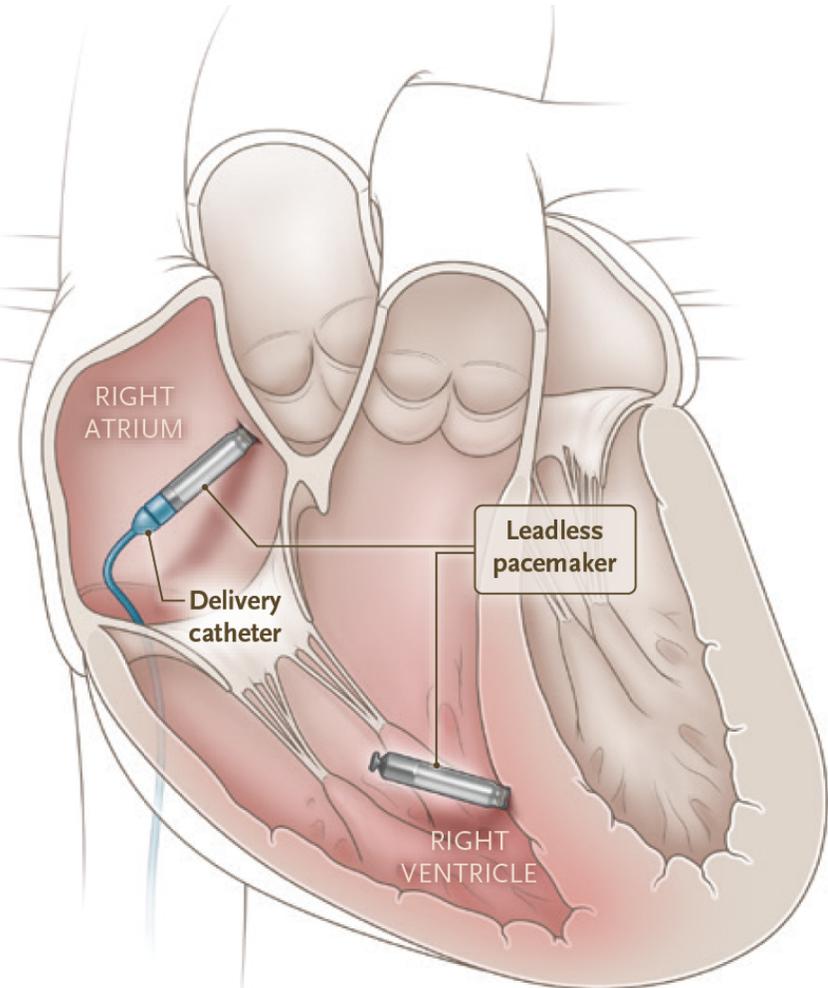


## TECHNOLOGIE i2i



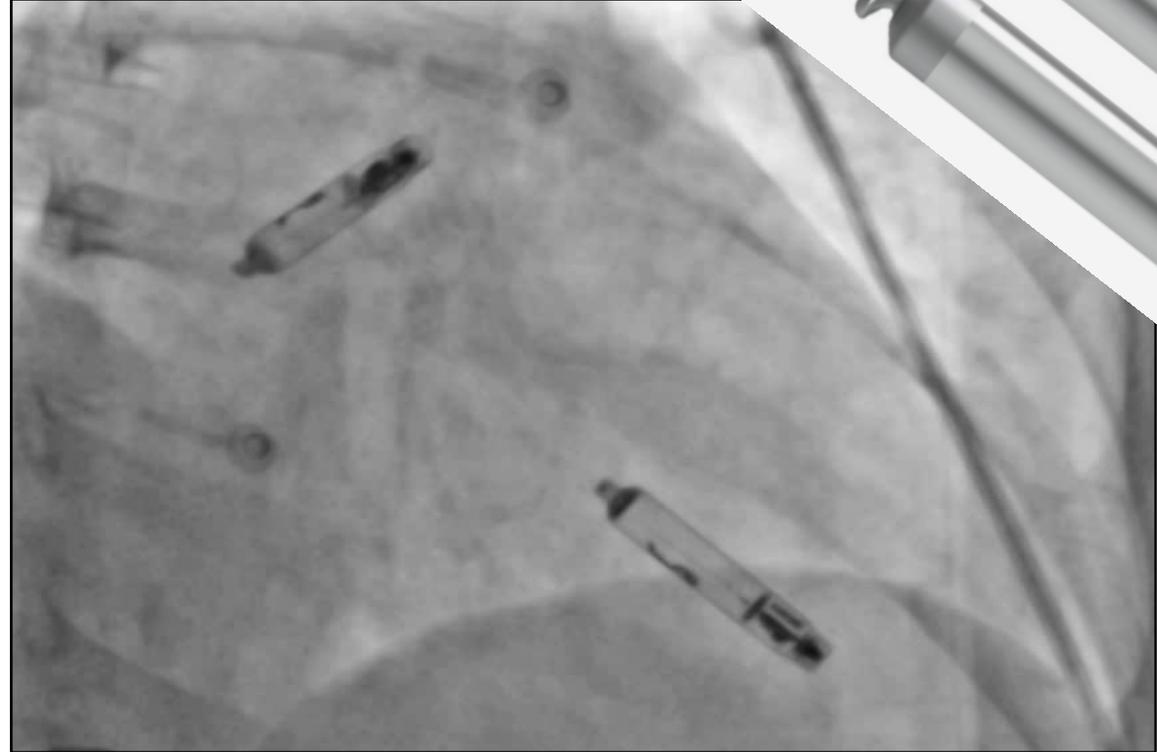
# A Dual-Chamber Leadless Pacemaker

Reinoud E. Knops, M.D., Ph.D., Vivek Y. Reddy, M.D., James E. Ip, M.D.,  
Rahul Doshi, M.D., Derek V. Exner, M.D., M.P.H., Pascal Defaye, M.D.,  
Robert Canby, M.D., Maria Grazia Bongiorno, M.D., Morio Shoda, M.D.,  
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Chris Hubbard, M.B.A., and Daniel J. Cantillon, M.D.,  
for the Aveir DR i2i Study Investigators\*



*New Engl J of Med May 2023*

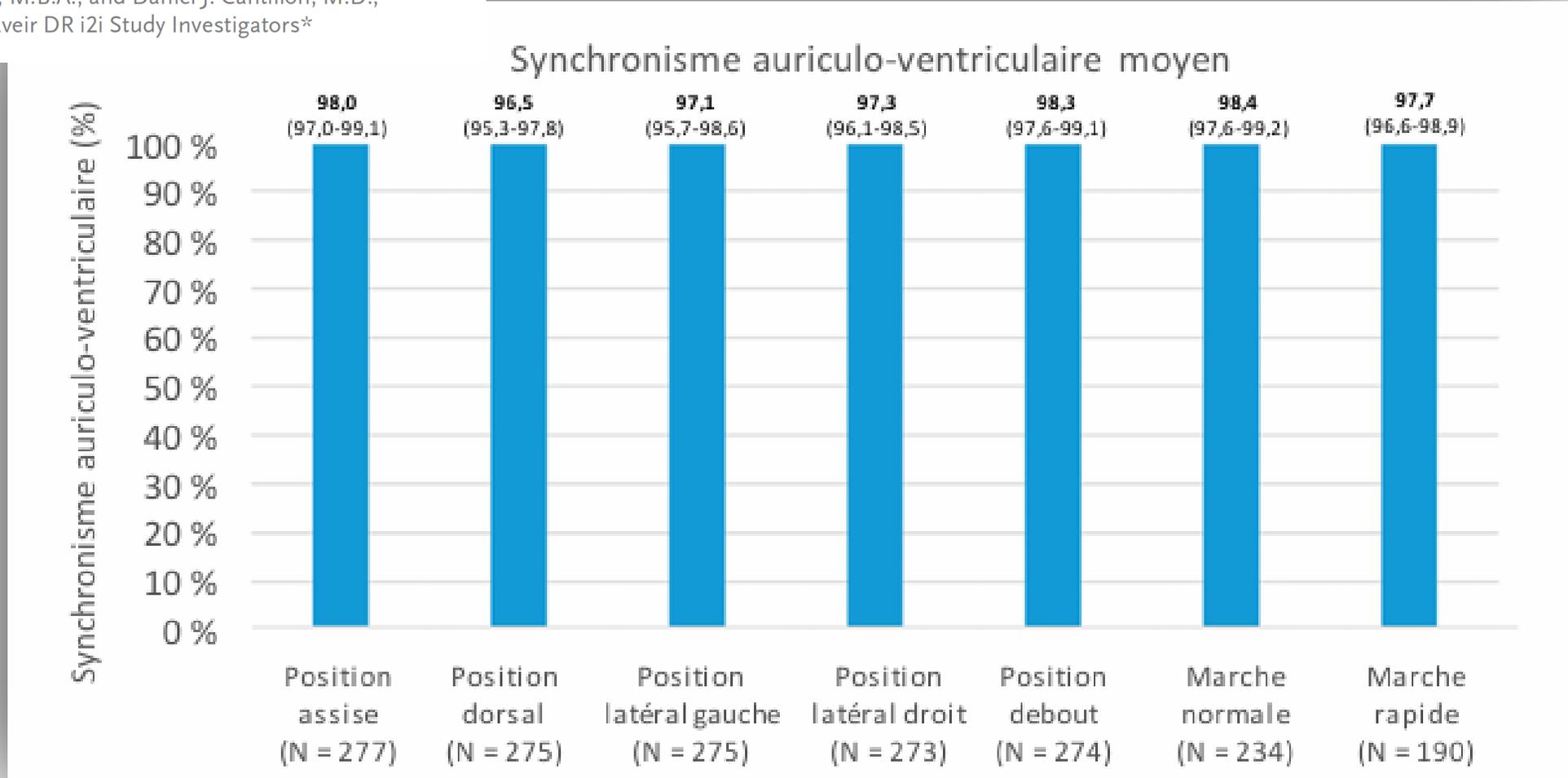
**Grenoble / April 2022**



*Succès d'implantation 98,3%*  
*Complications 3 mois 9,7% ( id PM DDD)*

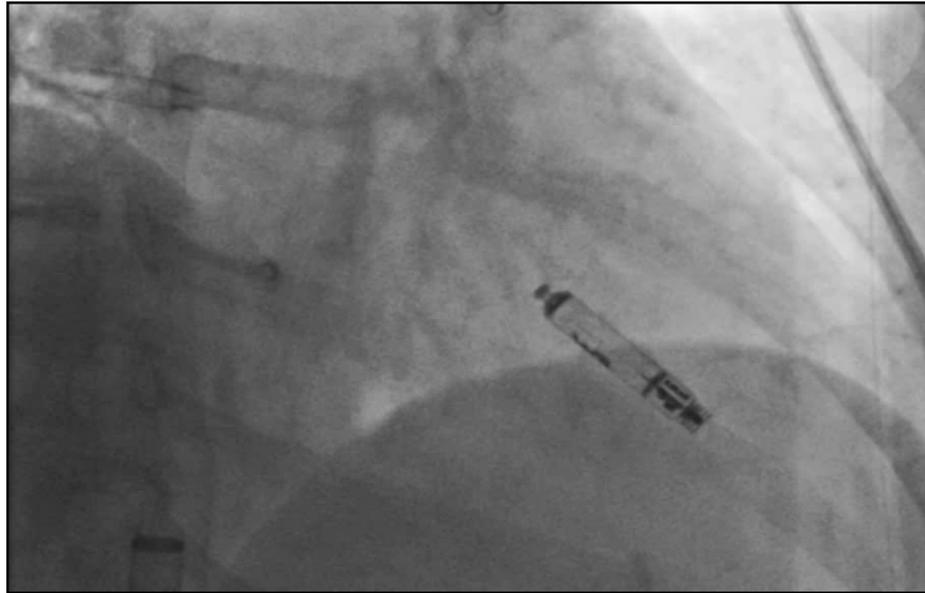
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## **Mrs R... G**

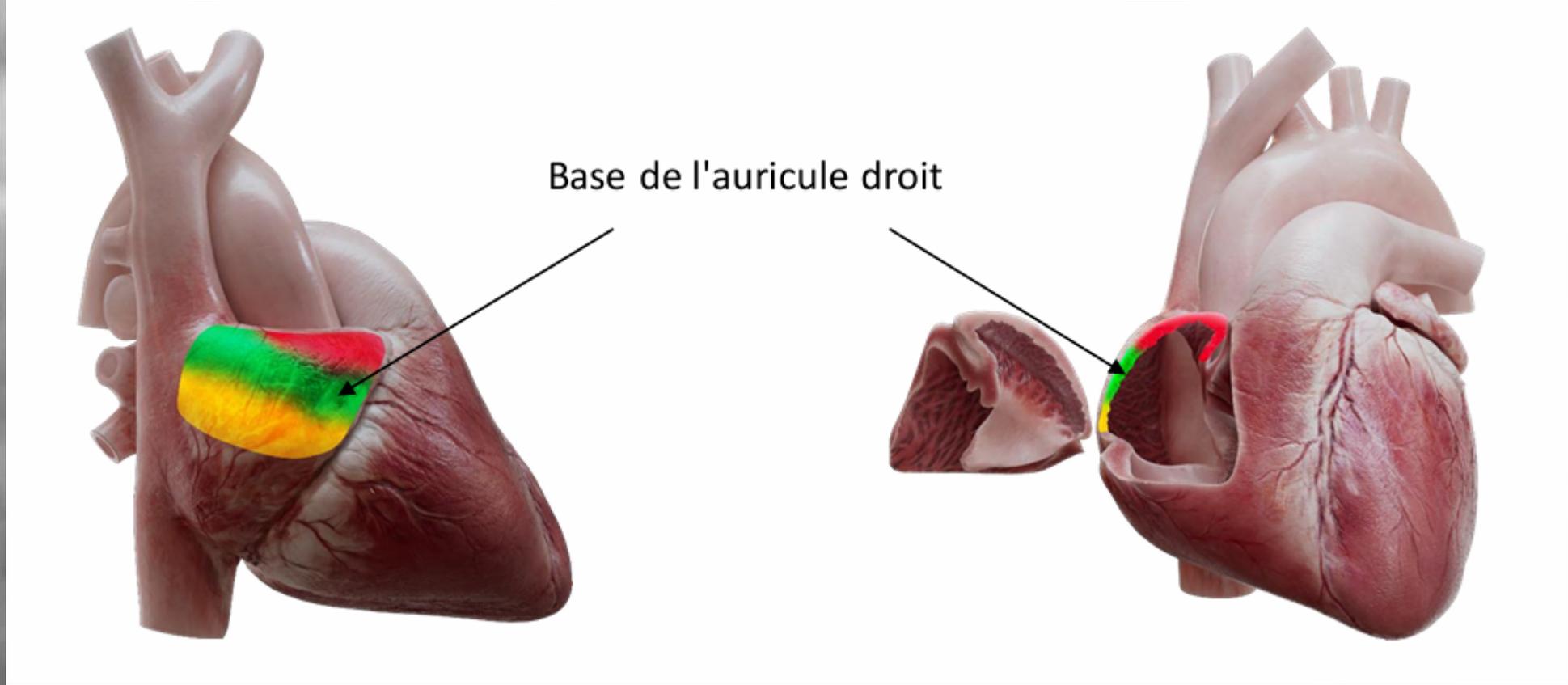
- **Sinus node dysfunction**
- **Dizziness with lipothymia**
- **Paroxysmal AF**
- **Female, 74 Years Old**
- **Height : 156 cm.**
- **Weight : 72 Kg.**



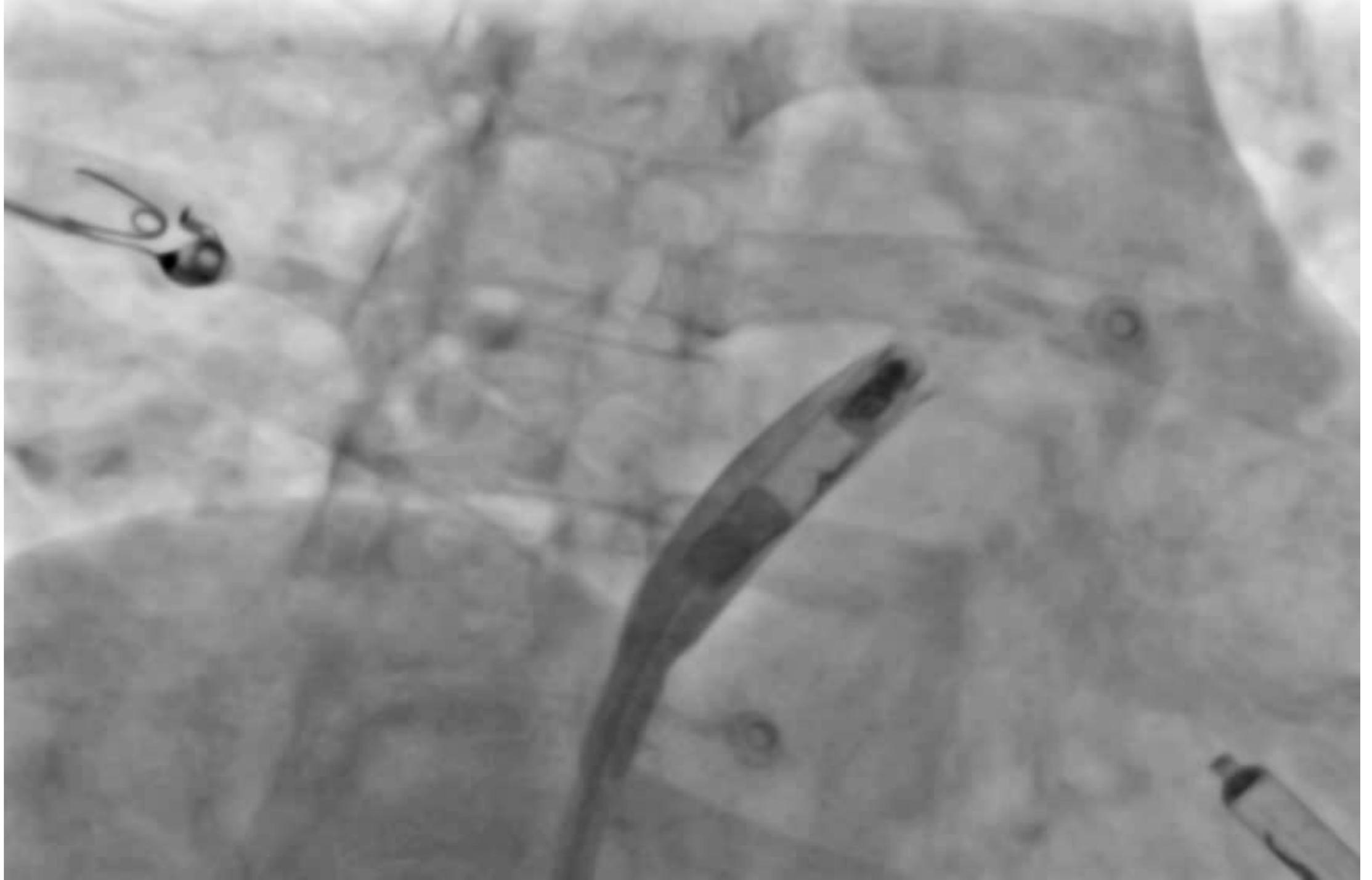
**DDD Pacemaker indication**

**Implant of AVEIR DR , March 8 2022**

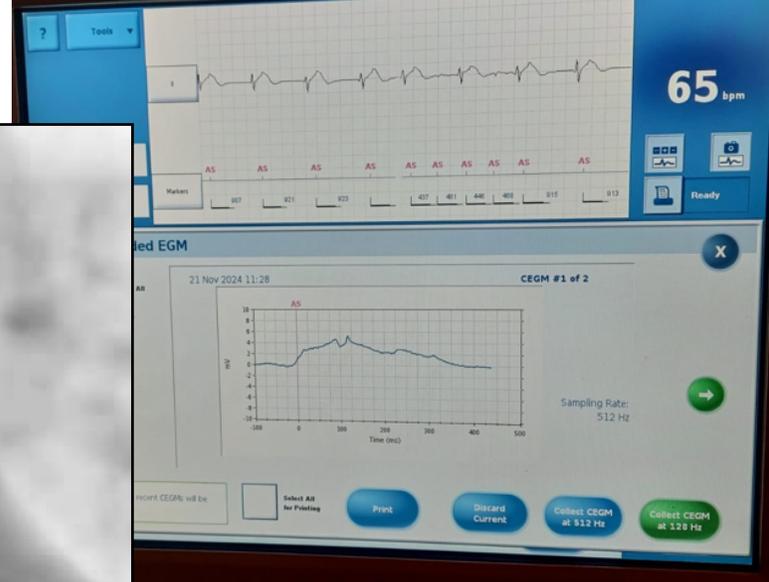
**Centre Hospitalier Universitaire Grenoble Alpes**

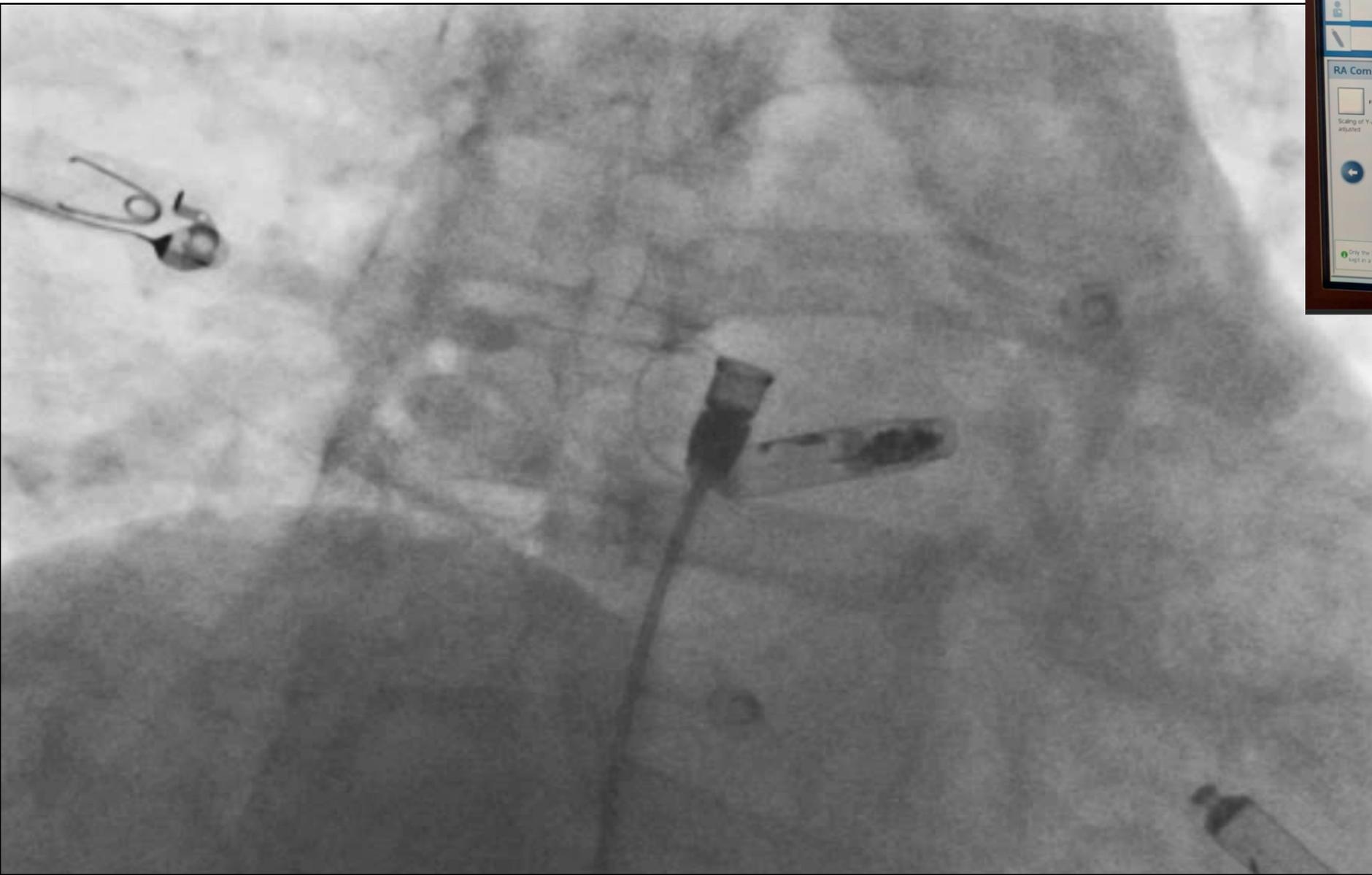




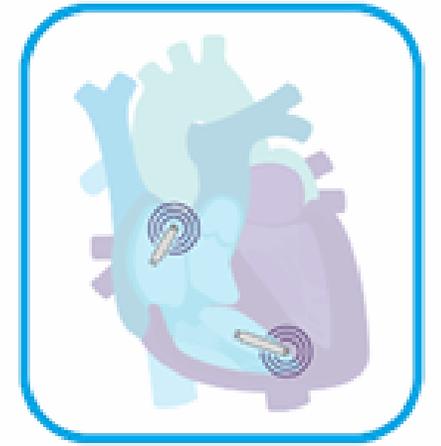




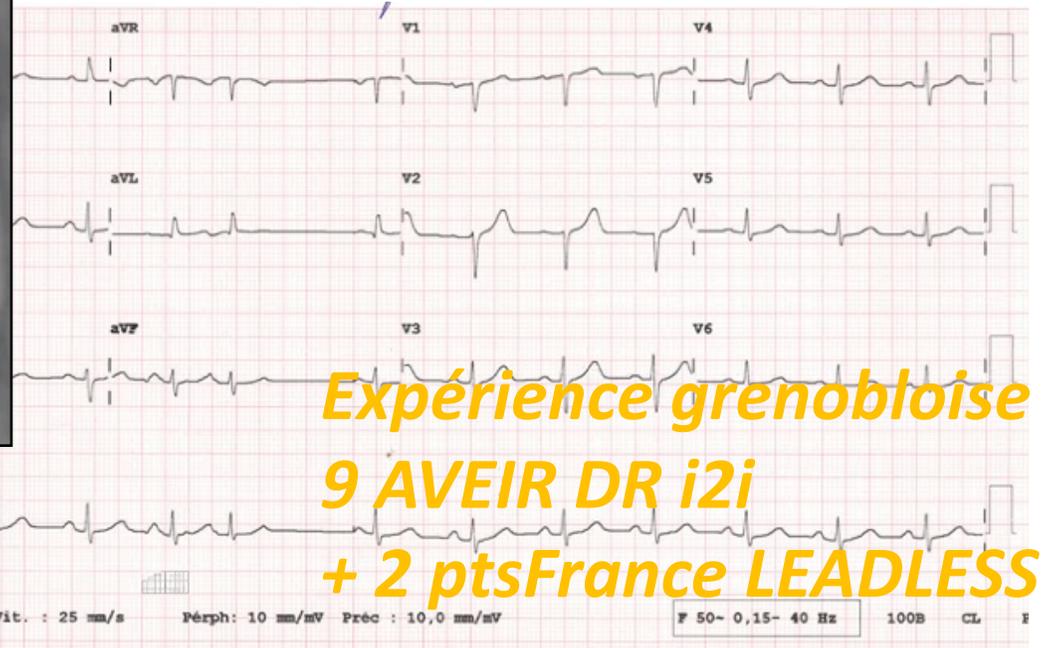
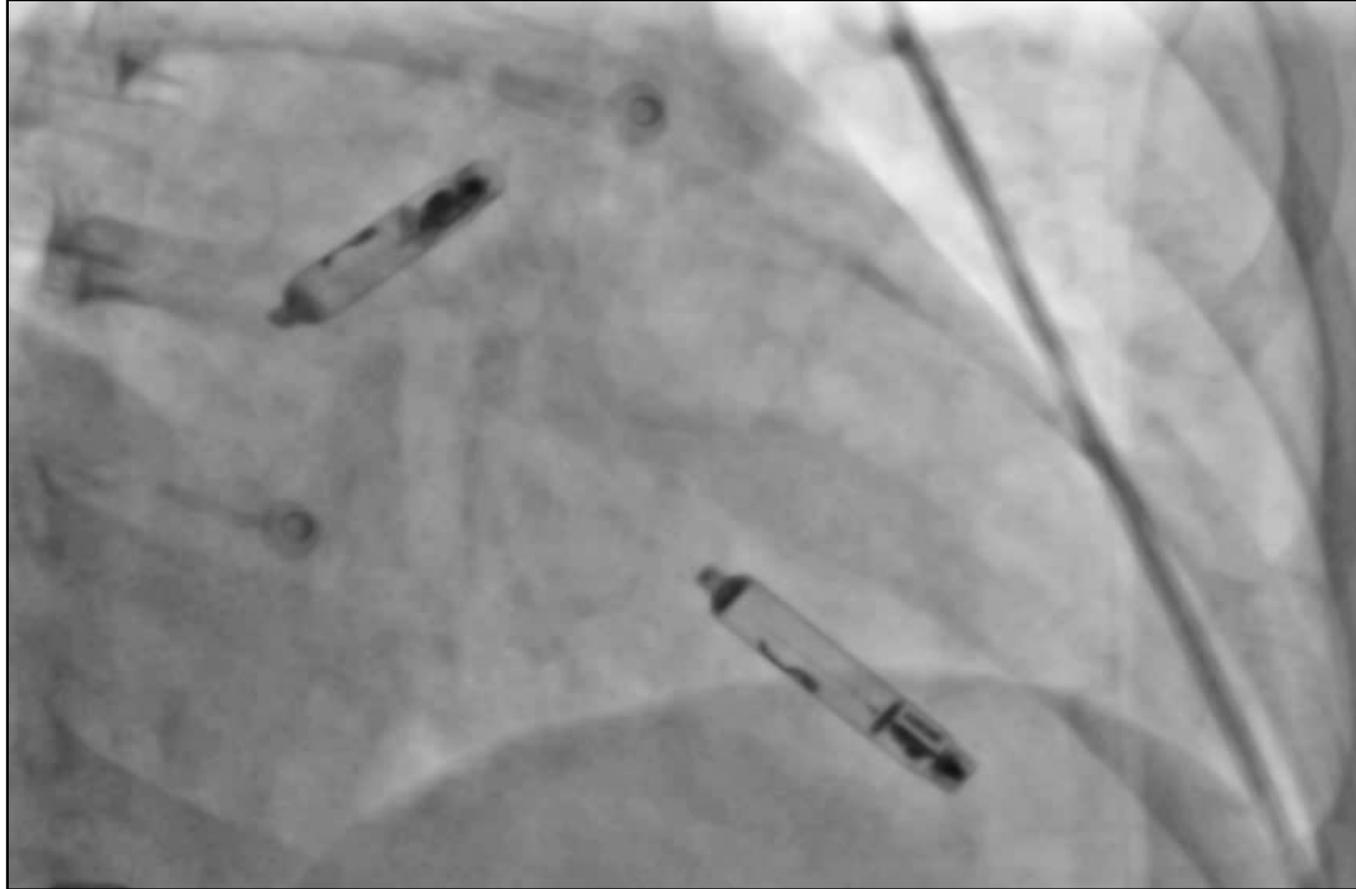




tests



Appareillement  
Reglage i2I  
Reglage DDD



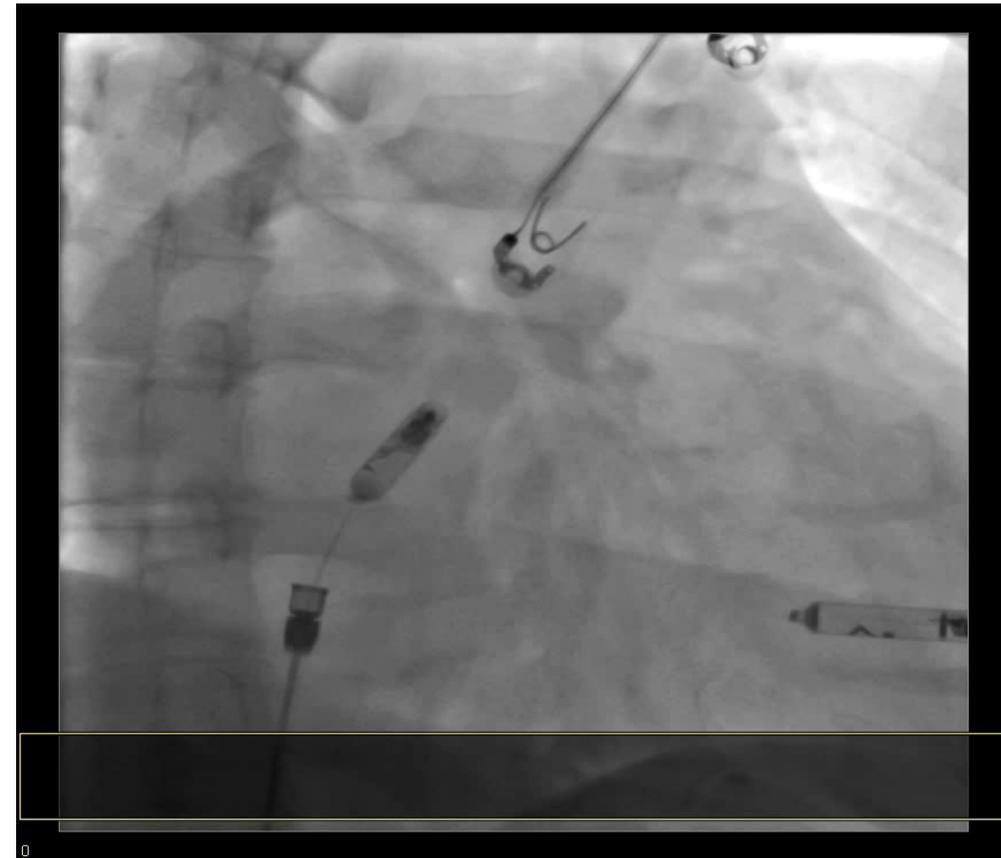
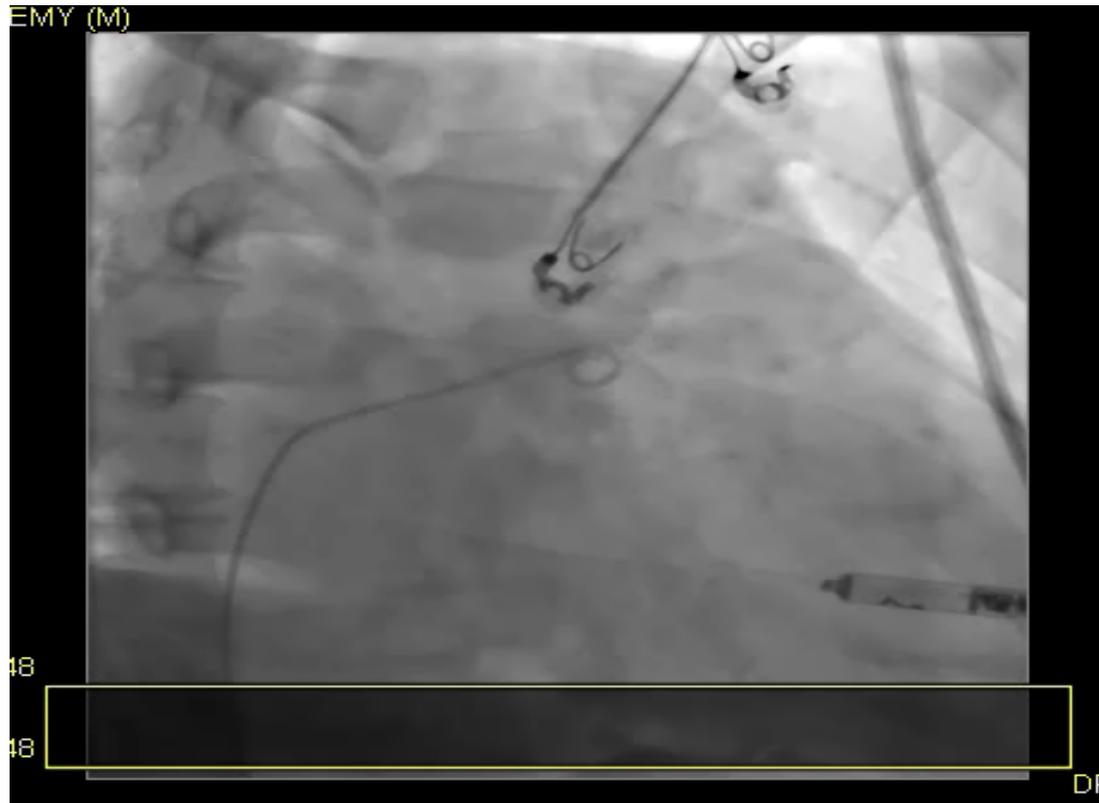
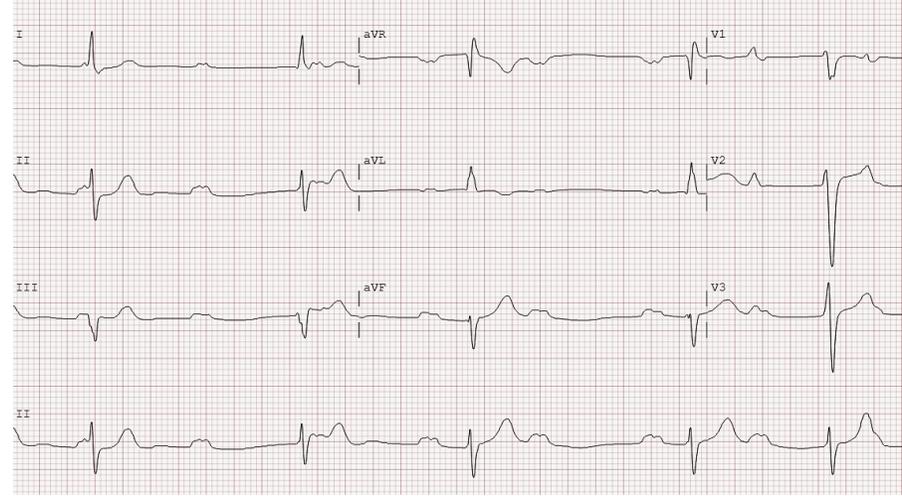
**Expérience grenobloise**  
**9 AVEIR DR i2i**  
**+ 2 ptsFrance LEADLESS**

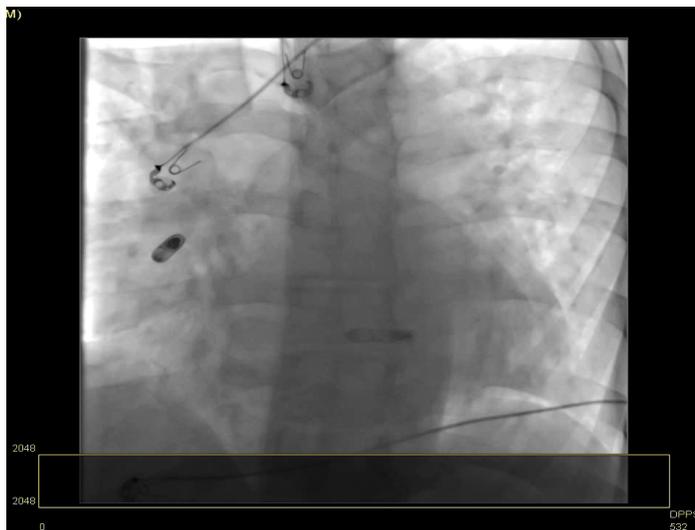
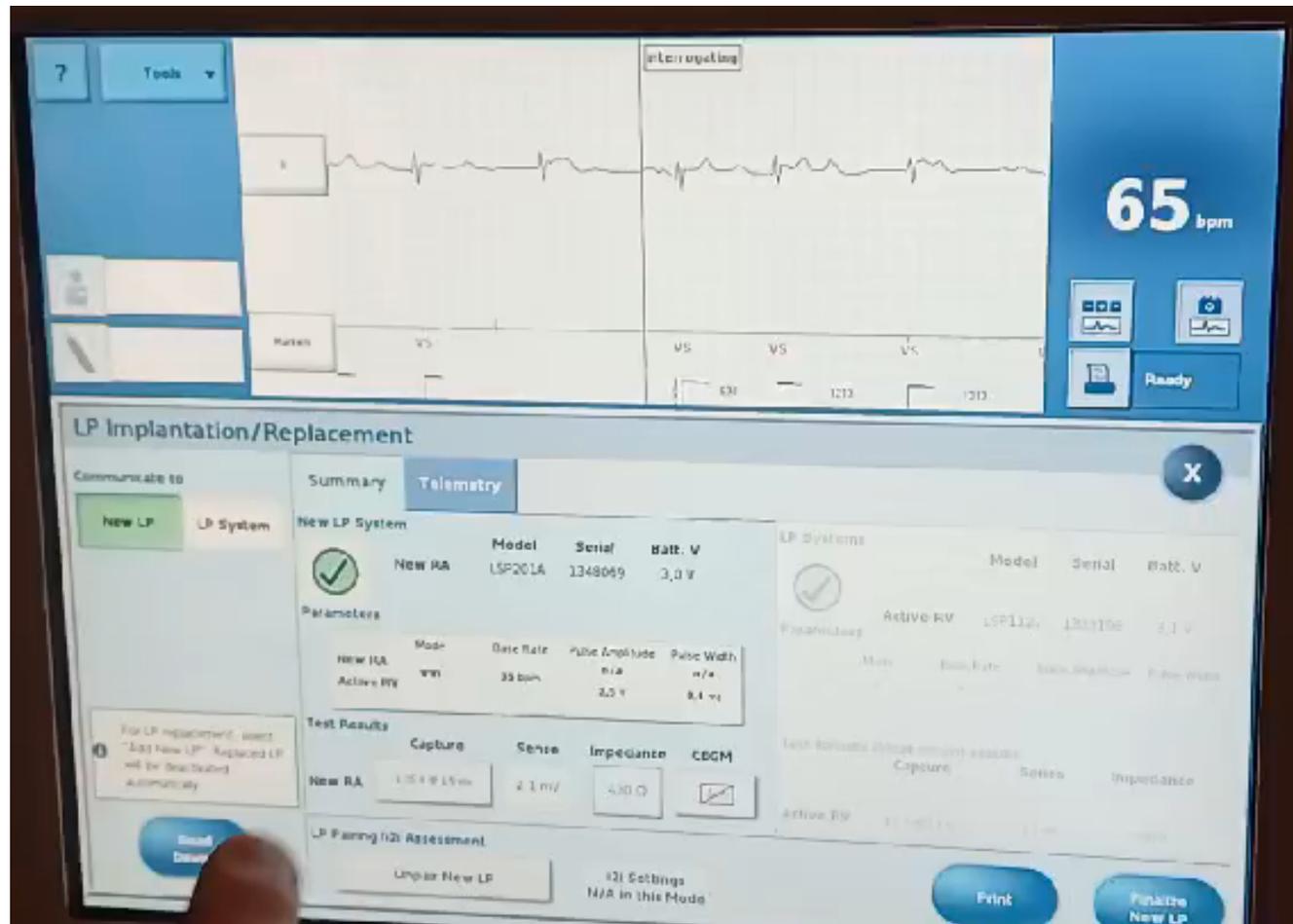
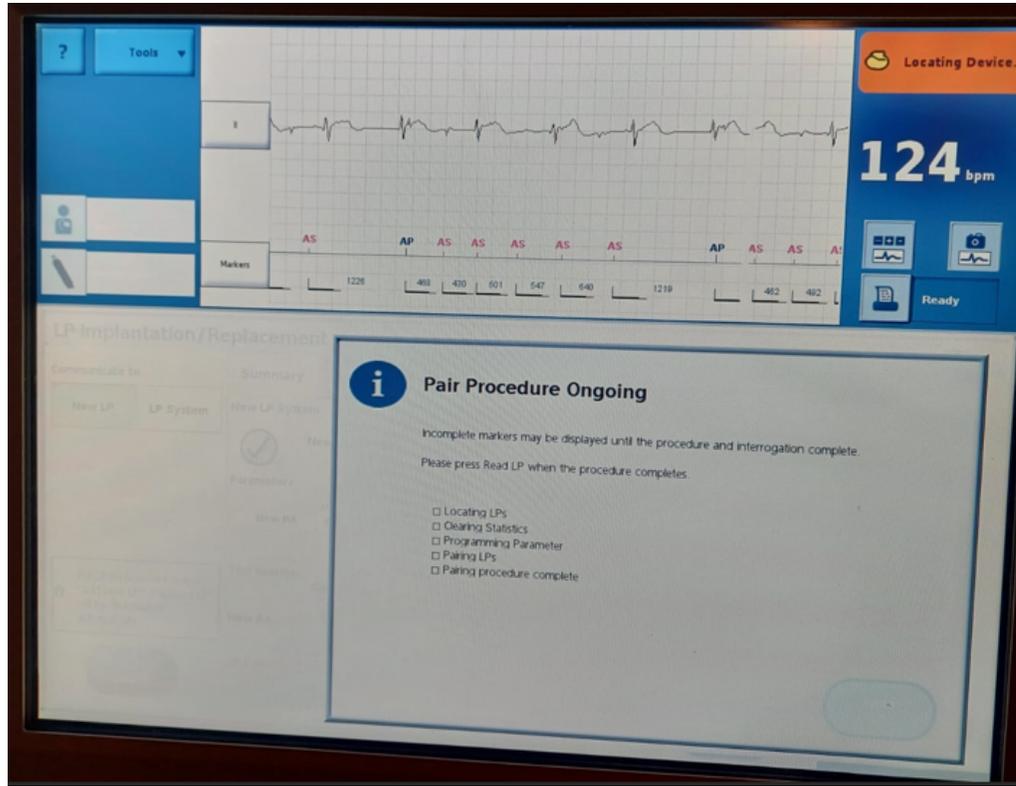
## Exemple 2 : UPGRADE

Mr S, 35 ans

BAV2M2 FC 35 bpm

Leadless AVEIR VR en juin 2023

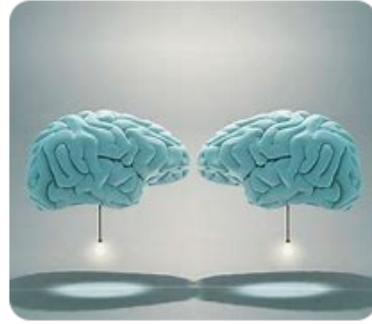






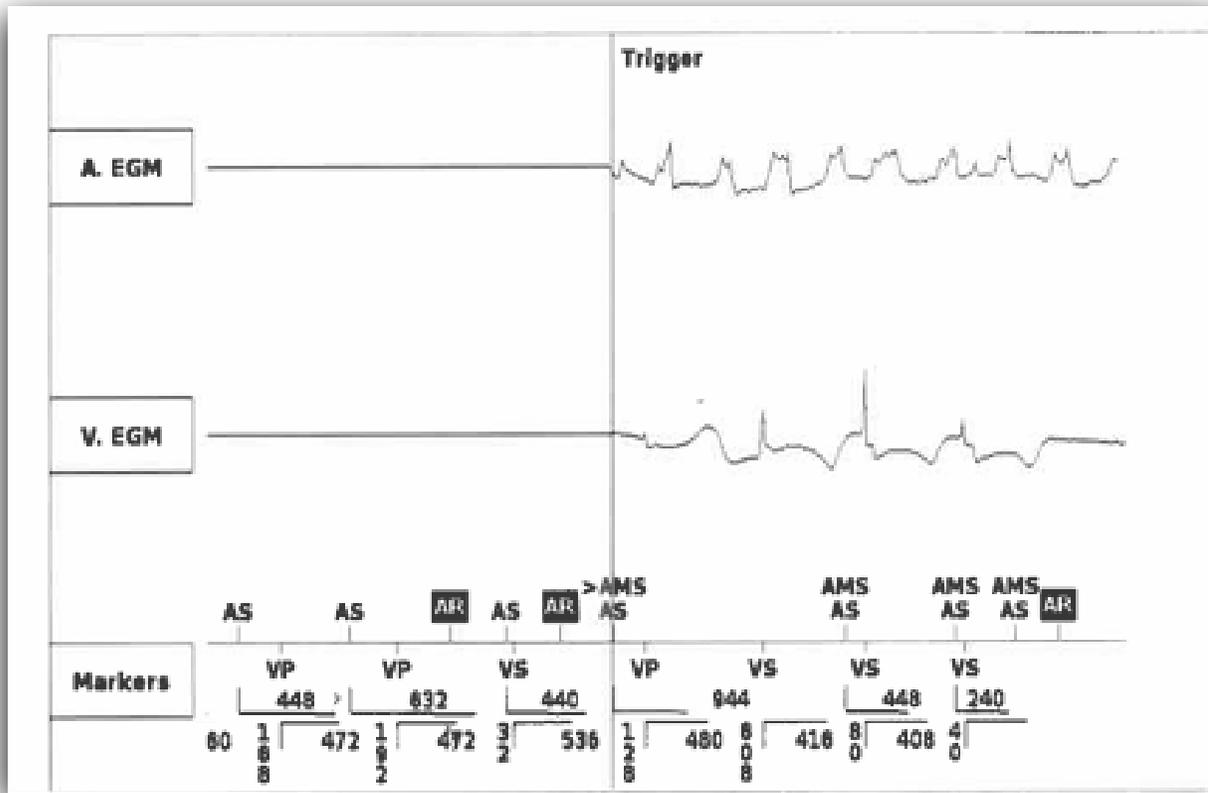
# Gestion à moyen terme : quels problèmes?

Madame R Gianna, première patiente implantée d'un DR  
Palpitations intermittentes



! Algorithmie disponible

- CAM et diagnostic associés
- Préférence Ventriculaire intrinsèque
- Hystérésis
- Stim A sur TRE
- Asservissement (température)



## AMS Log

EGMs	Date and Time	Peak A Rate	Duration (D:H:M:S)
1	7 Sep 2022 12:29 PM	256	
2	7 Sep 2022 2:37 PM	274	0:0:0:6
3	7 Sep 2022 2:06 PM	256	0:0:0:10
4	7 Sep 2022 1:55 PM	333	0:0:0:6
5	7 Sep 2022 1:55 PM	365	0:0:0:42
6	7 Sep 2022 1:44 PM	365	0:0:0:30
7	7 Sep 2022 12:41 PM	590	0:0:0:12
8	7 Sep 2022 12:40 PM	333	0:0:0:26
9	7 Sep 2022 12:37 PM	207	0:0:0:12
10	7 Sep 2022 12:36 PM	178	0:0:0:14
11	7 Sep 2022 12:36 PM	182	0:0:0:4
12	7 Sep 2022 12:35 PM	240	0:0:0:4
13	7 Sep 2022 12:35 PM	187	0:0:0:12
14	7 Sep 2022 12:35 PM	196	0:0:0:4
15	7 Sep 2022 12:34 PM	240	0:0:0:4
16	7 Sep 2022 12:32 PM	274	0:0:0:18
			0:0:0:20

...la communication en pratique... faut il s attendre à des difficultés?

# Gestion à moyen terme : quels problèmes?

## Interrogation patient étude AVEIR DR

Patient				
Patient Name: EU1617-406		Birth Date: n/a		
Chamber	Device	Device Model:	Device s/n:	Device implant
RA	Aveir™ LP	LSP201A	1305486	7 Apr 2022
RV	Aveir™ LP	LSP202V	1305397	7 Apr 2022
Battery Information				
Longevity: 5.8 yrs		Voltage 3.0 V		
RA		Battery Current 2.5 uA	Remaining Capacity to RRT 99 %	
Longevity estimate is based on patient history.				
Longevity: 11.5 yrs		Voltage 3.1 V		
RV		Battery Current 2.2 uA	Remaining Capacity to RRT 99 %	
Longevity estimate is based on patient history.				

....Expérience en récupérabilité Aveir AR limitée (hors phase précoce)

## AVEIR AR (en double chambre)

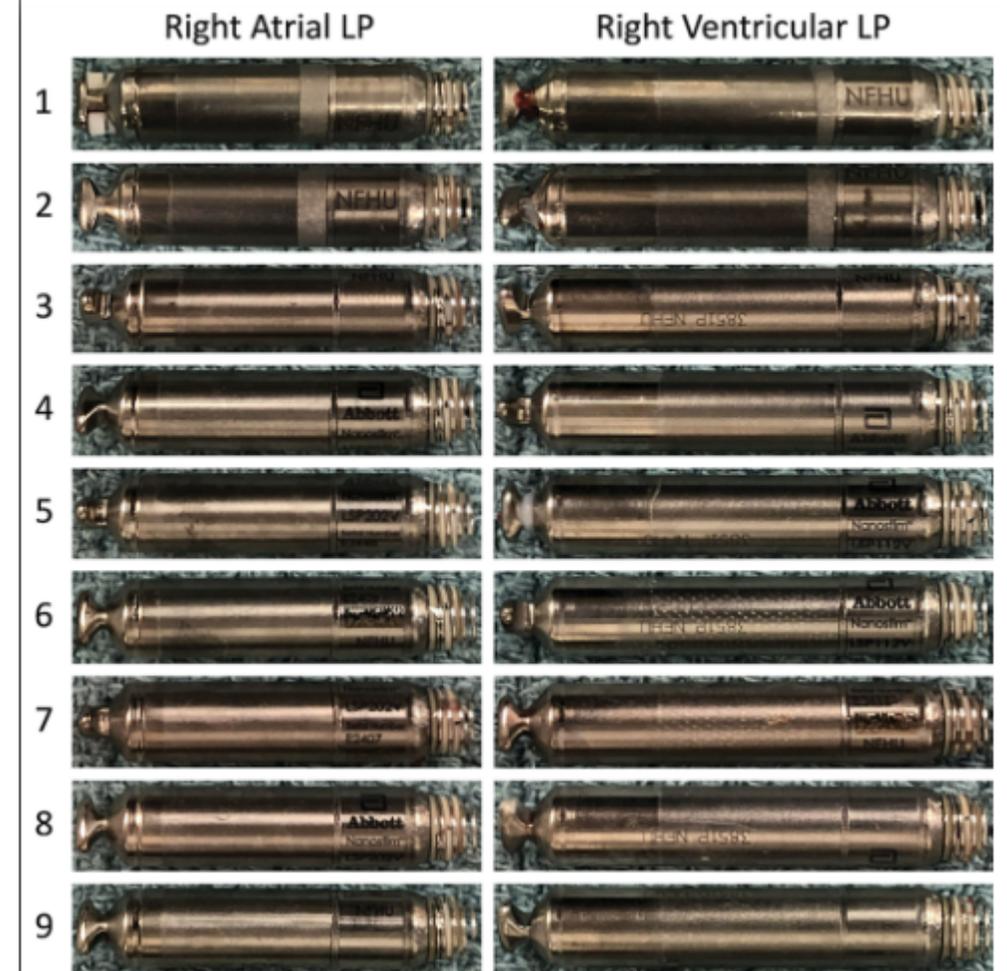
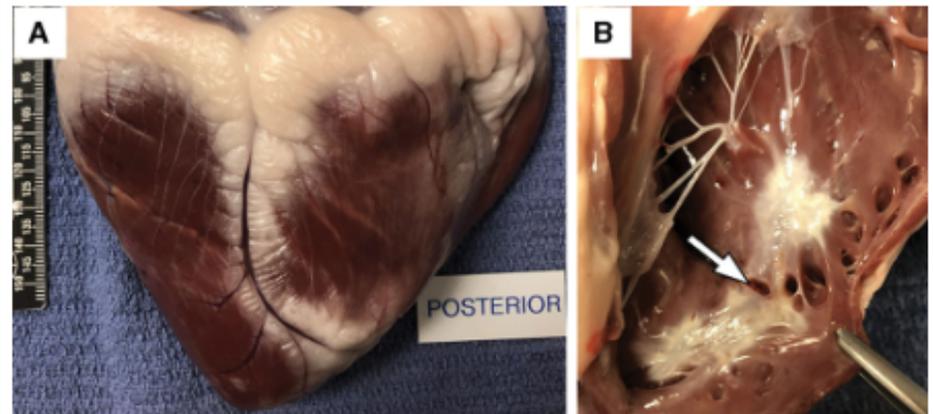
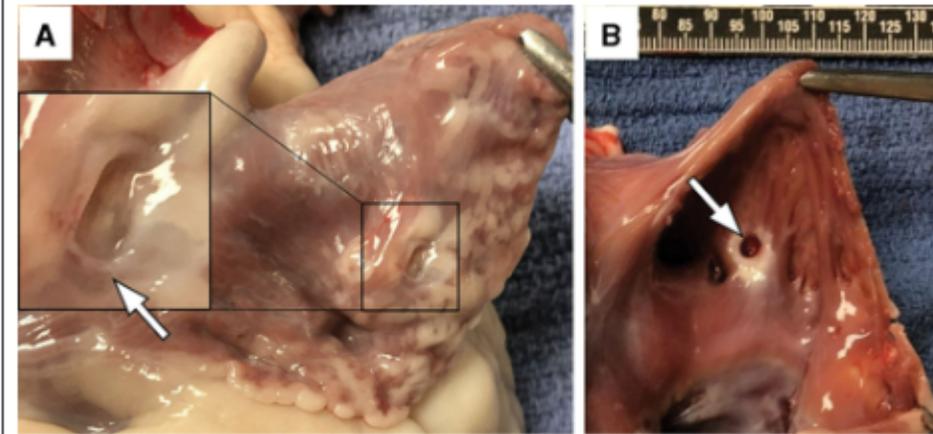
Fréquence de stimulation	Amplitude de stimulation	% de stimulation	LONGÉVITÉ (ANNÉES)	
			Impédance 300 Ω	400 Ω
50 bpm	1,25 V	100 %	6,2	7,1
		50 %	7,1	8,1
		0 %	8,3	9,3
50 bpm	2,5 V	100 %	3,9	4,7
		50 %	5,3	6,2
		0 %	8,3	9,3
60 bpm	1,25 V	100 %	5,3	6,1
	2,5 V	100 %	3,3	3,9
	5,0 V	100 %	1,1	1,4

 Impédance moyenne du dispositif auriculaire à 3 mois de suivi IDE<sup>2</sup>

ORIGINAL ARTICLE

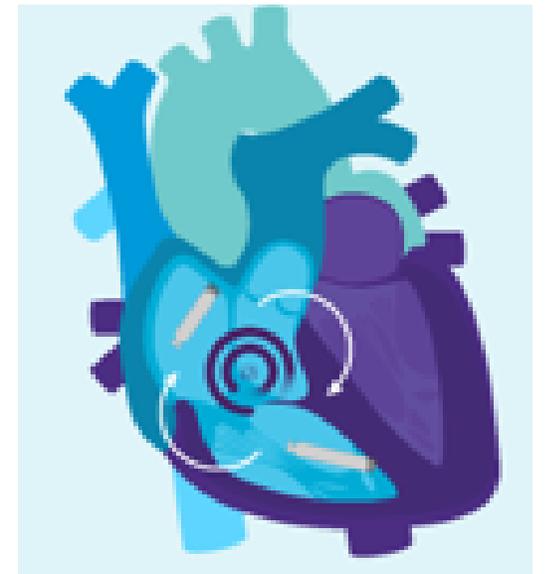
## Retrieval of Chronically Implanted Dual-chamber Leadless Pacemakers in an Ovine Model

9 healthy ovine subjects. After  $\approx$ 2 years



# AVEIR : pour quel patient ??

Hors CRT et stimulation de branche gauche ... indications théoriques très larges  
Limitation des conditions de remboursement/ diffusion propre aux leadless



# AVEIR : pour quel patient ??

Hors CRT et stimulation de branche gauche ... indications théoriques très larges  
Limitation des conditions de remboursement/ diffusion propre aux leadless

- **AVEIR VR vs autre leadless :**

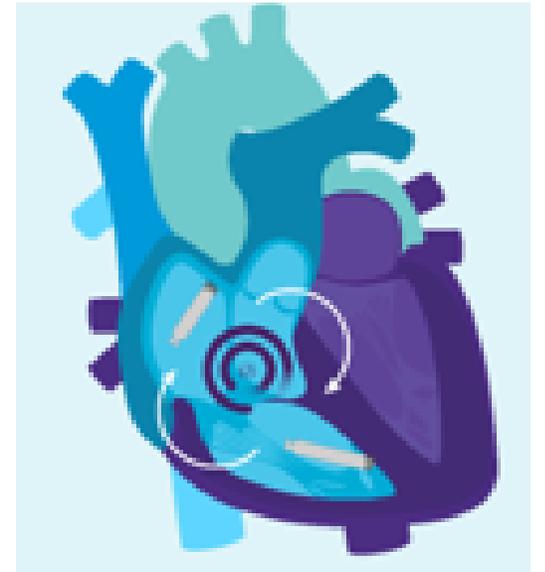
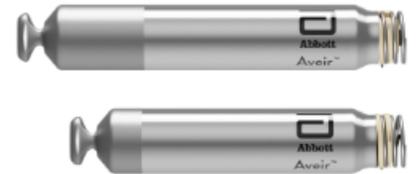
- Si espérance de vie très bonne
- Si rythme sinusal et risque de besoin d'atrialisation (BAV, maladie oreillette)

- **AVEIR AR :**

place dysfonction sinusale du sujet jeune??

- **AVEIR DR :**

- En upgrade si syndrome du pacemaker
- D'emblée chez le jeune??



# Génération Aveir... que retenir??

- **AVEIR VR...**

Dispositif leadless à vis « abouti »

Inconvénients : plus complexe pour l'implantation et le suivi?

Avantages +++ : Longévité/Recuperabilité/ Modulaire

- **AVEIR DR :**

Premier leadless Atrial

Un nouveau paradigme dans le monde de la stimulation (i2i ...)

Inconvénients : faible recul «vie réelle »

Avantages : stim A/ synchro AV / Recuperabilité/ modulable

