Hôpitaux de Toulouse

Pôle Cardiovasculaire et Métabolique

BIOPROTHESES VALVULAIRES AORTIQUES TRANSCATHETER :

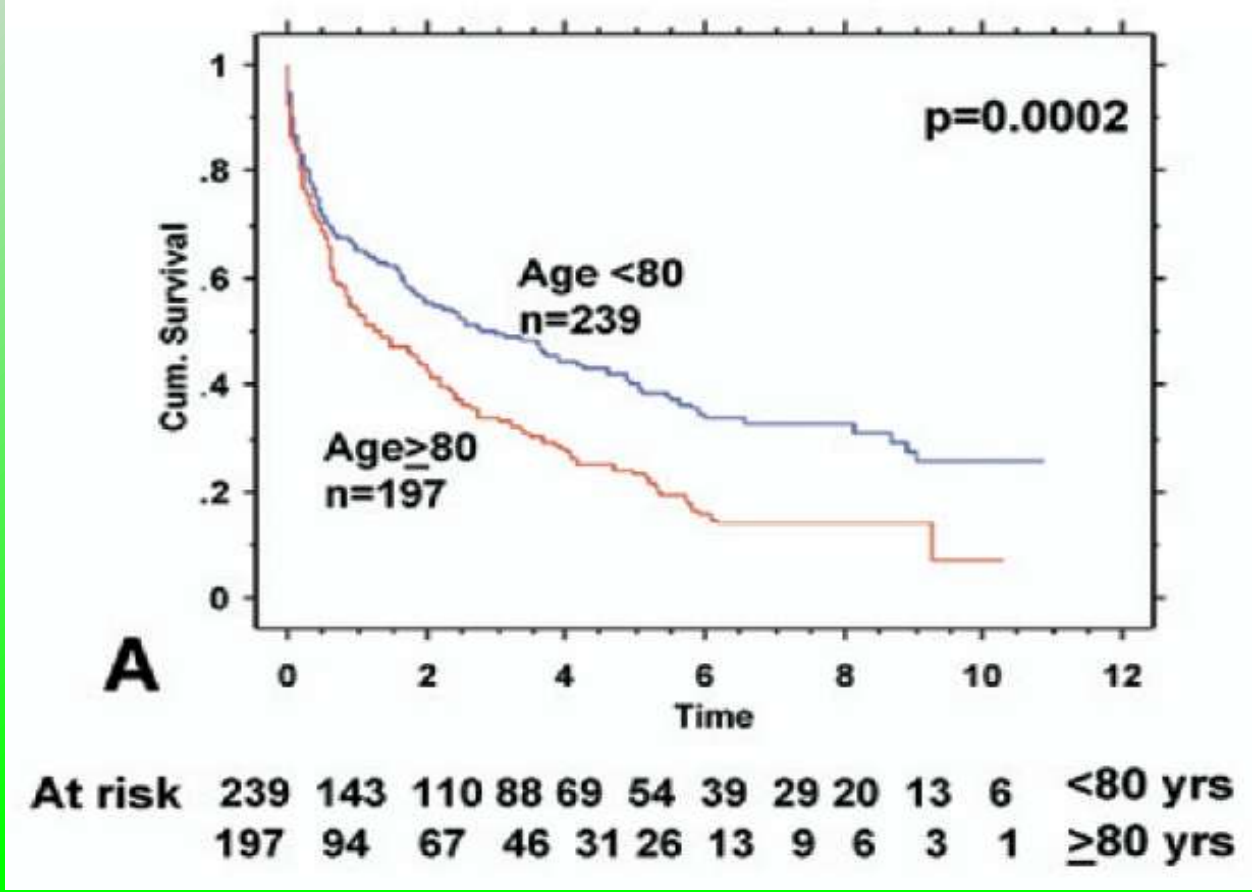
INDICATIONS, SELECTION DES PATIENTS, TECHNIQUE ET RESULTATS

Dr N. Dumonteil, Pr D. Carrié

Toulouse, 12 Octobre 2010

Le Rétrécissement Aortique (RAo)

- Valvulopathie la + fréquente des sujets âgés



Varadarajan P et al, ***Ann Thorac Surg*** 2006;82:2111–5

Le Rétrécissement Aortique (RAo)

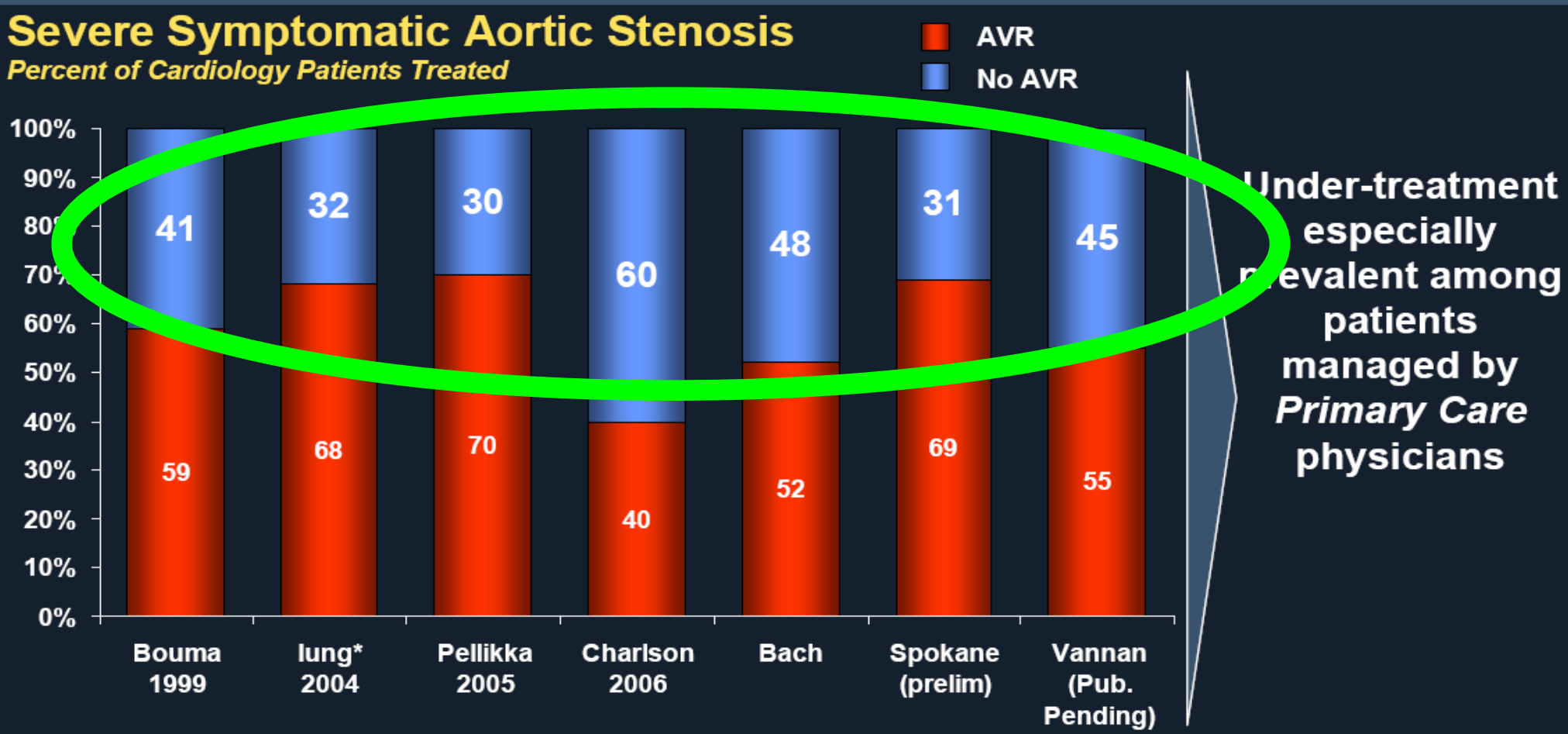
Traitement de référence

CHIRURGIE DE
REMPLACEMENT VALVULAIRE

Chirurgie cardiaque au risque de mortalité opératoire le plus bas :

4 à 6 %, y compris chez l'octogénaire

At Least 30% of Patients with Severe Symptomatic AS are "Untreated"!



1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. Circulation 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis2006;15:312-321

Bioprothèses implantables par cathétérisme

EDWARDS SAPIEN / XT ® PROSTHESIS

- TransFemoral access
- TransApical access

MEDTRONIC COREVALVE ® PROSTHESIS

- TransFemoral access
- Subclavian access

Bioprothèses VAo percutanées : pour qui ?

- Critères d'inclusion :

RAO serré (< 1 cm2), symptomatique,

récusé pour la chirurgie

Aorte porcelaine, Thorax irradié, etc ...

ou à haut risque chirurgical

Logistic EUROSCORE > 20 %

STS SCORE > 10 %

Bioprothèses VAo percutanées : pour qui ?

- Critères d'exclusion :

  - IdM récent
  - Embolie pulmonaire récente
  - AVC récent
  - Contre-indication aux anticoagulants
  - CMO ou CMH
  - FE VG < 20 % sans réserve contractile
  - Fonctions supérieures, cognitives ? Etat nutritionnel ? Fragilité physiologique ?

TAVR Patient Selection
Includes Careful Frailty Assessment

Patient A

vs.

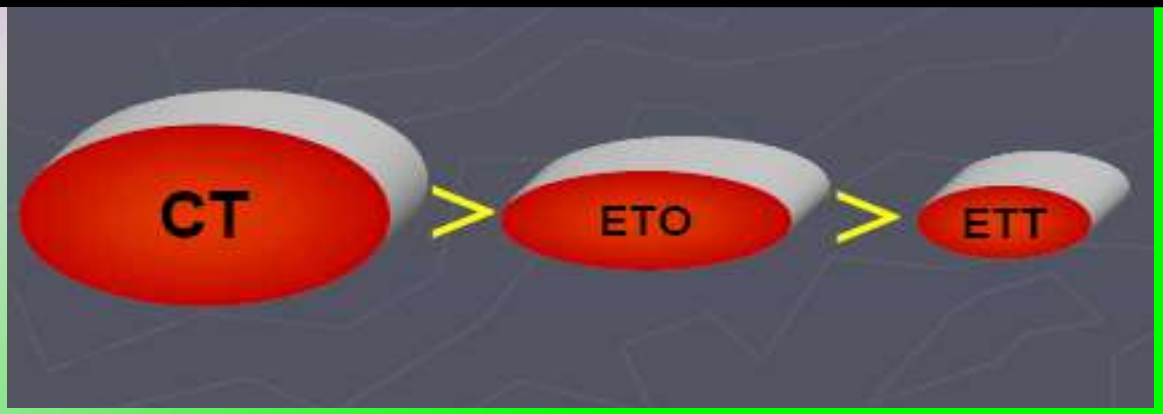
Patient B

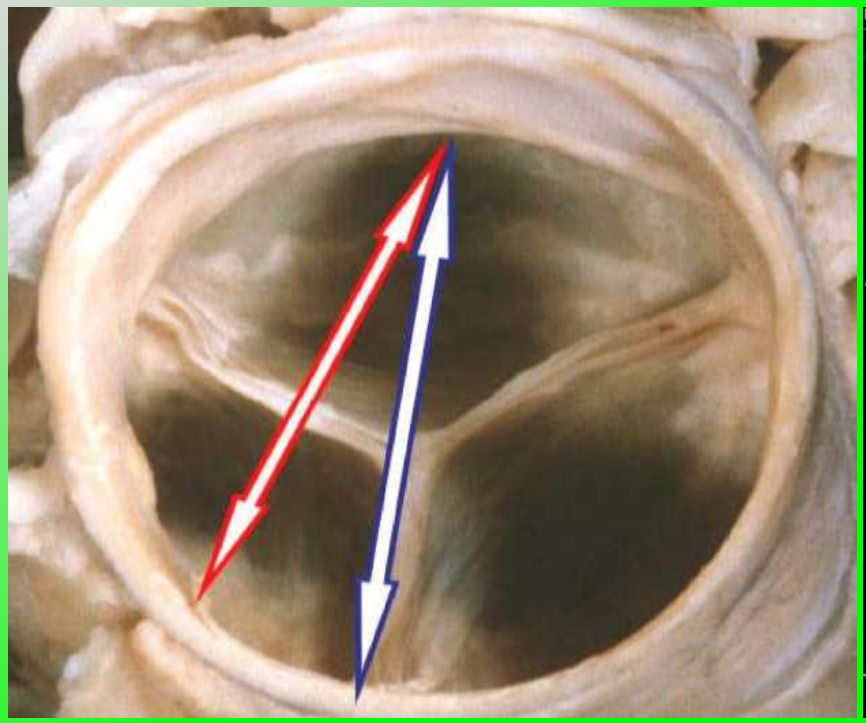
Same age and predicted risk
One passes the "eyeball test" – one does not

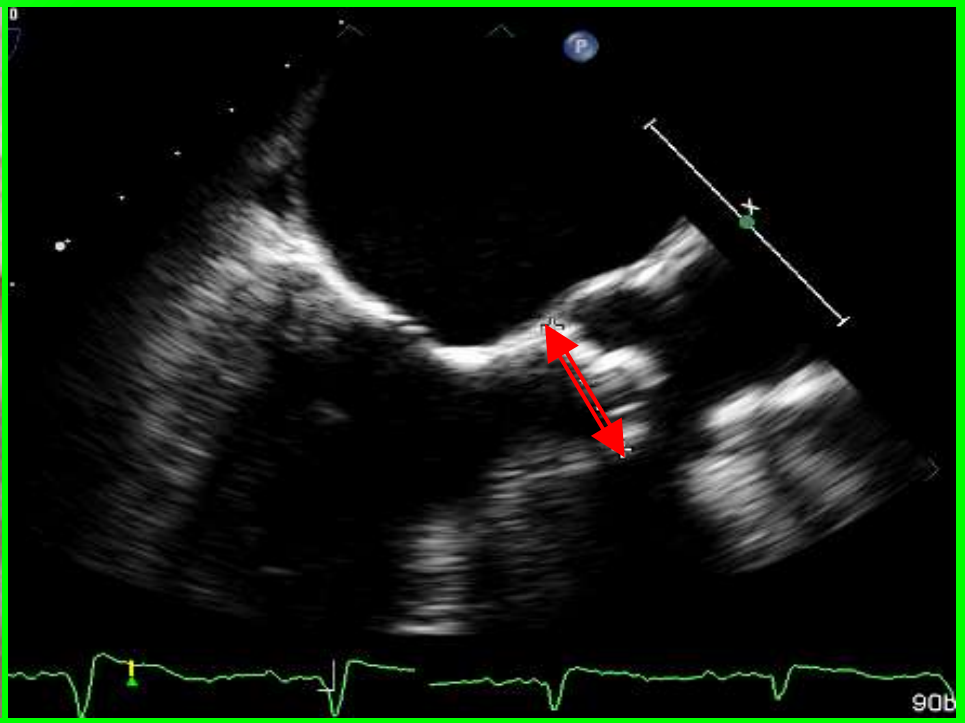
Frailty is being studied systematically as part of the PARTNER U.S. IDE study

Photos courtesy of Michael J. Mack, MD
Medical City Dallas

Measurement of the aortic annulus …







Piazza N et al, *Circ Cardiovasc Intervent.* 2008;1:74-81

Valve size selection

BALLOON-EXPANDABLE DEVICE

annulus 18-21 mm → 23 mm valve

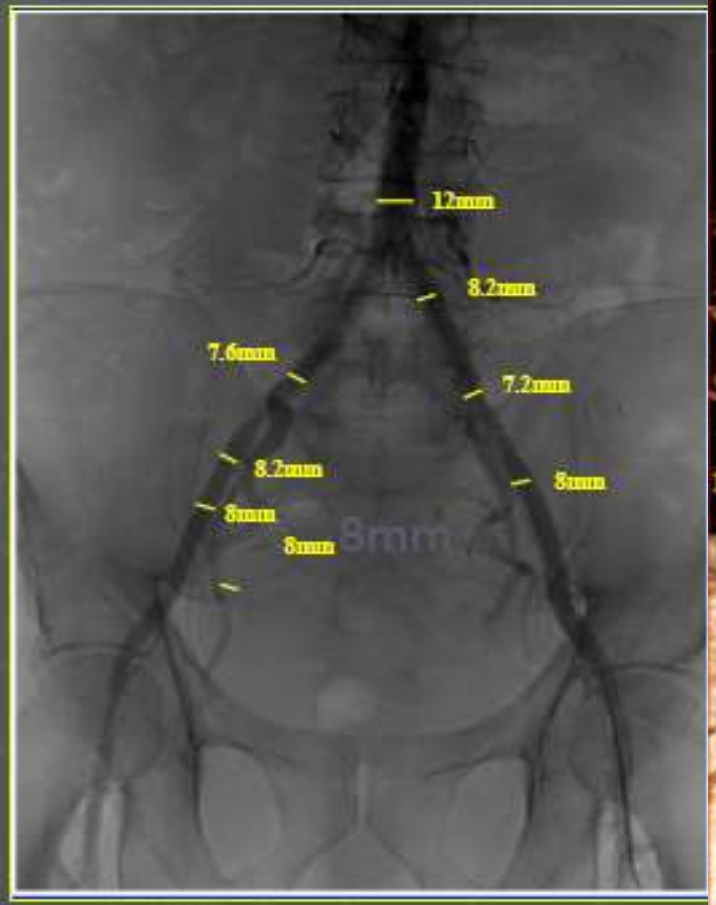
annulus 21-25 mm → 26 mm valve

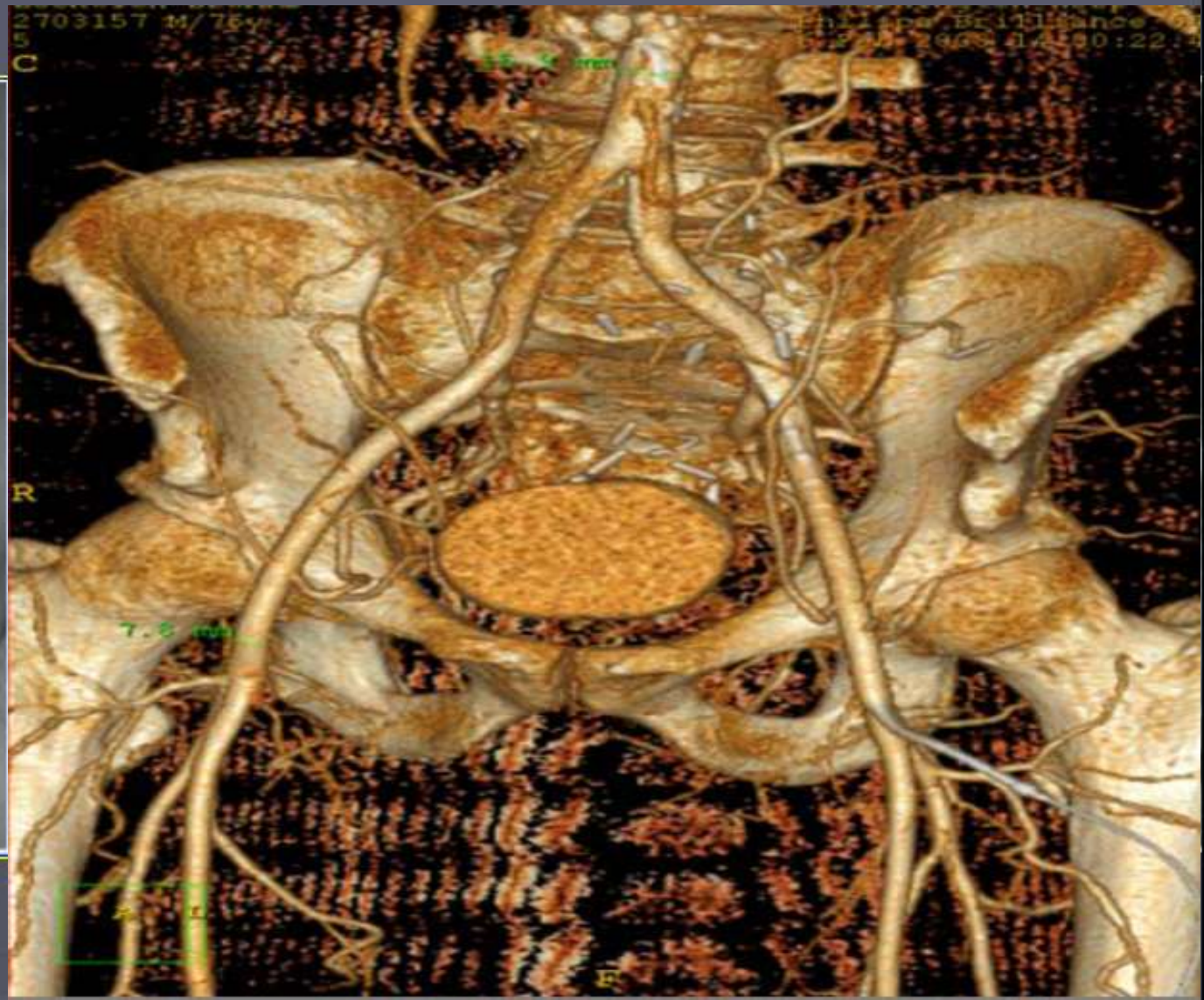
SELF-EXPANDABLE DEVICE

annulus 20-23 mm → 26 mm valve

annulus 24-27 mm → 29 mm valve

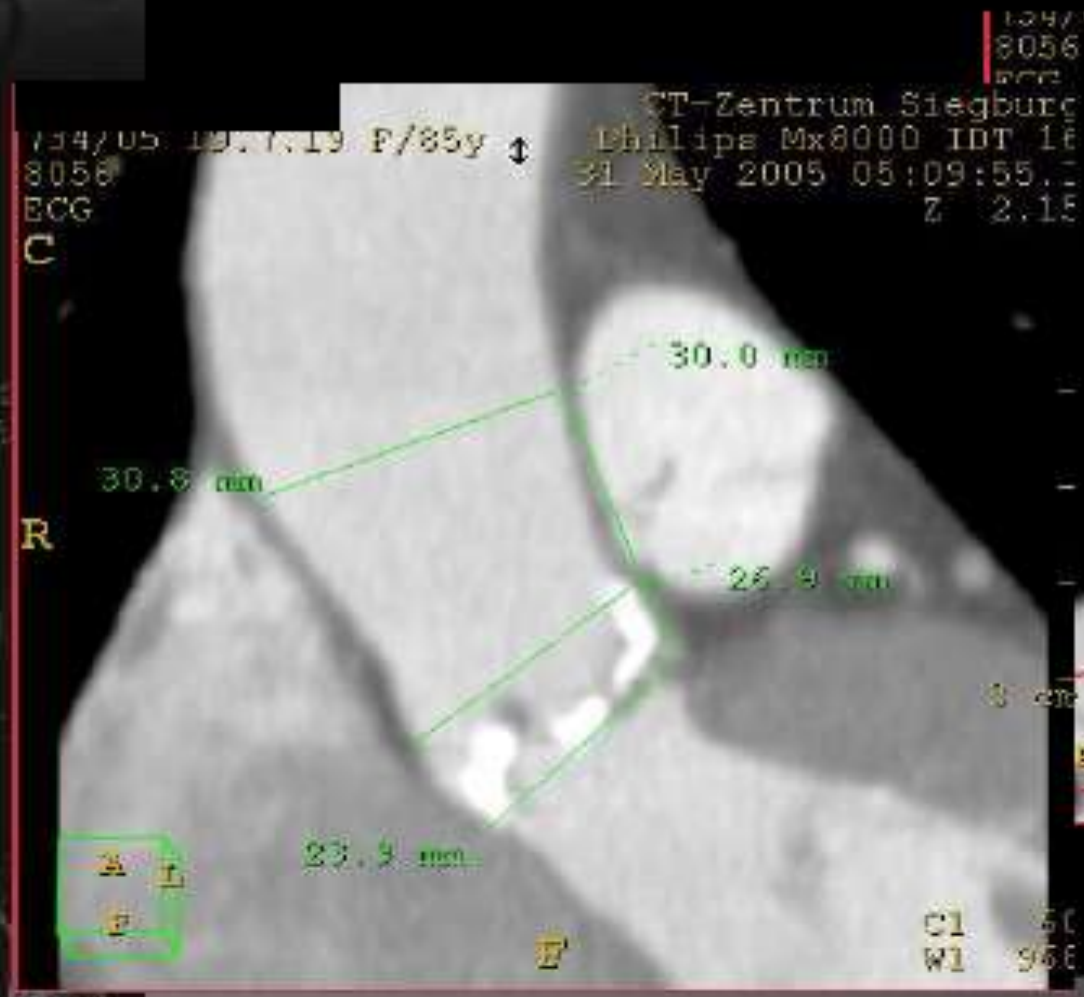
Angiographie et CT-Scan pour l'évaluation de l'axe ilio-fémoral





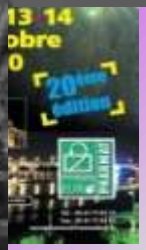
CoreValve CT Screening

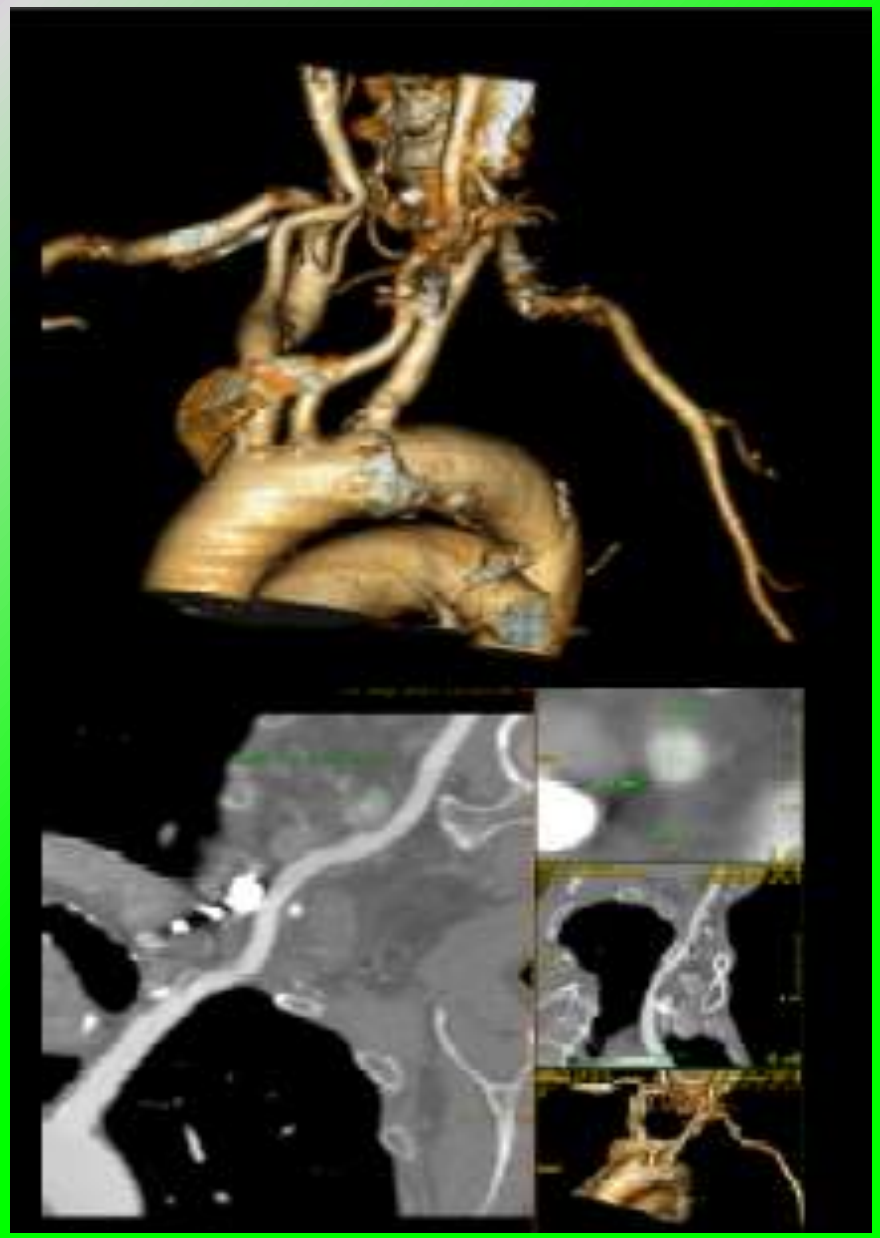
Morphological Quantification



Siegburg

Subclavian Access





Bioprothèses VAo percutanées : pour qui ?

Critères d'inclusion/exclusion

Taille d'anneau aortique : Edwards ou CoreValve ?

∅ fémoraux et iliaques ≥ 6-7 mm

Voie trans-fémorale

Alternative

Voie trans-apicale (Edw)

Voie sous-clavière (CV)

Mme B. M. 87 ans

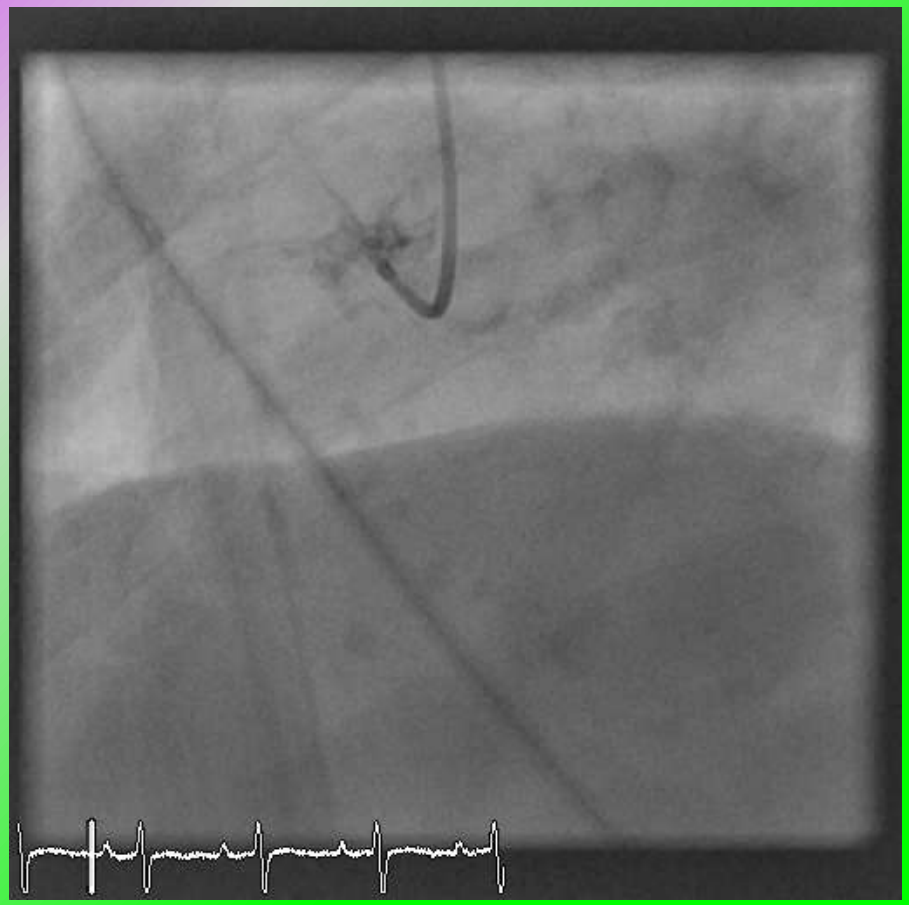
- RAO serré (0,5 cm2), symptomatique (OAP)

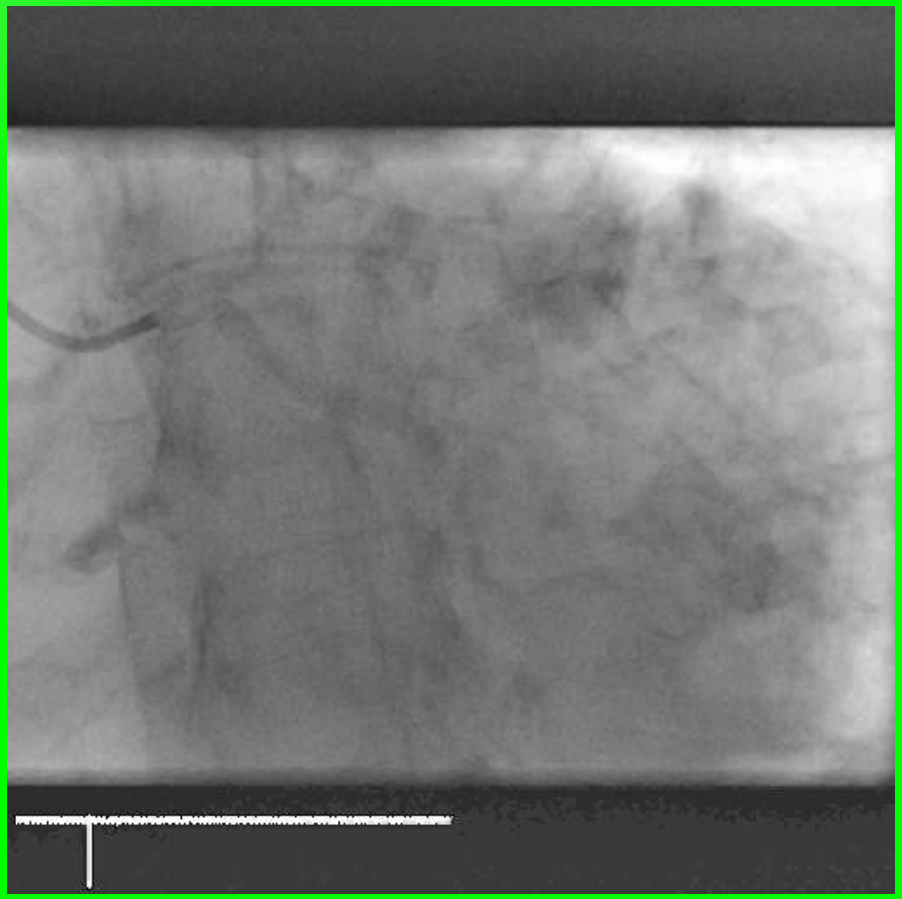
<u>Evaluation pré-opératoire :</u>

- 1m55, 70 kg,
- Ins. Rénale Chronique (ClCr 40 ml/min),
- FA permanente, AIT,
- BPCO,
- diabète type 2 InsulinoTraité
- FE VG 50 %,
- Bon état général et cognitif, vit seule à domicile

Mme B. M. 87 ans

- Coronarographie :





Mme B. M. 87 ans

- RAO serré (0,5 cm2), symptomatique (OAP)

<u>Evaluation pré-opératoire :</u>

- 1m55, 70 kg, Ins. Rénale Chronique (ClCr 40 ml/min), FA permanente, AIT, BPCO, diabète type 2 InsulinoTraité
- FE VG 50 %,
- Bon état général et cognitif, vit seule à domicile
- Lésions tritronculaires complexes

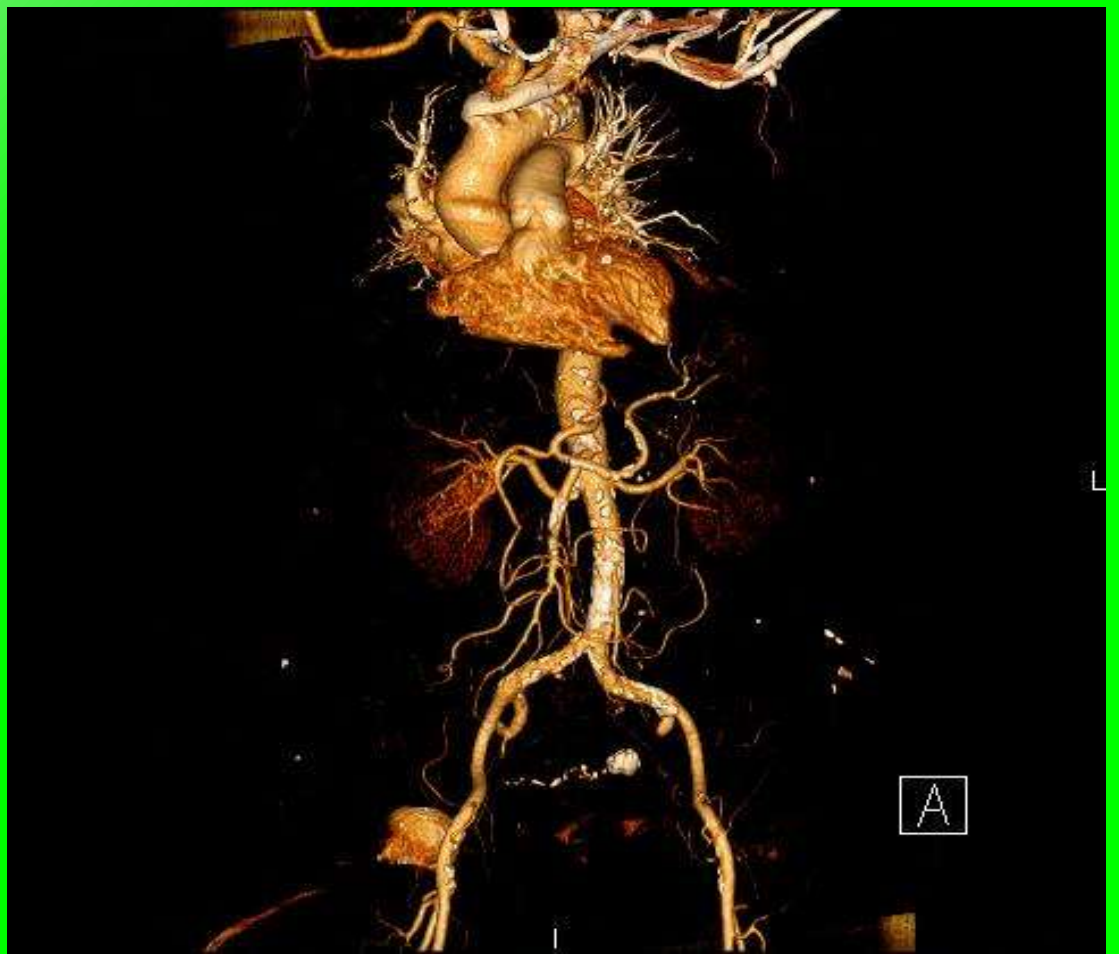
EuroScore Logistique : 18,37 %

Score STS : 12,4 %

Mme B. M. 87 ans

- Taille de l'anneau aortique :
  19 mm en ETT, 21 mm en ETO

- Angio TDM TAP :



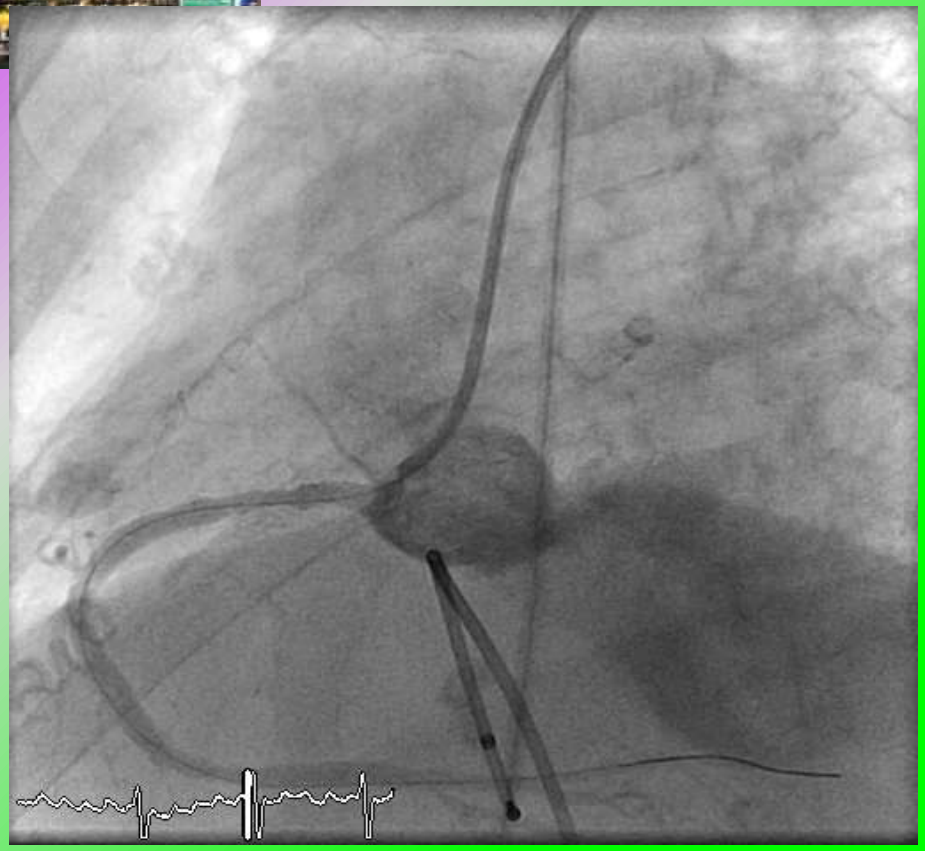
Mme B. M. 87 ans

Angioplastie des lésions coronaires

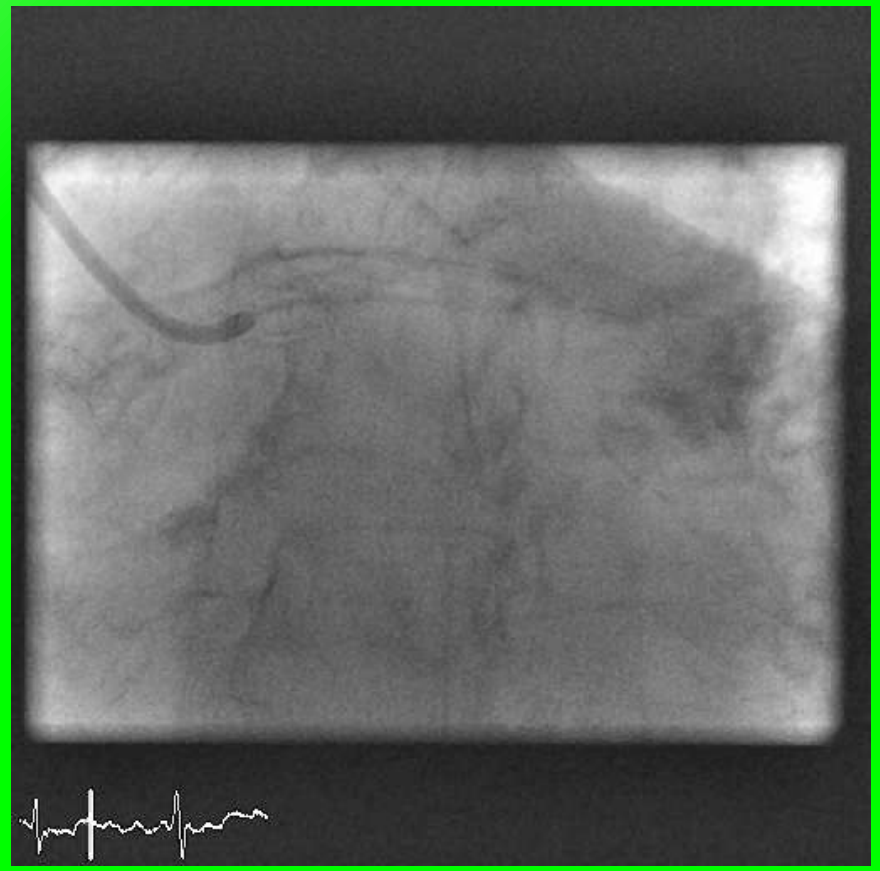
puis, un mois plus tard

Implantation par méthode de cathétérisme d’une bioprothèse Edwards Sapien n°23, abord transfémoral rétrograde

Mme B. M. 87 ans

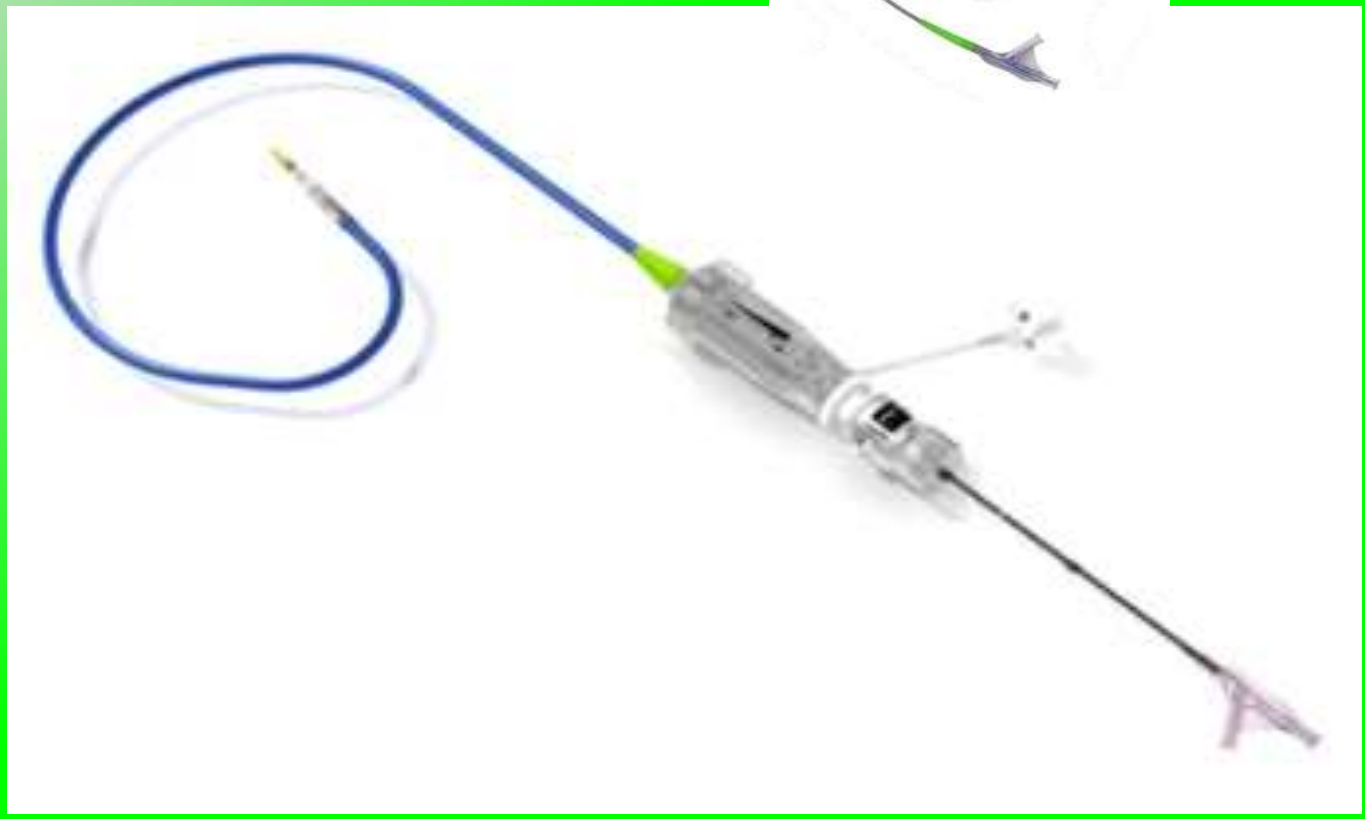


BMS CD ostiale

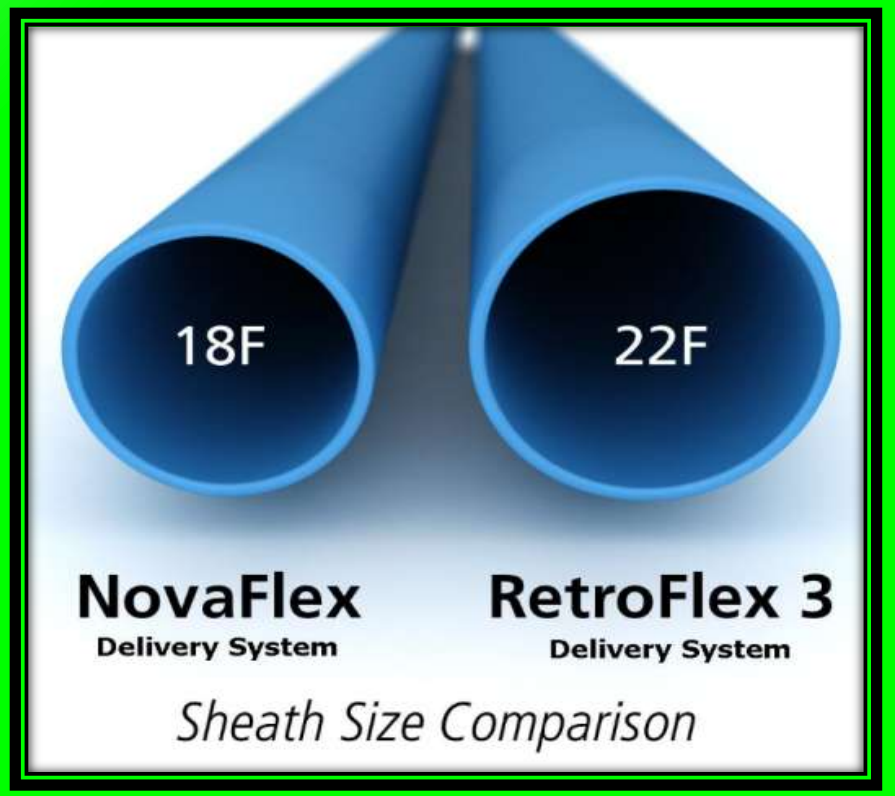


DES TCG

Système Novaflex / Valve Edwards XT



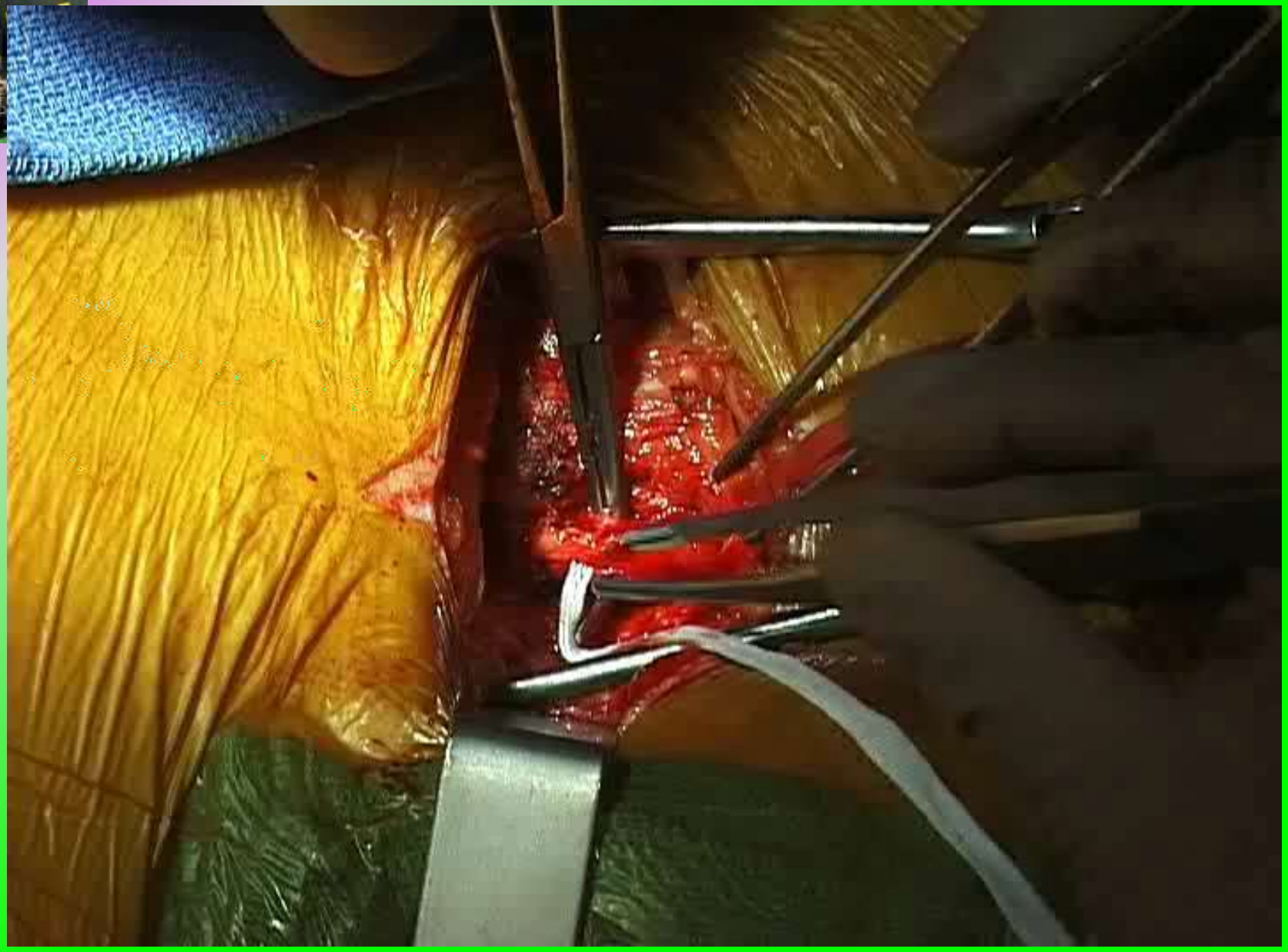
Système Novaflex / Valve Edwards XT



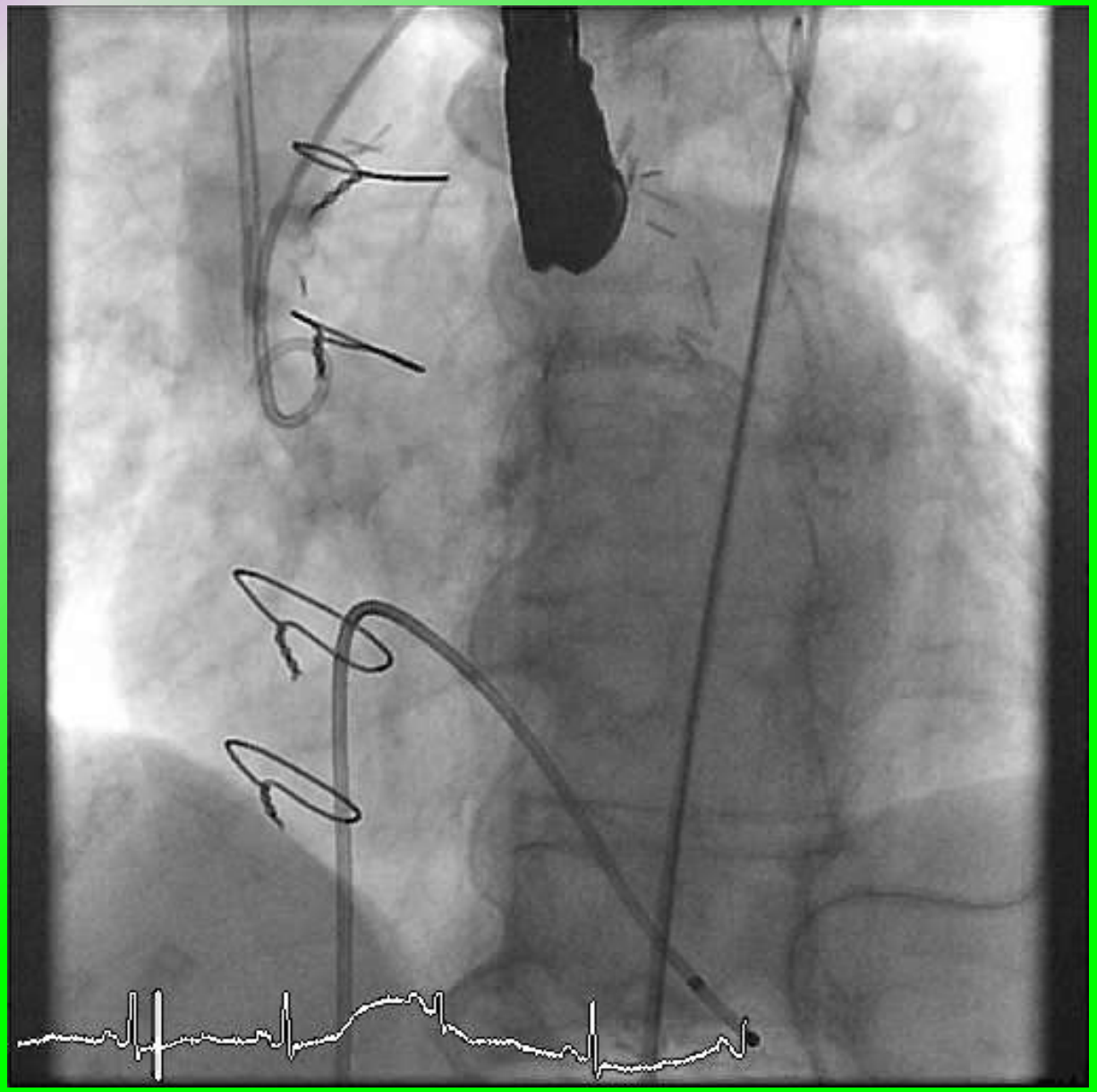
Edwards SAPIEN XT Valve Size	NovaFlex Sheath	Minimum Vessel Diameter
23 mm	18F	6.0 mm
26 mm	19F	6.5 mm

Intervention en salle de cathétérisme

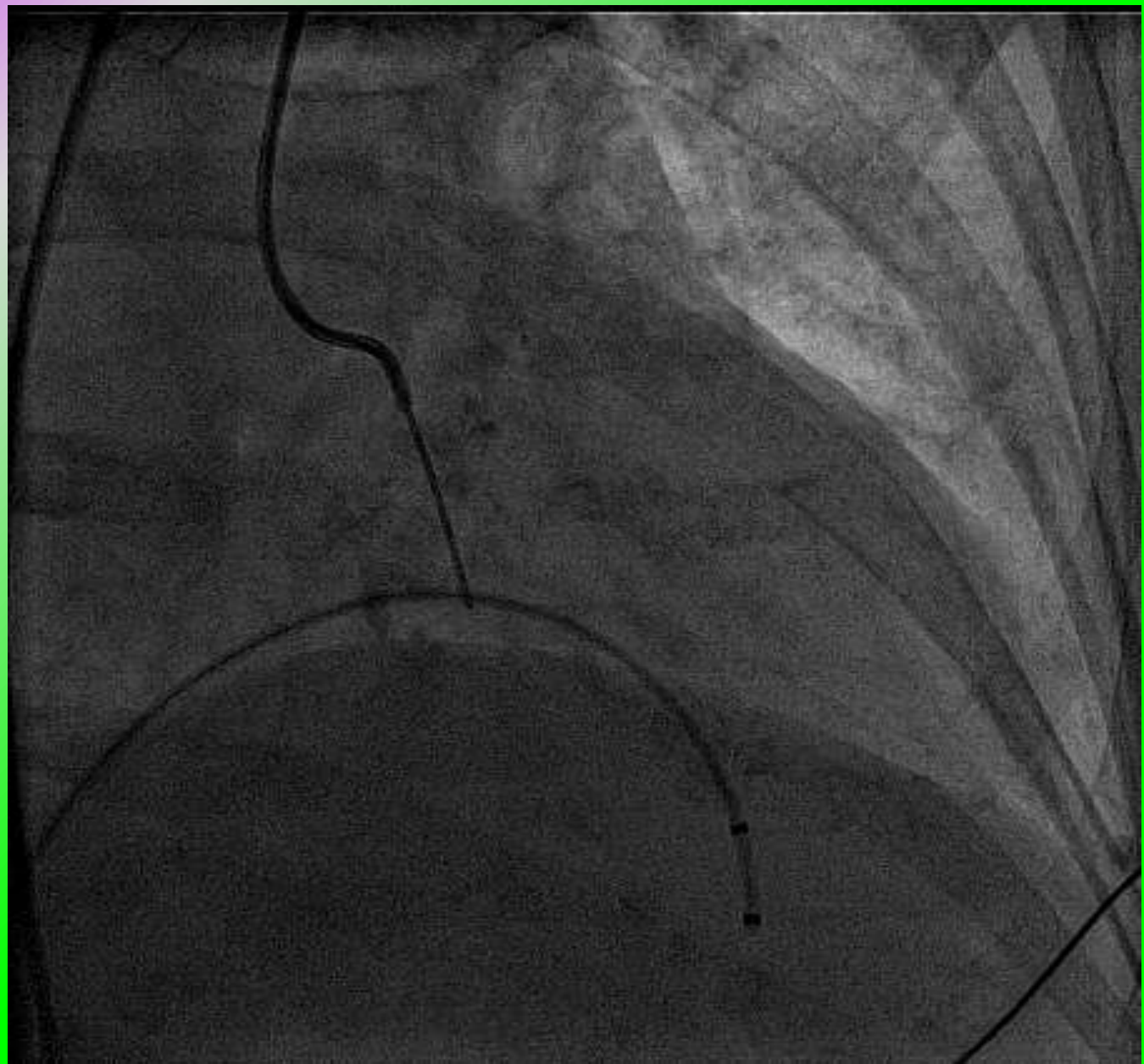
Exposition artère fémorale



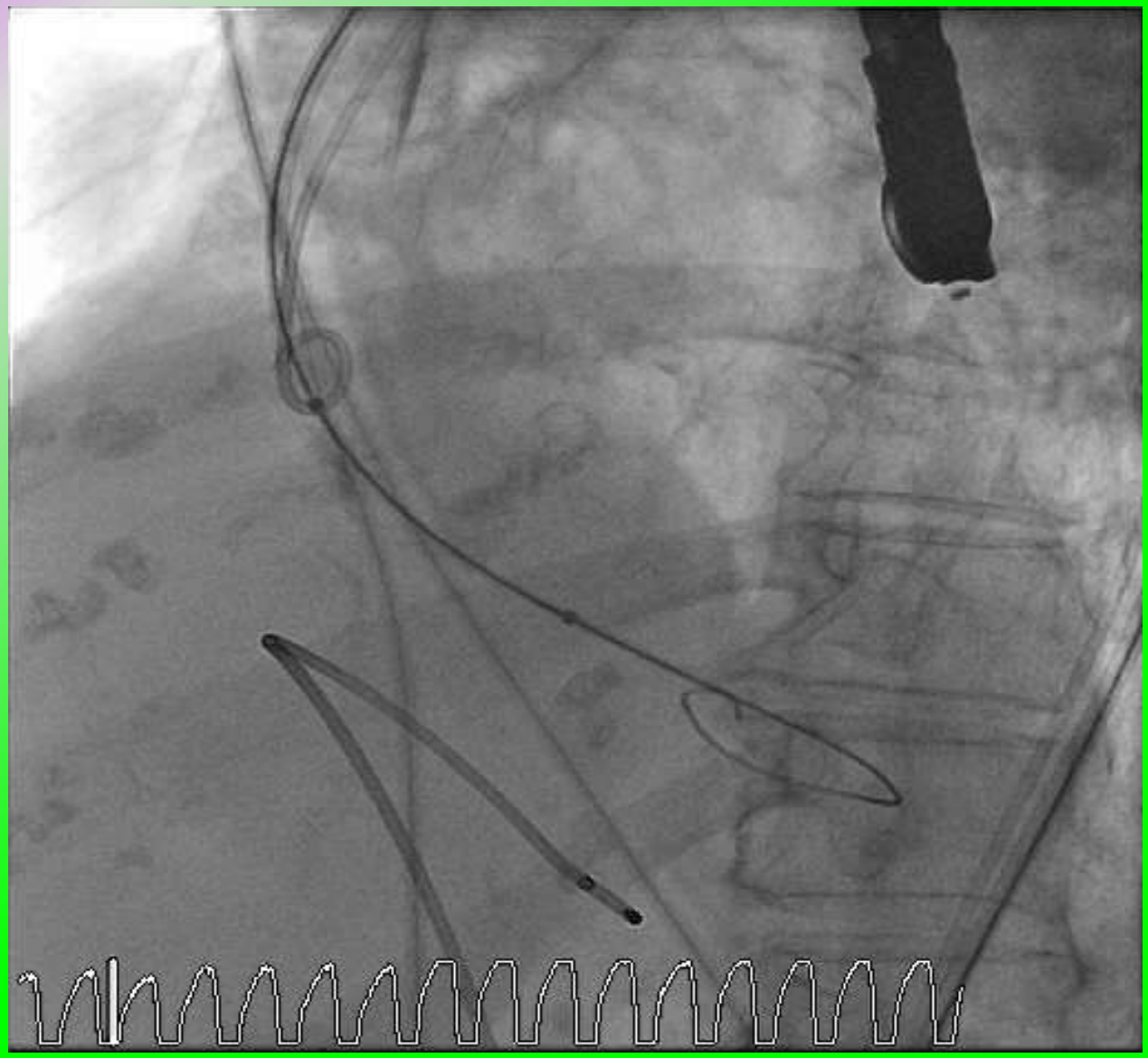
Aortographie de repérage



Franchissement valve aortique

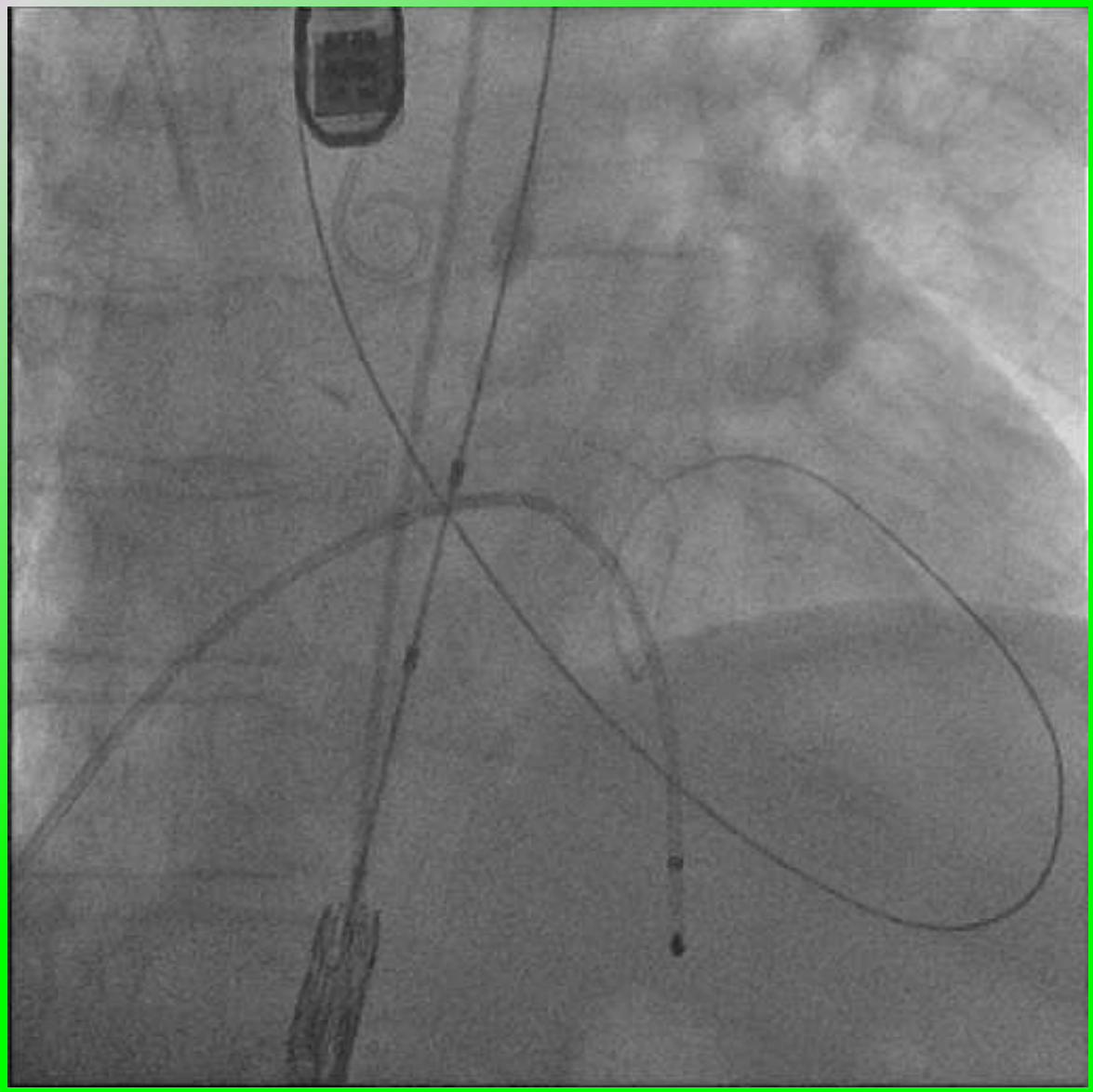


Valvuloplastie aortique au ballon

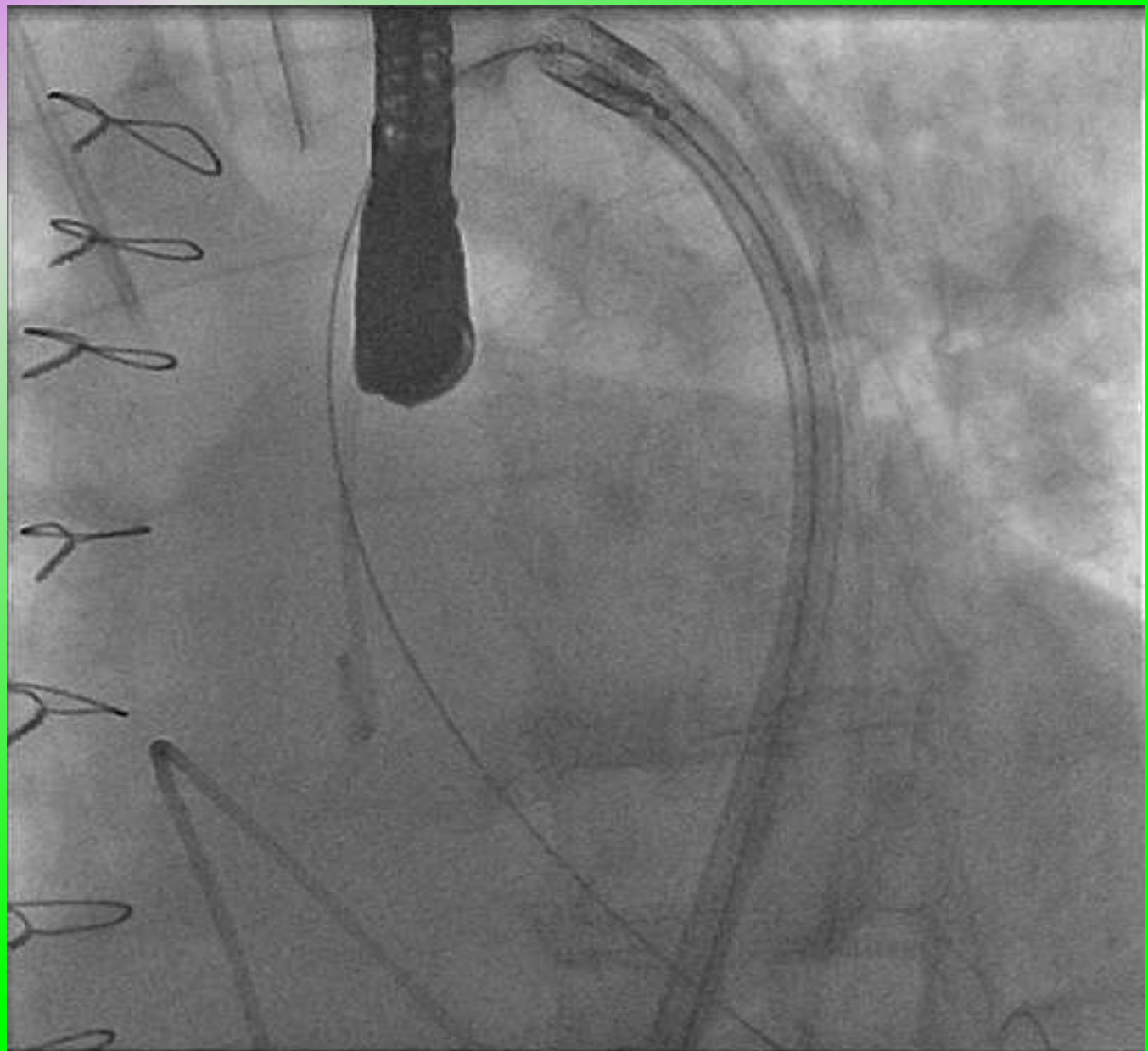


Mise en place de l'introducteur 18 ou 19 Fr

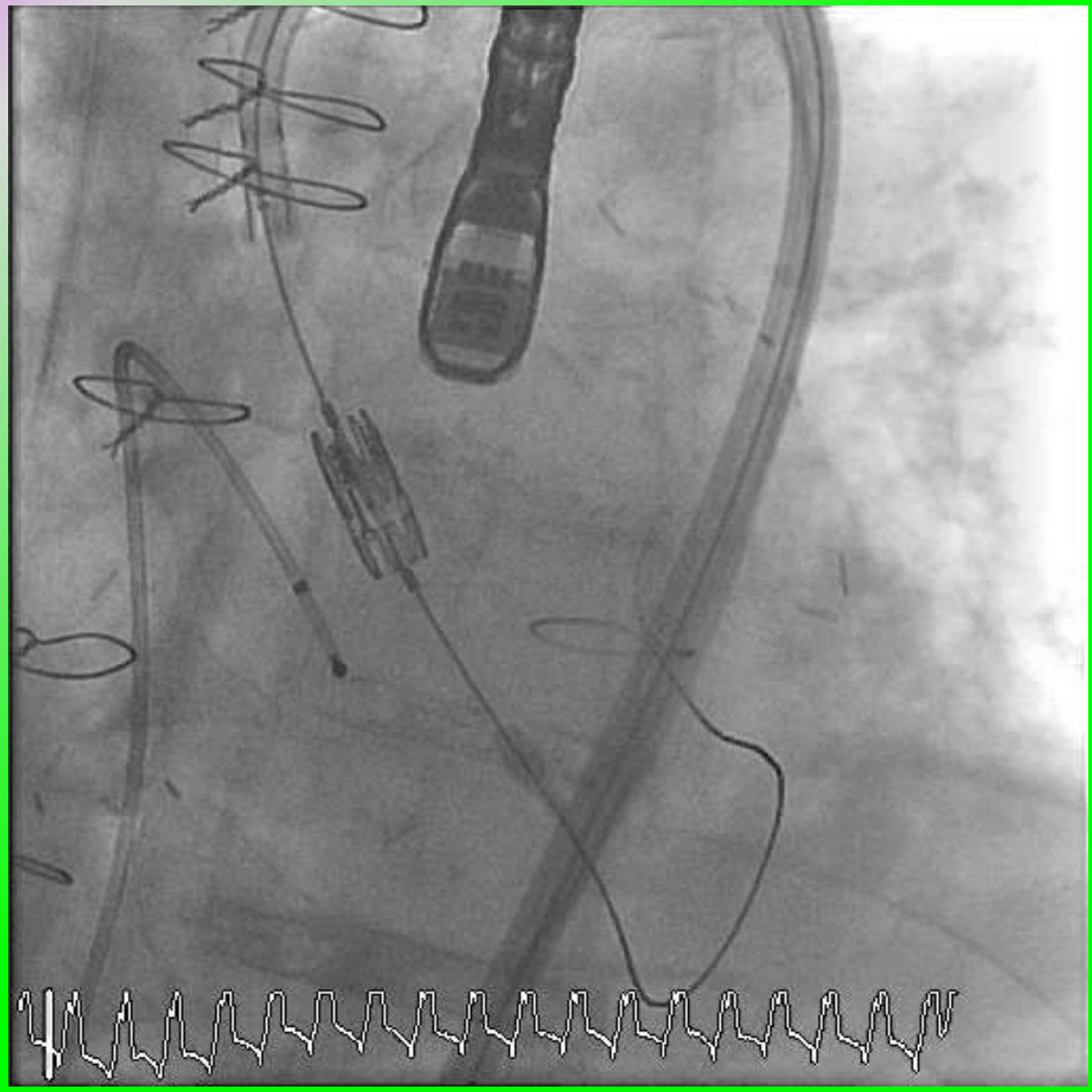
Sertissage de la prothèse Ao descendante



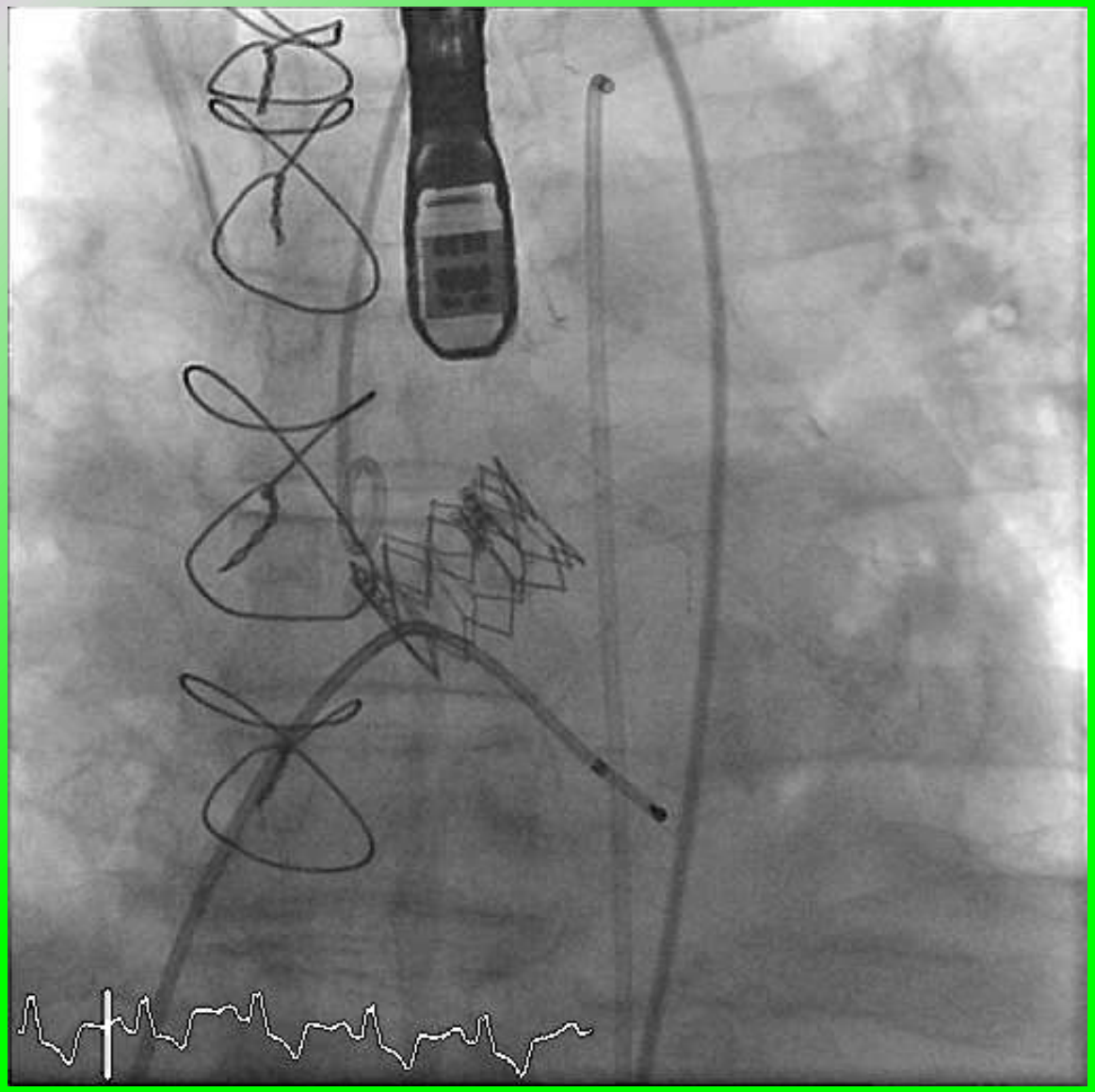
Montée de la prothèse



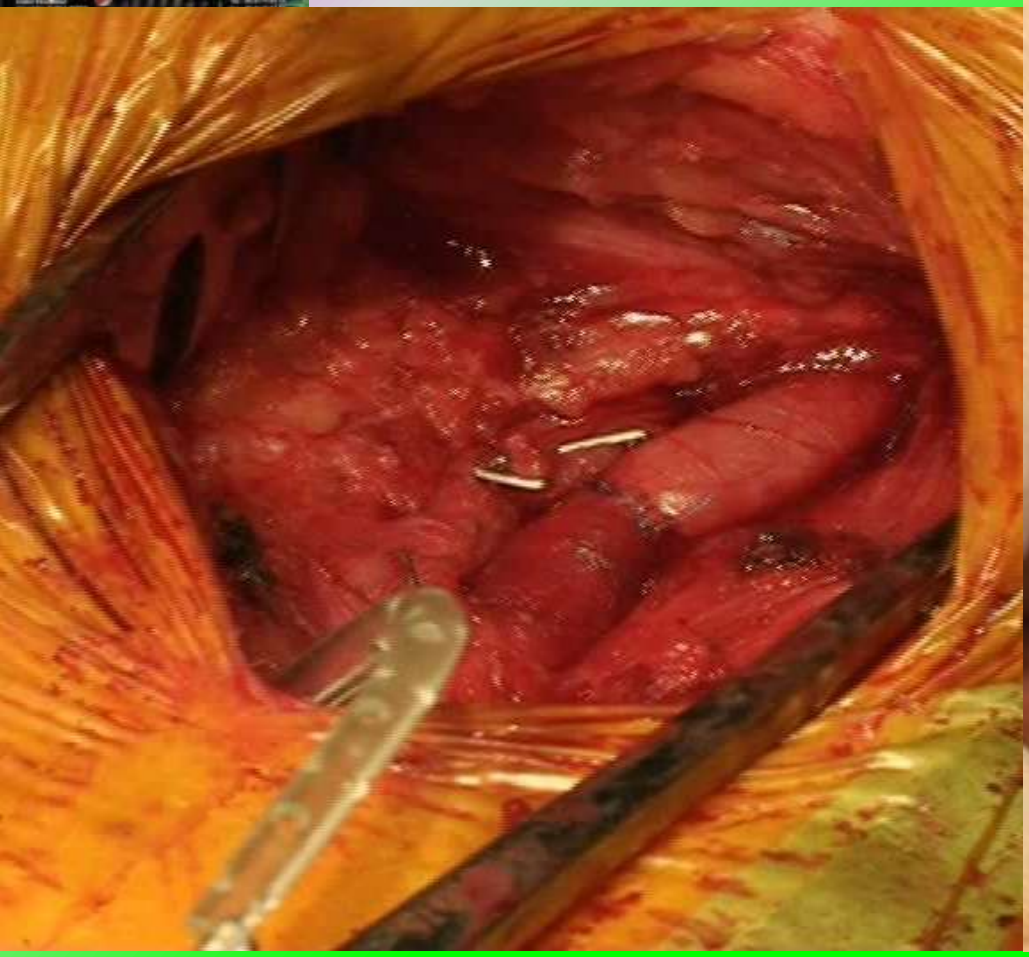
Déploiement

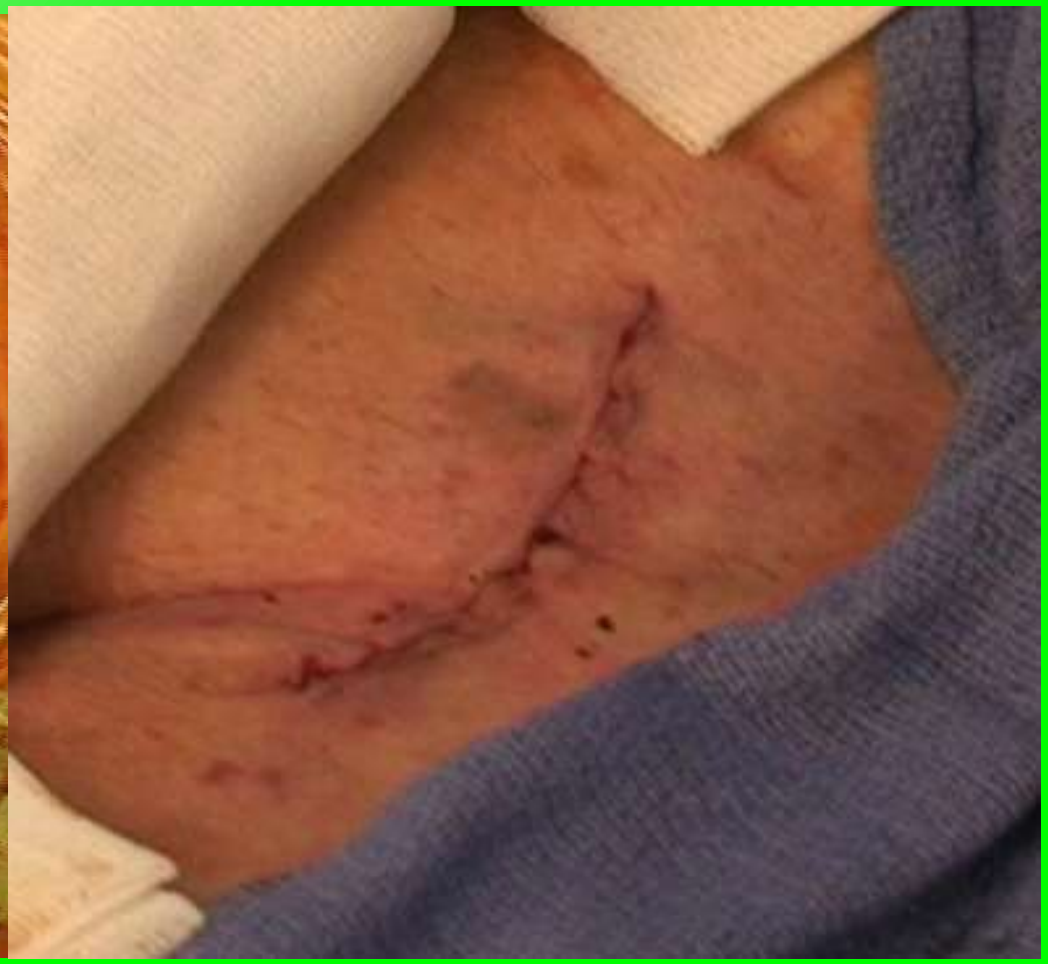


Contrôle angiographique final



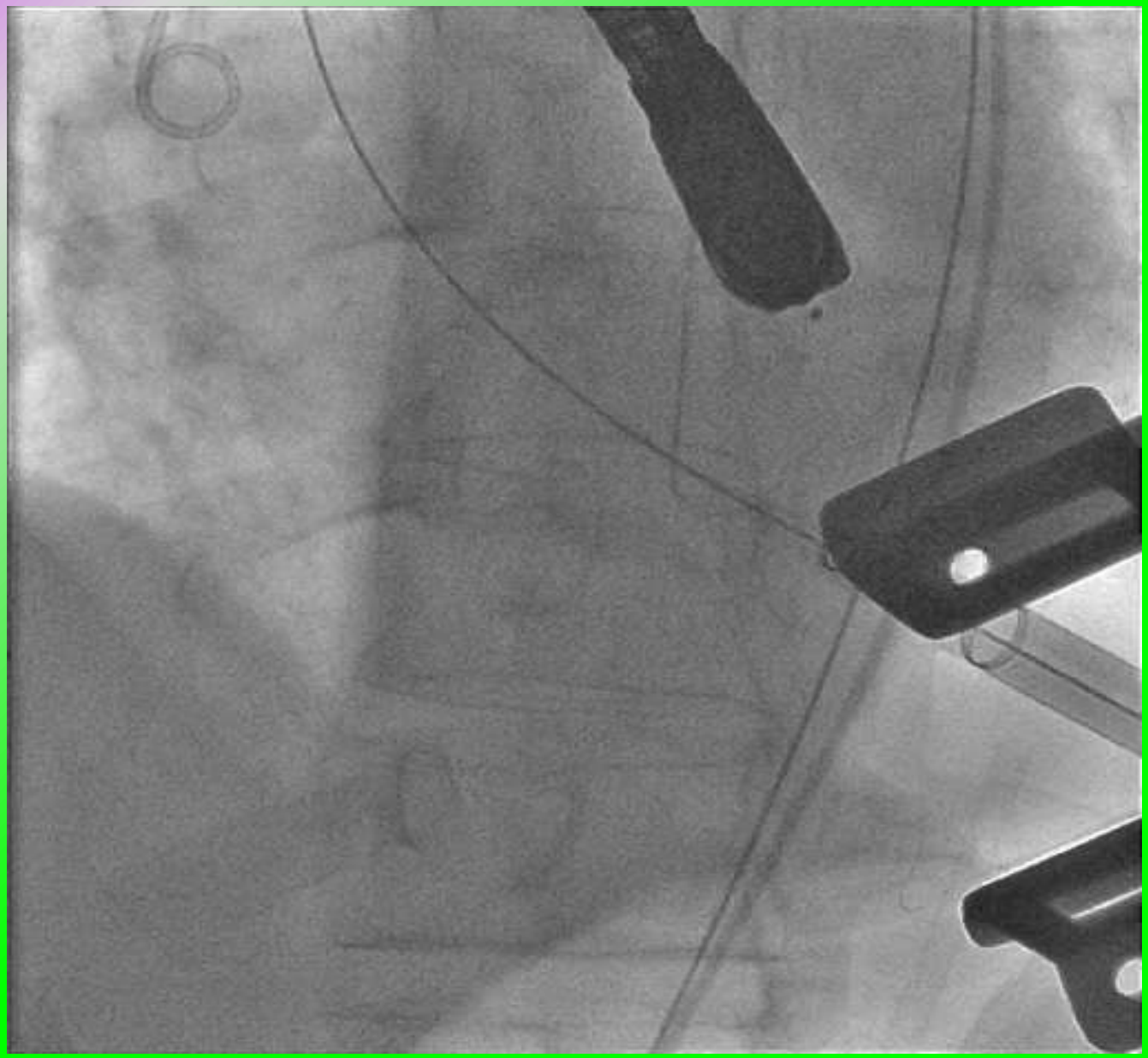
Fermeture de l’accès chirurgical



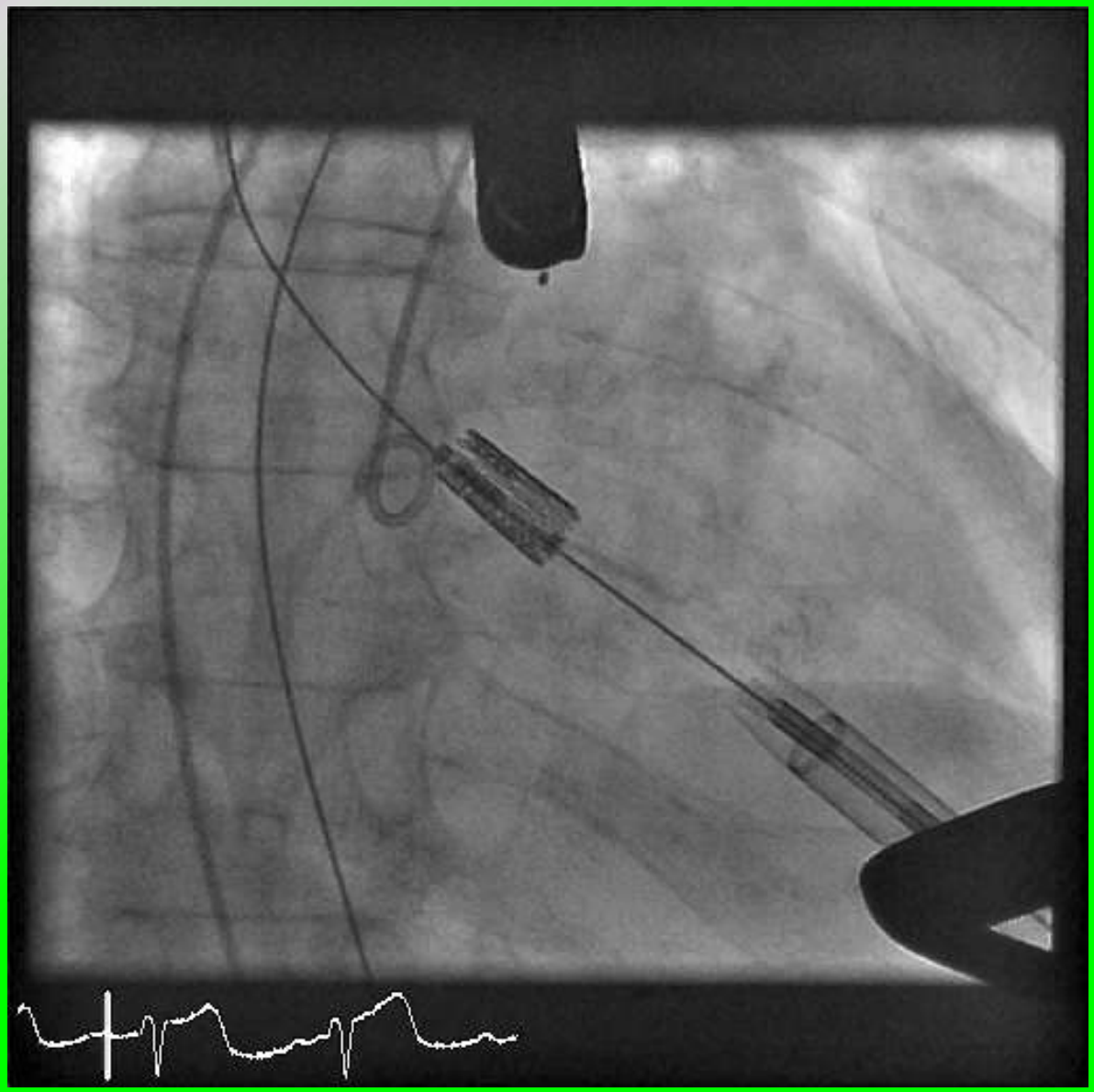


Alternative : voie transapicale VG cœur battant

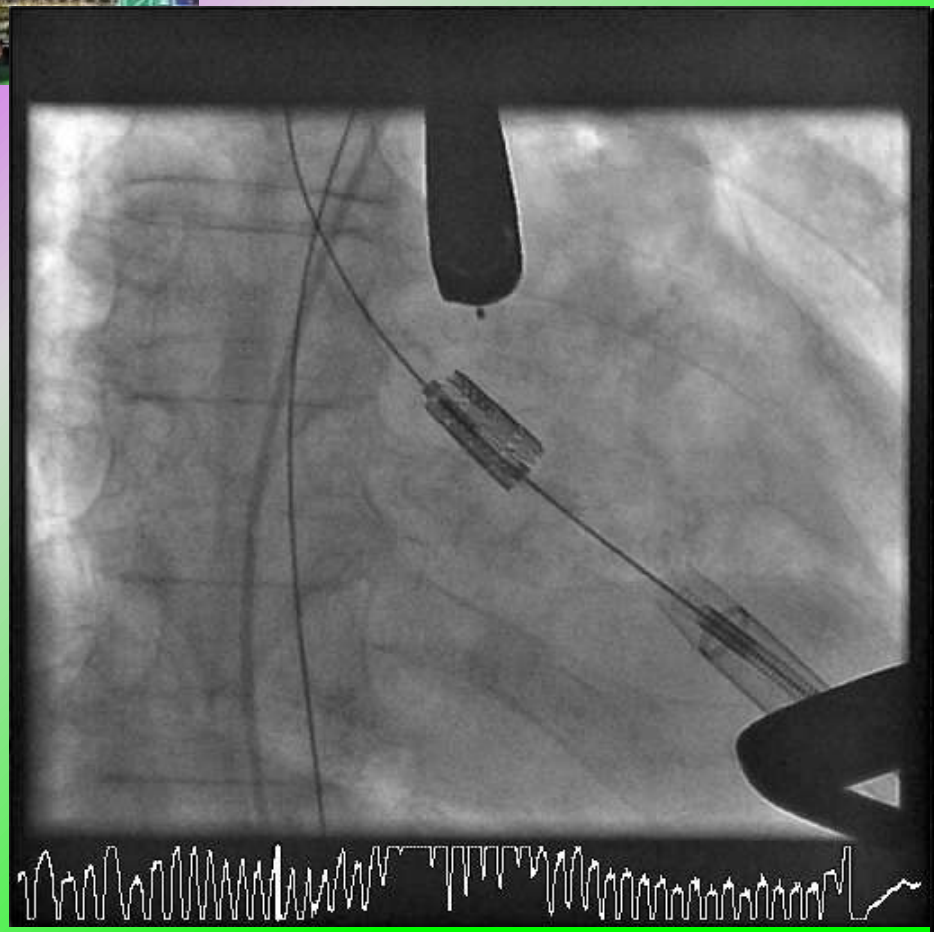
Alternative : voie transapicale

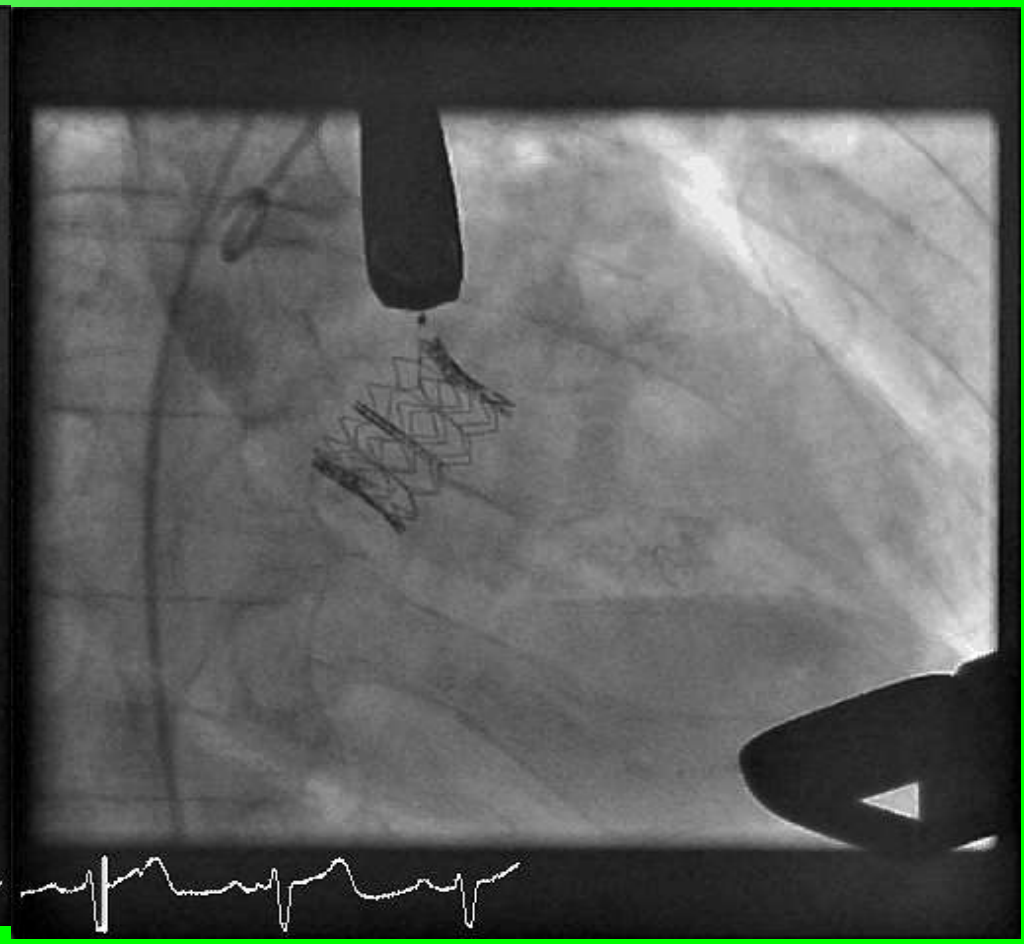


Alternative : voie transapicale



Alternative : voie transapicale





Medtronic CoreValve

- RAO serré (0,4 cm2/m2), symptomatique (IC globale)

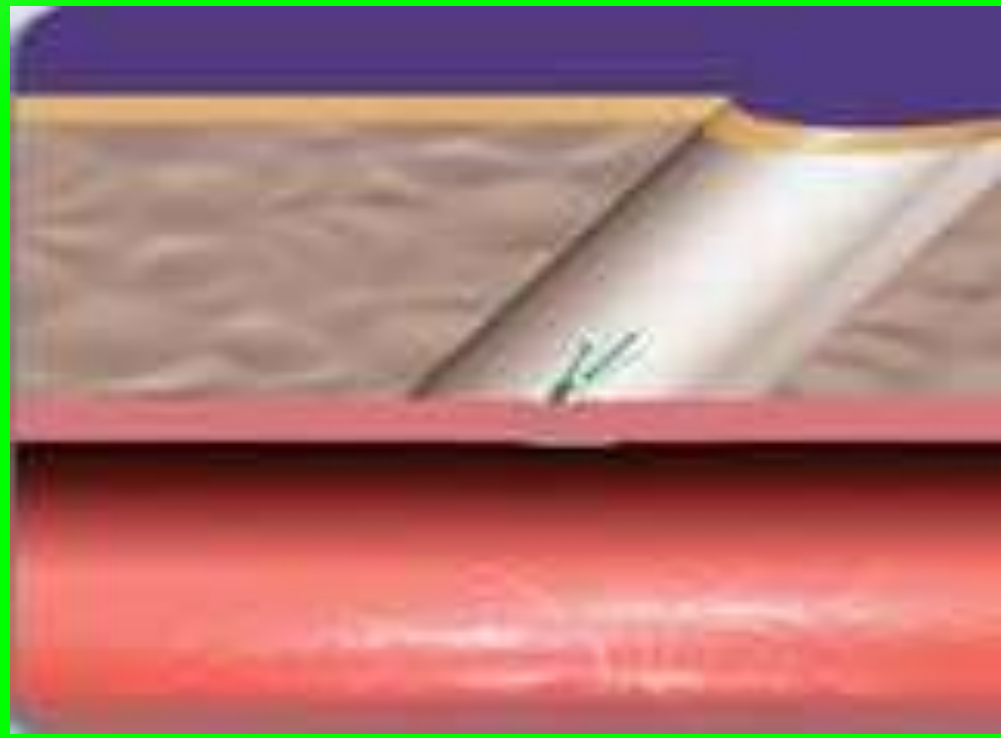
<u>Evaluation pré-opératoire :</u>

- 1m65, 83 kg, Ins. Rénale Chronique minime(ClCr 50 ml/min), diabète type 2 InsulinoTraité, HTA réno-vasculaire, Trouble ventilatoire obstructif (VEMS 1.2 l), Endartériectomie CI droite, sténoses artères rénales stentées
- FE VG 28 %,
- Pas de lésion coronaire significative
- Bon état général et cognitif, autonome à domicile, III NYHA

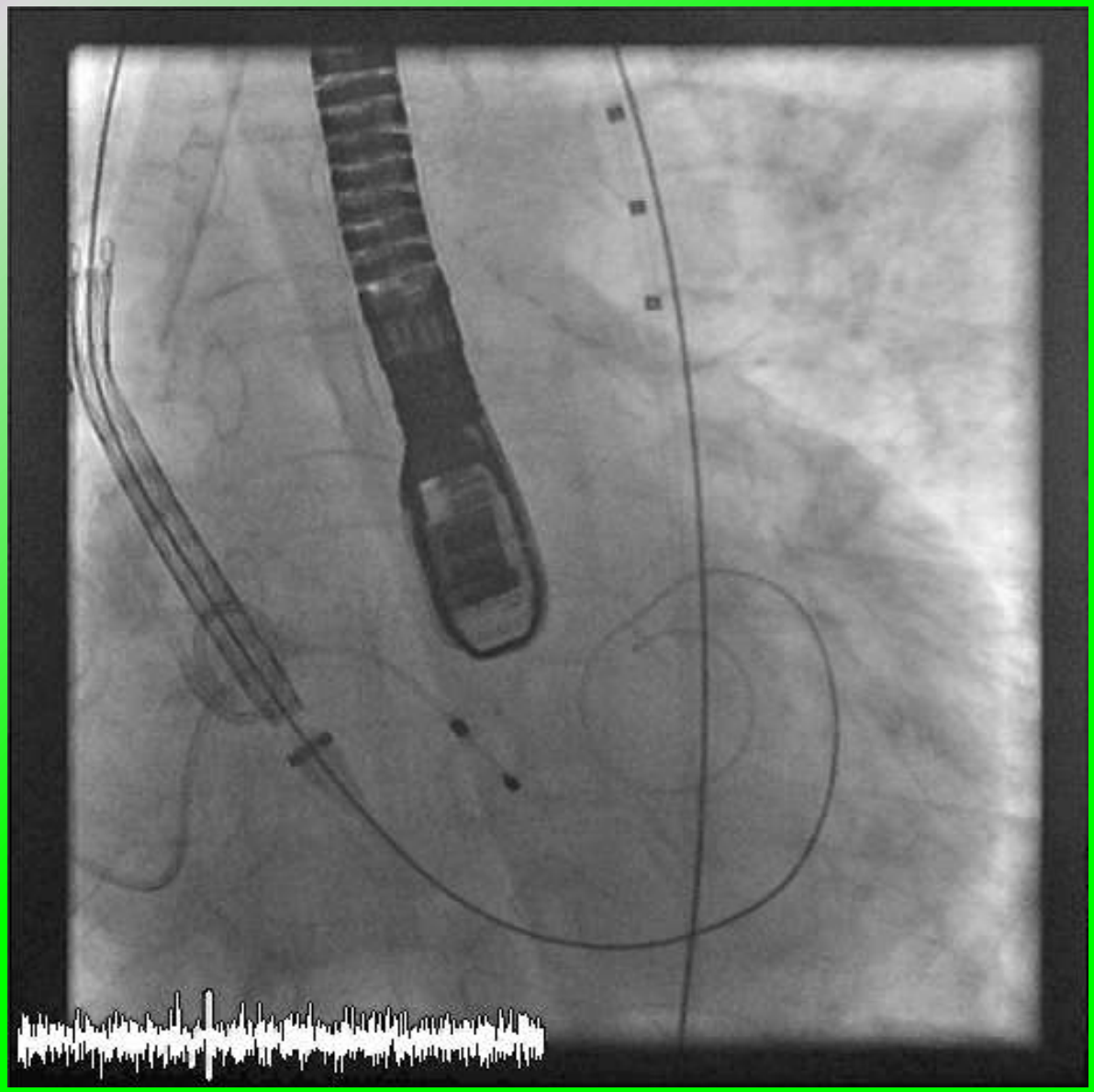
EuroScore Logistique : 36.18 %
Score STS : 8.6 %

Medtronic CoreValve

- Introducteur 18 Fr : mise en place ProStar



Medtronic CoreValve



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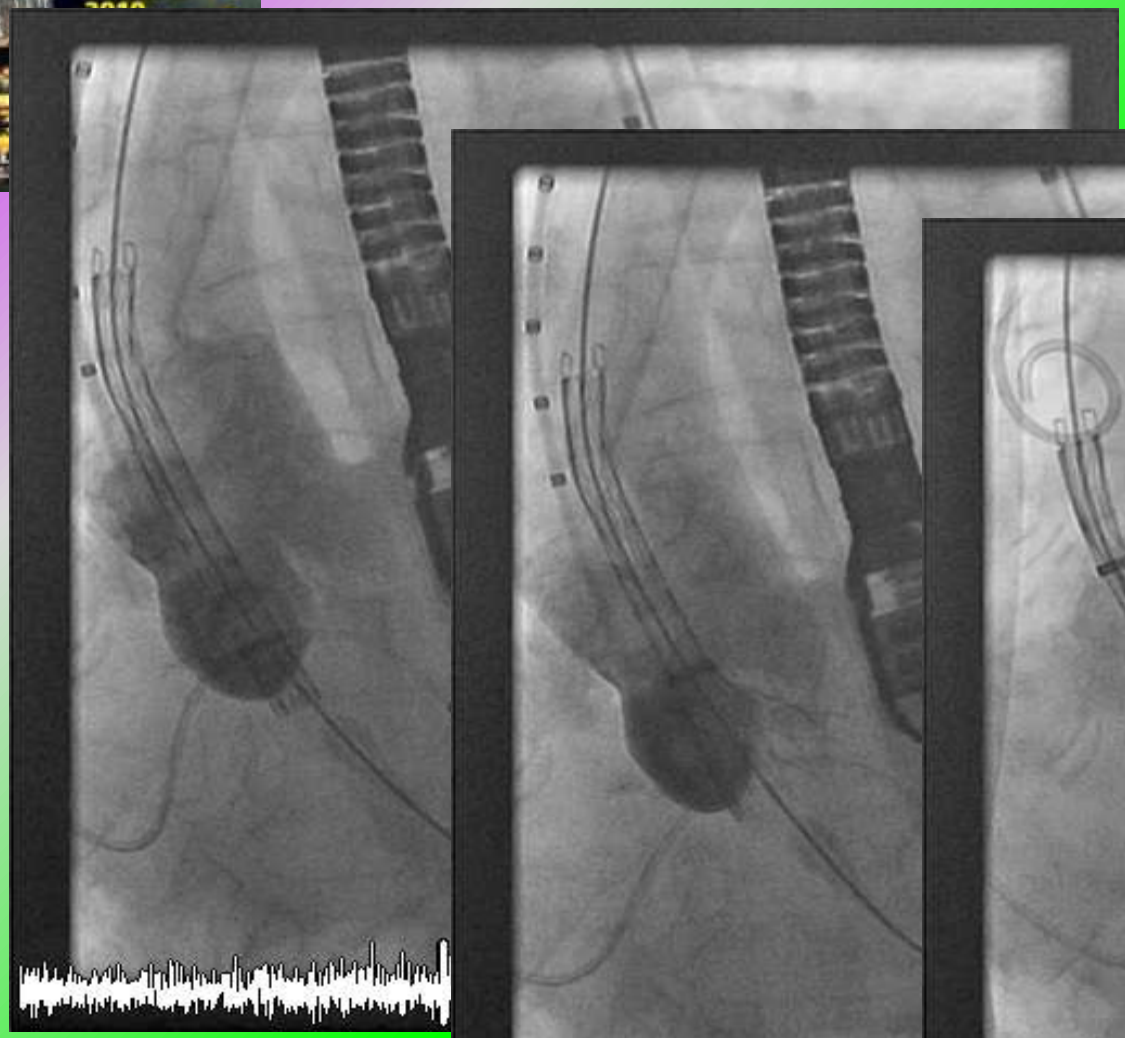

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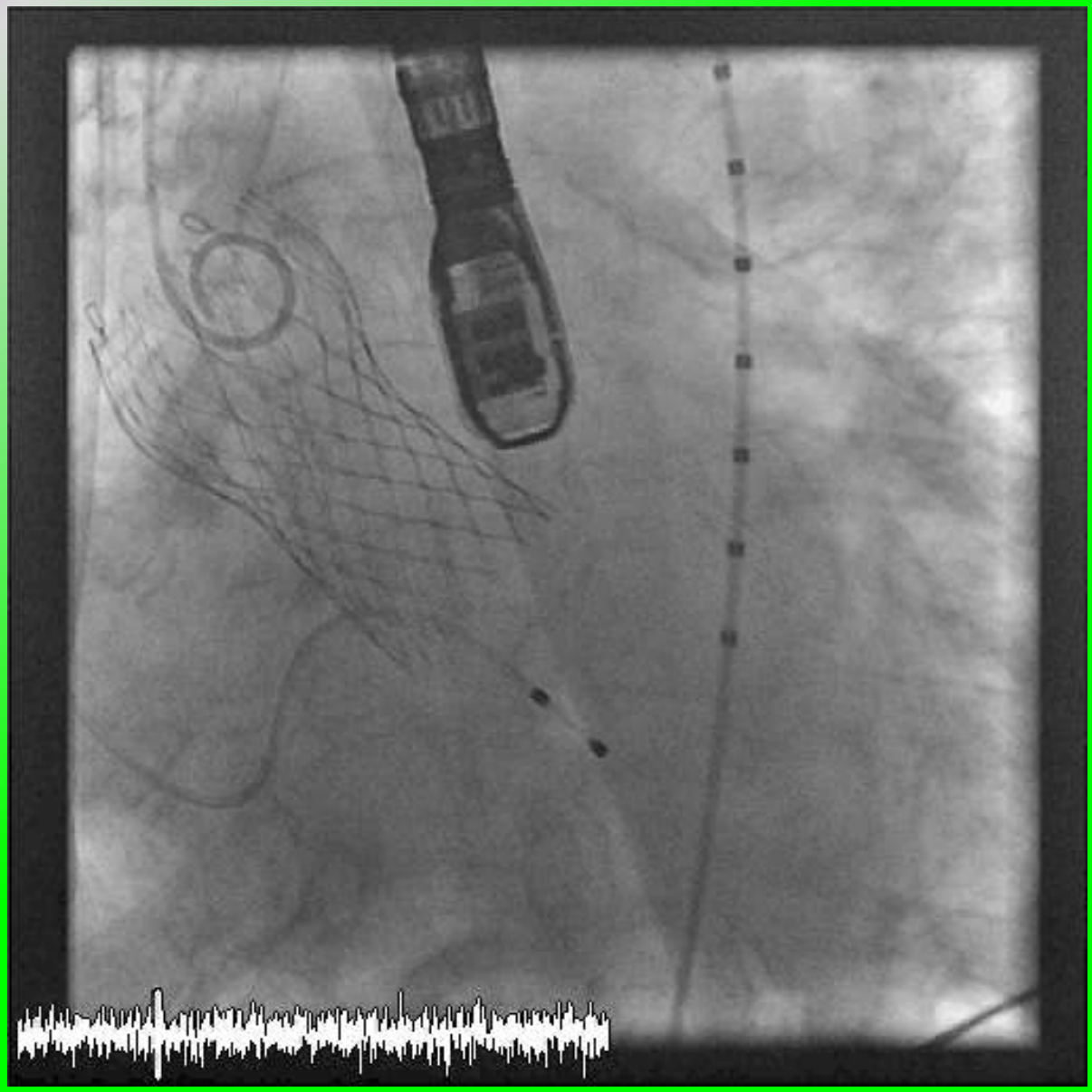
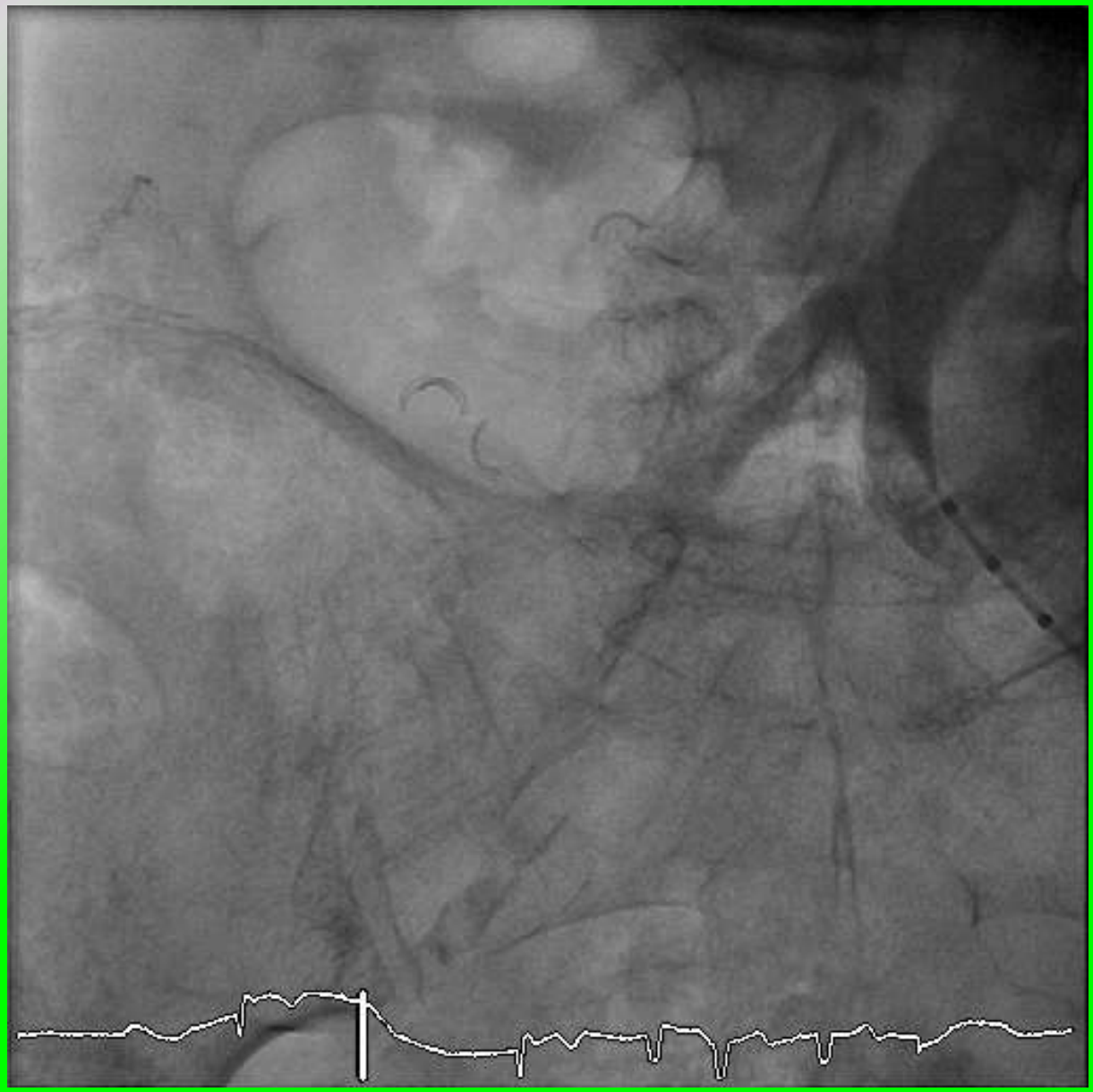
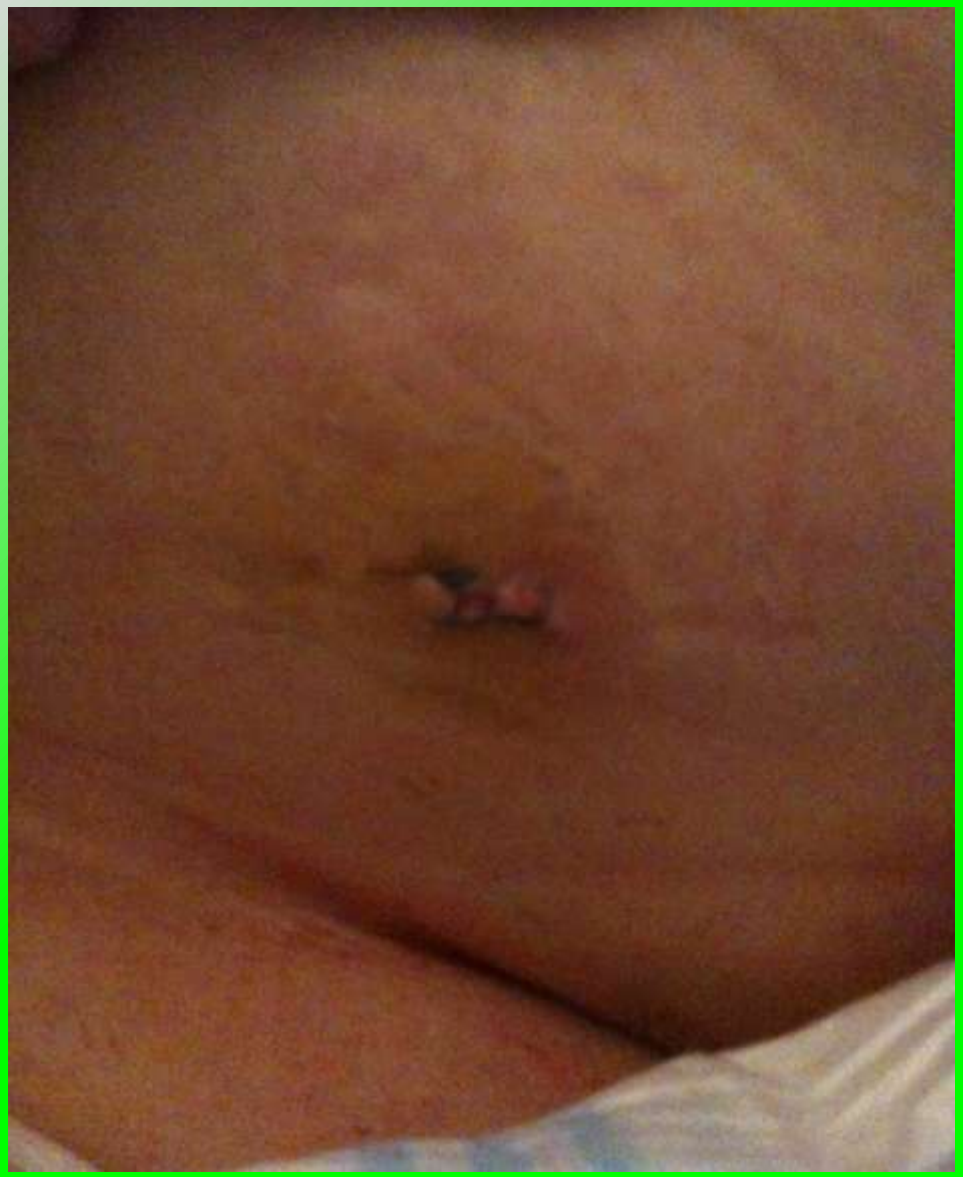


Medtronic CoreValve



Medtronic CoreValve



Bioprothèses VAo percutanées : résultats

FRANCE Registry:

FRench Aortic National Corevalve and Edwards Registry

Trans-catheter Aortic Valve Implantation in France Early results

Hélène Eltchaninoff, MD,
University of Rouen, France

On behalf of the FRANCE Registry Investigators

Bioprothèses VAo percutanées : résultats

Major Complications (30 days)

	Total	Edwards TF (n:95)	CoreValve TF (n:66)	Edwards TA(n:71)	CoreValve SC (n:12)	p
30-day mortality	31 (12.7%)	8 (8.4%)	10 (15.1%)	12 (16.9%)	1 (8.3%)	0.32
Tamponade	5 (2.0%)	2 (2.1%)	2 (3.0%)	-	1 (8.3%)	0.16
Stroke	9 (3.6%)	4 (4.2%)	3 (4.5%)	2 (2.8%)	-	0.94
Coronary occlusion	3 (1.2%)	2* (2.1%)	1 (1.5%)	-	-	0.77
New Pacemaker	29 (11.8%)	5 (5.3%)	18 (27.2%)	3 (4.2%)	3 (25%)	< 0.001
Vascular complications	16 (6.5%)	5 (5.2%)	5 (7.5%)	5 (7.0%)	1 (8.3%)	0.83
Infection	7 (2.8%)	1 (1.0%)	1 (1.5%)	5 (7.0%)	-	0.15
Transfusion ≥ 1 blood unit	52 (21.3%)	8 (8.4%)	9(13.6%)	25 (27.4%)	10 (83.3%)	< 0.001

* *One retroperitoneal case*

Bioprothèses VAo percutanées : résultats

Placement of Aortic Transcatheter Valves

PARTNER

High Risk Patients

Operable?

Yes

Surgical Arm

Randomized

Edwards-SAPIEN

Surgery

No

Medical Management

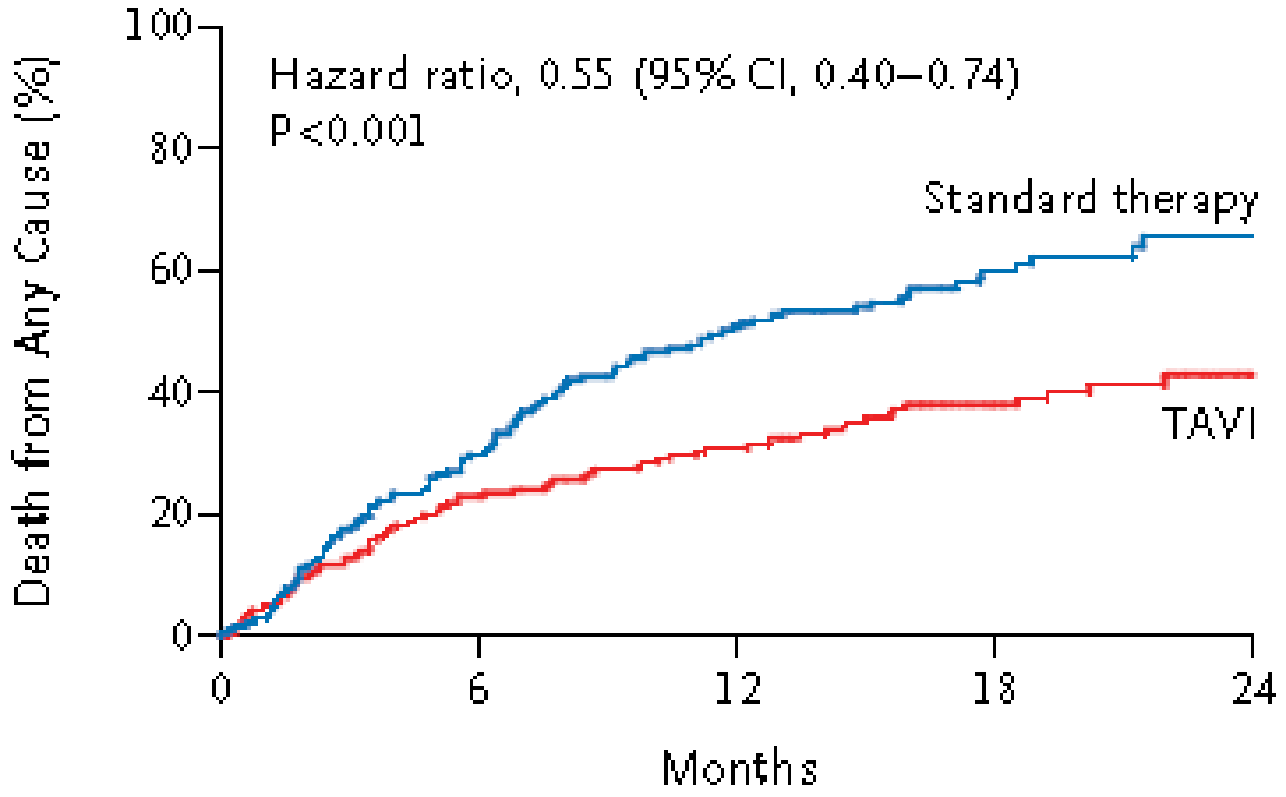
Randomized

Edwards-SAPIEN

Medical

Bioprothèses VAo percutanées : résultats

A



No. at Risk					
TAVI	179	138	122	67	26
Standard therapy	179	121	83	41	12

Leon M et al, ***New Eng J Med.*** Sept 2010

Bioprothèses VAo percutanées : résultats

Table 2. Clinical Outcomes at 30 Days and 1 Year.*

Outcome	30 Days			1 Year		
	TAVI (N=179)	Standard Therapy (N=179)	P Value†	TAVI (N=179)	Standard Therapy (N=179)	P Value†
	no. of patients (%)			*no. of patients (%)*		
Vascular complications						
All	55 (30.7)	9 (5.0)	<0.001	58 (32.4)	13 (7.3)	<0.001
Major	29 (16.2)	2 (1.1)	<0.001	30 (16.8)	4 (2.2)	<0.001
Major bleeding	30 (16.8)	7 (3.9)	<0.001	40 (22.3)	20 (11.2)	0.007

Leon M et al, ***New Eng J Med***. Sept 2010

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IMAGES IN INTERVENTION

Transfemoral Aortic Valve Implantation With Pre-Existent Mechanical Mitral Prosthesis

Evidence of Feasibility

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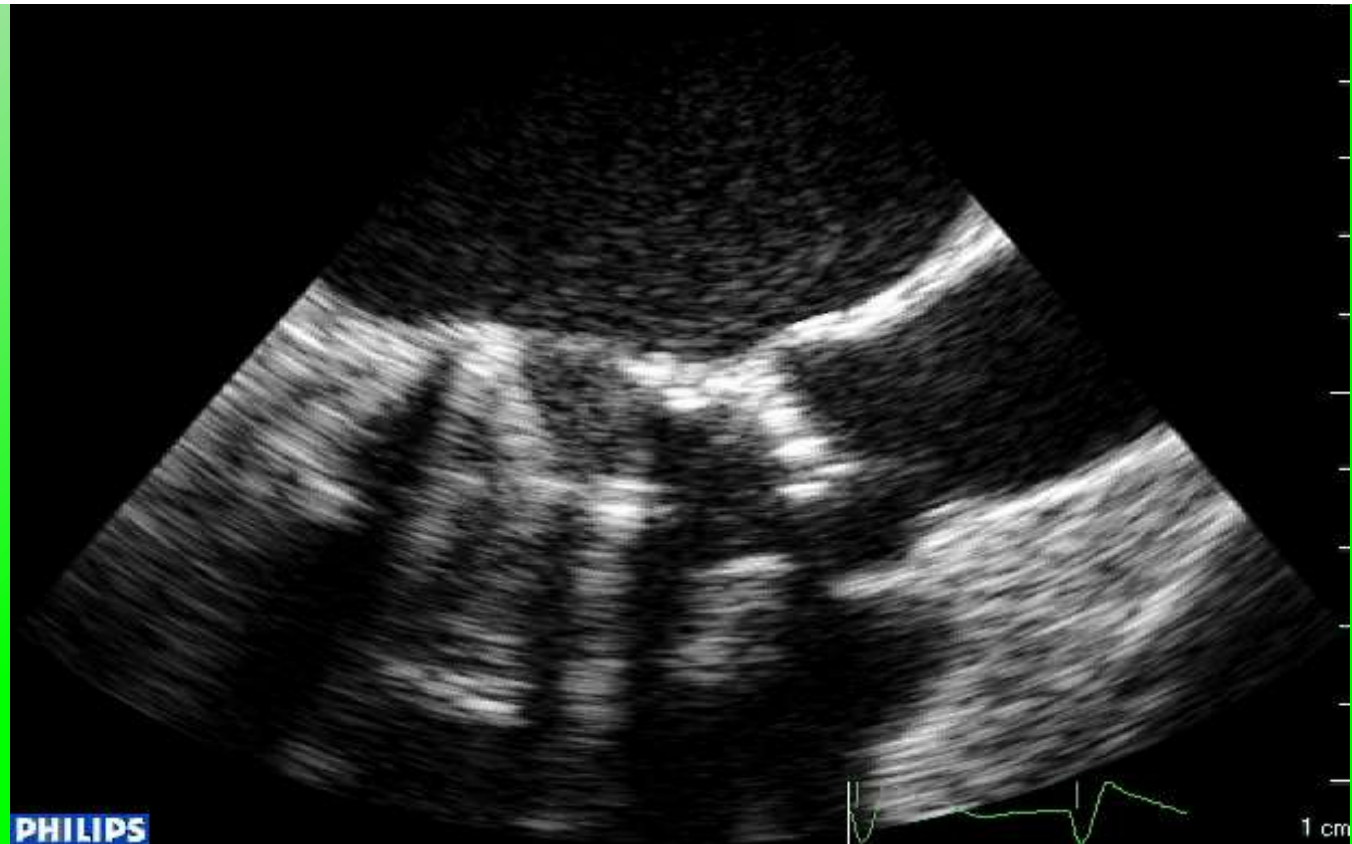
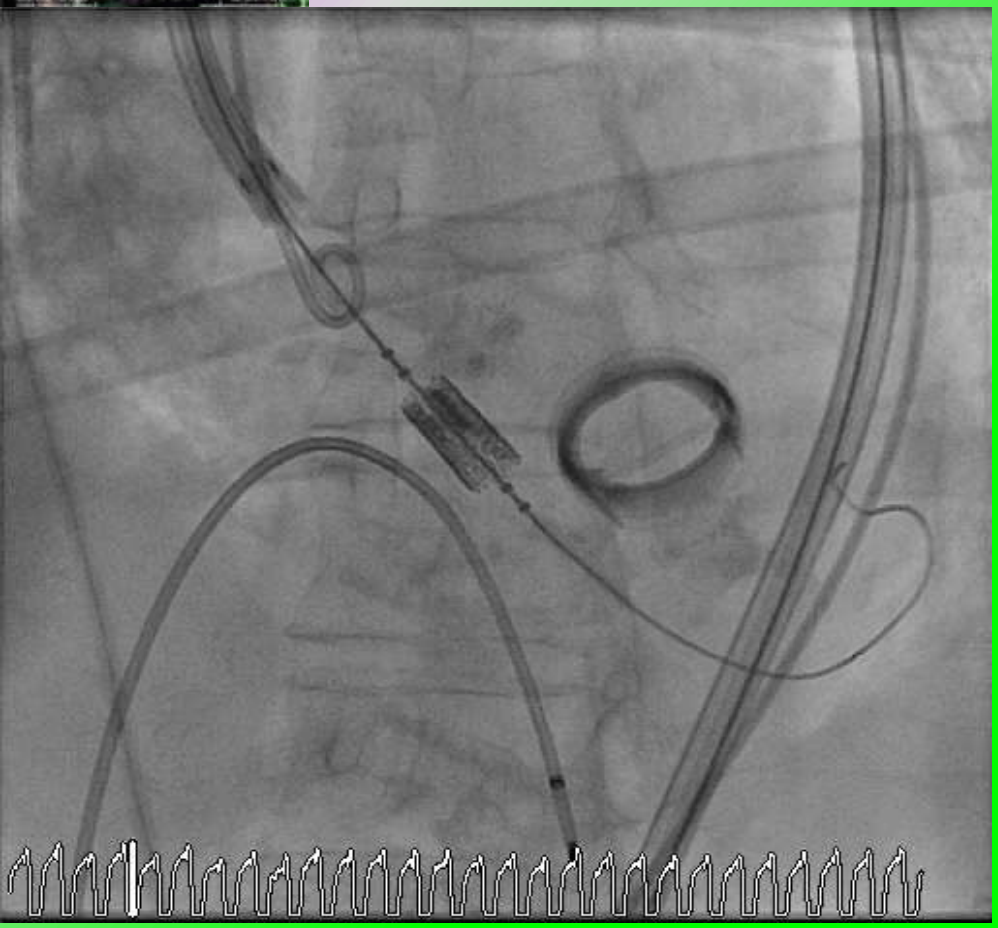
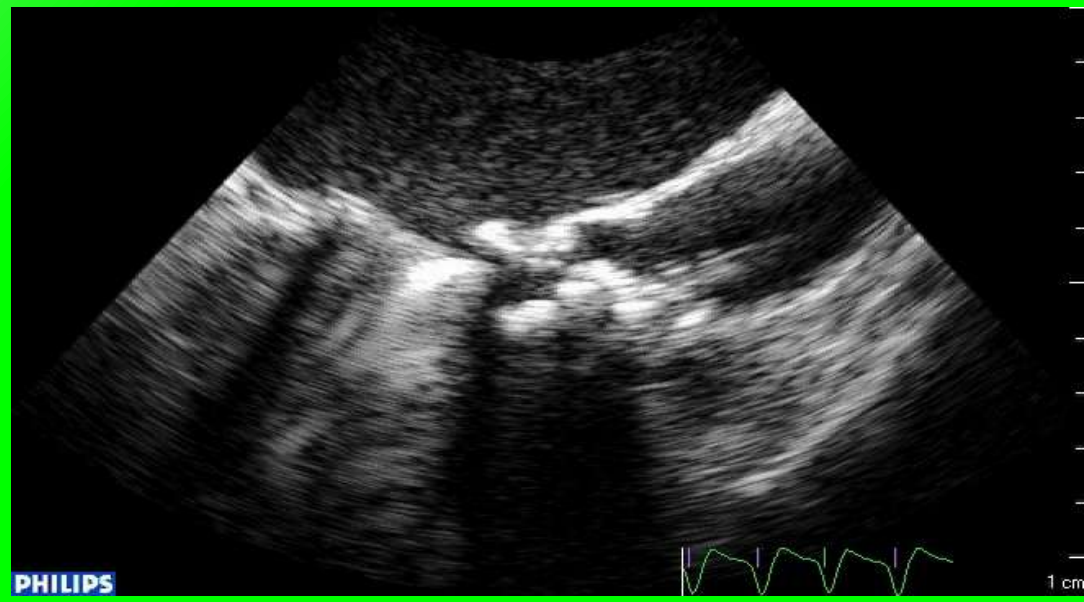
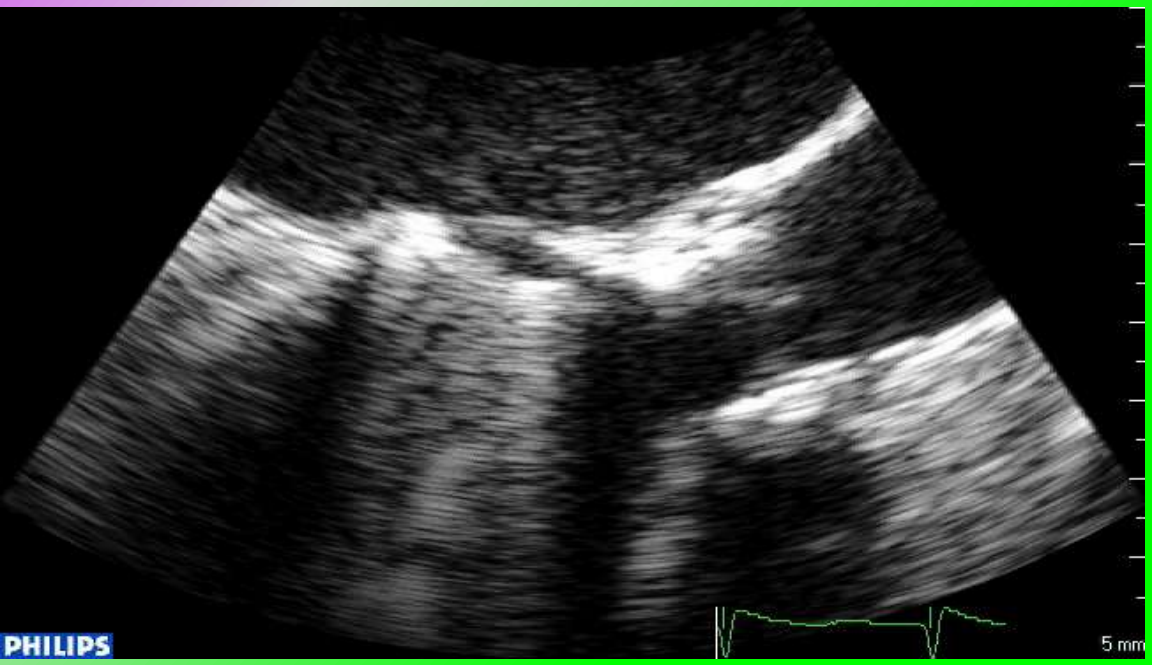


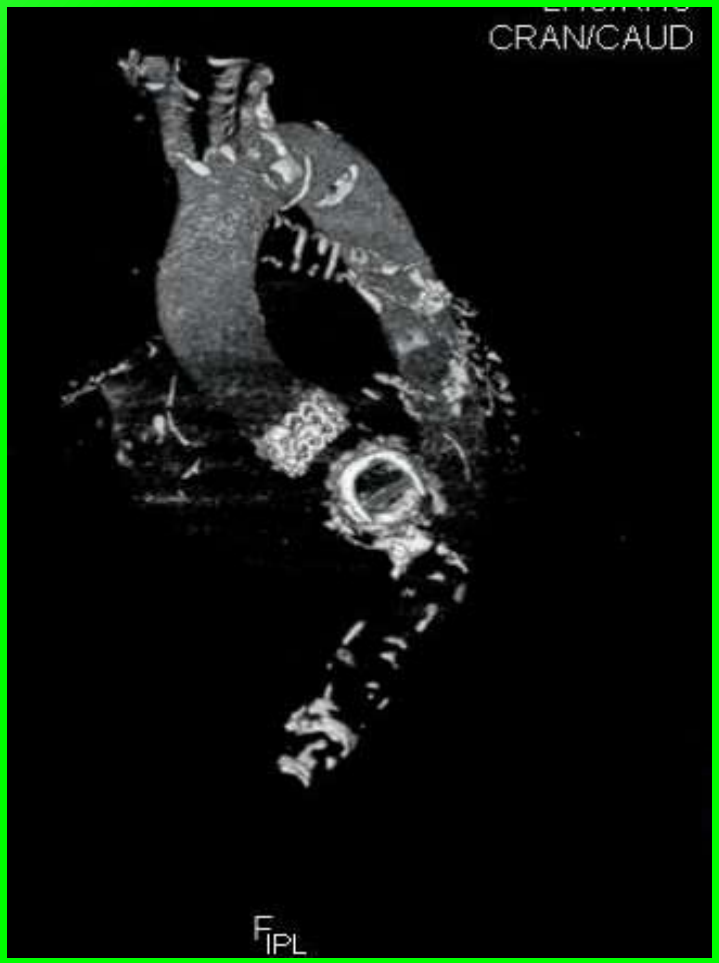
Elargissement des indications



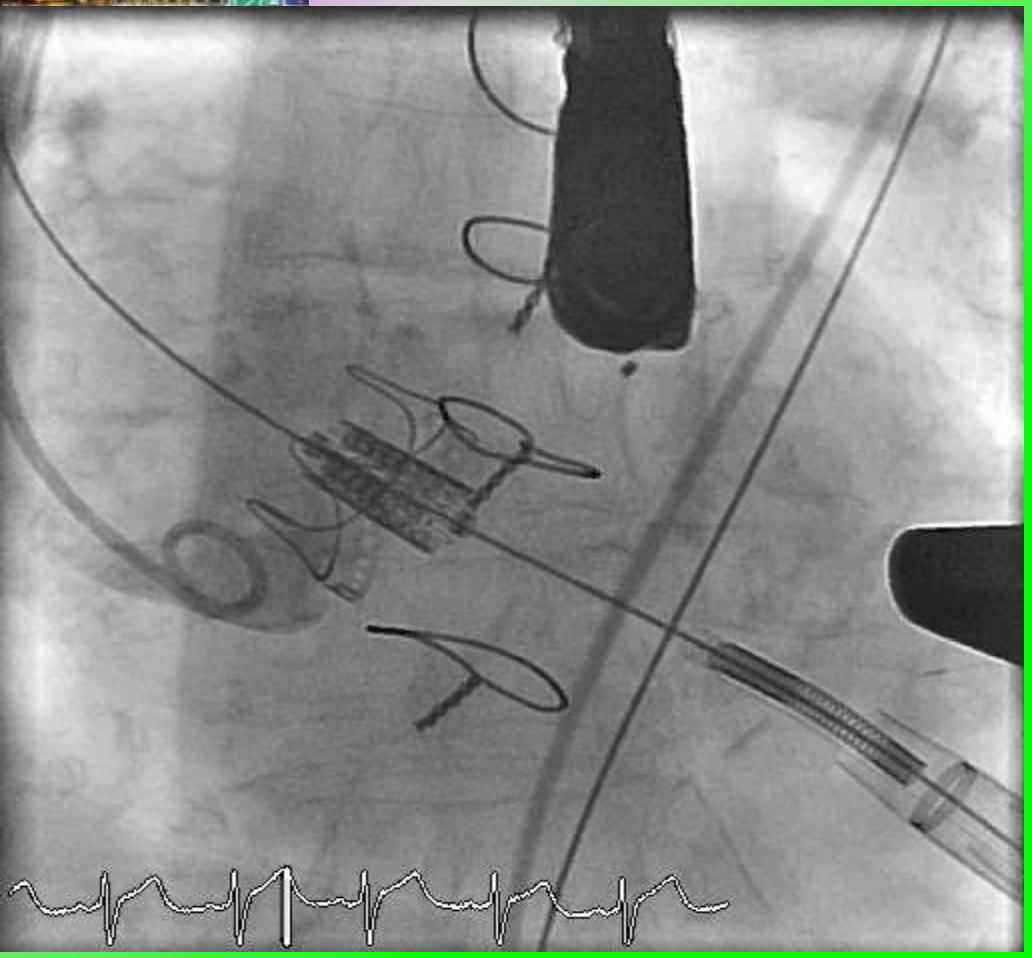


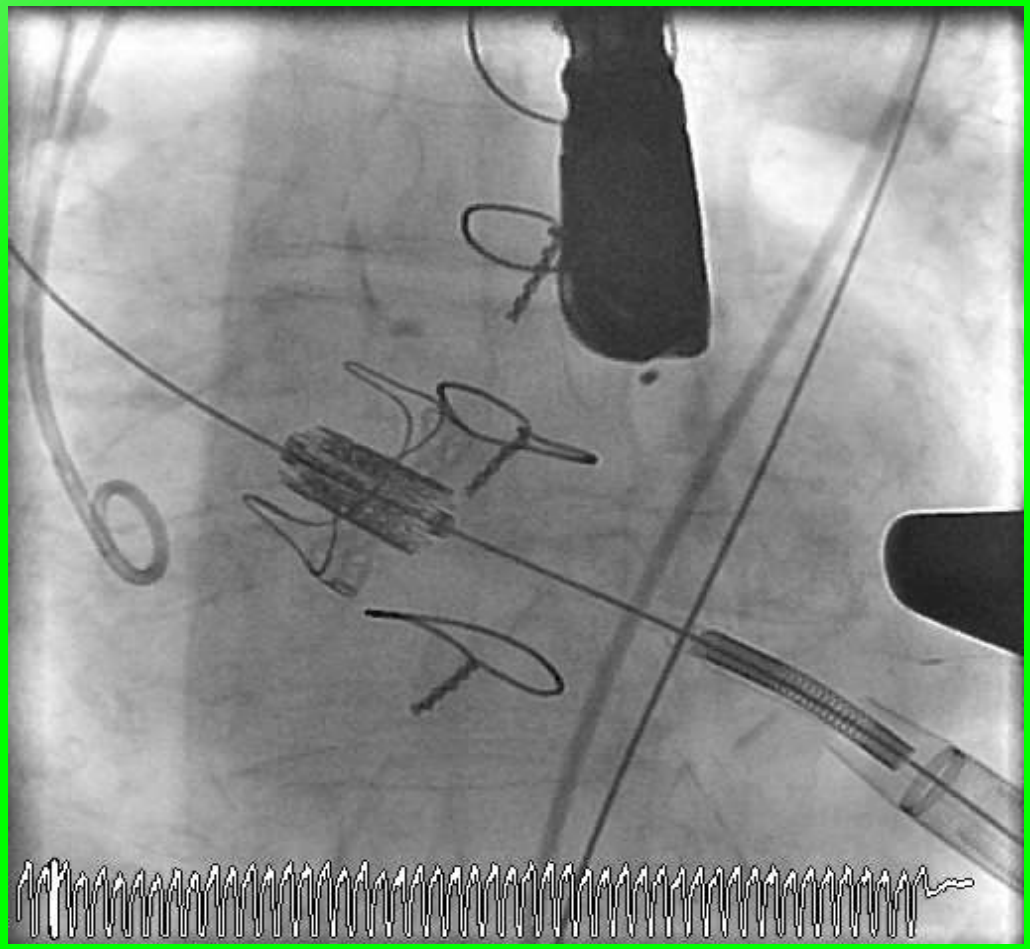
Elargissement des indications



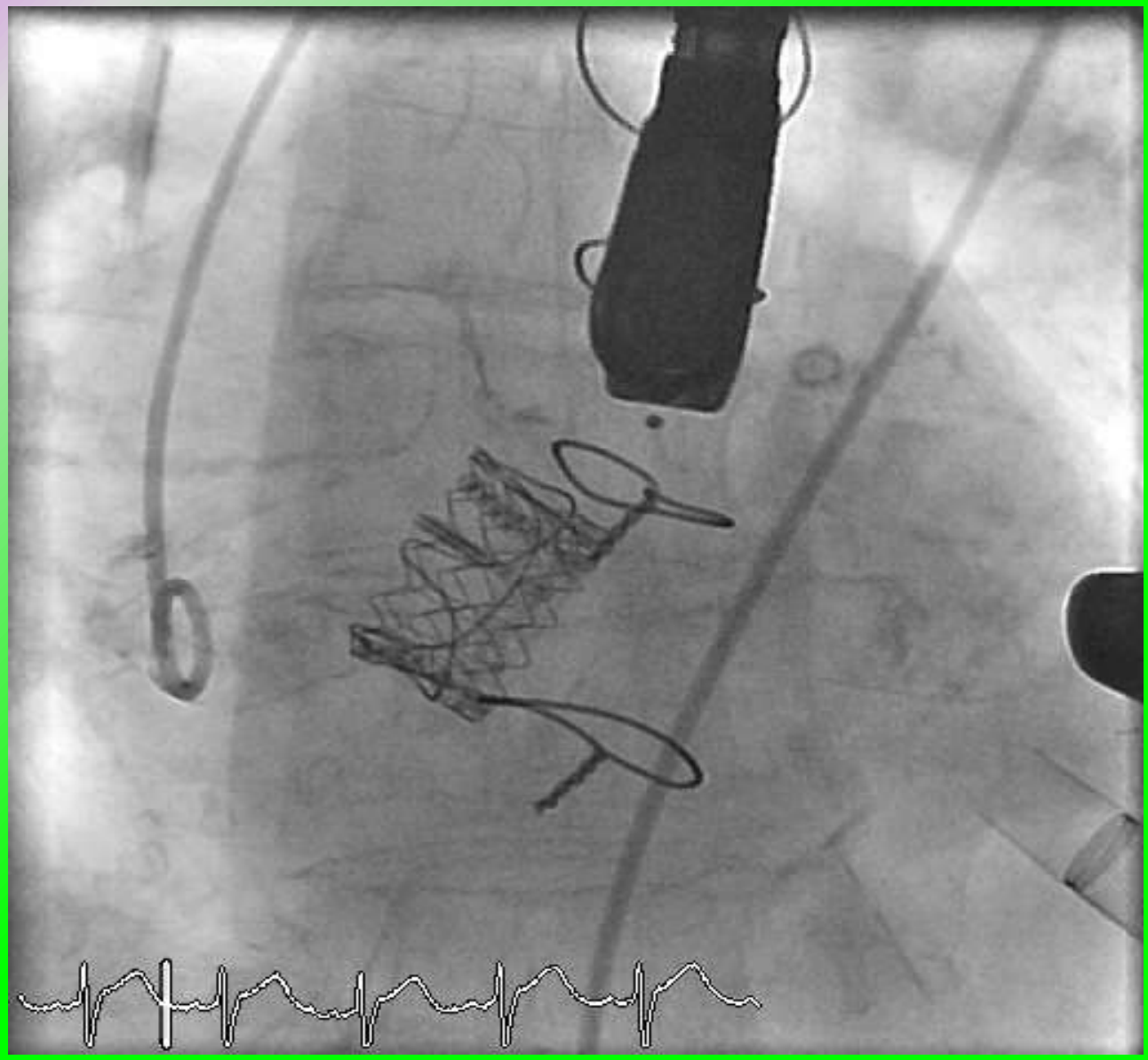


Elargissement des indications : valve in valve

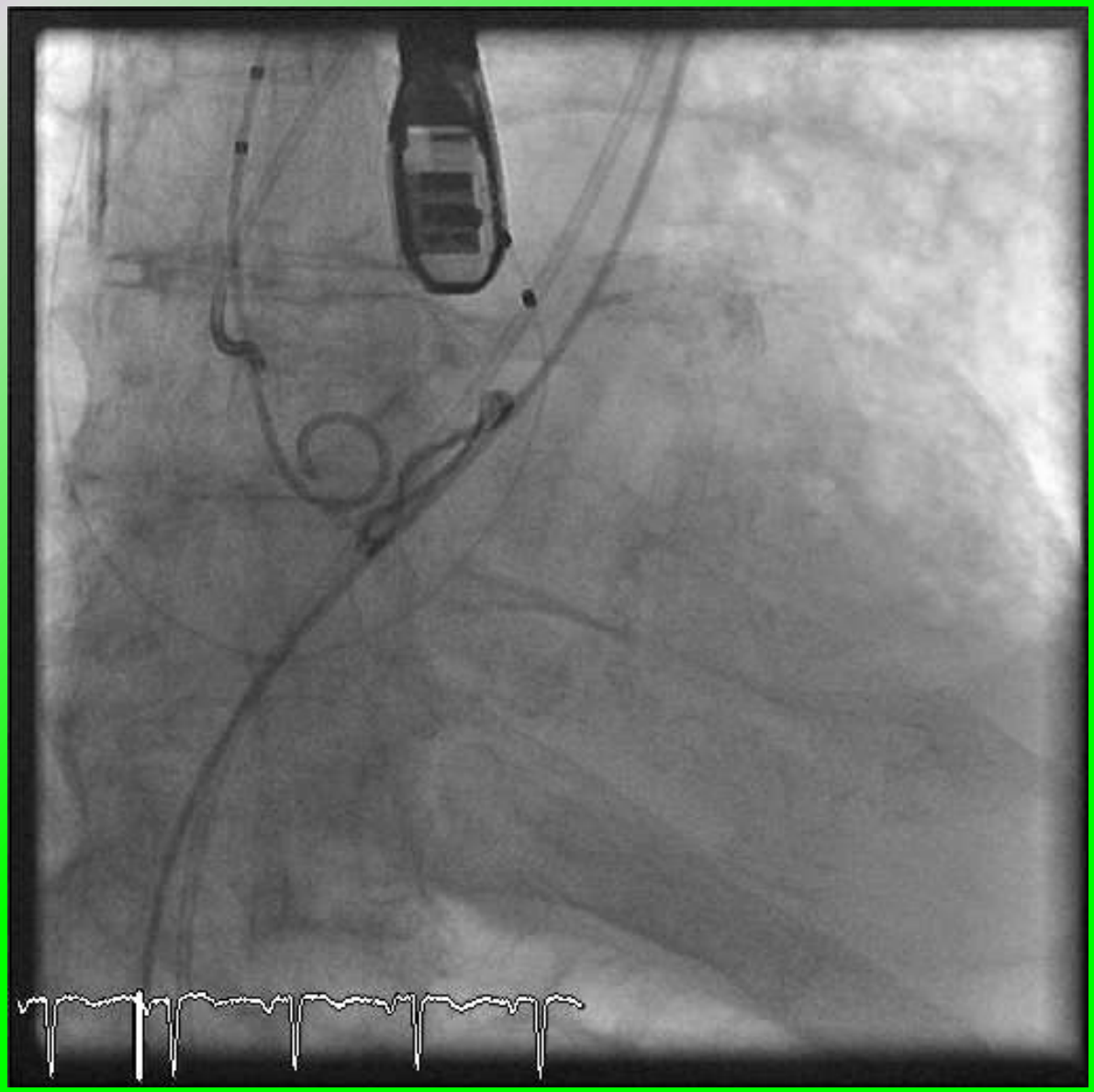




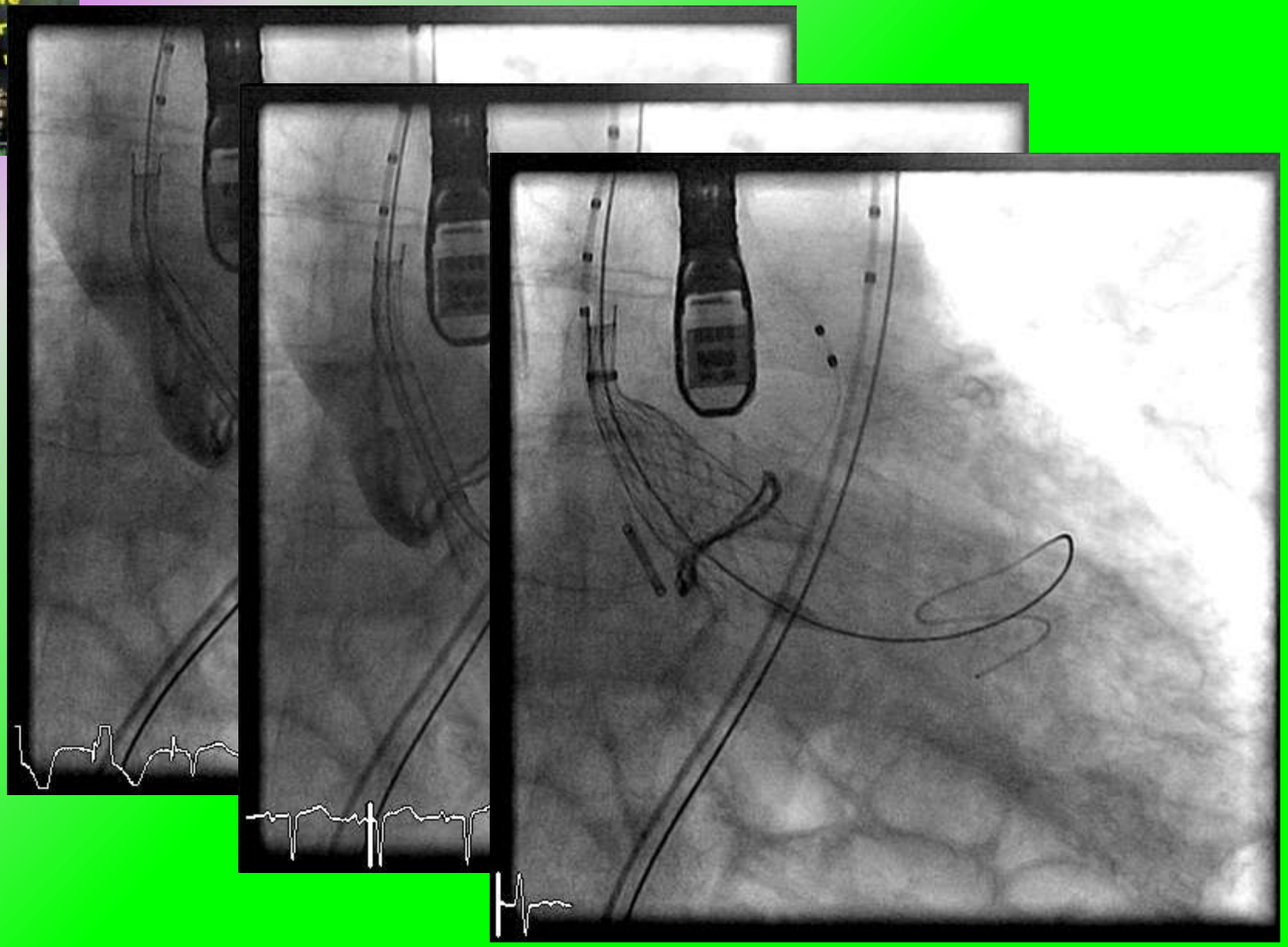
Elargissement des indications : valve in valve



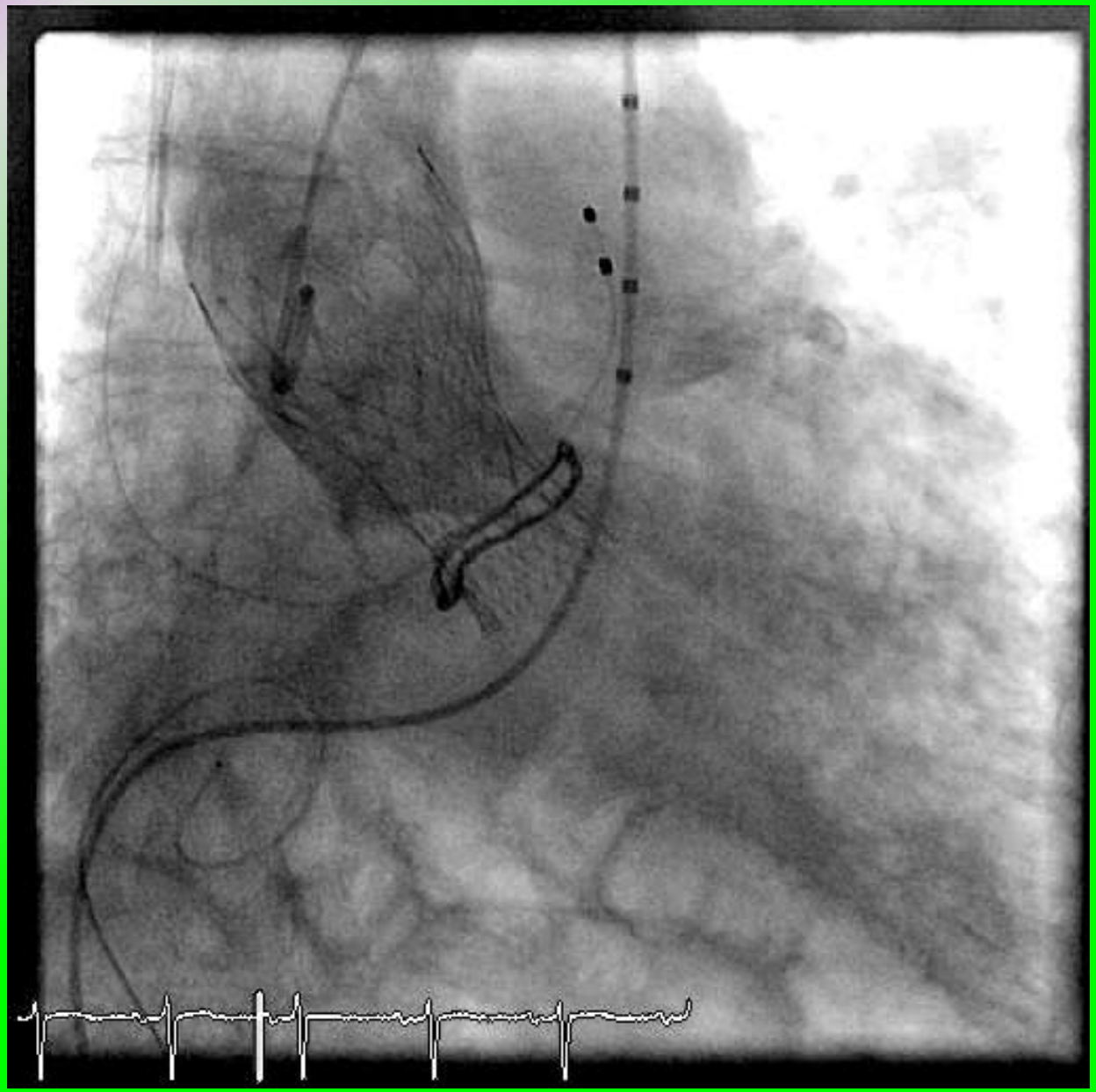
Elargissement des indications : valve in valve



Elargissement des indications : valve in valve



Elargissement des indications : valve in valve



Conclusion

- Faisabilité, bons résultats à court et moyen terme démontrés chez des patients à haut risque
- Coopération pluridisciplinaire
- Bonne fonction prothétique à 5 ans
- Pas de comparaison directe Edwards/CoreValve
- <u>Avenir :</u>
  - comparaison avec chirurgie (PARTNER cohorte A),
  - miniaturisation,
  - nouvelles prothèses,
  - élargissement des indications ?