Results of the TRAIL Multicenter, Observational Study

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for the TRAIL Investigator Group

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CoreLab

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Inclusion criteria

Patients harboring ruptured or unruptured intracranial aneurysms for which:

- The parent artery has a diameter ≥ 2.0mm and ≤ 4.5 mm
- Aneurysm neck size ≥ 4mm or dome-to-neck ratio < 2 (wide neck)
- Endovascular treatment by coils and one or more LVIS devices has been judged necessary to the patient
- Patient aged 18 or more
- Patient presenting with a WFNS score between 0 and 3
- The patient has accepted to be followed up

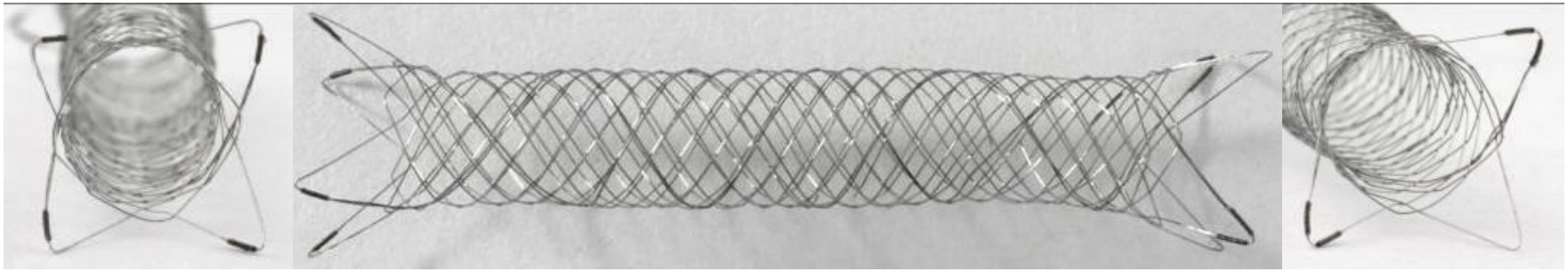
Exclusion criteria

The use of endovascular stent other than LVIS has been judged necessary

- Patient presenting with medical or surgical co-morbidities limiting his life expectancy to less than 12 mo
- CI to platelet inhibition treatment
- Patient requiring a re-treatment of an aneurysm previously treated with a stent
- Pregnancy
- Multiple aneurysms treated in one session

LVIS and LVIS Jr

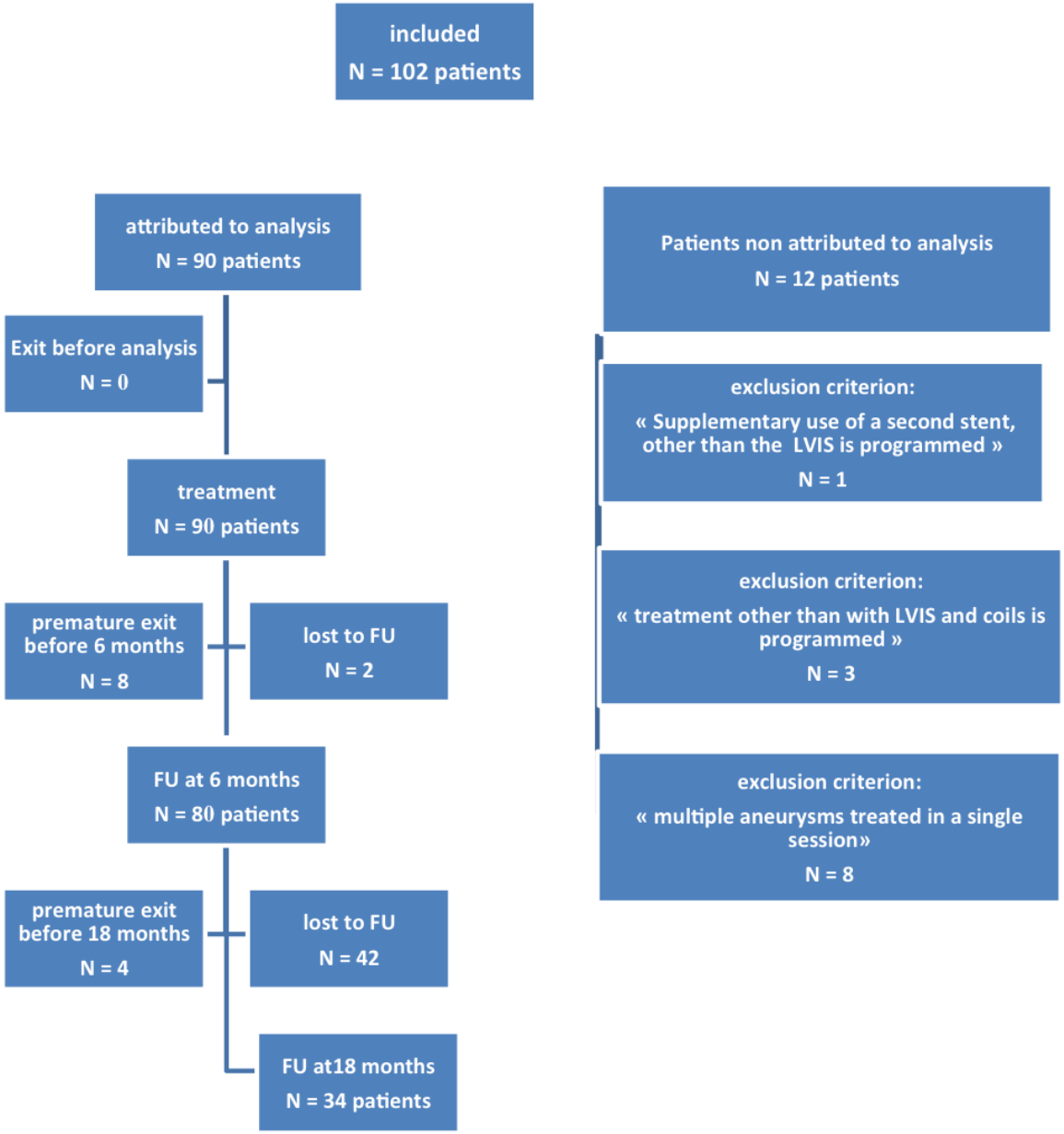
- - Ø 2.5 mm, suitable for vessels ranging from 2.0 to 2.5mm
- - Ø 3.5 mm, suitable for vessels ranging from 2.5 to 3.5mm
- - Ø 4.5 mm, suitable for vessels ranging from 3.0 to 4.5mm
- - Ø 5.5 mm, suitable for vessels ranging from 4.0 to 5.5mm



	Total N=90 patients / 90 treated aneurisms / 104 stents used / 92 stents placed
Number of aneurysms treated per patient – n (%)	90 (100.00)
• 1	90 (100.00)
Number of stents used per patient – n (%)	90 (100.00)
• 1	76 (84.44)
• 2	14 (15.56)
Number of stents placed per patient – n (%)	90 (100.00)
• 0	3 (3.33)
• 1	82 (91.11)
• 2 (dual stent-telescopic)	5 (5.56)
Reasons for non-deployment of stents – number / total number of stents used	12 / 104
• Inappropriate selection of stent size	3 / 104
• Failure of deployment during positionning	3 / 104
• Technical issues : premature detachment	2 / 104
• Nonuse due to sterility issues	4 / 104
Type of stent placed – n (%)	92 (100.00)
• LVIS	14 (15.22)
• LVIS Jr	87 (83.65)
Version of placed stents – n (%)	92 (100.00)
• Version A	44 (47.83)
• Version C	48 (52.17)
Treatment technique – n (%)	90 (100.00)
• Coiling passing through the stent LVIS (trans-stent)	13 (14.44)
• Coiling with the jailing technique	20 (22.22)
• Coiling and subsequent deployment of the LVIS stent (post-coiling)	3 (3.33)
• Balloon-assisted coiling before LVIS deployment	47 (52.22)
• Y stenting	4 (4.45)
• Other	3 (3.33)
Number of used coils (mean ± s.d. [median])	6.40 ± 3.91 (6.00)
Use of other material – n (%)	90 (100.00)
• Distal catheter	30 (33.33)
• Guiding catheter	90 (100.00)
• Catheter with balloon	53 (58.89)
Succès du positionnement du cathéter pour les stents posés – n (%)	92 (100.00)
Anti-platelet regimen before endovascular treatment – n (%)	90 (100.00)
• AAS*	56 (62.22)
• Clopidogrel (Plavix)	72 (80.00)
• Prasugrel (Efient)	15 (16.67)
Anti-platelet regimen during endovascular procedure – n (%)	90 (100.00)
• AAS*	32 (35.56)
• Clopidogrel (Plavix)	1 (1.11)

Clinical evaluation / morbidity rate

- Minor neurological deterioration was defined as an increase of 1 point in the mRS score at 6 mo
- moderate deterioration by an increase of 2 points
- severe deterioration by an increase of more than 2 points
- Death and complication rate analysis were performed for patients in the intent-to-treat population (ITT analysis)


included
N = 102 patients
attributed to analysis
N = 90 patients
Patients non attributed to analysis
N = 12 patients
Exit before analysis
N = 0
exclusion criterion:
« Supplementary use of a second stent, other than the LVIS is programmed »
N = 1
treatment
N = 90 patients
exclusion criterion:
« treatment other than with LVIS and coils is programmed »
N = 3
premature exit before 6 months
N = 8
lost to FU
N = 2
FU at 6 months
N = 80 patients
exclusion criterion:
« multiple aneurysms treated in a single session»
N = 8
premature exit before 18 months
N = 4
lost to FU
N = 42
FU at18 months
N = 34 patients

Of the 90 patients analyzed

- 27 (30.0%) had multiple aneurysms
- 23 (25.6%) ruptured aneurysms
  - 4 (4.4%) ruptured aneurysms were in acute phase (ruptured for less than 30 days)
- 10% (9/90) of the aneurysms were large (≥ 10 mm) and 90.0% (81/90) were small (<10 mm)
- Previously treated aneurysms accounted for 31.1% (28/90)
- Aneurysms were mainly localized in the MCA (36.7%) and AcoA (35.6%).

Safety assessment results:
Clinical outcome

- Majority of patients graded mRS 0 at post-procedure (86.7%) at 6-month F/U (90.0%)
- 7.8% of patients had neurological deterioration in the post-operative period
- 2.5% at 6-month
- MRS score did not vary significantly between post-procedure and 6 mo F/U (0.01 ± 0.41 point)

Safety assessment results: *Mortality*

- 1 procedure-related death (1/90, 1.1%) during post-procedural hospitalization (mesencephalic ischemia at day 1)
- 4 deaths (4/90, 4.4%), unrelated to the endovascular technique occurred during follow up:
  - 1 occurred at the day of the procedure (PE)
  - 1 during the 6-month follow-up (cancer)
  - 2 at 9-19 months post-procedure (cancer)
- mortality rate at 6-mo in the study was 5.5%
- procedure-related mortality rate was 1.1%
- no difference in mortality rates according to the type or version of stent placed (Fisher exact test: p=0.39) at 6 mo

Adverse events and procedure-related morbidity

- Adverse events (AEs) per-procedure were reported in 27.8% (25/90) patients and 6 AEs were reported during the 6-mo F/U (6.7%, 6/90)
- 34 adverse events were reported overall, involving 31/90 patients (34.4%)
- No difference in the adverse event rate depending on the type or version of stent placed post-procedure or at 6-mo (p=0.35)
- Of the 34 AE, 4 (11.8%) were unexpected and half (50%, 17/34) were vascular
  - aneurysm rupture: 1
  - arterial occlusive disease: 3
  - arterial rupture: 1
  - artery dissection: 2
  - cerebral hematoma: 1
  - stroke: 3
  - hypertension: 1
  - stent embolization: 3
  - TIA:1
  - venous insufficiency: 1
- Among the 34 adverse events, 4 events in 4 patients (4.4%, 4/90) resulted in permanent morbidity (healing with sequels or not resolved) at 6-mo
- Permanent complication rate was attributed as being 4.4% at 6-mo
- Permanent morbidity rate at 6-mo (defined as mRS score >2) was 1.2% (1/90)

CoreLab adjudicated Aneurysm Occlusion Rates

Aneurysm occlusion rate	Post procedure (N=90 patients)	At 6-month FU (N=79 patients)
	p-value = 0.43	
Missing data	2	2
Total occlusion– n (%), 95% C.I.	80 (90.91) [82.85 ; 95.55]	70 (90.91) [82.14 ; 95.80]
Residual neck – n (%)	8 (9.09) [4.45 ; 17.15]	4 (5.19) [1.64 ; 13.00]
Residual aneurysm – n (%)	0	3 (3.90) [0.88 ; 11.30]

- absence of statistically significant difference (Fisher's exact test: p=1.00) between LVIS and LVIS Jr
- The same for comparison of the 2 stent versions (A and C) regarding aneurysm occlusion rates at six months (Fisher's exact test: p=0.95)
- The aneurysm's size (small or large) did not seem to play a role in the 6-mo imaging outcome, regarding occlusion rate (Fisher's exact test: p=0.0739)
- None of aneurysms treated in the study was deemed amenable to re-treatment

CoreLab Adjudicated Parent Artery Patency

- immediate post-procedure and 6-mo F/U showed patency of the parent artery in 95.4% and 100.0% of the cases, respectively
- 3 patients had parent artery occlusion following the endovascular procedure
  - 1 had stent thrombosis without any possibility of arterial recanalization
  - 1 underwent parent artery occlusion (dissection with thrombosis of the ACA
  - 1 had partial in-stent thrombosis, resulting in occlusion of basal ganglia perforators and distal emboli, resulting in hemiplegia. The patient refused imaging F/U.

Conclusions

- LVIS and LVIS Jr devices have been shown to be safe and effective in the treatment of complex ruptured and unruptured intracranial aneurysms
- high immediate and mid-term total exclusion rates

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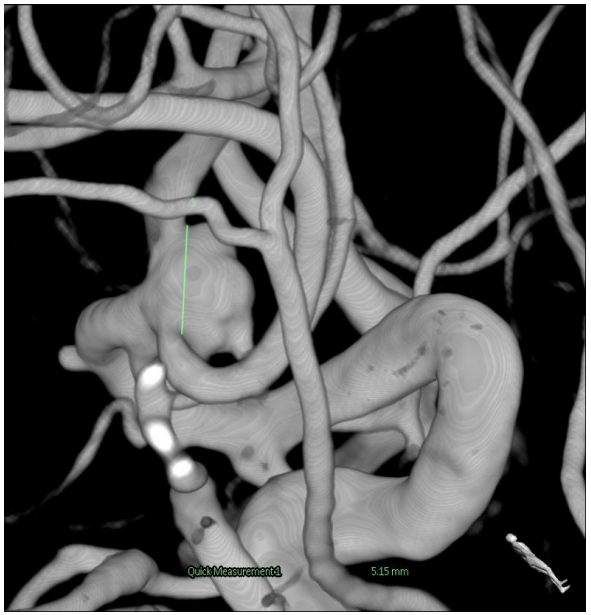
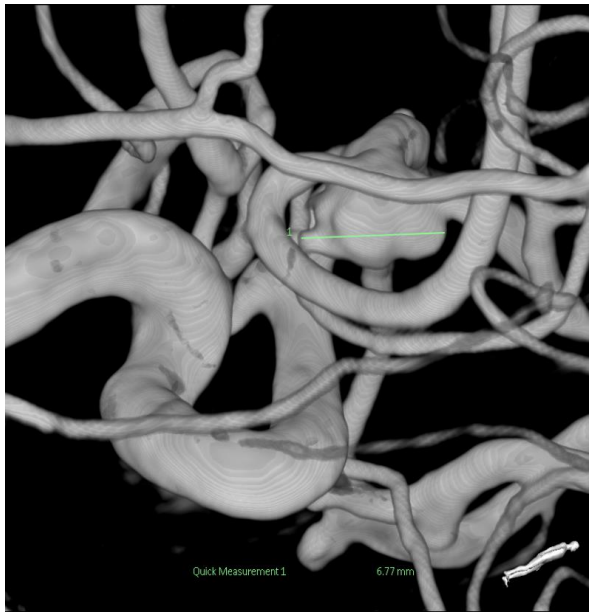
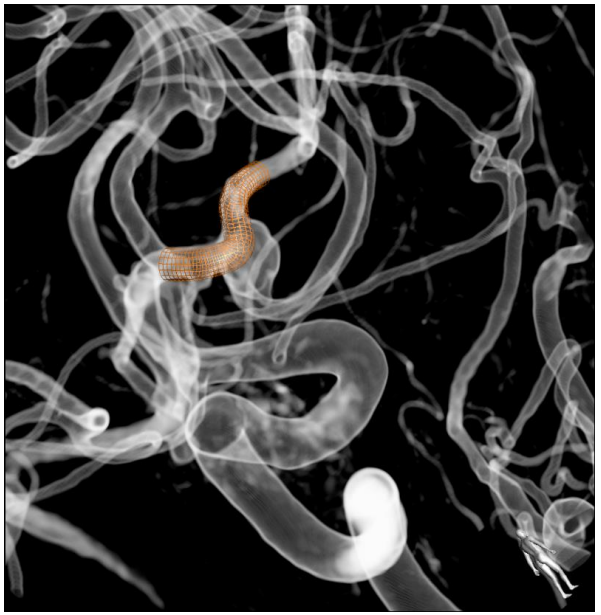
2 anévrismes fortuits

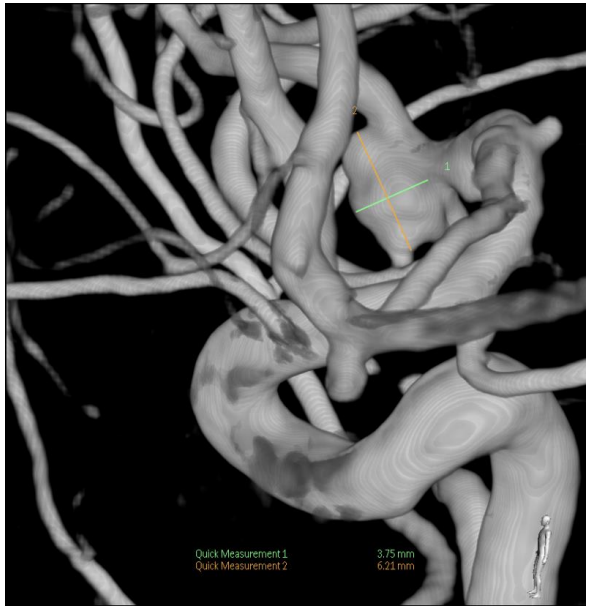
1 sylvien droit de 6 mm

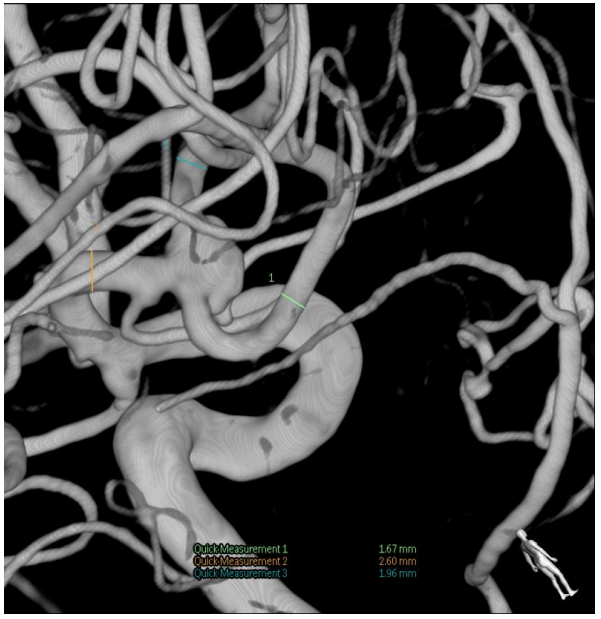
1 AcoA de 3 mm

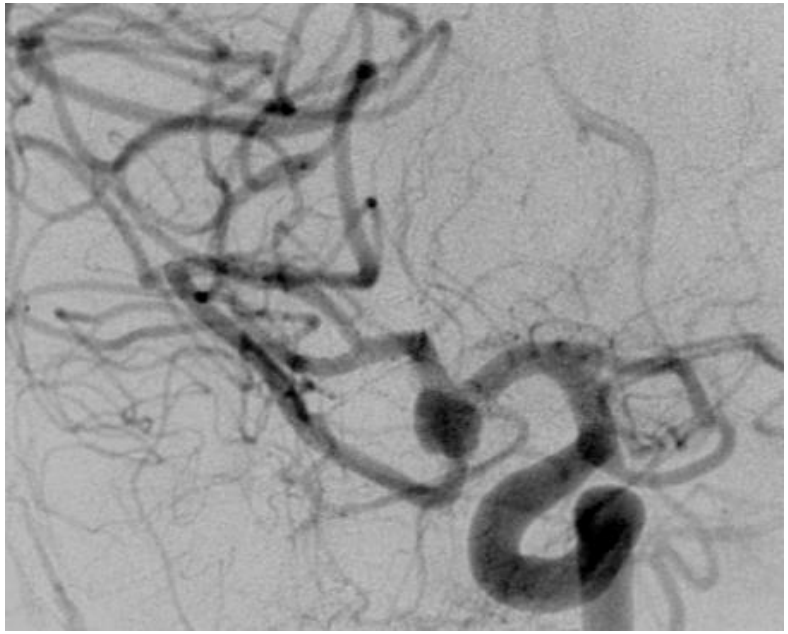

Quick Measurement 1
5.15 mm

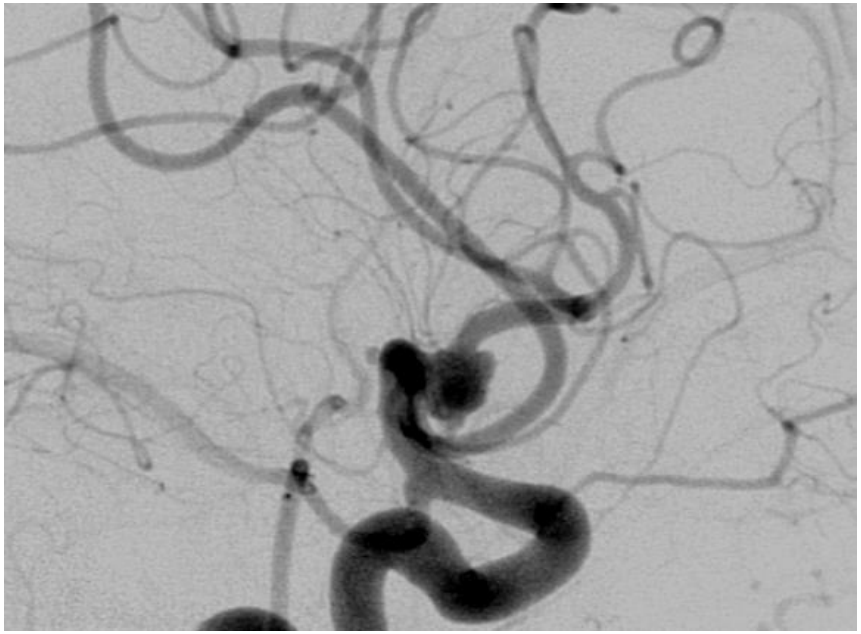

Quick Measurement 1
6.77 mm

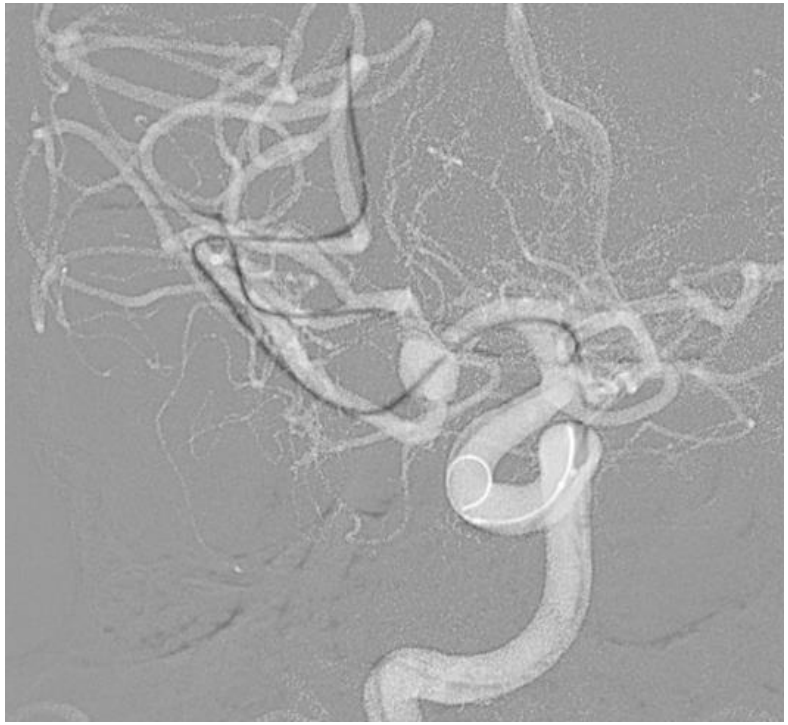


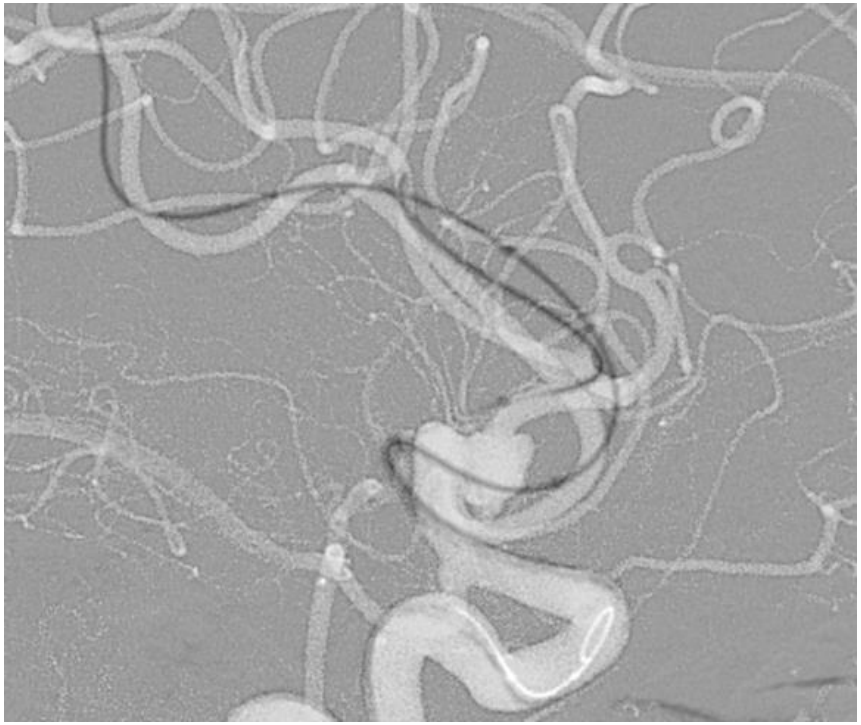

Quick Measurement 1
3.75 mm
Quick Measurement 2
6.21 mm

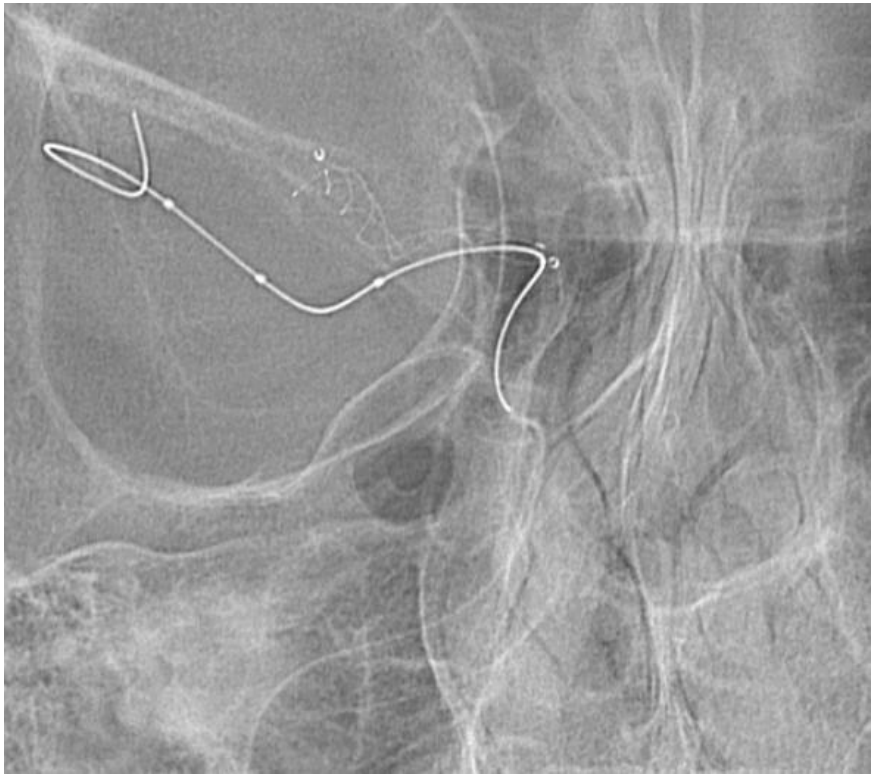

Quick Measurement 1
1.67 mm
Quick Measurement 2
2.60 mm
Quick Measurement 3
1.96 mm

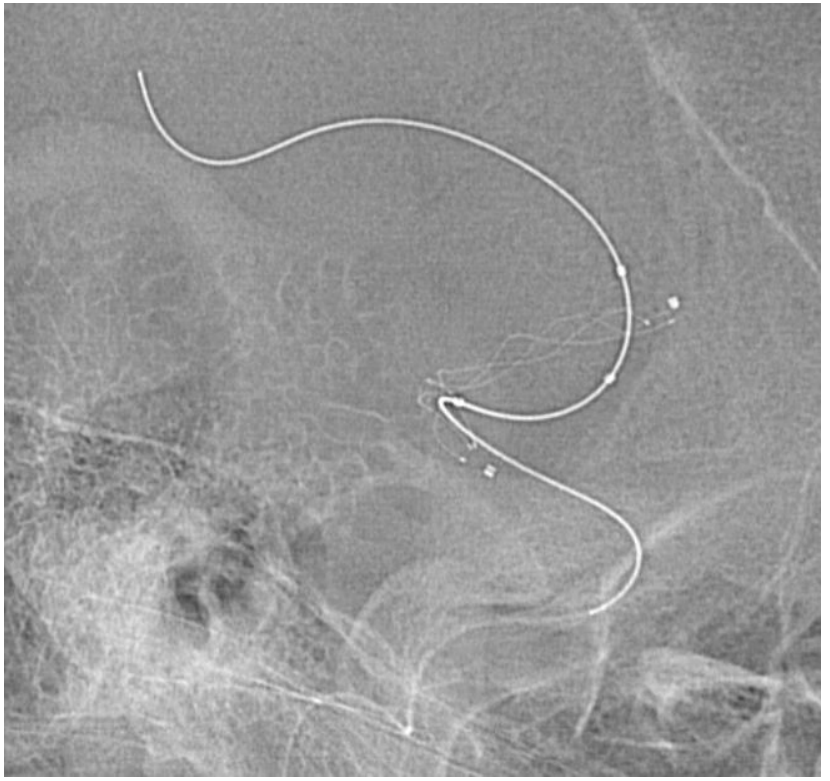


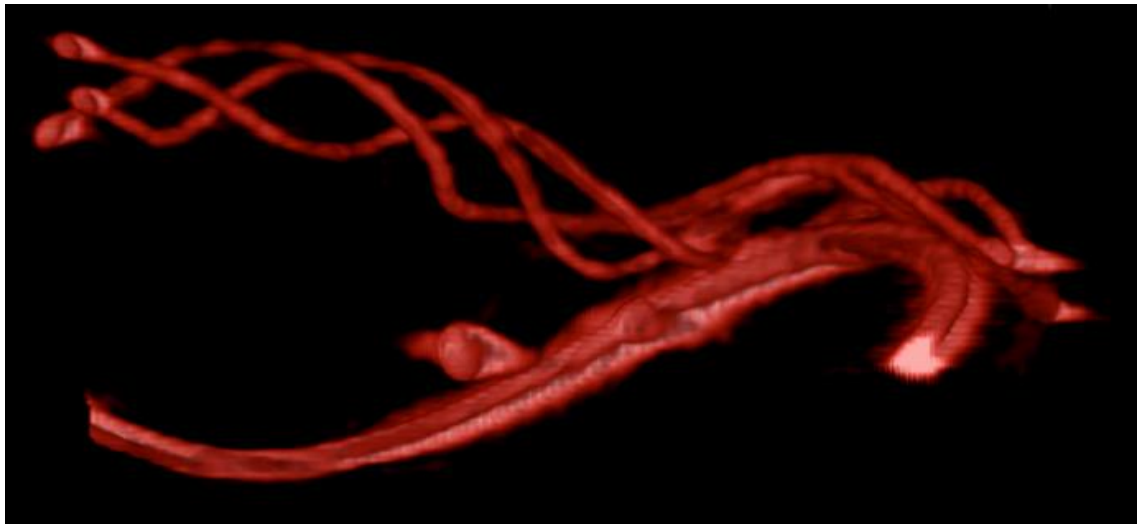


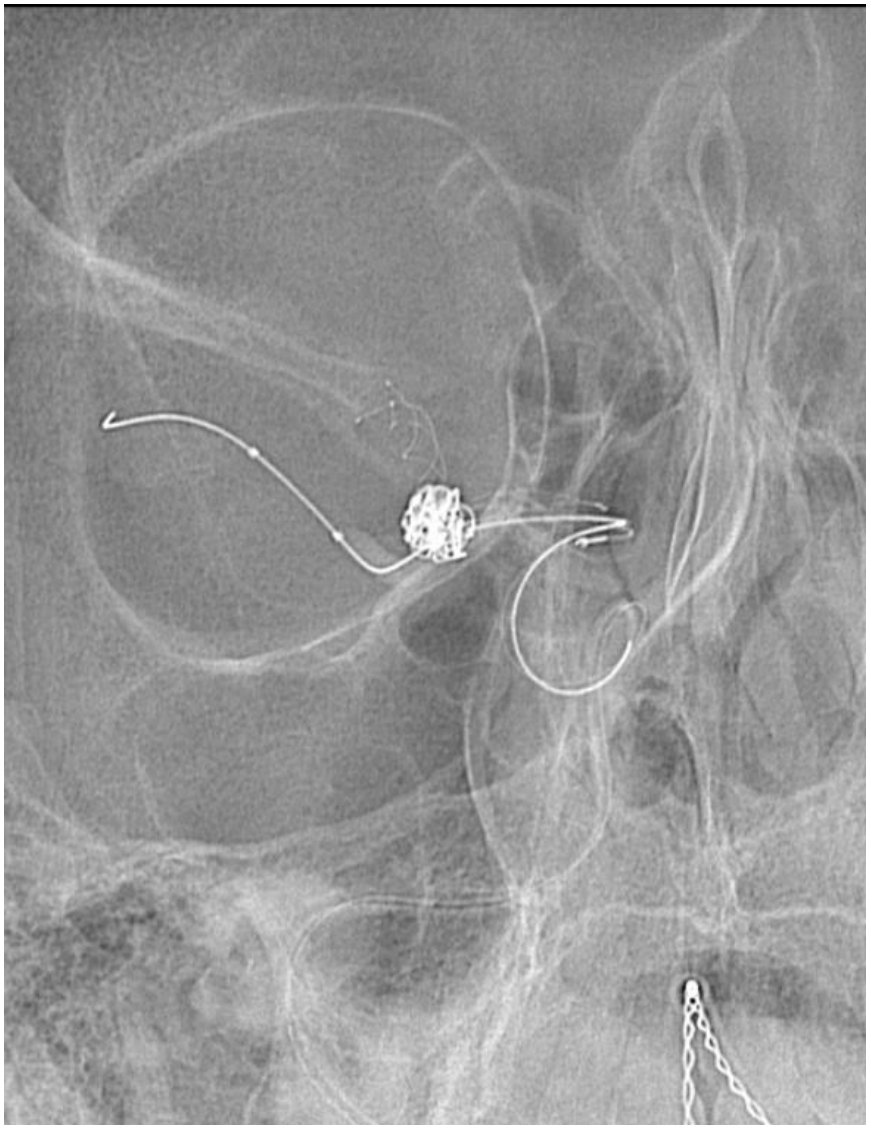


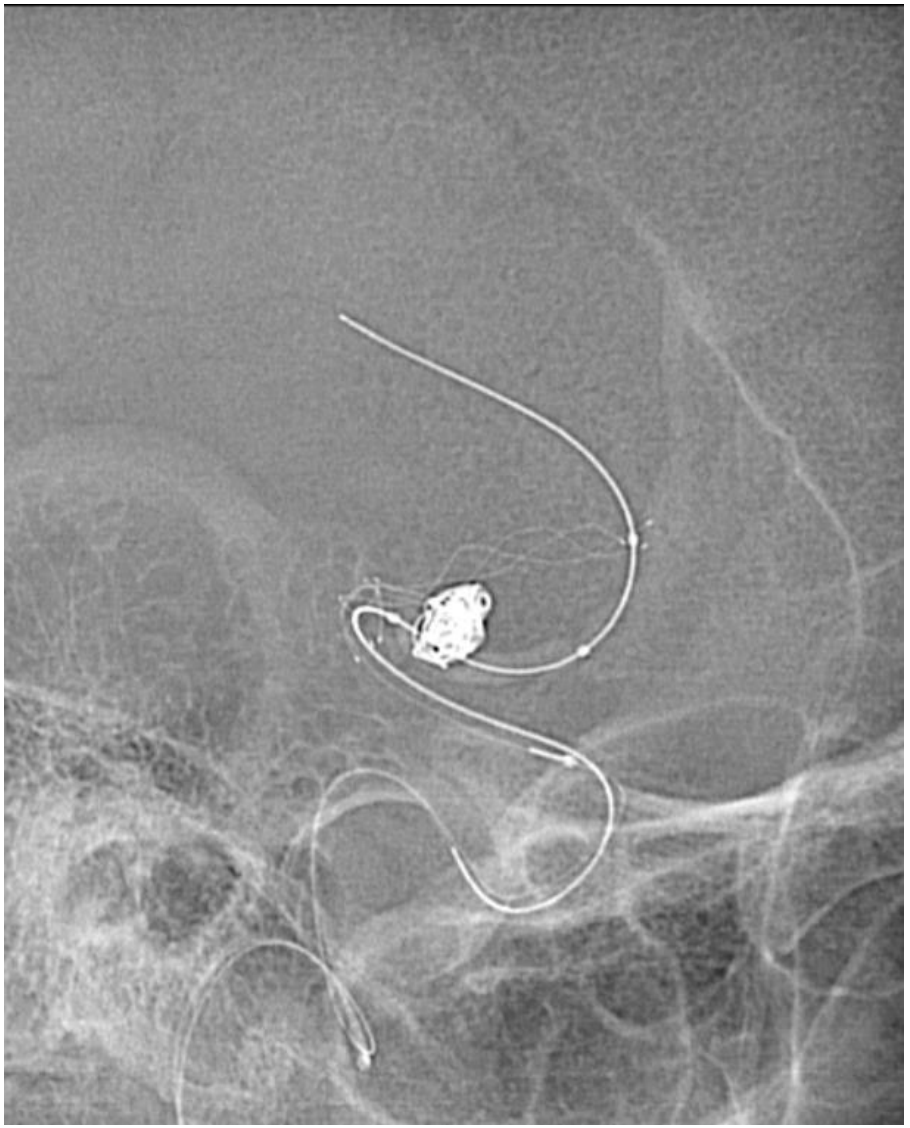




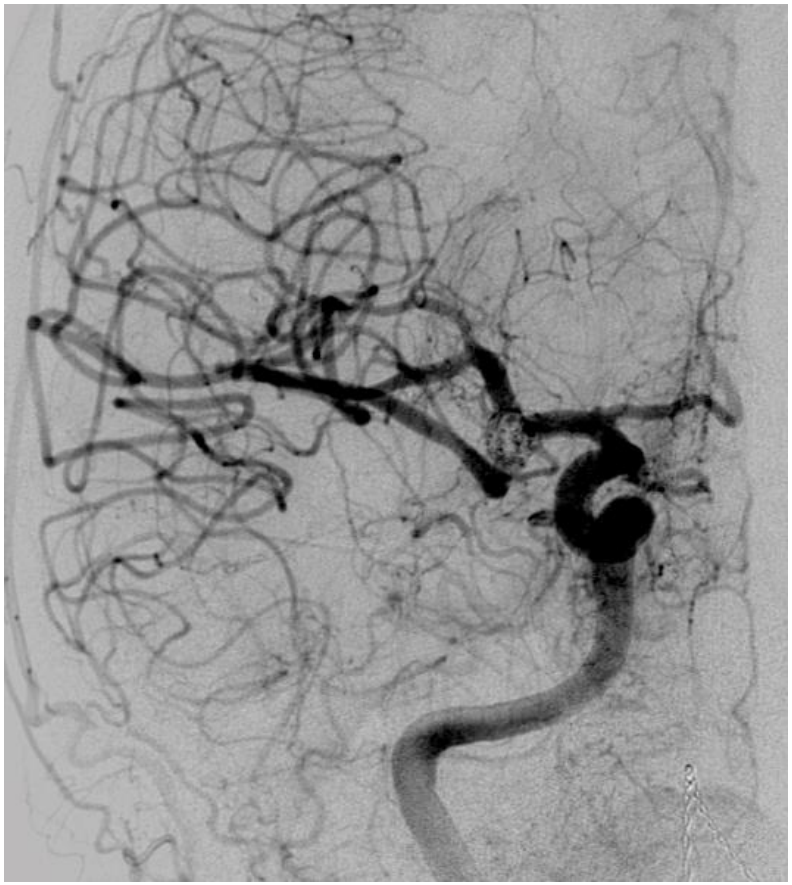


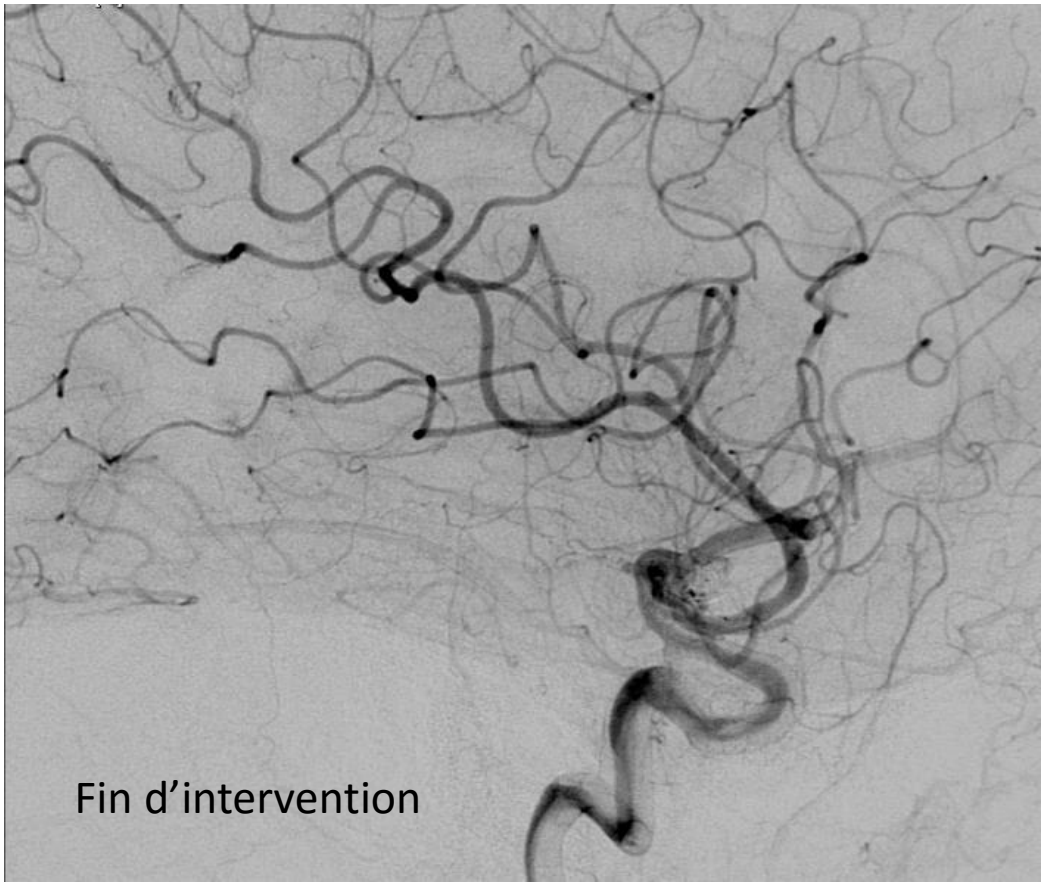


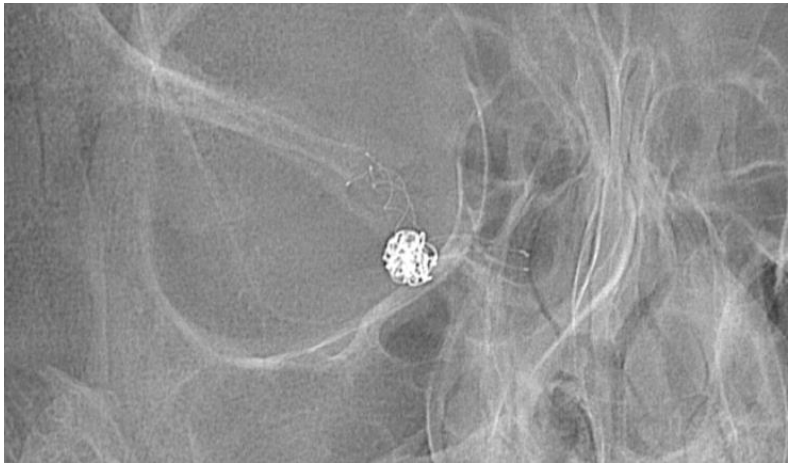


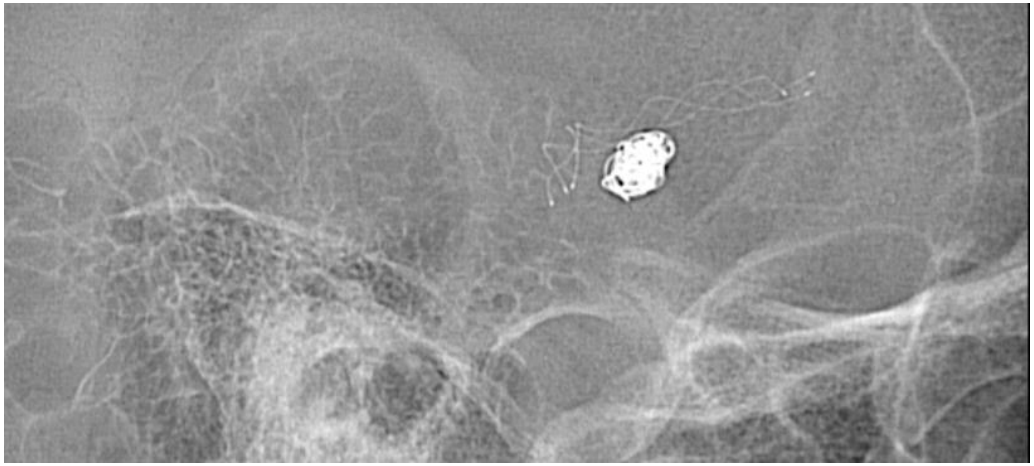


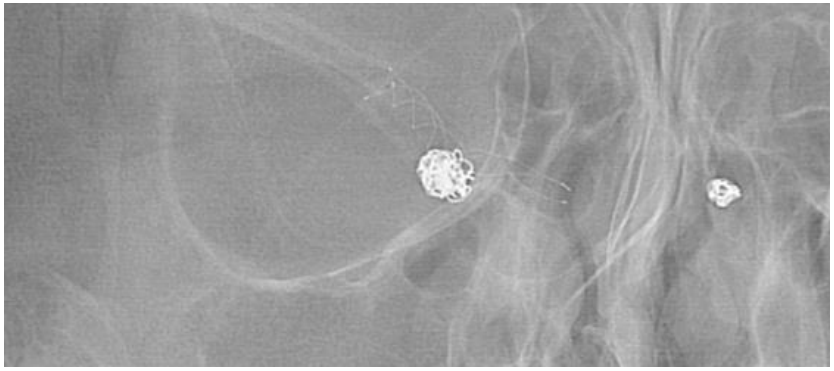
Septer C dans la branche de division inférieure

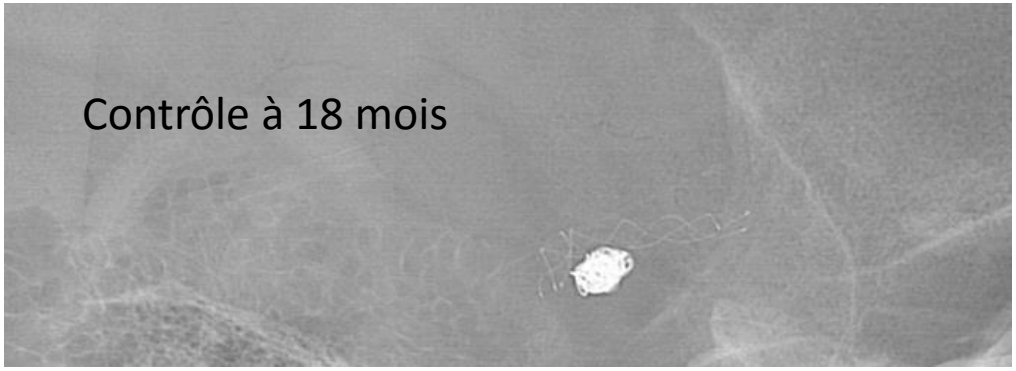


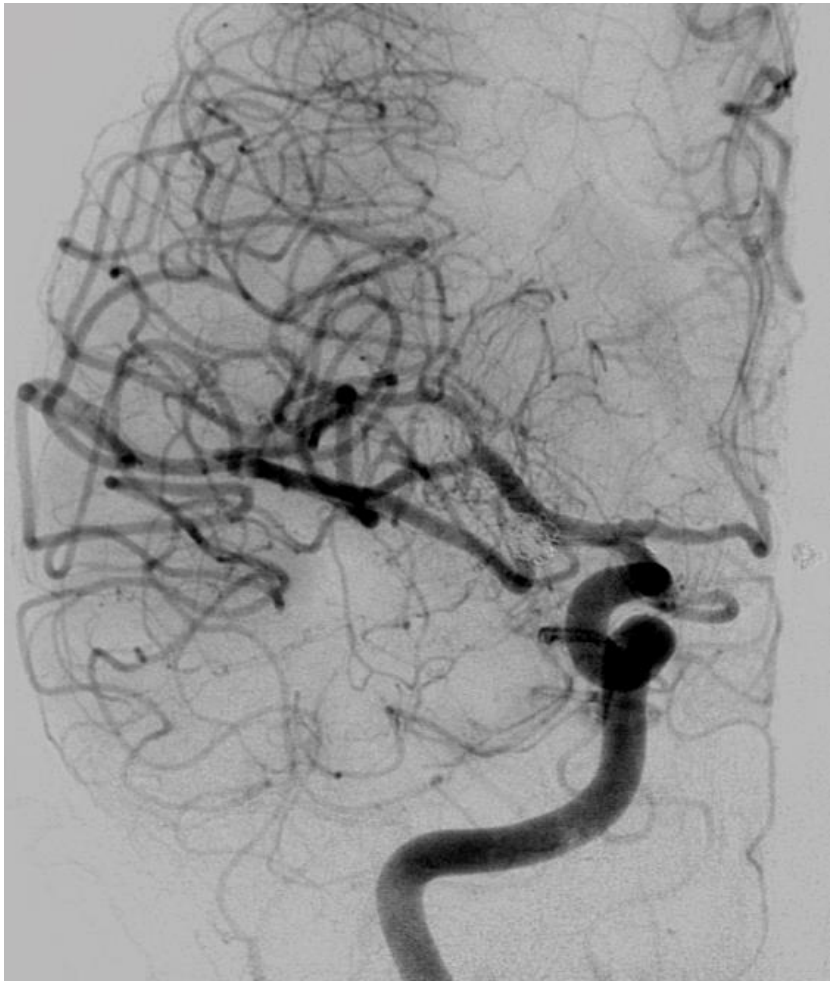

Fin d’intervention

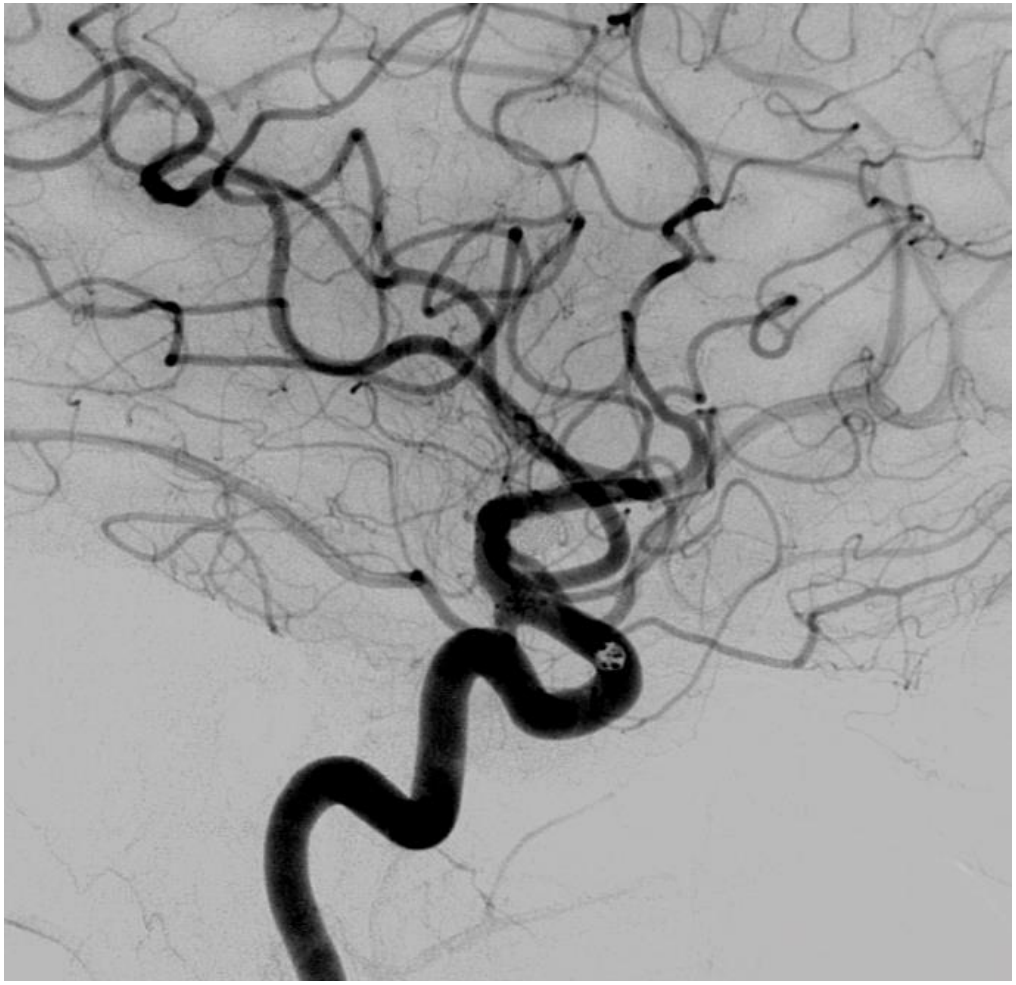







Contrôle à 18 mois





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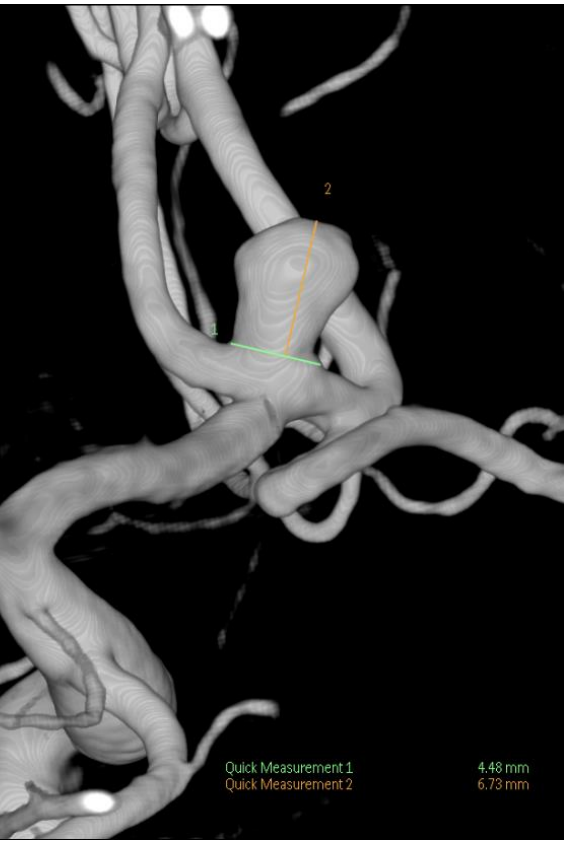
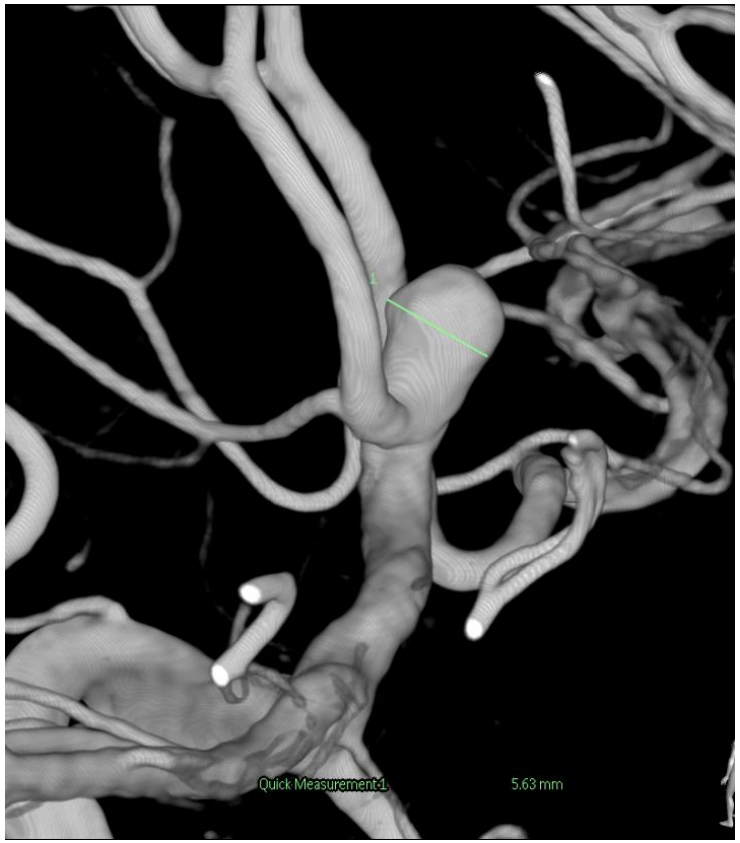
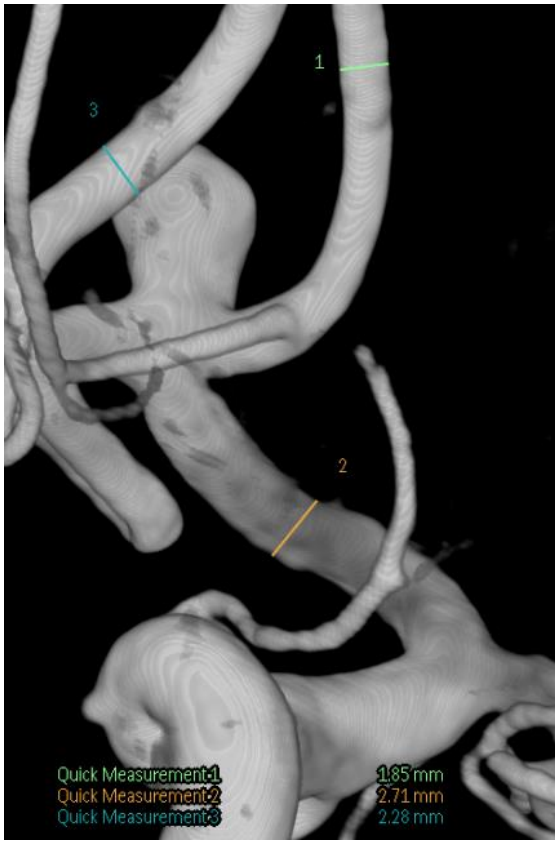
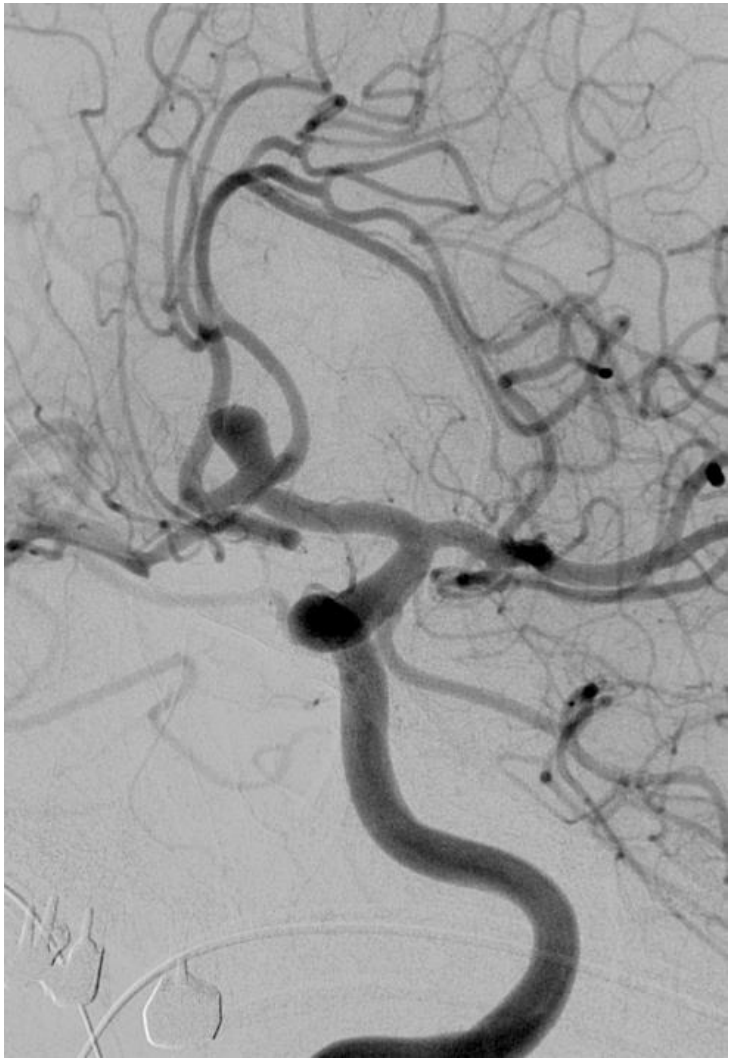
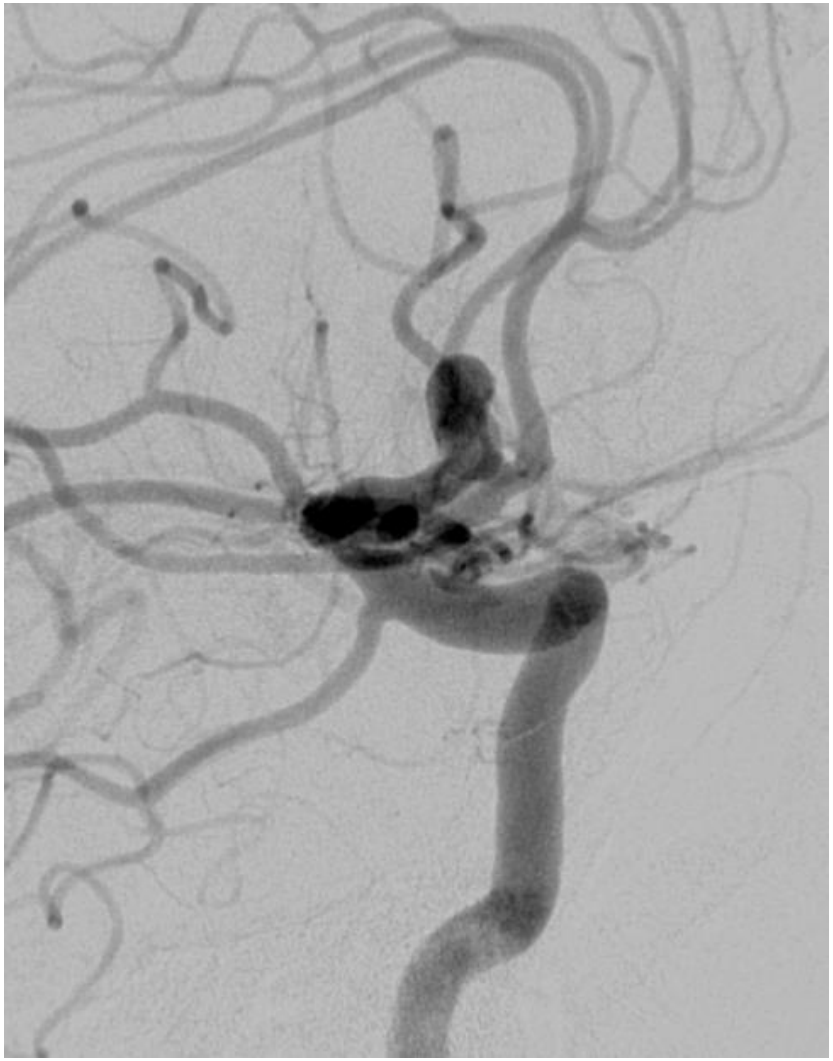
Anévrisme fortuit de l’AcoA
Occlusion chronique CID

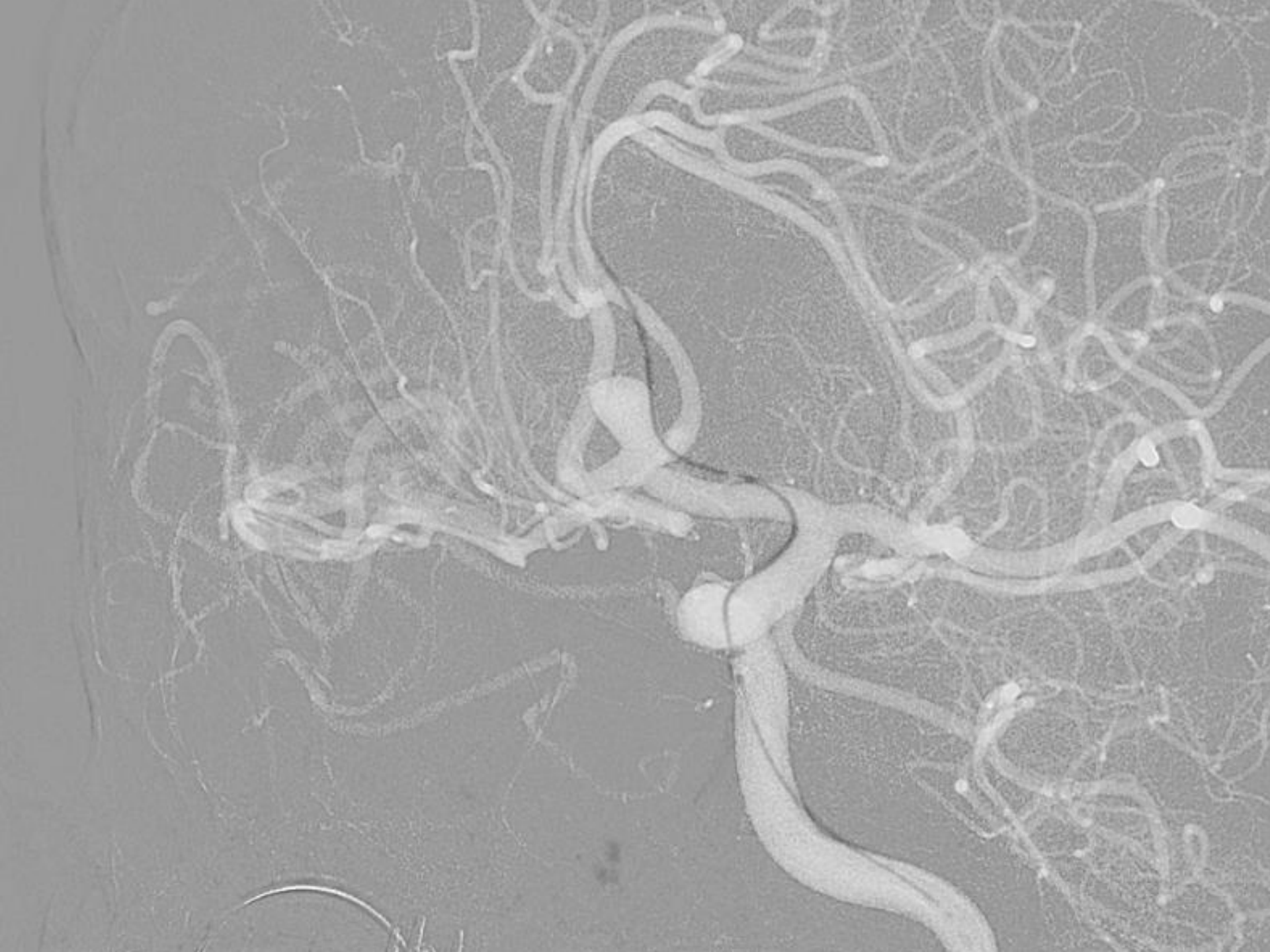

2
1
Quick Measurement 1 4.48 mm
Quick Measurement 2 6.73 mm

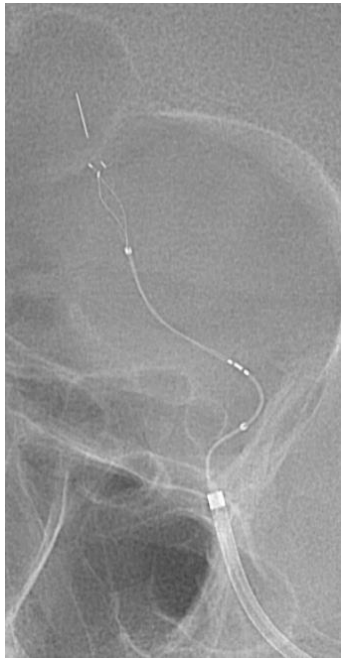
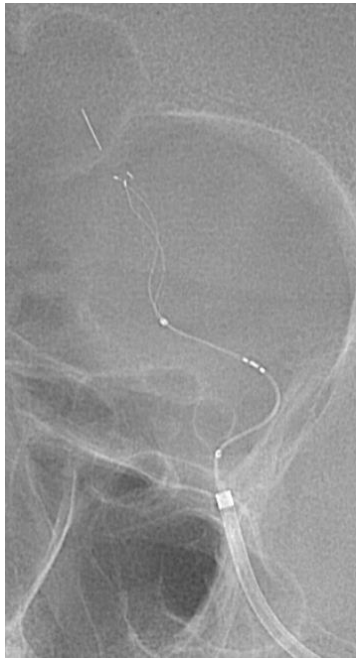
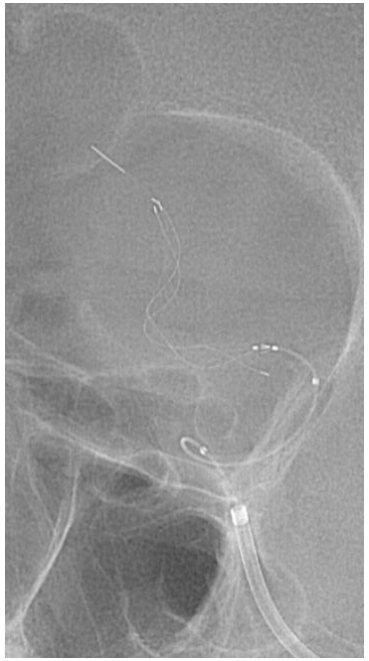
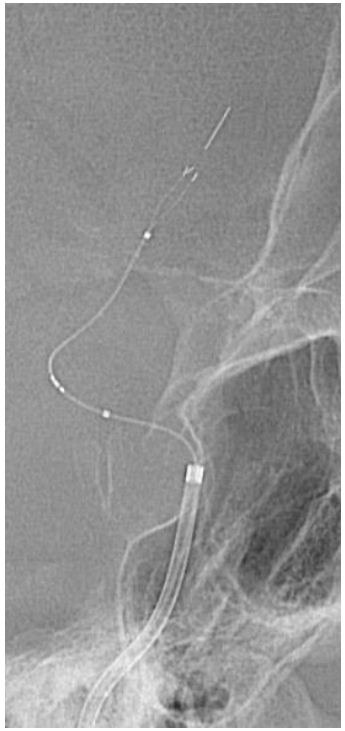
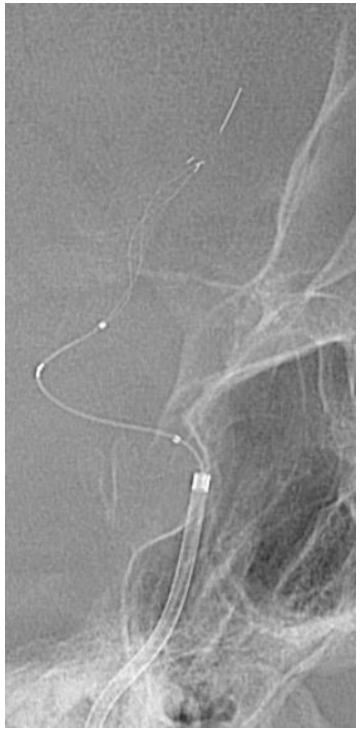
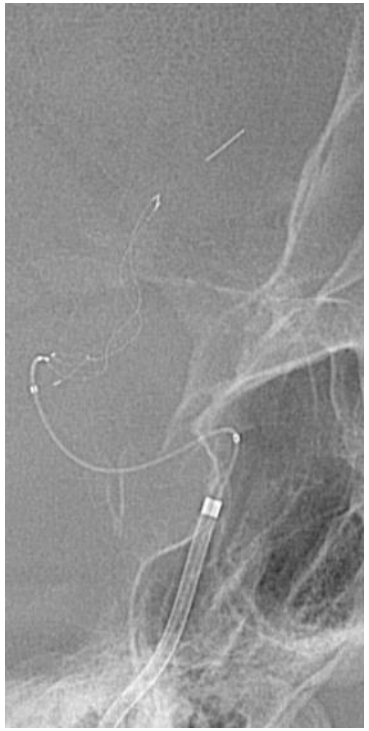

1
Quick Measurement 1 5.63 mm

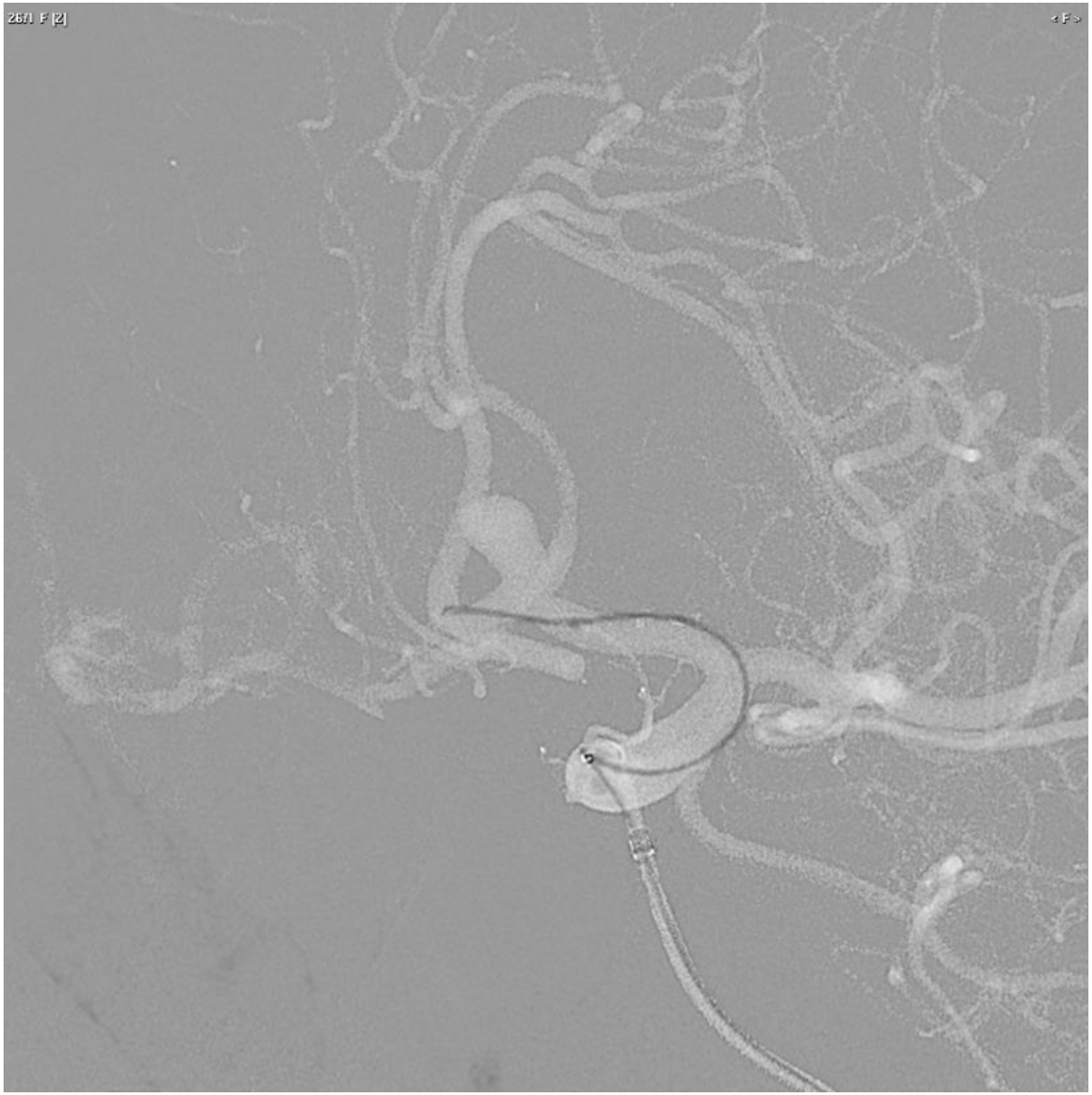

1
3
2
Quick Measurement 1 1.85 mm
Quick Measurement 2 2.71 mm
Quick Measurement 3 2.28 mm





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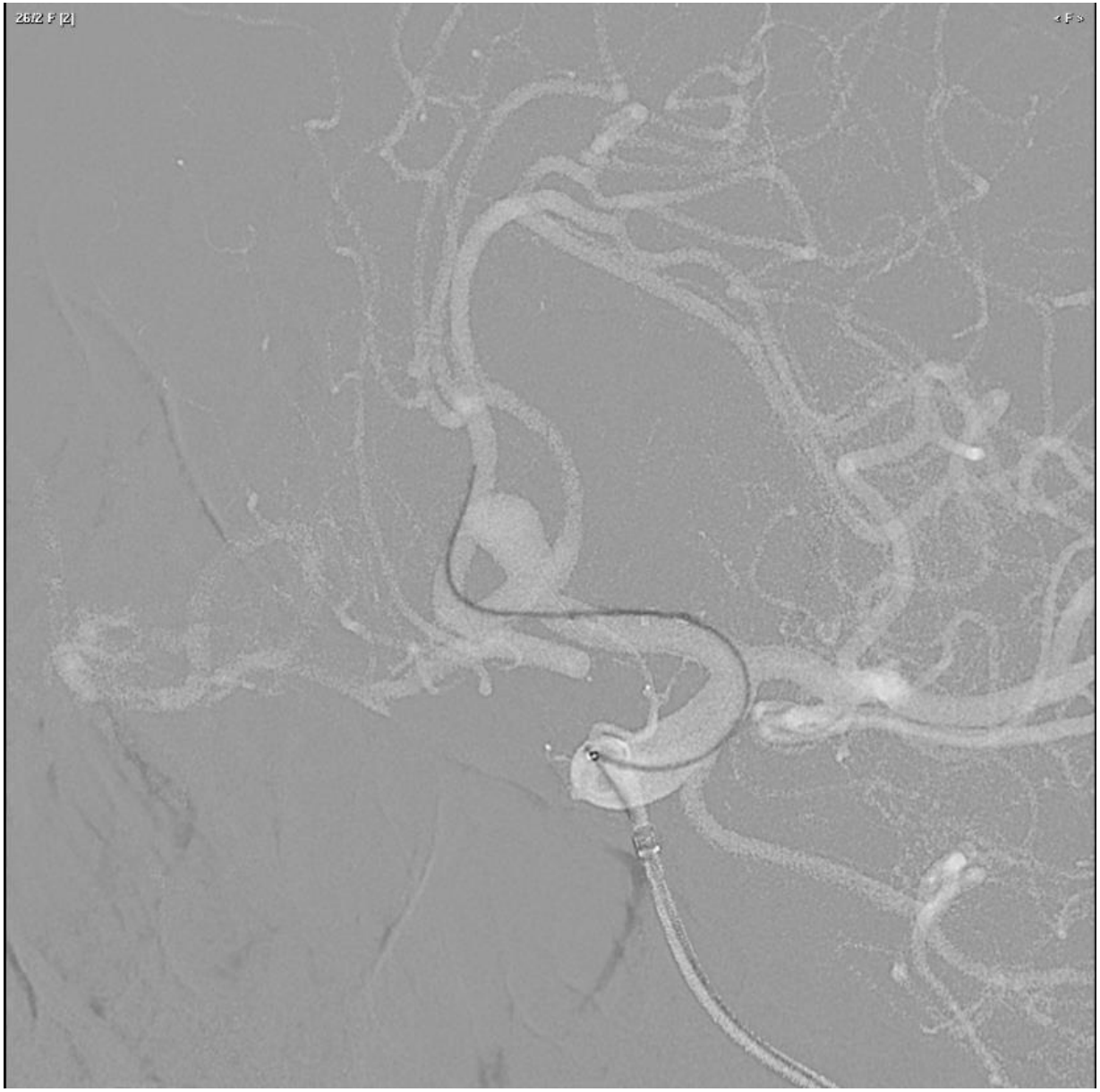
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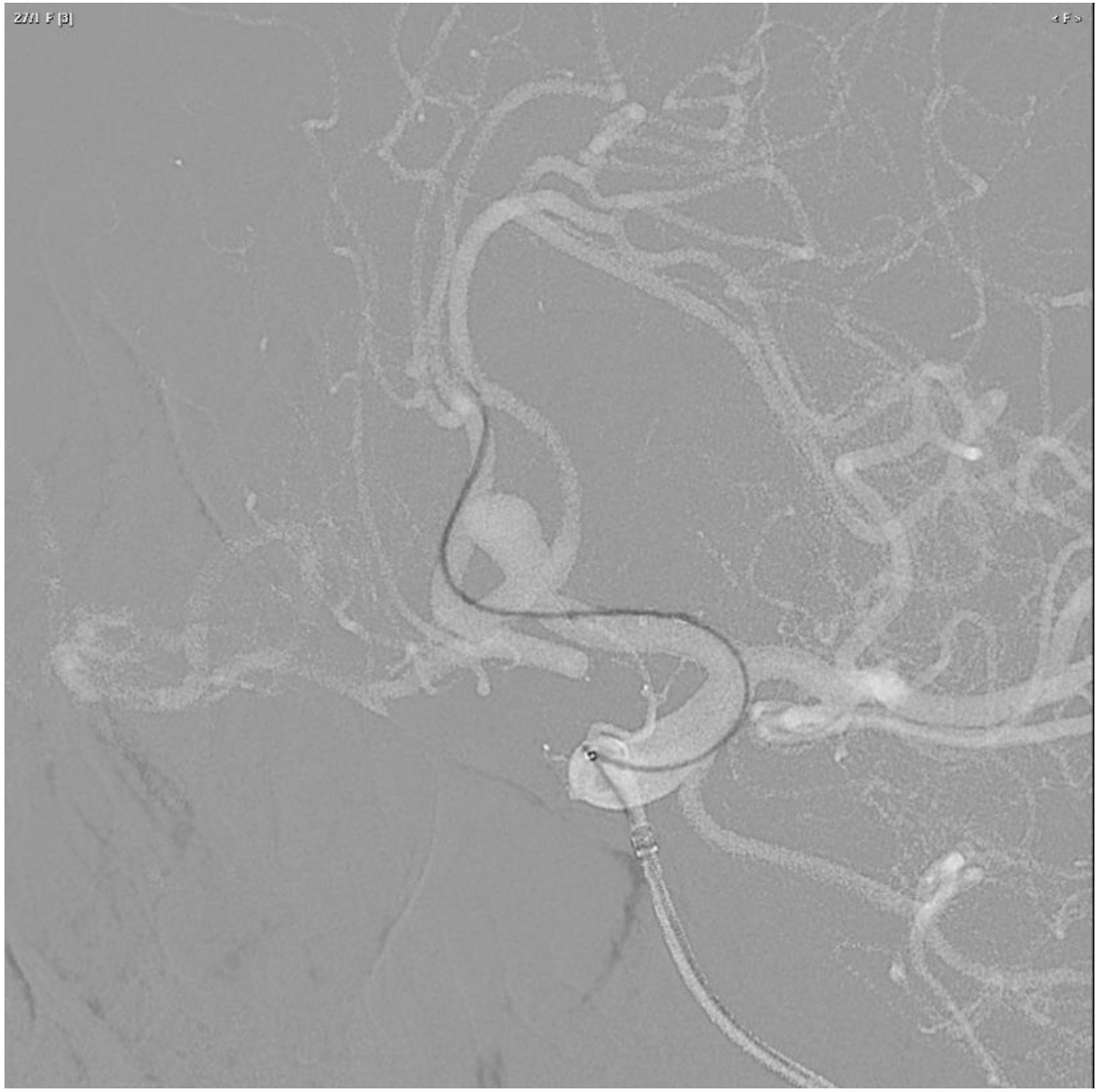
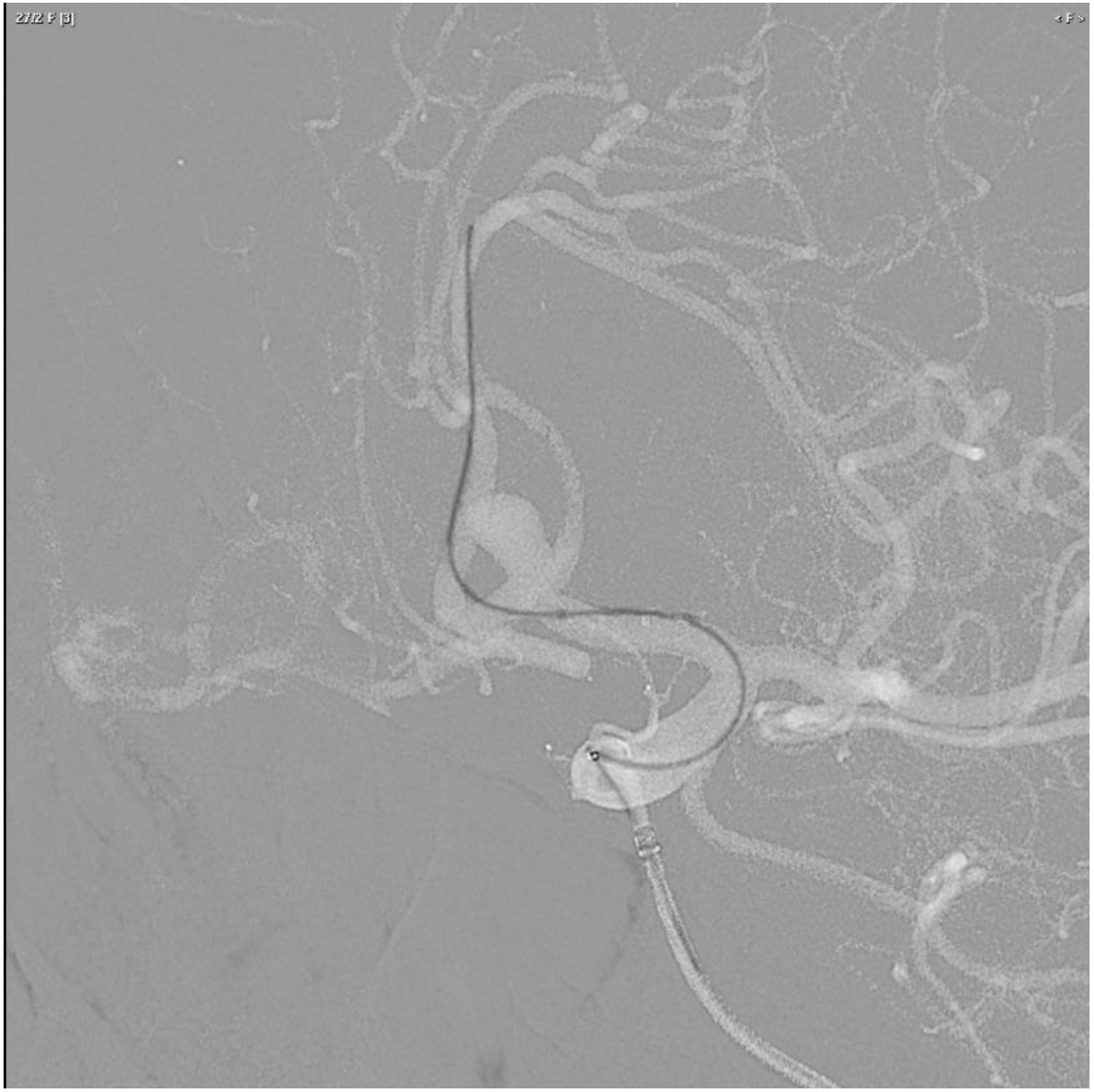
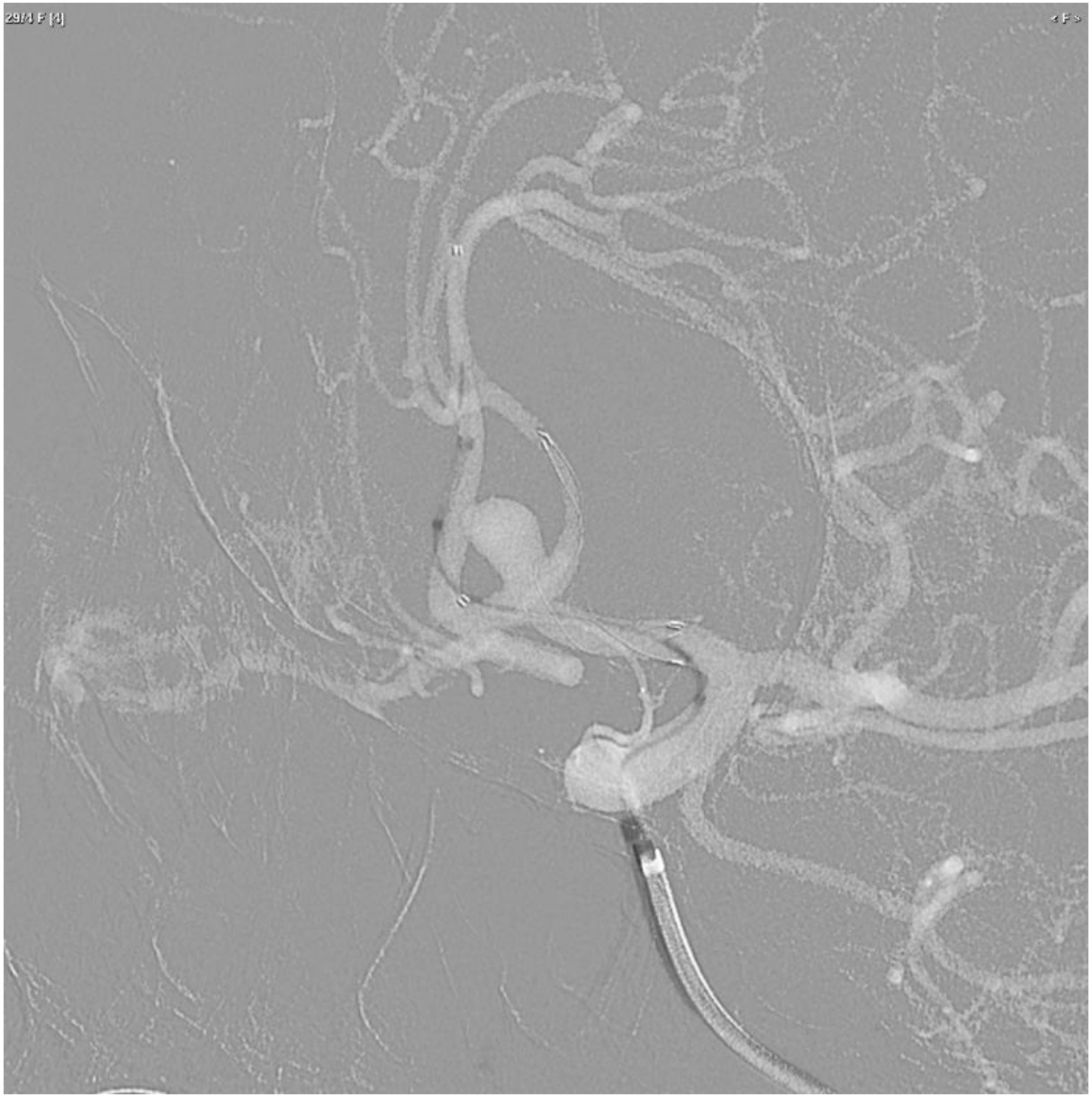
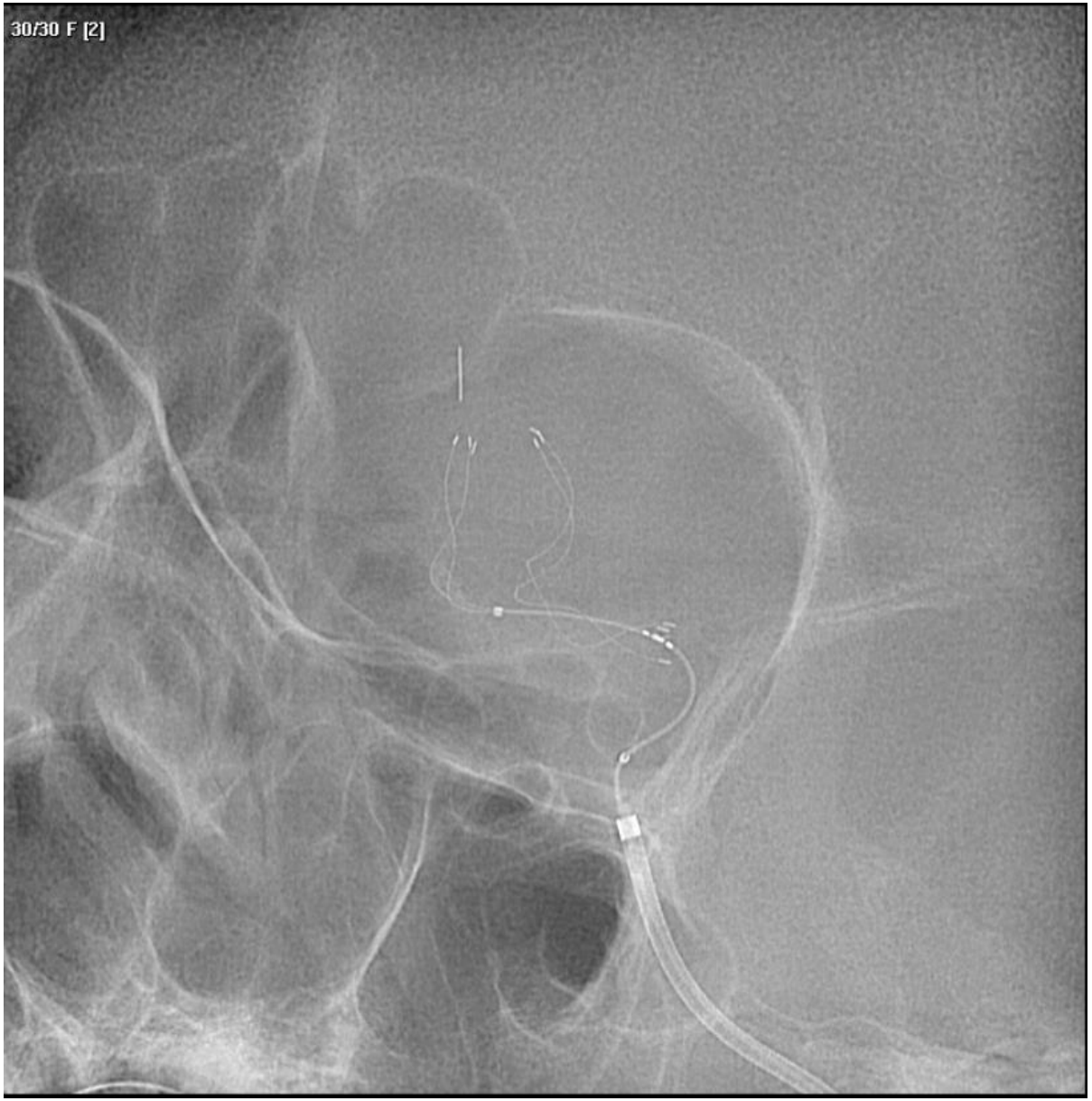

27/1 F [3]
◂ F ▸


27/2 F [3]
‹ F ›

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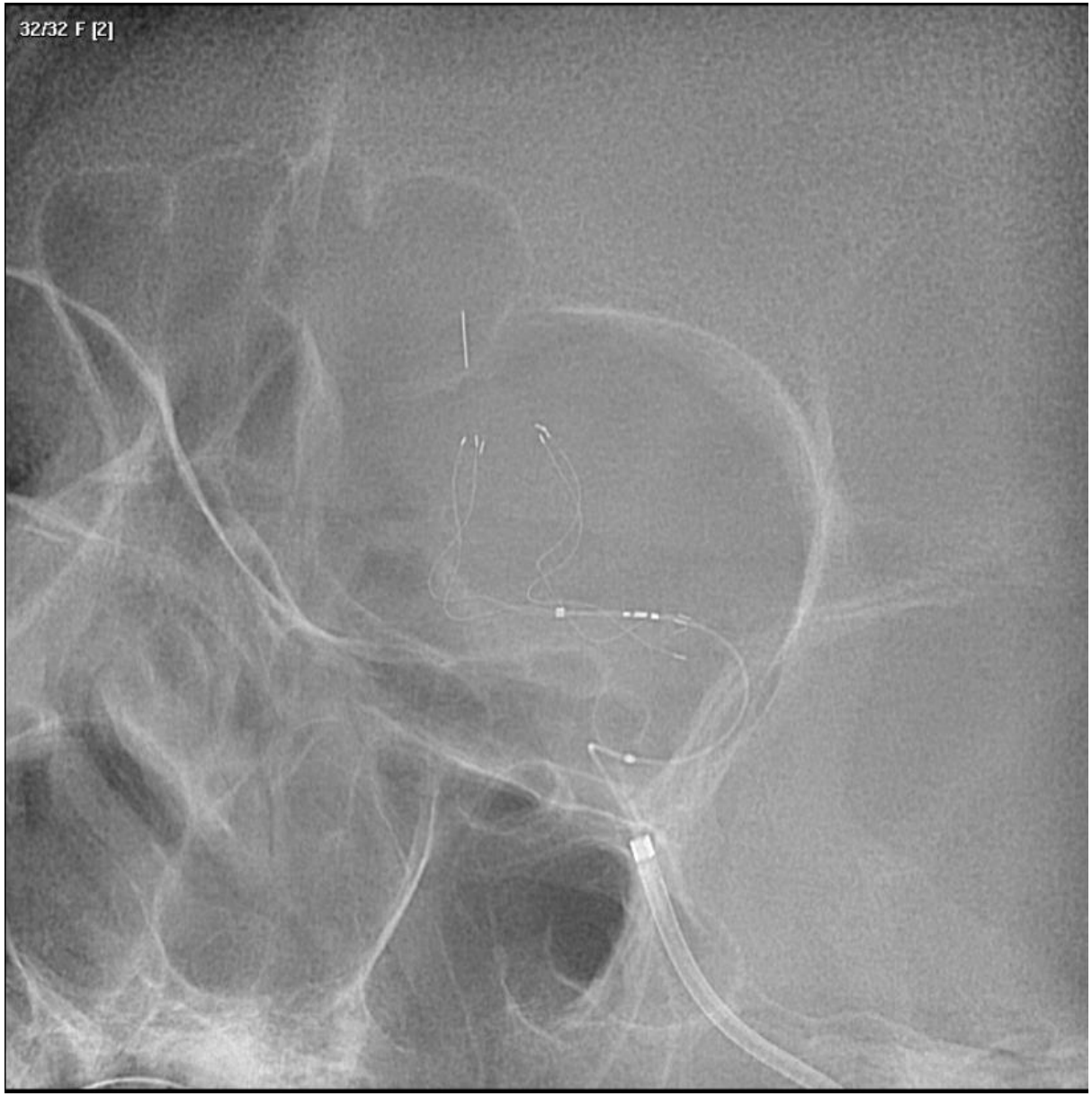
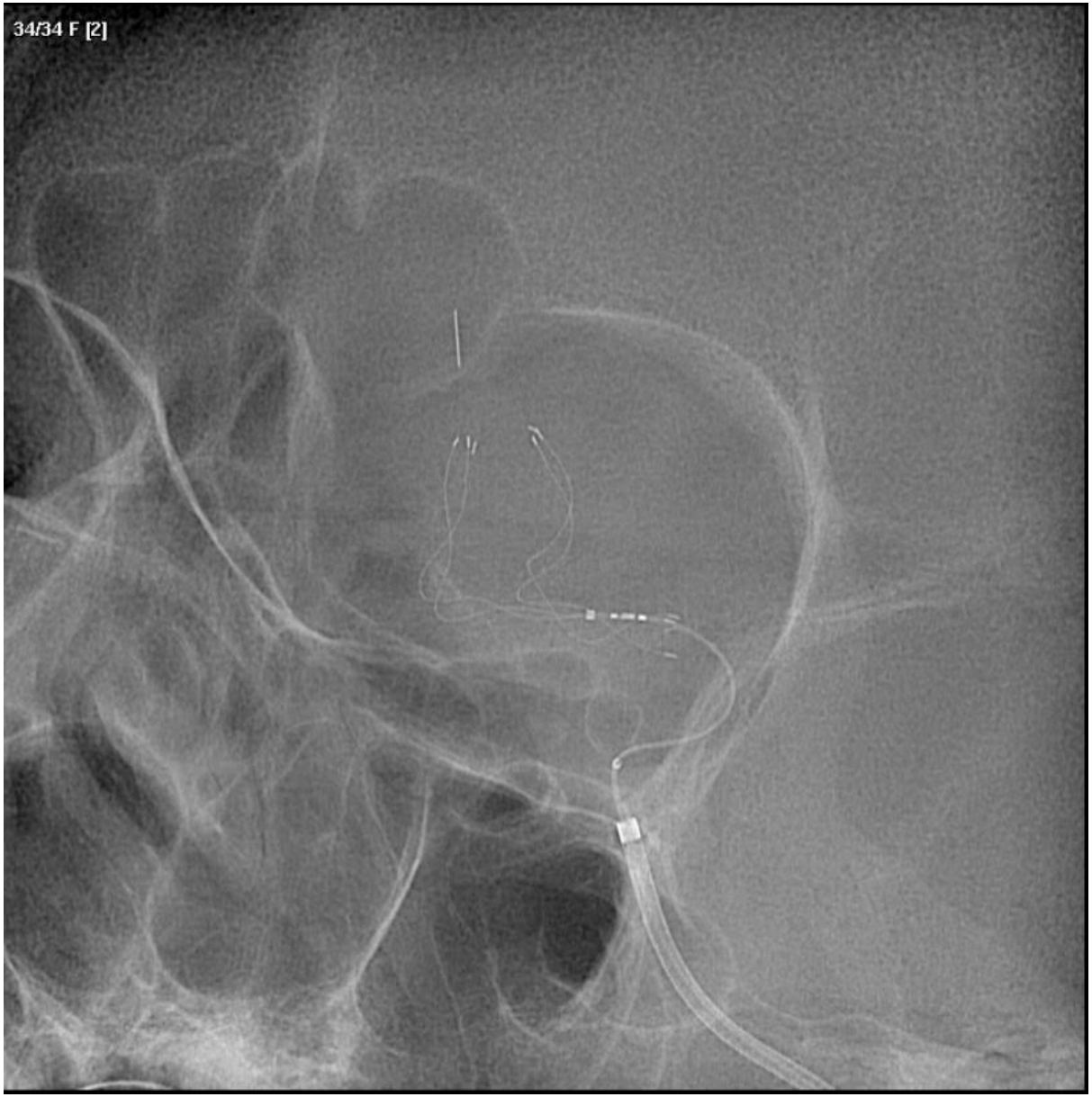
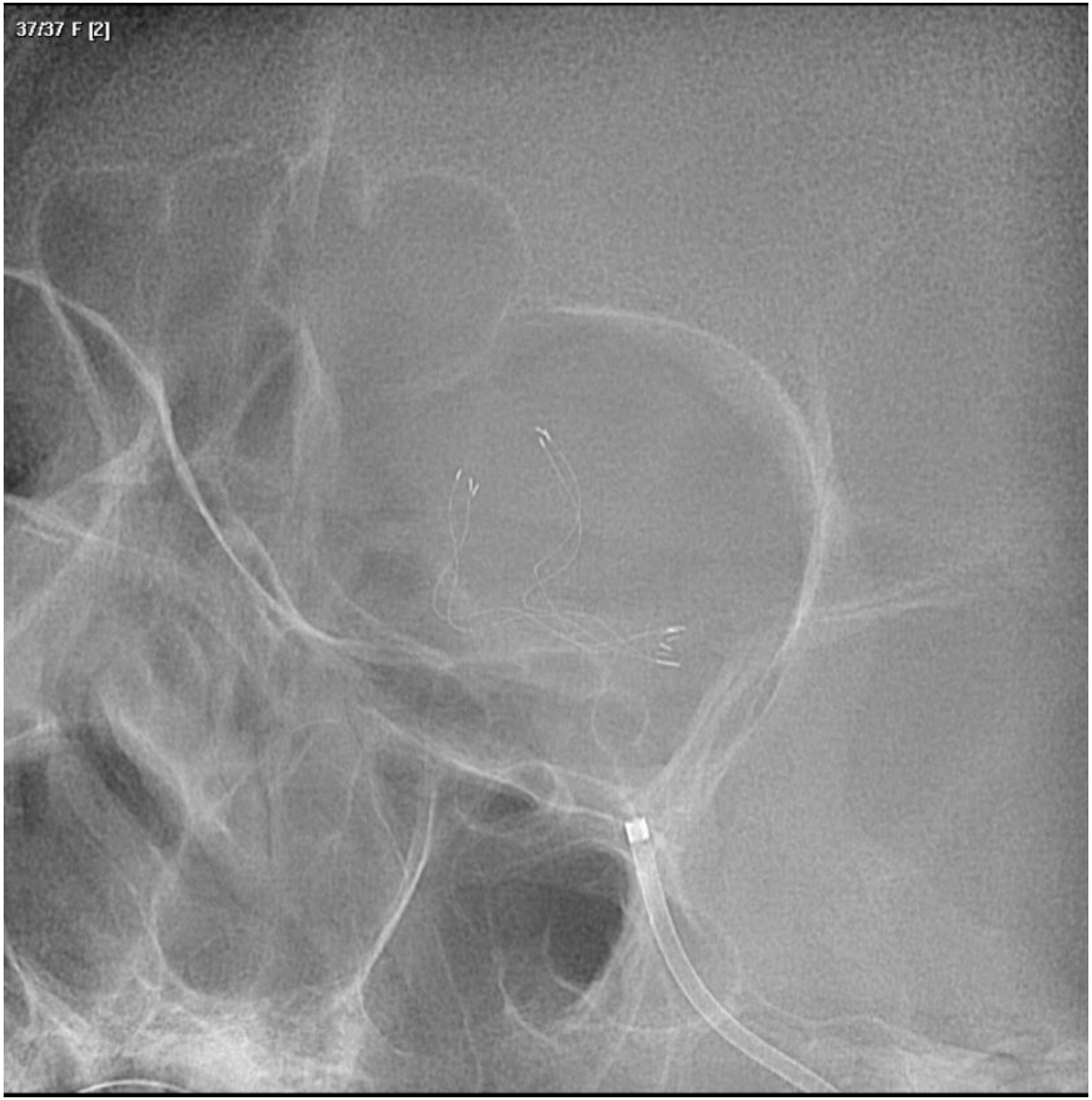
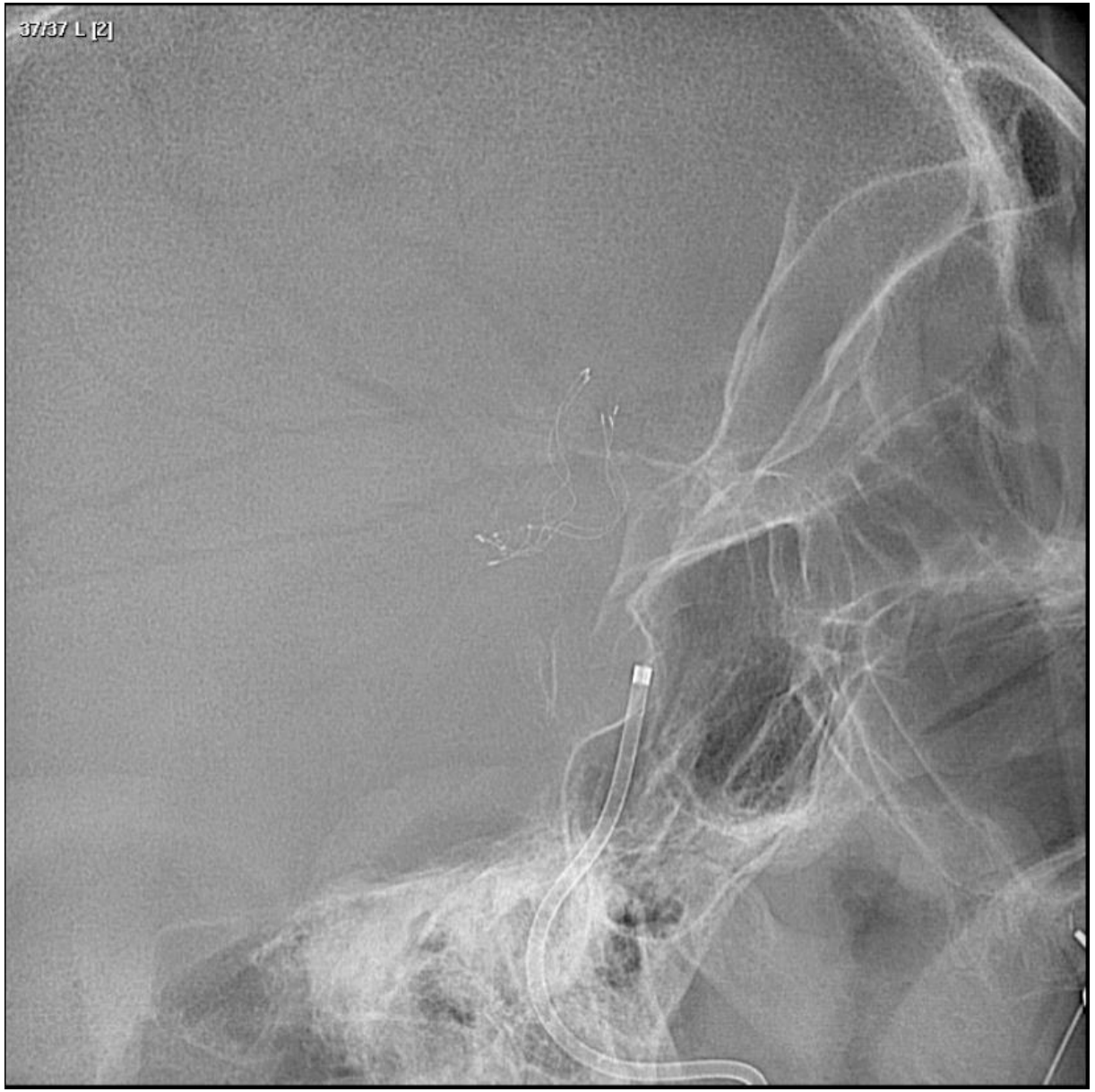
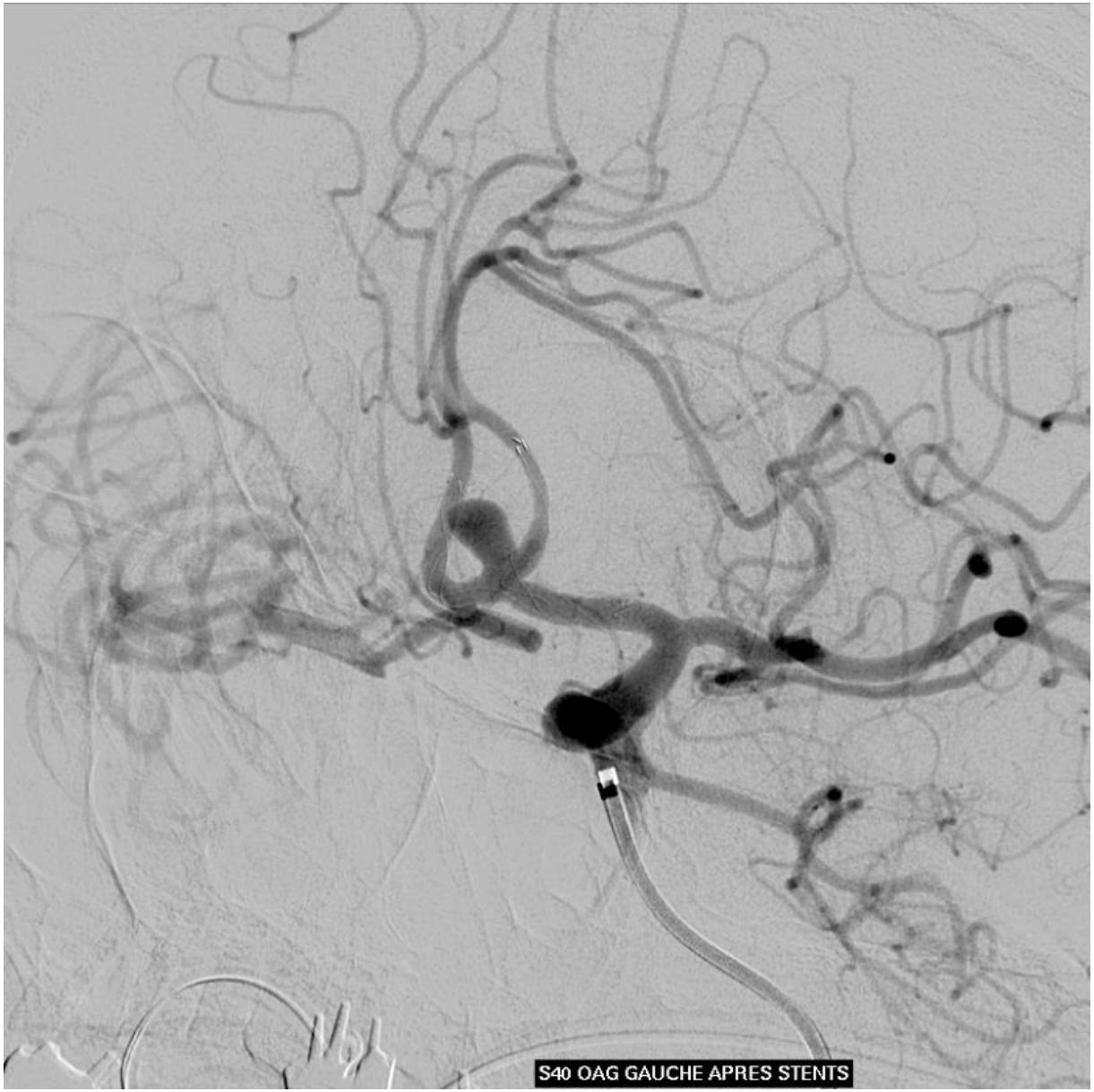
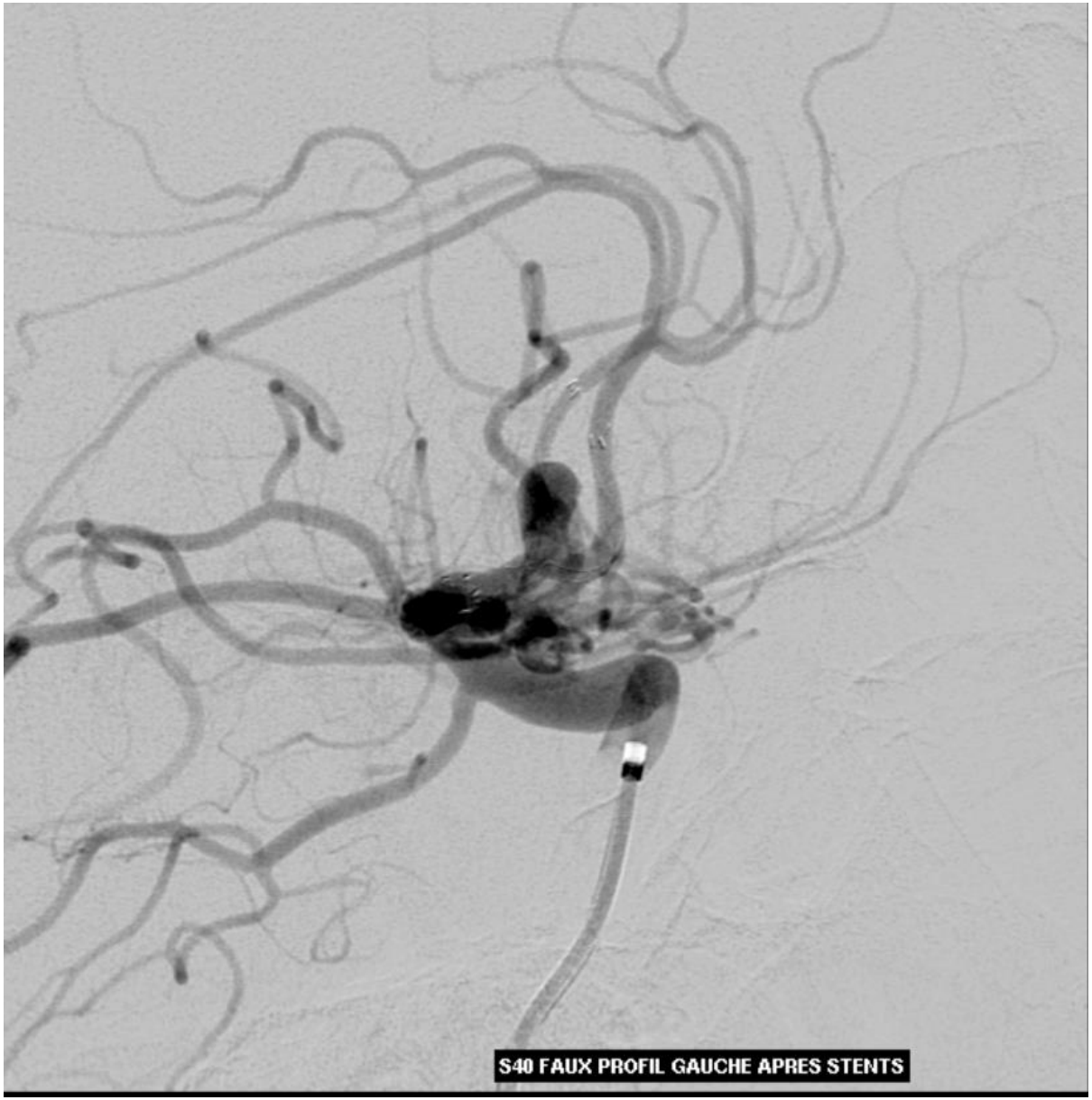

32/32 F [2]

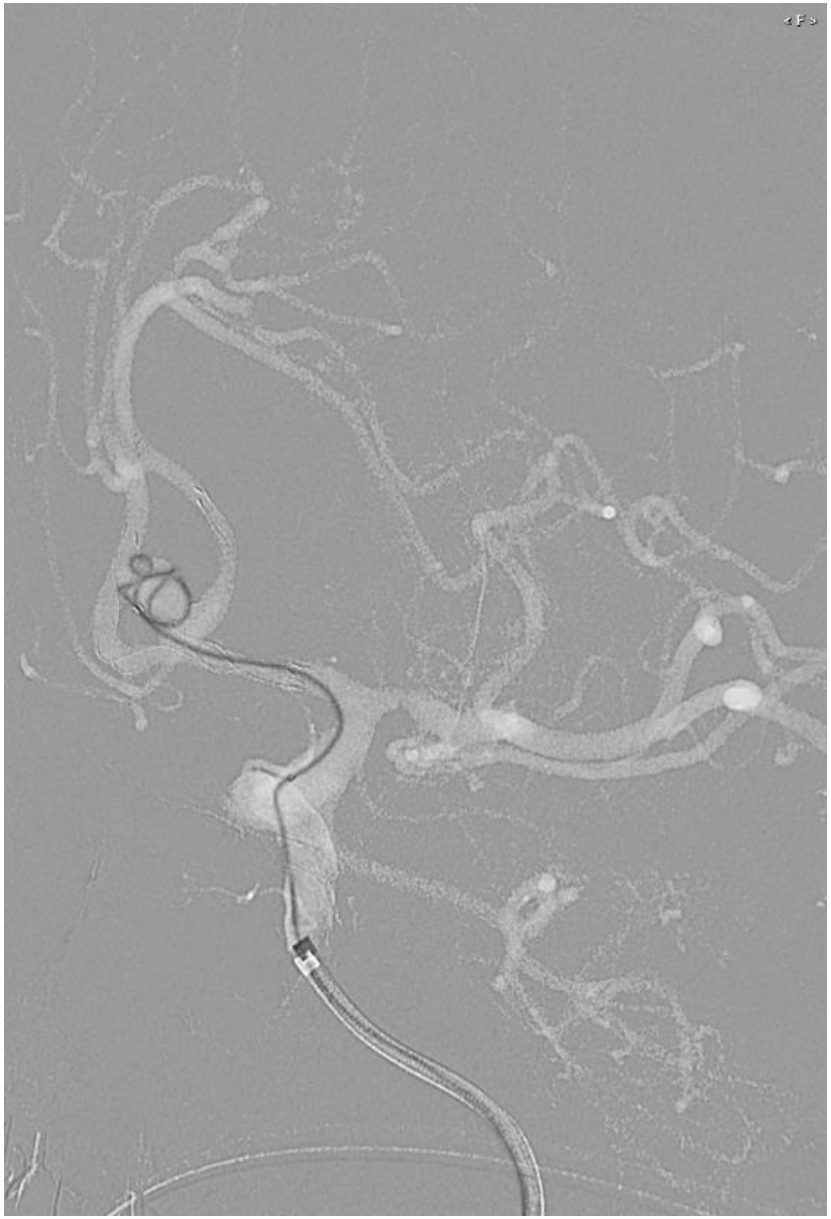

34/34 F [2]

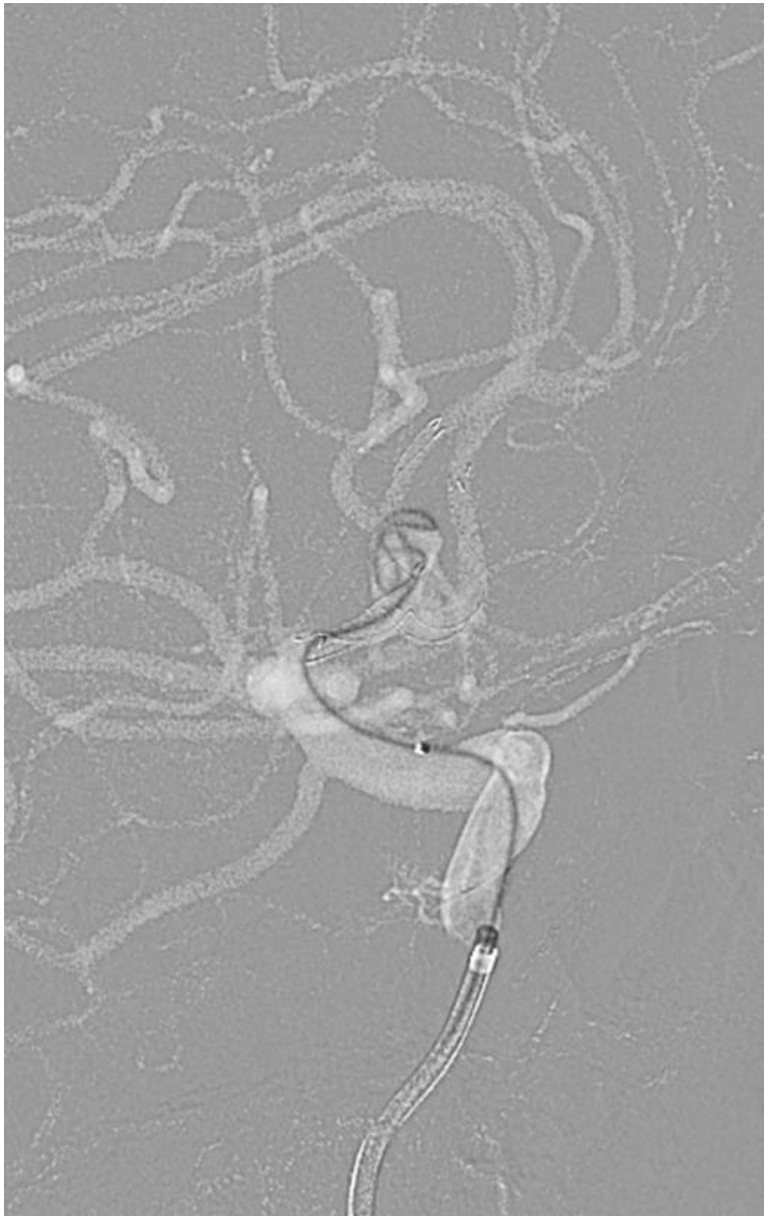

37/37 F [2]

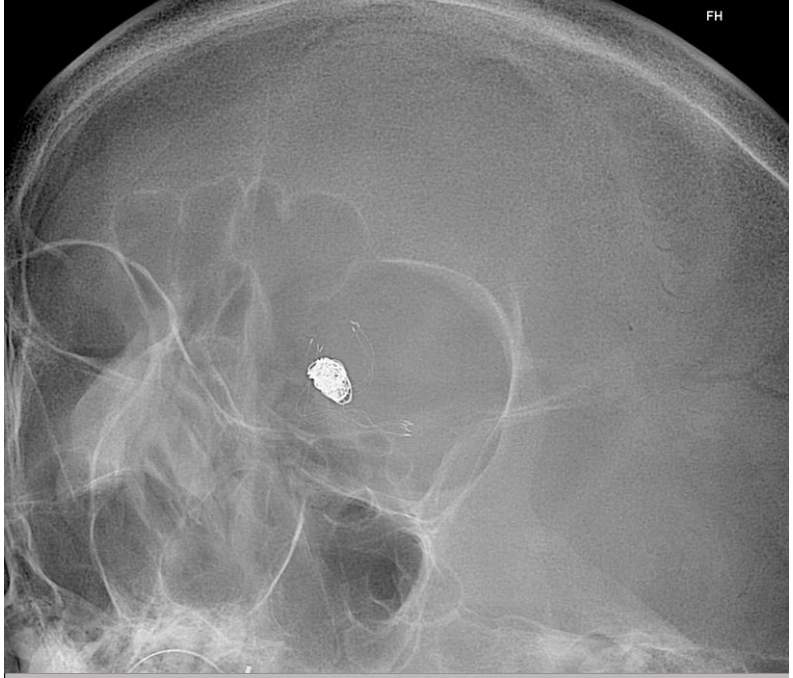

37/37 L [2]


S40 OAG GAUCHE APRES STENTS


S40 FAUX PROFIL GAUCHE APRES STENTS



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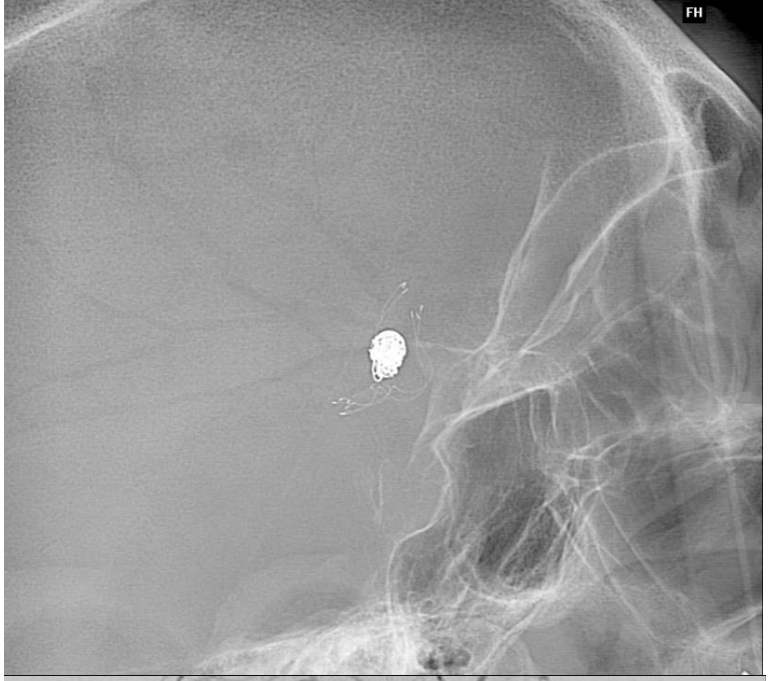
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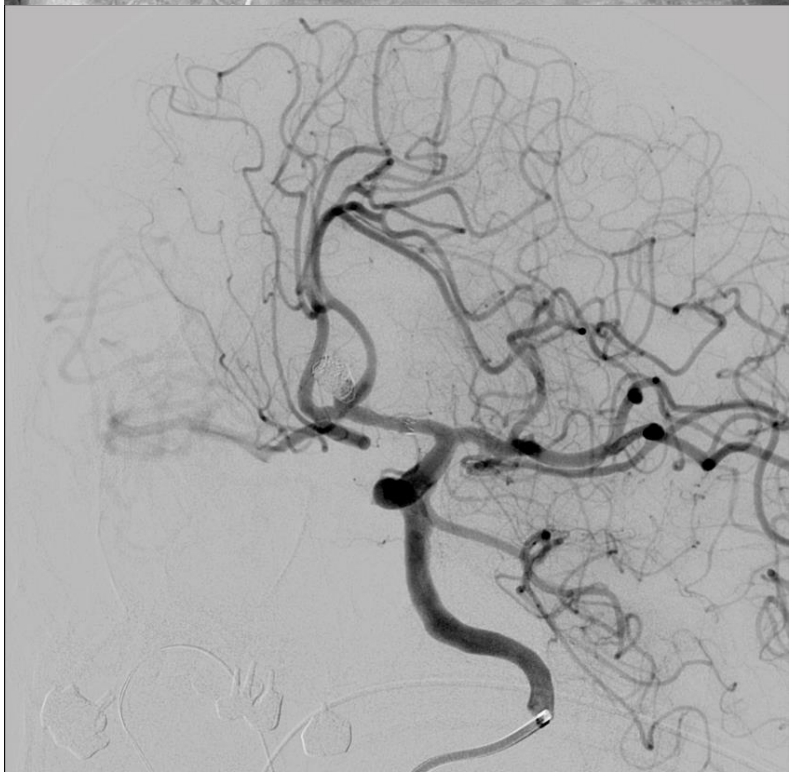
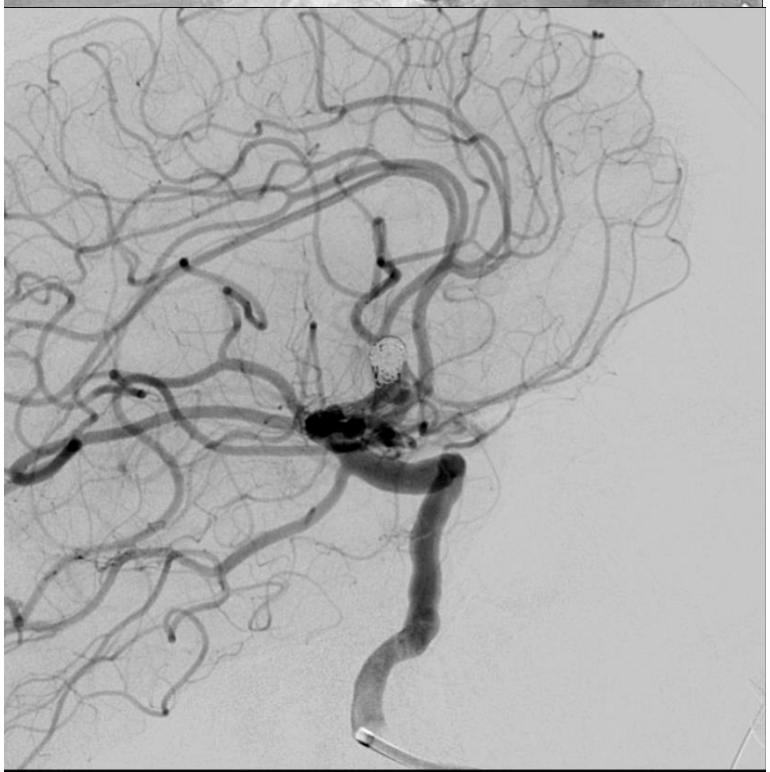
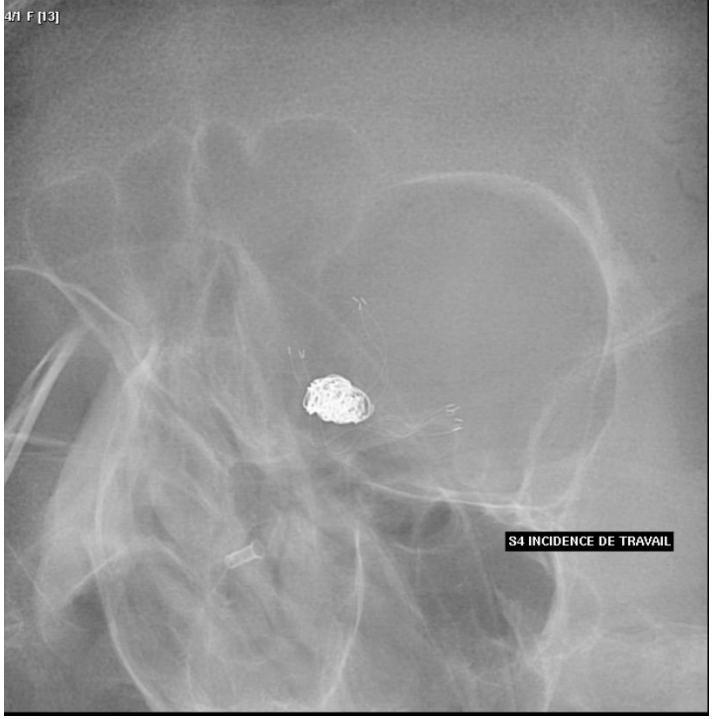
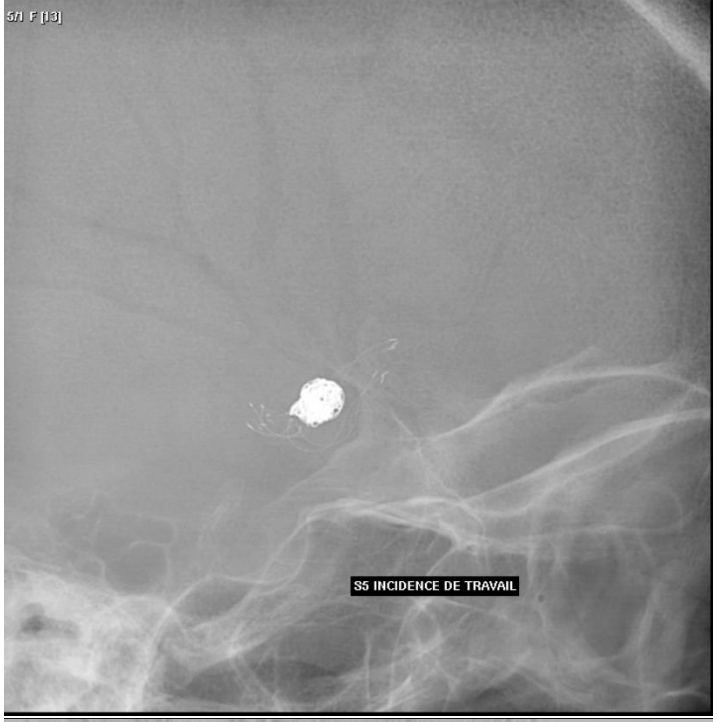
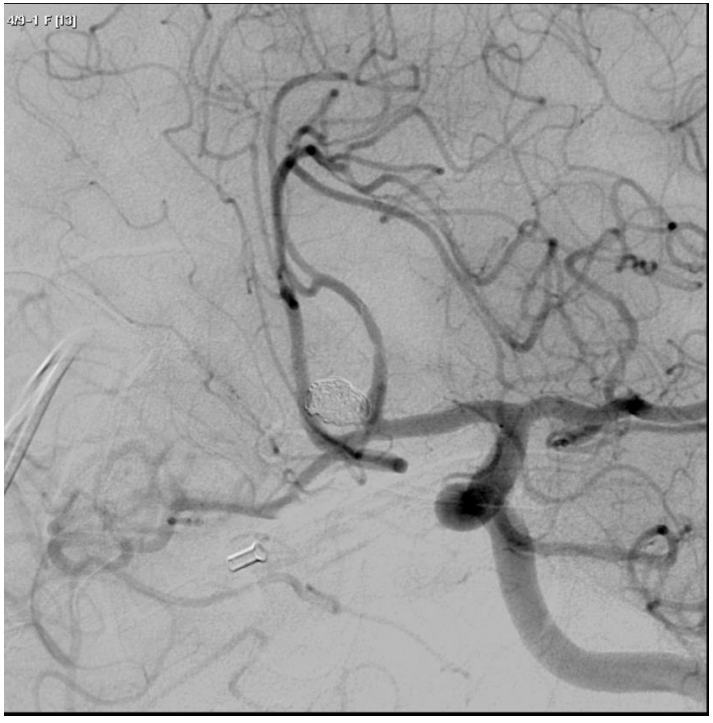
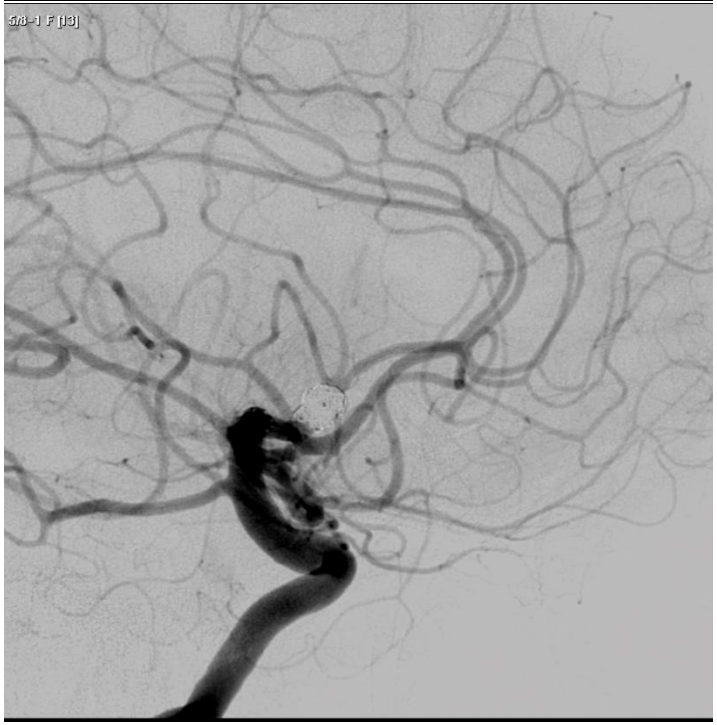





4/1 F [13]
S4 INCIDENCE DE TRAVAIL


5/1 F [13]
S5 INCIDENCE DE TRAVAIL


4/3-1 F [13]


5/3-1 F [13]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