ICCA STROKE 2019

»New generation of Neuroguard 3-in-1«

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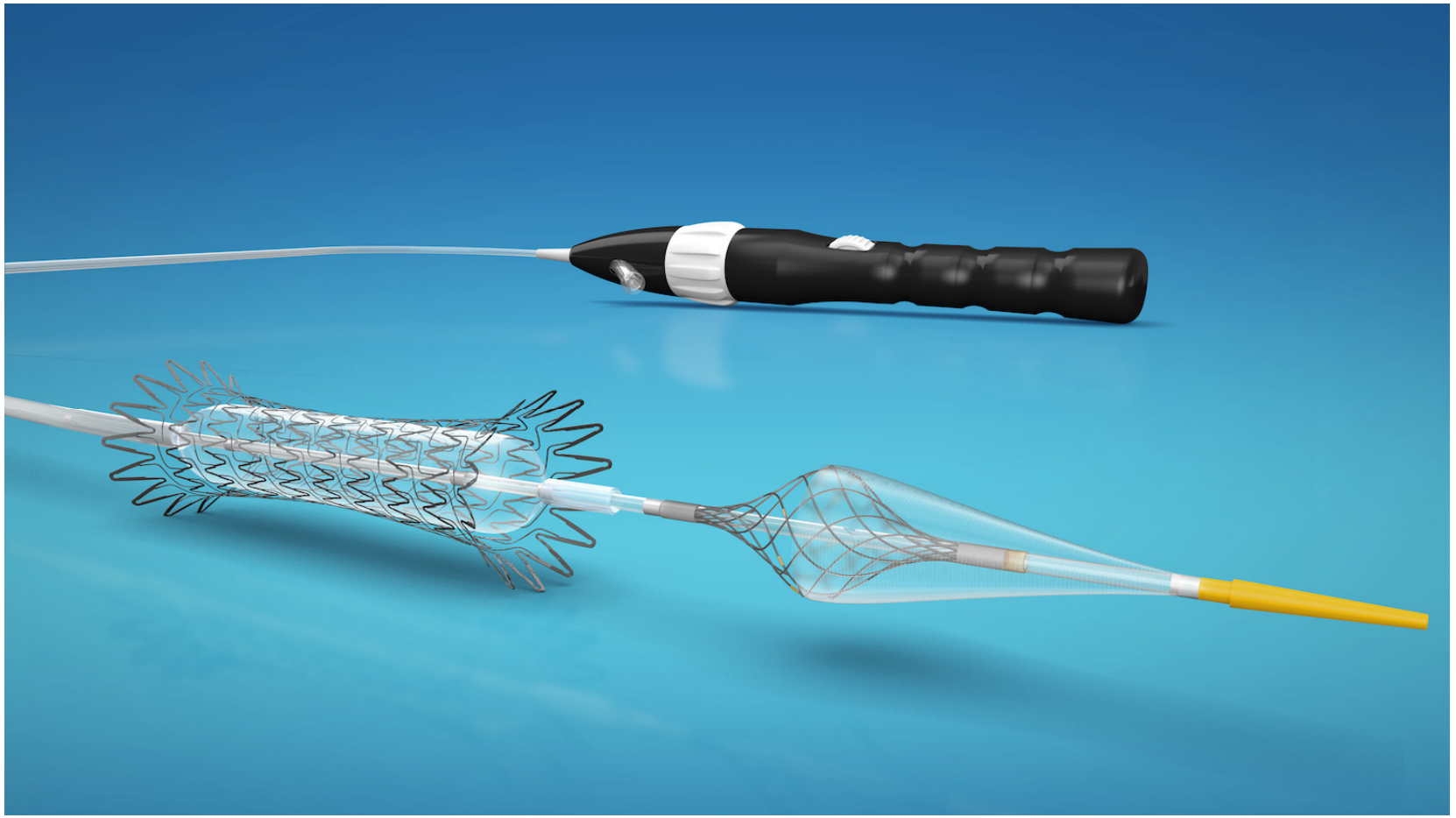
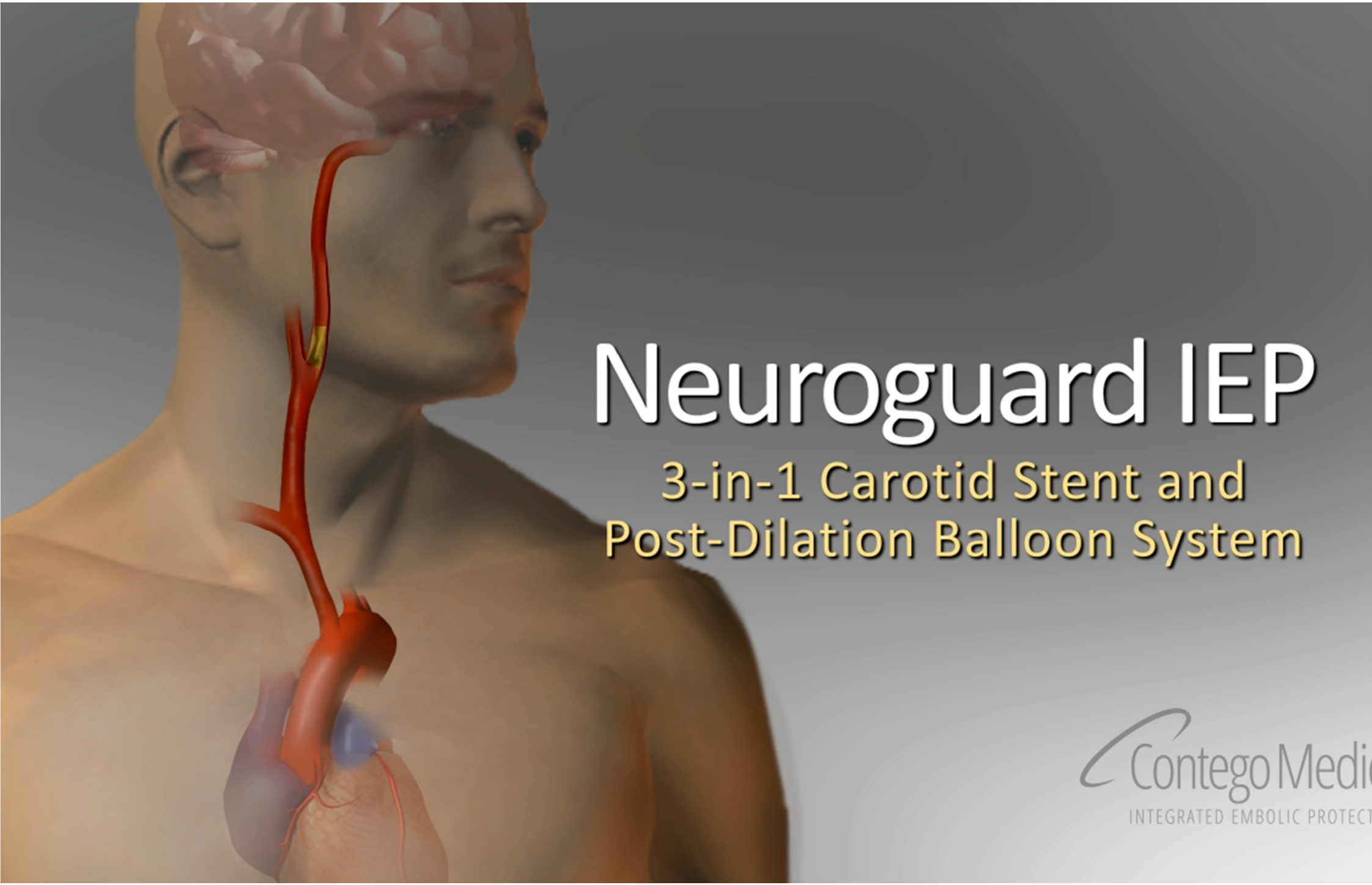
DISCLOSURE STATEMENT OF FINANCIAL INTEREST

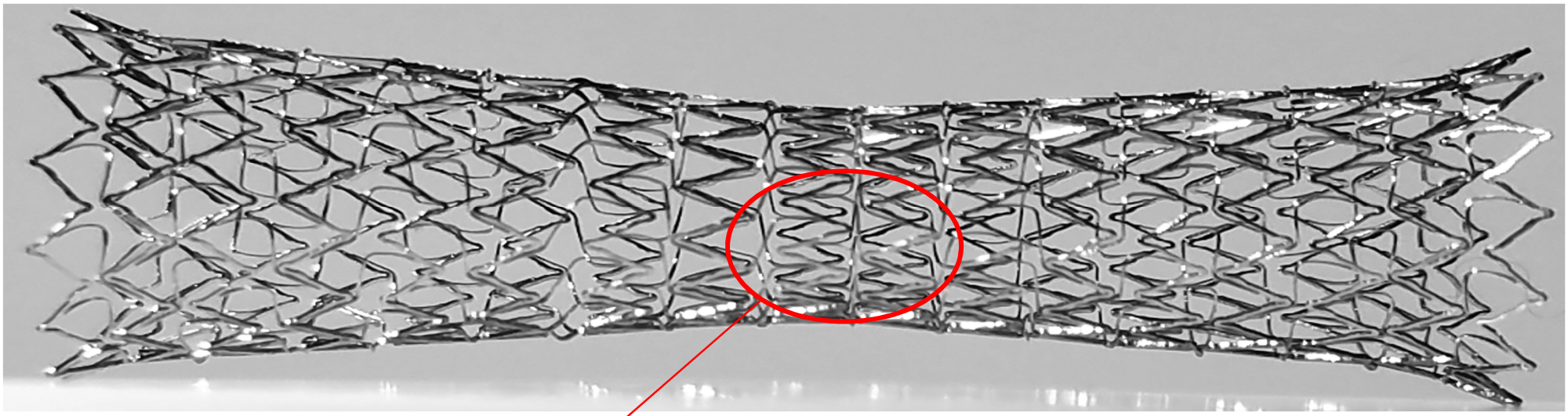
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

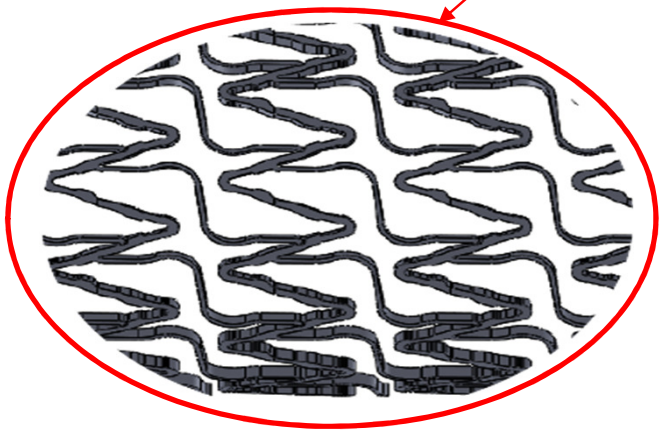
AFFILIATION/FINANCIAL RELATIONSHIP	COMPANY
• Consulting Fees/Honoraria	• Medtronic • Boston Scientific • Terumo • Contego

Neuroguard
3 in 1: Stent + PTA balloon + embolic protection



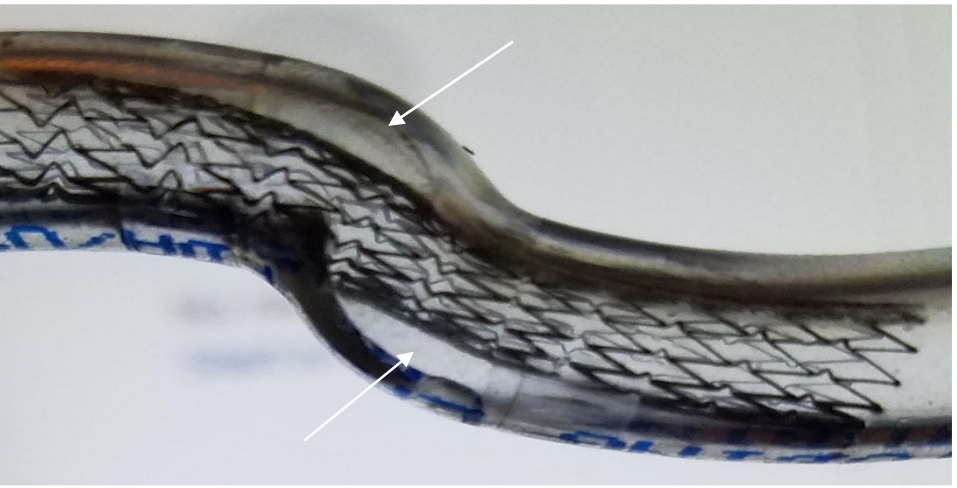

Neuroguard IEP
3-in-1 Carotid Stent and
Post-Dilation Balloon System
Contego Medi
INTEGRATED EMBOLIC PROTECT





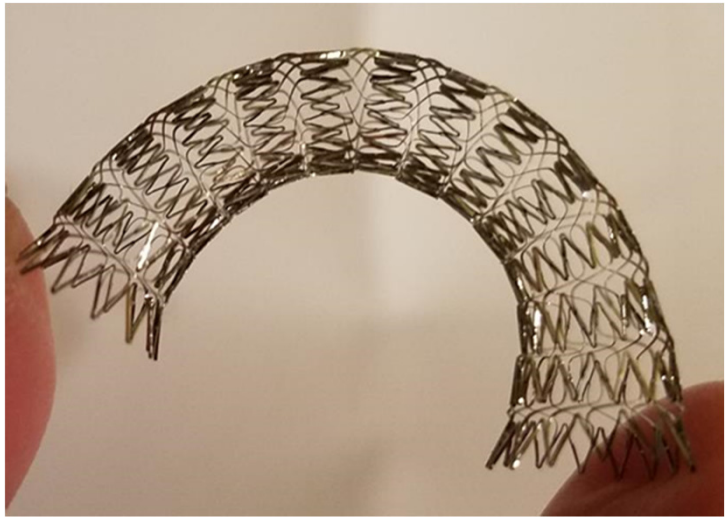
Stent Lengths (30, 40 mm)
Mid Stent OD (6, 7 mm)

Neuroguard Stent – Apposition / Flexibility



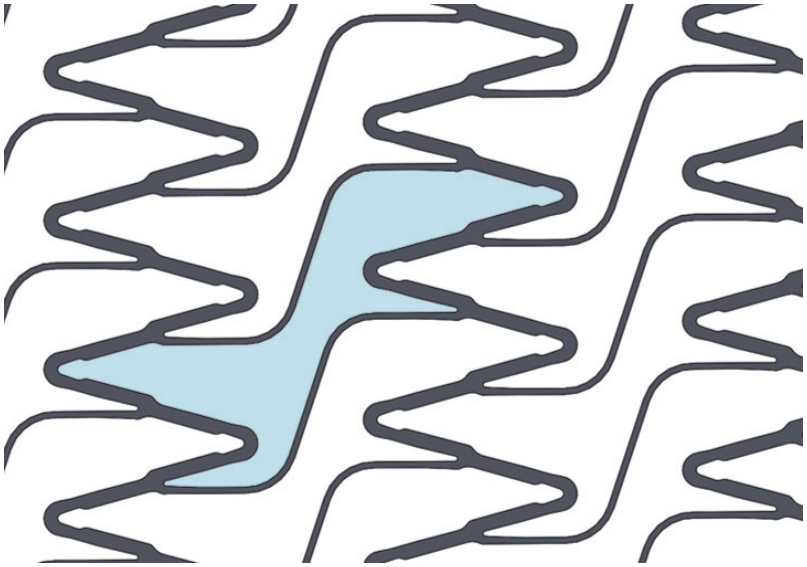
Abbott Xact Stent

Neuroguard

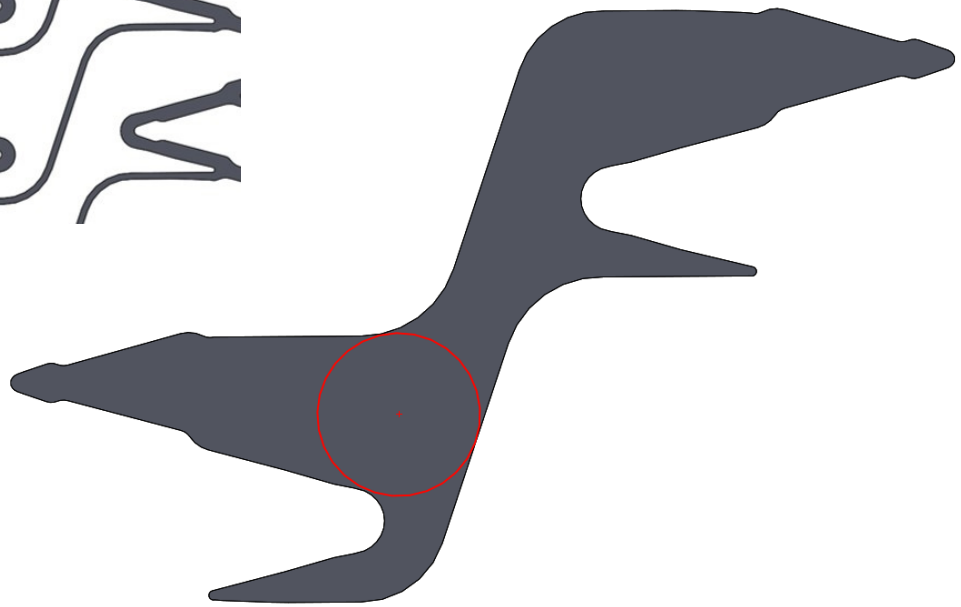


Neuroguard Flexibility

Stent Free Cell Area

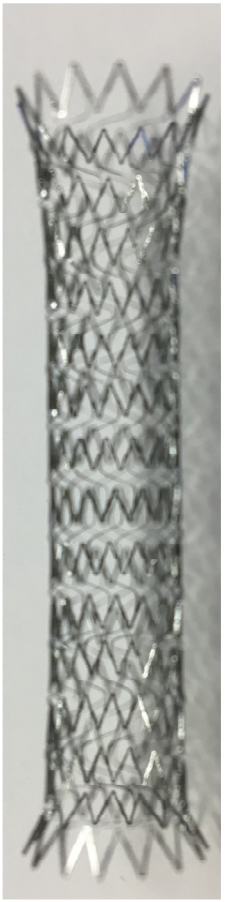


Unsupported Cell Area: 3.5 mm^2
Largest Inscribed Circle: 0.8 mm

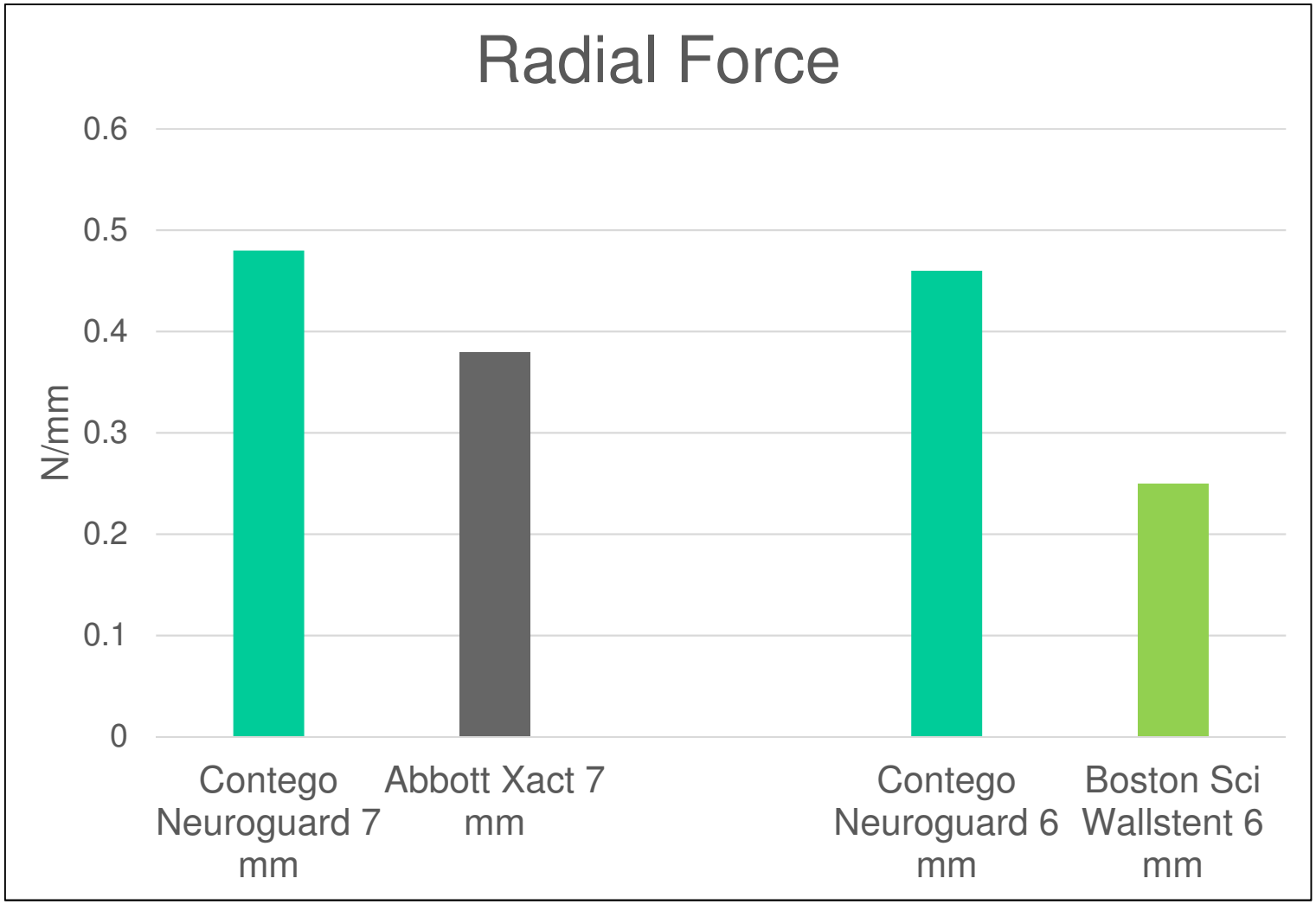


Stent Free Cell Area

Stent Type	Stent Design	Free Cell Area (mm^2)
Wallstent	Closed cell	1.08
Xact	Closed cell	2.74
Neuroguard	**Closed cell**	**3.5**
Nexstent	Closed cell	4.7
Precise	Open cell	5.89
Protégé	Open cell	20.71
Acculink	Open cell	11.48

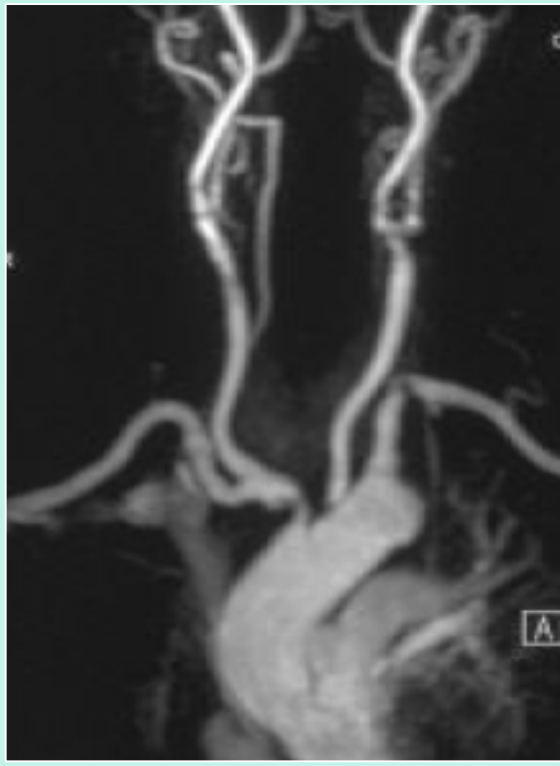


uroguard IEP Carotid Stent



Steps of Carotid Stenting

1. Vascular Access (femoral - brachial)
2. Angiographic evaluation
3. Guiding Sheath Placement
4. Crossing the Stenosis
   - without protection
   - with distal protection
   - with proximal protection
5. Lesion Predilatation
6. Removing the Balloon
7. Advancing the Stent
8. Stent Deployment
9. Removing the SDS
10. Advancing Postdilation Balloon
11. Removing Postdilation Balloon
12. Advancing the Filter Retrieval Catheter
13. Removal of Protection Device
14. Final Angiographic Control
15. Sheath removal/ Access Care



10 times crossing of the lesion

This can be reduced to 3 steps with Neuroguard IEP

PERFORMANCE I STUDY
INTERIM RESULTS 60 PATIENTS

- 84 Patients undergoing CAS
  - ASX – >80% stenosis
  - SX - >50% stenosis
- 64 patients enrolled, interim data available for 60 patients at 30 days and 25 patients at 6 months
- Pre-dilation as per operator
- Distal filter mandatory
- Femoral/radial/ulnar access

PERFORMANCE I STUDY –
NTERIM RESULTS 60 PATIENTS

tection against **E**mboli during carotid stenting using a 3-in-1 delivery system comp**R**ising o**F** a p**C**
tion balloon, integ**R**ated e**M**bolic filter **A**nd **N**ovel **C**arotid st**E**nt I

ntry	Principal Investigator	Hospital	Status
garia	Ivo Petrov, MD	Acibadem City Clinic, Sofia	23 patients
y	Alberto Cremonesi,MD (PI)	Maria Cecilia Hospital , Cotignola	2 patients
y	Eugenio Stabile, MD	University of Naples Frederico II, Naples	5 patients
many	Dierk Scheinert, MD	Universitätsklinikum Leipzig, Leipzig	3 patients
many	Ralf Langhoff, MD	Sankt Gertrauden Krankenhaus, Berlin	6 patients
many	Joachim Schofer, MD	Medizinische Versorgungszentrum, Hamburg	1 patient
many	Horst Sievert, MD	Sankt Kathariene Krankenhaus, Frankfurt	3 patients
edonia	Sasko Kedev, MD	University Clinic of Cardiology, Skopje	12 patients
venia	Zoran Milosevic, MD	MC Medicor, Izola	5 patients
l Patients Enrolled **n 30 day follow-up**			60 patients

patients have completed 30 day follow up
patients have completed 6 month follow up

PERFORMANCE I STUDY

Baseline Demographics	n = 60
Age at time of enrollment, mean ± SD (range)	69.1 ± 9.01 (45 – 85)
Male, % (n)	73.3 (44)
BMI, mean (SD)	27.41 ± 4.68
Diabetes mellitus, % (n)	36.7 (22)
COPD, % (n)	18.3 (11)
Renal impairment, % (n)	8.3 (5)
Hyperlipidemia % (n)	80.0 (48)
Hypertension, % (n)	93.3 (56)
Smoking history	63.3 (38)
Previous, % (n)	42.1 (16)
Current, % (n)	57.9 (22)
Prior PVD, % (n)	28.3 (17)
Carotid endarterectomy	1.7 (1)
Percutaneous carotid intervention, contralateral	11.7 (7)
Coronary artery disease	53.3 (32)
Myocardial Infarction	15.0 (9)
Known left ventricular dysfunction (EF < 49%)	1.7 (1)
Hx of TIA or Stroke	18.3 (11)

PERFORMANCE I STUDY

Procedural Characteristics n = 60	%
Lesion side, %	
Left	53.3 (32)
Right	46.7 (28)
Target lesion location, %	
ICA	73.3 (44)
ICA + Bifurcation	26.7 (16)
Target lesion length (mm), mean, SD	18.06 ± 7.83
Target lesion characteristics	
Eccentric	36.7 (22)
Concentric	60.0 (36)
Calcification	16.7 (10)
Ulceration	13.3 (8)
Target lesion stenosis (%), mean, SD	81.4 ±10.8
Target vessel reference diameter (mm), mean, SD (Minimum, Maximum)	5.47 ± 0.84 (4.1 – 8.0)
Filter landing zone vessel diameter (mm), mean, SD (Minimum, Maximum)	4.85 ± 1.17 (2.0 – 8.0)
Procedural arterial access site, % (n)	
Right Femoral	68.3 (41)
Right Radial	28.3 (17)
Left Femoral	3.3 (2)

PERFORMANCE I STUDY

Procedural Details n = 60	%
Procedural Success	100
Primary EPD type, %	
Distal embolic protection	98.3
Proximal embolic protection	1.67 (n=1)
Primary EPD used, %	
Emboshield® NAV 6	
FilterWire EZ ™	
Mo.Ma Ultra®	1.67 (n=1)
SpiderFX®	
Pre-dilation before Neuroguard placement, %	31.7
Neuroguard Filter successfully deployed, %	100
Neuroguard Stent successfully deployed at target lesion, %	100
Post-dilation with integrated Neuroguard angioplasty balloon, %	100
Dissection %	0
Second stent used in procedure, %	1.67 (n=1)

PERFORMANCE I STUDY – 30 Day Outcomes, n=60

Primary Endpoint	Total
Death	0
Stroke	0
Major	0
Minor	0
Myocardial Infarction*	1 (1.67%)
Total Death/Stroke/MI at 30 days	1 (1.67%)
Total Death/Stroke at 30 days	**0**

*One patient has a NSTEMI day 17 after CAS, discharged home without complications

PERFORMANCE I STUDY – 6 Month Outcomes, n=25

Primary Endpoint	Total
Neurological Death	0
Ipsilateral Stroke	0
Major	0
Minor	0
Total Neurological Death/Ipsilateral Stroke at 6 Months	**0**

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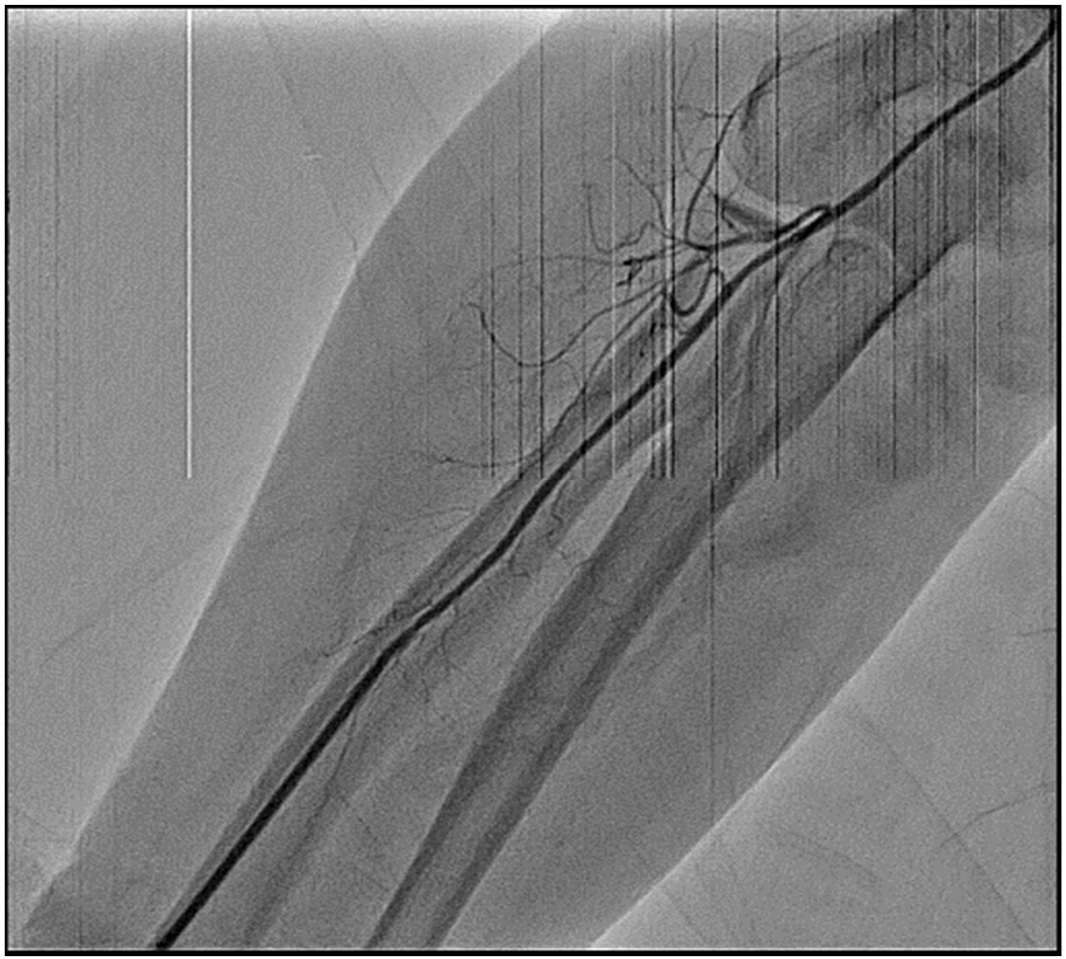
RRA CAS of LICA with Neuroguard IEP

K.J

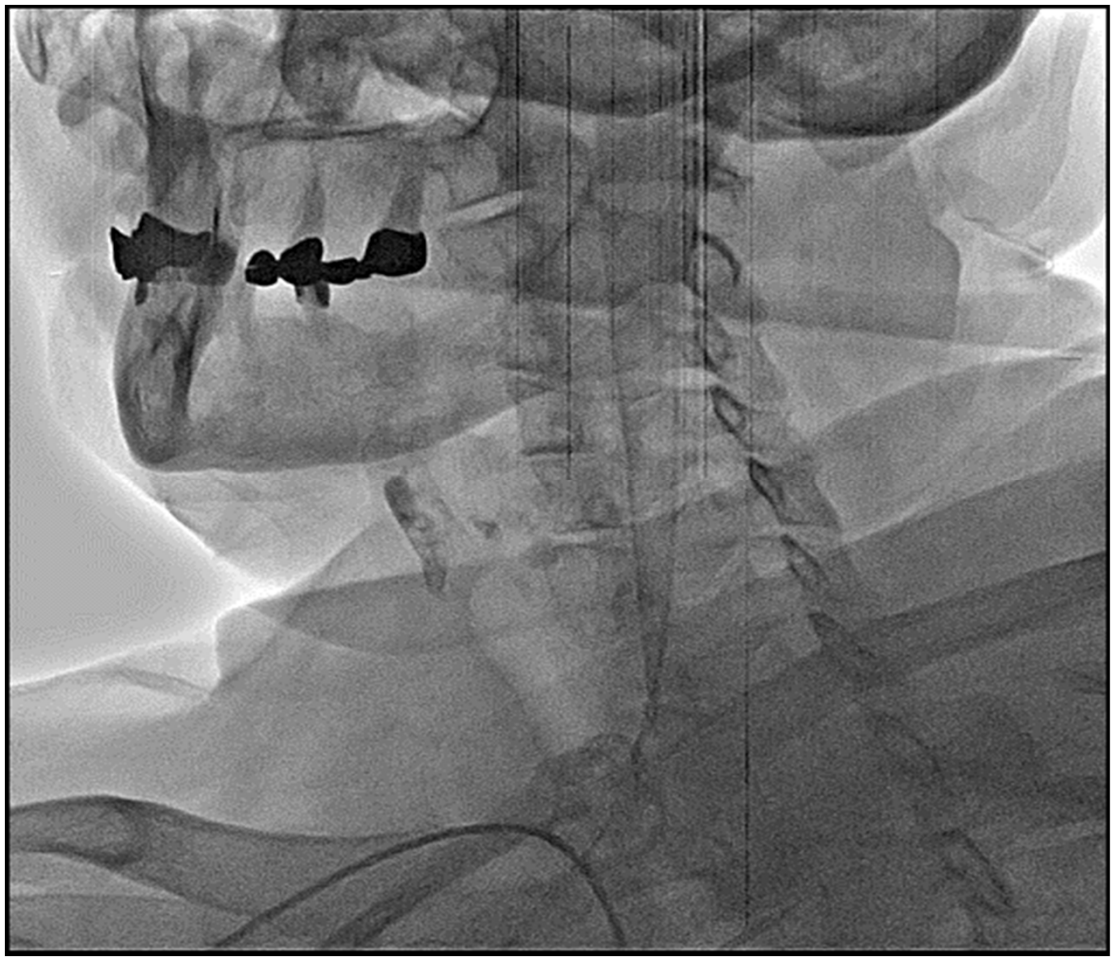
Female

62 y.o

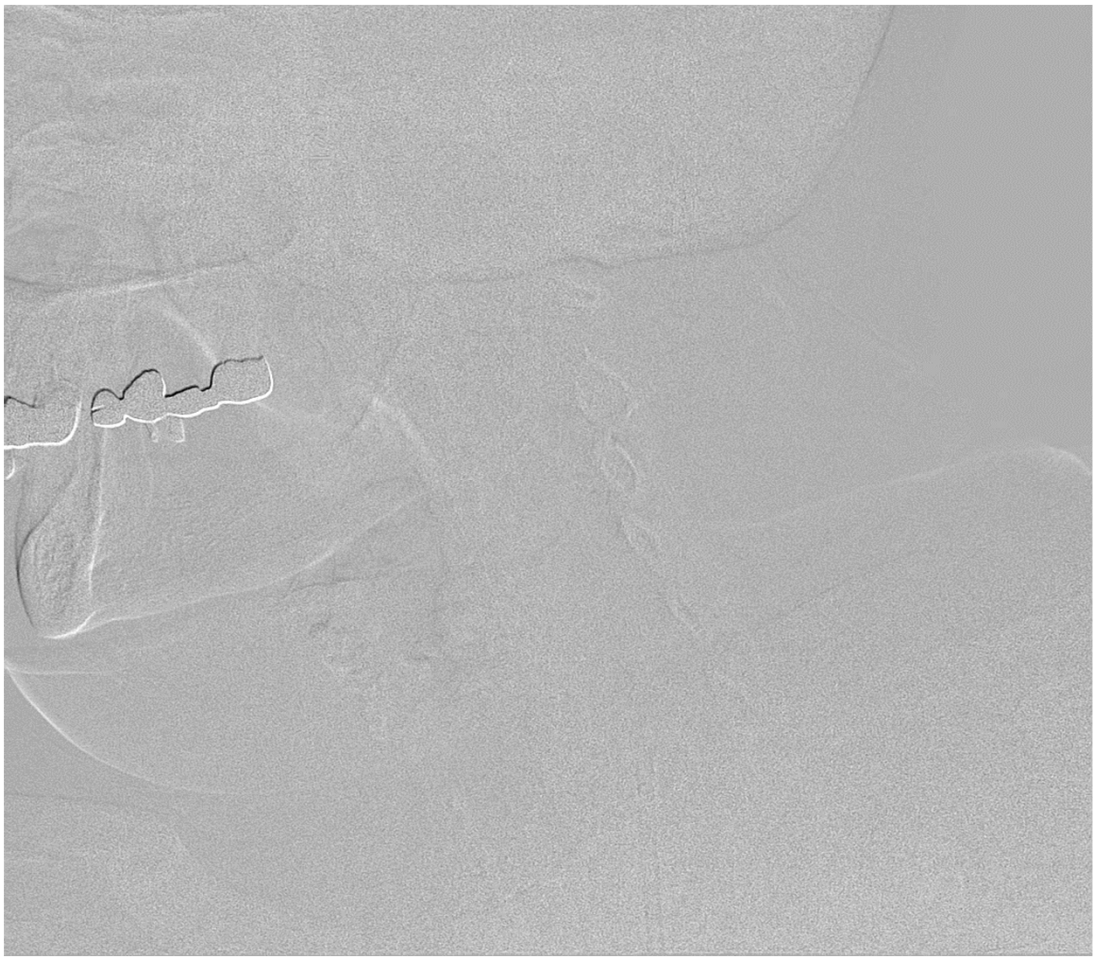
High take-off RA



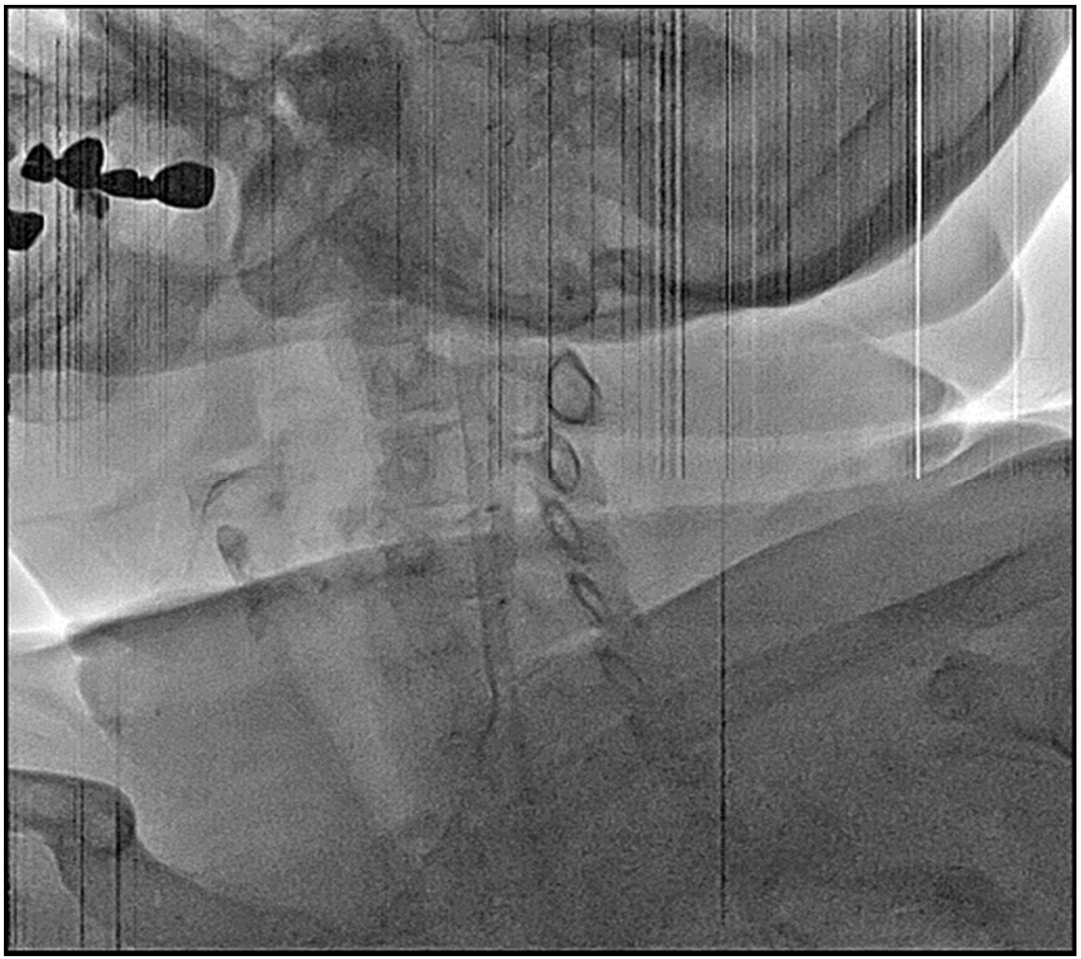
LICA 90%

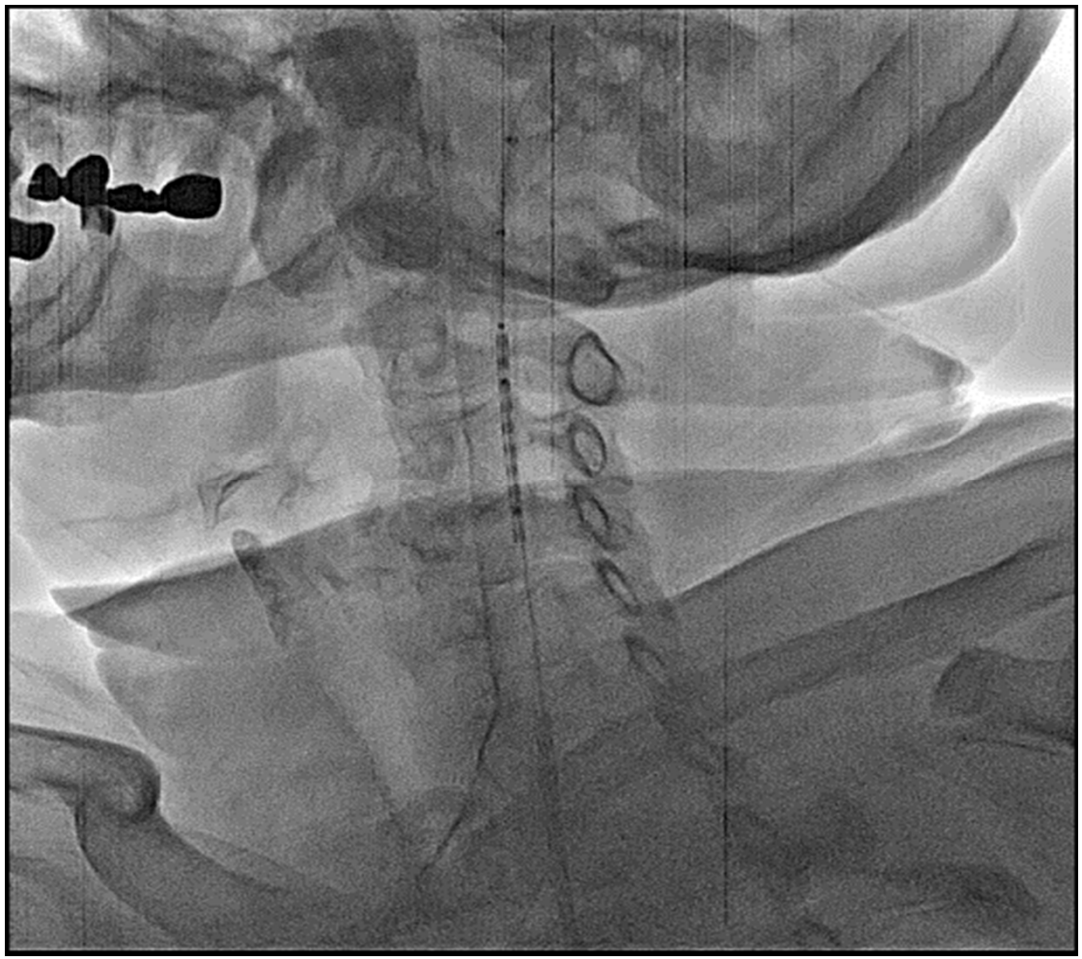


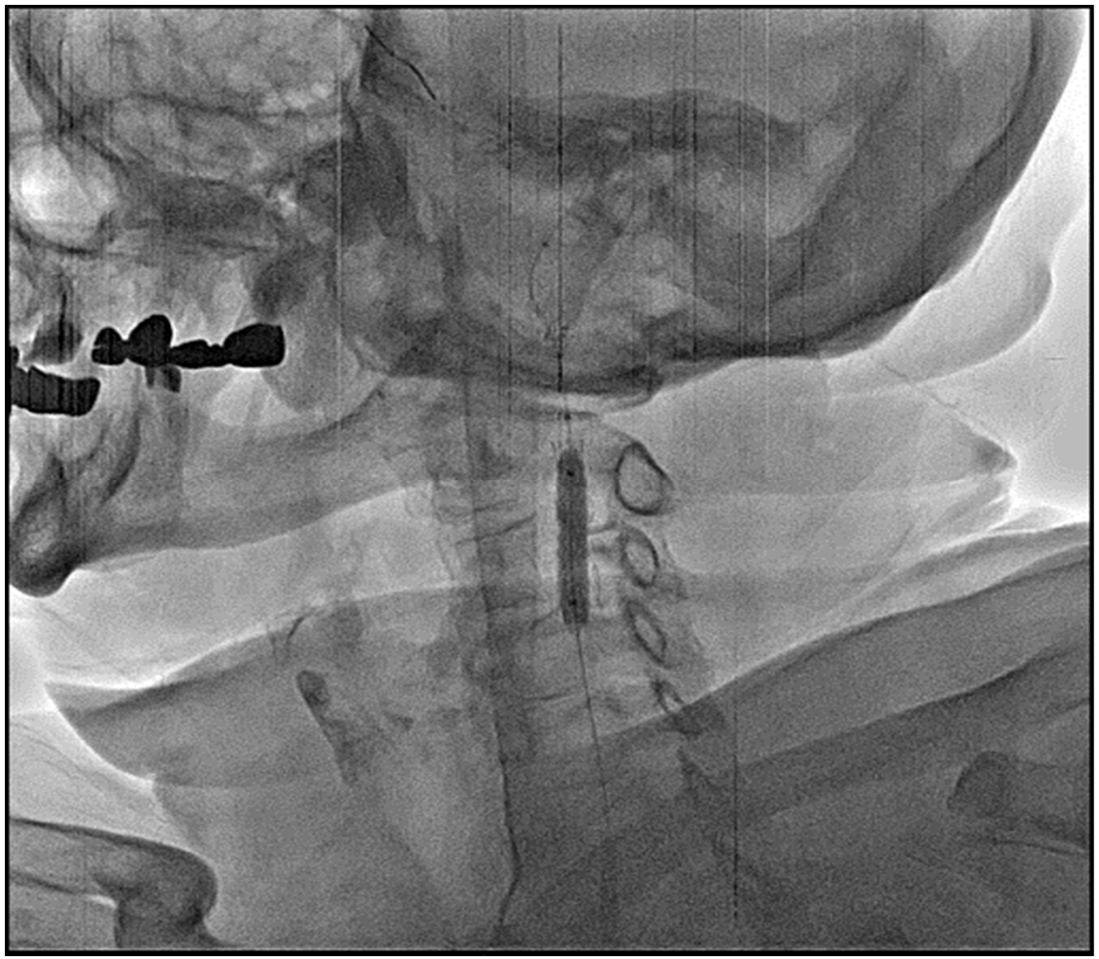
8F Asachi PV



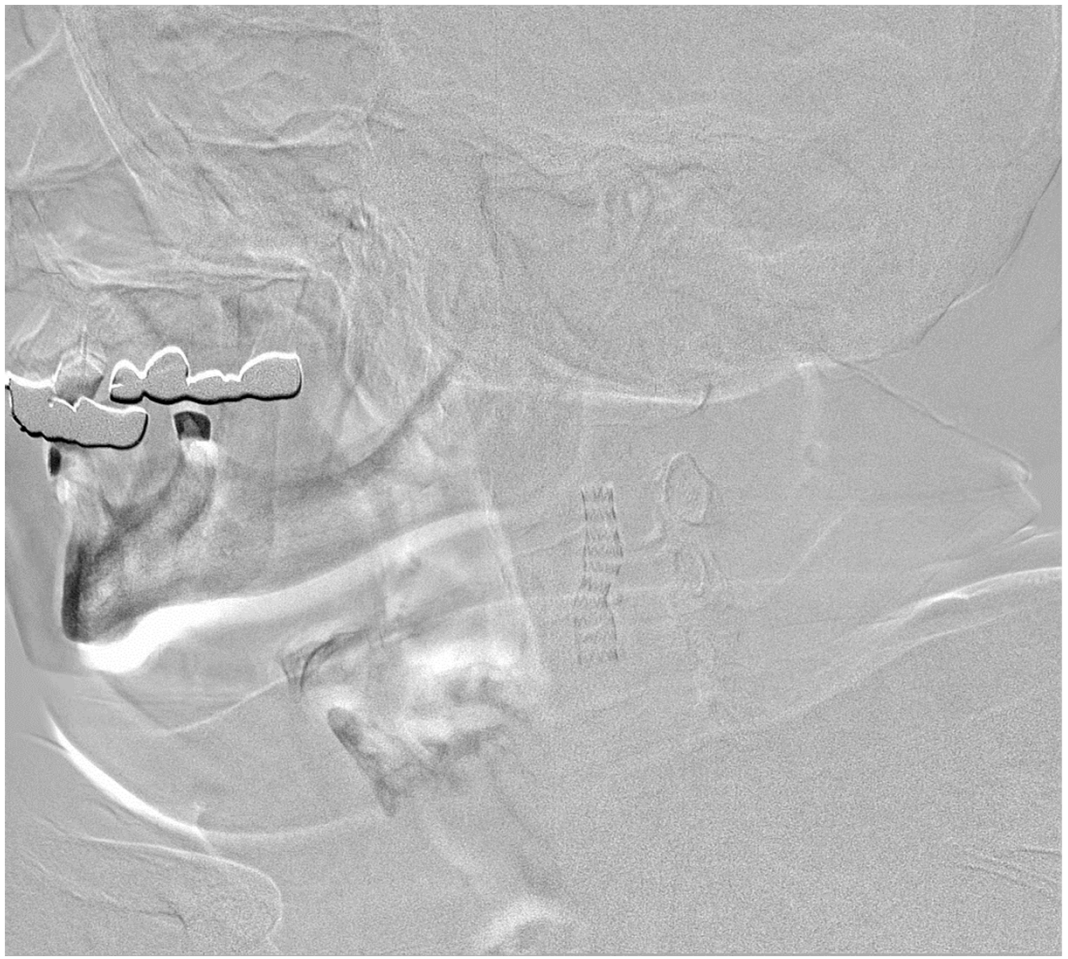
Stent: Neuroguard IEP







Final result



Conclusions

- The Neuroguard IEP combines balloon, filter and stent on one platform
- Hypothetically the use of Neuroguard IEP adds additional safety due to less procedural steps and a very unique, closed cell, flexible Nitinol stent integrating the Paladin System
- Interim results of 60 patients at 30 days and 25 patients at 6 months show excellent outcomes