

CGUARD™

Carotid Embolic Prevention System



Internal carotid atherosclerosis – Do mesh-stents improve outcomes: my experience with CGuard EPS

Dr. Antonio Micari

*Co-Director of Interventional Cardiology Unit – GVM Care & Research
Maria Cecilia Hospital – Cotignola*

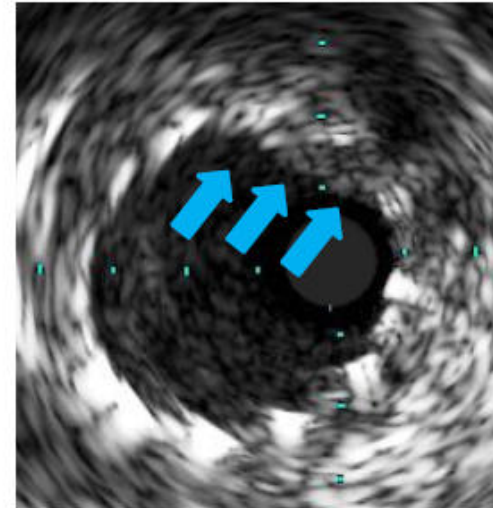
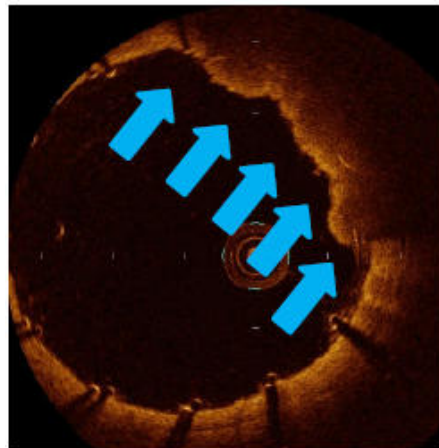
Post-Procedural Plaque Prolapse Through Conventional Stent Struts

30.7%

1/3 stents = Precise

2/3 stents = Carotid Wallstent

81 y.o. Female, Symptomatic



CGUARD™
Carotid Embolic Prevention System

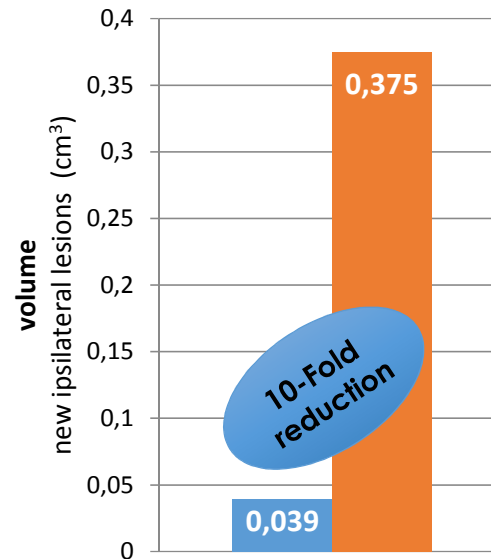
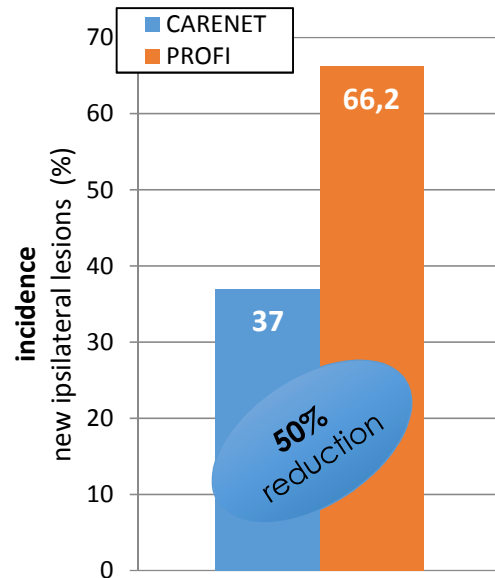
Clinical Datas



CARENET

DW-MRI Analysis

DW-MRI analysis @ 48 hours, n=27*



Incidence of new ipsilateral lesions at 48 hours was reduced by almost half compared to published data, and volume was reduced almost 10-fold.

All but one lesion had resolved completely by 30 days.

DW-MRI analysis @ 30 days, n=25**

Incidence of new ipsilateral lesions	4.0%
Average lesion volume (cm ³)	0.08 ± 0.00
Permanent lesions at 30 days	1

Prospective evaluation of All-comer perRcutaneous
cArotiD revascularization In symptomatic and increased-risk
asymptomatic carotid artery stenosis using CGuard™
Micronet-covered embolic prevention stent system:

The PARADIGM Study

P. MUSIALEK¹, A. MAZUREK¹, M. TRYSTULA², A. BORRATYNSKA³, M. URBANCZYK³,
A. LESNIAK-SOBELGA¹, P. BANYS³, A. BRZYCHCZY², L. PARTYKA⁴, K. ZMUDKA⁵, P. PODOLEC¹

(1) Dept Cardiac and Vascular Diseases, Jagiellonian University & John Paul II Hospital, (2) Dept Vascular Surgery,
John Paul II Hospital; (3) John Paul II Hospital, Krakow; (4) Krakow Cardiovascular Research Institute (KCRI);
(5) Dept Interventional Cardiology, Jagiellonian University & John Paul II Hospital, Krakow, POLAND



Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland





Objective

- to evaluate feasibility and outcome of routine anti-embolic stent system use in unselected, consecutive patients referred for carotid revascularization
('all-comer' study)

PARADIGM: Results



Index lesion quantitative characteristics (n=71 lesions)

	All (n=71 lesions)	Symptomatic n=37	Asymptomatic n=34	p
Before CAS				
PSV, m/s	3.8 ± 1.3	3.7 ± 1.1	3.8 ± 1.5	0.862
EDV, m/s	1.3 ± 0.7	1.4 ± 0.6	1.3 ± 0.8	0.687
Diameter stenosis % (QA)	82 ± 9	79 ± 9	84 ± 9	0.021
CAS				
EPD type				0.092
Proximal*	35% (25)	44% (16)	26% (9)	
Distal**	65% (46)	56% (21)	74% (25)	
post-dilat balloon [#] peak pressure, mmHg	18.4 ± 3.4	17.5 ± 3.6	19.2 ± 2.9	0.037
After CAS				
Stent length (QA) [§]				NA
Nominal 30 mm (min-max)	29.66 ± 0.30 (28.73-30.07)	29.66 ± 0.28 (29.02-30.07)	29.65 ± 0.32 (28.73-30.02)	
Nominal 40 mm (min-max)	39.73 ± 0.34 (38.88-40.22)	39.69 ± 0.41 (38.88-40.22)	39.77 ± 0.28 (39.14-40.04)	
Residual diam. stenosis	7 ± 4%	5 ± 4%	7 ± 5%	0.257
in-stent PSV, m/s	0.70 ± 0.28	0.66 ± 0.29	0.74 ± 0.27	0.266
in-stent EDV, m/s	0.17 ± 0.07	0.17 ± 0.07	0.18 ± 0.07	0.457

* Emboshield (n=7); FilterWire (n=14); Spider (n=25)

** Gore FlowReversal (n=4) or flow reversal with MoMa (n=21);

(NB. mean flow reversal time was 6min 48s, from 5min 18s to 11min 2s)

Ø 4.5mm (n=5); Ø 5.0mm (n=36); Ø 5.5mm (n=29); Ø 6.0mm (n=1);

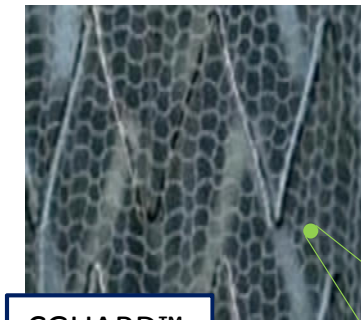
§ 30mm in 51 lesions; 40mm in 18 lesions (2 other lesions required two stents each)

PARADIGM: Results



- **Death/stroke/MI @ 48h** **0%**
- **Death/stroke/MI @ 30d** **0%**

Ideal Pore Size



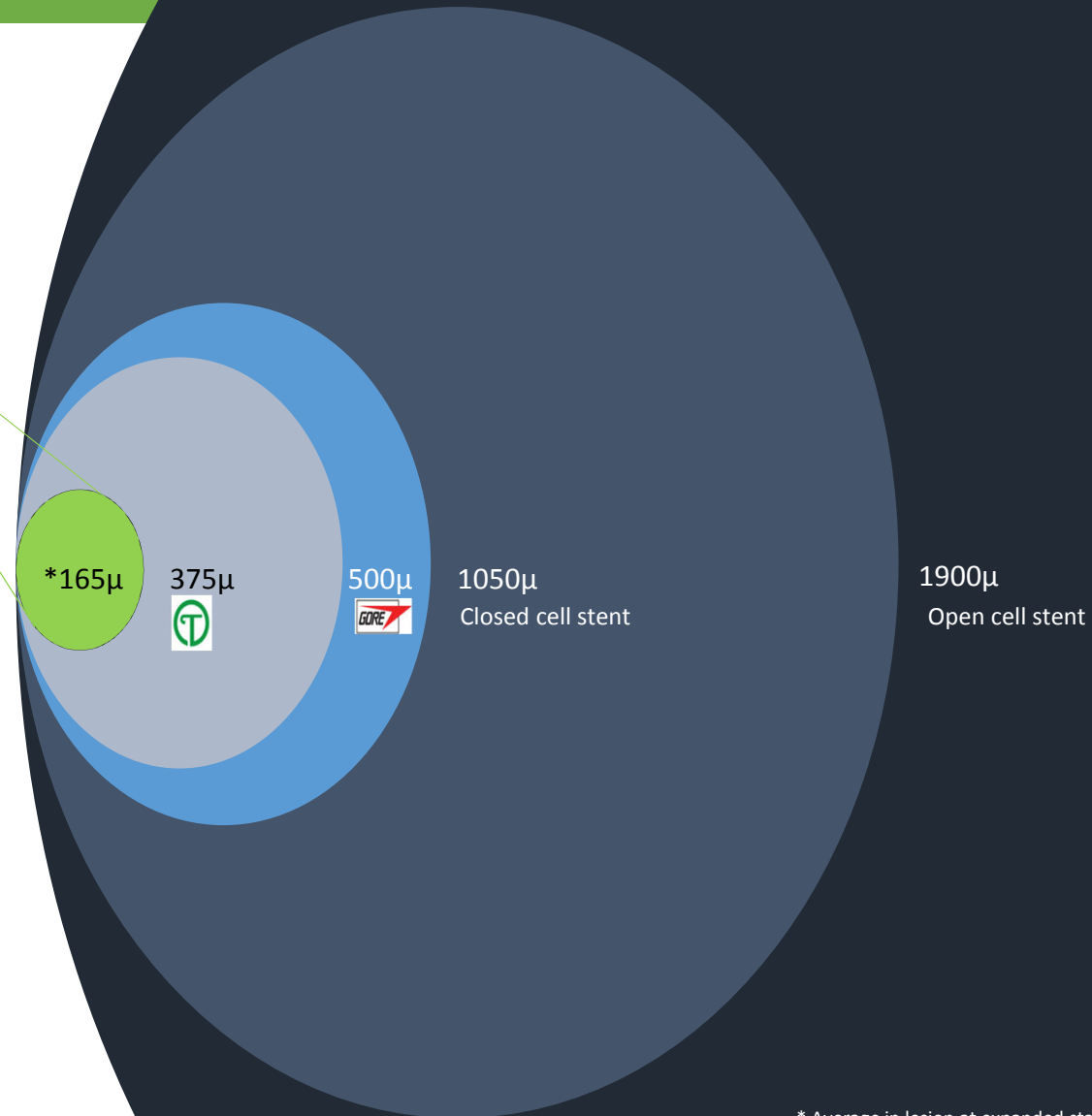
CGUARD™



TERUMO

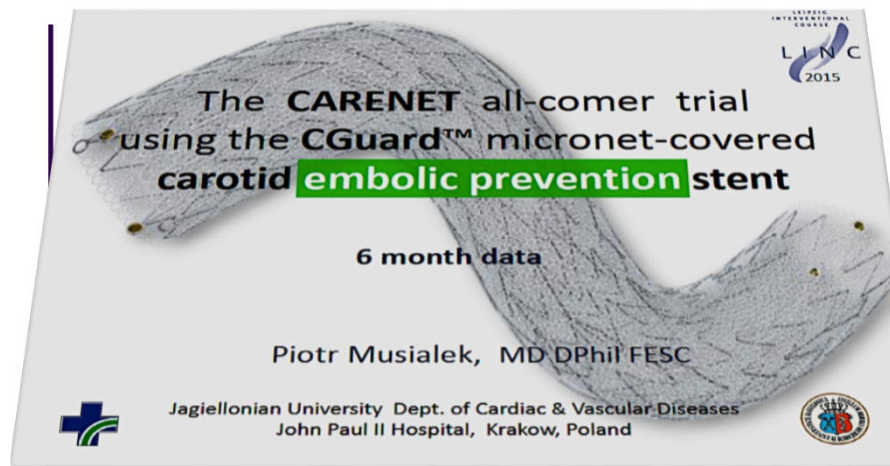


GORE



* Average in lesion at expanded state

Changing paradigms in CAS



CLEAR-ROAD trial

- Physician-Initiated Carotid Trial Investigating the Efficacy of Endovascular Treatment of Carotid Arterial Disease with the multi-layer ROADsaver stent
- multi-center trial with 100 patients
- **Primary Endpoint:**
30-day rate of major adverse events (MAEs), defined as the cumulative incidence of any peri-procedural (≤ 30 days post-procedure) death, stroke or myocardial infarction (MI).

Micromesh stents and sustained anti-embolic action to reduce cerebral embolization may contribute to solve the remaining limitations of carotid stenting

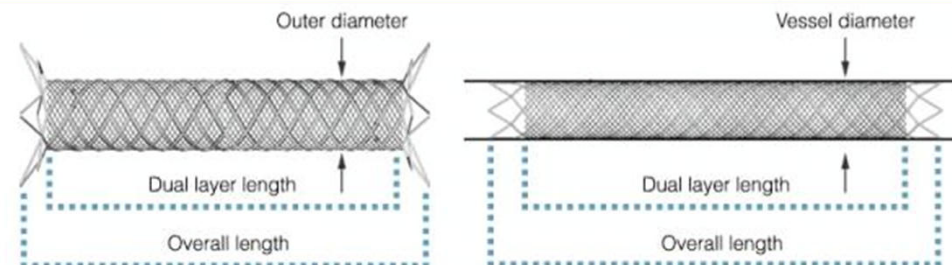
Roadsaver™

Carotid Stent System

A Novel Carotid Stent
for Sustained Embolic Protection



TERUMO



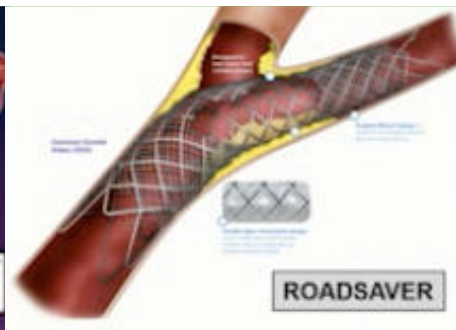
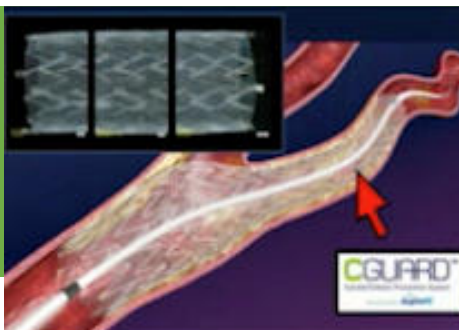
Stent delivery system

Guide wire compatibility	0.014" (0.36 mm)
Introducer sheath compatibility	5 Fr (I.D. > 0.074")
Delivery system construction	Rapid exchange, RX segment length 30 cm
Usable catheter length	143 cm

Item Specifications

Product reference	Unconstrained dimensions (mm)			Implanted dimensions (mm)					
	Stent diameter	Micromesh layer stent length	Overall stent length	Vessel Ø 1 mm smaller than unconstrained Ø			Vessel Ø 2 mm smaller than unconstrained Ø		
				Vessel diameter	Micromesh layer length	Overall length	Vessel diameter	Micromesh layer length	Overall length
RDS-0520-143RX	5	20	25	4	20	33	3	22	35
RDS-0530-143RX	5	30	37	4	35	47	3	38	52
RDS-0540-143RX	5	40	47	4	45	59	3	52	64
RDS-0616-143RX	6	16	22	5	20	32	4	23	22
RDS-0625-143RX	6	25	33	5	30	44	4	33	48
RDS-0630-143RX	6	30	40	5	40	53	4	43	58
RDS-0718-143RX	7	18	25	6	23	35	5	26	38
RDS-0725-143RX	7	25	35	6	30	47	5	36	52
RDS-0730-143RX	7	30	40	6	40	53	5	44	60
RDS-0820-143RX	8	20	25	7	25	36	6	27	40
RDS-0825-143RX	8	25	35	7	30	49	6	38	54
RDS-0830-143RX	8	30	40	7	40	55	6	45	61
RDS-0840-143RX	8	40	47	7	50	67	6	60	75
RDS-0920-143RX	9	20	33	8	30	45	7	33	48
RDS-0930-143RX	9	30	40	8	40	55	7	45	60
RDS-1020-143RX	10	20	35	9	30	45	8	35	50
RDS-1030-143RX	10	30	43	9	40	55	8	45	60

Summary of main characteristics



	CGUARD	ROADSAVER
Company	Inspire MD	Terumo
Material (Stent/ Micromesh)	Nitinol/ PET	Nitinol/ Nitinol
Size of delivery	6F	5F
Size of Pores μ	150-180	380
Flared tips	no	yes
Retrievable/Repositionable	no	yes
Accuracy	+++	++
Conformability	++	+++
Crossability	++	+++
ECA preservation	yes	yes
EPD compatibility	all	all

Case presentation

FEMALE, 83 years

Risk Factors

- Type II diabetes mellitus
- Hypertension

Previous cardiovascular history

- Previous PCI to LAD

Clinical presentation

- Minor Stroke in Nov '17 (right-sided hemiparesis, full recovery)
- DUS: severe LICA stenosis (mixed plaque)

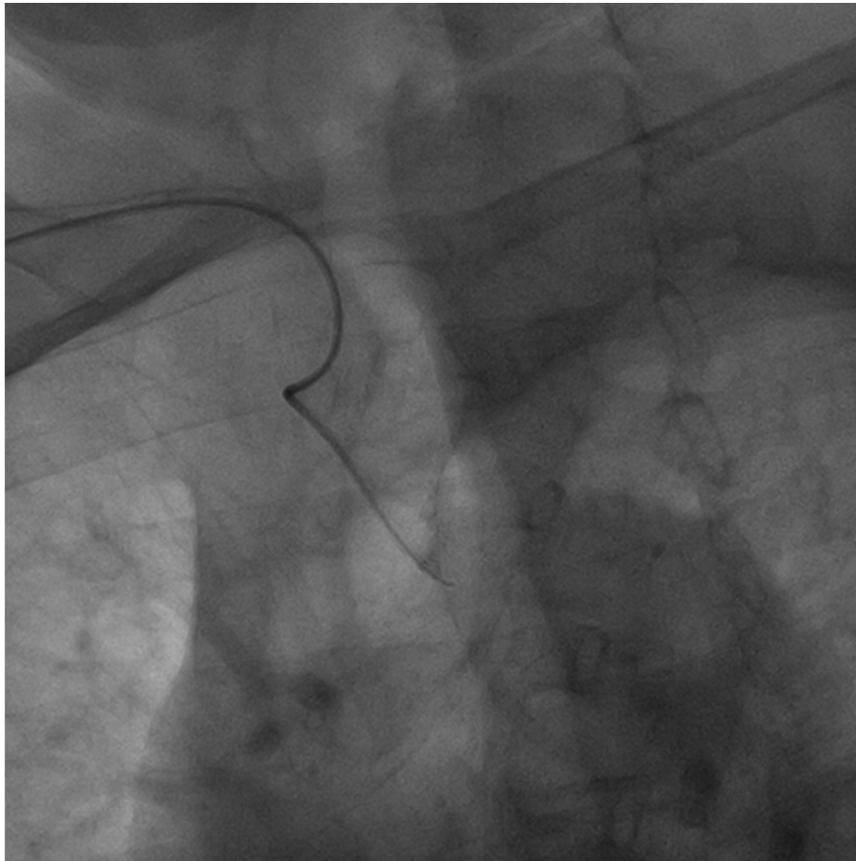
Main comorbidities

- Known severe PAD

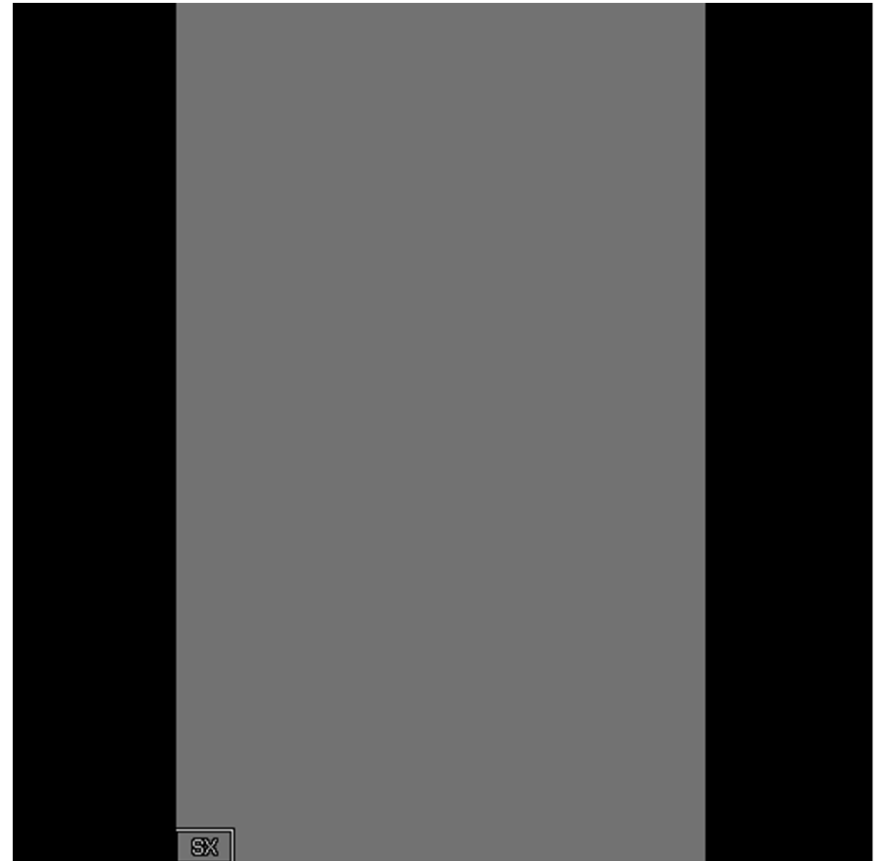
Challenging anatomy



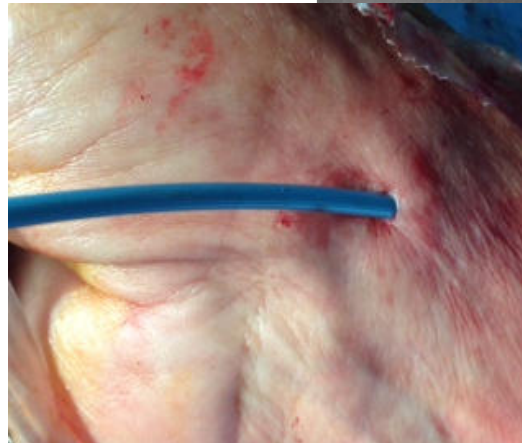
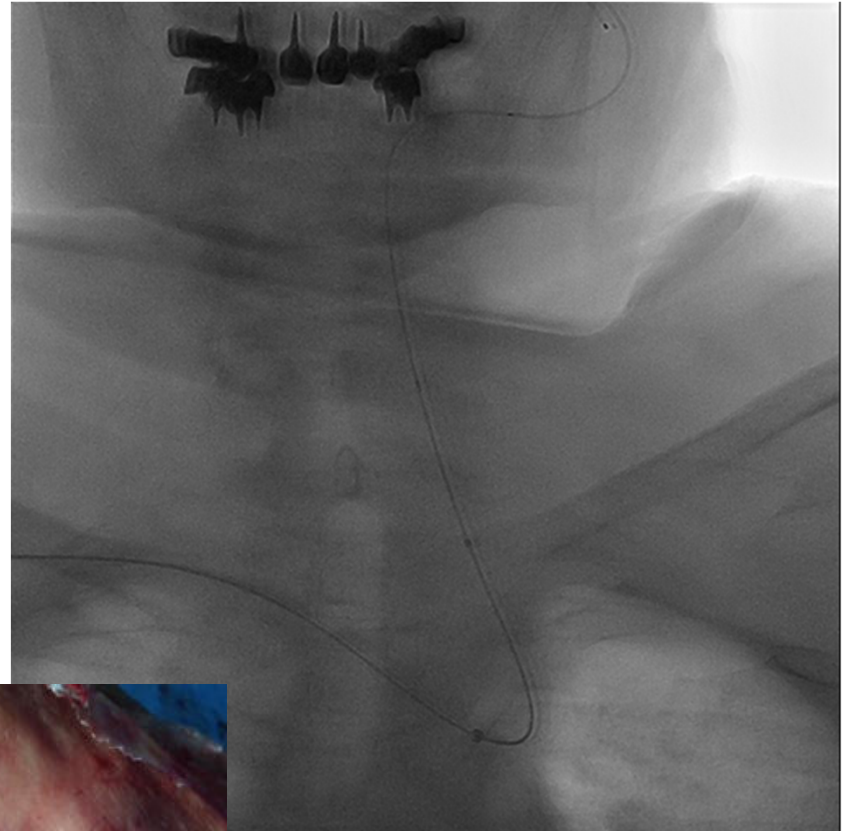
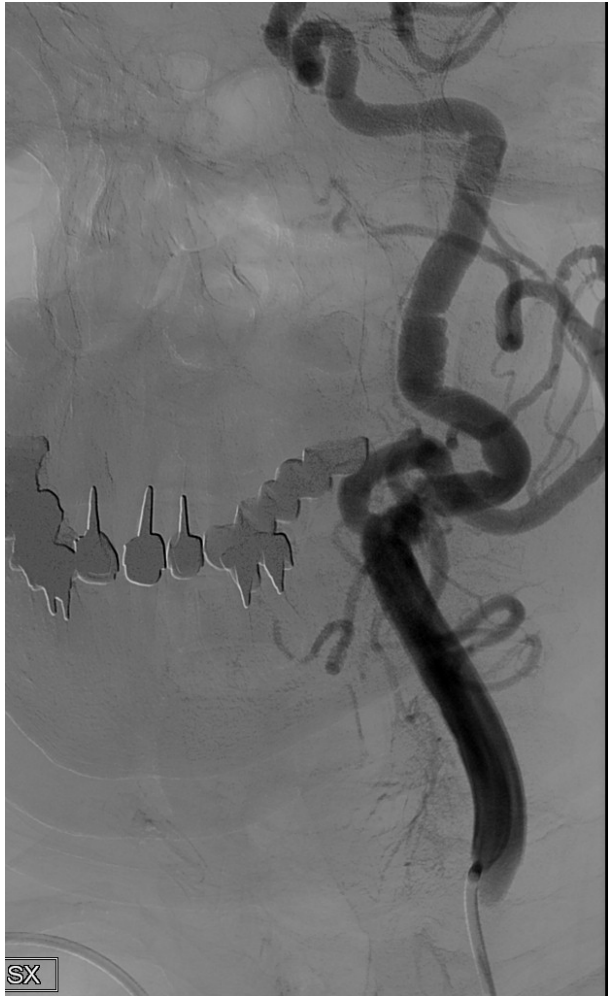
Transradial PTA



JR 4 catheter from RRA and
hydrophilic wire

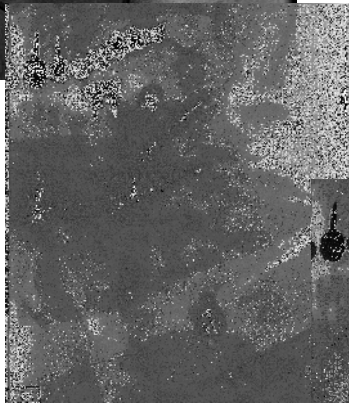
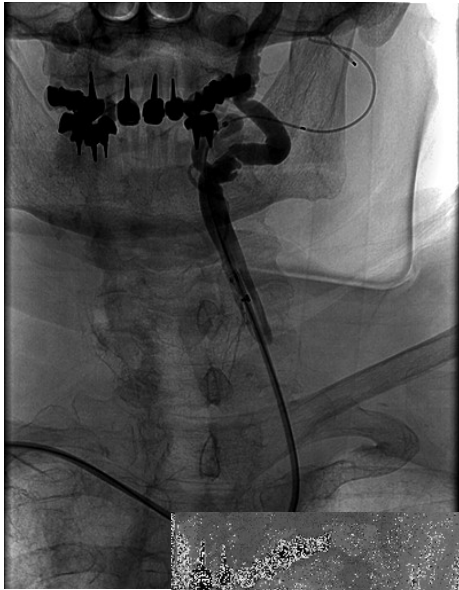


Proximal protection (MOMA)

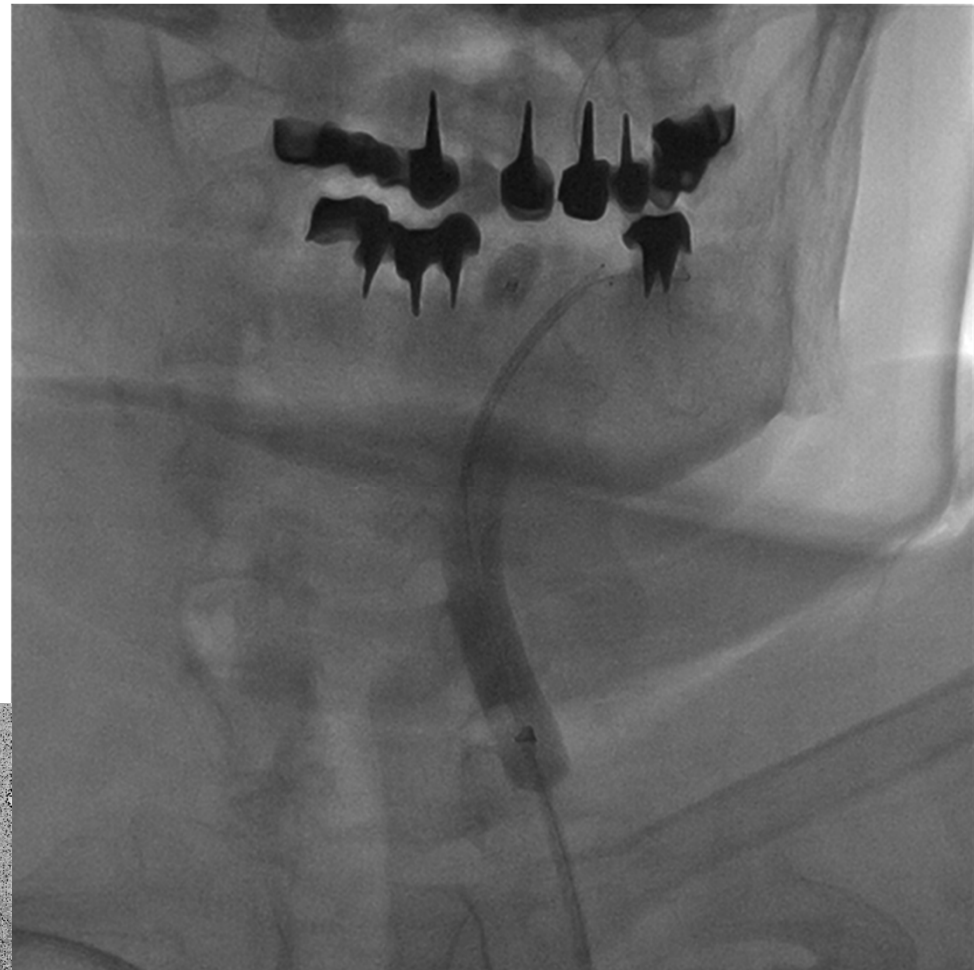


MOMA sheathless insertion

Proximal protection (MOMA)

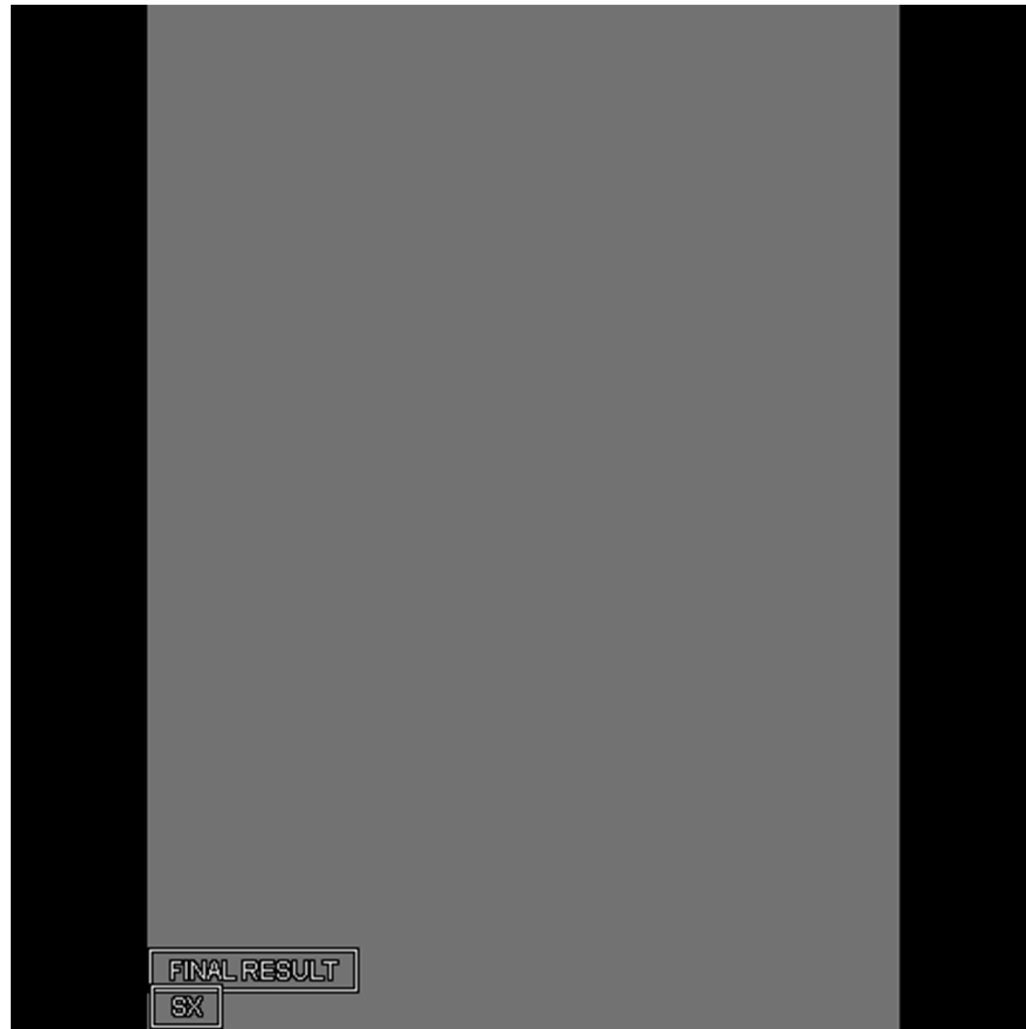


Postdilation with
5.5 balloon



C-GUARD 9/30 mm stent deployment

Final result





Thank You