

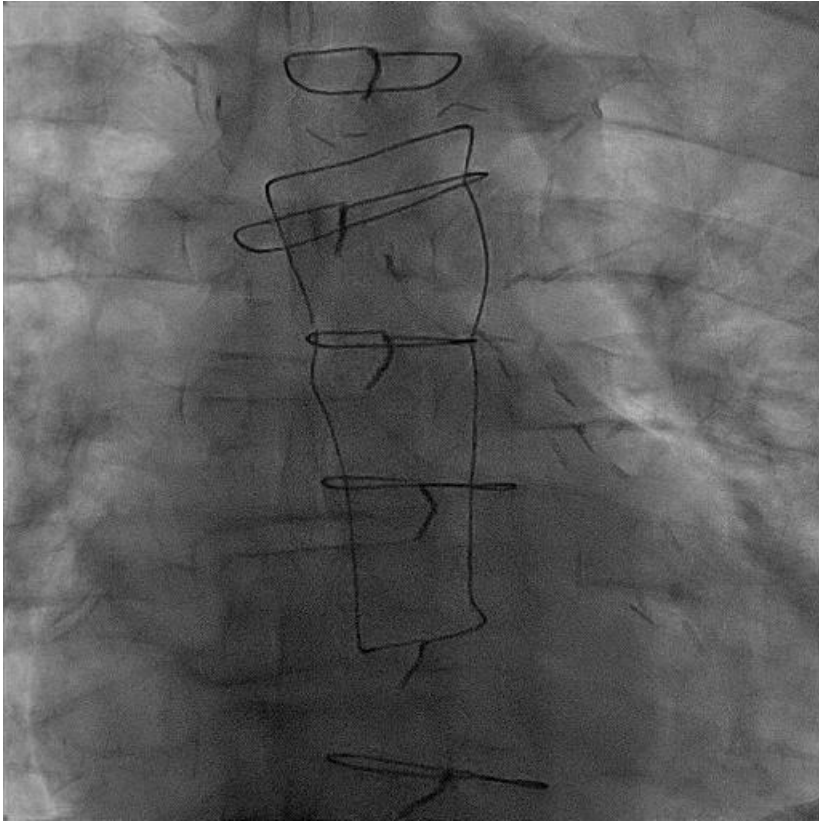
A Challenging Carotid Case

Max. Amor

Clinique Louis Pasteur

Essey-Les-Nancy, France

6years before : 64 years man



- **Double coronary vessel disease and right severe internal carotid stenosis .**
- **Right internal carotid Patch-Endartériectomy followed 2 months later by a double by-pass graft (Staggered Technic)**

Double Lesions RICA restenosis & De-novo LICA

1. Bilateral endarterectomy
2. Right Angioplasty et Left carotid endartectomy
3. Wait and See under Aspirine





Double Restenosis



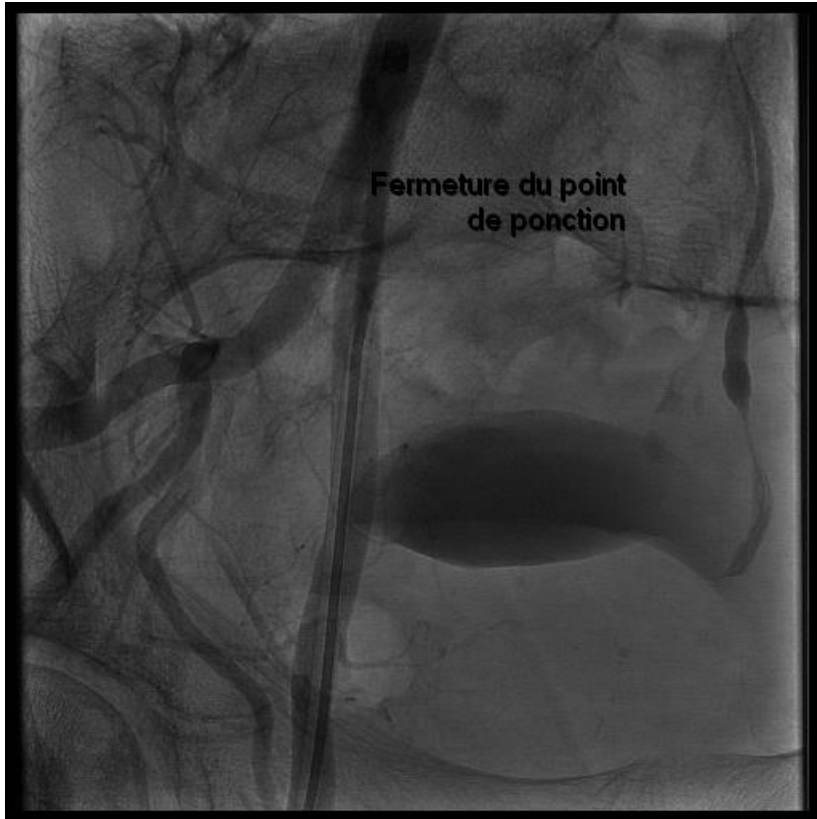
- **When ?** immediately ?, Same hospitalisation, Delayed (1, 2, 3)
- **Which Protecting Device ?** Filter, Moma, Silk Road (1,2,3)
- **Single stent ?**
- **Several stents ?**
- **Covered ?**



24 hours later, Two ADAPT stents 21mm, Filter Protection

3 stents : 2 Right 1 Left





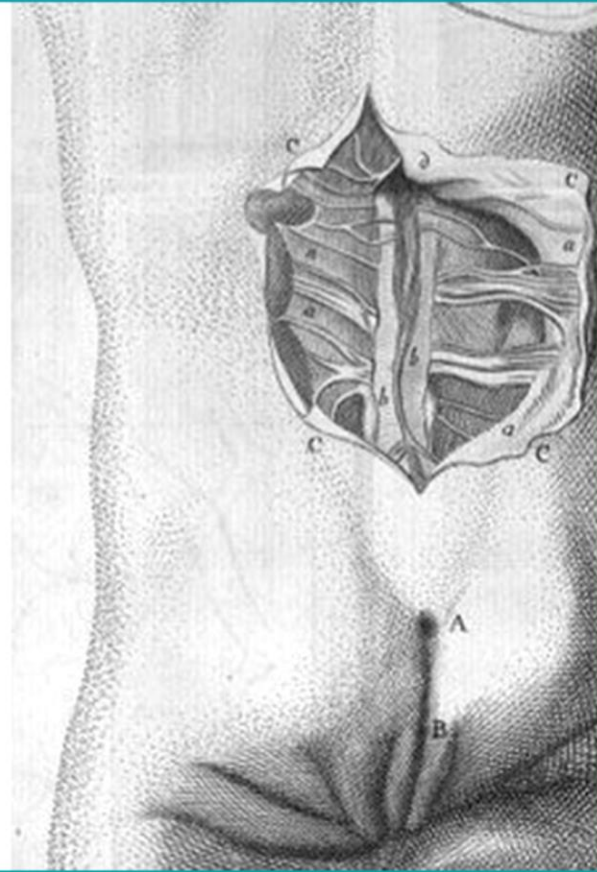
- Fermeture du point de ponction
- Bonne tolérance hémodynamique
- Très bon résultat échographique, pas d'embolies au scan
- Sortie après 72 h d'hospitalisation

Take home message

- In my
before
well t

ctomy
and

Musée
d'histoire
de la médecine



Paris - Musée d'histoire de la médecine

Selection of stent and protection technique

KOL: 84.1
Inc.: -7°

Max. Amor

**Clinique Louis Pasteur
Essey-Les-Nancy, France**

max-amor@wanadoo.fr

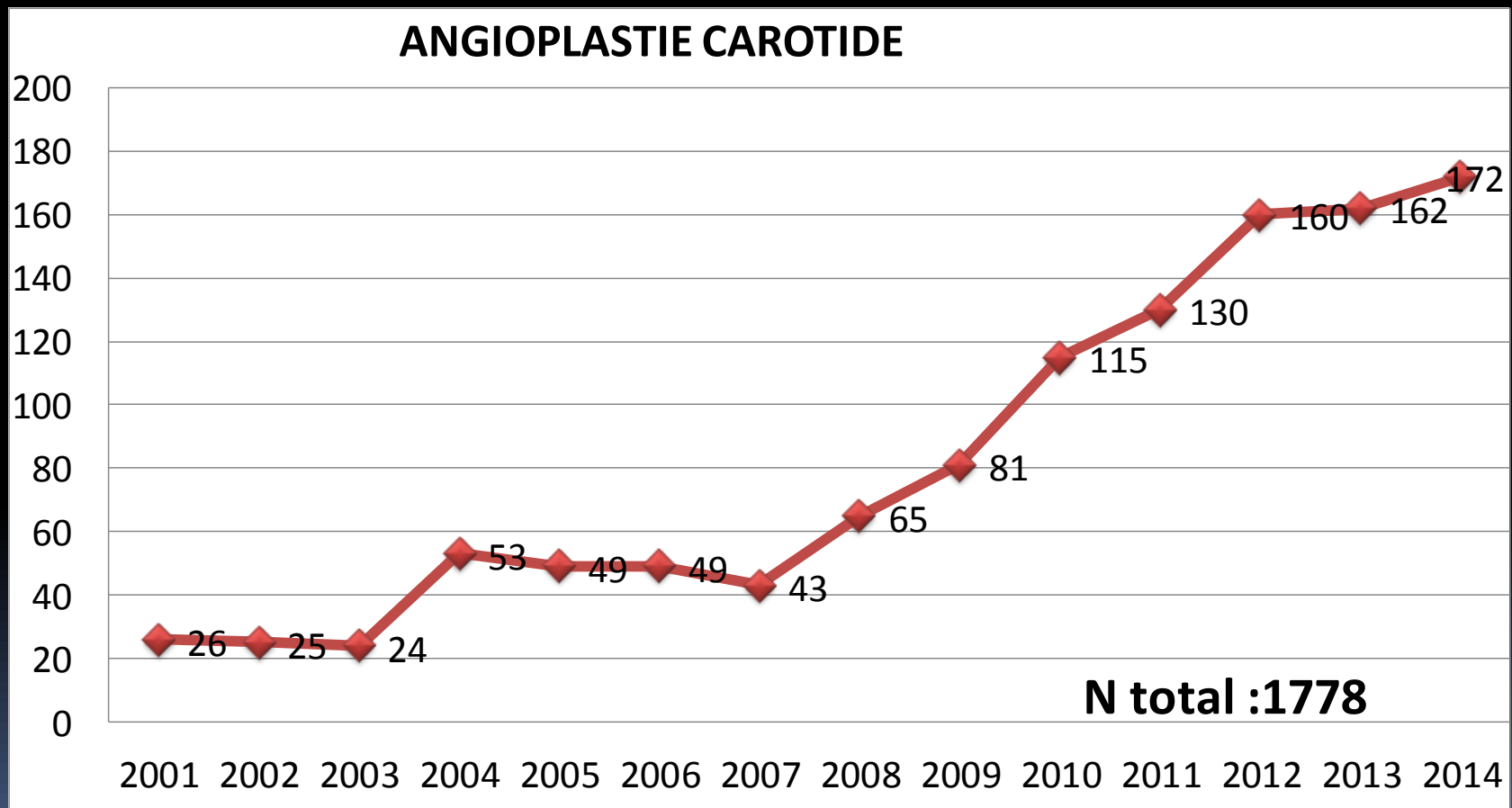


Potential conflicts of interest

Speaker's name: Max Amor

☒ **I do not have any potential conflict of interest**

Activité Carotide Protégée Louis Pasteur Essey –Les-Nancy



STENTING

SURGERY

RISKS

Embolic Risk

Durability

Antiplatelet Therapy

Bleeding

Local complication

Hypotension

Cardiac Risk

General Anesthesia

Cranial Nerves Injury

Scar&wound compli.

Hypertension

CEA>CAS: Minor Stroke

CEA=CAS: Major Stroke

CEA<CAS: MI

CEA<CAS: Cranial nerve injury

Reducing the embolic risk (Stroke Risk) of carotid artery stenting

Reducing the risk during the Procedure

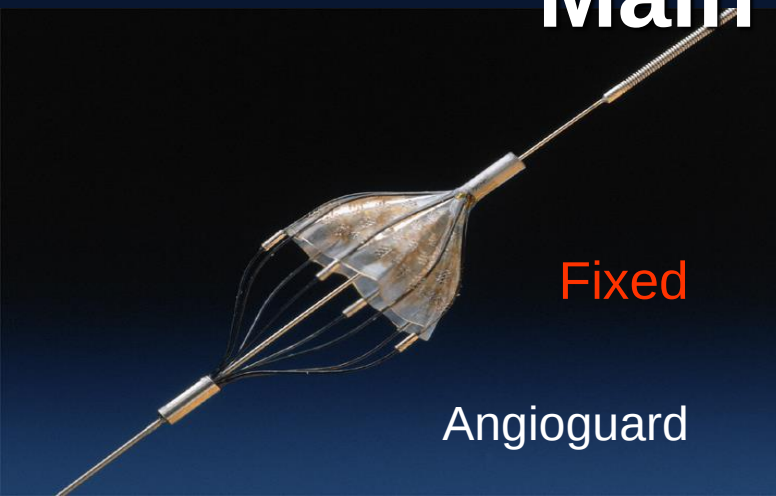
- Medical therapy : Dual antiplatelet therapy
- Managing usual procedural side effects: Hypotension, Bradycardia...
- Selecting and using the right device for Embolic protection: Filters, Flow- reversal
- Selecting and placing the right stent for carotid plaque containment, reducing residual stenosis

11 Systems of protection

- **7 Filters:**
 - Angioguard (J&J)
 - AccUNET (Abbott)
 - Easy Filterwire(BSC)
 - Emboshield(Abbott)
 - Interceptor (Medtronic)
 - Spider Rx(EV3)
 - Fibernet(Lumen-Invatec)
- **2 Flow Reversal**
 - Moma Device (Invatec)
 - Gore Neuro-protecting system (Gore)
- **2 Occlusive Balloon**
 - Percusurge (Medtronic)
 - Mini-invasys Theron double balloon(Mini-Invasys)

**SILK-ROAD
System**

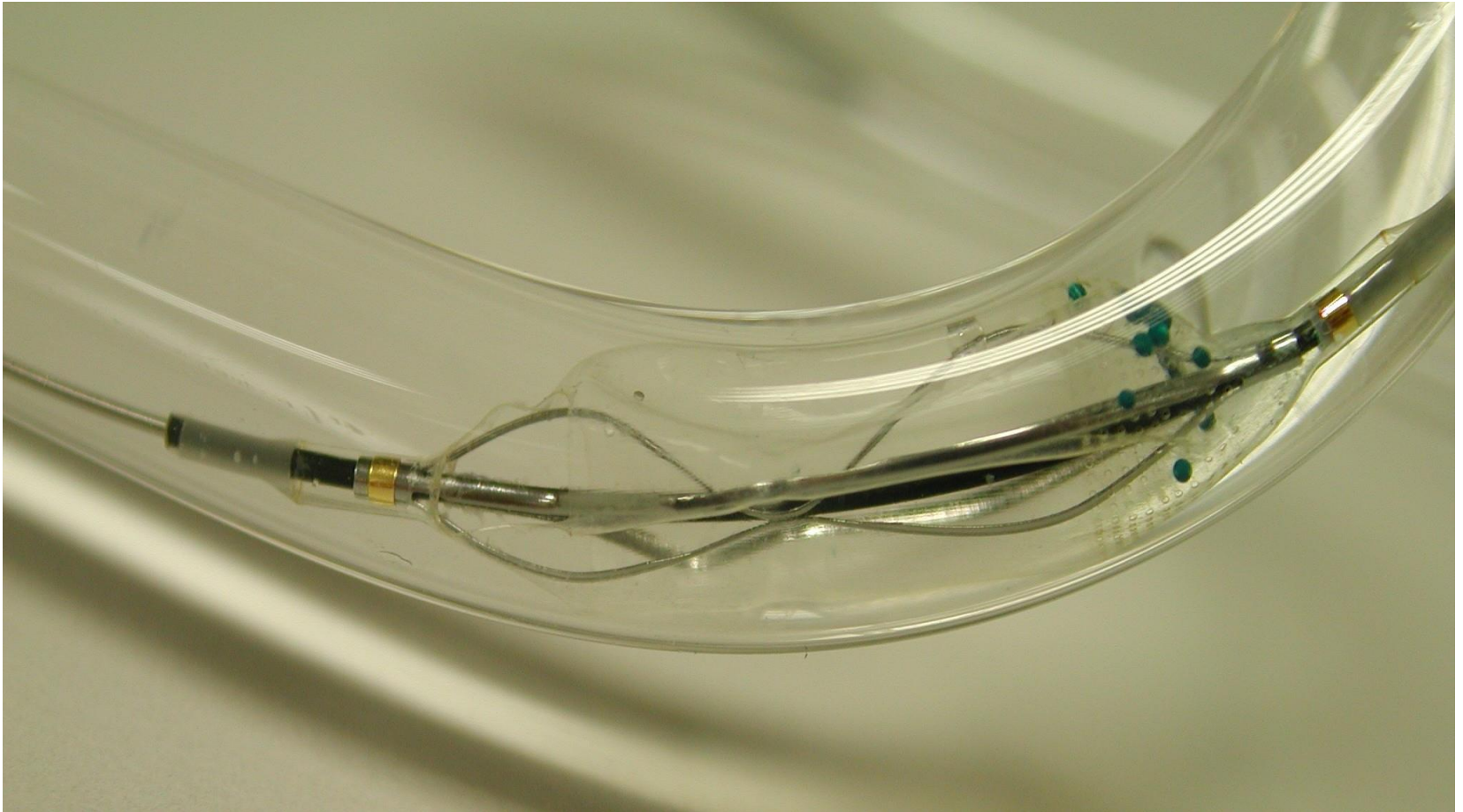
Main filters in 2010



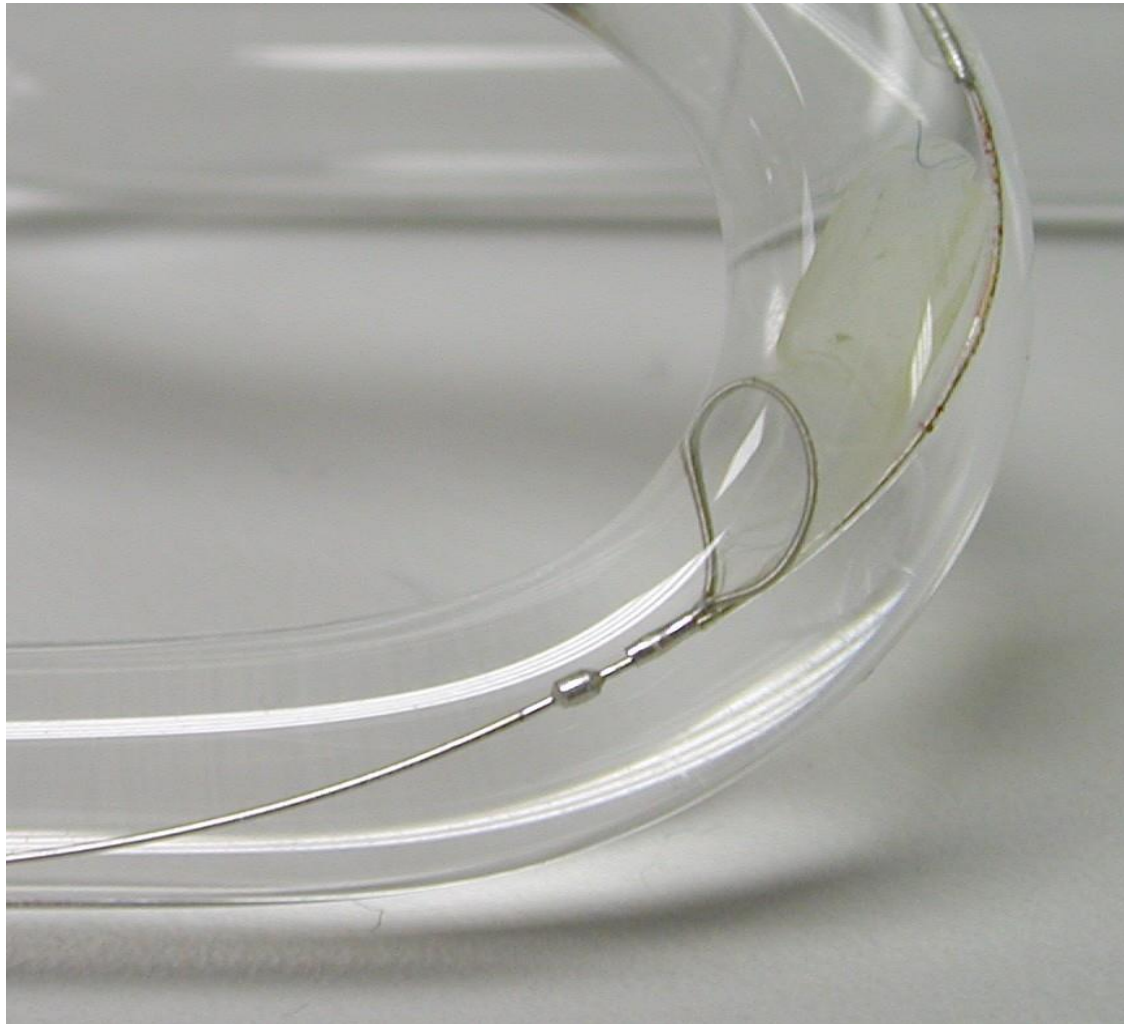
Geometric Factors for selecting filters

	EZ	Accunet	Emboshiel	SPIDER	Fibernet
$\varnothing \geq 6\text{mm}$	no	yes	yes	yes	yes
Tight stenosis	++	++	+++	+++±	+
Small landing zone	+	+	++	+	+++
Angulations	++	++	+++±	+++	+
Curved landing	+	++	++	+	+++
Complex crossing	+	+	++	+++	+

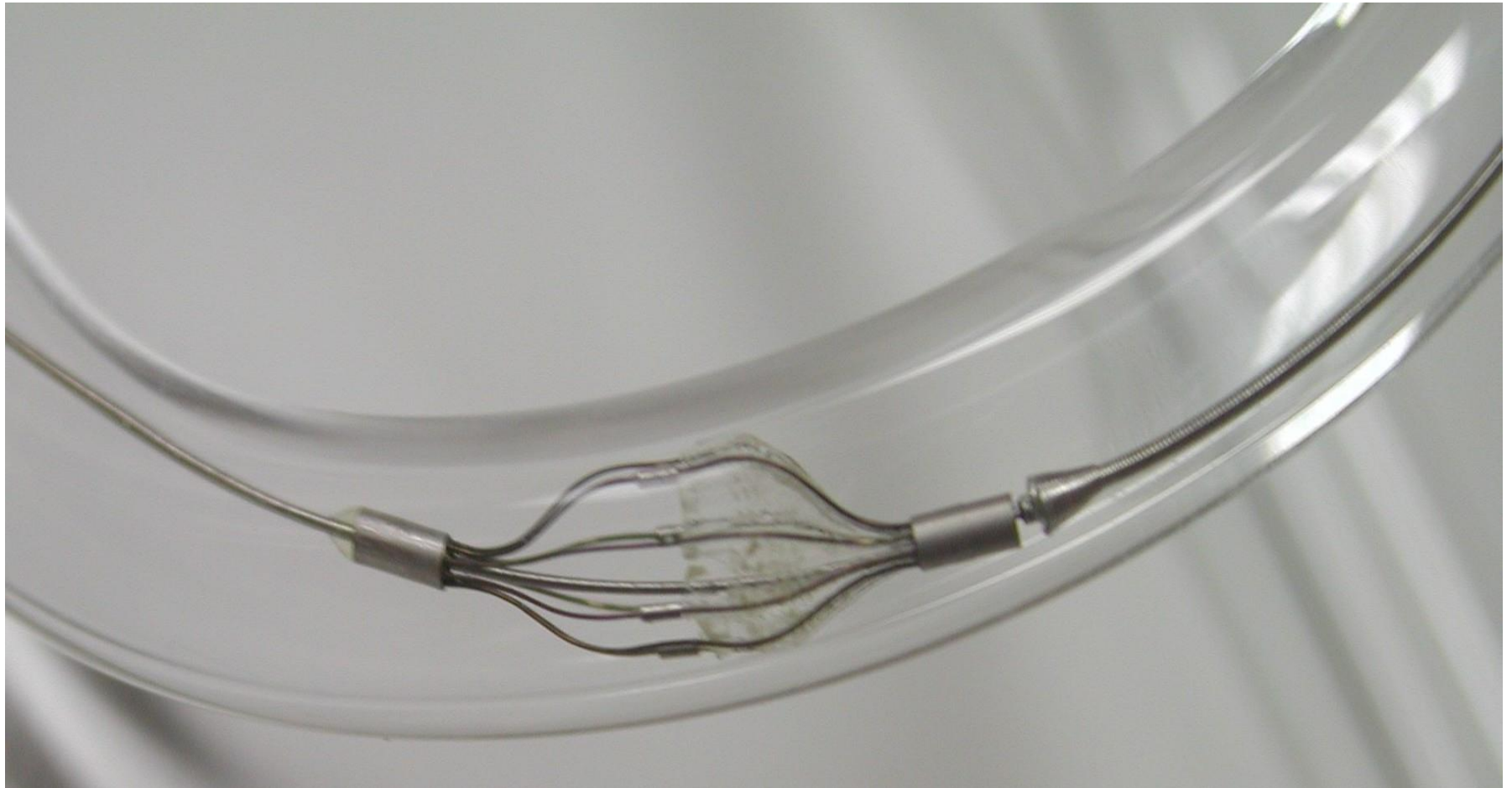
Abbott EmboShield



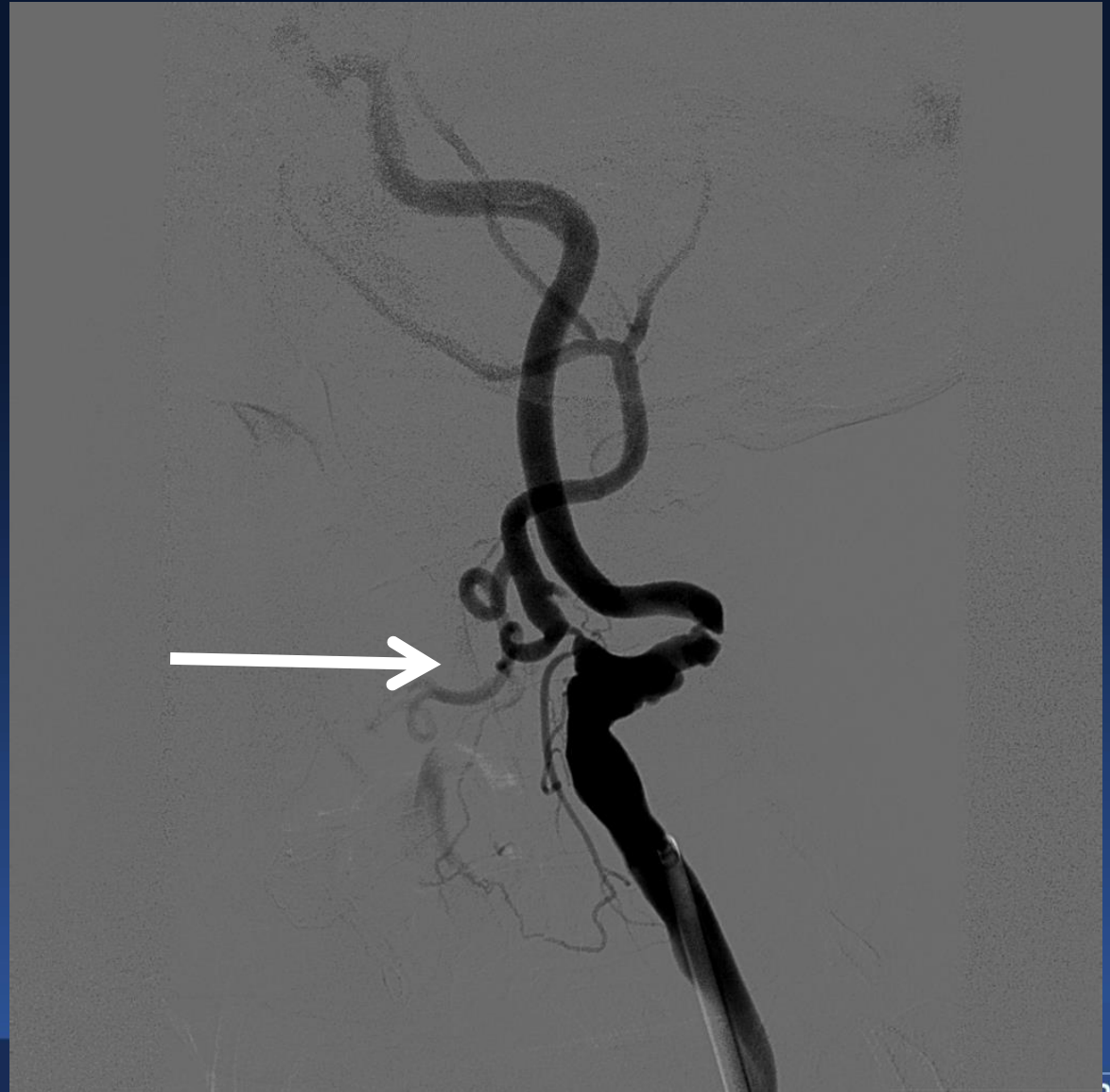
EPI



Angioguard



TORTUOSITIES: 2 examples of impossible filter placement





MO/NA

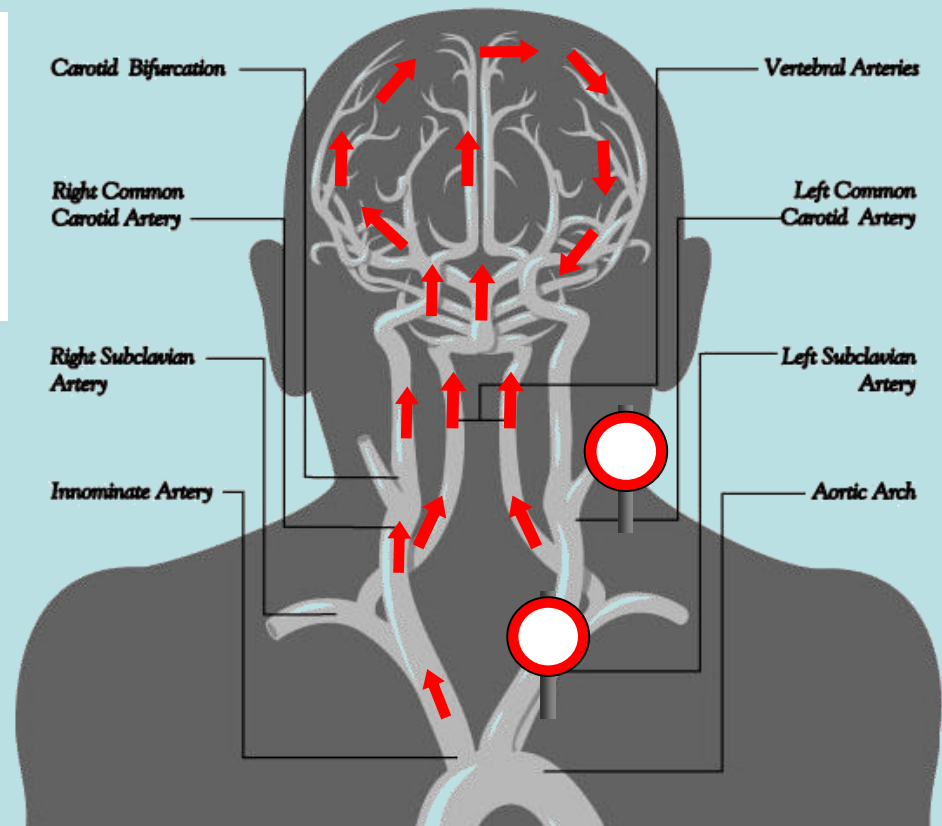
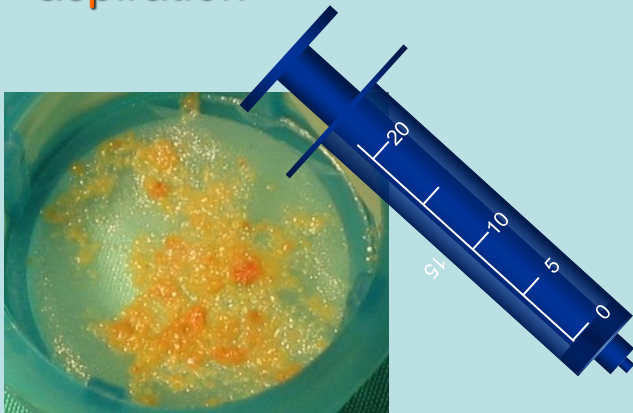
Overview

Proximal Flow Blockage Cerebral Protection Device

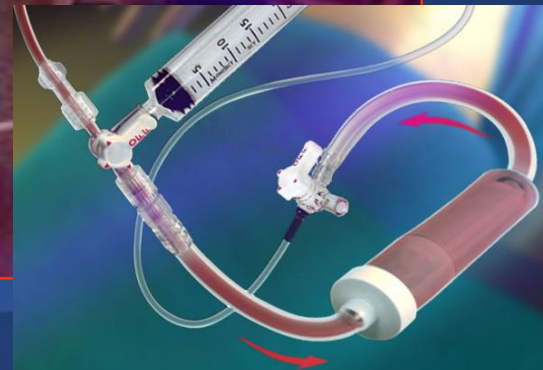
CCA clamping: blockage of antegrade blood flow

- ECA clamping: blockage of retrograde blood flow

- Debris removal: syringe blood aspiration



GORE Neuro-Protection System



Access selection for CAS

Femoral access

Direct Puncture

Possible

Impossible

Common Femoral

Radial Art.

Brachial Art.

Normal

Pathologic

5/6F Shuttle

**5/6F Shuttle
Guiding 7F**

**Guiding 8 or 7 F if
filter**

6F Shuttle

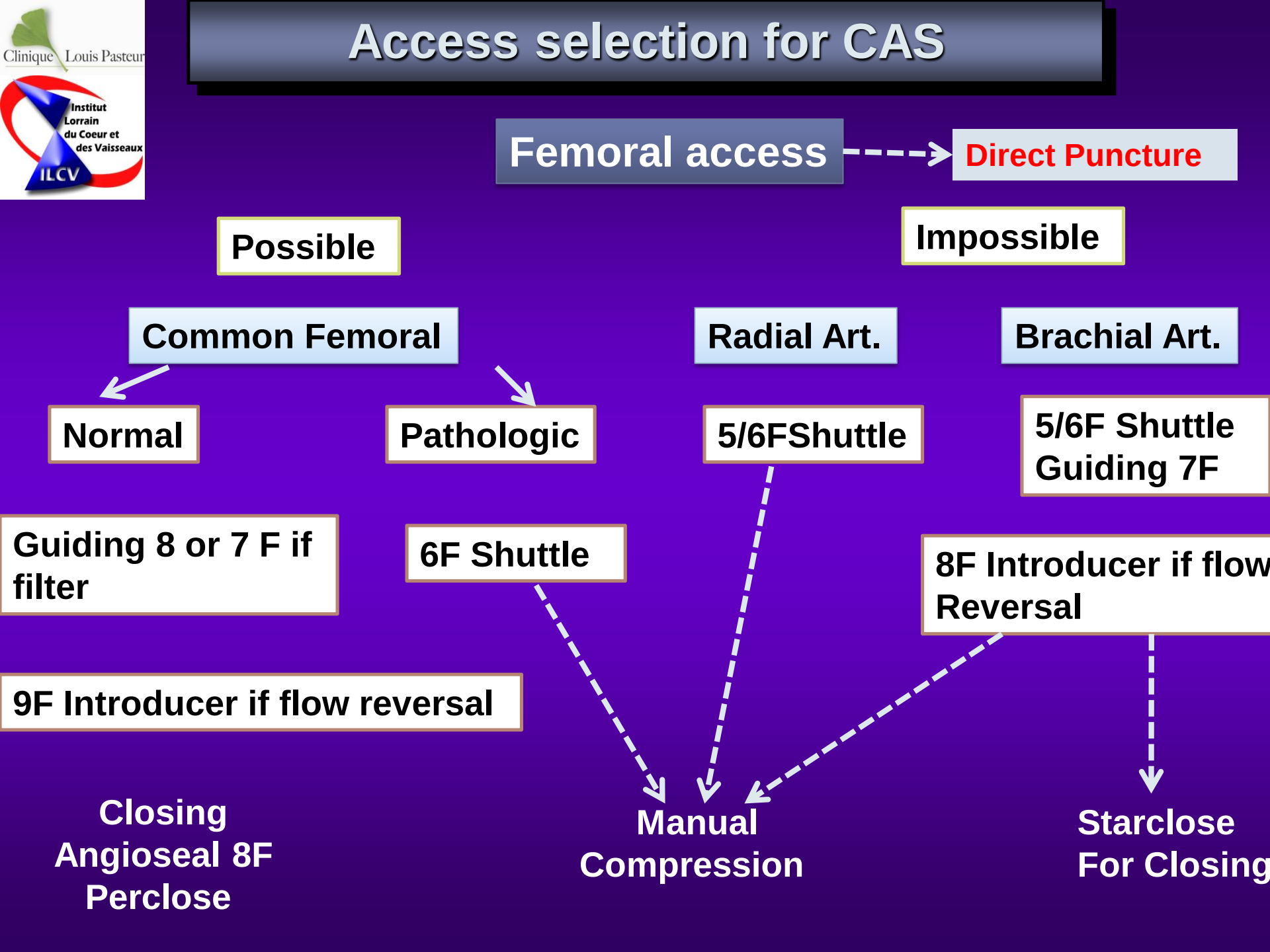
**8F Introducer if flow
Reversal**

9F Introducer if flow reversal

**Closing
Angioseal 8F
Perclose**

**Manual
Compression**

**Starclose
For Closing**



Selection according to the presence of symptoms or high risk factors for CAS (Hypo-echogenic, Ulceration)

Asymptomatic Low Risk

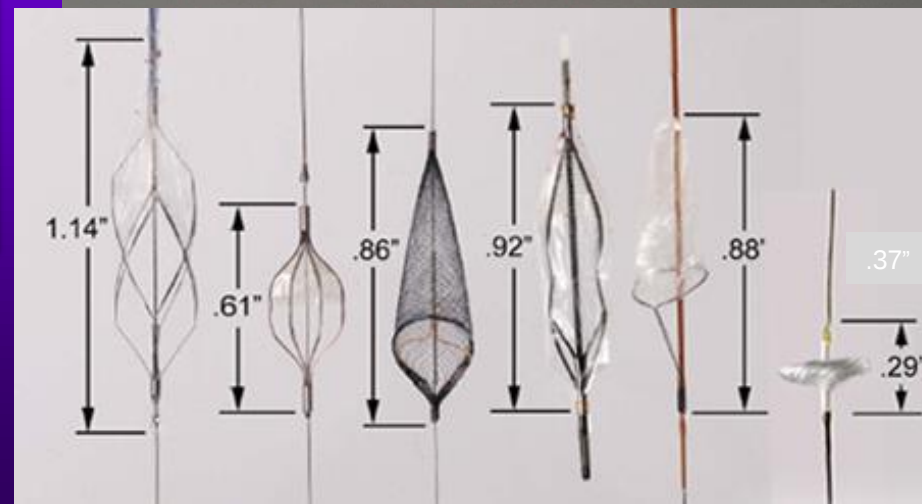
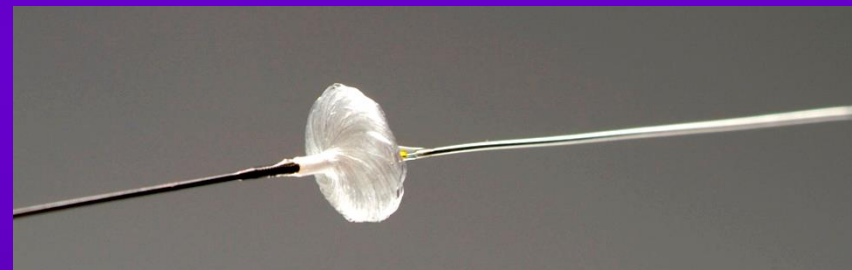
Filter

- **Distal IC**
 - $\leq 5\text{mm}$: Easy Boston, Spider Rx EV3
 - $> 5\text{mm}$: Emboshield, Accunet, Angioguard
- **Crossing**
 - Easy : Easy Boston
 - Difficult: Emboshield Abbott
 - Very Difficult: Spider RX
 - Failure : Surgery or ►

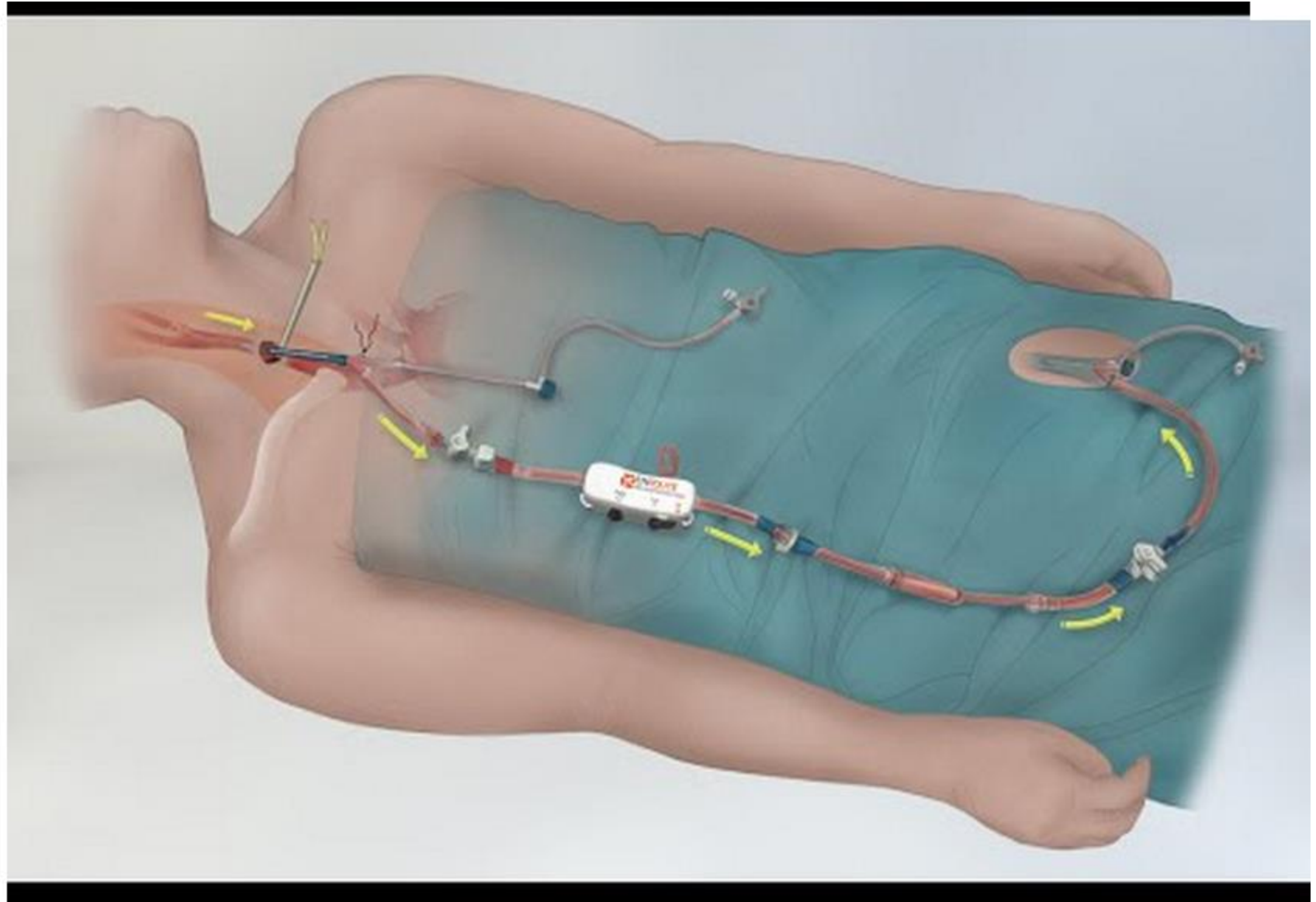
Symptomatic High Risk Octogenarians ?

Flow Reversal

Filter Fibernet Invatec



SILK ROAD CAROTID SYSTEM



CID hautement symptomatique chez Mr Mo. 75ans



Sténose complexe CID + Sténose CED

MONELLE, LUCIEN, 09000589, 18/03/1934, M

3 fps

Clinique Louis Pasteur

70kV, 58mAs

Zoom 63%

Run 1 - Frame 1 / 13

RAO -27,6°
Caudal -0,1°

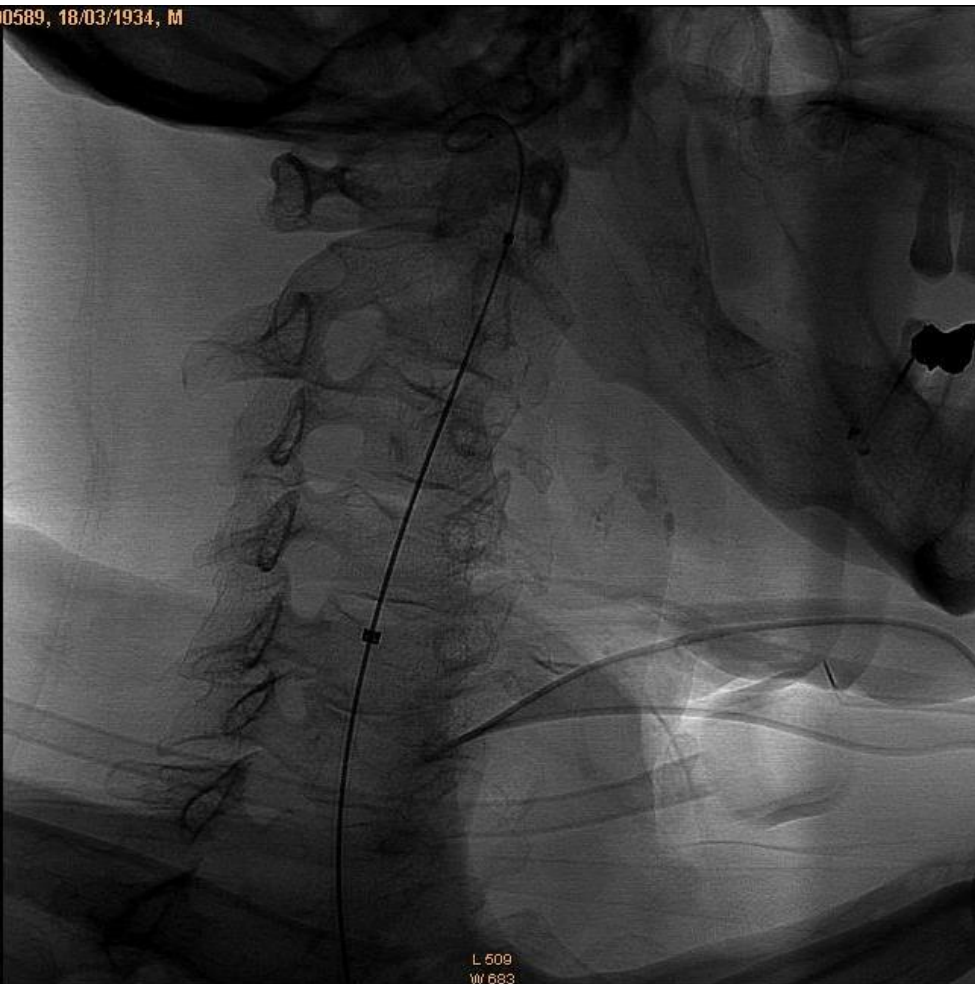
L 563
W 683

1 Terumo stiff et Simmons CED

2 Echange pour un guide extra stiff



00589, 18/03/1934, M



00589, 18/03/1934, M

Rot -28°
Ang 0°
FD 22 cm

CID PRE DILAT

0:00
2:00
11:46:34



1 inflation du ballon CED

2 le flux est interrompu dans CED



Inflation du second ballon CCD

MONELLE, LUCIEN, 09000589, 18/03/1934, M
Run 10 - Frame 1 / 1

Clinique Louis Pasteur
80kV, 12mAs
Zoom 63%

RAD -27,6°
Caudal -0,1°

L 509
W 683



Franchissement de la sténose par guide 0.014" type Pilot 50



1 Déploiement d'un stent Abbott X-act

2 Post dilatation par ballon 5x20mm



1 /stent déployé

2 /résultat Moma en place , les 2



Résultat final

MONELLE, LUCIEN, 09000589, 18/03/1934, M

Run 20 - Frame 1 / 13

3 fps

Clinique Louis Pasteur

70kV, 78mAs

Zoom 63%

RAO -27,6°

Caudal -0,1°

L 568

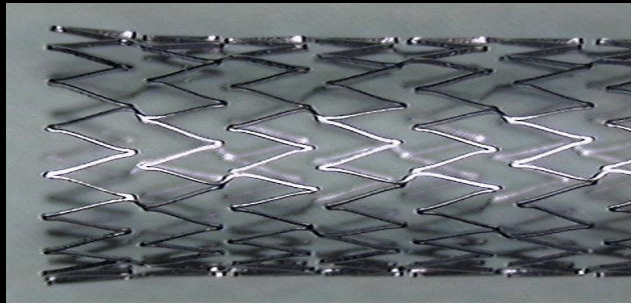
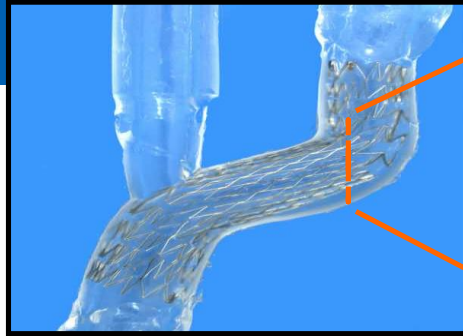
VV 688

d stents

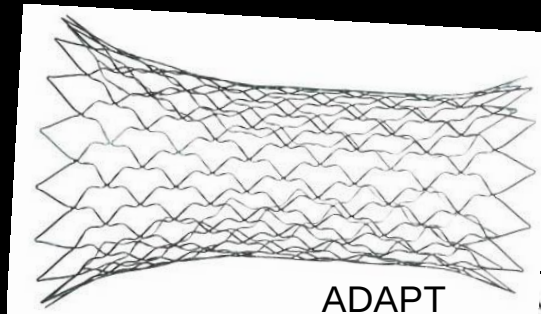
Straight



Tapered



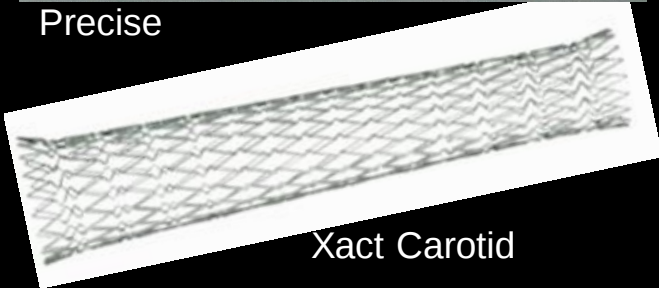
Precise



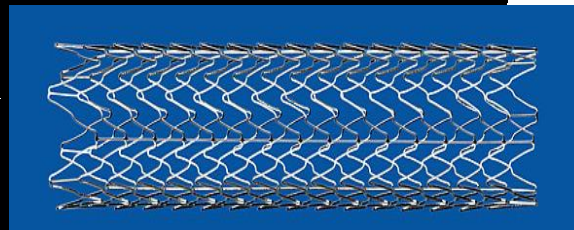
ADAPT



Exp



Xact Carotid



ProtégéRX



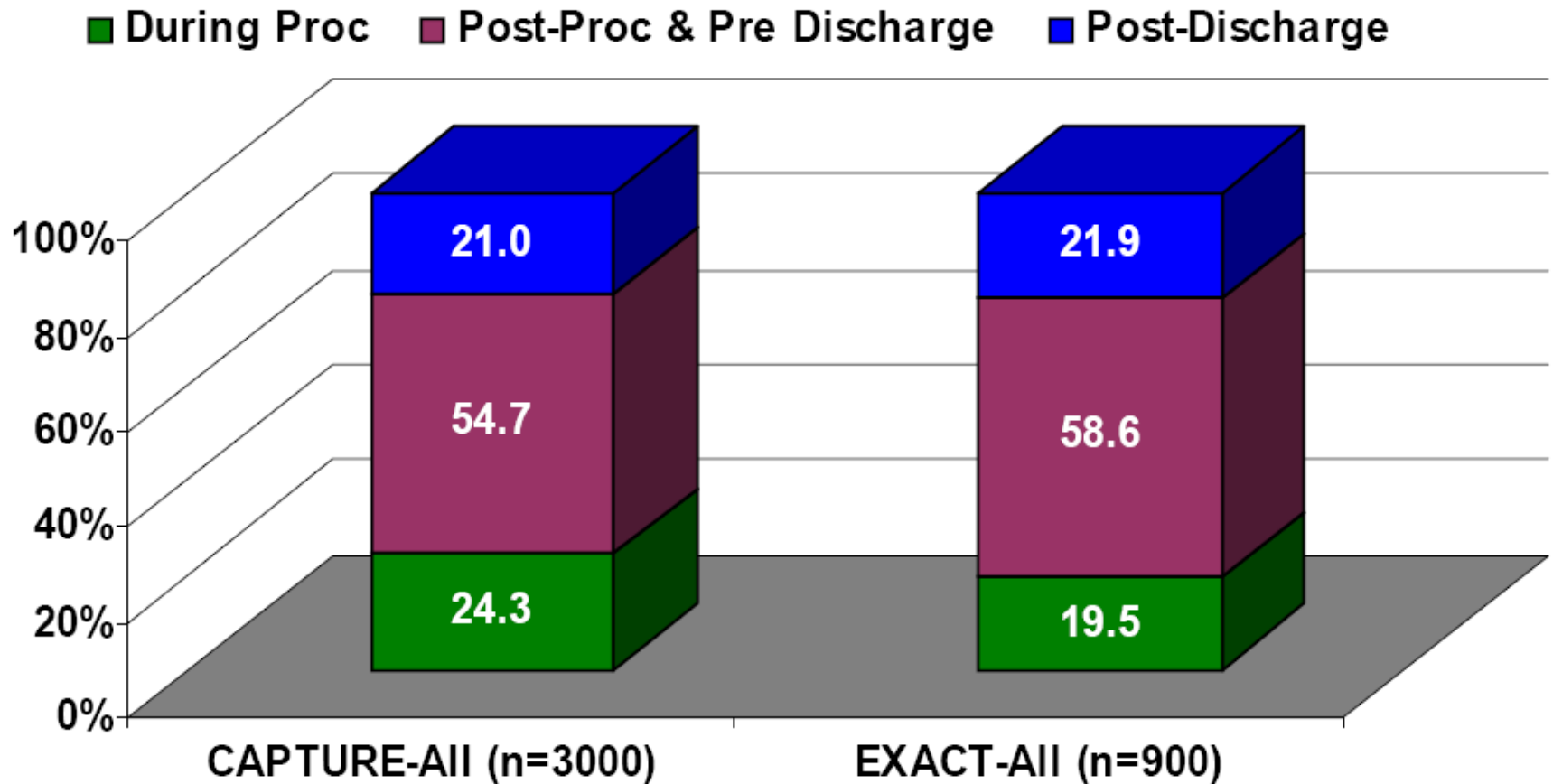
Carotid Wallstent



Stent Selection

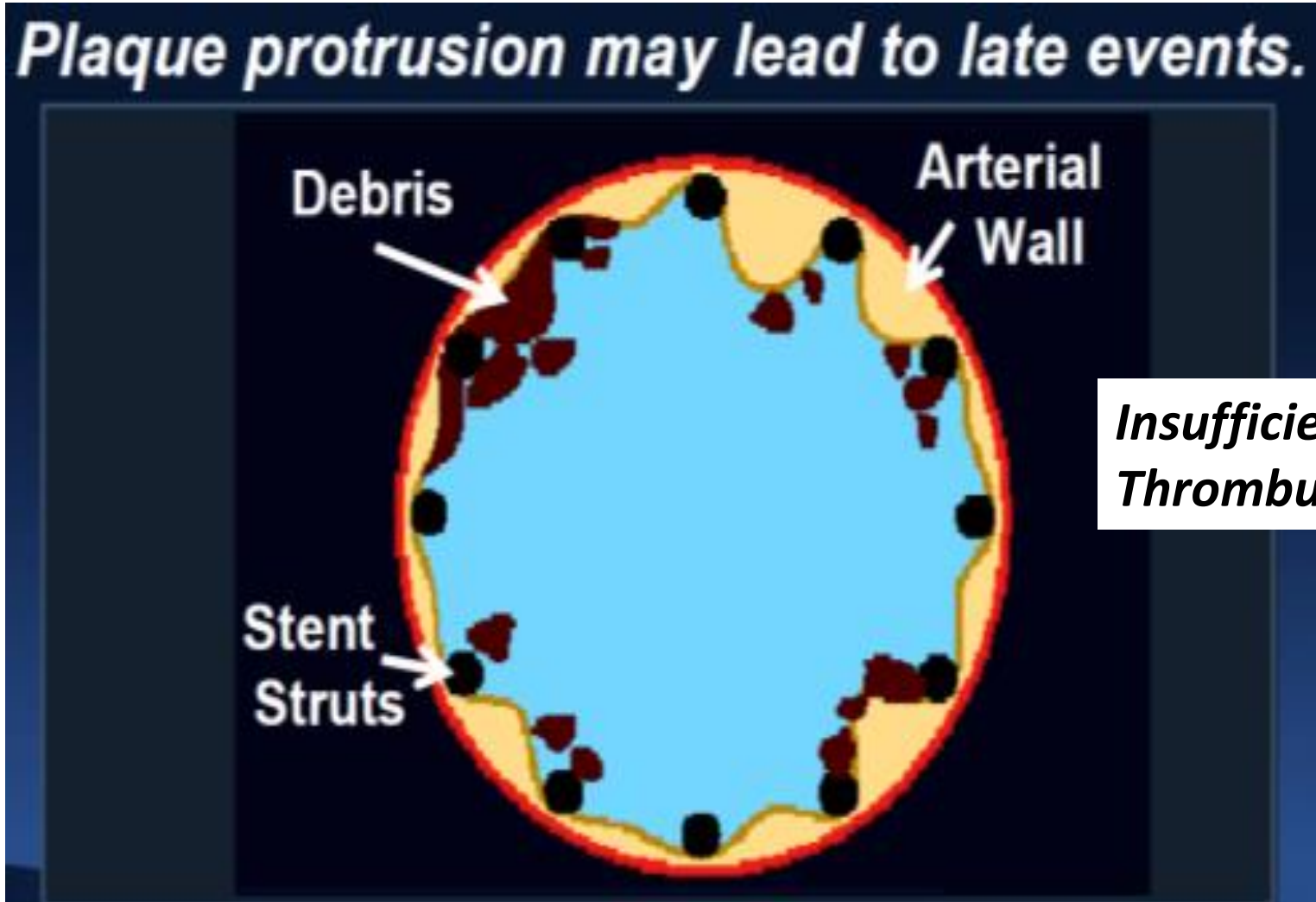
Type	Open Cells Stent			Closed Cells Stent		
Name Comp	Precise Cordis	Acculink Abbott	Proteg EV 3	Wallstent BSC	Adapt BSC	Xact Abbott
Sympto.	+	-	±	+++	+++?	++
Asymp.	+++	++	++	+	++	++
Bifurc.	++	+++	+++	+++	+	±
Ulcerate	++	-	++	+++	++?	+++
Calcified	++	+	++	+	++	+++
Short	+++	++	+++	-	++	+++
Long	++	++	++	+++	++	+
Irr/Coni.	+	+++	+++	+++	++	+++
Resteno sis	+++	+++	+++	+++	+++	+++
Radiothe	++	-	++	+++	-	+++

More than 70% of events after CAS occur after the procedure



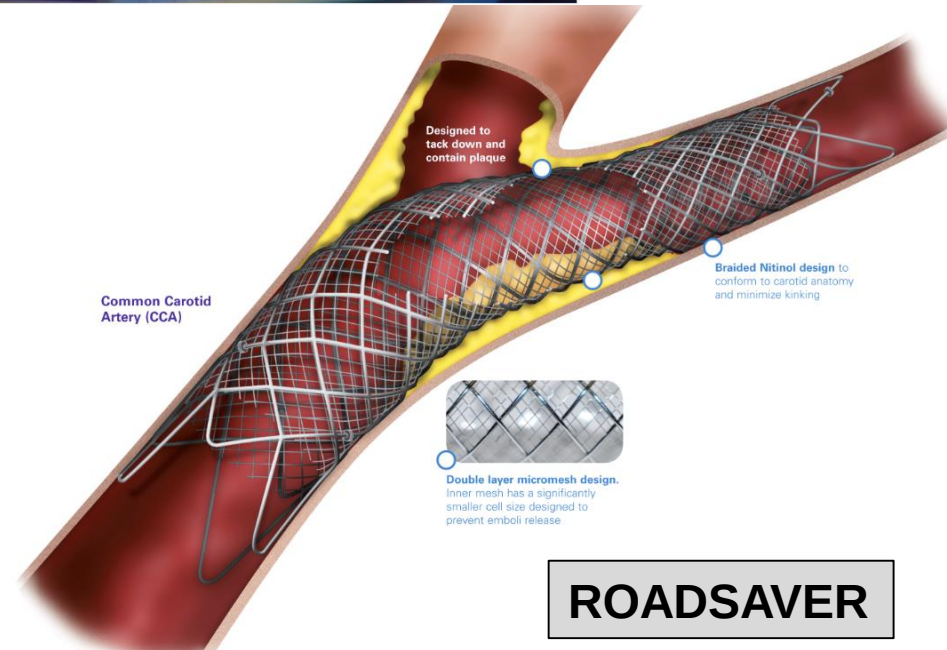
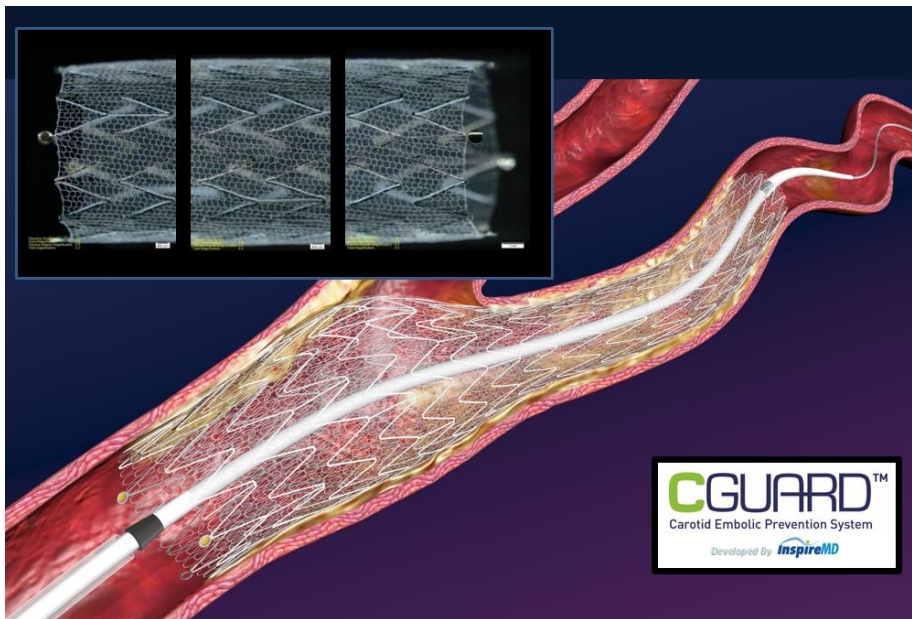
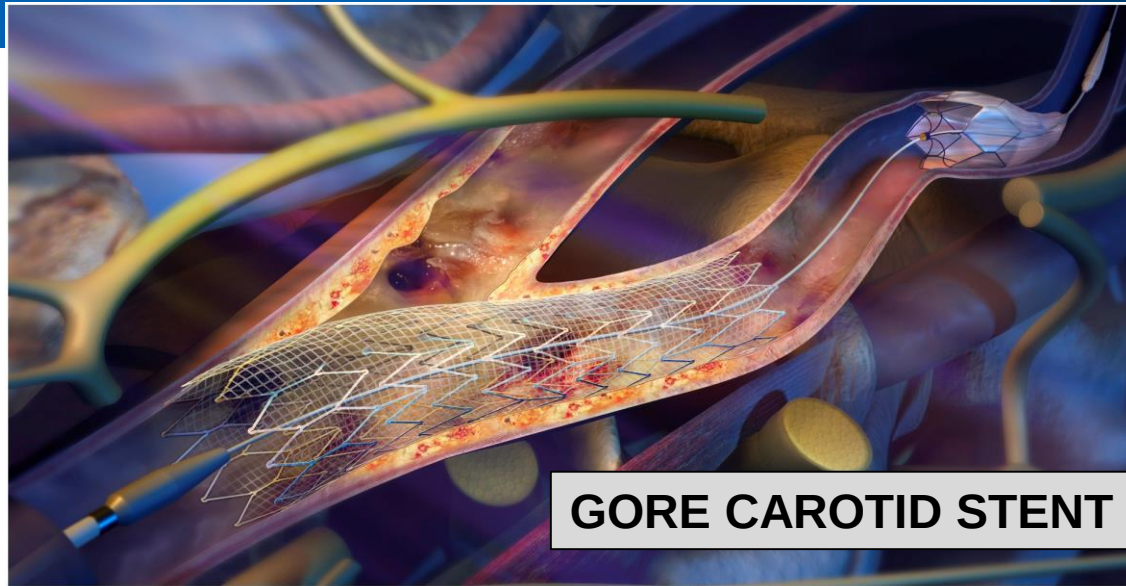
From M.Bosiers, and others

Causes of Late Embolization

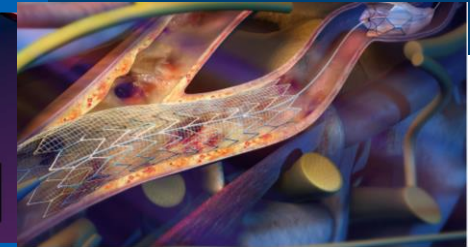
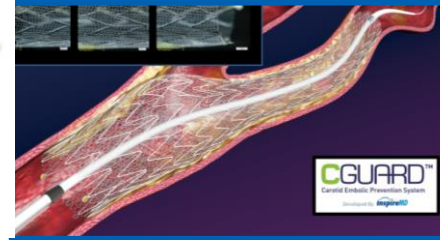
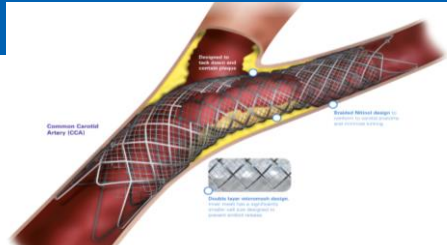


**Are we able to provide
delayed embolic protection
Without losing
the long term benefit of Carotid
Nitinol Stent ?**

THE THREE MICROMESH CAROTID STENTS



Tentative Summary of the main characteristics of the 3 Micromesh Stents



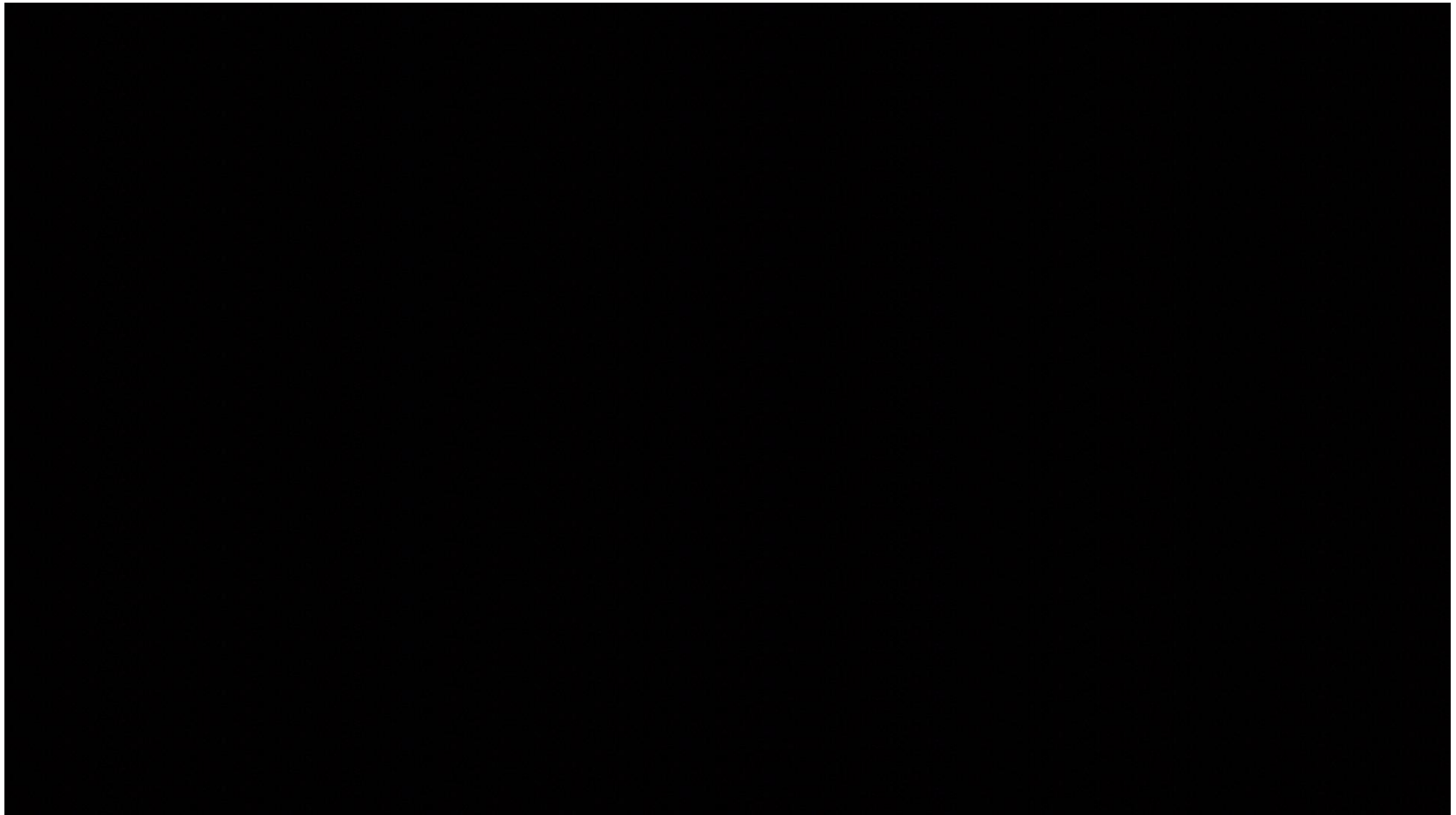
	Roadsaver	CGuard™	Gore Carotid
Company	Microvention /Terumo	Inspire MD	WL Gore
Material (Stent/Micromesh)	Nitinol / Nitinol	Nitinol/ PET	Nitinol/ PTFE/ CBAS Coating
Size of delivery	5F	6F	6F
Size of Pores μ	375-500	150-180	500
Flared tips	yes	no	no
Retrievable/Repositionable	yes	no	no
Accuracy	++	+++	+++
Conformability	+++	++	++
Crossability	+++	++	++
ECA preservation	yes	yes	yes
EPD compatibility	All	All	All

Stent Selection including Micromesh

Type	Open Cells Stent		Closed Cells Stent			Micromesh	
Name Comp	Precise Cordis	Proteg EV 3	Wallstent BSC	Adapt BSC	Xact Abbott	Roadsaver Terumo	Cguard Inspire
Sympto	+	±	+++	+++?	++	+++	+++
Asymp.	+++	++	+	++	++	+++	+++
Bifurc.	++	+++	+++	+	±	+++	+
Ulcerate	++	++	+++	++?	+++	+++	+++
Calcifie	++	++	+	++	+++	+	++
Short	+++	+++	-	++	+++	+	+++
Long	++	++	+++	++	+	+++	+
Accurac	+++	++	+	++	+++	+	+++
Irr/Coni	+	+++	+++	++	+++	++	+
Restenosis	+++	+++	+++	+++	+++	+++	+++
Radioth	++	++	+++	-	+++	+++	+

Highly symptomatic carotid stenosis

Interest of MOMA and Micromesh carotid stent



POTENTIAL RISK FOR PLAQUE PROTRUSION AND EMBOLIZATION

OPEN and CLOSED Cells



Manufacturer	W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
Device	GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE



CLOSED



CLOSED

***CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

COURTESY OF CLAUDIO SCHONHOLZ

First clinical cases
20 Patients with high risk
carotid artery lesions
6 months results

Single center experience

Clinique Louis Pasteur Essey Les Nancy France

Details of procedure

- DAPT before : All
- 15Men , 5 Women . From 49 y to 88 y
- 5 Symptomatic 15 Asymptomatic
- Sedation : Midazolam: All
- Femoral Approach : All
- Protection : 19 : Filters 16 , MOMA 3
- Atropine before inflation :All
- Direct Stenting : 6
- Post-Dilatation: All

Patient and Carotid Lesion Characteristics

Patient			Lesion					
N & initials	Sex& Age	Symp	Side & Severity	Including bifurcation	Calcified	Irregular & or Ulcerated	Echogenicity	Length mm
1 V.G	M80y	No	Right 80%	Yes	Yes	No	Mixed	15
2 R.H	M83y	No	Right 80%	Yes	Yes	Yes	Mixed	20
3 S.H	M65y	YES	Left 80%	No	No	Yes	Hypo	15
4 H.Y	M84y	No	Right 80%	No	Yes	Yes	Hyper	15
5 C.P	M75y	No	Left 90%	yes	No	Yes	Hypo	15
6 T.R	M85y	YES unsta	Right 99%	Yes	No	Yes	hypo	20
7 A.M	F80y	No	Right 75%	Yes	Yes	Yes	Mixed	20
8 T.G	M75y	No	Right 80%	Yes	Yes	no	Hypo	20
9 T.J	F62y	No	Left 85%	No	Yes	Yes	Hypo	15
10 R.C	M65y	No	Left 90%	No	No	Yes	Hypo	20

Patient and Carotid Lesion Characteristics

Patient			Lesion					
N & initials	Sex& Age	Symp	Side & Severity	Including bifurcation	Calcified	Irregular & or Ulcerated	Echogenicity	Length mm
11 G.P	M52y	No	Left 80%	No	Yes	Yes	Hypo	15
12 D.F	M73y	No	Left 80% Bilat stenosis	Yes	No	Yes	Hypo	20
13 S.B	F79y	Yes	Right 90%	Yes	No	Yes	Hypo	25
14M.M	F80y	No	Right 80% Bilat stenosis	Yes	Yes	Yes	Hyper	20
15 B.J	M49y	Yes	Right 50%	No	No	Floating	Hypo	20
16 R.S	M 81y	No	Left 80%	Yes	No	Yes	Mixed	20
17 A.M	M 77y	No	Left 80%	Yes	Yes	Yes	Hyper	15
18 P.J	M 75y	No	Left 70%	Yes	No	Yes	Mixed	20
19 L.C	M 66y	No	Left 80%	Yes	No	Yes	Hypo	20
		No	Right 75%	No	No	Yes	Hypo	15
20 T.J	F 88y	Yes	Right 80%	Yes	Yes	Yes	Hyper	20

Procedure & 48h Embolic Events & 30th day & 6 months

N	Access	Guiding : G Shuttle: I	Protection System	Pre- dilatation	Post – Stent Dilatation	Stent Size	48 h Embolic	30 th Day MAE	6 th Month
1	Fem	8F M.P	Filterwire	Yes	Yes	8x25	none	None	none
2	Fem	8F M.P	Filterwire	Yes	Yes	7x25	None/ Hyperfusion ++++	None	none
3	Fem	9F Moma	MOMA	Yes	Yes	8x25	NONE	None	none
4	Fem	8F	Emboshie	Yes	Yes	7x25	None	None	none
5	Fem	8F	Emboshie	Yes	Yes	8x25	NONE	None	none
6	Fem	9F Moma	MOMA	Yes	Yes	8x25	NONE	None	none
7	Fem	8F M.P	Filterwire	NO	Yes	8x25	None	None	none
8	Fem	8F M.P	Filterwire	Yes	Yes	7x25	None	None	none
9	Fem	8F M.P	Filterwire	Yes	Yes	8x25	None	None	none
10	Fem	7F Destin	Filterwire	Yes	Yes	8x25	None	None	none

Procedure & 48h Embolic Events & 30th day

N	Access	Guiding : G Shuttle: I	Protection System	Pre- dilatation	Post –Stent Dilatation	Stent Size	48 h Embolic	30 th Day MAE
11	Fem	8F M.P	Filterwire	NO	Yes	8x25	None	None
12	Fem	8F H.S	Emboshi	Yes	Yes	8x25	None	None
13	Fem	8F M.P	Emboshi	Yes	Yes	7x35	None	None
14	Fem	6F Shutt	Filterwire	Yes	Yes	7x35	None	None
15	Fem	9F Moma	MOMA	No	Yes	8x35	None	None
16	Fem	8F HS	Filterwire	NO	Yes	9x20	None	None
17	Fem	8F Saad L	Emboshi	Yes	Yes	8x25	None	None
18	Fem	8F H.S	Emboshi	Yes	Yes	7x25	None	None
19	Fem	8F H.S	Filterwire	Yes	Yes	9x30	Severe HT	None
		Idem	Idem	NO	Yes	8x25	HypoT	None
20	Fem	8F M.P	NO	NO	Yes	8x25	None	None

Complications after 48 h before discharge and 30th day

- No significant local complications requiring surgery

At 6months

No new strokes

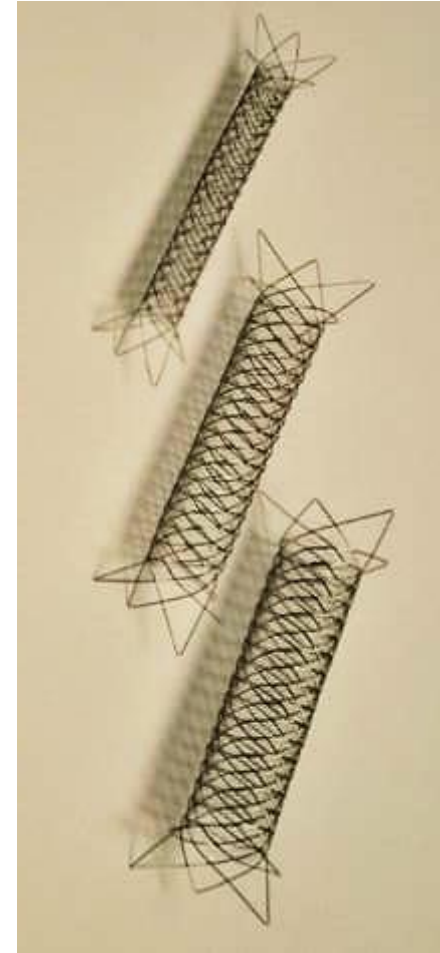
No restenosis

No stent deformation or fracture

No external carotid occlusion

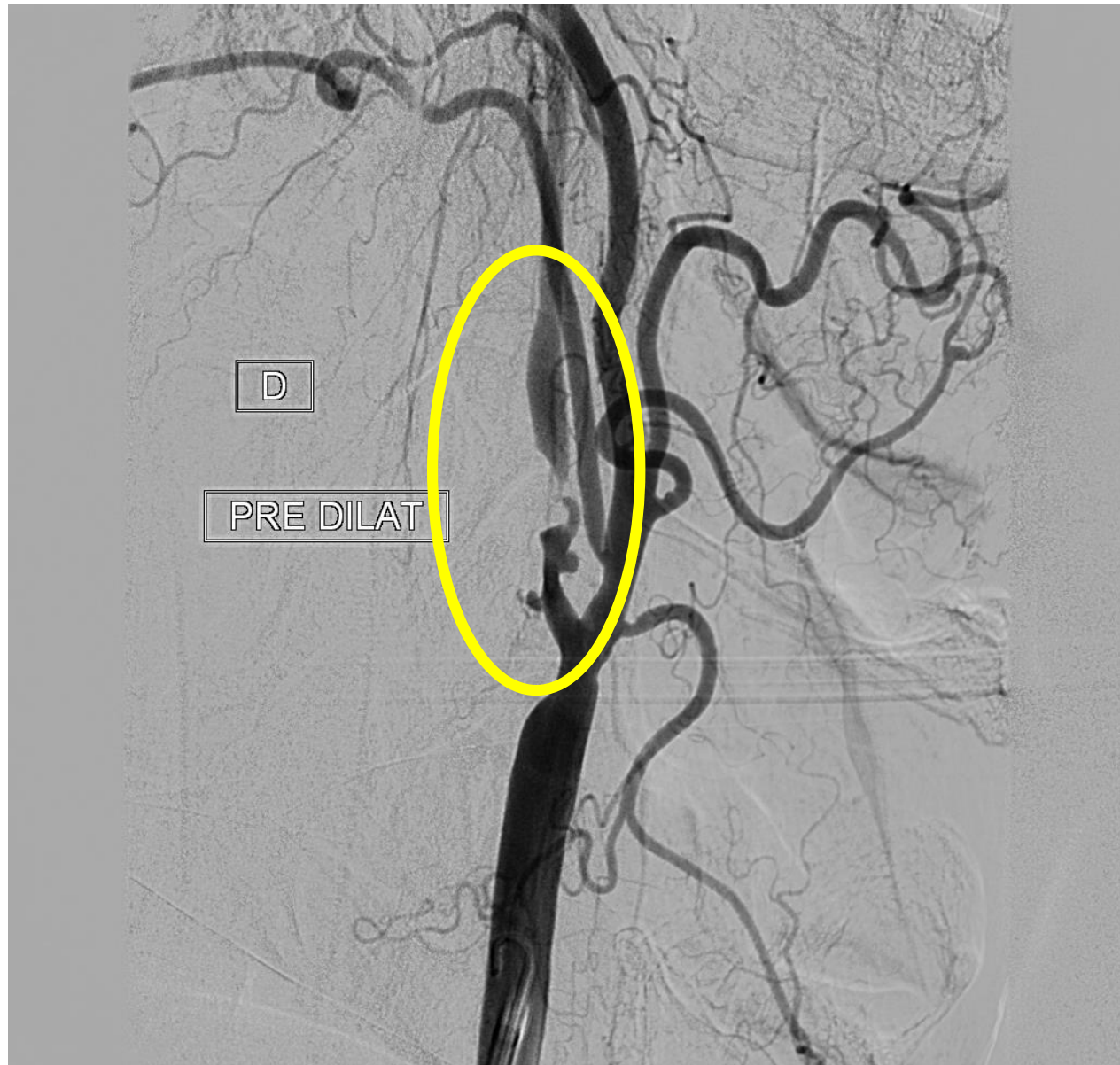
procedure (2D echo control)

83 y ,male , Right Internal asymptomatic carotid stenosis



Roadsaver Stent

Severe Symptomatic RCA stenosis with **multiple ulcerations**



After ROADSaver Stent 10x30mm placed under filter protection





Symptomatic chronic Dissection & Ulcerated RICA Stenosis



ip
P
2

N5 LICA



N 5 Final Result

Rot +26°
Ang -1°
FD 19 cm

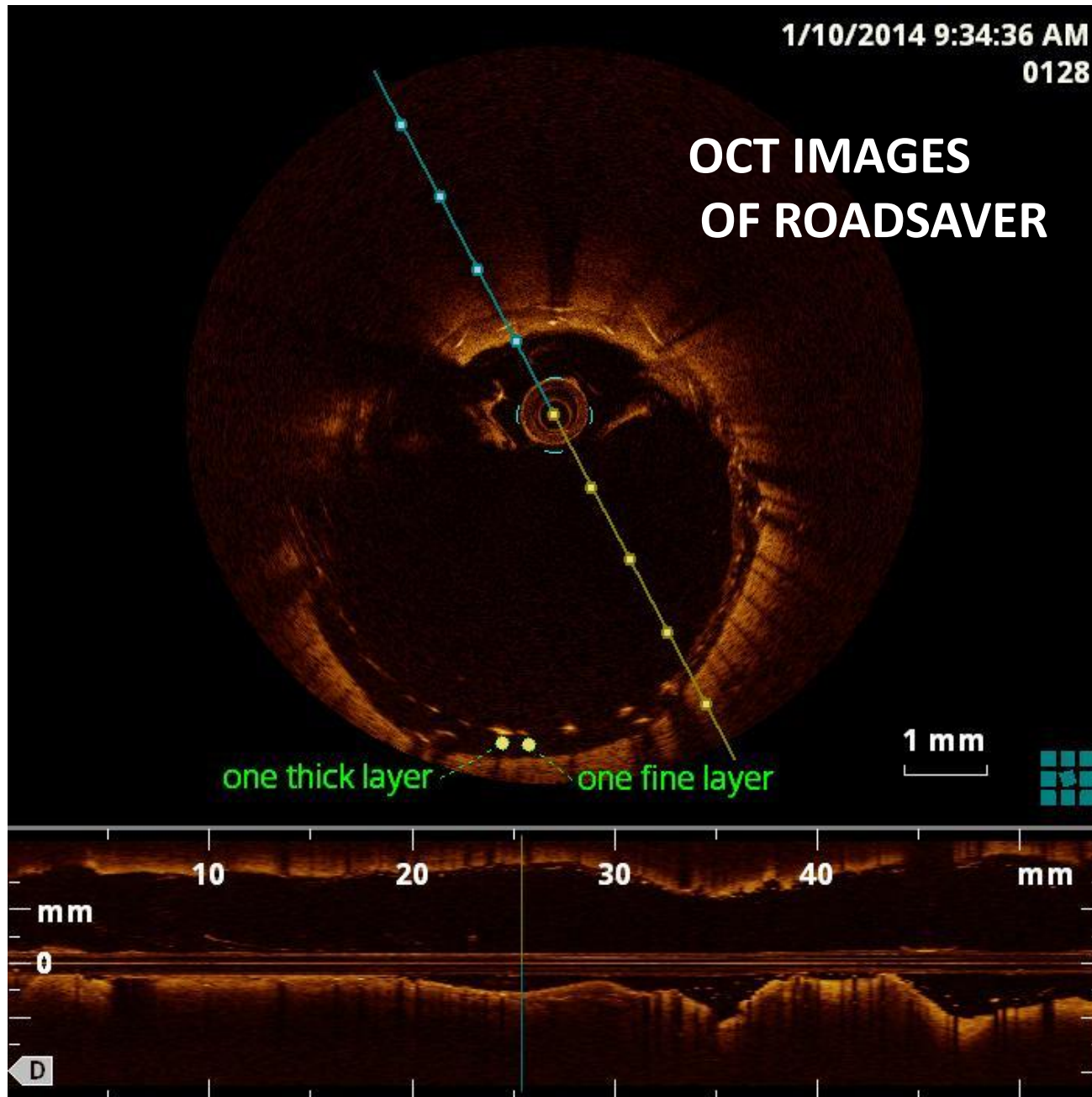


0:00
3:33
14:45:41

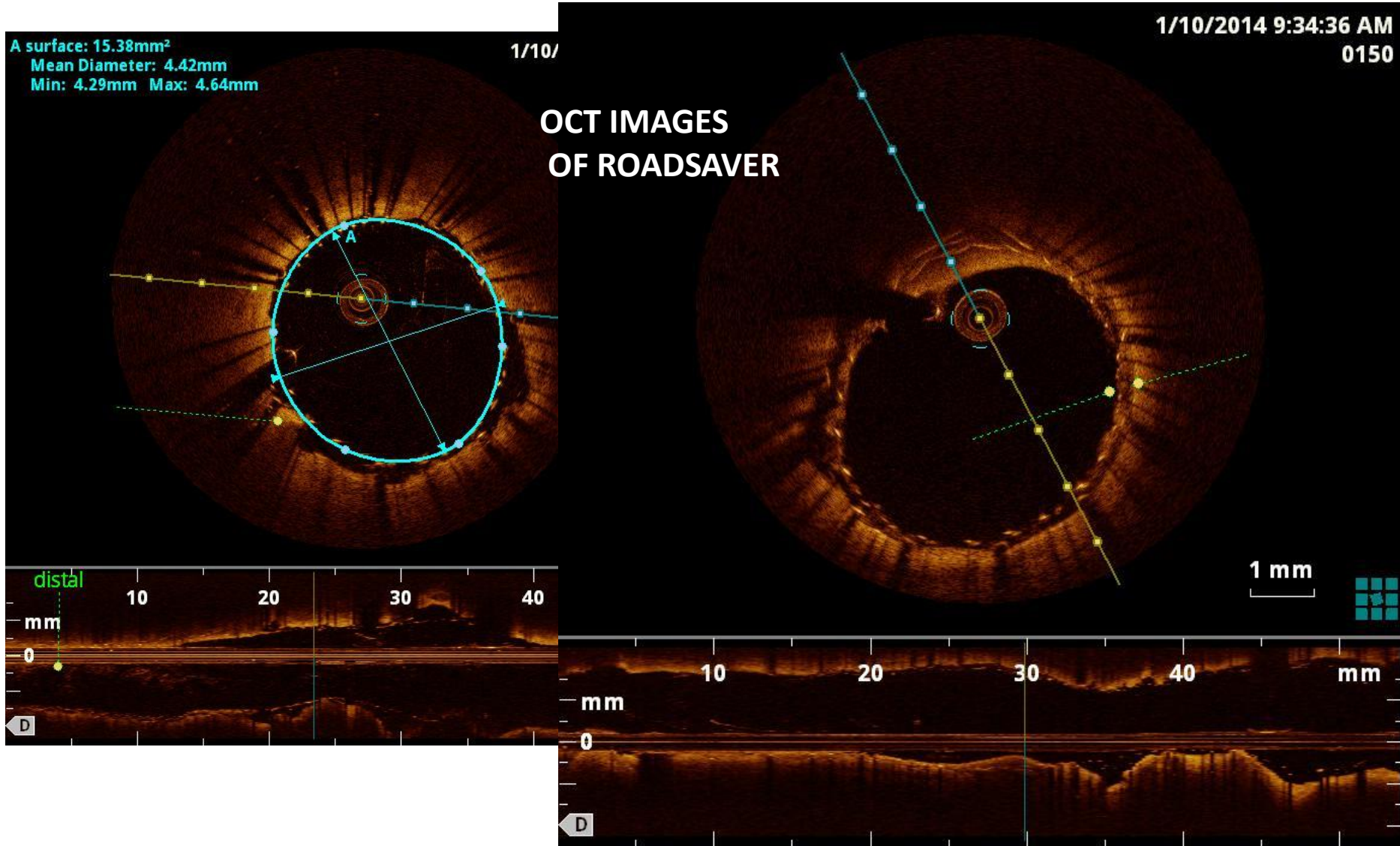


1/10/2014 9:34:36 AM
0128

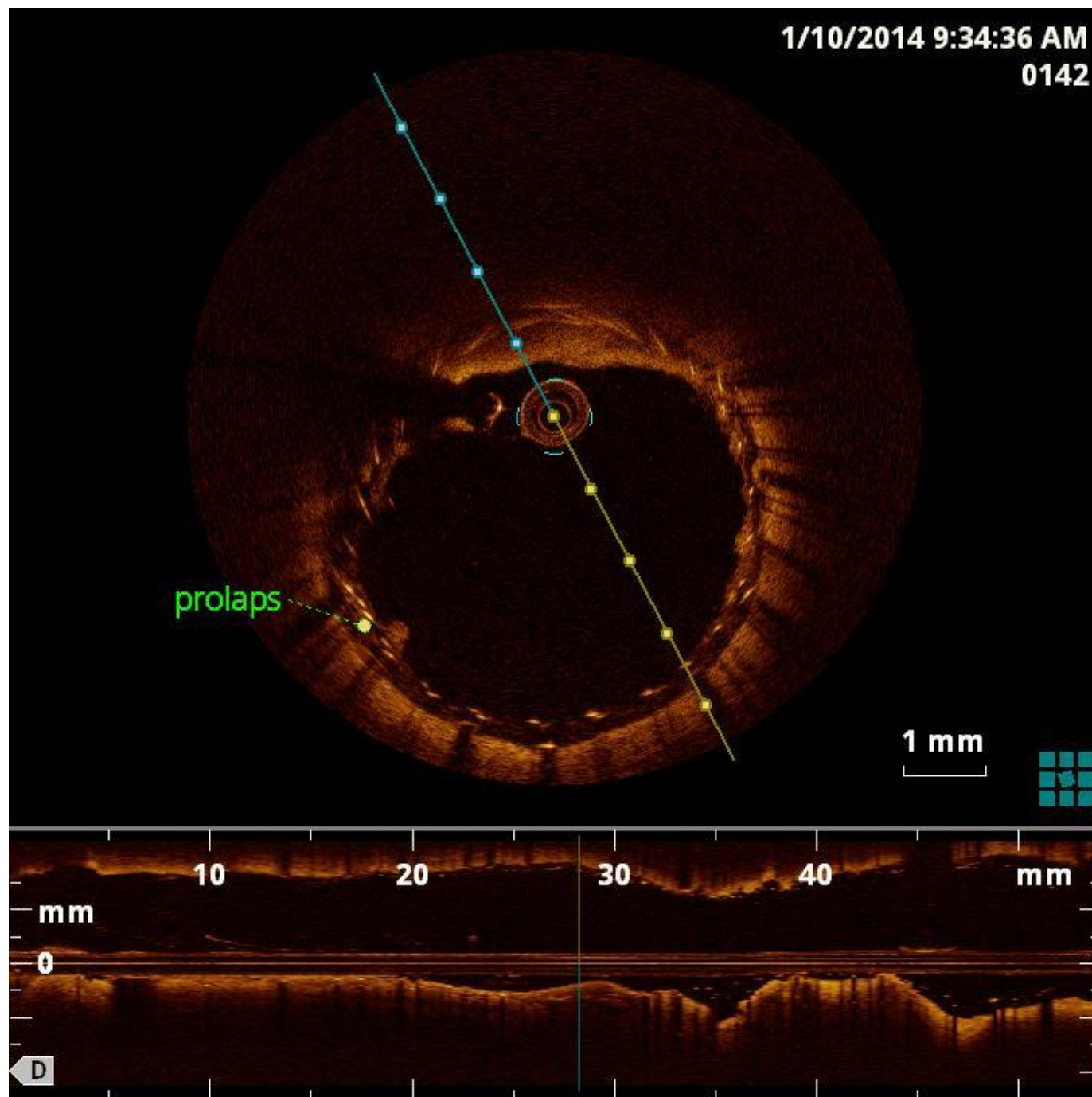
OCT IMAGES OF ROADSAVER



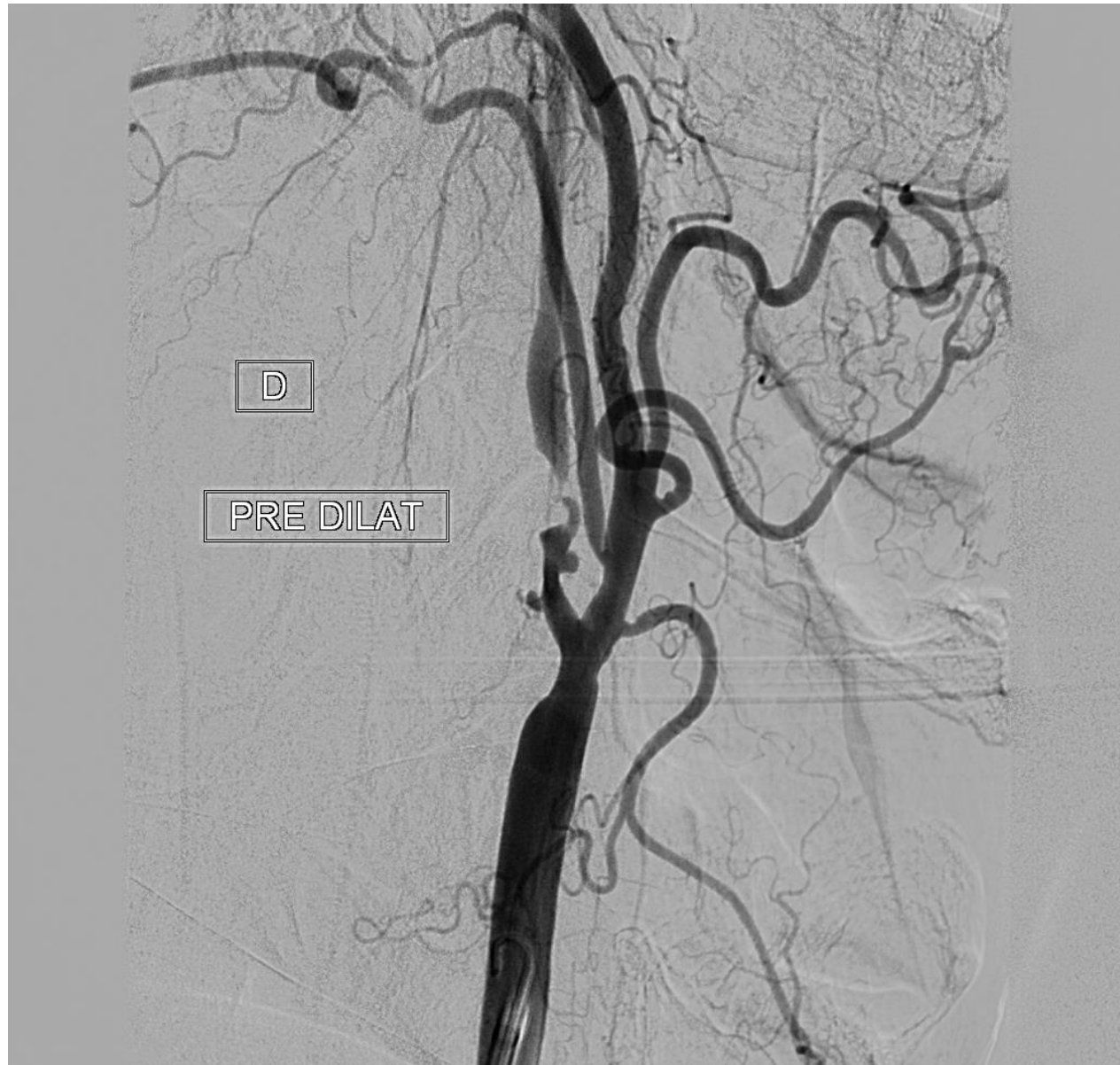
Harmonious deployment



1/10/2014 9:34:36 AM
0142

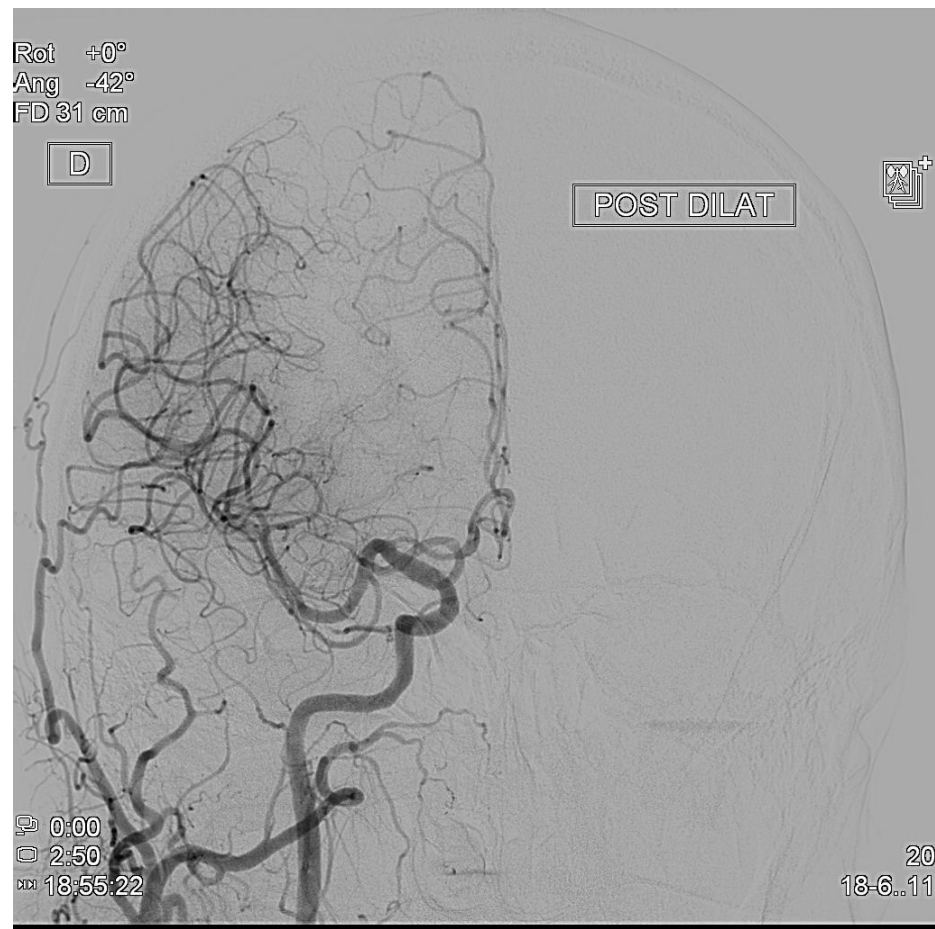


Severe Symptomatic RCA stenosis with multiple ulcerations



After ROADSaver Stent 10x30mm placed under filter protection







Symptomatic chronic Dissection & Ulcerated RICA Stenosis



Stent Selection including Micromesh

Type	Open Cells Stent		Closed Cells Stent			Micromesh	
Name Comp	Precise Cordis	Proteg EV 3	Wallstent BSC	Adapt BSC	Xact Abbott	Roadsaver Terumo	Cguard Inspire
Sympto	+	±	+++	+++?	++	+++	+++
Asymp.	+++	++	+	++	++	+++	+++
Bifurc.	++	+++	+++	+	±	+++	+
Ulcerate	++	++	+++	++?	+++	+++	+++
Calcifie	++	++	+	++	+++	+	++
Short	+++	+++	-	++	+++	+	+++
Long	++	++	+++	++	+	+++	+
Accurac	+++	++	+	++	+++	+	+++
Irr/Coni	+	+++	+++	++	+++	++	+
Restenosis	+++	+++	+++	+++	+++	+++	+++
Radioth	++	++	+++	-	+++	+++	+

Conclusions (more than 2000 CAS in our center)

- From this first 20 cases we conclude that Roadsaver micromesh stent represents a true and important progress in carotid stenting
 - Is very easy to place and to deploy (Re-sheathable and Repositionable ,5F compatible)
 - Compatible with all systems of carotid protection
 - Easy to recross and to visualize
 - Does not occlude external carotid
 - Contain plaque or debris against the arterial wall following stent deployment : Plaque coverage and Scaffolding
 - Seems superior to other stents on the market in preventing immediate and delayed embolization
- It is premature to recommend the widespread of these new stents before following them for several months, but the Micromesh stent represents a true progress in carotid stenting.

**LONG TERM
RESULTS
ARE the KEY!!!!!!**

END

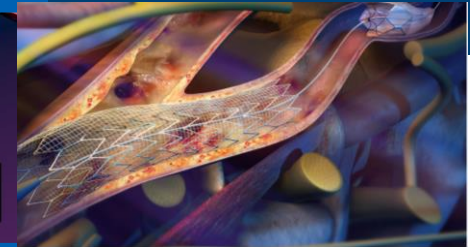
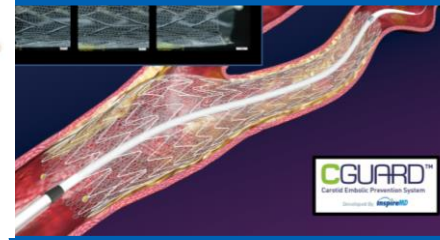
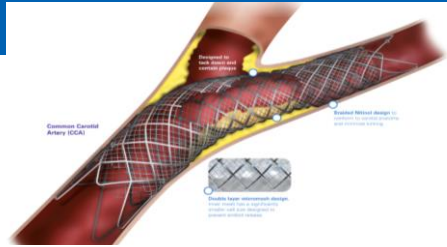
**Seven Roadsaver cases have been
recorded and commented by
Subbarao Myla and are visible in**

www.incathlab.com

Stent Selection

Type	Open Cells Stent			Closed Cells Stent			Micromesh
Name Comp	Precise Cordis	Acculink Abbott	Proteg EV 3	Wallstent BSC	Adapt BSC	Xact Abbott	Roadsaver Terumo
Sympto.	+	-	±	+++	+++?	++	+++
Asymp.	+++	++	++	+	++	++	+++
Bifurc.	++	+++	+++	+++	+	±	+++
Ulcerate	++	-	++	+++	++?	+++	+++
Calcified	++	+	++	+	++	+++	+
Short	+++	++	+++	-	++	+++	+
Lon	++	++	++	+++	++	+	+++
Irr/Coni.	+	+++	+++	+++	++	+++	++
Resteno sis	+++	+++	+++	+++	+++	+++	+++
Radiothe	++	-	++	+++	-	+++	+++

Tentative Summary of the main characteristics of the 3 Micromesh Stents



	Roadsaver	CGuard™	Gore Carotid
Company	Microvention /Terumo	Inspire MD	WL Gore
Material (Stent/Micromesh)	Nitinol / Nitinol	Nitinol/ PET	Nitinol/ PTFE/ CBAS Coating
Size of delivery	5F	6F	6F
Size of Pores μ	375-500	150-180	500
Flared tips	yes	no	no
Retrievable/Repositionable	yes	no	no
Accuracy	++	+++	+++
Conformability	+++	++	++
Crossability	+++	++	++
ECA preservation	yes	yes	yes
EPD compatibility	All	All	All

CARENET - CGuard Clinical Data 30 PATIENTS

50% reduction in incidence of new lesions
10-fold reduction in average volume of new lesions
100% of lesions disappeared by 30 days post procedure

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

	CARENET (Filter group) N=26	PROFI ¹ (Filter group) N=31	ICSS ² (Filter group) N=37
Incidence of New Lesions	48%	87%	73%
Avg Lesion Volume	0.06 cm ³	0.59 cm ³	NA

All Infarcts GONE at 30 days

Prof. Dr. Joachim Schofer, TCT

Unique Benefit of CGuard

Ability to dilate MicroNet with balloon to optimize blood flow into carotid side branches without any net rupture





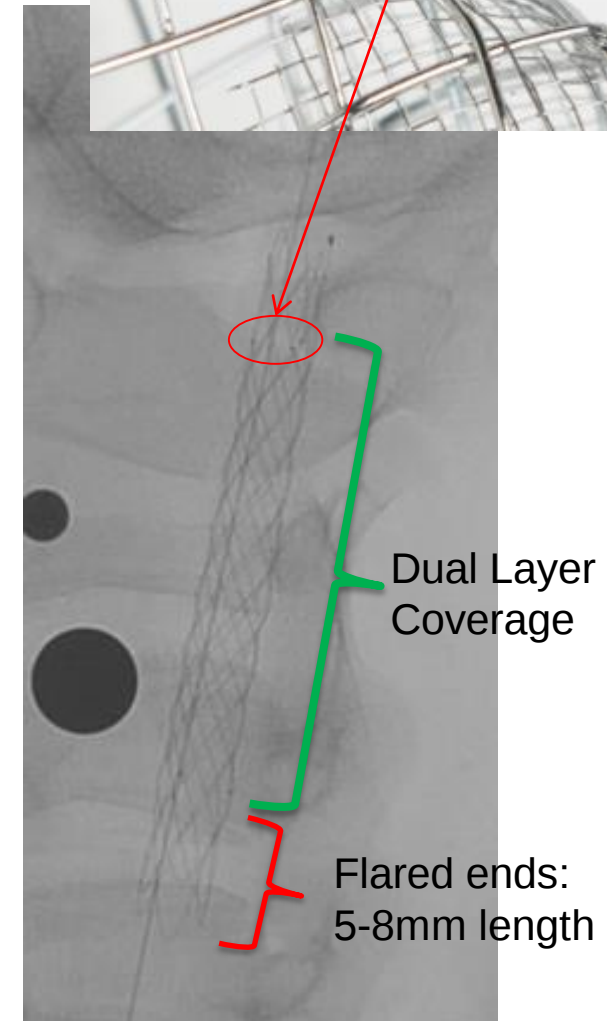
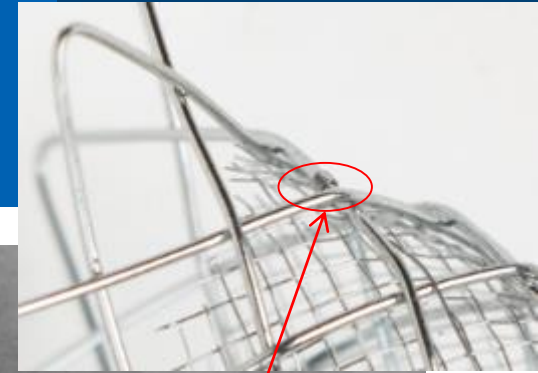
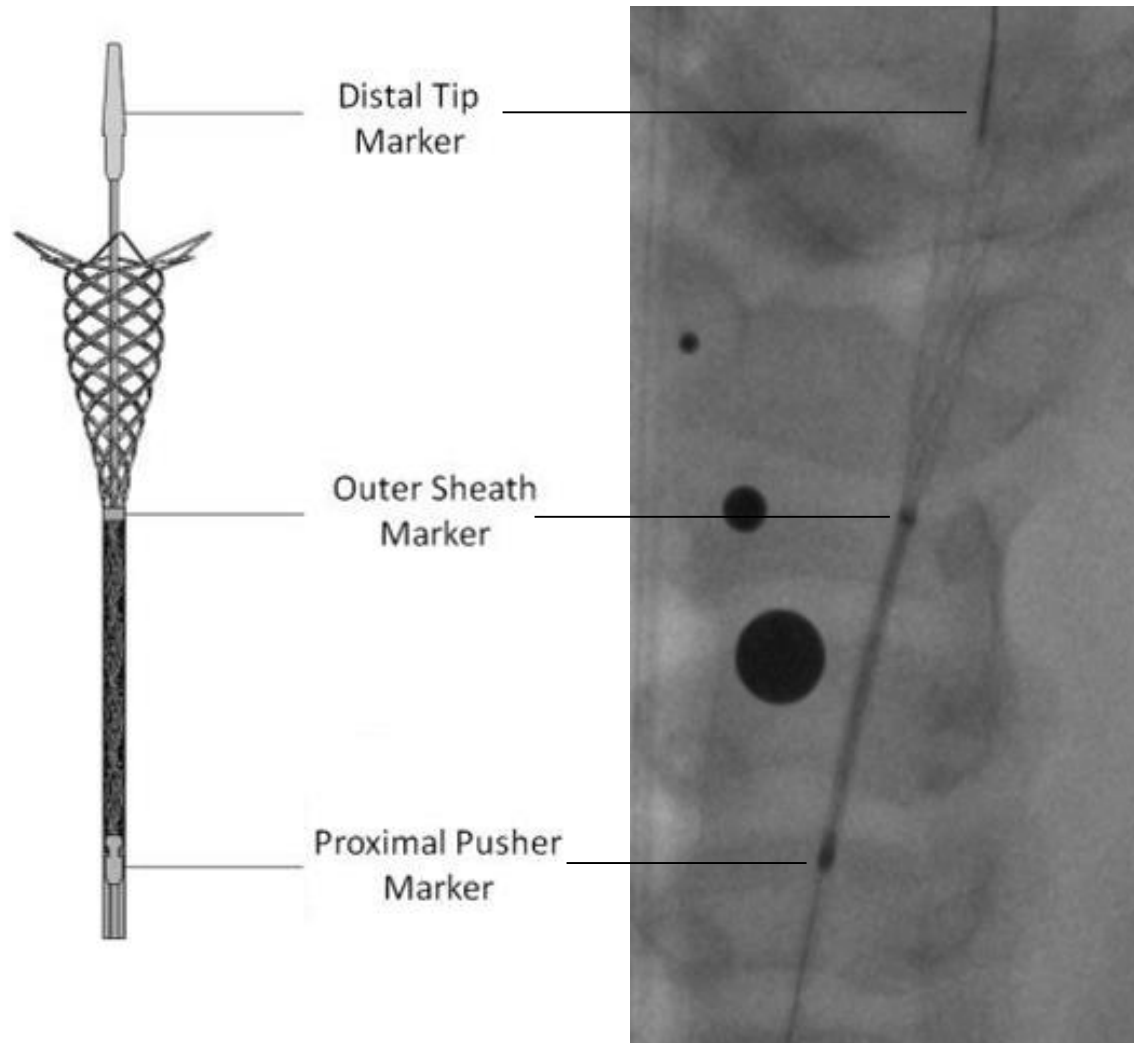
VEITH SYMPOSIUM SUPPORT SLIDES

ROADSAVER

Reasons for carotid stenting in our serie

- Age
- Symptomatic
- Presence of coronary insufficiency
- Bilaterality
- Before surgery
- Worsening during F/U
- Cranial nerve paralysis post contra-lateral CEA
- Patient and referral physician preference

Marker Configuration



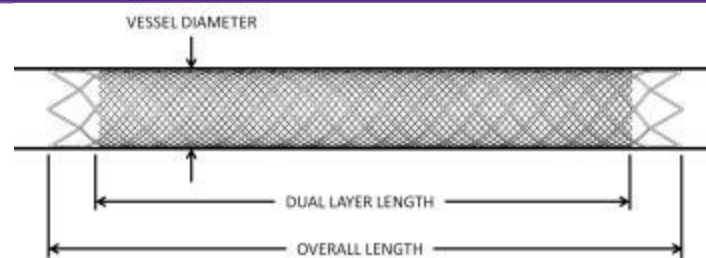
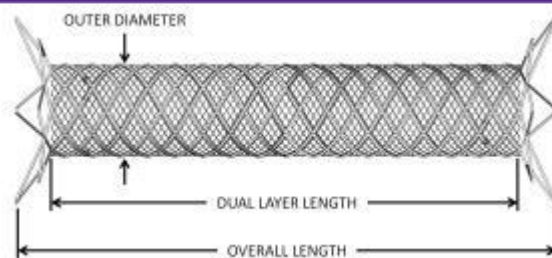
- Up to 50% Re-sheathable and Re-positionable

System Sizes

CASPER™ RX Carotid Artery Stent

1 per box

Product Code	Unconstrained Dimensions			Implanted Dimensions			
	Diameter (mm)	Dual Layer Length (mm)	Overall Length (mm)	1mm < Unconstrained Diameter		2mm < Unconstrained Diameter	
				Dual Layer Length (mm)	Overall Length (mm)	Dual Layer Length (mm)	Overall Length (mm)
CPR-0520-143X	5	20	25	20	33	22	35
CPR-0530-143X	5	30	37	35	47	38	52
CPR-0540-143X	5	40	47	45	59	52	64
CPR-0625-143X	6	25	33	30	44	33	48
CPR-0630-143X	6	30	40	40	53	43	58
CPR-0725-143X	7	25	35	30	47	36	52
CPR-0730-143X	7	30	40	40	53	44	60
CPR-0825-143X	8	25	35	30	49	38	54
CPR-0830-143X	8	30	40	40	55	45	61
CPR-0840-143X	8	40	47	50	67	60	75

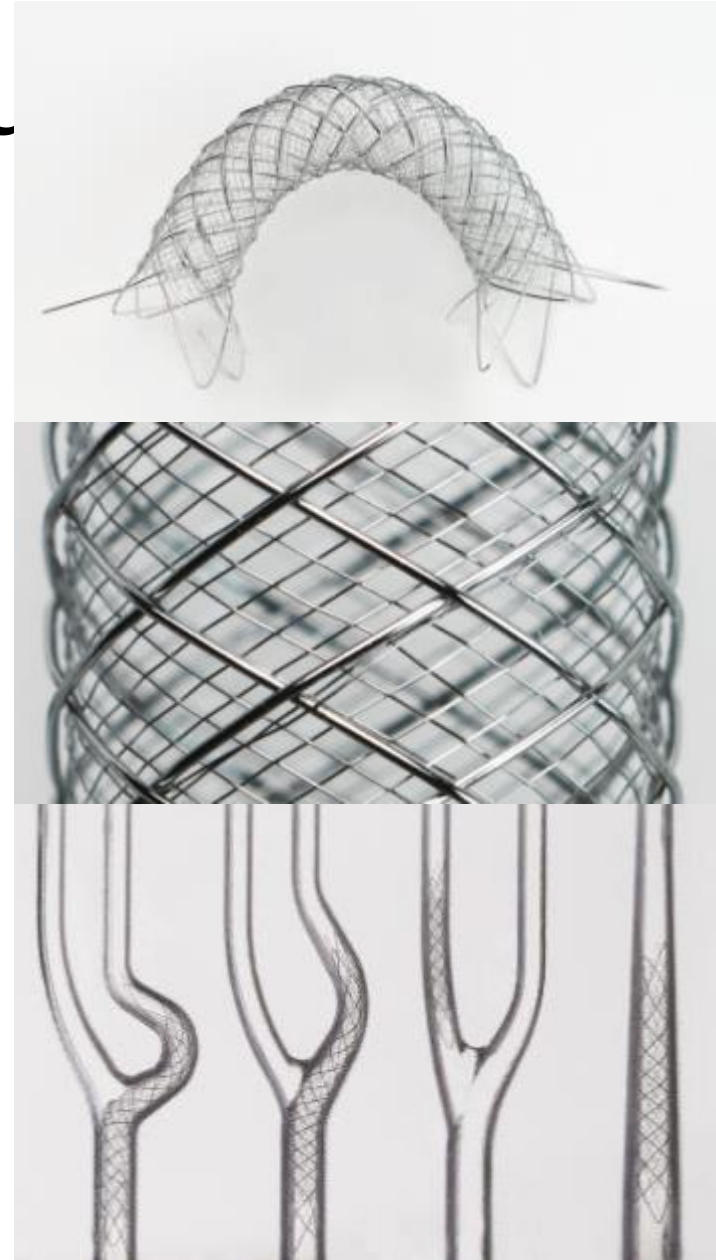


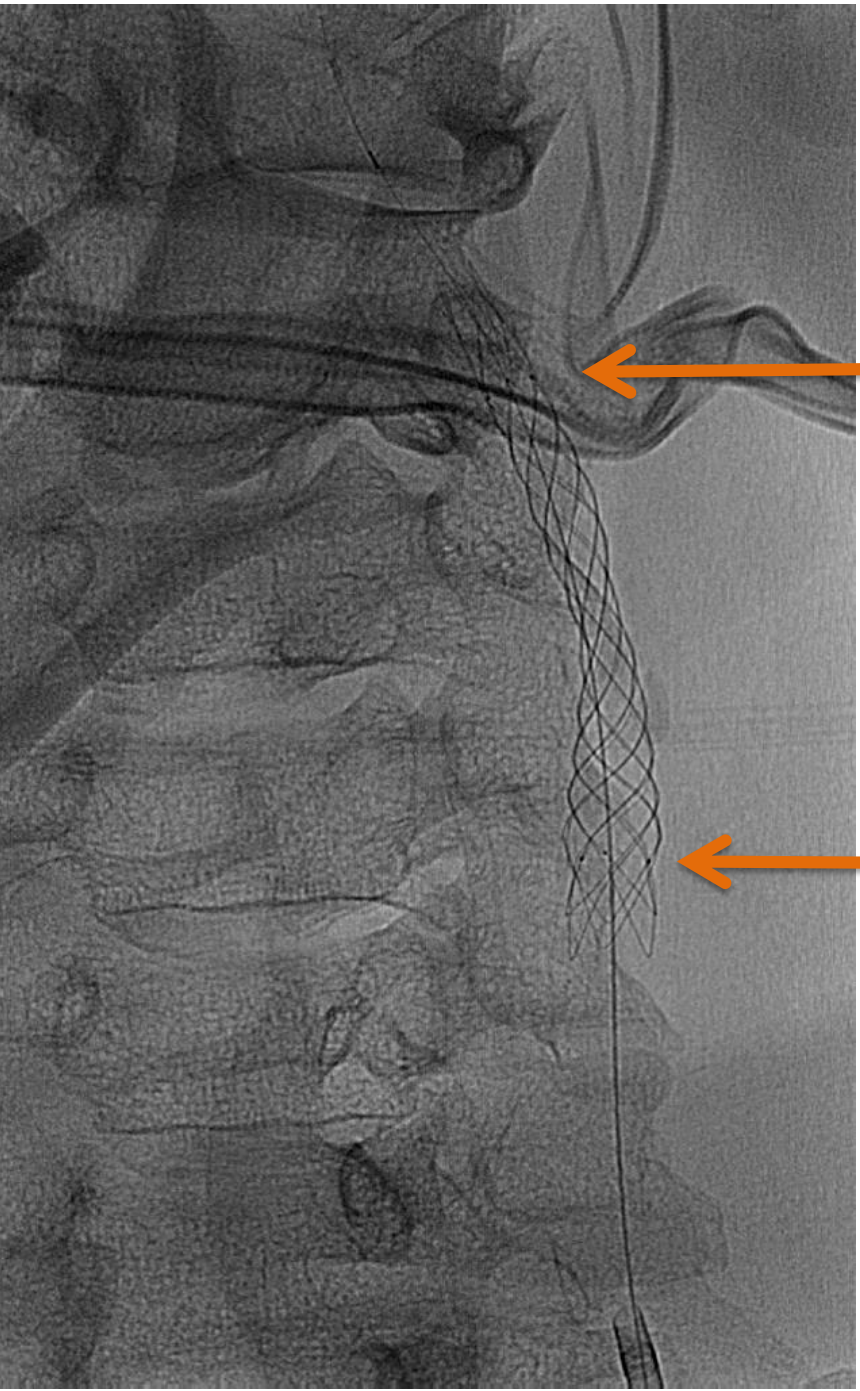
System Compatibility

Guide Sheath	Guide Catheter	EPD/Guidewire
• 5 Fr. (.074"Min) • Terumo Destination • Cook Shuttle	• 7 Fr. (.074"Min)	• 0.014" Wires • EV3 Spider • Abbott Accunet • Abbott Emboshield • Boston Filterwire • Cordis Angioguard

System Featu

- **Chronic Embolic Protection**
 - Double layer micromesh design
 - Smallest stent cell size, $\frac{1}{4}$ area compared to smallest on market ~ 375 – 500 μ
 - Tacks down/contains plaque, acting like a metallic covered stent
- **Lesion Specific scaffolding**
 - Extremely high plaque coverage
 - Superior in-vessel flexibility (compared to other braided mesh and closed cell lasercut stents)
 - Excellent wall apposition
- **Low Profile Delivery System**
 - 5Fr. Rapid Exchange for all sizes
 - Up to 50% deployment full re-sheathable and repositionable





Central Dual layer segment

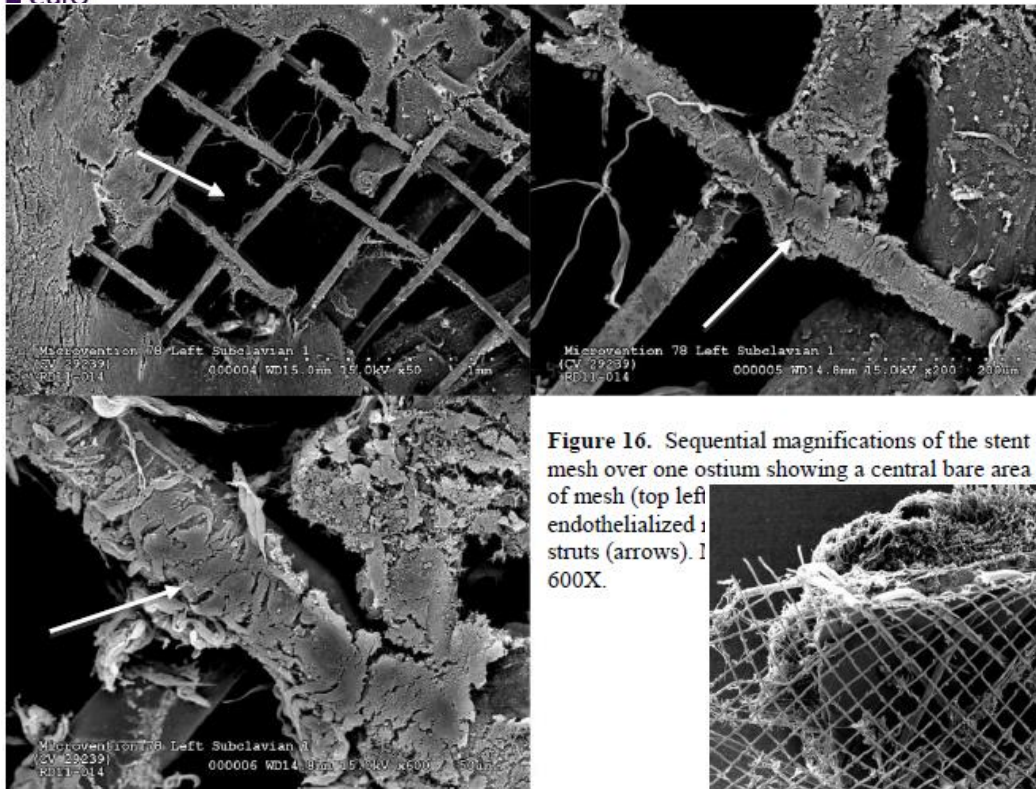
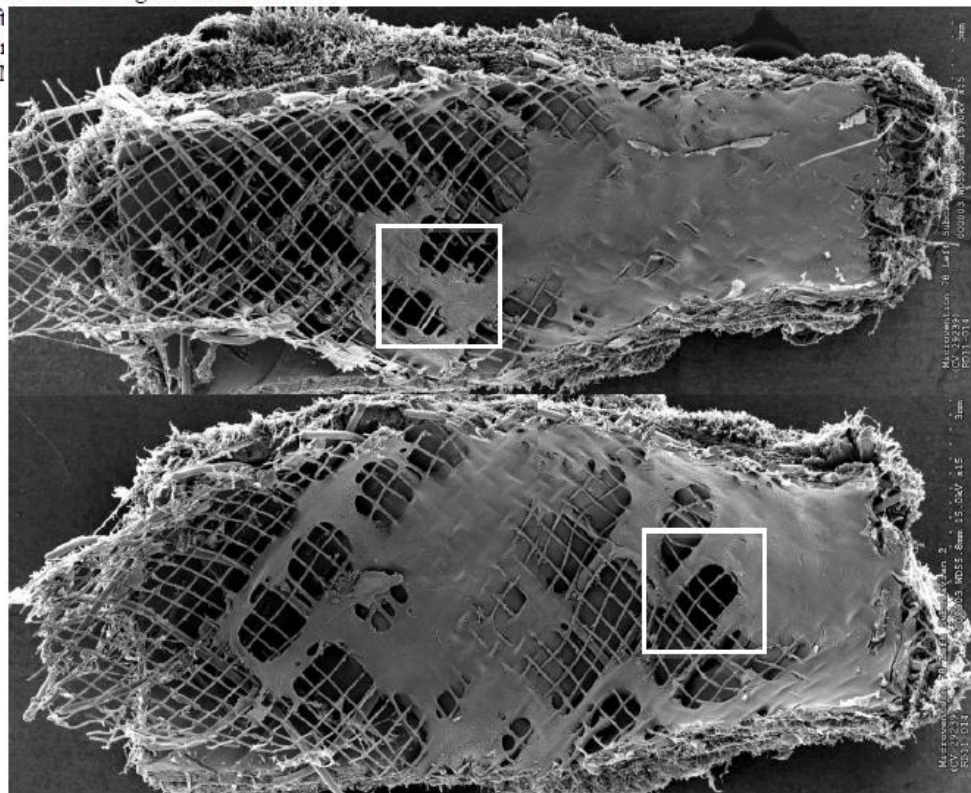


Figure 16. Sequential magnifications of the stent mesh over one ostium showing a central bare area of mesh (top left) endothelialized; struts (arrows). 1600X.



SEM Side Branch Ostia

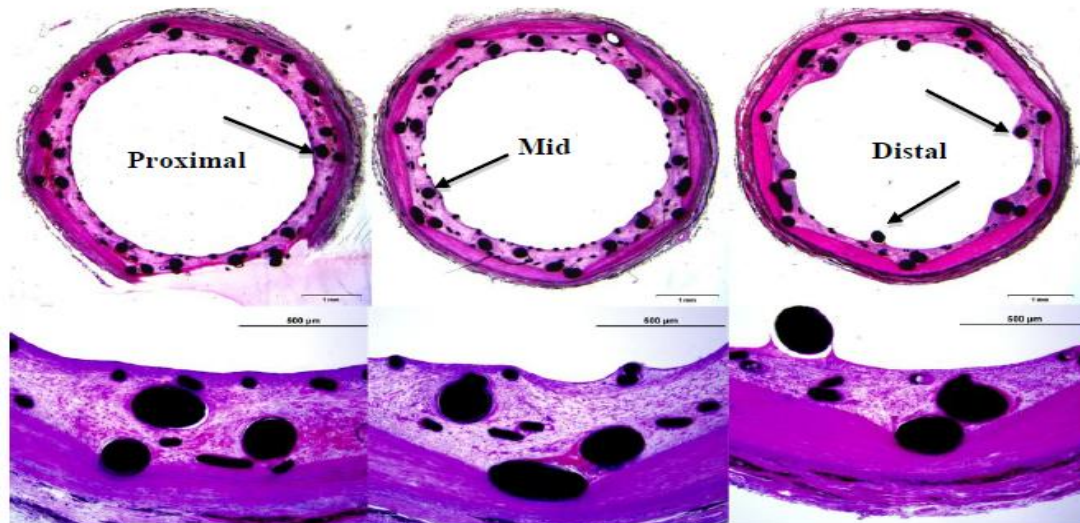
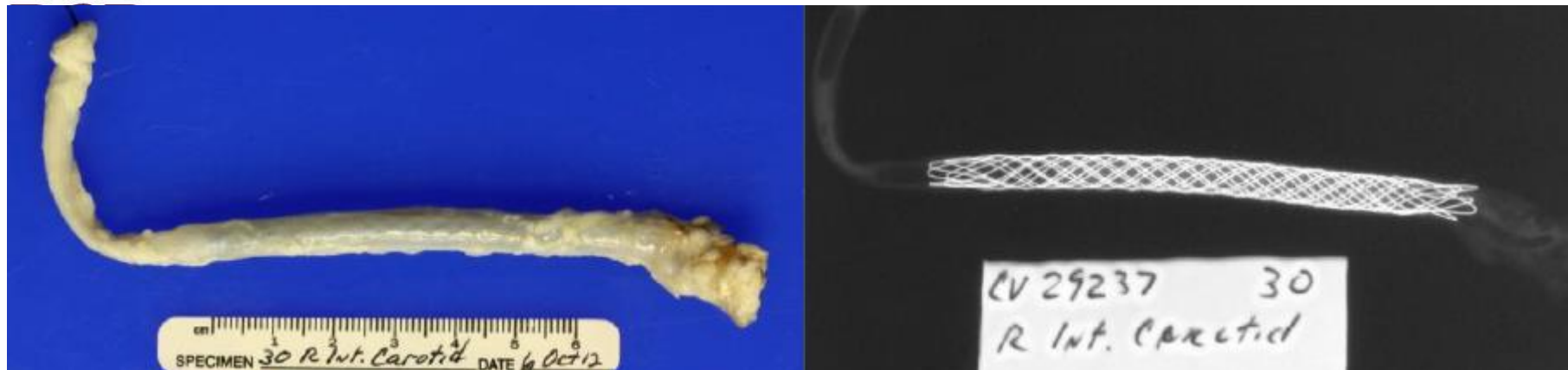
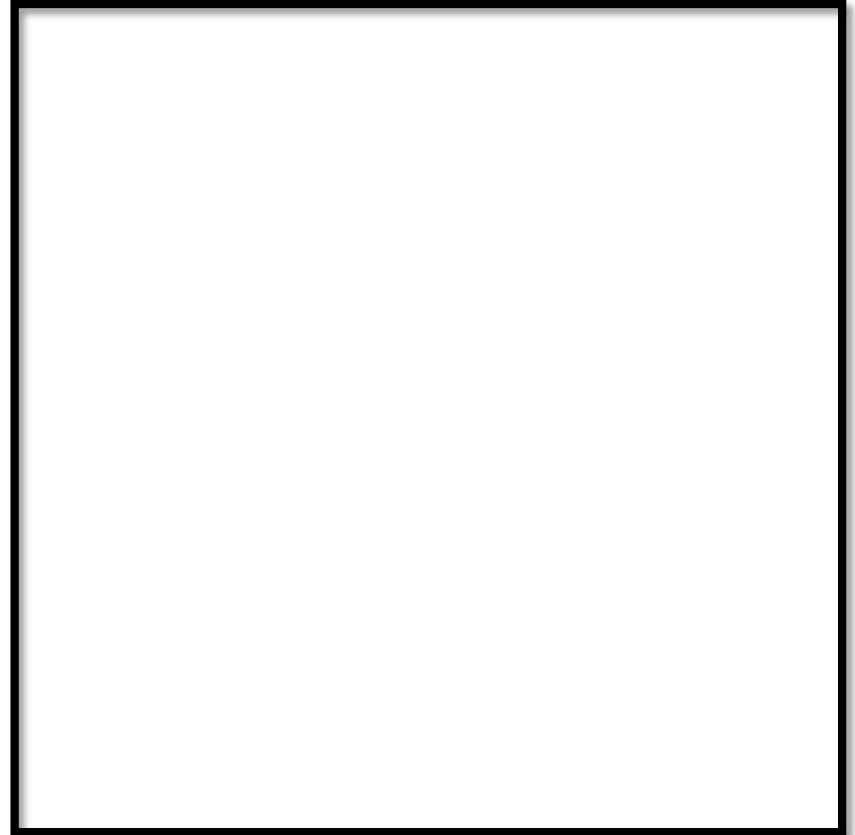


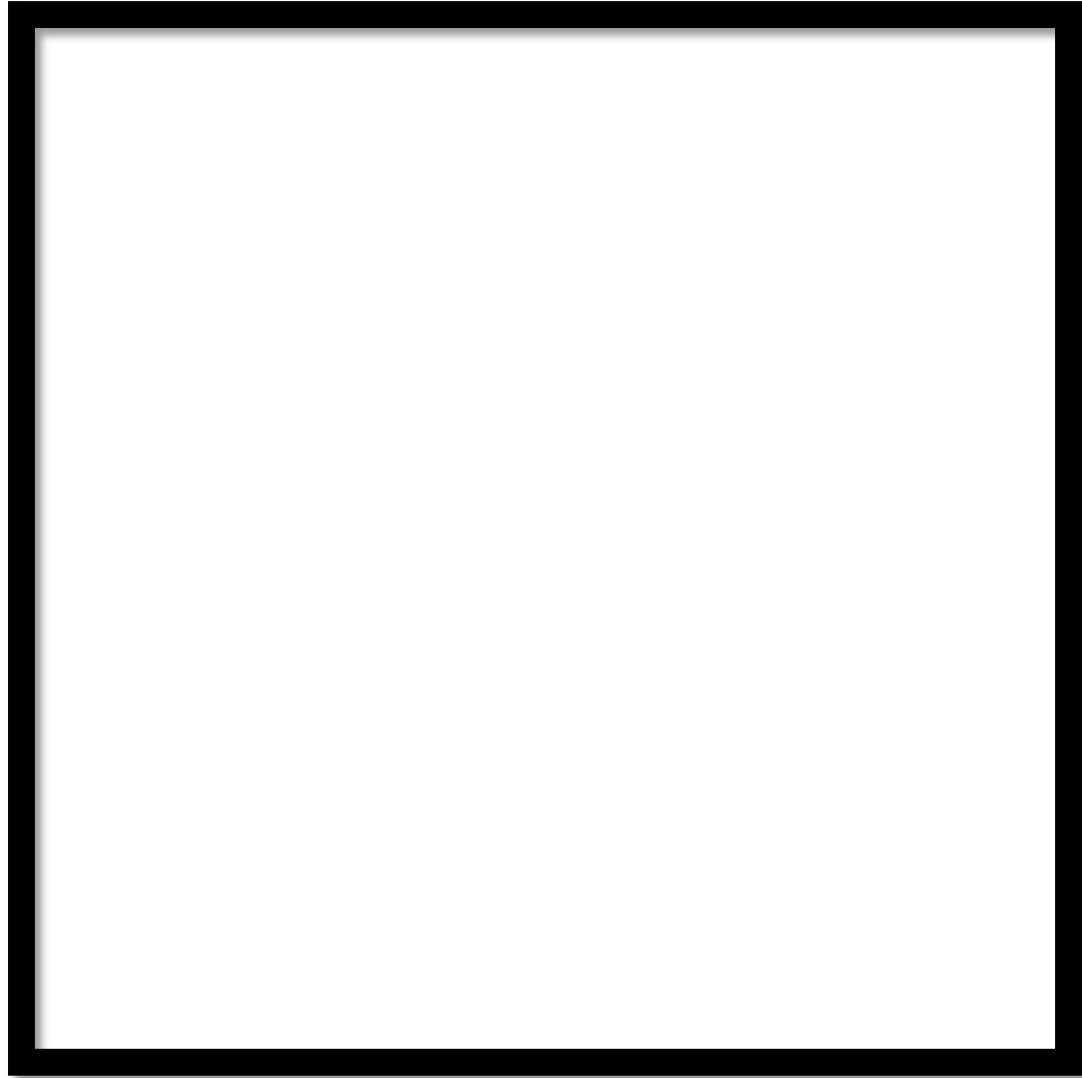
Figure 12. Proximal, mid, and distal overlapped cross-sections of the distal right common carotid artery from animal 78 (overlapping the proximal stent). All sections show a widely patent lumen with largely complete incorporation of the large and small stent wires with mild neointimal overgrowth. The stent struts appear evenly expanded around the lumen and overlapping stent struts from the other stent (arrows). All images with TB/BF stain.

Excellent Healing Despite Multiple Overlapping Stents

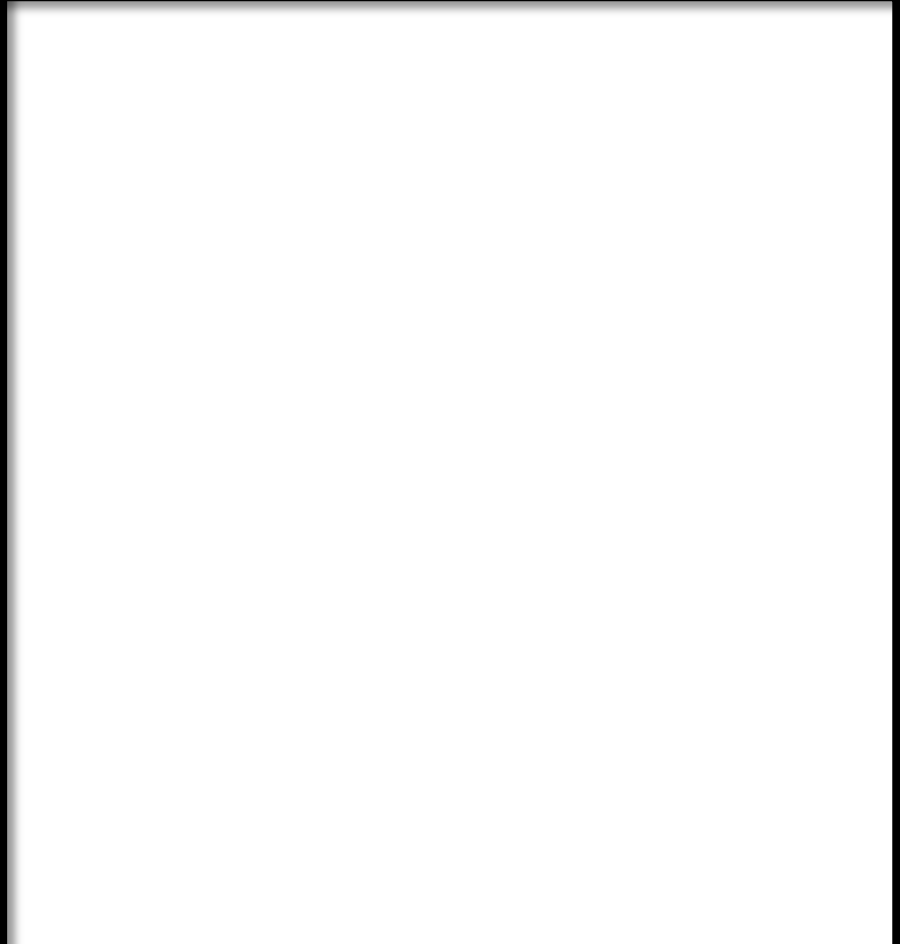
83 y ,male , Right Internal asymptomatic carotid stenosis



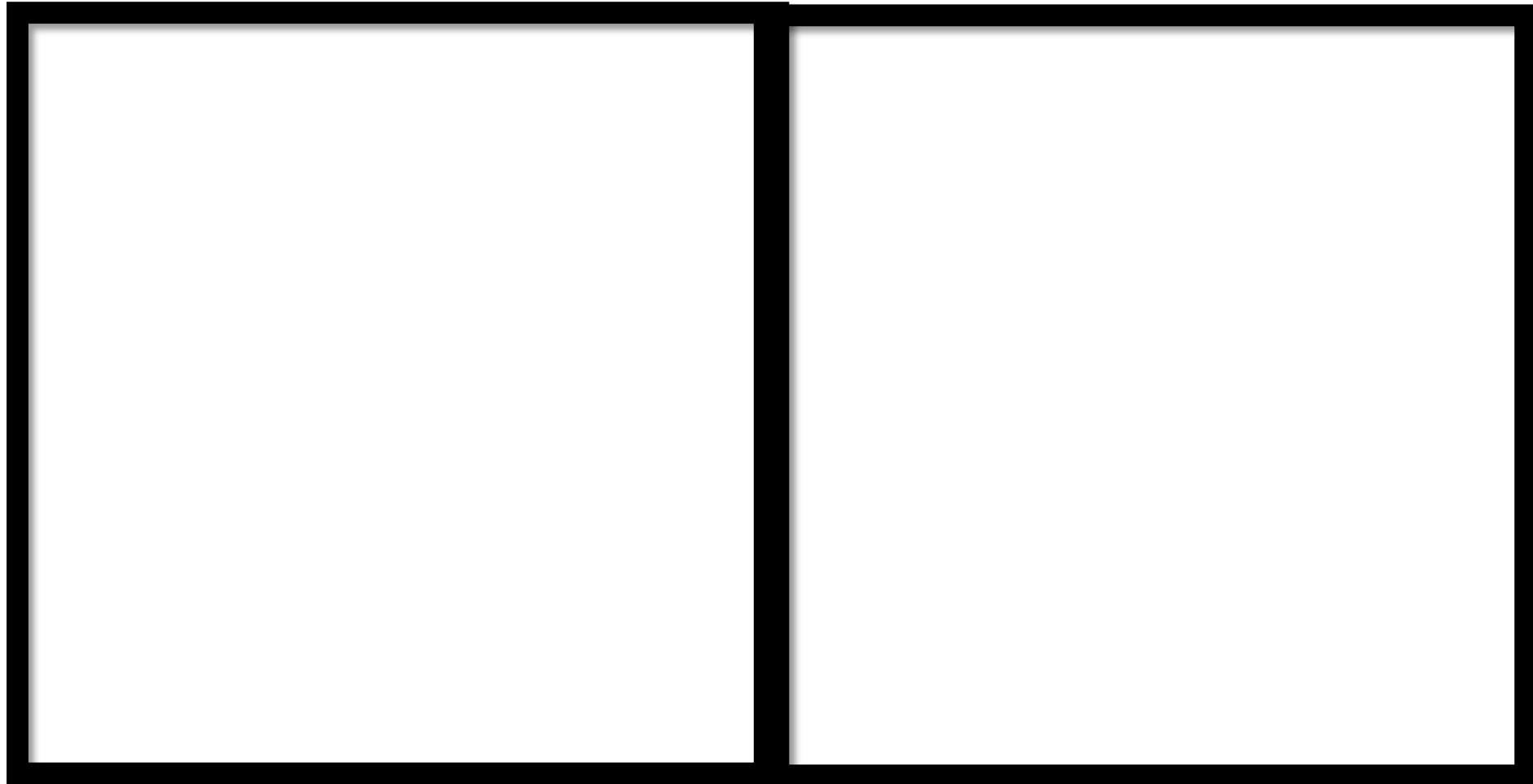
Patient n 2 , 8F Guiding catheter



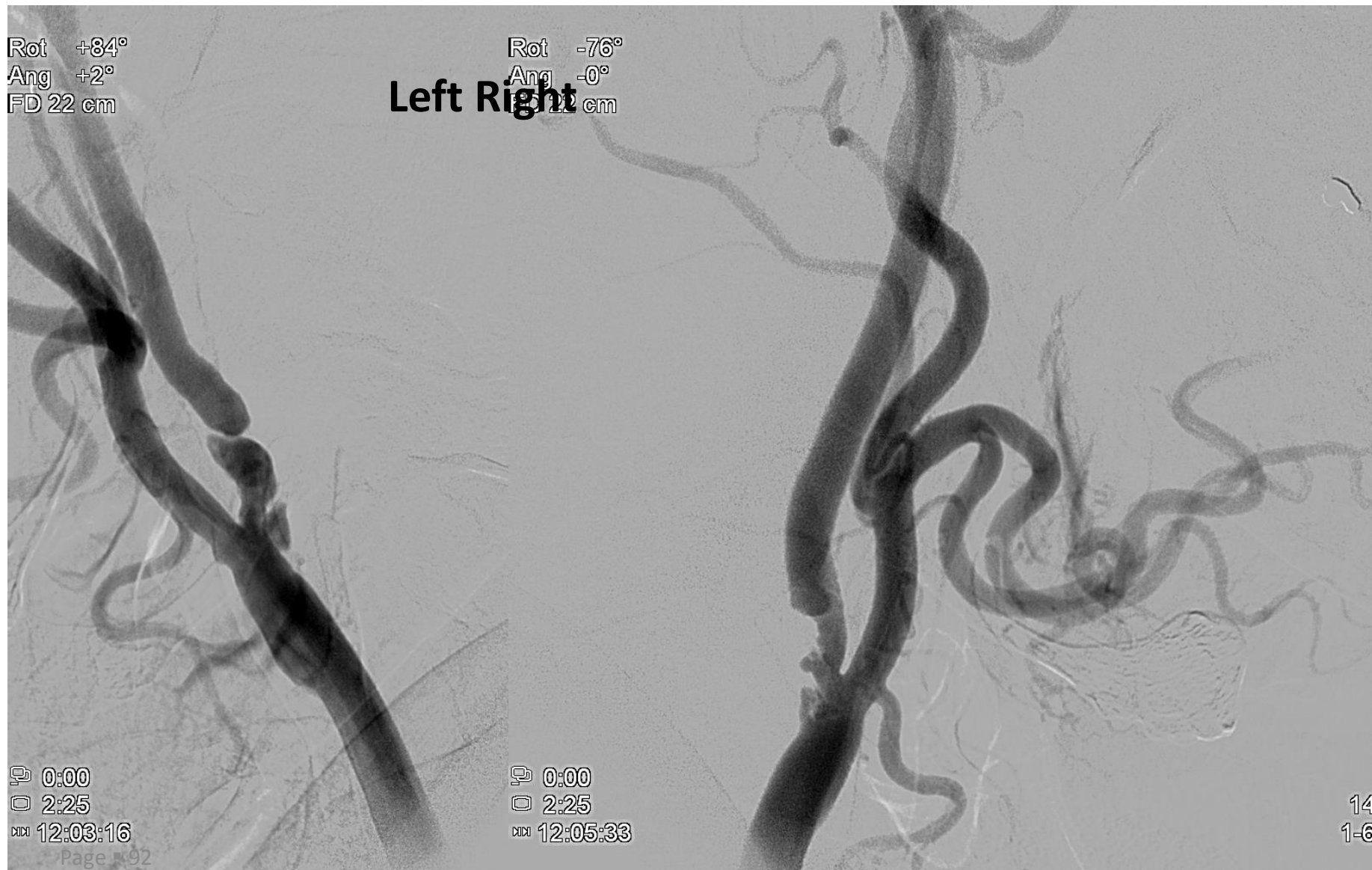
Patient n 2 , Post dilatation 5x20mm balloon



Retrieval of buddy wire & easy Filter



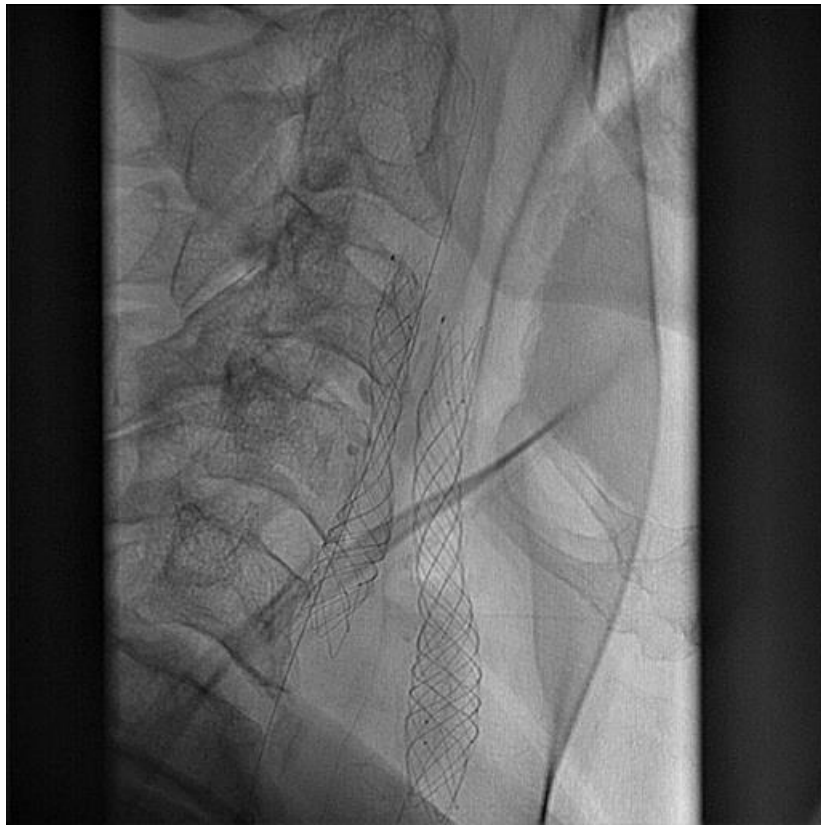
62y Male , bilateral severe carotid stenoses & Throat cancer with



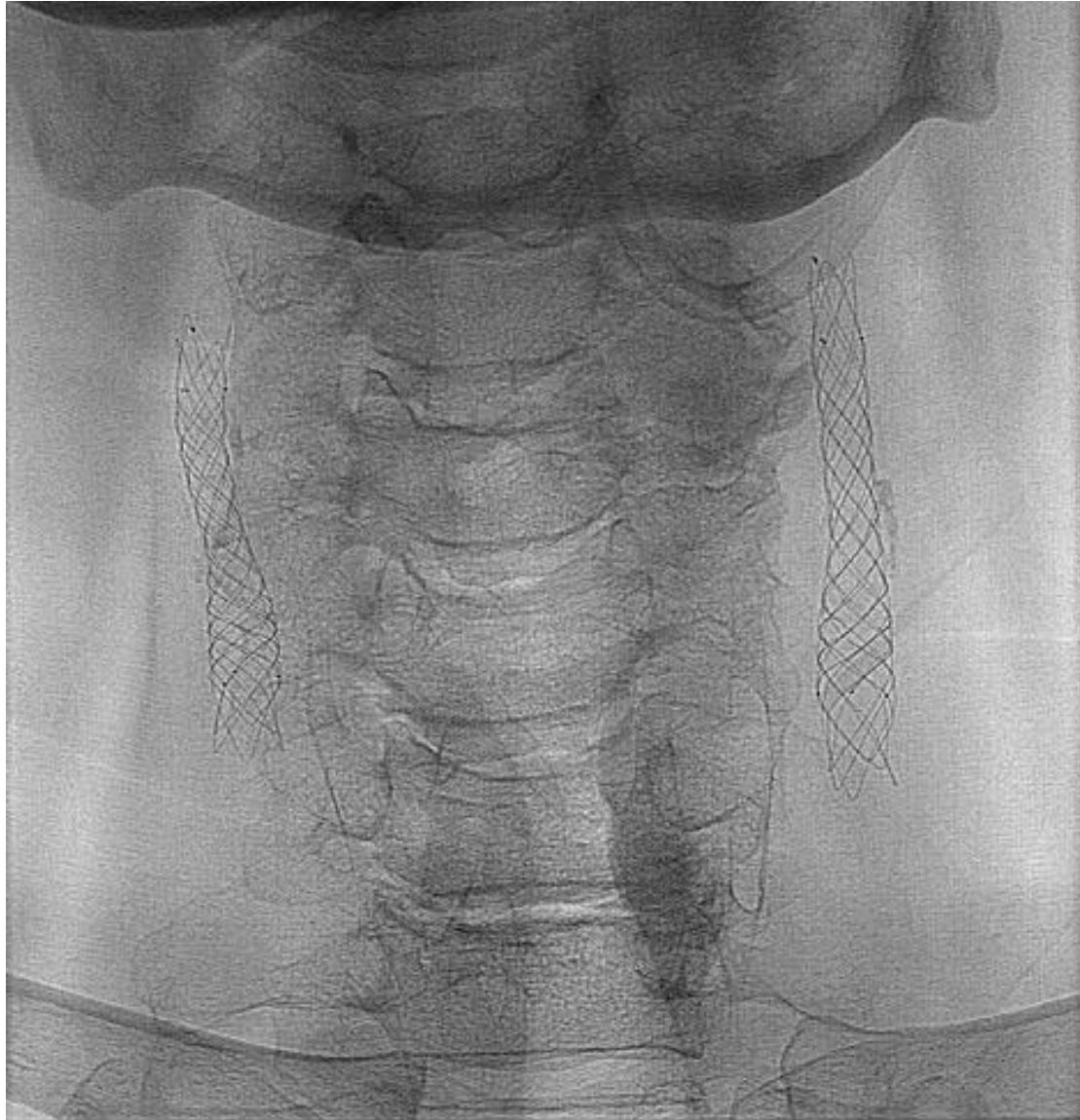
Step 1 : LICA Roadsaver Stent under protection covering an ulcerated lesion



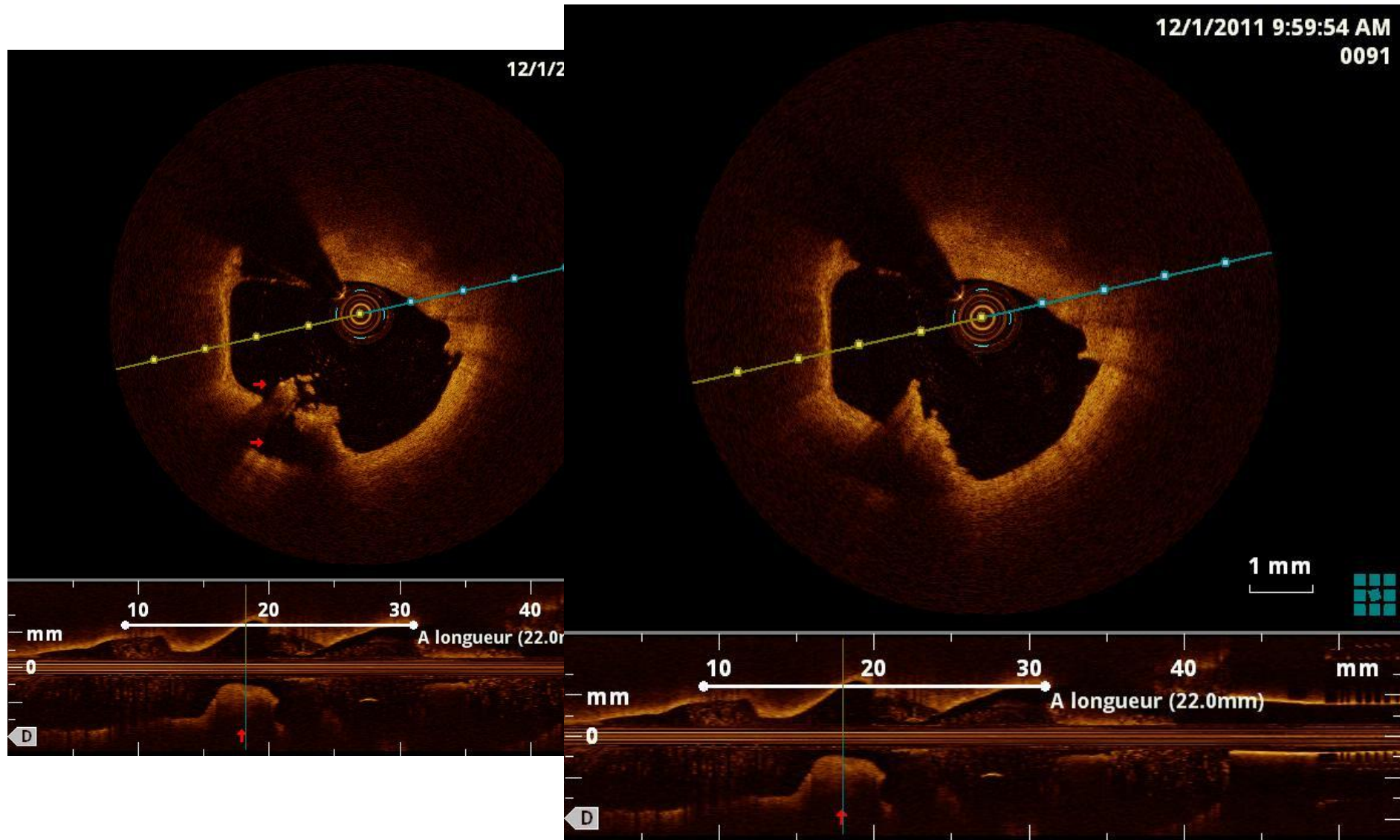
Step 2 :RICA Roadsaver Stent under protection covering an ulcerated lesion



Bilateral carotid stenting with double layer micro-mesh stents



OCT of Carotid Lesions



A longueur: 5.10mm
B longueur: 5.12mm

12/1/2011 10:15:20 AM

0071

6/1/2011 10:33:49 AM

0093

STRUT

1 mm

1 mm

10

mm

0 D

A longueur

10

mm

0 D

STENT 9-7 X 30 MM XACT

A longueur (30.0mm)

20

30

40

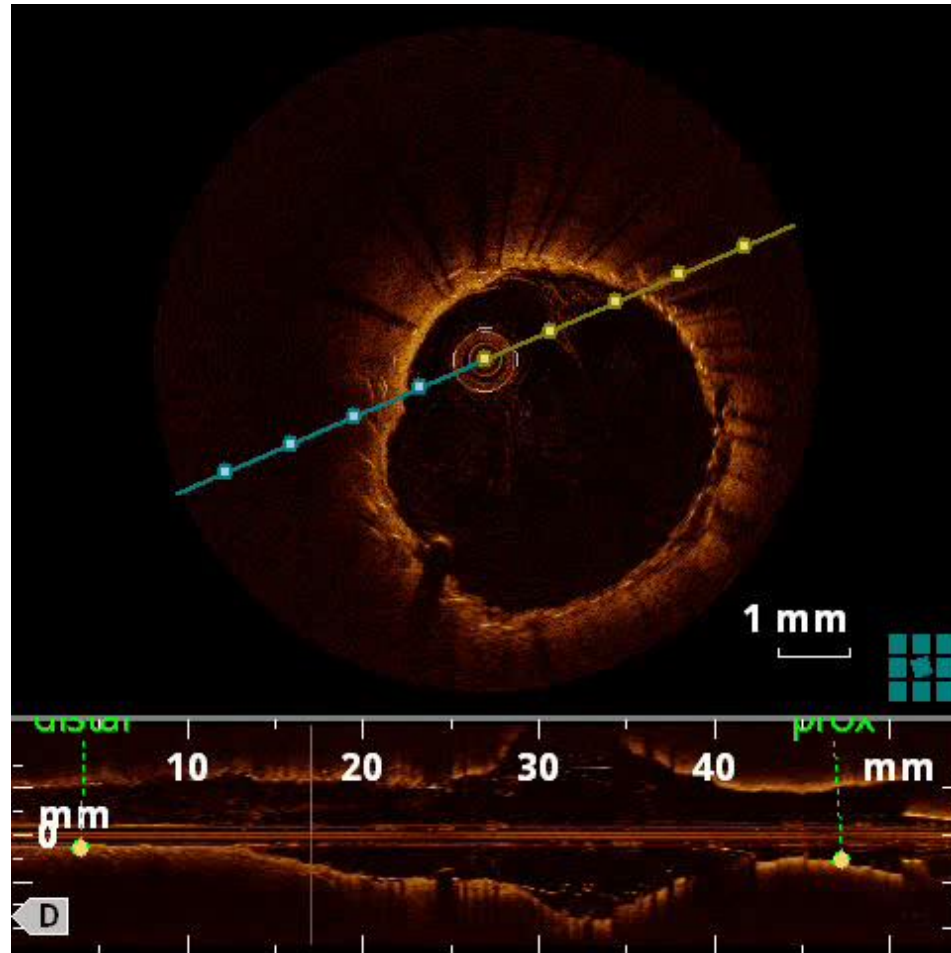
mm

P

40

mm

A longueur (33.2mm)



CGUARD

Evaluation of PET Mesh Covered Stent in Patients with Carotid Artery Disease

The CARENET-Trial (CARotid Embolic protection using microNET)

Joachim Schofer (PI)
Piotr Musialek (Co-PI)
On behalf of the CARENET Investigators

*Joachim Schofer, MD, PhD, Hamburg University Cardiovascular Center, Hamburg, Germany
Piotr Musialek, MD, PhD, Jagiellonian University Medical College at John Paul II Hospital, Krakow, Poland,
Ralf Kolvenbach, MD, PhD, Augusta Hospital, Dusseldorf, Germany,
Horst Sievert, MD, PhD, Cardiovascular Center Frankfurt, Frankfurt, Germany*

CARENET - CGuard Clinical Data

50% reduction in incidence of new lesions
10-fold reduction in average volume of new lesions
100% of lesions disappeared by 30 days post procedure

	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

	CARENET (Filter group) N=26	PROFI ¹ (Filter group) N=31	ICSS ² (Filter group) N=37
Incidence of New Lesions	48%	87%	73%
Avg Lesion Volume	0.06 cm ³	0.59 cm ³	NA

All Infarcts GONE at 30 days

Ideal Pore Size



CGUAR

D



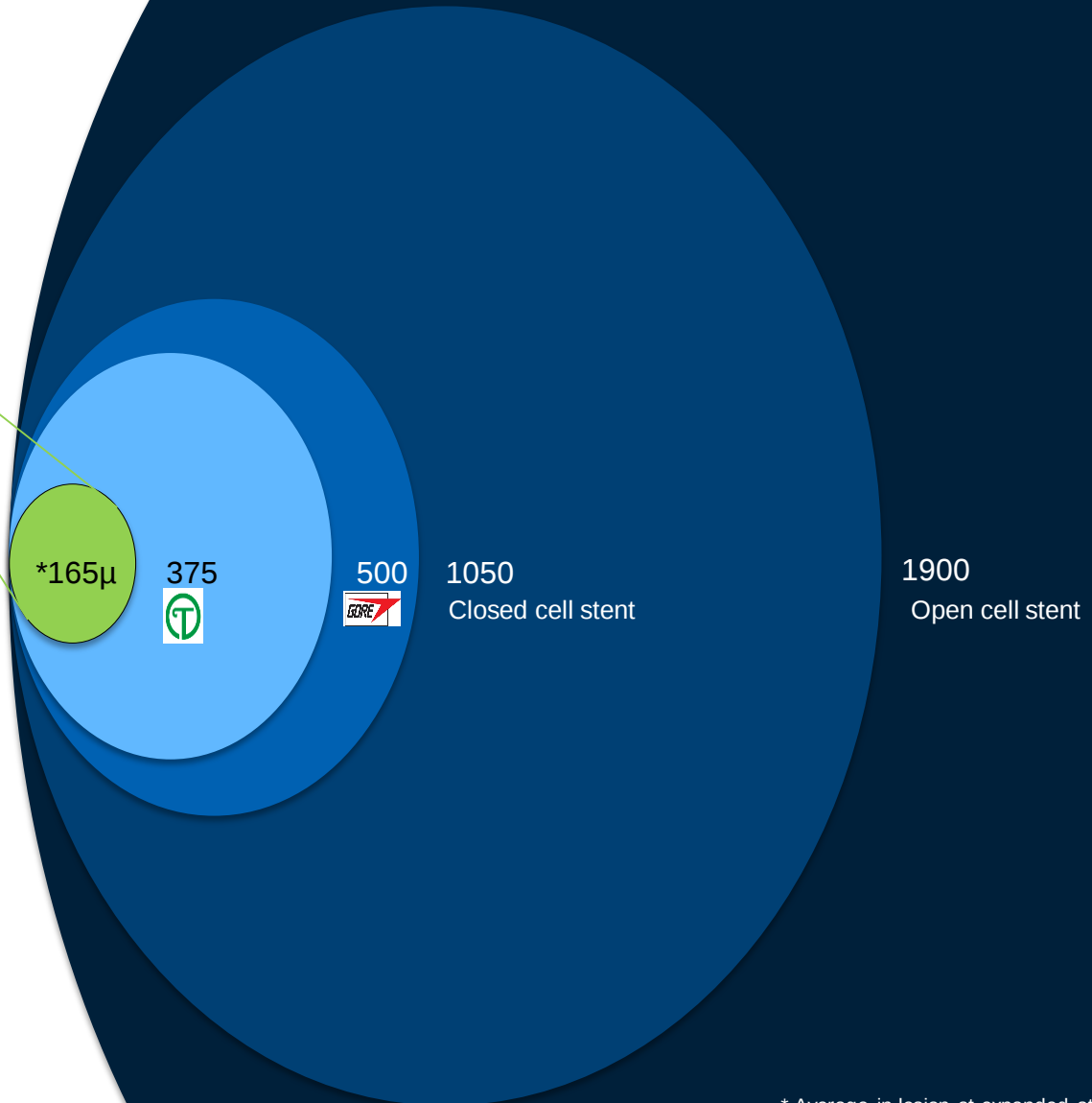
TERUM

O



GOR

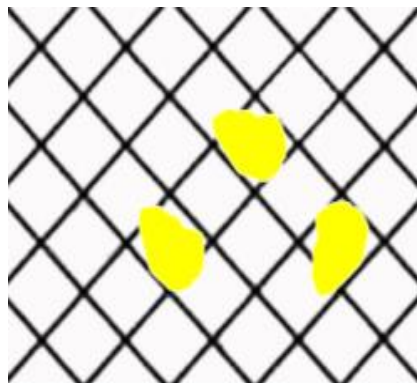
E



* Average in lesion at expanded state

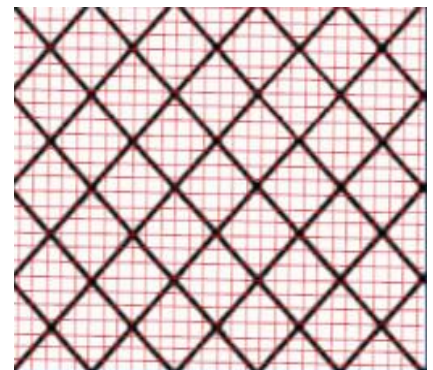
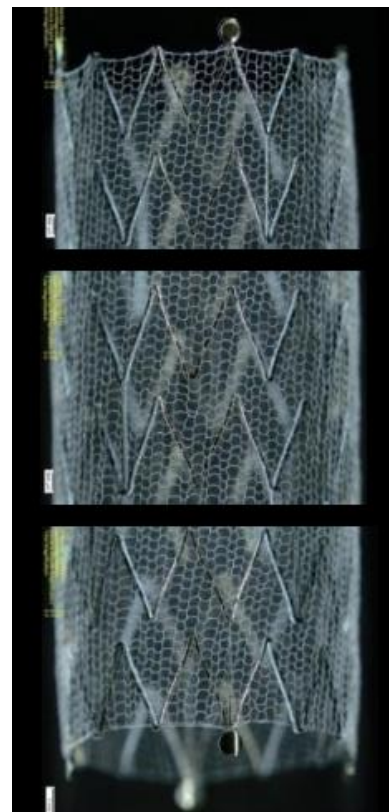
Conventional Stent vs CGuard

Conventional Carotid Stent



plaque prolaps through
stent meshes

CGUARD™
Carotid Embolic Prevention System



fine meshwork prevents
plaque prolaps

GORE

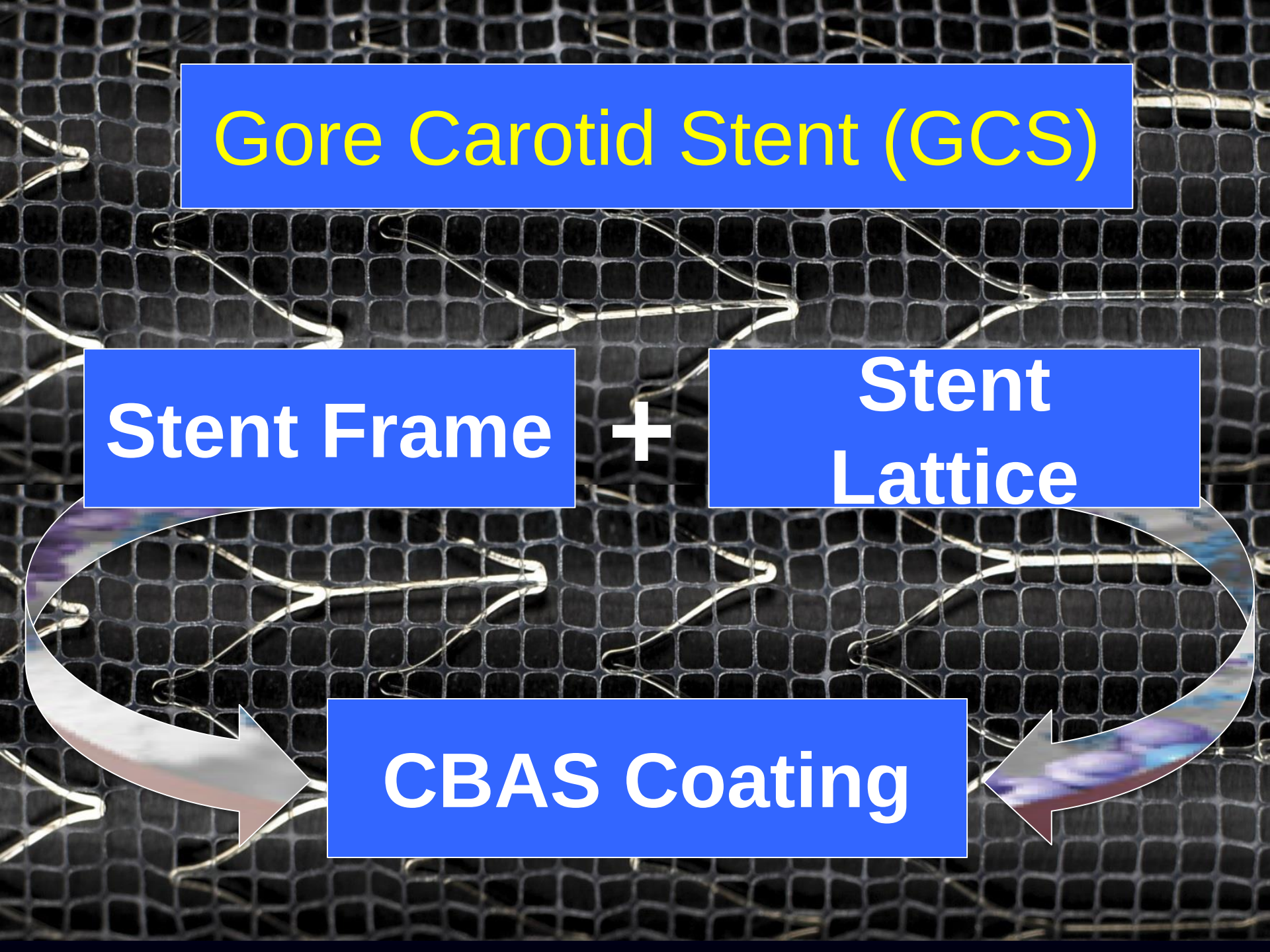
Gore Carotid Stent (GCS)

Stent Frame

+

**Stent
Lattice**

CBAS Coating



Stent Frame

- Laser cut frame from a solid tube of nitinol
- open cell design (high degree of flexibility and conformability to the native anatomy)
- Helical body with the end rows being of a closed cell construction in order to balance strain within the frame

Stent Lattice

- High strength expanded polytetrafluoroethylene
- High degree of plaque scaffolding that reduce plaque prolapse.
- Reduce amount of emboli released during and after stent deployment
- Stabilize the stent frame by resisting elongation as well as the “fish-scaling”

CBAS Coating



- The stent frame and lattice, once combined, are coated on all surfaces with the Carmeda Bioactive Surface (CBAS®)
- Action is limited only to the device surface and has no systemic anticoagulant effects

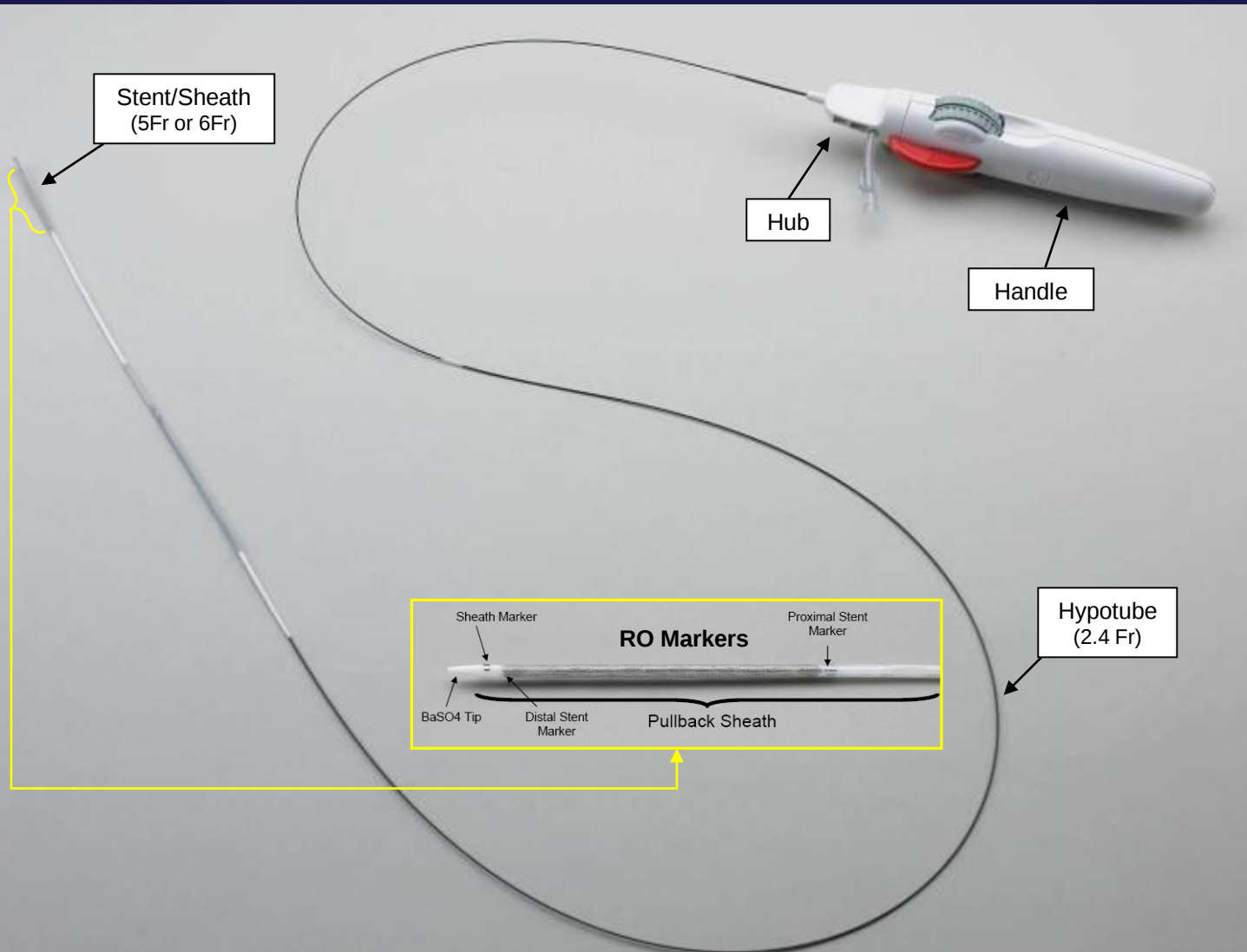
POTENTIAL RISK FOR PLAQUE PROTRUSION AND EMBOLIZATION



Manufacturer	W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
Device	GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE

***CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

Delivery System



Attributes

- Single handed delivery
- 5Fr Introducer Sheath Compatible (White Tip)
- 6Fr Introducer Sheath Compatible (Gray Tip)
- Hypotube Design
 - Allows for complete closure of hemostatic valve
- 135 cm Working Length
- 30 cm Rx

***CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

GORE® Carotid Stent System Sizing Summary

GORE® CAROTID STENT PART NUMBER		UNCONSTRAINED STENT DIMENSIONS (mm)	REFERENCE VESSEL DIAMETER (mm)	MINIMUM INTRODUCER OR GUIDING SHEATH CATHETER ID
5 Fr	GCS5530	5 x 30	3.7 – 4.5	0.073" (1.85 mm) White Tip
	GCS5540	5 x 40		
	GCS6630	6 x 30	4.5 – 5.4	
	GCS6640	6 x 40		
	GCS7730	7 x 30	5.4 – 6.3	
	GCS7740	7 x 40		
	GCS8830	8 x 30	6.3 – 7.2	
	GCS8840	8 x 40		
	GCS6830	6 – 8 x 30	4.5 – 5.4 x 6.3 – 7.2	
	GCS6840	6 – 8 x 40		
6 Fr	GCS9930	9 x 30	7.2 – 8.1	0.080" (2.03 mm) Gray Tip
	GCS9940	9 x 40		
	GCS0030	10 x 30	8.1 – 9.0	
	GCS0040	10 x 40		
	GCS7930	7 – 9 x 30	5.4 – 6.3 x 7.2 – 8.1	
	GCS7940	7 – 9 x 40		
	GCS8030	8 – 10 x 30	6.3 – 7.2 x 8.1 – 9.0	
	GCS8040	8 – 10 x 40		

***CAUTION:** Investigational Device. Limited by United States Law to Investigational Use only.

GORE® Carotid Stent Clinical Study for the treatment of carotid Artery stenosis in patients at increased risk For events From carotid Endarterectomy

The Gore SCAFFOLD Clinical Study

***CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

Study Overview

Design

Multicenter, single-arm, prospective study comparing the GORE® Carotid Stent to a performance goal developed from carotid endarterectomy (CEA) outcomes

Objective

Evaluate the safety and efficacy of the GORE® Carotid Stent for the treatment of carotid artery disease in patients at increased risk for adverse events from carotid endarterectomy

***CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

Study Design

- Number of Sites

Up to 50 sites in the US, Europe, and Japan

- Number of Subjects

312 subjects (max 40 at each site)

- General Population

Patients at least 18 years of age who have either a single *de novo* atherosclerotic or post-endarterectomy restenotic lesion in the internal carotid artery or at the carotid bifurcation, with either:

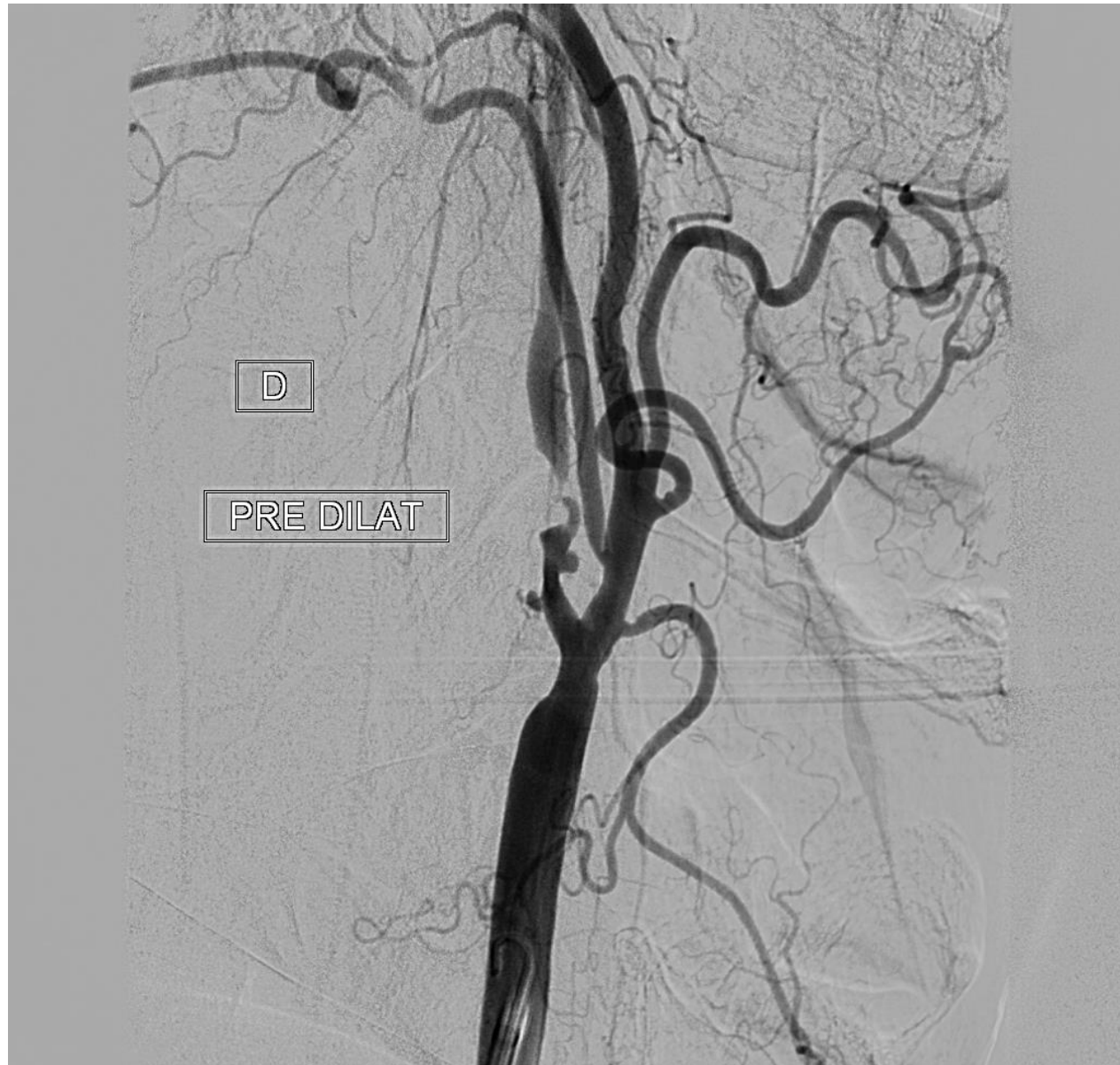
≥ 50% (by angiography) stenosis if symptomatic
(stroke, TIA, TMB within 180 days of procedure),

OR

≥ 80% (by angiography) stenosis if asymptomatic

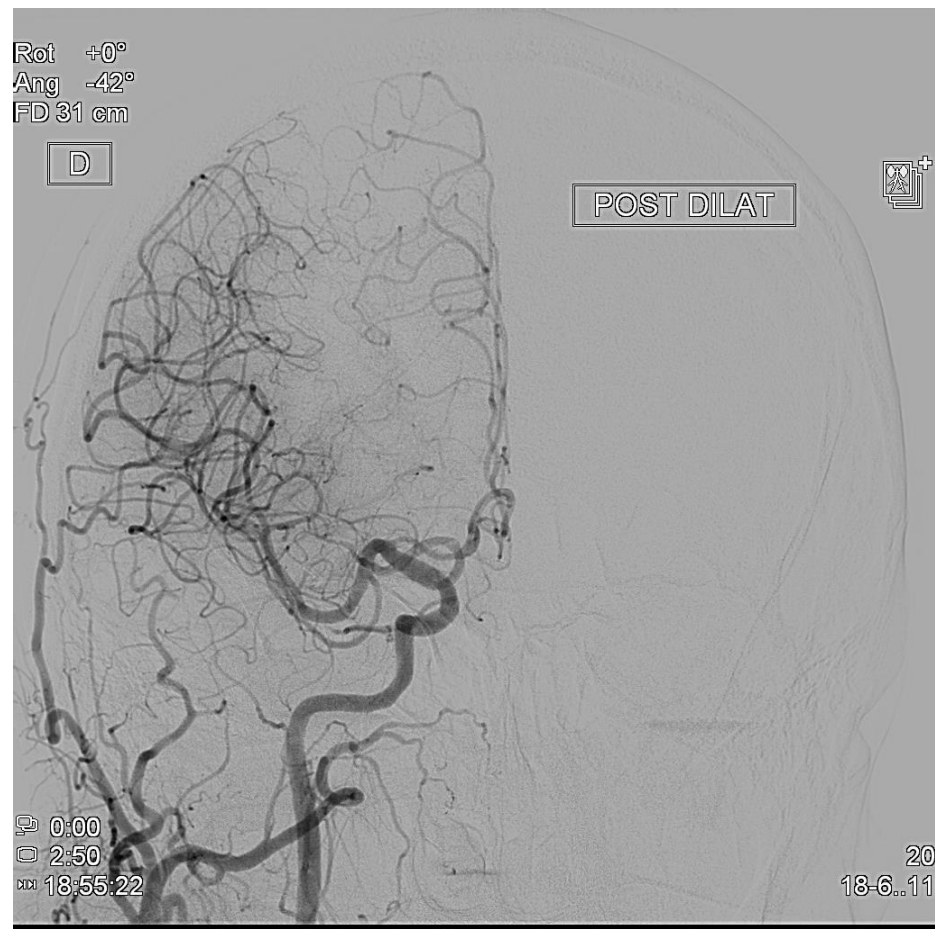
Patients must have either anatomic or medical co-morbidities that place them at high perioperative risk for CEA

Severe Symptomatic RCA stenosis with multiple ulcerations



After ROADSaver Stent 10x30mm placed under filter protection







Symptomatic chronic Dissection & Ulcerated RICA Stenosis



Nature de la lésion	Angioplastie	Chirurgie
Courte	équivalence	
Longue	+++	+
Ulcérée	++	+++
Hypo échogène*	+	+++
Calcification excentrique	++	+++
Calcification concentrique	0	+++
Bifurcation CE indemne	équivalence	
Bifurcation CE sténosée*	+	+++
Lésions en tandem	+++	+
Lésions bilatérales	+++	+
Sténose haut située	+++	+
De novo	+	+++
Resténose	+++	+
Post-Rx	+++	-