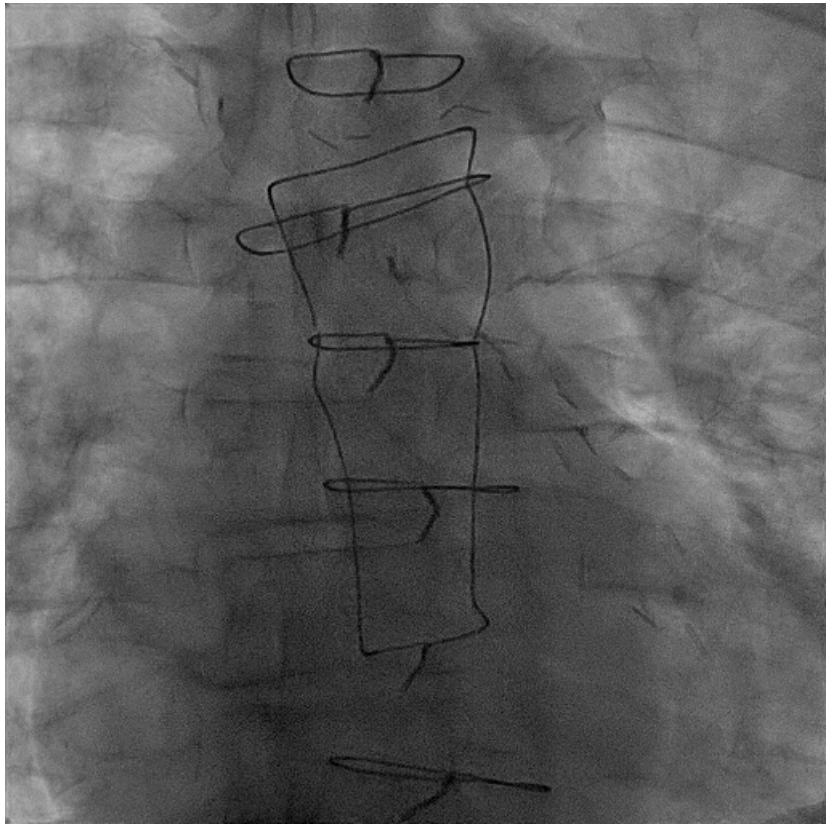
A Challenging Carotid Case

Max. Amor

Clinique Louis Pasteur

Essey-Les-Nancy,France

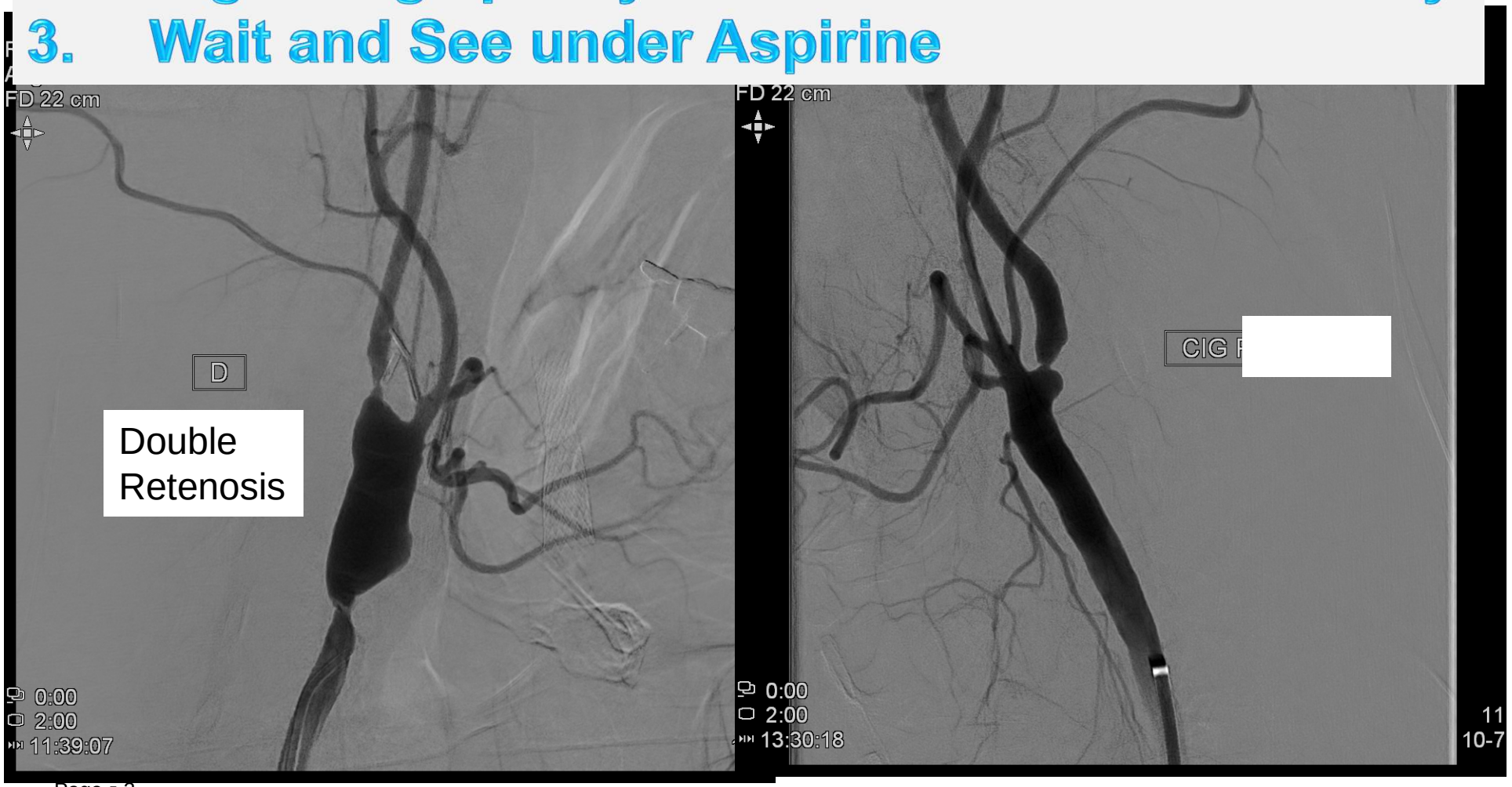
6years before : 64 years man



- **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 (Stagged Technic)**

Double Lesions RICA restenosis & De-novo LICA

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



J 0

Placement of a Precise Carotid Stent under filter Protection ?

Double Restenosis

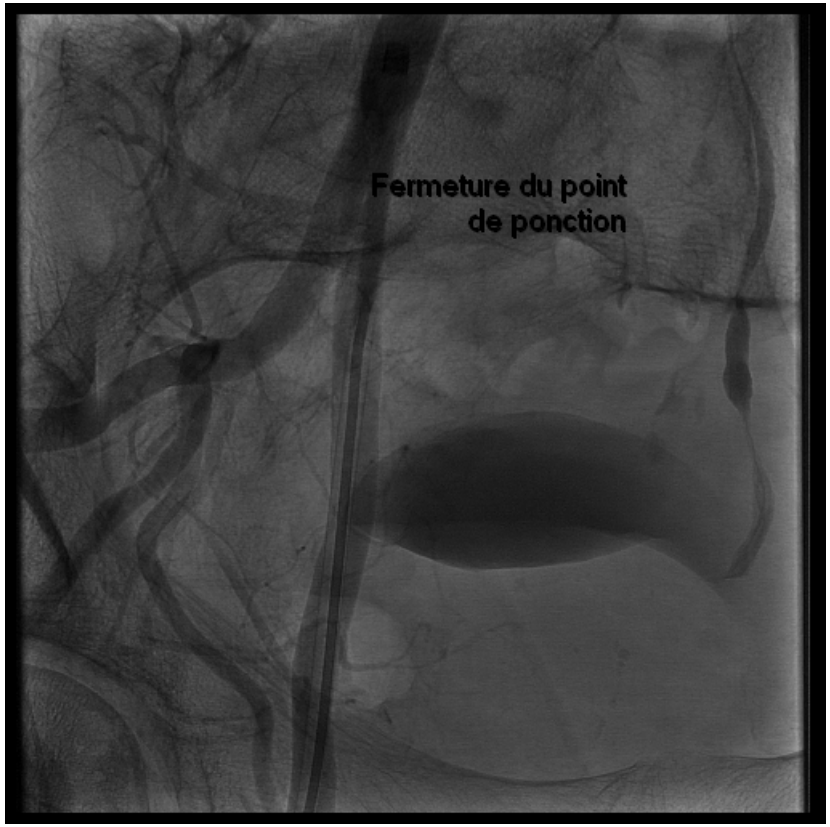
- **When ?** immediately ?, Same hospitalisation, Delayed (1, 2, 3)
- **Which Protecting Device ?** Filter,Moma,Silk Road (1,2,3
- **Single stent ?**
- **Several stents ?**
- **Covered ?**

J 1

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

3 stents : 2 Right 1 Left

J1

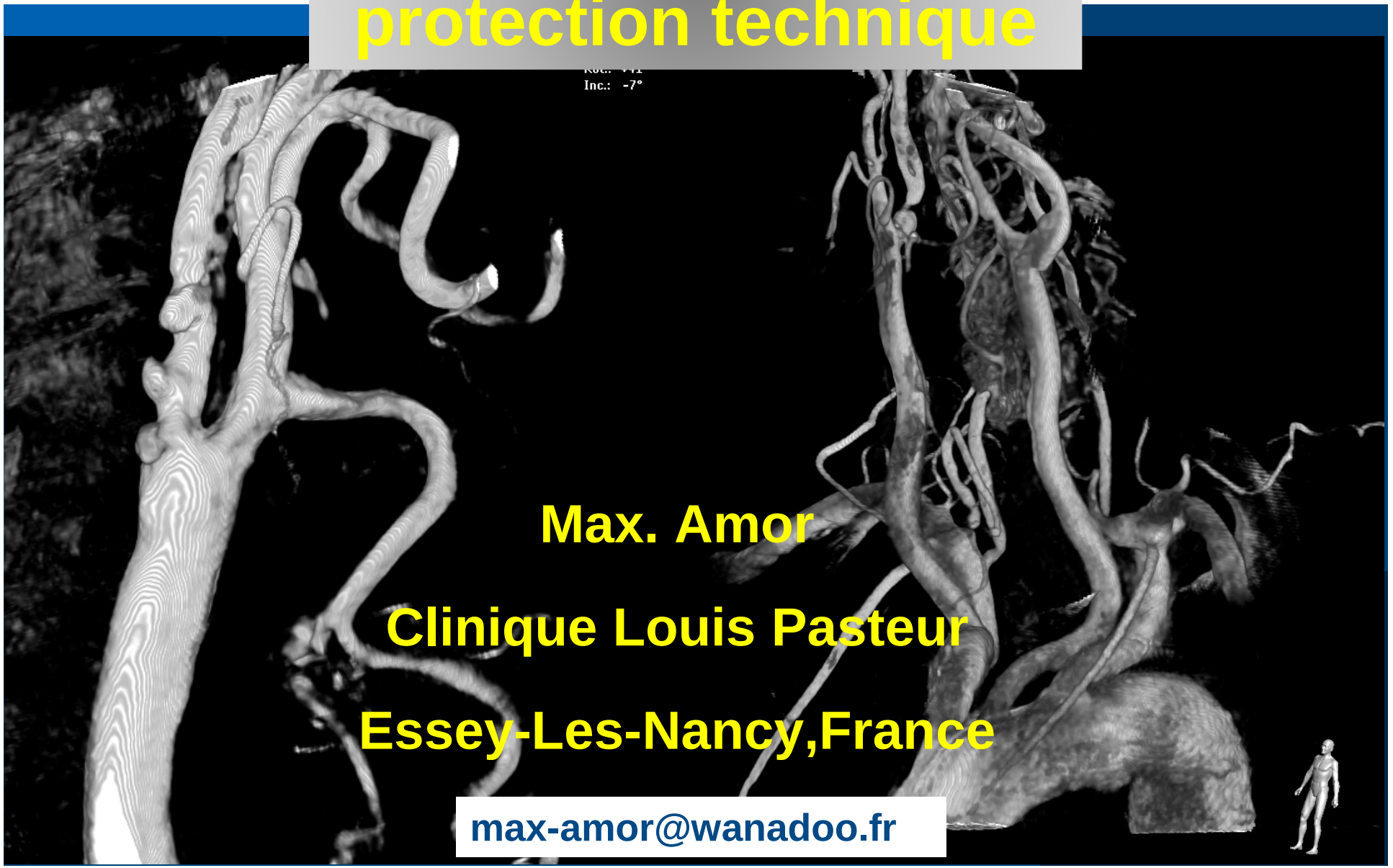


- **Fermeture du point de ponction**
- **Bonne tolérance hémodynamique**
- **Très bon résultat échographique, pas d'emboles au scan**
- **Sortie après 72 h d’hospitalisation**

Take home message

- **In my** **tomy**
  befor **and**
  well t

Selection of stent and protection technique



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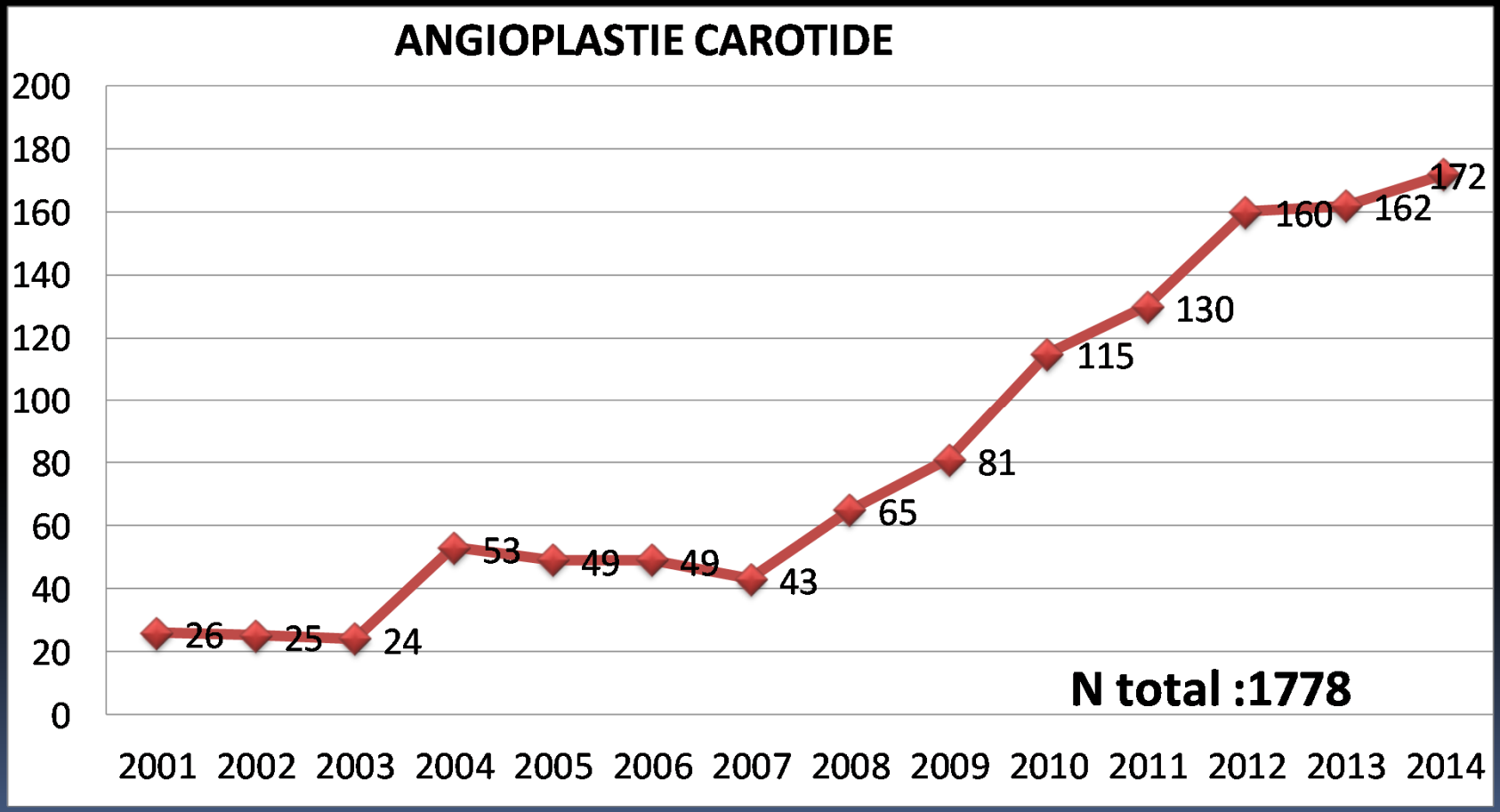
Potential conflicts of interest

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

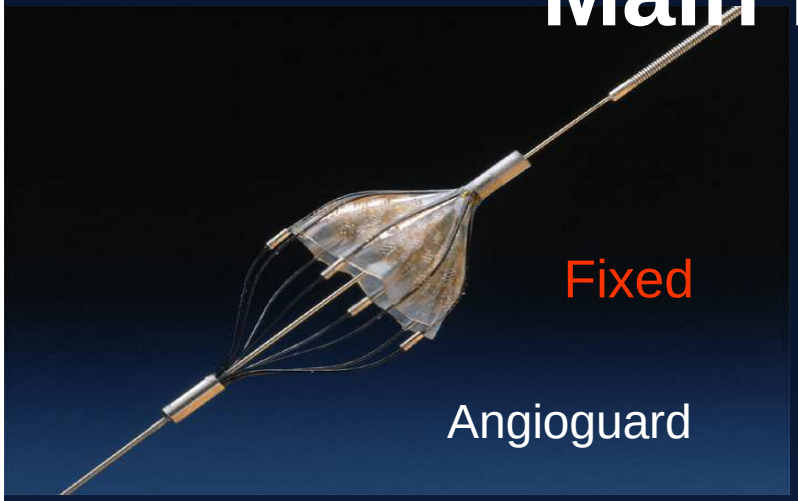
- **Medical therapy : Dual antiplatelet therapy**
- **Managing usual procedural side effects: Hypotension, Bradycardia…**
- **Selecting and using the right device for Embolic protection: Filters, Flow- reversal**
- **Selecting and placing the right stent for carotid plaque containment, reducing residual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



Fixed

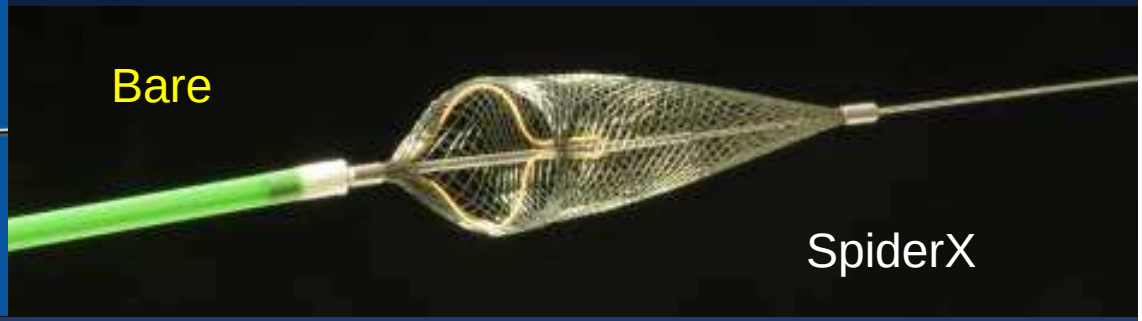
Angioguard

Filterwire EZ

Fixed

Accunet

Fixed



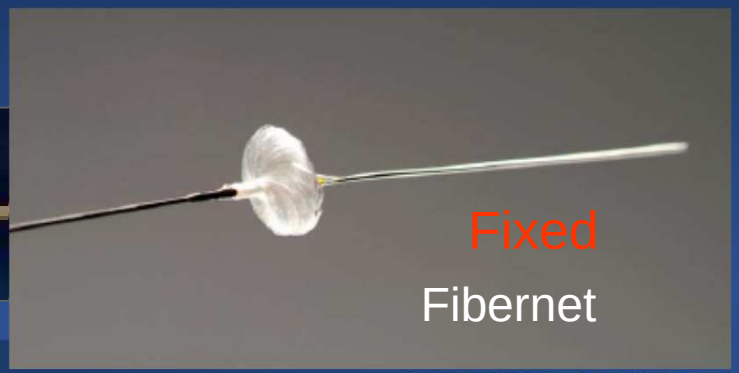
Bare

SpiderX

Nav6

Bare

Medtronic
Interceptor



Fixed

Fibernet

CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

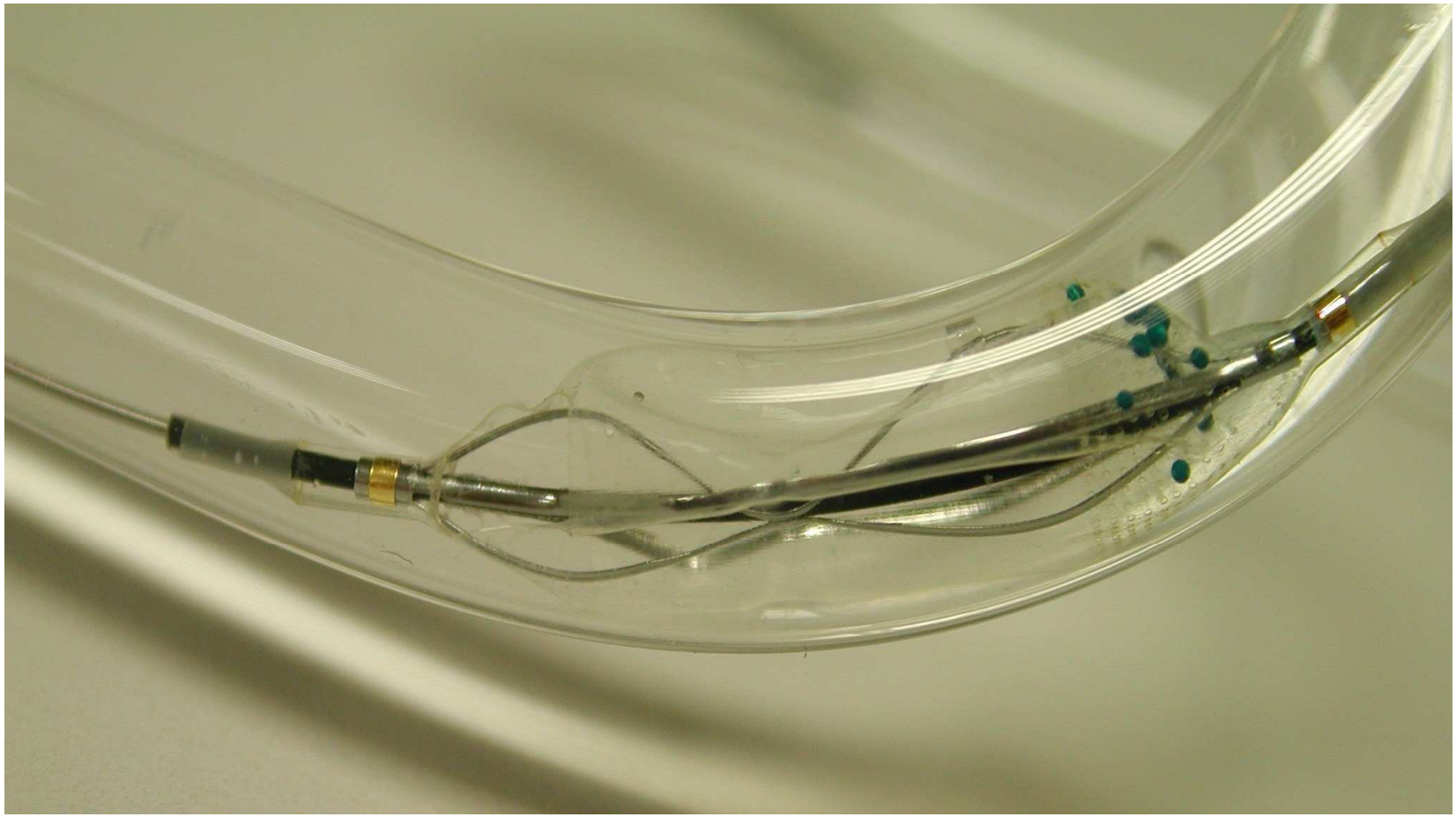
NewYork-Presbyterian
The University Hospital of Columbia and Cornell

TCT2010

Geometric Factors for selecting filters

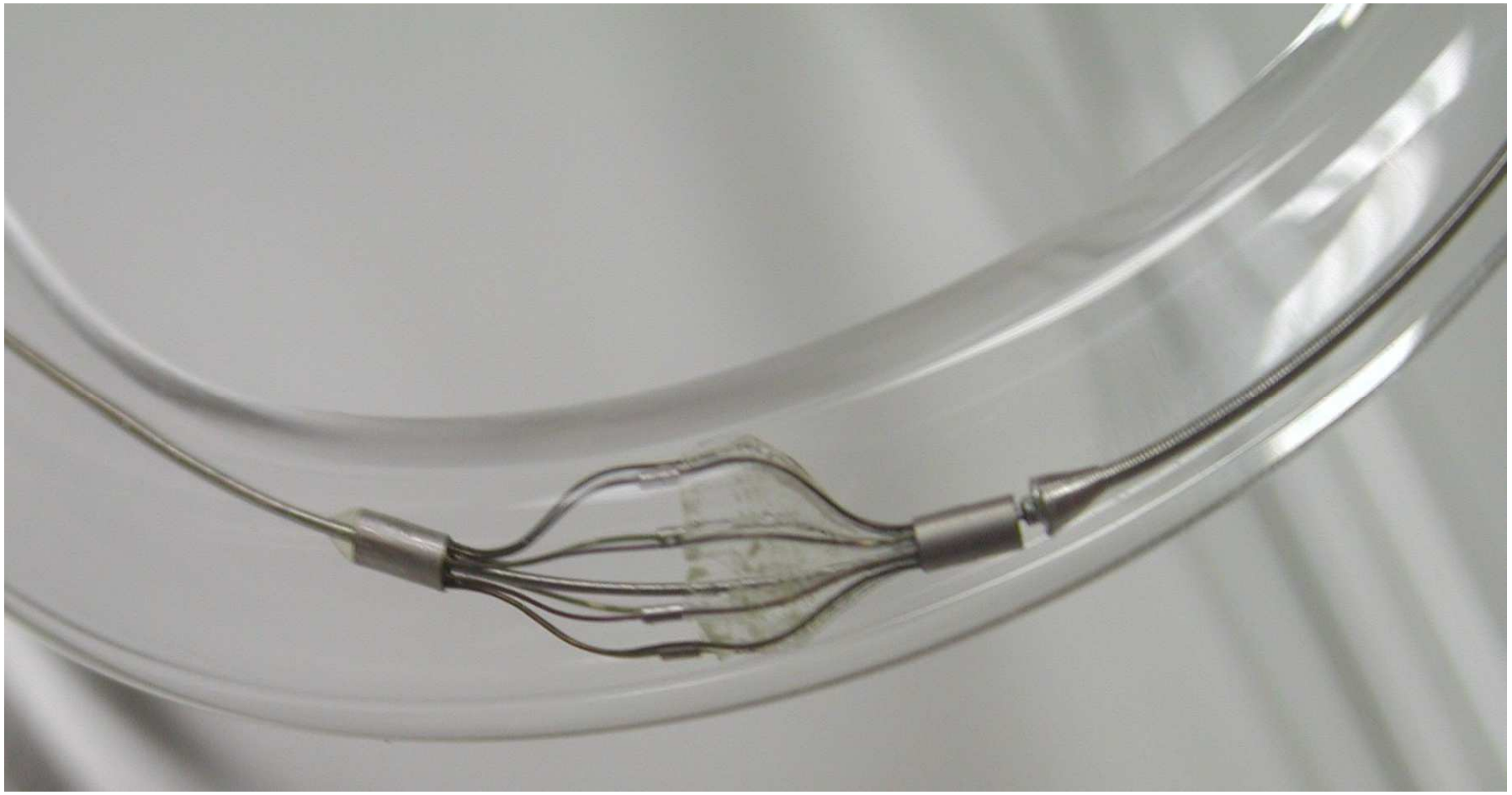
	EZ	Accunet	Emboshiel	SPIDER	Fibernet
ø≥ 6mm	no	yes	yes	yes	yes
Tight stenosis	++	++	+++	++±	+
Small landing zone	+	+	++	+	+++
Angulations	++	++	++±	+++	+
Curved landing	+	++	++	+	+++
Complex crossing	+	+	++	+++	+

Abbott EmboShield

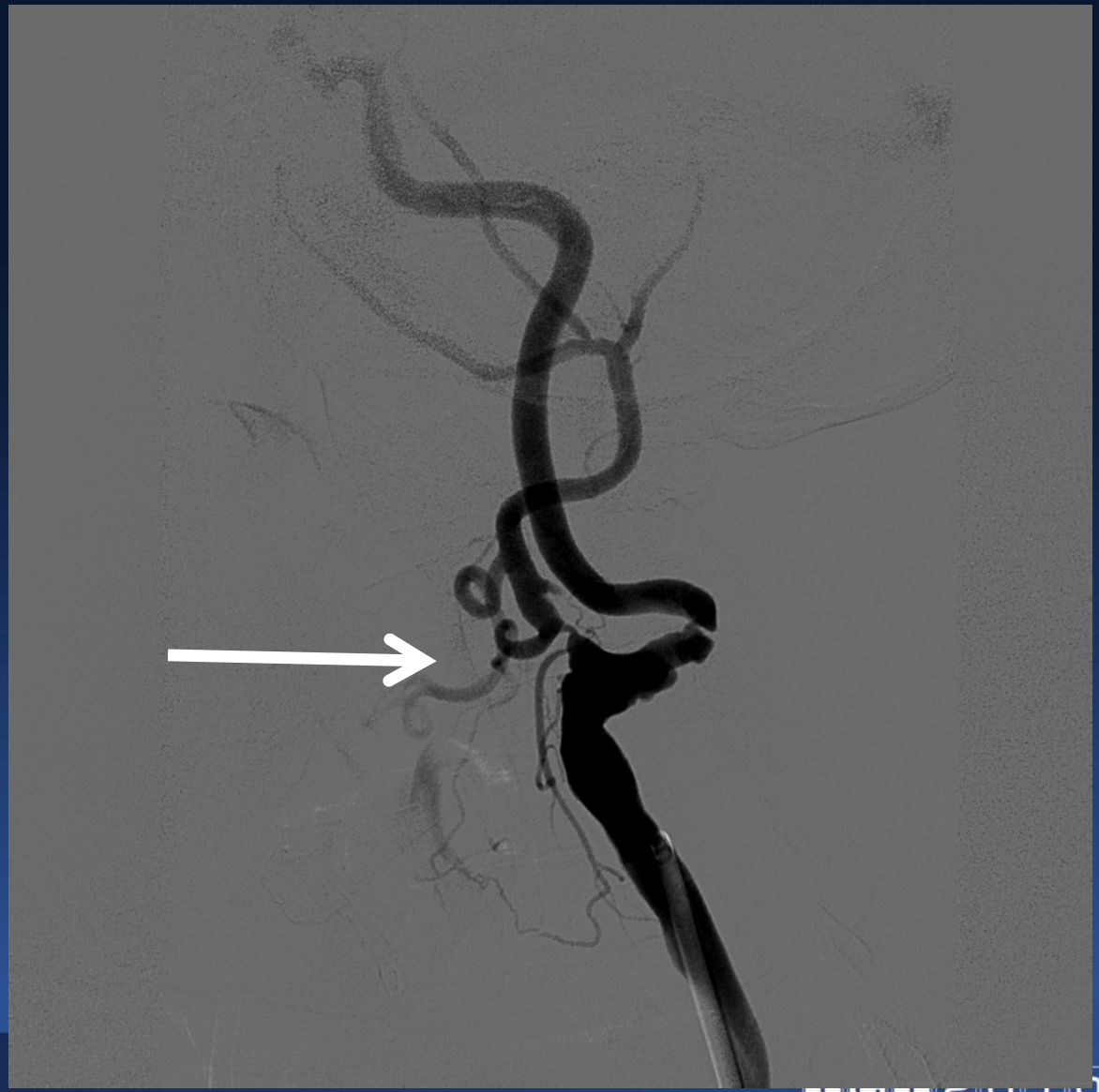


EPi

Angioguard



TORTUOSITIES: 2 exemples of impossible filter placement



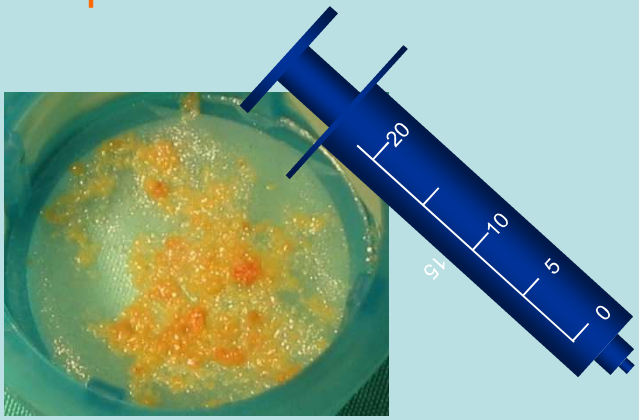
Overview

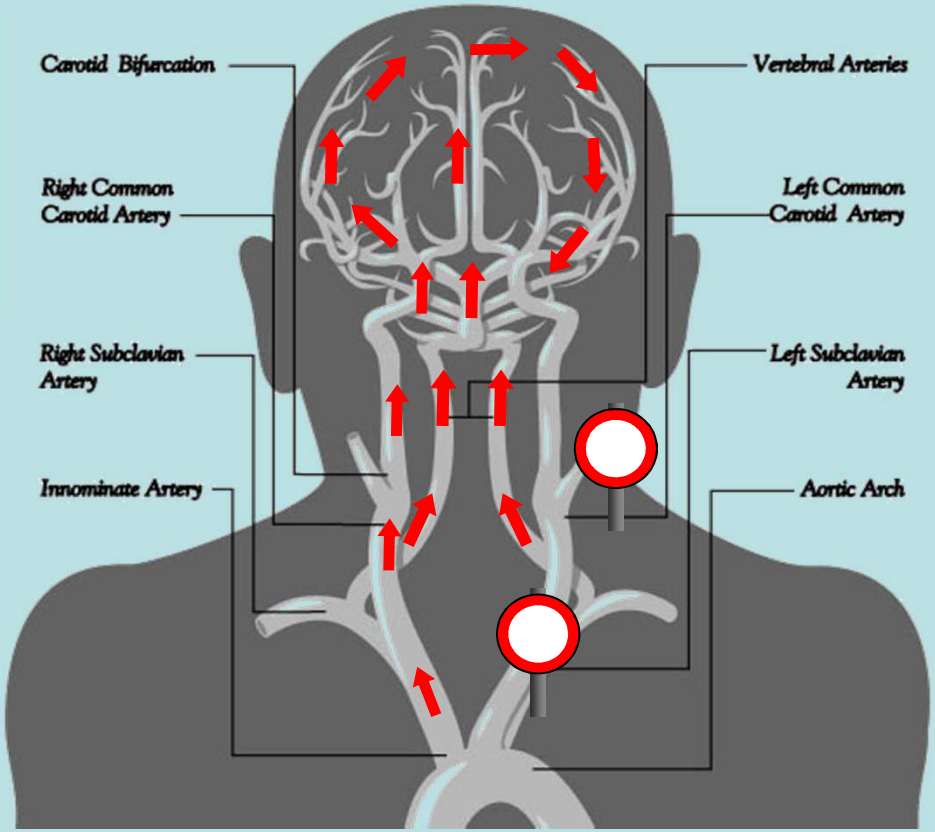
Proximal Flow Blockage Cerebral Protection Device

CCA clamping: blockage of antegrade blood flow

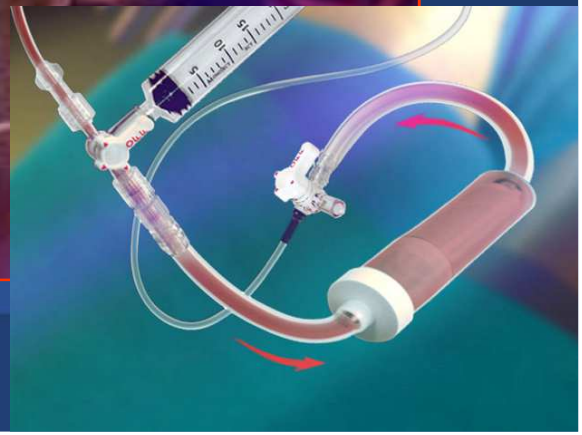
- ECA clamping: blockage of retrograde blood flow

- Debris removal: syringe blood aspiration





GORE Neuro-Protection System



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COLUMBIA UNIVERSITY MEDICAL CENTER
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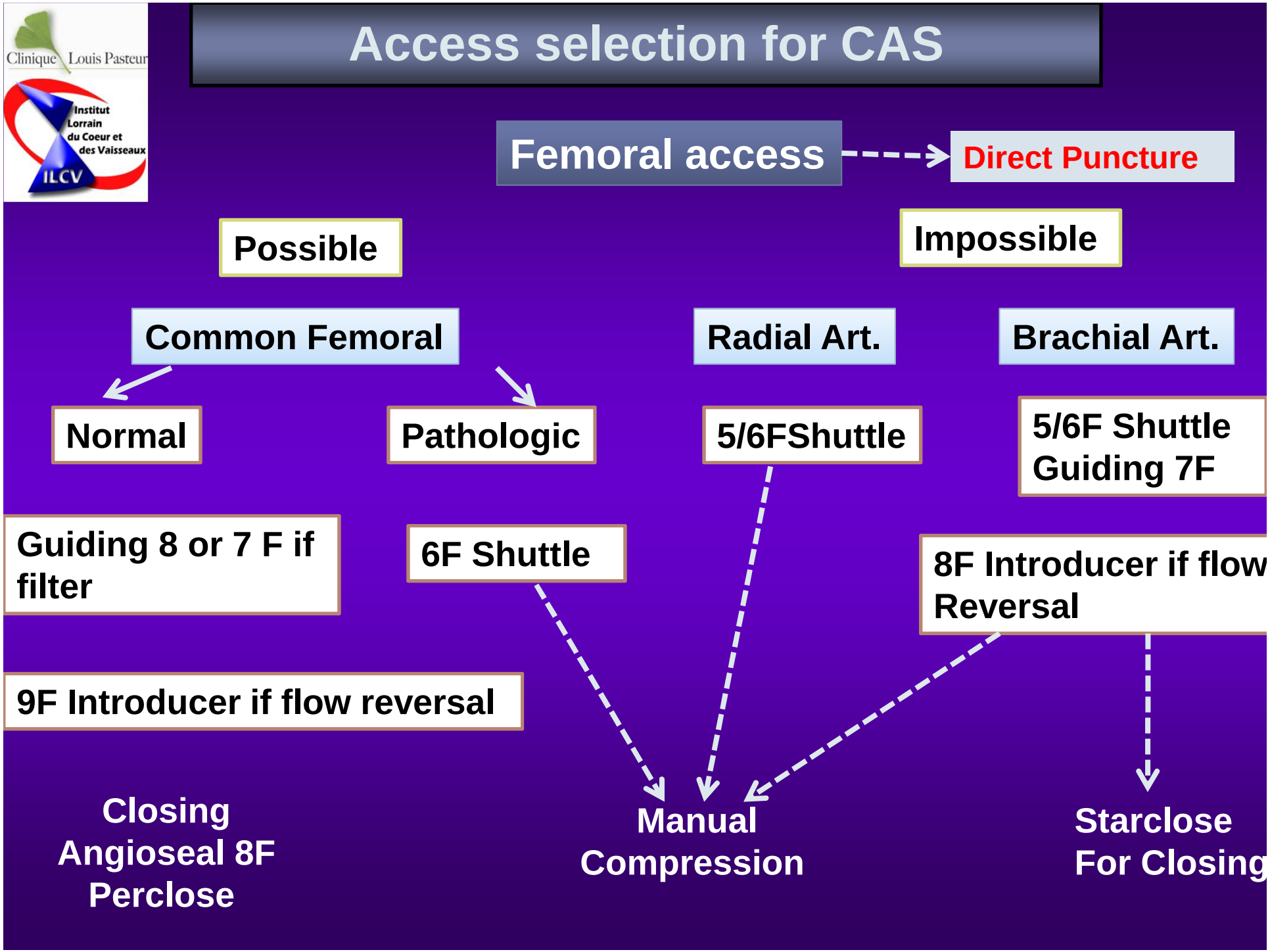

Clinique Louis Pasteur
Institut Lorrain du Coeur et des Vaisseaux
ILCV
Access selection for CAS
Femoral access
Direct Puncture
Possible
Impossible
Common Femoral
Radial Art.
Brachial Art.
Normal
Pathologic
5/6FShuttle
5/6F Shuttle
Guiding 7F
Guiding 8 or 7 F if filter
6F Shuttle
8F Introducer if flow Reversal
9F Introducer if flow reversal
Closing
Angioseal 8F
Perclose
Manual
Compression
Starclose
For Closing

Clinique Louis Pasteur

Institut Lorrain du Coeur et des Vaisseaux

ILCV

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

Asymptomatic Low Risk

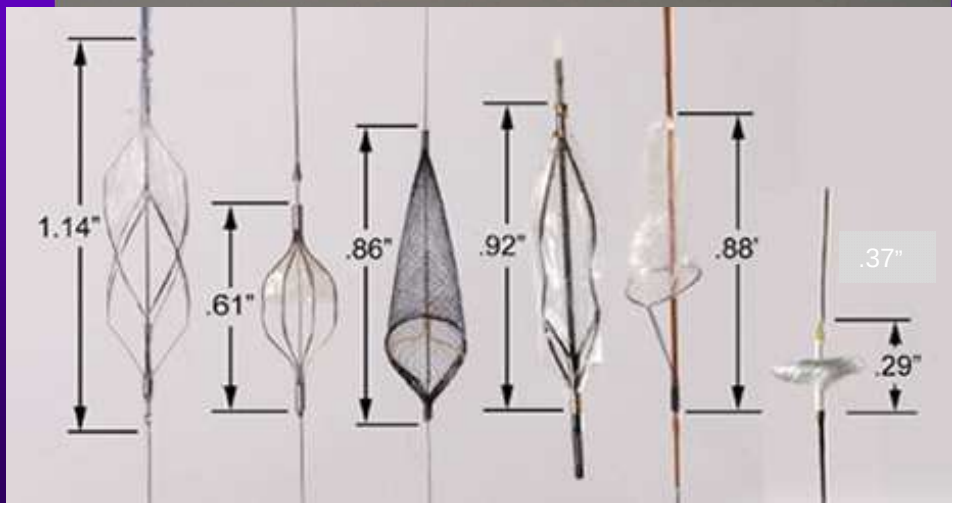
Symptomatic High Risk Octogenarians ?

Flow Reversal

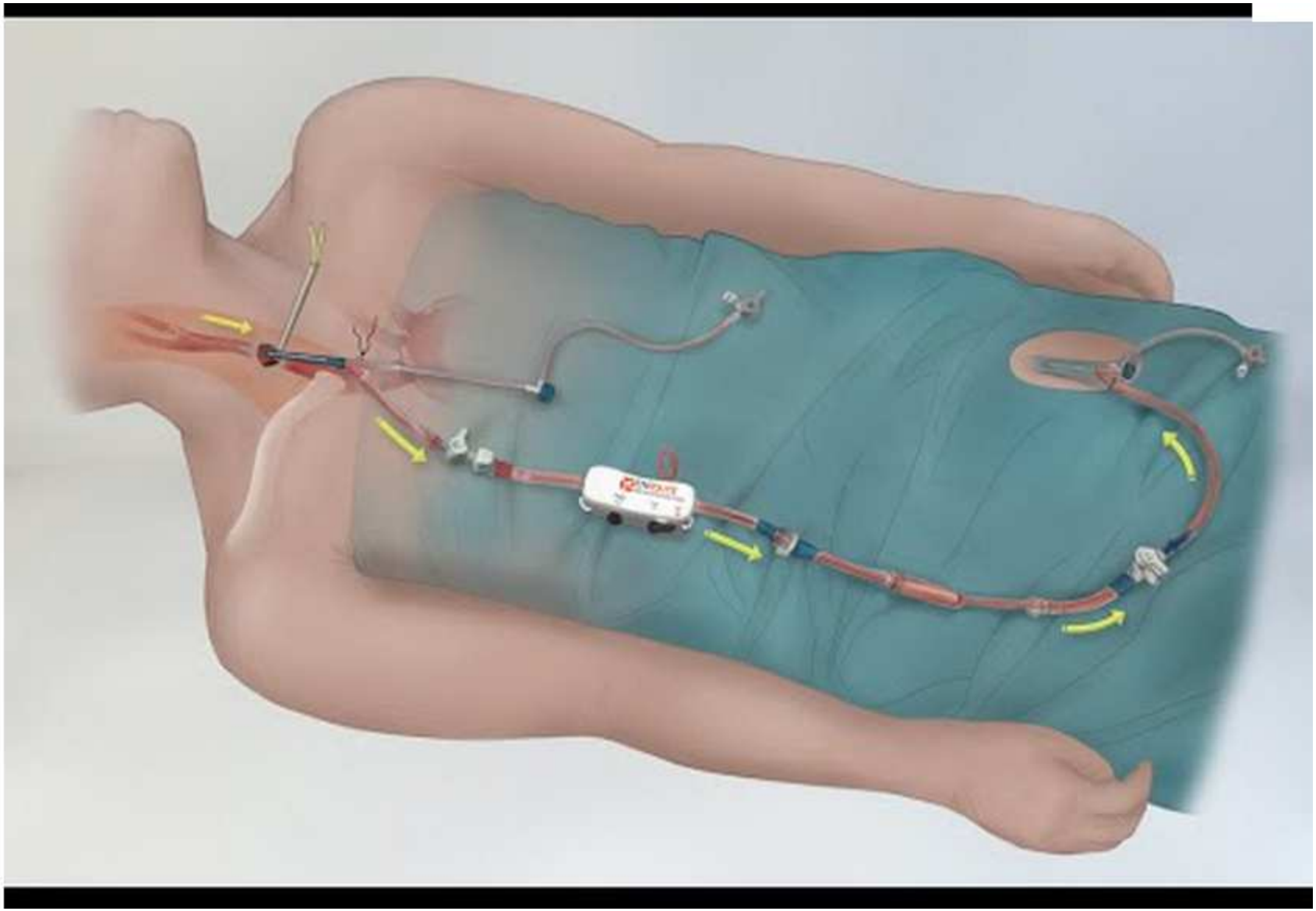
Filter Fibernet Invatec

Filter

- Distal IC
  - ≤5mm : Easy Boston, Spider Rx EV3
  - >5mm: Emboshield, Accunet ,Angioguard
- Crossing
  - Easy : Easy Boston
  - Difficult: Emboshield Abbott
  - Very Difficult: Spider RX
  - Failure : Surgery or ►



SILK ROAD CAROTID SYSTEM



CID hautement symptomatique chez Mr Mo. 75ans

Sténose complexe CID + Sténose CED

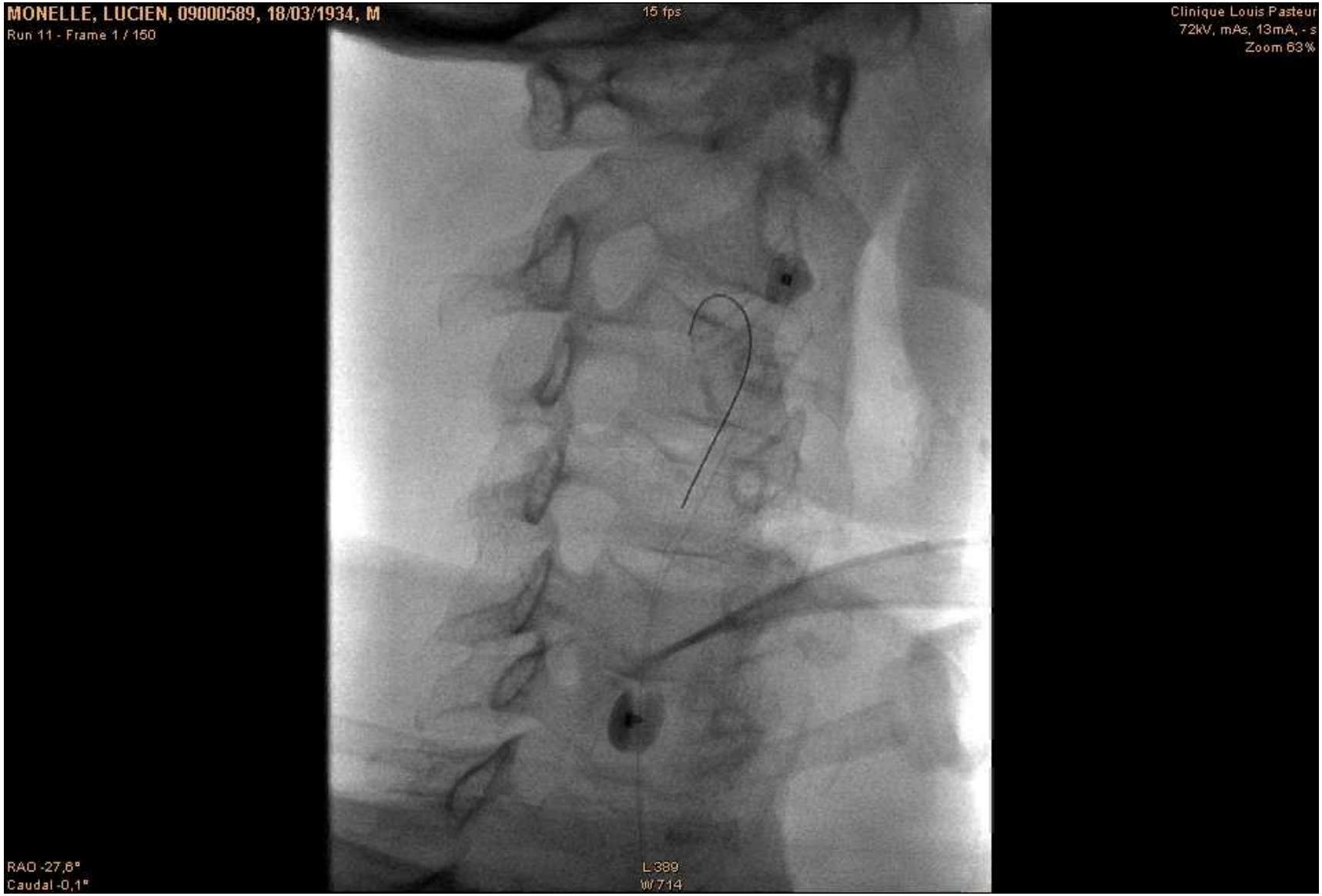
1Terumo stiff et Simmons CED
2 Echange pour un guide extra stiff

Moma™ Invatec

1 inflation du ballon CED
2 le flux est interrompu dans CED

Inflation du second ballon CCD

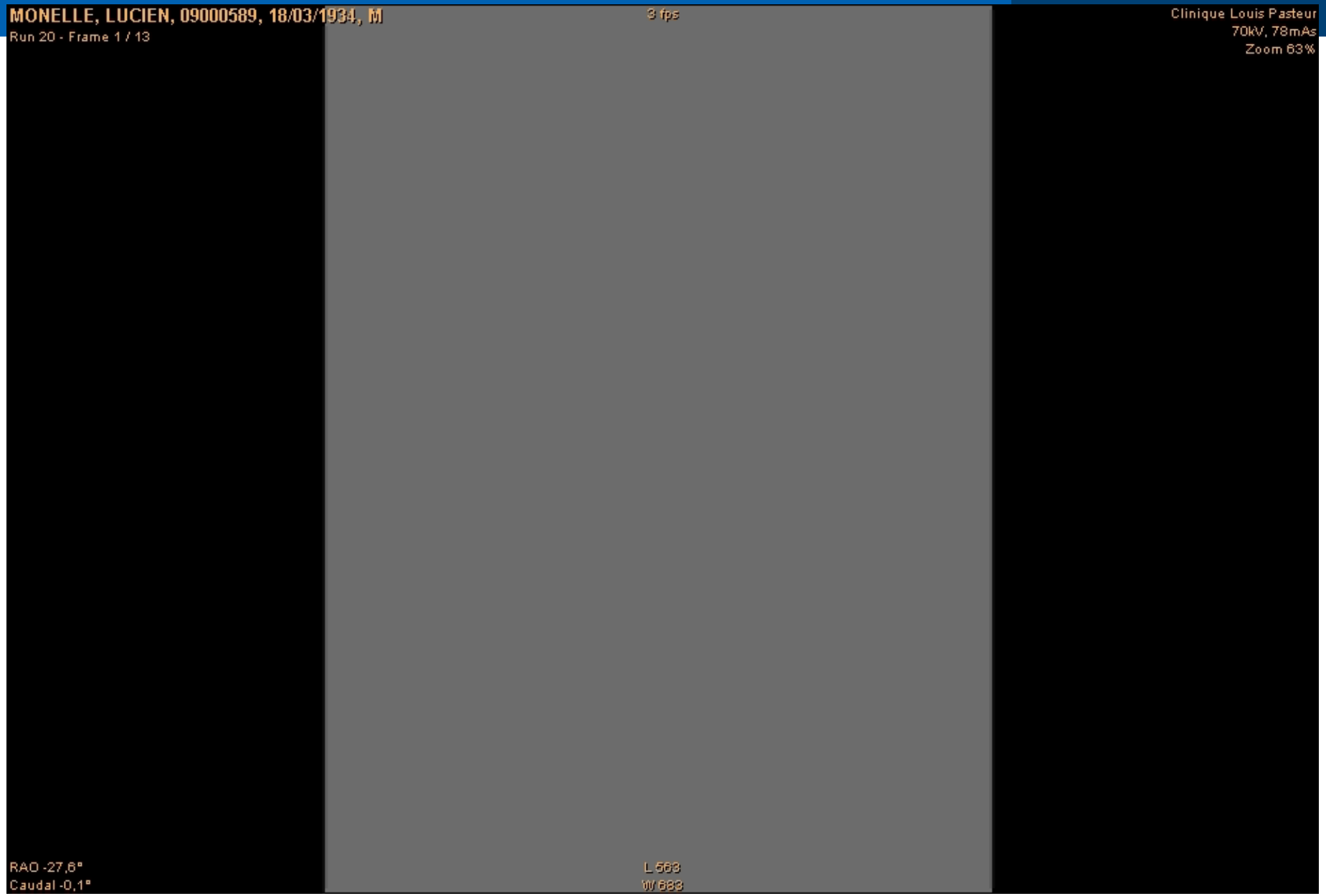
Franchissement de la sténose par guide 0,014” type Pilot 50



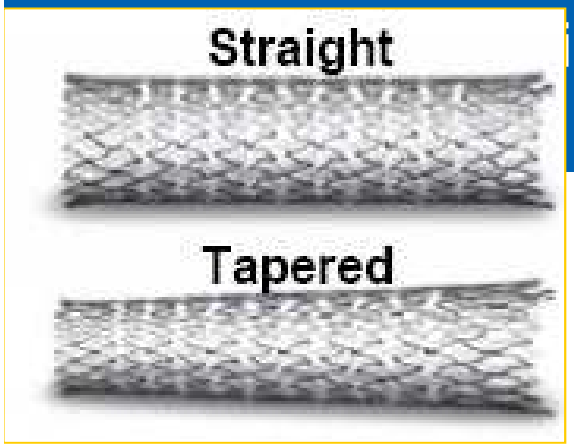
1 Déploiement d’un stent Abbott X-act
2Post dilatation par ballon 5x20mm

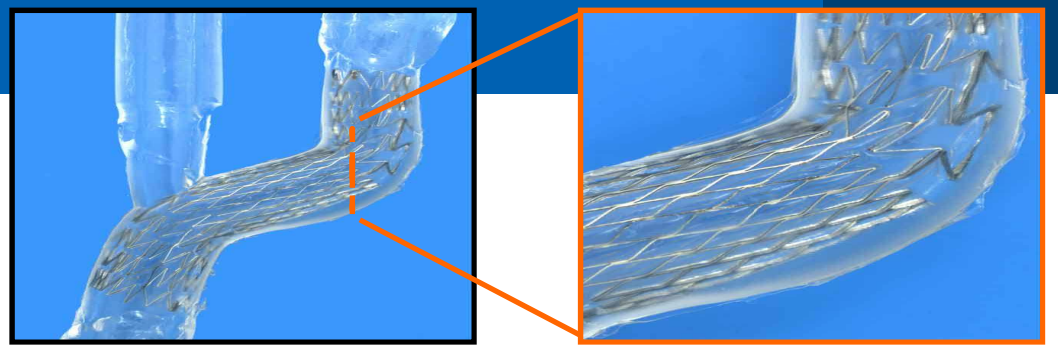
1 /stent deployé
2 /résultat Moma en place , les 2

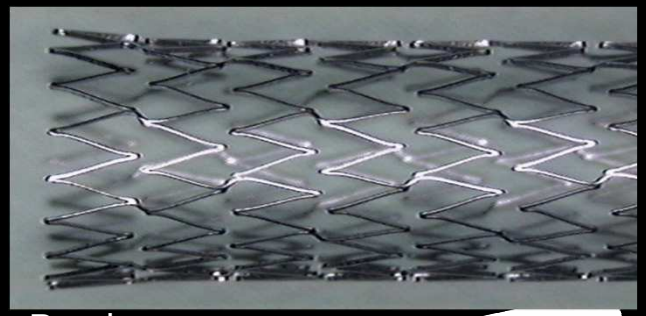
Résultat final

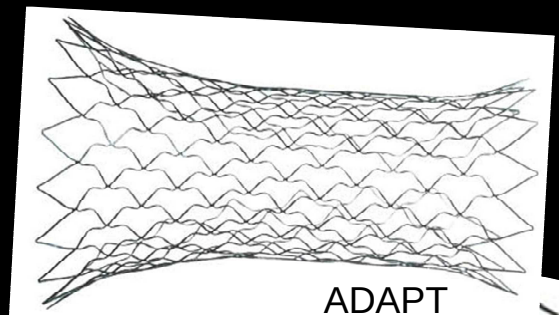


id stents

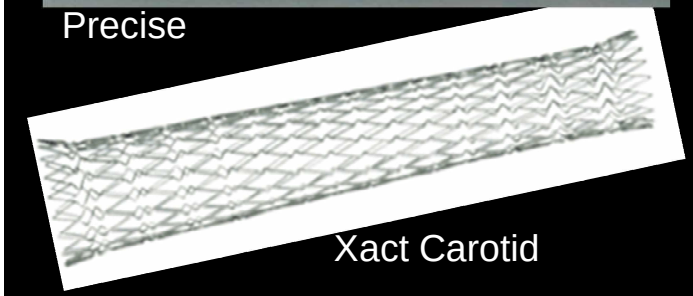


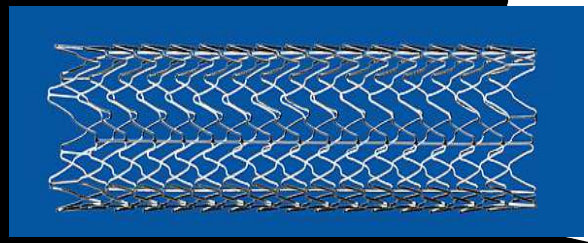



Precise

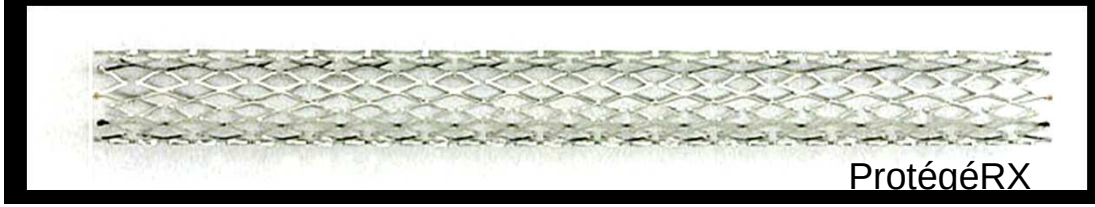

ADAPT


Exp


Xact Carotid



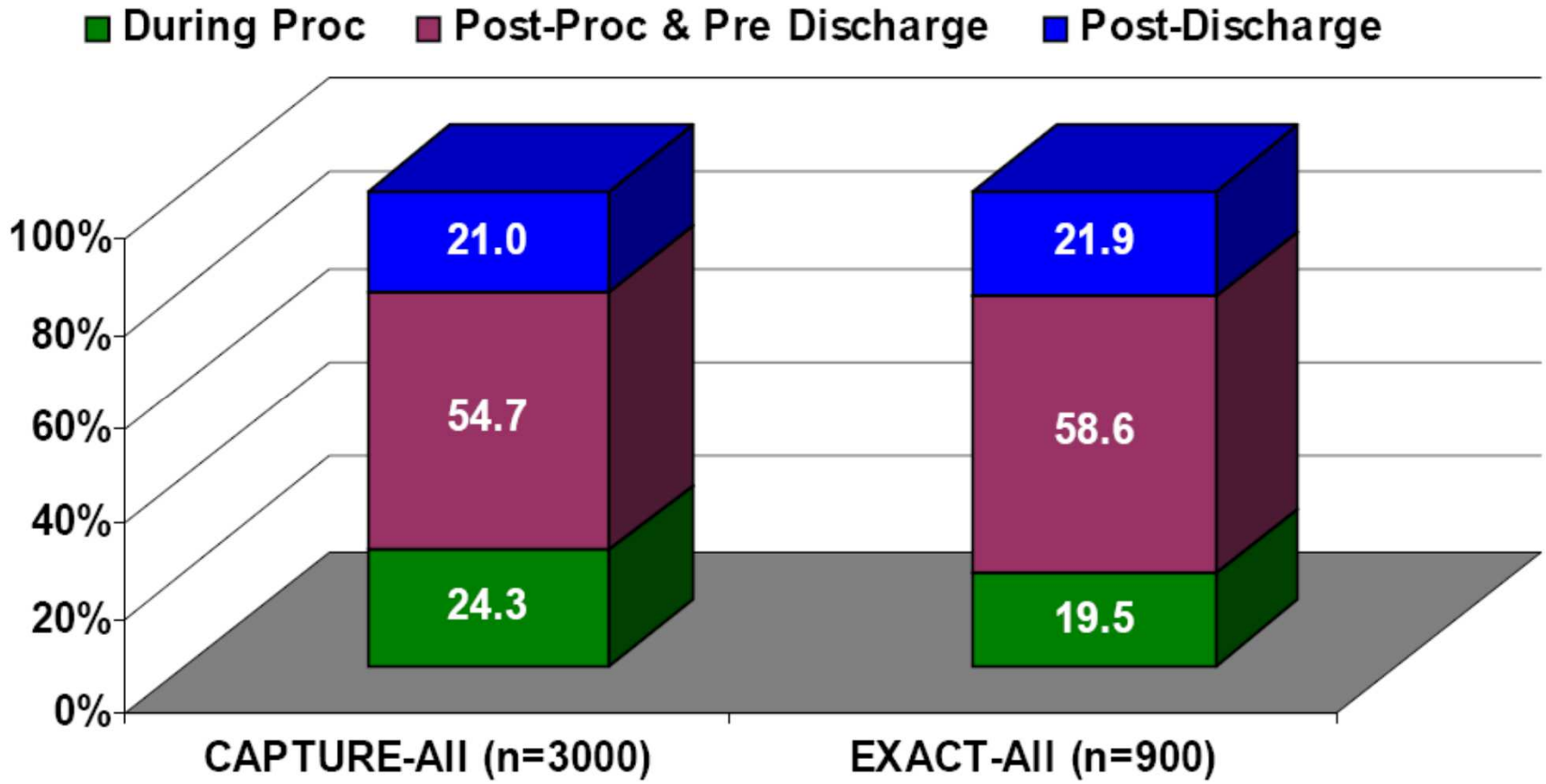

Carotid Wallstent


ProtégéRX

Stent Selection

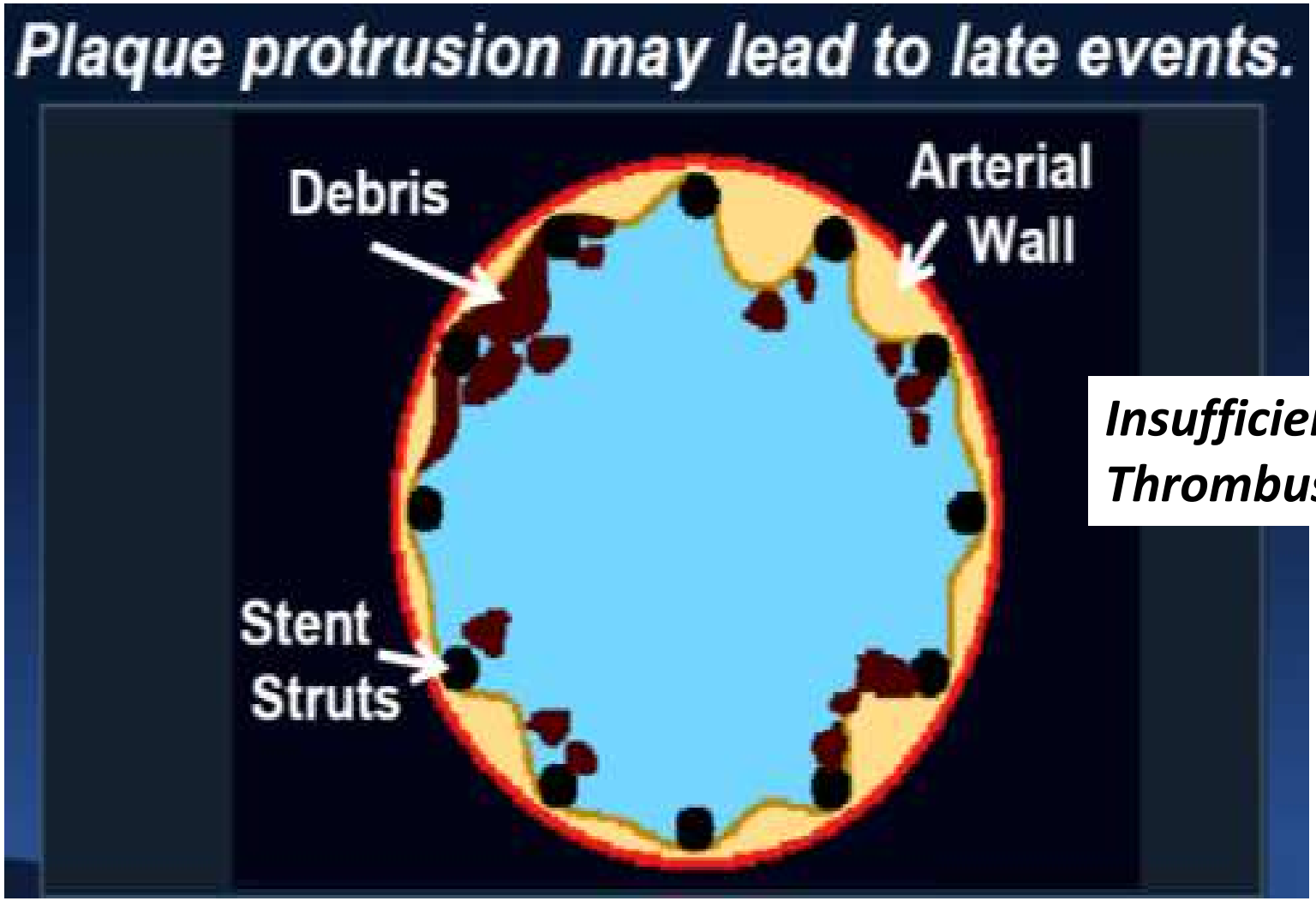
Type	Open Cells Stent			Closed Cells Stent		
Name Comp	**Precise** Cordis	**Acculink** Abbott	**Proteg** EV 3	**Wallstent** BSC	**Adapt** BSC	**Xact** Abbott
Sympto.	+	-	±	+++	+++?	++
Asymp.	+++	++	++	+	++	++
Bifurc.	++	+++	+++	+++	+	±
Ulcerate	++	-	++	+++	++?	+++
Calcified	++	+	++	+	++	+++
Short	+++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

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



From M.Bosiers, and others

Causes of Late Embolization

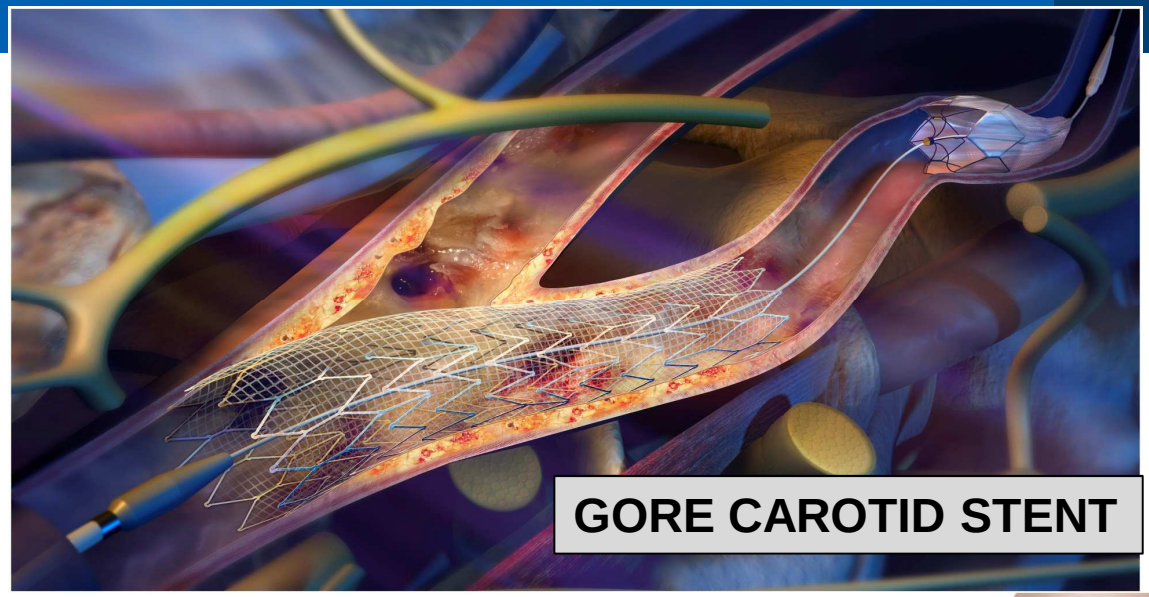


Insufficient coverage
Thrombus formation

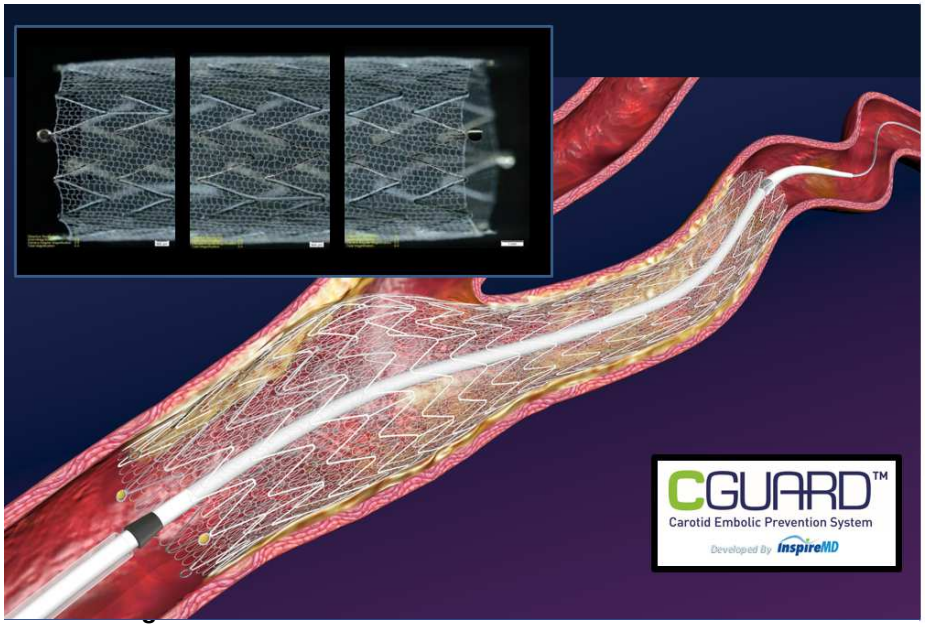
Prof. Dr. Klaus Mathias, TCT 2013

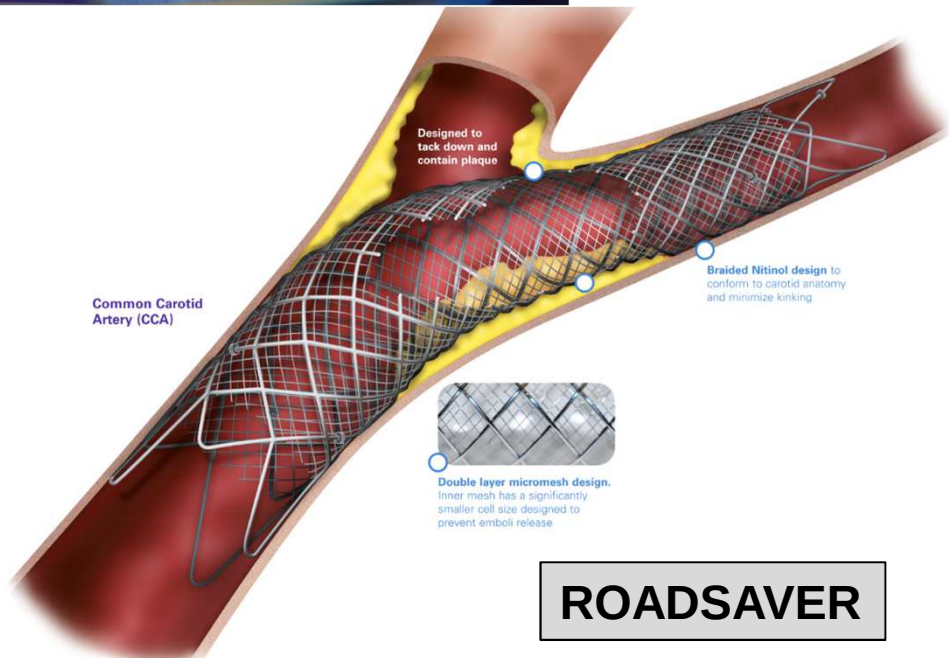
Are we able to provide
delayed embolic protection
Without loosing
the long term benefit of Carotid
Nitinol Stent ?

THE THREE MICROMESH CAROTID STENTS



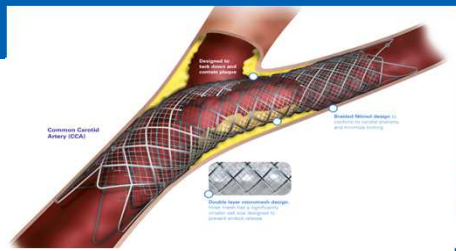
GORE CAROTID STENT

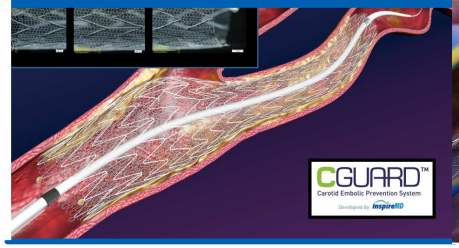


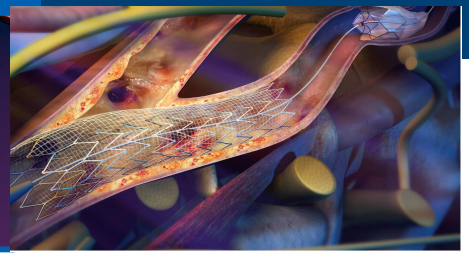


ROADSAVER

Tentative Summary of the main charcteristics 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

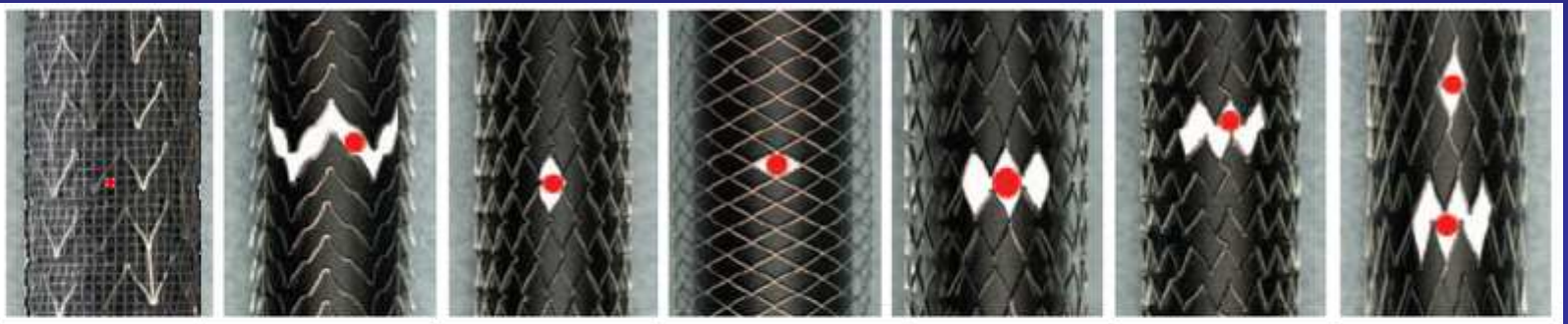
Stent Selection including Micromesh

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

INDIALIVE 2015

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&6months

N	Access	Guiding : G Shuttle: I	Protection System	Pre-dilatation	Post – Stent Dilatation	Stent Size	48 h Embolic	30th Day MAE	6th 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	30th 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

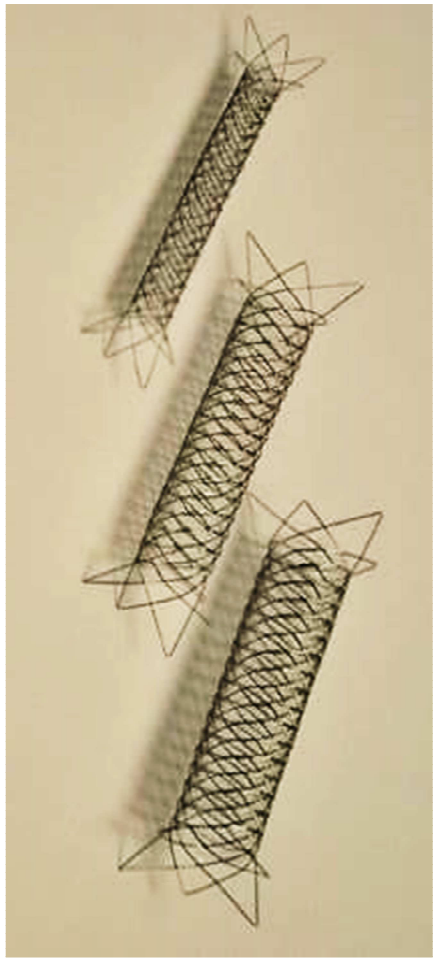
No restenosis

No stent deformation or fracture

No external carotid occlusion

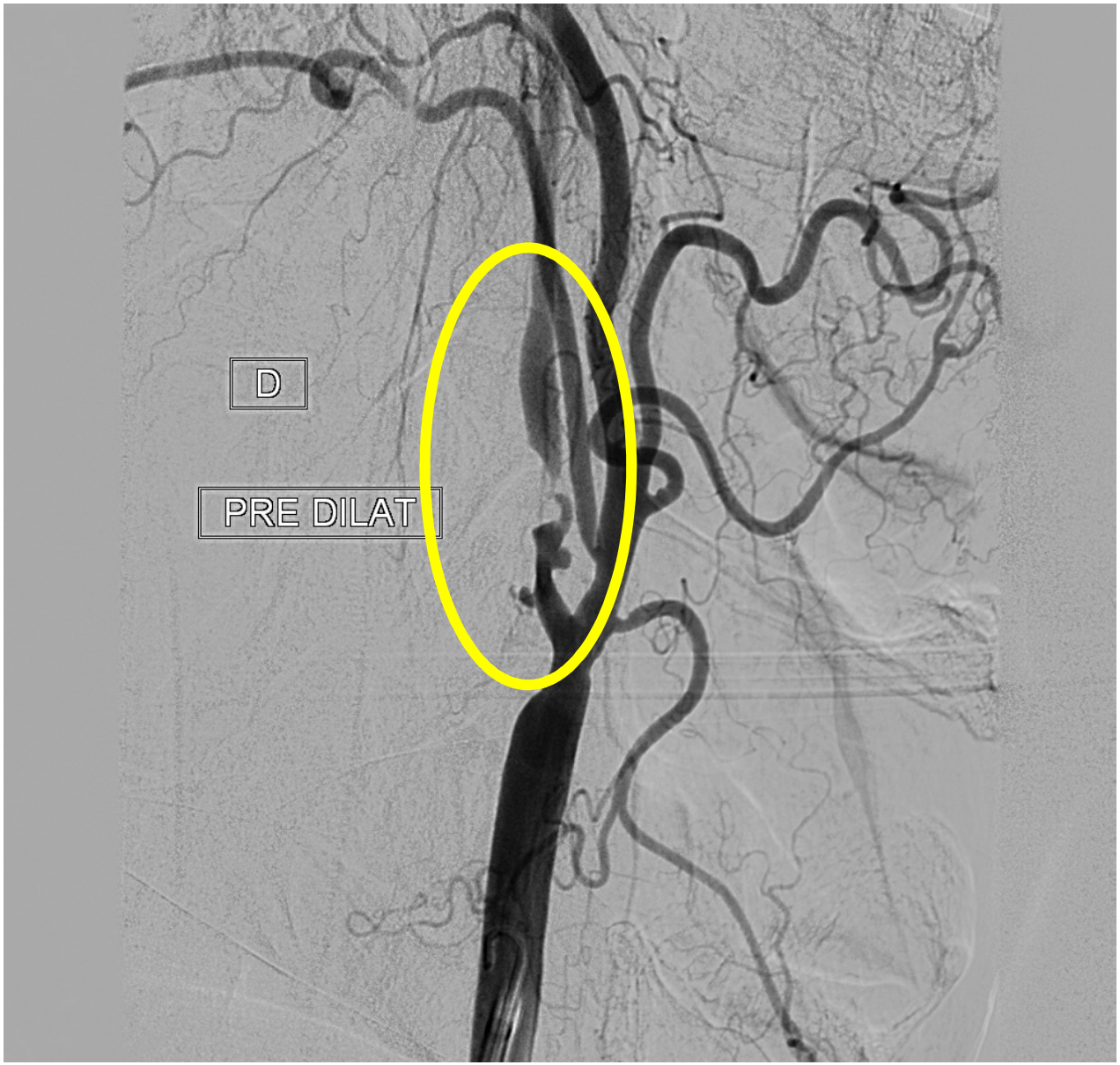
procedure (2D echo control)

83 y ,male , Right Internal asymptomatic carotid stenosis

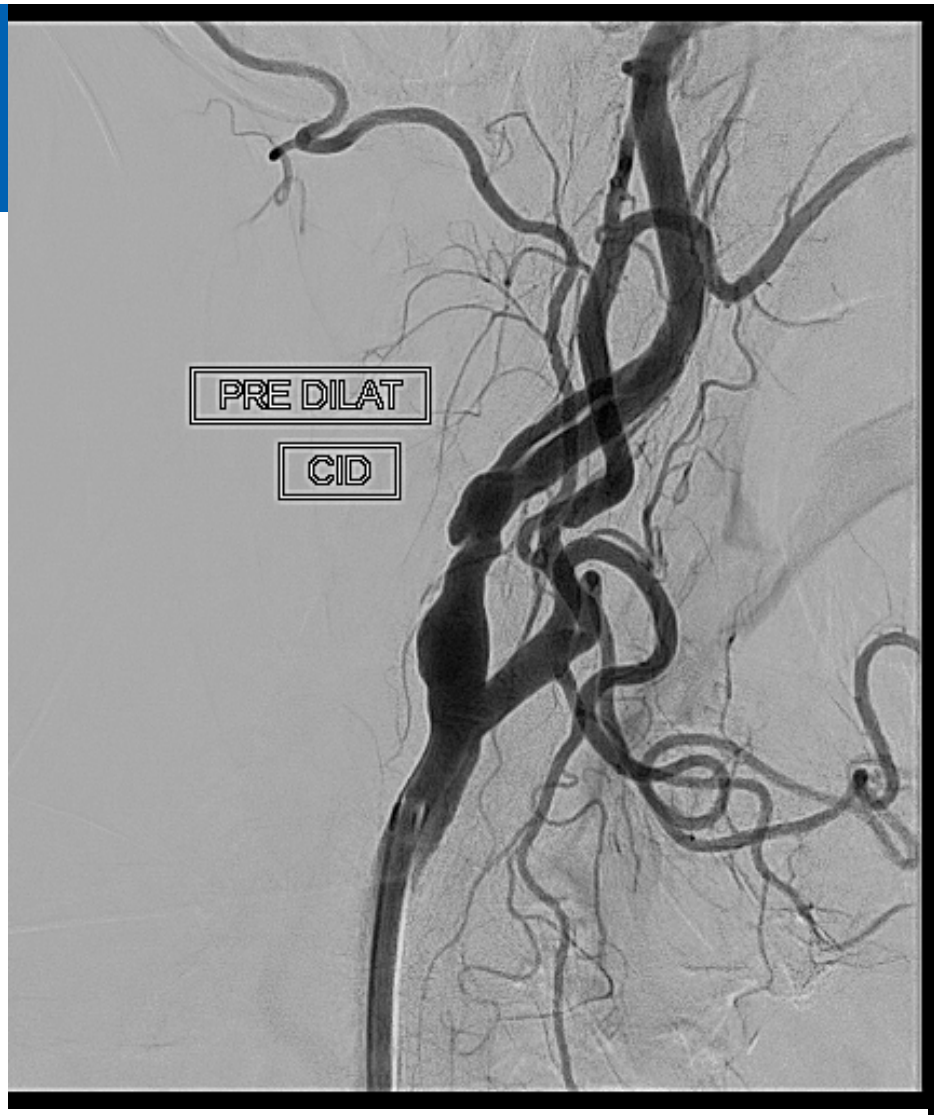


Roadsaver Stent

Severe Symptomatic RICA stenosis with multiple ulcerations

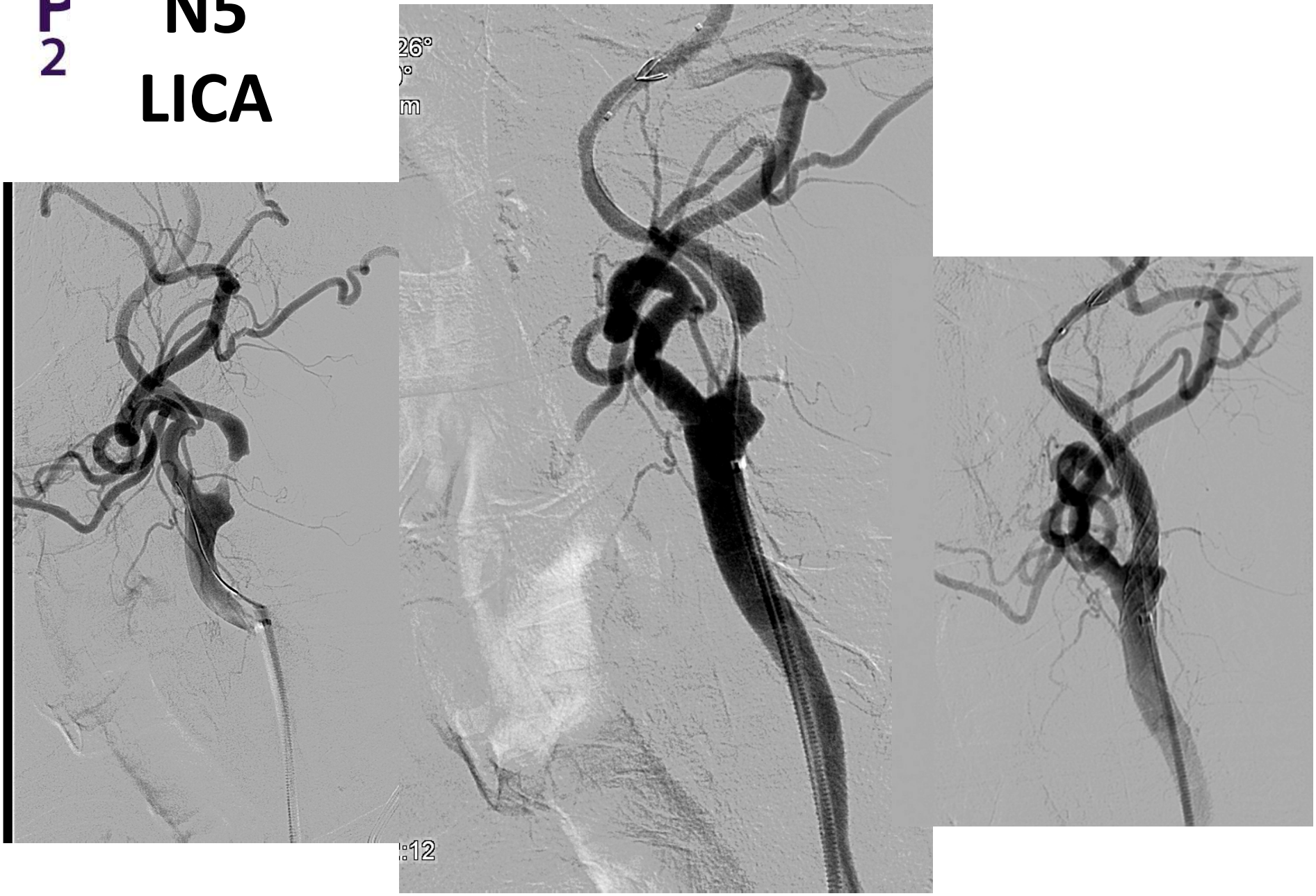


After ROADSAVER Stent 10x30mm placed under filter protection



Symptomatic chronic Dissection & Ulcerated RICA Stenosis

N5
LICA



N 5 Final Result

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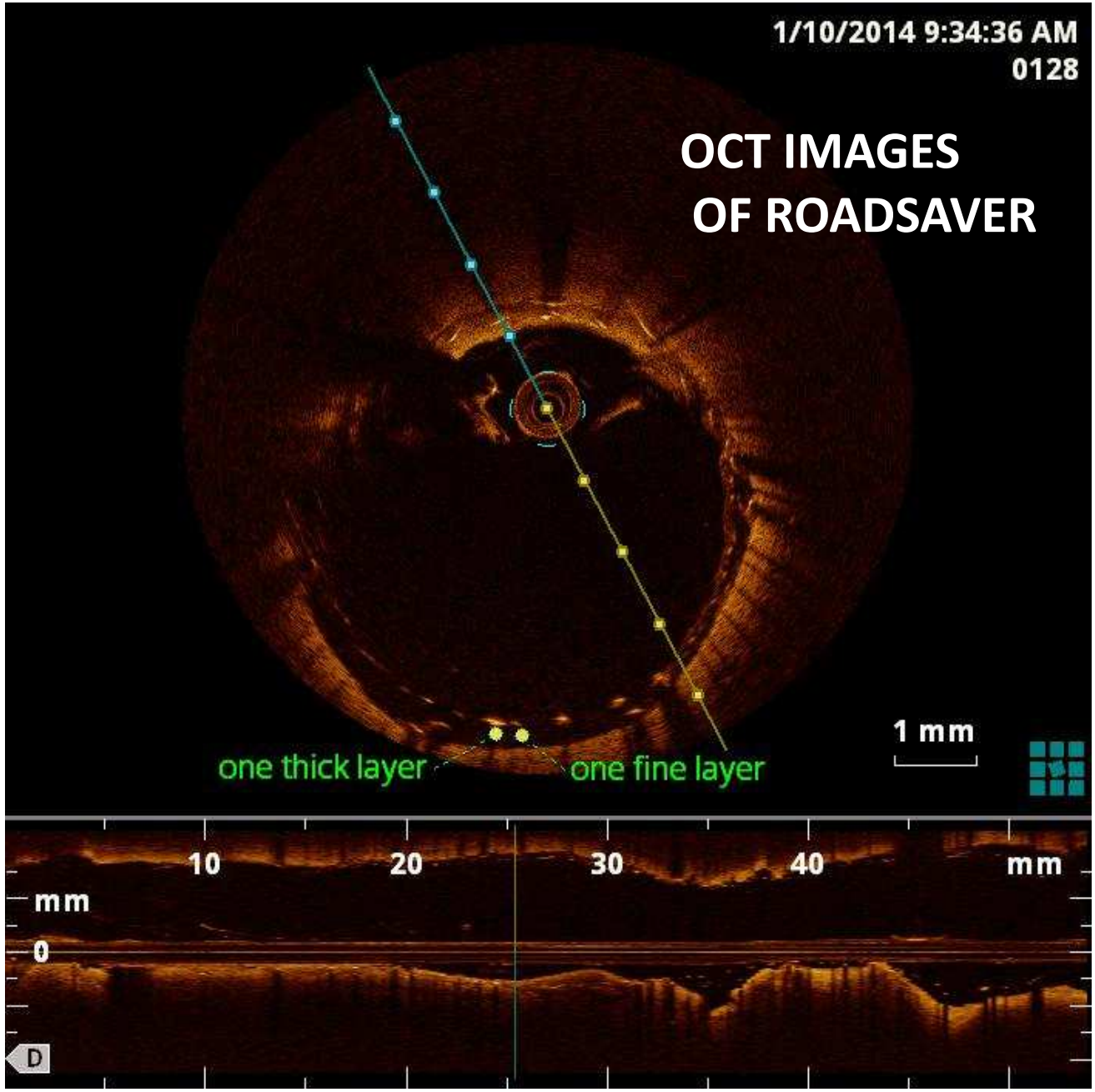

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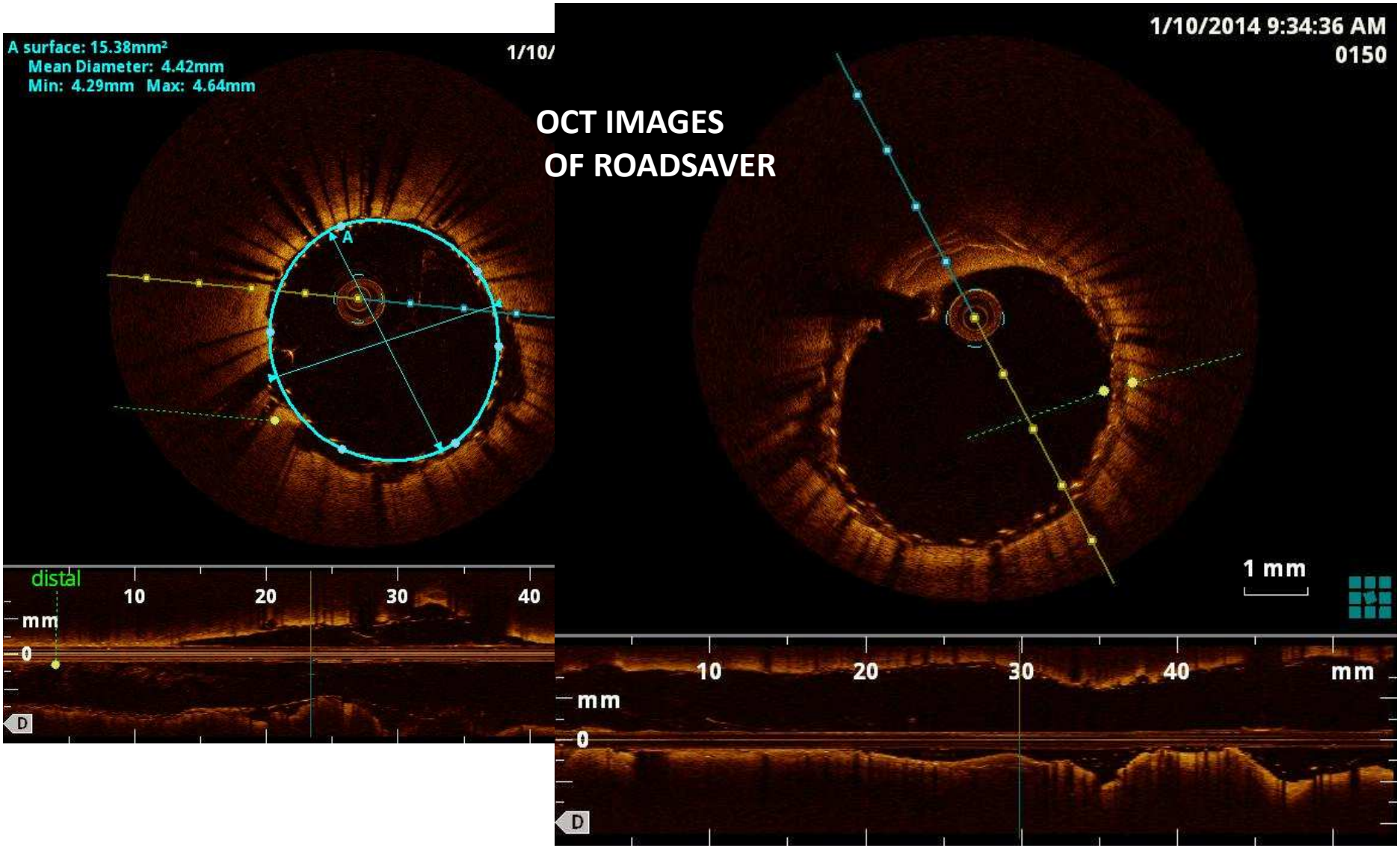
Harmonious deployment



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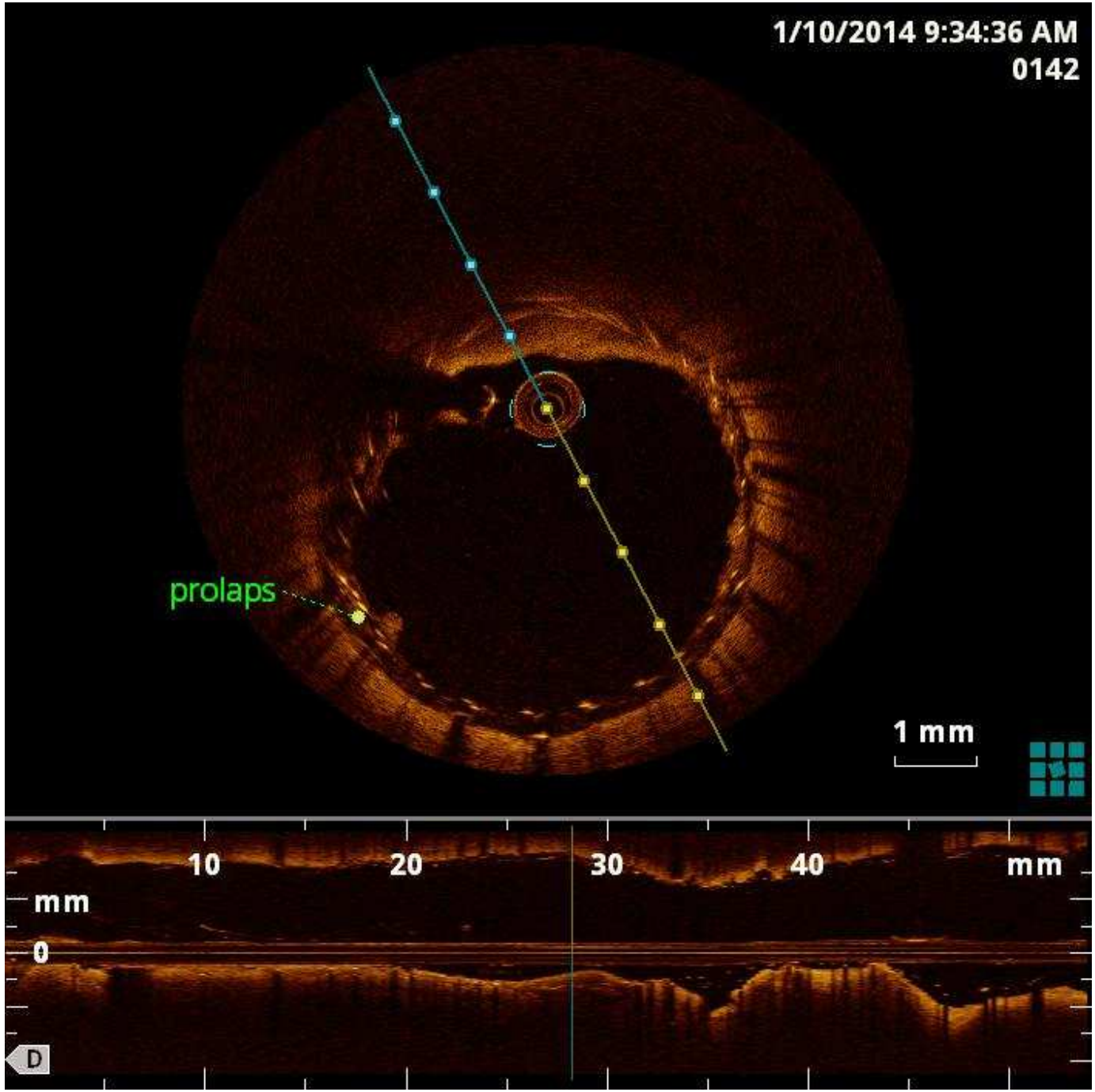
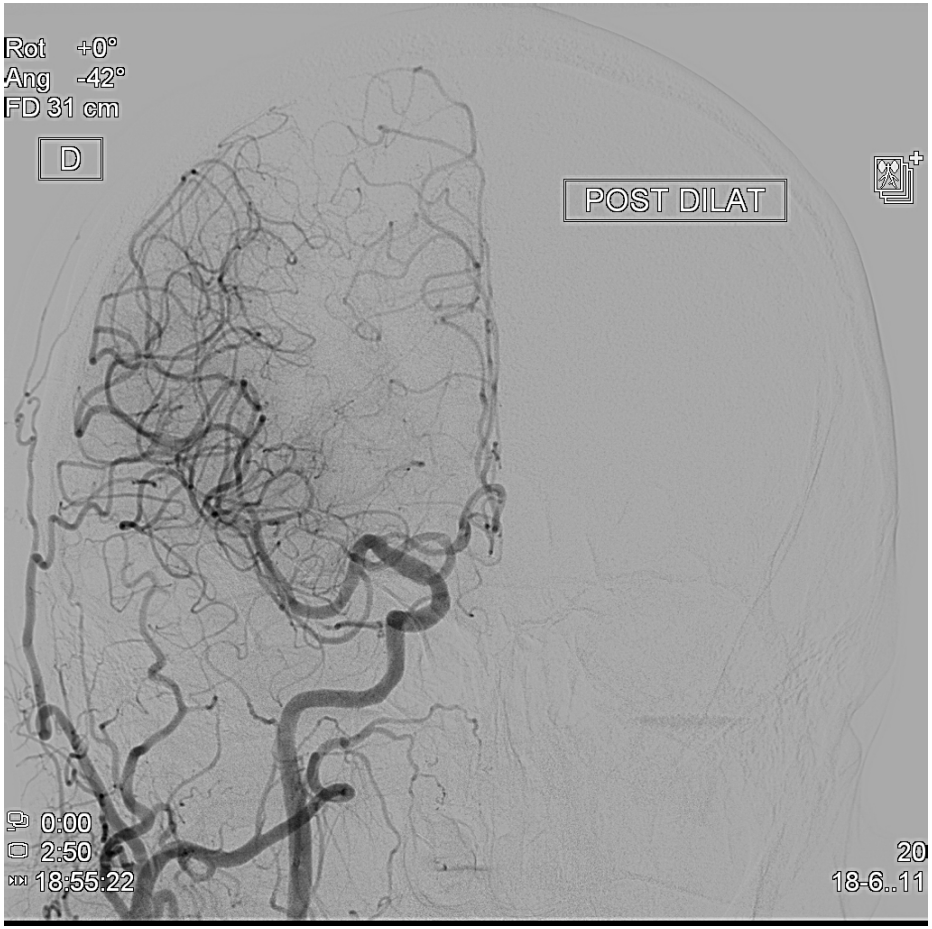
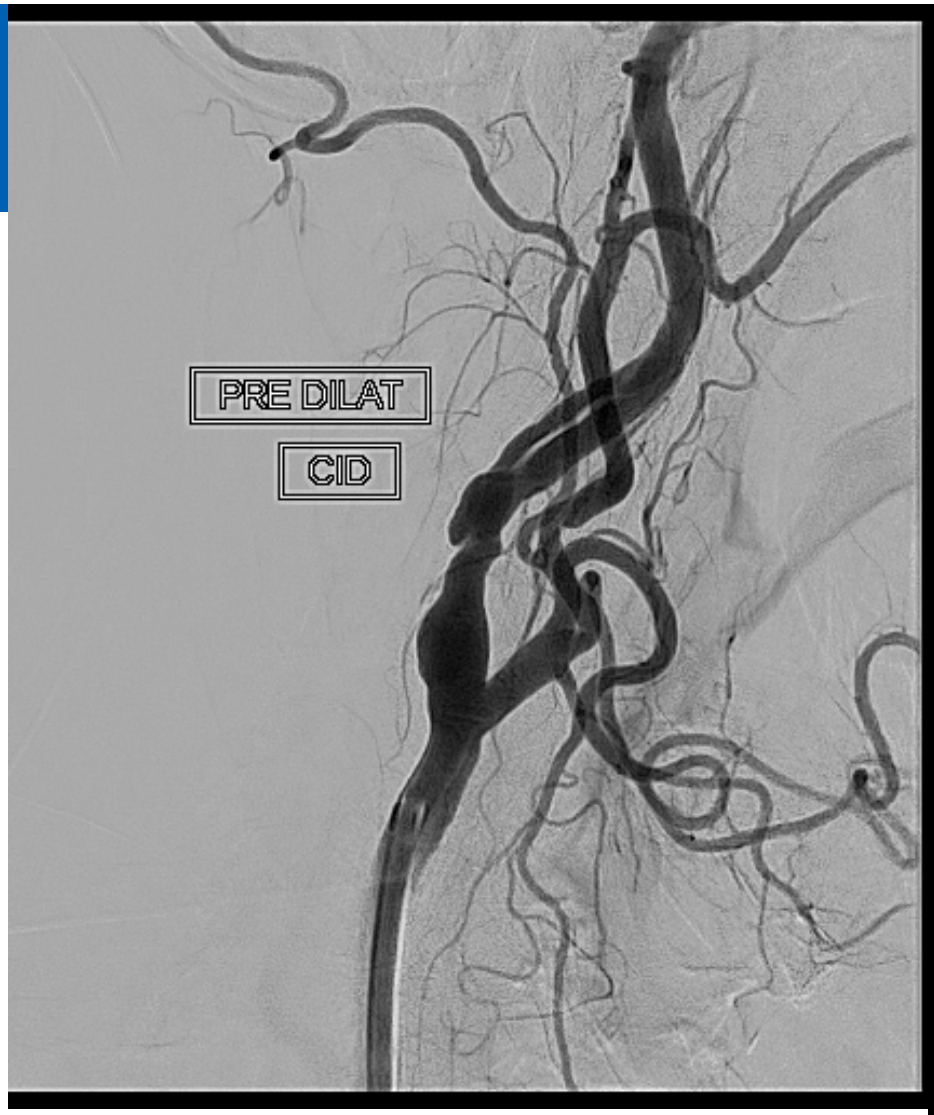


Severe Symptomatic RICA stenosis with multiple ulcerations

After ROADSAVER Stent 10x30mm placed under filter protection


Rot +0°
Ang -42°
FD 31 cm
D
POST DILAT
0:00
2:50
18:55:22
20
18-6..11



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 arteria wall following stent deployment : Plaque coverage and Scaffolding
  - Seems superior to other stents on the market in preventing immediate and delayed embolization

LONG TERM RESULTS ARE the KEY!!!!

- **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.**

END

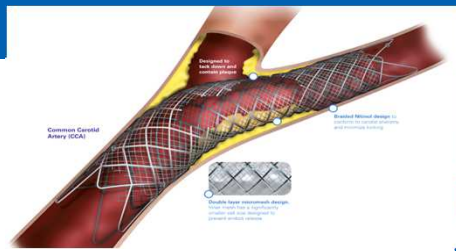
Seven Roadsaver cases have been recorded and commented by Subbarao Myla and are visible in

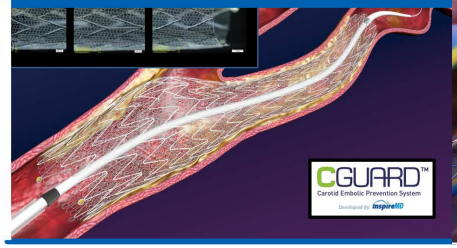
www.incathlab.com

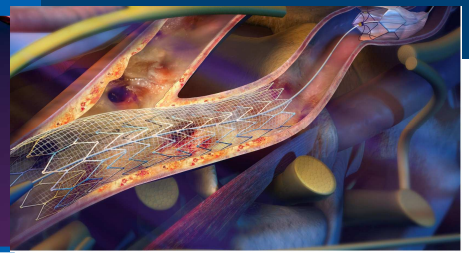
Stent Selection

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 charcteristics 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%

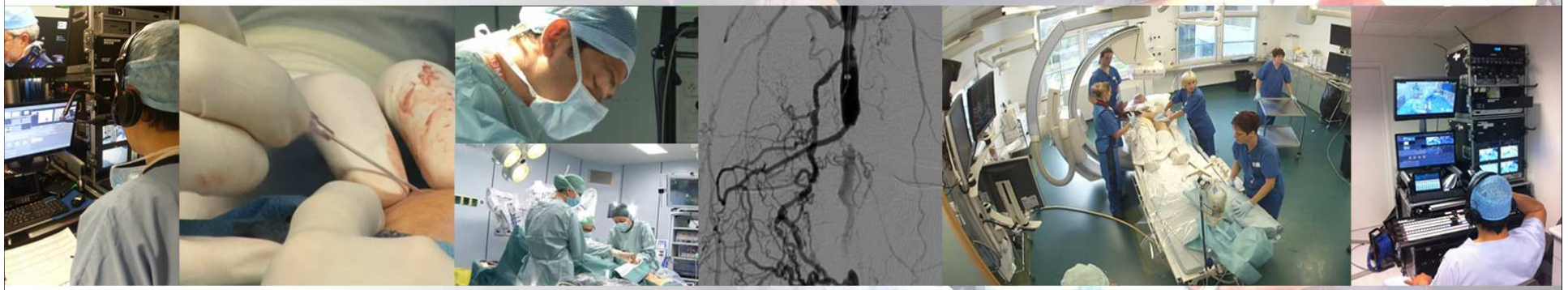
	CARENET (Filter group) N=26	PROFI[1] (Filter group) N=31	ICSS[2] (Filter group) N=37
Incidence of New Lesions	48%	87%	73%
Avg Lesion Volume	0.06 cm^3	0.59 cm^3	NA

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



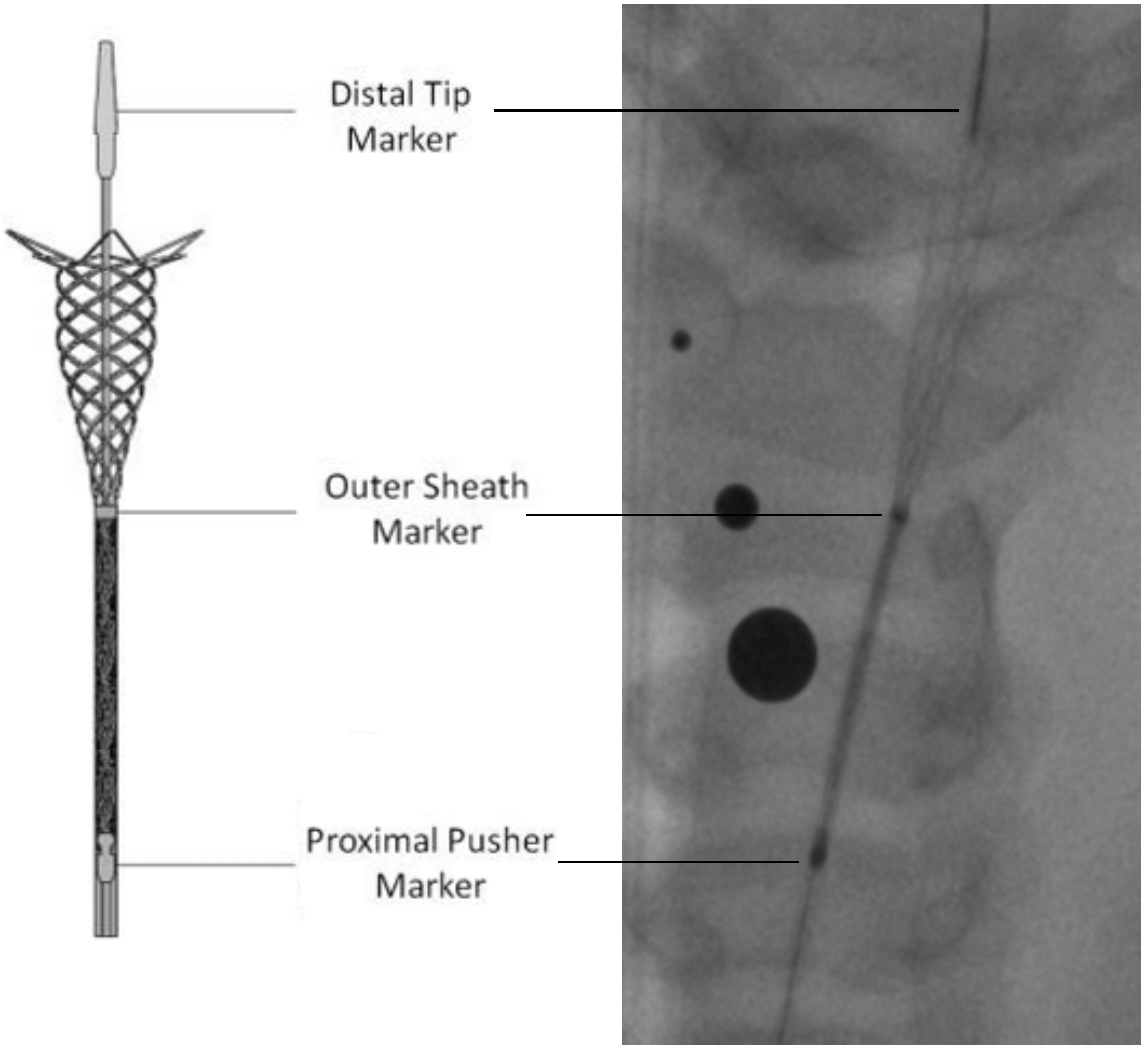
VEITH SYMPOSIUM SUPPORT SLIDES

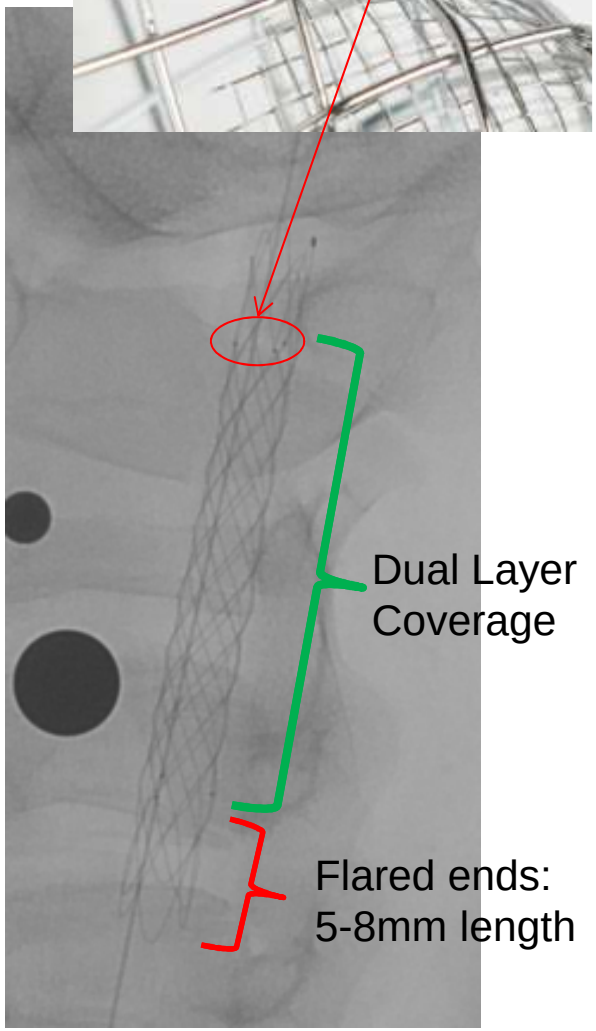
ROADSAVER

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**

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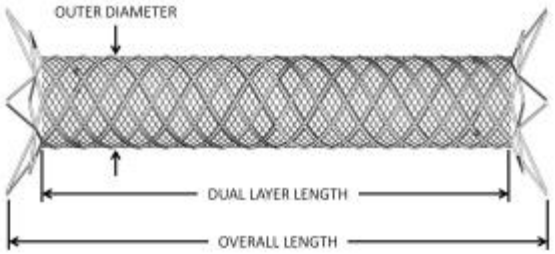
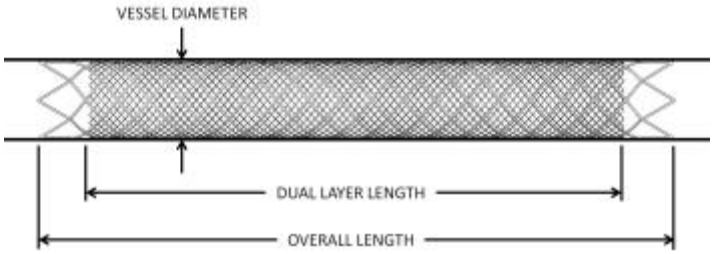
System Sizes

CASPER™ RX Carotid Artery Stent

1 per box

Product Code	Unconstrained Dimensions			Implanted Dimensions			
				1mm < Unconstrained Diameter		2mm < Unconstrained Diameter	
	Diameter (mm)	Dual Layer Length (mm)	Overall Length (mm)	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



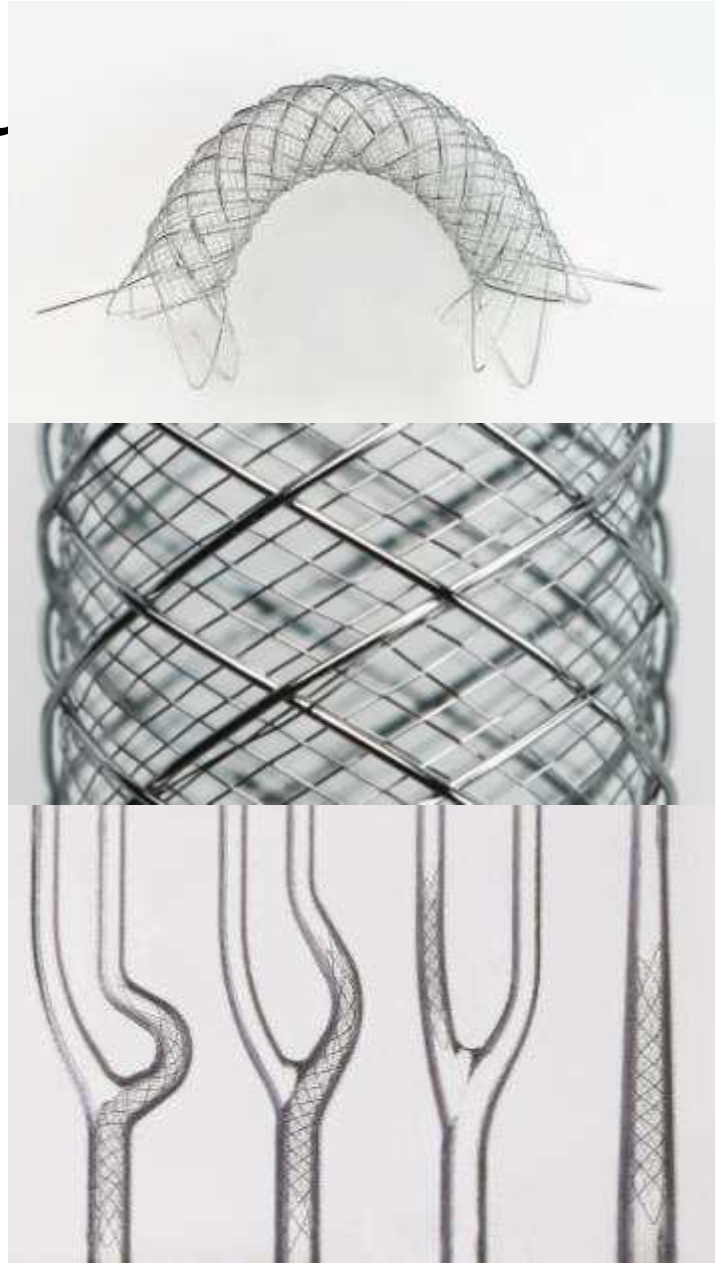


System Compatibility

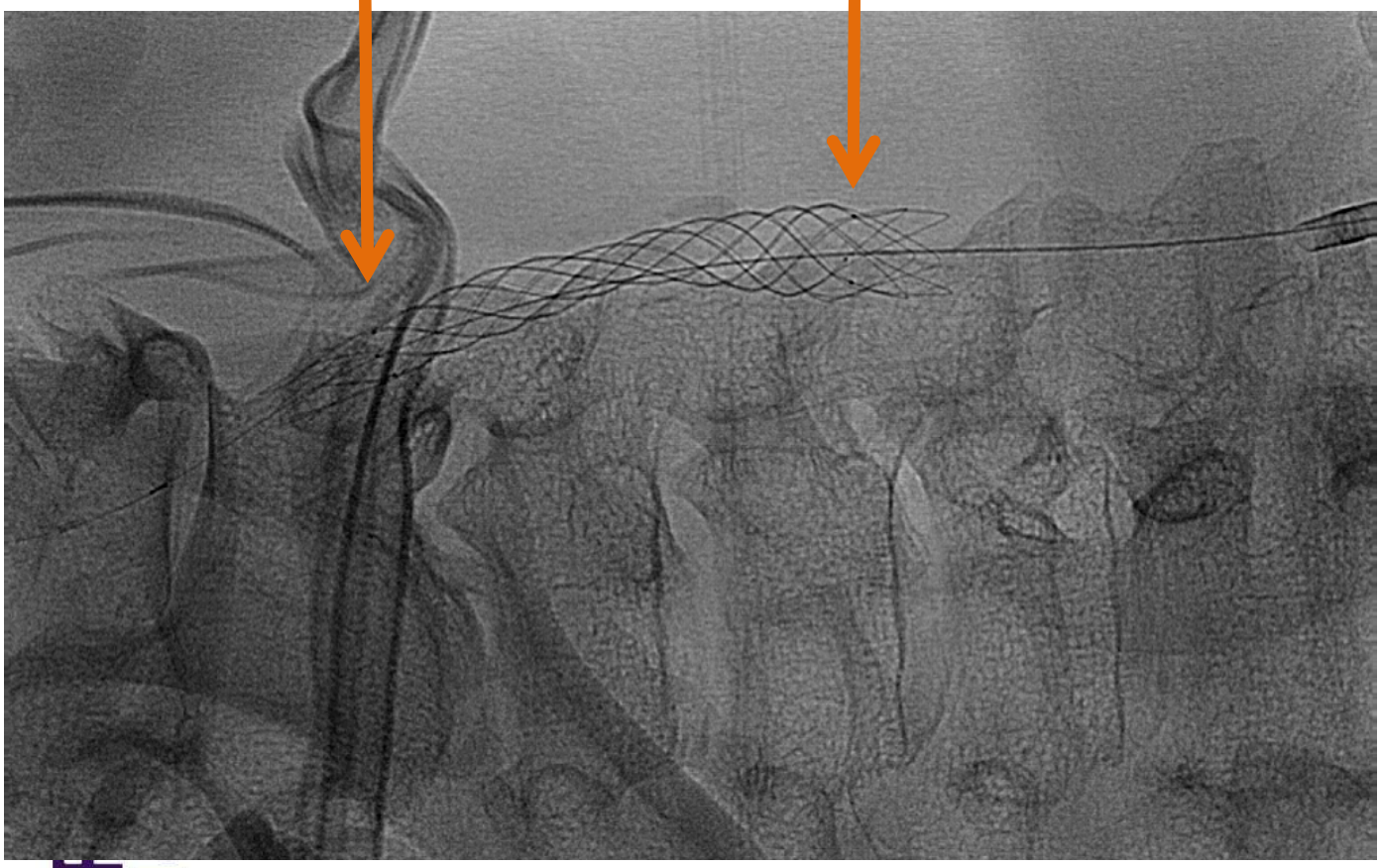
Guide Sheath	Guide Catheter	EPD/Guidewire
• 5 Fr. (.074”Min) • Terumo Destination • Cook Shuttle	• 7 Fr. (.074”Min)	• 0.014” Wires • EV3 Spider • Abbott Accunet • Abbott Emboshield • Boston Filterwire • Cordis Angioguard

System Featu

- **Chronic Embolic Protection**
  - Double layer micromesh design
  - Smallest stent cell size, ¼ 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



Cental Dual layer segment



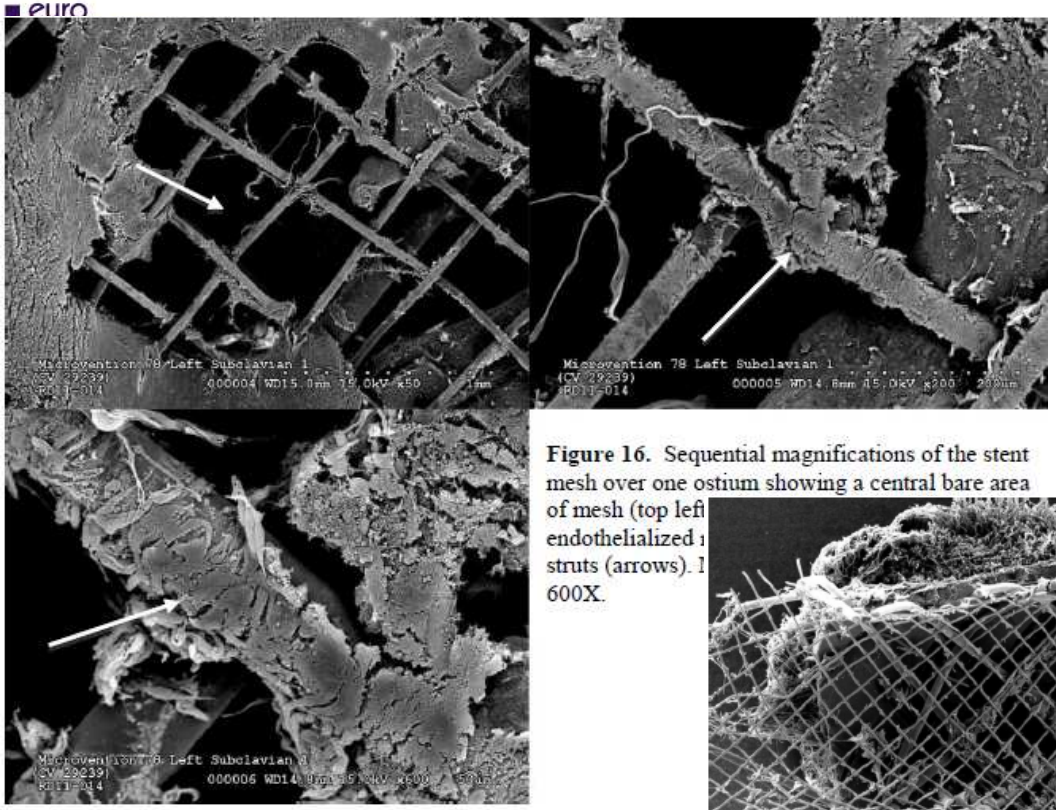
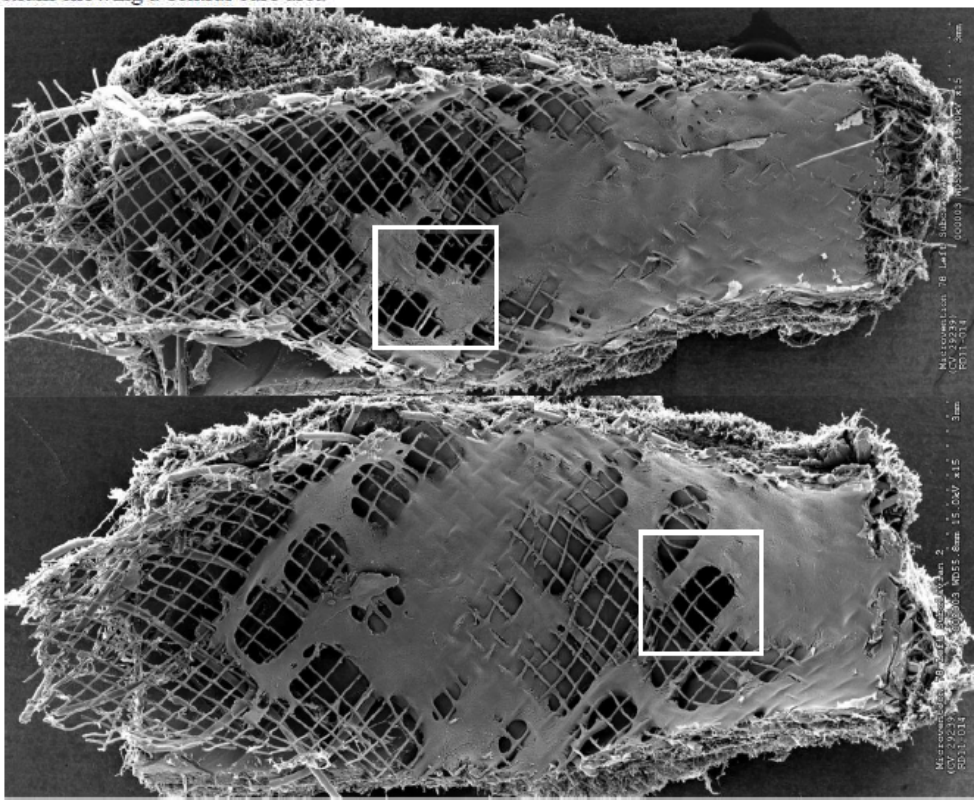
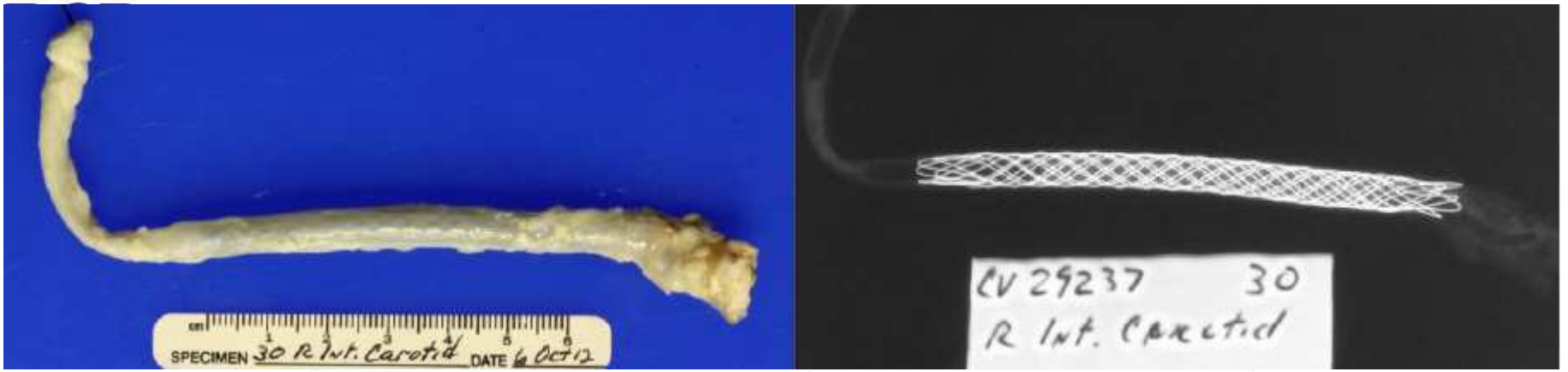


Figure 16. Sequential magnifications of the stent mesh over one ostium showing a central bare area of mesh (top left endothelialized struts (arrows). 600X.



SEM Side Branch Ostia



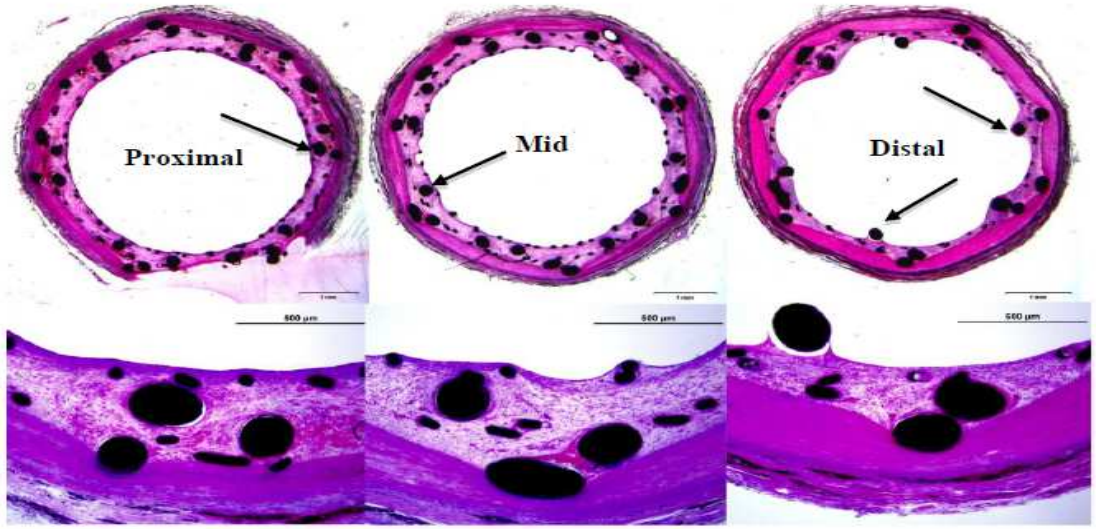


Figure 12. Proximal, mid, and distal overlapped cross-sections of the distal right common carotid artery from animal 78 (overlapping the proximal stent). All sections show a widely patent lumen with largely complete incorporation of the large and small stent wires with mild neointimal overgrowth. The 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

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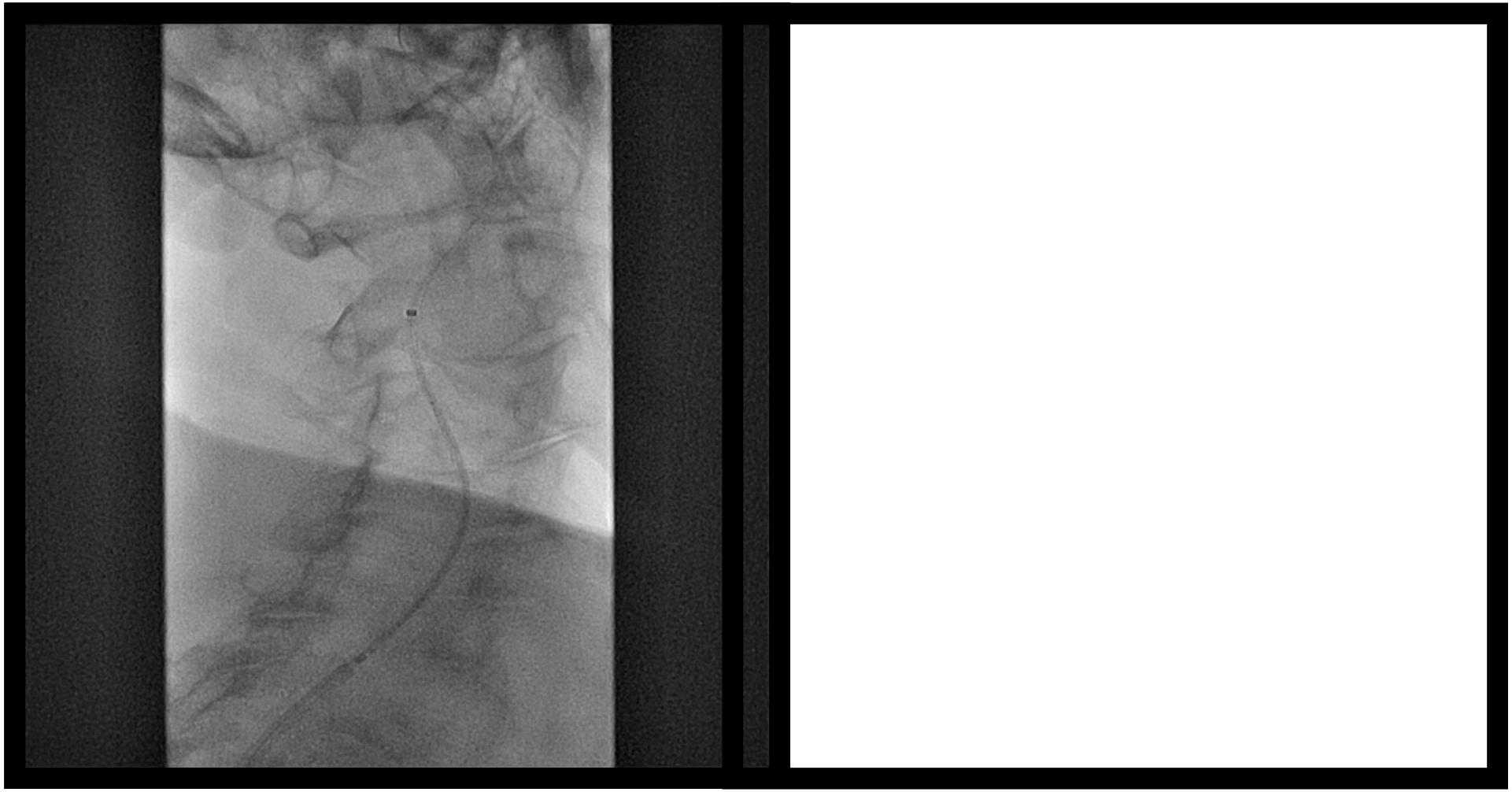
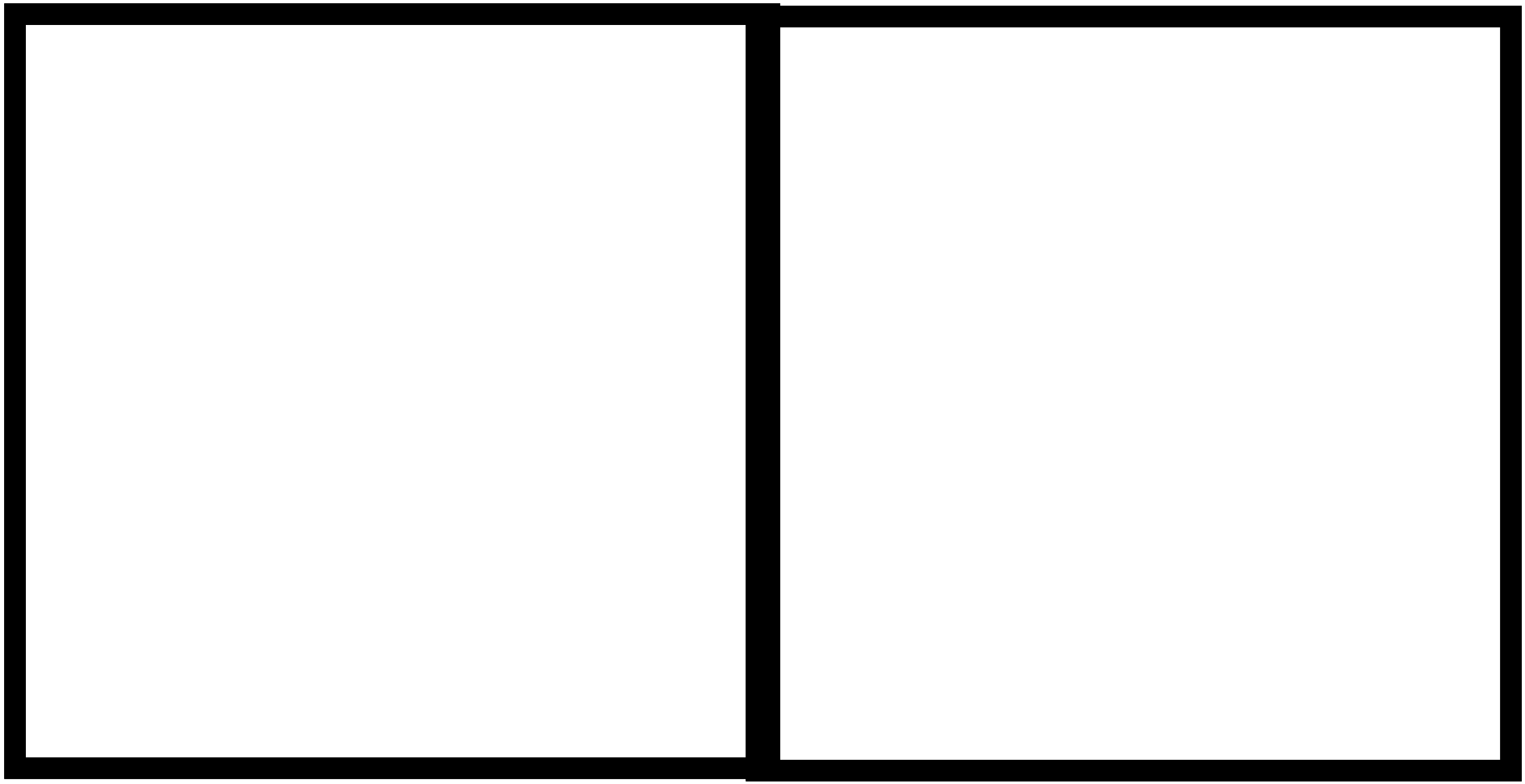
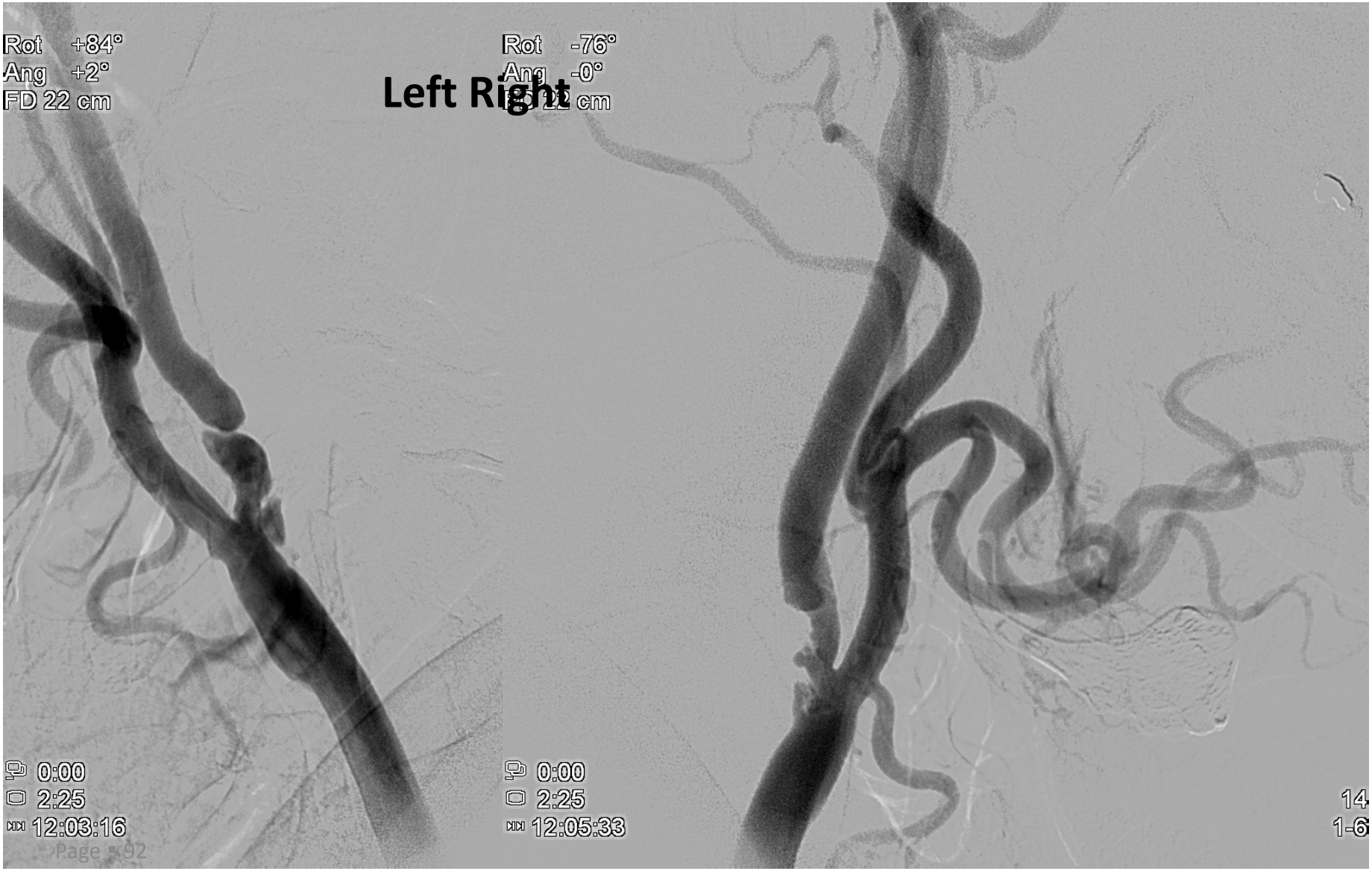


Retrieval of buddy wire & easy Filter

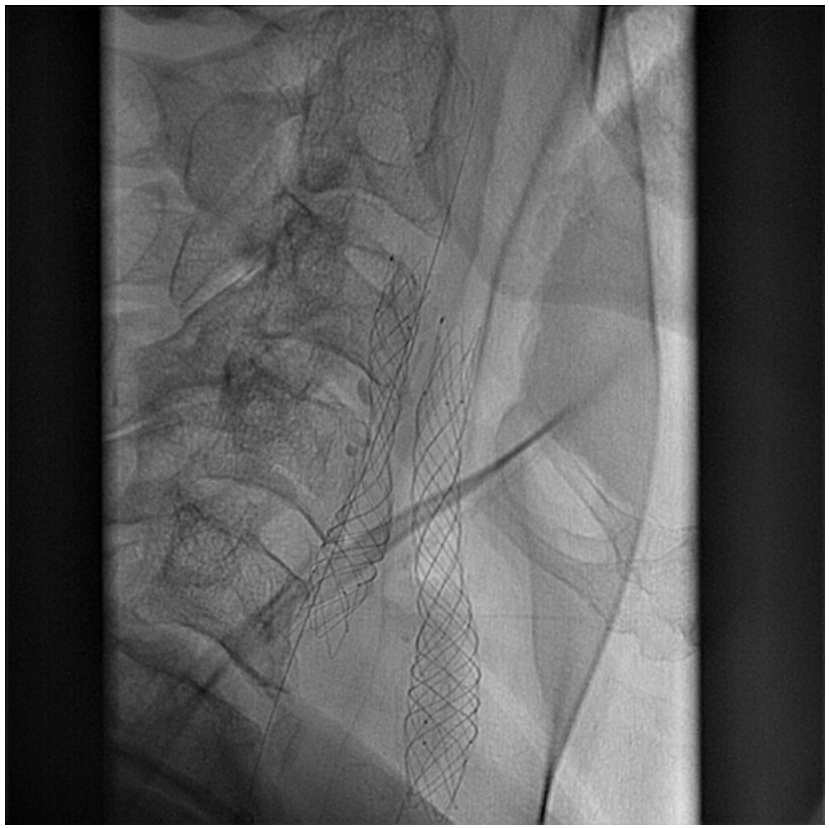


62y Male , bilateral severe carotid stenoses &Throat cancer with

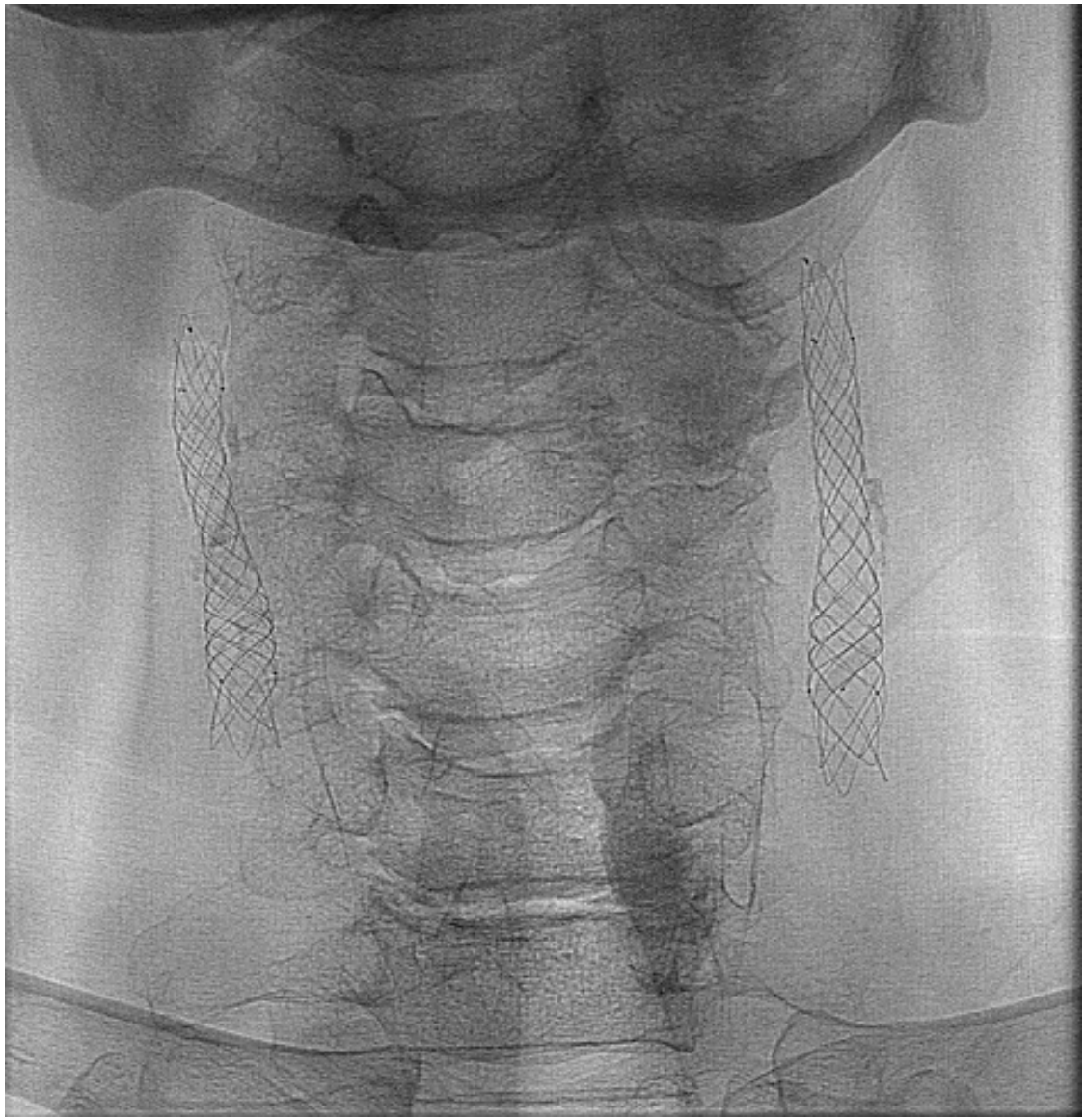


Step 1 : LICA Roadsaver Stent under protection covering an ulcerated lesion

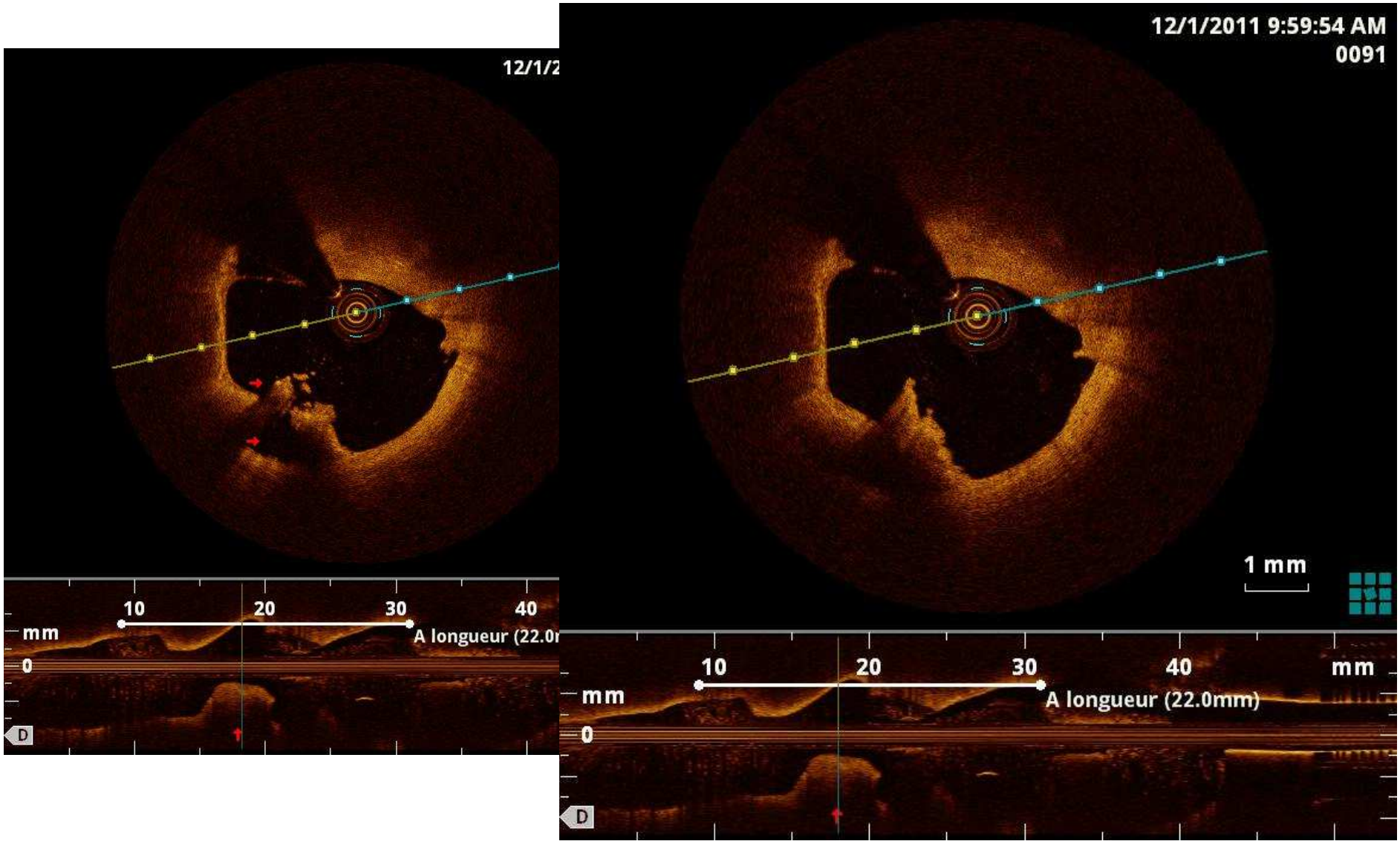
Step 2 :RICA Roadsaver Stent under protection covering an ulcerated lesion

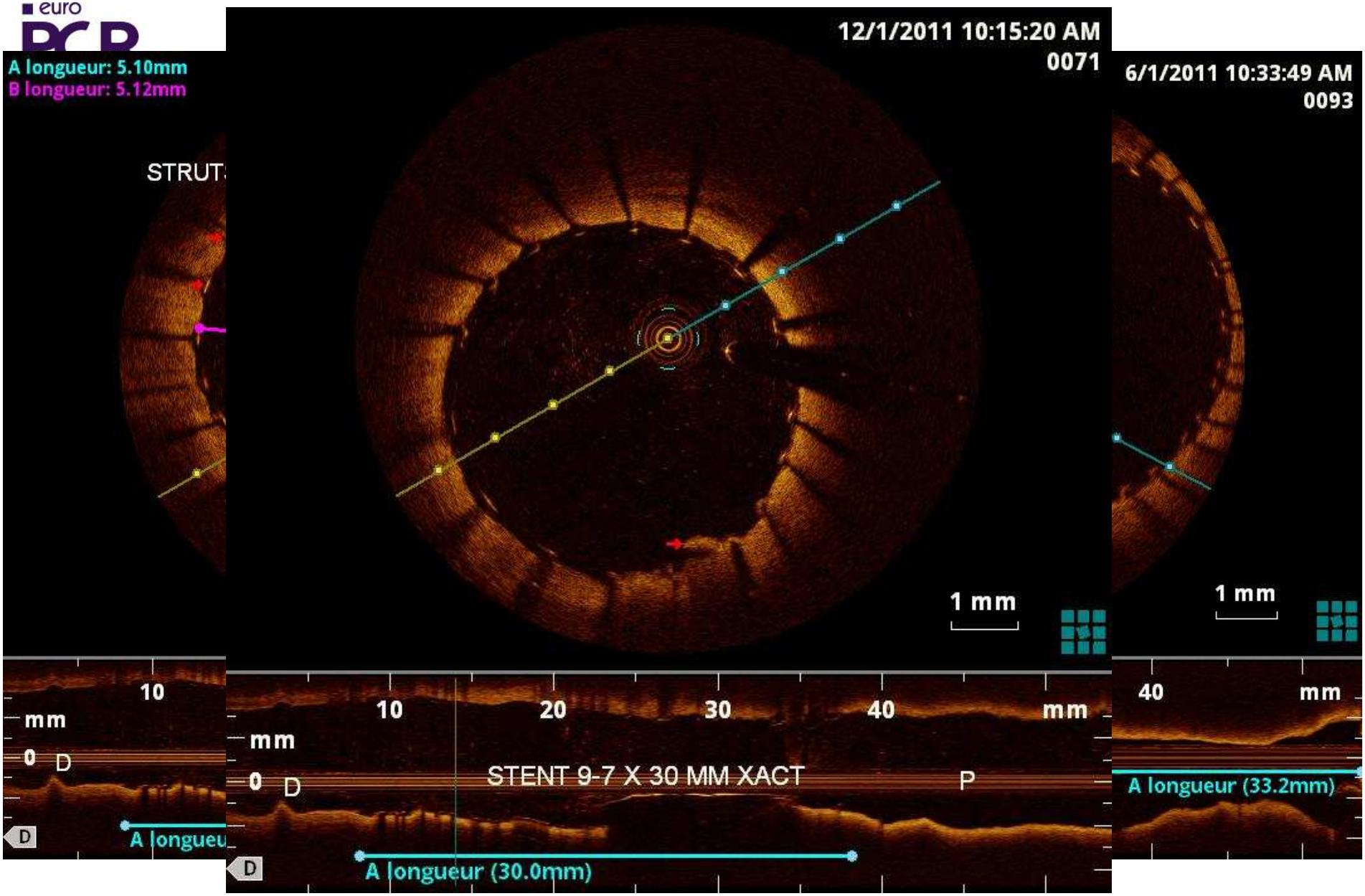


Bilateral carotid stenting with double layer micro-mesh stents



OCT of Carotid Lesions




A longueur: 5.10mm
B longueur: 5.12mm
STRUT
12/1/2011 10:15:20 AM
0071
1 mm
6/1/2011 10:33:49 AM
0093
1 mm
10
mm
0
D
A longueu
10
20
30
40
mm
mm
0
D
STENT 9-7 X 30 MM XACT
P
D
A longueur (30.0mm)
40
mm
A longueur (33.2mm)

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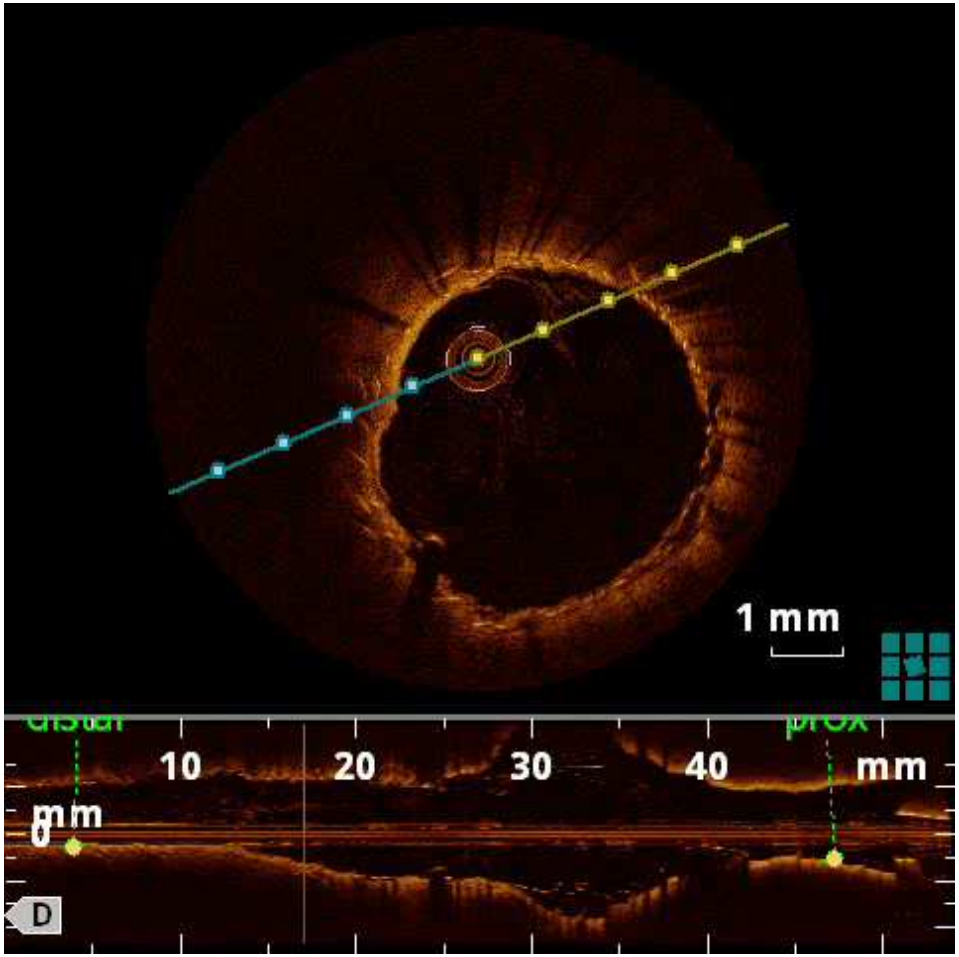
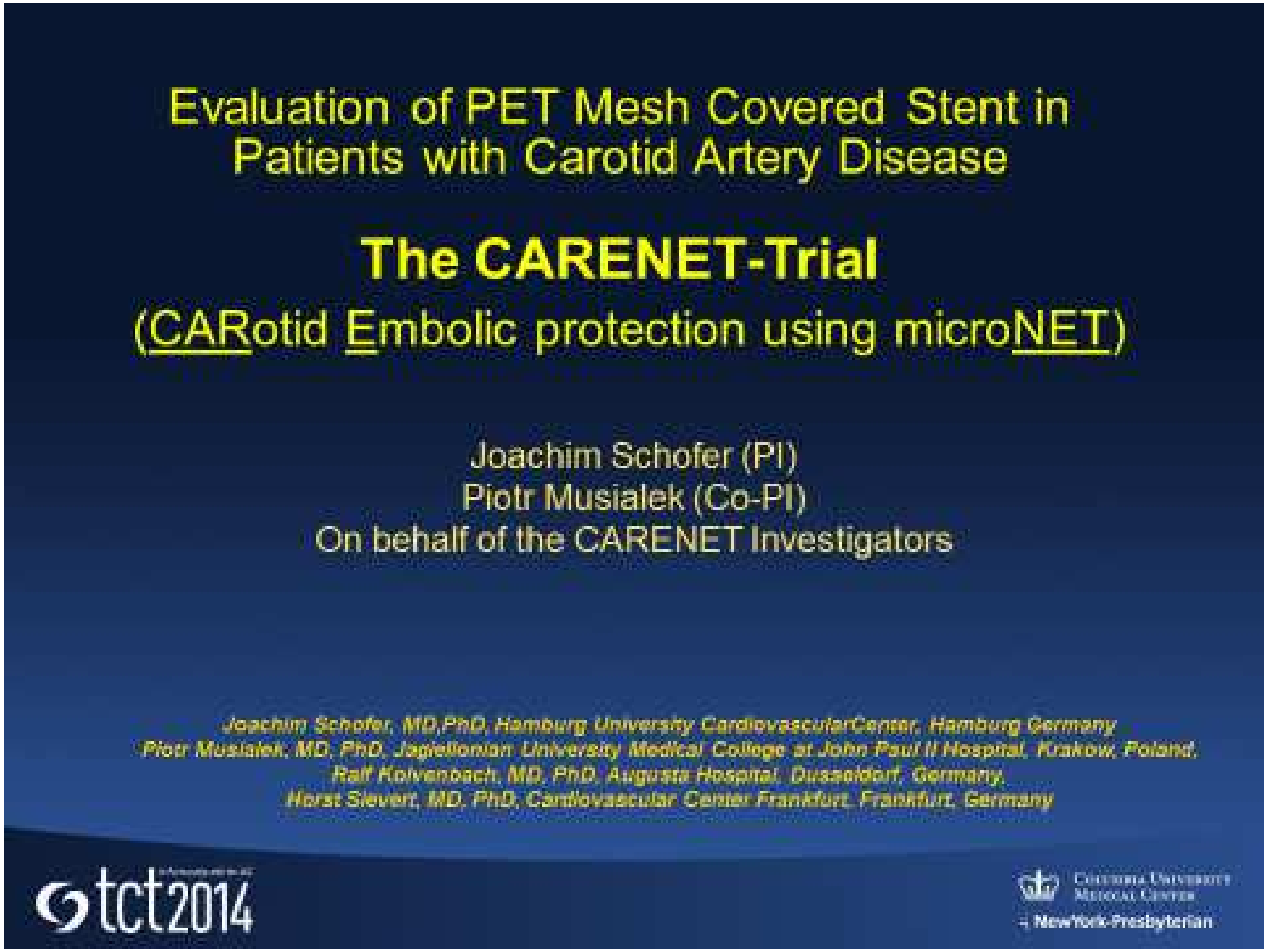


CGUARD

CARENET I – All Comer CAS Trial



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

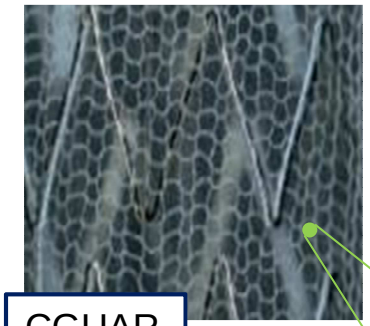
	Post Procedure	Discharge	30 days
Device success	100%	NA	NA
MACE	0%	0%	0%
Death	0%	0%	0%
MI	0%	0%	0%
Stroke	0%	0%	0%

	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

Prof. Dr. Joachim Schofer, TCT

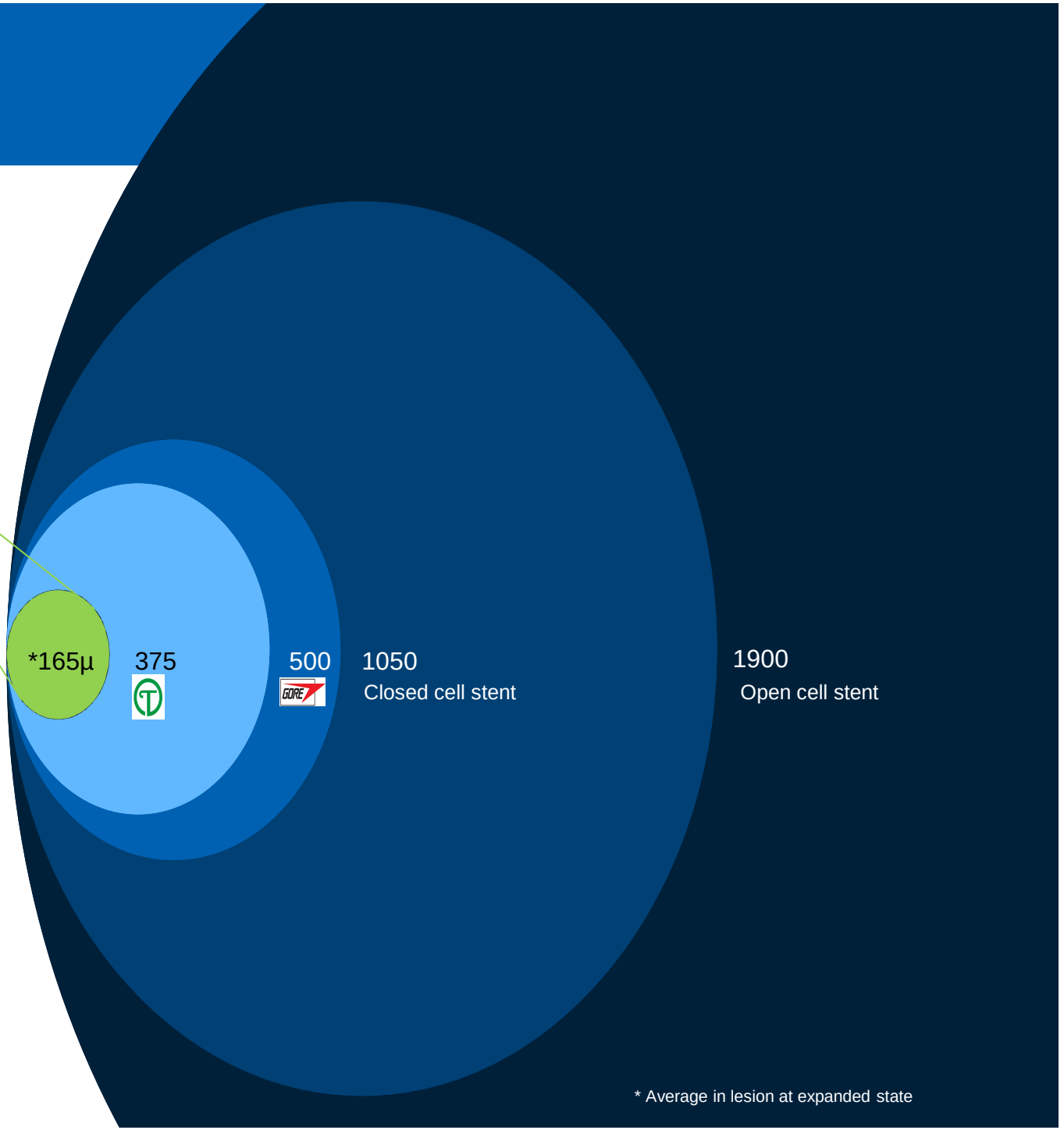
Ideal Pore Size



CGUARD

TERUMO

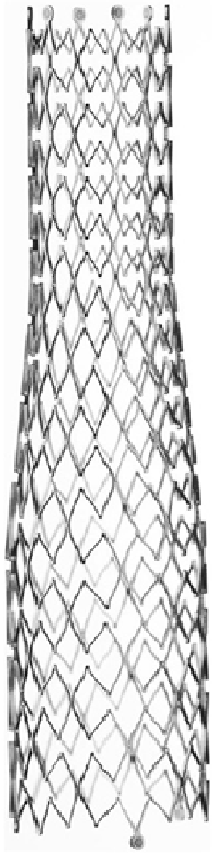
GORE

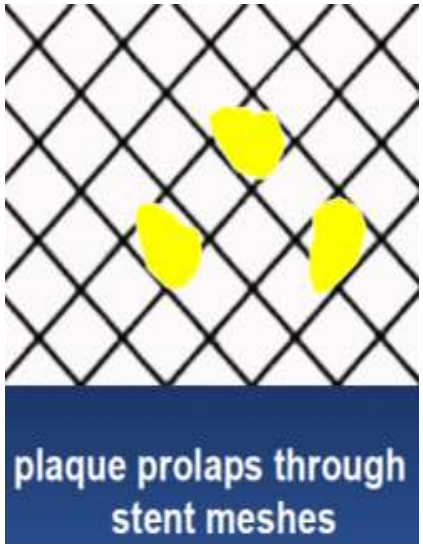


* Average in lesion at expanded state

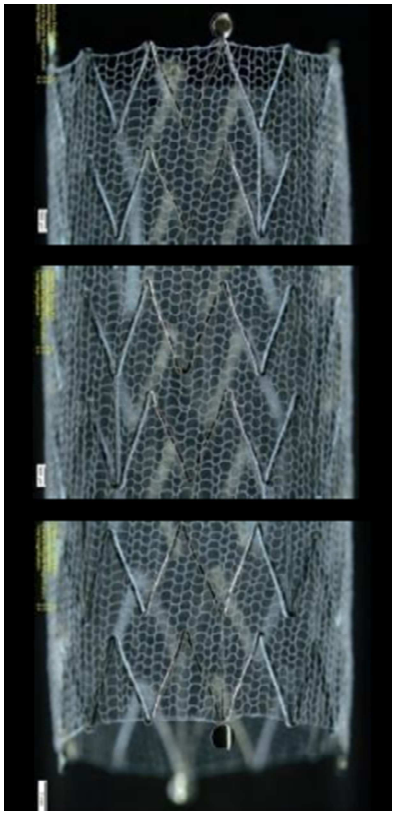
Conventional Stent v CGuard

Conventional Carotid Stent

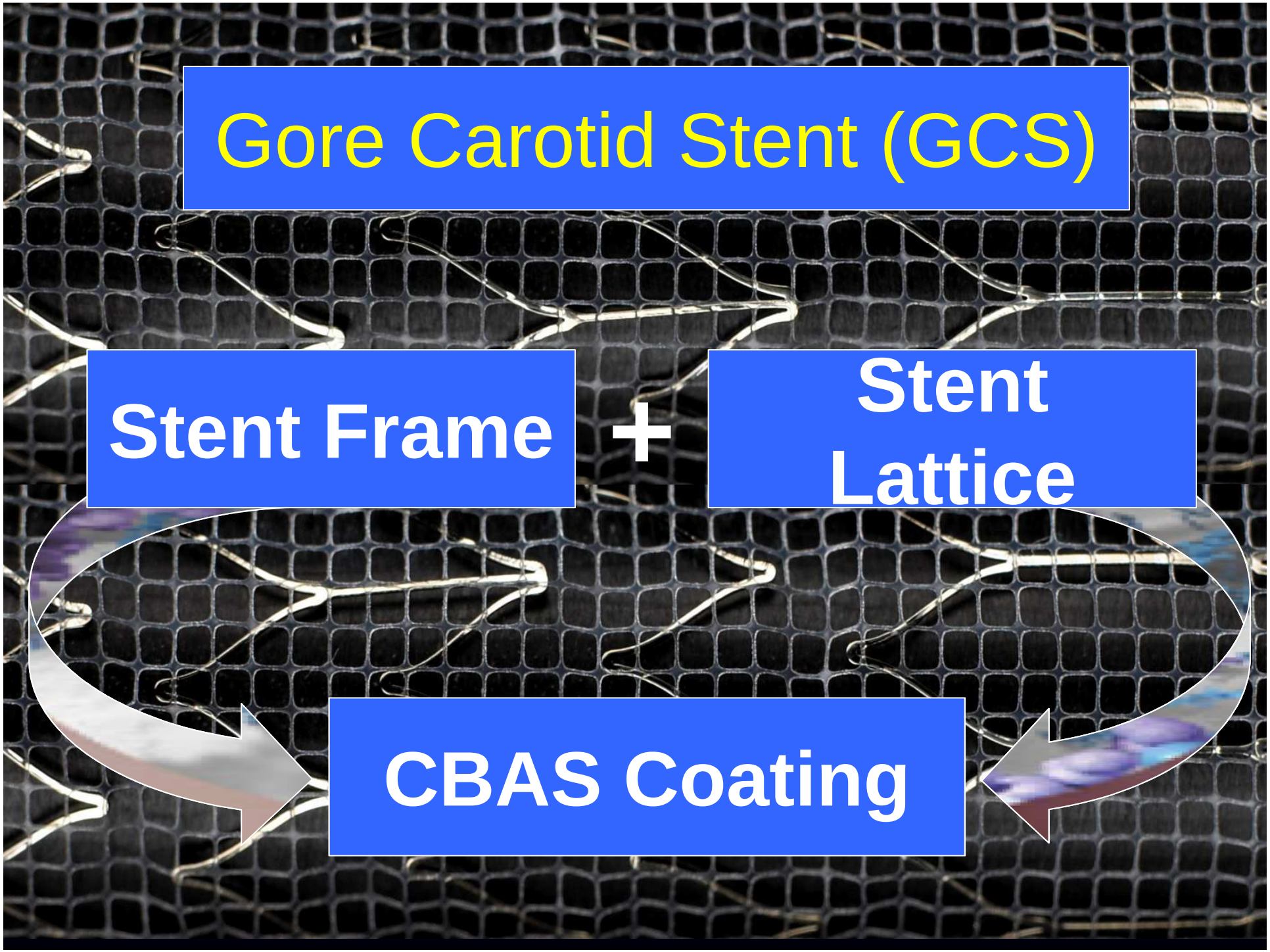




CGUARD™
Carotid Embolic Prevention System



GORE


Gore Carotid Stent (GCS)
Stent Frame
+
Stent Lattice
CBAS Coating

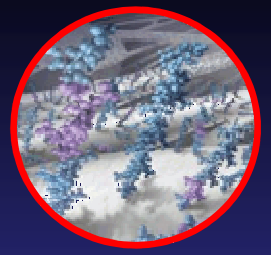
Stent Frame

- 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

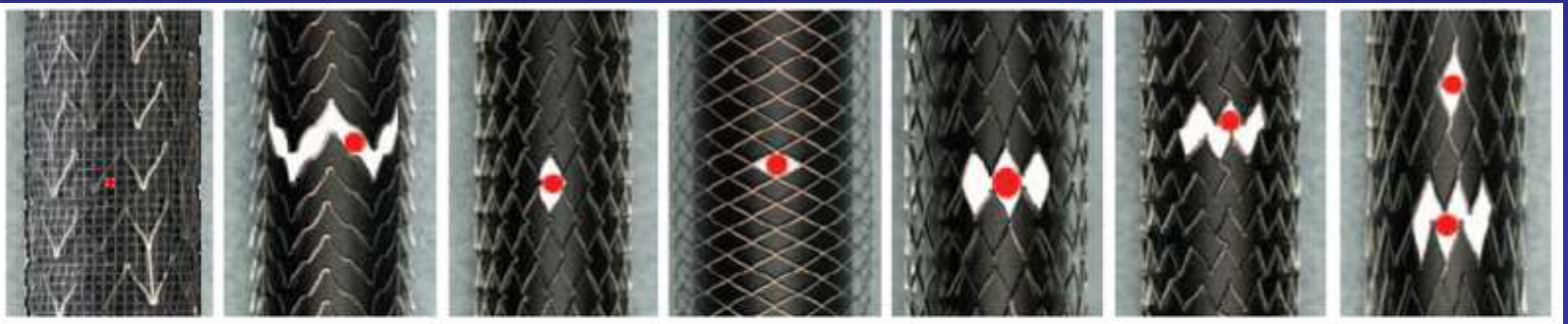
- High strength expanded polytetrafluoroethylene
- High degree of plaque scaffolding that reduce plaque prolapse.
- Reduce amount of emboli released during and after stent deployment
- Stabilize the stent frame by resisting elongation as well as the “fish-scaling”

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

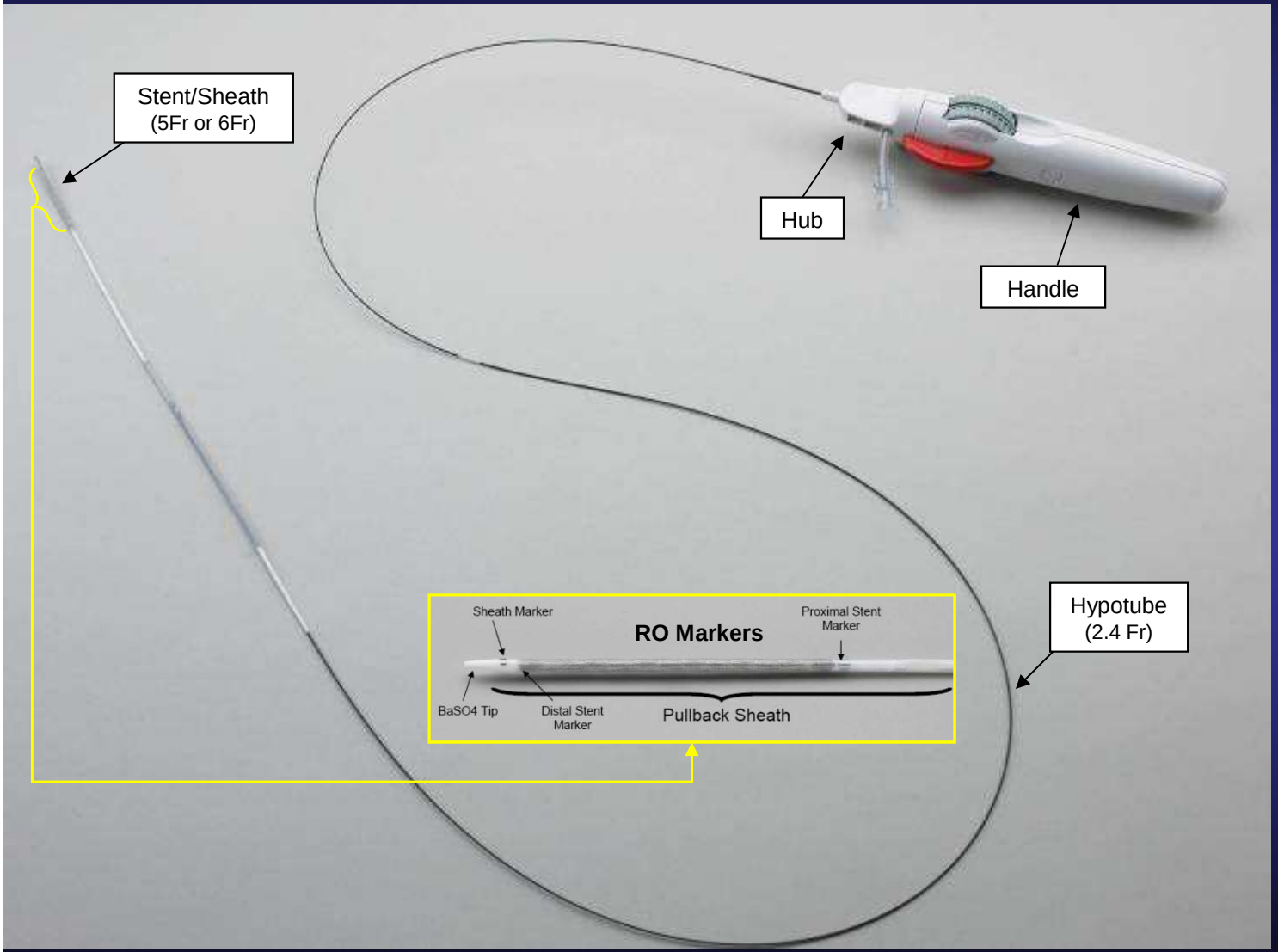
POTENTIAL RISK FOR PLAQUE PROTRUSION AND EMBOLIZATION



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),

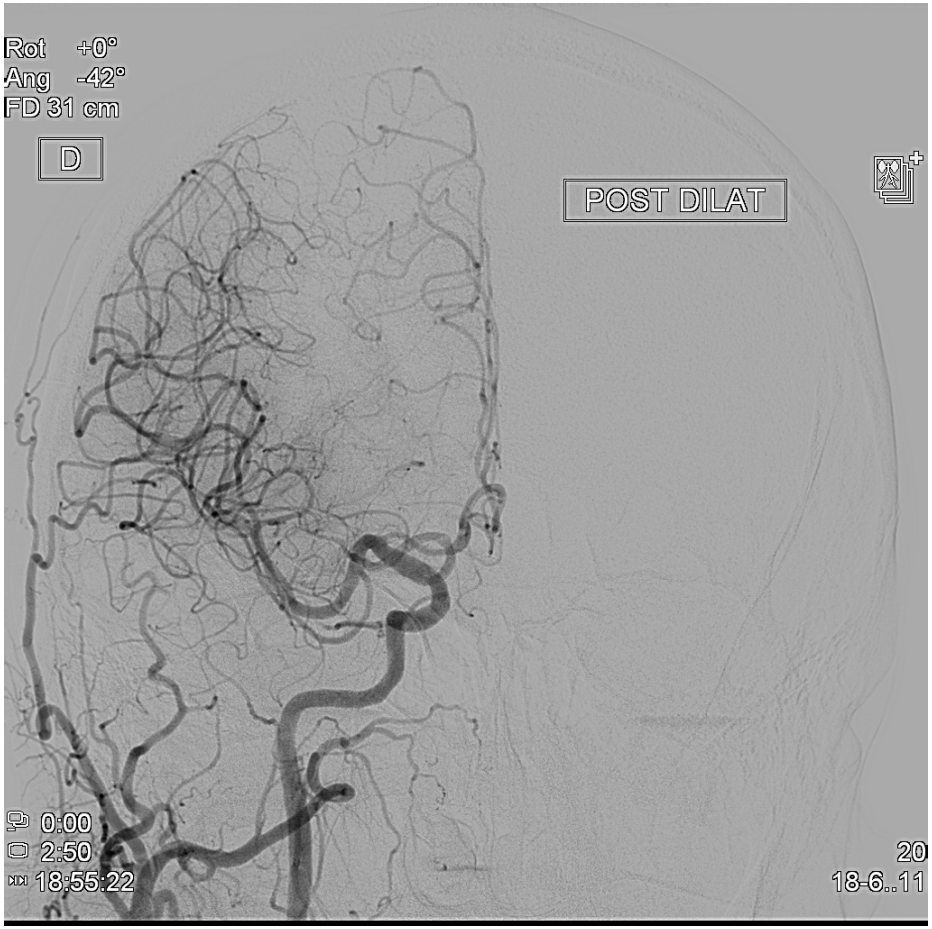
  OR

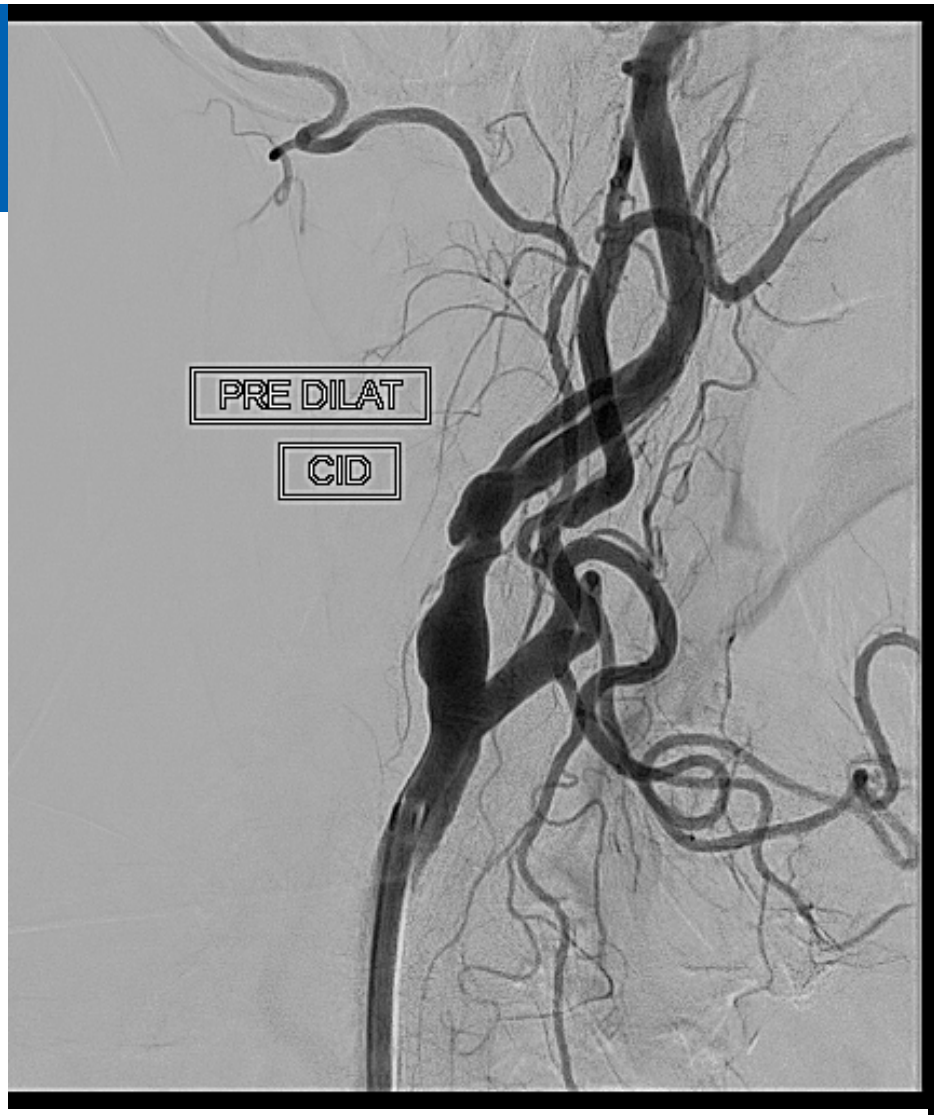
  ≥ 80% (by angiography) stenosis if asymptomatic

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

Severe Symptomatic RICA stenosis with multiple ulcerations

After ROADSAVER Stent 10x30mm placed under filter protection


Rot +0°
Ang -42°
FD 31 cm
D
POST DILAT
0:00
2:50
18:55:22
20
18-6..11



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	+++	-