Expanded Use Of Preloaded Catheters And Wires:

Advantages And Limitations

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Disclosures

- Honoraria / Consultant / Research
  - Cook Medical Inc
  - W. L. Gore & Assoc

- Some devices presented here are investigational and have not been approved by the FDA

- Acknowledgement
  - Gustavo Oderich, MD
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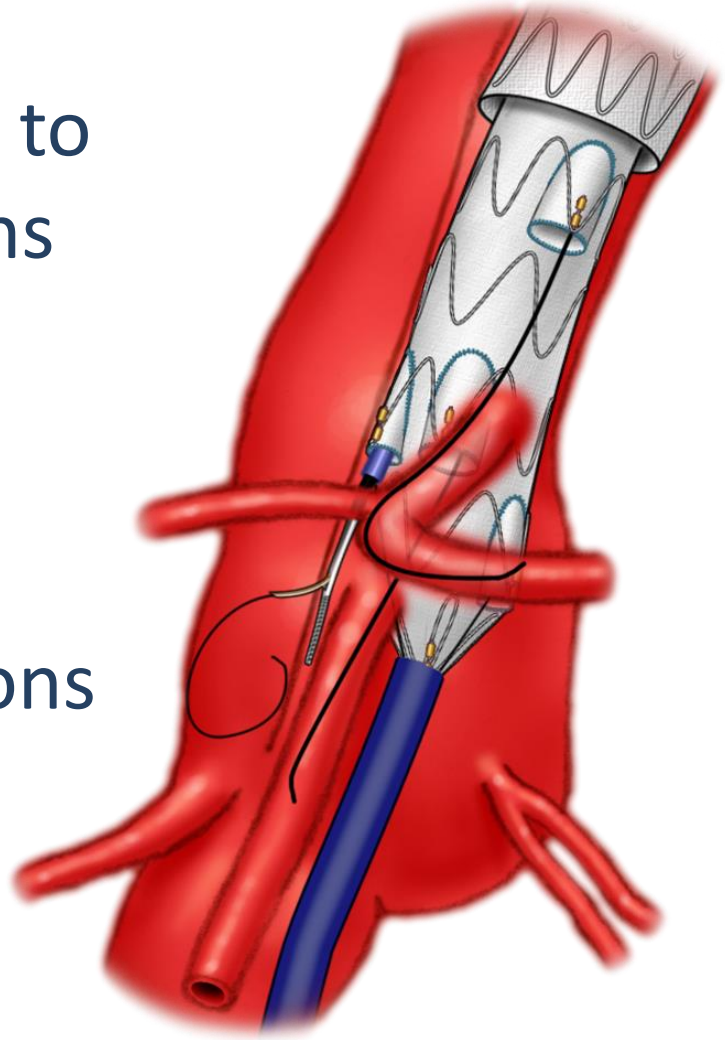
    Univ of Texas Health Sciences Ctr at Houston, Houston, TX, USA

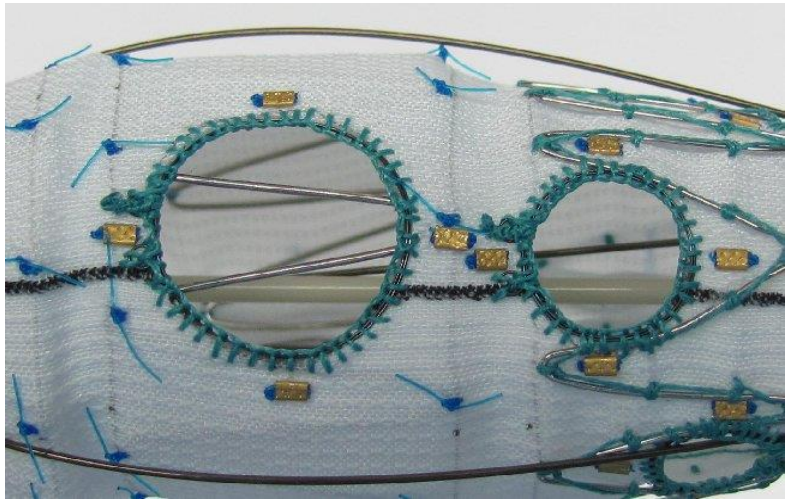
Background

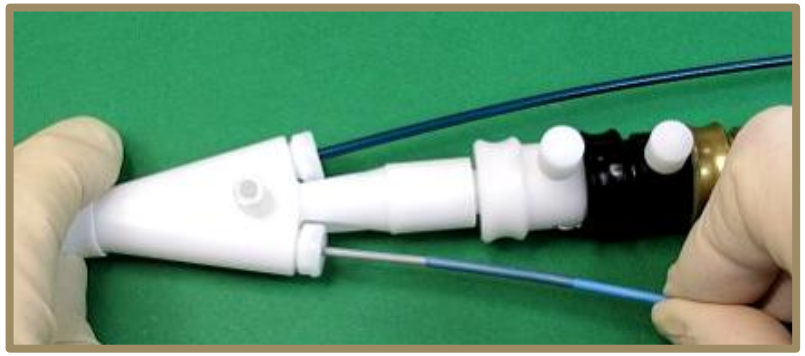
- Fenestrated-branched endovascular aortic repair (F-BEVAR) has been increasingly used to treat complex aortic aneurysms & dissections
- Technical challenges include true lumen compression, angulated and tortuous aorta and narrow aortic lumen
- Preloaded catheters and wires of fenestrations and directional branches facilitate access to target arteries during F-BEVAR

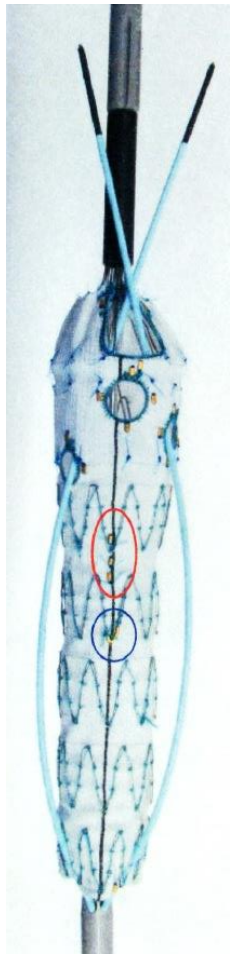


Preloaded Systems

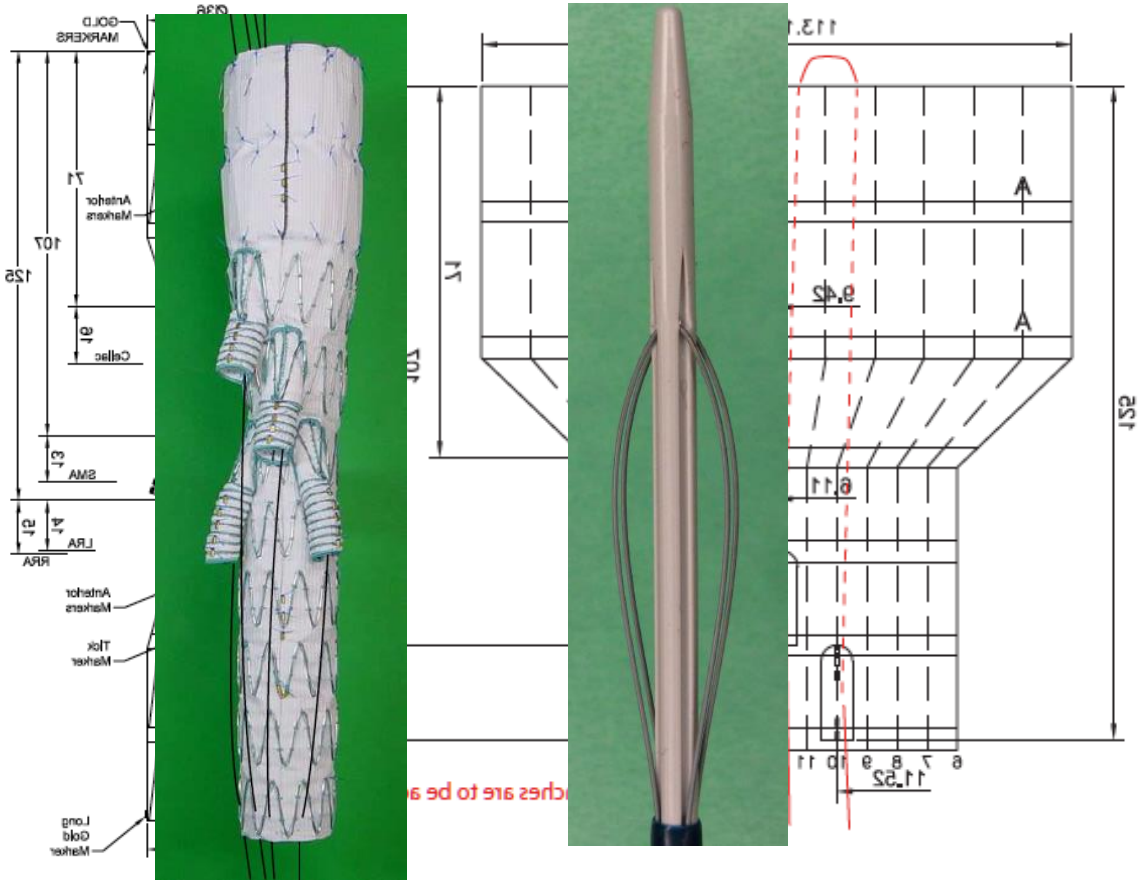
Femoral Access





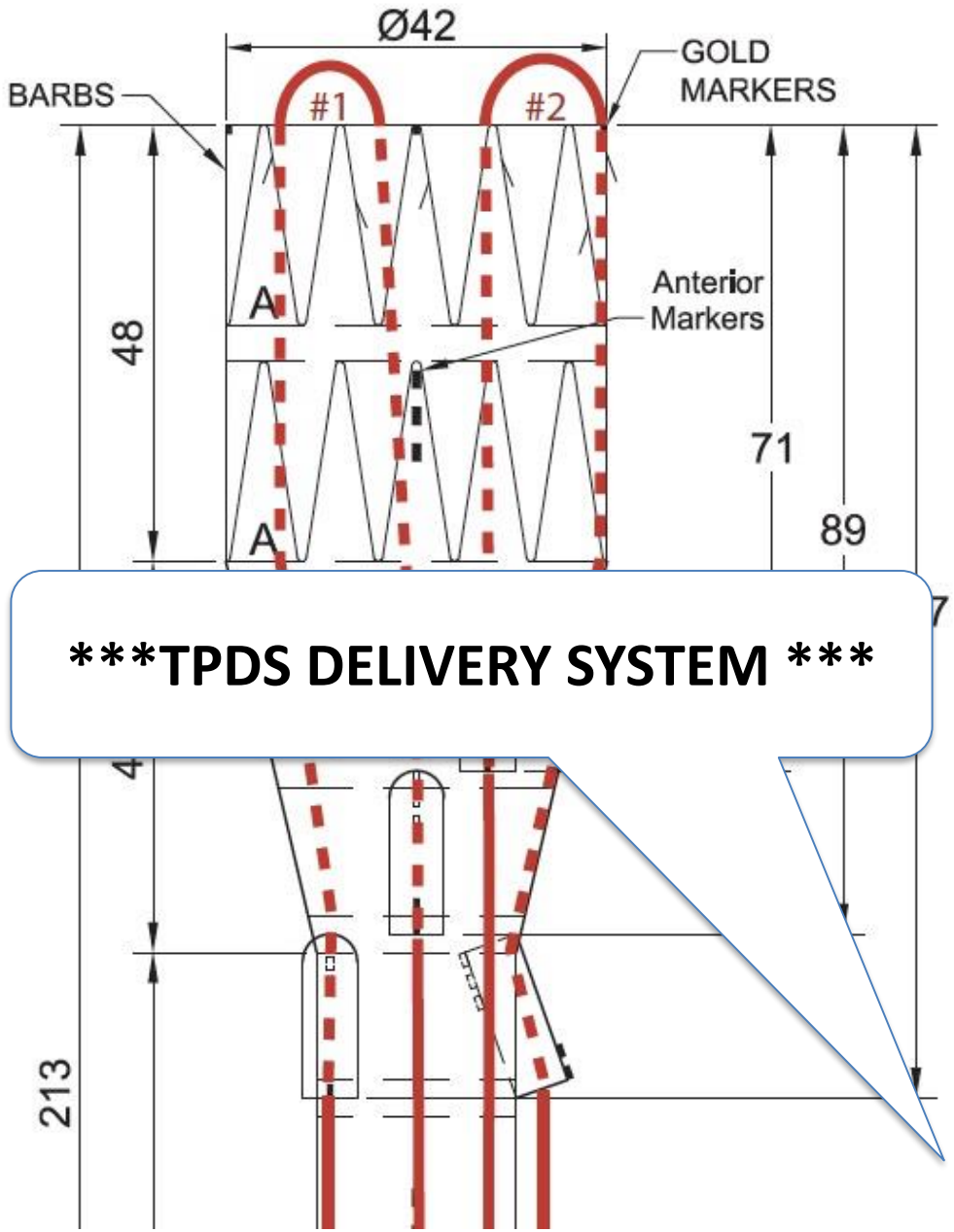


Brachial Access



CMDs with LEM

(length extended module)



***TPDS DELIVERY SYSTEM ***

CATHETER PATH

INTERNAL/EXTERNAL SIDEBRANCH #1
Preloaded Guidewire
DIAMETER: 6mm
LENGTH: 21mm
DIST FROM PROX EDGE: 71mm
CLOCK: 1:00
Access From Above Via Guidewire #2

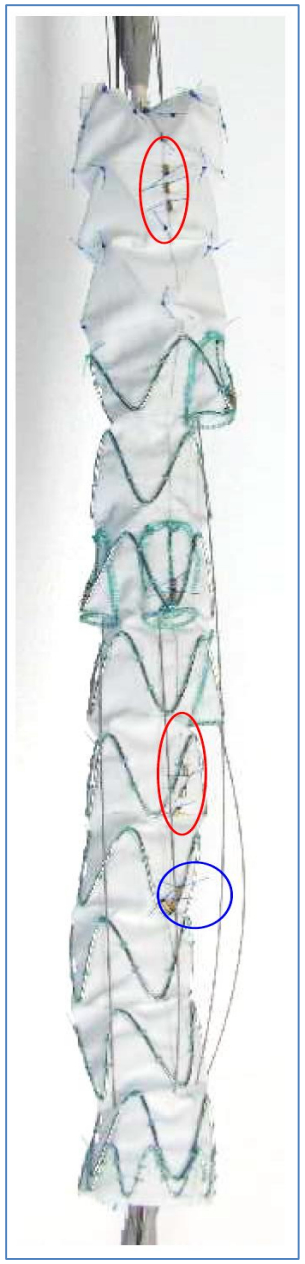
INTERNAL/EXTERNAL SIDEBRANCH #2
Preloaded Guidewire
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 89mm
CLOCK: 12:00
Access From Above Via Guidewire#1

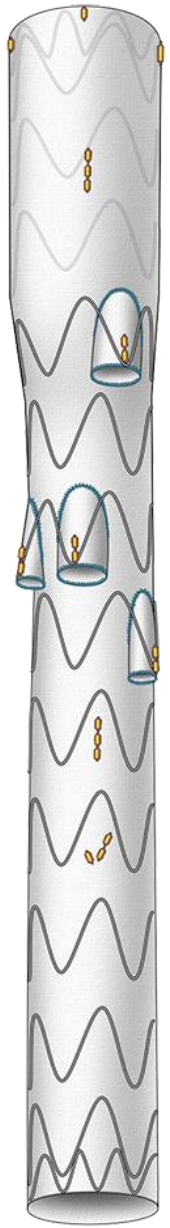
INTERNAL/EXTERNAL SIDEBRANCH #3
Preloaded Guidewire
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 107mm
CLOCK: 10:00
Access From Above Via Guidewire#1

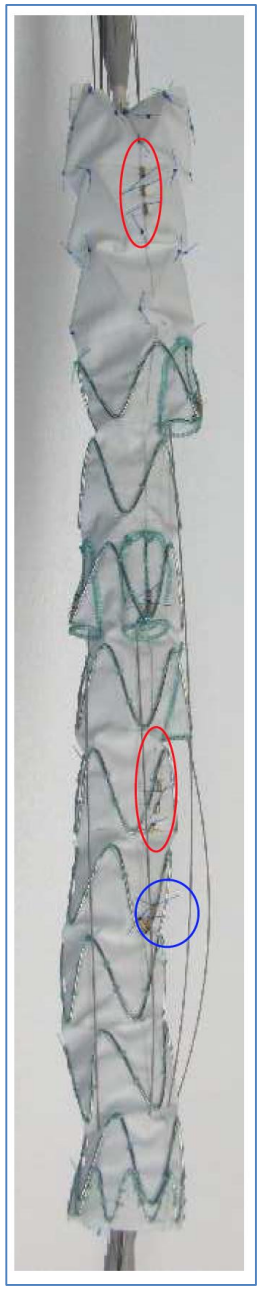
INTERNAL/EXTERNAL SIDEBRANCH #4
Preloaded Guidewire
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 107mm
CLOCK: 3:00
Access From Above Via Guidewire #2

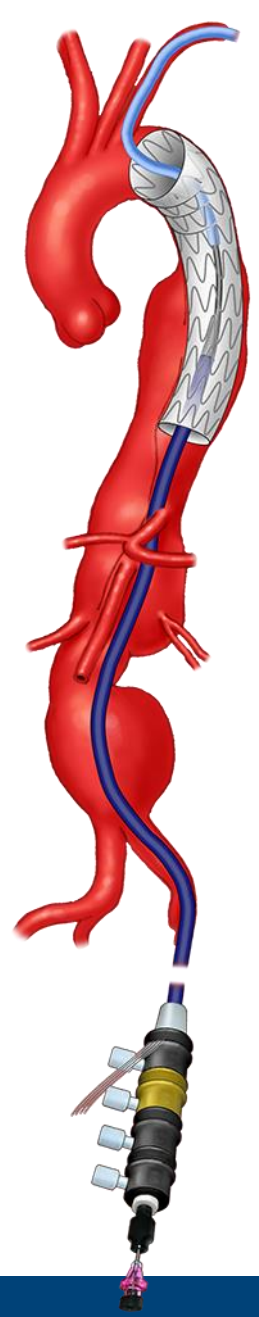
- SINGLE DIAMETER REDUCING TIES
- LOW PROFILE FABRIC

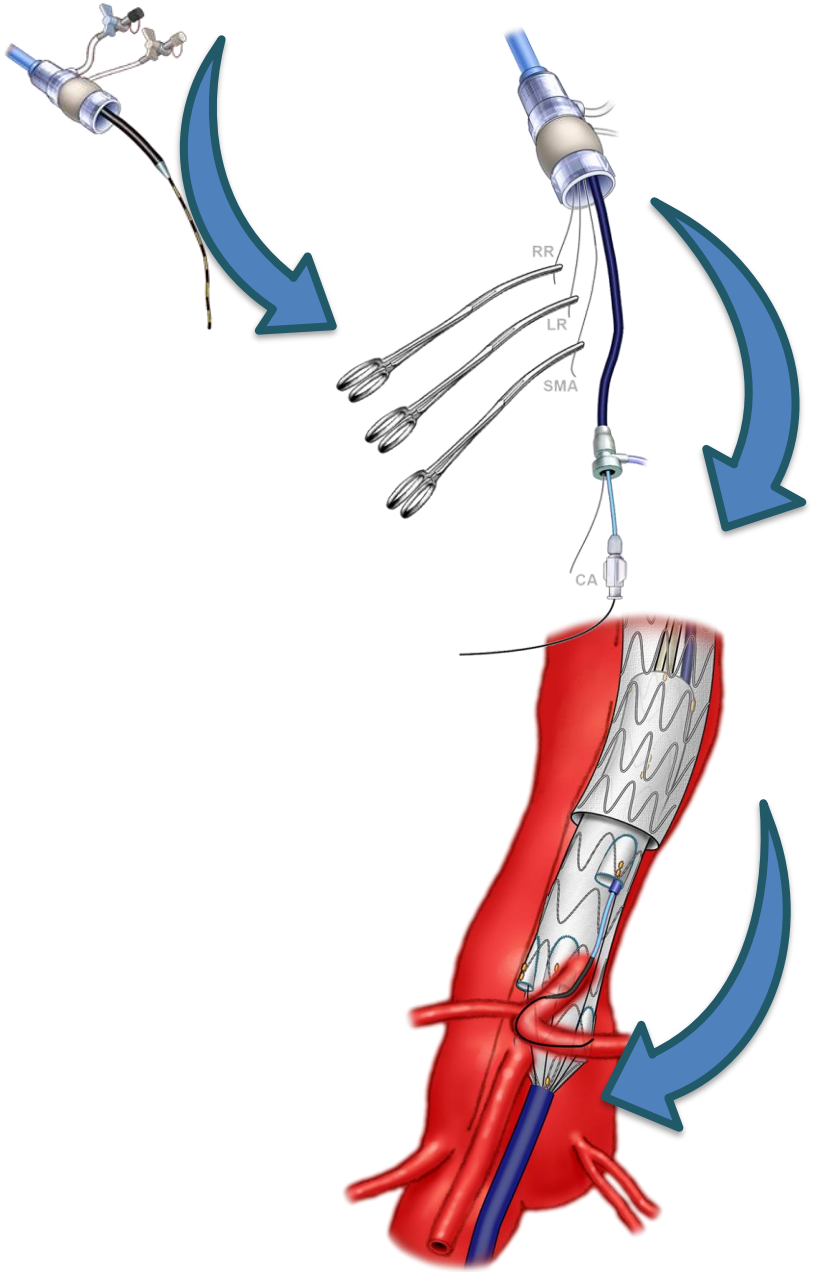
TPDS DELIVERY SYSTEM



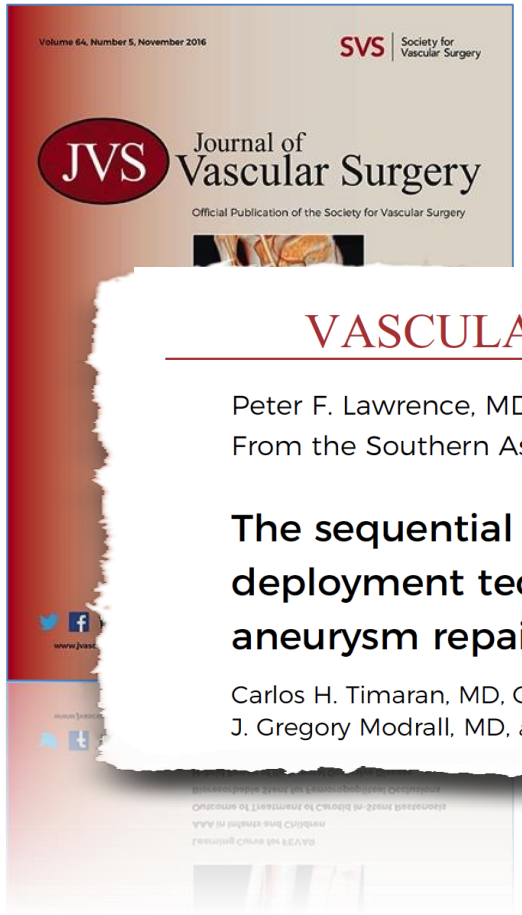







RR
LR
SMA
CA

SCAPE Technique

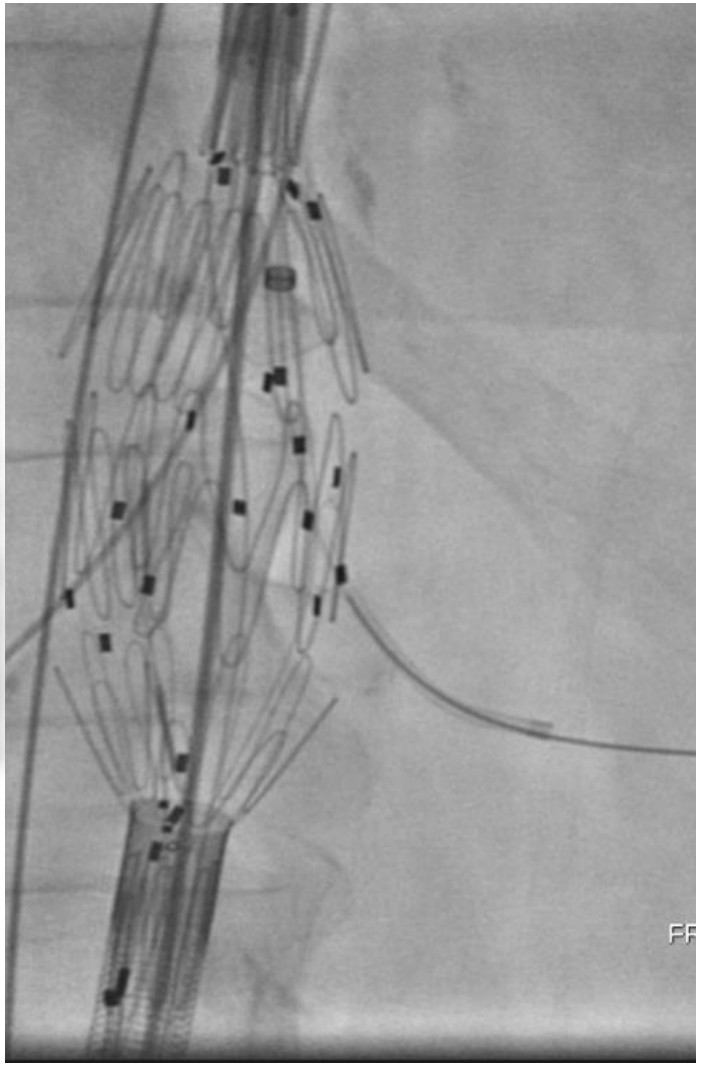


VASCULAR AND ENDOVASCULAR TECHNIQUES

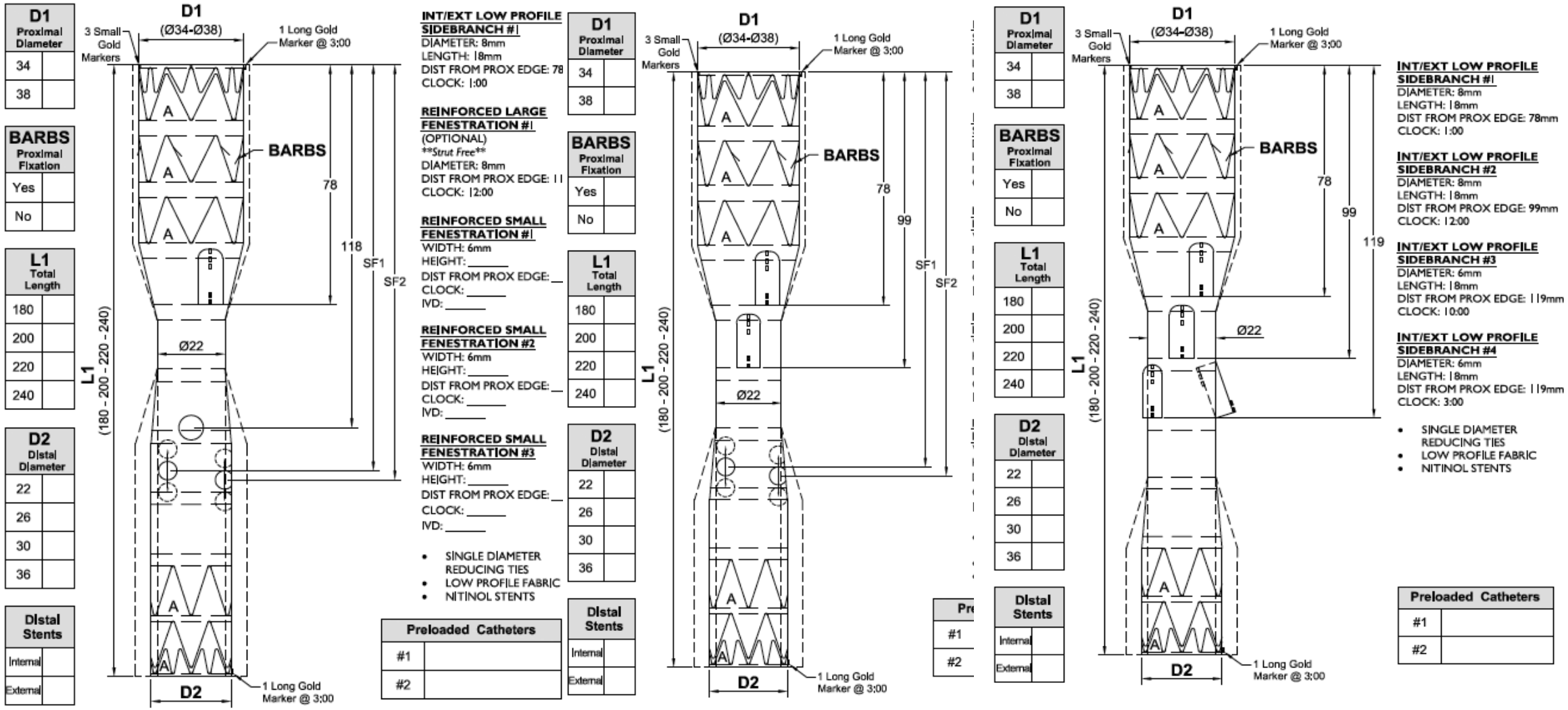
Peter F. Lawrence, MD, **SECTION EDITOR**
From the Southern Association for Vascular Surgery

The sequential catheterization amid progressive endograft deployment technique for fenestrated endovascular aortic aneurysm repair

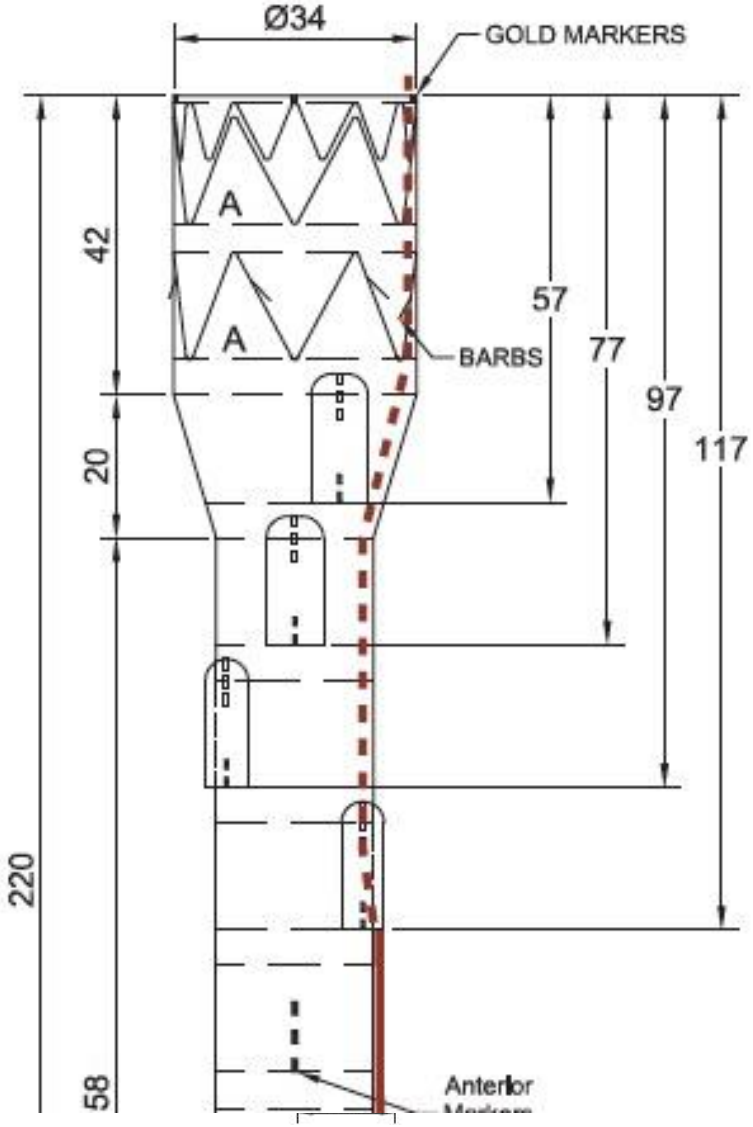
Carlos H. Timaran, MD, Gregory A. Stanley, MD, M. Shadman Baig, MD, David E. Timaran, MD, J. Gregory Modrall, MD, *and* Martyn Knowles, MD, *Dallas, Tex*



Low Profile Devices - *18 Fr*



Preloaded single (“indwelling”) guidewire



CATHETER PATH

INTERNAL/EXTERNAL SIDEBRANCH #1
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 57mm
CLOCK: 1:00

INTERNAL/EXTERNAL SIDEBRANCH #2
DIAMETER: 8mm
LENGTH: 18mm
DIST FROM PROX EDGE: 77mm
CLOCK: 12:00

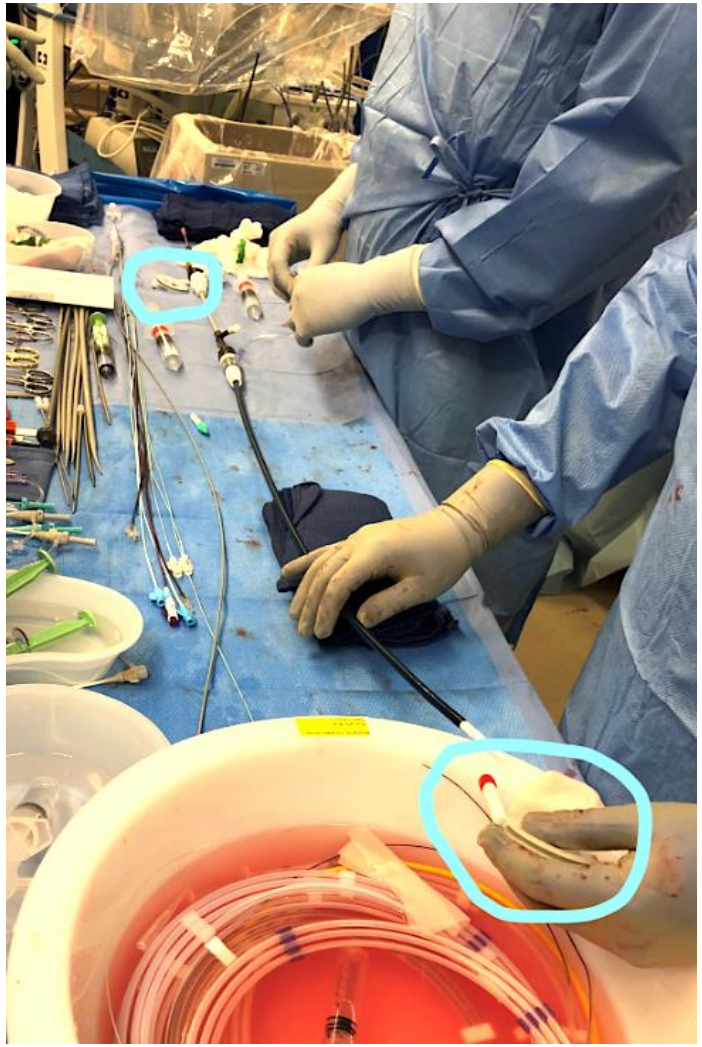
INTERNAL/EXTERNAL SIDEBRANCH #3
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 97mm
CLOCK: 10:00

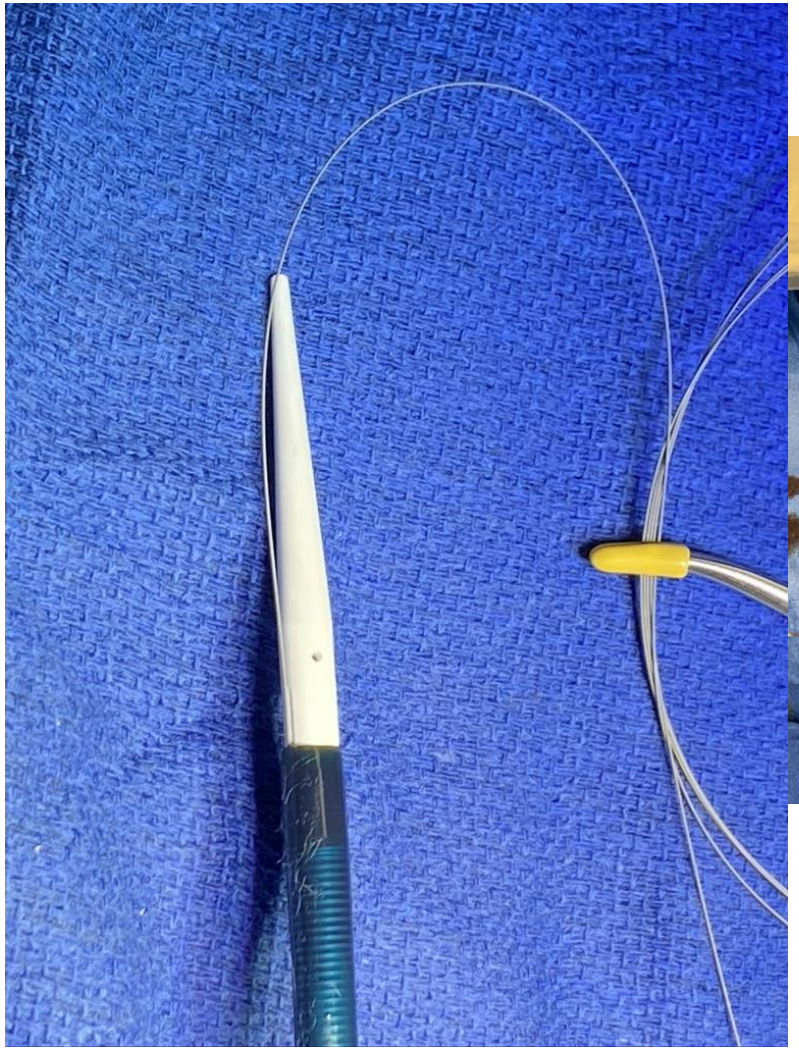
INTERNAL/EXTERNAL SIDEBRANCH #4
Preloaded Guidewire
Access From Above
DIAMETER: 6mm
LENGTH: 18mm
DIST FROM PROX EDGE: 117mm
CLOCK: 2:00

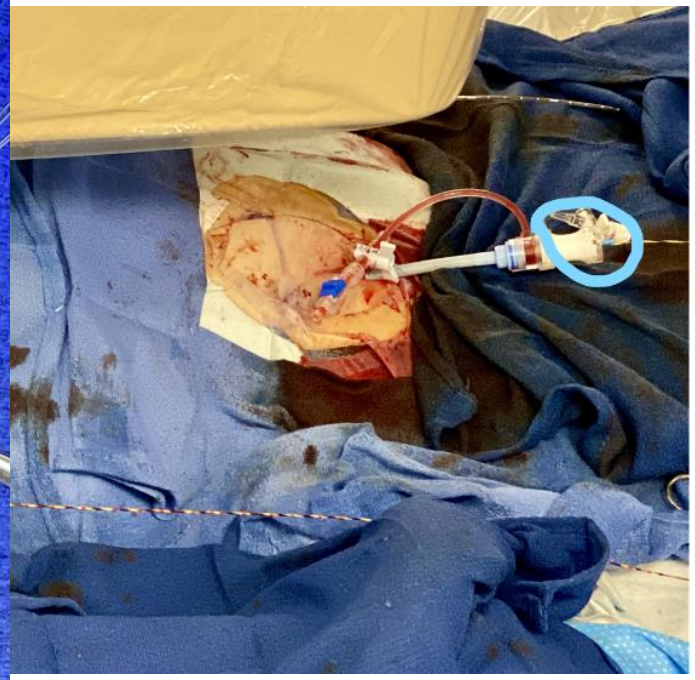
Sheath Size: 18FR FLEXOR		
O.D.: 7.1mm		
Sheath Length: 75cm		
US-ES	Drawn - SC	Date: 6-Apr-20
Not to scale	All Dimensions shown are in mm	

.014 in nitinol wire
8 m long

Preloaded single (“indwelling”) guidewire

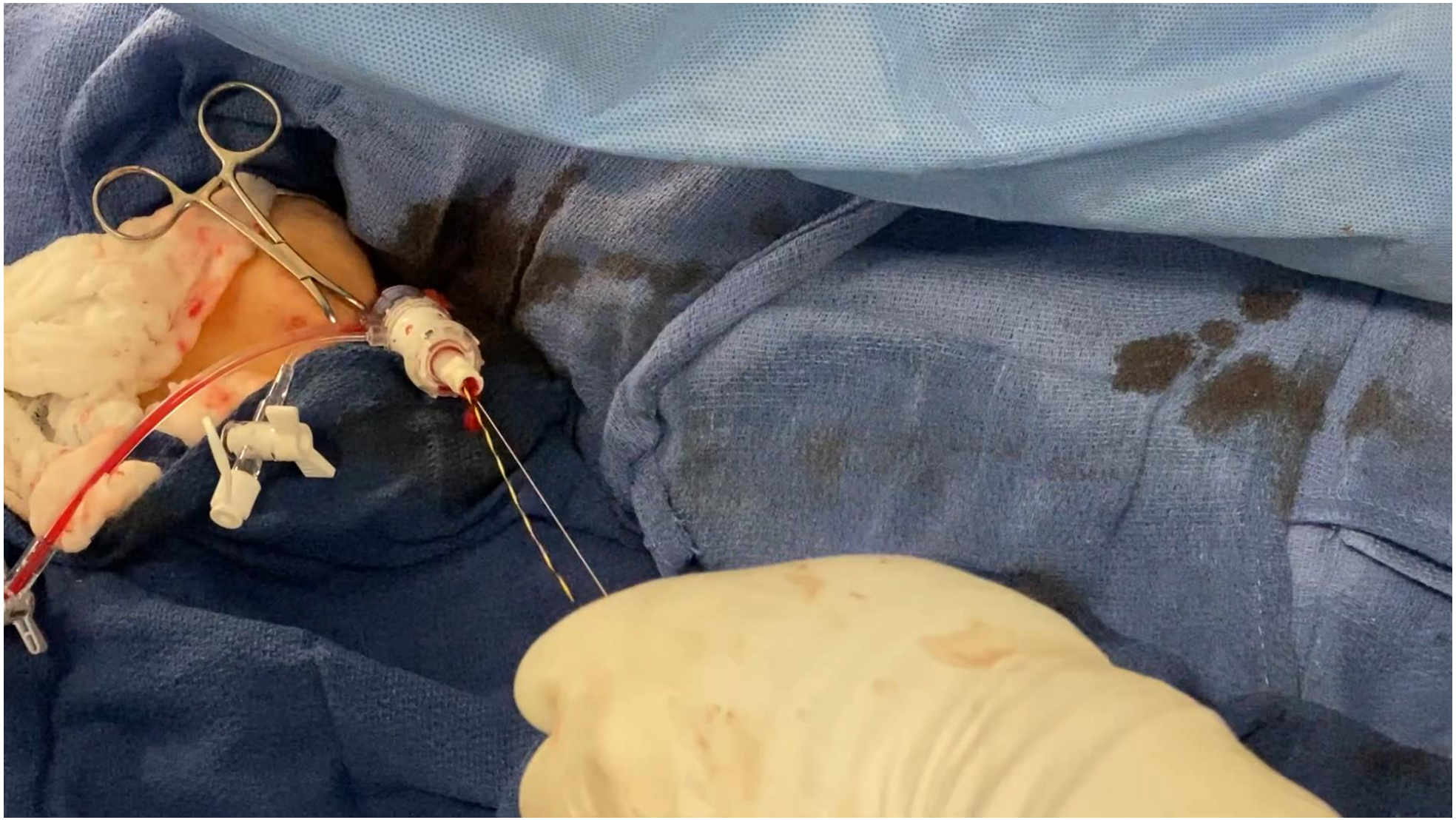






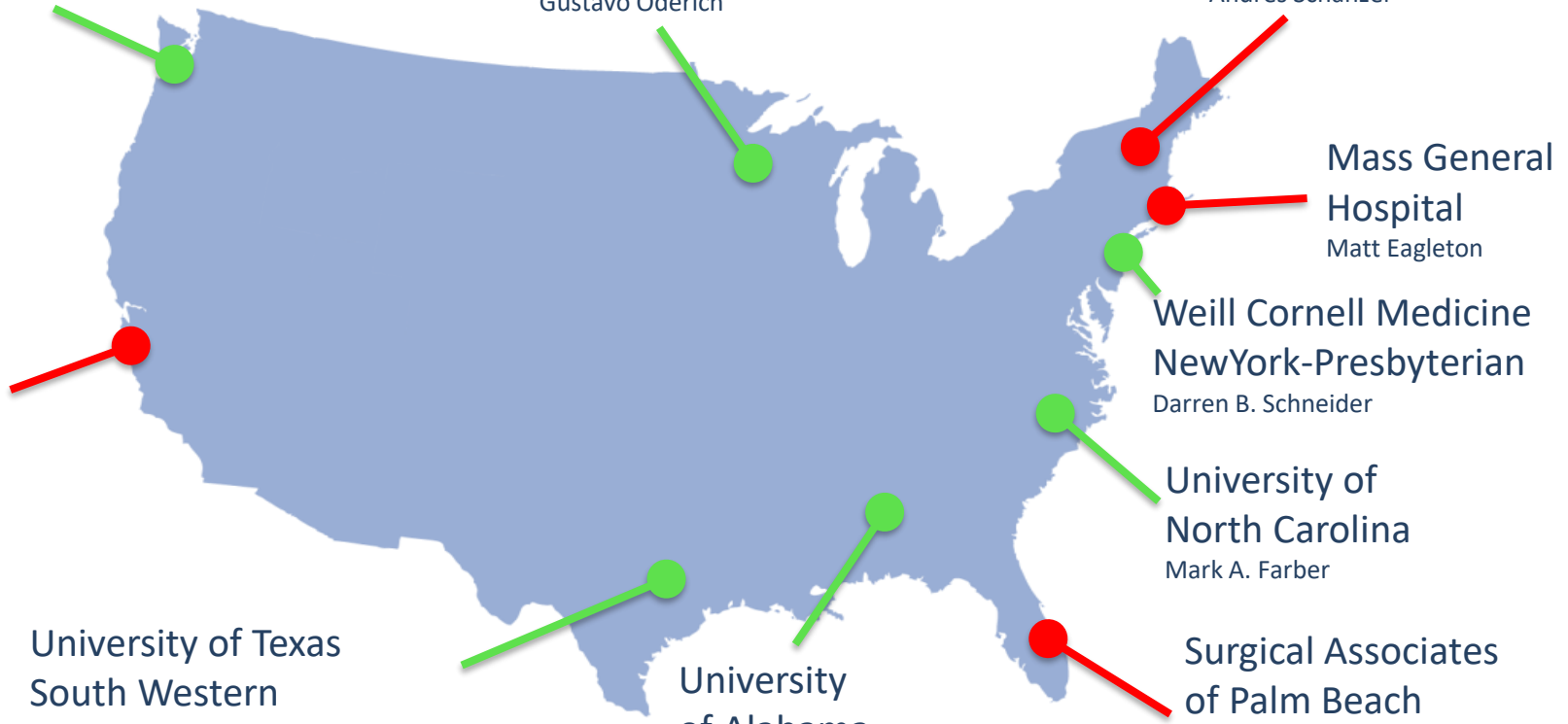
Preloaded single (“indwelling”) guidewire

Preloaded single (“indwelling”) guidewire



Preloaded single (“indwelling”) guidewire

United States Fenestrated Branched Research Consortium



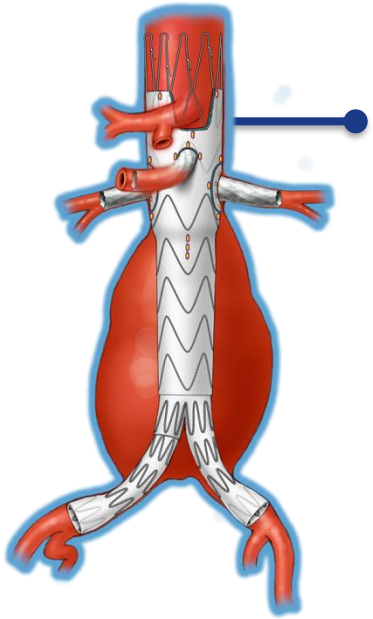
Independent review by CEC/DSMB

External auditing

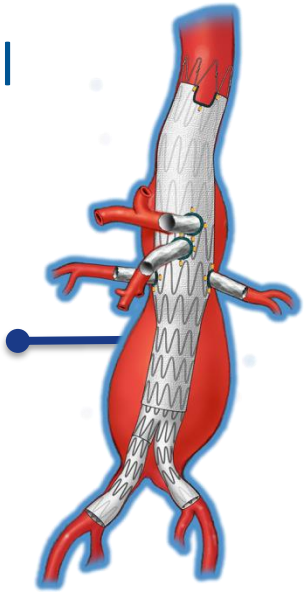
Purpose: To report the outcomes of preloaded vs. standard devices for complex EVAR

564 patients enrolled
(until January 1th, 2018)

All patients had implantation with
> 30-day follow up

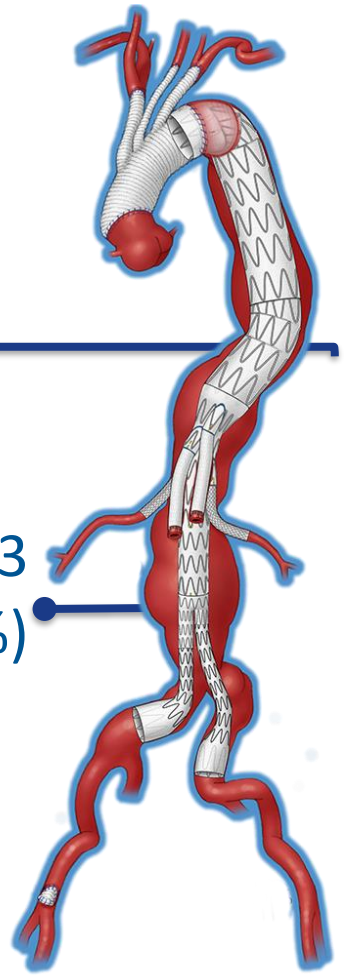


168 suprarenal
(30%)



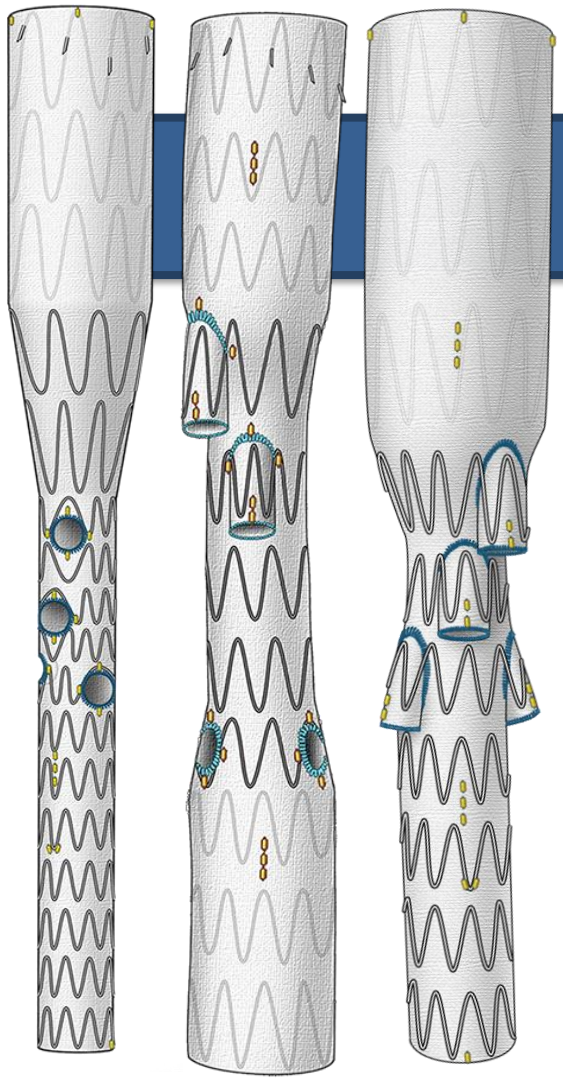
216 Extent 4
TAAA (38%)

180 Extent 1-3
TAAA (32%)



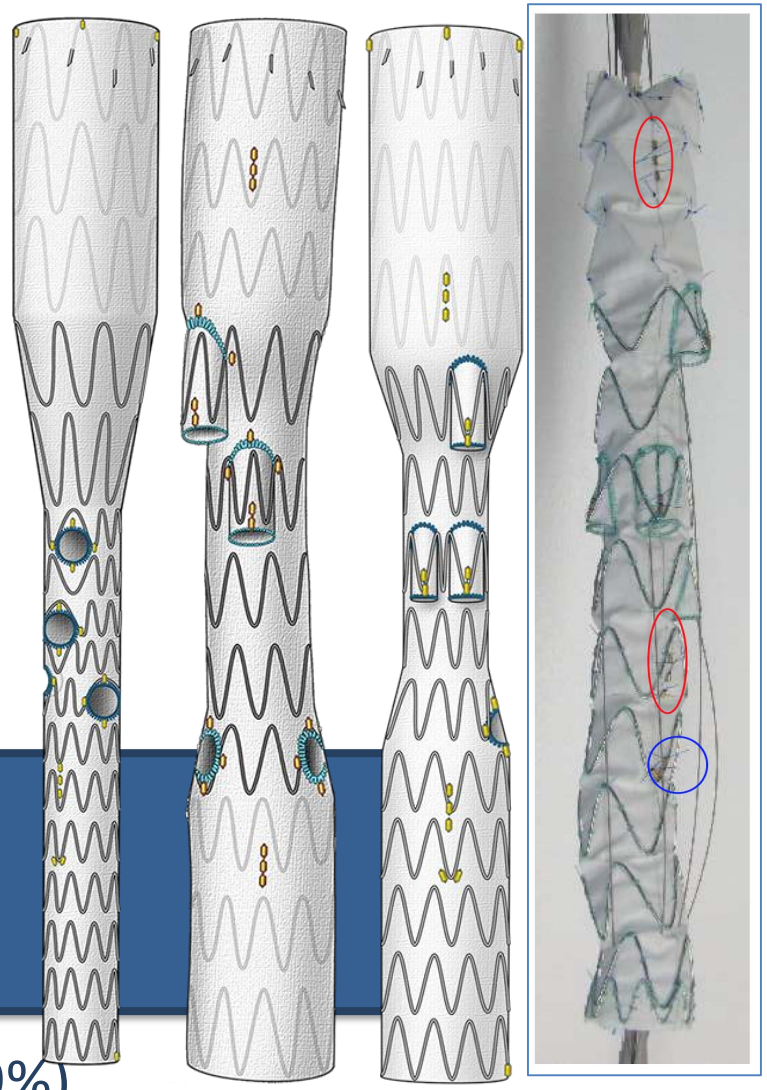
Mean follow-up, 15 ± 12 months (1 to 52)

Device design



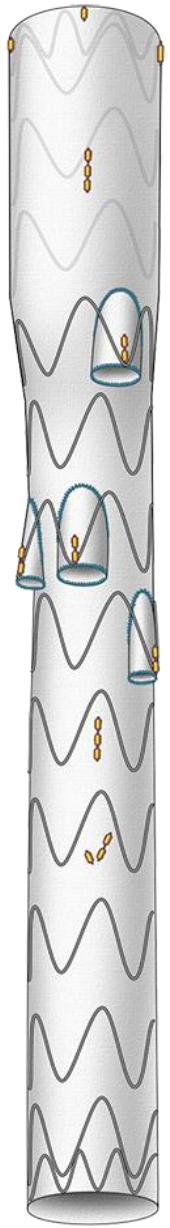
Standard
(CMD/Cook t-Branch®)

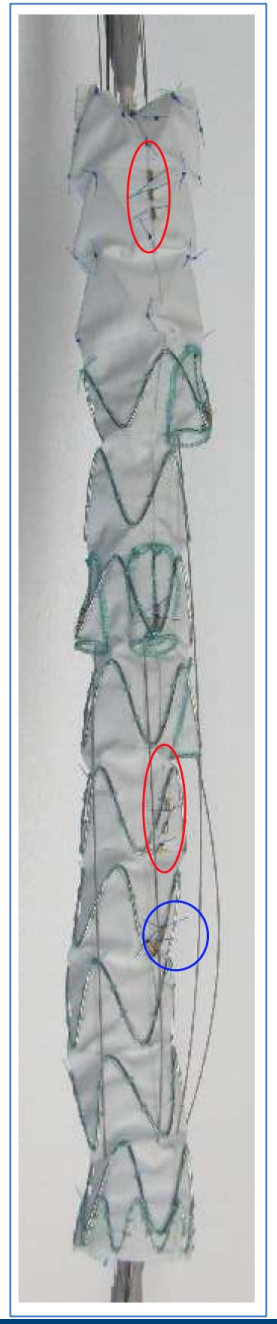
n = 177 (31%)
3.8±0.6 vessels/patient

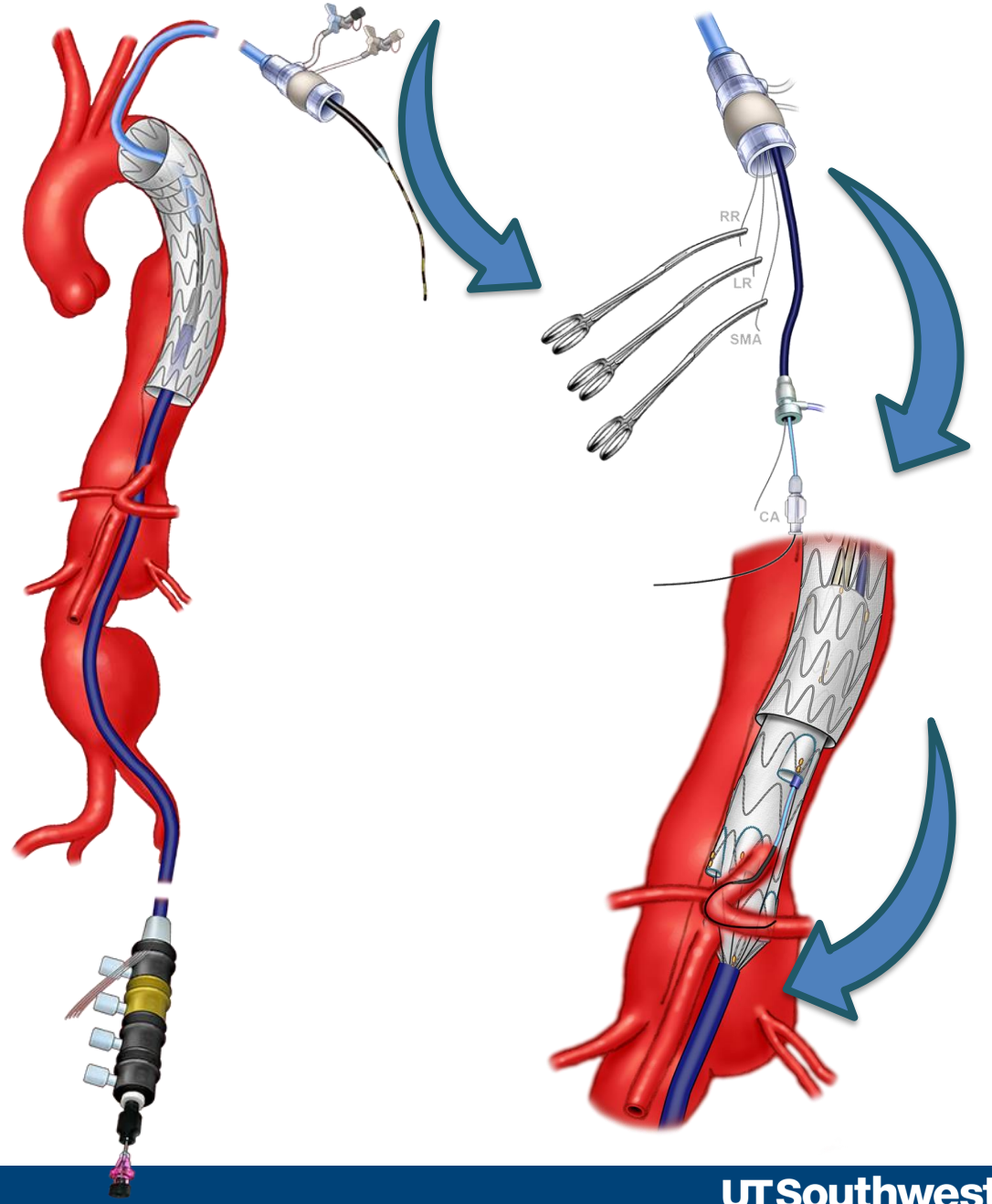


Preloaded
Fenestrations or branches

n = 387 (69%)
3.8±0.5 vessels/patient






RR
LR
SMA
CA

Demographics	Overall n = 564	Preloaded n = 387	Standard n = 177	P value
	n (Percent) or Mean ± Standard Deviation			
Mean age (years ± SD)	73±8	73±8	74±8	**0.49**
Age > 80 years old	126 (22)	78 (20)	48 (27)	**0.07**
Male gender	409 (73)	285 (74)	124 (70)	**0.37**
Cigarette smoking	464 (82)	344 (89)	120 (68)	**<0.001**
Hypertension	515 (91)	347 (90)	168 (95)	**0.03**
Hypercholesterolemia	399 (79)	281 (78)	118 (81)	0.52
Coronary artery disease	276 (49)	192 (50)	84 (48)	**0.67**
Chronic pulmonary disease	248 (44)	165 (43)	83 (47)	0.35
Chronic Kidney Disease III-V	243 (43)	166 (43)	77 (44)	0.93
Congestive heart failure	78 (14)	56 (15)	22 (12)	0.51
Prior aortic repair	251 (45)	177 (46)	74 (42)	**0.38**
Diabetes mellitus	126 (22)	94 (24)	32 (18)	**0.1**
Stroke	66 (12)	41 (11)	25 (14)	**0.22**
Chronic Dissection TAAA	37 (7)	28 (7)	9 (5)	**0.33**
Aneurysm Type				
Extent I-III	180 (32)	93 (24)	87 (49)	**<0.001**
Extent IV	216 (38)	174 (45)	42 (24)	**<0.001**
Pararenal	168 (30)	120 (31)	48 (27)	**0.37**

PROCEDURE DETAILS

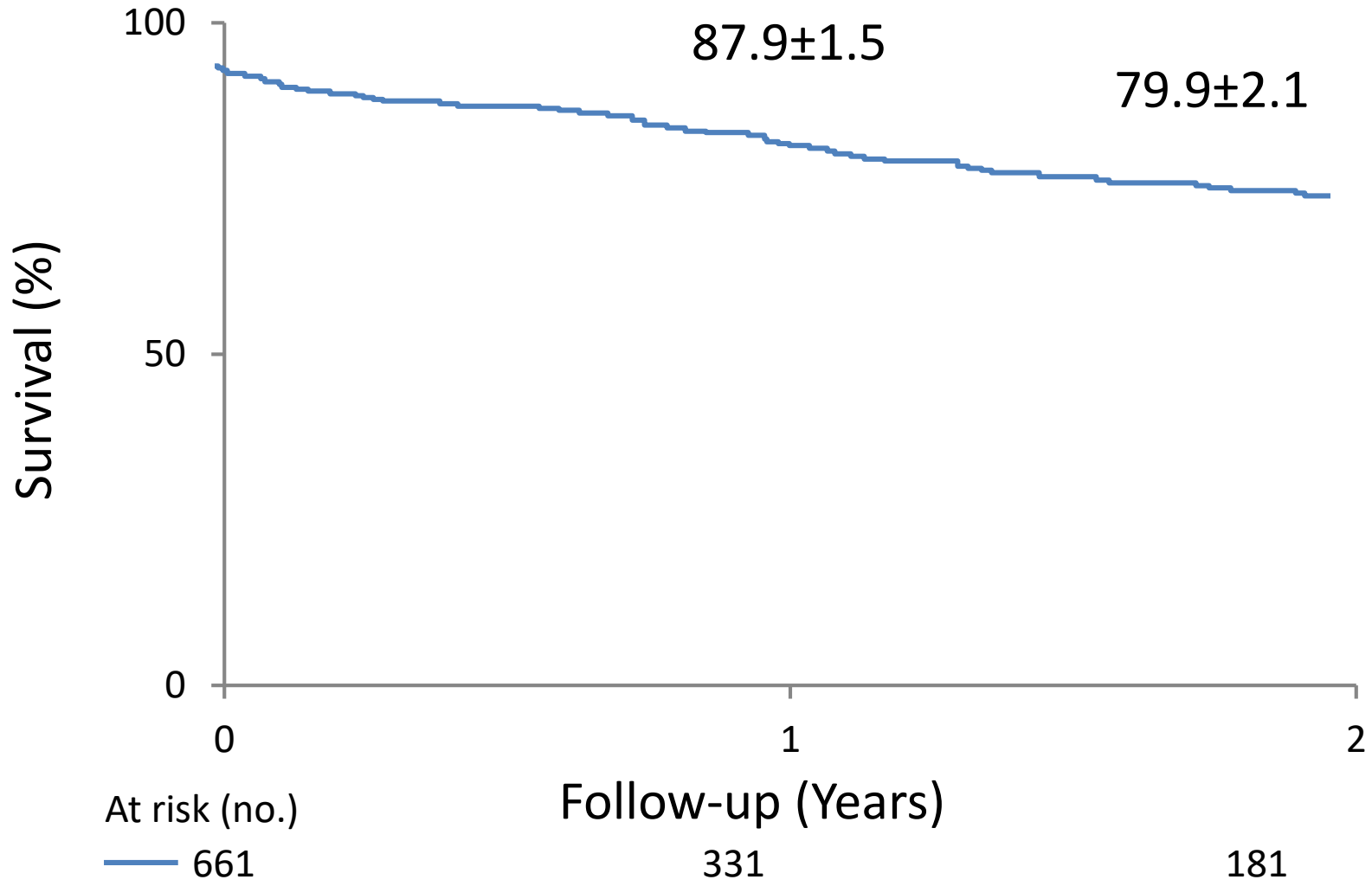
	Overall n = 564	Preloaded n = 387	Standard n = 177	P value
	n (Percent) or Mean ± Standard Deviation			
General anesthesia	100	100	100	NS
CSF drainage	336 (60)	219 (57)	117 (66)	**0.03**
Neuromonitoring	186 (33)	117 (30)	69 (39)	**0.04**
Percutaneous femoral	387 (69)	302 (67)	85 (75)	0.09
Iliac conduit	55 (10)	47 (12)	8 (5)	**0.005**
Femoral conduit	35 (6)	20 (5)	15 (8)	**0.13**
Upper extremity access	463 (82)	336 (87)	127 (72)	**<0.001**
Contrast volume (cc)	116±59	115±56	119±67	**0.56**
Fluoroscopy time (min)	84±36	85±35	82±37	**0.47**
Total radiation dose (mGy)	2519±1765	2474±1723	2672±1903	**0.31**
Total OR time (min)	278±96	279±93	275±104	**0.66**
EBL (ml)	463±490	459±485	471±502	**0.78**
Technical success	557/564 (98.8)	385/387 (99.5)	172/177 (97.2)	**0.022**

30-DAY RESULTS

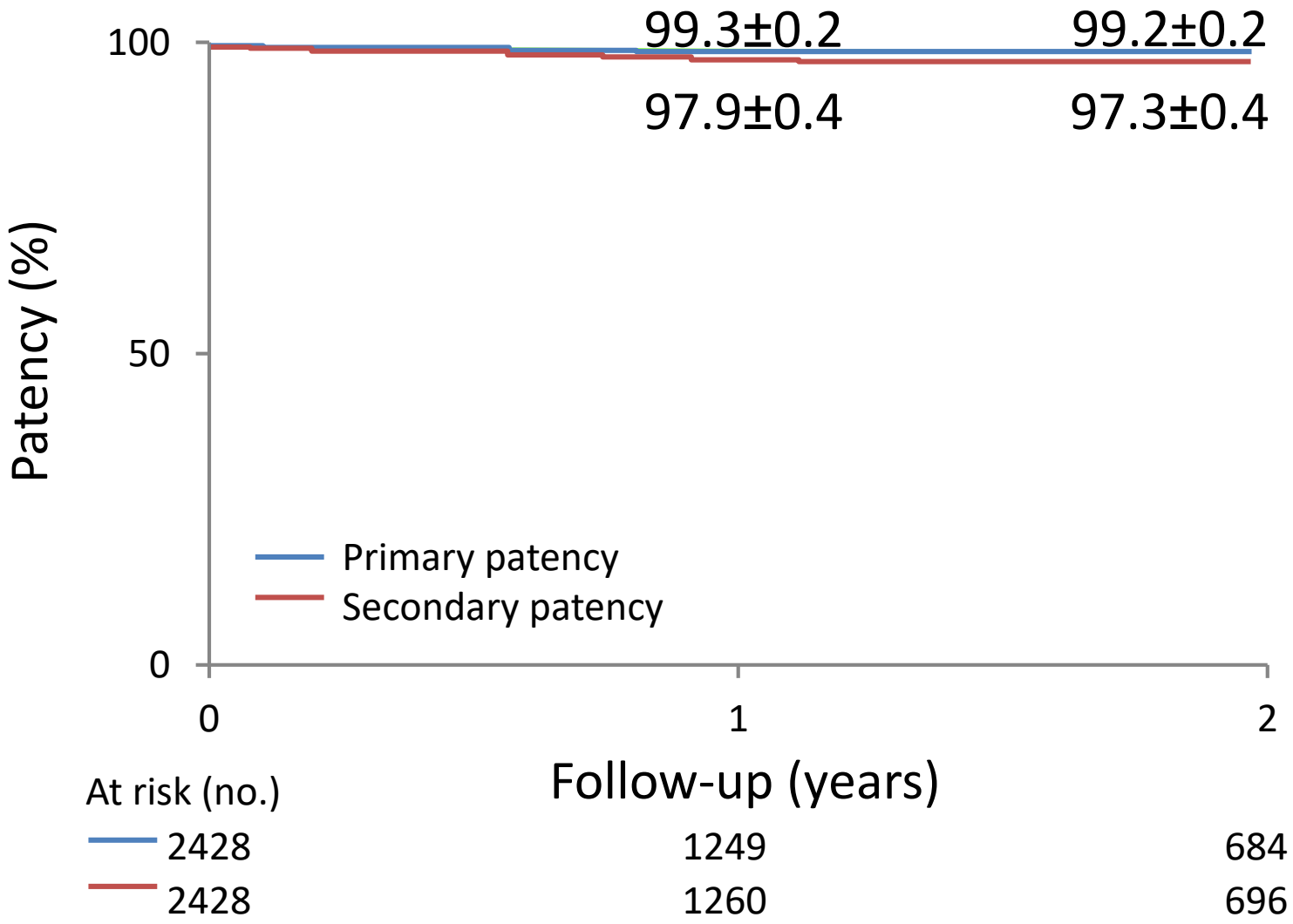
Mortality was 1.95%

	Overall n = 564	Preloaded n = 387	Standard n = 177	P value
	n (Percent)			
Any Mortality	11 (2)	3 (1)	8 (5)	0.003
Any MAE	136 (24)	93 (24)	43 (24)	0.95
EBL >1L	29 (5)	6 (3)	9 (4)	0.10
Acute Kidney injury	36 (6)	22 (6)	14 (8)	0.32
New-onset dialysis	9 (2)	6 (2)	3 (2)	0.89
Myocardial infarction	11 (2)	8 (2)	3 (2)	0.77
Respiratory failure	20 (4)	15 (4)	5 (3)	0.53
Paraplegia	11 (2)	3 (1)	8 (5)	**0.003**
Stroke	12 (2)	9 (2)	3 (2)	0.63
Bowel ischemia	21 (4)	15 (4)	6 (3)	0.78

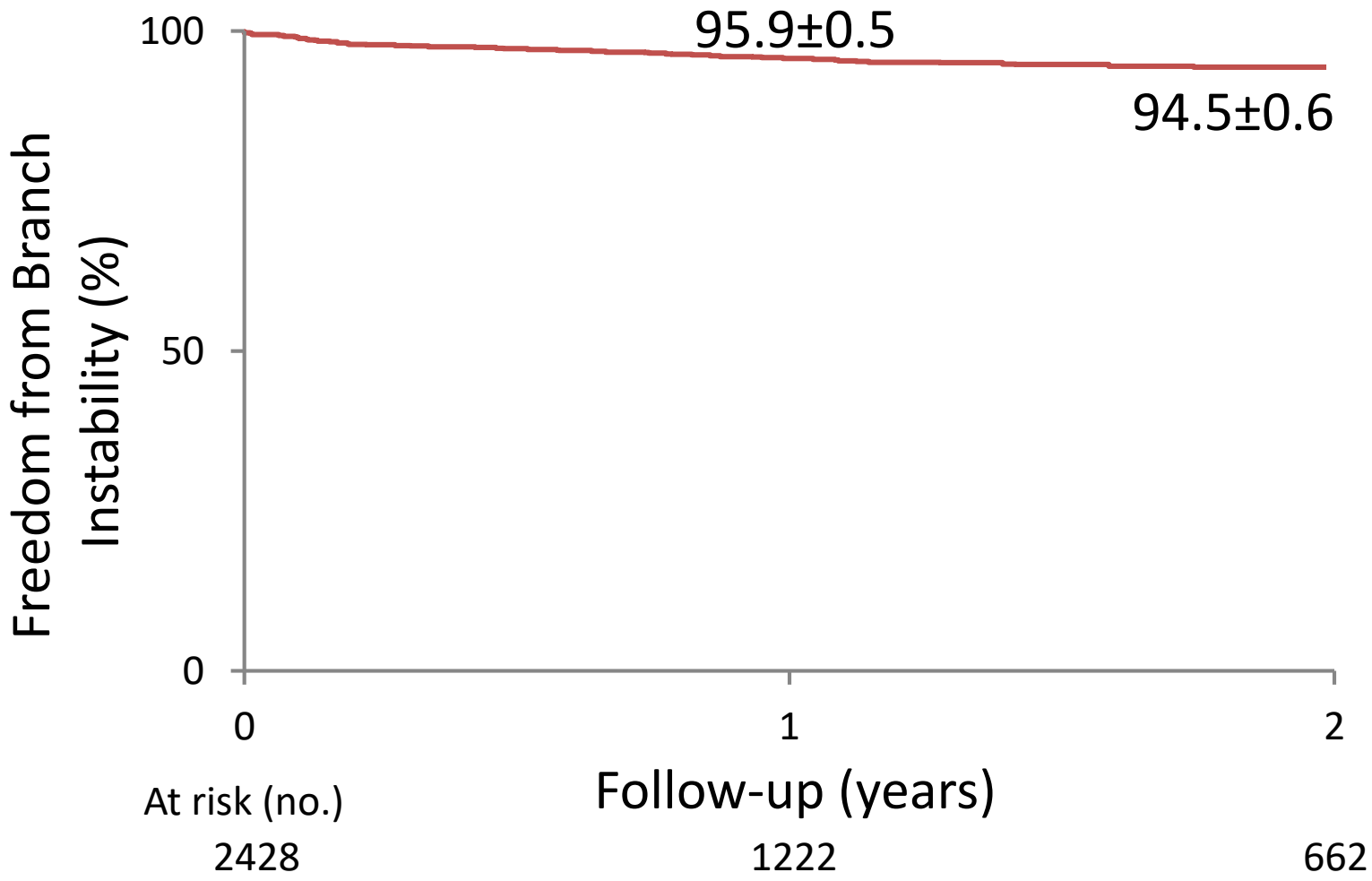
Survival


100
50
0
Survival (%)
87.9±1.5
79.9±2.1
0
1
2
Follow-up (Years)
At risk (no.)
661
331
181

Patency


99.3±0.2
99.2±0.2
97.9±0.4
97.3±0.4
100
50
0
Patency (%)
Primary patency
Secondary patency
0
1
2
Follow-up (years)
At risk (no.)
2428
1249
684
2428
1260
696

Freedom from Branch Instability



Conclusions

- Endovascular repair of complex aortic aneurysm is safe and effective

- The expanded use of preloaded catheters and wires of fenestrations and directional branches for target artery incorporation is associated with even higher technical success and lower early mortality.