

THE 24<sup>TH</sup> INTERNATIONAL EXPERTS SYMPOSIUM

# CRITICAL ISSUES

IN AORTIC ENDOGRAFTING

DECEMBER 17 & 18 2021

PULLMAN PARIS BERCY PARIS - FRANCE

## *Percutaneous Closure Devices, any interesting new players in the field?*

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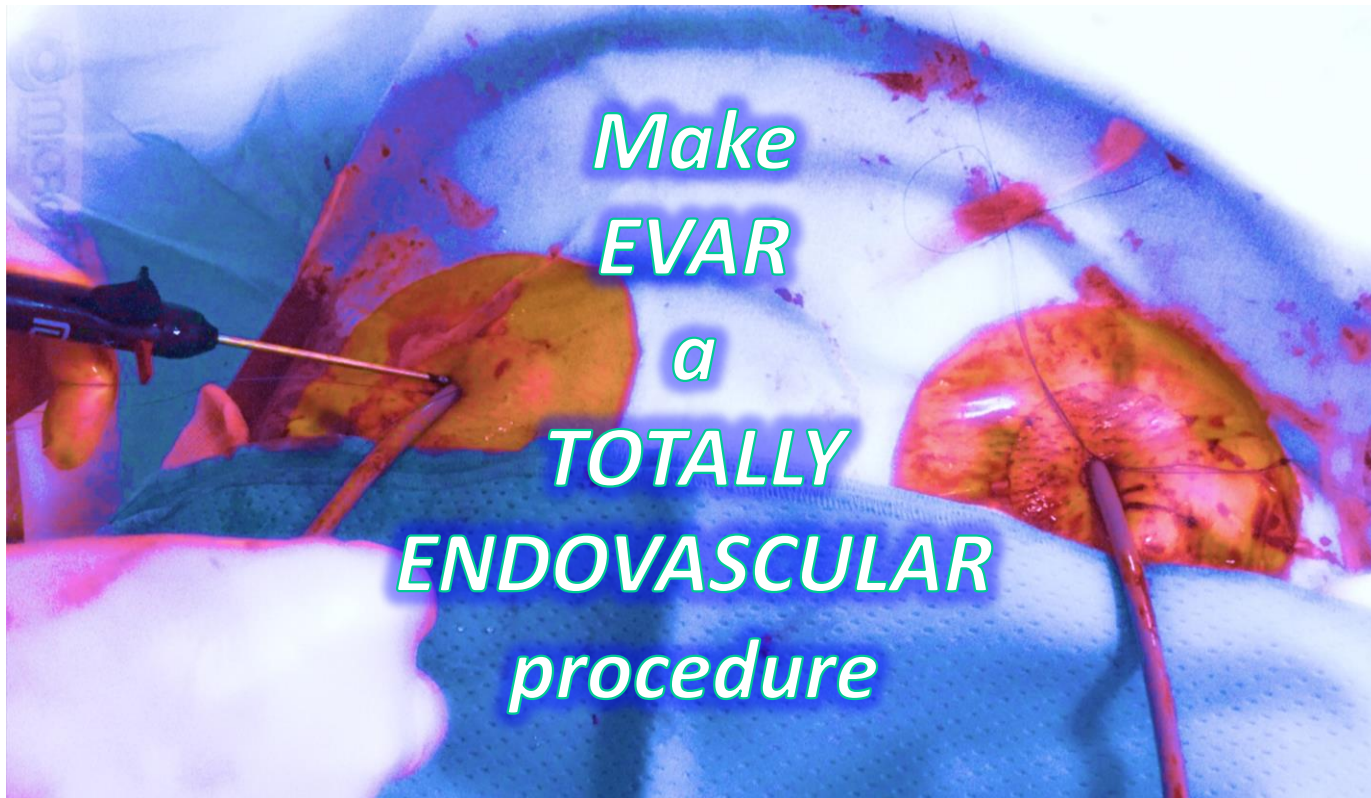


# *Disclosures*

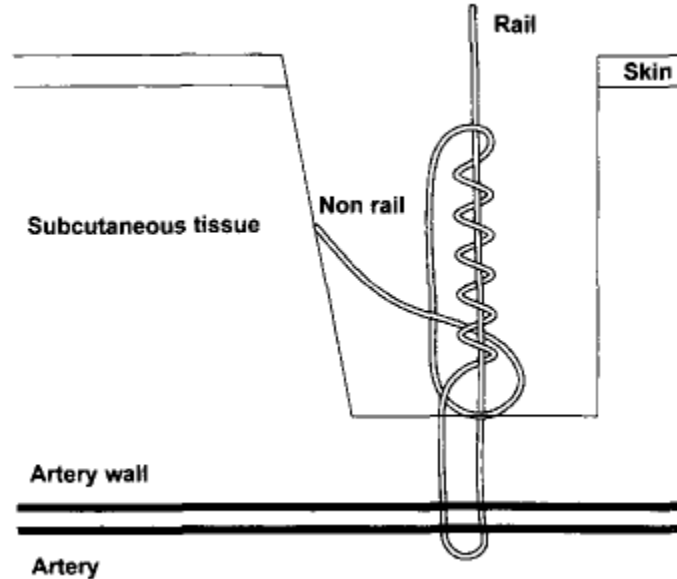
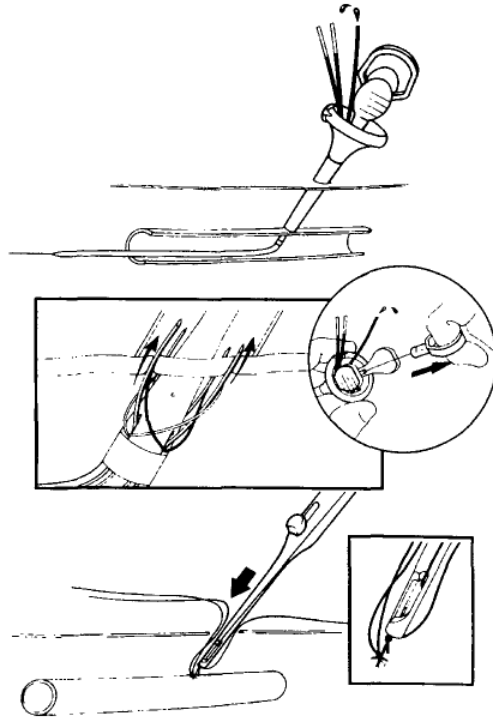
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- Consulting/grants and research support/ honoraria and travel support: Abbott, Cook, Cordis, Medtronic, WL Gore & Associates, Terumo Aortic

# *Percutaneous access for aortic endograft*



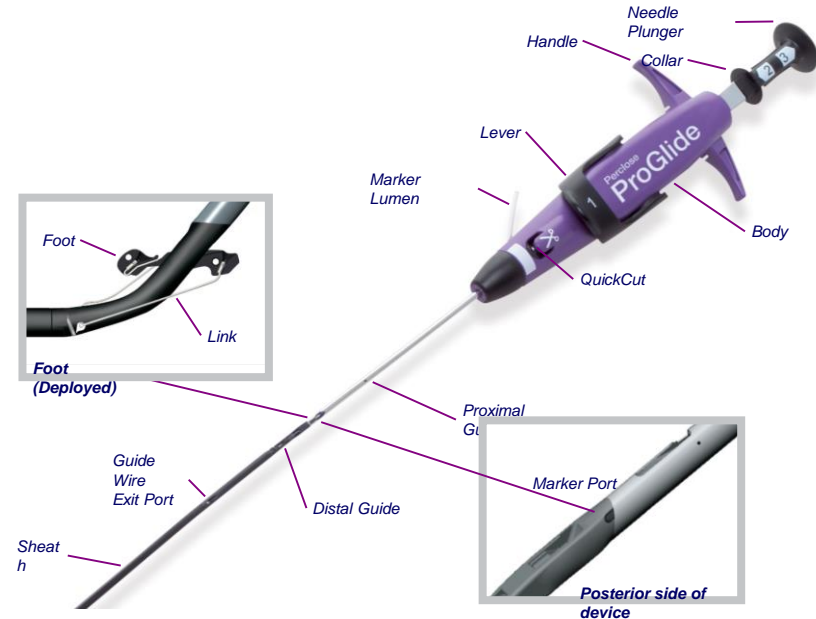
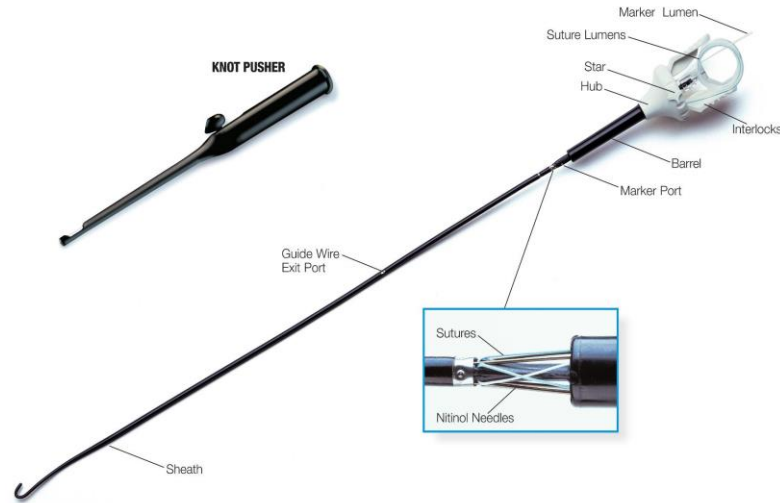
# Closure of Large Percutaneous Access Sites Using the Prostar XL Percutaneous Vascular Surgery Device



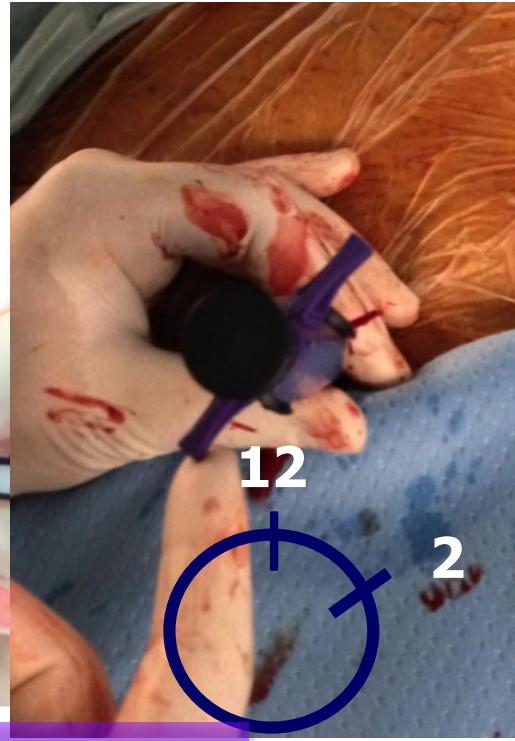
*Clay Haas P et al., J Endovasc Surg 1999*



# Suture-mediated closure devices: from Prostar to ProGlide



# *The evolution of pEVAR: “Preclose technique” with 2 ProGlide*



*Approved for large bore sheath up to 21 Fr*

# *pEVAR: clinical evidences*

## Comparing and Correlating Outcomes between Open and Percutaneous Access in Endovascular Aneurysm Repair in Aortic Aneurysms Using a Retrospective Cohort Study Design

Peter DeVito Jr <sup>1</sup>, Ali Kimyaghalam <sup>2</sup>, Sameh Shoukry <sup>3</sup>, Robert DeVito <sup>4</sup>, John Eashaa Kumar <sup>2</sup>, Eugene Vitvitsky <sup>2</sup>



## Percutaneous access for endovascular aortic aneurysm repair: A systematic review and meta-analysis

Shahin Hajibandeh <sup>1</sup>, Shahab Hajibandeh <sup>2</sup>, Stavros A Antoniou <sup>3</sup>, Emma Child <sup>4</sup>, Francesco Torella <sup>2</sup>, George A Antoniou <sup>5</sup>

REVIEW

## Arteriotomy Closure Devices in EVAR, TEVAR, and TAVR: A Systematic Review and Meta-analysis of Randomised Clinical Trials and Cohort Studies

B.P. Vierhout <sup>a,\*</sup>, R.A. Pol <sup>b</sup>, M. El Moumni <sup>b</sup>, C.J. Zeebregts <sup>c</sup>



## Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)

Gimzewska M, Jackson AIR, Yeoh SE, Clarke M

# Safety and Efficacy of Totally Percutaneous Femoral Access for Fenestrated–Branched Endovascular Aortic Repair of Pararenal–Thoracoabdominal Aortic Aneurysms

Mario D'Oria <sup>1</sup>, Gustavo S Oderich <sup>2</sup>, Emanuel R Tenorio <sup>2</sup>, Jussi M Kärkkäinen <sup>2</sup>, Bernardo C Mendes <sup>2</sup>, Randall R DeMartino <sup>2</sup>

**Table 3** Primary outcomes

	Totally percutaneous femoral access (N = 163)	Surgical femoral access (N = 68)	Total (N = 231)	P value
30-day mortality, N (%)				.56
Yes	1 (1%)	0 (0%)	1 (1%)	
30-day major adverse events, N (%)				.07
Yes	43 (26)	26 (38)	69 (30)	
Estimated blood loss ≥ 1L, N (%)	10 (6)	14 (21)	24 (10)	.001
Acute myocardial infarction, N (%)	4 (2)	6 (9)	10 (4)	.03
Respiratory failure, N (%)	3 (2)	3 (4)	6 (3)	.26
Stroke, N (%)	4 (2)	3 (4)	7 (3)	.43
Paraplegia, N (%)	4 (2)	2 (3)	6 (3)	.83
Permanent paraplegia, N (%)	1 (1)	1 (1)	2 (1)	.52
Acute kidney injury	25 (15)	9 (13)	34 (15)	.68
New-onset dialysis, N (%)	3 (2)	3 (4)	6 (3)	.26
Bowel ischemia, N (%)	0 (0)	0 (0)	0 (0)	1
30-day major vascular access complications, N (%)				< .001
Yes	9 (6%)	14 (21%)	23 (10%)	
Cause of major access complications, N (%)				.09
Ischemia	4 (44%)	3 (21%)	7 (30%)	
Hematoma/pseudoaneurysm	5 (56%)	3 (21%)	8 (35%)	
Infection/dehiscence	0 (0%)	2 (14%)	2 (9%)	
Seroma/drainage	0 (0%)	5 (37%)	5 (22%)	
Neuropathy	0 (0%)	1 (7%)	1 (4%)	
Complications of main body side, N (%)				.24
Yes	5 (55)	11 (78)	16 (69)	

**Conclusion:** A percutaneous-first approach for elective F/B-EVAR of PRAs/TAAAs is safe, feasible and effective when proper patient selection is provided. When the presence of hostile iliofemoral anatomy requires open-vessel exposure, higher rates of perioperative major bleeding, cardiac events and access complications may be expected.



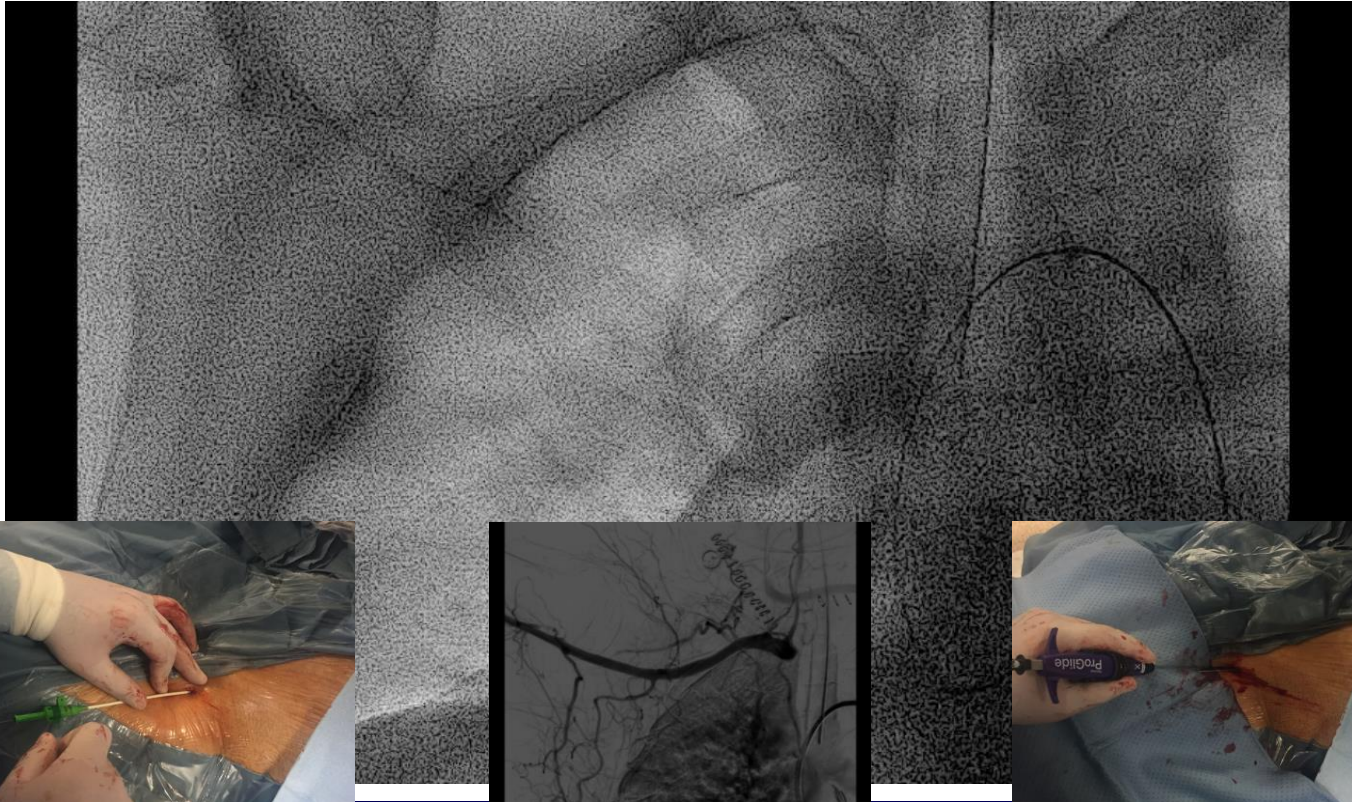
# European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms

Anders Wanhainen <sup>a,†,\*</sup>, Fabio Verzini <sup>a,†</sup>, Isabelle Van Herzeele <sup>a</sup>, Eric Allaire <sup>a</sup>, Matthew Bown <sup>a</sup>, Tina Cohnert <sup>a</sup>, Florian Dick <sup>a</sup>, Joost van Herwaarden <sup>a</sup>, Christos Karkos <sup>a</sup>, Mark Koelemay <sup>a</sup>, Tilo Kölbel <sup>a</sup>, Ian Loftus <sup>a</sup>, Kevin Mani <sup>a</sup>, Germano Melissano <sup>a</sup>, Janet Powell <sup>a</sup>, Zoltán Szeberin <sup>a</sup>

Recommendation 55	Class	Level
An ultrasound guided percutaneous approach should be considered in endovascular aortic aneurysm repair.	Ila	B



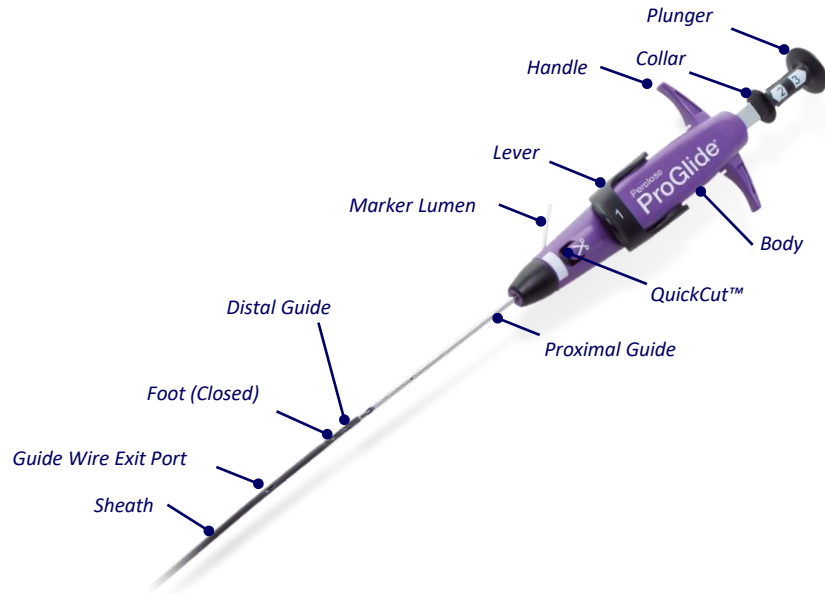
# *Percutaneous axillary access: preclose technique with Proglide*



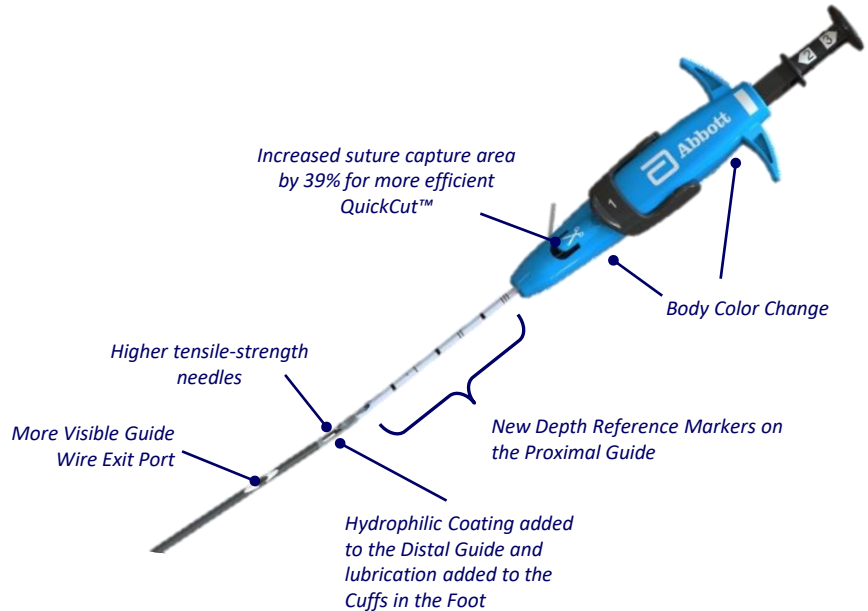
# Any new players in the field?

## Perclose ProStyle

*Perclose™ ProGlide™ device*



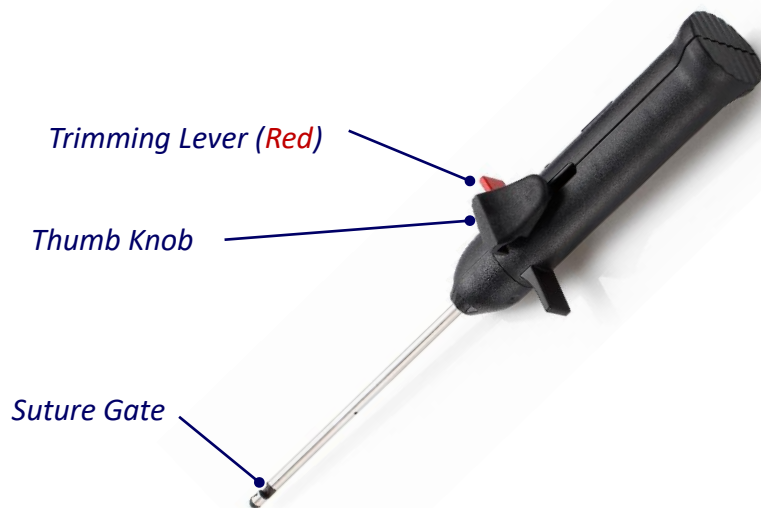
*Perclose™ ProStyle™ device*



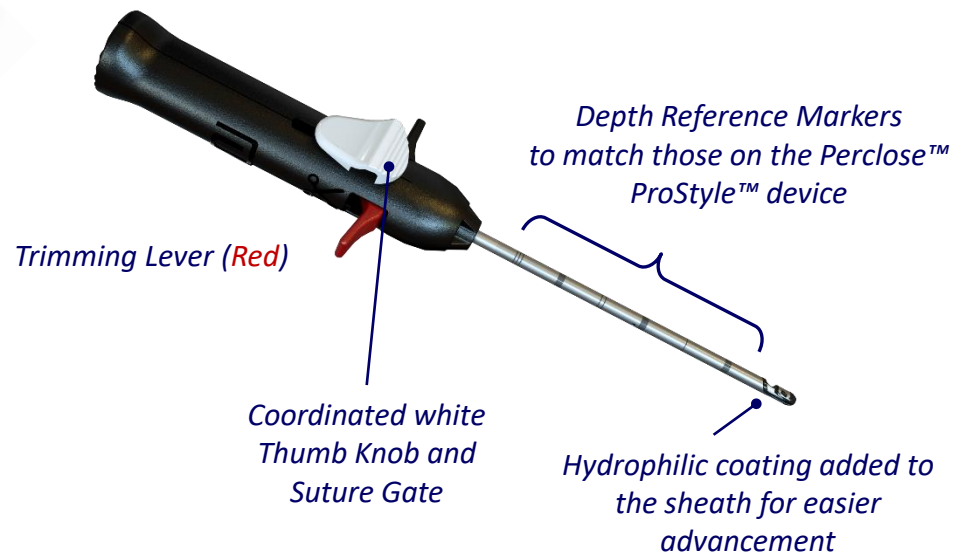
# Any new players in the field?

## Perclose ProStyle

*Original*  
*Perclose™ ProGlide™ Suture Trimmer*



*Updated*  
*Perclose™ ProStyle™ Suture Trimmer*

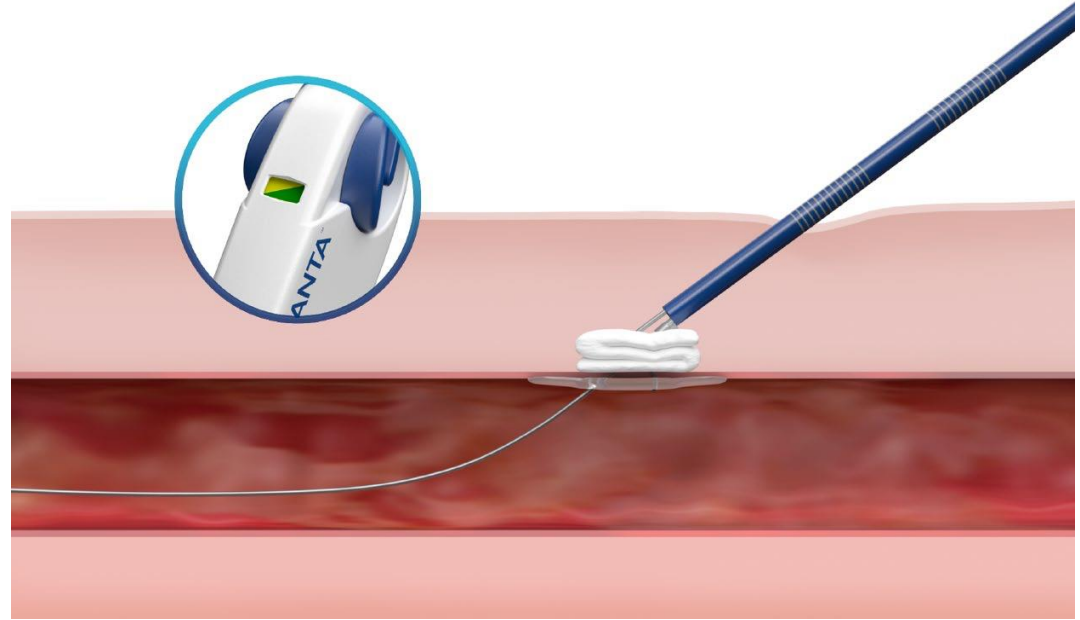
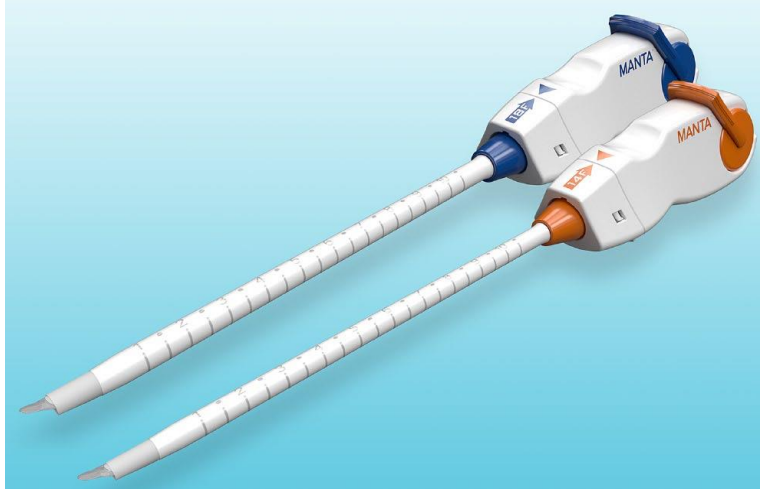




# *Vascular Closure Devices evolution: Perclose ProStyle*



# *Any new Player in the field: Manta vascular closure device*

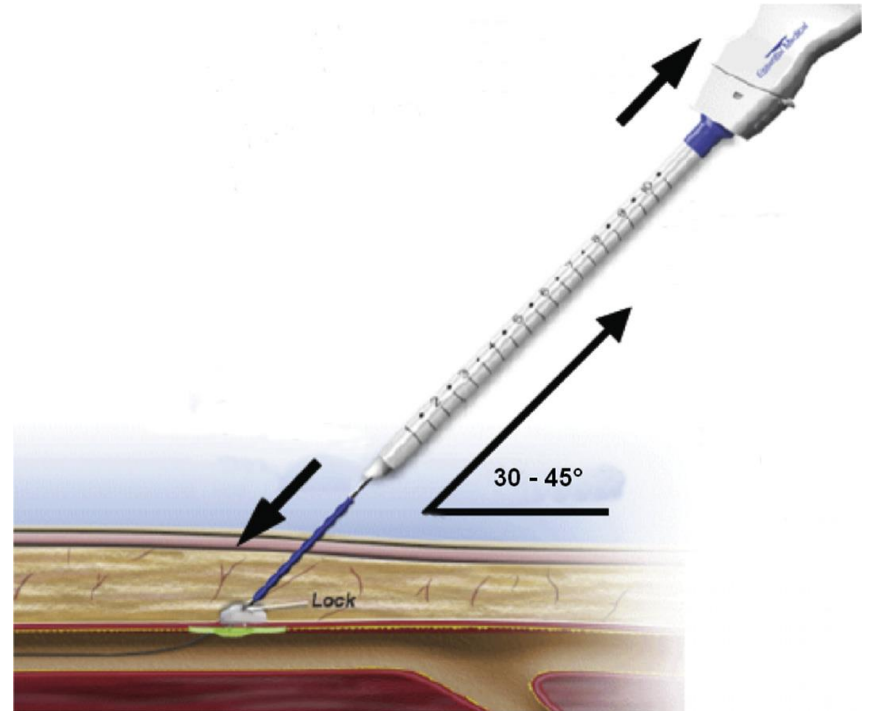


***14F for closing punctures of 10 to 14 F***

***18F for closing punctures of 15 to 22 F***

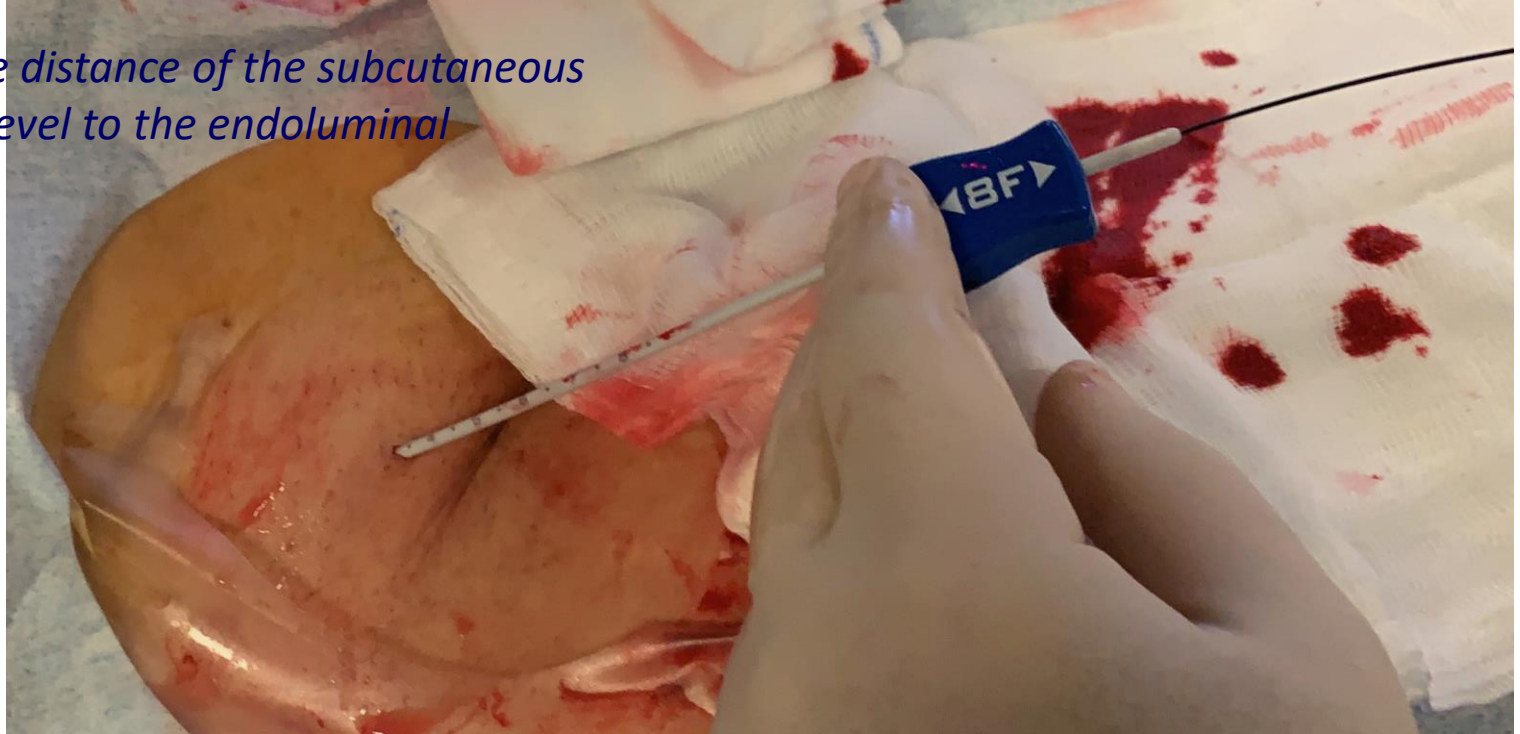
# *The Manta Concept*

- Resorbable polymer (poly-lactic-co-glycolic acid) intra-arterial toggle
- Extravascular hemostatic bovine collagen pad
- Connecting nonresorbable polyester suture
- Stainless steel suture lock



# *Manta vascular closure device: puncture location dilator*

*To determine the distance of the subcutaneous track from skin level to the endoluminal arterial space*

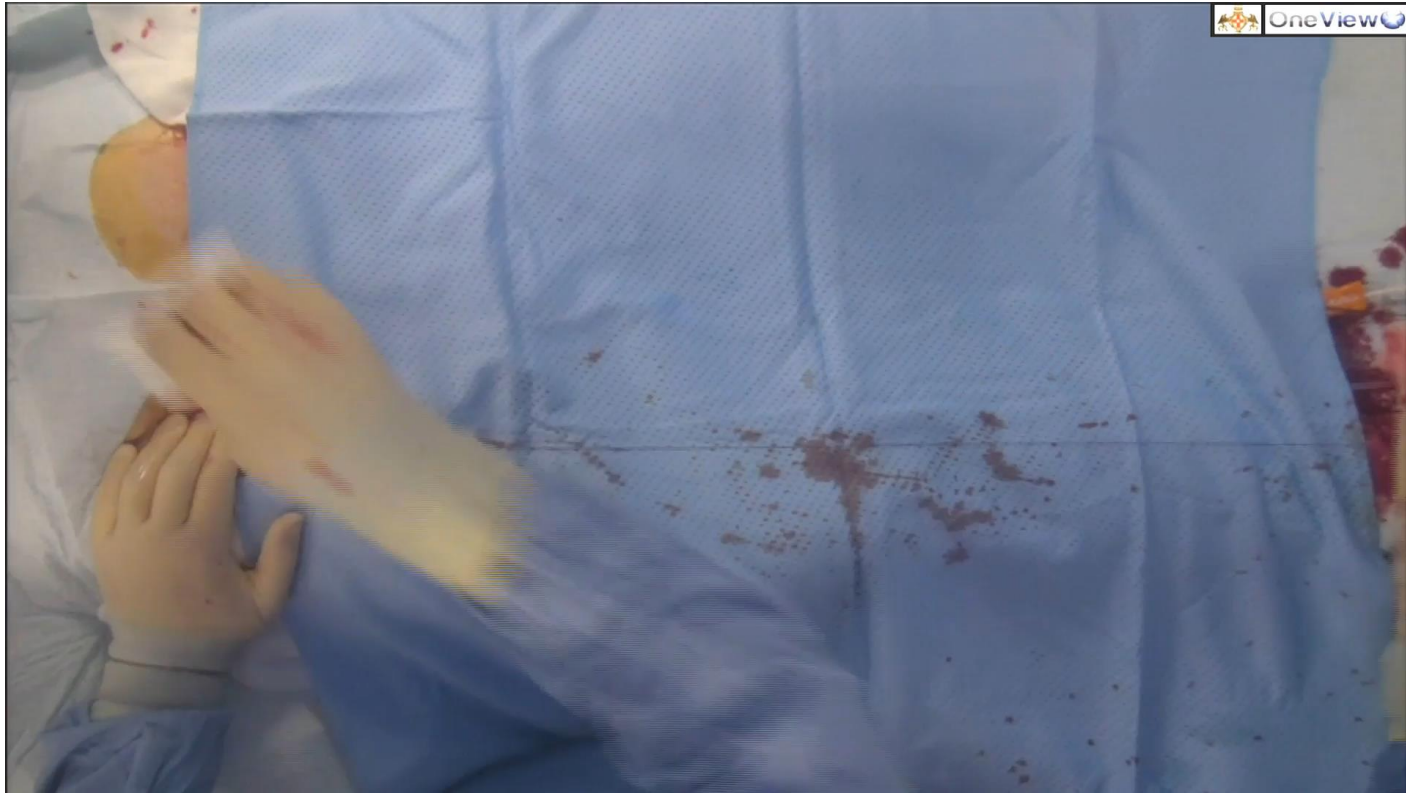




# *Manta vascular closure device: puncture location dilator*



# *Manta vascular closure device: closure unit*

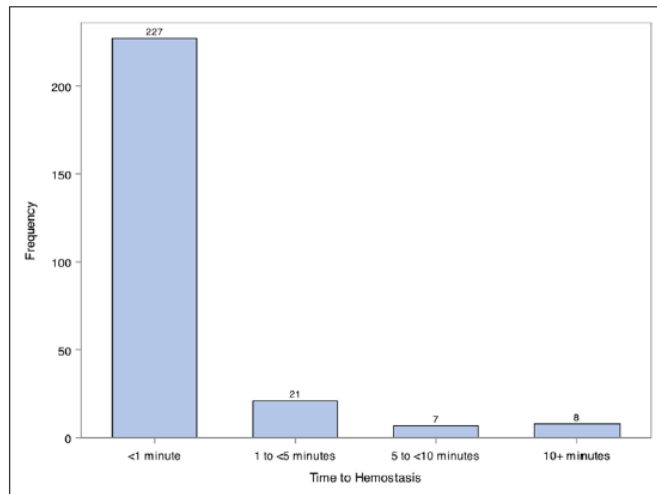


# *Manta vascular closure device: closure unit*



# Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device

## The SAFE MANTA Study



**CONCLUSIONS:** In a selected population, this study demonstrated that the MANTA percutaneous vascular closure device can safely and effectively close large bore arteriotomies created by current generation transcatheter aortic valve replacement, percutaneous endovascular abdominal aortic aneurysm repair, and thoracic endovascular aortic aneurysm repair devices.

Table 3. Procedure Sheath Information, Primary Analysis Cohort

Procedure Sheath	N	Procedure Sheath ID, F	Procedure Sheath OD, F
14F MANTA			
Cook CheckFlo*	3	12	15
	19	14	16.5
Gore DrySeal†	1	12	15
	5	14	16.5
	1‡	16	18.6
EnVeo delivery system§	5	14	18
Ovation IX delivery system	12	10–13	12–15
18F MANTA			
Ovation IX Delivery System	1	10–13	12–15
Gore DrySeal†	1	15	16.8
Cook CheckFlo*	1	16	18.6
	1	20	22.5
Endologix AFX¶	4	17	19
EnVeo delivery system§	1	14	18
	11	16	20
Gore DrySeal†	14	16	18.6
	3	18	20.4
	2	20	22.5
Medtronic Sentra‡§	1	16	18
	1	18	20
Edwards 14F eSheath#	127	14	23
Edwards 16F eSheath#	53	16	24.5

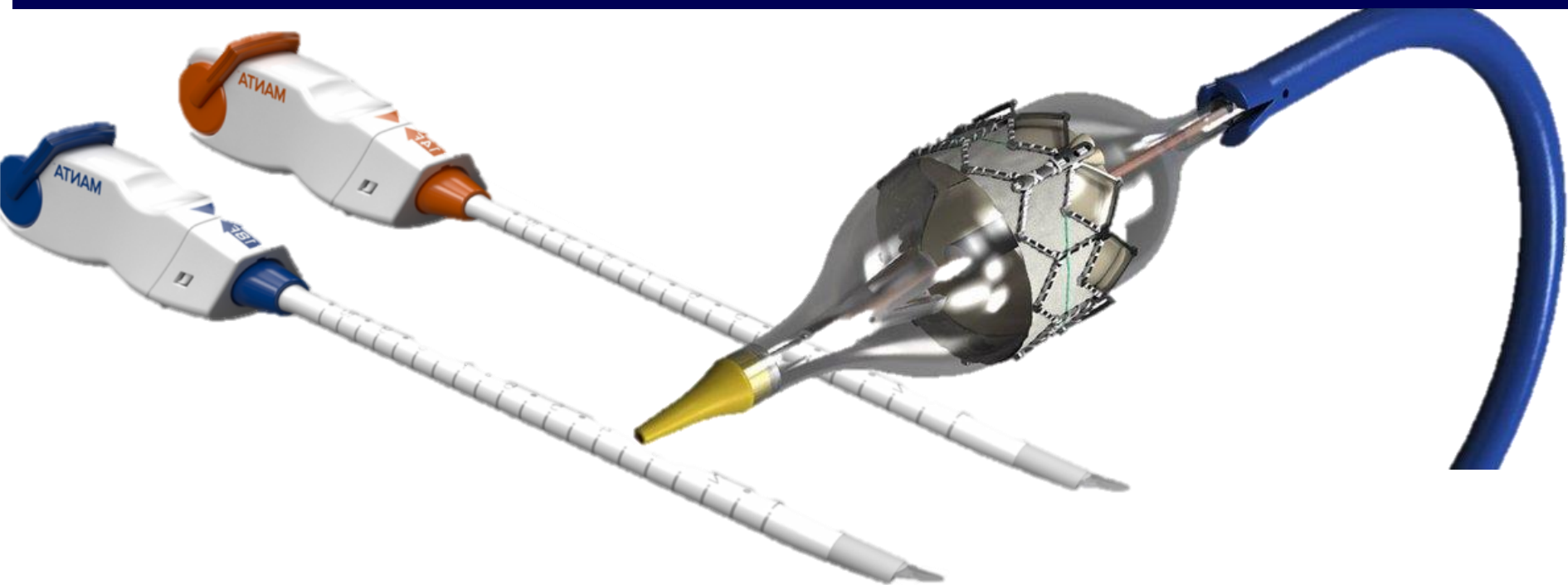
Wood DA et al., Circ Cardiovasc Interv 2019





# *MANTA Vascular Closure Device*

## *TAVR-oriented data*



# MANTA Vascular Closure Device TAVR-oriented data

Manta versus Perclose ProGlide vascular closure device after transcatheter aortic valve implantation: Initial experience from a large European center

Oliver Dumpies<sup>a</sup>, Mitsunobu Kitamura<sup>a</sup>, Nicolas Majunke<sup>a</sup>, Phillip Hartung<sup>a</sup>, Anna Haag<sup>a</sup>, Johannes W Steffen Desch<sup>a</sup>, Marcus Sandri<sup>a</sup>, Lisa Crusius<sup>a</sup>, Thilo Noack<sup>b</sup>, Philipp Kiefer<sup>b</sup>, Sergey Leontyev<sup>b</sup>, Michael Borger<sup>b</sup>, Holger Thiele<sup>a</sup>, David Holzhey<sup>b</sup>, Mohamed Abdel-Wahab<sup>a,\*</sup>

**Propensity-matched comparison of large-bore access closure in transcatheter aortic valve replacement using MANTA versus Perclose: A real-world experience**

Giorgio A. Medranda MD<sup>1</sup> | Brian C. Case MD<sup>1</sup> | Cheng Zhang PhD<sup>1</sup> |  
Hank Rappaport MD, MS<sup>1</sup> | Gaby Weissman MD<sup>2</sup> | Nelson L. Bernardo MD<sup>1</sup> |  
Lowell F. Satler MD<sup>1</sup> | Itsik Ben-Dor MD<sup>1</sup> | Toby Rogers MD, PhD<sup>1,3</sup> |  
Ron Waksman MD<sup>1</sup>

**Suture- or Plug-Based Large-Bore Arteriotomy Closure: A Pilot Randomized Controlled Trial**

Maarten P van Wiechen<sup>1</sup>, Didier Tchétché<sup>2</sup>, Joris F Ooms<sup>1</sup>, Thijmen W Hokken<sup>1</sup>, Herbert Kroon  
Francesca Ziviello<sup>1</sup>, Angie Ghattas<sup>2</sup>, Saifullah Siddiqui<sup>2</sup>, Clémence Laperche<sup>2</sup>, Ernest Spitzer<sup>1</sup>,  
Joost Daemen<sup>1</sup>, Peter P de Jaegere<sup>1</sup>, Nicolas Dumonteil<sup>2</sup>, Nicolas M Van Mieghem<sup>3</sup>

**MANTA versus Perclose for large-bore vessel closure: The evidence continues to grow**

Alexander Postalian MD<sup>1,2</sup> |  
Zvonimir Krajcer MD<sup>1,2</sup>

**Comparison of a Pure Plug-Based versus a Primary Suture-Based Vascular Closure Device Strategy for Transfemoral Transcatheter Aortic Valve Replacement: The CHOICE-CLOSURE Randomized Clinical Trial**

Mohamed Abdel-Wahab<sup>1</sup>, Philipp Hartung<sup>1</sup>, Oliver Dumpies<sup>1</sup>, Danilo Obradovic<sup>1</sup>,  
Johannes Wilde<sup>1</sup>, Nicolas Majunke<sup>1</sup>, Peter Boekstegers<sup>2</sup>, Ralf Müller<sup>3</sup>, Melchior Seyfarth<sup>4</sup>,  
Marc Vorpahl<sup>4</sup>, Philipp Kiefer<sup>5</sup>, Thilo Noack<sup>5</sup>, Sergey Leontyev<sup>5</sup>, Marcus Sandri<sup>1</sup>,  
Johannes Rotta Detto Loria<sup>1</sup>, Mitsunobu Kitamura<sup>1</sup>, Michael Andrew Borger<sup>5</sup>,  
Anne-Kathrin Funkat<sup>6</sup>, Sven Hohenstein<sup>6</sup>, Steffen Desch<sup>1</sup>, David Holzhey<sup>7</sup>, Holger Thiele<sup>1</sup>,  
CHOICE-CLOSURE Investigators



# Dedicated plug based closure for large bore access – The MARVEL prospective registry

Herbert G Kroon<sup>1</sup>, Pim A L Tonino<sup>2</sup>, Mikko Savontaus<sup>3</sup>, Giovanni Amoroso<sup>4</sup>, Mika Laine<sup>5</sup>, Evald H Christiansen<sup>6</sup>, Stefan Toggweiler<sup>7</sup>, Jur Ten Berg<sup>8</sup>, Janarthanan Sathananthan<sup>9</sup>, Joost Daemen<sup>1</sup>, Peter P de Jaegere<sup>1</sup>, Guus B R G Brueren<sup>2</sup>, Markus Malmberg<sup>3</sup>, Ton Slagboom<sup>4</sup>, Noriaki Moriyama<sup>5</sup>, Christian J Terkelsen<sup>6</sup>, Federico Moccetti<sup>7</sup>, Livia Gheorghe<sup>8</sup>, John Webb<sup>9</sup>, David Wood<sup>9</sup>, Nicolas M Van Mieghem<sup>1</sup>

- **TAVR 496(99%)**
- **High risk PCI with Impella MCS 1(<1%)**
- **BAV 2(<1%)**
- **EVAR 1(<1%)**

**TABLE 3** Overview of 30-day clinical outcomes

	Number of patients (N = 500)
<b>30-day outcomes</b>	
Mean follow-up (days)	40 ± 13
Manta related major vascular complication	20 (4.0%)
Manta related minor vascular complication	28 (5.6%)
<b>Bleeding</b>	
Minor bleeding	9 (1.8%)
Major bleeding	10 (2.0%)
Disabling bleeding	6 (1.2%)
<b>Red blood cell transfusions</b>	
1 packed cell	4 (0.8%)
2 packed cells	8 (1.6%)
3 packed cells	2 (0.4%)
4 packed cells	1 (0.2%)
8 packed cells	1 (0.2%)
Percutaneous closure device failure	12 (2.4%)
Median time to hemostasis (s)	50 [20–120]

*Catheter Cardiovasc Interv* 2021



# Incidence and Predictors of Access Site Vascular Complications Following Ultrasound-Guided MANTA Closure Deployment

- *378 consecutive TAVR patients (2018 - 2020)*
- *6.1% MANTA-related VC (major VC: 1.9%, minor VC: 4.2%)*

Model 1		Univariate			Multivariate		
Variables	OR	(95% CI)	p value	OR	(95% CI)	p value	
Minimum lumen diameter	1.37	(0.84, 1.97)	0.06	1.24	(0.58, 2.40)	0.57	
Eccentricity	4.61	(1.02, 9.31)	0.05	2.31	(0.06, 30.2)	0.56	
SFAR	5.26	(0.89, 27.1)	0.07	1.47	(0.03, 34.5)	0.84	
Anterior calcification	4.74	(1.71, 12.1)	0.002	3.78	(1.23, 10.6)	0.02	
Model 2							
Variables	OR	(95% CI)	p value	OR	(95% CI)	p value	
SFAR	5.26	(0.89, 27.1)	0.07	1.52	(0.16, 33.6)	0.34	
Anterior calcification	4.74	(1.71, 12.1)	0.002	3.96	(1.32, 10.9)	0.02	

*Incomplete apposition of the toggle due to anterior calcification of the CFA may lead to ongoing vascular and bleeding complications.*

*Miyashita H et al., J Endovasc Ther 2021*

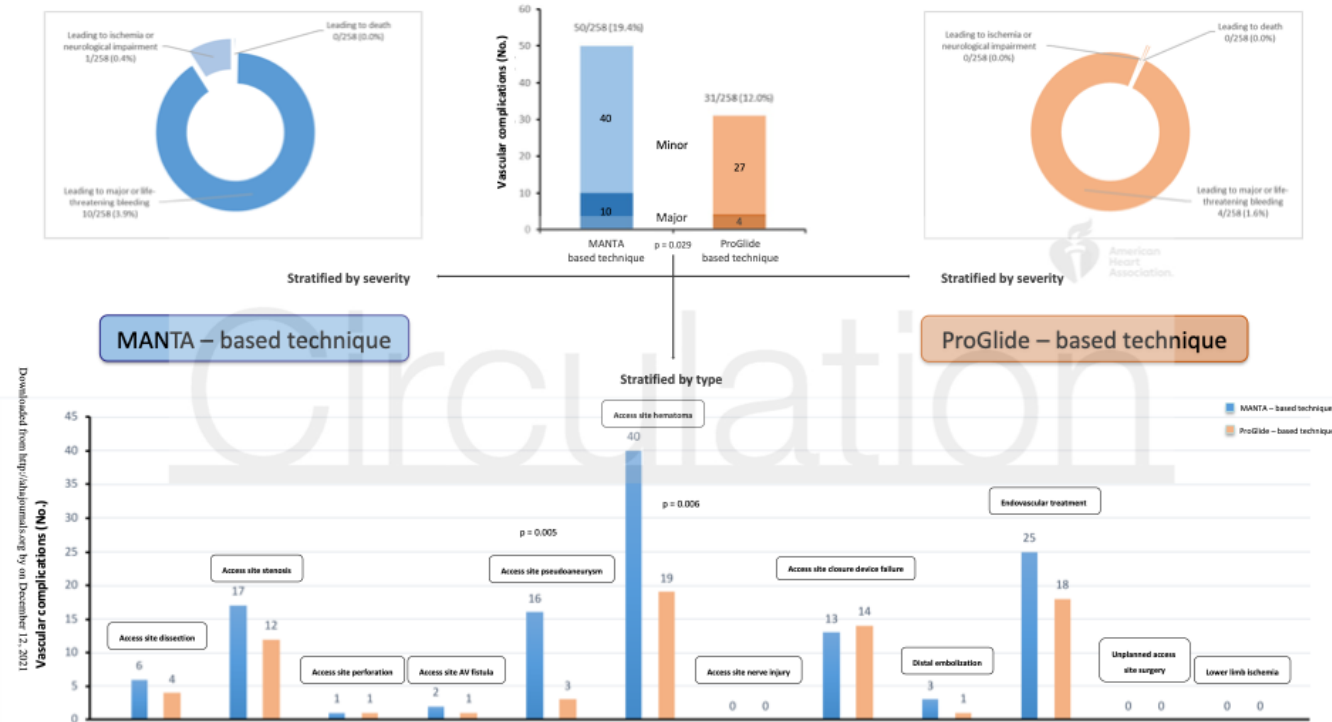


# *Suture-mediated vs Plug-based closure device*



# Comparison of a Pure Plug-Based versus a Primary Suture-Based Vascular Closure Device Strategy for Transfemoral Transcatheter Aortic Valve Replacement: The CHOICE-CLOSURE Randomized Clinical Trial

- A total of 516 TAVR patients were included
- Vascular complications occurred in 19.4% (50/258) of the pure plug-based group and 12.0% (31/258) of the primary suture-based group ( $p=0.029$ )
- Time to hemostasis was significantly shorter in the pure plug-based group (80 vs. 240 sec.,  $p<0.001$ ).



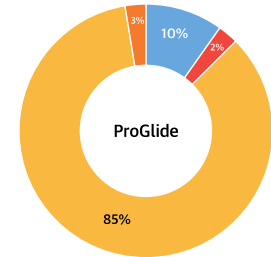
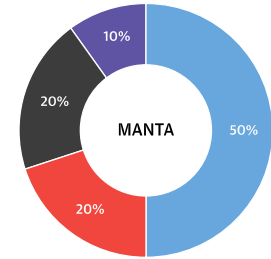
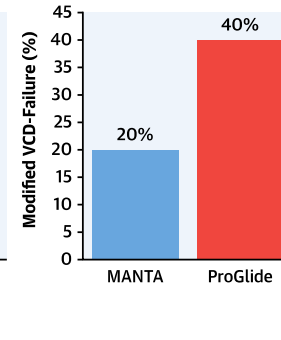
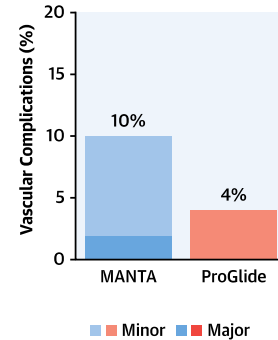
Abdel-Wahab M et al., Circulation 2021

# Suture- or Plug-Based Large-Bore Arteriotomy Closure

## A Pilot Randomized Controlled Trial



	Overall (N = 206)	MANTA (n = 102)	ProGlide (n = 104)	p Value
Composite access site-related major and minor vascular complications, <30 days	14 (7)	10 (10)	4 (4)	0.16
Major vascular complications	2 (1)	2 (2)	0 (0)	0.24
Minor vascular complications	12 (6)	8 (8)	4 (4)	0.35
Any bleeding, <30 days	21 (10)	10 (10)	11 (11)	1.00
Access site-related	15 (7)	9 (9)	6 (6)	0.57
Need for RBC transfusion				0.30
None	186 (90)	92 (90)	94 (90)	
1 U	5 (2)	4 (4)	1 (1)	
≥2 U	15 (7)	6 (6)	9 (9)	
Modified VCD failure*	62 (30)	20 (20)	42 (40)	<0.01
Immediate hemostasis	88 (42)	49 (48)	39 (36)	0.18
Time to hemostasis, s†	77 (40–202)	53 (35–200)	120 (61–216)	0.02
Procedural length, min	58 (46–70)	61 (47–75)	57 (45–68)	0.14
Length of hospital stay, days	7 (5–9)	7 (5–9)	7 (5–9)	0.96



■ Prolonged Manual Compression
 ■ Prolonged Balloon
 ■ Endovascular Stent Inflation
 ■ Vascular Surgery
 ■ Additional Vascular Closure Device
 ■ Bail-Out MANTA Closure Device

*The dedicated plug-based MANTA device was not superior to suture-based vascular closure with double ProGlide. Bailouts with plug-based VCD involved more covered stents and vascular surgery, whereas suture-based VCD required more often additional VCDs.*

van Wiechen MP et al., J Am Coll Cardiol Interv 2021



# *Suture-mediated vs plug based closure device: our strategy*

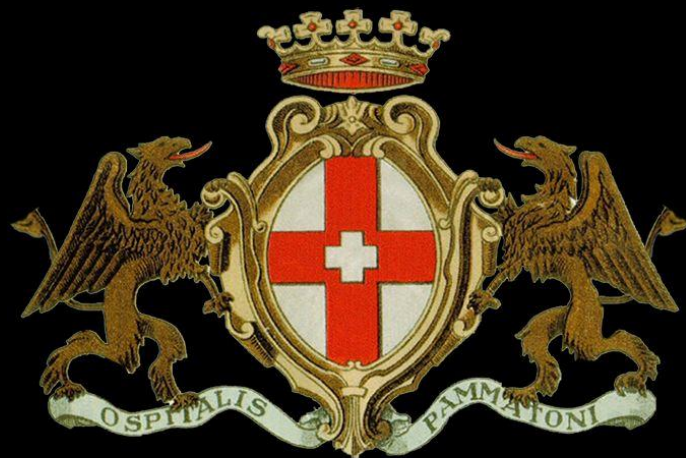
- Duplex US puncture 100%
- ProGlide first choice  
(additional device in case of partial efficacy)
- Manta in case of severe access vessel tortuosity/occlusion  
(only post-closure)



# Conclusions

- The totally percutaneous access for aortic procedures is a well-established option after an appropriate patient selection
- Technical success is multifactorial; however operator's experience allows to overcome most of the previously identified anatomical predictors of percutaneous access failure
- The Perclose ProGlide VCD is the standard of care for PEVAR
- New generation vascular closure device can be effective in additionally increase the applicability of percutaneous access





**OSPEDALE POLICLINICO SAN MARTINO**

Sistema Sanitario Regione Liguria

*Istituto di Ricovero e Cura a Carattere Scientifico*