

The logo for LINC (Limb Ischemia Network Consortium) features the letters 'LINC' in a white, sans-serif font. To the left of the text is a stylized graphic consisting of several overlapping, curved lines in shades of red, orange, and yellow, resembling a flame or a dynamic, flowing shape.

LINC

Management of Large Bore Access, Closure, and Acute Limb Ischemia in Structural Heart and Hemodynamic Support Cases

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Disclosures:

- **Phillips/Volcano/Spectranetics Corporation:** Medical advisory board, consultant, speaker, educational grants, trainer, investigator
- **Boston Scientific:** Medical advisory board, speaker, fellow training faculty, educational grants, trainer, investigator
- **Abbott:** Medical advisory board, speaker, research funding, educational grants, trainer, investigator
- **Medtronic Corporation:** speaker, educational grants, investigator
- **St Jude:** investigator
- **Bard:** Medical Advisory Board, Continuum Study Clinical Events Committee, Investigator
- **Ostialcorp:** Medical Advisory Board; stock holder
- **Asia Pacific Medical Technologies:** Stock Holder
- **Endoshape, Inc.:** Stock Holder
- **Morris Innovative:** Stock holder
- **Vasorum:** Stock Holder

Peripheral Vascular Skill Sets for Large Bore Access and Closure are Necessary for :

- TAVR
- EVAR
- TEVAR
- (ASD, VSD, PFO closure)
- Hemodynamic Support (ECMO; Impella)
- **Above typically 14F-18F, ECMO up to 24F!**

All Structural Heart Interventionists must possess basic peripheral vascular interventional skills!!

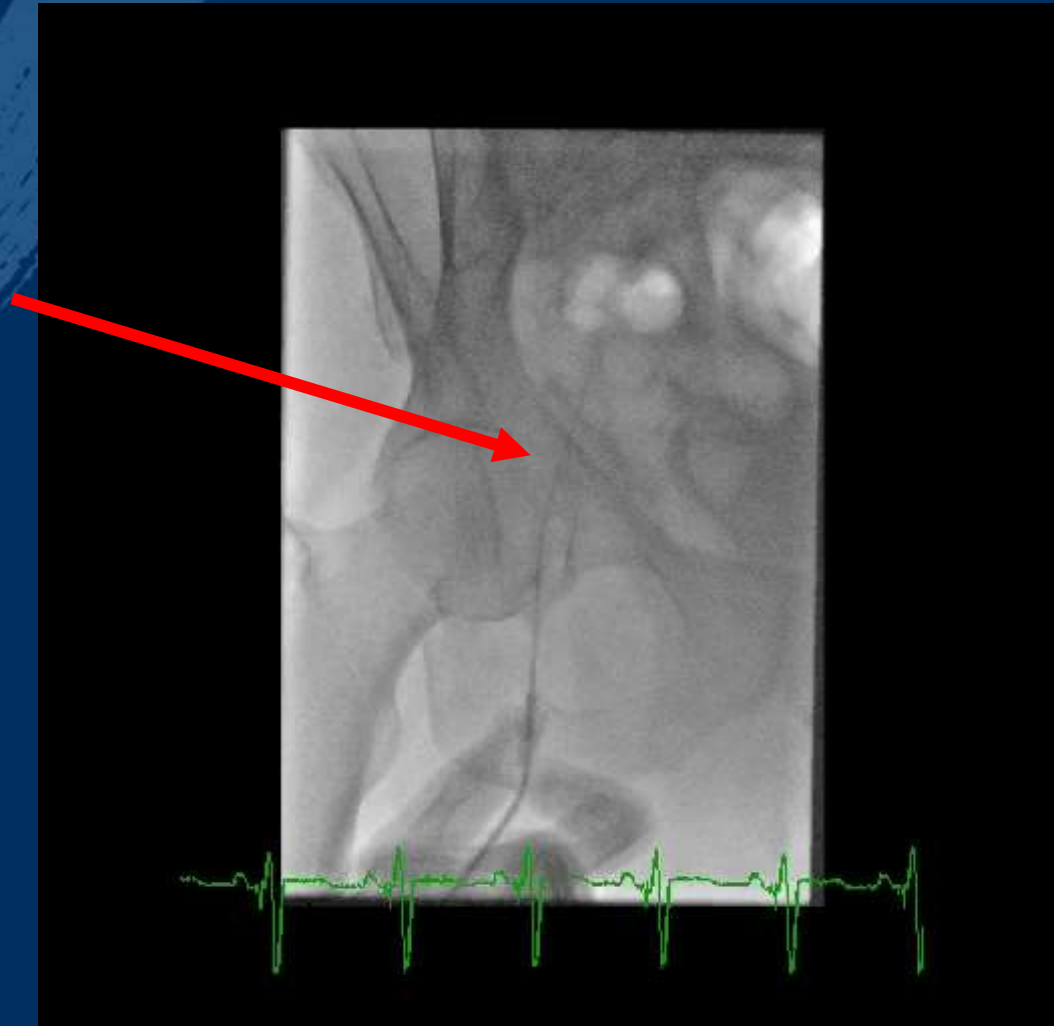
In the US, most, however do not have these skill sets.

Large Bore Closure Begins With Pre-procedure Evaluation and Access

- CTA or prior angiogram
- US
- Micro-puncture access (US guided if available)
- Understanding of vascular anatomy for alternative access should complications occur

Baseline Angiography After Access is mandatory!!

**Bulky plaque
at puncture site**



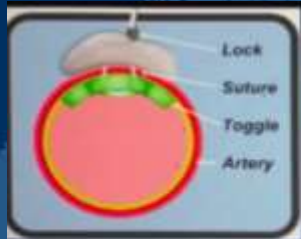
“Pre-Closure” Options

- Perclose Prostar[®]
- Perclose Proglide[®]



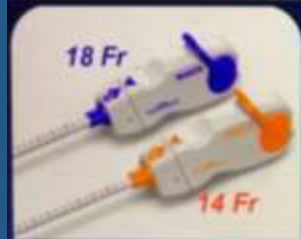
Post-Procedure Closure

- **Manta[®]**



Achieves hemostasis by "sandwiching" arteriotomy

- Poly-lactic-co-glycolic acid Intra-arterial toggle
- Extra-vascular bovine collagen plug
- 2-0 Polyester Suture
- 316L Stainless Steel Suture Lock
- Over-the wire design
- 14 F MANTA (maximum OD/profile of 18F)
- 18F MANTA (maximum OD/profile of 25F).



CE Mark Study

- 50 patients
- Jul2015-Feb2016

US IDE Pivotal Study

- 263 patients
- Nov2016-Dec2017

Finland Registry Study (Ongoing)

Planned 500-Patient EU Registry Study

- Beginning Q1 2018

EU Post-Market Surveillance



Surgical option: open surgical cut down and repair

Failed Closure: Persistent Leak

Options:

- Additional closure devices (even if wire access is maintained, additional devices may not pass.)
- Covered Stent mediated closure (requires second access point)

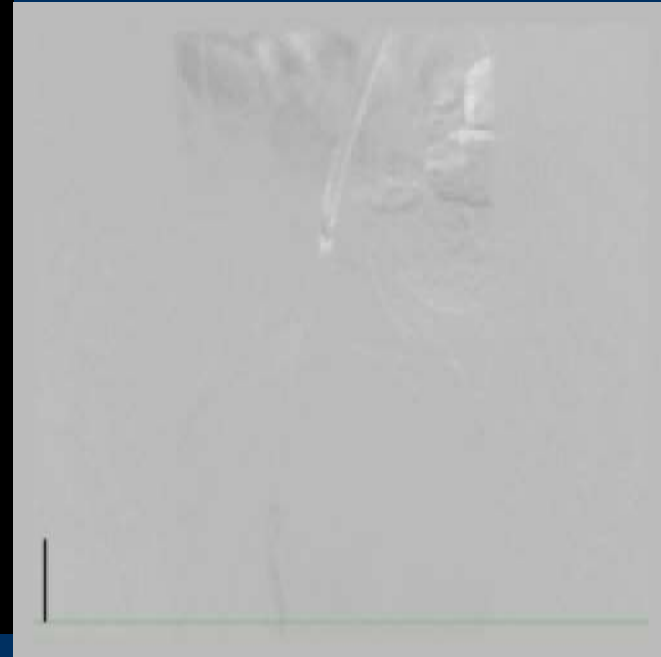
Covered Stent Mediated Closure



Micro-puncture access
("preclosed" with 2
Perclose devices.



Failed closure in spite
of successful capture of
both Perclose devices



US guided retrograde
contralateral CFA
access, sheath and
covered stent

Failed Closure: Acute Vessel Occlusion

(Following TAVR sheath removal)



Site closed with 2 Perclose Proglide devices; ACT > 300 (Occlusive 14F TAVR sheath)



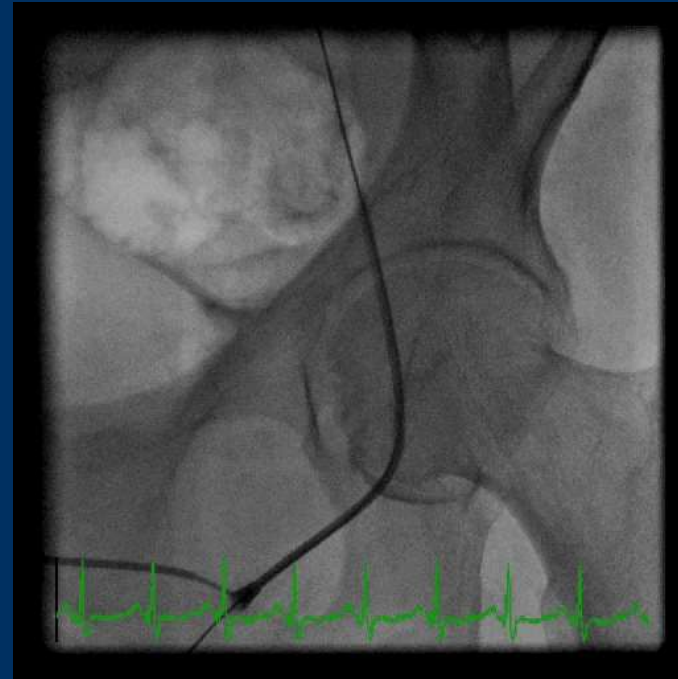
US guided retrograde micro-puncture distal CFA access, sheath and SE stent placement.

Acute Limb Ischemia Following Impella CP Insertion

(unable to remove CP pump due to cardiogenic shock)



Micro-puncture access left CFA



SFA 100% but caliber OK and
profundal run-off good

**Shortly after urgent Impella CP pump placement,
LLE cold, cyanotic and painful**

Contralateral Access-Diseased EIA



**Micro-puncture
access R CFA**



**Obstruction
by 6F sheath**



**POBA
to prevent
RLE acute
ischemia**



Adequate flow

Left side Antegrade Profunda Access



**US guided left profunda
micro-puncture access**



Small antegrade sheath

Right CFA to Left Profunda

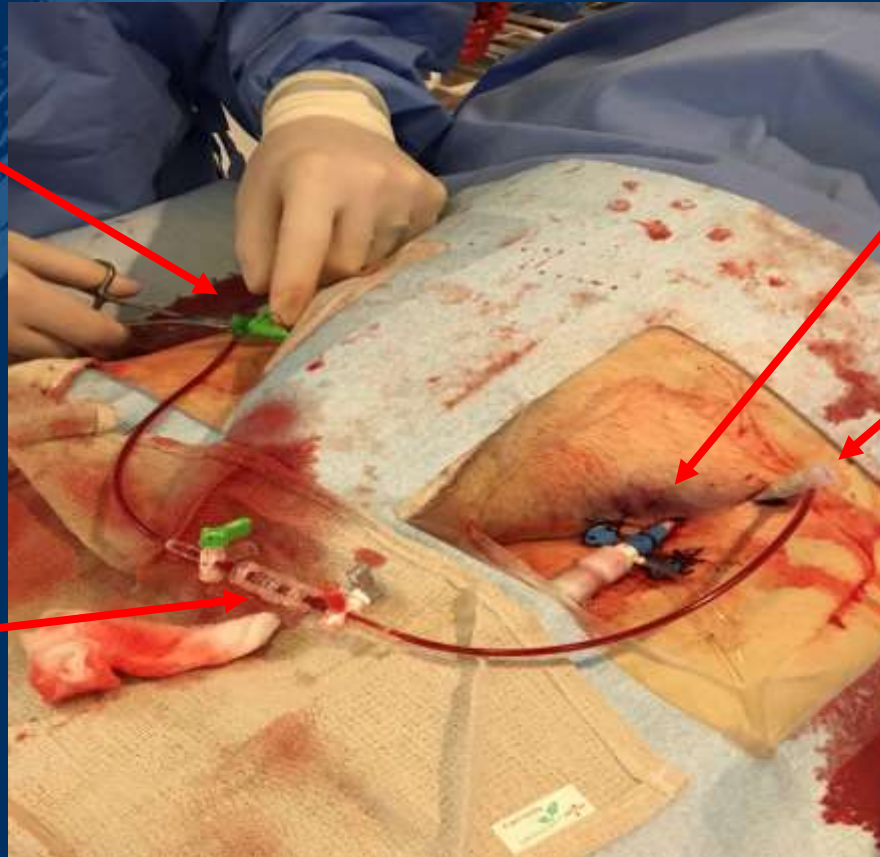
External Bypass Below Impella Sheath

Right SFA sheath

Impella sheath

Antegrade left profunda sheath

Male to male adapter



Conclusions

- Vascular complications will invariably be more frequent with large bore access and closure
- Know the vascular anatomy before hand, have a plan for access and closure, and be prepared for complications
- Be proficient with micro-puncture access and comfortable with gaining access at all possible vascular entry sites
- Be competent with available large bore closure devices and have a plan to manage any possible vascular complications if and when they fail.

Thank You



Deborah



NCVH
New Cardiovascular Horizons

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