

Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest

دبي

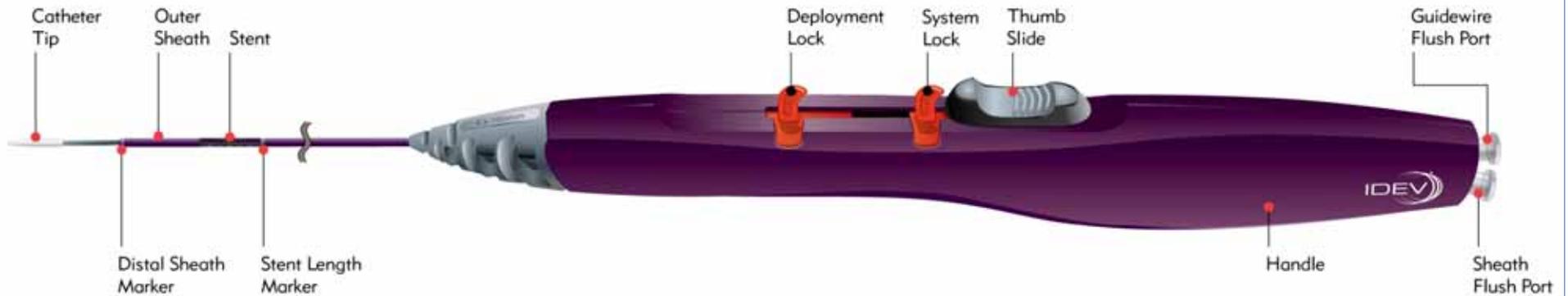
LINC

Optimal implantation deployment for optimal outcomes with SUPERA

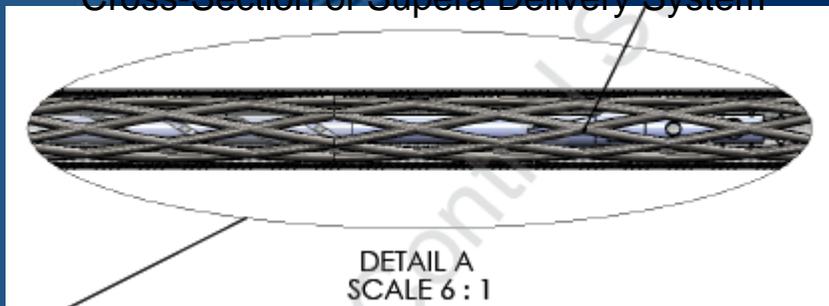
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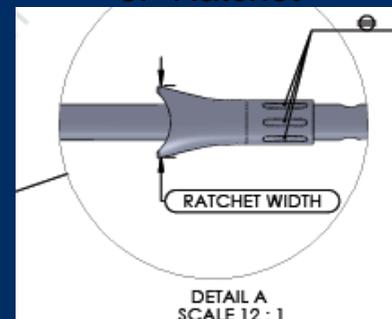
Delivery System



Cross-Section of Supera Delivery System



6F Ratchet



7F Ratchet

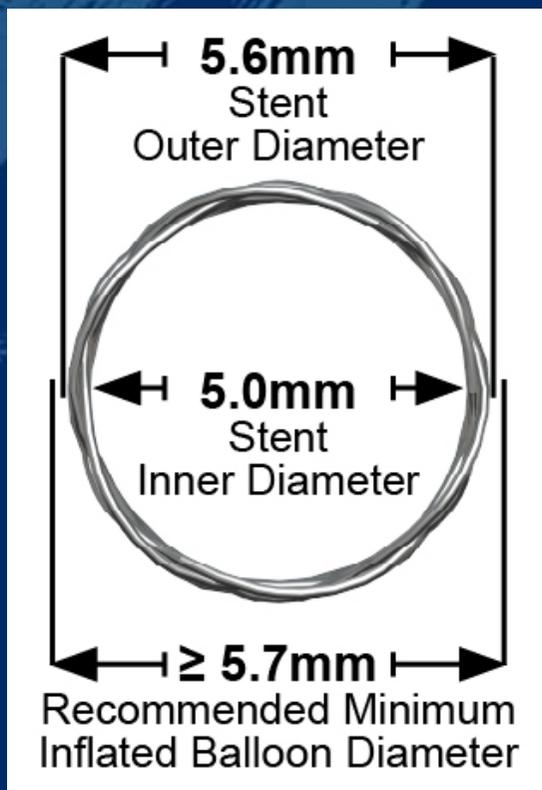


Ratchet (6F & 7F)

- Function → drives the stent out of the stent catheter
- Method → 1-way pick-up; as the thumb slide is pushed forward, the ratchet connects with the constrained stent wire(s) and pushes the entire stent forward
- Sharp component and is controlled by the Deployment Lock

Supera Sizing Chart

- Supera's label diameter = Inner Diameter
- Match the Supera label diameter (ID) to the RVD



Do NOT Oversize Supera

**e.g., the RVD is assessed at 5mm,
do NOT choose the 6mm Supera**

Please refer to and follow stent sizing guidelines per the IFU.

Preparing the Vessel to Accept Supera

- **REQUIREMENT:** Pre-Dilate the lesion with PTA before Supera is introduced
- Pre-Dilation is a **MUST** for optimal Supera deployment
- Evaluate **QUALITY** of pre-dilation
 - Assess for refractory locations
 - Awareness of recoil
 - Be attentive to calcified segments
- Why?
 - If pre-dil is not to the right diameter to accept Supera's OD, then elongation occurs
 - Closed-loop wire design dictates this behavior

invest the time to prepare artery properly
Deployment experience will be optimal

Most Importantly → Patient will receive the most benefit

Pre-Dilation Sizing Table

Labeled Stent Diameter (Inner Diameter)	Outer Stent Diameter	Recommended Minimum Inflated Balloon Diameter
4.0mm	4.6mm	≥4.7mm
5.0mm	5.6mm	≥5.7mm
6.0mm	6.7mm	≥6.8mm
7.0mm	7.7mm	≥7.8mm
8.0mm	8.8mm	≥8.9mm

- Effective pre-dilation creates a lumen designed to accept the OD of Supera. Supera's ID is matched to the patient's RVD
- The result is:
 - optimal blood flow
 - minimized chronic inflammatory responses
 - strongest and most flexible stent in the market holding the artery open and dynamically adapting to movement/motion of the anatomy

Sizing Stents- Oversize or Right-Size?

Standard Nitinol Stent

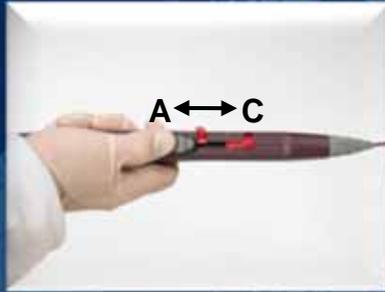
Unconstrained Diameter (mm)	Recommend RVD (mm)
5.0	3.5 – 4.5
6.0	4.3 – 5.4
7.0	5.0 – 6.3
8.0	5.7 – 7.3
9.0	6.4 – 8.2
10.0	7.1 – 9.1

Supera

Unconstrained Diameter (mm)	Recommended RVD (mm)
4.0 (4.6 OD)	4.0
5.0 (5.6 OD)	5.0
6.0 (6.7 OD)	6.0
7.0 (7.7 OD)	7.0
8.0 (8.9 OD)	8.0

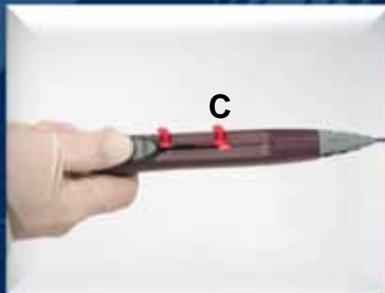
Stent Deployment

1



Retract thumb slide to proximal-most position (A), then advance distally to deployment lock (C). **Repeat in slow controlled motion.** Repeat under fluoroscopy until the proximal end of the stent is distal to the stent driver.

2



When final deployment is desired, retract thumb slide into the proximal-most position and **turn deployment lock (C) to the left.**

3



Under fluoroscopy **advance the thumb** slide to complete stent deployment.

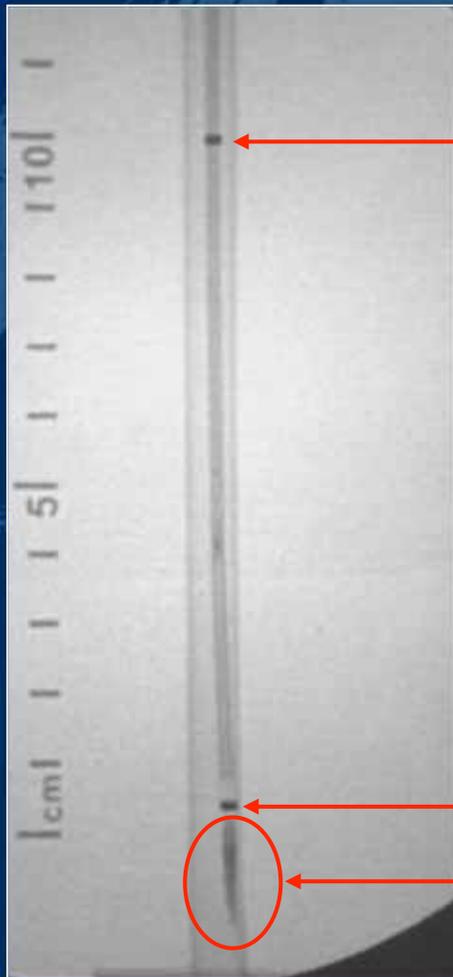
After Deployment

1



Once deployment has been confirmed, under fluoroscopy, gently **retract the thumb slide** to the proximal-most position and rotate system lock to the right. Withdraw the stent delivery system over the guidewire and out of the introducer sheath.

Locate Distal and Proximal Markers



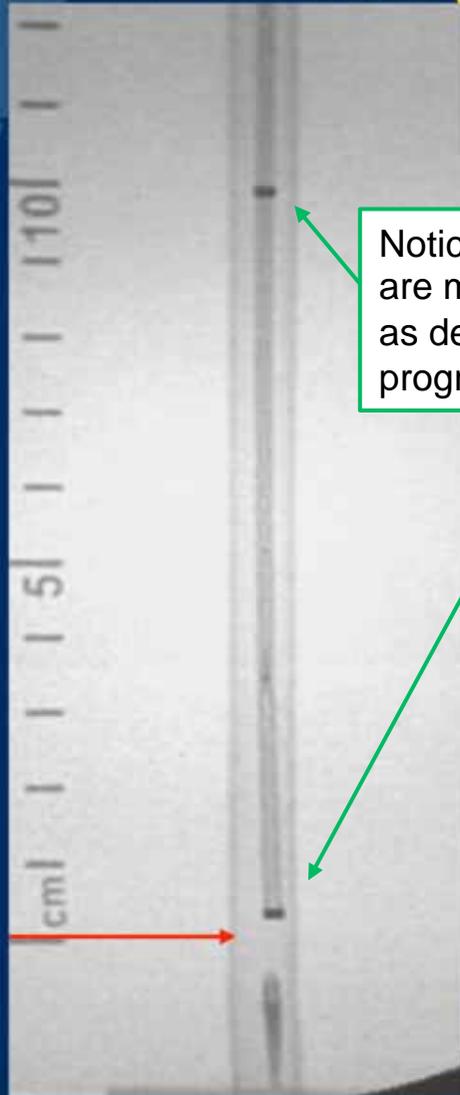
Proximal Marker

Distal Marker

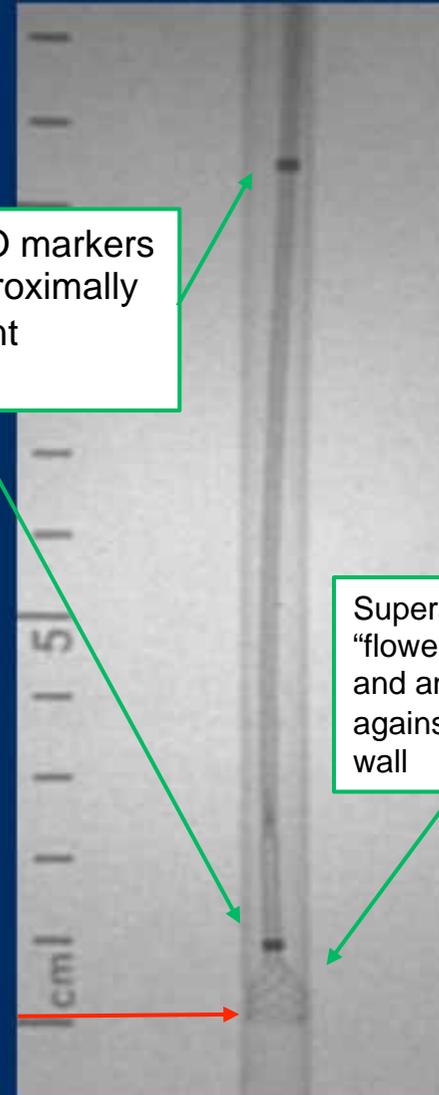
Catheter Tip

- The radiopaque markers on the stent delivery catheter denote the **nominal length** of the deployed stent (assuming effective vessel prep is completed)
- The RO markers are only for positioning and identifying the distal landing zone
- Once deployment begins, the RO markers are ignored
- Then the **focus is on the Supera!**

First Throw Landing Location



Notice the RO markers are moving proximally as deployment progresses



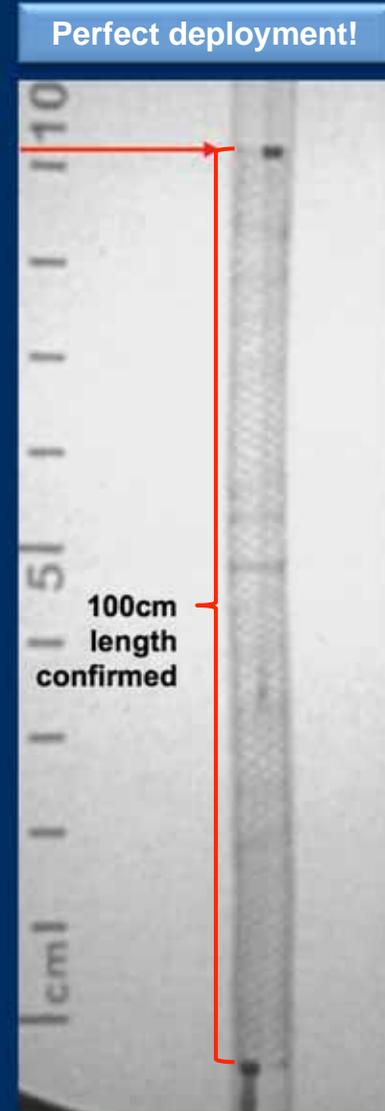
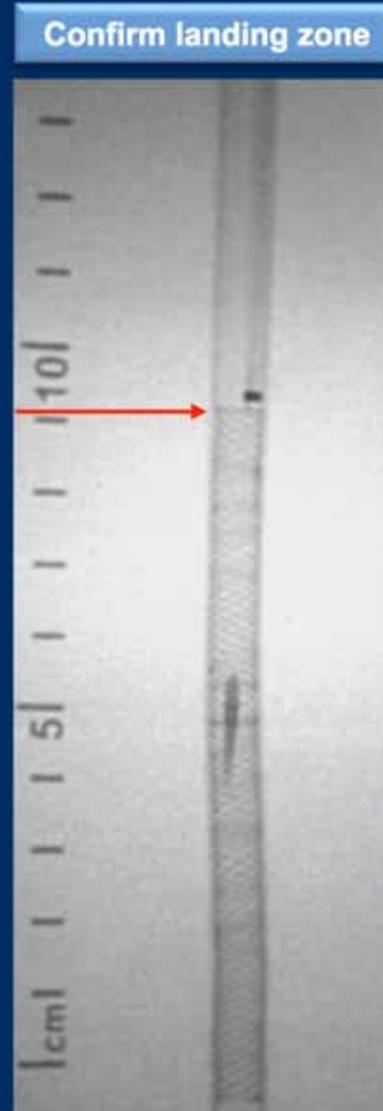
Supera "flowered" and anchored against the wall

Identify Proximal Landing Zone

- Use the “1/3” rule
- Constrained stent is approximately 3x longer than deployed stent
 - e.g. 8cm stent is about 24cm in the catheter
- To estimate landing zone at end of deployment
 - With 3 cm of constrained stent remaining, there is 1 cm of stent left to be deployed

Understanding the 1/3 Rule

- ① End of stent in the catheter
- ② Apply the 1/3 Rule
- ③ Locate proximal landing zone



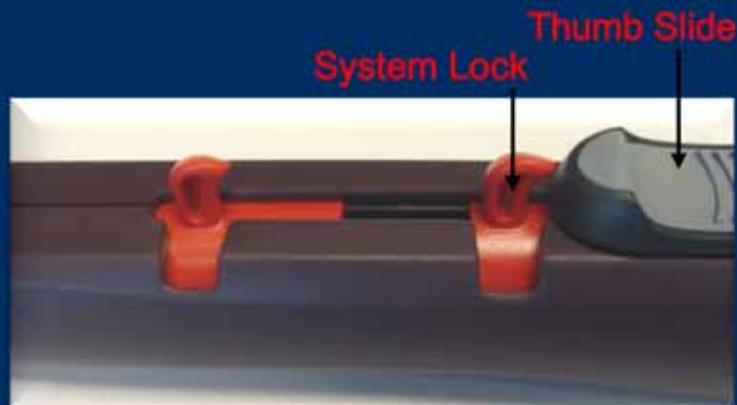
Final Step

Once deployment has been confirmed, under fluoroscopy (magnification suggested), gently **retract the thumb slide to the proximal-most position and rotate the system lock to the right.**

Closed Catheter Tip Position



Secured Thumb Slide

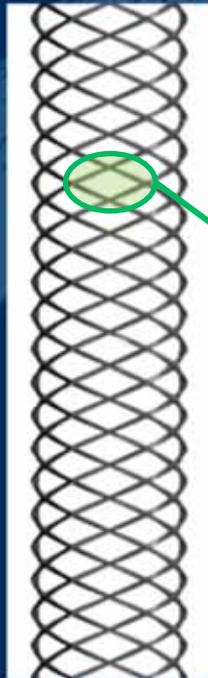


Tip Closed/Locked



Stent Deployment

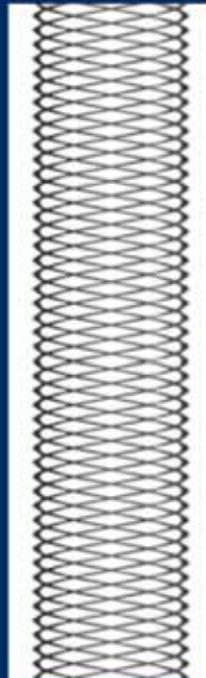
Nominal/Optimal Interwoven Segments ("Horizontal Diamonds")



~2X wider horizontally than the height

Width : Height ~2:1

Stacked Interwoven Segments ("Compressed Diamonds")



As the Width : Height ratio gets larger, radial strength may not change much, but the stent is shorter overall

"Smoke rings"

Elongated Interwoven Segments ("Vertical Diamonds")



As the Width : Height ratio gets closer, radial strength is less and the stent overall is longer

Deployment Behavior- Supera Delivery Catheter

- Supera delivery system **pushes the stent out** the end of the catheter tip
- Once Supera **is anchored at the distal landing zone** and as the thumb slide is pushed forward, the outer stent sheath **moves backward** and out of the introducer
 - Anchored = After the distal stent “flowers” and the 1st 0.5 – 1cm oppose the artery wall
 - E.g. If the thumb slide is pushed 3cm forward, 1cm of stent is pushed out (deployed), and the remaining 2cm is the outer stent sheath backing out
- **The back-out of the outer stent sheath HAS TO happen**
 - The physician may slow this back-out by braking the outer stent sheath with the left hand to customize the cell configuration
- **The outer stent sheath is never pulled during deployment**

Summary

- Choose Supera Size (label = ID) based on RVD
- *Pre-dil...pre-dil...pre-dil...to* > than the OD of Supera
- Assess the quality of the pre-dil & recommend additional dilation if necessary
- Mag up during deployment to improve visibility
- Advance the thumb slide slowly and evenly
 - Physician may choose shorter throws with the thumb slide
- Allow the outer stent sheath to back-out with thumb slide advancement
- Post-dilation is recommended

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