# TECHNICAL PROPERTIES OF NITINOL:

# The Ideal Alloy for Venous Stenting?

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# Disclosure

Speaker name: Erin Murphy, MD FACS

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I have the following potential conflicts of interest to report:

X Consulting: Medtronic, Boston Scientific, Philips, Vesper, Cook

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest

# VENOUS STENT LANDSCAPE

## Stent Design

- Similarities exist between arterial, venous, and non-vascular stents but stent design for one indication may not necessarily be appropriate for all indications
- Focus on improving outcomes of venous obstruction has led to the development of venous specific stents
  - EU (CE Mark): 7 dedicated venous stents
  - US (FDA approval and various phases of IDE trial): 4 dedicated venous stents (Trials: VIRTUS, VIVO, VERNACULAR, and ABRE)[1]

[1]Murphy, E. H. (2019, July). Surveying the 2019 Venous Stent Landscape. *Endovascular Today* , *18*(7), 53–64.

# VENOUS STENTS

Open-Cell

Closed-Cell

Nitinol

Elgiloy

Stainless Steel

**Stents Currently used in Venous Space [1]**

| Device | CE Mark | FDA Approval |
|---|---|---|
| **Abre**™ Venous Self-Expanding Stent System (Medtronic) | 2017 | In progress |
| Sinus–Obliquus self-expanding nitinol stent system (optimed Medizinische Instrumente GmbH) | 2015 | --- |
| Sinus–Venous self-expanding nitinol stent system (optimed Medizinische Instrumente GmbH) | 2013 | --- |
| **Venovo**® Venous Stent System (BD Interventional) | 2015 | 2019 |
| **Zilver® Vena**™ Self-Expanding Stent (Cook Medical) | 2010 | In progress |
| **Vici** Venous Stent™ System (Boston Scientific Corporation) | 2013 | 2019 |
| Blueflow (plus medica GmbH & Co. KG) | 2018 | --- |
| Wallstent™ Endoprosthesis (Boston Scientific Corporation) | 2015 | ++ |
| Cook-Z® Tracheobronchial Stent (Cook Medical) | --- | ++ |

++In progress of applying for FDA approval outside of IDE trial

[1]Murphy, E. H. (2019, July). Surveying the 2019 Venous Stent Landscape. *Endovascular Today*, *18*(7), 53–64.

***Disclaimer:*** *Stents noted as "In progress" are not commercially available in the United States.*

# VENOUS STENT LANDSCAPE

## Why is venous stenting different?

| Stent Design Influences | Arteries | Veins | Venous Stent Design Implications |
|---|---|---|---|
| Nature of Disease | Atherosclerotic and aneurysmal, high pressure | Thrombotic & compressive, low pressure | Radial Resistive Force and Compression Resistance |
| Vessel Diameter | 5 mm – 14 mm | 10 mm – 20 mm | Range of large diameters |
| Vessel Flexion | Muscular and straight | Tortuous | High flexibility in pelvic region, stent forces with leg extension/flexion |
| Patient Age | 65+ | 30+ | Long-term durability |
| Flow Dynamics | High flow | Low flow | • Need for precise landing<br>• Need large cell design to mitigate clot formation at confluences |

Young age of venous occlusion patients (typically 30+ years of age) may present additional considerations on duration of stent performance.[1]



1 Mousa AY, AbuRahma AF. May-Thurner Syndrome: An update and review. *Ann Vasc Surg* 2013; 27: 992.

# VENOUS NITINOL STENT DESIGN

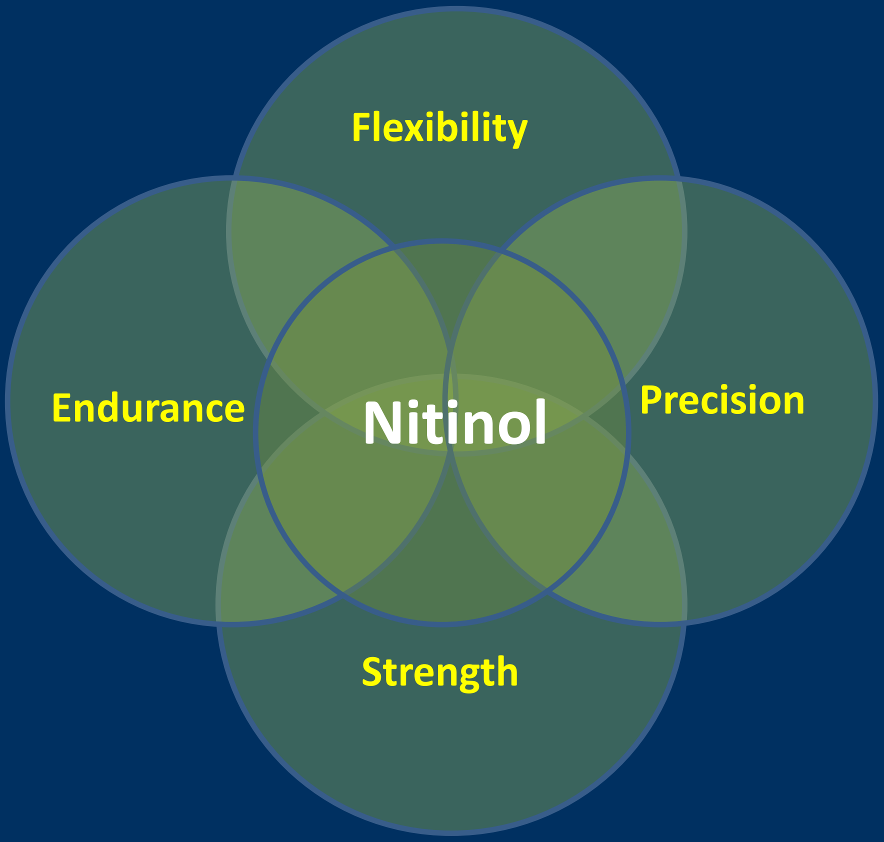
## How can Nitinol enable stent design for venous system?

Anatomical differences between the arterial and venous system has led to specific stent designs to meet the demands of veins.

All new designs are nitinol

Nitinol properties needed for venous stent design attributes:

- Flexibility
- Endurance
- Precision
- Strength



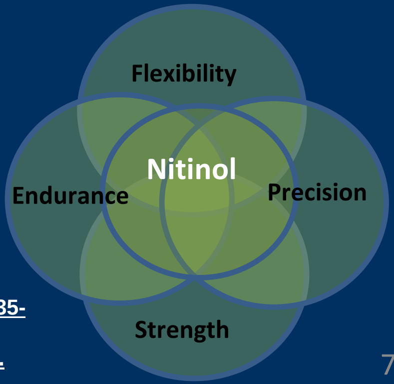
# TECHNICAL PROPERTIES OF NITINOL

## Flexibility, Endurance, & Precision Capabilities

**Stents made with nitinol can recover from different forces and can be deployed with more precision due to its unique alloy abilities:**

- **Shape Memory:** Response of materials to temperature (thermal transformation to original shape responsible for self-expanding nature ).[1,2]

- **Superelasticity:** The ability of a material to **fully recover** following large deformations or force (stress).[1,2]




[1] Duerig, T., D. Tolomeo and M. Wholey (2000). "An overview of superelastic stent design." Minimally invasive therapy & allied technologies **9(3-4): 235-246.**
[2]Stoeckel, D., A. Pelton and T. Duerig (2004). "Self-expanding nitinol stents: material and design considerations." European radiology **14(2): 292-301.**

# TECHNICAL PROPERTIES OF NITINOL

## Clinical Impact:

- One of the few alloys that can be **superelastic at body temp**[1]
- Superelastic nitinol **changes crystal structure** (austenite to martensite) in response to load[1] and then can change back when load is removed
  - Nitinol stent **self-expansion** upon deployment from sheath[1,2] and and **original shape recovery after deformation (superelasticity)**.[1,2]
- Ideally superelasticity of nitinol **limit lifetime displacement controlled fatigue of the stent to endure beyond ordinary metals[1]**
- Superelastic properties **allow for enhancements in non-braided designs**
  - Improves deployment accuracy/presicion and avoids foreshortening[3]
- Combination of **nitinol plus key stent design features such as open-cell[3] strut[1,2] & connector[2,3] design** = flexibility, presicion, durability & strength

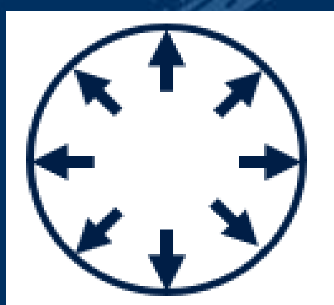
[1] Duerig, T., D. Tolomeo and M. Wholey (2000). "An overview of superelastic stent design." Minimally invasive therapy & allied technologies **9(3-4): 235-246.**
[2]Stoeckel, D., A. Pelton and T. Duerig (2004). "Self-expanding nitinol stents: material and design considerations." European Radiology **14(2): 292-301.**
[3]Murphy, E. H. (2019, July). Surveying the 2019 Venous Stent Landscape. *Endovascular Today* , *18*(7), 53–64.

# TECHNICAL PROPERTIES OF NITINOL: STRENGTH CAPABILITY

- Self-expanding alloy producing strength with **chronic outward force**[1,2]
- Ability to **resist vessel recoil** and **withstand compressive external forces** with key stent design features[1]

## Chronic Outward Force:

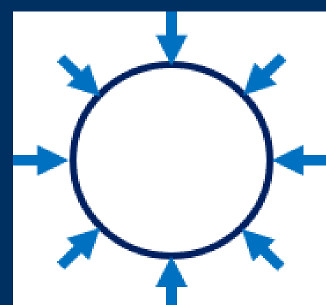
**Radial force when the stent is expanding**



After deployment, continuing opening force of the stent acting on the vessel wall.[1,2]

## Radial Resistive Force:

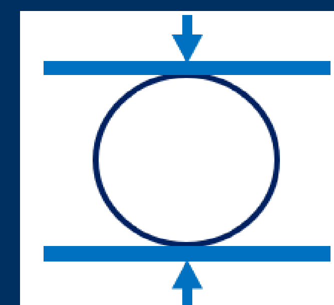
**Radial force when the stent is contracting**



The forces generated by the stent to resist contraction (vessel recoil)[2]

## Compression Resistance:

**Force when stent is laterally compressed**



Ability to resist compressive or crushing forces (i.e. compression from overlying vessel)[1]

Images recreated by Medtronic

**Stent w/o post-dilation**

**Stent With post-dilation**

[1] Duerig, T., D. Tolomeo and M. Wholey (2000). "An overview of superelastic stent design." Minimally invasive therapy & allied technologies **9(3-4): 235-246**
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# TECHNICAL PROPERTIES OF NITINOL

## Nitinol alloy can be reinforced with balloon dilation techniques:

| Nitinol Stent without post-deployment balloon dilation | Nitinol Stent with post-deployment balloon dilation |
|---|---|
| ▪ Chronic outward force is achieved once the stent is deployed<br>▪ Stent will attempt to reach nominal size in vessel<br>▪ Primary strength = Chronic Outward Force (minimum stent force)[1] | ▪ Radial Resistive Force achieved by transforming crystal alloy structure of the stent with balloon dilation<br>▪ Primary strength = Radial Resistive Force (maximum stent force) [1]<br>  ▪ **Radial Resistive Force is often 1.5x – 2x higher than Chronic Outward Force**[2]<br>  ▪ Key stent feature when treating Post-Thrombotic vessels<br>  ▪ Achieved by post-dilating stent to nominal diameter [1] |

**Clinical Impact on Venous Stenting:**

- **Post-dilation allows for full expansion to nominal diameter at maximum strength**
- Post-dilation of nitinol stents changes nitinol structure to **improve radial resistive force and the ability to resist compressive force**
- Actual diameter gain after post-dilation of a nitinol stent will depend on vessel stiffness[2]

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# TECHNICAL PROPERTIES OF NITINOL

## Summary

**With proper material, stent design and technique we can perhaps achieve the flexibility strength, precision, and endurance stents need in the venous system:**

- **Nitinol sets us up with has the ability to fully recover following large deformations[1,2] contributing to strength, flexibility, durability and expanding options for stent design**
- **Key stent design features combined with nitinol properties can improve stent's ability to withstand vessel recoil and compressive forces[1] and endure deformations over time**
- **Post-dilation makes a nitinol stent stronger through the transformation of crystal alloy structure[1]**


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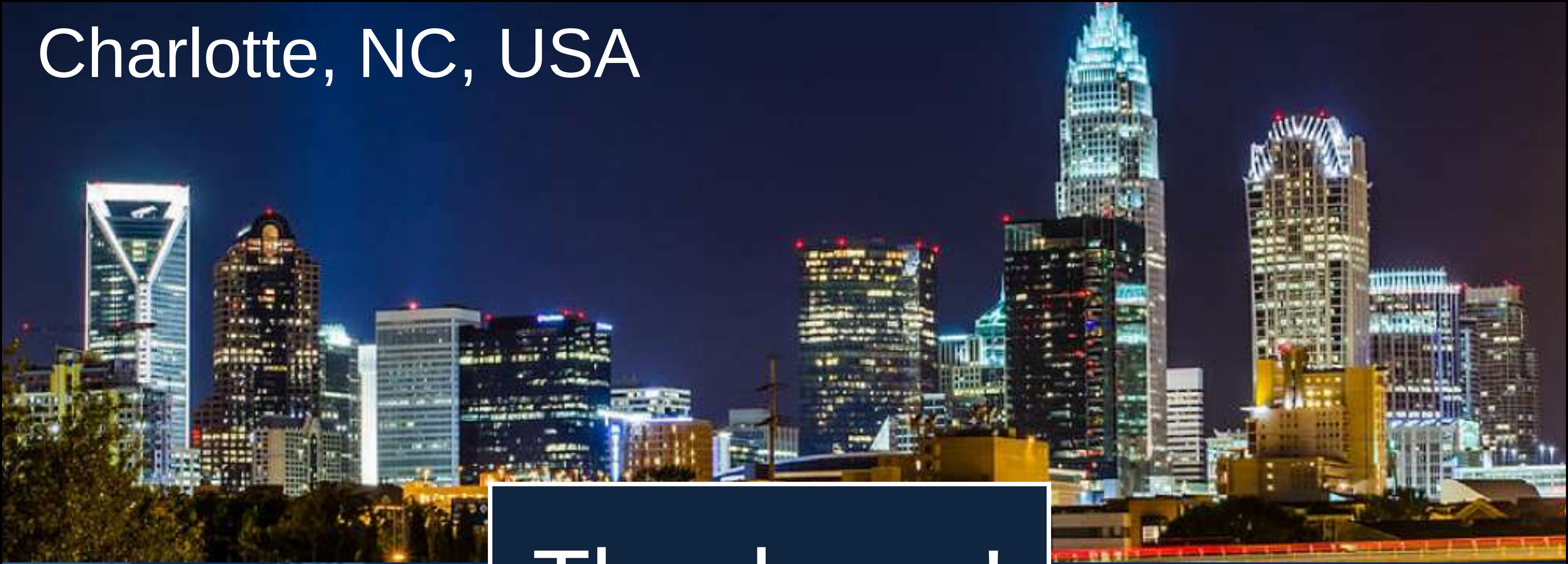
[2]Duerig, T., D. Tolomeo and M. Wholey (2000). "An overview of superelastic stent design." Minimally invasive therapy & allied technologies **9(3-4): 235-246.**

# Charlotte, NC, USA



# Thank you!

Carolinas HealthCare System

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