Introduction to Self-Expanding Stents

Introduction, Modeling and Mechanics of Self-Expanding Stents

Self Expanding Stents

Ansys

Introduction

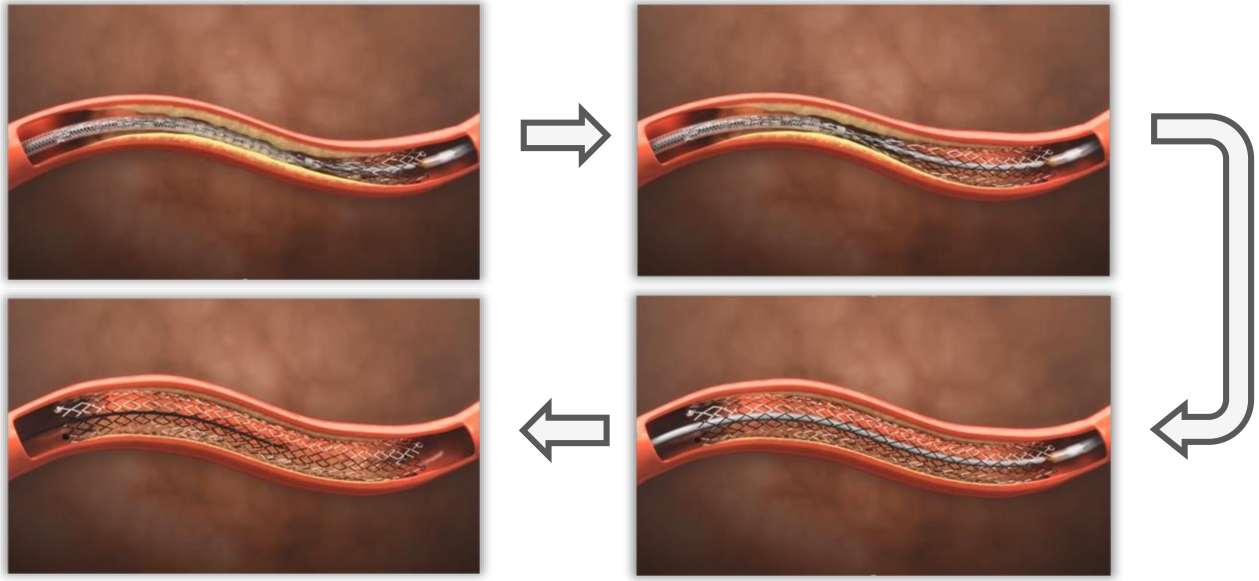
- In this and the next 4 lessons of this section we will progress along these topics, getting into the details in the respective sections;
  - Introduction to the self-expanding stent and drawing parallels between physical manufacture and setup and simulation based “manufacture” and setup
  - Geometric Representation of the Stent
  - Material Modeling - Shape Memory Alloy – Nitinol Characteristics
  - Stent Expansion, Shape Setting, and Crimp
    - Expansion to desired Diameter
    - Shape Set annealing of stent
    - Crimping to the desired delivery diameter
  - … Continued

Introduction (continued)

- Preliminary Stent Design Assessments
  - Before proceeding further with a stent deployment into a simulated vessel, which will be computationally more expense, these preliminary assessments can determine if the design is viable.
  - Verification of little to no plastic strain during crimp - A stent that plastically deforms during crimp may not return to original shape.
  - Device Crimps to required diameter adequately without buckling or interference – Metal to Metal contact can cause locally high strains, disrupt the stents finish or coating and is typically not desired.
  - Radial reaction forces of the stent during inward and outward changes in diameter to investigate the radial resistive force and the chronic outward force. We will discuss this in detail in an upcoming lesson.

Mechanics of Self-Expanding Stents – Big Picture

- Self-Expanding stent in its free state is slightly larger than the vessel diameter, typically 10%, then it is crimped and constrained typically in a sheath to a smaller diameter for delivery.
- The sheath is retracted during delivery and the stent recovers its original shape in apposition with the vessel wall.

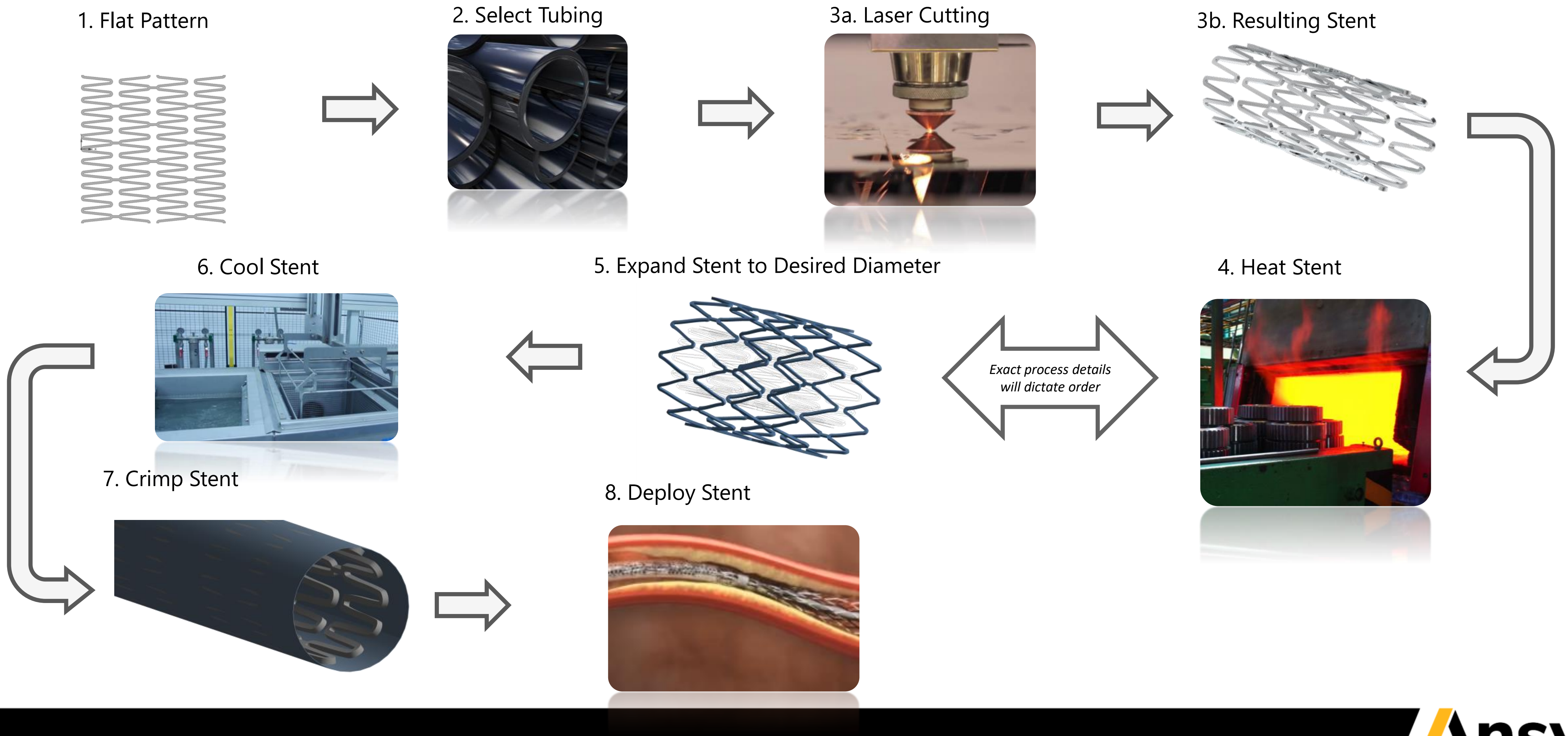


Mechanics of Self-Expanding Stents – Overview of *Physical* Steps

Note: The following are the general steps in the typical physical fabrication to deployment steps of a self-expanding stent. Note the focus here is on capturing the stent and material behavior, so additional steps such as polish, disinfect, etc. are omitted. Also, different companies may use different procedures, such as expanding stent at room temperature to desired shape and then shape setting.

1. Construction of a stent flat pattern design.
2. Select Nitinol tubing of desired wall thickness and diameters.
3. Laser cut the stent from the tubing using stent flat pattern.
4. Heat stent to typically 500 °C to 550 °C.
5. Mechanical Expand Stent to desired diameter. (Note, steps 4 and 5 may be changed inorder or repeated more than once, and the actual process depends on the stent manufacturer).
6. Cool Stent (typically quickly) to shape-set anneal the stent into desired final diameter, keeping constrained during this process.
7. Crimp stent to delivery system/sheath diameter at room temperature or cooler and stent undergoes superelastic deformation.
8. Retract delivery system/sheath inside vessel resulting is elastic recoil/deployment.

Mechanics of Self-Expanding Stents – Overview of *Physical* Steps



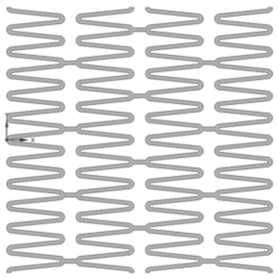
Mechanics of Self-Expanding Stents – Overview of *Simulation* Steps

The corresponding simulation steps are performed to mimic the physical steps;

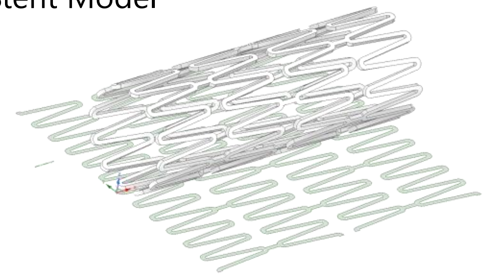
1. Start with stent flat pattern design curves.
2. Wrap and expand stent to form 3D solid CAD model.
3. Expand stent to desired free shape diameter.
4. Pass deformed stent shape to a new analysis, effectively shape-set annealing the Nitinol to zero stress and strain.
5. Crimp stent to required delivery/sheath diameter and stent undergoes superelastic deformation.
6. Vary sheath diameter to investigate radial forces.
7. Retract delivery system/sheath inside vessel resulting is elastic deployment against vessel wall.

Mechanics of Self-Expanding Stents – Overview of *Simulation* Steps

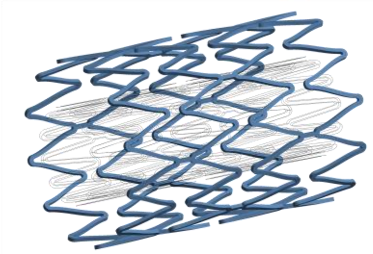
1. Flat Pattern



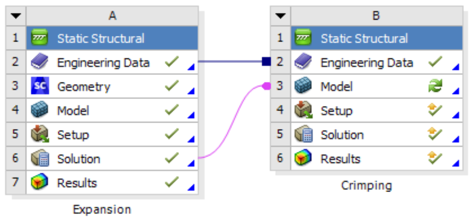
2. Wrap Flat Pattern and form 3D Stent Model



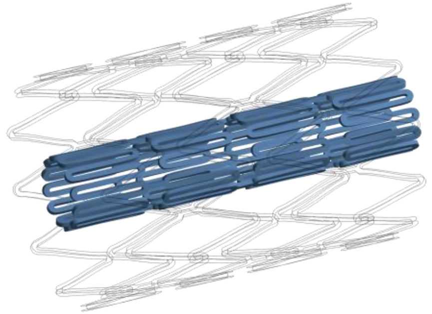
3. Expand Stent to Desired Free Shape Diameter



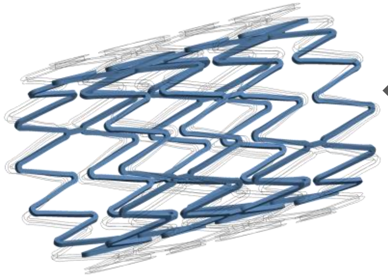
4. Pass to new Analysis System to "Shape Set"



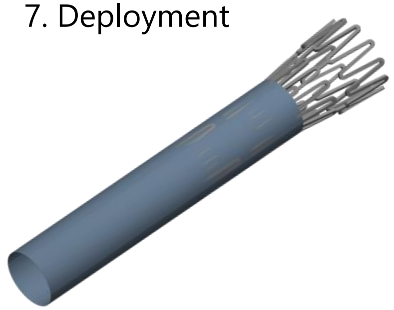
5. Crimp to Delivery Diameter



6. Investigate Radial Forces



7. Deployment



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