Nitinol for Medical Devices



Fundamentals of Shape Memory

- **Nitinol Processing**
- **Design and Application**
 - Where is Nitinol Used?
 - **Medical Device Characteristics**
 - **Design Case Studies**
- **Environmental Effects**

Applications of Nitinol



- 1970 First aircraft applications
- 1975 Orthodontic arches first superelastic application
- 1980 Guidewires
- 1985 Instrument components
- 1990 Stents



Constrained Recovery





Actuators







Actuators

Grado Zero Espace S.l.r.











Thermal Actuation



Dr. Charles Dotter







Biomechanical Compatibility

Elastic Deployment

Thermal Deployment

Kink Resistance

Constancy of Stress

Dynamic Interference

Hysteresis / Biased Stiffness

Fatigue Resistance

Biocompatibility

MR Compatibility

MR Compatibility





Guidewires





Elastic Deployment Kink Resistance Fatigue Resistance Biocompatibility MR Compatibility

SMA, Inc.

Bone Reamers





Kink Resistance Fatigue Resistance Biocompatibility MR Compatibility

Zimmer

Needle/Wire Localizer





Homer Mammalok® (Mitek)

RF Tissue Ablation





RITA Medical Systems, Inc.

Baskets





Elastic Deployment Kink Resistance Dynamic Interference Fatigue Resistance Biocompatibility MR Compatibility

Organ Retrieval





Elastic Deployment Kink Resistance Fatigue Resistance Biocompatibility MR Compatibility

Covidien

Snares





Elastic Deployment Kink Resistance Dynamic Interference Fatigue Resistance Biocompatibility MR Compatibility

Embolic Protection Devices













Abbott

Elastic Deployment Kink Resistance Dynamic Interference Fatigue Resistance Biocompatibility MR Compatibility

Deflectable Instruments





Flexible Micrograsper





Elastic Deployment Kink Resistance Fatigue Resistance Biocompatibility MR Compatibility

Heart Valve Sizer





Deformable Martensite Fatigue Resistance Biocompatibility

St. Jude

Vascular Closure Devices









Perclose



Abbott

Elastic Deployment Kink Resistance Fatigue Resistance Biocompatibility

Suture Anchor







Biomechanical Compatibility Elastic Deployment Biocompatibility MR Compatibility

25

Bone Staples





Biomechanical Compatibility Thermal Deployment Fatigue Resistance Biocompatibility MR Compatibility



BME, Inc.

Spinal Cage





Depuy Spine

Biomechanical Compatibility Elastic Deployment Biocompatibility MR Compatibility

Septal Occlusion







AGA Medical



Biomechanical Compatibility Elastic Deployment Biocompatibility MR Compatibility

Vena Cava Filters













C.R. Bard



Stents use a wide range of properties

Biomechanical Compatibility Elastic or Thermal Deployment Kink Resistance Constancy of Stress Dynamic Interference Hysteresis / Biased Stiffness (COF and Crush Resistance) Fatigue Resistance Biocompatibility MR Compatibility

Neuro Carotid Esophagus Coronary Trachea Biliary Aorta "The human body is a lliac Colon series of tubes just waiting to be stented" Femoral **Urinary Tract** Dr. Paul S. Teirstein, 1998 Popliteal

31



Coil Stents Woven Wire Stents "Wiggle Wire" Stents "Slotted Tube" Stents



Abbott



Medtronic





Design: Case Studies of Engineering Challenges of Selected Nitinol Medical Devices

Case Study 1: Homer Mammalok





$A_{\rm f} = -10^{\circ} {\rm C}, 14^{\circ} {\rm C}, 27^{\circ} {\rm C}$

Challenge: Determine the Effect of A_f on Deployment Stress and Strain

Effect of A_f on Tensile Properties





FEA of Hook Retraction





FEA Strain Distribution



 $\delta A_f = T_T - A_f$



FEA Stress Distribution



 $\delta A_f = T_T - A_f$



Case Study 2: Stents



Challenges: Determine stresses and strains during loading and deployment Optimize *in vivo* forces







Loading into the Catheter





Chronic Outward Force





Radial Resistive Force (RRF)





Stress and Strain Analysis





Stress - Strain Distribution





Radial Force Testing





Is there an ideal A_f for a stent? What are the effects of A_f ?