Plastics Technology for Minimally Invasive Medical Devices

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Definition

Less traumatic alternatives to traditional surgeries

Devices inserted through natural openings or small incisions

Broad application for diagnosis and treatment

Boston Scientific Corporation

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MIS Growth

Population: increasing, aging

New innovations

New treatments

Funding for development

Good medical coverage

New and better materials

and …

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Examples

- **Arthroscopy** – orthopaedic joint
- **Endoscopy** - ear, gallbladder, knee, nose, throat
- **Laparoscopy** - abdominal, gynecologic and urological
- **Video-Assisted Thorascopy** – chest
- **Ureteroscopy** - urological : stones, tumors, strictures
- **Endovascular Surgery** - from within the blood vessel

Ref: Cooper University

Endovascular MIS

2 major problems

- Aneurysm – abnormal dilatation
- Stenosis or occlusion - narrowing

Catheter Access

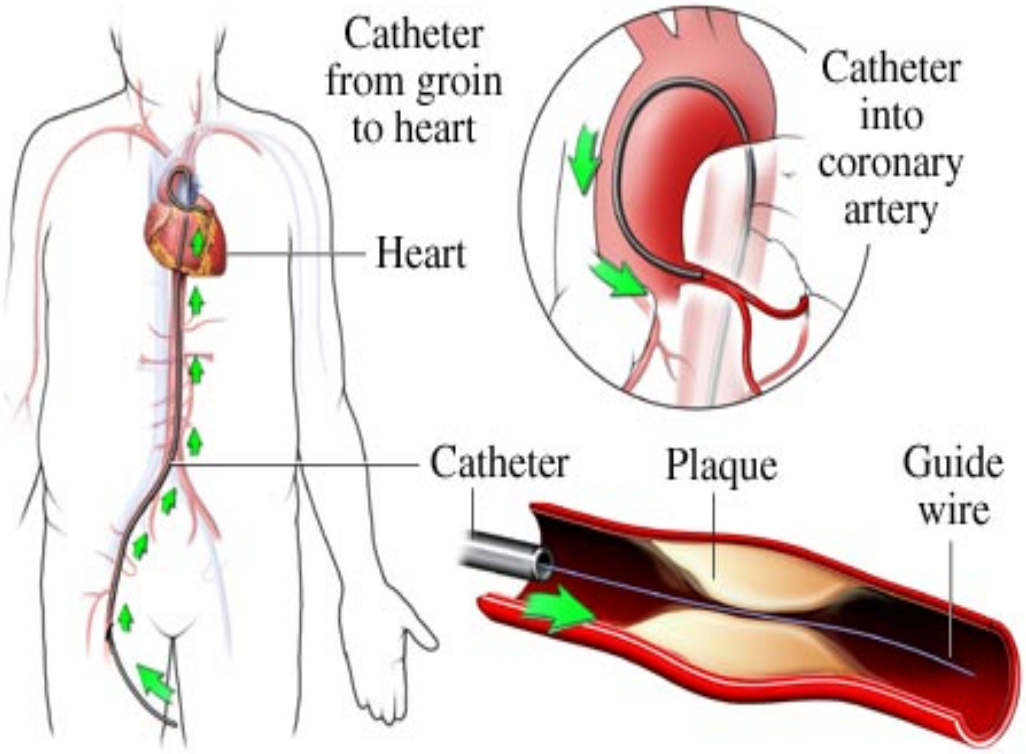
- Tube inserted into a smaller artery
- X-ray imaging may be used
- Femoral artery (groin) access

Common Procedures

- Aneurysm: hollow tube to site & anchor
- Stenosis: angioplasty with stenting

Ref: Cooper University

Common Procedure



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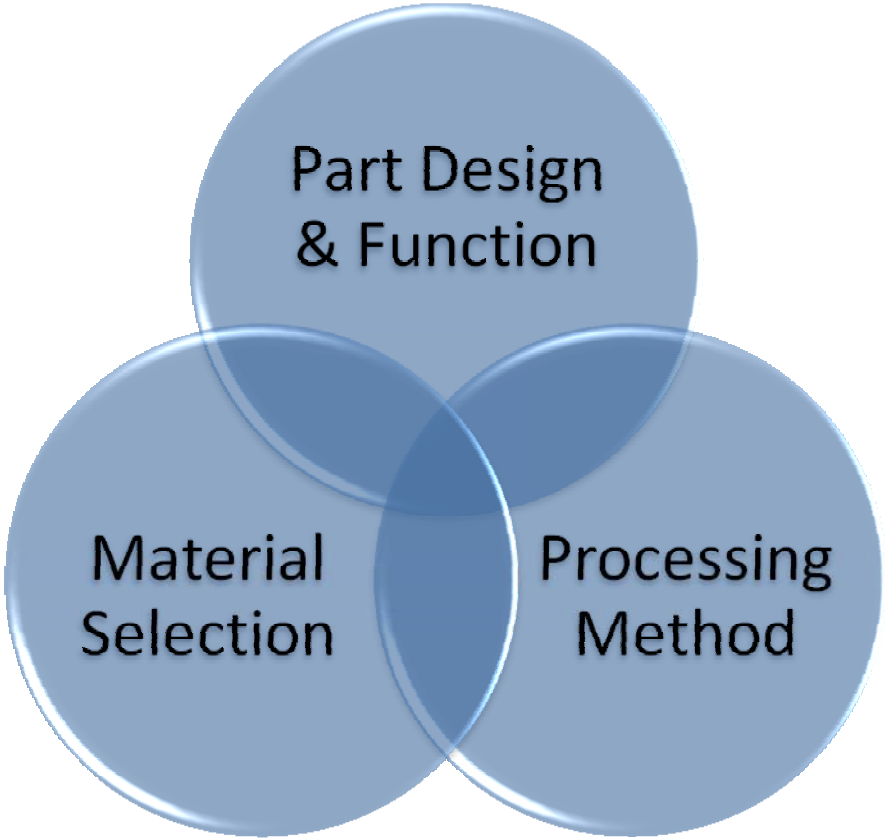
Vascular Device Considerations



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Design Challenges

Angiographic Catheter

1989

OD .131” max PSI 500

1999

OD .081” max PSI 900

2009

OD .039” max PSI 1200

Jim Culhane, Navilyst Medical

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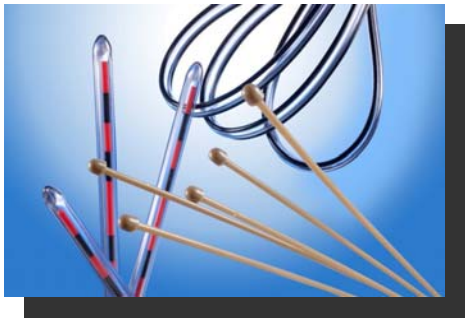
Design ‘Tradeoffs’



Shape of catheter can reduce trauma

No single material for all applications

Surface coatings modify catheter properties

Tradeoffs:

- Flexible catheters - endothelial injury, BUT difficult to insert
- Rounded tip - less traumatic BUT more difficult to insert

ref: www.nc3rs.org

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Desired Material Properties

High tensile strength
Resists compression – maintains lumens
Flexible – minimizes trauma
Low friction
Dimensional stable
Tolerates sterilization
Ease of fabrication – forming & bonding
Non-permeable
Accepts surface coatings

ref: www.nc3rs.org

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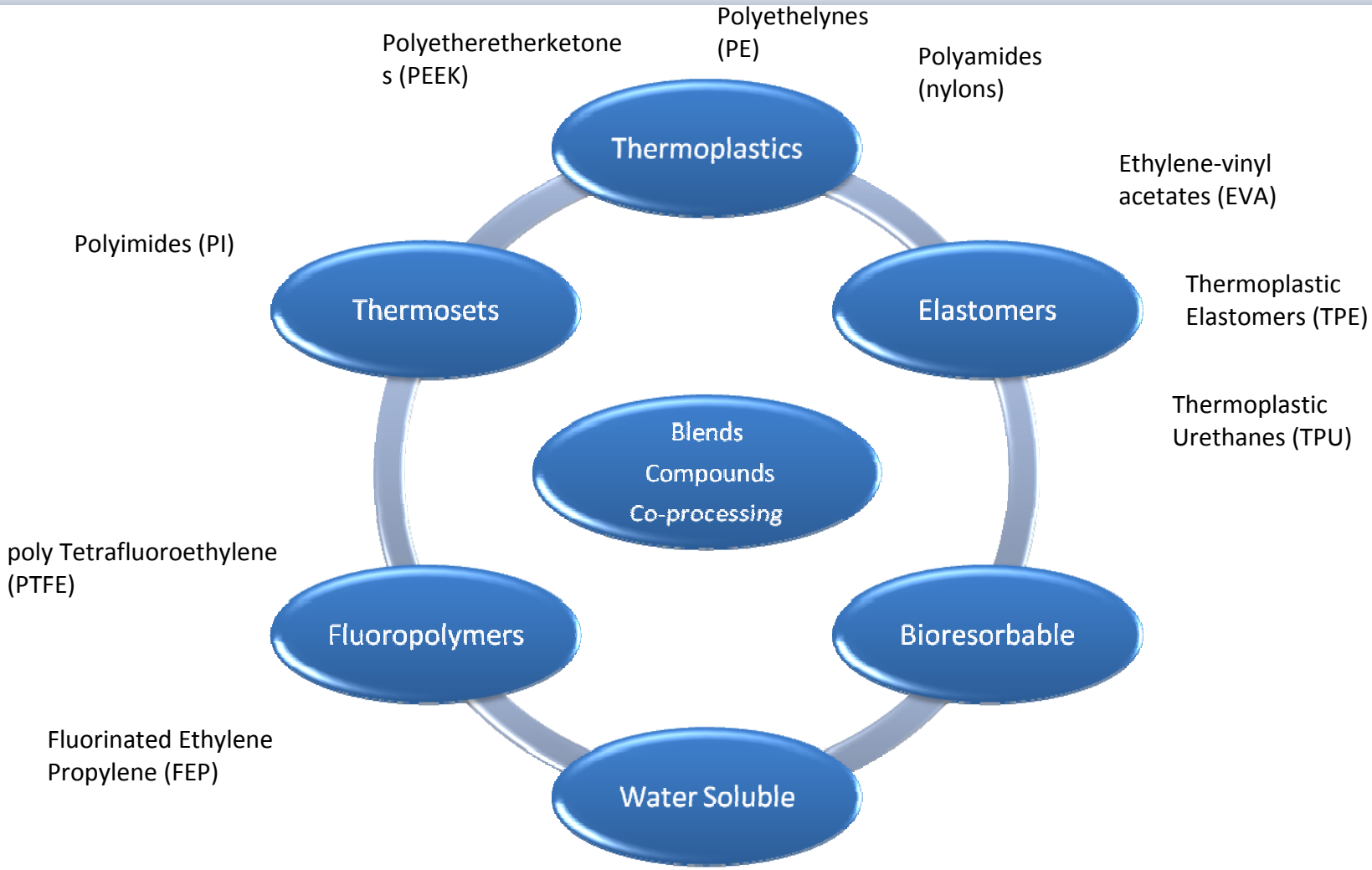
Material Options



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Choose Materials Carefully

Validate material change to Manufacturing Process

~8 month & $150K

Validate material change to Design

Design Validation ~4m & $75K

Sterility Validation ~ 2m & $50K

Biological Testing ~ 4m & $100K)

Product Life Cycle 2-3 years

Jim Culhane, Navilyst

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Common Used Materials

Engineering TPE's

- PEBA--Polyether Block Amides
- COPE--Copolyesters
- TPU--Thermoplastic Polyurethanes

Specialty TPE's

- DVA--Dynamically Vulcanized Alloys
- SBC--Styrenic Block Copolymers
- TPO--Thermoplastic Olefins
- PVC--PVC Blends and Alloys

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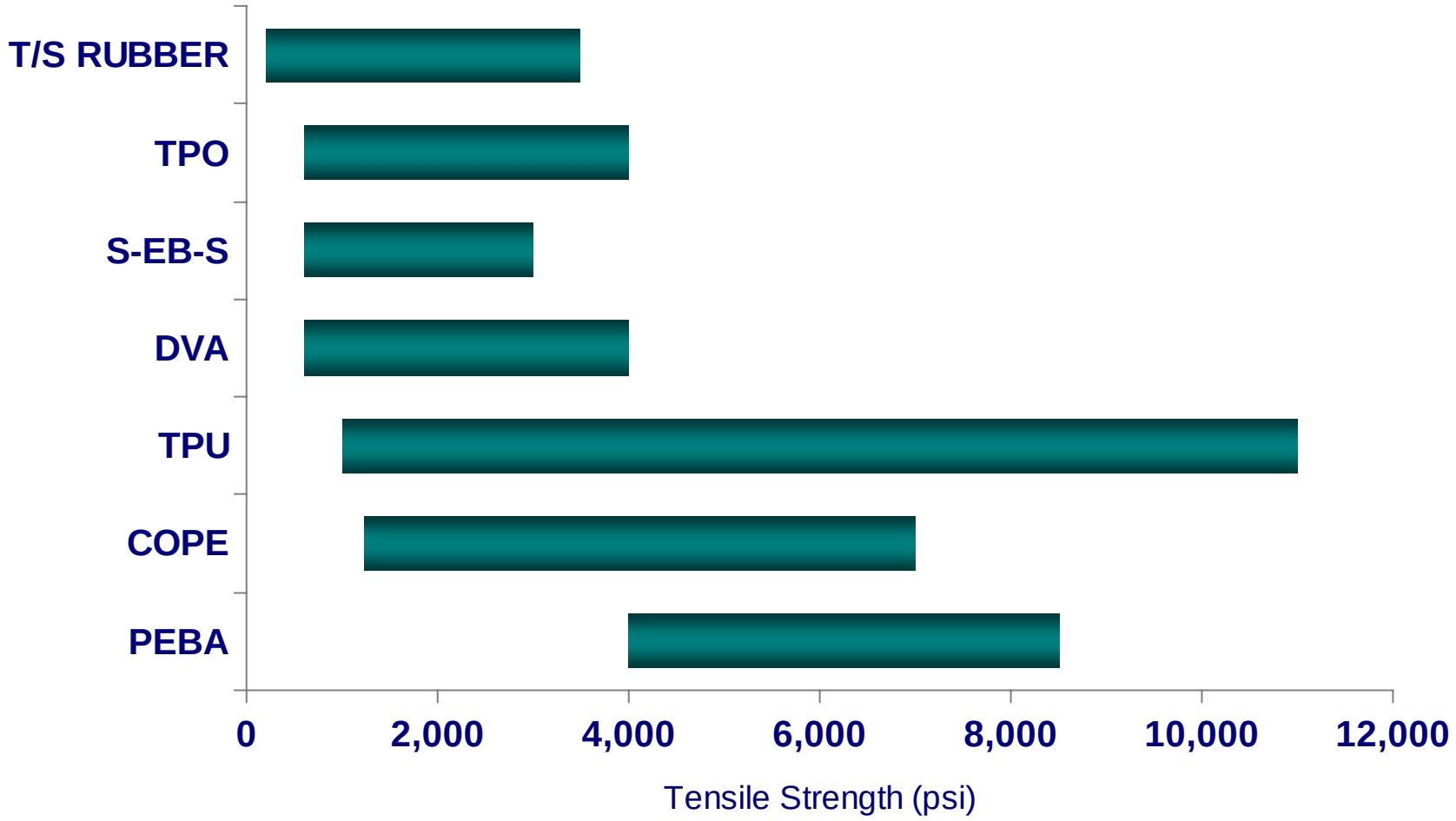
Strength



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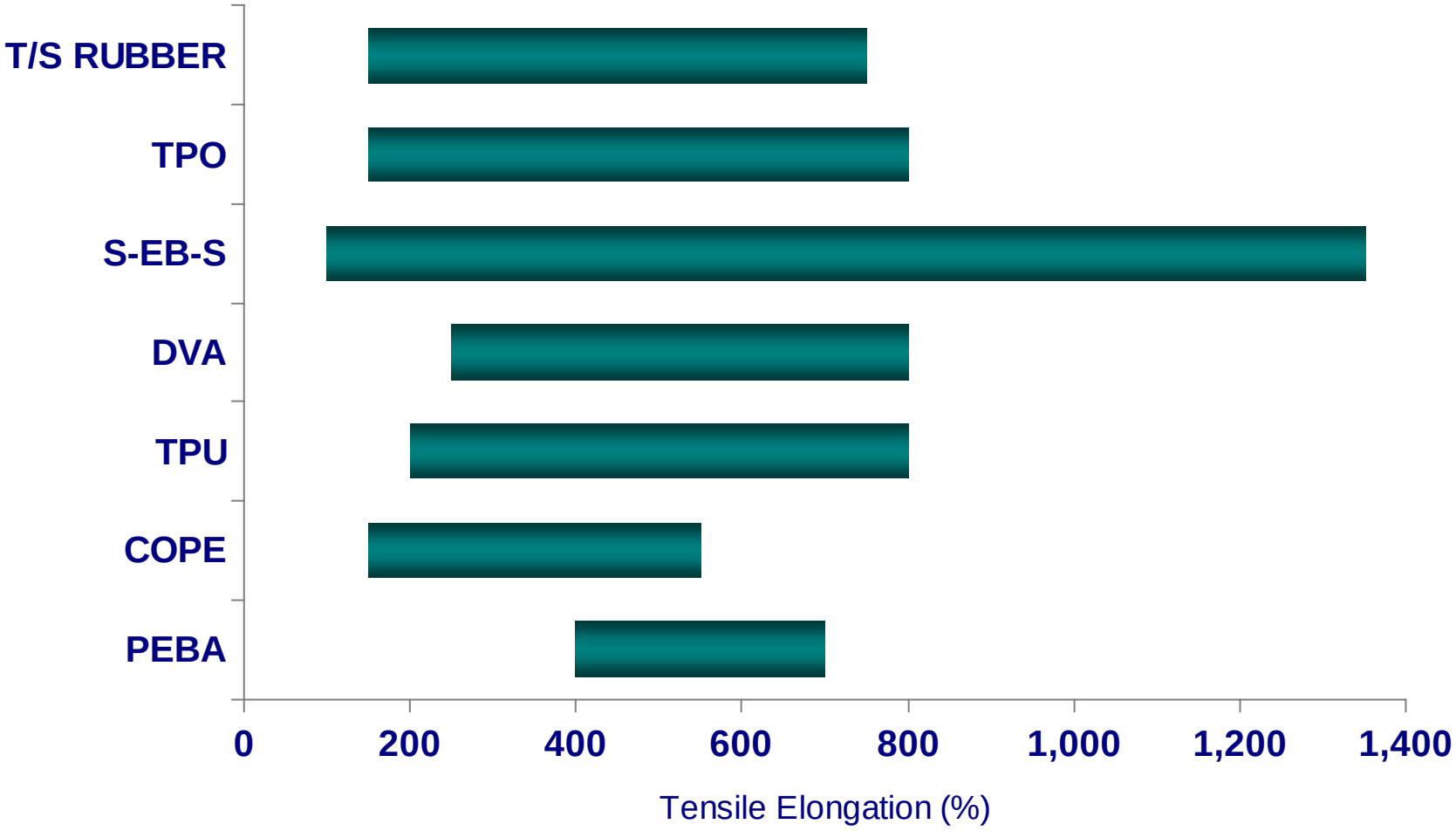
Elongation



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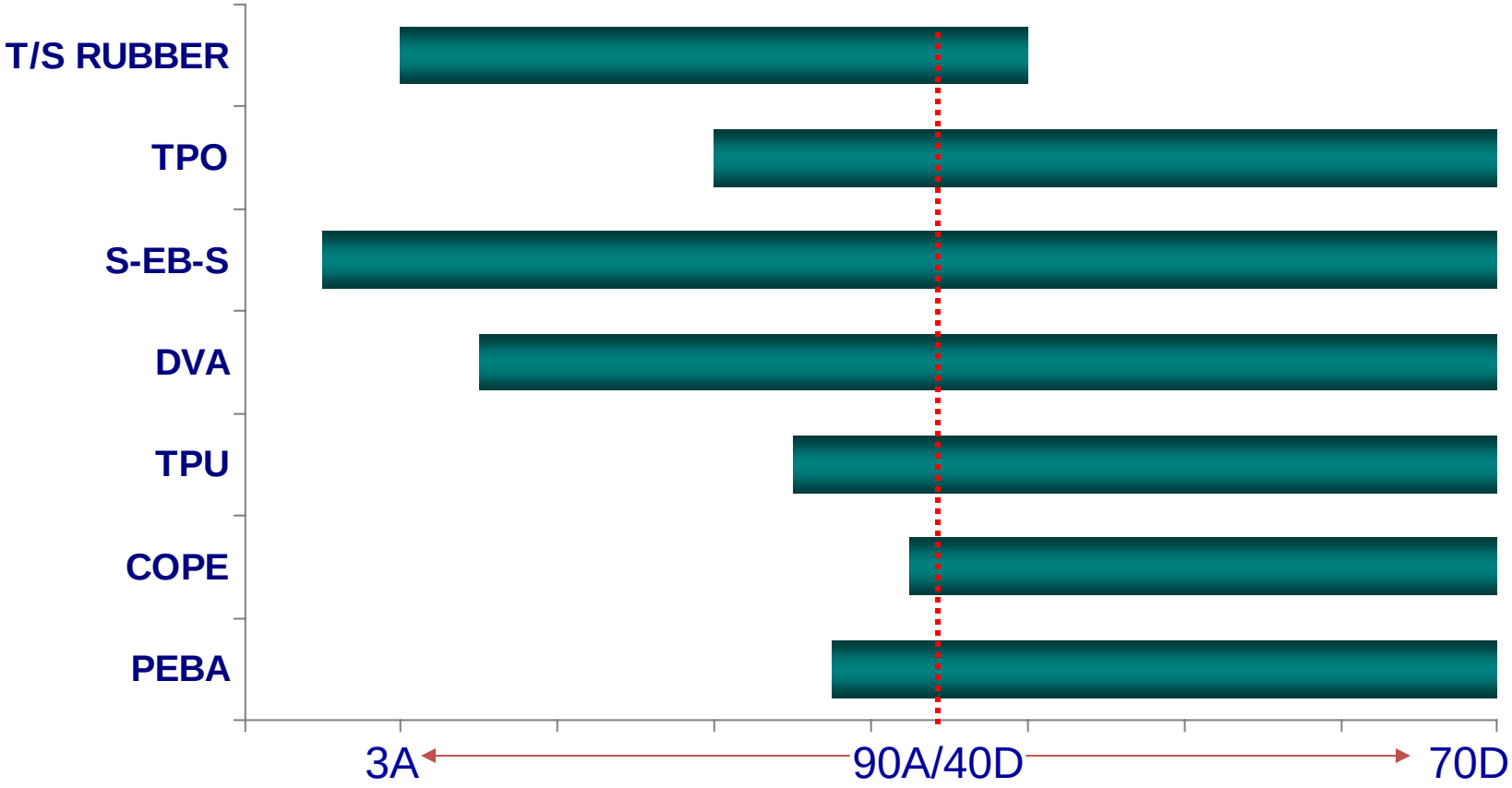
Hardness



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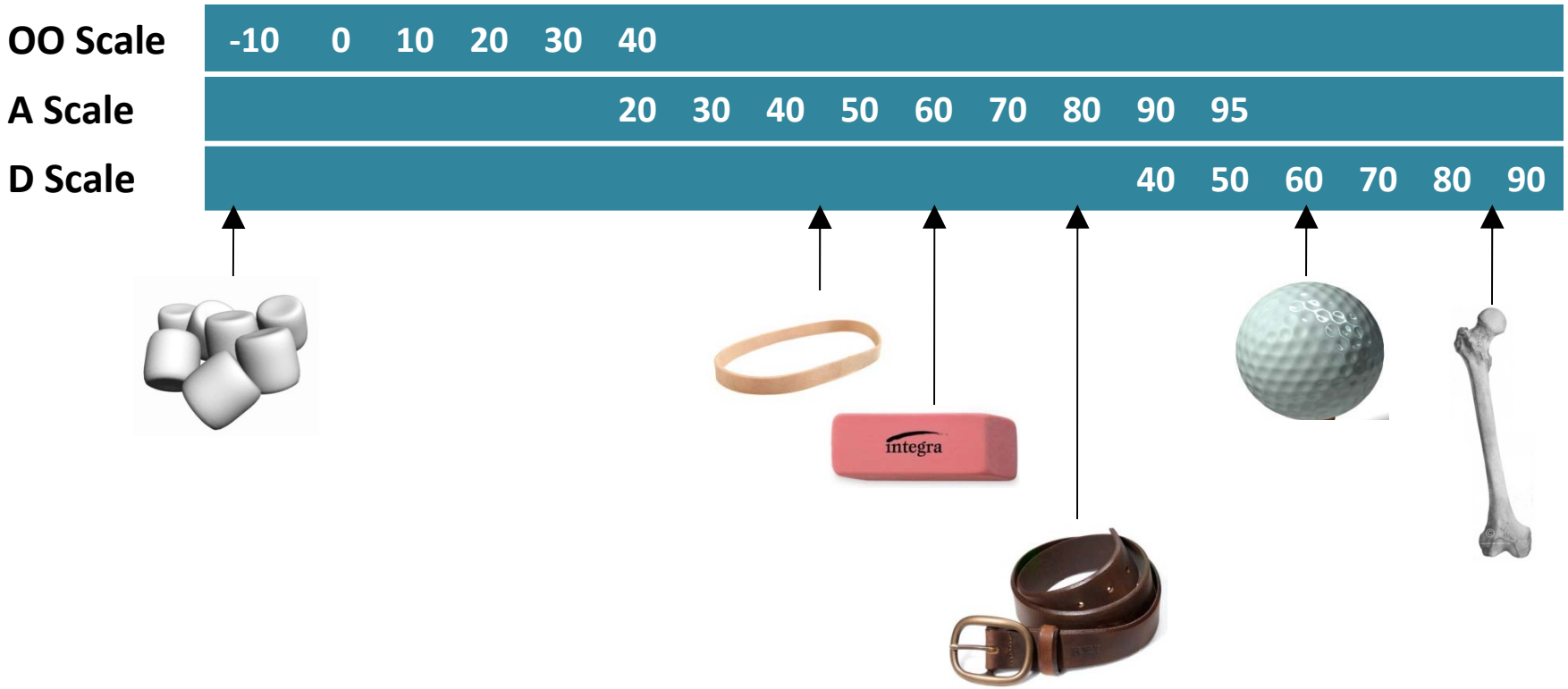
Hard Language



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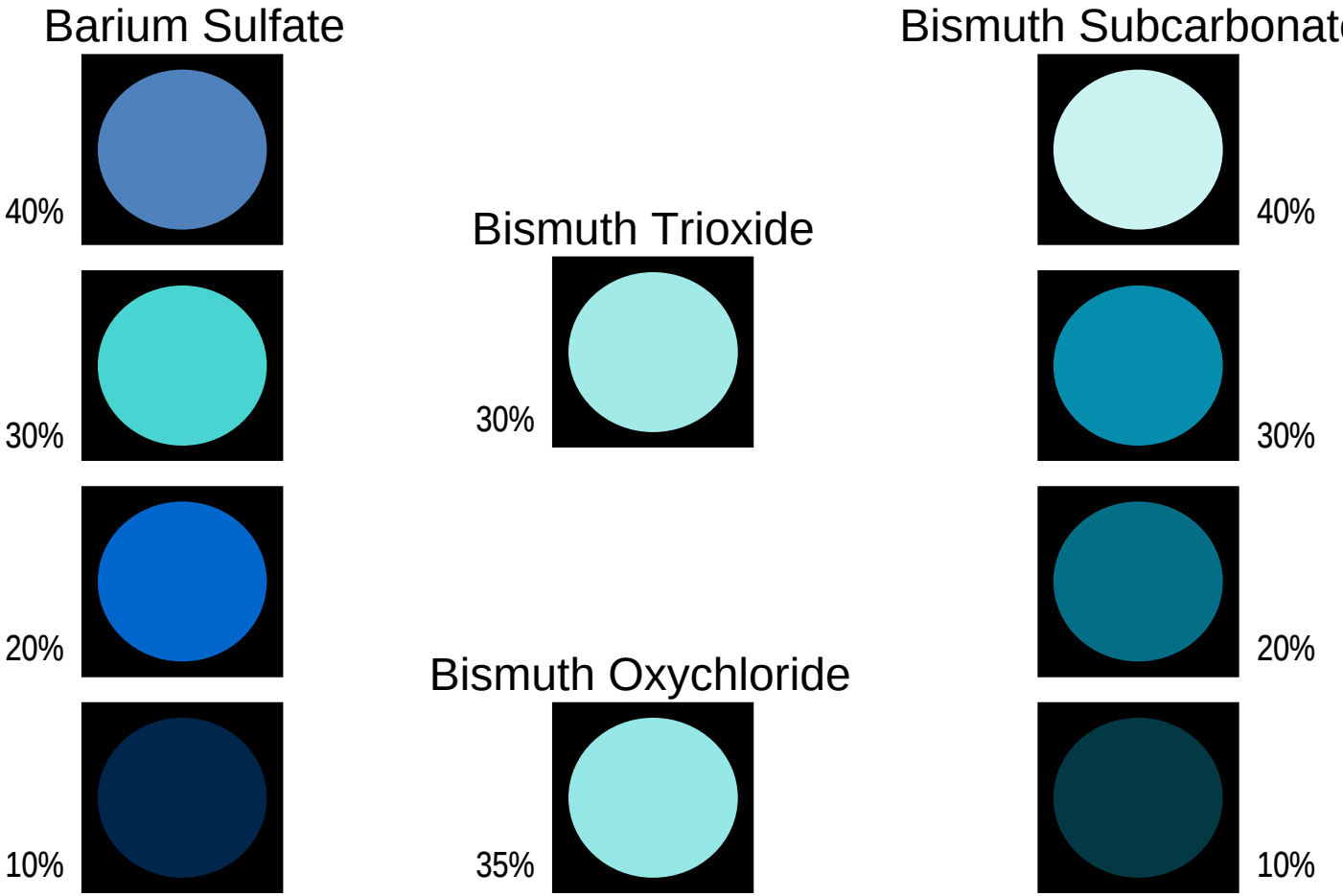
Visibility Required?



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Other Modifications

- Colors
- Heat stabilizers
- Antioxidants
  - added to resins susceptible to process degradation
- UV stabilizers
- Processing aides
  - Internal/external lubrication
- Lubricants
  - surface lubrication for COF

Special Treatments

Hydrophylic & Antimicrobial

Surface coating options

- Duration of efficacy
- Subject to wiping/removal

Polymer blended options

- Permanent
- Material & process dependant

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Multilumen Extrusions

Provide working channels

Insertion of wires; transport fluids

Round & complex inside and out

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Co-Extrusions

Multiple materials

Catheter shafts

- portion radiopaque, remaining clear for visibility of lumens

Guide wire

- inner member hard/lubricious, soft/bondable outer surface

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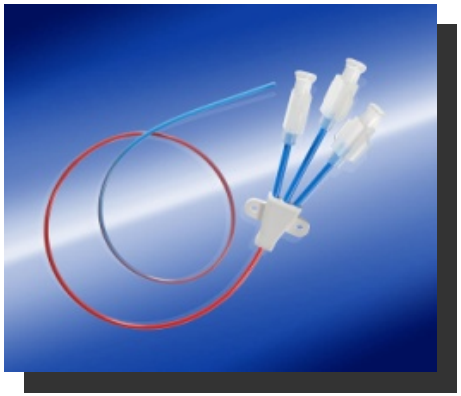
Total Intermittent Extrusion



Durometer varied along length

Soft tip

Combination flexibility/pushability.

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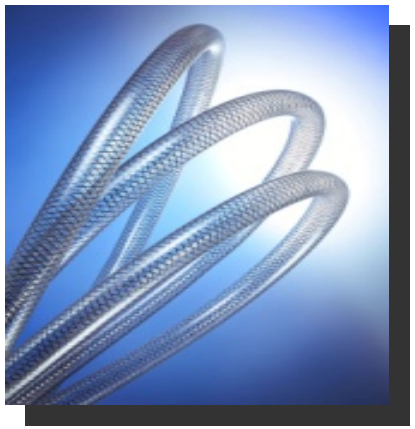
Coil & Braid Reinforcements



- Coil resists collapse/buckling
- Braid improves burst/torque
- Single lumen & multi-lumen
- Stainless steel, Nitinol, polymer fibers

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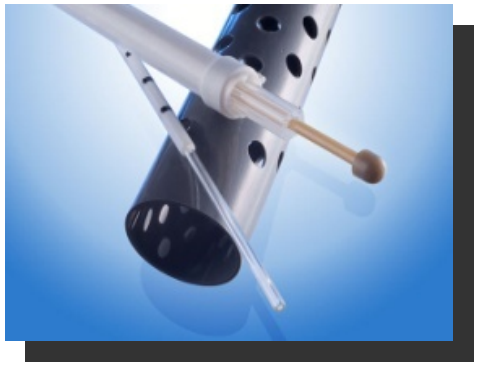
RF Forming



- Post extrusion shaping
- Tip ends closed
- Flare ends open for insertion
- Welding extrusions
  - variations in geometry and/or hardness

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Insert Molding

- Injection molding connectors
- Luers or hubs
- Eliminates manual assembly
- Provides a strong bond
- Ideal for complex multi-lumens
  - Access to each lumen is required

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Pad Printing

Inked graphics to outer surfaces

Orientation of catheter during use.

Surface pre-treatment technologies

For polyethylene, PEEK & polyimides.

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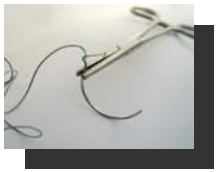
Enabling Polymer Technologies to Improve the Quality of Life™

polymer distribution

foster compounds

putnam extrusions

custom components



drug delivery & implants