

# MORE ROBUST & SAFER CATHETERS

During the material selection process, we often see customers focused on:



Improved patient outcomes



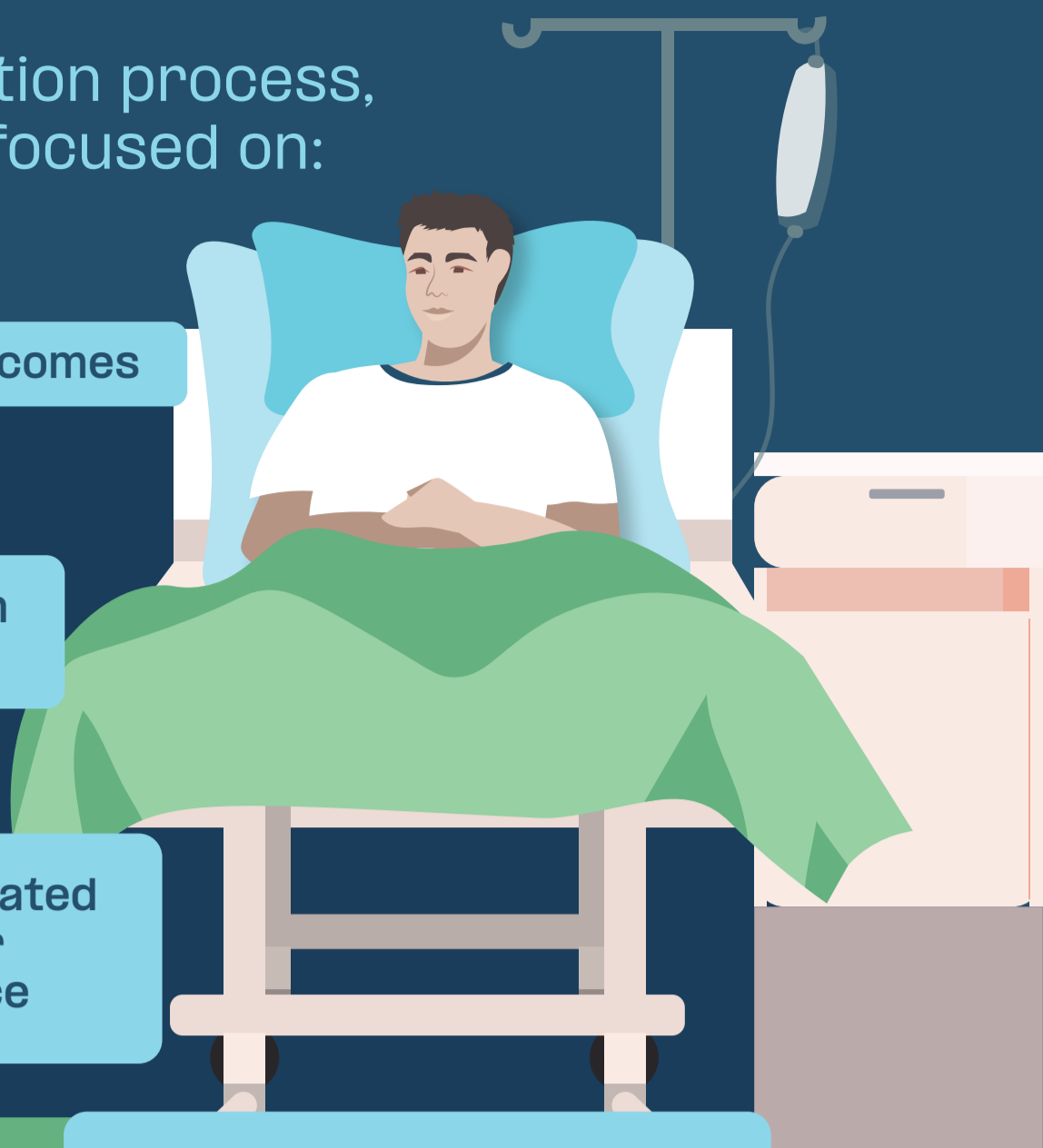
Reducing end to end system costs for devices



Developing differentiated products that deliver superior performance



Staying ahead of a dynamic and ever-changing regulatory environment



## FREQUENTLY USED MATERIALS FOR CATHETERS INCLUDE:

### PE

- High chemical resistance, strength and permeability
- Sometimes stiff and exhibits kink memory

### LATEX OR POLYURETHANE ELASTOMERS

- Thromboresistant, good tensile strength and resistant to wear and chemicals
- More expensive than other materials

### PVC

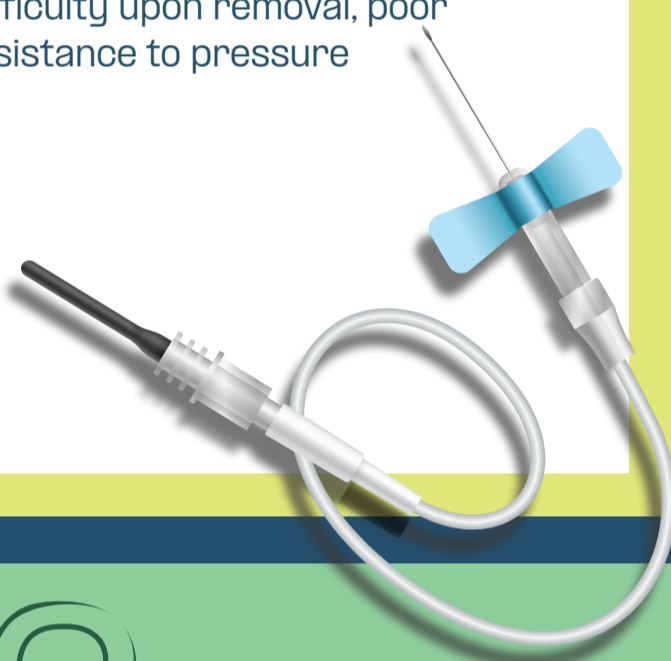
- Strong material, stiff on insertion but softens after entering the body
- Rigid and inflexible, uncomfortable for long use

### BLOCK CO-POLYAMIDE POLYETHER ELASTOMERS

- Biocompatible, sterilizable, extrudable, kink resistant
- Difficult to process and absorb moisture

### SILICONE

- Extremely biocompatible, thromboresistant, good alternative for patients with latex allergies
- Cuffing of balloon may cause difficulty upon removal, poor resistance to pressure



## Did you know?

Up to

**40%**



of device recalls are material related?

### 2020 FDA Class 1 Catheter Recalls<sup>2</sup>

**138k**  
Devices

**189**  
Complaints  
**9**  
Companies

**17**  
Injuries  
**7**  
Deaths

## There is a high-performance material solution you can trust

### ARNITEL® CARE

is used by many of the world's leading medical device manufacturers



#### – Compliance

- ~ FDA food contact
- ~ USP Class VI
- ~ ISO 10993-5 & ISO 10993-10

#### – Strong Track Record of Quality

- ~ Zero material-related failures or recalls
- ~ 97% of customers say DSM materials meet or exceed their expectations for quality\*

#### – Manufacturing benefits:

- ~ Simple and predictable extrusion reduces scrap
- ~ Easily welded or glued to many other materials and itself, increasing overall strength and reducing potential failures
- ~ Shrinkage is more predictable
- ~ Less dimensional change with annealing
- ~ Gel-Free extrusion, reduces scrap, improves product quality and eliminates risk of bond point failures.

#### – Clinical Benefits:

- ~ Easy and predictable extrusion and secondary assembly – reducing potential for clinical failures
- ~ Stiffness is independent of moisture absorption, so catheters perform the same in all humidity environments
- ~ Better snap back performance



#### Sources

1. Jeffrey Ellis, "Material failure is root cause of many medical device recalls" *Plastics Today*
2. Danielle Kirsch, "The Worst Catheter Device Recalls of 2020", *Medical Tubing and Extrusion*, Feb 19th, 2021

**Envalior**

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