

# How Many Consultants Does It Take To Build A Medical Device?

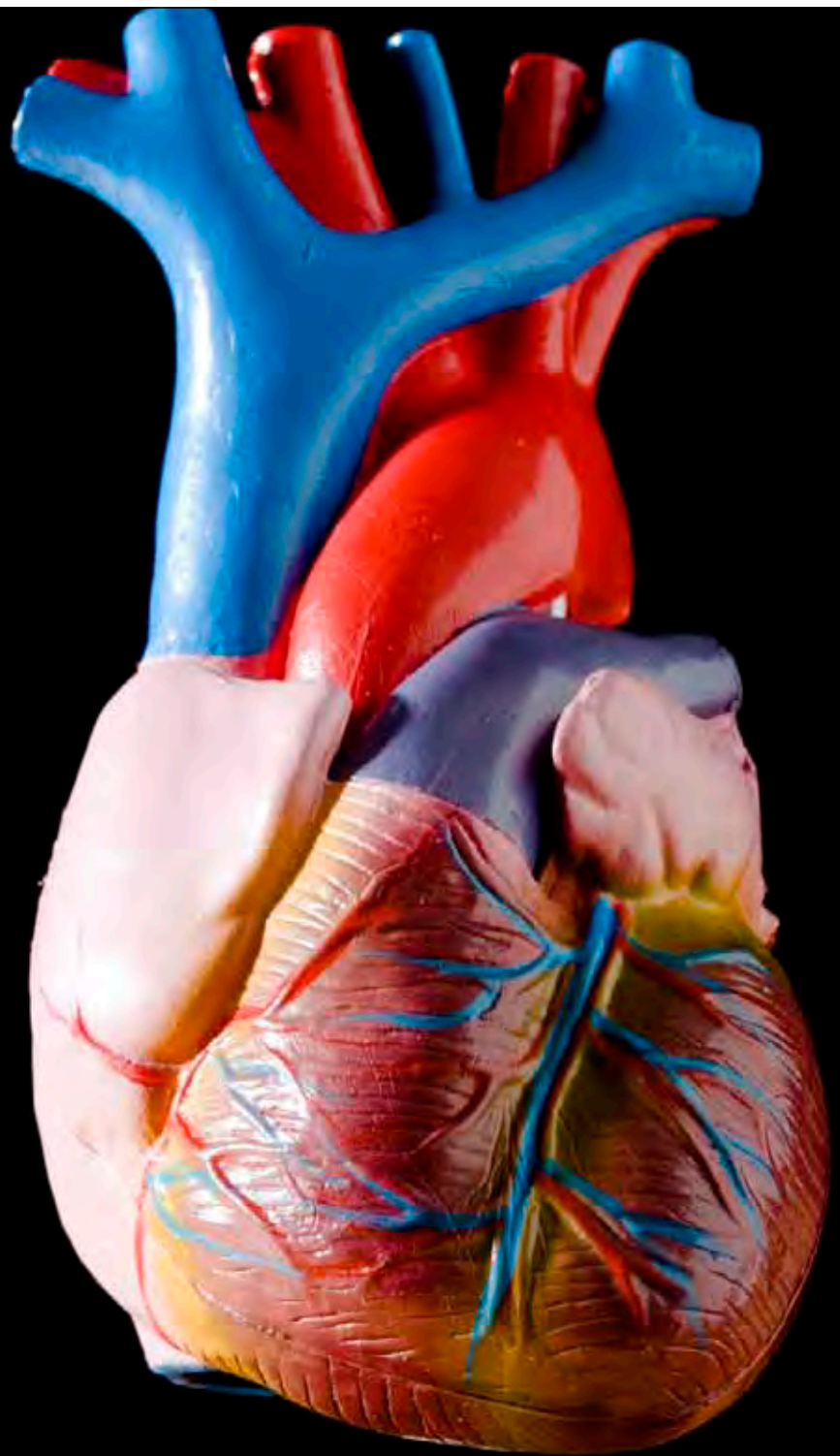
Kendall R. Waters, PhD  
Manager, IP and Technology Development  
[kendallw@svmii.com](mailto:kendallw@svmii.com)

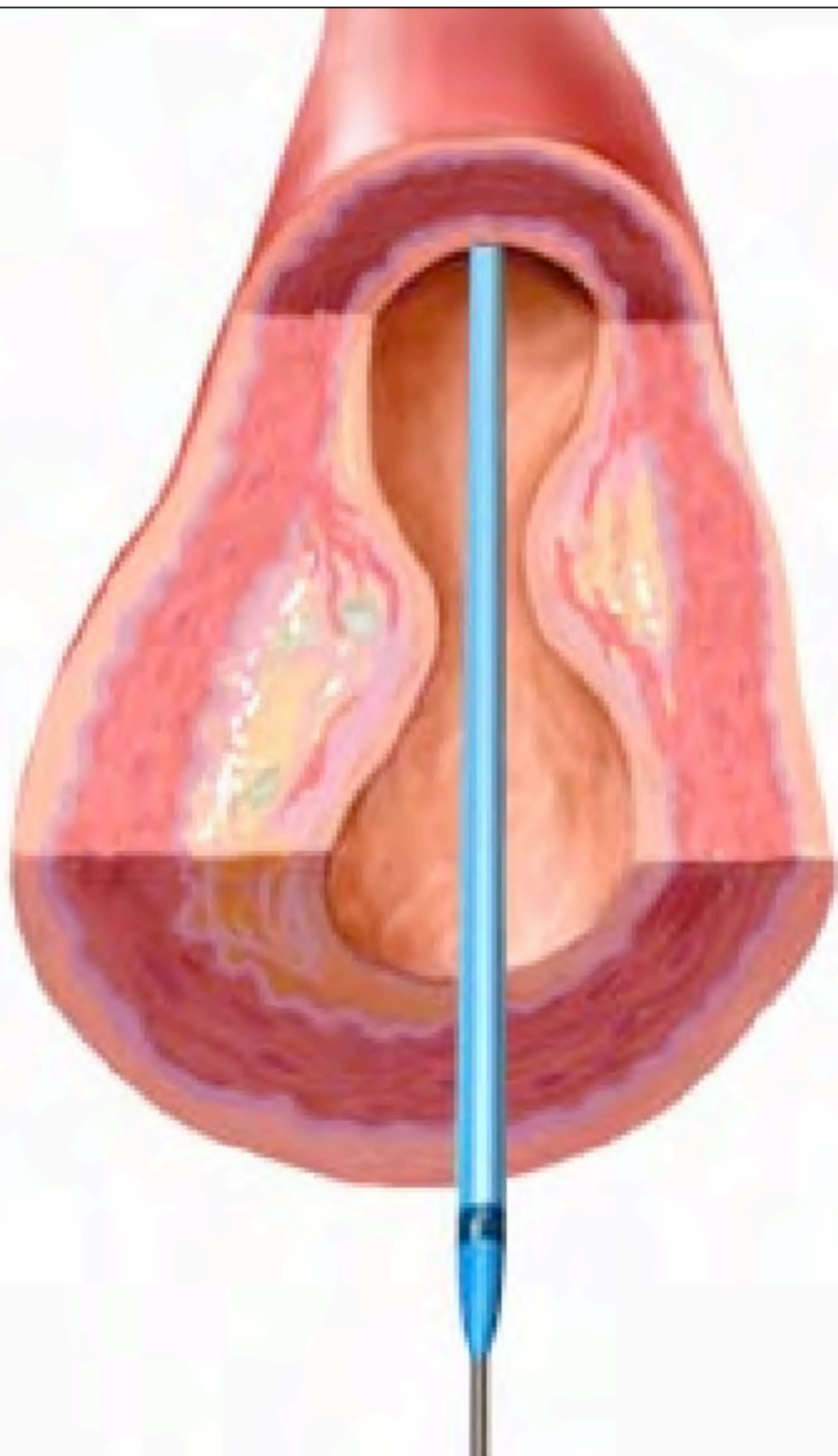
SVMI

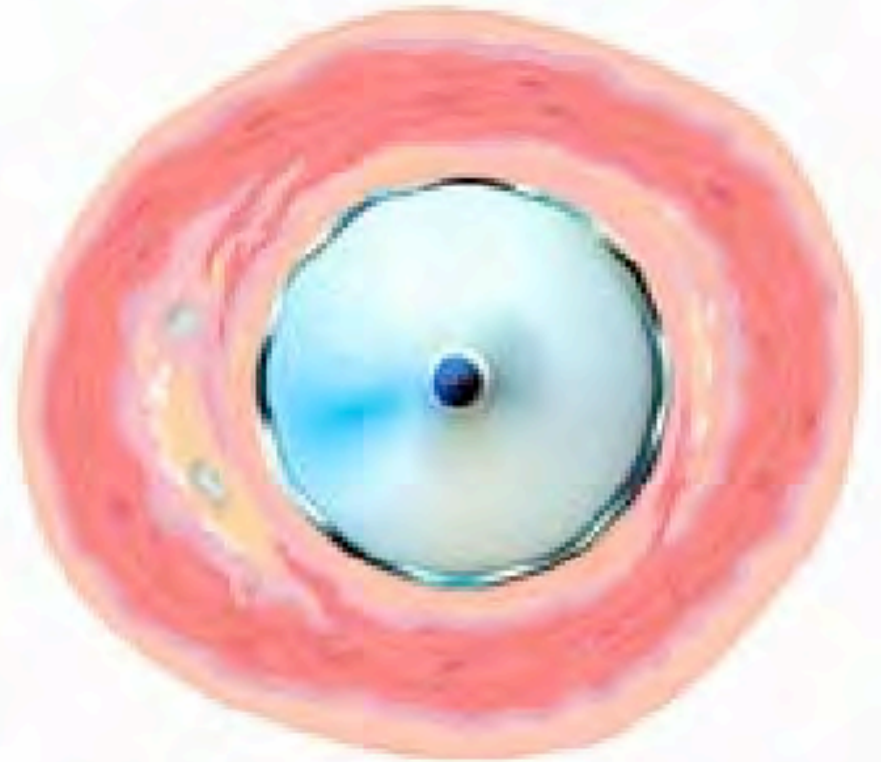
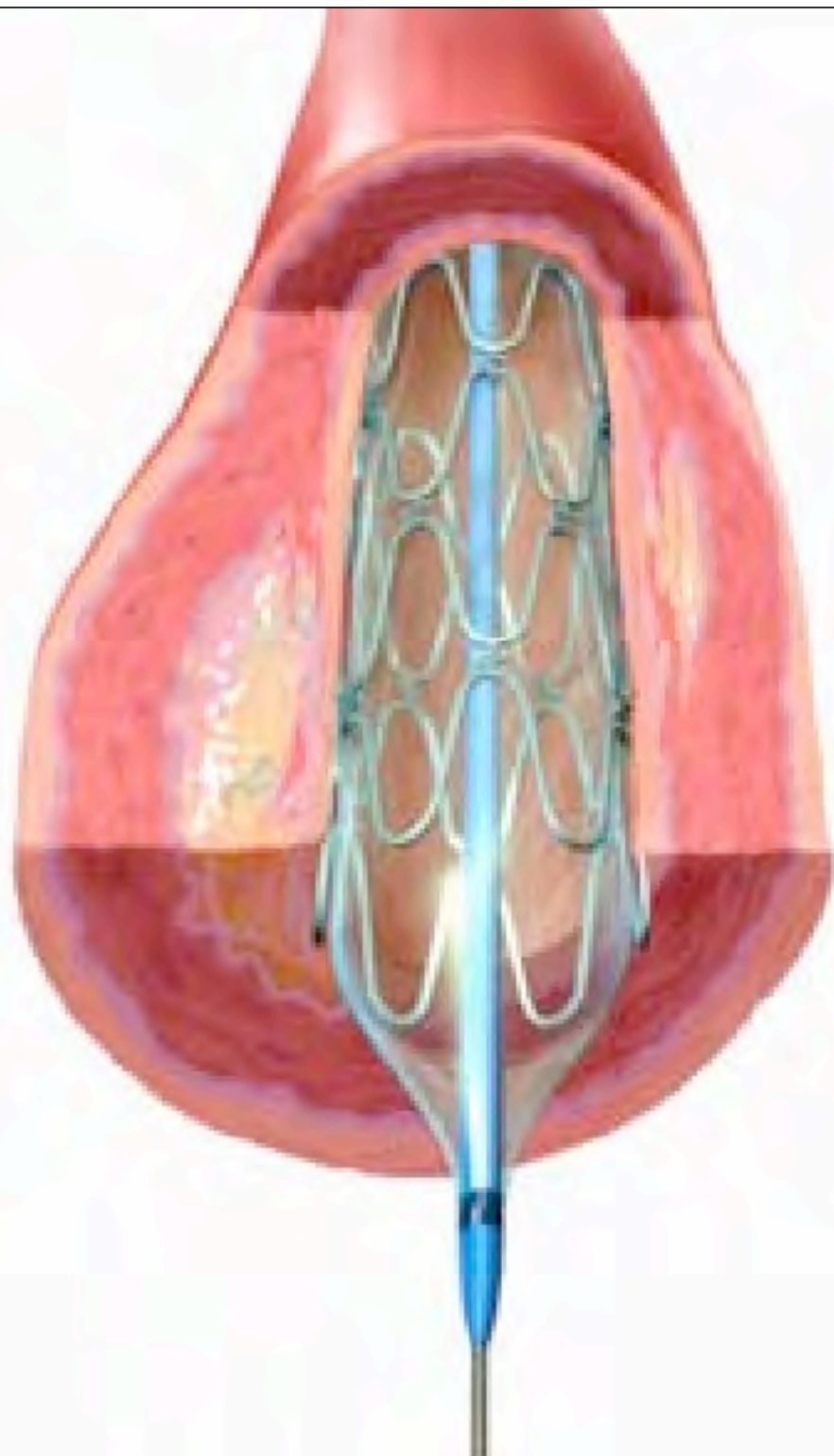
HD  
IVUS

30

(and counting)









# Vulnerable Plaques



Animation from CardioTube







HD-IVUS products are investigational and not approved for use in humans.



Last, First Name  
Patient ID

Mon 11-10-2010  
12:02:25 PM  
Frame: 879

SVMI <sup>IVUS</sup>  
Silicon Valley  
Medical Instruments Inc. \*

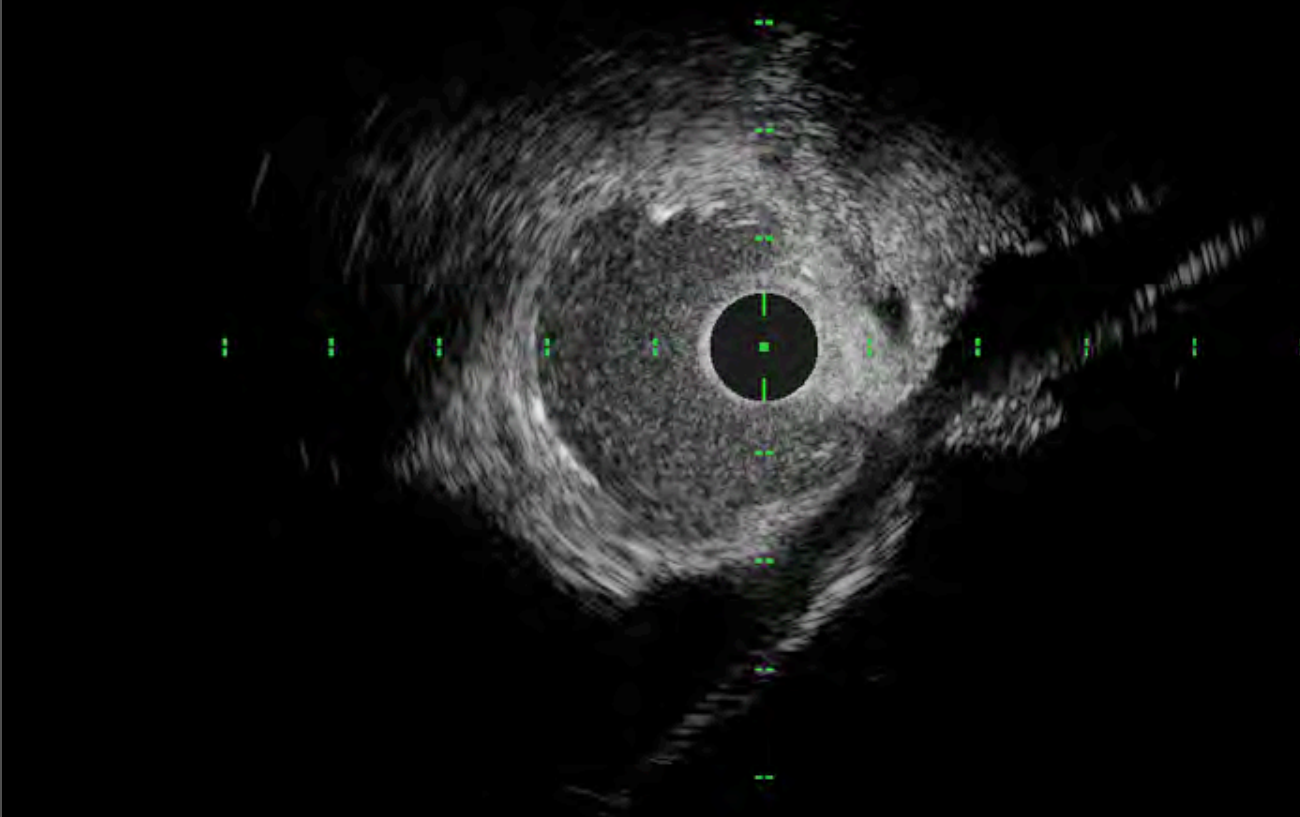
60MHz

Archive Analysis Acquire

Frame RWD Play Frame FWD

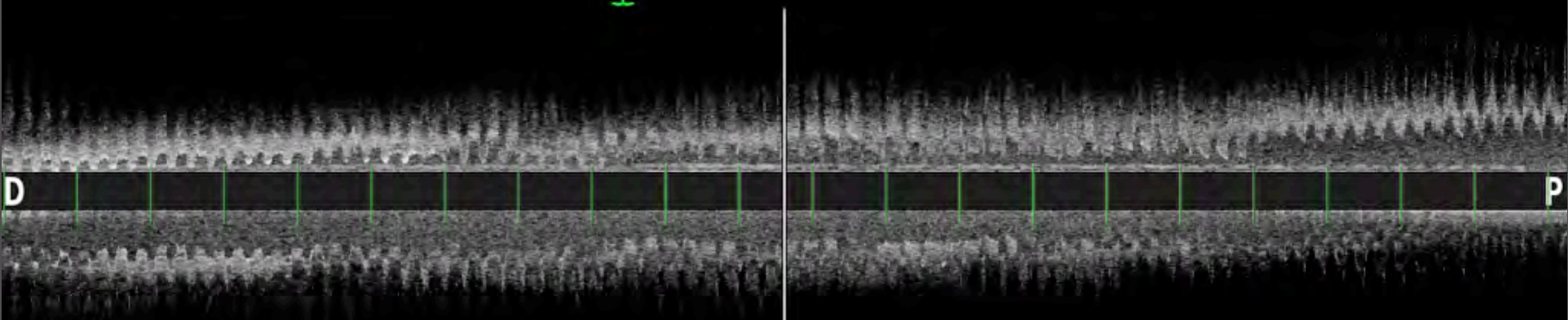
Length Distance Area

Large View

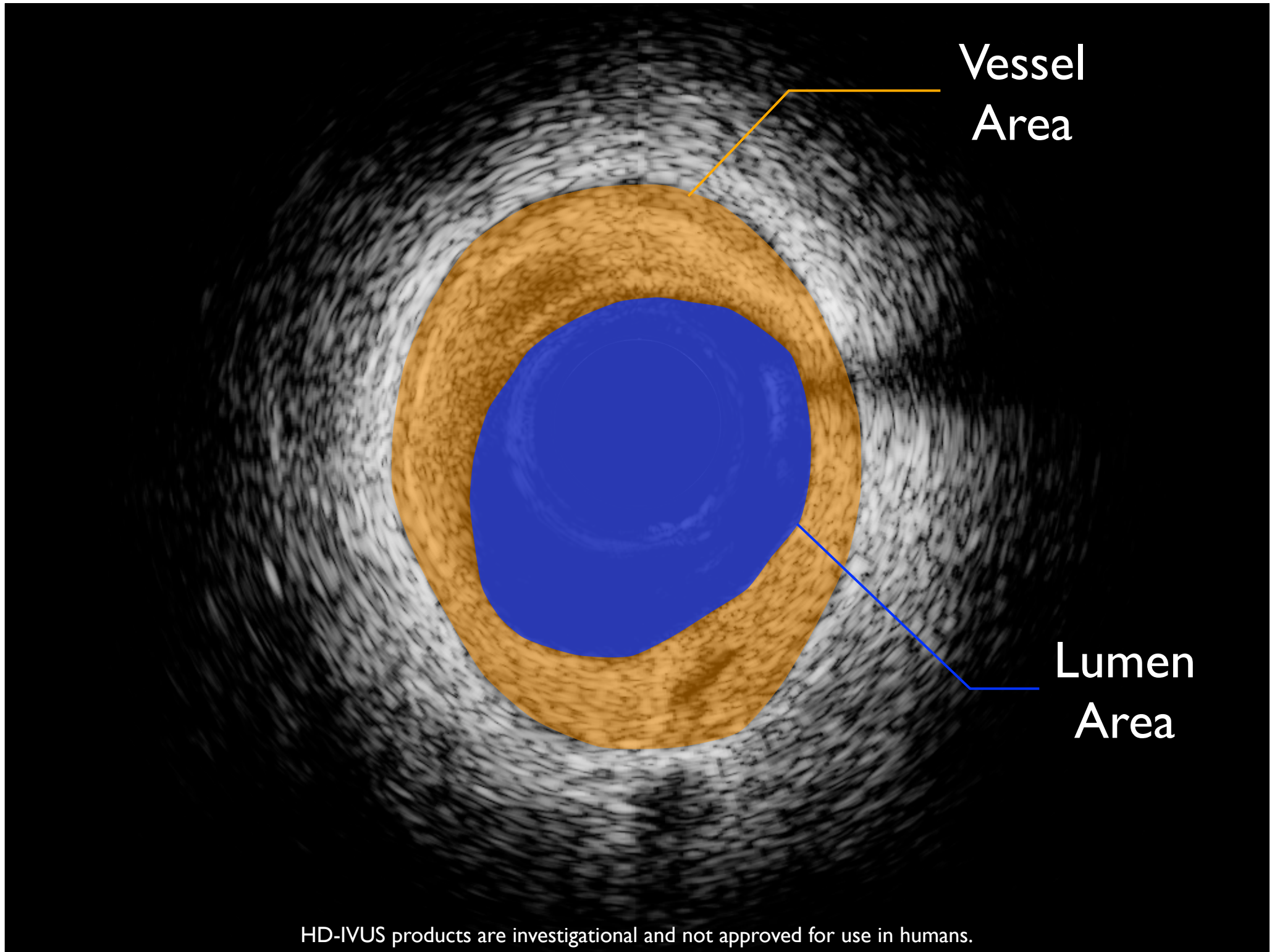


Hospital Name

DIA:10.0mm  
GRAT: 1.0mm



HD-IVUS products are investigational and not approved for use in humans.



Vessel  
Area

Lumen  
Area

HD-IVUS products are investigational and not approved for use in humans.



Region  
of  
Interest

Vessel  
Border

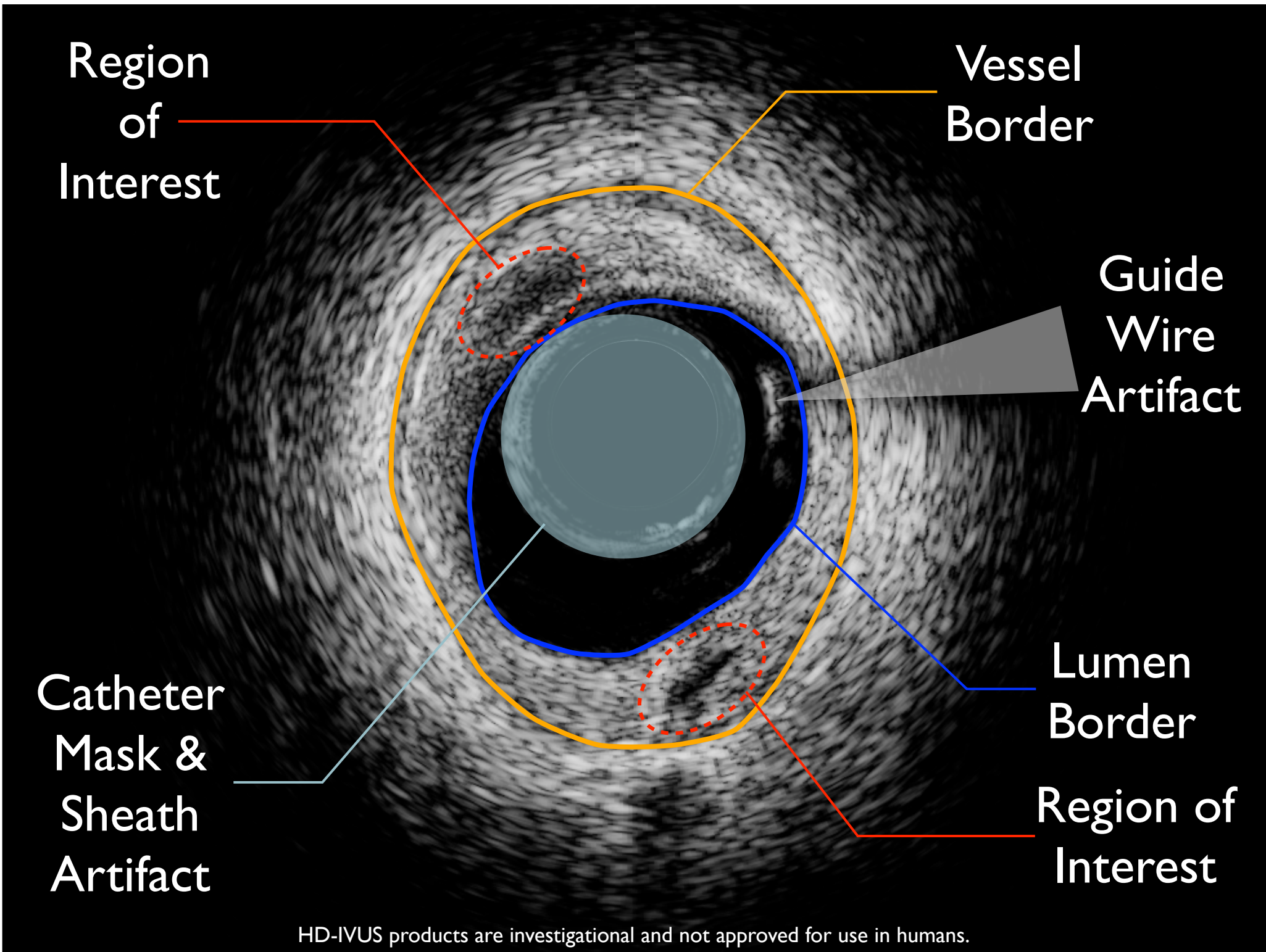
Guide  
Wire  
Artifact

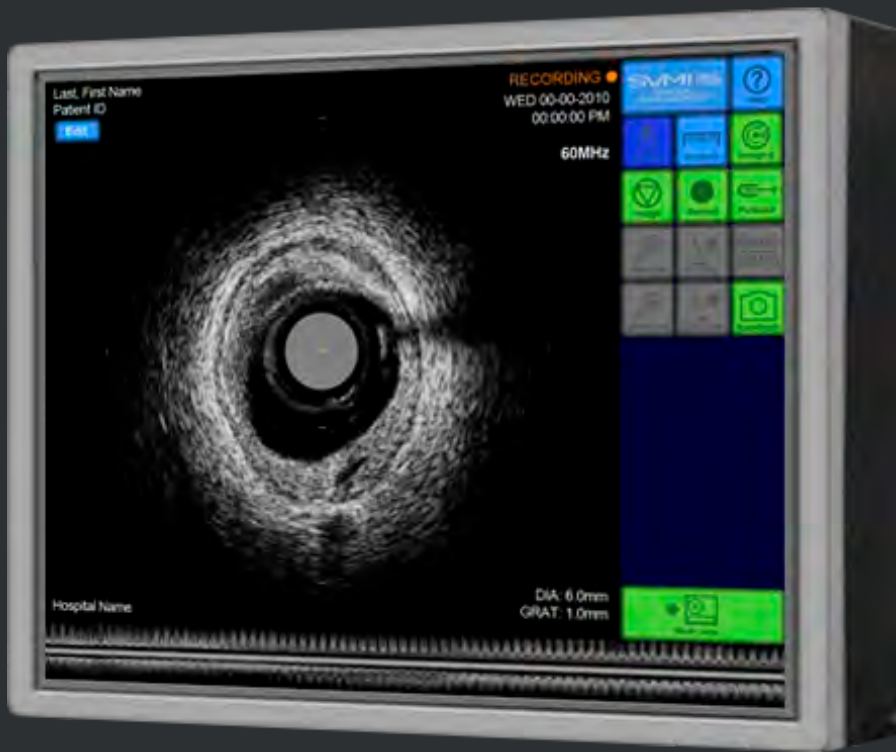
Catheter  
Mask &  
Sheath  
Artifact

Lumen  
Border

Region of  
Interest

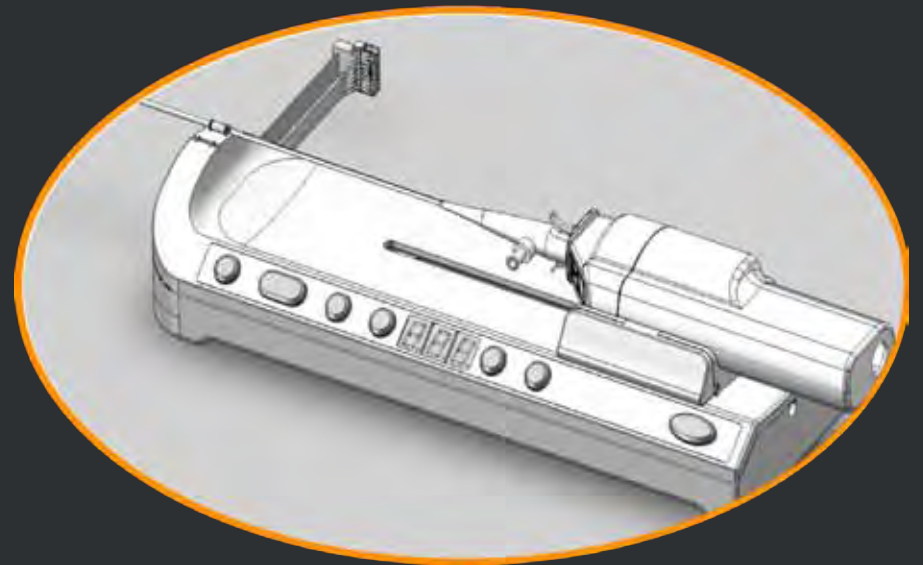
HD-IVUS products are investigational and not approved for use in humans.





Touchscreen Console

Imaging Catheter  
Patient Interface Module

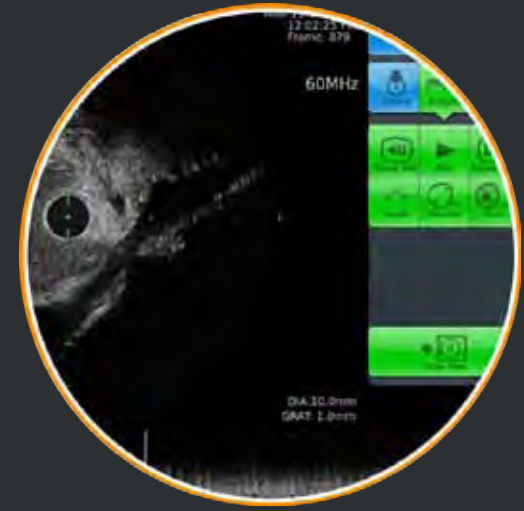




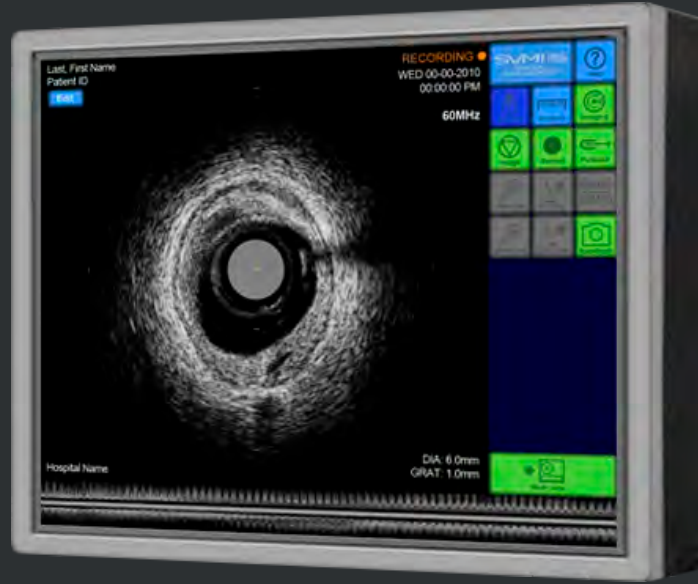
Touchscreen



User Interface



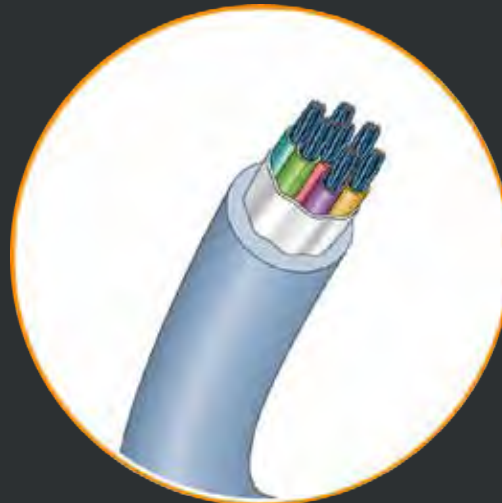
Console



Mixed Signals



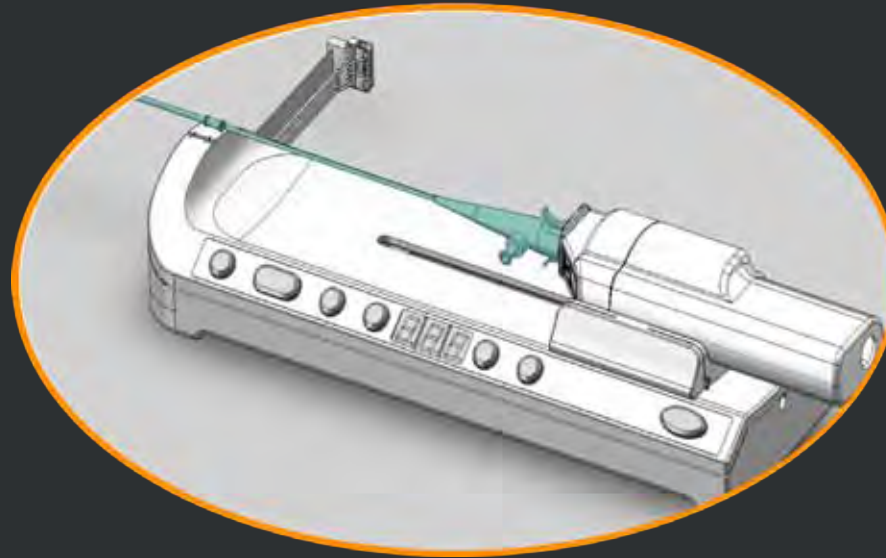
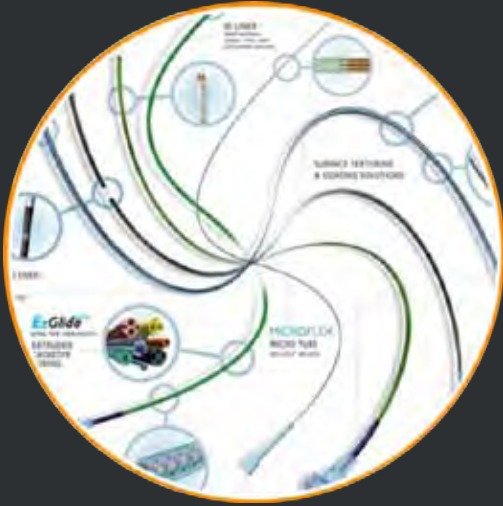
Cabling



OS



# Catheter Design



# Imaging Catheter

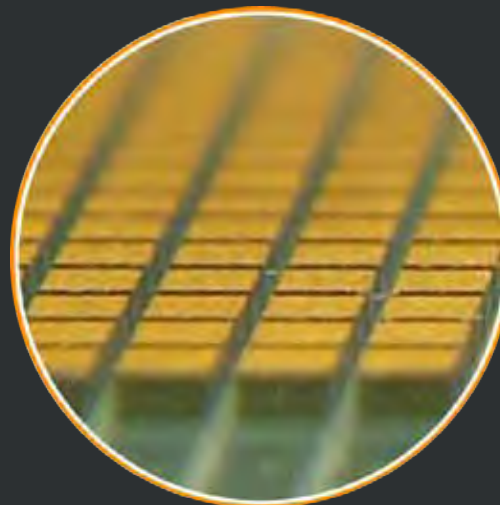
# Transmission Line



# Extrusions



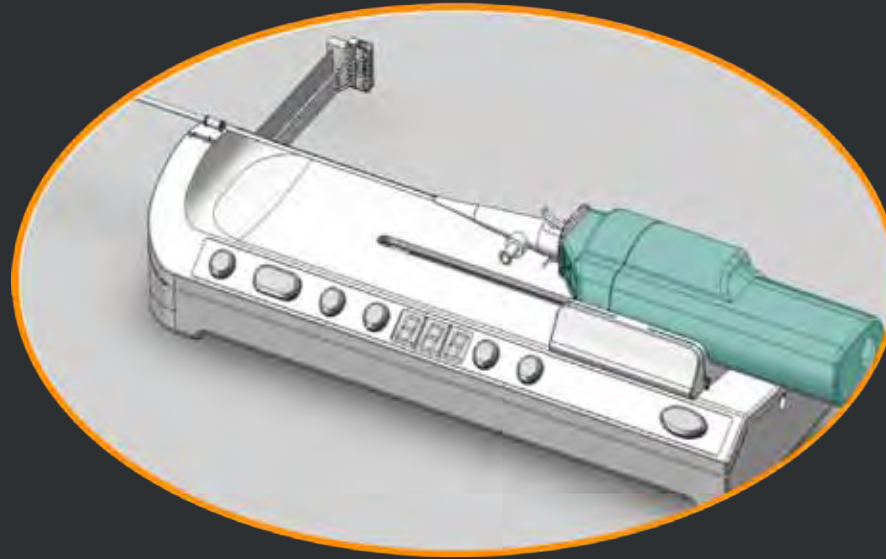
# Transducers



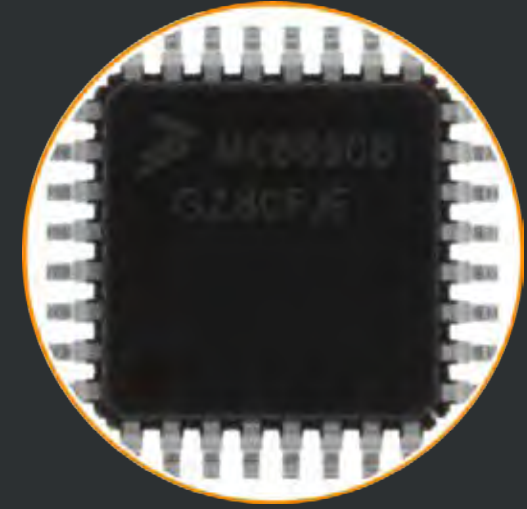
# Drive Cable



Industrial  
Design



Micro-  
Controller



Patient Interface Module

Analog



Mechanical  
Design



Motion Control





Legal & IP



Infrastructure

Clinical



IT



Quality



Regulatory







## Making the Match



# Thank You

Kendall R. Waters, PhD  
Manager, IP and Technology Development  
[kendallw@svmii.com](mailto:kendallw@svmii.com)

**SVMI**

**HD  
IVUS**