



Micromachining • Micromolding • Insert Micromolding

Micromolding: Maximizing the Benefits of Converting from Micromachining to Micromolding for Your Next MIS Device

April 5, 2011

Presented by:

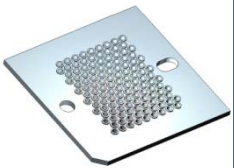
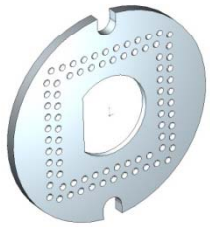
John Whynott





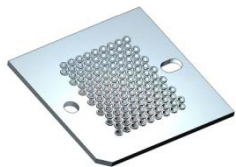
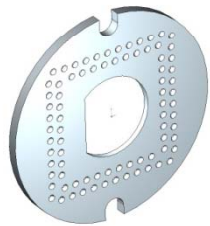
Problem Statement

- Medical device OEM's may be missing an opportunity cost (next best choice) associated with submitting their next medical device for FDA approval





Typical Medical Device Launch

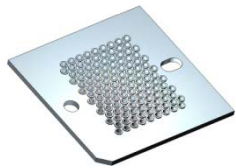
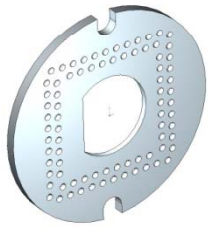


- **Micromachining**
 - Prototyping (proof of concept)
 - Design verification
 - Product validation
 - Process validation
 - FDA Submittal
 - “X” period after approval (on the market)
- **Convert to Micromolding**

What’s wrong with that methodology.....



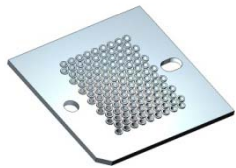
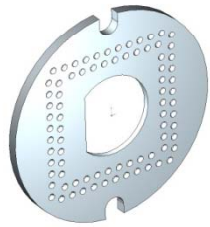
Micromachining



- Prototyping or short run production
- Show proof of concept
- Short lead time
- Little or no tooling cost
- Tolerances of +/- .005 mm (plastics)
- Tolerances of +/- .012 mm (stainless steel)



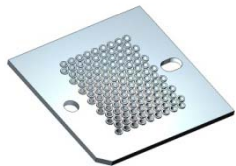
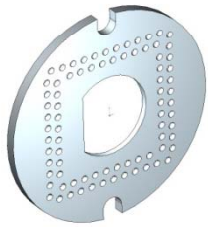
Micromolding



- Mid to high volume production
- High repeatability
- Tolerances of +/- .005 mm
- Wall thicknesses as low as .08 mm
- Less material waste
- Lower piece price cost



Micromachining vs. Micromolding



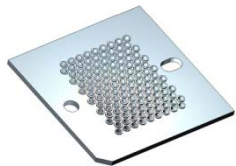
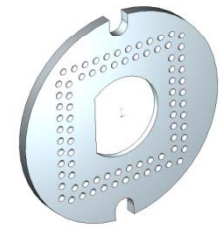
- Advanced Materials
- Design Complexity
- Precision Tolerances
- Part Count Reduction
- Particle Contamination
- Surface Finish
- Tooling Cost
- Piece Part Cost
- Delivery

Micro Machining	Micro Molding
✓	✓
	✓
✓	✓
	✓
	✓
✓	✓
	✓
✓	

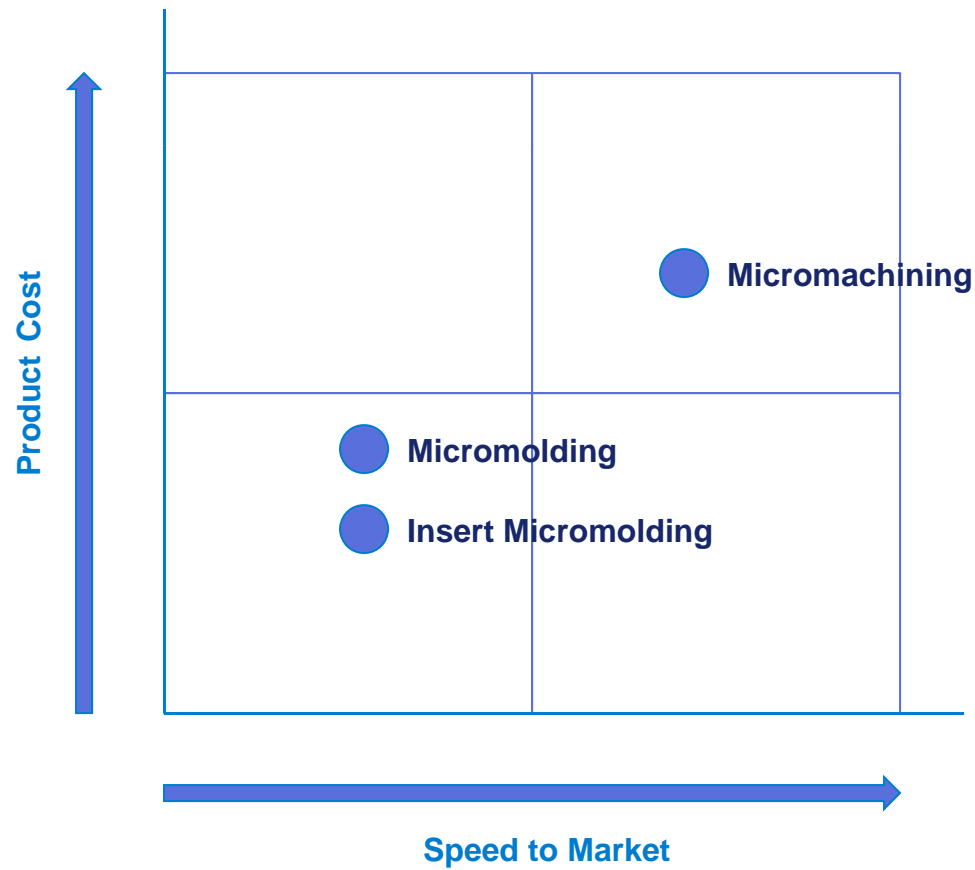
ADVANTAGES



Micromachining vs. Micromolding

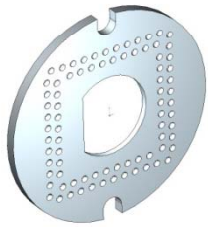


Product Cost vs. Speed to Market





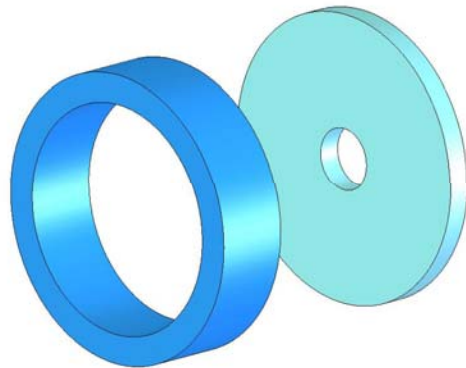
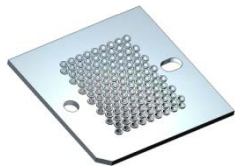
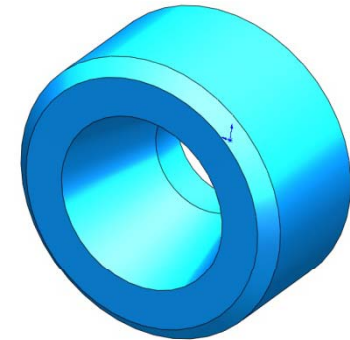
MIS Manufacturing Processes



Devices are manufactured by highly skilled labor (artisans) using a microscope



Devices use expensive machined components

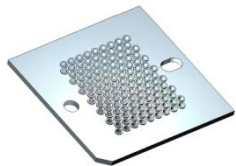
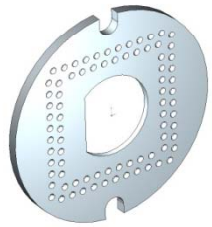


Devices require complex secondary operations which results in low production yields

Difficult to obtain a reliable manufacturing process



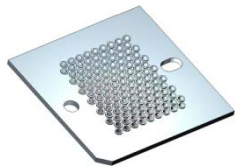
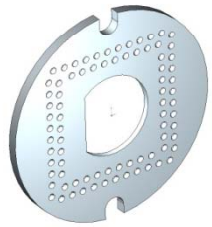
Benefits/Value of Micromolding



- Manufacture medical devices more efficiently
- Reduce costs by reducing the number of components, assembly complexity, cycle time and production yield
- Spur continuous improvement and innovation



Typical Medical Device Launch

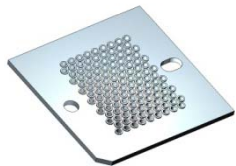
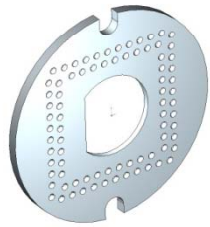


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What’s wrong with that methodology.....



Traditional Obstacles to Conversion

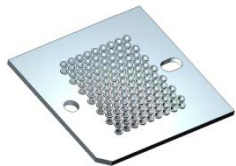
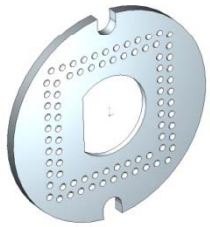


- **Materials Concerns**
“Is a suitable polymer available?”
- **Revalidation Process**
“Takes time and money.”
- **Tooling Costs**
“We are already in production.”
- **Risk of Failure**
“If it ain’t broke ...”

And perhaps the biggest obstacle.....



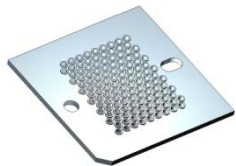
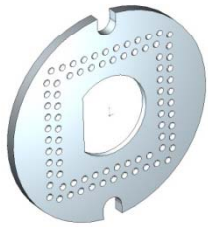
The FDA



- Can make it difficult and lengthy process to convert
- FDA chastised under current administration
- Too friendly to business
 - 510(k) testing doesn't come out the same
 - New device might not be as robust as existing design (precedent)



Recent Issue



- Customer submitted 510k comparable
 - Claim equivalence
 - Not as strong as competitor
 - Existing device stronger than needed
 - FDA feedback = device must equal competitors

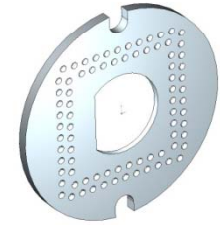


Plastic Selection Guide



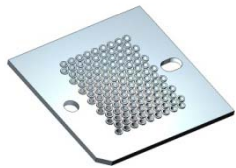
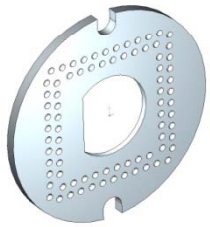
High Performance Plastic Selection Guide for Micromanufacturing Medical Devices

Acronym	Common Name	Trade Name	Bonding	Chemical Resistance	Creep Resistance	Dielectric Strength	Dimensional Stability	Heat Resistance	Impact Strength	Reinforcement	Strength & Stiffness	Surface Finish	Toughness	Wear Resistance	USP Class VI	ISO 10993	Implantable	High Flow into Thin Walls	Laser Friendly	Micromachining Friendly	Metal Replacement	Autoclave	ETO	Radiation		
Amorphous Plastics																										
PC	Polycarbonate	Lexan®	+	+		+	+	+	+				+		+	+			+	+				+	+	
PC	Polycarbonate	CALIBRE™	+	+		+	+	+	+				+		+	+			+	+				+	+	
PEI	Polyetherimide	Ultem®	+	+	+	+	+	+			+	+	+		+						+			+	+	
PES	Polyethersulfone	Radel®A			+	+	+						+							+					+	+
PPSU	Polyphenylsulfone	Radel®R		+	+	+	+	+	+				+		+	+				+					+	+
PPSU	Polyphenylsulfone	Veriva®		+	+	+	+						+		+	+									+	+
PSU	Polysulfone	Udel®	+	+	+	+	+	+			+		+		+	+				+					+	+
PSU	Polysulfone	Eviva®	+	+	+	+	+	+			+		+		+	+				+					+	+
SRP	Self-Reinforced Polyphenylene	PrimoSpire®		+	+		+				+	+	+		+	+		+	+						+	+
SRP	Self-Reinforced Polyphenylene	Proniva®		+	+		+				+	+	+		+	+		+	+						+	+
TPU	Thermoplastic Urethane	ChronoThane™													+			+							+	+
TPU	Thermoplastic Urethane	Pellethane™																+	+						+	+
Semi-Crystalline Plastics																										
LCP	Liquid Crystal Polymer	Vectra®		+	+	+	+	+			+	+		+	+	+		+			+			+	+	+
PARA	Polyarylamide	Ixef®		+	+		+				+	+	+		+	+		+			+			+	+	+
PEBA	Polyetherblockamide	Pebax®		+					+	+		+		+	+			+	+					+	+	+
PEEK	Polyetheretherketone	Victrex®PEEK™	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	Invibio®PEEK-Classix™	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	Invibio®PEEK-Optima™	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	KETRON®PEEK	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	KETRON®PEEK LSG	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	KETRON®PEEK-Classix™ LSG	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	KetaSpire®PEEK	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PEEK	Polyetheretherketone	Zeniva®PEEK	+	+			+	+	+	+		+	+		+	+			+	+	+			+	+	+
PMP	Polymethylpentene	TPX®		+		+					+		+					+							+	+





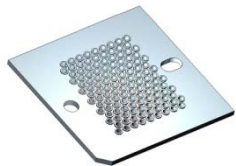
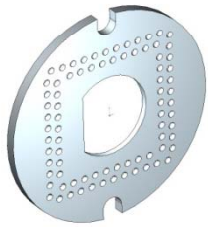
Specific Barriers



- Waiting for design to settle in
- Capital cost and time needed for development
- Surgeon's familiarity with product. Changing something may give the perception that it may not work. Looks different
- Geometrical changes required
- Functional changes
- New process (injection molding)



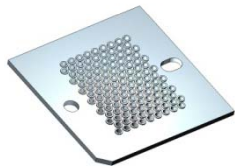
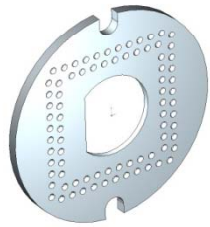
What Could Go Wrong?



- Stress cracks – gating
- Residual stresses – warping
- Appearance – fillets, added geometry
- Testing – crystallinity, trapped air, flow lines, gate, fillets



But.....



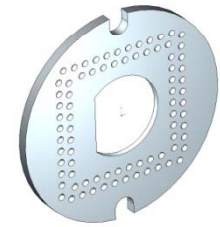
- Utilizing new micromanufacturing technologies such as micromolding can reduce or eliminate labor-intensive manufacturing operations
 - Reduce complexity (eliminate operations)
 - Improve quality
 - Increase production yield

Here's an example.....



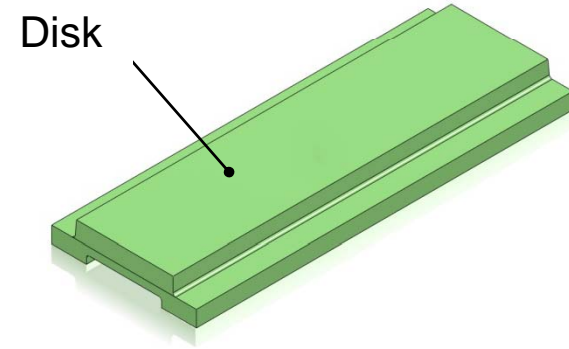
Conversion Case Study

Part Description: Disk



Disk → PEEK-Machined

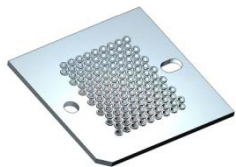
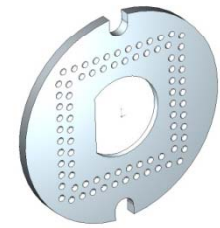
Disk → PEEK-Molded



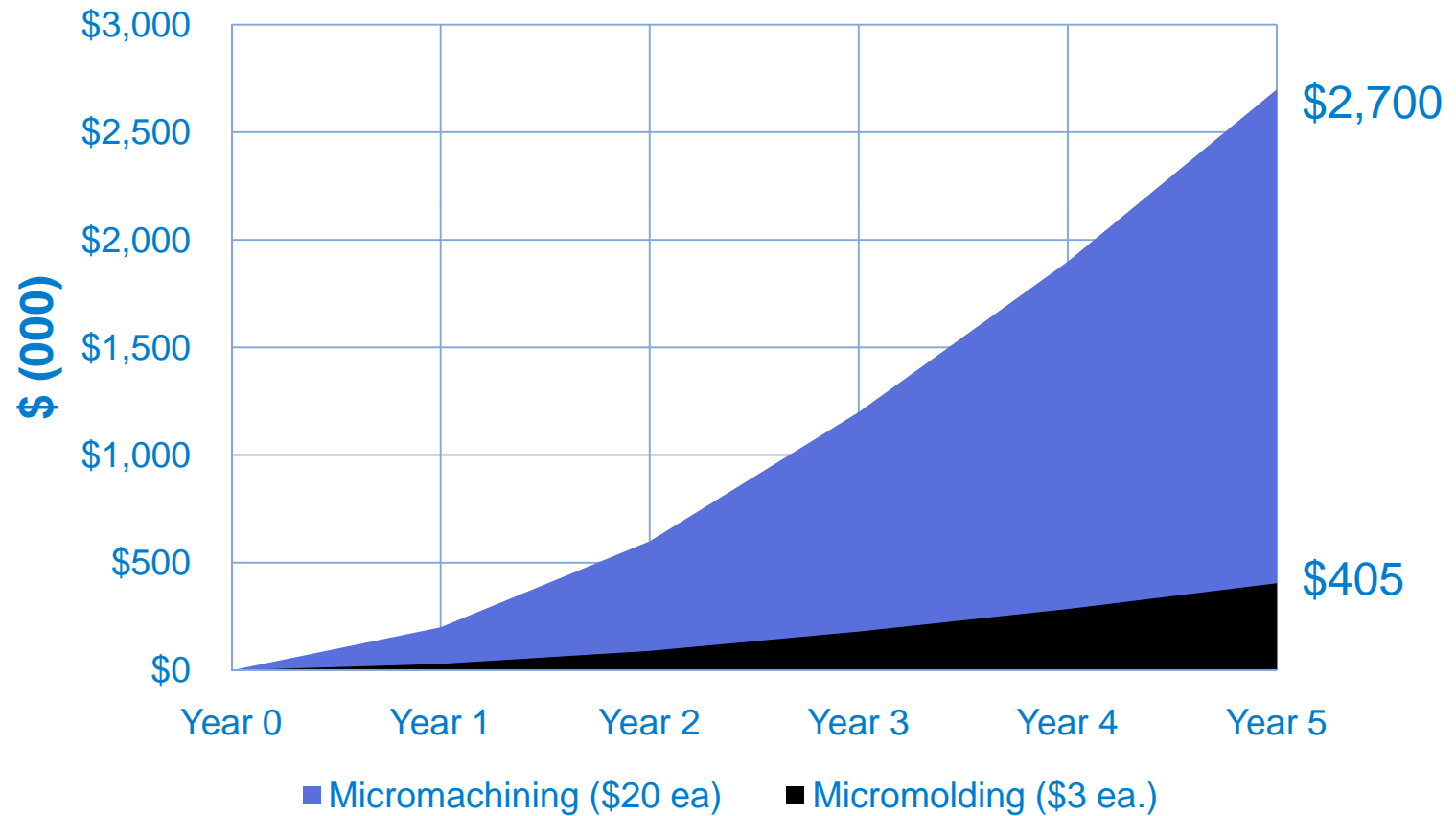
EAU	36,000
Machined Cost	\$20.00
Micromolded Cost	\$3.05
Annual Savings	\$610,200
Tooling Cost	\$65,000
Re-validation cost (est.)	\$30,000
5 Year NPV	\$2,546,847
IRR	5%



Micromachining vs. Micromolding



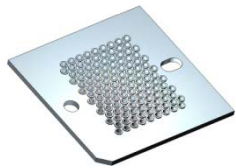
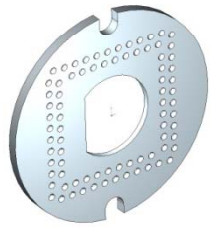
Opportunity Cost w/o IRR



Assumption: EAU is constant



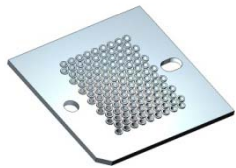
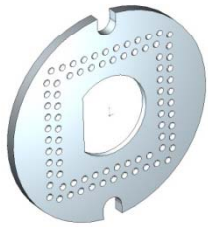
Proposed Medical Device Launch



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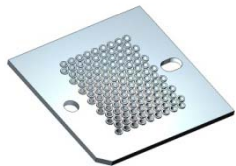
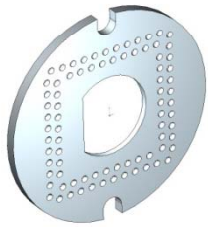
Summary/Conclusion



- There will always be a difference between machined and molded components
- This is not a procedure for everyone
- Submit medical device w/micromolded components for FDA approval
 - Maximize ROI - obtain full benefit of lower piece cost
 - Avoid re-verification and re-validation
 - Avoid lengthy delays with conversion



Questions



John Whynott
Technical Director
Mikrotech, LLC
5811 99th Avenue
Kenosha, WI
Ph. 262-857-5128
E-mail: jwhynott@asysttech.com
Website: www.mikrotech.com

