Healthcare & Medical Industry

Brian Pelley

Technical Specialist – Moldflow & Advanced Manufacturing Technologies

AUTODESK

Agenda

Healthcare & Medical Industry

- Applications
- Trends & Challenges
- Advanced MFG Technologies
- Moldflow Case Studies
- Edwards Lifesciences
- Idex Health & Science

https://thebestschools.org/rankings

Applications
Trends & Challenges

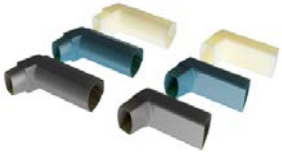
Applications

Wide Breath

- Equipment & Disposables
- Diagnostics / Labs
- Home Healthcare
- Surgical Devices
- Implants
- Dental
- Prosthetics

https://www.a-dec.com/gallery/dental-equipment

- Injection / Drug Delivery
- Blood / Plasma Systems
- Dialysis Equipment
- Packaging / labeling
- Vision
- Hearing
- Cable & Connectors
- Wearables?



https://www.wired.com

When your activity tracker becomes a personal medical-device
Seeking FDA

Trends

4th Industrial Revolution

- The Internet of Things
- Artificial Intelligence
- VR, AR
- Automation
- Surgical Devices
- Implants
- Reused vs Disposable
- Metal -2- Plastics
- Machined -2- Molded

WIRED

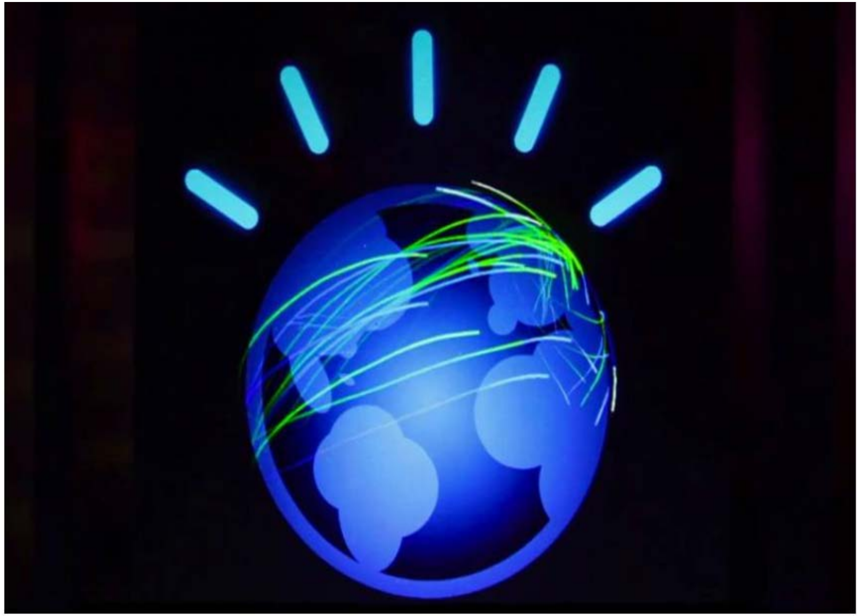
Technology | Science | Culture | Gear | Business | Politics

By IAN STEADMAN

Monday 11 February 2013

IBM's Watson is better at diagnosing cancer than human doctors

"The hope is it will improve diagnoses while reducing their costs at the same time."



Credit **IBM**

Trends

4th Industrial Revolution

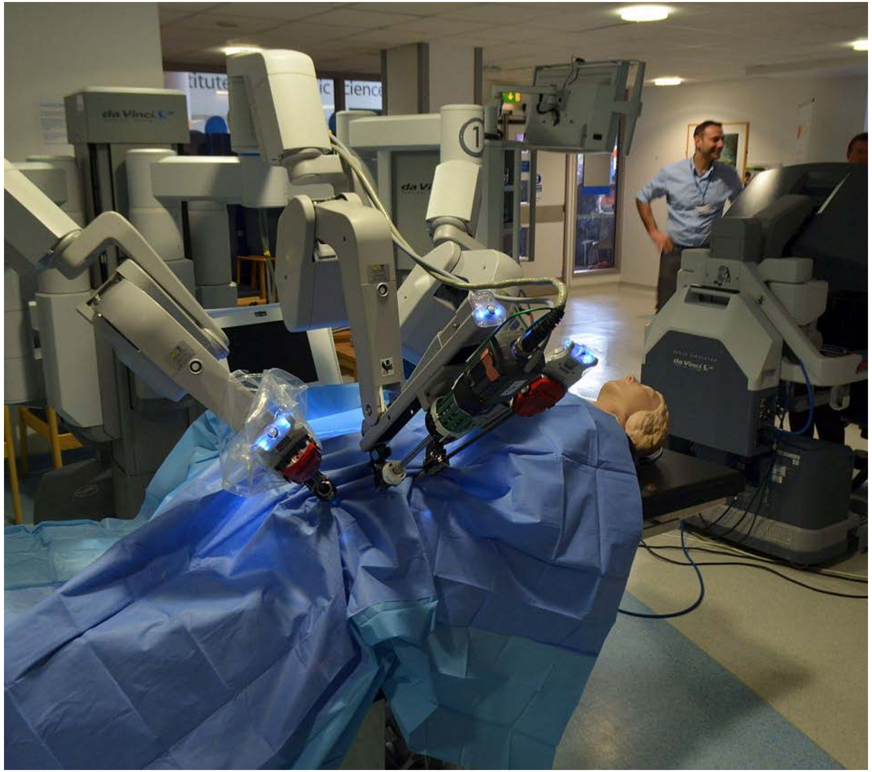
- The Internet of Things
- Artificial Intelligence
- VR, AR
- Automation
- Surgical Devices
- Implants
- Reused vs Disposable
- Metal -2- Plastics
- Machined -2- Molded

VR Surgery https://www.cnn.com/2016/04/21/health/virtual-reality-cancer-surgery/index.html

Trends

4th Industrial Revolution

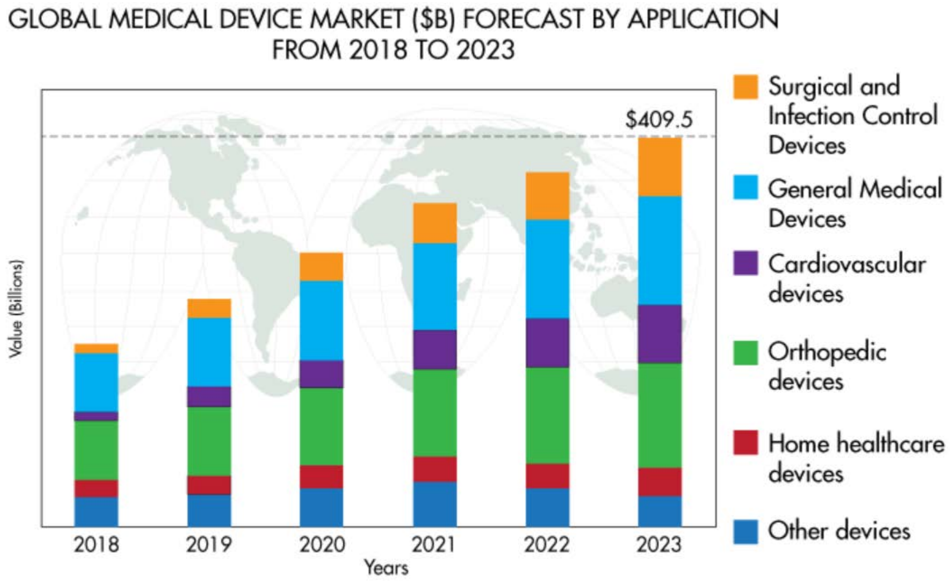
- Surgical Devices
- Implants
- Reused vs Disposable
- Metal -2- Plastics
- Machined -2- Molded



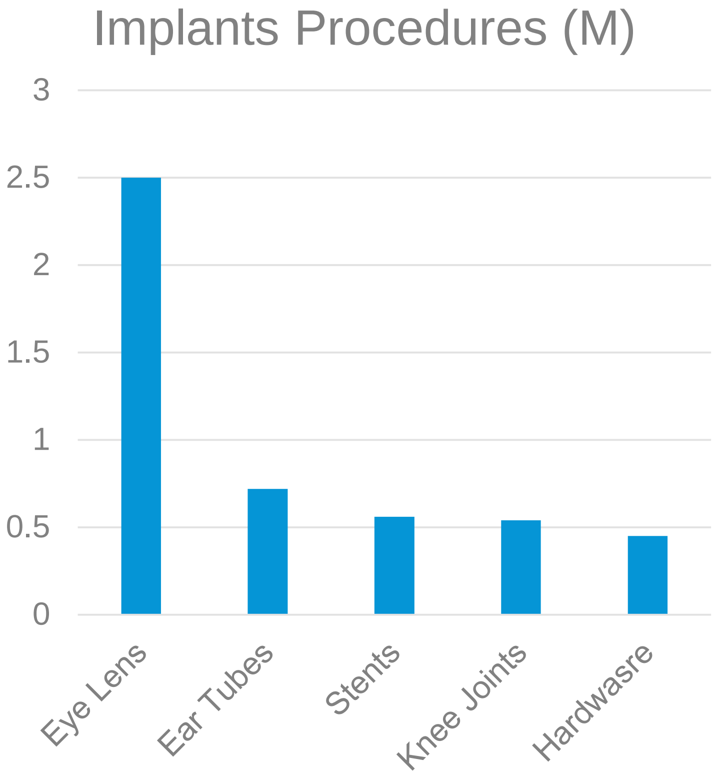
https://en.wikipedia.org/wiki/Da_Vinci_Surgical_System#/media/File:Cmglee_Cambridge_Science_Festival_2015_da_Vinci.jpg

Projected Growth

Medical Devices On The Rise



https://www.machinedesign.com/medical/analysts-say-medical-devices-are-rise

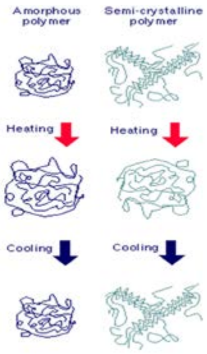


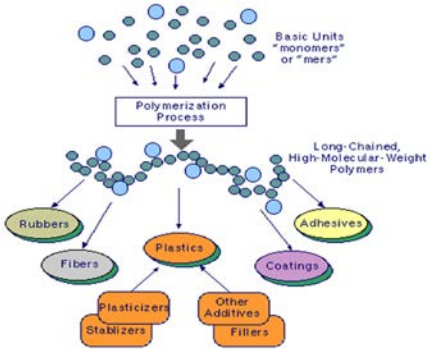
https://www.businessinsider.com/the-11-most-implanted-medical-devices-in-america-2011-7#6-intra-uterine-devices-iuds-6

Challenges

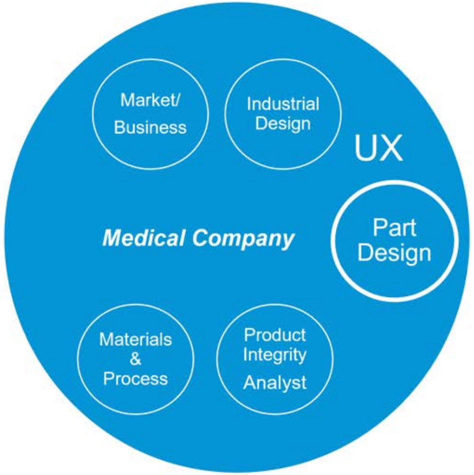
Plastics

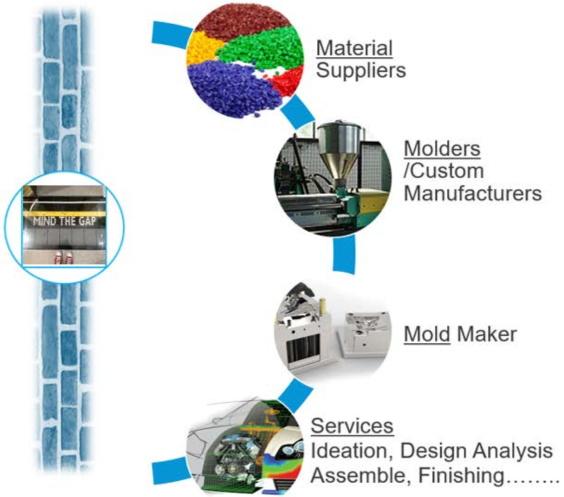
- Material Properties
  - Availability & Quality
  - Short Term Integrity
  - Long Term Integrity
- Product Development
  - Validation Short-Cuts
  - Prototype -2-Production
- Plastics Design Experience
  - Experience with metals
  - Start-ups with few resources
  - Recognizing Plastics Defect





Plastics Industry





Challenges

Medical

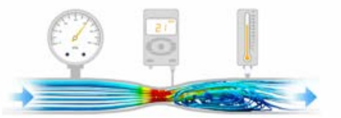
- Material Properties
  - Data Availability & Quality
  - Short Term Integrity
  - Long Term Integrity
- Product Development
  - Validation Short-Cuts
  - Prototype -2-Production
- Plastics Design Experience
  - Experience with metals
  - Start-ups with few resources
  - Recognizing Plastics Defect
- Validation & Regulatory
  - Design & Process Validation
  - Class I, II, III…Tracking
- Environment
  - Sterilization
  - Tissue / Fluid contact (removed vs absorbed)
  - Drug flow path exposure
- Liability
  - Outsourcing
  - Qualified Suppliers
  - User Experience Engineering

Advanced MFG Technologies

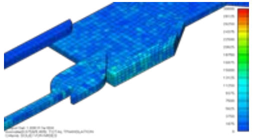
Autodesk Make

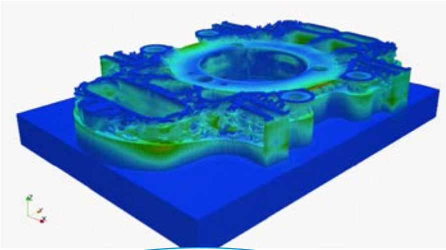
Process Types

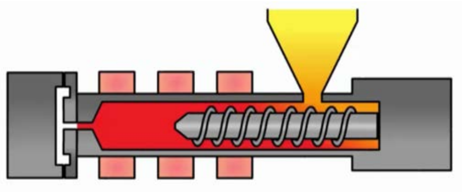
Up Front Virtual Testing

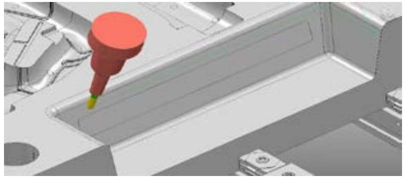


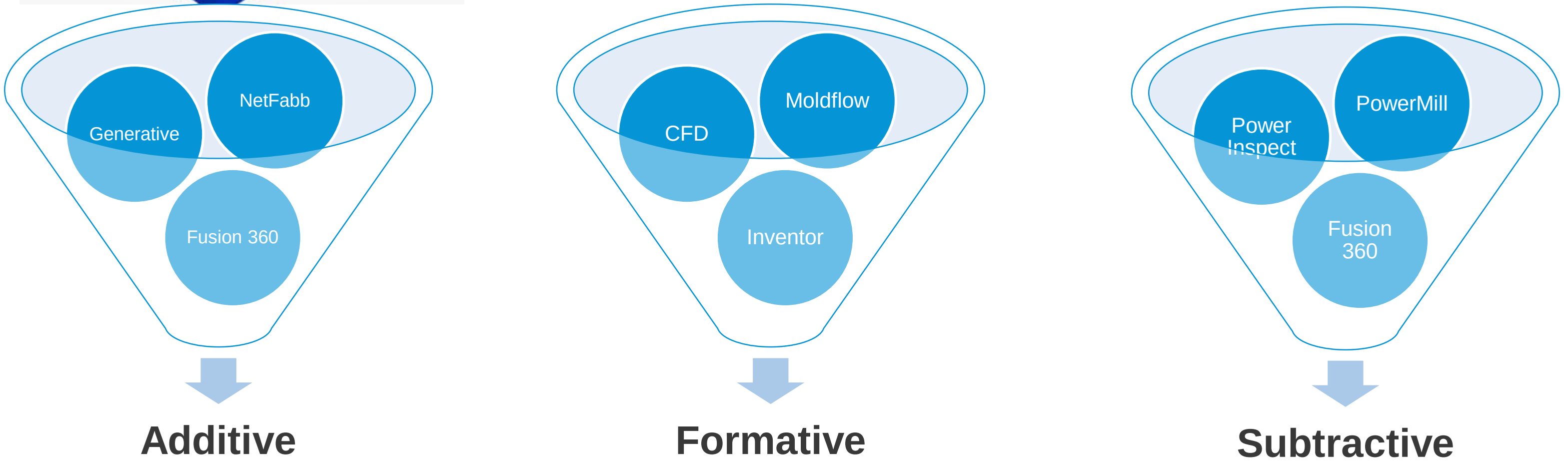
CFD & FEA







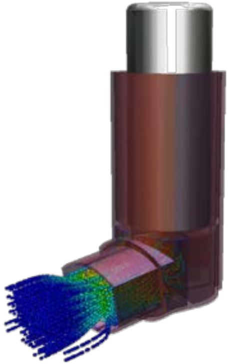


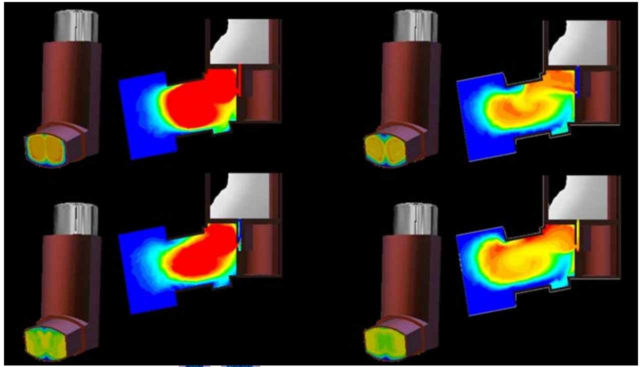


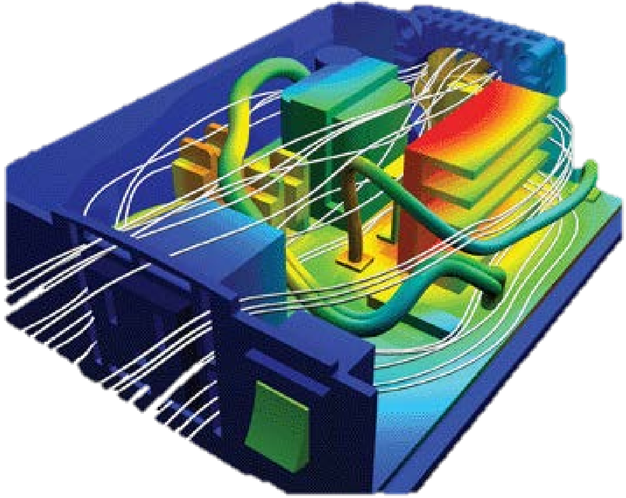
CFD Insight

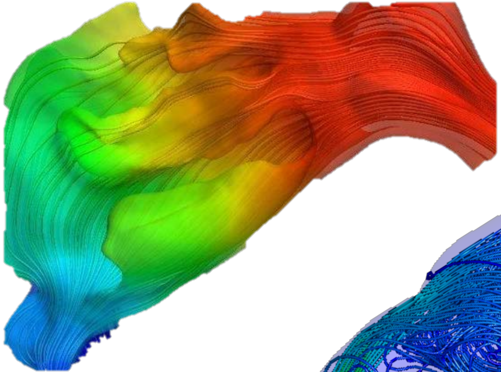
Advanced MFG Technologies

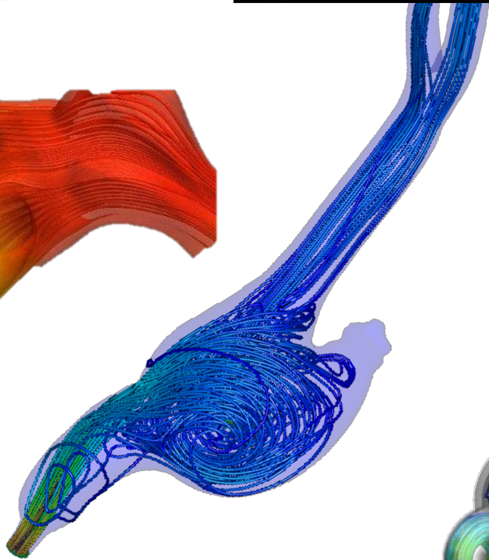
Performance of Medical Devices & Equipment

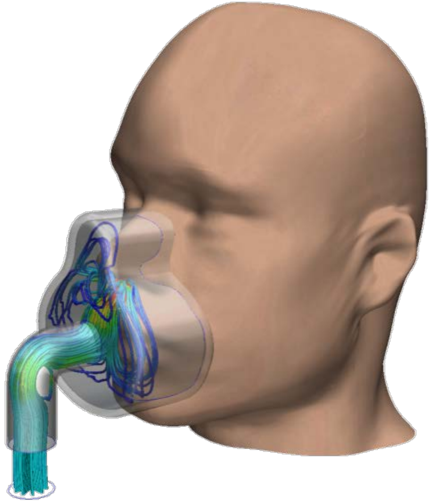










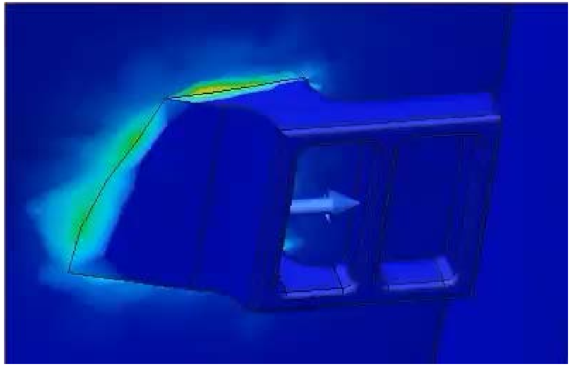


Simulate Thermals & Fluid Flow

FEA Insight

Advanced MFG
Technologies

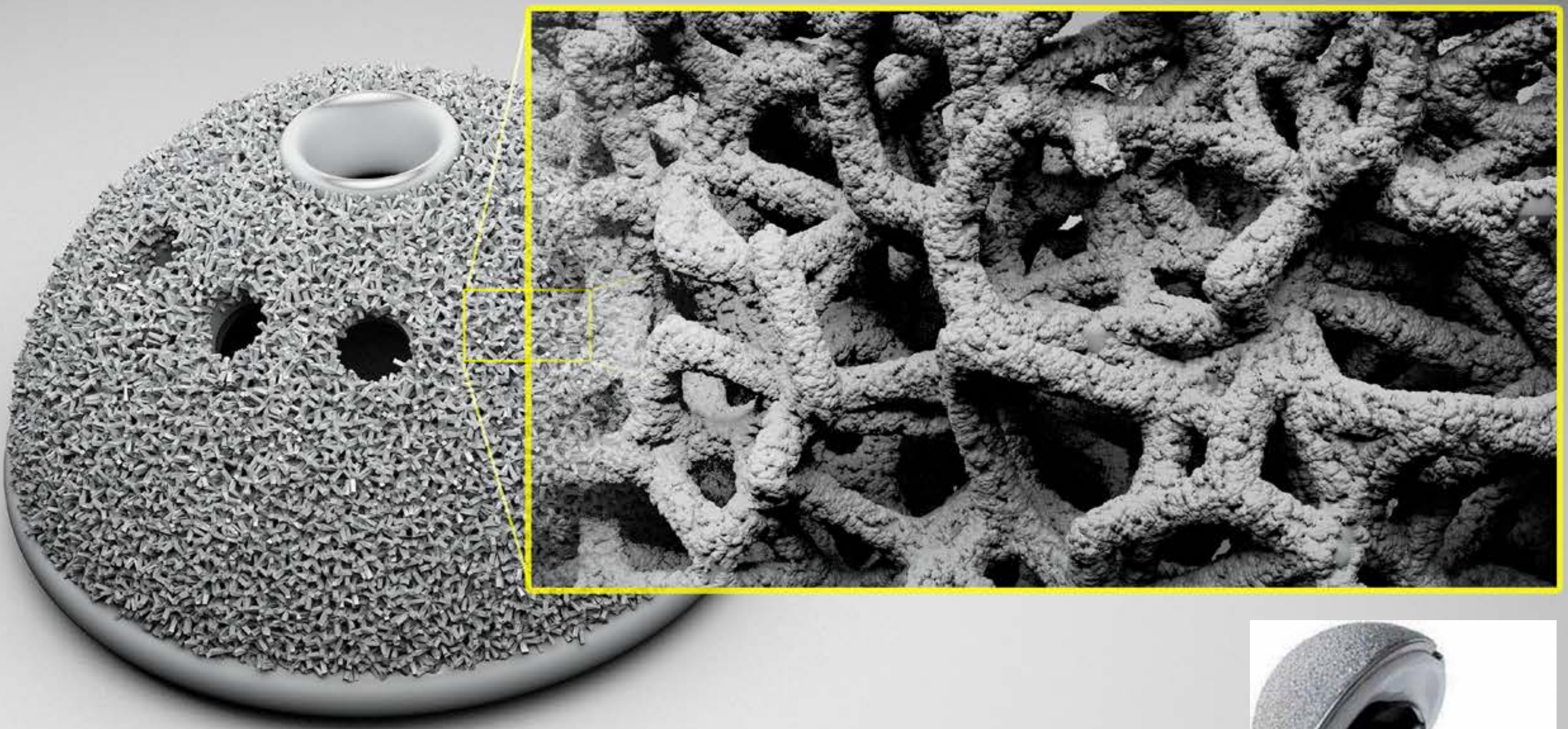
Performance of Medical Devices & Equipment



Simulate static stress on the prosthetic socket buckles

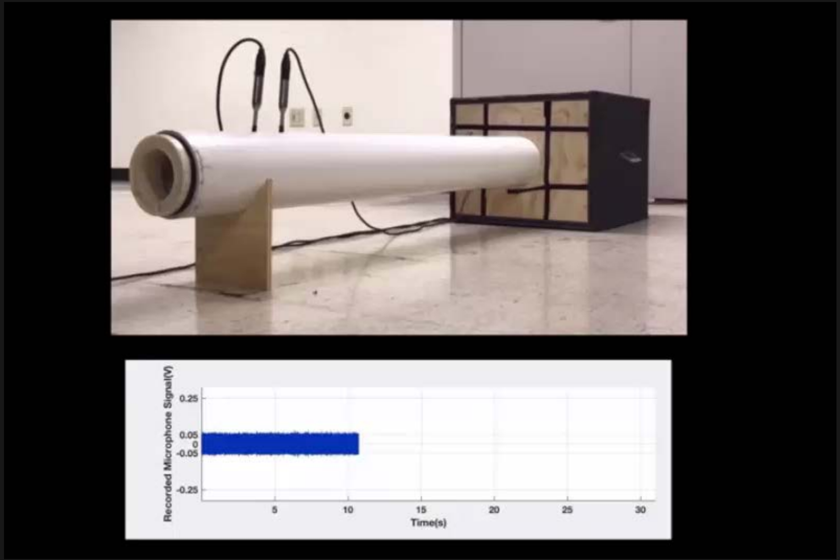
Additive

Advanced MFG Technologies



Within Medical Porous random latticing. Design porous random lattices for orthopedic implants tailored for osseointegration

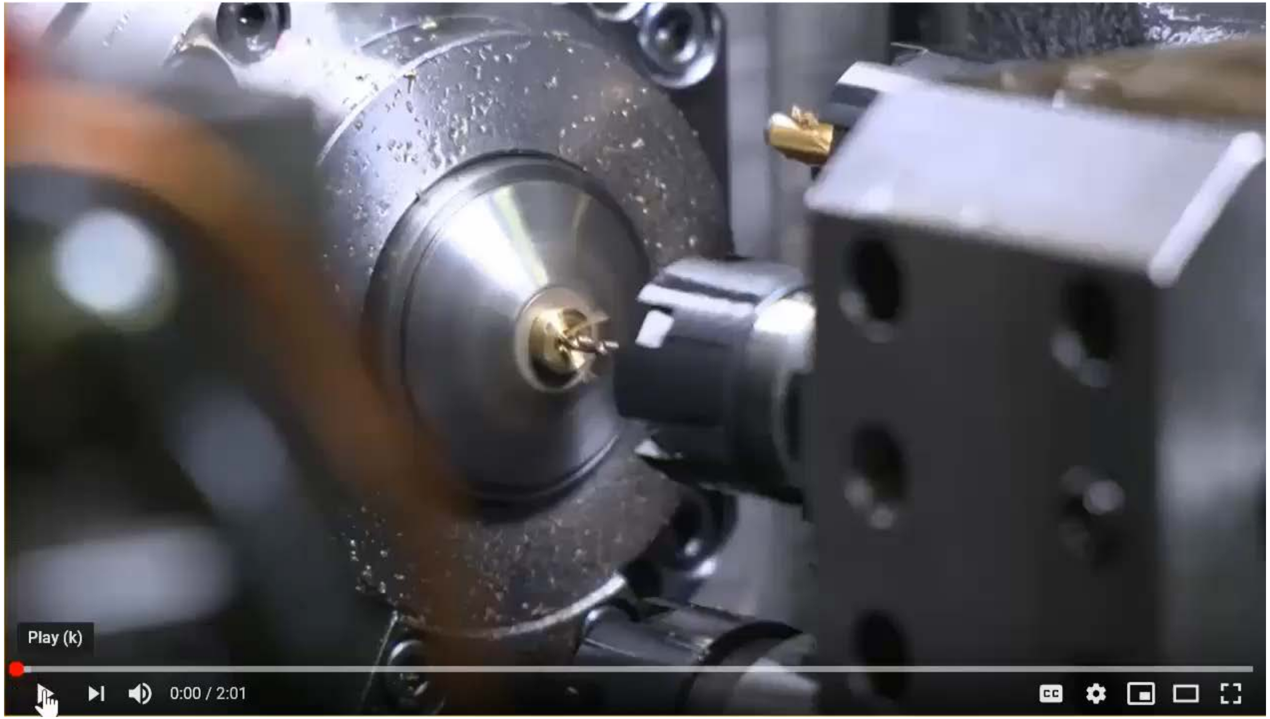
Deceptively simple, the 3D-printed material is a mathematical marvel. (Photo: Cydney Scott, Boston University)



Subtractive

Advanced MFG Technologies

Medical CAM Applications



Enables high precision programming for Swiss-type lathes

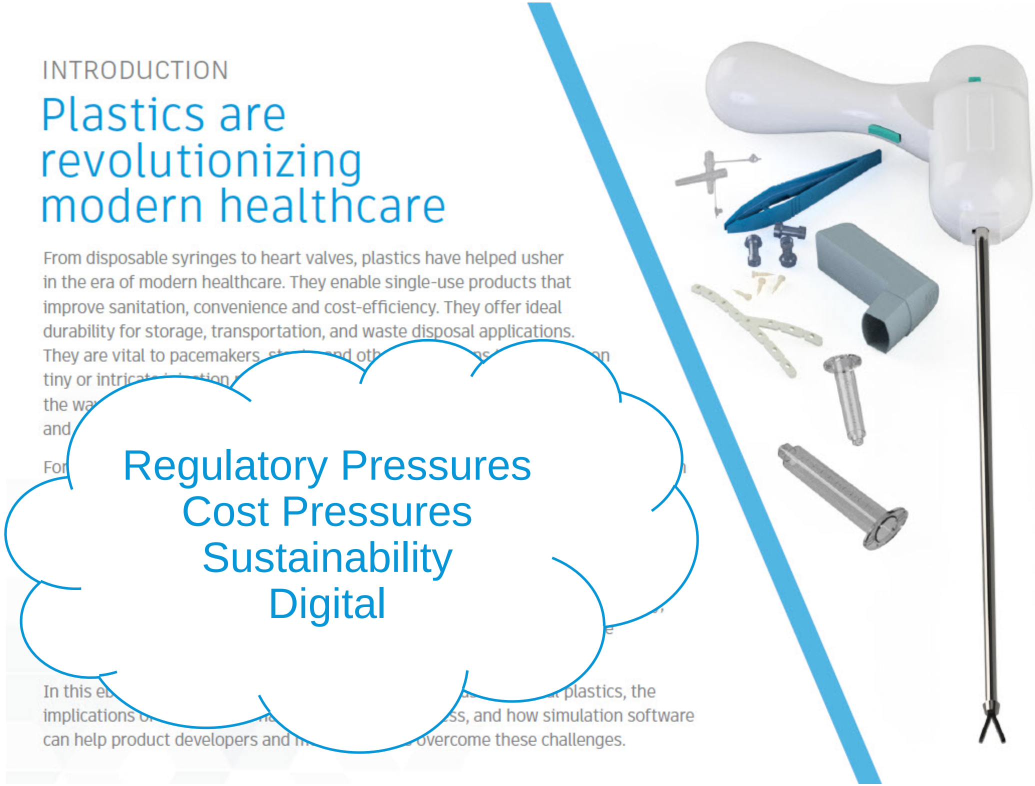
Moldflow

Advanced MFG Technologies

How Moldflow Helps

Design - Make

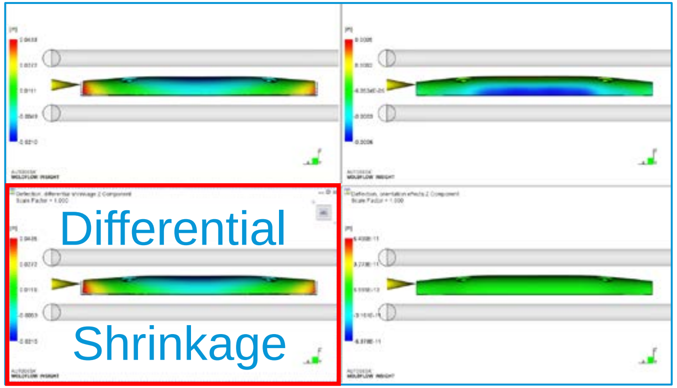
- Regulatory & Sustainability
- Exploration at a low cost
- Identifying Alternative Cost Models
- Complex Design Feasibility

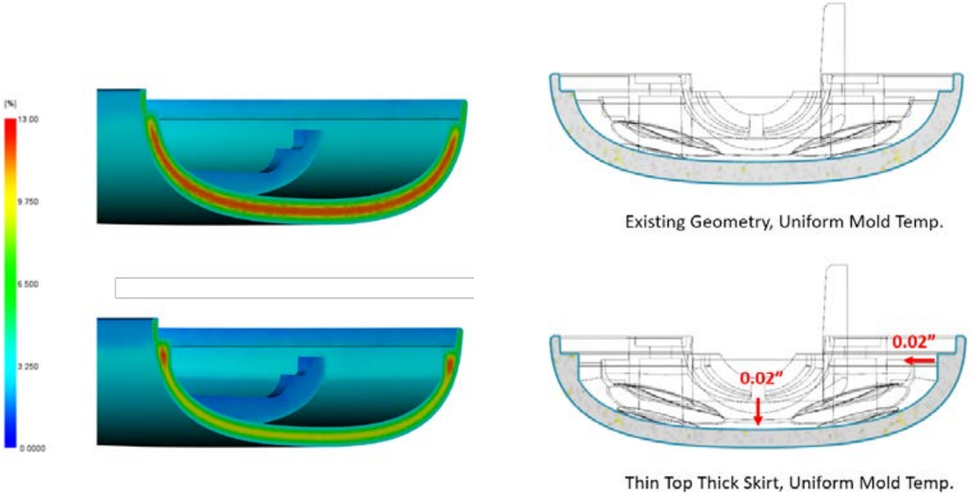


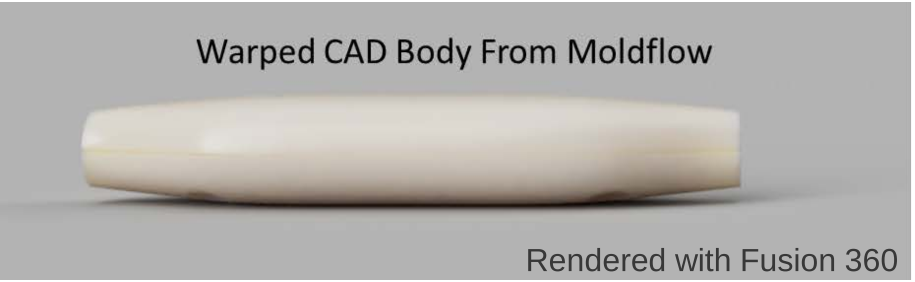
Regulatory Pressures
Cost Pressures
Sustainability
Digital

AUT-MFG1441_Medical device ebook_en

Patient Monitoring







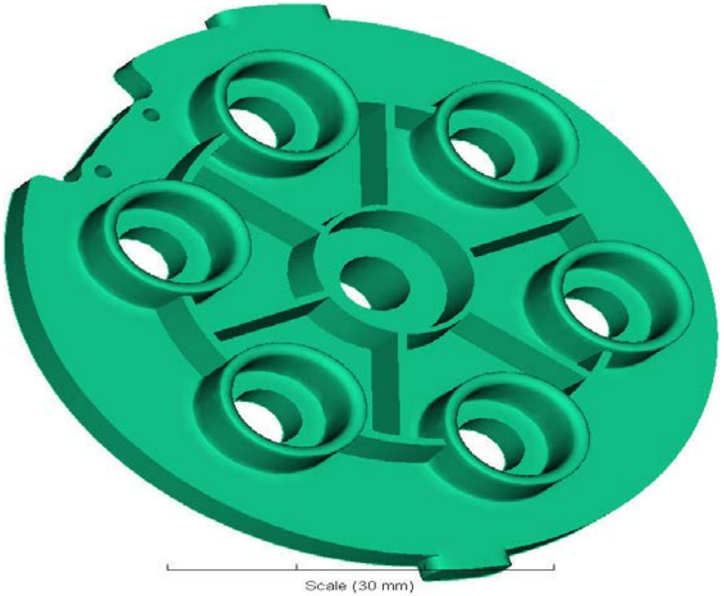
The Prototypes were flat…………… ¯_(ツ)_/¯

Medical Valve Assembly

Shrinkage Molding Summary

	Melt Temperature C	Mold Temperature C	Flow Rate (R) cm^3/s	Flow Rate (F) cm^3/s	Ram Diameter mm	Ram Displacement mm	Thickness mm	Pac
1	241.7	36.1	47.4	34.3	45	30.9	2	
2	246.2	38.7	47.3	36.3	45	30.9	2	
3	251.8	37.5	47.1	36.3	45	30.9	2	
4	245.9	34.7	23.7	19	45	30.8		
5	246.4	37.3	70.2	52.9	45	30.9		
6	222.2	34	46.7	32.6	45	30.9		
7	225.7	34.7	47.3	33.4	45	30.9		
8	230.8	37	46.8	37.4	45	30.8		
9	224.7	38.3	23.8	17.9	45	30.9		
10	225.1	35	69.9	57.7	45	30.9		
11	262.4	38.3	47.1	34.3	45	30.9		
12	267.1	40.2	47.3	37.4	45	30.9		
13	272.4	37.4	47.1	33.4	45	30.8		
14	266.4	36.2	23.7	18.7	45	30.9		
15	266.9	39.2	71.4	57.7	45	30.9		

Thickness in	Parallel Shrinkage %	Perpendicular Shrinkage %	Volumetric Shrinkage %
0.059055	1.45	1.28	4.85
0.059055	1.37	1.19	4.14
0.059055	1.26	1.06	3.5
0.059055	1.47	1.17	4.03
0.059055	1.31	1.18	4.21
0.07874	1.39	1.47	4.48
0.07874	1.28	1.28	3.72
0.07874	1.15	1.16	3.09



	Case 1	Case 2	Case 3	Case 4
Observed nominal shrinkage				
Parallel	0.1326 %	0.753 %	0.1534 %	0.274 %
Perpendicular	0.9854 %	0.7245 %	1.152 %	0.9323 %
Observed shrinkage				
Minimum Parallel	0.08595 %	0.5135 %	0.1111 %	0.224 %
Maximum Parallel	0.1609 %	0.9218 %	0.2469 %	0.3224 %
Minimum Perpendicular	0.732 %	0.454 %	0.871 %	0.8032 %
Maximum Perpendicular	1.198 %	0.9925 %	1.722 %	1.116 %

Required top face flatness tolerance within 0.15mm

Material Comparison

Unfilled Material

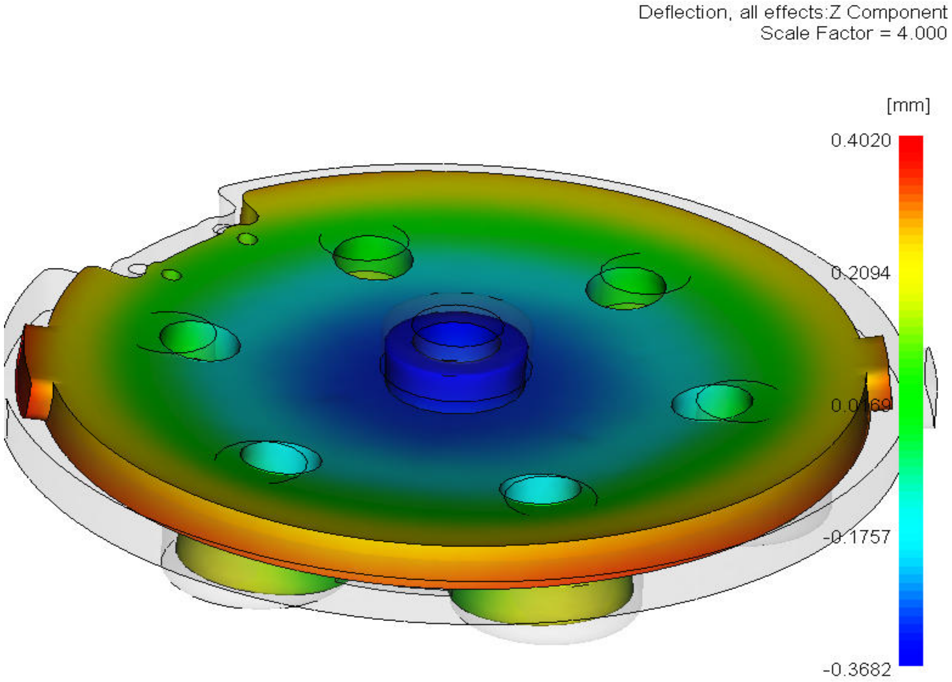
- bows 0.64mm

30% GF Material

- bows 0.19mm

15% GF + Mineral

- bows 0.08mm



Healthcare & Medical Industry

Robert Pozzo

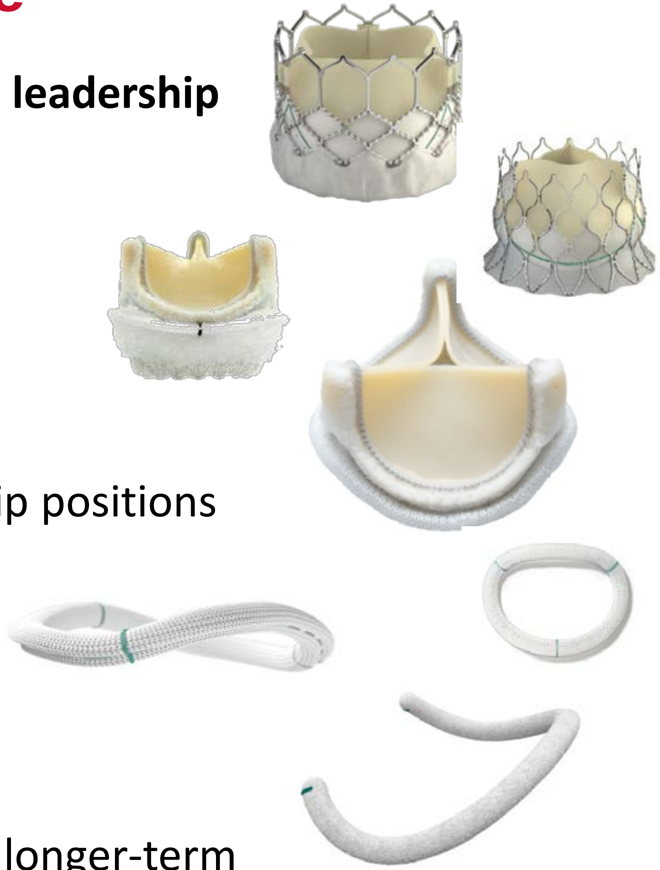
Tool Engineer

Edwards

Our History

- Founded by Miles “Lowell” Edwards in 1958
  - Inventor and visionary, held 60+ patents
- Trusted partner with physicians to introduce innovative medical devices
  - Albert Starr, Jeremy Swan, William Ganz, Thomas Fogarty, Alain Carpentier, Delos Cosgrove, Alain Cribier
- Company evolution
  - 1958 Edwards Laboratories
  - 1968 American Hospital Supply
  - 1985 Baxter International
  - April 2000 Edwards Lifesciences (NYSE:EW)

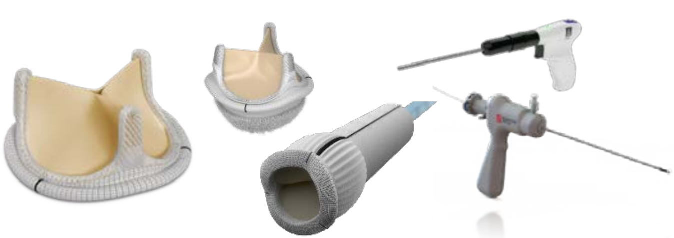
Surgical & Transcatheter Heart Valve



- **Investing to transform patient experience and extend leadership**
- **Global growth opportunities**
  - Aging populations, emerging markets
- **Transcatheter therapies expand treatment options**
  - Clinical evidence, new technologies extend leadership positions
  - Focused on procedural success
- **Global growth opportunities**
  - Untreated patient populations
  - Moderate and low-risk patients may seek treatment longer-term

Edwards' Growth Primarily Fueled by Innovation

- Multiple THV growth opportunities
  - Expanded indications and device innovations
  - New interventional platforms including mitral

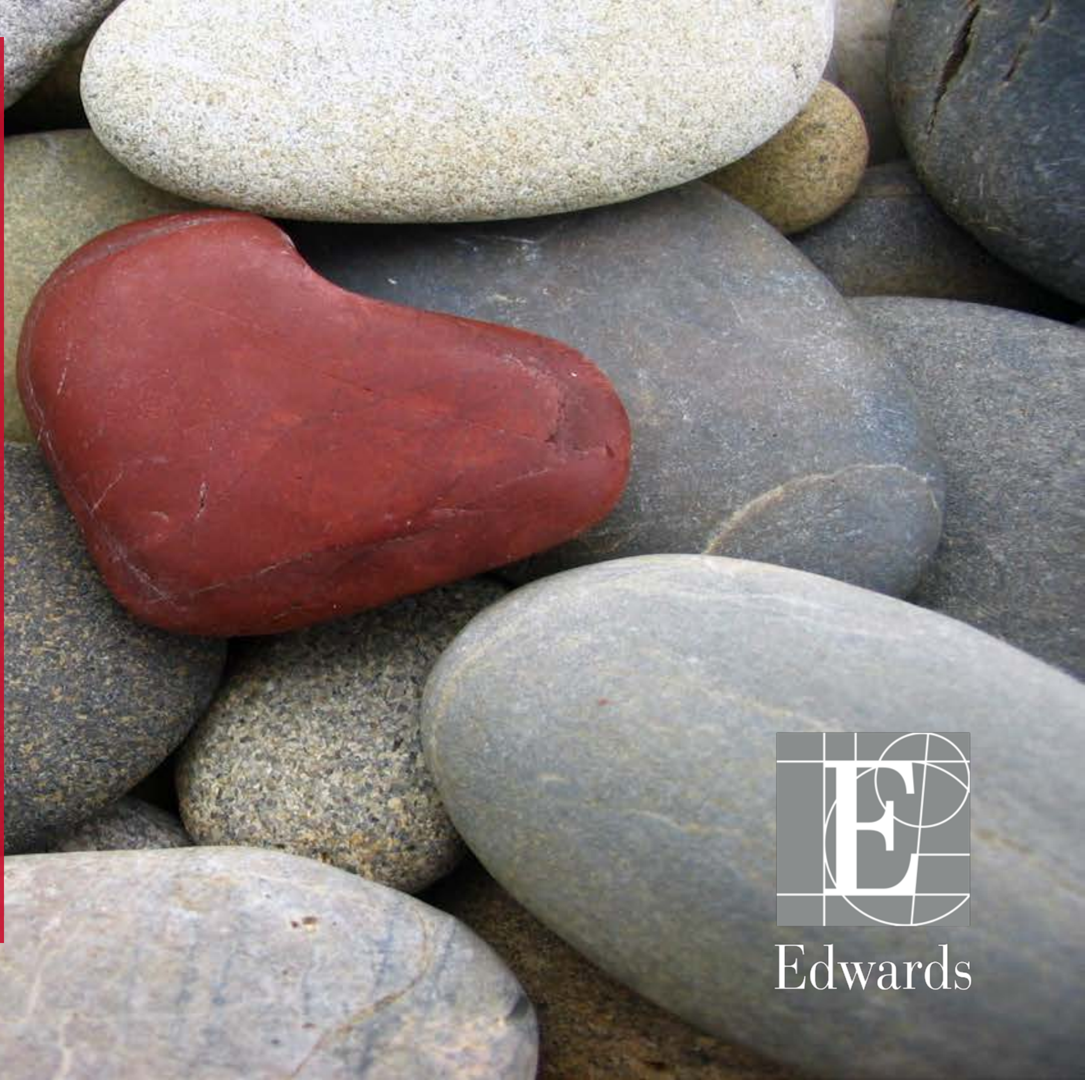


- Transformation of Valve Surgery
  - MIS platforms potential to be standard of care
  - Innovative options for younger patients

- Critical Care expansion
  - Non-invasive technology increases penetration
  - Pioneering smart monitoring innovations

- Expansion in emerging markets

Medical Molding
Case Studies



Edwards

Weld Line Prediction Study

Predetermine weld lines formations to incorporate features

Material: Sabic, Lexan HPX8R (High flow PC 35 MFR)

Processing Temperature: 581° F

Mold Temperature: 180° F

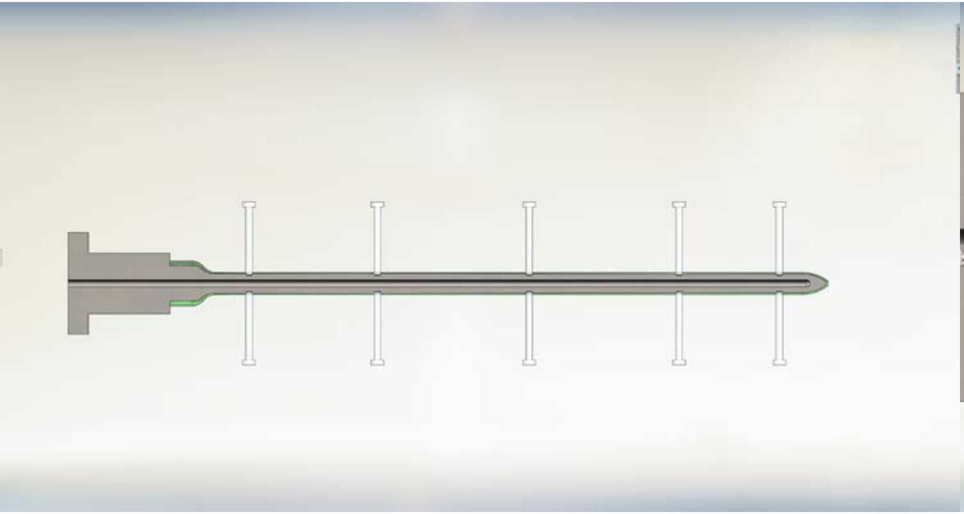
Challenges:

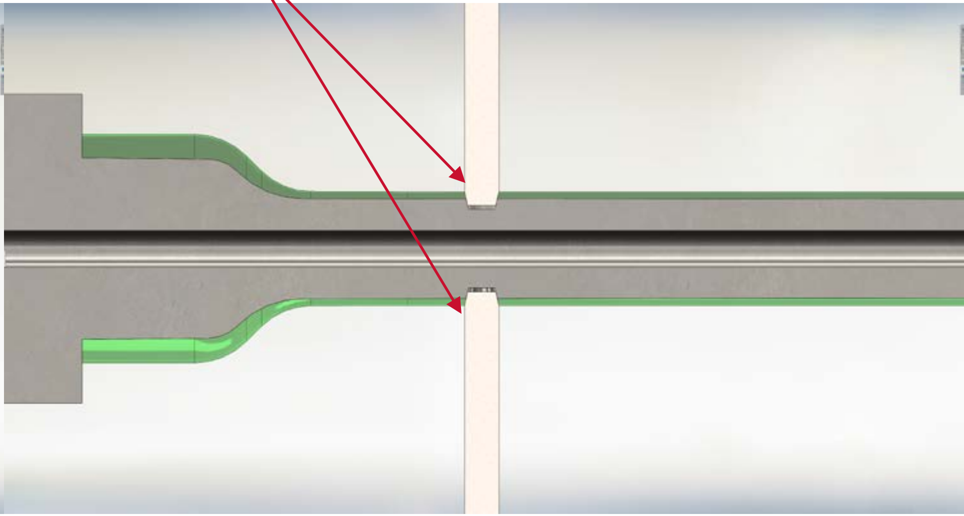
- Nominal and Thick Wall Sections
- Over-Molded Wire Will Have Pull Force and Torsion Requirements

Weld Line Prediction Study

Core pins to support Main Core Pull from deflection will also be vented to atmosphere.

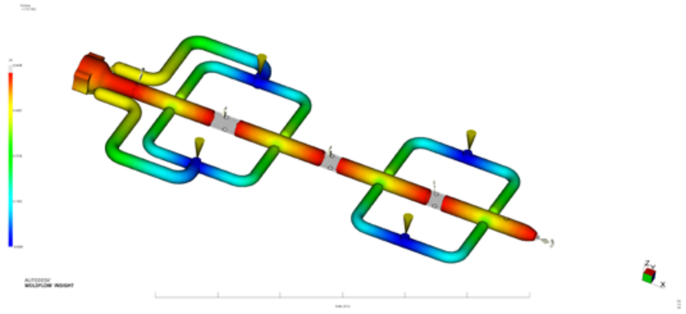
Placement of the core pins is predetermined by the weld lines formation prediction.

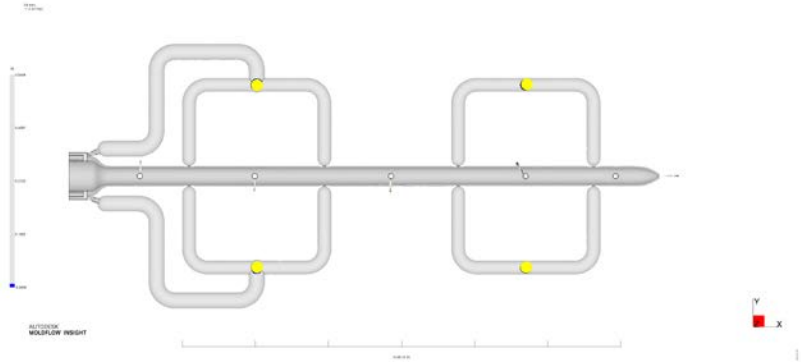


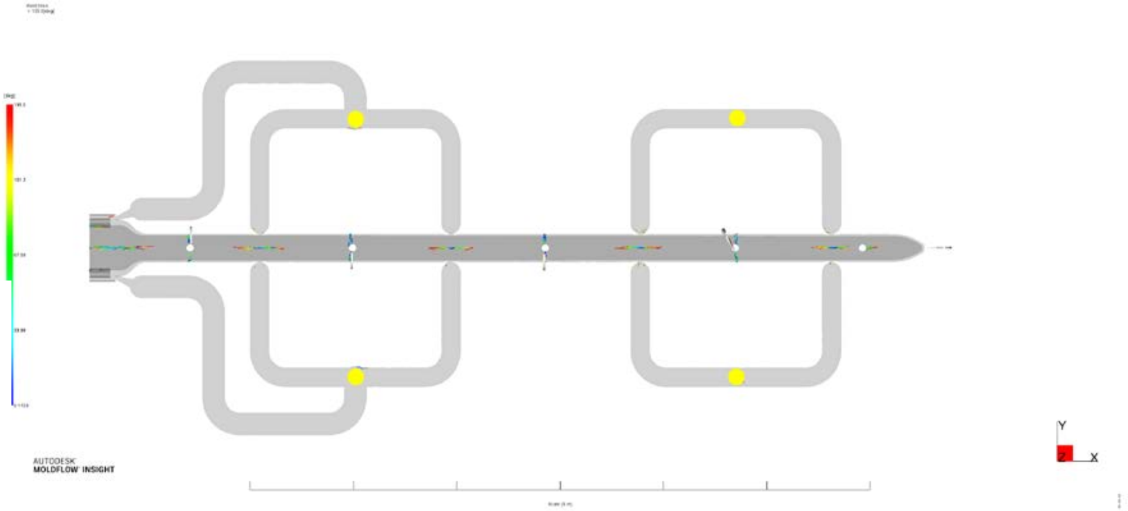


Weld Line Prediction Study

Predetermine weld line formations to incorporate features





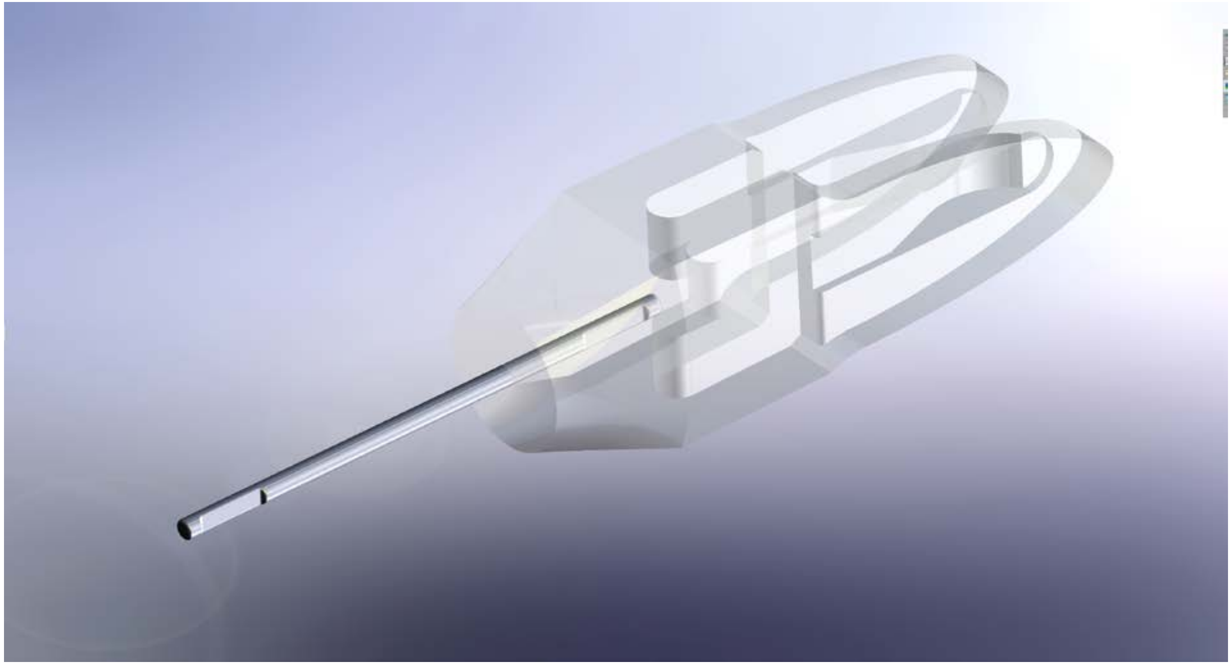


Shrinkage Void Mitigation

Material: Solvay Udell P1700 (PSU)

Processing Temperature: 675° F

Mold Temperature: 300° F

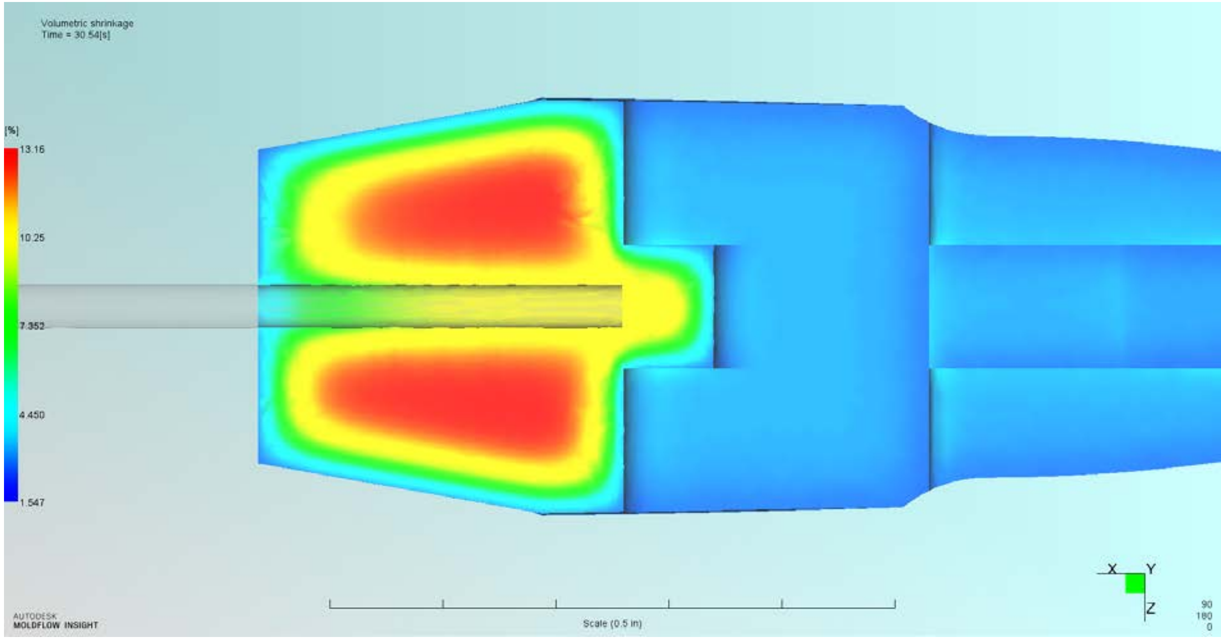


Challenges:

- Nominal and Thick Wall Sections
- Over-Molded Wire Will Have Pull Force and Torsion Requirements

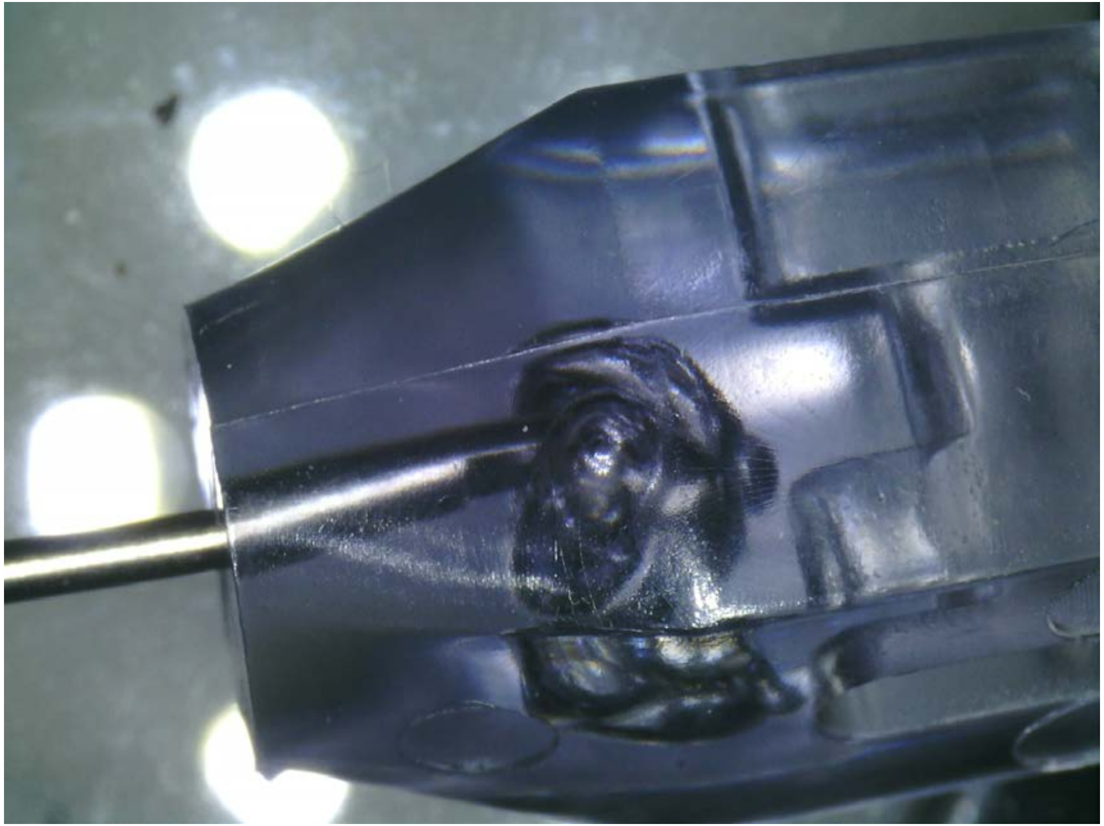
Shrinkage Void Mitigation

Observation:
Heat Concentrated in Thick Areas Created a Void After Pack and Hold Causing Wire to Slip Out.



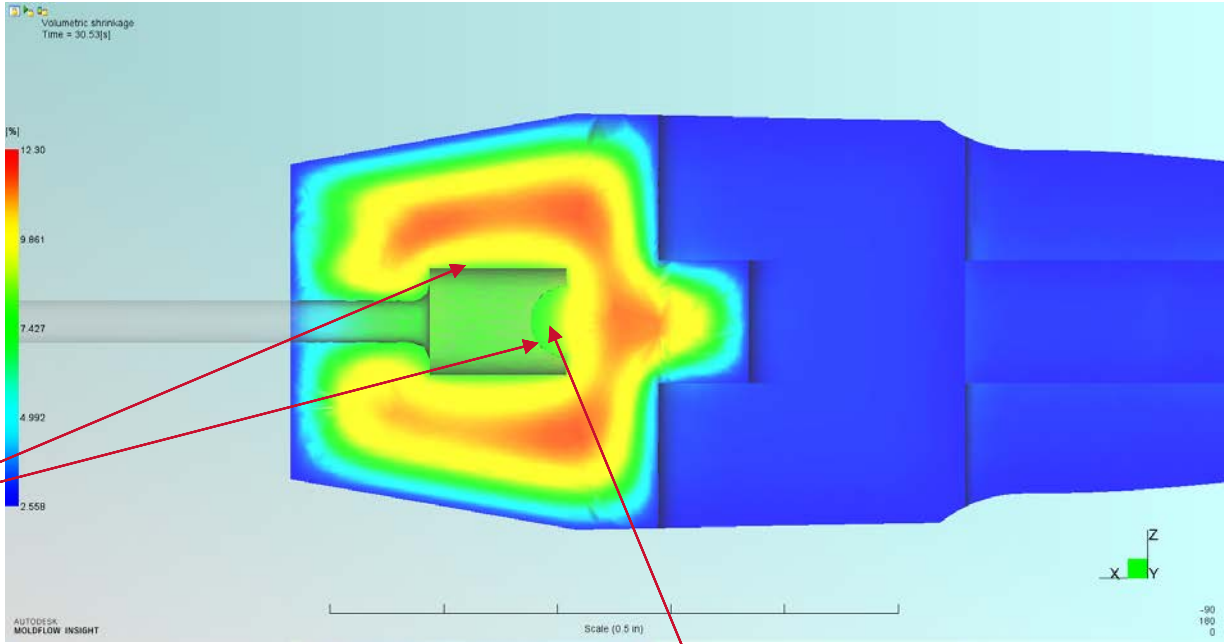
Processing Was Not Successful In Removing The Void. Temperature Variations and Profile Injection Helped Reduce The Void, But No Significant Change.

Shrinkage Void Mitigation



Shrinkage Void Mitigation

Approach A:
Adding Material to The Wire To Reduce Material Wall Thickness Thus Removing Concentrated Heat and Shrinkage.
Different Wire Configurations Were Evaluated

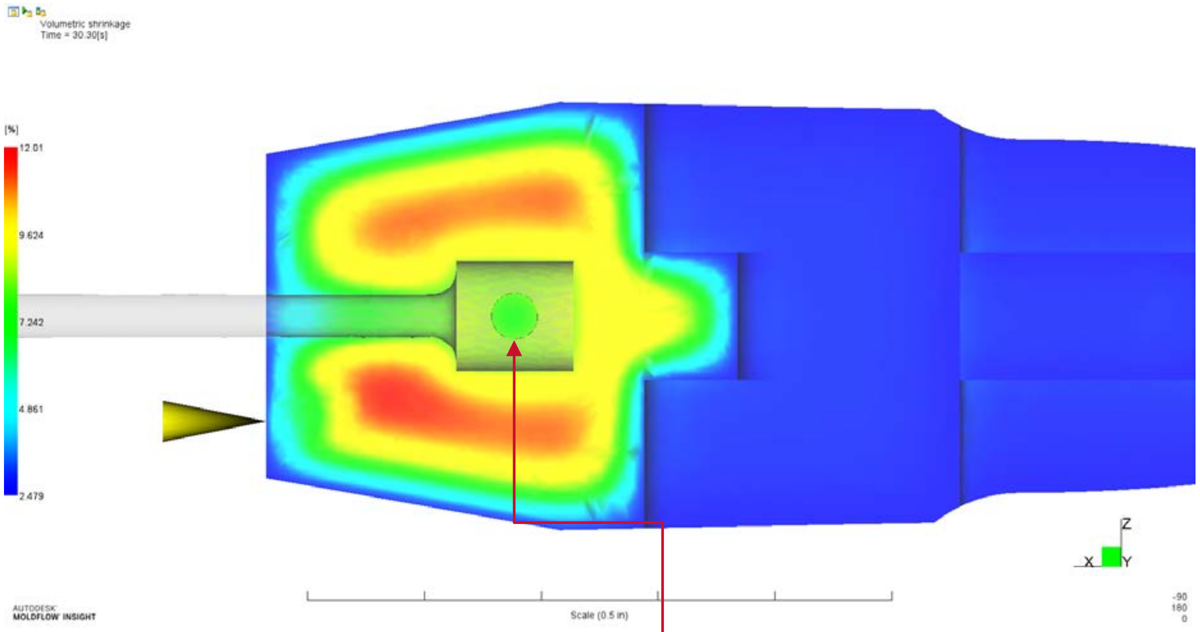


Wire With a Larger Step To Add Material and a Groove To Prevent Rotational Movement

Air Trap Identified During Flow Analysis.

Shrinkage Void Mitigation

Approach B:
Adding Material to The Wire To Reduce Material Wall Thickness Thus Removing Concentrated Heat and Shrinkage.
Different Wire Configurations Were Evaluated

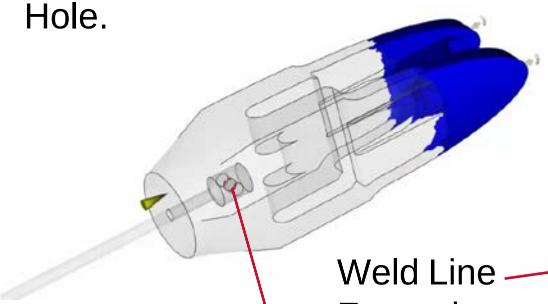


Wire With a Larger Step To Add Material and a Hole Thru To Prevent Rotational Movement

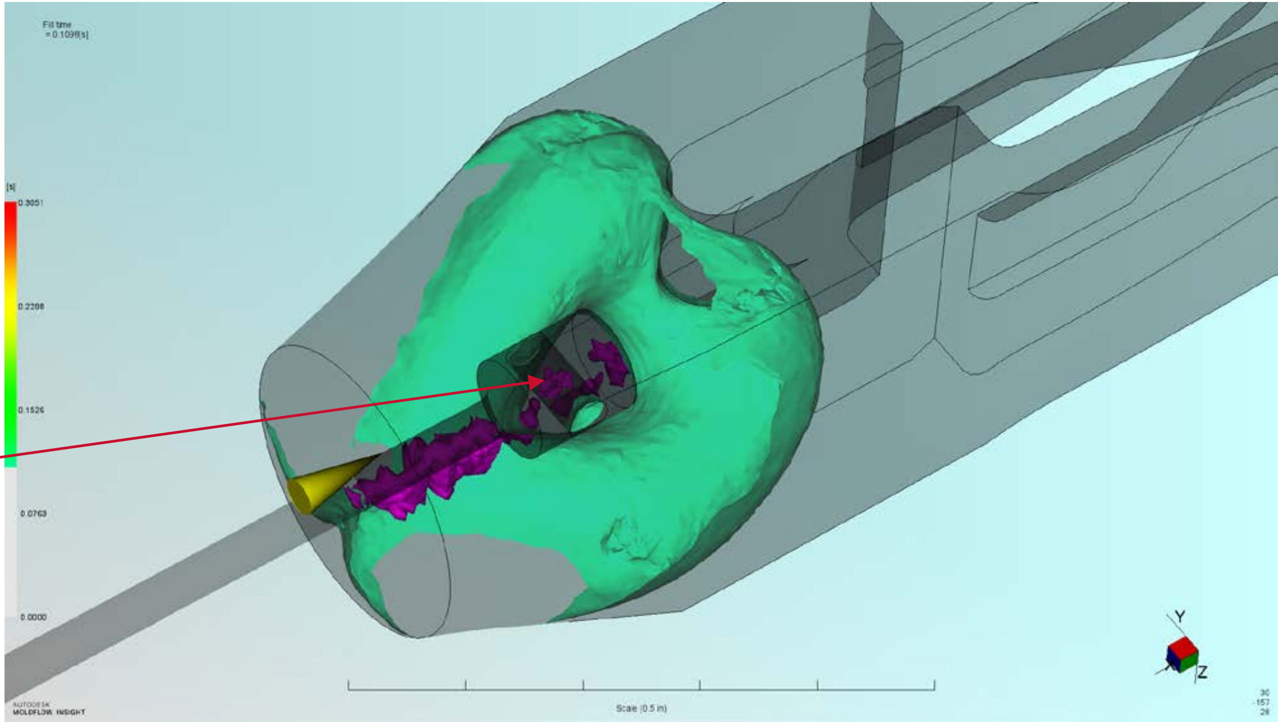
Trapped Air Preventing Fill

Shrinkage Void Mitigation

Approach B:
Weld Line Formation Identifies Trapped Air Pocket in the Wire Hole.

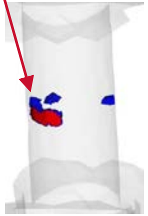


Weld Line Formation



Vent / Back Pressure

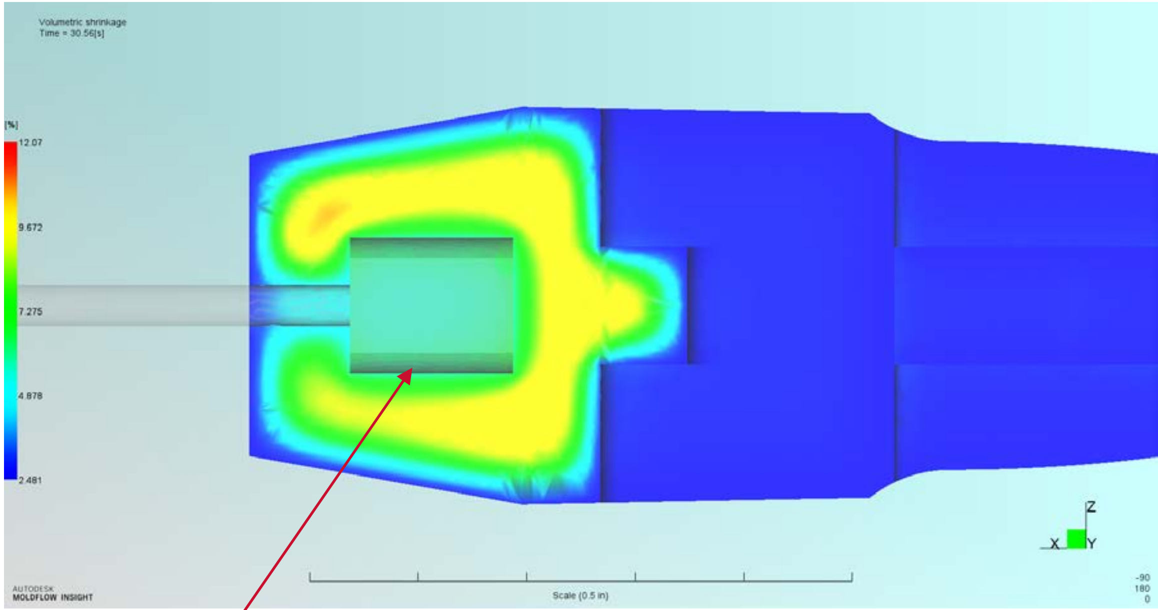
Unfilled Cavity predicted



Shrinkage Void Mitigation

Approach C:
Adding Material to The Wire To Reduce Material Wall Thickness Thus Removing Concentrated Heat and Shrinkage.

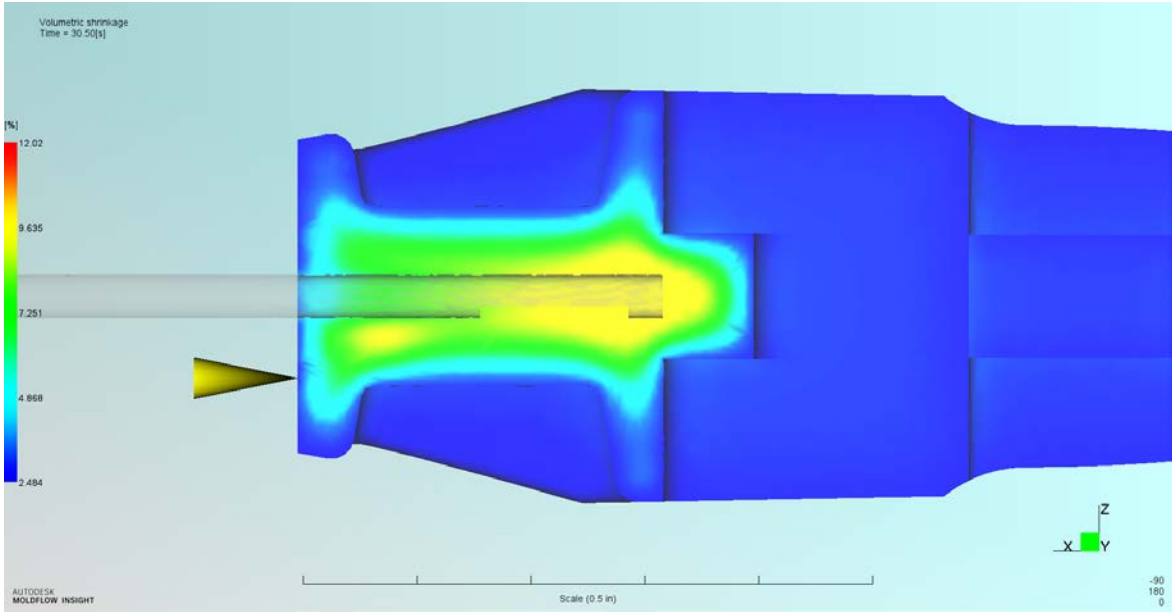
Wire With a Larger Step To Add Material and Two Flats To Prevent Rotational Movement



Larger Head Diameter Was Used. Heat Concentration Was Lowered Thus Reducing Heat Void Significantly.

Shrinkage Void Mitigation

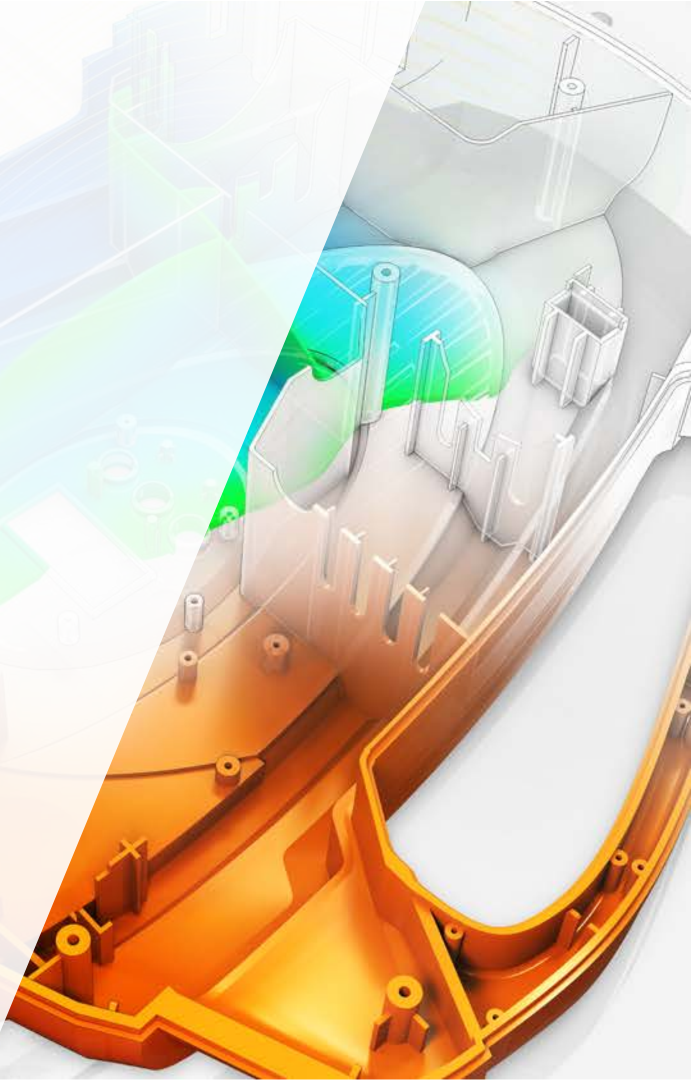
Ideal Scene:
If Feasible, The Core-Out Option Is The Optimum Solution. Not An Option On This Project



Edwards

Helping Patients is Our Life's Work, and *life is now*

Health Care & Medical Industry



Gabe Hill

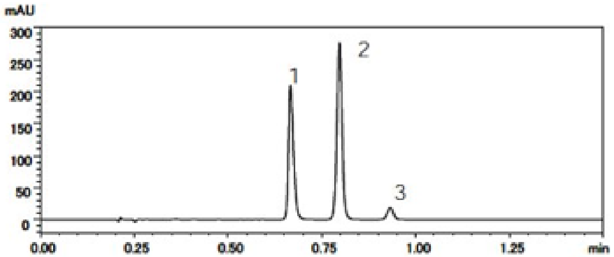
Associate Product Development Engineer

IDEX HEALTH & SCIENCE

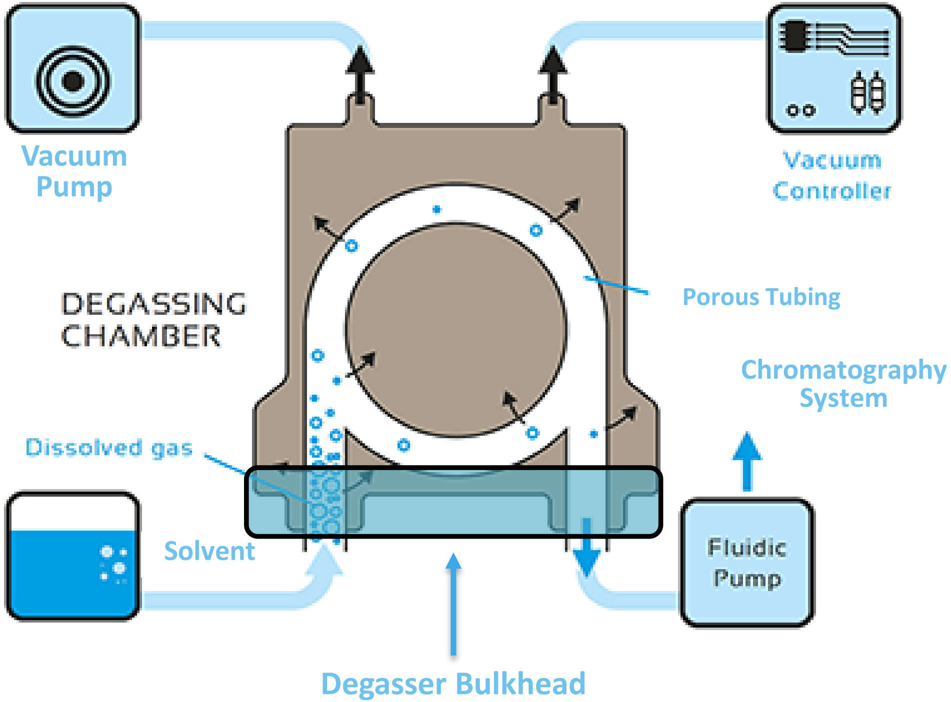
Three divisions:
- Fluid & Metering
- Health & Science
    - Analytical Instruments
    - Automotive
    - Food & Pharmaceuticals
    - Industrial
    - Life Sciences
    - Medical & Dental
    - Semiconductor & Electronics
- Fire & Safety

- Separation of substances into their components
- Quantification of components
- Ranging from sample volumes of µL (Analytical) up to Liters (Industrial)
- Result quality based on:
  - Sample prep
  - Procedure development
  - System performance
    - Column efficiency
    - System volume
    - **Solvent performance**

Typical analytical chromatography system (Agilent 1290)



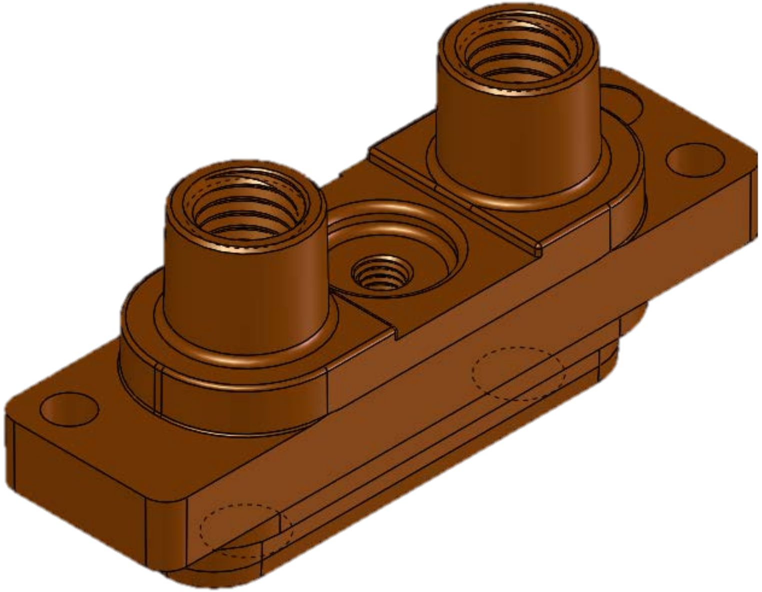
Example chromatograph


Vacuum
Pump
Vacuum
Controller
DEGASSING
CHAMBER
Porous Tubing
Chromatography
System
Dissolved gas
Solvent
Fluidic
Pump
Degasser Bulkhead

IDEX
HEALTH & SCIENCE

Part Functions:

- **Fluidic connections**
    - **1/4”-28 Flat-bottom**
    - **10-32 Cone Port**
- **System mounting**
    - **M3 bolt hole**
    - **Bracket alignment**
- **Vacuum Seal**
    - **O-ring seat**
    - **Tank alignment**



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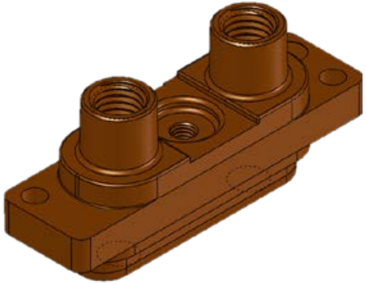
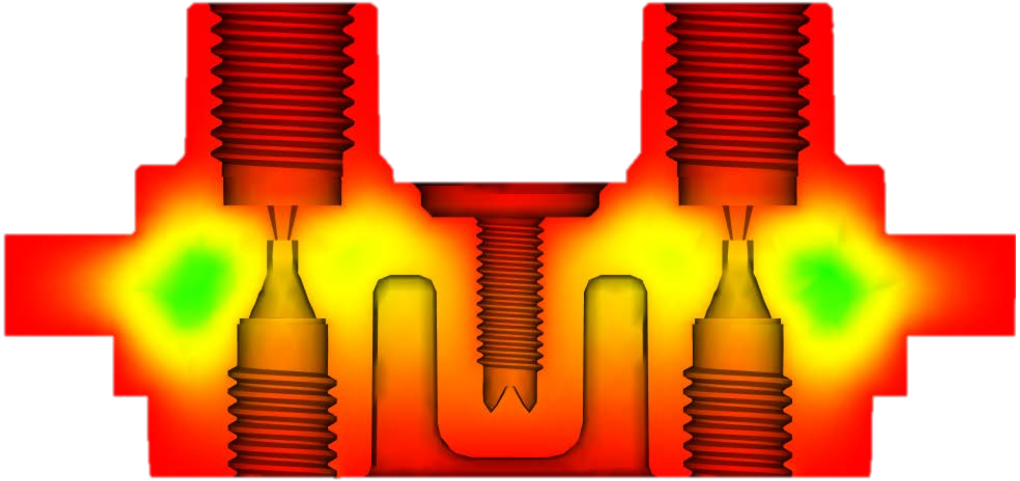
Thick sections in current design results in voids. These voids periodically result in mechanical failure





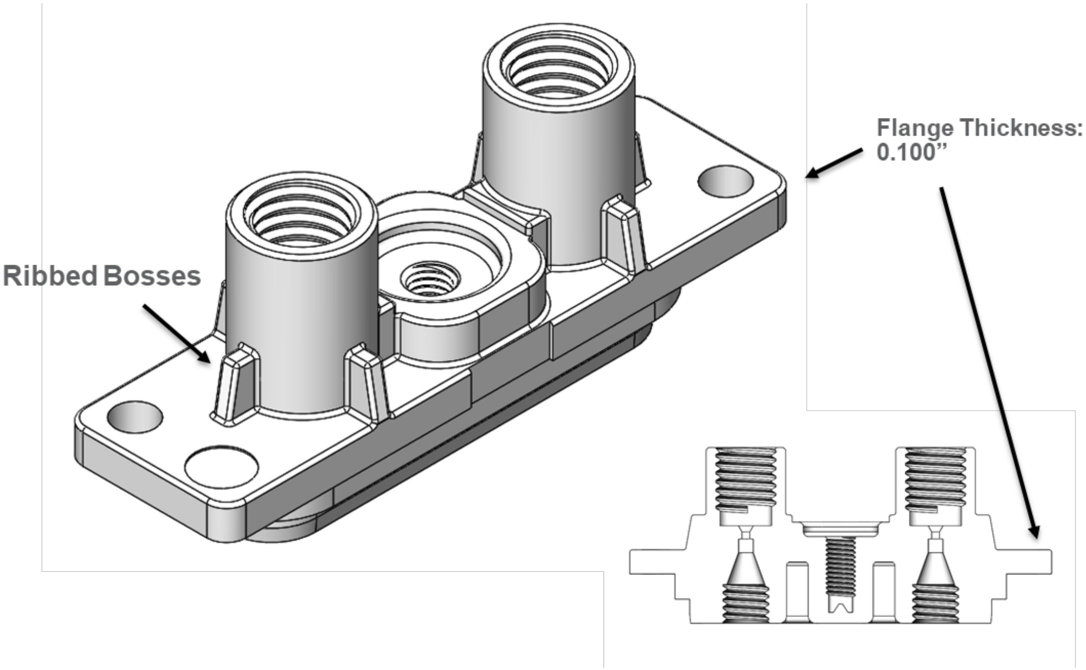
Moldflow Density Result: shows low density (4% decrease) in thick sections. Mold contact freezes outer material first while inside continues to contract creating voids

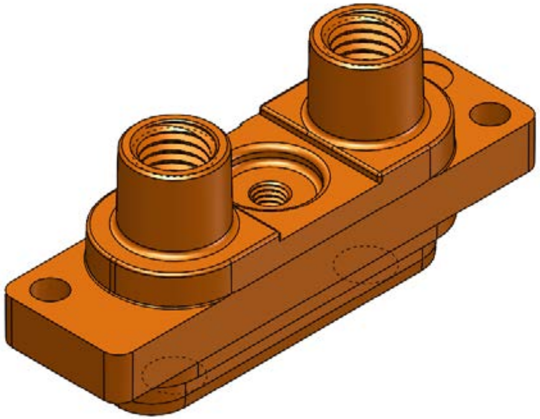
Design Changes:

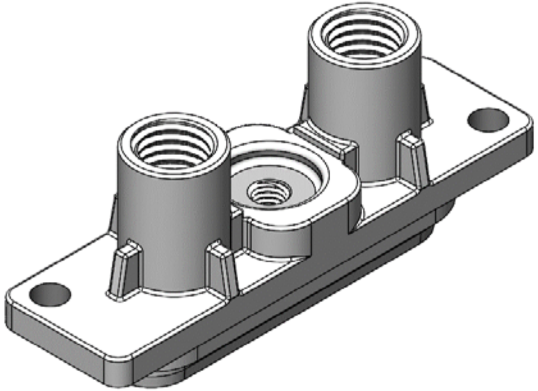
- Reduce mounting flange thickness
- Remove material around ¼-20 port bosses and replace with ribbing

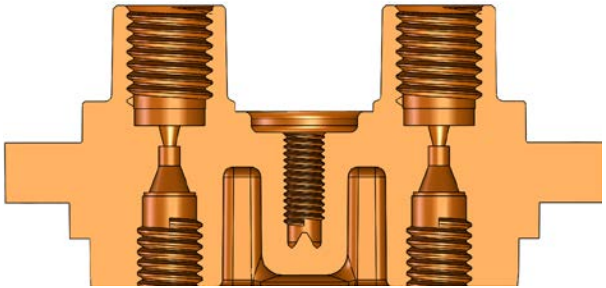
Results:

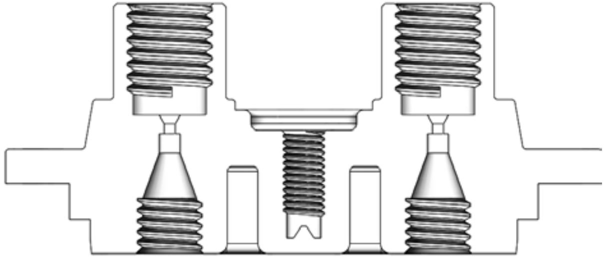
- Reduce wall thickness
- Reduce overall part height
- Reduce shot size (cycle time)









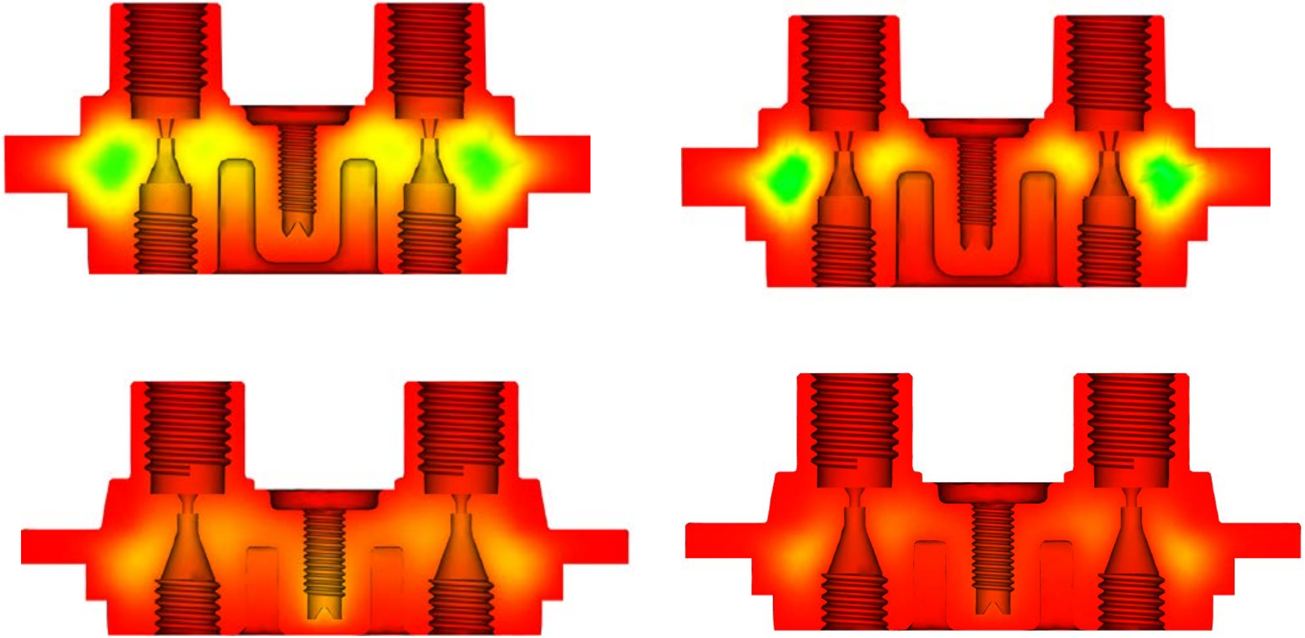


HEALTH & SCIENCE

PPS PEEK

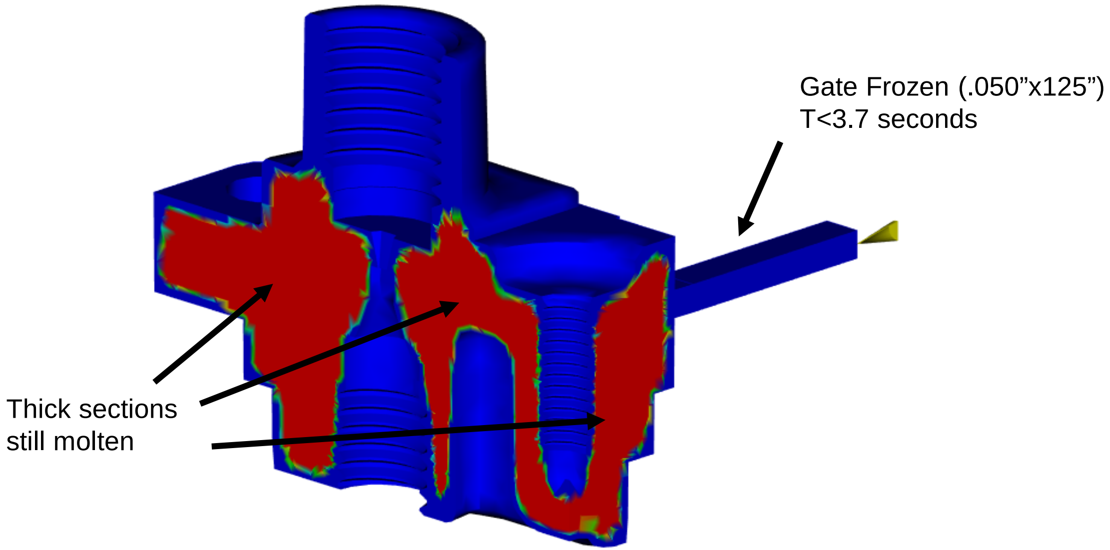
Existing

Re-Design

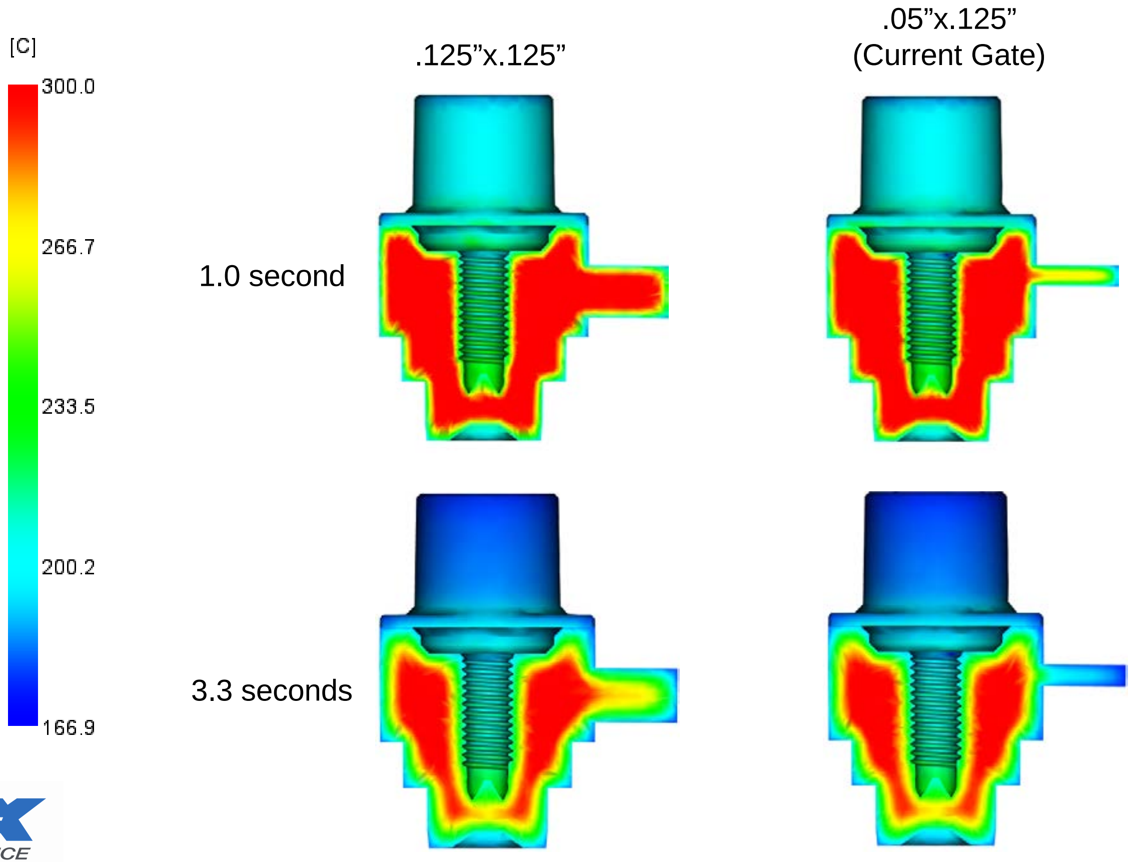


Material	Design	Density			
		Max	Min	Δ	Δ (%)
PPS	Existing	1.642	1.574	0.068	4%
PPS	New	1.656	1.629	0.027	2%
PEEK	Existing	1.274	1.175	0.099	8%
PEEK	New	1.28	1.255	0.025	2%

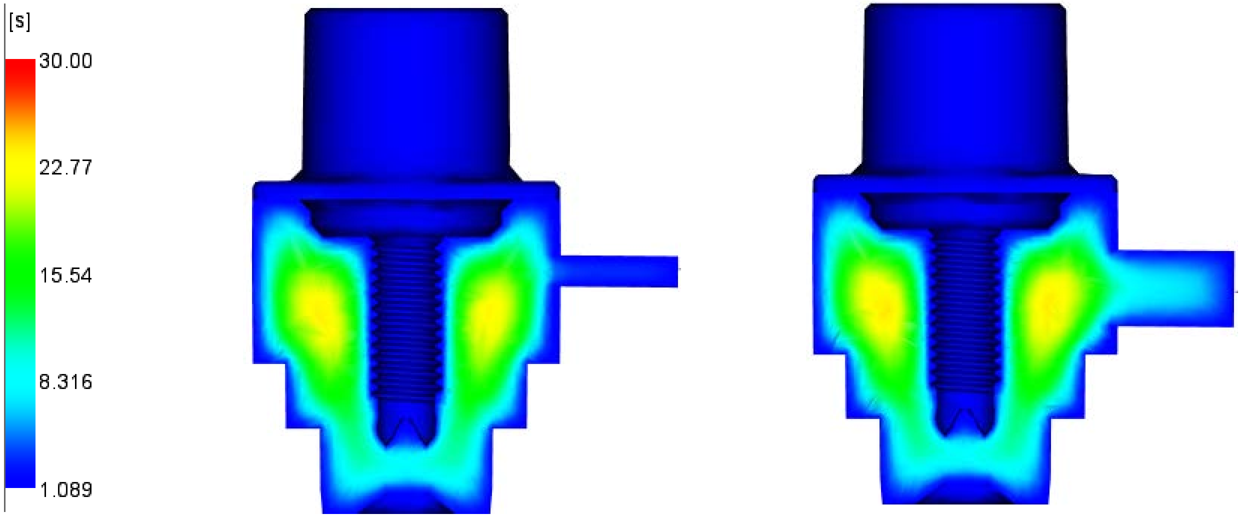
IDEX HEALTH & SCIENCE



- **Gate is too small for current part thickness**
- **Thickness should be closer to %70 of nominal wall thickness**


[C]
300.0
266.7
233.5
200.2
166.9
.125”x.125”
.05”x.125”
(Current Gate)
1.0 second
3.3 seconds

Gate Size Comparison

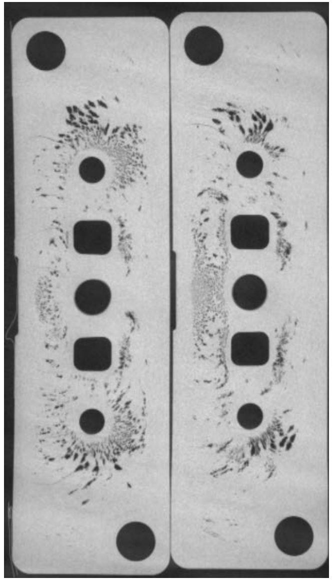


.05”x.125”
(Current Gate)

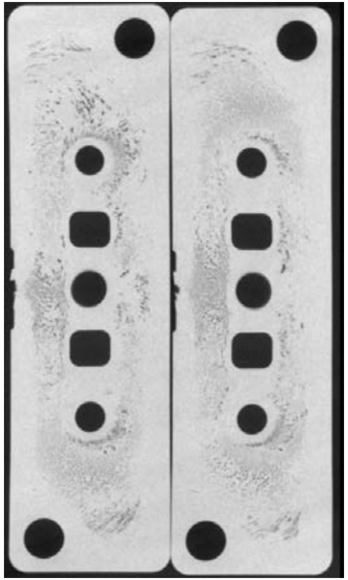
.125”x.125”

Comparison of Standard vs. Modified

- Gate increased 2.5X from standard
  - Parts molded with standard process
- X-ray section analysis to determine differences (attribute data for comparison)
- Void content reduced by increasing gate size
- Voids still present with modified gate and standard process



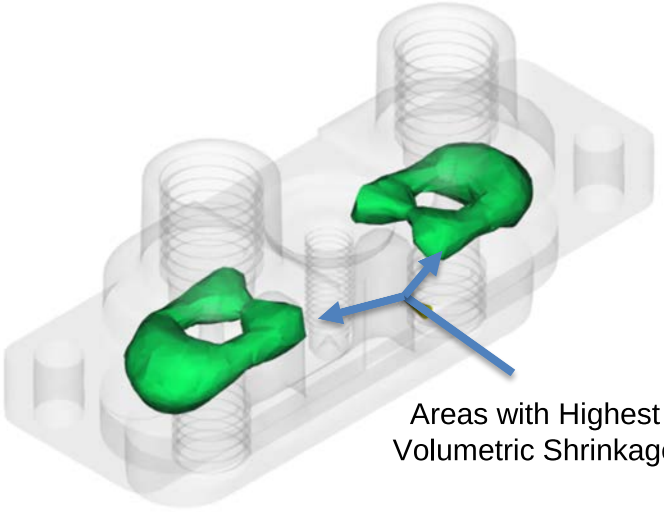
Standard Gate (X-ray image from 1/4/19)



Modified Gate (X-ray image from 4/2/19)

HEALTH & SCIENCE

Volumetric Shrinkage



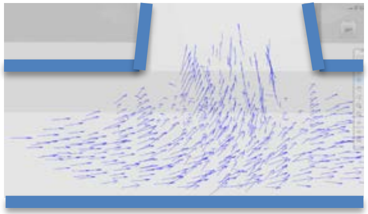
Areas with Highest
Volumetric Shrinkage

Velocity During Solidification

Velocity directions as high shrink areas are freezing

Arrows pointing towards wall indicate voids

Arrows pointing towards center indicate sink

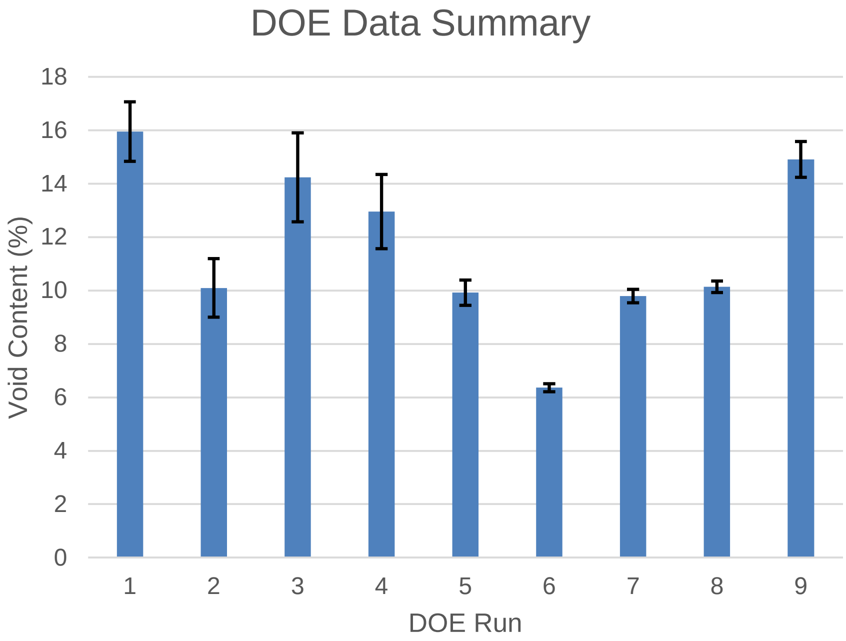


HEALTH & SCIENCE

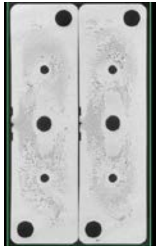
3 Factor, 2 Level, Full Factorial, with Center Run

- DOE utilized modified gate (0.125” x 0.125”)
- Factors – Injection speed, hold pressure, nozzle temperature
- Samples were X-ray imaged for porosity analysis
- ImageJ software utilized to quantify void content
- Void content observed in all runs

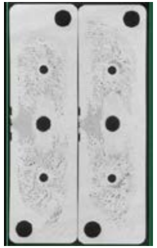
Processed X-ray image (Run 9)



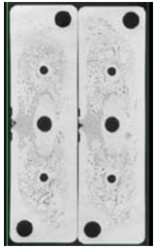
Run 1



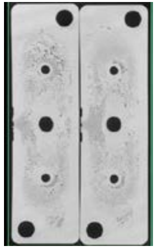
Run 2



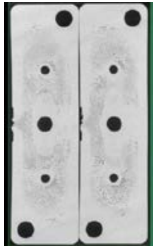
Run 3



Run 4



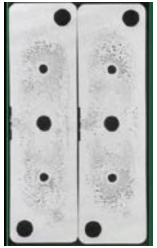
Run 5



Run 6

Run 7

Run 8

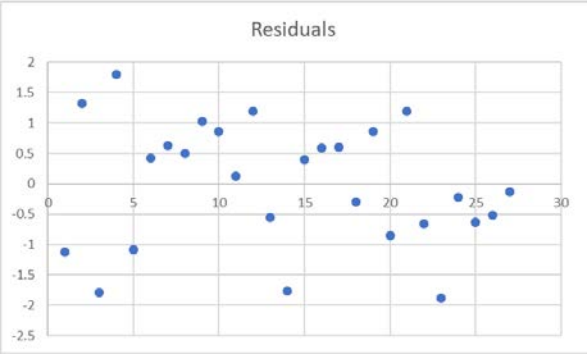


Run 9

Excel Regression Analysis

- 95% Confidence Interval ($p<0.05$)
- Random and homogeneous residuals
- Predictive equation
  - Injection Speed (A) is not significant outside of interaction terms
  - All other factors are significant
- **Minimum void content with:**
  - High injection speed
  - High hold pressure
  - Low nozzle temperature

	Coefficients	*Standard Error*	*t Stat*	*P-value*
Intercept	11.5400	0.2276	50.6995	0.0000
A	-0.1148	0.2414	-0.4757	0.6397
B	-1.2602	0.2414	-5.2198	0.0000
C	1.6027	0.2414	6.6384	0.0000
AB	0.7683	0.2414	3.1825	0.0049
AC	1.9190	0.2414	7.9487	0.0000
BC	0.9693	0.2414	4.0151	0.0007
ABC	0.3660	0.2414	1.5160	0.1460



Prediction Equation		
Intercept	11.53996	
A		1
B	-1.26017	1
C	1.602667	-1
AB	0.768333	
AC	1.919	
BC	0.969333	
Predicted Result		
6.55712963		

3 Factor, 2 Level, Full Factorial, with Center Run

- Optimum process condition is: high injection speed, high hold pressure, low nozzle temperature

DOE Results Comparison Explorer

Study: 8000_1835_modeled_gate_125x125_heaters)

Select the study/studies to add to your project

Reset Column Ranges | Show/Hide Columns

Select Studies	Study Number	Status	Process controller defaults: Filling	Process controller defaults: Melt te…	Process controller …faults_Packir pressure vs	Standard Deviation:Part heat flux [Standard …	Standard …viation:Maxim part temperature	Standard Deviation:Mold surface temperature	Standard Deviation:Time to reach ejection te…	Cavity surface temperature - average	Cycle time Unit: s	Injection pressure Unit: psi	Clamp force Unit: ton(US)	Maximum:Sink mark depth [Maximum] Unit: in	…mum:Tempera at flow front [Maximum] Unit: F	Standard Deviation:Tim to reach ejection te…	Standard …iation:Volume shrinkage at ejection [S…d	Tota mas Unit:
	3		2.5	599.99	0.000145	1826.4	27.78	16.46	6.81	304.8	35	552.03	2.95	0.0036	633.52	7.4	1.16	0.2
	6		1	599.99	0.000145	1826.4	27.78	16.46	6.81	304.8	35	742.22	2.42	0.0039	606.06	7.33	1.29	0.2
	12		1.75	630	0.000145	1991.6	30.38	18.06	7.08	306.97	35	391.65	3.61	0.0041	656.99	8.29	1.42	0.2
	15		1.75	630	0	1991.6	30.38	18.06	7.08	306.97	35	391.65	1.5	0.0054	632.8	8.19	1.51	0.2
	2		1	660	0.000145	2157.3	33	19.71	7.3	309.15	35	326.68	2.28	0.0043	672.49	9.01	1.57	0.2
	8		2.5	660	0.000145	2157.3	33	19.71	7.3	309.15	35	226.51	5.89	0.0045	691.32	9.25	1.66	0.2
	9		1.75	599.99	0	1826.4	27.78	16.46	6.81	304.8	35	611.7	2.46	0.0053	623.43	7.63	1.71	0.2
	13		1	630	0	1991.6	30.38	18.06	7.08	306.97	35	488.76	1.6	0.0058	632.81	8.48	1.9	0.2
	14		2.5	630	0	1991.6	30.38	18.06	7.08	306.97	35	357.63	2.58	0.0059	645.29	8.53	1.92	0.2
	1		1	599.99	-0.000145	1826.4	27.78	16.46	6.81	304.8	35	742.22	1.24	0.0074	601.88	7.96	2.08	0.2
	10		1.75	660	0	2157.3	33	19.71	7.3	309.15	35	255.68	2.73	0.0065	684.36	9.39	2.08	0.2
	5		2.5	599.99	-0.000145	1826.4	27.78	16.46	6.81	304.8	35	552.03	1.32	0.0075	602.97	7.94	2.12	0.2
	11		1.75	630	-0.000145	1991.6	30.38	18.06	7.08	306.97	35	391.65	0.954	0.0078	631.01	8.76	2.21	0.2
	7		1	660	-0.000145	2157.3	33	19.71	7.3	309.15	35	326.68	1.07	0.0089	661	9.67	2.42	0.2

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