KEY TRENDS FOR PLASTICS IN HEALTHCARE

UNDERSTANDING THE SCOPE OF OPPORTUNITY AND USING SIMULATION TO MAKE SMARTER DECISIONS FASTER

AUTODESK.

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INTRODUCTION

INTRODUCTION

Plastics are revolutionizing modern healthcare

From disposable syringes to heart valves, plastics have helped usher in the era of modern healthcare. They enable single-use products that improve sanitation, convenience and cost-efficiency. They offer ideal durability for storage, transportation, and waste disposal applications. They are vital to pacemakers, stents, and other innovations that depend on tiny or intricate injection molded parts. And advanced materials are paving the way for medical-grade plastics that have superior temperature, chemical, and corrosion resistance.

For all of these reasons, the medical plastics niche is growing rapidly. This $20 billion market includes everything from handheld surgical tools and heart monitors to breathing masks and disposables, and is part of the larger injection molded plastics market, which is expected to reach nearly US$500 billion by 2025.[1]

To capture opportunities in this rapidly growing market, product developers and engineers need to explore ideas quickly, create innovative designs very efficiently, meet strict regulatory requirements, and address rising concerns about the sustainability of plastics.

In this ebook, we will take a look at four important trends in medical plastics, the implications of these trends have on the design process, and how simulation software can help product developers and mold engineers overcome these challenges.

KEY TRENDS

KEY TREND

Cost pressures are increasing

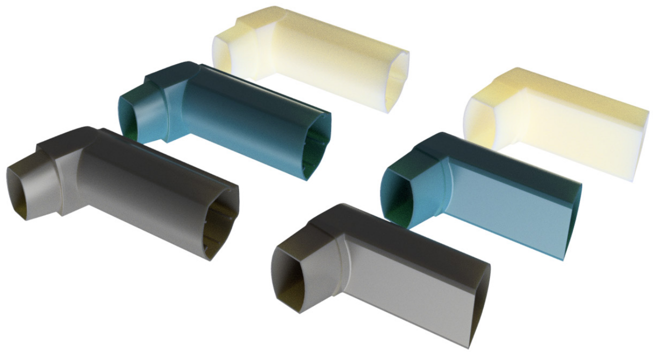
Cost pressures in healthcare are intense, especially for medical products.

The medical device excise tax, introduced by the Affordable Care Act in 2013, is returning in 2018, increasing overall manufacturing costs for many medical devices. At the same time, hospitals are increasing scrutiny of budgets for medical devices through specialized "value analysis committees," which evaluate device effectiveness and price. Not surprisingly, price weighs more heavily on the final assessment of value.[2]

Manufacturers need to alleviate this pressure and plastics offer a sensible, straightforward solution. Plastic parts can be mass produced affordably and used in a wide range of applications. And they exhibit a long list of other characteristics that make them more cost-efficient than metals, including:

- Longer life spans
- Better impact and dent resistance
- Increased corrosion resistance for lower maintenance costs
- Molded-in assembly features that are easier to sterilize
- Lower risk of reaction with the human body, which is critical for implantable products
- Lower weight for reduced material costs and shipping costs
- Colorability that eliminates secondary painting costs

As we will see in the next section, the advantages of plastic over metal are particularly relevant to one of the most exciting trends in healthcare.



KEY TREND

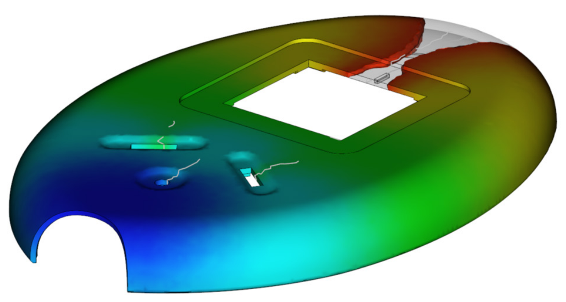
Digital health is in full swing

Digital health refers to a broad spectrum of technologies in healthcare that use information and communication technology to deliver care more efficiently and improve patient outcomes. It is part of the broader Internet of Things (IoT) trend, which is reshaping how many industries capture, transmit, and use data. After years of promise, digital health solutions are finally gaining market momentum, from telemedicine to mobile apps to wearable devices.

Digital health has big implications for manufacturers. More medical products – and not just medical devices – will need to accommodate embedded sensors and electronics. This will raise product costs, so manufacturing costs will need to come down to protect margins. Products may also need to withstand new environments and operating conditions to capture the right data. In all likelihood, digital health solutions will require product designs that are more complex and intricate.

Plastics are ideal for digital health applications, especially compared to metals. Plastics offer better electrical insulation properties, which will be necessary for embedded electronics. Injection molding can mass-produce sophisticated designs – including electronics housings – more cost-effectively. This process also allows engineers to pursue more complex innovations without sacrificing part strength.

Finally, advanced plastics – made with the help of additives, fillers, composites, and secondary operations – give designers, engineers, and manufacturers many more options for finding the precise combination of characteristics required to create groundbreaking medical devices and tools.



KEY TREND

Regulatory pressure raises the stakes for material selection

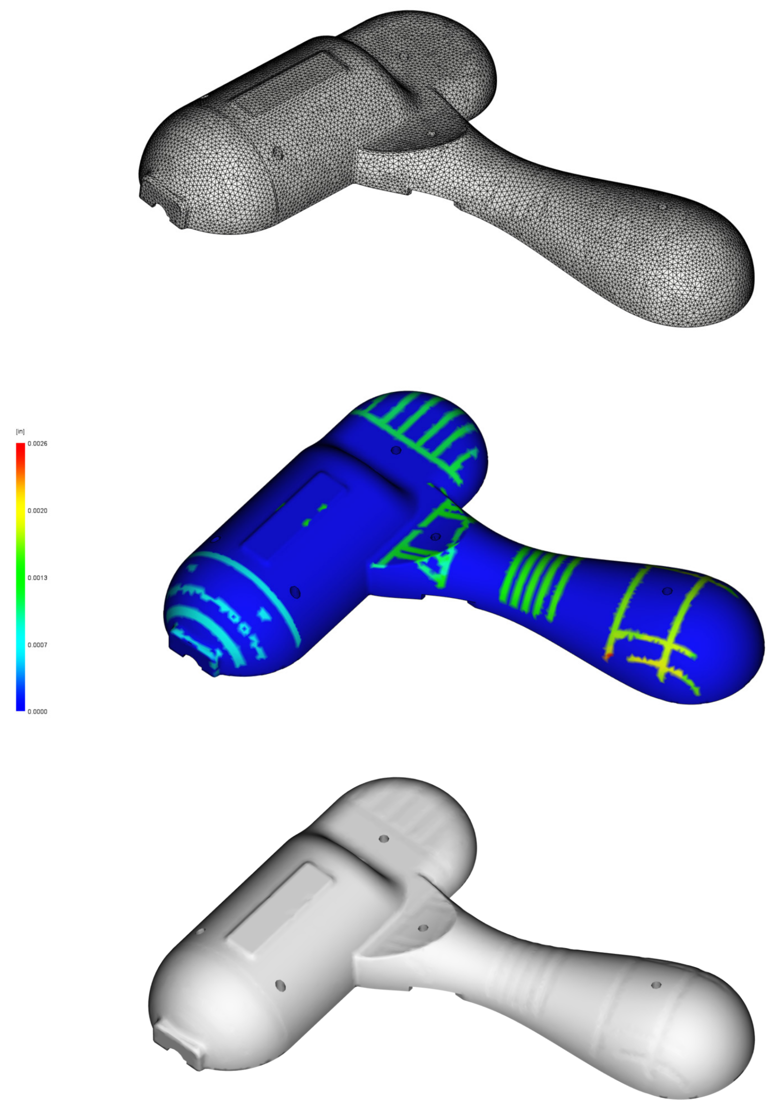
Around the world, the regulatory environment for medical products is becoming stricter in order to increase the safety of patients and healthcare professionals. Agencies in the U.S., Europe, and Asia continue to develop new guidelines and tighten existing ones. Keeping up with evolving regulations is a constant challenge for engineers.

For manufacturers of medical products, one of the biggest obstacles is material selection. Material selection is responsible for up to 40% of FDA recalls for U.S. medical devices.[3] Often, manufacturers must work from a list of pre-approved materials. However, they can still run into challenges for device approvals, requiring alternate materials to be included in device submissions.

This means the stakes are high. Material selection is complicated. It requires insight into the final device’s usage, which can involve competing factors such as product type, lifespan, and degree of exposure to the patient’s body. At the same time, choosing a new material after the product is engineered is not only expensive and time-consuming; it slows time to market and affects competitive positioning.

During selection, engineers can't lean too heavily on material data sheets. These tests are performed under ASTM conditions (usually 23°C and 50% relative humidity), which may differ greatly from actual operating environments. In other words, engineers need to better understand the tradeoffs and nuances in design, earlier in the process. As we will see, simulation software holds the key to making more confident material selection decisions.

It's also important to note that plastics can help manufacturers comply with tighter regulations. Hospital-acquired infections (HAIs) are just one example. Nearly 1 in 20 inpatients experiences an HAI4, which can increase hospital stays by 350%[4] and have led to new sterilization recommendations from several regulatory bodies. Fortunately, plastics offer new alternatives to traditional sterilization techniques, such as non-stick coatings that prevent bacteria from colonizing the surfaces of medical products as well as antibiotic polycarbonate that can kill bacteria on contact.



KEY TREND

Sustainability concerns are growing

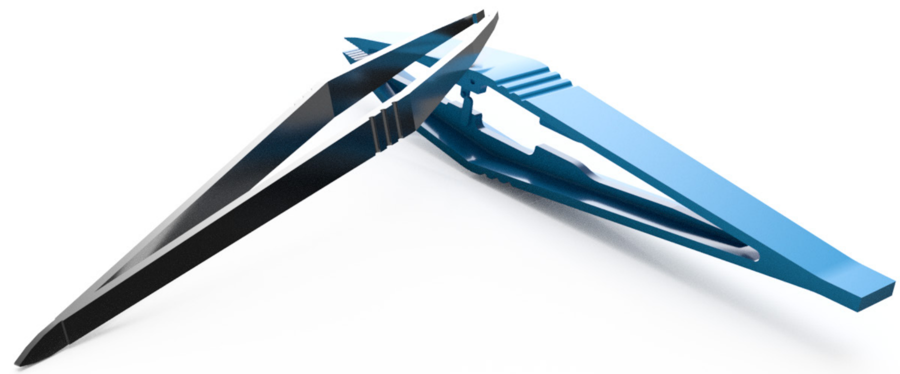
Sustainability is a growing concern for all manufacturers, including those that make medical products. Of course, every material has an environmental impact, from its extraction to its end of life. Plastics are no different, and their negative impacts are well known. Still, some plastics have distinct advantages over other materials that can help offset those negative traits. This makes it challenging for designers and engineers to make informed decisions when using plastics.

In general, plastics require less energy to produce (62 to 108 megajoules of energy per kilogram (MJ/kg)) when compared with two alternate, popular materials used for medical products, silicone (230 to 235 MJ/kg) and titanium (900 to 940 MJ/kg). If there is an option to replace a silicone or titanium component with a polymer, this manufacturing savings could present the engineer with an advantage to help justify the decision.

The manufacturing process matters too. Specifically, injection molding has less impact than machining or 3D printing for large production runs because its fixed impacts (tooling and setup) are divided across (potentially) millions of parts.[5]

Engineers can also look to bioplastics, which can help address the lack of recyclability of medical products due to contamination hazards. Bioplastics are made from renewable resources (like corn and sugarcane), biodegradable materials, or both. And they can be produced with conventional processes, including injection molding. In fact, the bioplastics market is growing rapidly due to the introduction of bio-based PE and PET, as well as PHA, which is used to make dissolvable stitches and the pins, tacks, and screws that help bones heal during reconstructive surgery.

As with the other key trends, the upshot is that engineers need to carefully evaluate tradeoffs during material selection and product design. This is where simulation software comes in.



HOW SIMULATION HELPS

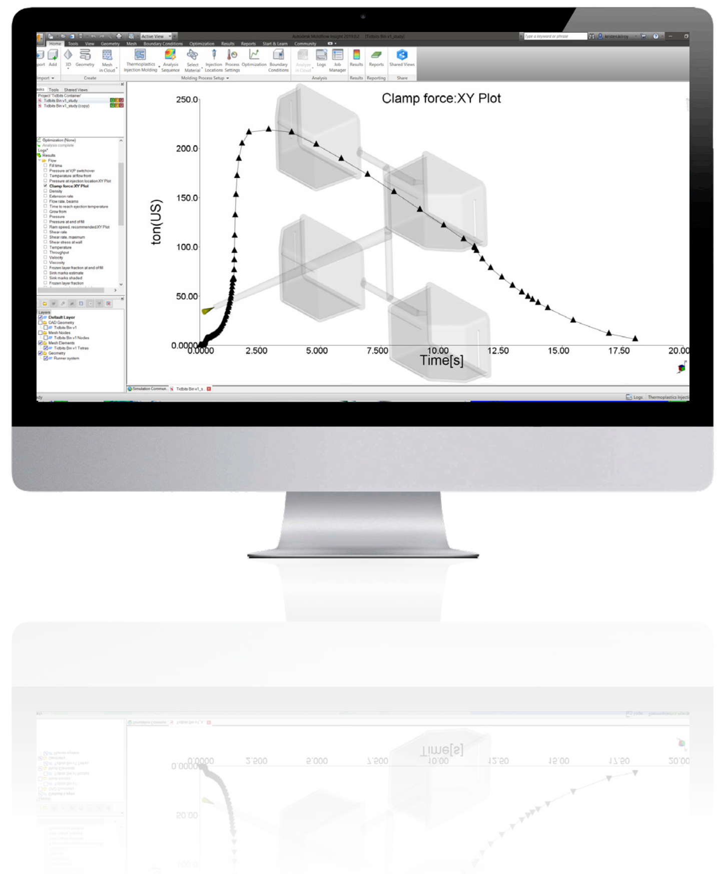
HOW SIMULATION HELPS

Engineers explore more ideas more rapidly

To take advantage of all the new opportunities these key trends present, designers and engineers can't settle for familiar approaches. They need to explore more options more quickly, earlier in the development process, and improve the accuracy of new designs.

Simulation software, including Autodesk Moldflow®, helps address all of these challenges. Essentially, it automates many of the steps required to optimize the injection molding process. It helps users visualize mold and part designs to evaluate the effects of design decisions, compare materials, and adjust every step in the process – from part geometry to total cycle time.

These capabilities give users everything they need to address key trends in the medical plastics.

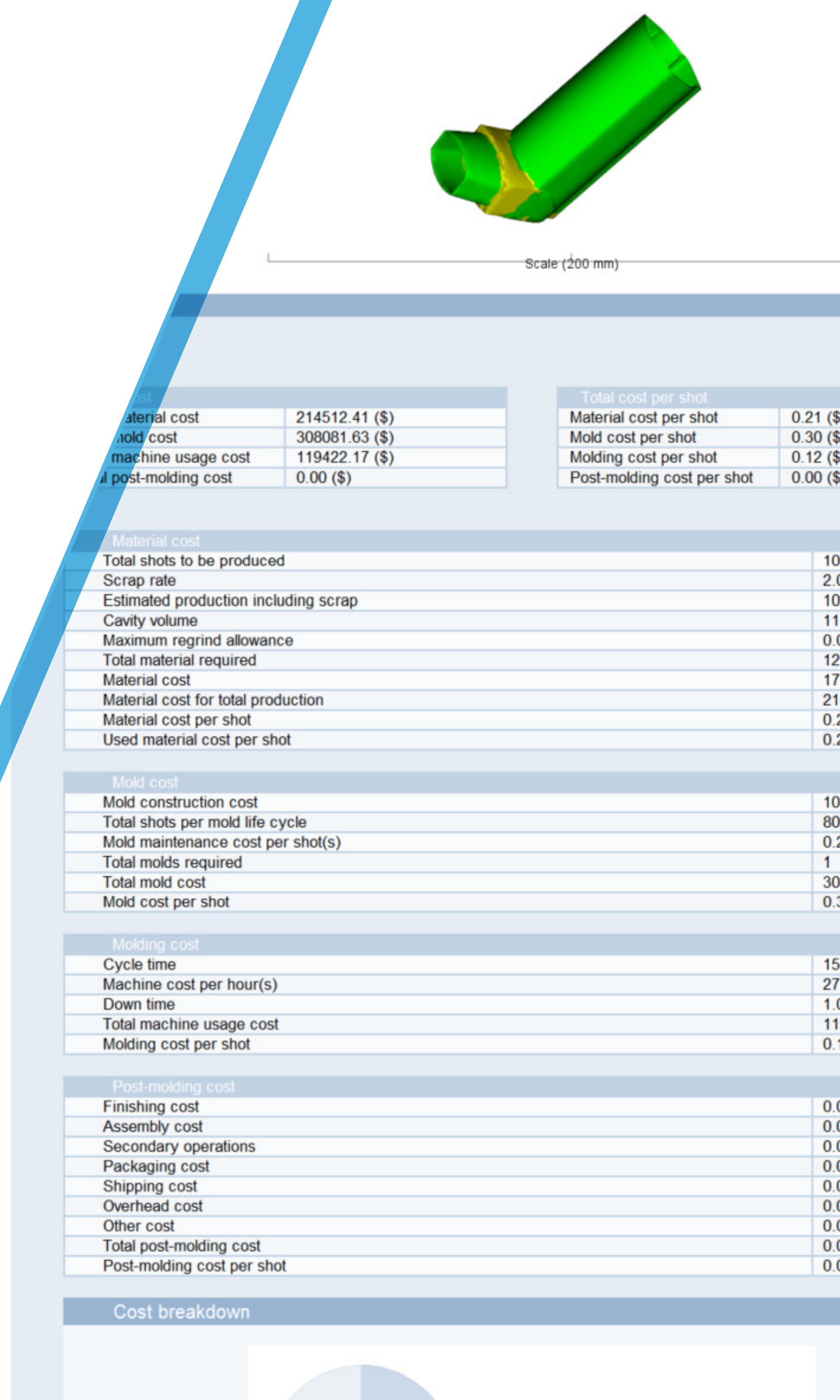


HOW SIMULATION HELPS

Alleviate cost pressures

To contend with increasing cost pressures, for example, designers and engineers can calculate part costs according to material choice, scrap rate, regrind allowance, energy costs and other inputs (a capability called the Cost Adviser within Moldflow).

These calculations make it easier for engineers to compare manufacturing costs when considering various materials or mold cavitation changes. Moldflow also lets users add tooling costs to the estimate, as well as analyze energy consumption. The result is a more in-depth picture of total manufacturing cost and how specific choices affect that cost.



HOW SIMULATION HELPS

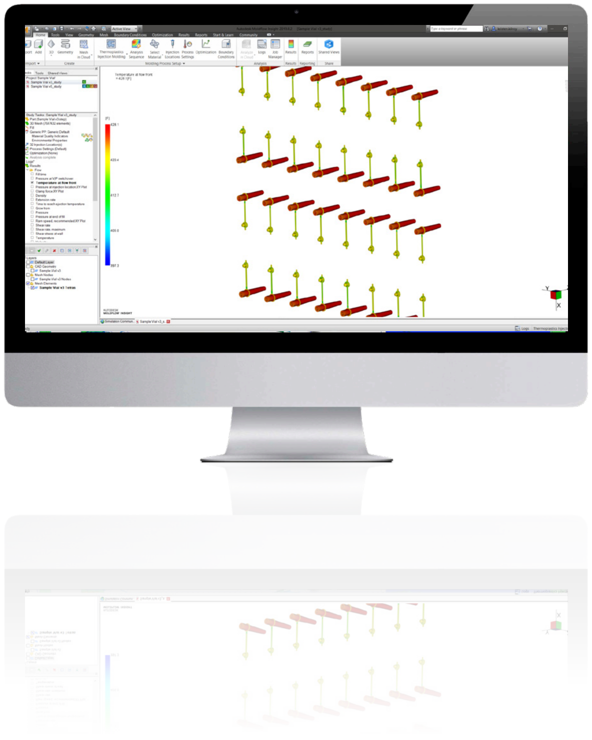
Deliver more complex designs

As noted earlier, digital health solutions will require more complex product designs. In these cases, it can be difficult to identify manufacturability. Simulation software can help here as well. Moldflow's Design Adviser, for example, helps pinpoint design issues that could cause part filling, quality, and ejection issues through draft, undercut, and thickness results.

Simulation can also validate the choices product designers and mold engineers make. In this context, validation explores whether the particular combination of part design, material choice, and molding processes will perform as expected – and if not, how it might fail. This helps prevent errors that delay time to market and ensures products are prepared to meet strict regulatory requirements.

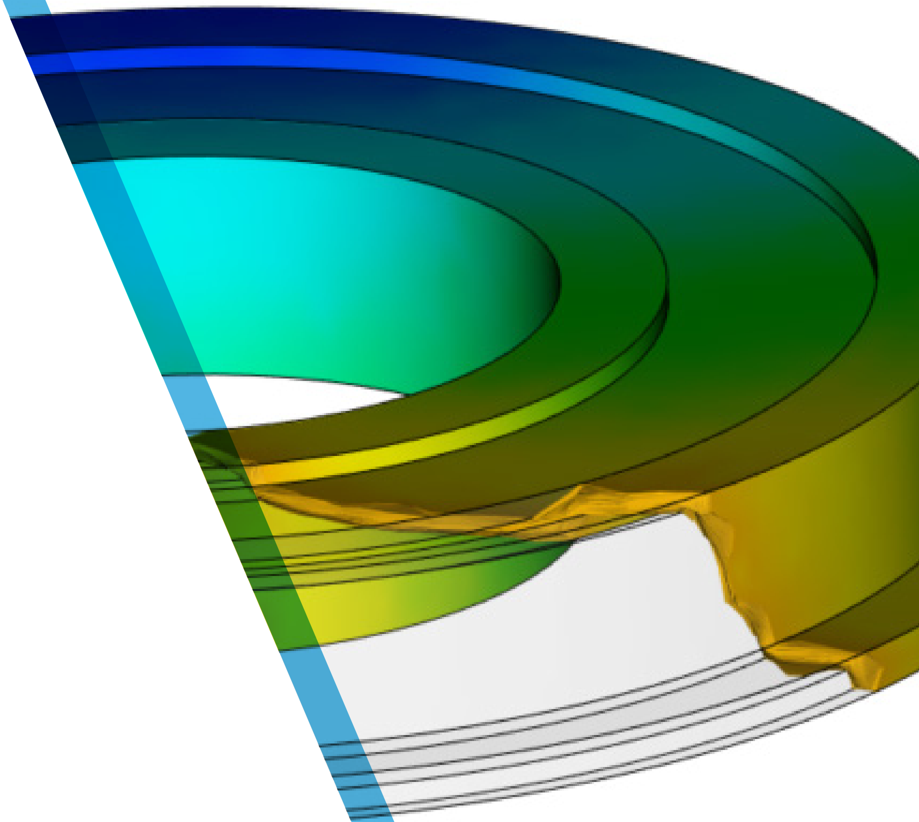
Taking this concept further, engineers can use simulation software to perform a deeper investigation of manufacturability. This involves optimizing specifications such as part flatness, roundness, critical dimensions, and warpage through automated design of experiments (DoE) and parametric analyses, which can help engineers to consider more design options in less time.

Moldflow's comparison tools enable fast and easy interpretation of results and can export options to finite element analysis (FEA) software for further structural analysis. Instead of manually adjusting the design for each variable, engineers can simply define a range of values to investigate for wall thickness, fill time, melt temperature, gate sizes, or another parameter.



Each analysis represents one possible combination of the selected parameter values. For example, engineers can specify a range of values to investigate wall thickness in order to minimize the amount of plastic used in the design, while still being able to manufacture the part and meet structural requirements. The simulation software will then run several analyses on a local machine or through a cloud-based solver. This way, engineers can adjust multiple factors and move toward a better decision, all without changing the original CAD design and reimporting the model each time.

Moldflow's result export options also allow engineers to include the impact of the manufacturing process in the structural analysis. The connection with Autodesk Helius PFA allows as-manufactured properties to be sent to FEA programs, including Autodesk Nastran® In-CAD. Engineers can use this to analyze structural properties while under load when considering an injection molded part's fiber orientation or weld line strength.



HOW SIMULATION HELPS

Support regulatory compliance and sustainability

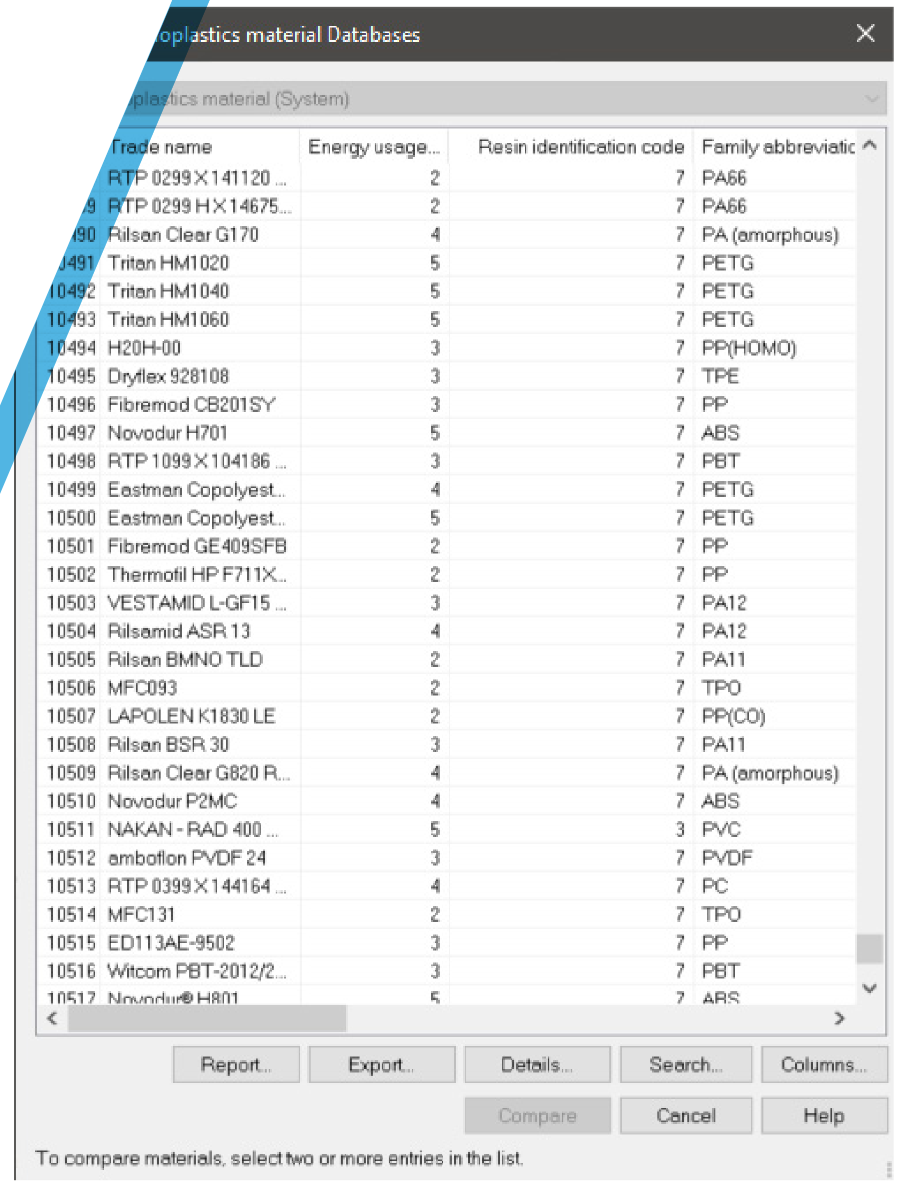
Finally, recall that the key trends of increased regulation and sustainability both depend heavily on material selection and comparison. Simulation software makes these processes more efficient.

To aid with material selection, Moldflow includes a material database with more than 10,000 pre-loaded materials that can be simulated. Detailed analyses of energy consumption and recyclability requirements allow engineers to understand the environmental impact of different materials, so they can make more informed decisions.

The material database also contains a handful of bioplastics. Because bioplastics are difficult to develop, manufacturers tend to keep the details about formulations private. And if engineers are considering a material that is not in the database, Moldflow gives designers the opportunity to have the material tested and fitted for simulation by the [Autodesk Moldflow Plastics Lab] or a partner lab.

To help with comparison, simulation software enables users to understand the unique characteristics and tradeoffs of candidate materials.

With simulation, designers can compare cost and part quality side by side to evaluate the effects of material choices on warpage, sink marks and surface finish. They can narrow down choices faster—and with greater confidence. And they can discover – and address – potential issues long before prototyping, when making changes is much more expensive and time-consuming.



	Trade name	Energy usage...	Resin identification code	Family abbreviatic
	RTP 0299 X 141120 ...	2	7	PA66
9	RTP 0299 H X 14675...	2	7	PA66
90	Rilsan Clear G170	4	7	PA (amorphous)
0491	Tritan HM1020	5	7	PETG
10492	Tritan HM1040	5	7	PETG
10493	Tritan HM1060	5	7	PETG
10494	H20H-00	3	7	PP(HOMO)
10495	Dryflex 928108	3	7	TPE
10496	Fibremod CB201SY	3	7	PP
10497	Novodur H701	5	7	ABS
10498	RTP 1099 X 104186 ...	3	7	PBT
10499	Eastman Copolyest...	4	7	PETG
10500	Eastman Copolyest...	5	7	PETG
10501	Fibremod GE409SFB	2	7	PP
10502	Thermofil HP F711X...	2	7	PP
10503	VESTAMID L-GF15 ...	3	7	PA12
10504	Rilsamid ASR 13	4	7	PA12
10505	Rilsan BMNO TLD	2	7	PA11
10506	MFC093	2	7	TPO
10507	LAPOLEN K1830 LE	2	7	PP(CO)
10508	Rilsan BSR 30	3	7	PA11
10509	Rilsan Clear G820 R...	4	7	PA (amorphous)
10510	Novodur P2MC	4	7	ABS
10511	NAKAN - RAD 400 ...	5	3	PVC
10512	ambotlon PVDF 24	3	7	PVDF
10513	RTP 0399 X 144164 ...	4	7	PC
10514	MFC131	2	7	TPO
10515	ED113AE-9502	3	7	PP
10516	Witcom PBT-2012/2...	3	7	PBT
10517	Novodur® H801	5	7	ABS

CONCLUSION

Conclusion

Plastics are vital to the medical industry. The four key trends explored here, indicate that the role of plastics will only become more essential. That is precisely why product developers and mold engineers have such a huge job ahead of them – one that will involve intense cost competition, more complex designs, stricter regulatory requirements, and greater awareness of sustainability.

Simulation software, including Autodesk Moldflow, empowers all stakeholders – including product developers, designers, engineers, and analysts – to make the right choices. From product design to material selection to process optimization, simulation makes it easier to understand what choices are feasible, how small changes affect the big picture, and how to manage all of the tradeoffs necessary to deliver an innovative, high-quality and cost-efficient result.

GET STARTED

To learn how Autodesk Moldflow software can help you take full advantage of opportunities in the fast-growing medical plastics market, contact us today or visit www.autodesk.com/products/moldflow/free-trial.

Footnotes

1. Injection Molded Plastics Market Size Report By Raw Material (PP, ABS, HDPE, PS), By Application (Packaging, Consumables & Electronics, Automotive, Construction, Medical), And Segment Forecasts, 2018 - 2025, Grand View Research, February 2018. https://www.grandviewresearch.com/industry-analysis/injection-molded-plastics-market

2. "Will Pressures in Medical Manufacturing Reach Your Production Floor?" Massachusetts Medical Device Industry Council, March 14, 2016. https://www.massmedic.com/2016/03/14/will-pressures-in-medical-manufacturing-reach-your-production-floor/

3. "Material failure is root cause of many medical device recalls," Plastics Today, March 3, 2017. https://www.plasticstoday.com/medical/material-failure-root-cause-many-medical-device-recalls/35098188456422

4. "Stop bugging me!: Using polymers to reduce infections," Medical Plastics News, December 14, 2016. https://www.medicalplasticsnews.com/news/stop-bugging-me/

5. The Next Production Revolution: Implications for Governments and Business, chapter 5, "3D printing and its environmental implications." https://www.oecd-ilibrary.org/sites/9789264271036-9-en/index.html?itemId=/content/component/9789264271036-9-en

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