BRIDGING THE HYBRID ERA OF ADDITIVE MANUFACTURING

A Look at How Direct Manufacturing at Scale for PPE Demonstrates That AM Can Move the Cost Curve

ESSENTIUM™

INTRODUCTION

Manufacturers succeed when they are innovative, customer-focused, efficient, and agile. Agility gives companies an edge in two ways. First, it enables companies to respond to consumer demand, including changing trends or emerging technology, and second, it prepares them for force majeure. In manufacturing, force majeure describes unprecedented crises that can disrupt supply chains, damage companies, or even put employee health at risk.

In 2020, the entire globe faced force majeure unlike any in more than a century when COVID-19 became a worldwide pandemic. This crisis brought the global supply chain to a screeching halt, forcing manufacturers to face the repercussions of having processes that were unprepared to respond with agility.

One of the most widely felt supply chain failures occurred in the medical supply industry, specifically for personal protection equipment (PPE). In this white paper, we will highlight Essentium's response to the PPE shortage and illustrate how using Essentium technology for direct manufacturing can help companies react to customer demand and better prepare them to respond to force majeure events down the road.

WHITE PAPER HIGHLIGHTS

36 HOUR
Time-to-part

>26k PARTS
Printed in 90 days

4 MILLION
Mask equivalents

SUPPLY CHAIN DISRUPTION IN 2020

What Happened?

On March 11th, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a global pandemic. The announcement introduced the world to a force majeure circumstance that would lead to the loss of millions of lives and jobs, eventually causing the breakdown of the global supply chain.

In the early days of COVID-19, the crucial need from healthcare systems paired with panicked marketplace behavior caused a critical shortage in PPE. Due to the shortage, doctors and paramedics were forced to reuse disposable masks, which were selling for more than 10X the normal cost because of demand. In addition to the PPE shortage experienced by medical staff, other first responders like police, firefighters, and military were unable to secure any at all.

In a healthy supply chain, when demand goes up for a product, supply goes down, prompting manufacturers to increase supply to meet the demand. However, due to the growing number of COVID-19 cases and mandatory quarantines, factory floors around the world were short-staffed or even shuttered, crippling the global supply chain. This made it difficult if not impossible to get the jigs and fixtures, tools, and equipment required to mass-produce PPE.

Though the global supply chain for PPE was in shambles, the critical need for supplies grew day by day. Instead of waiting for traditional manufacturing methods to recover from the damage from this force majeure, companies like Essentium turned to direct manufacturing, leveraging additive manufacturing (AM) to print reusable mask frames with disposable filtration media for first responders and other front-line workers.

2020 PPE SHORTAGE BY THE NUMBERS

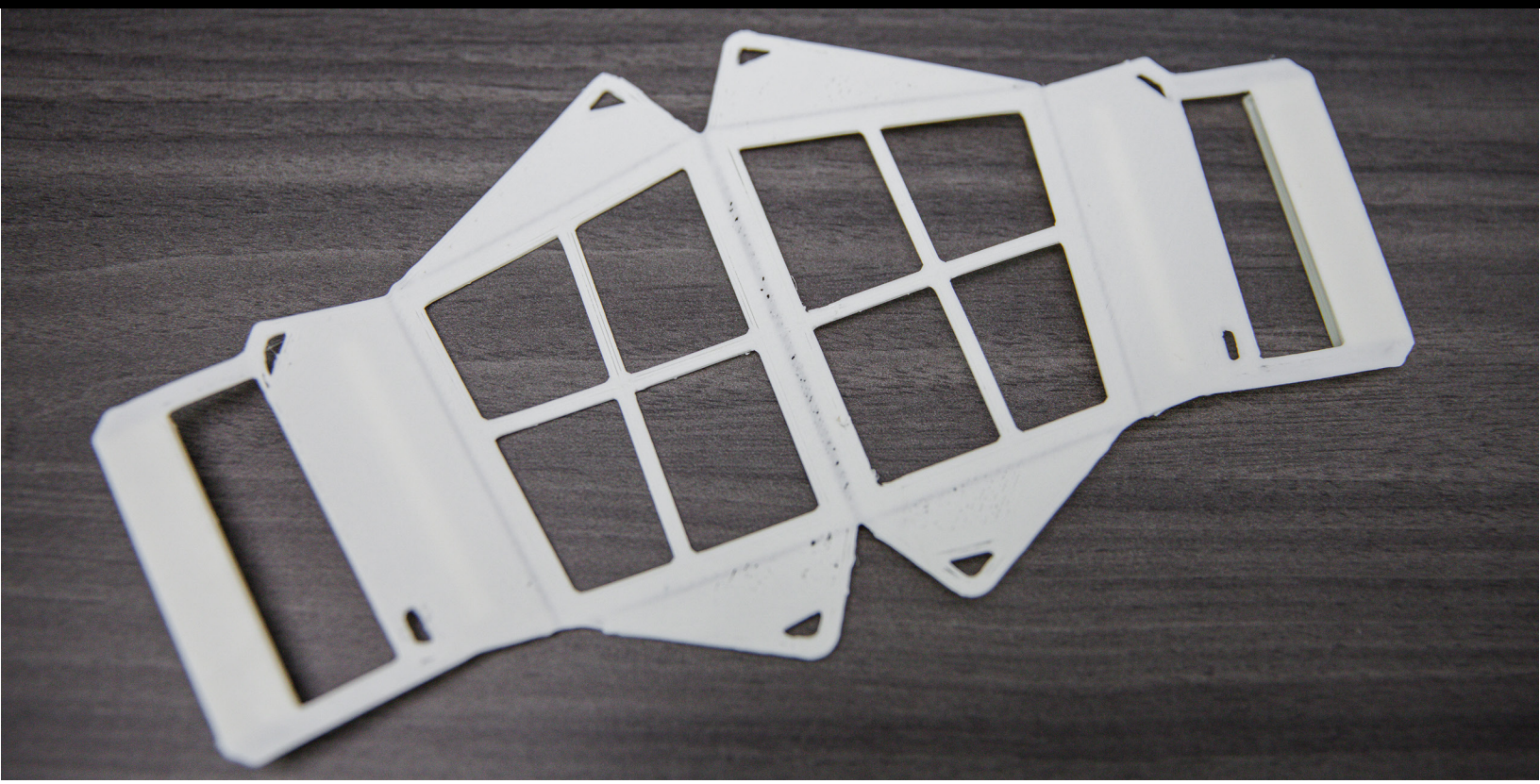
Due to healthcare system needs the United States experienced a severe shortage of PPE in early 2020.

1,300%

price increase in N95 masks since early 2020.

86%

of facilities in need of N95s in January were reusing masks.



Positioned to Respond

The Essentium mask initiative was born as a response to a crisis. U.S. military, police officers, firefighters, and EMS needed masks without taking from the limited supplies available for medical personnel. In response, the National Guard asked that Essentium join the Texas governor's strike force to respond to the damaged supply chain for masks. Recognizing that its machines and materials uniquely positioned its ecosystem to respond, Essentium accepted.

In those days, it was the wild, wild west of PPE. Masks were not only hard to come by, blue surgical masks that were normally 40 cents per mask jumped to four to six dollars per mask in April 2020. To solve these issues, Essentium aimed to create a design that could be delivered with reliable and repeatable quality, at scale, while keeping the cost per use below a dollar per piece.

"During this force majeure event, we didn't lay off anybody, stayed on track with our time schedules, and met our operating targets because of our HSE 3D Printers and materials. We also have an amazing team that worked their hearts out, but our successful response was more than hard work and luck, having additive in our tool belt ***positioned us to respond.*** *That is why investing in AM is vital for future-proofing your company."*

Blake Teipel, Ph.D., CEO, Essentium, Inc.

Rapid Prototyping

When developing a new product, designing and iterating with traditional manufacturing methods can cost thousands of dollars, and it can take weeks to complete. Manufacturing companies face this challenge constantly, and when supply chain disruptions happen, weeks can turn into months.

Having the Essentium HSE 3D Printer and industrial-grade materials ready to go made it possible to create the first mask prototype in eight hours, quickly iterate through 25 designs and different materials, and land on a final design after only 36 hours.

RAPID PROTOTYPING TIMELINE

FIRST PROTOTYPE 8 HOURS	ITERATE THROUGH 25 DESIGNS 28 HOURS

TIME-TO-PART 36 HOURS

During this design phase, the team at Essentium gave their time, effort, and even their faces. To speed up design time, the masks were printed and test-fit on many people inside the company. Since these iterations were made in the final use material, it allowed them to get instant feedback on design and make real-time edits. This immediate feedback is not possible with injection molding without impacting the tool design and causing longer lead times.

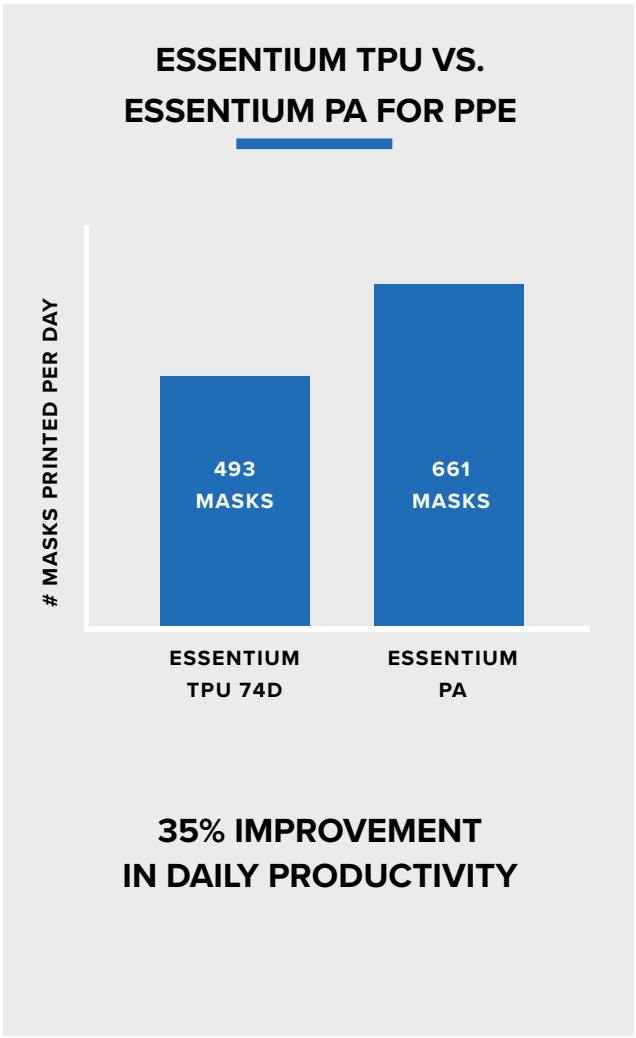
Material Selection

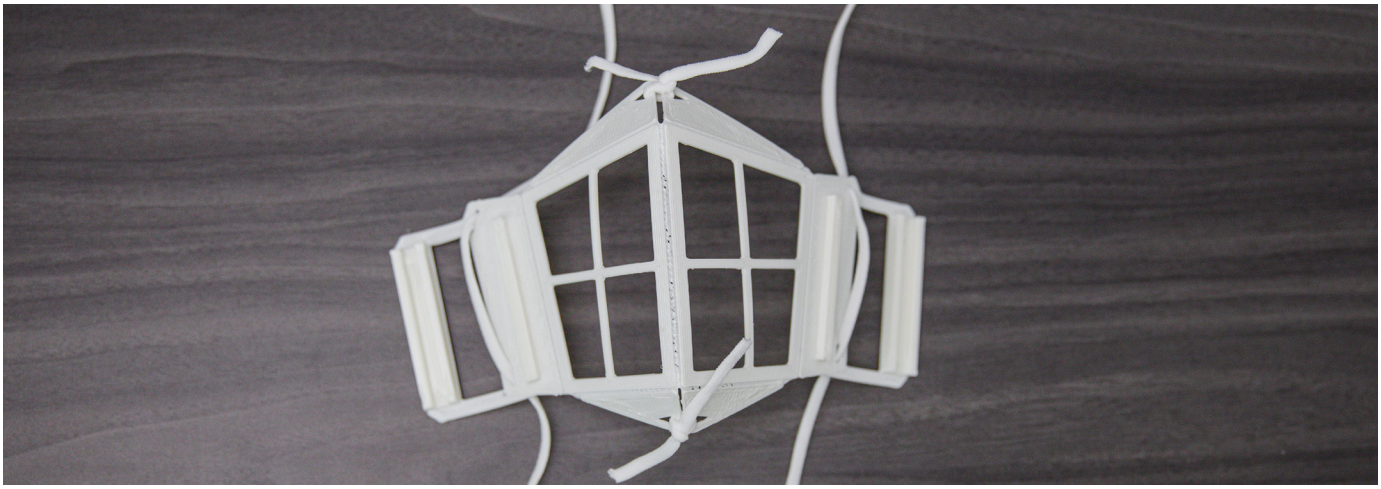
Material selection is more than choosing the best material for the application. Manufacturers also have to take production time, cost, and post-production time into consideration. Once the material is selected and parts are produced, it is costly to pivot to another option.

With AM, material changes can be executed quickly and without any costly tool changes. Essentium leveraged these benefits during mask production. At the beginning of the project, Essentium TPU 74D was selected as the mask material. It printed nicely, but once it was off the printer, it required a four-step post-processing method. To solve this bottleneck, Essentium decided to switch to Essentium PA.

Initially, Essentium TPU 74D was chosen instead of Essentium PA because polyamide-based materials readily absorb moisture, which can lead to a reduction in mechanical properties. However, in this case, it led to a more pliable and comfortable mask frame that printed quickly and required little post-processing.

The agility to make a material change in the middle of production not only saved Essentium time, it got masks to first responders 35% faster than if Essentium was stuck using the original material.





ADDITIVE MOVES THE COST CURVE

Facing the Reality of Lead Time

Traditional manufacturing methods are driven by CNC machines and injection molding machines, both of which require tools to be made, iterated, manufactured, and shipped. This entire process can take months, even with the best suppliers on the planet.

Due to the initial high demand from customers, Essentium decided to purchase injection molds and set up off-site production. Initial estimations promised to get Essentium's mask production to tool in two weeks, but because of COVID-19, the tools were quoted a seven-week lead time. With mask shortages growing more critical day by day, nearly two months of waiting for tools was not an option.

When traditional manufacturing fell short, AM bridged the gap. While Essentium waited for the tool, it used a fleet of 10 Essentium HSE 180•ST 3D Printers to produce more than 25,000 masks in 90 days.

WHAT FASTER CAN DO

10
HSE 180•ST 3D Printers

26,317
35 gram mask frames

90 days
from start to finish

Reducing CapEx One Product Order at a Time

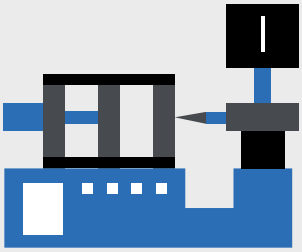
When looking at the cost savings that AM can provide, many make the mistake of looking only at operational expenses (OpEx). These expenses include items like labor time, tool costs, etc. Though AM provides cost savings for OpEx, when factory managers consider both OpEx and capital expenses (CapEx), that is when AM really starts to move the cost curve.

For manufacturers that use traditional methods, CapEx compounds with every new tool made for product orders. For any tool created, manufacturers face cost for tooling material storage, creation of the tool, and the storage of the tool after use. This storage crisis can be particularly difficult to manage because every tool has to be stored in case the customer comes back to do another run. With AM, manufacturers can directly manufacture the part with speed and agility and without extensive CapEx costs.

ARE YOU COMPARING APPLES TO ORANGES?

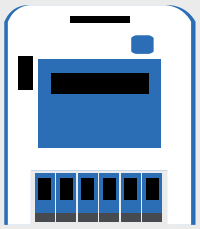
When looking at the cost savings that high speed extrusion can provide, it is important to compare both operational expenses (OpEx) **and** capital expenses (CapEx). When factory managers consider both OpEx and CapEx, that is when AM really starts to move the cost curve.

INJECTION MOLDING



OpEx Costs	CapEx Costs
Wages	Machine
Repair	Material storage
Material	Tool creation
	Tool storage

HIGH SPEED EXTRUSION



OpEx Costs	CapEx Costs
Wages	Machine
Repair	
Material	

Choosing a Distribution Model

Once the masks were ready for distribution, Essentium decided to steer away from the distributed model. This common model for distributing AM parts involves utilizing countless local printers to print parts. This model presents several challenges. First, maintaining a high standard of quality across tens, hundreds, or thousands of locations is nearly impossible, which is critical when creating FDA emergency use equipment. The second challenge is revision control. When Essentium made updates to the design to facilitate assembly and comfort, the distributed model would have required massive rollouts with these design changes to all printers in the network. Finally, the transportation logistics costs are high. At a glance, it seems like locations close to the end-user (in the case of PPE, a large hospital, for example) would provide a lower transportation cost per unit, however, a consolidated truckload shipment from a single location is much more cost-effective than many smaller shipments to a single destination.

To solve these issues, Essentium decided to use a hub and spoke distribution model. This model uses a single location or a few regional AM hubs to deliver burst capacity for production. This allows for a more focused approach to quality with trained personnel using standardized sampling and exemplar parts. In the mask case, the “hub” in the Greater Austin, Texas Area designed and iterated the final mask, then two of the “spokes” printed updated versions in North Carolina and Wisconsin. This model allowed Essentium to use a single operator to operate multiple HSE 3D Printers, and quality inspectors were able to inspect larger production lots at a time. Additionally, revisions or material changes were able to quickly and efficiently be deployed to all printers, and operators could be retrained in a very short period through the use of standard work processes and shift turn-over processes at the hub location. Finally, Essentium leveraged truckload shipping methods to a limited number of end-user locations keeping the per unit transportation cost very low.

The ability to deliver burst capacity at scale from a single AM site or a few regional AM sites has similar advantages to any large manufacturing plant. The technology itself allows for agility in production and the hub and spoke concept provides economies of scale in overhead, operating costs, and logistics costs that aren’t available with a distributed model.

Solving for QMS

If a manufacturer needs 10,000 parts a year, it is a no-brainer to choose AM, but what if their usage is 100,000 parts a year? Can they still produce at that quantity and maintain quality management systems (QMS)? With the HSE 3D Printing Platform, Essentium says yes. However, the printing platform is critical.

Due to the machine-to-machine variation in desktop printers, piece-to-piece variation is too high, preventing any statistical process control (SPC). The Essentium HSE 3D Printing Platform has all linear servo motors and log files, allowing users to track quality on an ongoing basis to have a statistically relevant manufacturing capacity.

Essentium’s mask initiative proved that using the HSE 3D Printing Platform in conjunction with the hub and spoke model is not only a cost-effective way to distribute a product, it’s the answer for achieving critical mass and maintaining QMS for the factory of the future.

PROVIDING MASKS IN RECORD TIME

The Outcome

In the end, Essentium was able to set up a manufacturing process and scale it amidst a pandemic with a high degree of uncertainty. Manufacturers all over the world did not have the same outcome when facing this force majeure because they weren't positioned to respond with agility.

In conjunction with its partners, Essentium shipped more than 71,000 reusable mask frames made with Essentium PA (thermoplastic nylon). The frames were designed for single-use, replaceable filtration media that is BFE95 certified, which created more than 4 million mask equivalents.

These masks went to the guardsmen and women of the National Guard deployed at testing sites, the Pflugerville Police Department, the Sulzer Corporation, and other local manufacturers in Austin, TX.

Like any force majeure, COVID-19 turned the global supply chain on its head. Despite the challenges that came with production during a pandemic, the Essentium High Speed Extrusion (HSE) 3D Printing Platform and industrial-grade materials gave Essentium the agility to design, prototype, produce, and distribute direct manufactured end-use parts in a matter of weeks. That kind of agility positions companies for success.