



Driving Innovation and Adoption

Presented April 5, 2018 by Rick Gillespie, Business Development Manager at Fisher Unitech at MDTX, the Medical Device Technology Exchange

Rick Gillespie: Good morning. As Joe said, my name is Rick Gillespie. I represent a company called Fisher Unitech. I'll talk a little bit about them this morning.

Just to give you a little bit of my background, I'm excited to be here for this inaugural event. I worked for Stryker Orthopedics for 12 years in their sales and marketing department. And I have a real interest in medical device, so I'm very happy to talk to you today about 3D printing and how that can impact your company and the types of products you're developing.

This morning we'll talk a little bit about 3D printing mostly in medical and, at the end of the presentation, we'll have a couple of case studies that we'll share with actual companies that are 3D printing.

A little bit about who we are — Fisher Unitech partners with a company called Stratasys. Stratasys, for the last 25 years, has been the foremost company in the 3D printing world. Over half of all printers in existence in America in companies today were manufactured by Stratasys. They lead the market.

And Fisher Unitech is the largest Stratasys reseller in North America. We have over 50,000 customers who are in 22 states. We have the largest technical support staff of any company in the 3D printing industry. So, that's a little bit about who we are.

Let's talk a little bit about how important is 3D printing. I thought it was appropriate to actually put up a quote from one of our customers. This is an Israeli startup. That's a Stratasys customer, and this is a very



Del Mar Fairgrounds - Wyland Center

Conference: October 2-4, 2018
Exhibits: October 3-4, 2018

Del Mar (N. San Diego), CA



bold statement that this particular engineer made — “we don't think, we print.” Well, when you think about that, that tells you how important 3D printing is in their development process.

So let's talk about that a little bit. First of all, who in here has had any experience with 3D printing in any way shape or form? Raise your hand. Okay, a few people. For those of you that aren't familiar with exactly what 3D printing is, it's also called additive manufacturing and it's the process where we can actually create a physical model from a 3D computer file.

And there are many different ways to 3D print using different materials. We promote several different types of 3D printing. One is called a fused deposition modeling or FDM where we utilize a high-performance thermoplastic, heat that, and apply layer by layer from the bottom up to create a 3D object.

We also promote a technology called PolyJet. PolyJet uses photopolymer resins and, in something very much like an inkjet printer, lays down a very thin layer of this resin and then passes it with an ultraviolet light to cure that.

We have an example of a 3D printer right in our booth right behind the audience in the orange Fisher Unitech booth, and we also offer a product that prints actual metal parts. Okay?

So why 3D printing in medical? Every other industry in the world is utilizing 3D printing, including medical. It's been a little bit of a slower start in a medical field. There are some regulations and things that have to be adhered to in the medical field that makes it a little bit more difficult to rapidly grow into this field, but it's very viable and we are doing 3D printing in medical to try to keep pace with some of the challenges in that field, as you well know.

And there really are three that are major challenges right now that 3D printing is able to address and help.

One of those is the rising cost of healthcare. In most countries around the world, the healthcare costs are outpacing inflation. So it's very expensive. You know, companies like yours are forced to find ways to be able to deliver their products in a more efficient fashion and a cost-effective fashion in order to be profitable.

The aging population — people are living longer these days. They're requiring more of our resources for healthcare. So it's incumbent upon companies again to find efficiencies and find different ways to do things.

The third one is in relating to insurance companies. Insurance companies are now paying hospitals differently than they have in the past. Instead of the traditional fee-for-service model where surgeons would perform or doctors would perform an operation and the hospital would get paid by the insurance company, hospitals are now requiring and reimbursing based on outcomes, patient outcomes.

And that takes into consideration many different factors including patient satisfaction after the fact. Did they get readmitted after the procedure? Many things enter into this. In some cases, hospitals that can't meet those guidelines are actually being penalized or having reimbursement monies being held back until they're able to basically improve those processes to be able to meet all the guidelines.

So, it's a whole different landscape out there, and 3D printing in the medical field is very important because we address each and every one of these.

Let's talk a little bit about 3D printing in your world. If we look at the product development lifecycle, which are the arrows across the top in the white. These are the major buckets that you deal in when you're developing products. And the arrows in the blue are some of the solutions that 3D printing offers to help improve upon some of those areas.

Let's take a look at those one at a time. We will go through them quickly. In terms of research and development, this is where ideas come to life. 3D printing is giving companies the ability to rapidly develop prototypes of the ideas and the products that they are trying to bring to market, and they're able to do so much quicker and it's such a less expense than they have in the past.

And that's important because in many cases, as you well know if you're in the product development area, there are a lot of changes that are made along the path, along that continuum. And the ability of companies to be able to print actual models that they can deliver to a physician or a surgeon and actually give them the ability to hold on to that thing and spin it around in your hand and try it out, here's nothing like that. I came from Stryker, and I can tell you that the implants that we would design and develop went through stringent testing and iterations with our surgeon consultants.

Prototype tooling — Not only are you able to develop aesthetic prototypes that look good, but with 3D printing and some of the materials that are available, we're actually able to put those prototypes through a testing process. And actually, we can make injection mold production parts rather quickly and very inexpensively.

Injection molding and tooling is very costly, takes a lot of time, but more importantly, it takes a lot of money. Being able to print these molds out in hours or days versus weeks or months is invaluable to companies, reducing the costs by over 60% and reducing time by over 90%, being able to bring products to market much quicker than they have in the past.

Let's talk about some about testing of these products.

With 3D printing, we are able to produce realistic anatomical models, and these models are made of various materials. They can mimic bone. They can mimic soft tissue. As you see the picture here, this is a vascular model that is used at the Jacobs Institute in Buffalo, New York. They literally are able to hook these models up to devices to test fluid pressures, heat. They put them under realistic human environments to be able to test medical devices in these models.

Being able to test the device prior to taking it into the operating room is so important to our surgeons. So we're able to help eliminate the trial and error that used to be by developing these models. And the beauty of this is these models can be printed out with specific pathologies. They're not generic models off the shelf. These are patient-specific models, in some cases, that they're able to do these real-life testing on. And then the beauty is they can store them digitally and use them down the road again to train other surgeons and other residents.

3D printed medical devices and components

The manufacturing process — the benefits of that. With 3D printing, as you can see in this picture, we're able to actually produce production quality parts off the 3D printer to be able to share designs of the

model of the products that your companies are developing, and we're able to put these in the hands of the clinicians to be able to test these devices.

Situations like this where it might be a rather low-volume production run of, let's say, the housing on this particular device right here, being able to do those directly from a 3D printer in a high quality enough that it looks like a finished product is a great thing and can help move the process along rather quickly.

Also in the manufacturing area, with a 3D printer in-house, companies are able to produce jigs and fixtures and tools in a manufacturing process to speed up the design, to speed up the actual putting together of the materials into parts. These things can be built onsite in a short amount of time, literally hours or days versus weeks or months.

I can't tell you how valuable that is, to be able to cut the time from concept to finished product. Using 3D printing is a big value. Also, the materials that we have developed through Stratasys probably has the largest library of 3D-printable materials in the world, and these materials that you know have electrostatic capabilities biodegradable capabilities, they have properties where they are chemical resistant. So, you name it, there are materials either existing or in development right now to accommodate your needs.

We looked at a device, a few seconds ago from Acist. Let's take a moment to hear from some of the folks at Acist exactly how they're using 3D printing.

Acist Medical Systems

Acist is a medical device company. We primarily design and develop injection systems for delivering contrast. Acist has revenues of approximately 100 million dollars. We have 220 employees worldwide. We have automated the process of injecting dye into the vascular system that allows physicians to visualize anatomies in order to do therapeutic solutions.

Ed Miller: Since 1998, we've performed over 10 million procedures.

Clint Viliks: Our key customers are the physicians and clinical technicians that use our product on a day-in, day-out basis.

Dave Scott: Where our efficiency really comes from is 'how do you get that solution in front of the next physician?'. How do you get it quickly? The FDM process allows us to develop machines and design that overall solution very quickly.

It's a world of difference between machining versus something that you can print in a day.

When we bought into the FDM technology. We never pigeonholed ourselves into a particular arena. We like to use it for everything. We do it for functional testing, we use it for making fixtures. We're also looking at using it for parts of some products.

We use this technology for production of parts.

The CTA is a lower-pressure injector. We're going through a product update, but we're really looking at reducing the first production run using the FDM process.

It makes a great substrate for the process and for the parts, but also it allows us to really do some design-to-manufacturing and eliminate a lot of pieces. You can reduce part count by putting complexity into one part. What also allowed us to develop the products and get a new updated version to our customers is pushing out our decision on the moldings. You don't want to invest in a new mold or a new technology until you make quite sure that's what they want.

This is a truly just-in-time, on-demand inventory. If three years from now, the customer that bought the machine may say, "Hey. We dropped it," and they want the replacement part. With this process, all I have to do is go back to my file and I can reprint that part and only one part that day, but I've never carried the inventory. When you look at all the lean technologies and the opportunities out there, this is probably the leanest, best example of managing inventories and then keeping only what you need and parts you can handle. And if you can design with that end in mind, you should see the benefits that you can have, but it has to become a mindset

Dave Scott: What the technology allows you to do is it really allows you to put a plastics manufacturing center inside of a lab, and it allows you to make any geometry out of any file and you're never stuck with one design.

Kevin Phillips: I think it facilitates the creative process.

Ed Miller: It really has changed the whole industry significantly as far as how long it takes to get products to market.

It kind of changes the dynamic. It really upsets the traditional manufacturing world. And if you've got the right volume, the right product, FDM can solve a lot of problems.

Joe Hage: Are you doing fine? I'm just going to take a moment of your time. Hey, who in the audience is using 3D printing right now [raises hand]? Wow, that's a lot.

How many of you are thinking that you may use 3D printing in the next year at your company? Wow. How many of you would like to use 3D printing, think you should use 3D printing but 'yes, my management isn't going to go for that just yet'. Not a lot of hands on that.

There you go, your audience.

Rick Gillespie: Thank you, Joe. That's great. I'm glad to see that there is a wide use of this.

Feel free to stop over. We're in booth 25. Our booth did not show up yesterday. I wish I could have 3D printed that yesterday afternoon, but unfortunately we weren't able to do that.

Marketing and education

Another thing that some of our customers are doing is they're utilizing their 3D printers to create realistic sales models that the sales team and the marketing teams can take out to visit hospitals and physicians to demonstrate their medical devices and some of the features and benefits of their device with these 3D models.

Once you have a 3D printer, understand there's so many things that you can do and how important it can impact many other departments within your company.

And from a clinical standpoint, companies now are actually creating patient-specific implants, patient-specific cutting guides, things that can aid in the operation like the operating room.

Folks, I can tell you, I've been working with Stryker and working with physicians in the operating room. Nothing is worse than having these physicians get into a situation where something comes up that they didn't anticipate.

3D printing gives the physicians the ability to practice ahead of time and do that. And these types of models here save time in the operating room like you can't believe. And with the operating room time costs at anywhere from 60 to 120 dollars a minute, that's important. And that's important to a hospital and that's important to your physicians to be able to save time.

Surgical preparation

We just touched on that. Again, think about the aerospace industry. How many of you would fly with a pilot that never once got into a plane and practiced or never spent time in a simulator? We just wouldn't do it.

But in the medical industry unfortunately, up until now with 3D printing, they've really had no way to have that simulator and here, through 3D printing, surgeons are actually able to print out a specific model of a patient's pathology, practice with their device first and feel comfortable going in there that they're going to do the right thing for the patient.

Take a short video here to talk about one other aspect and how surgeons use this technology —

Redmond Burke: --with an abnormal aortic arch. It's a rare problem, but we see it a lot.

Katherine Gonzalez: Because it mimics asthma so much. I think that it's often goes misdiagnosed.

Redmond Burke: So Mia lucked out. She had a really good doctor who said, "I don't think this is right."

Juan Carlos Muniz: So when we were able to make the diagnosis of a double aortic arch, it was very satisfying.

Redmond Burke: So then the challenge as a surgeon is how you divide this double aortic arch and save her life without hurting her. One of these babies' hearts are like Rubik's cubes, and you can't give somebody a piece of paper with a picture of a Rubik's Cube on it and say, "How do you solve this?" You have to hold that three-dimensional object in your hands and then come up with a solution.

Juan Apolinar: At Nicklaus Children's Hospital, we are actually using 3D printing to assist the surgeons with their surgical planning and teaching of new medical students.

So having the ability to make these 3D models, to look at them on the screen, but also to print them out and hold them in our hands has really made a fundamental change in how we view a lot of these diseases.

Redmond Burke: Make a 3D model of her very complex aortic arch vessels, we were able to figure out which part of her arch should be divided to achieve the best physiologic result. I showed the family their daughter's heart.

I hate opening up a textbook and saying, "This isn't really your baby's heart, but kind of looks like it. Here's how we're going to do the operation." That doesn't resonate with them.

I showed it to them. I said, "This is what's choking your baby. This is why she's taking all those medications and why they won't work." It's very powerful when you show a family, 'this is your baby's heart, and this is how I'm going to repair it.'

We've gone through planning an operation on a patient who was told, "Hey, you're an inoperable." We made a 3D model. I literally carried it around in my gym bag for a couple of weeks. So I would reach in, take it out and look at it until it finally dawned on me that there was a relationship that we could exploit.

Why experiment? Why go into the operating room and hope, when we've got a model and we can actually test the device in the model and know with certainty — this is going to work.

They could feel confident that we're going to do our thing. And we did the operation, we took intraoperative images and they looked exactly like that model.

Katherine Gonzalez: From having four and a half years of not knowing to all of a sudden in less than a two-month time frame, she's back out of her surgery. Yes, so it has been a great experience for us.

She's very active. She loves dancing. She loves baseball. She likes doing everything. So now she's just going back to normal life and not being worried.

Redmond Burke: Show them the level of sophistication that you have. Show them what you're capable of. The 3D-printed heart, accurate to the most minute detail, has been the difference maker for me. It's helped me take somebody from being inoperable to operable, and we've saved their life.

Rick Gillespie: Folks, I'll close with this — 13 years ago, I had my hip replaced. And as amazing as that operation was, and it took the pain away and I feel better and a better quality of life, that did not save my life. 3D printing saves lives.

If you have a company or if you're part of a company that would like to 3D print, but don't have a 3D printer, we are able to offer those services to you as an outsourced basis to get started to see if it's something that would be viable for your company. So there's ways to do it if you want to do it. Okay?

So I want to leave you with that. 3D printing is an exciting technology and I'm excited to be part of this industry, and actually, Joe, I wanted to thank you so much for this event. This has been fantastic.

Joe Hage: Thank you.