

Hospital develops 3D-printed simulation and education devices to help empower children with bleeding disorders and improve patient outcomes

About our customer

Orlando Health, headquartered in Orlando, Florida, is a not-for-profit healthcare organization founded more than 100 years ago. The healthcare system is recognized globally for Central Florida's only pediatric and adult Level I Trauma program, is the home of one of the nation's largest neonatal



intensive care units, and is one of the only systems in the southeast to offer open fetal surgery. Orlando Health has pioneered life-changing medical research and is committed to providing excellent community care.

Challenge

- Difficult to create a functional, scalable prototype
- · Discouraged patients, families and care teams
- The need to educate patients on how to self-medicate
- Commercializing innovative solutions for the greater patient population

As a strategic imperative, Orlando Health takes pride in innovating new solutions to help its patients. Their physicians and team members are encouraged to bring ideas and collaborate with the innovation team. In this case, Orlando Health had been working on building task trainers that utilize 3D-printed tissue blocks that would allow patients with bleeding disorders to practice self-infusion safely.

The majority of patients are kids — often as young as four years old — who could benefit from a practice device. It was disappointing not to have a life-like and easy-to-use tool to help teach patients and their caregivers how to self-infuse. By becoming proficient in self-infusing factor medication by practicing with a tissue-realistic venous access infusion simulator, patients with bleeding disorders can treat themselves at home and prevent repeat emergency visits and life-threatening situations. Self-infusion skills are especially vital for patients who live in rural areas where hospitals are far away. Bleeding disorders, such as hemophilia and Von Willebrand disease (often associated with sickle cell disease), are worldwide conditions affecting approximately four million people, predominantly in South America, India and Africa.

"We can do better for our patients," said Keely DeGroot, Director of Innovation, Design & Research for Orlando Health. "We knew if we could create a customized skin sleeve device with a similar texture, color and feel of our skin with simulated blood bags, we could safely inspire the confidence and experience to create better outcomes for the kids." As the innovation team prepared to scale up their operation to produce a 3D-printed simulation and education device —VainSim (short for Venous Access Infusion Simulator) — at a larger volume, they turned to Ricoh as a reliable and reputable partner with product development expertise and 3D printing.

Solution

- Partnered with RICOH 3D for Healthcare to create a perfect VainSim prototype
- · Worked with Ricoh to create packaging, instructions and shipping of devices
- Solved the hemophilia education treatment gap among patients
- Spearheaded a patient survey with intent to commercialize VainSim

With the Ricoh team on board, they transitioned the project for manufacturing VainSim at scale to the Ricoh 3D for Healthcare team, utilizing Stratasys 3D printers with Digital Anatomy Printing (DAP) capabilities at the Ricoh facility. The Ricoh and Orlando Health teams collaboratively redesigned and perfected the skin sleeves, making about 200 prototypes before achieving the right feel of the skin, which took several months to develop. VainSim was revitalized, bringing a safe way to teach patients how to infuse their medication when they have a bleeding disorder.

"Ricoh has experience with 3D-printed medical devices, task trainers, quality management systems, and the manufacturing expertise to help bring this to market with us. We credit Ricoh with helping us scale the first-of-its-kind 3D-printed trainer and enabling us to ensure VainSim is available to help patients and healthcare workers around the world," explained Anthony Mango, Manager of Product Development & Commercialization with Orlando Health. "Ricoh helped with many of the design elements and where we are today."

Within the first weeks, VainSim (patent pending) received an overwhelmingly positive response from patients testing the product, demonstrating its great need and usefulness for those with bleeding disorders. DeGroot and Mango began traveling globally to conferences to build awareness for VainSim and self-infusion education. "We've had so many medical professionals approach us with a sense of relief that help was on the way for their communities and patients. It felt very rewarding to offer our device to professionals in developing countries where this could impact so many children," DeGroot noted.

As Orlando Health moves toward a widespread release of VainSim, they began a pilot study to determine if patient and caregiver confidence in self-infusion is affected by practicing with VainSim and to determine the tool's usability by utilizing the System Usability Scale (SUS). Thirty-six patients with bleeding disorders and their caregivers were enrolled in the study, with patient ages ranging from six to their mid-twenties.

"We wanted to measure confidence and system usability. The VainSim study was part of a self-infusion education workshop that seeks to determine if participant confidence in infusion is raised by using VainSim and attending the workshop. Study results show a 51.07% increase in confidence in infusion skills among participants with previous experience after using VainSim, and 80% of participants who had never infused before reported feeling "Confident" or "Very Confident" after practicing with VainSim," said Dr. Shveta Gupta, M.D., Pediatric Hematology & Oncology at Orlando Health.

"Since beginning our study, patients and their families have expressed gratitude and immense appreciation. There was a large gap in teaching kids how to take care of themselves on a global scale. This innovation is designed to help and improve patient's health safely and confidently," stated Mango. "The survey results are great news as we look to take the next steps and release the solution to the world." Kids are trained on the tool for about two hours to become adept and confident in their abilities, removing the danger of piercing themselves.

"From our very first discussions with healthcare providers, parents and healthcare industry leaders, we've known that VainSim addresses a critical skillset development need. Ricoh is helping us ensure that we provide our toolkit to programs that facilitate the learning that empowers patients."

— Stephanie Sharon, Registered Nurse, Orlando Health

Results

- Significantly raised confidence in infusion skills in patient and caregiver testing
- Simulator usability ranked in the 95th percentile
- Increased awareness globally for self-infused simulations
- Immense relief, confidence and joy to patients, families, and the medical communities
- Correct amount of medication injected without accidental waste
- Paving the way for innovation using 3D-printed task trainers

The breakthrough for VainSim's refinements and achievements of Orlando Health and Ricoh are driving education and changing lives for the better. Orlando Health can print any skin color, size and depth of vessels — very realistic to the human skin, vasculature and fascia.

"We know there is an increased demand from the lack of resources. We've talked with many of our Hemophilia Treatment Center partners and they are eager to utilize the trainer in their practice. Now that VainSim is available in the market, it is important to get the word out, especially to underserved communities. Education, practice and prevention are critical steps within the healthcare industry—and now, we have a way to help our patients become more self-sufficient," explained Sharon.

"When we teach patients to use VainSim, it's amazing to see little kids' faces light up. It means so much to them to go from being petrified of needles and the process to now being able to infuse their own medication. It's really cool," DeGroot smiled. "With younger kids, Orlando Health will often start by letting them play and touch the device, so it seems less scary. Pretty soon, they want to try it themselves!"



Hearing from patients and their families has been rewarding for Orlando Health. Here are a few comments:

"I wanted to reach out and say thank you for yesterday. It was a fantastic class that gave our whole family some much-needed confidence to possibly attempt an infusion at home. Your whole team was a delight to work with and the sleeve definitely gave me the confidence to try on a human. I loved seeing that Blake felt confident knowing that this is his reality. Blessed to be in your care."

— Jamie Sugar, Parent

"Good morning, I am writing to thank you for today's workshop, it was very gratifying for us to see Luis doing this practice and leading him towards his independence and personal safety. The device was very positive, especially for my husband, who does not like the use of needles, and the device managed to give him the confidence to do so, being a very valuable tool in an emergency. Many blessings and thank you again."

— Parent

"First, I want to thank you all, for the amazing class on Friday. Saturday and Sunday we were able to give him the factor with the butterfly (his IV stopped working). We will keep working on his fears, but for sure made a huge difference on his last infusions."

— Parent

Orlando Health is paving the way for innovation and leadership to help solve patient needs with the use of 3D-printed simulation and education devices for bleeding disorders with more ideas coming soon. Currently, the organization has four other innovative simulation products actively in development. VainSim has inspired and encouraged physicians, staff and the innovation team at Orlando Health to continue experimenting and using 3D-printing for task trainers and patient-specific medical devices to solve more health challenges.



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— Anthony Mango, Manager of Product Development & Commercialization, Orlando Health

To learn more about VainSim and purchase the toolkit, visit <u>VainSim.com</u>. To learn more about how 3D printing can be deployed to help healthcare organizations, <u>click here</u>.

