



CASE STUDY

Pyng Medical Drug Delivery



Updating a classic medical device design for new markets brings insights and savings





Pyng Medical Corp. commercializes award-winning trauma and resuscitation products for emergency medical responders and hospitals. Their FAST1® Intraosseous (IO) Infusion System is the first FDA-cleared IO system designed specifically for use in the sternum during adult and adolescent emergency intervention.

When normal peripheral intravenous access fails, FAST1® helps emergency care providers—in a hospital or during pre-hospital response—quickly establish vascular access and administer emergency fluids and medications safely and effectively through the bone marrow of the manubrium. For over 10 years the product has been widely used in military markets because of its rugged construction and portability.



With 10 years of military success, Pyng Medical Corp. wanted to re-energize the product line, and keep it ahead of marketplace competitors.

"I get better solutions if I maximize the people and resources working with me in their area of expertise. I value most that StarFish Medical has a very strong skill set at the front-end of the R&D process. They can look at a problem and come up with a unique design and plan at an affordable price. Many find it easy to come up with a design that solves the problem. But not so easy to come up with a solution that meets the need, is affordable, able to be completed in an acceptable timeframe, and doable."

Mark F. Hodge
Pyng Medical President
& Chief Executive Officer



The product weight is cut by almost 50%, which reduces the medic's backpack burden.

The Process

Working together, StarFish Medical and Pyng Medical Corp. engaged with key military and civilian customers and end-users to identify the strengths and weaknesses of the FAST1® product. The team visited various military installations with senior medical training officers and battlefield medics and spent time shadowing civilian ground and airborne ambulance teams in the field.

Preliminary research was followed up with focus groups of emergency medicine thought-leaders to corroborate the initial findings from the field. An extensive report detailed the differences between military and civilian markets.

The insights gathered as part of the process helped the StarFish team to create a Product Definition for the next IO device including DFx (Design For x) goals.

Results

Updating the military device for civilian appeal makes the FASTResponder™ a more useful device on the battle field. Less needles with a mechanical redesign that shields them in a transparent plastic shell creates an easier to handle device and improves civilian end-user perceptions.

Reducing the size, weight, appearance and the force required for insertion allowed a more intuitive

and ergonomic product appropriate for all civilian providers. The original force to operate the device is reduced making it easier to use by all.

Together, StarFish Medical and Pyng Medical Corp have taken the FASTResponder™ product through the requirements testing process.

Empowering Medtech Innovation™



Bottomline

FASTResponder™, Pyng Medical Corps. next generation IO Infusion device, received the CE Mark in Europe and is cleared by the United States Food and Drug Administration (FDA) for marketing in the United States. The FASTResponder™ was also cleared by Health Canada.

The FASTResponder™ product has received initial positive input from medical professionals for being easy to learn and easy to use. This feedback indicates the possibility of Pyng Intraosseous Infusion products being used in a wider range of applications and markets. This market expansion opportunity is anticipated to enhance Pyng Medical Corp sales potential moving forward and the company is increasing marketing activity.

Visit starfishmedical.com/tools for more medical device commercialization tools.

“StarFish Medical helped us take a rugged battlefield device and add a level of sophistication and usability. Pyng Medical has high standards and we found StarFish Medical to be a creative and talented team of engineers and designers. They helped us generate new intellectual property and steer us through the unique requirements testing.”

Nicole Ranger

Pyng Medical VP Engineering
and Product Development

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StarFish Medical provides award-winning design, development, and flexible manufacturing outsourcing services —100% dedicated to the medical device and life science marketplace.

StarFish partners with innovative companies to create and manufacture breakthrough products for a full range of medical specialty areas including: Cardiovascular, Digital Health, IVD, Ophthalmology, Optics, and Ultrasound. StarFish expertise includes electronics, mechanical, human factors and software systems engineering.

Our proprietary Pathfinder™ process for medical device product definition saves clients time and resources throughout the technology and product development phases to commercialization. Prototype and low volume complex electro-mechanical production are delivered in an ISO 13485 certified facility with FDA registration, including cleanroom capabilities.