

A LIFE-CHANGING DEVICE



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Rapid Prototyping Allows Kablooe Design to Quickly Develop Products and Put Them in the Hands of Physicians

"We saved at least \$250,000 and 12-14 weeks using RedEye On Demand and FDM."

— Tom KraMer, President, Kablooe Design

For Kablooe Design, creating devices that transform the medical industry is not a new endeavor. Nearly seventy-five percent of the product design firm's creations are medical devices. Kablooe, located in Minneapolis, Minnesota, has worked with some of the nation's largest medical technology companies creating prototypes for medical devices which have changed the way patients are treated, significantly improving quality of life for thousands of people.

Recently a medical technology company approached Kablooe for assistance in the development of a device that would radically transform the treatment of Benign Prostatic Hyperplasia (BPH). BPH is commonly known as enlarged prostate and is estimated to affect ninety percent of men by age eight-five. The most common surgical procedure used to treat BPH is Transurethral Resection of the Prostate (TURP). This invasive procedure involves inserting a resectoscope into the urethra where the overgrown prostate tissue can be cut away using an electric current. The urethral lining is also removed during BPH surgery, leaving many patients with bleeding, scarring and the need for a short hospital stay. Post-procedure patients often require a urinary catheter for an extensive period of time – some never regain regular urinary function again.

This new device could offer patients a minimally invasive procedure; no cutting, no bleeding. By design, it would allow physicians to inject steam vapor into the prostate where it gently denatures prostate cell membranes. Overgrown prostate cells injected with steam would die, cause the prostate to shrink and return patients to normal urinary function within a matter of hours.

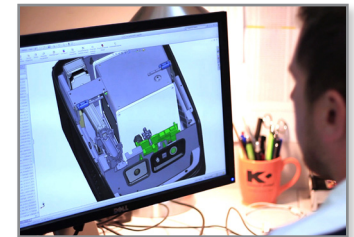
Although the idea of injecting the needle along with a steam vapor into the prostate had been invented, Kablooe's task was to design a tool for surgeons to use during delivery of the therapy. Kablooe had to invent many mechanical functions for this device; including: a saline flush function, a vapor delivery function, a needle deploy and retract function, a drain function, a video adapter function and a rotation mechanism. Kablooe had to mechanically design, invent, and discover how all these functions were going to work in a handheld tool connected to a generator unit.

The development of the device would require a rapid prototyping method that would allow lessons to be learned and changes to be made quickly. And the new device would require a durable plastic enclosure that houses complex computer and motor components. The Kablooe designers estimated they would need seven to ten iterations to get the design perfected. And they knew they would be required to perform product feasibility testing for the FDA.

It would not have been feasible to spend the hundreds of thousands of dollars to make traditional injection molded tooling on early designs, only to find that changes would have to be made. According to Tom KraMer, President of Kablooe Design, "The device is very complicated. It has RF energy generators, computer circuit boards, and power transformers. It is a very complex geometry that will need to be tested for EMI (electromechanical interference) and against UL (Underwriters Laboratories) standards prior to manufacturing."



A 3D rendering of the working prototype.



Kablooe engineer designing prototype device with 3D software.



RedEye On Demand's facility houses a large number of Fortus machines.

The Kablooe design team is working in collaboration with other groups responsible for making changes to the circuit boards and other components for this device. As Kablooe receives specifications for changes to these components, ABS models built with FDM (Fused Deposition Modeling) allow them to more aptly modify the device. FDM® is an additive manufacturing process that builds plastic parts layer by layer, using data from CAD files – the only additive technology that uses production-grade plastics.

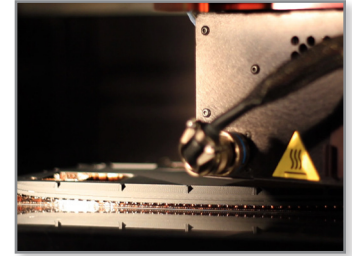
Kablooe does not own an FDM machine, so they chose to print FDM functional prototypes through RedEye On Demand. RedEye On Demand provides rapid prototyping and direct digital manufacturing services with a global network of more than 100 systems. With RedEye, Kablooe was able to produce key FDM components for the functional prototype in a convenient and economical way.

Familiar with various rapid prototyping methods, the designers at Kablooe knew that alternatives to FDM would be too brittle for use on this device. Traditional tooling and injection molding would be far too costly and time consuming. The prototypes had to use FDM with ABS plastics because the plastic had to endure complex and heavy components being screwed and mounted into the device. It had to be strong enough for drop testing while also maintaining a level of aesthetic appeal. Because FDM models are made from the same tough thermoplastics used in injection molding, they are able to withstand rigorous testing. If Kablooe had chosen other prototyping methods like SLA, their model would have cracked or even shattered during testing.

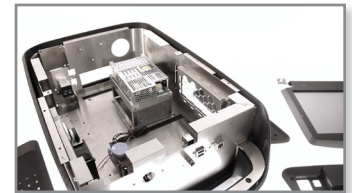
Ordering FDM models through RedEye On Demand during the prototyping process saved a minimum of \$250,000.00 and 12 weeks of time versus going to tooling and production. Kablooe was able to print a model, test the mechanics and human factors of the device, quickly make changes and reprint their model as they improved upon their design. FDM allowed for the discovery of dozens of things that need to be perfected in the model before it was sent to production. For example, Kablooe went through four prototypes of the handheld unit. Using FDM through RedEye On Demand allowed them to put together a functioning unit to test in animal trials and bench testing. Kablooe originally designed the handheld unit in a cylindrical form like a catheter handle. They discovered through feedback from physicians and technicians that operators preferred a pistol shaped grip.

Printing a working prototype with FDM at RedEye was very important in helping Kablooe quickly get the device into the hands of physicians so that they could in turn quickly provide feedback. Kablooe was able to fine tune and tweak the design and shape of the components in a fast and timely manner. Printing these parts through RedEye was a cost efficient way for Kablooe to make changes without going through tooling and then testing. And with RedEye, Kablooe didn't have to invest in capital equipment. They only paid for the units they printed.

"A device of this nature must not only meet the needs of patients, doctors, hospital administration staffs, the FDA and other regulatory bodies, but its design and creation must be timely and cost effective as a worthy investment for the creating company. Stratasy's FDM technology allows us to create these devices in a timely and cost effective manner, and in essence, is helping us transform the medical industry," said KraMer.



RedEye FDM print in action.



A disassembled prototype with FDM parts.



A fully assembled working prototype.

For more information about RedEye On Demand, call **866-882-6934** or visit www.RedEyeOnDemand.com

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