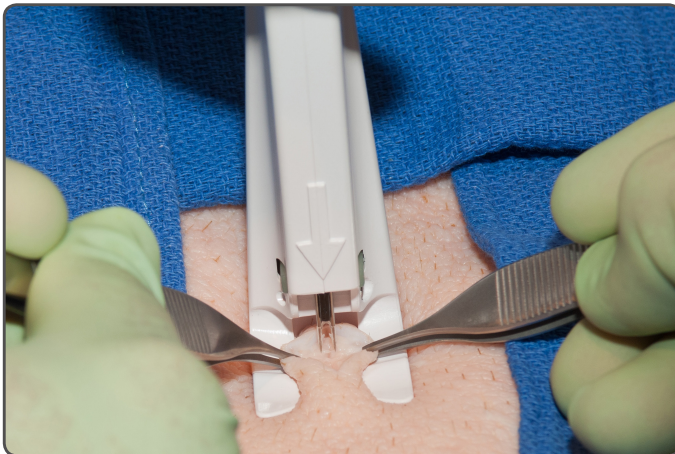


Saving Your Skin

A new medical device developed by Opus KSD closes incisions from minimally invasive surgery with subcutaneous, bio-absorbable fasteners.

Modern science has allowed surgeons to fix the human body amazingly fast, yet leave behind only small traces that repairs were performed. One of the more commonly used methods to achieve this is by a minimally invasive technique called laparoscopic surgery, where small incisions are made into a patient's skin, a laparoscope is inserted to provide a magnified view of the patient's organs, the procedure is performed, and the incision is closed by stitching or surgical staples. You can have your gallbladder removed before breakfast and be binge-watching Netflix from the comfort of your couch by dinner.

Typically, the small openings created during laparoscopic surgery are closed in one of two ways: manually stitching subcutaneously (beneath the skin) with a bio-absorbable, thread-like material and a curved needle that moves from one side of the hole to the other to close it tight, or with a surgical stapler that inserts metal staples into the skin to close the wound.



The SubQ It! is used to close a short incision similar to those seen in laparoscopic surgery.

The first technique is more time consuming, but leaves less surgical evidence. The latter method is faster, but can cause scarring and infection. Chuck Rogers, Ph.D., and Kenneth Danielson, M.D. of Massachusetts-based Opus KSD are nearing the launch of a device that combines the best of both worlds: the ease of a stapler with proprietary bio-absorbable subcutaneous fasteners.

“General surgeons are finding themselves under pressure because the user-friendly metal staplers that became very popular in the 1990s are not cost effective,” explains Rogers, CEO of Opus and Ph.D. biomedical engineer. “When people really began doing cost analysis, the five minutes that a surgeon saved in the operating room did not compensate for the fact that their patient still had to come back to have the staples removed.”

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Danielson, a Harvard M.D. with more than 30 years of surgical experience, approached Rogers with a concept for a new stapler and shortly thereafter the two began development on the SubQ It! skin closure system — a disposable, handheld surgical stapler that delivers bio-absorbable fasteners beneath the skin with one click of the device.

The first step in development was to design, build and test the tiny fastener, since that would ultimately guide the design of the actual device. Rogers and Danielson worked on refining the fastener including its distinctive shape, the length required to suture properly, the number of barbs it would need, and other critical features. Due to the extremely small size of the SubQ It! fastener with a mass of only 0.0064 grams, they were 3D printed by both the extrusion process of fused deposition modeling (FDM) and laser-curing method of stereolithography (SL).

After Rogers and his team knew what the fastener itself would look like, development of the multi-part device began. “Like the fasteners, we initially

used FDM and SL on the delivery device in order to inexpensively modify the parts as the device evolved,” says Rogers. The SubQ It! stapler is composed of nine plastic parts, including two exterior shell halves, a plunger operated by the user and internal parts that feed the fasteners. Proto Labs manufactures all of them through injection molding.

However, before a shift from additive to injection molding was made, Opus had each part milled through Proto Labs’ CNC machining service. The milled parts were designed as if they were being molded, with proper draft built in, so the form, fit and function of the device could be studied before tooling up for molding. “Once we put the prototypes together, we could test to make sure the fasteners were feeding correctly, and if the sliding action of the plunger was operating smoothly without jamming. If there were any problems, we would modify the part and have another one machined,” explains Rogers. “Once everything was working, we made molds.”

“We were really pleased with being able to match the performance of the mold to what we achieved in the machined parts.”

Although the design remained consistent from machining to molding, the material employed did not. In the stapler’s first iteration, the material used for the machined parts closely resembled the resin that would be used to mold it, but they discovered that surface finishes between processes varied. In subsequent iterations, they switched to machined acetals like Delrin, for example, even though final parts would be molded in an FDA-approved Lustran ABS, which provides more structural rigidity and can handle gamma sterilization.

“Most of the parts were only modified one or two times, and we were really pleased with being able to match the performance of the mold to what we achieved in the machined parts,” says Rogers.

It has been a busy 2014 for Opus, getting trademark approval for SubQ It! in January, additional patent protection in February and FDA approval in April for use in “abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery” — all while scaling up for manufacturing in parallel.



A CAD model of the SubQ It! device illustrates the entire assembly.

With the SubQ It! now in low-volume injection molding production, Opus is preparing for a full-market release of the stapler by actively working with surgeons to garner valuable feedback and testimonials. An early-2015 launch targeted at doctors specializing in minimally invasive surgery is planned.

Once established for use in humans, SubQ It! will expand to the veterinarian field. Rogers says that even if pet owners don’t care if scarring is visible on their pet’s skin, the benefit to vet and pet owner is the time and money saved from not having to return to the clinic to have the staples removed since they will have dissolved. Also, because SubQ It! fasteners are underneath the pet’s skin, the potential for biting or scratching them is reduced, which may in turn reduce the chances of having to don the unflattering Cone of Shame.

The SubQ It! system is designed to make life easier for surgeons and better for their patients, whether human or animal — something Proto Labs is always excited to help accelerate.