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Med-tech startup looks to take physical, financial pain out of brow lifts

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Zift Medical has a small footprint, but it's hoping to have a major impact in aesthetic medicine.

The 4-year-old med-tech startup has eschewed staff in favor of contract work and outsourcing. Rather than create a headquarters, Zift is crashing with colleagues at Resolution Medical in suburban Minneapolis who had extra office and clean-room space. Instead of pinning its hopes on venture capital, Zift Medical is raising money itself and spending judiciously.

The result is that this two-person startup has conceived, designed and begun human testing of a tiny medical device while raising $3 million. Zift hopes to sell the device one day to an established player in aesthetic medicine, like Botox-maker Allergan or breast-implant maker Sientra.

Zift's device, which is about the size of a gnat when implanted, is intended as a cheaper, less painful way to get brow-lift surgery. Ongoing experiments will determine how long it works. But even Zift's first-in-human experiments are different from standard industry practice, thanks to a Food and Drug Administration program that is allowing the first implants to happen in the U.S. instead of overseas.

"Initially, we were thinking we'd end up in Paraguay or something for the clinical trial," said Zift Medical CEO Eric Simso, an industry veteran who founded the company with engineer and fellow med-tech vet David Blaeser. "It is so nice to be able to go across town (to view) a procedure,

and then the follow-up is all done."

Zift Medical used an alternative pathway to get the FDA to approve its first-in-human study. Known as an early feasibility study investigational device exemption, or EFS IDE, the approval is allowing Zift to do its initial pilot study of 20 people from Minnesota and Wisconsin to gather early data on proof of principle and safety.

Ultimately, the company's innovative approach and efficient cost structure will matter less than the ultimate question: Does the Zift device work as intended?

The device consists of a thin nitinol tube about as wide as the tip of a disposable pen, which is placed in a millimeter-wide "incision" in the forehead and then fired a few millimeters into the skull using a hand-held tool that looks a bit like a glue gun.

With the forehead skin pulled taut and the bone anchor in place, the tool is withdrawn and several curved "petals" of metal flex out from the thin tube and invisibly grab onto tissue above the eyes. The anchors then hold the top layers skin more taut than before, theoretically creating the same kinds of results as a traditional surgical brow lift but without the pain, expense or extensive post-surgical bruising.

Although it's tough to give specific price estimates for a procedure that's not even proved safe yet, Simso said the ultimate goal is to have a "Zift Lift," - the company's current name for the procedure - cost a third of a traditional open-surgical or laparoscopic brow lift.

As of earlier this month, five patients have had the Zift procedure. It typically involves implanting six to eight anchors, which are intended to be permanent even though soft tissues age and develop laxity over time.

Principal investigator Dr. Peter Hilger, a facial plastic surgeon and University of Minnesota professor, said it's too early to say how long the anchors will maintain the patient's desired lift and how that time frame compares to a traditional surgical brow lift.

"You might legitimately ask me, are those going to be enough to hold up the weight of the skin over the long term? I don't know the answer to that," Hilger said. "I do know it held at 90 days (in animal studies), and it is holding a week afterward in patients. But ... it's a first-in-human study."

The ongoing feasibility study will look at results at 90 days, six months, and annually thereafter, potentially leading to refinements in implant technique and device design. At some point the company will also launch a larger clinical trial to gather extensive data on safety and effectiveness that can be used to get full commercial clearance, likely through the FDA's 510(k) program.

Although the 510(k) pathway isn't known for requiring extensive preclearance testing, Simso and Blaeser said strong data will ensure the device is safe while also making the company more valuable in the process.

So far Zift has raised its funds mainly through "angel investors" in Minnesota. One near-term goal is to attract the interest of "strategic" investors like big, established med-tech companies that could offer a modest funding up front while helping direct Zift's future. One day a full acquisition by an investing company could be possible, though Zift is also working on plans to go it alone if need be.

Simso said the company has deliberately avoided venture capital thus far, because VC firms typically demand some level of control over the company and may end up with terms that greatly dilute original

investors' holdings.

"Venture is not bad necessarily," Simso said. "You just need to know that it's not free money, by any means."