



INNOVATION UPDATE



Celebration of Innovation:

CELEBRATING THE 50TH ANNIVERSARY OF THE FOGARTY® CATHETER.

“Everybody thought it was a crazy idea, that it wouldn’t work, and some young kid was messing around. I did not listen to the thinking of that day.”

Thomas Fogarty, MD and founder with Ann Fyfe, CEO

Innovation is thriving at the Fogarty Institute for Innovation, and we want to share highlights of some of the latest developments in our programs. This newsletter touches on improvements we’ve made to our facilities with the addition of the Fog Shop, describes milestones like the 50th anniversary of the Fogarty® Catheter, and introduces the latest crop of entrepreneurs we are mentoring. You’ll also see updates on our most recent graduates. Last but certainly not least, in honor of our dear friend, Tracy Lefteroff, we have created the Lefteroff Leadership Program. Tracy was taken much too soon, and we have lost a friend, colleague, and great mind in medical innovation.

We encourage you to catch up on our progress, and if you can make a donation to support our efforts, we would appreciate your help in our quest to advance innovation and improve patient care.

Thomas Fogarty, MD is renowned as the “Edison of Medicine” for good reason. With more than 150 patents to his credit, he has been a prolific innovator and has made an indelible mark on patient care. But one of Dr. Fogarty’s first inventions, the balloon catheter, is perhaps his best known, as it revolutionized the way heart disease is treated and set the stage for many more developments in the field of interventional cardiology. The Fogarty® Catheter has been used to save millions of lives and is still widely in use today — 50 years later — in almost its original form.

Edwards Lifesciences holds the patent on the catheter and partnered with Tom from the beginning. Recently Edwards celebrated the 50th anniversary of the Fogarty® Catheter at a two-day event that included their annual Edwards Scientific Symposium and quarterly Employee Meeting. Held at their headquarters in Irvine, CA., the events gave more than 1200 Edwards’ employees the opportunity to hear directly from Dr. Fogarty about his experiences. He gave the keynote address and participated in a Q & A session with Chairman/CEO Mike Mussallem. Dr. Fogarty is considered a legacy founder of the company and is revered for his contributions to the company, the industry and patient care.

Edwards and Dr. Fogarty have enjoyed a successful five-decade relationship that speaks volumes about what can be accomplished with a true collaborative spirit. Mussallem says, “From the beginning, the Fogarty® Catheter and Edwards have been one — we share a philosophy to look at less-invasive technology.”



Thomas Fogarty, MD and Mike Mussallem, Chairman/CEO Edwards Lifesciences

The catheter was essentially the first vascular intervention and it led to the development of coronary angioplasty and stenting and all the catheter-based interventions in use today. Its value was not apparent to all at the outset. Dr. Fogarty recalls, “Everybody thought it was a crazy idea, that it wouldn’t work, and some young kid was messing around. I did not listen to the thinking of that day. I was contrary.”

Millions of patients have Dr. Fogarty’s persistence to thank for their lives, and millions more will have him to thank for his relentless pursuit of medical innovation through the Fogarty Institute for Innovation.

Introducing the Fog Shop: New Space Gives New Ideas Room to Grow.

“We wanted to provide our innovators with the space, environment and tools to do their best thinking.”

— Thomas Fogarty, MD

Perhaps the newest innovation at the Fogarty Institute this summer is the Fog Shop, the additional office and laboratory space we've opened in the previous El Camino Hospital building for our Companies In Residence (CIR). Our program was growing faster than our space in the Melchor Pavilion could accommodate, and because of our strong partnership with El Camino Hospital, they offered us the previous hospital cafeteria space. It is just what we needed and now we have the additional space to welcome more innovators.



Above left: Hiroki Igeta, Clinical Engineer Innovations Fellow from Aso Iizuka Hospital, Japan. Above right: Dr. Fogarty with Fletcher Wilson, CEO, InterVene



“The additional space gives us a great collaborative environment for our entrepreneurs to work alone and in teams, meet with mentors, hold brainstorming sessions, and conduct research to further their ideas,” explained Fred St. Goar, MD and FII Board Member. The new Fog Shop, named after Dr. Fogarty's original think tank in his garage, offers 14,000 square feet of mixed-use space. The new lab alone provides 7,000 square feet, which includes wet bench areas, refrigerators, special power accom-



Kevin McDermott (left), summer intern at Prescient, with Jeremy Koehler (right), Design Engineer at Prescient

“With the Fog Shop up and running, the pace of our progress has really started to kick into high gear.”

— Insoo Suh, MD, Prescient, Chief Medical Officer

modations, and room for bench work and prototype development. In the office area, we have spacious work and meeting areas. The location makes it easy for hospital physicians to stop by and work with our entrepreneurs.

Essentially, the new Fog Shop offers a multipurpose hub. “As in any business, sometimes the best ideas come from the lunch table or the water cooler. We are already seeing a great exchange of ideas, and a little healthy competition,” said Nathan Bachtell, MD, CEO of First Pulse, one of our CIRs. Another entrepreneur, Insoo Suh, MD from Prescient commented, “It's a privilege to work every day in an environment with so many talented entrepreneurs and experienced mentors in the med-tech industry. With the Fog Shop up and running, the pace of our progress has really started to kick into high gear.”

UPDATES ON RECENT GRADUATES.



Niveus Medical was one of the first companies in residence at the Institute, spending several years here developing an advanced muscle stimulator system to prevent muscle weakness and debilitation during extended periods of bed rest. They left the Institute in December of last year to establish their own offices in Mountain View, and have received 510 (k) clearance on their innovative device.



PQ Bypass, a graduate of the Institute's incubator program, is developing a less invasive approach to bypass the femoral artery, designed to match the performance and safety of more invasive, traditional bypass surgery. Since leaving FII, they have moved into a new facility, started manufacturing the device, and initiated preclinical testing. They plan to do their First In Man (FIM) studies at the end of this year.

Stories of Support.



*Mike Mussallem,
Chairman/CEO of
Edwards Lifesciences*

The Institute is a 501(c) (3) educational nonprofit organization that relies entirely on donations for financial support. Contributions have come from many generous individuals who have been directly influenced by Dr. Fogarty's work or those who share his passion for improving patient care. In addition to individuals, we are thrilled that several companies are supporting us through their philanthropic foundations. For example, **Edwards Lifesciences** has a relationship with Dr. Fogarty and the Institute that goes well beyond their partnership in the development of the Fogarty® Catheter (story on Page 1). Edwards has given to FII for the last 4 years and contributes annually. This year, the company gave us an **additional grant of \$50,000 in honor of the 50th anniversary of the balloon catheter**. Mike Mussallem of Edwards Lifesciences explains, "Because of our interest in the great work that Dr. Fogarty does, we have a philanthropic interest in helping him with the Institute. I can't imagine a more worthy cause, and we are proud to support these invaluable efforts."

A TRIBUTE TO A TITAN. The Tracy Lefteroff Leadership Program.



Like so many in the Silicon Valley and across the country, we mourn the recent passing of Fogarty Institute for Innovation Board Member Tracy Lefteroff. Tracy was an incredible force with an unmatched combination of skills, and beyond that, a truly fantastic person. His insights into every facet of business made him a valuable mentor for the growth of the Institute as a whole, and for our entrepreneurs. While his own successes put demands on his time, he made himself accessible and invaluable to our team. To recognize his contribution to the industry overall and to the Institute specifically, we are dedicating our expanding Educational Outreach Program in his name; The Lefteroff Leadership Program. In this small way, we hope to honor him as a mentor, a colleague and a friend.

"Tracy was a driving force in healthcare innovation, the likes of which we may not see again. His special blend of brilliance, relationship building, and generosity benefited innumerable companies and countless individuals. We all miss his counsel, his wisdom, his vision...but mostly his friendship!"

— Jim Joye, DO and CMO of the
Fogarty Institute for Innovation



Innovation: Cultivation

Meet Our Companies in Residence.

First Pulse Medical: Developing a novel technology platform to improve fetal monitoring during labor and delivery. The intrauterine technology utilizes a non-fetally invasive sensor to capture valuable fetal vital signs that will give obstetricians critical information related to fetal well-being.

InPress Technologies: Developing a single-use medical device to treat postpartum hemorrhage (PPH) by specifically addressing uterine atony. By avoiding the use of pharmaceuticals, hysterectomy, or other invasive surgical procedures, InPress may dramatically reduce the cost of healthcare during childbirth and save women's lives.

nVision: Developing a device designed to significantly advance the diagnosis and treatment of female infertility caused by fallopian tube dysfunction.

Materna Medical: Working to reduce the incidence of childbirth-related injuries to women during vaginal delivery with a device designed to prevent tearing and pelvic floor damage during childbirth.

Medical Cue: The NeoCue System intends to solve a major need in newborn monitoring and resuscitation by automatically sensing key physiologic data and offering decision guidance through neonatal resuscitation and rapid venous access.

Prescient Surgical: Working on CleanCision™, a platform technology developed to reduce the risk of surgical wound infections. The company's first product targets a patient segment having the highest risk of infection: obese patients undergoing colorectal surgery.

Clear Ear: The Total Ear Care (TEC) system, is a cost-effective set of instruments designed to provide easier, safer, and faster care for a range of outer-ear procedures, including ear wax removal, the number-one cause of hearing loss and hearing-aid failure worldwide.

InterVene: The ReLeaf Catheter System™ is the first ever percutaneous, venous valve creation platform that does not require a permanent implant. The system fashions new venous valves out of a patient's own vein wall to prevent blood from flowing backwards, thus decreasing venous blood pressure, and alleviating the devastating symptoms of chronic venous insufficiency (i.e. painful ulcers and severe swelling).

Vida Systems: Developing VidaBody, a 3D content teaching engine for anatomy and physiology. VidaBody makes learning easy by engaging students with interactive, rich content, interwoven game mechanics, and a social layer.



Announcing the Birth of a New Area of Focus — Women's Health and Birthing.

Our latest group of in-house entrepreneurs includes 5 that coincidentally fall into an entirely new area of focus for the Institute — women's health and birthing. This field is historically underdeveloped and underfunded in terms of medical innovations, yet it offers an opportunity to impact patient care across the world by helping to enhance the safety of pregnant women and newborns. The issues in this area are not as common or widespread as heart disease, our initial focus area, yet the problems that need addressing often have catastrophic and costly results. Having these companies share space at the Fog Shop enables them to share relevant mentors and benefit from the cross-pollination of ideas. Kerry Pope, FII mentor, shared that the new companies have also "widened the Institute's network, generating interest from new supporters," and we look forward to introducing our passion for improving patient care with that broader audience.

LEARN MORE.

If you'd like more information or would like a personal tour of the Institute and our new "Fog Shop," please contact Ann Fyfe at ann.fyfe@fogartyinstitute.org or call 650-988-7590.