# Pennsylvania Pediatric Medical Device Consortium

## FUNDED PROJECTS

# PROJECTS BY SPECIALTY

# Anesthesia

## SecureTube™

The University of Illinois at Chicago, in partnership with Olifant Medical Inc., will receive support for Dr. Girish Deshpande's work on the SecureTube™, a new endotracheal tube with several features designed to mitigate various factors that lead to unplanned extubations in pediatric patients. Unplanned extubations can lead to significant complications, especially in young infants, who could suffer cardiac arrest requiring CPR and may need an emergency re-intubation. Unplanned extubations are also associated with increased respiratory tract infections, increased length of ICU and hospital stays, and an overall increase in healthcare cost. The unique two-port design of the SecureTube™ and its specially designed holder will standardize the way endotracheal tubes are secured to the patient. It will replace the currently used Y-adapter and bite-block and will eliminate the use of tape that will minimize, if not eliminate, the unplanned extubations and associated complications.

## TrachAlarm™


Innovations Unlimited, LLC of Pennsauken, NJ, is creating the TrachAlarm™ to alert pediatric caregivers in a home care or other non-hospital setting if a patient's tracheostomy tube becomes dislodged. Tracheostomy tubes allow patients to breathe while undergoing treatment for certain chronic and congenital diseases. Fast recognition of tracheal dislodgement reduces risk for complications such as hypoxia, respiratory failure, cardiac arrest, and death.

# Cardiology

## PeriPath: Thoracic Access Tool for Epicardial Pacing and Defibrillation

PeriPath is the first access tool that enables single incision delivery of cardiac therapies to the pericardial space under direct visualization.

## Pulmonary Valved Conduit

A decellularized and PGG cross-linked novel bovine jugular vein (BJV) valved conduit device to augment the already recognized qualities of BJV.

# Critical Care Medicine

## Actuated Medical, Inc: TubeClear

TubeClear
In-Patient Tube Clearing System

*Real world challenges in taking a medical device from adults to pediatrics to revolutionize the way clinicians clear occluded feeding tubes.*

Feeding tubes are required when critically ill or severely compromised patients are unable to swallow food or medication. Patients requiring long-term feeding assistance typically use a surgically placed gastrostomy (G), jejunostomy (J) or a gastrostomy-jejunostomy (GJ) tube. For short term feeding assistance, nasoenteral (NE) tubes are normally used. In the United States (USA), approximately 7 million feeding tubes are placed each year. The problem is that these tubes often become clogged at reported rates from 12.5% to >35%. This results in millions of clogged tubes each year. When tubes remain clogged, patients can go without nutrition and medication for hours or even days. The interruption in nutrition and medication negatively impacts recovery. Healthcare practitioners spend significant time trying to clear clogged tubes, often spending more than 20 minutes per clog.

Actuated Medical, Inc. (AMI)* has developed the TubeClear device. TubeClear aims to reduce interruptions to feeding and medication regimens for the patient, reduce the time healthcare practitioners spend on hardware issues, and save significant time and money by quickly restoring patency to occluded feeding tubes. TubeClear is comprised of a reusable Control Box paired with a single use Clearing Stem. The healthcare practitioner attaches a Clearing Stem to the Control Box and inserts the Stem a few centimeters into the tube. Then the healthcare practitioner turns on the Control Box and manually directs the Clearing Stem further into the tube. The Clearing Stem has a specially designed tip that moves in a forward and backward motion that chips away at the clog to restore patency. TubeClear helps the healthcare practitioners to rapidly clear the tube without the expense and risk of tube replacement. The system is FDA cleared and CE Marked specific to NE, NG, G and J feeding and decompression tubes for adult patients.

For the pediatric market, clogged feeding tubes can occur more often due to the narrow diameters. The lack of nutrition and medication quickly exhausts the patient's energy reserves and the patient may develop dehydration with electrolyte abnormalities more quickly than in adults. When a tube cannot be cleared by standard practice, it is replaced which then puts the patient at risk for surgical intervention, tube misplacement and dislodgement.

But, as commonly found, there were challenges to successfully transitioning an adult device to the pediatric market. Often the adult device is too big, too strong, or simply inappropriate for pediatrics. In this case, even though TubeClear is considered by the FDA to be "a non-significant risk device" there was still concern with moving TubeClear into the pediatric market.

The challenge to expand TubeClear's indications to the pediatric population is threefold:

- The first was scale. Pediatric tubes are inherently smaller and the Clearing Stems now had to work in a much smaller tube. This is largely an engineering challenge.
- The second is regulatory. Rightly so, FDA assesses safety and efficacy in pediatric patients differently than in adults. AMI needed to comply with FDA requirements for pediatrics, which in some aspects can be more stringent than for the adult population.

- Third is market size. While there is certainly a medical need, the market is relatively small. Because developing a medical device is expensive, medical device firms typically look for a large market to offset their up-front R&D investment. Sadly, this combined with the regulatory burden often keeps larger firms out of the pediatric market.

To receive FDA clearance, AMI needed to investigate several factors. Among them was to investigate the behavioral response in a pediatric clinical study setting – a factor that was not required for clearance in the adult population. AMI needed a research partner at a recognized children's hospital, which brought the team to CHOP and the PPDC. After reading a paper by a CHOP nurse, as well as a press release announcing the PPDC, AMI contacted our team to conduct the clinical study necessary to expand TubeClear's indications. Since then, AMI has been working closely with the PPDC team to design a safe and informative study with submission to CHOP's Medical Device Committee and internal IRB.

While the PPDC continues to work closely with AMI to assist in the indication expansion of TubeClear, the following are some key takeaways from their experience thus far:

- There are unique regulatory challenges with the pediatric market including a much higher bar for FDA clearance.
- Smaller market size makes it financially difficult to invest heavily into up-front R&D. Finding outside funding sources is critical to commercializing a pediatric device.
- Finding the right clinical research team is critical to your success. Start the process early.

**Actuated Medical, founded in 2006, is located in Central Pennsylvania with the vision to Improve Patient Outcomes by developing medical devices that move in such a way as to enhance the intervention. Their innovations enable healthcare practitioners to perform faster, easier, and safer procedures by integrating electronically controlled Innovative Motion® technologies. As a business, they constantly look for new opportunities that fit their scientific and technological skill set. When the right opportunity is discovered, they seek R&D funding from SBIR grants from the NSF and NIH – in 2014, Actuated Medical received a Small Business Administration Tibbetts Award for SBIR Excellence. To learn more about Actuated Medical or the TubeClear device, please visit ActuatedMedical.com.*

## EyeBOX

Oculogica Inc., of New York City, is creating the EyeBOX, an eye-tracking based test to noninvasively and instantaneously assess intracranial pressure (ICP) in under four minutes. Quick and accurate detection of ICP in children following a traumatic brain injury would facilitate timely treatment and prevent further injury.

## InfraScan, Inc: The Infrascanner


*Clinical expertise and advanced technology come together to provide the best possible care to save the brain following traumatic brain injury.*

Traumatic brain injury (TBI) is one of the most debilitating medical conditions, as it can lead to potential lifelong complications. It is also the leading cause of death in children. The quality of treatment provided following a moderate to severe TBI is extremely important due to the way in which TBIs evolve. Traumatic brain injuries progress through several phases. The first stage is the primary injury phase. This is the damage that is directly caused by the impact or blow to head; this initial injury may be relatively small in size and have limited permanent effect on the brain tissue. The second phase is the secondary injury phase. As the brain reacts to the initial injury it goes through a cascade of changes which can result in swelling, brain bleeds (hematoma) and chemical imbalances. All of these are injurious to brain tissue. The final magnitude of injury to the brain is the combination of the primary and secondary injury. “Time lost is brain lost”. Early detection and treatment of secondary injury is critical to limit permanent brain damage. The Infrascanner handheld, hematoma detector was developed to aid clinical personal in the detection of developing hematomas. Early detection means early treatment, usually resulting in surgery for large and growing hematomas. Computed tomography (CT) scans are used to identify and track hematomas but with the addition of the Infrascanner, scans can be done frequently at the patient bedside reducing the exposure to radiation and movement of the patient yet providing clinicians with current information. This helps clinicians identify and track developing hematomas so that they can intervene in a timely manner.

Britton Chance from the University of Pennsylvania and Claudia Robertson from Baylor College of Medicine invented a Near Infrared (NIR) system for detection of brain Hematomas and tested it successfully in 305 patients at Baylor College of Medicine. An entrepreneurial team formed a company, InfraScan, Inc., around this technology in Collaboration with Drexel University. Office of Naval Research and later the Marine Corps funded the technology development. Subsequently the Infrascanner handheld brain hematoma detector was developed, winning an Excellence in Design gold award in 2007 and in 2009 the system was featured as a transformational technology in Better World Report. The company also attracted $1.8M in funding from BioAdvance, the Biotechnology Greenhouse of Southeastern Pennsylvania, from Ben Franklin Technology Partners of Southeastern Pennsylvania, and from Philadelphia Industrial Development Corporation.

Severe TBI has become one of the most common battlefield injuries. The newly released Infrascanner Model 2000 was developed based on input from the US Marines. A rugged, compact design was created to support the rigors of military emergency use.

InfraScan, Inc. is in the process of bringing the scanner to market throughout the world. The European CE regulatory approval was obtained in 2008 and US FDA clearance for use in hospitals on adults was obtained in 2013. With support from PPDC a study is currently underway in CHOP to expand the FDA clearance and to show the efficacy and safety of the Infrascanner in children. Infrascanner provides the unique portable solution for helping clinicians detect and treat emerging hematomas in time to limit permanent brain damage.

## Life Flow©

410 Medical, Inc., of Durham, NC, is developing the Life Flow© device, a hand-powered infuser used to quickly deliver fluids to critically ill patients. A newer version of the Life Flow© is in development for rapid delivery of blood products in patients with severe hemorrhage. The grant will enable the company to conduct research supporting a second FDA application for blood delivery, which will have important applications for the care of injured children.

## noddle™

Voxello, LLC, of Coralville, Iowa, is developing the to address the communication barriers faced by pediatric patients. The noddle™ uses patented technology to detect the smallest intentional gesture and allow patients to access the nurse call system and control a speech generating device. Thus, children who may only be able to produce a tongue click, head nod or other small gesture would be able to summon help and effectively communicate with their caregivers. PPDC funding will be used to support further development and clinical trials of the Voxello technology with hospitalized children, as well as children with developmental disabilities whose barriers to communication may impact their care and medical outcomes.

## Precynge

Assure Technologies, LLC, of Chapel Hill, NC, will receive support for the Precynge device to provide consistently accurate small volume medication measurements critical to pediatric care. Neonatal and early pediatric patients are particularly vulnerable to dosing errors; exposure to potential adverse drug events occurs three times more frequently in pediatric than in adult inpatients. While the majority of IV doses are made in the pharmacy, nurses frequently prepare IV push medications at the bedside for small volumes in neonatal and pediatric patients, especially for high alert medications like narcotics and insulin. The Precynge will provide nurses the same safety

## SOLUtion Medical: TwistJect™

SOLUtion Medical, LLC, of Philadelphia, is developing the TwistJect™, a device that enables caregivers to manage children during an adrenal crisis. Adrenal crisis is a life-threatening condition resulting from insufficient levels of the hormone cortisol. Children and adolescents experience some of the most severe morbidities of all patients who experience adrenal crisis due to the difficulties in managing adrenal insufficiency in younger populations and the difficulties in providing rescue injections. The TwistJect™ is a one-step delivery device that reconstitutes hydrocortisone sodium succinate and removes all entrapped air in one user step.

## ThreadRiteIV Catheter

The University of Pittsburgh is developing the ThreadRiteIV Catheter to improve the placement of peripheral intravenous catheters. These catheters are widely used for drug delivery in healthcare, but often require multiple attempts for insertion. ThreadRite detects blood vessels through a sophisticated system that measures differences in electrical resistance, and instantaneously alerts the operator of vessel entry via a light, audible, and vibratory signal. This eliminates the dependence on blood return for confirmation of insertion.

## ThoraciCair

William J Weiss, PhD, of Penn State College of Medicine is leading efforts to develop the ThoraciCair to reduce the need for invasive and other labor-intensive techniques to treat respiratory distress syndrome in children. The ThoraciCair technology consists of a wearable device to move the chest wall and ventilate the patient by externally applying negative pressure. The ThoraciCair method creates a unique and novel platform for noninvasive ventilation strategies.

# Diagnostic

## Point-of-Care Rapid Platelet Function Testing

FloBio, LLC, of Philadelphia, is developing a novel, point-of-care microfluidic chip and reader for rapid platelet function testing. Using minimal amounts of blood, the device will monitor anticoagulation pharmacology used in newborns undergoing corrective heart surgery or on life-sustaining circulatory or pulmonary support. The device will help to control thromboembolic events in infants and children suffering from congenital heart defects.

# ENT

## OtoNexus Medical Technologies: Otitis Media Detection Device


*Changing the way clinicians diagnose middle ear infections to decrease the amount of unnecessary antibiotic prescriptions and reduce healthcare costs.*

OtoNexus Medical Technologies, Inc. is commercializing a Doppler ultrasound medical device to rapidly and accurately diagnose middle ear infections, called Otitis Media (OM), in children and adults. 17.6 Million patient visits each year are coded to OM at a cost of more than $5 Billion/year, yet clinical studies show a 50 percent error rate in diagnosis. Otitis Media is the No. 1 reason for antibiotic prescriptions in children, as well as the No. 1 cause for surgery in children. Current diagnostic methods are decades old and cannot distinguish the type of infection behind the eardrum.

With funding in part from the PPDC, OtoNexus is developing a handheld device to quickly and accurately detect both the presence and type of fluid behind the eardrum in one second or less. This would provide, for the first time, objective, definitive diagnostic data which could lead to increased accuracy, earlier and better treatment, reduced antibiotic use, and reduced healthcare costs.

## Sinusitis Diagnostic Device


ENTvantage Diagnostics, of Austin, Texas, is developing a device to improve the accuracy of diagnosis of sinusitis (sinus infections). Although bacteria cause sinusitis only about 10 percent of the time, physicians commonly prescribe antibiotics, which are ineffective against non-bacterial sinusitis. Because diagnostic tools are not currently available for a proper diagnosis, clinicians have to rely on imprecise diagnostic algorithms based solely on the patient symptoms. ENTvantage aims to create a point-of-care assay device to provide rapid results that are simple to interpret with ease of use and minimal staff training. In a manner similar to that of rapid influenza A and B tests commonly used in primary care clinics, this new device is envisioned to reduce unnecessary antibiotic usage.

# Gastroenterology

## Pediatric PUMA-G

CoapTech, Inc., of Baltimore, MD, is developing the Pediatric PUMA-G, which is expected to provide a safer way to place feeding tubes for children. Gastrostomy tubes (G-tubes) provide a path for nutrition delivery directly into the stomach, bypassing the mouth and esophagus, for patients who have difficulty swallowing. Traditional technology used in these procedures cannot “see through” tissue, and G-tube malposition causes acute harm and other complications. The alternative fluoroscopic approach requires the use of ionizing radiation, which presents serious long-term risk of cancer. The use of ultrasound imaging is expected to make the Pediatric PUMA-G safer, timelier, and less costly than conventional G-tube placement methods used in children.

# General Hospital

## SafeBoard

SafeBoard, LLC, of Youngsville, LA, is creating SafeBoard, a patented extremity stabilization device designed to assist in the placement of ultrasound-guided PICC lines and IV catheters in neonates and children. Historically, repeated unsuccessful needle sticks and use of general anesthesia and sedation can be traumatic and dangerous to both the patients and their caregivers. SafeBoard aims to minimize the amount of time it takes to successfully insert a PICC/IV in a child, minimize needed personnel, reduce the use of medications, minimize discomfort, and decrease the rates of catheter-related complications.

# Neonatology

## Little Sparrows Technologies: Bili-Hut

About 8 percent of all newborns have severe neonatal jaundice. It’s one of the most common conditions affecting infants, and the incidence jumps to 80 percent for preterm newborns in the first week of their lives. An estimated 6 million newborns worldwide do not receive treatment for severe jaundice because they lack access to effective phototherapy devices. Annually, jaundice causes an estimated 30% of newborn deaths in underdeveloped areas, and many survivors suffer lifelong neurological disability as a result of the disease.

The Bili-Hut is a portable, high-intensity phototherapy device for treating newborns with neonatal jaundice. Little Sparrows offers a three-pound, collapsible enclosure that uses low-energy-requiring LED lights, enabling use with either line power or alternative sources such as a 12-volt battery. With funding from the PPDC combined with other funding sources, including the Saving Lives at Birth Grant Competition, Little Sparrows is refining the device and is seeking FDA approval.

### Neoneur

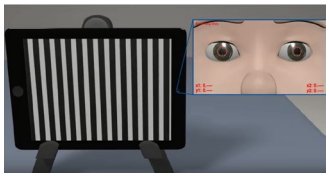
Neoneur, LLC, of Pennington, NJ is creating the Neoneur, a telehealth-enabled device that provides objective measurements of infant oral feeding capability and developmental status. An infant's feeding skills consist of patterns driven by the brain to enable adequate nutrient consumption and respiratory protection at the same time without hindering growth. All infants must have feeding skills to thrive, but currently clinical observation is the only means to assess them. The Neoneur will enable the ability to monitor feeding and skill development for at-risk infants both in the hospital and through telemedicine at home to enable earlier discharge, decrease readmissions, and aid in early identification of developmental issues.

### TheraB Medical: SnugLit

TheraB Medical, a pediatric startup out of Michigan, is developing SnugLit, a wearable infant swaddle that treats neonatal jaundice with phototherapy. Neonatal jaundice affects 2.4 million infants in the United States and as many as 20 million globally. The most common treatment involves light therapy systems, which require constant monitoring by nursing staff and cause prolonged separation of mother and child. With SnugLit, babies no longer have to be separated from their parents during phototherapy, but instead can receive complete treatment in the arms of their caregivers.

## Ophthalmic

### Digital Platform to Identify Vision Acuity Impairment



Vifant, LLC, of Philadelphia, is developing a digital platform that identifies vision acuity impairment in preverbal children. Waiting to treat visual impairment until children are old enough to verbally communicate may result in reduced early learning development or blindness. This device could enable physicians and parents to be proactive about their child's vision health without the need for verbal communication with the child.

## Orthopedics

### DE-AFO

A compact and comfortable smart ankle orthosis for children with cerebral palsy (CP), to help them walk more easily and for longer distances.

### Dynamic Hip Stabilization Tether

A device to dynamically stabilize the hip in patients with dysplasia who must undergo an open surgical procedure, where, post-operatively, natural movement promoting healing and re-development is allowed.

## MyoPro©

Myomo, Inc., is currently developing a child-sized version of the company's MyoPro© powered orthotic device to assist with motion and function in children with a range of neuromuscular disorders, potentially including cerebral palsy, brachial plexus injuries, spinal muscular atrophy (SMA), traumatic brain or spinal cord injuries, and other diagnoses. Myomo empowers individuals with a neuromuscular condition who have lost movement in a hand and arm to perform activities of everyday life.

## RasLabs, LLC: Polymer-based Liner for Prosthetic Sockets

*Developing an adjustable prosthetic liner to revolutionize the fit and function of prosthetics.*

RasLabs believes in developing, fabricating, and distributing customized products that have the power to heal and save lives. They produce Synthetic Muscle, electroactive polymer (EAP) based materials and actuators that contract and expand at low voltages. This EAP material could improve the interface between a child and his/her prosthetic limb. Without using gears or motors, the material contracts or expands like muscle, in response to low-voltage electricity. Using this biomimetic material to line the socket of a pediatri-sized artificial leg or other limb could provide a more snug fit of the prosthetic device during normal daily use, and improve a child's experience using it. With funding in part from the PPDC, as well as support of the Synthetic Muscle Project from the US Department of Energy, MassChallenge, CASIS, and the US Department of Defense, the prosthetic liner device is in early development.

Most polymers, once cooled, do not move or change shape. Ras Labs Synthetic Muscle™ are electroactive polymers (EAPs) that undergo controlled motion and shape-morphing with electric input. Synthetic Muscle™ incorporated into self-adjusting EAP based pads for prosthetic liners and sockets will allow amputees and children born without fully formed limbs to go about their active lives without needing to adjust the fitting of their prosthetic device(s) throughout the day. The purpose of this development is to resolve major issues facing amputees, such as prosthetic slippage and the inconvenience of removing or adding prosthetic sockets to maintain fit. For pediatric patients, this is of paramount importance because of the brain mapping that occurs with full function during childhood, and for all children to comfortably and easily enjoy the full freedom of motion.

Ras Labs Synthetic Muscle™, comprised of electroactive polymers (EAPs), expand and contract at low voltages, and can create a dynamic prosthetic liner or socket to maintain proper fit for the amputee throughout the day (prototype stage). In addition, these polymers offer impact resistance and pressure sensing, and have the potential to combine these properties in one integrated solution. The pressure sensing property of these polymers potentially allows Ras Labs' prosthetic pads to adjust to the shape of the patient's residuum without manual adjustment.

When mechanical pressure is applied to Ras Labs' electroactive polymers, the change in resistance can be recorded. This allows Ras Labs to use these EAPs as resistive sensors in addition to their contractile properties for multiple applications. As resistive sensors, these electroactive polymers have the potential to advance prosthetic technologies by creating self-adjustable dynamic prosthetic liners and sockets. Multiple pads can be placed in the prosthetic liner or socket as different sensor zones to detect changes in pressure. This detection can lead to an automatic adjustment of the prosthetic pads by contracting or expanding to maintain proper fit and can also give feedback to patient on the use of the device in static and dynamic states. Feedback from the device can help the patient and prosthetist adjust rehabilitation practices to improve the patient's locomotion and balance, and automatic adjustment of dynamic prosthetic pads would enhance proper fit and comfort of prosthetic devices for the amputee patient. The sensing the sensing properties of Ras Labs' Synthetic Muscle™ through compression and impact. Based on preliminary results, Ras Labs Synthetic Muscle™ can register pressure at different magnitudes by a change in resistance. In the compression sensing tests, the polymer senses that a large amount of force is being applied over a set period of time. For the impact sensing tests, the polymer registers the blunt impact by showing a spiked decrease in resistance followed by an exponential climb to a stable state.

Ras Labs is collaborating with United Prosthetics, Inc., which is taking care of the majority of the Boston Marathon victims, including pediatric patients, is assisting with prototyping, and has offered to help with human clinical trials. The addition of the sensing properties of Ras Labs Synthetic Muscle™ to its shape-morphing actuation properties has the potential to greatly advance prosthetic devices. Due to a combination of activity and dehydration, the amputee's residuum can undergo volume changes throughout the day causing improper fit and discomfort. These changes can eventually lead to skin and tissue degradation if the patient does not manually adjust his or her prosthetic device to maintain a proper fit.  Dynamic fit is crucial to maintaining a proper fit of the prosthetic device, and the goal of Ras Labs is to increase the patient's level of comfort and proper fit by incorporating Ras Labs EAPs polymers into prosthetic liners and sockets. A combination of contractile actuation, impact attenuation, and pressure sensing from Ras Labs Synthetic Muscle™ to create dynamic self-adjusting prosthetic pads and liners can enable amputees and children born without fully formed limbs to go about their active days without constant manual adjustment of their devices.

# Other

## Bone Access System

A bone access system proposed by Actuated Medical, of Bellefonte, Pa., aims to reduce patient discomfort, improve the success rate for first-attempt samples, reduce clinician fatigue, and shorten procedure times for bone biopsy and bone marrow aspiration procedures. Physicians performing these procedures on children currently face multiple challenges. This patient population requires deep sedation or anesthesia to tolerate bone access procedures. Children also have small, curved bones, which increase the risk of needle slippage and damage to surrounding tissue. The lack of CT or other image guidance during pediatric bone access increases the difficulty of maintaining the desired needle trajectory, which results in failed access and repeated insertions, as well as increased post-operative pain and risk of infection. This new device under development will reduce insertion force and needle slippage, allowing for faster and more reliable bone penetration.

### DOVE Device

Jacob Brenner, MD, PhD of the University of Pennsylvania is developing the DOVE device. Adolescents remain extremely vulnerable to the adverse effects of opioid use and overdose. During an overdose, individuals only have a matter of minutes to receive life-saving measures, including naloxone, an opioid overdose antidote. There is an urgent need for novel solutions that passively monitor respiratory drive and trigger automated responses to reverse an overdose when detected. The DOVE device is a wearable biosensor that senses and responds to critically low respiratory rate by automatically injecting naloxone and/or alerting first responders, a trusted contact, or a naloxone-equipped bystander.

### Tychermont Products: OrVac™

Tychermont Products, LLC, of Philadelphia, will receive support for the OrVac™, a portable oral aspirator to assist patients with pediatric dysphagia and other swallowing disorders. To date, these patients do not have a way to self-suction oral waste without assistance. The OrVac™ returns control and independence to the patient by providing a portable, non-invasive, and user-controlled device to evacuate oral liquids.

## Plastic Surgery

### InfantEar

A device designed by Talex Medical, LLC, of Philadelphia, aims to correct ear deformities in infants. The InfantEar System uses silicon conformers placed along the ear to reshape and correct the deformity over time. It would avoid the need for costly, labor-intensive and painful surgical procedures.

### Device for Distraction Osteogenesis

Ostiio LLC of Philadelphia is developing a novel device for distraction osteogenesis (DO) within the cranio-maxillofacial skeleton. For many years, DO has been used to correct congenital skeletal defects by promoting the growth of new bone. Unlike current DO methods, the Ostiio device would be fully internalized and remote-controlled, thereby decreasing the risk of infection, and improving patient and surgeon satisfaction.

## Pulmonary

### Neo™


Dymedso, Inc. of Montreal, Canada, is developing the Neo™, a non-percussive acoustic airway clearance device specifically designed for infants and young children with lung diseases such as cystic fibrosis. The Neo™ uses sound waves for chest physiotherapy, which is more appropriate for toddlers and infants than clapping or percussive treatment.

# Urological

## Bedwetting Mitigation Device

Global Continence, Inc. of Atlanta, GA is creating a bedwetting mitigation device. Nocturnal enuresis, or bedwetting, affects 200 million children globally and can impact a child's self-esteem and behavior. The device will sense moisture and immediately activate a painless neuromodulation system to prevent bedwetting and alert the child and/or parents. The device, the first of its kind, can be used in children of all ages and is expected to prevent the need for long-term treatment of bedwetting.

## Device to Detect Vesicoureteral Reflux

Kite Medical of Galway, Ireland, is developing a device to detect vesicoureteral reflux (VUR) in children. VUR is a condition that can potentially lead to kidney damage. Current diagnostic procedures require catheterization and radiation exposure. This device could offer a noninvasive, child-friendly alternative.

## Home Device to Track Urinary Flow Rate

Jason Van Batavia, MD, of Children's Hospital of Philadelphia is creating a home device for pediatric patients and their families to keep track of urinary flow rates and patterns. Real-time biofeedback is invaluable for the treatment of dysfunctional voiding. Data will be sent wirelessly to a smart phone or tablet and will be visualized in a mobile app. The patient's physician will also be able to remotely monitor the progress of the patient's treatment.