TRUE CONCEPTS
— MEDICAL TECHNOLOGIES —
DESIGNING A SAFER TOMORROW

The Committee on Small Business

Upskilling the Medical Workforce

Opportunities in Health Innovation

November 13th, 2019

Business Summary

True Concepts Medical Technologies (TCMT) is a medical device innovation engine that delivers novel and manufacturable solutions based in clinical experience. Our devices are designed by clinicians for clinicians with a focus on areas that have significant morbidity and mortality such as sepsis and sudden cardiac arrest. Our goal is to save lives and reduce healthcare costs of care with intelligently designed solutions that eliminate the opportunity for human error.

TCMT was formed in early 2017 by Michael J Hopkins, a registered nurse with 24 years of experience in critical care, emergency medicine, and trauma. Coupled with 25 plus years of design experience he has to developed a series of next generation dual-syringe technologies which have the potential to save the US healthcare system upwards of a billion dollars, while improving patient outcomes. Partnering with Dr. Arash Babaoff in June 16th, 2017, we filed two US patents and two PCT (Patent Cooperation Treaty) patent applications for which we received notification of clean reviews, placing us on the Patent Prosecution Highway. Within a year of filing we received two US patents. We currently hold three US utility patents and have several continuation patents in process. We have filed internationally in the EU, Canada, Mexico, India, Israel, Japan, and Hong Kong.

As a small business medical device startup in the state of Ohio raising capital has its unique challenges. We have relied on friends, family, and physicians to secure our initial raise, with 70% of our investment coming from physicians who see the immediate need for these technologies. We've been frugal and have accomplished a great deal. Relationships with other small local businesses have been the key to our progress. Pixel & Timber, an industrial design firm in Cincinnati, Ohio was able to streamline our initial designs and create beautiful CAD models for us. 3D-Technical solutions, located in Dayton, Ohio then took those models and created our alpha prototypes. Minco Tool & Mold, a family owned business in Dayton, Ohio has refined our initial design and is developing molds to prepare us for manufacturing. Regulatory Mark, a FDA regulatory consulting firm in Cincinnati, Ohio prepared a robust regulatory report which has prepared us for FDA 510k submission. The relationship with The Entrepreneur Center (TEC) in Dayton, Ohio that has led us here today to testify before The Committee On Small Business. In August 2018 we became a client of the entrepreneur services program (ESP) which has provided us with valuable resources and connections. In May 2019 we were invited by the QSEN Institute at Case Western Reserve University to participate in "Evolving Ideas in Healthcare" highlighting new medical device technologies, where 150 nursing leaders from acoss the nation evaluated and our dual syringe technologies the "Most Promising Innovation for Quality & Safety", further validatiing the need to bring these technologies to the bedside. Many of the participants were asking how they go about purchasing our technologies for their institutions.

Sepsis is the body's overwhelming and life-threatening response to infection that can lead to tissue damage, organ failure, and death. Populations that are at greatest risk include the most vulnerable: children, the elderly, those with chronic illnesses, and those with a weakened or impaired immune system. With 30 million cases of sepsis recognized worldwide, every three seconds someone dies of sepsis. Of the 8 million annual deaths internationally, 3 million are pediatric deaths, making it the leading cause of pediatric deaths worldwide. One in three patients who dies hospital, dies of sepsis, making it the leading cause of death in US hospitals. Sepsis kills more Americans than breast cancer, lung cancer, and opioid overdoses combined. At $27 billion annually it is the leading cost of hospitalization.

However, 80% of sepsis deaths may be prevented with rapid diagnosis and appropriate treatment. Rapid diagnosis starts with the proper collection of blood cultures, which have long been the gold standard in confirming infectious etiology, identifying the etiologic agent, and guiding antimicrobial therapy.

Current blood culture collection techniques are highly flawed, leading to sepsis misdiagnosis or delayed diagnosis. In the US, there are 45 million blood cultures drawn annually of which 8% are positive. Up to 40% of those positives are considered false-positives, making an accurate and timely diagnosis of sepsis very difficult.

Annually, the US health care system spends billions of dollars treating 1.5 million false-positive blood cultures (FPBC's) as a result of contamination that occurs during the collection and processing of blood cultures. With 40.7% of the US population covered by Medicaid (19.4%), Medicare (16.7%), and Veterans Affairs (4.6%), the financial impact to the US government is $3 billion annually and accounts for upwards of a million unnecessary inpatient hospital days. The three main sources of contamination include skin preparation, subsurface bacteria, and human factors. Up to 20% of bacteria remain after preparing the skin with Chlorhexidine prior to venipuncture. More significantly there are subsurface bacteria that colonize beneath the skin in the sebaceous glands and the subsurface portions of the hair follicles where antiseptics are not efficasious. Human factors also play a role in contamination, occurring during the assembly of supplies/devices, the preparation of the skin, palpation after the skin has been prepped, and waste tube handling.

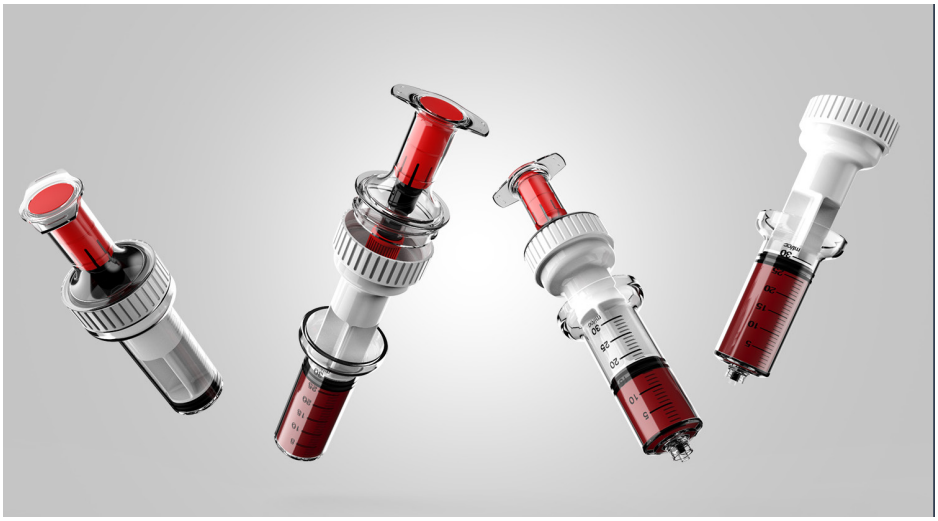
Recent research by Patton & Schmidt has shown that isolating the initial 1.5- 2 ml of blood during the peripheral collection of blood cultures reduces contamination by up to 92%, dramatically reducing false-positive blood culture rates[1]

Patients with false-positive blood culture are admitted to the hospital an additonal number of days, subjected to unnecessary laboratory procedures and placed on broad spectrum antibiotics, further putting them at risk for dangerous secondary C-difficile infection. Excessive use of antibiotics is the main cause for the spread of antibiotic-resistant bacteria. Decreasing unecessary antibiotic use is essential in combating increasing antibiotic-resistant micro-organisms. Overall, 1.5 million FPBC's result in millions of uncessary additional hospital days signicantly impacting healthcare expenditures and the US economy.

6. Patton RG and Schmitt T. Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique. Journal of Clinical Microbiology, December 2010, p. 4501-4503 Vol. 48, No. 12

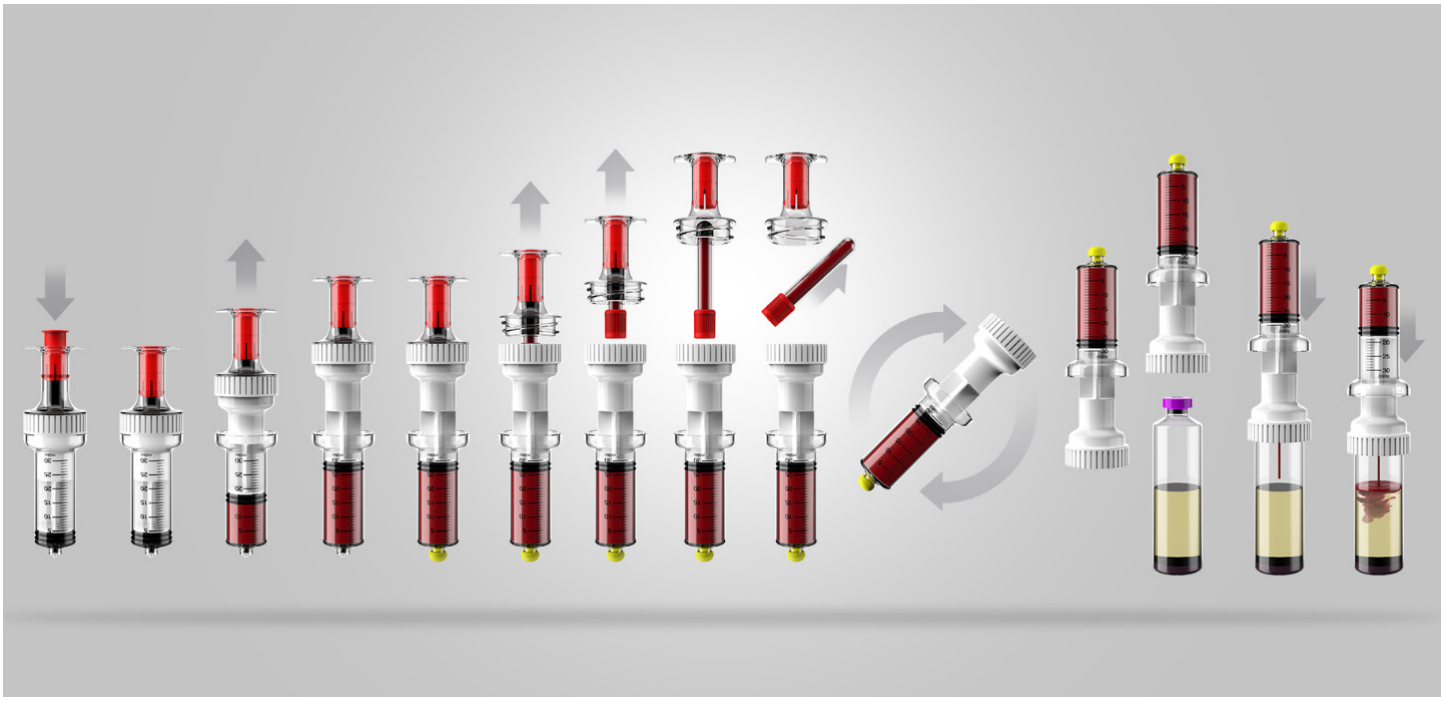
Customer Solution: DIVERSYN

DIVERSYN isolates the initial 3 ml of blood from the rest of the sample within one syringe, ensuring contaminate-free blood culture collection. A novel plunger design with an integrated transfer device allows the user to transfer collected blood from the syringe to blood culture bottles via a closed system, minimizing the opportunity for contamination, and all but eliminating false-positive blood cultures. The initial 3 ml of blood is sent to the clinical laboratory for other blood tests and a Procalcitonin level, whose concentration has been found to be elevated in sepsis. Owing its specificity to bacterial infections, Procalcitonin (PCT) has been proposed as a pertinent marker in the rapid diagnosis of bacterial infection, especially for use in hospital emergency departments and intensive care units. The use of PCT measurements to efficiently treat patients with antibiotics has been shown to decrease patient hospital stay. With proper training and without change to existing workflows, DIVERSYN will significantlly improve timely, accurate sepsis diagnosis.



DIVERSYN

- US 10,022,079
- All 20 Claims
- Filed In EU, Canada, Mexico, India, Israel, Japan, Hong Kong



US010022079B2

(12) **United States Patent**
Hopkins

(10) **Patent No.: US 10,022,079 B2**
(45) **Date of Patent: Jul. 17, 2018**

(54) **SYRINGE SYSTEMS AND METHODS FOR BODILY FLUID COLLECTION AND SAMPLING**

(71) Applicant: **Michael Hopkins**, Springboro, OH (US)

(72) Inventor: **Michael Hopkins**, Springboro, OH (US)

(73) Assignee: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/624,467**

(22) Filed: **Jun. 15, 2017**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 62/350,341, filed on Jun. 15, 2016.

(51) **Int. Cl.**

A61B 5/15	(2006.01)
A61B 5/153	(2006.01)
A61B 5/154	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/150251*** (2013.01); ***A61B 5/15003*** (2013.01); ***A61B 5/153*** (2013.01); ***A61B 5/154*** (2013.01); ***A61B 5/150221*** (2013.01); ***A61B 5/150351*** (2013.01); ***A61B 5/150992*** (2013.01)

(58) **Field of Classification Search**

CPC A61B 5/150251

See application file for complete search history.

(56) **References Cited**

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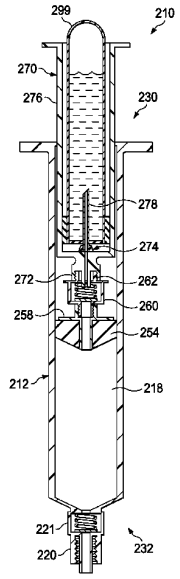
Thomas, Shane; International Search Report and Written Opinion of the International Searching Authority, issued in International Application No. PCT/US2017/037778; dated Sep. 6, 2017; 11 pages.

Primary Examiner — Daniel Cerioni
Assistant Examiner — Yasmeen S Warsi
(74) *Attorney, Agent, or Firm* — Ulmer & Berne LLP

(57) **ABSTRACT**

Embodiments of a syringe-based device for procuring bodily fluid samples can include a housing having a port that can be coupled to a lumen-defining device for receiving bodily fluids, an actuator mechanism retained at least partially within the housing, the actuator mechanism including a pre-sample reservoir, a plunger operably coupled with pre-sample reservoir, a plunger cap, a plunger tube, a valve, a plunger seal, an a selectively attachable collection vial for capturing a bodily fluid sample.

20 Claims, 26 Drawing Sheets



Current delivery of Adenosine and Epinephrine to the central compartment is flawed, inefficient, and ineffective. Three main factors are responsible: failed delivery systems, inadequate flush, and the pharmacologic properties of the medications. We can improve the first two factors to ultimately impact the third.

Adenosine is the medication of choice to treat supraventricular tachycardia (SVT). SVT is defined as an abnormally rapid heart rhythm having an electro-pathologic substrate emerging above the bundle of His (atrioventricular bundle) causing the heart to escalate to rates often higher than 200 beats per minute. If vagal maneuvers are unsuccessful administration of adenosine is necessary. With a half-life of less than ten seconds, adenosine must be administered by rapid IV push followed by a 20 ml normal saline flush. However, 90% of healthcare clinicians fail to administer an adequate volume of normal saline following adenosine administration.

Furthermore, we lack a standardized delivery method for adenosine. Current methods are archaic at best, with many institutions using a three way stopcock method which involves lengthy setup time (5-7 minutes) followed by a delivery system that offers multiple opportunities for failure. Pre-hospital delivery methods include two syringes with needles into one port or administering adenosine through an existing IV line then squeezing the IV fluid bag to push the adenosine to the heart.

These same problems also hold true for epinephrine delivery during sudden cardiac arrest. World-wide there are > 135 million cardiovascular deaths each year and the prevalence of coronary heart disease is increasing. In the United States, >500,000 children and adults experience a cardiac arrest and < 15% survive. Epinephrine is the primary drug given in all causes of cardiac arrest. It is used for its potent vasoconstrictive effects and also for its ability to increase cardiac output.

The American Heart Association recommends a 20 ml normal saline flush following the administration of 1 mg of epinephrine to ensure delivery into the central compartment. During sudden cardiac arrest the heart isn't pumping, high quality CPR only circulates 30% of blood volume and 64% of blood resides in the systemic vasculature. In a average sized adult, administration of epinephrine (1mg in 10 ml) through a peripheral intravenous line followed by a 5 or 10 ml normal saline flush does not result in epinephrine reaching the heart; rather it is rapidly absorbed into the bloodstream before it can have a positive impact on the heart. With its potent vasoconstrictive properties, it becomes even more difficult for subsequent doses to reach the heart.

Customer Solution: S.A.F.E. Syringe Technology

S.A.F.E. Syringe is a dual action syringe prefilled with 1mg of Epinephrine & 20 ml of normal saline flush ensuring a Safer, more Accurate, Faster, and more Effective delivery of Epinephrine. The clinician simply removes the S.A.F.E. syringe loaded with 1 mg of Epinephrine from the packaging, pulls red safety tab, attaches syringe to patients line and administers 1 mg of Epinephrine, followed by 20 ml NS flush in one fluid motion, getting Epi to the heart from the start.

Further applications for this technology include but are not limited to:

- Adenosine 6 mg & 20 ml Normal Saline Flush
- CLEANZE:10 ml Normal Saline Flush & 5 ml of 10 Unit Heparin for the maintenance of Central Venous Catheters
- Rapid Sequence Intubation Medications
- S.A.F.E. Mini, a 10ml dual action syringe prefilled with 5 ml of Normal Saline. Clinicians are able to draw up and administer drug of choice followed by a 5 ml Normal Saline

S.A.F.E.

- US 9,962,489
- US 10,369,285
- 3 Continuations
- Filed in EU, Canada, Mexico, India, Israel, Japan, Hong Kong

US009962489B2

(12) **United States Patent**
Hopkins

(10) **Patent No.: US 9,962,489 B2**
(45) **Date of Patent: May 8, 2018**

(54) **SYRINGE SYSTEMS AND METHODS FOR MULTI-STAGE FLUID DELIVERY**

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(72) Inventor: **Michael Hopkins**, Springboro, OH (US)

(73) Assignee: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days. days.

(21) Appl. No.: **15/624,593**

(22) Filed: **Jun. 15, 2017**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 62/350,341, filed on Jun. 15, 2016.

(51) **Int. Cl.**

A61M 5/19	(2006.01)
A61M 5/315	(2006.01)
A61M 5/32	(2006.01)
A61M 5/178	(2006.01)
A61M 5/31	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/19*** (2013.01); ***A61M 5/31513*** (2013.01); ***A61M 5/31596*** (2013.01); ***A61M 5/32*** (2013.01); *A61M 2005/1787* (2013.01); *A61M 2005/3128* (2013.01); *A61M 2202/04* (2013.01)

(58) **Field of Classification Search**

CPC A61M 5/19; A61M 2005/1787; A61M 5/31596

USPC 604/191

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

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9,155,495	B2	10/2015	Bullington et al.

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Thomas, Shane; International Search Report and Written Opinion of the International Searching Authority, issued in International Application No. PCT/US2017/037789; dated Sep. 6, 2017; 9 pages.

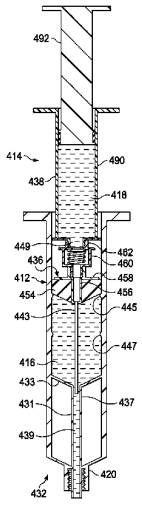
(Continued)

Primary Examiner — Nathan R Price
Assistant Examiner — John Doubrava
(74) *Attorney, Agent, or Firm* — Ulmer & Berne LLP

(57) **ABSTRACT**

Embodiments of a syringe-based device for delivering fluid include a housing, a port, the port being positioned at about the distal end of the housing, a plunger assembly, the plunger assembly including, a plunger seal, a valve, and a cannula, a first fluid reservoir, where the first fluid reservoir retains a first type of fluid, a syringe including a syringe body, a syringe port, a plunger, and a second fluid reservoir, the second fluid retaining a second type of fluid, and where the syringe transitions from a first configuration in which a first portion of the first fluid type is delivered through the port, to a second configuration in which the second type of fluid in the second fluid reservoir is delivered through the port, to a third configuration in which a second portion of the first fluid type is delivered through the port.

20 Claims, 23 Drawing Sheets



Customer Solution: RECON Pen

RECON PEN is a dual-chamber, prefilled, single-dose injection device for the accurate reconstitution and administration of lyophilized medications/vaccines/biologics. Designed with the end user in mind, this device is simple, intuitive, compact, and lightweight yet durable, ensuring accurate administration of vaccines in house-to-house campaigns by low skilled healthcare workers and self-administration of next-generation, long-acting, injectable contraceptives by patients at home or in other non-clinical settings.

Below is an accurate visual representation of RECON PEN's sequence of operation (Fig. 1). Once the RECON PEN is removed from its packaging, the user depresses the red plunger allowing 0.5 ml of sterile water to enter the glass cylinder where the MR/contraceptive lyophilized powder is located. The red plunger snaps into place once fully depressed. The user then agitates the RECON PEN until MR/contraceptive dry powder is fully reconstituted. The red locking tab is then removed, the PEN is inverted and the plunger is advanced to the red line, purging any residual air. By re-inverting the PEN after prepping the proper dose and firmly pressing the PEN onto the injection site, the guard retracts and the needle injects into the patient. The user depresses the plunger fully, administering vaccine/contraceptive. The guard automatically covers the needle after injection and locks into place, disabling the needle, and the PEN is ready for disposal.

With the reconstitution fluid located within the plunger mechanism outside of the syringe (body), liquid is securely separated from the glass cylinder where the lyophilized powder is located, keeping the powder stable in its dry form until reconstitution is initiated. The red safety tab prevents the user from prematurely depressing the main syringe plunger, accidentally expelling the vaccination/contraceptive prior to completing reconstitution. The needle guard not only disables the needle, but also protects against accidental needle stick injuries and transmission of Hepatitis B & C as well as HIV.

Fig. 1

US010369285B2

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Hopkins

(10) **Patent No.: US 10,369,285 B2**
(45) **Date of Patent: Aug. 6, 2019**

(54) **SYRINGE SYSTEMS AND METHODS FOR MULTI-STAGE FLUID DELIVERY**

(71) Applicant: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(72) Inventor: **Michael Hopkins**, Springboro, OH (US)

(73) Assignee: **TRUE CONCEPTS MEDICAL TECHNOLOGIES, LLC**, Springboro, OH (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/948,471**

(22) Filed: **Apr. 9, 2018**

(65) **Prior Publication Data**

US 2018/0221577 A1 Aug. 9, 2018

Related U.S. Application Data

(63) Continuation of application No. 15/624,593, filed on Jun. 15, 2017, now Pat. No. 9,962,489.
(Continued)

(51) **Int. Cl.**
A61M 5/19 (2006.01)
A61B 5/15 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 5/19*** (2013.01); ***A61B 5/15003*** (2013.01); ***A61B 5/153*** (2013.01); ***A61B 5/154*** (2013.01); ***A61B 5/150221*** (2013.01); ***A61B 5/150251*** (2013.01); ***A61B 5/150351*** (2013.01); ***A61B 5/150992*** (2013.01); ***A61M 5/31513*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 5/19; A61M 2005/1787
See application file for complete search history.

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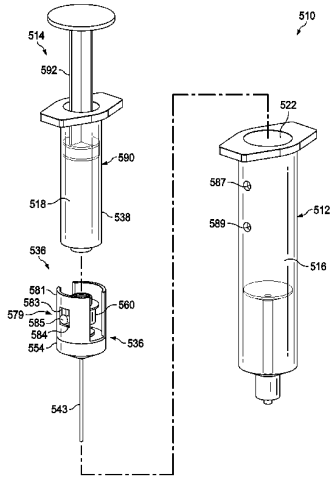
Primary Examiner — Nathan R Price
Assistant Examiner — John A Doubrava
(74) *Attorney, Agent, or Firm* — Ulmer & Berne LLP

(57) **ABSTRACT**

Embodiments of a syringe-based device for delivering fluid include a housing, a port, the port being positioned at about the distal end of the housing, a plunger assembly, the plunger assembly including, a plunger seal, a valve, and a cannula, a first fluid reservoir, where the first fluid reservoir retains a first type of fluid, a syringe including a syringe body, a syringe port, a plunger, and a second fluid reservoir, the second fluid retaining a second type of fluid, and where the syringe transitions from a first configuration in which a first portion of the first fluid type is delivered through the port, to a second configuration in which the second type of fluid in the second fluid reservoir is delivered through the port, to a third configuration in which a second portion of the first fluid type is delivered through the port.

18 Claims, 23 Drawing Sheets



Our Team

Michael J Hopkins RN II, BSN
CEO/Founder
True Concepts Medical Technologies

Michael has 24 years of critical care experience, recently retired from Cincinnati Children's where he worked in emergency medicine and trauma. He also has 25 + years of design experience and currently holds three US patents with multiple US & International patents pending.

Arash Babaoff, MD
CMO/Human Factors
True Concepts Medical Technologies

Dr. Babaoff has worked in the pediatric emergency setting for over 21 years and as an adolescent medicine specialist for nearly four years at Cincinnati Children's Hospital in. He has volunteered in over 60 international missions on five continents with various organizations. He has been instrumental in raising capital and the growth of True Concepts Medical Technologies.

Timothy J Hopkins, R.Ph, MBA.
Advisor/Business Development
True Concepts Medical Technologies

In his 26 years of progressive experience within pharmacy industry, Tim Hopkins played critical roles at PillPack, Inc., Omnicare, Inc. and WellPoint, Inc. In his most recent position as President and CEO for Resource Global Health, his focus is providing consulting services in the healthcare space.

Scientific Advisory Board

Joe Thomas, R. PH
Intellectual Property Expert
Chair of Ulmer & Berne's Life Sciences Group

Mr. Thomas's unique background as a licensed pharmacist, a member of the patent bar, an author of peer-reviewed scientific literature, and clinical researcher gives him a deep understanding of the science behind his clients' work.

Mary Beth Privitera, PhD
Human Factors Expert

Dr. Privitera holds an appointment as Associate Professor at the University of Cincinnati, working collaboratively among the Colleges of Medicine, Engineering and Design. She is the Director of the Medical Device Innovation and Entrepreneurship Program at the University of Cincinnati.

Sean Barnett, MD
Chief of Surgery Dayton Children's

Dr. Barnett is an associate professor at the Boonshoft School of Medicine, Chief of the Division of Pediatric Surgery, and the Chairman of the Department of Surgery at Dayton Children's Hospital. Coupled with his devotion to the surgical treatment of children, he has a keen interest in medical device design with experience in all aspects fo develpment.

Frank Pokrop, BS
FDA Regulatory Expert

Mr. Pokrop has over 20 years of experience in regulatory affairs and manufacturing experience with parenteral drugs and medical devices. Formally designated liaison between industry, FDA, trade and standards associations and patient safety groups, he is experienced with domestic submissions and international product registrations.

Thank You

Michael J Hopkins
CEO/Founder
True Concepts Medical Technologies

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