BioWorld MedTech

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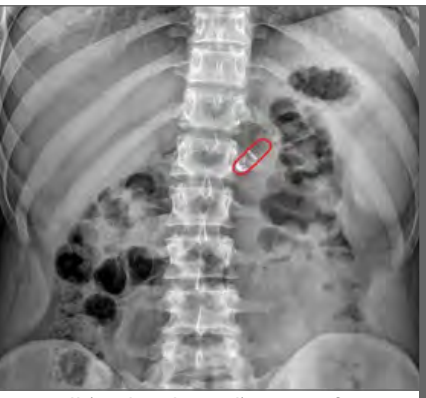

Ranipill (outlined in red) moving from stomach to intestines; Rani Therapeutics

Rani says robotic, auto-injection pill shows safety in first human trial

By Stacy Lawrence, Staff Writer

Startup Rani Therapeutics LLC has gotten positive safety results in a first-in-human trial of its pill that's designed to enable painless injections of biologic drugs into the small intestine. Later this year, the San Jose, Calif.-based company plans to start a clinical trial with the robotic pill that includes a drug-filled resorbable needle – the initial safety test was without any drug.

Known as Ranipill, the capsule is triggered when an enteric coating dissolves to trigger the inflation

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With revised registration guidelines, China moves closer to harmonization

By Elise Mak, Staff Writer

HONG KONG – This week, China reported a plan to revise the registration guidelines for medical devices to facilitate product registration for med-tech developers and better align regulation with international norms.

"The registration guidelines contain the basic technical requirements for medical devices and in vitro diagnostics (IVDs) manufacturers. Although

See China, page 4

Rare Disease Day

Centogene, Sarepta to collaborate on identifying DMD patients in MENA region

By Liz Hollis, Staff Writer

Centogene AG is teaming up with Sarepta Therapeutics Inc., of Cambridge, Mass., to identify patients with Duchenne muscular dystrophy (DMD) in the Middle East and North Africa region. As part of the collaboration, Rostock, Germany-based Centogene will perform complete molecular diagnostic testing, as well as provide diagnostic

Centogene, page 5

FDA races full throttle ahead following historic shutdown

By Mari Serebrov, Regulatory Editor

The five-week government shutdown that ended earlier this month was "the most difficult operational challenge we have faced in modern times," U.S. FDA Commissioner Scott Gottlieb told a House Appropriations subcommittee Wednesday.

Despite that challenge, "I feel confident that things are back on track. I don't think we're going to see significant impacts on our work going

See FDA, page 6

ACC tackles access issues for imaging and catheterization

By Mark McCarty, Regulatory Editor

The American College of Cardiology (ACC) has unveiled an initiative that would increase access to the latest medical technology for patients, a move backed by prospective registry data and partnerships with device makers and payers. The plan includes measures to help keep costs in check by means of price reductions for therapies and expanded patient follow-up, all in an effort

See ACC, page 7

Patent Highlights

BioWorld MedTech presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

BioWorld MedTech's Diagnostics Extra

Regulatory Editor Mark McCarty on one of med-tech's key sectors

Read this week's edition

Appointments and advancements

Biotelemetry Inc., of Malvern, Pa., has elected two new members to its board, Laura Dietch and Tiffany Olson. Dietch is the president and CEO of Biotrace Medical Inc., a company she co-founded. Olson is the president of nuclear and precision health solutions at Cardinal Health.

Pavmed Inc., of New York, said its Lucid Diagnostics Inc. subsidiary has appointed David Wurtman as Lucid's chief medical officer. Lucid has also appointed a medical advisory board to include Nicholas Shaheen as board chairman and Prateek Sharma as one of four additional board members. Wurtman most recently served as president, CEO and co-founder of Lyric Pharmaceuticals.

Sensus Healthcare Inc., of Boca Raton, Fla., said it has appointed Ziv Karni as chief scientific officer, a position Karni will take immediately. Karni was founder and CEO of Alma Lasers.

Zynex Inc., of Englewood, Colo., said Christopher Brown will take the role of VP for sales and marketing. Brown previously held vice presidencies with Safeop Surgical and Steris Corp.

Financings

Berkeley, Calif.-based **Inkspace Imaging Inc.**, a medical device startup based out of the University of California at Berkeley has closed its first round of private funding, securing funds for continued growth of the company. Details of the funding were not disclosed. Inkspace, founded in 2016, is developing new MRI coil technology that is designed to be more comfortable to patients and provides reliability and great performance during exams.

Neovasc Inc., of Vancouver, British Columbia, closed its previously reported underwritten public offering of 11,111,111 common shares at a price to the public of US$0.45 per common share, for aggregate gross proceeds of about US$5 million, before deducting the underwriting commission and offering expenses payable by the company. H.C. Wainwright & Co. acted as sole book-running manager for the offering. After deducting the underwriting discounts, commissions and other offering expenses, Neovasc received net proceeds of about US$4.050 million.

Rehovot, Israel-based **Todos Medical Ltd.** raised $1,350,500 from private investors. With financing secured, Todos has closed the joint venture transaction with **Amarantus Bioscience Holdings Inc.**, whereby Todos Medical issued to Amarantus 19.99 percent of the outstanding ordinary shares of Todos, in exchange for 19.99 percent of Amarantus's wholly owned subsidiary Breakthrough Diagnostics Inc. In addition, as part of the transaction, Amarantus has assigned to Breakthrough all of Amarantus's rights to the Lympro test, an immune-based neurodiagnostic blood test for detection of Alzheimer's disease, and other diagnostic assets. Under the terms of the JV agreement, Todos has an exclusive option to acquire the remaining 80.01 percent of Breakthrough in exchange for an additional 30.01 percent of Todos Medical's shares.

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Our newsroom

Lynn Yoffee (News Director), Holland Johnson (Executive Editor), Mark McCarty (Regulatory Editor), Andrea Applegate (Production Editor)

Staff Writers: Liz Hollis, Bernard Banga, David Godkin, Stacy Lawrence, Nuala Moran, Alfred Romann, Tamra Sami

Business office

John Borgman, Director of Commercial Competitive Intelligence, Donald Johnston, Senior Marketing Communication Director, Life Sciences

Contact us

newsdesk@bioworldmedtech.com

John Borgman, +1-831-462-2510 | Donald Johnston, +1-678-641-0970 | Lynn Yoffee, +1-434-964-4011 | Holland Johnson, +1-470-252-8448 | Andrea Applegate, +1-470-236-3994 | Liz Hollis, +1-571-287-0146 | Mark McCarty, +1-703-966-3694

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Rani

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of a balloon that pushes a dissolvable microneedle into the intestinal wall. That results in a painless injection, since there are no sharp pain receptors in the intestine. The pill can deliver the equivalent of up to 3 milligrams of drug, which is enough to enable its use with subcutaneously injected biologic drugs such as insulin and the inflammatory disease treatment Humira (adalimumab).

Safety first

"The study was designed to test for safety and tolerability. That was the primary endpoint because no one has ever, so far, delivered a robotic capsule or pill that does this mechanical action inside the gut ever in humans," explained Rani chairman and CEO Mir Imran to *BioWorld MedTech*.

"So, this was the first human study of such a platform and there's no precedent for it. We were primarily focused on safety, so we decided not to put any drug in this first human study. Because we can track a capsule by X-ray, we had these subjects take the capsule and the capsules' progress with the stomach and the intestine was tracked by taking X-ray snapshots every 30 minutes."

Imran is a serial med-tech entrepreneur who also runs life science incubator Incube Labs, from which Rani emerged. He had founded more than 20 life sciences companies, including 15 that have gone public or been acquired. He is perhaps most well-known for his contributions to the first U.S. FDA-approved automatic implantable cardioverter defibrillator.

This first study found that the capsule did not cause any adverse events in healthy human subjects. At the size of a fish oil capsule, it was easily swallowed. It also worked with and without food in the stomach, an important quality if it is to be used with insulin that is often injected following meals. The pill was tested both in fasting and post-meal subjects.

The remainder of the pill was safely excreted in one to four days. None of the subjects reported any sensation associated with the pill, including when the balloon was deployed.

Of biologics and biosimilars

The next study, which is slated to start in the second half of this year, will be with off-patent biologic octreotide, which is used to treat a rare growth disorder. It will monitor subjects not only with X-rays every 30 minutes, but also with similarly timed blood-draws to verify uptake.

Imran noted that in animal models, the device has resulted in 10 percent to 15 percent higher blood levels of drug. He expects this is due to the highly vascularized nature of the intestines – and that this could prove a positive feature of the device.

Ranipill has been tested in animal models with 10 biologic drugs, including octreotide, that include antibodies, peptides and proteins. The capsule is expected to work with any biologic, although its 3 mg capacity would have to be enlarged to function for a handful of them.

The regulatory path for the capsule is still a bit unclear, but Imran anticipates that each biologic drug will require separate testing and approval once initial clinical trials have been passed. The Ranipill also seems like a good potential breakthrough device designation candidate, given its novel technology and the evident patient need. Imran said that discussions with the FDA are just getting started, but that this could eventually be on the table.

One issue the company knows it will have to address in the long-term is the safety of routine intestinal injections over a long period of time. Outside the body, routine injections can cause scarring and collapsed blood vessels. But Imran noted that the intestines are an unusually fast-healing tissue, much more so than the skin. He did note that the FDA is likely to find this subject of interest as well.

Rani plans on a dual path forward for biologics, pursuing its own path with off-patent drugs as well as partnering with pharmaceutical companies to adapt their branded biologics for use with this novel drug delivery method.

The company already has partnerships with Novartis and Shire Pharmaceuticals, now part of Takeda, to develop this internal injection technology for use with some of their biologics. Imran said that Rani is already in conversation with four or five additional pharma companies to start testing their biologics in Ranipill. A long-term development contract with a pharma is a clear goal for Rani as it progresses.

Biosimilars have thus far failed to gain much market traction but pairing them with a distinct drug delivery technology such as this capsule could offer a further advantage. Price was supposed to be the differentiator for biosimilars, but that has failed to be as helpful as had been expected. But pairing a lower-priced biosimilar with a novel, more convenient drug delivery system could offer an unprecedented boost to the ailing segment.

Rani has raised a total of $142 million, most recently with a $53 million round in February 2018. Its investors include GV, the investment arm of Google parent Alphabet Inc. After the upcoming trial later in 2019, the company expects to raise another round of financing. Any potential IPO is likely a way off, and Imran expects Rani would need substantial human efficacy data, a clear regulatory path as well as at least one long-term pharma development partnership in-hand to be attractive to public market investors.

"The impact of this technology on the biotech industry if we are successful, could be very profound," summed up Imran on the potential for Ranipill. "It has the potential impact to the landscape and the competitive positioning of different pharma companies who partner with us. The impact on patients will also be significant with patient compliance and comfort." ♦

China

Continued from page 1

not binding, they are highly recommended and similar to the [U.S.] FDA guidance," Grace Fu, CEO of Boston-based regulatory advisory firm Chinamed Device LLC, told *BioWorld MedTech*.

As the plan is laid out, med-tech developers will need to meet the new guidelines to renew registration of product or when applying for new registrations.

"Even if their renewals, which are required by the regulators every five years, have no changes, they still have to prove that the originally approved products can meet the new requirements," said Fu.

"As a result, your originally approved products will still need to go through local type testing to show that you are current with the new guidelines."

Last year, Chinese regulators published 372 final and draft technical guidelines, including guidelines for non-clinical studies, clinical trials, design, manufacturing and registrations. Fu added that this is the first time Chinese regulators have made a plan that only concerns registration guidelines.

The move underlines China's efforts to streamline registration processes for medical devices. The plan includes looking into documentation methods, such as guidelines on submitting supplementary information for priority review and guidelines on digital submission.

The plan also covers technical requirements for 86 medical devices, ranging from active devices, non-active devices to IVD devices.

The active devices included in the plan are endoscopy electrosurgical unit, endoscopy for gastrointestinal tract, X-ray computed tomography system, artificial intelligence (AI)-aided medical devices, noninvasive transcutaneous pacing, implantable and non-implantable magnetic resonance device, dental digital impression instrument, home-use pulse oximeter and so forth.

Meanwhile, the plan puts non-active devices such as bioresorbable polymer drug-eluting coronary stents, balloon dilatation catheters, knee replacements, dura mater patches, intraocular lenses, orthokeratology corneal reshaping lenses, metal intramedullary nails, firm embryo transfer catheters for assisted reproduction, fallopian tube catheters and facial prosthesis under its scope.

Added to the list are also IVD devices, such as hepatitis B virus E antigen and E antibody detection reagents, thalassemia gene detection reagents, dengue virus nucleic acid detection reagents, EB virus nucleic acid detection reagents, rheumatoid factor detection reagents and home-use IVD devices.

"Most of the guidelines that are to be revised according to the plan are published for the first time. For example, 'AI-aided medical device' is a new category," said Fu.

"The Medical Device Classification Catalogue, which came into effect in August last year, includes AI diagnostics for the first time. This means the regulators are looking to classify medical devices first before coming up with registration guidelines," she added.

> *"The registration guidelines contain the basic technical requirements for medical devices and in vitro diagnostics (IVDs) manufacturers. Although not binding, they are highly recommended and similar to the [U.S.] FDA guidance.*
>
> Grace Fu
> CEO, Chinamed Device LLC

Most notably, five 3D-printed devices also appear on the list in the plan. They are 3D-printed spine fusion cages, acetabular cups, spinal implants, bone implants and mandibles. The move follows the publication of a general version of the 3D Printed Medical Device Guideline in February 2018 by China's Center for Medical Device Evaluation.

"The series of 3D-printed medical device guidelines will propel China to be the leader in innovation and market acceptance in orthopedic and dental applications," she said.

Fu said for innovative medical devices, there is no predicate device to compare to. Patient volume is limited and there are no readily available referenced devices.

"As such, Chinese regulators are only asking for 10 to 20 pairs of observatory studies. They can be used in conjunction with history data to conduct the general analysis. A three-month follow up period is the minimum requirement to determine the observatory clinical benefits. It is relying on post market follow up evidence with such a short endpoint and small sample size," she explained.

Fu said the detailed outline helps manufacturers generate clinical data for different clinical indications a lot faster and cheaper.

"With the orthopedic sector growing at some 20 percent annually, those guidelines can certainly put China in the forerunning position in orthopedic and dental 3D printed devices," she added.

Last year, Chinese regulators announced a three-year plan to produce more than 300 industry standards for medical devices, IVDs and quality systems by the end of 2020. ♦

Centogene

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services to physicians treating patients exhibiting symptoms related to DMD.

No financial details related to the deal were disclosed.

"Our collaboration with Sarepta Therapeutics further demonstrates Centogene's commitment to accelerating the development of new orphan drugs by using our knowledge of the global rare disease market – in particular our expertise in the identification of DMD patients," explained Arndt Rolfs, the company's CEO and founder. "Today [Feb. 28], as the world recognizes Rare Disease Day and the tremendous challenges that people living with a rare disease face on a daily basis, we remain dedicated to transforming the science of genetic information into solutions and creating hope for patients with rare diseases and their families."

According to the Muscular Dystrophy Association, symptoms of DMD onset occur in early childhood, and the condition almost entirely affects boys. It is a genetic disorder that affects about 1 in 3,500 to 5,000 newborn boys and causes progressive weakness and muscle wasting. That weakness and wasting is related to a lack of dystrophin, an essential protein that helps keep muscle cells intact. As the children age, muscle weakness becomes increasingly noticeable, resulting in their inability to walk. During adolescence, cardiac and respiratory muscle deterioration lead to life-threatening complications.

Making the diagnosis

"What I think we've realized over the years is that although developing a therapy is extremely important, in many ways the diagnosis of patients and the recognition that a patient actually has a particular rare disorder is still a very limiting step. Because those diseases are rare, physicians don't always think of those conditions when they see a patient," Oved Amitay, chief business officer at Centogene, told *BioWorld MedTech*. There is a gap between the availability of a therapy and the diagnosis of a condition so a patient can benefit.

He noted that this new collaboration will aim to help in a diagnosis of the condition in certain patients. "The Sarepta treatment is extremely precise in the sense that it works only for a subset of patients that have a particular genetic mutation," he added. "It's not only important to have the patients diagnosed with the correct diagnosis of DMD, the genetic information is extremely important to make sure that they can benefit from the right treatment."

Sarepta gained the FDA's nod for Exondys 51 (eteplirsen) to treat DMD. The decision to grant accelerated approval, made by Janet Woodcock, director of the agency's Center for Drug Evaluation and Research, came in spite of a thumbs-down from the agency's Peripheral and Central Nervous System Drugs Advisory Committee. (See *BioWorld MedTech*, Feb. 13, 2017.) The injection is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping.

Amitay also noted that the agreement focuses on a part of the world in which the infrastructure for diagnosis is not as developed as in other areas. "Centogene as a company has been active in that part of the world since its inception . . . so we have a lot of experience working in that region and we have our own network of physicians that we have developed over the years."

When asked if the collaboration could be extended, he noted that is very possible. "Both parties are very eager to see what the outcomes are. Obviously, based on that, I am very confident that we will increase the scope and the timing." He added that both sides wanted to have a concrete scope starting out to measure the impact accurately.

Centocard

"One of the key aspects of what we do is that we use a very simple solution we call the Centocard, which is a proprietary filter paper that we use to collect a few drops of blood from the patient." With that paper, there is no longer the need to ship blood or another specimen across borders. "It's actually a card that can be sent in the mail," allowing for genetic and other testing.

Once samples are dry, they can be mailed directly and are not considered biohazardous. In addition, it is for use for every analysis and testing method, including whole exome and whole genome sequencing.

"We do those types of collaborations now with a number of different companies, and we certainly are working on . . . other disease areas in other parts of the world, but with a similar concept of enabling a very simple testing in rare diseases." Amitay also noted that an announcement should come shortly in a separate rare disease in a different region.

Vexing problem

While DMD has proven difficult to treat, companies are trying to help patients. For example, in January, Sarepta noted that the FDA had granted priority review status for golodirsen (SRP-4053), with a regulatory action date of Aug. 19. The candidate is a phosphordiamidate morpholino oligomer engineered to treat those individuals with DMD who have genetic mutations subject to skipping exon 53 of the dystrophin gene.

The U.S. FDA also has approved Emflaza (deflazacort) tablets and oral suspension for DMD patients age 5 years and older. It is a corticosteroid that works by decreasing inflammation and reducing the activity of the immune system. ♦

FDA

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forward as a result of the shutdown," he added, noting that the agency will meet all its user fee goals related to drugs and medical devices.

That's not to say all the programs at the agency escaped unscathed. One of the hardest hit across the FDA's centers may have been inspections. Gottlieb predicted that the number of inspections conducted this year could be down by as much as 10 percent. It would have been worse had it not been for the timing of the shutdown, which began Dec. 22. Normally, the agency conducts few inspections during the year-end holidays, Gottlieb explained.

Certain policy development, including some guidances, also were delayed, as the shutdown hindered the agency's assessment of public comments and ability to work on policy issues. Now that the FDA is at full throttle again, it seems to be making up for the lost time. At the hearing, Gottlieb raced through a lineup of new guidances and programs the agency plans to roll out in the coming months, including ones that would hammer down on the opioid crisis and drug safety.

For instance, he said the FDA is "undertaking one of the most significant policy modernizations at the agency in decades." It will include the use of standardized templates for the review of investigational new drug protocols and the launch of a safety signal tracker that will serve as a repository for potential safety signals throughout the lifecycle of a drug.

The tracker will consolidate information about safety concerns during drug development and postmarket use in a single location, so safety questions can be more consistently tracked and continuously evaluated, Gottlieb said.

The modernization isn't just about safety, though. For the first time in more than 20 years, the FDA will update guidance on how it assesses a drug's clinical effectiveness, including real-world evidence in that assessment.

While the agency is speeding ahead on policy development, some lawmakers are revving up efforts to protect the FDA's device center from future funding lapses. Rep. Tom Emmer (R-Minn.) introduced the Medical Innovation Never Stops Act in the House this week to keep new device reviews on track during a shutdown by allowing sponsors to continue to pay MDUFA fees.

"This common-sense fix will allow the FDA to access funds that companies have already agreed to pay for the review process," Emmer said in introducing the bill. "Patients deserve access to life-saving devices, and companies dedicated to providing these innovations should not have their hands tied by the government's inability to provide adequate funding for its agencies."

Pricing detour

While Wednesday's hearing was called to check in on the status of the FDA following the funding lapse, several lawmakers took advantage of Gottlieb's presence to detour the conversation to other issues. Ranking Member Jeff Fortenberry (R-Neb.) steered the first detour when he asked Gottlieb what the FDA could do about drug prices.

> *"I don't think we're going to see significant impacts on our work going forward as a result of the shutdown.*
>
> Scott Gottlieb
> Commissioner, FDA

Gottlieb identified three issues leading to high prices – lack of competition, payment systems such as Medicare Part B that don't allow the government to take advantage of competition and the failure to pass on the discounts from back-ended rebates to patients. The only one of those three the FDA can help address is competition.

Gottlieb gave a rundown on efforts the agency is making to shorten approval timelines and to prioritize generic applications when there are fewer than three generic competitors on the market.

Rep. Chellie Pingree (D-Maine) wanted Gottlieb's take on importation, a remedy several lawmakers have proposed as a way to lower Americans' prescription drug spend by allowing them to get their drugs, at a lower price, from pharmacies in Canada or other highly regulated markets. Pingree said people in her state could drive across the border into Canada and buy a vial of insulin for $35. That same vial would cost them $200 at a pharmacy in Maine.

While Gottlieb agreed that "Canadians have safe drugs," he said his concern with importation is the online sites that purport to be legitimate Canadian pharmacies when, in reality, they're based in countries with few regulations, and they're pushing suspect products. The FDA has formed a working group to explore ways to navigate those importation concerns.

About opioids

Another detour covered what the FDA is doing about opioids. The agency is currently considering under what circumstances it would be appropriate to require the co-prescribing of an overdose reversal drug with an opioid product. "Mandating co-prescription of naloxone across the board for all opioids would be costly to the system," Gottlieb said, "but there might be circumstances where there is a strong public health justification for mandating that."

The agency also is in the process of requiring sponsors of marketed opioids and those being developed to conduct rigorous studies evaluating the effectiveness of the long-term use of opioids. If those studies demonstrate a decline in effectiveness, as has been suggested, the FDA could further restrict opioid labeling to contraindicate certain uses, Gottlieb said.

In other steps to contain the opioid crisis, the FDA is looking at the opportunities offered by abuse-deterrent formulations (ADFs) and nonaddictive alternatives to the potent pain drugs. "What we do to address this crisis is going to be an all-of-the-above approach," Gottlieb said. "There is no single tool, given

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ACC

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to improve access for patients at high risk of cardiovascular disease.

The ACC said the effort is part of a five-year strategic plan, which will entail collaboration with other elements in health care, such as drug and device makers, employers, health plans and clinicians. The objective is to reduce mortality due to heart disease, and the ACC said both costs and prior authorization requirements "continue to pose challenges to patient access to novel therapies," such as procedures for imaging and cardiac catheterization.

Discussions going on for a year

The association said it will "work with like-minded stakeholders to proactively identify and address the behavioral and system challenges that clinicians and patients face in prescribing novel therapies," although there is at least some brief history behind this effort. The ACC said many of these stakeholders and the ACC have been working over the past year in a series of discussions led by the ACC, discussions that tackled questions such as clinical standards in addition to the prior authorization and access issues.

Once this program is up and running, data from registries such as the National Cardiovascular Data Registry for both inpatient and outpatient care, and the Pinnacle Registry for coronary artery disease, hypertension, atrial fibrillation and heart failure, will be available to feed these programs with the needed data. Those data will be used to help clinicians and health systems identify which patients are at greatest risk for an infarct, and who are eligible for the latest therapies that could ward off another infarct. However, the ACC statement said the initiative will add insight into physician treatment patterns, such as their patient follow-up patterns and prescriptions for patient lab tests. Patient factors will also be tracked, and these data points will help physicians and clinics to understand how to ease barriers to access.

The initiative will tackle the cost end of the equation by obtaining price reductions from manufacturers and distributors, as well as by streamlining the associated administrative work. Patients will also be engaged in an effort to improve adherence to medication regimes, and therapies will be optimized by more focused targeting of "specific high-risk patient cohorts."

The ACC said it will announce specific programs and partnerships over the next few months, adding that those early programs will build on the groundwork the collaboration has already laid. Joe Allen, ACC's senior director of clinical policy, said in the ACC statement that this new approach avoids the problem of looking at registry data retrospectively and waiting for patients to show up in a doctor's office in a dire state before medical care can be provided. "As a result, the impact of cardiovascular disease burden can be reduced in an accelerated time frame to reach clinical and personal goals for these patients," Allen said.

Allen told *BioWorld MedTech*, "What we wanted to do was focus on the highest risk from a clinical perspective and a financial perspective," adding that much of the early focus will be on pharmaceutical agents. These early programs will be driven by an interest in getting away from subjective criteria for writing a prescription or ordering a diagnostic procedure, but he noted that many clinicians are concerned about their patients' ability to pay as well, particularly patients on high-deductible plans.

Some stakeholders have little to lose

Allen said that when it comes to cholesterol statins, such as PCSK9 inhibitors, it was a lot easier to sell payers and employers on this program, given that the registry data allowed the ACC to take a data set for 1.8 million patients and winnow it down to 10,000. Employers also were reminded that many of their employees that could take part in such a program would not be very productive if they suffered a second infarct, but there were some who were already not working, giving employers less reason to resist the proposal.

As for making life easier for physicians, Allen said, "the way the administrative burden is lowered is that we have objective criteria that should align with appropriate use criteria." The patient record database should fairly quickly identify which of a physician's patients are eligible for one of these programs, but Allen said the use of objective criteria was a draw for other stakeholders as well as the physicians.

"There is a lot of concern by FDA and others about safety" when it comes to rapid translation into clinical practice, Allen said, a concern that received quite a bit of coverage in connection with the stent thrombosis question for drug-eluting stents in 2006. "I think there has been much more transparency about those issues," he said, particularly with the help of drug and device registries that pick up these signals much more rapidly than was the case 13 years ago. ♦

Product briefs

Premstaetten, Austria-based **Ams** introduced the AS7026, an optical sensor for continuous cardiovascular health monitoring that performs blood pressure measurement to medical-grade accuracy. When included in the Ams Vivavita accessory design, this provides a turnkey solution for customers needing a fast time-to-market and is supplied with a mobile app for both the Ios and Android mobile operating systems.

U.K.-based **Angle plc** received ethics approval from the University of Rochester Medical Center Wilmot Cancer Institute for its ovarian cancer clinical verification study. The first subjects already have been enrolled into the study, which includes a 70-subject prestudy followed by a 200-subject clinical study, evaluating the use of the company's modified Parsortix and Hycead Ziplex platforms as a simple blood test to detect the presence of ovarian cancer in women with a pelvic mass.

Mechelen, Belgium-based **Biocartis Group NV** reported the CE-IVD marking of its fully automated Idylla Microsatellite Instability (MSI) test, which allows for fast and accurate information on a patient's MSI status directly from a single sample of formalin fixed, paraffin embedded colorectal cancer tumor tissue.

FDA

Continued from page 6

the magnitude of the public health crisis we're facing."

The FDA issued guidance last year on developing generic opioids with abuse-deterrent features, and it's revising the nomenclature used to describe ADFs. The intent is to put a robust regulatory framework in place "to allow these products to go forward," Gottlieb said.

As for non-opioid alternatives, the agency has withdrawn an outdated guidance that Gottlieb said was overly burdensome to sponsors developing non-opioid pain drugs. The agency plans to replace that guidance with a series of at least four new guidances that discuss what is needed to develop drugs to treat specific kinds of pain.

CBD research

Several committee members pressed Gottlieb about the status of cannabidiol (CBD) research at the agency, which approved the first U.S. CBD product last June – GW Pharma plc's liquid Epidiolex. Given the scheduling of marijuana and hemp in the U.S., Epidiolex was derived from plants grown in the U.K.

Since the ability to conduct research with marijuana in the U.S. is more restricted and heavily regulated than elsewhere, companies interested in the pharmaceutical use of CBD and other compounds derived from marijuana or hemp have been going overseas to do their research.

Although Congress voted last year to remove hemp from Schedule 1 controls, the legal question of whether CBD derived from hemp also was descheduled remains to be answered, Gottlieb said, adding that he expects that question to be resolved soon.

"The environment here is changing quickly," Gottlieb acknowledged. "We will certainly support more research."

In the meantime, the agency is laying out a course to protect pharmaceutical opportunities for CBD and other cannabis compounds while maintaining congressional intent to make them available for use in foods and dietary supplements. ♦

Product briefs

Dexcom Inc., of San Diego, reported an update for its Dexcom G6 app with features designed to simplify diabetes management. One feature will allow Ios device users to ask Siri to read Dexcom glucose readings aloud and display graphs directly on the lock screen.

Menlo Park, Calif.-based **Ischemaview Inc.** launched Rapid Angio, a complete neuroimaging solution for the angiography suite that integrates Ischemaview's Rapid software with Syngo DynaCT Multiphase from **Siemens Healthineers**, of Erlangen, Germany. The Syngo DynaCT Multiphase is a 3D image acquisition technique employing multiple rotations of a C-arm system to acquire a multiphasic 3D representation of the brain and its perfusion. This technology, when combined with the Rapid platform's clinically validated CTP product, delivers a powerful imaging solution to the angio suite for acute stroke patients.

Fukuoka, Japan-based **Jiun Corp.** reported the release of SonicDICOM PACS Cloud, a cloud-based medical image management system. SonicDICOM PACS Cloud enables any computer or tablet with an Internet connection to view medical images hosted in the cloud from anywhere in the world, simply by accessing a URL. Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing and transmitting information in medical imaging, while picture archiving and communication system (PACS) allows for storage and access to images.

Dublin-based **Medtronic plc** reported the Japanese launch of the Grafton demineralized bone matrix (DBM) bone grafting product for spine and orthopedic procedures. Grafton DBM is the first demineralized bone matrix product available in Japan, the company noted. Grafton DBM received Pharmaceuticals and Medical Devices Agency approval in August 2018.

Pulse Biosciences Inc., Hayward, Calif., reported its 510(k) submission to the U.S. FDA for its Cellfx system. The company is seeking clearance of the system for commercial use in common dermatologic procedures to remove general benign lesions including sebaceous hyperplasia.

Houston-based **Soliton Inc.** said it may have discovered in preclinical testing that the Rapid Acoustic Pulse technology also could provide the ability to reduce cellulite.

The FDA has granted Lexington, Mass.-based **T2 Biosystems Inc.** breakthrough device designation for the T2resistance Panel, which can detect 13 resistance genes from both gram-positive and gram-negative pathogens from a single patient blood sample, without the wait for blood culture. Several of the genes are listed on the CDC's Urgent Threat list for antibiotic resistance.

Other news to note

Bardy Diagnostics Inc., a Seattle-based provider of ambulatory cardiac monitoring technologies, entered a distribution agreement with **Jnc Medical Inc.**, a medical technologies distributor based in Ottawa, Ontario. The agreement grants Jnc Medical the right to distribute the BardyDx Carnation Ambulatory Monitor, a P-wave centric ambulatory cardiac patch monitor and arrhythmia detection device, in the Canadian market.

Biolase Inc., an Irvine, Calif.-based developer of dental lasers, said **Sinclair Dental Co. Ltd.**, a North Vancouver, British Columbia-based dental supply company, is its exclusive distributor for all of its products and services in Canada, effective immediately.

Bioventrix Inc., of San Ramon, Calif., reported that Inek, the German Institute for Hospital Remuneration, has reconfirmed the award of NUB Status 1 for its Revivent TC transcatheter ventricular enhancement system, which is a closed-chest procedure for plication of scar tissue in post-myocardial infarction, ischemic cardiomyopathy patients. The NUB process recognizes select medical devices for reimbursement support in Germany. It enables participating hospitals to receive full reimbursement for the product and a supplemental payment when utilizing groundbreaking technologies not listed in the existing German health care system. Revivent TC achieved this status for the third consecutive year in 100+ hospitals in Germany.

Other news to note

Kaiku Health, a Helsinki-based developer of personalized digital health interventions in oncology, and Thousand Oaks, Calif.-based biotechnology company **Amgen Inc.** reported a partnership to advance the use of digital symptom management and personalized patient support in routine care of multiple myeloma, a common blood cancer, in Finland.

Mts systems Corp., a Eden Prairie, Minn.-based supplier of high-performance test systems, motion simulators and sensors, said **Nexxt Spine LLC**, of Noblesville, Ind., is using Mts material test systems to develop 3D-printed, porous titanium spinal implants.

Omnicomm Systems Inc., a Fort Lauderdale, Fla.-based provider of electronic data capture (EDC) and clinical data management solutions signed a multiyear agreement with Heinrich Heine University Düsseldorf's Coordination Center for Clinical Trials (KKS). Under the agreement, the university will use Omnicomm's Trialmaster EDC technology to develop and conduct clinical trials at multiple sites. In addition to building new clinical trials in Trialmaster, the university will migrate a number of ongoing trials to the Trialmaster platform. The agreement provides KKS with the opportunity to enhance the efficiency and effectiveness of its clinical trials.

Qt Ultrasound LLC, the Novato, Calif.-based developer of an FDA-cleared transmission ultrasound breast imaging technology, said it has now created the first 3D printing of the breast duct system in a living woman, using its technology. Unlike traditional breast imaging, the Qtscan has no radiation, no compression and no injections. The technology produces high-fidelity detailed scans, providing clarity even for women with dense breasts. The company has now demonstrated that the technology has the ability to produce 3D-printed images of a person's breast tissue-specific microanatomy.

Staar Surgical Co., a Monrovia, Calif.-based developer of implantable lenses and companion delivery systems for the eye, reported a strategic cooperation agreement with **Vista Oftalmólogos**, a 49-clinic ophthalmology group spanning Spain, France, Portugal and Morocco with more than 200 eye doctors and 1,000 employees. The agreement positions the Evo Visian ICL family of lenses as a premium and primary refractive procedure for patients suffering from nearsightedness (myopia). Evo is the latest version of Staar Surgical's implantable collamer lens (ICL) that works with the patient's natural eye to correct vision and provide patients visual freedom from spectacles and contact lenses.

Diagnostics Extra

Keeping you up to date on recent developments in diagnostics

By Mark McCarty, Regulatory Editor

Technique provides measurement of regurgitation after Mitraclip

The mitral valve has proven more difficult to access than the aortic valve, but cardiologists have also been frustrated by the difficulty associated with measuring regurgitation of the mitral valve, which is still important after mitral valve repair procedures. Researchers in the U.S. are proposing, however, that transesophageal echocardiography (TEE) can provide that information when used to measure vena contracta area (VCA). The researchers used 3D TEE to evaluate the degree of regurgitation in 245 "prohibitive risk" patients undergoing mitral valve repair with the Mitraclip (Abbott Vascular, Santa Clara, Calif.) between March 2014 and June 2017 in Houston, and between March 2014 and December 2016 in Seattle. The imaging data sets were forwarded to a blinded, independent investigator who conducted the post-hoc VCA evaluation using Qlab 3DQ software (Philips Medical Systems, Andover, Mass.). That analysis rested on a definition of VCA as "the smallest cross-sectional area of the largest regurgitant jet identified during any systolic phase." Of the 245 patients who underwent the mitral valve repair procedure, 155 were included in the analysis, with 69 of the losses due to lack of raw data. Only about 1 in 10 patients (15) exhibited a single jet, but one patient remarkably was diagnosed with five jets. Patients with normal and reduced left ventricular function demonstrated no significant difference in baseline VCA, but percentage change in VCA was higher in patients with primary regurgitation than those with secondary or mixed-etiology regurgitation. The decrease in total VCA was 0.90 cm^2 at baseline to 0.25 cm^2 post-procedure, while average VCA reduction was 0.77 cm^2. The authors said inter-observer variability was 0.84 for baseline measurements and 0.93 post-procedure. In an accompanying editorial, Paul Grayburn of Baylor University Medical Center noted that there is at present no gold standard for measurement of mitral valve regurgitation periprocedurally, but pointed to several problems with the study, including that the VCA measurement occurs at a single time point and thus does not capture mean systolic VCA. Grayburn said 3D VCA is at present "the only method that allows summation of all residual MR jets during Mitraclip," adding that this procedure is perhaps best suited to instances in which the cardiologist is considering the use of an additional device. The authors explain their findings in the March 8, 2019, issue of *JACC: Cardiovascular Interventions* under the title "3D Vena Contracta Area for the Quantification of Residual Mitral Regurgitation after Mitraclip Procedure."

Faster RNA sequencing proposed

Single cell RNA sequencing is not exactly the latest thing, but it's not exactly inexpensive, and current technologies are often a bit cumbersome. Researchers at Virginia Polytechnic Institute in Blacksburg, Va., have come up with a design they say is compact and convenient, thus resolving a lot of the problems currently encountered in single-cell RNA sequencing. This novel design moves past the single cell trapping problem with a four-channel design that allows horizontal multiplexing or a six-channel design that allows vertical multiplexing, both of which employ a diffusion-based reagent swapping scheme. The concept provides cell trapping, lysis, reverse transcription and polymerase chain reaction amplification in "one simple microfluidic device," the authors said. This design, dubbed microfluidic diffusion-based RNA sequencing (MID-RNA-seq) is credited with providing data that is comparable in quality to existing single-cell sequencing methods, albeit with a simple design that provides multiplexing capability. However, the authors also claim that this design can be scaled to provide effective and efficient transcriptomic studies for "scarce cell samples." The authors explain their findings in the Feb. 22, 2019, online issue of *Lab on a Chip* under the title "A Diffusion-based Microfluidic Device for Single-cell RNA-seq."

Tri-agency coordination announced

The U.S. FDA said it and two other U.S. federal government agencies have launched the Tri-Agency Task Force for Emergency Diagnostics, an effort to leverage the capabilities of each of the agencies to more rapidly make tests available in public health emergencies. In addition to the FDA, the Centers for Disease Control and Prevention and the Centers for Medicare & Medicaid Services will standardize their interactions, and the task force will provide the three agencies with a forum for accelerating the usual interagency processes called upon during public health emergencies. Jeff Shuren, director of the Center for Devices and Radiological Health at the FDA, said the more predictable regulatory response may foster greater innovation in diagnostics.

New Alzheimer's markers identified

The U.S. National Institutes of Health said an analysis of genetic data from slightly less than 95,000 individuals has disclosed the existence of five genes associated with a higher risk of developing Alzheimer's disease, and confirmed the associations with 20 genes. The agency said mutations of genes specific to tau may exert an influence in the development of Alzheimer's at an earlier stage than was previously believed to be the case. Among the newly identified genes are IQCK and ADAM 10, although NIH said it will have to conduct further research in order to spell out precisely how these genes promote the development of the disease. These developments are explained in an article appearing in the Feb. 28, 2019, online issue of *Nature Genetics* under the title "Genetic Meta-analysis of Diagnosed Alzheimer's Disease Identifies New Risk Loci and Implicates Aβ, Tau, Immunity and Lipid Processing."

BioWorld MedTech Patent Highlights

From Current Patent Gazette
Week 08

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Clarivate Analytics

WO2019035886-A1: “Method and device for packing a body cavity and delivering a medicament to a subject.”

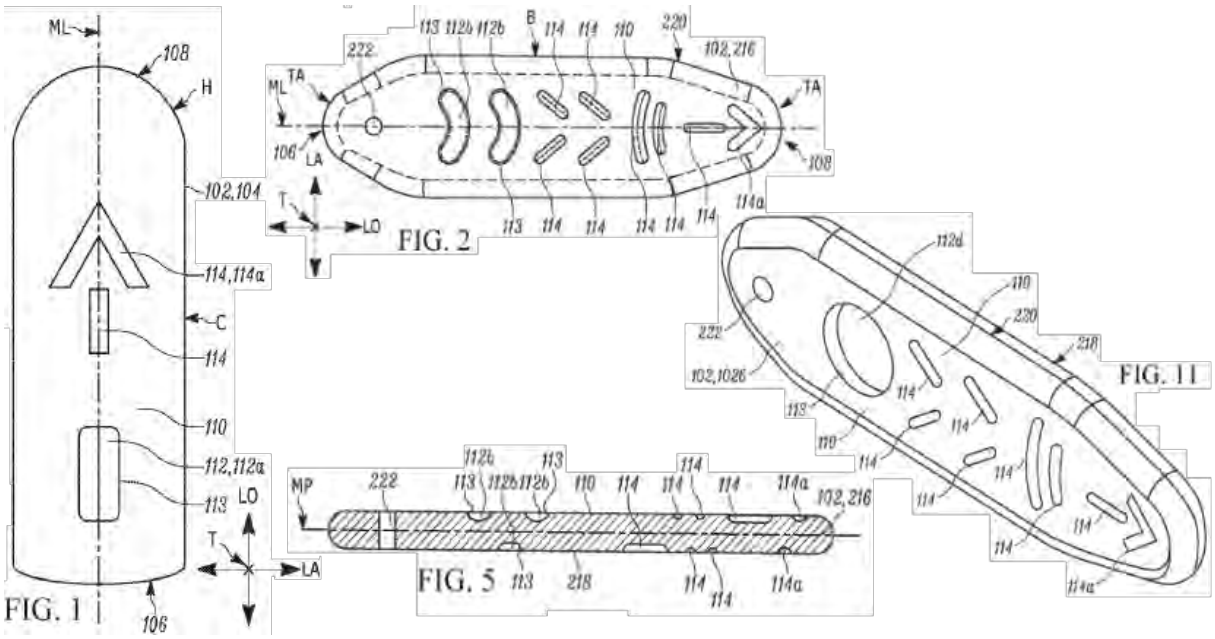
Assignee: Binyarco LLC

Inventors: Binder, Jeffrey, E.; Clements, Arthur, L.; Erickson, Paul, L.; Harrington, Stephanie, A.; Weisberg, Gregory

IPC Codes: A61F 2/04; A61M 29/02; A61F 13/36; A61F 2/18; A61M 31/00; A61L 31/16; A61F 13/15

Publication Date: 21-Feb-2019

Earliest Priority Details: US2017545850, 15-Aug-2017



Medical packing device for use within a body cavity of a subject, particularly for the intranasal delivery of medicaments for treating epistaxis/nosebleeds. The device comprises an absorbent member (foam or sponge) with depressions therein that serve as reservoirs for receiving a medicament (a hemostatic compound, a vasoconstriction agent, a liquid pharmaceutical excipient, a drug or pharmaceutical, or combination thereof) that is to be delivered to anatomical tissue adjacent to the depressions in the body cavity.

The inventor Dr Jeffrey Binder is an ENT-otolaryngologist in Cleveland, Ohio who can be seen to be affiliated with multiple hospitals in the area. The address he provides on this patent application matches that of the assignee, and it would appear to actually be that of his family’s home.

For patenting in which Dr Binder previously described a composition comprising bismuth subgallate and the vasoconstriction agent oxymetazoline, that is administered as a paste for treating nosebleeds, see WO2007027236. Said family of patenting includes family members that have been issued as recently as February 2016, namely US9248186-B2 that within the present invention’s disclosure is said to have been incorporated by reference, with the paste composition it describes being able to be applied to the absorbent member of the present invention’s medical packing device.

US10206572-B1: “Systems and methods for quantification of, and prediction of smoking behavior.”

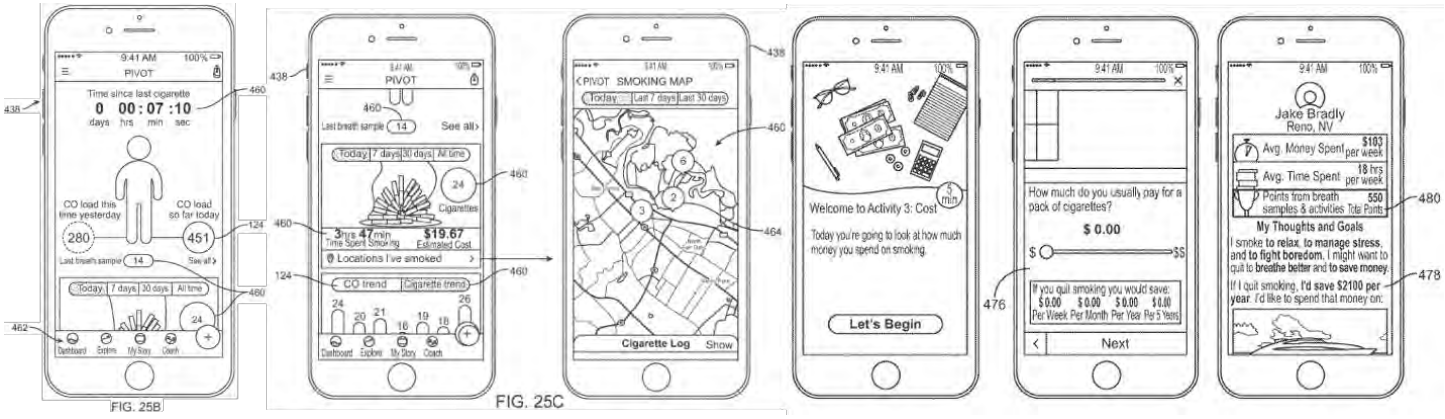
Assignee: Carrot Inc

Inventors: Jameson, Allen; Marler, Jennifer; Utley, David S.

IPC Codes: A61B 5/00; A61B 5/08; A61B 5/024

Publication Date: 19-Feb-2019

Earliest Priority Details: US2017729529, 10-Oct-2017



Systems and methods for monitoring of biometric and contextual variables to assist in screening for, quantification of, and prediction of smoking behavior, and for assisting in smoking cessation. Among its many elements, the systems incorporate the measurement of exhaled carbon monoxide levels from portable sensors as an indicator of smoking activity. The methods and systems may allow an individual's behavioral data to be tracked to identify potential triggers to smoking or simply to educate the individual on the extent of their smoking. The methods and systems also allow for more active monitoring of the individual that has decided to engage in a "quit" program, where such monitoring allows the individual to self-monitor as well to be monitored by peers, coaches, or counselors. Lastly, the methods and systems disclosed herein can be used to monitor the individuals who successfully quit smoking to ensure that smoking behavior does not re-occur.

This patent was given prioritized examination, through the USPTO’s TrackOne Request process, meaning that it was not seen initially as a patent application, but instead appeared publicly for the first time as this fully granted patent. TrackOne Requests can be viewed as an indicator of the assignee being particularly keen to see their invention protected as quickly as possible.

One of the inventors, Utley, previously described methods for quantification and prediction of smoking behavior in WO2016164484. David Utley is the founder, President and CEO of Redwood City, California-based Carrot Inc (that was formerly known as Carrot Sense Inc), a digital health company whose flagship product, Pivot™, delivers evidence-based smoking cessation strategies through web-based and mobile applications, that are facilitated by data from novel wearable devices that quantify smoking exposure. Pivot™ uses an FDA-cleared carbon monoxide breath sensor for at-home use, that then pairs with Bluetooth to a smartphone, so it can track levels over time through an app.

In October 2018, Carrot announced the raising of a $25 million round of investment, led by Johnson & Johnson Innovation to help commercialize its Pivot™ smoking cessation program.

US20190053744-A1: “Assay and point of care device utilizing saliva for diagnosis and treatment of neurological conditions affecting brain health.”

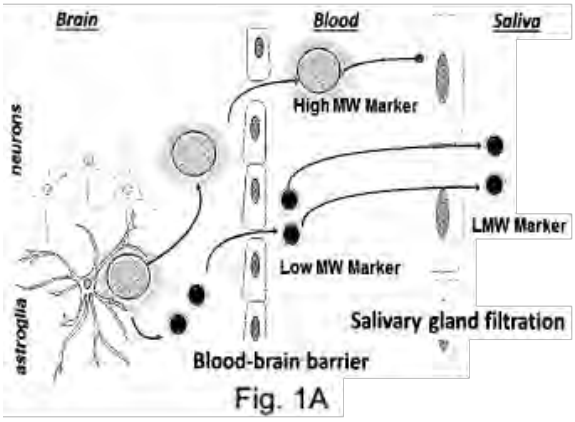
Assignee: FloTBI Inc

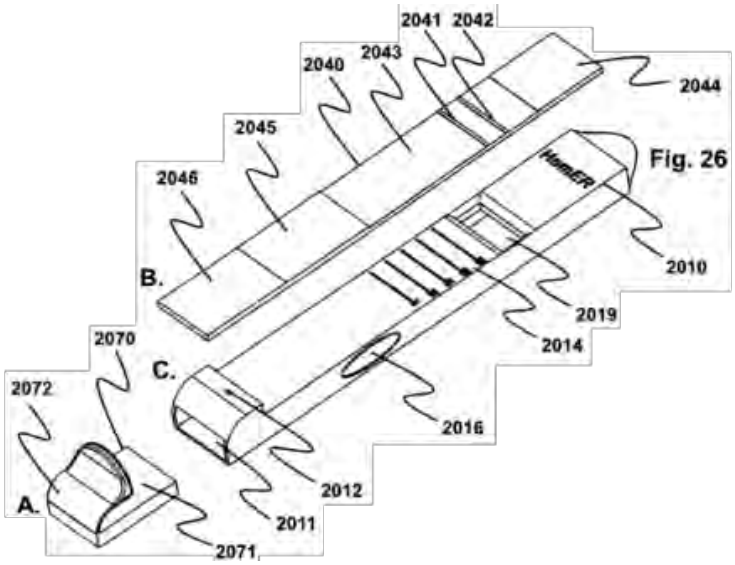
Inventors: Dadas, Aaron; Janigro, Damir; Rapp, Edward J.

IPC Codes: C12Q 1/6883; G01N 33/68; A61B 5/145

Publication Date: 21-Feb-2019

Earliest Priority Details: US2015240152, 12-Oct-2015





Methods and assays useful in determining with increased accuracy the true levels of a given marker (S100B) of blood-brain barrier (BBB) disruption and brain damage in saliva that provide for improved, faster and less invasive diagnosis of diseased states such as traumatic brain injury. Within the invention’s disclosure there is the referencing of family members of WO2004078204, in which the inventor Dr Janigro described markers of blood barrier disruption and a peripheral marker of BBB permeability.

As well as being founder, CEO and CSO of FloTBI, Dr Damir Janigro is founder and CSO of Flocel Inc (whose address matches that of FloTBI in Cleveland, Ohio, and that describes itself as being the first BBB company in the US, offering an array of pre-clinical tools to study and understand the BBB and its function). He is also an Adjunct Professor at Case Western Reserve University and the inventor of the dynamic in vitro model of the BBB that is felt constituted one of the founding blocks of 3D modeling of the cerebrovasculature, and he identified S100B as a marker of BBB function (see WO2012154889) and has been collaborating with hospitals in the US and Europe to broaden the scope and use of this technology.

This patent application represents the first patenting to have been published in FloTBI’s name, and as evidenced from the above imagery, it would appear to be describing its HomER disposable saliva test for on-site determination of head injury, and determining a need for diagnostic CT imaging. FLoTBI is also developing a medical-grade diagnostic device called NoscanER to be utilized in ambulances and Emergency Rooms (ERs) when a more precise measurement of salivary biomarker levels is needed. While HomER provides a simple “Yes/No” for visiting the ER, NoscanER allows the EMT or doctor to carefully track changes in these readings over time.

US20190054253-A1: “Implant syringe.”

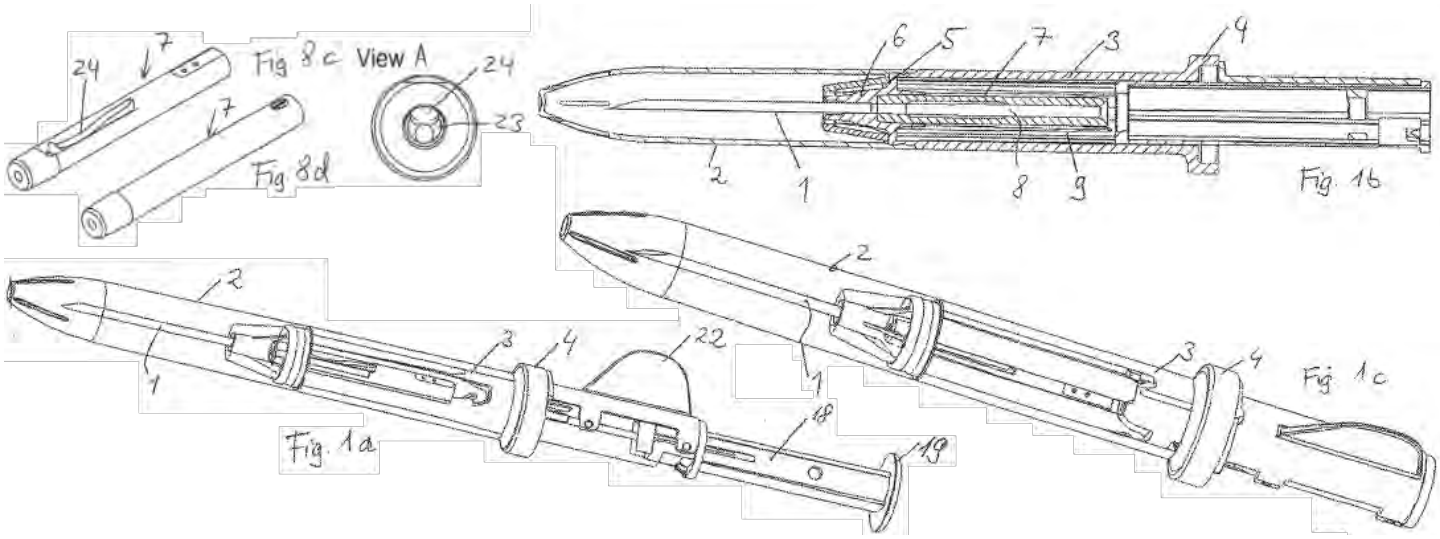
Assignee: Gaplast GmbH

Inventors: Kneer, Roland; Kneer, Stephan

IPC Codes: A61M 5/32; A61M 5/315

Publication Date: 21-Feb-2019 (also published as DE102017007893, 21-Feb-2019)

Earliest Priority Details: DE102017007893, 19-Aug-2017



An implant syringe with a syringe needle holder, having an axially adjoining preparation receptacle; an outer sleeve with a radially projecting front gripping section, connected together for common axial movement; an inner sleeve, on which the outer sleeve is slidably located and in which the syringe needle is movable with the preparation receptacle. This invention comes just over 18.5 years after Roland Keer, who is CEO of the German assignee, previously described an implant syringe in WO0143811 - a family member of which (DE19961197) is discussed within the present invention’s background as having had drawbacks in the way that it is operated, and the way in which it poses a risk of needlestick injury after the retracting of its syringe needle.

The present invention would seemingly therefore relate to the implant syringe currently seen of Gaplast GmbH's website. It is described as being an innovative combination of medical packaging and syringe applicator, that enables safe and precise injection of rod-shaped, long-acting (retarding) tablets into the subcutaneous tissue of a patient, with the tablet being inserted into the tissue through a needle. Due to a smooth and constant injection process, the implant it says may be placed at an ideal depth and not pressed any further than necessary into the tissue. By withdrawing the needle evenly, injuries in the fabric layers are avoided. Taking the form of a pre-filled syringe reduces the risk of mis-use and fail loading, as well as saving cost and time to manufacture and use. The syringe is said to enable safe and simple administration for medical staff, and less pain for patients (who may historically have received local anesthetics prior to injection). Finally, through the device’s integrated needle protection, there is no risk of injury for users of the device.

Gaplast’s implant syringe was recipient of a 2016 German Packaging Award from the German Packaging Institute (dvi), in the category “Functionality and convenience”.

US20190054232-A1: “Intravenous infusion adaptation for tricycles, strollers, and related devices.”

Assignee: Genin, Guy; Cashin, John Laurin; Richards, Angela

Inventors: Genin, Guy; Cashin, John Laurin; Richards, Angela

IPC Codes: A61M 5/14; B62J 11/00; B62K 27/00; F16M 11/42

Publication Date: 21-Feb-2019

Earliest Priority Details: US 2017545589 , 15-Aug-2017

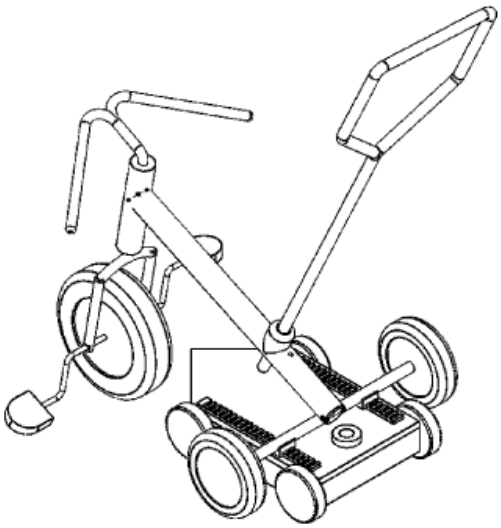


FIG 4

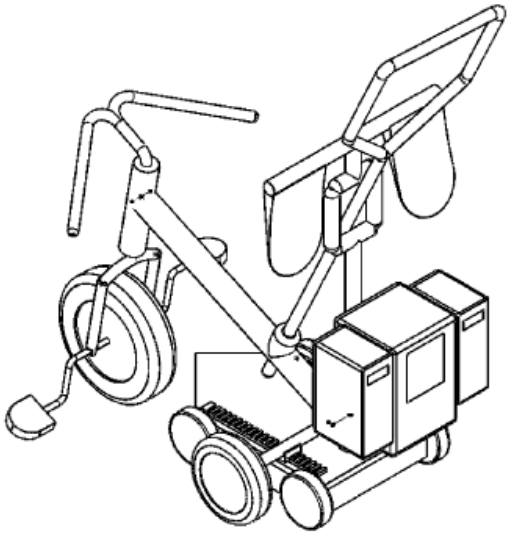


FIG 7

The application describes an adaption for a tricycle, bicycle, toy motor vehicle, stroller or similar to enable it to be used by the patient whilst receiving an intravenous infusion. The vehicle is fitted with a balast compartment, as shown in figure 4 positioned between the back wheels of the tricycle, and a pump, as shown added in figure 7.

This appears to be the first application from the team.

WO2019034773-A1: “Personal health monitoring system, multiple user health monitoring system, and method.”

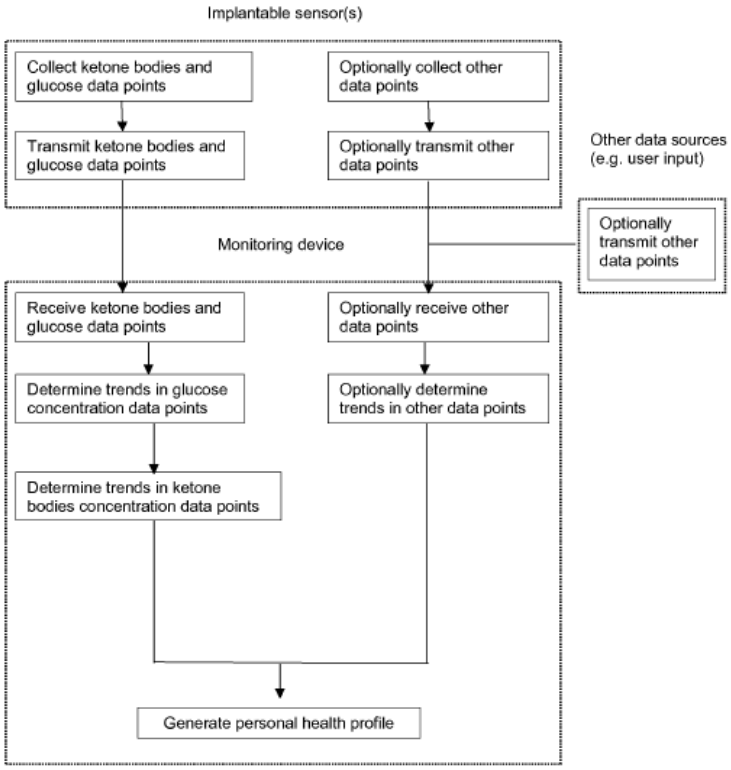
Assignee: Indigo Diabetes NV

Inventors: Delbeke, Danaë; Van Schuylenbergh, Koenraad; Pollet, Wim; Ordonez Orellana, Juan Sebastian; Nijlunsing, Rutger

IPC Codes: A61B 5/145; A61B 5/00; A61B 5/1473; A61B 5/1459

Publication Date: 21-Feb-2019

Earliest Priority Details: EP 2017186763 , 18-Aug-2017



The application describes a system for the continuous monitoring of at least the concentration of glucose and ketone bodies in a patient, and the transmission of that data to a receiver capable of determining the trends of both parameters and generating a personal health profile of the patient.

The application appears to be in support of the company's continuous glucose monitoring system and to continue the interests of the company see WO2018197722 on a photonics sensor.

WO2019034896-A1: “Wound dressing.”

Assignee: Medtrade Products Limited

Inventors: Hoggarth, Andrew; Hardy, Craig; Grist, Matthew

IPC Codes: A61F 13/02

Publication Date: 21-Feb-2019

Earliest Priority Details: GB 201713272 , 18-Aug-2017

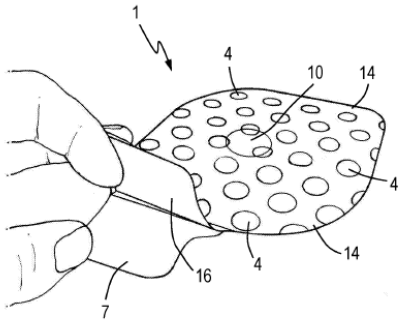


Fig. 2

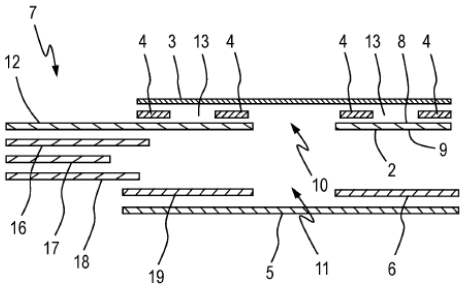


Fig. 3

The application describes a wound dressing suitable for use on a penetrating chest wound where a lung has been penetrated and the patient is in danger of suffering tension pneumothorax, open pneumothorax or haemothorax.

Figure 2 shows the dressing and figure 3 a cross-section through it. In use (figure 3), protecting layer 5 is removed and the dressing put in place with aperture 10 over the wound. This allows the wound to be in fluid communication with voids 10, 11 and the area outside the wound. When the patient exhales, pressure builds in the wound, forcing fluid to press top layer 3 away from base layer 2 releasing the fluid from the dressing. When the patient inhales, pressure drops in the wound, causing top layer 3 to be pulled closed against base layer 2 forming a fluid seal. Subsequent exhalation and inhalation causes the process to be repeated.

The application continues the interests of the company, see WO2016174419 on wound dressings, and to be in support of the company's Foxseal product.

WO2019036609-A1: “Bone growth stimulator and methods of use.”

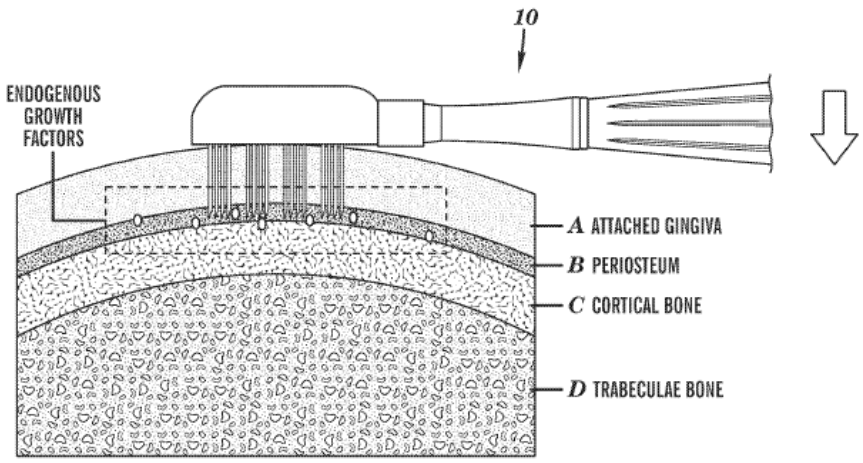
Assignee: New York University

Inventors: Alikhani, Mani; Teixeira, Cristina; Sangsuwon, Chinapa; Alansari, Sarah; Oliveira, Serafim; Roque, Candido

IPC Codes: A61M 37/00

Publication Date: 21-Feb-2019

Earliest Priority Details: US 2017546799 , 17-Aug-2017



The application describes a device in the shape of a tooth brush but where the brush hairs are micro-needles. The device may be used to stimulate cortical bone growth by stimulating the production of endogeneous growth factors, particularly in the jaw (see figure). The micro-needles may also be used to deliver exogeneous growth factors.

The application continues the interests of four of the team, see WO2018009848 on an orthodontic system and device.

WO2019035133-A1: “Device, system and method for non-invasive monitoring of physiological measurements.”

Assignee: Wear2B Ltd

Inventors: Bar-Sakai, Giora; Bashan, Oded; Bashan, Ohad; Dekel, Ben Zion

IPC Codes: A61B 5/145; A61B 5/1455

Publication Date: 21-Feb-2019

Earliest Priority Details: US2017546565, 17-Aug-2017

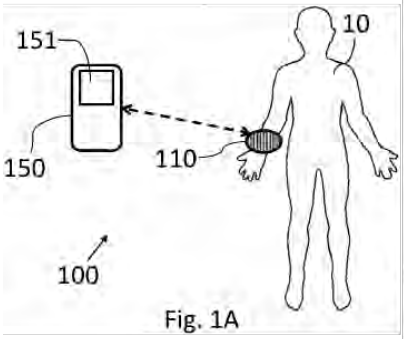


Fig. 1A

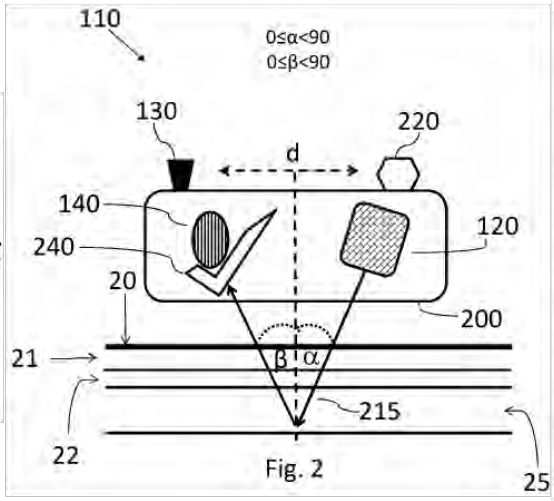


Fig. 2

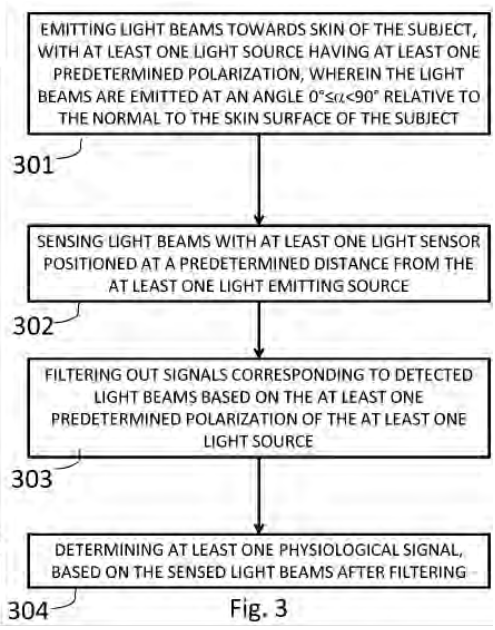


Fig. 3

Wearable device, system and method of non-invasive monitoring of physiological measurements, such as glucose levels. Represents the second family of patenting to have been published in the assignee’s name; see WO2017115361 in which Dekel and the two Bashans described a similar such wearable device that may be useful to monitor cholesterol levels, albumin levels, for monitoring glucose levels in the blood, and for monitoring levels of pain relieving medications such as acetaminophen.

The address provided by the assignee in Rosh Pinna, Israel, matches that of IR-MED that specializes in infrared light-based diagnostics. IR-MED claims to possess unique knowhow on the interface between harmless infrared light radiation and human tissues, and says that its knowledge of infrared-human matter interphase, combined with big data and machine learning processing tools, is enabling its development of new diagnostic modalities. Perhaps IR-MED has established Wear2B with the specific commercialization of a range of wearable mobile health devices in mind.

The inventor Dr Ben Zion Dekel is the Head of Electrical and Electronics Engineering Department, Ruppin Academic Center, Israel. An electro optical engineer, specialized in IR spectroscopy for medical applications, he serves on the Scientific Advisory Board at IR-MED. Oded Bashan meanwhile, who serves as IR-MED’s Chairman, was the founder and CEO of OTI (On Track Innovations), a NASDAQ traded global technology company that designs, develops, and markets cashless payment solutions worldwide.

US20190053841-A1: “Bone hemostat and carrier.”

Assignee: WNDM Medical Inc

Inventors: Bagley, Sherlene F.; Mart, Robert K.

IPC Codes: A61B 17/88

Publication Date: 21-Feb-2019

Earliest Priority Details: US2017547675, 18-Aug-2017

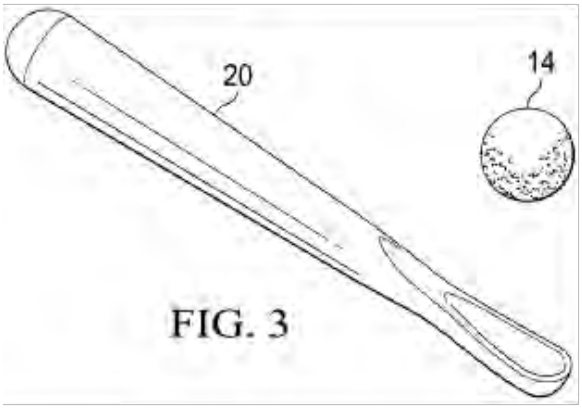


FIG. 3

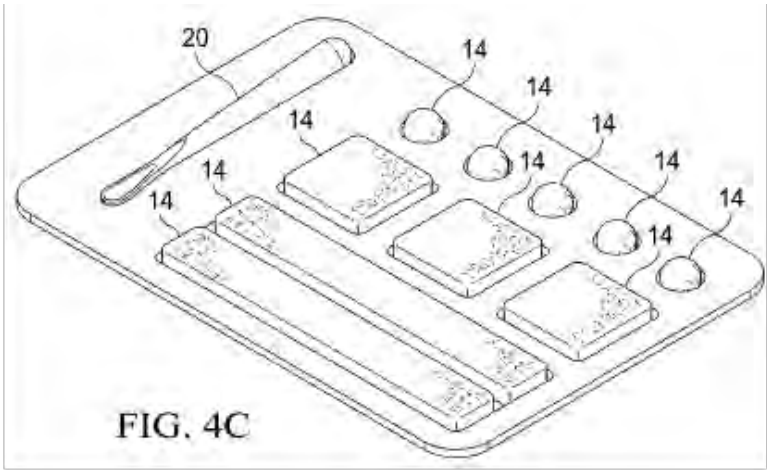
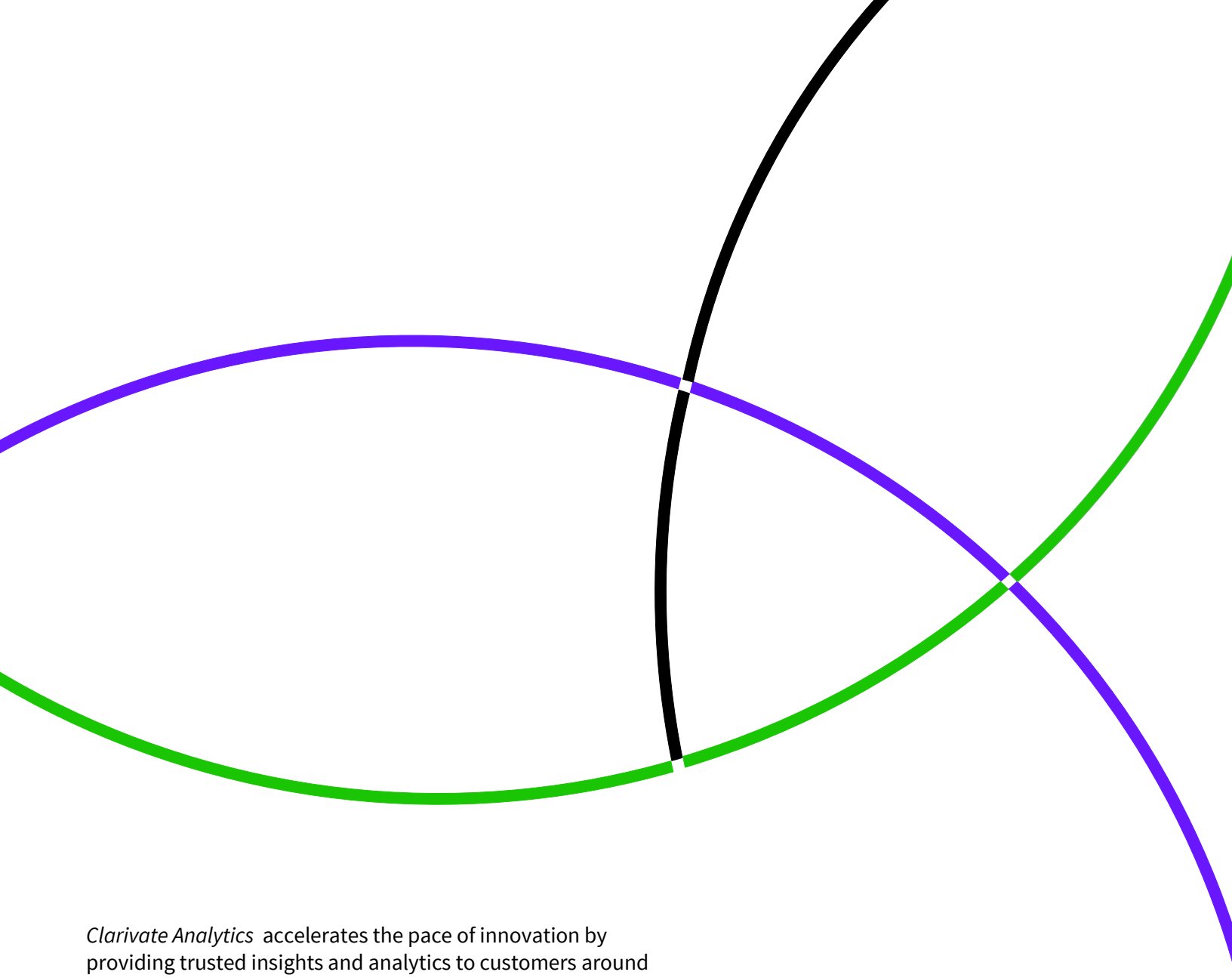


FIG. 4C

Compositions and methods for treating bone injury and surgical bone incisions and openings that include a bone hemostat material and tape delivery system comprising: one or more dots, beads, strips, tapes or ribbon-shaped beads of bone hemostatic material provided on a tray capable of being sterilized.

In December 2017, Fort Worth, Texas-headquartered Wound Management Technologies Inc (WNDM), that changed its name to WNDM Medical in April 2018, announced the first sale of its FDA-cleared HemaQuell® Resorbable Bone Hemostat. WNDM acquired a multi-faceted bone hemostasis and bone void filler patent in 2009 that led to its development of this product (see US7074425, originally assigned to Bonewax LLC, that describes resorbable hemostatic agents comprising polyethylene glycol, which controls bleeding in tissue and does not delay or interfere with healing).

HemaQuell® Hemostat is described as being a water-soluble, puttylike bone hemostat that controls bleeding from bone surfaces on application. It is said to be delivered in a unique applicator that allows surgeons to directly apply the product on bleeding bone surface, with said applicator presumably having been described within US20160278786 - that as with the aforementioned granted patent (US7074425-B2) can actually be seen to be assigned to Resorbable Orthopedic Products (ROP), a wholly-owned subsidiary of WNDM Medical, that was organized as a Texas limited liability company on August 24, 2009, as part of a transaction to acquire the multi-faceted patent for resorbable bone hemostasis products. In 2014, WNDM Medical entered into a commercial license for a bone void filler and in 2016 ROP received US FDA 510(k) clearance for ROP Bone Hemostasis Material (whose registered tradename is HemaQuell®).



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