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FOR RELEASE

September 20, 2022 | News

PFD Management Opportunity Fund 3001, LLC Announces:

PFD Capital Partners, LLC Director and Fund Manager for PFD Management Opportunity Fund 3001, LLC, Robert Pryke, announced today additional points of interest relating to its portfolio project PFD/iOrthopedics, Inc.

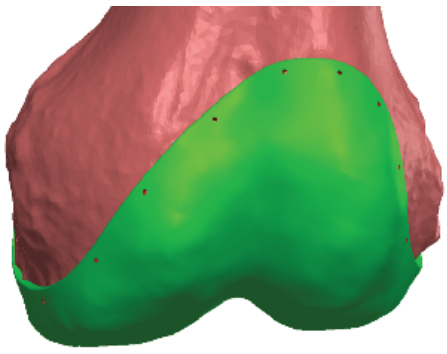
PFD/iOI Release of Development Update on the Resilient Arthroplasty Device (RAD) – iKnee

September 20, 2022 | News

Lake Forest, CA: PFD Management/iOrthopedics Inc. (PFD/iOI) has updated its development status on the **Resilient Arthroplasty Device – iKnee.** The update includes the latest design enhancements by our engineering team at **EnginuityWorks.** The finalized prototype design, currently being reviewed by **Dr. Thomas Grotz** and **Dr. Christopher Woodson,** will be sent off to **ArBurg** for 3D Print and initial **Proof of Concept (POC)** with **First In Human (FIH)** implant and the launch of our **iKnee Comfort Study.**

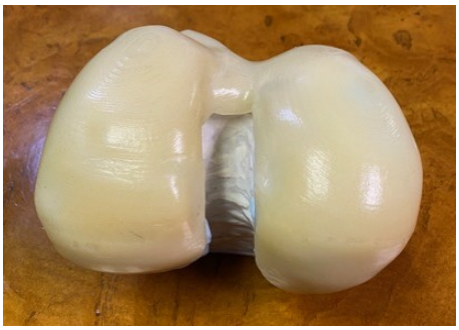
The **PFD/iOrthopedics Inc Resilient Arthroplasty Device (RAD)**, and its first product candidate the **iKnee,** has been **IRB IDE** authorized for human use in the first **10,000** qualified patients. Dr. Christopher Woodson is the **Principal Investigator** in the study. The device bridges the existing gap between non-invasive and totally invasive, ablative, barbaric, and antiquated surgery.

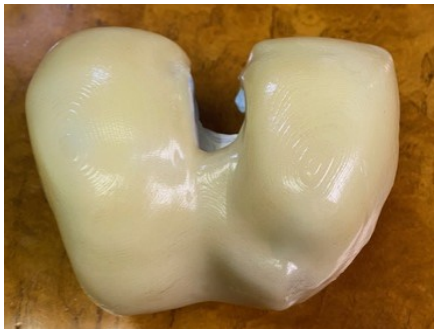
The update also shows the prototype post-production smoothing process has been approved. The prototype smoothing process occurs after the prototype is transferred from the 3D Printer and the exterior surface needs some additional refining. The smoothing process developed by **AM Technologies,** revolutionized specifically for **RAD/iKnee**, uses a green plant-based consumable solution on the **iKnee Quadrathane PU** material for optimum and exceptional results.



The images above show the **iKnee** prototype model with the perimeter borders being drawn out on the digitally prepared post sculptured processed knee of our first human candidate. The technology for the pre-surgical sculpturing was developed by **Materialise** and uses their **Mimics** software applied to CT manufacturers workstations. The images also show the **iKnee** initial drawings on the candidate's femoral head and also the actual **STL file** image to be used for 3D printing.

PFD/iOI will market the **iKnee** orthopedic implant along with the **iKnee** Revenue program to hospitals, ASCs and payers, and will market a complete program based on superior outcomes, more economical treatment and pain reduction, and improved activities of daily living (ADL).





The images above show the smoothed iKnee surface created by the POST PRO smoothing process by AM Technologies.

About PFD/iOrthopedics

The **PFD/iOrthopedics INC (PFD/iOI), Resilient Arthroplasty Device (RAD)**, and its first product candidate the **iKnee,** has been **IRB IDE** authorized for human use in the first **10,000** qualified patients. **PFD/iOI** is introducing a 21st Century, personalized, patient driven, novel and highly disruptive restorative joint salvage outpatient approach and effective solution to fill the gaping, costly, inefficient, and non-therapeutic void between pills, shots, bracings, physical therapies and limiting of daily activity for patients suffering from osteoarthritis and the much more dramatic, life altering and barbaric surgical replacement of joints with a simple outpatient procedure.

The intent was that the principle would be used in all mammalian joints: knee, hip, shoulder and such throughout the long bone interfaces (appendicular skeleton). The **Resilient Arthroplasty Device (RAD)**, also known as the **iKnee**, is a patented implantable medical device by which patients presenting with osteoarthritis will find pain relief through the padding, cushioning, and protecting of the damaged joint surfaces.

The **iKnee** will change the pain profile by covering the dominant surface of the damaged joints.

QUADRATHANE BIOMERICS

Quadrathane™ ARC is a family of aromatic polycarbonate-based thermoplastic polyurethane. It offers superior biocompatibility, superior chemical resistance, and oxidative stability for use in long term body implantable applications. It is naturally clear, hemocompatable, and is USP Class VI and ISO-10993 compliant. Quadrathane™ ARC is used across a wide range of medical applications including chronic indwelling catheters, feeding catheters, pacemaker leads, coatings, orthopedics, and other applications where superior chemical resistance is required. The iKnee will use Quadrathane ARC 70 A.

Mimics Innovation Suite 

In furtherance to complete comprehensive personalized medicine, PFD/iOI has utilized Materialise, as the industry-standard medical image-based engineering software and service, MIS puts you in control with the most advanced tools to support your mission to improve patient care. Medical image data thus serves as a powerful basis for engineers and researchers striving for solutions that will lead to safer and more predictable personalized patient outcomes.

The Mimics Innovation Suite was designed to make using medical image data for engineering purposes as easy and rewarding as possible.

PRODUCTION OF A 3D PRINTED PART DOESN'T STOP AT THE PRINTER. 

Post-processing is required to finish 3D printed parts for end-use. Traditional methods are slow, difficult to predict consistency, and can account for up to 60% of the part cost.

PostPro, developed by AMT, is a digital post-production technology platform that automates the manual and costly steps associated with legacy 1.0 'low volume and prototyping' post-processing and enables functional 'high-volume end-use parts' production from 3D printers.

PostPro allows companies to leverage the benefits of additive manufacturing at scale, by providing an order of magnitude improvement in part throughput, performance, quality, cost, and safety.

Benefits of vapor smoothing to seal surfaces for easier cleaning and sterilization are a game changer for the medical and food industries.

Vapor smoothing surfaces prevents liquid absorption, allowing for development of new applications in numerous industries. Vapor smoothing the parts in preparation for surface coating and dying will significantly reduce the time needed to get perfect results.

Repeatability and consistency of performance results, directly enable scaling up of manufacturing processes and volumes.

UNIQUE TECHNOLOGY ADVANTAGES 

- Utilize injection molding grade pellets
- Print rigid & flexible thermoplastics
- Multi-material printing – Up to 3 materials
- Very low material costs – Quadrathane specialized pellets
- Variable printing densities (high or low)

MEDICAL PARTS & MATERIALS

- FDA Approved Original Materials
- Bio-Compatible
- Bioabsorbable
- Implantable
- Drug Delivery Devices
- Clean Room Approved Usage

IRB

Under FDA regulations, an Institutional Review Board is a group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

Institutional Review Board (IRB) Services Solutions to Safeguard Trial Participants

Regardless of your project's scope, therapeutic niche, or number of investigators, Advarra is your partner in the conduct of efficient, responsible research. Objectivity and concern for participant well-being drive all review decisions.

IKNEE COMFORT STUDY

iKnee brief study description: iKnee seeks to provide temporary comfort and improved function for patients awaiting total knee replacement arthroplasty (TKA). Reasons to delay a TKA include but are not limited to need for weight loss, wound infection healing, implant availability, and required medical or psychological patient preparations. iKnee use determinations are made between the patient and care taker. The subject population is individuals with refractory disabling knee pain who failed other conservative measures and are on track for TKA. The iKnee is to provide comfort, it is not intended to treat a disease, or underlying cause leading to TKA.

Objective: To study iKnee efficacy on quality of life and activities of daily living in patients awaiting TKA. The data will be used to improve possible design to enhance patient comfort.

Procedure: A rolled polymer is inserted through a small parapatellar incision then expanded to fit and pad the distal femur, providing a stable cushion made of medical polymers used safely and reliably for decades. The procedure is expected to take about 30 minutes, involves an incision of 2-3 cm and subcutaneous tissue into the joint capsule, an incision less than one cm in depth. Then the iKnee device is inserted into the knee capsule. No muscle, tendons, or ligaments are cut.

Study Rationale: Total Knee Arthroplasty (TKA) has become one of the leading operations for senior citizens, both in cost and frequency. When a patient has a disabling knee condition limiting mobility and quality of life there is only one medical option, TKA. The TKA operation is a significant procedure, involving the removal of the bottom of the femur, top of the tibia, part of the patella to make space for the artificial metal and polyethylene prosthesis. The study is designed to increase patient quality of life, functionality, and comfort while they await the knee replacement operation (TKA). The iKnee procedure poses almost no medical risk to the patient, either as a procedure or as a risk to the patient knee as the decision has already been made to remove the joint.

Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study and;
- required records and reports.

First In Human (FIH)

A type of clinical trial in which a new drug, procedure, or treatment is tested in humans for the first time. Also called first-in-human study.

STL File

The STL file format is the most commonly used file format for 3D printing. When used in conjunction with a 3D slicer, it allows a computer to communicate with 3D printer hardware.

The STL file format has been adopted and supported by many CAD software packages. Today it is widely used for rapid prototyping, 3D printing, and computer-aided manufacturing.

Enginuity Works

Enginuity Works provides our engineering consultation for the full range of product development services; Industrial Design, Mechanical Engineering, Electrical Engineering, Prototyping, R&D, Manufacturing Management. Their approach identifies the best-fit of our own expertise and capabilities with their engineering team.

FDA Pathways

FDA designation of the **iKnee** as a **Non-Significant Risk** (NSR) Device. Pathways for commercialization to be determined based on commercialization path of purchaser of IP.

7 FDA Pathways to Bring A Medical Device to Market

1) Premarket Notification 510(k)

The **Premarket Notification 510(k)** pathway is the most common route taken when launching a medical device. Almost all Class II devices and certain Class I devices will require a 510(k).
The purpose of a **510(k) submission** is to provide the FDA with documented evidence showing that a medical device is substantially equivalent in terms of safety and effectiveness to a predicate device.

A predicate device is one that is already legally marketed and shares the same intended use and technological characteristics as the new device. The requirement is to compare and contrast the new device with the predicate by summarizing information from the design controls process, such as design features and verification testing.

The FDA typically processes 510(k) applications in 30-90 days. Depending on the robustness of the initial application, there may be a period of back and forth discussions, of which can delay the process. It is important to plan ahead and provide all appropriate documentation at the time of initial submission.

2) Premarket Approval (PMA)

Class III devices, and any device that cannot provide substantial equivalence to a Class I or Class II device through the 510(k) process, must use the **Premarket Approval (PMA) pathway.**

The PMA process is the most involved as scientific evidence, typically in the form of a clinical trial, is needed to prove the safety and effectiveness of the new device.

The FDA will either approve or reject the application within 180 days. The different steps of the review process include:

1. FDA staff will determine completeness through an administrative and limited scientific review
2. FDA staff will conduct an in-depth scientific, regulatory, and Quality System review
3. An advisory committee will review and offer any recommendations.
4. Any final deliberations will occur, and the FDA will document and notify the applicant of their final decision

Although the premarket approval process sounds intimidating, it is the right option for a high risk, Class III device.

3) De Novo

If the applicant is developing a lower risk, “novel” device and struggling to find a predicate, the **De Novo** pathway might be the best option.

The De Novo pathway has actually been around since 1997 but many people do not know about it since it is not very commonly used. Companies that do not qualify for 510(k) clearance, due to the fact that they cannot provide substantial equivalence to a device on the market, should learn more about the De Novo pathway.

Since comparison to a predicate is not needed, companies have a "blank canvas" when it comes to labeling and can set a standard that may give them a competitive advantage over others. One of the key things to remember about the De Novo pathway is that the device must present low to moderate risk through a robust risk mitigation strategy.

4) Humanitarian Device Exemption (HDE)

The **Humanitarian Device Exemption (HDE)** pathway is for devices that are intended to treat or diagnose conditions or diseases that affect small or rare populations.

This pathway involves a two-step process. The FDA must grant a Humanitarian Use Device (HUD) exemption and the device company must then submit an HDE application to the appropriate review center.

Another important requirement is that there cannot be another comparable device on the market that shares the same intended use. The FDA will consider the following when determining if there are comparable devices on the market:

- The device's indications for use and technological characteristics.
- The patient population to be treated or diagnosed with the device.
- Whether the device meets the needs of the identified patient population.

Part of the rationale for providing this pathway is there may not be a large enough patient population with clinical data to satisfy regular FDA requirements of safety and efficacy. Since these devices may be very crucial to patients with rare conditions, the FDA put it in place to do a proper review to determine if the device can be sold.

5) Custom Device Exemption (CDE)

Is the company developing a custom device for a specific patient? If so, the device falls under the **Custom Device Exemption (CDE)** pathway and must meet a very narrow set of criteria.

The device must be created or modified in order to comply with the order of an individual physician or dentist, typically in the form of a prescription. Not only must the clinician order the device, but it must also be used in the normal course of the professional practice of that physician or dentist.

The product should be specifically designed to treat a unique pathology or physiological condition that no other device is domestically available to treat. It must be assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of the patient.

The FDA even states that companies are limited to no more than 5 units per year of a particular device type.

CDE devices are exempt from PMA or 510(k) submission process but the company still needs to comply with the following regulations:

- Design Controls (21 CFR Part 820)
- Medical Device Reporting (21 CFR Part 803)
- Labeling (21 CFR Part 801)
- Corrections and Removals (21 CFR Part 806)
- Registration and Listing (21 CFR Part 807)

6) Expanded Access Program (EAP)

The **Expanded Access Program**, often referred to as the compassionate use or emergency use provision, is fairly self-explanatory.

It allows an investigational device to be used, outside of a clinical trial, in situations where a seriously ill patient has few if any alternatives.

Although there are often ethical considerations, it may be appropriate to evaluate this option as a way to get early feasibility data for high-risk devices, especially when suitable animal models are unavailable. Like the HDE, this data could then be used to expand the label in the future.

Expanded access may be an appropriate pathway for you to choose when all the following apply:

- Patient has a serious disease or condition, or whose life is immediately threatened by their disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible.
- Potential patient benefit justifies the potential risks of treatment.
- Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

7) Product Development Protocol (PDP)

The **Product Development Protocol (PDP)** is a subset of the PMA process that allows for another pathway for companies with devices in which the technology is well established in the industry.

This pathway allows the company to come to an early agreement with the FDA about how safety and effectiveness of the device will be shown. The two parties are essentially creating a contract that describes design and development activities, including the outputs of these activities, and acceptance criteria for these outputs.

The company can follow the plan on their own time and report back to the FDA on the agreed upon milestones. At the end of the process, the company is considered to have "completed" a PDP, which gives them an "approved" PMA.

PFD Managers, Sponsors and Fund Relationships

PFD Capital Partners, INC

- PFD Capital Partners, INC, is Managing Sponsor of the PFD Management Opportunity Fund, LLC (PFDMOF3001)
- www.PFDCap.com

PFD Management, LLC

- PFD Management, LLC, is the account receivable origination, underwriting and auditing portfolio manager of PFDMOF3001
- www.PFDManagement.com

PFD Management 1000 Series Funds, LLCs

- PFD Management Funds 1001 – 1007 have in excess of USD $400M assets under management

PFD Management Opportunity Fund 3001, LLC (PFDMOF3001)

- PFDMOF3001 is a venture fund holding company consisting of Medical Account Receivables and 5 core medical technology products.
- www.PFDMOF3001.com

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