

FOR RELEASE

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PFD Management Opportunity Fund 3001, LLC Announces:

Announced today by Eric Hansen, Clinical/ASC Operations Manager for the PFD Management Opportunity Fund 3001, LLC, additional information related to its PFD/iOrthopedics portfolio project.

ADVARRA Extends Contract To Act As IRB for PFD/iOI iKnee Research Studies

PFD Capital Partners, LLC is releasing the following information about the progress of one of the medical technology companies within the **PFD Management Opportunity Fund 3001, LLC. PFD/iOrthopedics, Inc. (PFD/iOI)** has been in the development of an innovative solution for individuals with severe debilitating joint issues related to injury or Osteoarthritis (OA).

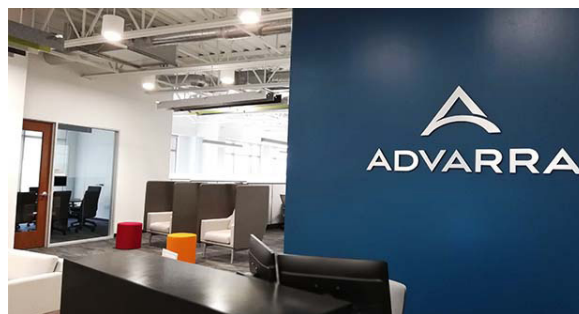
As has been discussed in previous releases, **PFD/iOI** is the developer of several novel, patented medical devices that are all focused on bringing renewed function to patients suffering from a variety of orthopedic issues. Specifically, over the past two years, the company has focused on the development of its **Resilient Arthroplasty Device (RAD)** technology and its first product candidate using the **RAD** technology; the **iKnee**.

The **iKnee** was created to fill the gap between the costly, inefficient, and non-therapeutic conservative care approaches and the invasive metal joint replacements of a Total Knee Arthroplasty (TKA) that limit care options to deal with knee pain and reduce daily activities and quality of life for patients suffering from osteoarthritis. By creating an arthroscopically implantable device that does not require the wide open joint resection in a patient, with the removal of large sections of bone, and the implantation of heavy hardware made from metals and hard polyethylene prosthetics, the **RAD/iKnee** allows a patient to be back on their feet in less time, at a lower cost, and with less chance of complications as those of TKA's.



PFD/iOI's iKnee technology will provide an important alternative to invasive surgery currently used to alleviate knee issues.

Today, **PFD/iOI** announced that its agreement with Advarra, Inc. to act as **PFD/iOI's** Investigational Review Board (IRB) partner has been extended for another year. This announcement helps solidify preparations for the first-in-human implantation of its **iKnee** technology which is scheduled for Q2/2024.



Advarra, Inc. is headquartered in Columbia, Maryland seven additional offices located around the world. Pictured on the left is Gadi Saarony Advarra's CEO and Lukle Gelinas, PhD, the Senior IRB Chair Director and chief contact for the PFD/iOI project.

In conducting clinical trials, the FDA requires the IRB to conduct reviews and assessments related to investigations. In various contexts, the IRB evaluates and oversees investigations into the ongoing development and research related to specific medical devices and procedures to ensure protocols and documentation meet the requirements of the regulatory bodies that determine the advancement of technology into an accepted standard of care that provides benefit and safety to the patient, the community, and the healthcare field as a whole. The IRB ensures objectivity and impartiality and operates independently of the parties directly involved in the investigated matter. This independence helps in providing a fair and unbiased assessment.



The PFD/iOI iKnee is manufactured at the RAD/iKnee Lab at its Los Angeles facility. The composite printing is performed by the Arburg Freeformer using Quadrathane, an implantable medical grade polycarbonate material

Advarra, Inc. is the largest provider of IRB services in North America. More than 3,500 hospitals, research facilities, healthcare systems, and academic centers rely on Advarra, Inc. for providing trusted and comprehensive IRB review of their processes and procedures. Advarra, Inc. has provided services for more than 1,000 federally funded research programs and has been a key partner for several medical device technology companies in bringing new and novel innovations to commercial acceptance.



Over the past year, **PFD/iOI** has been working with Advarra, Inc. in preparing the protocols, QMS, and data recording processes for its upcoming first-in-human study. All the pre-operative certification requirements have been completed and ten **iKnee** prototypes have been manufactured, passed Cytotoxicity Testing, and have been certified for the procedure. The FIH implant of the **iKnee** will be conducted at the Memorial Care Surgical Center in Long Beach, CA. later this year. Eric Hansen, who is **PFD's** Director, Co-Founder, and Clinical/ASC Operations Manager, has been selected as Patient One in the study's cohort group. The surgery will be performed by **PFD/iOI's** Chief Investigator, Dr. Christopher

Woodson, who is a board-certified orthopedic surgeon and sports medicine physician, and founder of Beach Orthopedic Specialty Institute.

This first implant will be part of **PFD/iOI's** ongoing **iKnee Comfort Study** which is being done to determine the **iKnee's** impact on quality of life issues and its ability to allow normal activities of daily living in patients awaiting TKA. The data will be used to improve possible designs to enhance ideal patient comfort.

The **PFD/iOI Comfort Study** is designed to allow **PFD/iOI** to gather critical data in three major areas:

- The ability of the patient to tolerate the **iKnee** implant both from a bio-compatibility standpoint and an ortho-comfort level.
- The ability of the **iKnee** implant to decrease or eliminate the patient's pain level as it applies to the use of the impacted joint.
- The ability of the **iKnee** to maintain or expand the patient's quality of life as it pertains to daily activity, leisure and recreational movement, and active sports engagement.

In addition, the study will be looking at additional areas of impact including the **iKnee's** ability to provide better patient outcomes, faster recovery, lower cost, and lower risk.

PFD/iOI is very proud to have Advarra, Inc. continue to be a strategic partner as it moves to bring its novel **RAD** technology to the world.

[**CLICK HERE TO VIEW THE AGREEMENT TO CONTINUE**](#)

SAFE HARBOR DECLARATION

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Eric Hansen, patient one for the iKnee Comfort Study, and Dr. Christopher Woodson discuss the upcoming surgery which to correct the decade long disability Eric has been living with.