

Praxis Medical DevicesRevolutionizing Biopsy Procedures

hice its introduction in 1879, biopsy as a diagnostic avenue has helped the healthcare and medical communities tackle the management and treatment of several clinical conditions. However, the most minimally invasive approach to collecting cells from a patient's affected organ has more or less

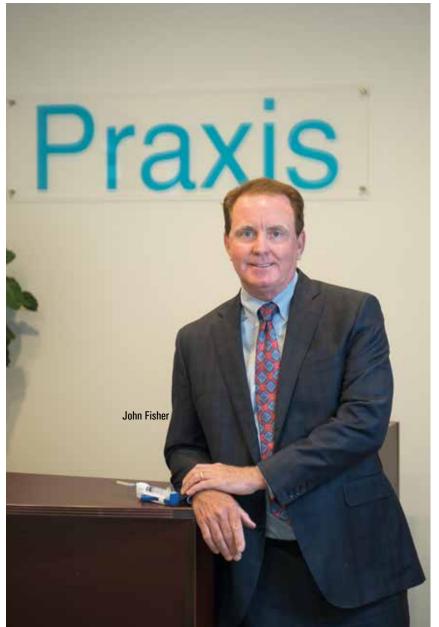
been the same in the last 150 years. Even today, physicians often have to perform multiple needle passes to obtain the cell collection necessary to run further tests effectively. And with the repetitive nature of the existing approach, most physicians lose valuable time that could be spent performing other critical tasks; also,

the longer procedure times drive undesirable anxiety among patients. So how can healthcare professionals improve the cellular yields of their biopsy procedures while minimizing instances of patient discomfort?

Florida-based Praxis Medical

Devices has the answer. A trailblazer in soft tissue biopsy, Praxis Medical Devices has developed a unique minimally-invasive device, CytoCore, that leverages its patented rotating soft tissue collection method to significantly boost cellular yields while using small gauge needles. After performing extensive research and development studies, Praxis' team recognized that rotating the beveled tip of a fine needle yields significantly increased cellular material when compared with the traditional approach. Subsequently, the company patented this method and developed the CytoCore to help clinicians save time and resources while driving enhanced patient compliance with biopsies.

At its helm, the company has John Fisher, who has two-decade experience in inventing, patenting, and launching MedTech devices. Fisher leveraged his expertise and network of partners to gain ergonomic feedback from doctors and pathologists before utilizing a comprehensive distribution network to boost the release of his CytoCore product, "Unlike traditional fine needle aspirations (FNA) that need at least three passes, the CytoCore product allows clinicians to acquire the desired volumes of cellular material in as few as one pass," says John Fisher, CEO at Praxis Medical







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Devices. The company launched CytoCore in the U.S. in the middle of the COVID-19 pandemic—July 2020—and since then, has gained its CE mark approval, which will allow the company to release the product in the EU, Middle East, and the world at large. And as the pandemic drove a meteoric surge in patient volumes, CytoCore quickly became a mainstay for clinicians as it allowed them to significantly lower the time taken for biopsy procedures.

CytoCore is designed to harvest more cellular material in fewer passes, and the product achieves this with its proprietary spinning motion that enables needles to shear off large intact clusters of cells. From a design standpoint, CytoCore is compatible with a variety of needle gauges and lengths, has an ergonomic slide switch that draws back to initiate a single stroke motor,

and includes a 5ml syringe with adjustable suction. This allows the product to perform in any soft tissue, be it lymph node, parotid, thyroid, lung, and/or any other mass of cells. Furthermore, CytoCore showcases minimal bleeding complications and risks compared with more invasive biopsy devices such as core biopsy CytoCore's ability to obtain such significant cellular yields has also boosted its usage in cancer patients as an avenue to determine point mutations without the need for multiple biopsy passes or larger gauge, firing biopsy devices.

According to Fisher, CytoCore will revolutionize the soft tissue biopsy space and become a new gold standard of care. "We are continuously working hard to showcase the efficacy of CytoCore in enabling better patient experiences as the product is a paradigm-shifting device in the world of biopsies," explains John. To achieve this, Praxis Medical Devices leverages its expert customer support personnel to help doctors and clinicians become comfortable with the new way of performing biopsies while maximizing CytoCore's efficacy.

Moving forward, Fisher aims to launch a second product called EndoCore that leverages the same oscillating capabilities of CytoCore to enhance the efficiencies of bronchoscopy and GI endoscopy procedures. The company is presently in the advanced development stages of the EndoCore device, with diligent work being put in to acquire FDA and CE mark approvals. "We have seen that our oscillating mechanism and the wonderful results that we're getting in image-guided, CT, and ultrasound-guided biopsy, will be replicated with the bronchoscopy and endoscopy biopsy," concludes Fisher.