OnePass medical operates within the Endoscopic ultrasound-guided fine-needle aspiration biopsy (EUS-FNA/B) domain.

EUS-FNA/B is a useful procedure that is used to diagnose both tumor and inflammatory lesions located in and adjacent to gastrointestinal tract.

In recent years, a pathological diagnosis based on EUS-FNA/B has made it possible to provide accurate treatment methods in other fields such as in respiratory organs and otorhinolaryngology.

EUS needles are widely used for collection of specimens from the liver and the lymph nodes for diagnosis of cancer and other chronic diseases, while most of the procedures are being done on the Pancreas.
Pancreatic tumor is currently the 7th leading cause of cancer related deaths in the industrialized countries, the 3rd most common cause of cancer related death in the US and is anticipated to be the 2nd most common cause by 2030.

EUS-guided FNA (EUS-FNA) is an established technique for tissue acquisition and is considered the most sensitive imaging tool for evaluation of malignant and benign pancreatic lesions.

Pancreatic endoscopic ultrasound-guided FNA diagnosis has a very low false-positive rate. The major cause of a false-negative cytology diagnosis is due to sampling error.
Today’s Endoscopic Biopsy Solutions are Not Sufficient

- **High False Negative Results Up To 20%-40%** (strongly dependent on the clinical center)
- **Difficult to Perform**
  - Require Significant Training
- **Time Consuming**
  - Performing the same procedure for 5-7 times.
  - The assistance of rapid on site evaluation (ROSE) is also needed
- **Vulnerable to Technical Malfunction (Needle Kinking-15%)**
  - During multiple passes, the risk of needle buckling or kinking increases, *Meaning (1) There is a need for an additional needle (costs) (2) The endoscope’s working channel can be damaged and prevent the doctors from continue the procedure*
Our Solution: OnePass’ InstaFan™

- Safety release button of the peripheral needle
- Peripheral needles handle
- Central needle handle
- Central, single 22 gauge needle and handle
- Four peripheral 25 gauge pre-bent needles with handle
- Peripheral needles safety activation mechanism
How Does InstaFan™ Work?

The InstaFan™ device is easy to function and deployed in a more convenient way than standard needle.

In the middle of the device you have 22 gauge needle (FNB) while in the periphery there are four 25 gauge needles (FNA).

The physician can choose weather to discard only the central needle (22 gauge needle (FNB)) or the all five needles.

Addressing the procedure’s final outcome:

- No bleeding
- No leak
- No damage to the tissue
- Good histology specimen

https://www.dropbox.com/s/ppbj345188eyupb/InstaFanNeedleDevice.mp4?dl=0
Key Benefits

• Cuts procedure time in half which both lowers procedure cost and allows for more patients per day
• Reduced needle costs (In 15% of the cases the needle is kinked) which can also damage the endoscope’s working channel and prevents the doctor from continue to work
• Decreases the need for on-sight cytopathologists which further reduces procedure cost

• Lowers the false negative effect. Effective tumor diagnosis due to better sampling distribution; hence-Saving lives!
• Lowers probability of complications and Repeat visit

• Eliminates procedure complexity and reduce time while getting better result in only One pass.
• Tilting of the needle requires high skilled doctors, InstaFan ease the process

• Can be used as a single needle or use all needles as suits to the doctor’s needs.
North America dominates the market
With $310 Mn in sales, 2019

Asia Pacific is expected to emerge as the second lucrative region
CAGR 8%

CAGR 4.9%
2019-2025
Market Drivers

Technology

- EUS is the superior and preferred way to visualize pancreatic tumors (over CT and MRI)
- Rising Preference for Minimally Invasive Surgeries
- Technological advancements in EUS biopsy needles
- Additional applications such as bronchial endoscopy and endoscopy of organs other than the gastrointestinal organs are likely to offer growth opportunities to the global endoscopic ultrasound needles market in the near future

Disease

- New pancreatic cancer incidence is on the rise internationally. Hence, the use in simpler procedures such as EUS-FNA/B as a preventive measurement can be highly useful
- Growing geriatric population coupled with rising prevalence of disease such as gastrointestinal, lung, liver and hepatobiliary and pancreatic worldwide.
- Pancreatic cancer diagnoses account for 3.2% of all cancer diagnoses but account for a staggering 7% of all cancer deaths
- Rising awareness about healthcare and increasing healthcare expenditure
- Rise in the investment by governments across countries in the healthcare sector
Market players

The global endoscopy device market is highly competitive and the prominent players in the market have adopted various strategies for increasing their market share.

August 2017
PENTAX Medical announced the launch of the Slim Linear Ultrasound Endoscope in US.

May 2018
Olympus Corporation announced a strategic alliance with Hitachi Medical Systems Europe.

June 2018
Olympus corporation and Hitachi Healthcare announced a distribution agreement in the US for ARIETTA 850, an ultrasound processor.

PENTAX Medical

Olympus Corporation

Hitachi Medical Systems Europe

ARIETTA 850, an ultrasound processor.
## Main Competitors

<table>
<thead>
<tr>
<th>Company</th>
<th>Needle Type</th>
<th>Cost (USD)</th>
<th>Added Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>OnePass Medical</td>
<td>*InstaFan</td>
<td>350</td>
<td>5 site biopsy in one pass</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Beacon EUS Delivery System with SharkCore FNB preloaded needle</td>
<td>464 (22 Gauge, 25 Gauge) 750 (19 Gauge)</td>
<td>Needle tip has parallel geometry with 2 cutting edges. Same delivery system as FNA needles</td>
</tr>
<tr>
<td>COOK Medical</td>
<td>Echotip ProCore FNB</td>
<td>410</td>
<td>Beveled core trap hole near needle tip. Needle dimpling to improve visualization</td>
</tr>
<tr>
<td></td>
<td>Echotip Ultra Coil Sheath FNA</td>
<td>315</td>
<td>Coil sheath with increased flexibility</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Expect Slimline FNA</td>
<td>357</td>
<td>fiducial marker compatibility, strong cobalt chromium construction against kinking</td>
</tr>
<tr>
<td></td>
<td>Acquire FNB</td>
<td>395</td>
<td>capability for chemotherapy injection</td>
</tr>
</tbody>
</table>

*Key takeaway: OnePass’ pricing strategy is at market prices*
Upcoming Milestones

2018
Founded

October 2018
Incubated by Galil Ofek (3M NIS)

2019 Successful POC

2020
Now:
• Raising 4M USD (1M USD is secured, they are raising 3M USD)
• First in man study

H1-2021
510K submission

H2-2021
Expected Marketing Clearance

*Prior to the founding of OnePass the company stems from FNA Technology founded in 2013
OnePass’ Strategic Channels

Product as a Platform

- Therapeutics
  - Drug Delivery
  - Chemotherapy
  - RF Ablation

- Prevention
  - Early detection as the procedure is easy and fast

- Diagnostic
  - A variety of additional biopsies options such as for prostate cancer

Go To Market Channels

- GPOs
  - Sell to hospitals via GPOs (Group Purchasing Organizations).

- Hospitals
  - GPO purchases represent about 75 percent of total hospital supply purchases.
Shifting Focus of Care: From Sick care to Healthcare to Health

- Chronic disease human and financial costs are the key driver of health system costs globally.
- To impact the large population of chronic disease patients – while lowering costs – requires leveraging technology and lower cost clinical personnel.
- Technologies that increase engagement, automate interactions, and screen individuals for risk assessment will contribute to care delivery transformation.

Healthcare Spending by Type of Activity, Global, 2007–2025

<table>
<thead>
<tr>
<th>Year</th>
<th>Prevention</th>
<th>Diagnosis</th>
<th>Treatment</th>
<th>Monitoring</th>
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<tr>
<td>2007</td>
<td>10%</td>
<td>70%</td>
<td>15%</td>
<td>5%</td>
</tr>
<tr>
<td>2012</td>
<td>12%</td>
<td>64%</td>
<td>17%</td>
<td>7%</td>
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<tr>
<td>2025</td>
<td>16%</td>
<td>51%</td>
<td>21%</td>
<td>12%</td>
</tr>
</tbody>
</table>

Source: Frost & Sullivan
Our Unique Advantages

OnePass aims in receiving FDA clearance (510K pathway) as soon as Q4-2020

InstaFan™ is Cost Competitive

Due to the device smart design, it is impossible to sample the same site twice

Reimbursement codes are in place

The use in InstaFan™ reduces false negative rate, thus saves lives.

The use in InstaFan™ reduces the complexity of the procedure

Physicians have the flexibility to deploy one or all fine needles
Our Team

Jesse Yishai Lachter
Inventor

Jacob Ben Arie
CEO
B.E. & MBA EE.

Eli Ben Porat
Head of Business Development

F R O S T & S U L L I V A N
<table>
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<td>G&amp;A</td>
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<tr>
<td>R&amp;D</td>
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<tr>
<td>M&amp;S</td>
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</tr>
<tr>
<td>Operation Cost</td>
<td>332,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>????</strong></td>
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</tbody>
</table>
Thank you

jacob@onepassmedical.com
+972-4-7799729

F R O S T  &  S U L L I V A N