LEONI

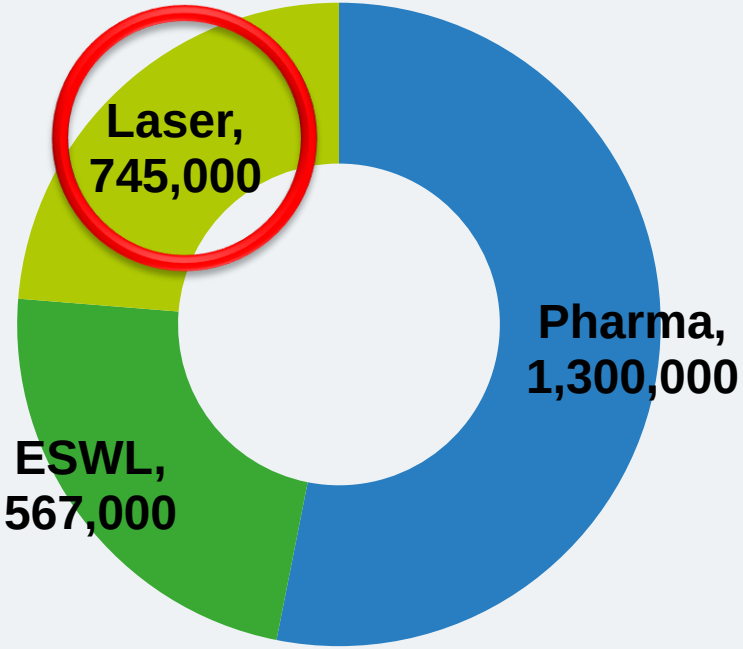
Lithotripsy Market Size

ESWL

1. Non-invasive treatment
2. Designed in Germany in 1980 by Dornier GmbH
3. Utilizes external acoustic sound waves to break-up stones
4. Physician owned companies in the U.S.

Holmium Laser

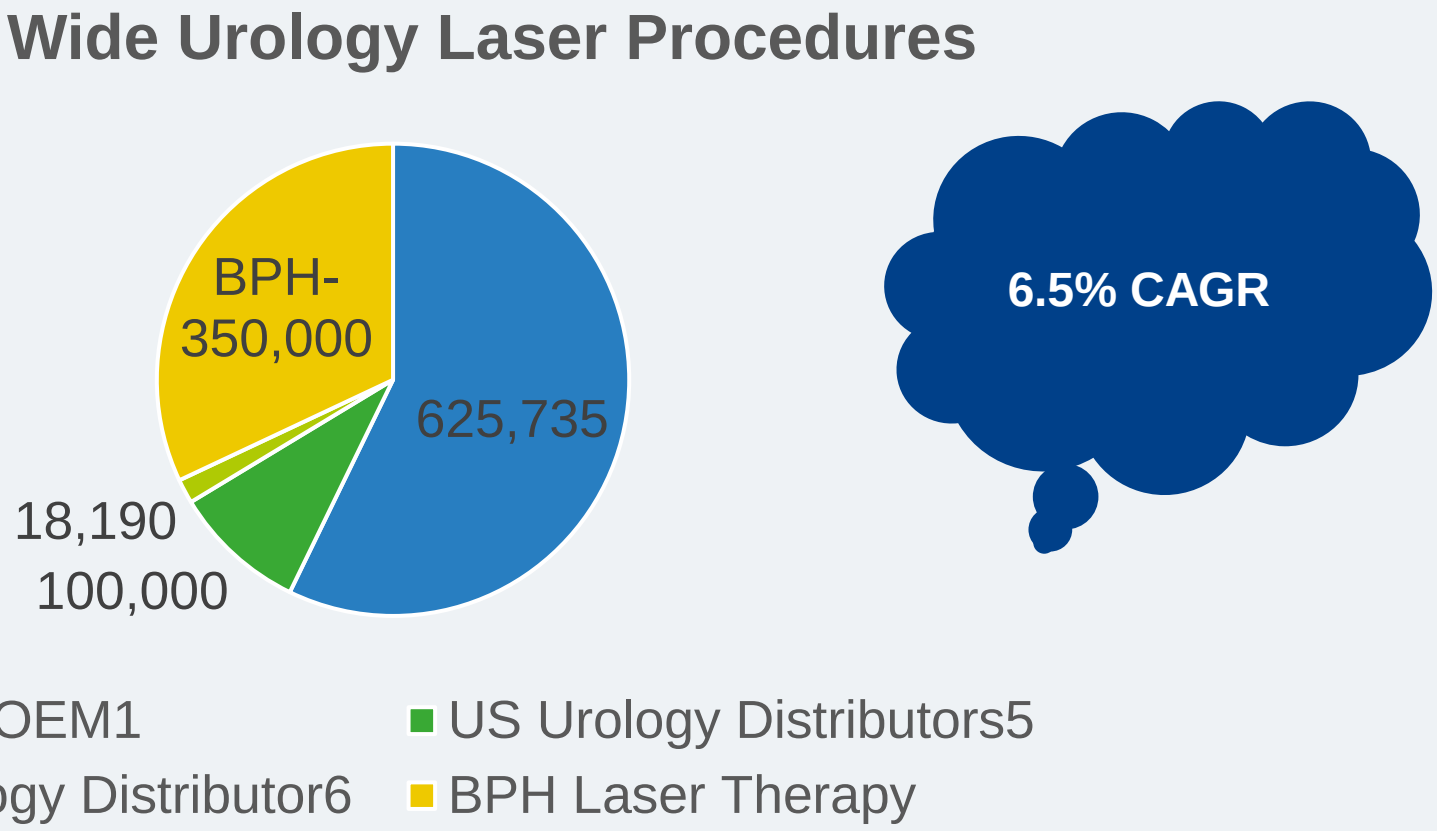
1. A laser fiber delivers 2.1nm laser energy to the stone to break it up.
2. Minimally invasive procedure performed in a hospital OR setting
3. ~4% CAGR Globally[3]



1. Wikkipedia
2. Chart Data: National Kidney Stone Foundation
3. 2016 Global Medical Laser fiber Market Report

Global Market Volume

Laser Lithotripsy/Laser BPH Therapies



Market Challenges For Manufacturers

Regulatory

- Implementing MDR for specialty FO medical device manufacturers like LEONI
- Increasing scrutiny and oversight from notified bodies for product entry into new global markets

Consolidation

- Global mergers of med device companies means less competition and stifled R&D/new product development
- Puts negative price pressure on FO medical device companies—especially holmium laser fibers

More Options For Patients

- Non-laser treatments for BPH offer:
  - Local anaesthesia
  - Fast procedure usually less than 1 hour
  - Office based

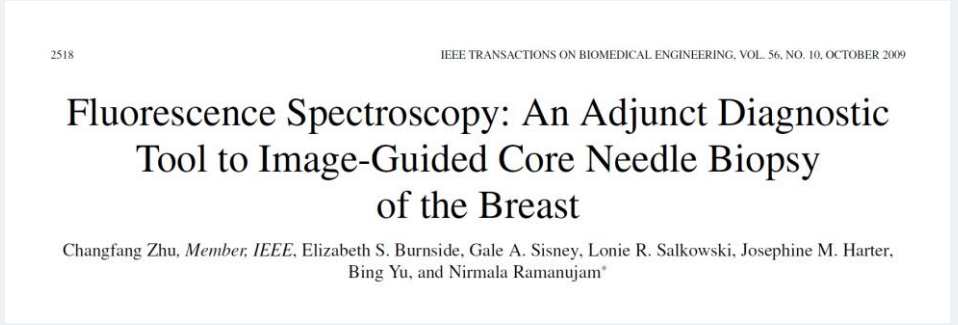
Technological Challenges For FO Manufacturers

- **Ongoing “Power War”**
  - To increase effective vaporization during laser BPH procedures, laser manufacturers keep increasing power output
    - Silica fibers and capillaries have a limit, especially depending on the laser wavelength
    - In the past 5 years, average power for a holmium laser litho procedure increased from 12.5w to 22.8 watts citing harder stones
    - Smaller core sized fibers
- **More Hertz Please!**
  - Increased repetition rate for holmium lasers constrains connector design and assembly
  - Extremely high reps can damage the fiber core and cause burn-back effect
  - Assembly is still largely not automated due to alignment of fiber into the connector

Emerging Technology: Raman Spectroscopy for cancer detection

LEONI has partnered with several OEMs and start-ups to gain relevant experience in Raman spectroscopy for cancer cell detection

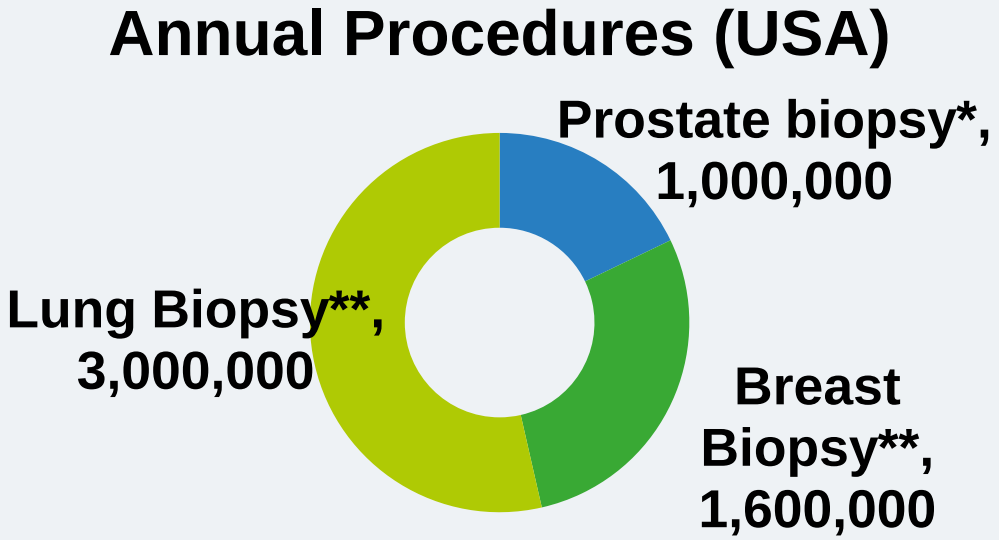
LEONI's Raman Spectroscopy Strategy:
"*Replace bulky filters, optics, apertures,etc.in the back of the probe with advanced fiber optic fibers developed and manufactured by LEONI*"



2518 IEEE TRANSACTIONS ON BIOMEDICAL ENGINEERING, VOL. 56, NO. 10, OCTOBER 2009

Fluorescence Spectroscopy: An Adjunct Diagnostic Tool to Image-Guided Core Needle Biopsy of the Breast

Changfang Zhu, *Member, IEEE*, Elizabeth S. Burnside, Gale A. Sisney, Lonie R. Salkowski, Josephine M. Harter, Bing Yu, and Nirmala Ramanujam*



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