

Case History 35

Optical Cancer Detection

Market

Ob-Gyn

Client Type

VC-funded Startup (MediSpectra)

Unmet Need

The standard of care in the US for cancer screening during colposcopy (visual examination of the vaginal cervix) is excisional biopsy and histology. However, diagnostic accuracies for this procedure were poor, so an improved screening methodology was needed during gynecological examinations.

Approach

The system was positioned as an adjunct to colposcopy. It was custom developed from the ground up to meet specific clinical needs. Multi-site studies were completed, and the system received PMA clearance from the FDA.

Product Features

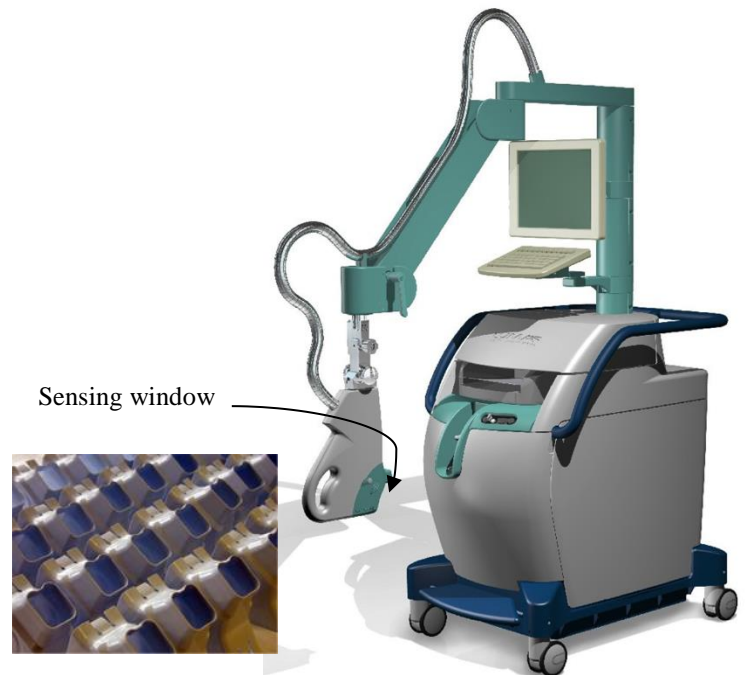
The system is comprised of capital equipment (at right, above) and a single-use disposable (at left, above). The capital equipment includes a nitrogen laser with raster scanning, white light illumination system, spectrometer, video camera, and control electronics. The disposable is placed over the sensing window of the instrument, where it comes in close proximity to the patient. With the patient's cervix exposed by a vaginal speculum, the sensing window is positioned at the opening of the speculum and aimed at the cervix. A live, white light video image is displayed in real time, while the nitrogen laser scans the cervix. At each scan point, the spectrometer captures fluorescence and diffuse reflectance data from the tissue. These data are processed and overlaid on the white light image of the cervix using false color rendering. Red indicated areas suspected of carcinoma in situ. This display then guides an excisional biopsy of the suspicious areas. Clinical study results showed that this "guided biopsy" technique resulted in a significant increase in diagnostic accuracies. All of the measurements are taken through the window of the disposable. This window had to have very low transmitted wavefront error, high transmittance at UV and visible wavelengths without fluorescing, an anti-fog coating, and very low cost.

Areas of Expertise Provided by OTI

- Disposable concept development
- Optical-, mechanical-, and opto-mechanical engineering, including injection molded part development
- Prototype fabrication & design verification testing
- Supply chain development
- Design & fabrication of assembly & test fixtures
- Pilot product of 3000 units, including test & packaging

Client Comment -- "Optimum was charged with developing this disposable with very high optical requirements and a very low cost point. They carried the ball from concept through low volume, FDA-compliant production. This was a key assignment, because the disposable was a critical component for capturing procedure revenue".

-- David Dalke, Vice President of Development



The optical cancer detection system (at right is used during colposcopy). A disposable cover (at left) provides a clean barrier.

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