NEXT GENERATION

Remote Diagnostics System Development

Why develop your own **Smart Capsule-Based Diagnostics** and **Delivery Systems**?

StarFish MEDICAL

No strings attached:

Endoscopy has been state-of-art since 1853 but is limited in reach (literally) and needs to be tethered to the operator.

Even modern PillCam® devices require the patient to wear an external communications antenna and relay.

The smart capsule approach eliminates the need for external communications and intervention through clever design and advances in electronic and mechanical engineering.

A Smart Capsule Platform-Based System cuts the tethers and allows for truly remote patient diagnostics.

Food for thought:

The digestive system is a complex, convoluted **30-foot** pathway with multiple specific regions of anatomy.

On average, transit times take **36 hours** but that time varies greatly from patient to patient.

To meaningfully sample, treat or analyze one of the largest, most complicated organs in the human anatomy, an autonomous, smart capsule-based approach is a clinician's best option.

Sample, treat or analyze:

Current platforms, like the PillCam®, can provide real-time images, but that's all.

In contrast, a Smart Capsule-Based Diagnostics and Delivery Systems can be configured to image, sample, analyse and even treat a specific area—marking a significant departure from simple imaging.

StarFish Medical has helped clients develop the following capsules:

- A capsule that can acquire targeted biopsies or microbiome samples, obtain preserved samples from specific targeted regions of the digestive tract and return safely for research and external analysis.
- A capsule that can provide targeted (temporal and anatomical) delivery of specific high value therapeutics and provide real time monitoring.
- A capsule that can acquire a specified sample from the GI tract and perform real-time analysis of the sample with an on board photo spectrometer and then transmit the data to a wrist-worn receiver in real time.
- Capsules are custom manufactured under ISO13485 design control in-house at low volume (100s to 1000's of capsules) for early prototyping and clinical trial development.

But wait there's more... Peripherals:

The various capsule architectures (sample, treat, analyze) have bespoke companion peripherals designed to support the specific applications:

Clinical deployment capsules interact with a physician medial application (PMA) that can be configured to receive 433MHz data (signed/encrypted) from the capsule via the wrist-worn receiver and communicated through a HIPAA compliant cloud-based private network.

Research recovery capsules have discrete capsule recovery systems and bespoke sample extraction and preservation technologies and procedures that are custom designed to be implemented in standard clinical diagnostic lab work flows.

On board diagnostic systems acquire and transmit data that can be integrated into secure LIMS architectures.

Outer Space Vs. Inner Space:

The space program presented engineers with an extremely challenging use case.

The NASA program in the 1960s lead to a rapid technology development fueled by the significant engineering challenge of putting a man on the moon.

This resulted in the development and spin off of major technologies we rely on today.

In the same vein, the challenge of overcoming the autonomous exploration of the **inner space** of human anatomy has led to the cultivation of a unique skill and tool set that StarFish engineers can bring to your next medical device engineering challenge!

On-board capabilities

Power Supply
- 3 year shelf life
- 4 day operational life
- Custom with associated power requirements (SiPMT)

On Board Sample Analysis
- Silicon PMT (low photon count capabilities)
- Integrated LFI and on board reader
- On board optical analysis
- Photospectrometer

On Board Data Processing
- Flex rigid PCB to position sensors and connect components in challenging geometry
- Integrated Sensors: Temperature, pH, optical, hall effect sensor, reed switches

Autonomous Localization Algorithms
- Autonomous Localization sensing to determine bulk position within the GI tract (with or without external worn guidance)
- Custom localization algorithm design
- Integration of multi-sensor input for precision localization

Radio Frequency Communications
- 433MHz data (signed/encrypted)
- 2.4 GHz receiver ISM band
- Near field communications (~3m) 2 way to wrist worn receiver
- Custom antenna design with functional and safety emissions verification protocols

Drug Delivery Subsystem
- Integrated micro DC (high gear ratio) drive motor with challenging movement scheme with constrained power draws.
- On board H_2 generation subsystem as motive force for delivery and sampling subsystems

Sample Acquisition, Preservation and Archiving
- Multi cavity independent sampling 50µL to 1000µL (Pr- and RNA preservation) Localized or time-based triggering events.
- Capillary microfluidic subsystems
- Integrated analyte preservation architectures

Custom Hull Design
- pH resistant Hull
- Hull resistant to contamination and peristaltic pressure
- Variable hull dimension 000 through 5
- Micromachined or IM with vapor polishing to facilitate optical requirements

Cloud Enabled Data Sharing
- HIPAA compliant
- Cloud based private network
- Physician Medical Application (PMA)

On Board Data Storage
- On board storage for data buffering pre-communications or fully autonomous operations

StarFish MEDICAL

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