

FUTURE OF BIOTECH

1:45-2:45PM

BEACH
WOMEN IN
ENGINEERING

CONFERENCE 2022

CSULB COLLEGE OF ENGINEERING | 100+ Women Strong

#BWIE22

**FUTURE OF
BIOTECH**
Moderator



WAN JAE LEE

Lecturer, CSULB Department of
Chemical Engineering

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FUTURE OF BIOTECH

Speakers



HANA MOSHIRVAZIRI

Technical Program
Manager, Medtronic



ELIZABETH RONEY

Systems Integration
Engineer, Thermo
Fisher Scientific



DINAMARIE STEFANI

Divisional Vice
President, Abbott



SHOBA VARMA

Systems Integration
Engineer, Thermo
Fisher Scientific



SERENE WACHLI

Group President,
Applied Medical

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Dinamarie Stefani

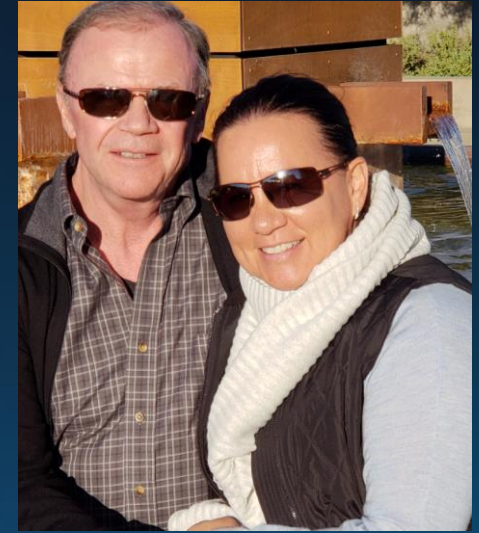
- Divisional Vice President QA & Compliance @ Abbott diabetes care division
- 25+ years in Pharma and Medical Device Industries (R&D, IT, Clinical, QA)
- BS Engineering, emphasis in Biomedical & Clinical Engineering, CSULB



- MS Jurisprudence-Pharma & MedDev Compliance & Law,



- Harvard Business Analytics Program





Abbott

life. to the fullest.®

Abbott at a glance

109,000

PEOPLE

130+

YEARS IN BUSINESS

160+

COUNTRIES

\$34.6B

2020 SALES

TRUSTED PRODUCTS

FreeStyle Libre[®]



MitraClip[®]

Similac[®]

Alinity

Ensure[®]

ID NOW[™]



Xience

BRUFEN[®]

Abbott has more than 100,000 global employees!



What types of engineers are involved in medical devices?

• ROLES

- Feasibility/Research
- Design
- Development
- Testing
- Clinical
- Quality
- Regulatory
- Manufacturing
- Sales
- On-market support
- Marketing



• ENGINEERING DISCIPLINES

- Biomedical
- Chemical
- Software/Computer
- Electrical
- Materials
- Hardware
- Mechanical
- Process/Systems
- Data
- Industrial
- Environmental

We help people live fuller, healthier lives, maximizing their potential at all ages and stages of life

CARDIOVASCULAR CARE

Keeping hearts healthy with medical technologies that help people and their doctors better manage cardiac health



NEUROMODULATION CARE

Treating chronic pain and movement disorders by targeting specific areas of the brain



DIABETES CARE

Giving people with diabetes the freedom to continuously monitor and track their glucose levels with unsurpassed 14-day accuracy and no painful finger sticks



NUTRITION

Using the latest science to create better ways to nourish bodies from infancy to adulthood



DIAGNOSTICS

Providing accurate, timely information to guide effective treatment decisions



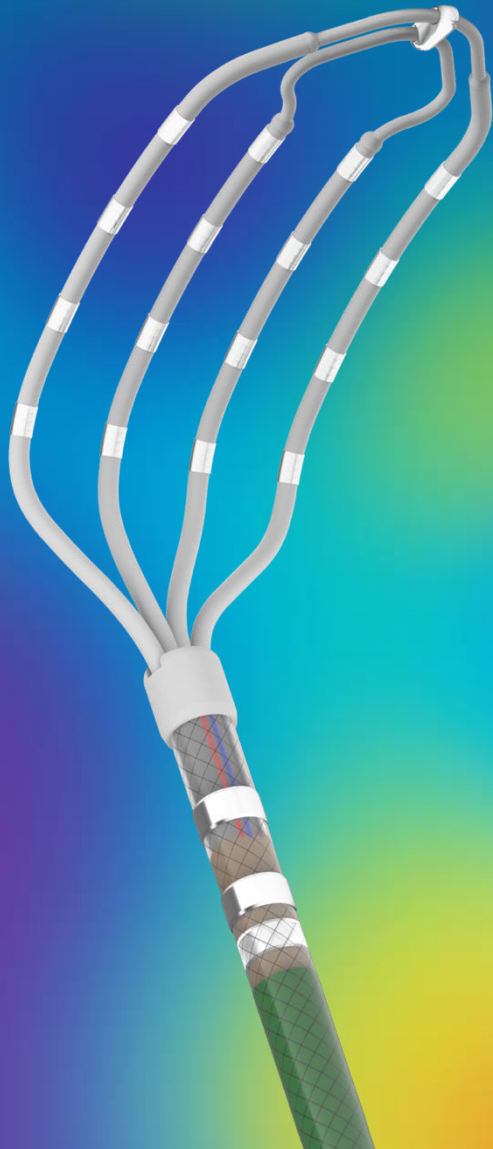
MEDICINES

Helping people get and stay healthy with quality medicines they can trust



CARDIOVASCULAR DEVICES

Electrophysiology



Portfolio includes:

ADVISOR HD GRID MAPPING CATHETER, *SENSOR ENABLED*

First-of-its-kind electrode configuration to create more highly detailed maps of the heart



ENSITE X

Best-in-class cardiac-mapping system provides 3-D images of the heart and its activity



TACTICATH ABLATION CATHETER, *SENSOR ENABLED*

Next-generation device that is designed for ease of use



CARDIOVASCULAR DEVICES

Heart failure

Therapies across the heart-failure disease spectrum:

CARDIOMEMS HF SYSTEM

Pulmonary-artery-pressure monitoring provides early detection of worsening heart failure



HEARTMATE 3 LEFT-VENTRICULAR ASSIST DEVICE

Mini heart pump for patients in advanced-stage heart failure is the first to use *Full MagLev* flow technology



CENTRIMAG CIRCULATORY SUPPORT SYSTEM

Machine that temporarily takes over the function of the heart and lungs so they can rest and heal



CARDIOVASCULAR DEVICES

Cardiac rhythm management

Portfolio includes:

CONFIRM RX

World's first and only insertable cardiac monitor that is smartphone-compatible



CARDIAC RESYNCHRONIZATION DEVICES

Help the heart pump in a more coordinated way



IMPLANTABLE CARDIAC DEFIBRILLATORS

MRI-safe devices that help slow abnormally fast-beating hearts



PACEMAKERS

MRI-safe devices that restore normal heart rhythm



CARDIOVASCULAR DEVICES

Structural heart

Broadest portfolio of heart-valve repair and replacement technologies

CUTTING-EDGE TRANSCATHETER VALVE-REPAIR DEVICES

- **MITRACLIP and TRICLIP**
Repair for leaking mitral and tricuspid valves
- **TENDYNE**
Novel mitral-valve-implantation system



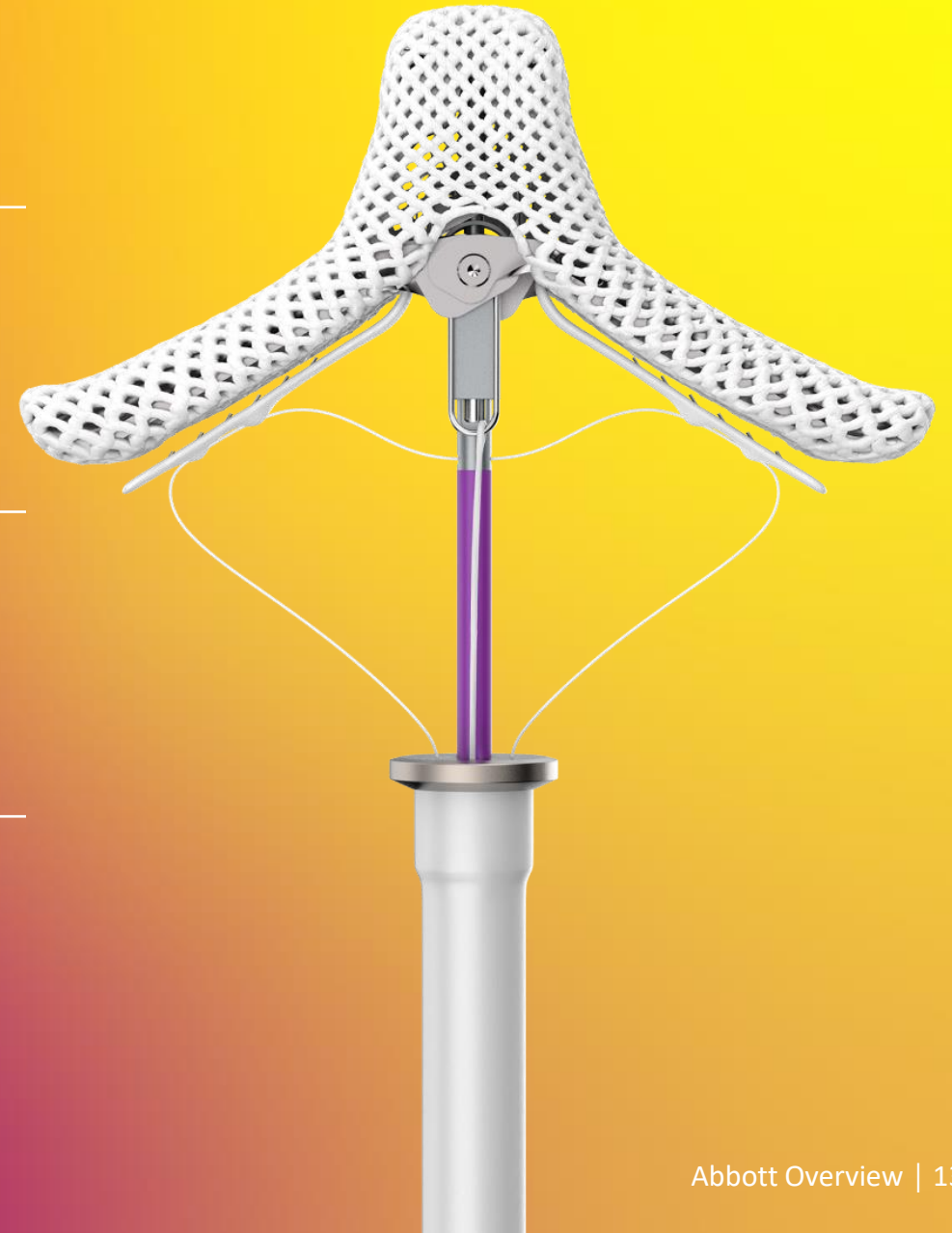
TRADITIONAL MECHANICAL AND TISSUE HEART VALVES

- **EPIC**
Aortic and mitral stented tissue valves
- **MASTERS HP 15 mm**
The world's smallest rotatable mechanical heart valve



DEVICES TO TREAT HOLES WITHIN THE HEART

- **AMPLATZER PFO and AMPLATZER AMULET**
Reduce the risk of stroke
- **AMPLATZER PICCOLO**
A tiny, first-of-its-kind device designed to fix a congenital heart defect in premature babies



CARDIOVASCULAR DEVICES

Vascular care

Broad portfolio of devices designed to optimize percutaneous coronary intervention (angioplasty) procedures

MARKET-LEADING STENTS

Xience Sierra system designed for complex cases



DIAGNOSTIC AND IMAGING DEVICES

Help doctors assess arterial blockages prior to placing our market-leading stents



FULL PORTFOLIO OF VESSEL-CLOSURE DEVICES AND CATHETERS

Allows physicians to make optimal treatment decisions for each individual patient



DIABETES CARE DEVICES

Continuous glucose monitoring

Providing accurate results faster and with greater convenience, so people can continuously monitor their glucose levels with minimal pain or disruption

#1 worldwide, with nearly 3 million users

FREESTYLE LIBRE

- Eliminates routine painful fingersticks
- Delivers unsurpassed 14-day accuracy and real-time glucose readings every minute
- Provides actionable insights for improved outcomes
- Affordable and accessible to millions of people worldwide
- Compatible with FreeStyle LibreLink and LibreLinkUp, smartphone apps that let people monitor their glucose without the use of a separate device, then share their data with caregivers remotely



LIBRE SENSE

- Collaboration with sports technology company Supersapiens allows athletes without diabetes to learn more about their glucose levels and the correlation between fueling and athletic performance



96 mg/dL

116 mg/dL



NEUROMODULATION DEVICES

Chronic-pain and movement-disorder therapies

Global leader in chronic-pain solutions

UNIQUE PAIN-MANAGEMENT PORTFOLIO INCLUDES:

- Radiofrequency ablation
- *BurstDR* spinal-cord stimulation
- Dorsal-root-ganglion stimulation



INFINITY DEEP-BRAIN-STIMULATION (DBS) SYSTEM

Targeted patient-specific treatment to help address the symptoms of Parkinson's disease and essential tremor



DIAGNOSTICS

Transforming care by providing timely information to better manage health

ADVANCED INSTRUMENT SYSTEMS

for hospitals, reference labs and blood banks

LAB-BASED TESTS

for health screening, disease diagnosis and monitoring

MOLECULAR DIAGNOSTICS

for managing infectious diseases and serious illnesses

PATIENT-SIDE DIAGNOSTICS

for lab-quality results in minutes

SOPHISTICATED INFORMATION SOLUTIONS

that uncover insights to improve productivity and patient outcomes



DIAGNOSTICS

Point of care

World leader in point-of-care testing, with more than 1 billion tests provided in 2020

PATIENT-SIDE TESTING

Designed to improve the overall quality of care and help our customers provide better clinical and economic healthcare outcomes



RAPID DIAGNOSTIC TESTING

Gives doctors the insight they need – in just minutes – to deliver the right care at the right time in any environment



LATERAL FLOW TESTING

Provides results in minutes, even in remote areas



DIGITAL SOLUTIONS

Innovative apps that manage test results and help track diseases as they move through populations



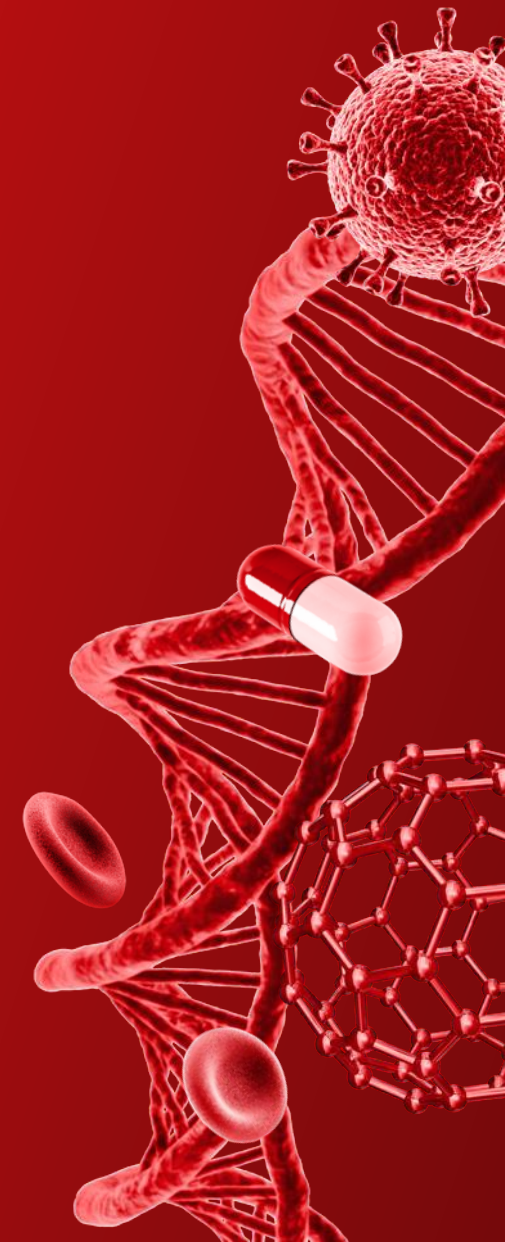


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Welcome

The presentation will start shortly



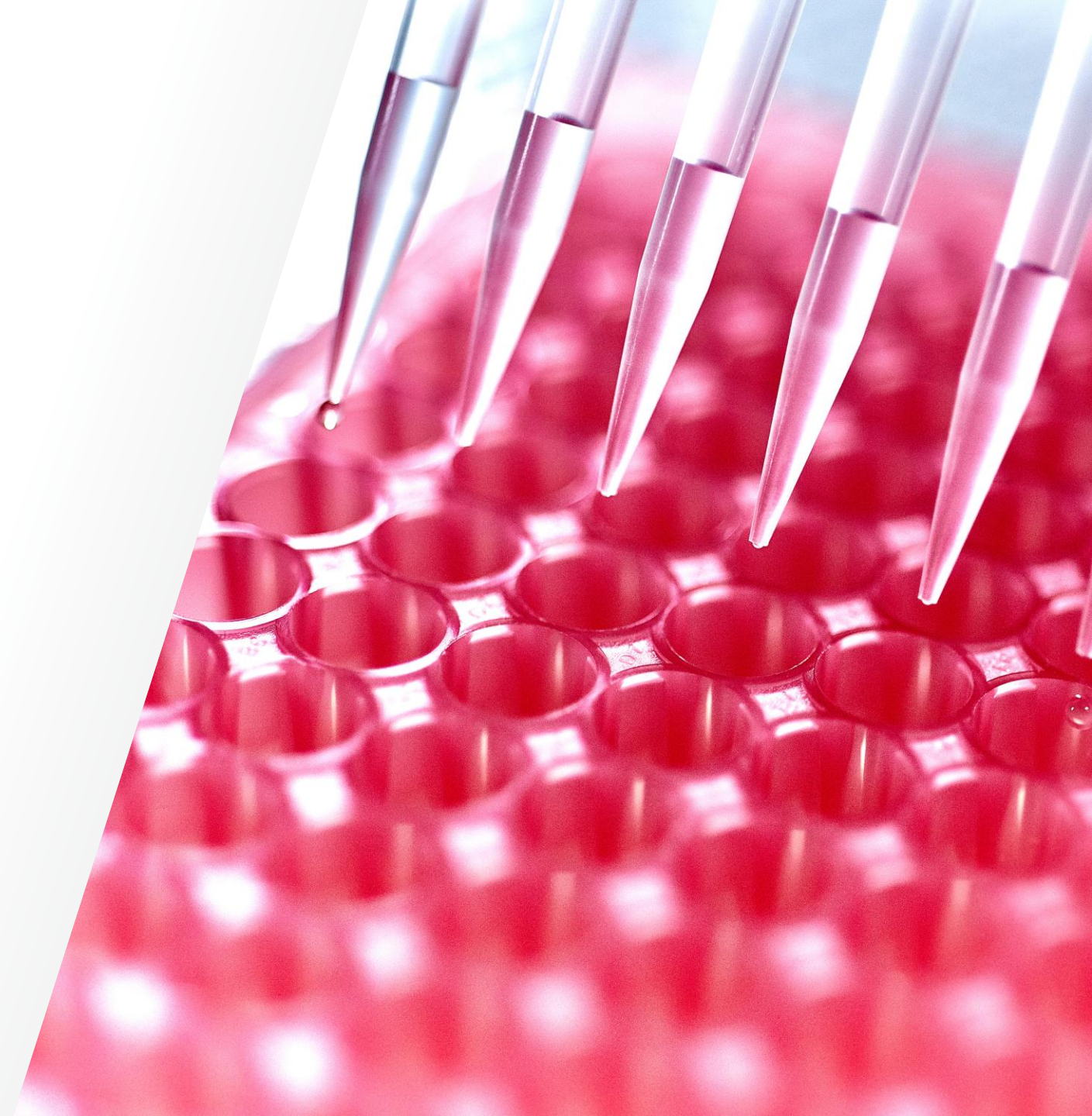
Thermo Fisher Scientific R&D Amplitude Solution

Elizabeth Roney and Shoba Varma

System Engineer II (x2)

April 9, 2022

 The world leader in serving science



Mission:

We enable our customers to make the world healthier, cleaner and safer.



>100,000

colleagues



5,700

R&D scientists/engineers



>50%

COVID-19 tests using
Thermo Fisher equipment




→20M

COVID-19 tests
manufactured per week

 The world leader in serving science

About Us


5,700
R&D scientists/engineers



Elizabeth Roney

Engineer II, Systems Integration



Shoba Varma

Engineer II, Systems Integration



South San Francisco, California

- Employs nearly 700 team members
- Rapid viral testing (Zika, Ebola, Covid-19)



Elizabeth Roney

Engineer II, Systems Integration

- M.S. Biomedical Engineering, Tulane University '20
- B.S. BME, B.A. English, Tulane University '19
- Member of Theta Tau Engineering Fraternity
- Specialized in Orthopedic Bioengineering and Cell Mechanics at Tulane
- Began Systems Engineering as a contractor doing DNA Microarrays with Thermo Fisher Scientific spring of 2020, transitioned to automated diagnostics (COVID-19 Testing) fall of 2020



Shoba Varma

Engineer II, Systems Integration

- Spent 4 years on an all-girls FIRST Robotics team in HS
- Worked with UCB-Engineers Without Borders to build water purification and distribution systems in Panama and Peru
- Phi Sigma Rho, Sorority for Women in Engineering & Tech
- B.S. Mechanical Engineering, UC Berkeley '19
- Joined ThermoFisher Scientific's Genetic Testing Solutions Group in November 2020

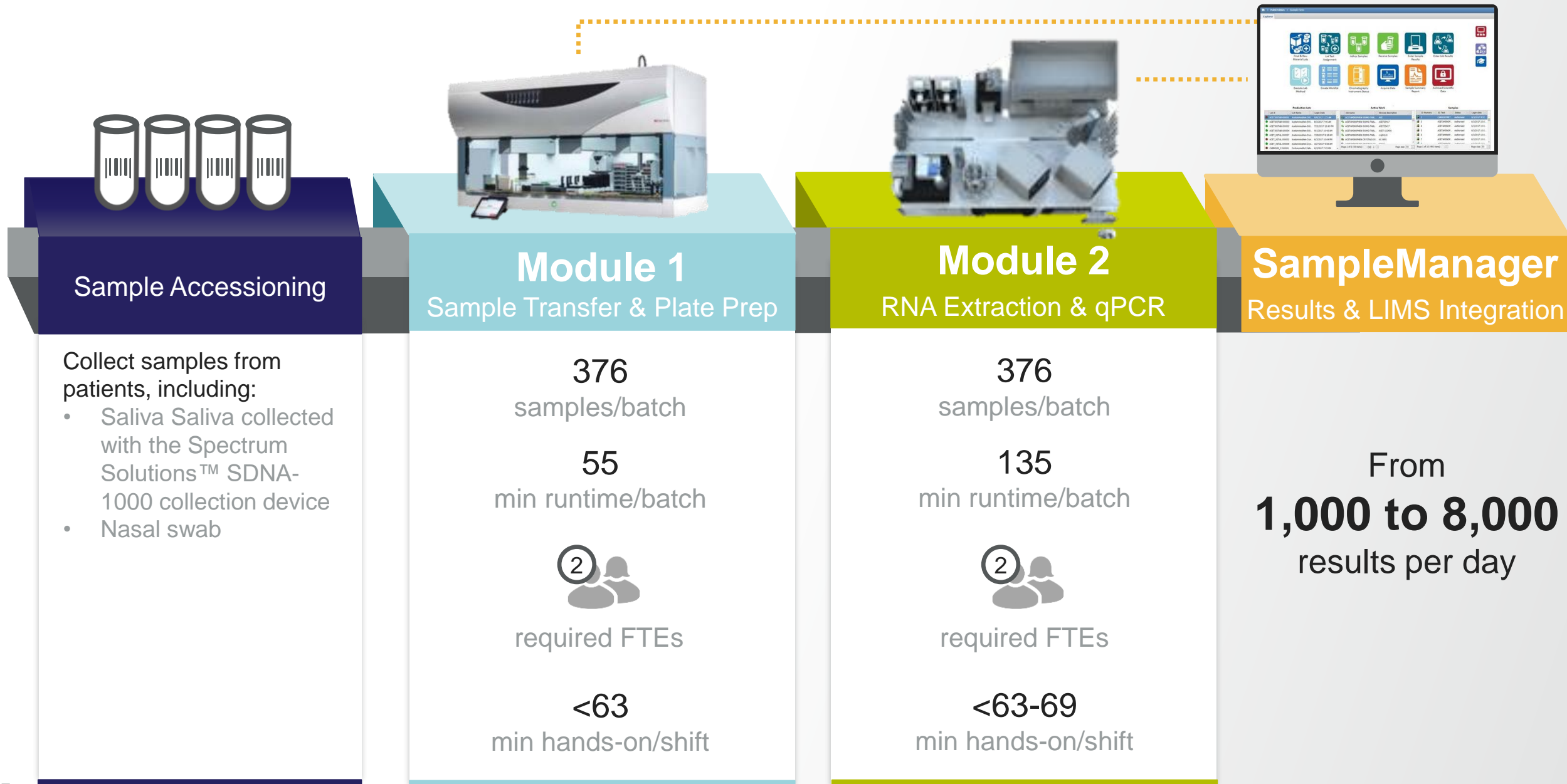
Our Team: Clinical Systems Integration

What is integration?

- Gather input and requirements
- Draft designs and test plans & documentation
- Develop software
- Integrate software and hardware components
- Test features and verify system architecture
- Manufacture integration components
- Support customers worldwide



Streamlined Workflow, Minimal Resources, Scalable Throughput



Sample Accessioning

Collect samples from patients, including:

- Saliva Saliva collected with the Spectrum Solutions™ SDNA-1000 collection device
- Nasal swab

Module 1

Sample Transfer & Plate Prep

376

samples/batch

55

min runtime/batch



required FTEs

<63

min hands-on/shift

Module 2

RNA Extraction & qPCR

376

samples/batch

135

min runtime/batch



required FTEs

<63-69

min hands-on/shift

SampleManager

Results & LIMS Integration

From

1,000 to 8,000

results per day

Benefits of Automation



Maximize throughput

1,000 to 8,000 test results per day



Minimize labor resources

Only 4 FTEs per shift with minimum hands-on time



Increase reproducibility

Tracks and ensures uniform sample processing and reduces human error



Make Multi-Use Platforms

Expand current automated platforms to apply to a wide range of applications



Future of Automated Testing



Changing use cases

Testing landscape is shifting to include:

- Surveillance testing for
 - back to school
 - back to work
 - back to life efforts
- On-going diagnostic testing
- New variant screening efforts



Evolving Markets

- 25-minute rapid test vs 2-hour PCR test
 - Surveillance testing = High Volume, High Accuracy
 - Diagnostic testing = Low Volume, High Speed
- Automation to accommodate all markets



Emerging Technology

- AI and ML to deliver better test results
- Faster and more accurate pipetting and automation to reduce errors
- Testing beyond COVID-19

Thermo Fisher Scientific worldwide locations



Challenges of a Global team

What was it like to join Thermo Fisher mid-pandemic?

- Tight deadlines, high expectations, high stress, late nights
- Many, many situations where we needed urgent support from teams in Texas, Singapore, India, and the UK all at once
- Simultaneously working on several projects → balancing competing priorities
- Translating complicated customer needs into features
- Going to work in-person when everyone else was locked down

Thank you

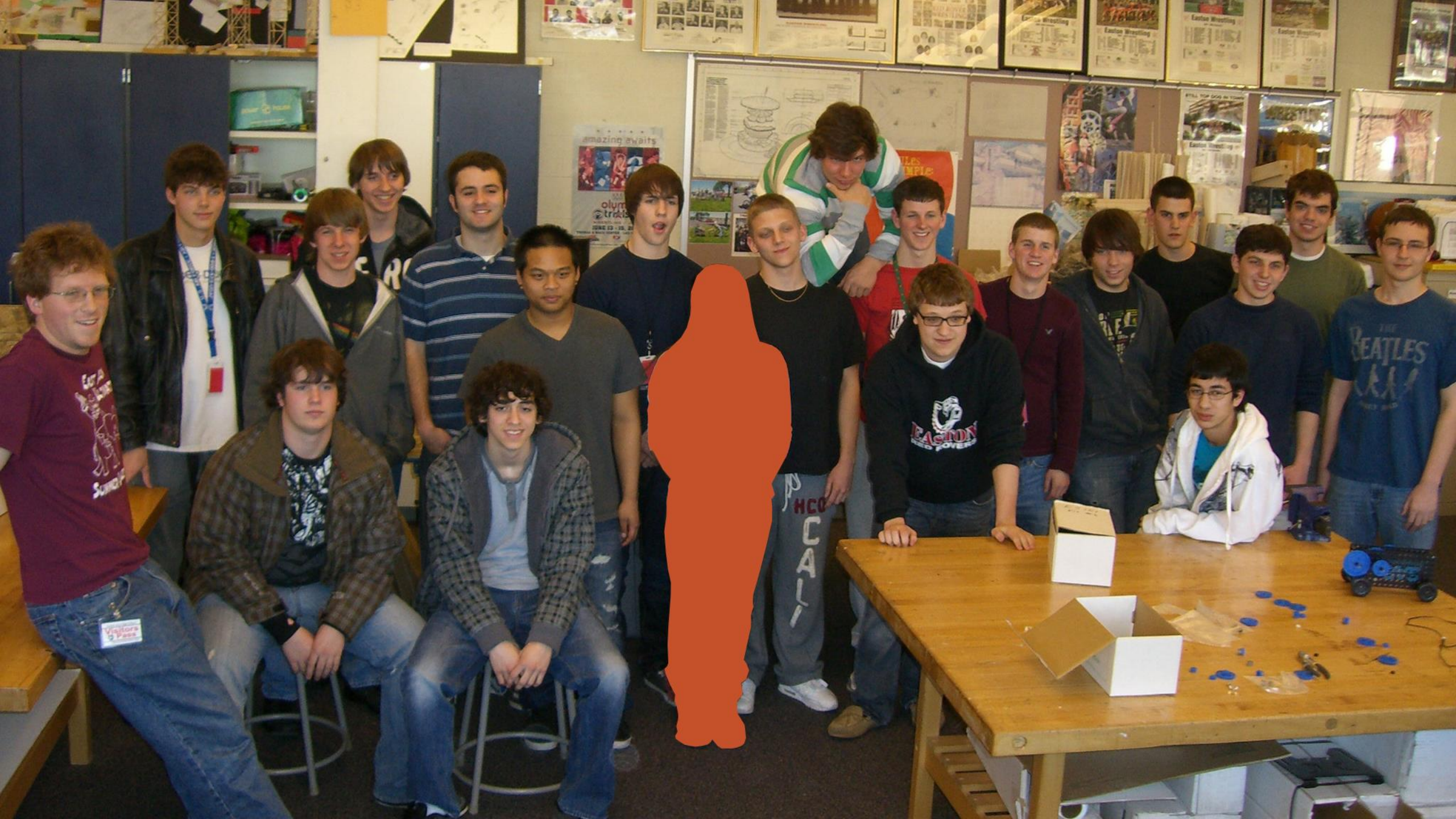




PURPOSEFUL ENGINEERING

Serene Wachli | Applied Medical





MAKE A DIFFERENCE

POSITIVELY AFFECT THE WORLD



IMPROVE DIAGNOSTICS

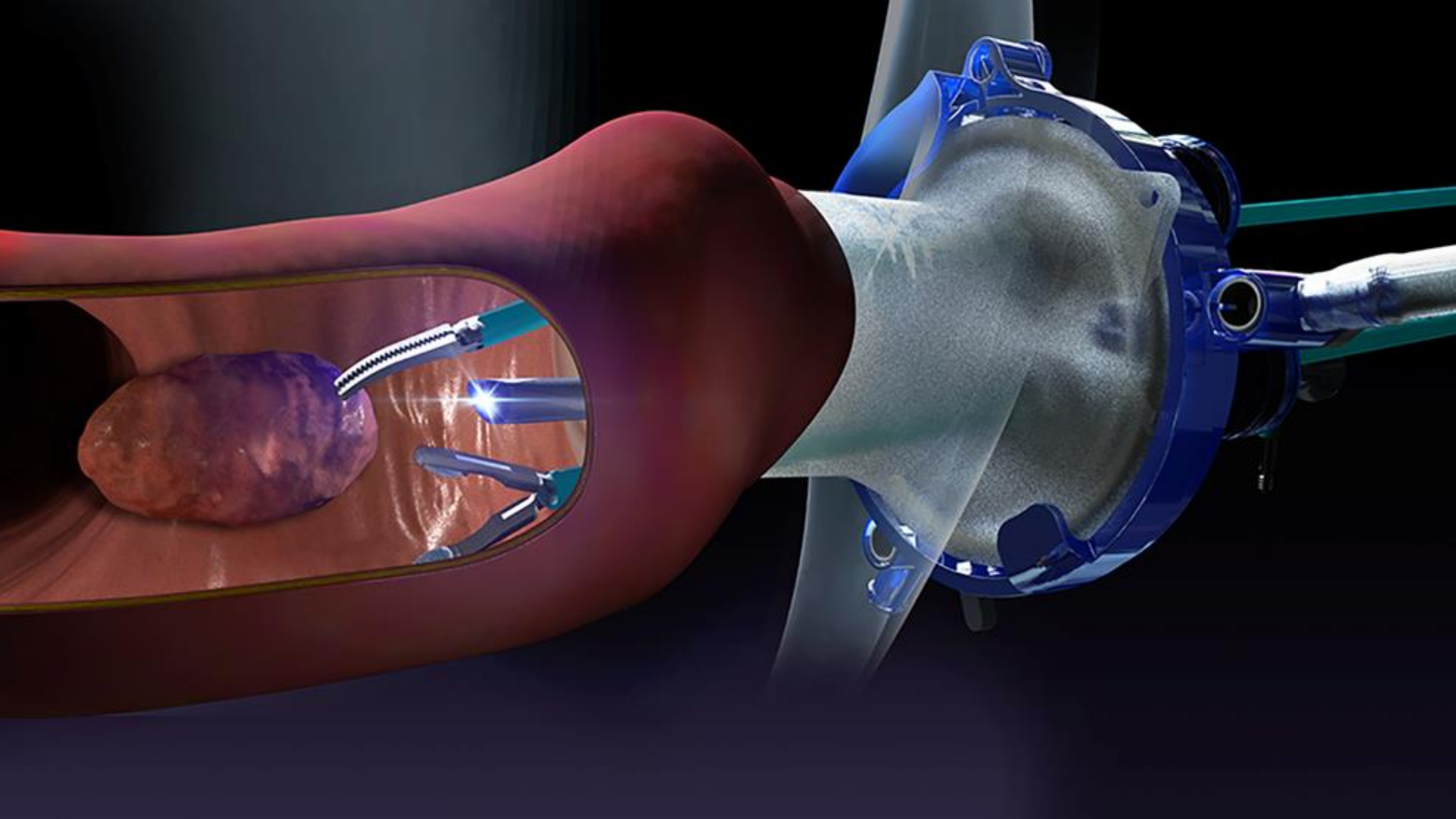
REDUCE PAIN

ENHANCE OUTCOMES







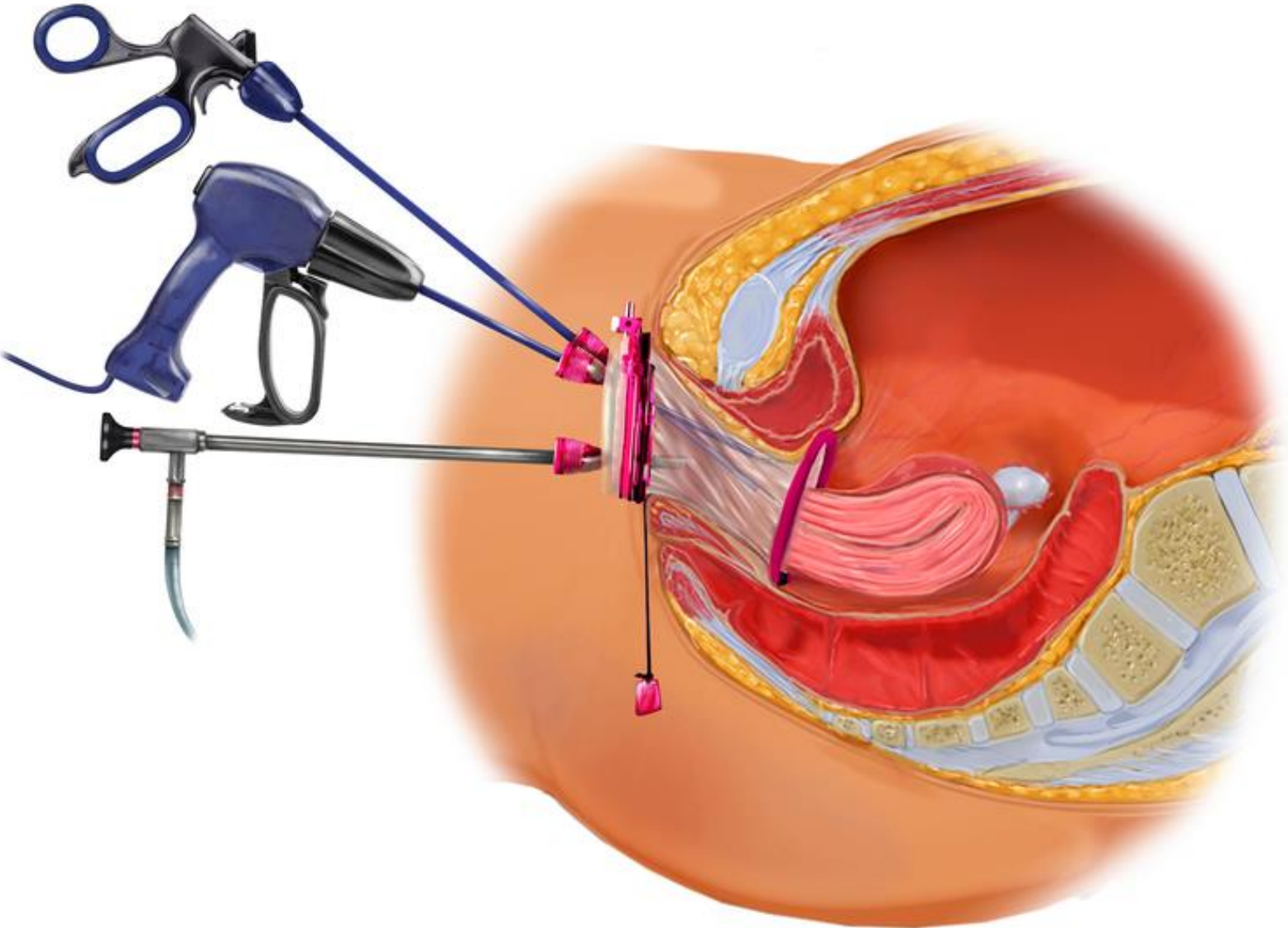


**“I was in and out in two
and a half hours... I went
home, I was fine and got
to sing my daughter to
sleep that night.”**

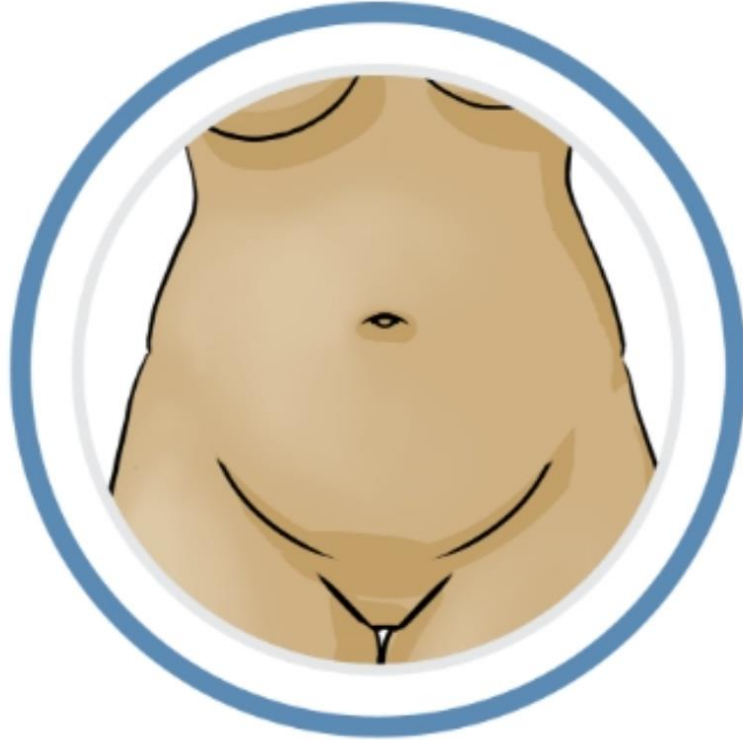
FOX 26

fox26houston.com

vNOTES



NO VISIBLE SCARS
FASTER RECOVERY



LESS PAIN
GREAT OUTCOMES





A STORY AND A WISH



AWKWARD...





COMMITTED TO EXCELLENCE

PROGRESSIVE

RESPONSIBLE

CREATIVE INVENTIVE

MOTIVATED

DRIVEN

ENGINEERING

LAB







THANK YOU!

swachli@appliedmedical.com

FUTURE OF BIOTECH

LIKE THIS SESSION?

Please share your feedback!

<https://bit.ly/BWIE-S7>



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