



# Medical Device Development Capabilities and Portfolio



**PADT is the Southwest's leading provider of Numerical Simulation, Product Development, and 3D Printing products and services.**

**We are in the business of helping those who make things, make them better.**

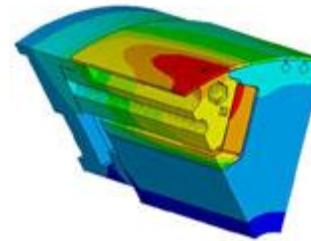
**We are professional engineers, sales people, technicians, and administrators who apply experience, enthusiasm, and a win-win approach to everything we do.**

**We are PADT**

**We Make Innovation Work**

# About PADT

- Products and Services for Physical Product Development
- Founded in 1994
- Three Areas of Focus:
  - Simulation, Product Development, 3D Printing
- Services
  - Product Development, Medical Devices, Simulation, Manufacturing Consulting
- Sales
  - ANSYS, Stratasys, Flownex, Zeiss, Geomagic, Concept Laser
- Products
  - Support Cleaning Apparatus, CUBE Computers
- 70+ Employees
  - Based in Tempe, Arizona
  - Albuquerque NM, Denver CO, Salt Lake City UT, Torrance CA



# Medical Device Development

Capabilities and Process



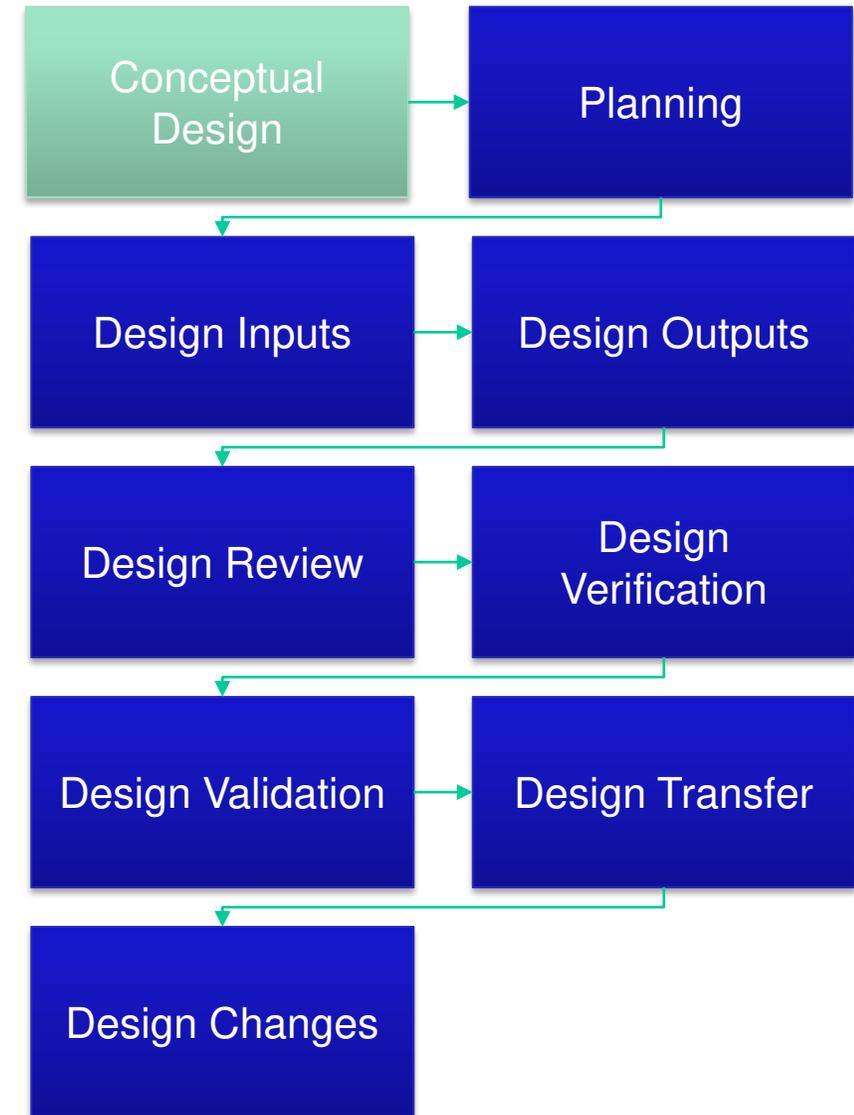
# Dedicated Development Team

- Experienced Engineers and Technicians
- Focused on Medical Device Specification, Design, Testing, QA, Manufacturing Coordination
- 10+ Years experience on Medical Devices
- Startups, small companies, and large multinationals
- Strong partnership with test, quality, and manufacturing partners



# Product Development Process

- A simple and consistent industry accepted process
  - Captures product requirements
  - Defines how the design is to be done
  - Establishes what needs to be done
  - Documents what was done
  - Captures met requirements
- Documented by Design History File
- Controlled by Quality Management System



# Medical Device Development with PADT Advantages

- Advanced engineering capability
- Industry experience across devices
- Very strong vendor network
- Manufacturing partner
- Smart and Flexible application of Quality
- ??????

# Medical Device Project Portfolio

Making Innovation Work for our Device Customers



# Case Study: Novel Tissue Expander to Minimize Tissue Damage During Minimally Invasive Surgery

## Background

Needed device to improve access for minimally invasive surgeries i.e. laparoscopic surgical procedures

Replace metal expander with thermally actuated balloon catheter

## Challenges

Develop a compelling prototype and solve operation and packaging concerns

## Process & Solution

Work with Doctors to understand technology and needs

Document requirements

Develop concepts and down select best design

Simulate thermal actuation/control system

Design, build, and test prototype device



## DISCIPLINES EMPLOYED

Mechanical Engineering  
Electrical Engineering

## TESTIMONIAL

*"I found there to be great benefit in going through PADT's disciplined steps for the development of an updated prototype of our device. Restarting with a more systematic approach, and analyzing each component fresh, made me feel confident about every aspect of the new design."*

- Neil R. Crawford, PhD  
Associate Professor, Spinal Biomechanics  
Barrow Neurological Institute

# Case Study: Development of Clearview, A Novel Medical Measurement Device



## Background

Custom acquired IP for a novel low cost diagnostic tool

## Challenges

Help customer navigate the product commercialization process

## Process & Solution

Redesign electronics to solve performance issues including high-voltage circuit and firmware

Fabricated 4 clinical testing units

Assist in submission of 510(k)

Develop production device specifications

Detail design and improved performance

Transfer the design to contract manufacturer



## DISCIPLINES EMPLOYED

Electrical/firmware engineering

Mechanical engineering and industrial design

Verification testing

Manufacturing to support clinical trials

FDA 510(k) submission support

## TESTIMONIAL

*"For the last 2 years we have worked with PADT to develop our ClearView technology. Their team has helped us with many aspects of product development and commercialization. They have been a very valuable asset and I would highly recommend them to any startup that needs to navigate the pathway to market."*

- Tom Blondi  
President, Epic Research Diagnostics

# Case Study: Design and Test of Intelligent Orthopedic Device, Wireless Knee Balancing System



## Background

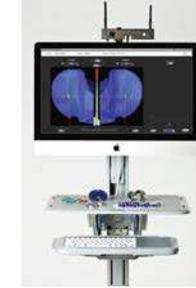
Custom was tasked with developing the first Intelligent Orthopedic Device to optimize soft tissue balance and leg alignment during Total Knee Arthroplasty.

## Challenges

Work with customers conceptual design for four years through design, test, and commercial success.

## Process & Solution

- Work with customer on conceptual design to prove out technical approach and materials
- Establish design plan and quality control for development
- Conduct detail design with co-located customer engineers
- Assist in 410(k) submission
- Work through sterilization, packaging, and biocompatibility with customer and vendors
- Produce clinical devices at PADT
- Transfer design to Contract Manufacturer
- PADT continues to work on new designs with Orthosensor



## DISCIPLINES EMPLOYED

- |                           |                                |
|---------------------------|--------------------------------|
| Concept Development       | Quality Control                |
| Detail Design             | 510(k) Submission Support      |
| Sterilization & Packaging | Biocompatibility Design        |
| Biocompatibility Test     | Clinical Use Device Production |
| Design Transfer           |                                |

## TESTIMONIAL

*"PADT's Design Team was instrumental in working with Orthosensor throughout the design and development activities of the Orthosensor Knee Balance. Their commitment and flexibility to our business needs allowed us to bring our product to market in a significantly shortened period of time."*

- Juan C Fernandez  
COO, Orthosensor Inc

# Case Study: Development of Specimen Collection System

## Background

Current biopsies often sit for one or more hours before heading to the lap for freezing. During this time the tissue decays. The NIH was looking for novel way to freeze tissue samples in an operating room.

## Challenges

Provide an inexpensive and self contained solution.

## Process & Solution

Meet with clinical and research professionals to understand the true requirements. Then study existing products and processes. Computer simulation was then used to drive the design of the ReadyFreeze system. A bench prototype was then constructed and tested.

Once the final functional design was determined, the product was styled and modified for manufacturing and ergonomics.



## DISCIPLINES EMPLOYED

Mechanical Engineering Industrial Design

Thermal Simulation

Verification Testing

Collaboration with a Leading Cancer Research Center

# Case Study: Germicidal light for Endotracheal Tubes

## Background

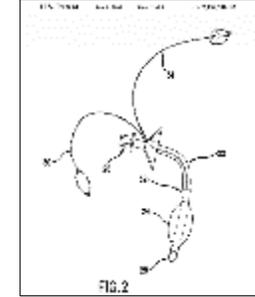
Endotracheal tubes can cause infection in patients, so the customer wanted to place an antimicrobial light next to the cuff where bacteria can build up.

## Challenges

Provide an inexpensive and self contained he focus of this project was to provide a low cost, quick-turnaround, proof-of-concept prototype. PADT engineers worked closely with the customer/inventor to produce a demonstration-ready prototype.

## Process & Solution

The design and development tasks started with the development of a light source, a power source, and the control circuitry. Once that was accomplished CAD models were constructed and prototypes were made. These were functionally tested to understand: balloon inflation and deflation, flexing behavior, endurance under cyclic loading, and testing of the lights and circuitry.



## DISCIPLINES EMPLOYED

- Material Science
- Mechanical engineering and industrial design
- Verification testing
- Electromechanical System Integration
- Rapid Prototyping
- Functional Prototyping of Medical Devices

## TESTIMONIAL

*“The PADT experience was a positive one from my first phone conversation with them to the delivery of the end product. The engineers delivered a prototype that was exactly what I envisioned in a short 8 weeks. PADT will be my choice in the future.”*

- Bob Rife, R.R.T.

# Case Study: An Intraluminal Gastroplasty Device Tool for the Treatment of Obesity

## Background

PADT worked with Safestitch Medical to develop a transoral system that could provide a gastroplasty and avoid the conventional open procedure.

## Challenges

Significant technical challenges existed in how human tissue reacted to being suturing and gripping via suction.

## Process & Solution

Started with Safestitch' initial patent to develop early models of endoscopic system.

Bench testing to develop and prove out the high-risk components

Proof-of-concept fabrication and testing in animal models.

Development of complementary components including an airway biteblock and a suture knotter.



## DISCIPLINES EMPLOYED

- Mechanical Engineering
- Verification Testing
- Low Volume Manufacturing
- Support Animal Testing
- FDA 510-k Submission

## TESTIMONIAL

*“For the last 3 years I have worked with PADT Medical as a physician/inventor of medical devices. Their engineering team is professional, punctual, and responsible. Their management is exemplary. I recommend PADT Medical to any potential Client.”*

- Bob Rife, Charles J. Filipi M.D.  
Medical Director  
SafeStitch Medical, Inc.

# Case Study: Freedom Portable Driver for Artificial Heart Verification Testing

## Background

The SynCardia device is a temporary total replacement heart and the Freedom portable driver required verification testing.

## Challenges

Translate design requirements into a series of verification tests for the portable driver and meet a very strict delivery schedule.

## Process & Solution

The verification tests encompassed the full range of design requirements for the Freedom driver, including:

- Functional testing
- Battery testing and power management
- Physical requirements
- Electrical connection life cycle testing
- Driveline pull tests
- System integration and environmental testing
- Battery housing performance
- Battery physical life cycle testing



## DISCIPLINES EMPLOYED

Mechanical Engineering  
Verification Testing  
Project Management

## TESTIMONIAL

*“SynCardia has chosen to work with PADT based on their ability to develop close personal relationships, to create and implement engineering solutions rapidly, and to support SynCardia’s innovative drive for our lifesaving technology.”*

- Douglas A. Nutter  
Chief Operating Officer  
SynCardia Systems, Inc.

# Case Study: Ulthera Handpiece Redesign for Ultrasound Therapy Device



## Background

The Ultherapy system uses high density, focused, ultrasound and the body's own natural healing process to lift, tone, and tighten loose skin.

## Challenges

Redesign the handpiece to resolve Transducer engagement and reliability issues, reduce manufacturing costs, and enhance the operator interface experience through improved ergonomics and pushbutton modifications.

## Process & Solution

The major activities included:

Modify components to improve performance and reliability

Develop custom silicone membrane keypad

Redo injection molded components for ergonomics, robustness, and manufacturability

Redesign to reduce assembly labor

Verification and Clinical Testing



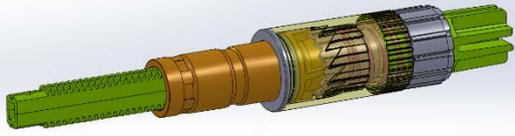
## DISCIPLINES EMPLOYED

Mechanical Engineering  
Industrial Engineering  
Electrical Engineering  
Verification and Validation Testing

## TESTIMONIAL

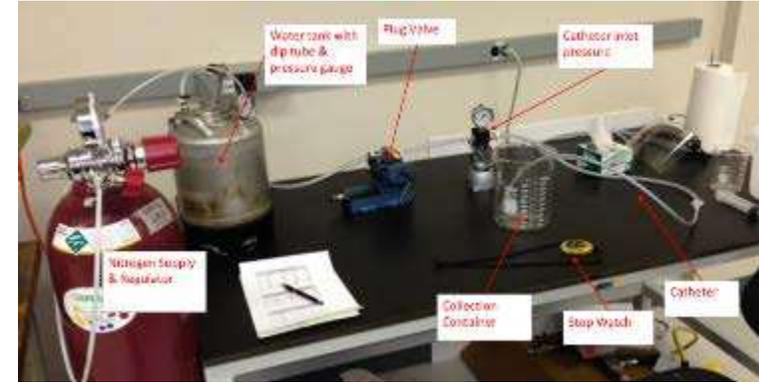
*"PADT has provided a number of valuable services for Ulthera ranging from design work and ergonomic improvements, to manufacturability and V&V testing. Over the past 18 months, PADT worked closely with our engineering staff to ensure the successful launch of our redesigned Deep See® Handpiece. Ulthera's successful collaboration with PADT allowed us to focus our internal resources on our core competencies while leveraging the PADT skill sets. Ulthera® also benefited from PADT's adaptable, customer specific, Design Control process to minimize the QC documentation requirements on the Ulthera® staff"*

- Michael Peterson, Vice President, R&D Ulthera® , Inc



Metered Dosage Device – Product Improvements

### Confidential Client #1

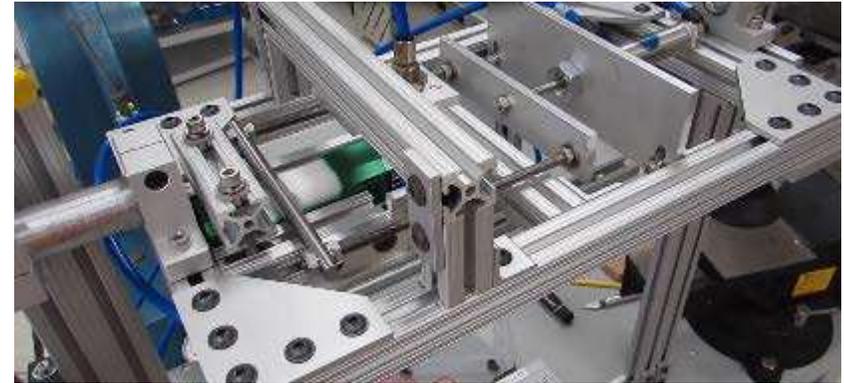


Balloon Inflation Test Rig

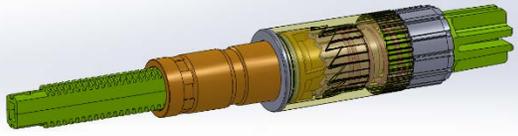


Hemolung Product Improvements, Packaging Redesign

### Confidential Client #1



Biopsy Device Test Rig



EndoGraber – Design and Test of Endoscopic Surgical Device

### Confidential Client #1

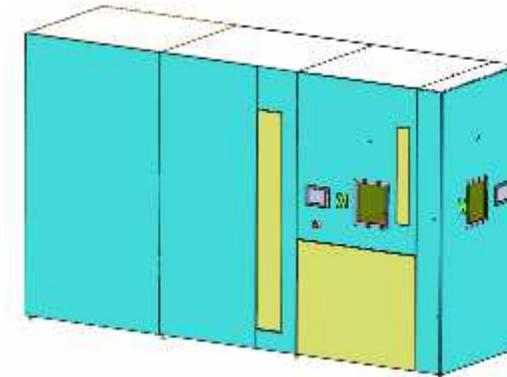
Other Projects (No Images Allowed):

- Biopsy Tool Conceptual Design
- Catheter Welding Study
- Tolerance Studies on Multiple Devices
- Wound Compression Device Conceptual Design
- Evaluate Bonding Options for Connector

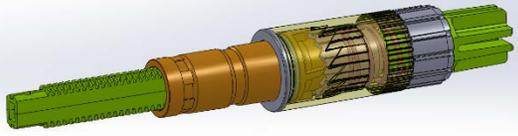
DISIMPACTOR®



Disimpactor – Design and Manufacturing Consulting



Conceptual Design for Automated Medicine Dispensary



EndoGraber – Design and Test of Endoscopic Surgical Device

### Confidential Client #2



Bone Screw – Testing of Conceptual Designs

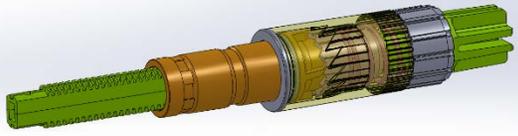
### Rife



Edotracial Tube – LED Lighting Design and Test



Bite Block – Design, test, and manufacturing consulting



Design and Test Support for Endoscopic Knotting Device

### Confidential Client #3



Design and Manufacturing Improvements to Brachytherapy Device

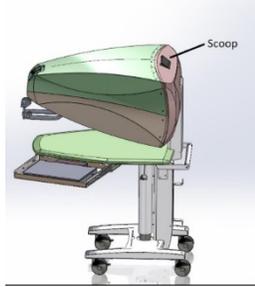
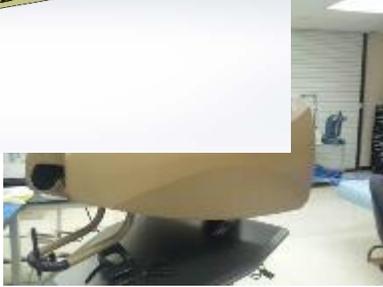
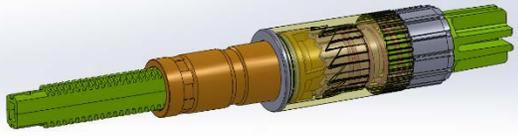


#### Other Projects (No Images Allowed):

- Gastric Suture Device – Design and Test
- Dilator – Conceptual Design
- Gastric Stapler – Conceptual Design
- Barrets Surgery Device – Conceptual Design



EndoGraber – Design and Test of Endoscopic Surgical Device



Ocular Diagnostic Tool – Design, Prototype, and Test

**Jeff Skiba, MD**



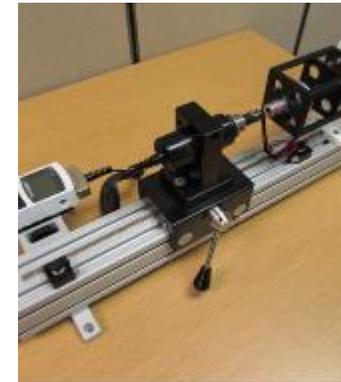
Bone Paste Injector Design and Test

***XO-Thermix***  
*Medical*



Asthma Therapy Device Conceptual Design and Feasibility Study

**Confidential Client #4**



Device Test Rig