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

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 where constructed and prototypes were made. These were functionally tested to understand: baloon 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

Balloon Inflation Test Rig

Hemolung Product Improvements, Packaging Redesign

Confidential Client #1

Biopsy Device Test Rig
EndoGraber – Design and Test of Endoscopic Surgical Device

Disimpactor – Design and Manufacturing Consulting

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

Conceptual Design for Automated Medicine Dispensary
EndoGraber – Design and Test of Endoscopic Surgical Device

Bone Screw – Testing of Conceptual Designs

Edotracial Tube – LED Lighting Design and Test

Bite Block – Design, test, and manufacturing consulting

Rife
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

Bone Paste Injector Design and Test

Asthma Therapy Device Conceptual Design and Feasibility Study

Device Test Rig

Jeff Skiba, MD

Confidential Client #4