

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







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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



Phoenix Analysis & Design Technologies

Medical Device Development with PADT Advantages

- Advanced engineering capability
- Industry experience across devices
- Very string vendor network
- Manufacturing partner
- Smart and Flexible application of Quality
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Medical Device Project Portfolio

Making Innovation Work for our Device Customers



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

BARROW Neurological Institute

St. Joseph's Hospital and Medical Center A Dignity Health Member

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

Phoenix Analysis &

Design Technologies

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.

Medical Device

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

Phoenix Analysis &

Design Technologies

- 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

ulthera

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





Hemolung Product Improvements, Packaging Redesign

Confidential Client #1



Balloon Inflation Test Rig







EndoGraber – Design and Test of Endoscopic Surgical Device

DISIMPACTOR*



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







EndoGraber – Design and Test of Endoscopic Surgical Device



Edotracial Tube – LED Lighting Design and Test

Confidential Client #2



Bone Screw – Testing of Conceptual Designs



Phoenix Analysis & Design Technologies

PA





Design and Test Support for Endoscopic Knotting Device



Other Projects (No Images Allowed):

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

Confidential Client #3

Creighton



EndoGraber – Design and Test of Endoscopic Surgical Device





Jeff Skiba, MD



Bone Paste Injector Design and Test

Confidential Client #4



Device Test Rig



PA