



Product Design & Commercialization Services



Partners from Idea to Reality

Minimally Invasive Device Solutions

Make your device concept a reality and achieve your milestones with support from our expert design team, proven systems and ready-to-go infrastructure.

Whether you are looking for full product development, concept design or you need to meet a specific milestone, our services are customized to deliver your goals on time and within budget.

From initial engagement, our focus is to add value to your development project. We bring the latest ideas and technologies to your project. With the support of an in-house supply chain of quality components, regulatory consulting and global contract manufacturing capability, we deliver your product to market. We are experts in the following therapy areas:

Cardiovascular

Structural Heart

Electrophysiology & CRM

Peripheral Vascular

Neurovascular

MI Orthopaedic

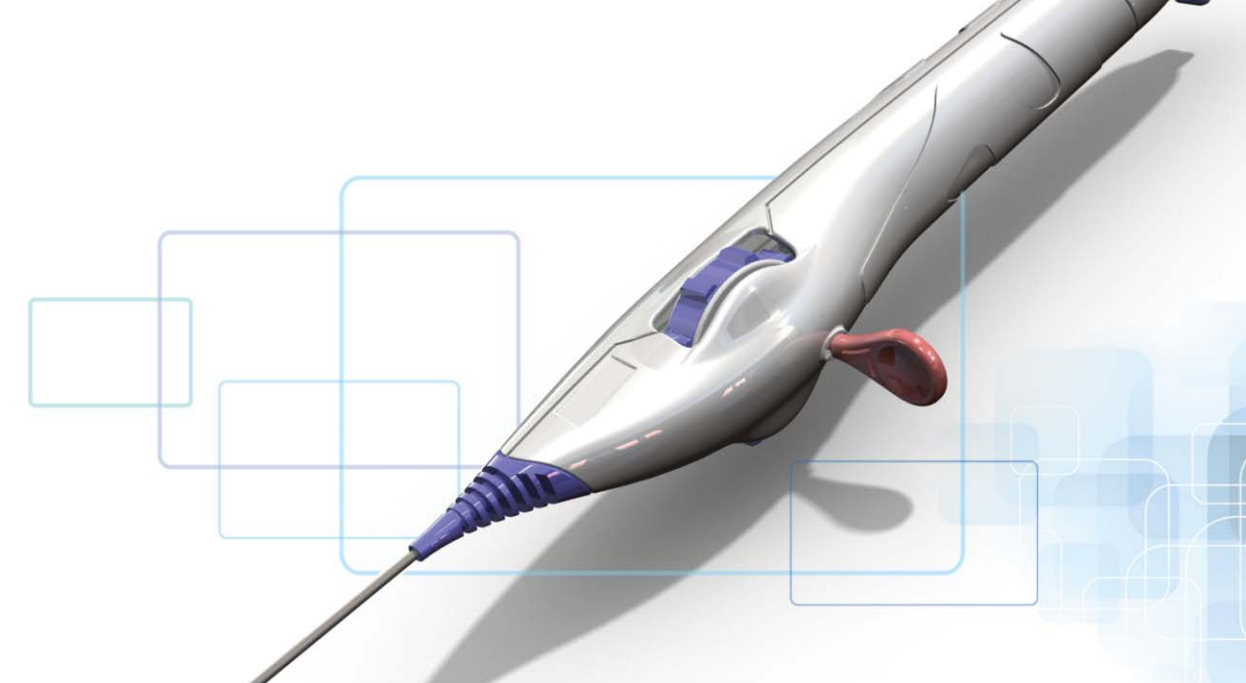
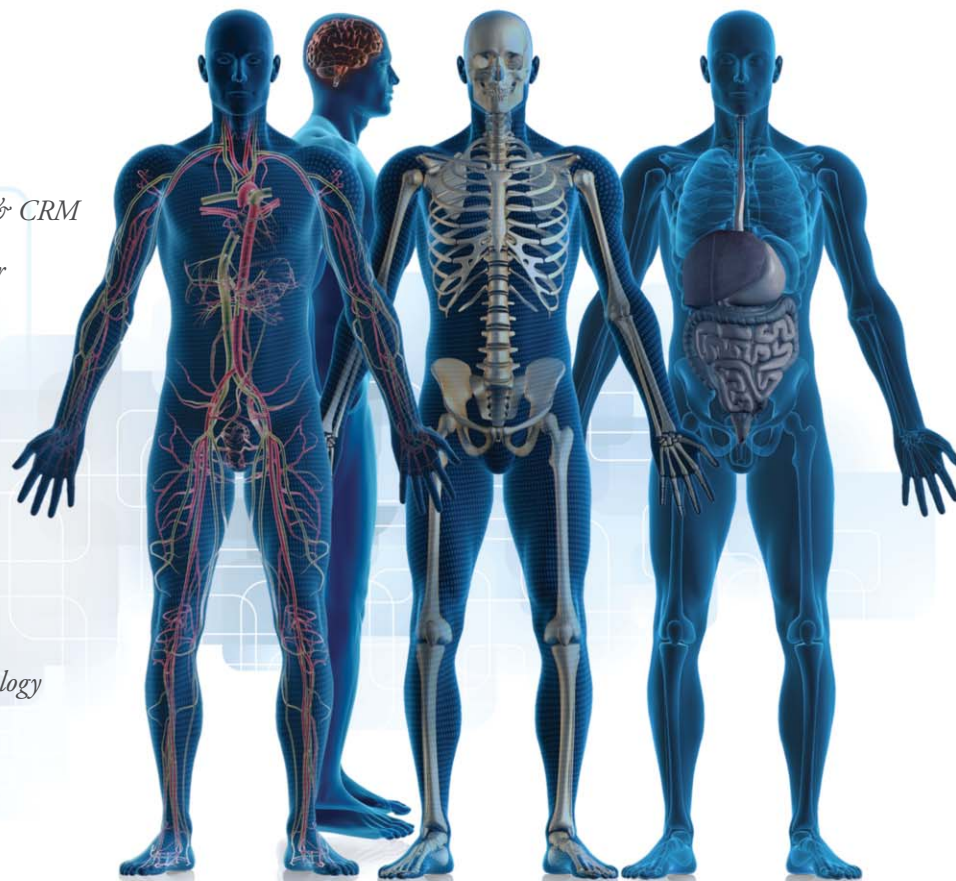
Pulmonary

Oncology

Endoscopy

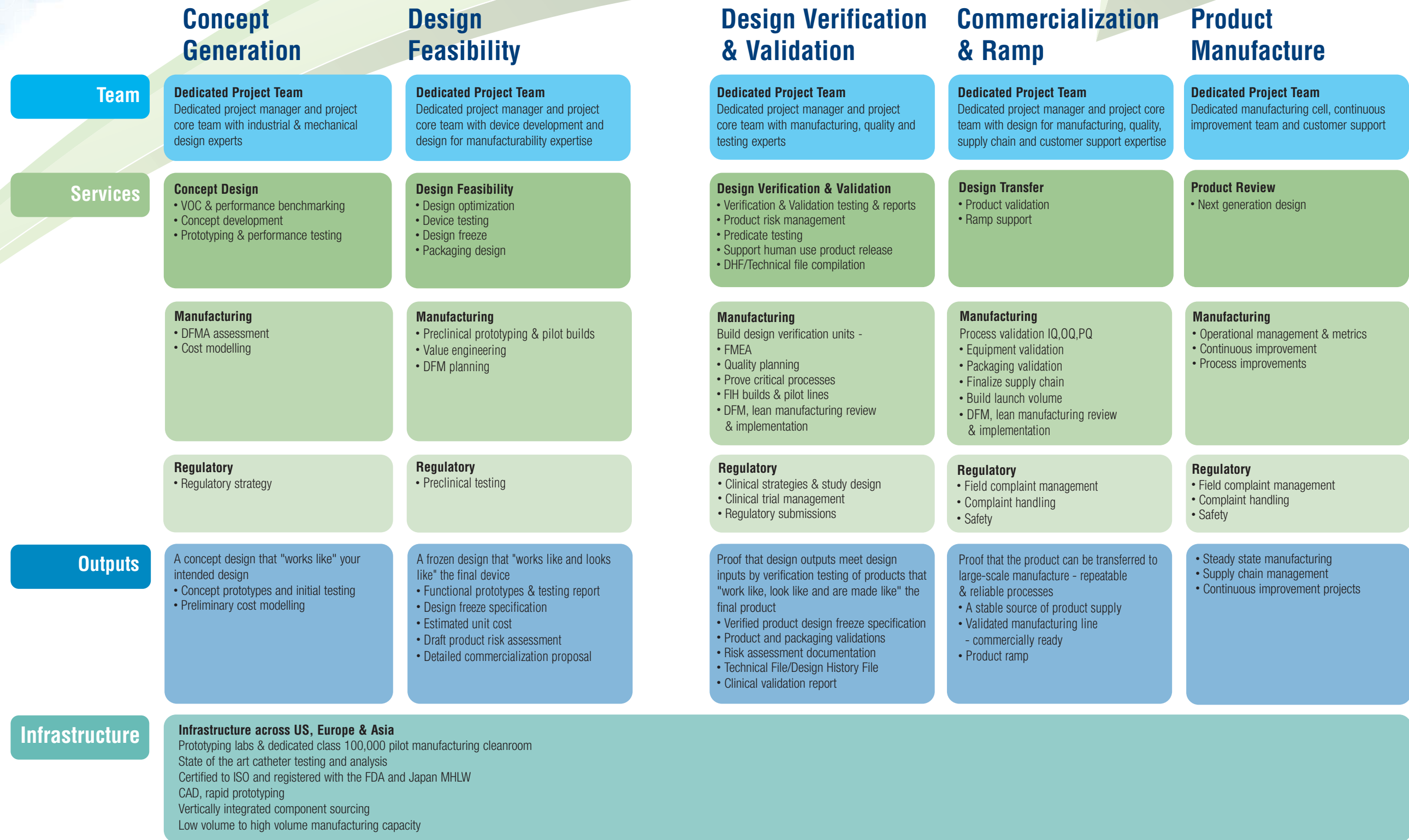
Laparoscopy

Urology & Gynecology



Sample Project Portfolio	Client Profile	Project Overview	Achievements
Laparoscopic Device for SILS	World's leading medical device company	Laparoscopic device - focus on human factors inputs, mechanical & industrial design and plastics design for molding. Line set-up for volume ramp	Project delivered with full design history file and supporting 510k submission - from concept development to steady state commercial manufacture
Self Expanding Stent and Handle Development	US based start-up, medical device company	Low profile RX delivery system and handle for novel implant device. Technical, industrial & mechanical design. Concept development, quick turn prototyping, review & testing	Enabled customer to focus resources on implant device while Creganna-Tactx Medical led catheter development to achieve FIH trials and CE mark approval
Stem Cell Delivery Catheter	European based start-up: medical biotechnology company	Development of catheter system to deliver cardiac bio therapeutics. Focus on catheter, deployment mechanism, sheath & needle devices	Working in parallel with therapeutic development project, supported customer through GLP testing, product verification/validation and CE mark submission process
Kyphoplasty Balloon and Stent Delivery System	US emerging medical device company	Kyphoplasty device - Industrial & mechanical design and prototyping, human factors design, ergonomics and video ethnography	Product was brought from concept to initial European market release
NOTES Access Device	A world leading global medical device company	Novel steerable peritoneal access system - sheath, balloon device, needle access system	Concept & product development, supported client through initial IDE submission and FIH builds
CTO Catheter	Start-up company, EMEA	Specialty catheter delivery system - rapid development cycle	CE mark achieved, client acquired in major buyout by world leading medical device company
Implant Delivery Systems - DFM	A world leading global medical device company	Development of new deployment mechanism and handle for existing device shaft. Technical, industrial & mechanical design. Concept development, quick-turn prototyping, review & testing	Handle design delivered, including full drawing specification for each component
PTCA Balloon Catheter	A world leading global medical device company	PTCA balloon catheter - from concept design to market launch	510k submission, FDA approval, steady-state manufacture & sterilization management

Product Development Process



Technologies:

Catheter technologies

Metal shafts

Braided shafts

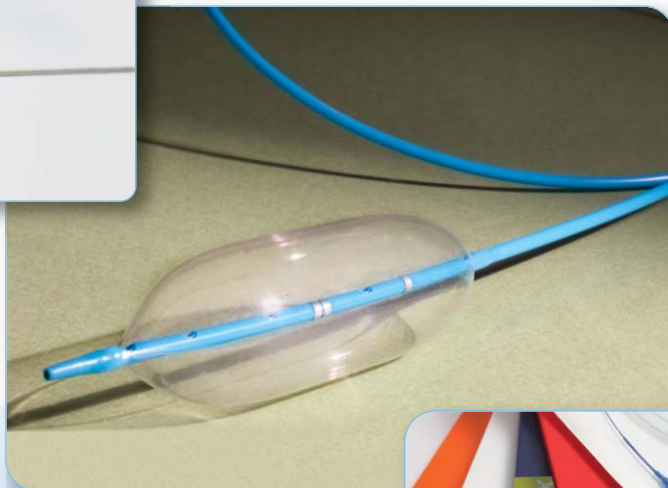
Extruded shafts

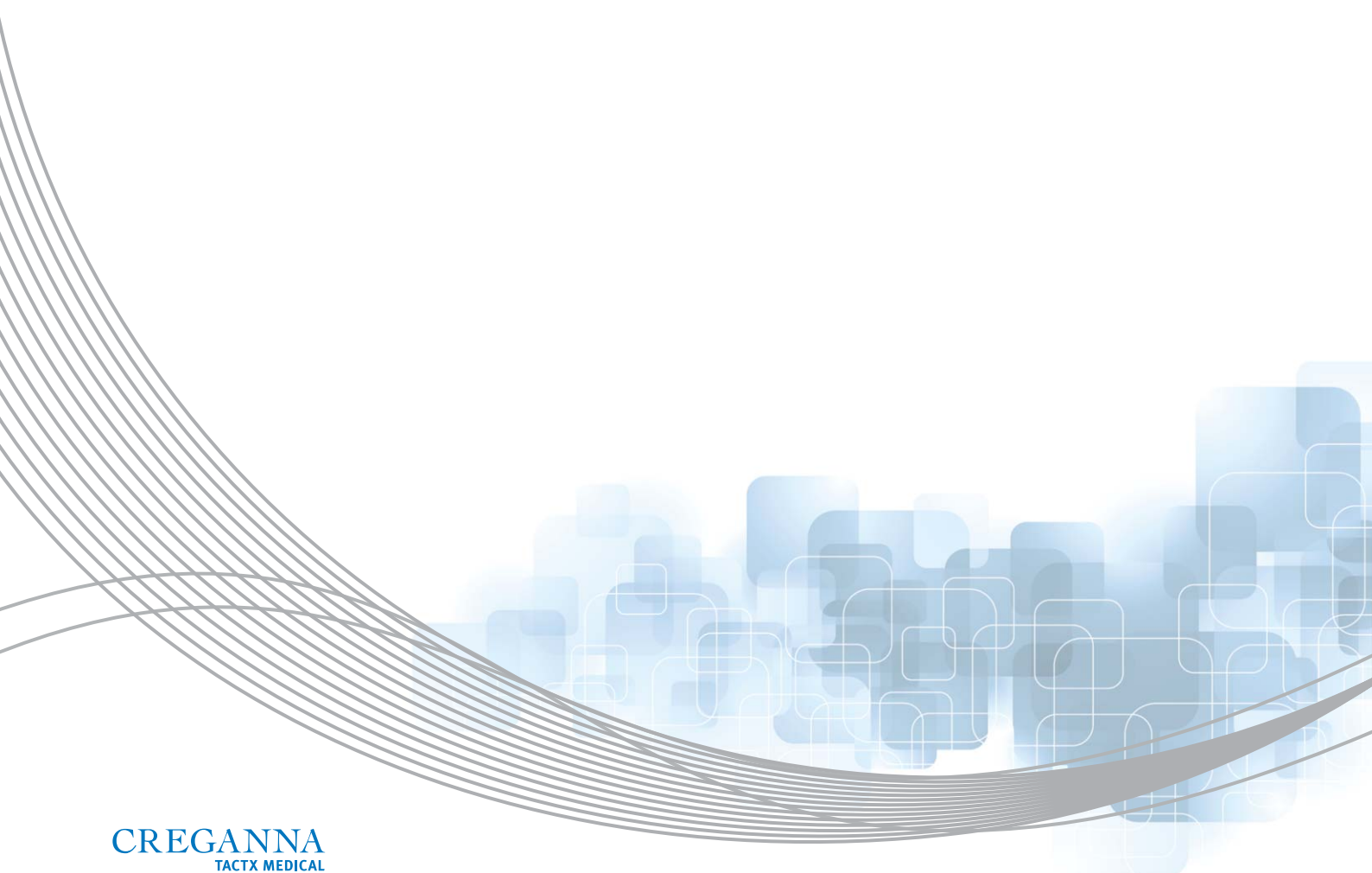
Medical balloons

Injection molding

Device manufacture & assembly

Speciality needles





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