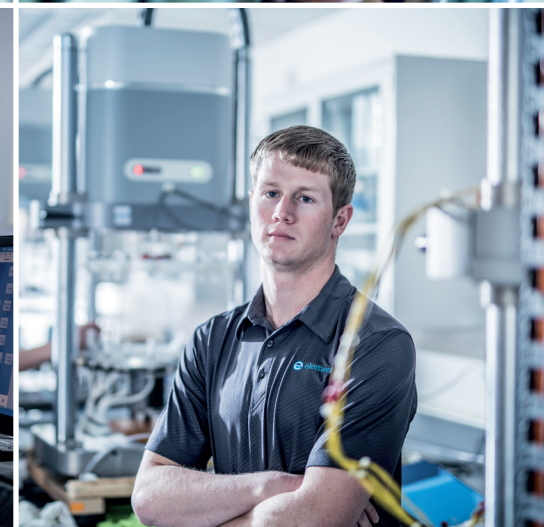
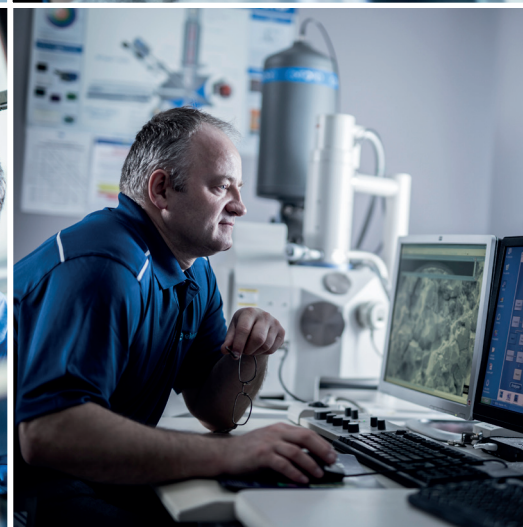
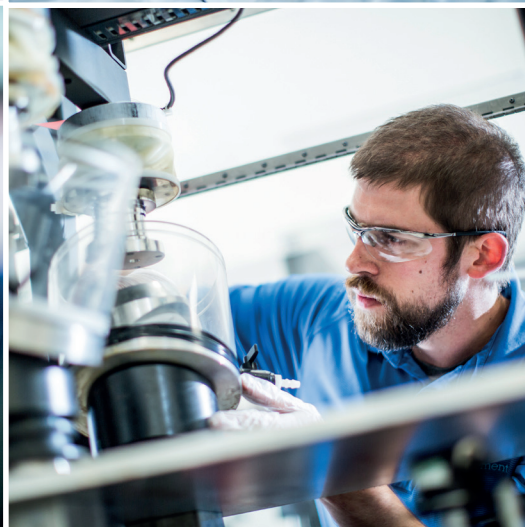
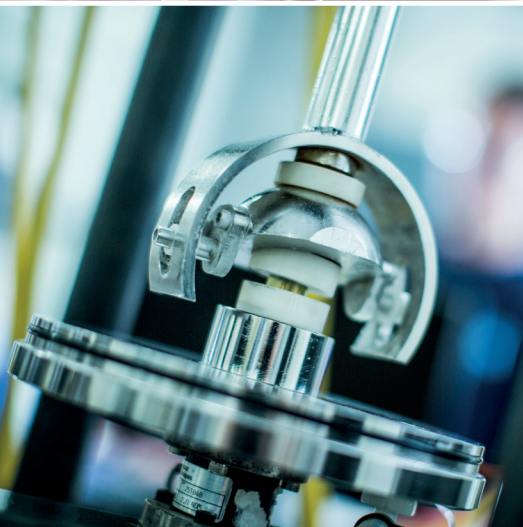


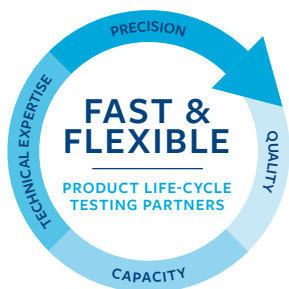


## SERVICES CAPABILITY SUMMARY



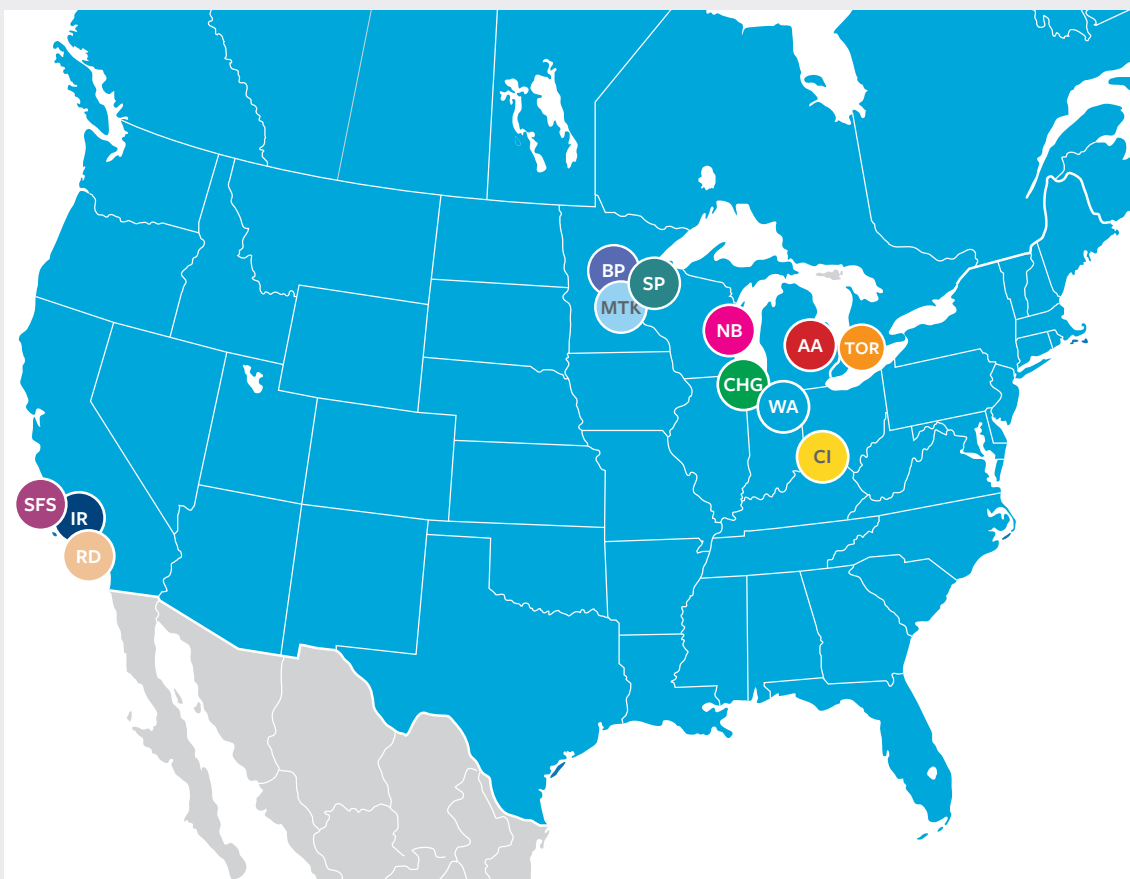
MEDICAL DEVICES

# SERVICES OFFERED



Element is a global medical and pharmaceutical testing provider specializing in orthopedics, cardiovascular, diagnostic and therapeutic segments in our Life Sciences division. With more than 14 U.S locations within the life sciences division and more than 200 locations worldwide, Element is the fastest-growing testing laboratory in the world.

At Element, our dedicated team of experts have hundreds of years of experience in a wide range of testing services for Class I, II and III medical devices and drugs to help you meet medical device regulations and ensure that every aspect of your medical device product is properly tested. As a comprehensive medical device testing partner, you'll enjoy the benefit of a single-source supplier for all of your testing needs, from feasibility and R&D to product development and production quality control.



- AA Ann Arbor, MI
- BP Brooklyn Park, MN
- CHG Chicago, IL
- CI Cincinnati, OH
- MTK Minnetonka, MN
- IR Irvine, CA
- NB New Berlin, WI
- RD Rancho Dominguez, CA
- SFS Santa Fe Springs, CA
- SP St. Paul, MN
- TOR Toronto, ON, Canada
- WA Warsaw, IN

# PRODUCT EXPERTISE

- **CARDIOVASCULAR**

- Stents & Grafts
- Heart Valves
- Occluders
- Catheters
- Stimulators

- **ORTHOPEDICS**

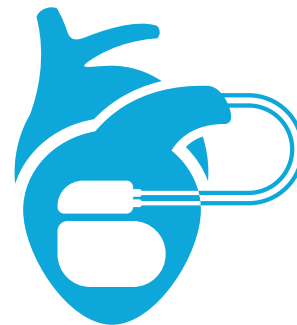
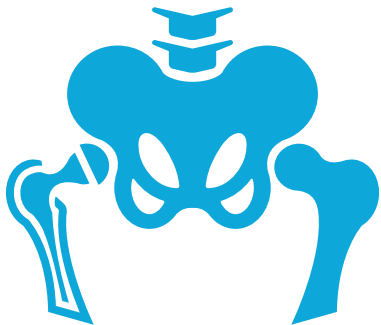
- Hips
- Knees
- Shoulders
- Spine
- Small Extremities
- Dental
- Coatings
- Prosthetics
- Breast Implants
- Trauma

- **INSTRUMENTS**

- Surgical Tools
- Endoscopes
- Ultrasound Probes
- CPAP Components
- Light Guides

- **DIAGNOSTIC & THERAPEUTICS**

- Pacemakers
- Ultrasound
- Hearing Aids
- Ventilators
- Patient Monitoring/Diagnostic Devices
- Implantable Pulse Generators/Stimulators (IPGs)
- Active Implants
- Medication/Supply Management & Storage Solutions
- Drug Delivery Systems
- Surgical Navigation Systems
- Connected/IoT Devices



	INDUSTRY SERVED			
	Cardiovascular	Orthopedics	Diagnostic & Therapeutic	Instruments
SERVICE				
Product Qualification				
Pulsatile & Durability Testing	MTK	CI		
Axial & Torsional Fatigue	MTK	CI	CI	CI
Static Product Testing	MTK	CI	CI	CI
Wear Testing	TOR	CI		CI
Multi-Axis Testing	MTK	CI	CI	CI
Particulate Characterization	TOR	SFS CI TOR	TOR	CI TOR
Radial Force	MTK			
Nickel Ion Leaching	CI TOR	TOR	TOR	TOR
Gait Motion Simulation	MTK			
Biomechanical & Cadaveric Testing		CI	CI	CI
Corrosion	MTK	CI		CI
IEC 60601 and IEC 60601-1-2	BP IR	BP IR	BP IR	BP IR
ANSI C63.27 Wireless Coexistence	BP IR	BP IR	BP IR	BP IR
AIM 7351731 RFID Immunity	BP IR	BP IR	BP IR	BP IR
OTA 3D Antenna Testing & SAR	BP IR	BP IR	BP IR	BP IR
Burst, Pressure and Leak Testing	CI	CI		
Materials Characterization				
Tensile Testing		CI CHG		CHG
Chemical Analysis	TOR	CI CHG SFS TOR	CI CHG SFS TOR	CI CHG SFS TOR
Rotating Beam Testing		CI		
Metallurgical (hardness, grain size, etc.)	CHG	CHG		
SEM/EDS	CHG TOR SFS	CHG TOR SFS	CHG TOR SFS	CHG TOR SFS
Non-destructive testing (FPI, CT, Xray, ultrasonic, etc.)	RD	RD		RD
Fracture Mechanics		CI		
Additive Coupon and Validation Testing	CHG CI	CHG CI		CHG CI
Powder Characterization	CHG TOR	CHG TOR	TOR	CHG TOR

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	INDUSTRY SERVED			
	Cardiovascular	Orthopedics	Diagnostic & Therapeutic	Instruments
SERVICE				
Microbiological Testing				
Endotoxin	WA MTK	WA MTK	WA MTK	
Bioburden	WA MTK	WA MTK	WA MTK	
Cytotoxicity	WA MTK	WA MTK	WA MTK	MTK
Sterilization Validation		MTK		MTK
Sterility Testing		MTK		MTK
Implant Reprocessing Validation		MTK		MTK
Gamma and E-Beam Irradiation Validation		MTK		MTK
Bacterial Water Analysis				
Cleanroom Sampling and Validation				
Environmental Monitoring				
Intrathecal Delivery Devices				
Compressed Air/Gas Testing				
Microbial Identification				
Cleanliness				CI MTK
Antimicrobials				MTK
TOC (Total Organic Compound)	WA TOR	WA TOR	WA TOR	WA TOR
Water Analysis (HPC<LAL, RO/DI)	WA	WA	WA	WA
Analytical Testing				
Extractables and Leachables	TOR SFS	TOR SFS	TOR SFS	TOR SFS
Trace Metals Analysis	WA TOR SFS	WA TOR SFS	WA TOR SFS	WA TOR SFS
ICP-MS	TOR SFS	TOR SFS	TOR SFS	TOR SFS
Drug / Device Interaction Studies	AA	AA	AC AA	AA
Analytical Testing to Support Stability	AA	AA	AA	AA
Chemical Characterization	AA	AA	AA	AA
Contaminant Investigation	AA	AA	AA	AA
FTIR	AA	AA	AA	AA
GC	AA	AA	AA	AA
HPLC	AA	AA	AA	AA
ICH Q1A (R2) Stability	AA	AA	AA	AA

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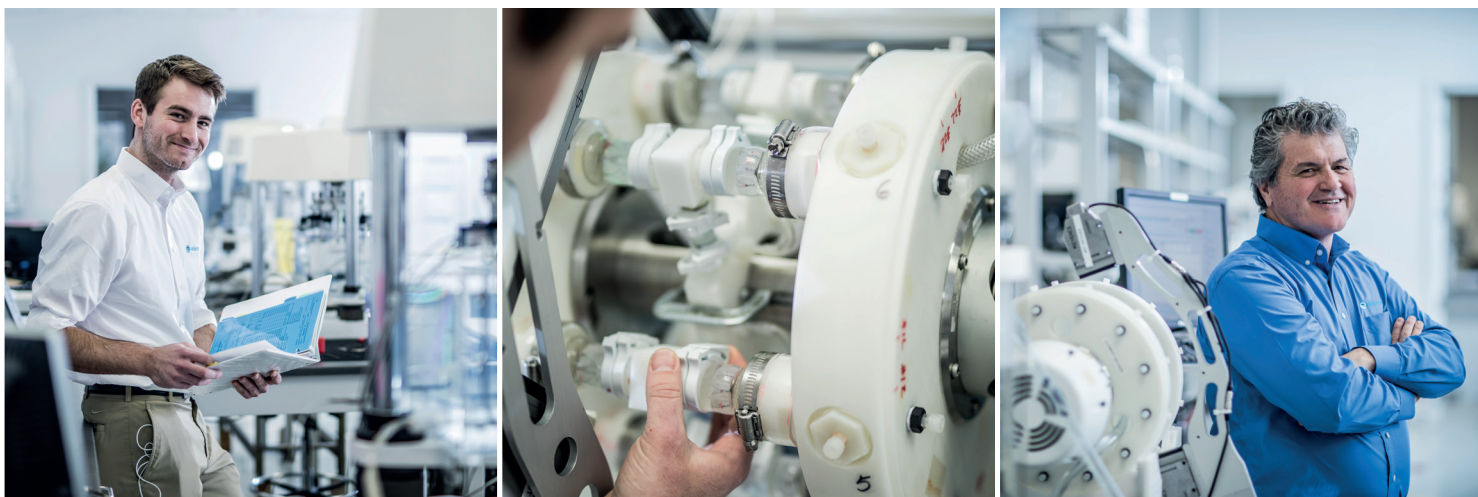
	INDUSTRY SERVED			
	Cardiovascular	Orthopedics	Diagnostic & Therapeutic	Instruments
SERVICE				
Analytical Testing				
ICH Q2R1 Method Validation	AA	AA	AA	AA
Karl Fischer	AA	AA	AA	AA
Optical Microscopy	AA	AA	AA	AA
Preliminary Analysis	AA	AA	AA	AA
Product Testing	AA	AA	AA	AA
Raw Materials Analysis	AA	AA	AA	AA
Storage Stability (accelerated and long-term)	AA	AA	AA	AA
Impurities Characterization (ICH Q3A, Q3B, Q3C, Q3D, M7)	AA	AA	AA	AA
Biocompatibility	AA	AA	AA	AA
Packaging				
Shelf Life	TOR		TOR	
Accelerated Aging	TOR		TOR	
Integrity Testing (microbial, immersion, dye leak)				AC MTK
Consulting Support Services				
Regulatory consulting, utilizing partnerships	ECI	ECI	AA	AA
510(k) and other submission filing, utilizing partnerships	ECI	ECI	AA	AA
Regulatory responses and justification, utilizing partnerships	AA	AA	AA	AA
Failure Analysis	CHG ECI TOR	CHG ECI TOR	CHG ECI TOR	CHG ECI TOR
Reprocessing IFU Development	AA	MTK	MTK	MTK
Digital Simulation	CI	CI	CI	CI

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# TRUST THE CERTAINTY OF



With almost 200 years of experience and a global network of world-class laboratories, we make certain that the materials and products we test, inspect and certify for our customers are safe, quality, compliant and fit for purpose.



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