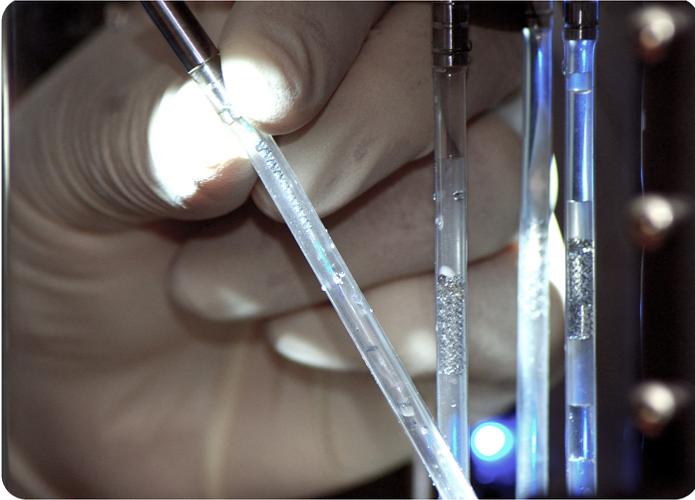


# Testing Services



## Dedicated partnership – the Dynatek advantage

For over 30 years, Dynatek has been delivering an unrivalled blend of expertise, innovation and customer care – and we bring it all together in our testing services. When you have your stent or heart valve device tested by us, rest assured that you're not just cutting costs, but you're mitigating business risk and overcoming regulatory concerns as well. We're experts at testing stents and heart valves and our testing professionals can design the best testing protocol for your device in collaboration with you. We rate our success on your satisfaction with our services and we work hard to earn your trust and your loyalty.

When you test with Dynatek, we deliver fast, complete and accurate results to you – securely and confidentially.

## Why outsource your testing?

If your company is looking for regulatory approval of a cardiac valve, stent or vascular prosthesis, then you know that one of the most important business decisions you will make is whether you will test your device in-house or have it tested by a third party. Cutting costs and reducing time-to-value are the two mantras driving medical device development today. Other challenges for device companies are the twin risks of regulatory rejection and the lack of in-house testing experience and staff expertise. Dynatek has over 30 years of experience in the field of medical device testing. Our M6 Heart Valve Tester is the industry benchmark and our innovative stent testers and coating durability testers offer cutting-edge technology that is unsurpassed. With Dynatek in your corner, you're not just cutting costs, you are speeding your way through pre-clinical testing to successful regulatory approval.

## Expertise that helps you hit your regulatory target

- Regulatory knowledge
- Unsurpassed technology
- Deep domain expertise

Technology and staff expertise are the twin drivers of device testing timelines. The hurdles posed by regulatory agencies can be daunting and the technical challenges associated with navigating these hurdles are unfamiliar territory to many device manufacturers. Dr. James Conti, Dynatek's Executive VP, is on several standards committees and is intimately involved in the formulation of draft requirements and standards at these bodies. When you partner with Dynatek, you're tapping into a deep wellspring of regulatory knowledge and domain expertise that supports all our testing projects.



**DYNATEK** LABS  
Leading the world in medical device testing



## Broad portfolio of testing capabilities

As an independent testing facility, we routinely test to FDA/ISO/ASTM/AAMI/ANSI and other national standards and guidelines and provide accurate, auditable test methodologies with outstanding customer service. Exceptional testing professionals and innovative technology support our wide portfolio of testing capabilities for stents and heart valves:

- Accelerated and real-time coating durability testing with real-time particulate counting
- Accelerated and real-time radial fatigue testing
- Accelerated heart valve durability testing
- Failure mode analysis/Test to failure/Test to fracture
- Accelerated testing of percutaneously-delivered valves
- Acute phase particulate evaluation during deployment and withdrawal
- Custom torsional and bending fatigue testing
- Drug-eluting balloon particulate evaluation
- Custom device test-bed design and manufacturing
- Custom mock vessel design and manufacturing
- Inferior vena cava (IVC) filter evaluation

## Services

Dynatek provides the highest quality service in physiological and accelerated durability testing. Our routine testing services include the following services:

- Daily visual inspection of devices
- Customer-defined measurement of pressure amplitudes/differentials (pressure-controlled testing)
- Scheduled periodic device deflection measurements (deflection-controlled testing) using high-speed photography
- High-speed video of device motion in silicone mock vessels
- Comprehensive final report suitable for submission to regulatory agencies

In addition to the above, we provide customized services based on your specific requirements and will collaborate with you to design a testing protocol that meets your company's testing needs.

## Proven performance

Over three decades of experience in both the regulatory environment and sophisticated stent and heart valve testing technology allows us to consistently exceed your requirements by:

- Understanding your device testing needs thoroughly
- Employing the most advanced testing technology
- Tailoring and delivering industry-leading best practices in testing methodologies

***“Is it possible to cut costs and design a testing program that will drive my device through regulatory approval?”***

To receive a customized proposal, contact us today at:

## Dynatek Labs, Inc.

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