Acute Particulate Tester

Dynatek’s patented\(^1\) Acute Particulate Tester

International standards require the acute phase testing of stents, balloons, occluders, and delivery systems for particulate shedding. Dynatek has leveraged its world-class particulate analysis technology for assessing the particle-shedding behavior of these vascular devices.

Dynatek’s innovative Acute Particulate Tester includes a temperature-controlled, closed loop into which the test sample is deployed.

The vascular device is moved down this loop until it reaches the tortuous path, a section of the test tracking fixture that is described in ASTM F2394-07, or alternatively, a tortuous path furnished by the client.

After navigating the tortuous path, the device is advanced into a mock vessel for deployment. Particles shed by the device during tracking and deployment flow directly into a debubbler and then through custom laser-based particle counters that both count and size particles into user-defined virtual bins.

Downstream of the particle counters, the particles are captured by optional particle capture filters, for SEM/EDX/FTIR analysis, giving you critical information about the composition of the shed particles.

After particulates have been captured for further analysis, the testing fluid flows into a capacitance tank to maintain temperature, and lastly through a 0.2 micron scrubbing filter. From the scrubbing filter, fluid re-enters the flow loop, providing a continual supply of particle-free water, while minimizing waste.

\(^1\) US Patent # 9,453,788
The real-time particle counting advantage

Particle-shedding activity is continuously monitored throughout the duration of a sample run, and counts may be subdivided into multiple data packets based upon client preferences. This allows the user to know discrete particle counts for each phase of device advancement into the system, tracking through a tortuous path, sample deployment, and device withdrawal.

Particle data is divided into virtual bins ranging from 5-100 micron. The user may choose to up to six virtual bins with a resolution of +/- 1 micron up to 50 microns, and +/- 5 micron from 50-100 microns. Particles ranging from 100-1000 micron are counted, but not sized.

Testing fluid is passed through each of the five particle counters at a rate of 100 mL/min, for a total of 500 mL/min, providing minimal down time between sample runs.

Particulate Matter Evaluation during Deployment and Withdrawal

Particulate Matter Evaluation during Deployment and Withdrawal at Dynatek Labs references the following standards and regulations:


iii. FDA Guidance for Industry and FDA Staff – Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, April 18, 2010

iv. FDA Guidance – Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Angioplasty (PTCA) Catheters

v. ASTM F2743-11 – Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems

vi. AAMI TIR42:2010 – Evaluation of Particulates Associated with Vascular Medical Devices


viii. ISO 12417-1:2015 – Cardiovascular Implants and Extracorporeal Systems -- Vascular device-drug combination products

ix. ISO/TS 17137:2014 – Cardiovascular implants and extracorporeal systems -- Cardiovascular absorbable implants


xi. ASTM WK60510 - New Test Method for Simulated use testing of neurointerventional device in tortuous vasculature

xii. ASTM WK60511 - New Test Method for Particle evaluation and characterization for neurointerventional devices
Available Add-ons

- Eight-foot positive pressure flow hood to maximize working platform.
- Customized flow lines to discretely evaluate guide system particle contribution.
- Capture filter tower mounted within hood to facilitate easy capture filter replacement.
- Alternative capacitance tanks and fluid heaters for elevated test temperatures.
- UPS (Uninterruptable Power Supply) system.
- Custom particle counter calibration for atypical particle size ranges.
- Capture filters to aid in chemical analysis of particles.
- Tortuous path to customer specifications; silicone or glass.
- Other custom modifications at customer request.

Tuohy Borst access point.

The flow path can be adjusted to accommodate different design purposes.

Silicone tortuous path according to ASTM F2394-07 or custom designed to meet client's specifications. Silicone design can be adhered to a silicone base for stability or without.
## Dynatek Labs Acute Particulate Tester Specification

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment site configuration</td>
<td>Mock vessel or custom deployment model</td>
<td>Additional special configurations upon request</td>
</tr>
<tr>
<td>Mock vessel configuration</td>
<td>Straight, curved, or bifurcated</td>
<td>Customizable to accommodate various delivery accessories</td>
</tr>
<tr>
<td>Typical number of flow paths</td>
<td>Up to 5</td>
<td>Addition of glycerin possible</td>
</tr>
<tr>
<td>Testing fluid</td>
<td>PBS or distilled water</td>
<td>Temperature control accurate to +/- 1 °C of set temperature</td>
</tr>
<tr>
<td>Fluid temperature</td>
<td>Ambient to ≤ 45 °C</td>
<td></td>
</tr>
<tr>
<td>Flow rate (at sensors)</td>
<td>500 mL/min total</td>
<td></td>
</tr>
<tr>
<td>Test monitoring</td>
<td>Pressure, temperature, flow rate, particle count and size</td>
<td></td>
</tr>
</tbody>
</table>

## Dynatek Labs Particle Counter Product Specification

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of particle counters</td>
<td>5</td>
<td>The use of 5 particle counters reduces cleaning time of each sample or experiment to 20% of the time needed with one counter.</td>
</tr>
<tr>
<td>Particle size range</td>
<td>5-900 micron</td>
<td>Size and count up to 100 micron</td>
</tr>
<tr>
<td>Max. particle concentration</td>
<td>15,000 p/mL @ 10 micron</td>
<td>Count up to 900 micron</td>
</tr>
<tr>
<td>Particle bin range</td>
<td>2-6 bins</td>
<td>Approx. 8,000 p/mL above 150 microns</td>
</tr>
<tr>
<td>Particle counter calibration standard</td>
<td>USP &lt;788&gt;, ASTM F658</td>
<td>5 bins of 5-100 micron</td>
</tr>
<tr>
<td>Sizing resolution</td>
<td>5-50 micron: +/- 1 micron</td>
<td>1 bin for 100-900 micron</td>
</tr>
<tr>
<td>Capture filter assembly</td>
<td>47 mm diameter filter housing</td>
<td>Included filter assembly will allow for easy swap of filter without test interruption</td>
</tr>
</tbody>
</table>

*Specifications are subject to change without notice.

To receive a customized proposal, contact us today at:

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