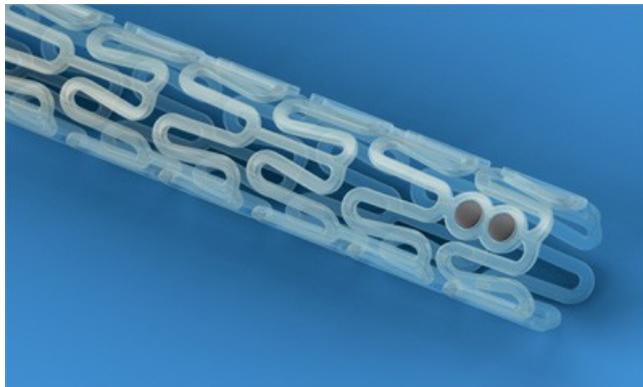


# New Standard Focuses on Testing of Absorbable Stents

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 A new standard by West Conshohocken, PA-based ASTM has been developed to create consistency in the way vascular scaffolds are evaluated from the manufacturing stage to absorption in the body. To guide the medical device industry, academia, government agencies, and others involved in evaluating the performance of vascular scaffolds, ASTM F3036, or Guide for Testing Absorbable Stents, provides criteria for evaluating absorbable stents' physical and mechanical properties.



"Absorbable stents, or vascular scaffolds, are designed to be absorbed by the body after vessel support is no longer needed," remarks Julia Fox, program manager at Santa Clara, CA-based Abbott Vascular and chair of ASTM's

Abbott Vascular's polymer-based Absorb bioresorbable stent.

Subcommittee F04.30 on Cardiovascular Standards. "Whether by molecular weight degradation, in the case of biodegradable polymers, or erosion of the material surface, in the case of absorbable metals, the material properties and/or device-level mechanical performance decline until functionality is lost and the scaffold is fully absorbed."

Scaffold radial strength is one example of a device-level mechanical property that declines over time in the body or in a physiologically relevant aqueous solution in the lab, Fox explains. In the case of bulk-eroding absorbable polymers, the progressive reduction in molecular weight eventually leads to a decrease in the ultimate strength and modulus of the material, reducing the scaffold's radial strength. In the case of surface-eroding metals, the gradual decrease in the strut cross section results in a similar loss of radial strength over time.

"Based on clinical need, the acute performance of absorbable stents is generally expected to be consistent with that of permanent metallic stents," Fox says. "However, because the physical and mechanical properties of vascular scaffolds are designed to change over time, there are unique considerations for bench

testing, extending beyond the devices' acute performance into characterizations of the decline and, ultimately, loss of functionality." To address this issue, ASTM F3036 provides absorbable-specific modifications to the test methods used to evaluate permanent stents, including pretest conditioning, handling before and during testing, and time-dependent evaluations.

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