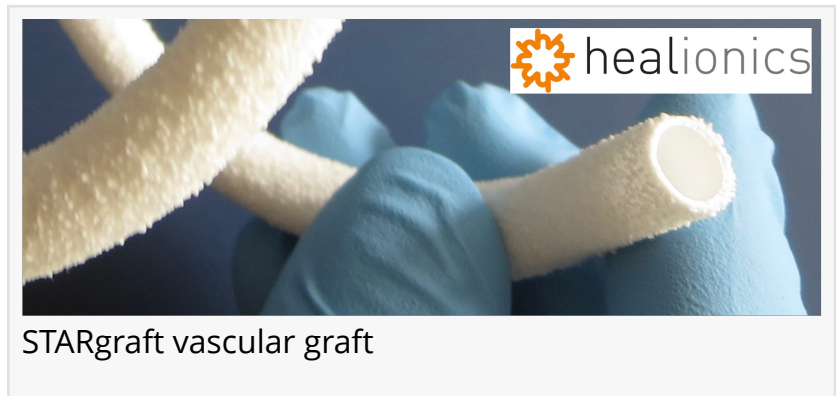


Healionics' STARgraft Receives FDA Breakthrough Device Designation

SEATTLE, WA, UNITED STATES,
November 14, 2024 /

EINPresswire.com/ -- [Healionics Corporation](#),

a developer of synthetic biomaterial-based medical devices, today announced that its STARgraft arteriovenous graft – designed to provide a safer and more reliable means of bloodstream access for kidney failure patients needing dialysis – has been granted Breakthrough Device designation by the FDA.



STARgraft vascular graft

The FDA's [Breakthrough Devices Program](#) aims to identify important new medical devices that provide more effective treatment of life-threatening and irreversibly debilitating conditions, and fast-tracks their regulatory review in order to provide timely access for patients and healthcare providers. This Breakthrough designation signifies FDA acknowledgment that STARgraft clinical outcomes show evidence of significant advantages over existing alternatives for dialysis access. The benefits of receiving Breakthrough designation include expedited interactions with FDA regarding market clearance and with Medicare regarding potential added reimbursement for healthcare providers.

“FDA recognition of STARgraft’s potential to significantly improve the standard of care and quality of life for dialysis patients is a major company milestone and validation of our team’s efforts,” said Healionics CEO Mike Connolly.

About Dialysis and Vascular Grafts

More than 550,000 people in the United States suffer from kidney failure and require frequent dialysis to filter waste from their blood. Current methods of creating and maintaining regular bloodstream access for dialysis are risky, unreliable and costly, driving a significant portion of the \$50 billion the U.S. spends each year to treat kidney failure. An arteriovenous vascular graft (synthetic blood vessel) is often implanted to create an access site with sufficient flow rate for dialysis, but existing grafts frequently fail due to occlusion and/or infection. Healionics’ innovative STARgraft arteriovenous graft, based on proprietary synthetic biomaterial technology, is designed to resist both problems.

STARgraft is an investigational device not yet available for commercial sale.

About Healionics Corp.

Healionics is a privately held medical device company in Seattle that aims to improve the health, longevity, and quality of life of kidney failure patients while reducing treatment cost.

www.healionics.com

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