

Healionics announces 12-month clinical results for STARgraft

SEATTLE, WA, USA, August 7, 2024 /EINPresswire.com/ -- <u>Healionics</u> <u>Corporation</u>, a developer of synthetic biomaterial-based medical devices, today announced 12-month clinical results in the ongoing human trial of its STARgraft arteriovenous (AV) graft (NCT05729620).



STARgraft vascular graft

STARgraft is a new AV graft technology

designed to provide kidney failure patients with a safer and more reliable way to access the bloodstream for hemodialysis treatment. Its design is aimed at resisting the most common causes of failure in on-market AV grafts: flow blockage and infection.

After refinement of the device over a series of clinical trials, STARgraft is showing remarkable promise in addressing these issues and reducing the need for interventions to maintain function. The cohort of twelve patients implanted with the current version of STARgraft has maintained 100% Primary Unassisted Patency (PUP) through 12 months post-implant, meaning zero interventions were required to maintain sufficient blood flow for dialysis therapy. The STARgraft devices have also maintained 0% infection rate.

"Achieving an AV graft design that reached the 12-month clinical endpoint with 100% unassisted functional performance and no need for surgical interventions is a huge milestone for our team," said Healionics CTO Andrew Marshall, PhD. "It's a big step toward addressing a major problem that has frustrated the vascular access field for decades."

These successful outcomes imply the potential to significantly improve upon the current standard of care. Nearly 60% of all on-market AV grafts suffer flow blockage or require surgical intervention to maintain flow within the first 12 months after implant, and 9% of these devices become infected per year, according to an extensive review of historical literature (Halbert et al. 2020).

The clinical trial is ongoing, with continued periodic patient follow-up exams to monitor longerterm performance. These results are slated to be presented at the October <u>Controversies in Dialysis Access</u> <u>Symposium</u>, a leading clinical educational forum for physicians and medical staff who care for dialysis patients.

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 vascular 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. <u>www.healionics.com</u>

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