

DuraGraft[®]

The World's 1st Endothelial Damage Inhibitor

The First ENDOTHELIAL DAMAGE INHIBITOR

DuraGraft[®] is first-in-class and the only CE marked product intended for the preservation, storage and flushing of vascular conduits, which is a pivotal step in cardiac and peripheral bypass surgeries.

As the only clinically proven Endothelial Damage Inhibitor, DuraGraft is critical to successful patient outcomes.



DURAGRAFT® ENDOTHEL

The Pivotal Step

DuraGraft is the First Endothelial Damage Inhibitor (EDI)

developed to address the pivotal step of vascular graft preservation, storage and flushing in coronary artery and peripheral bypass surgeries. Despite advances in medical management and surgical techniques, there has been little improvement in bypass outcomes and vein graft failure (VGF) remains one of the leading causes of poor long-term outcomes after CABG and peripheral bypass surgeries.



Need for Change

Frequently, Vascular Grafts are Stored

in saline- or blood-based solutions; many of which are cytocidal and clinically proven to be associated with the poorest clinical outcomes and highest VGF rates. Forty-six percent of CABG patients whose vein grafts were stored in saline- or blood-based solutions experienced VGF within one year of surgery.* DuraGraft has been shown to preserve the structural and functional integrity and viability of the vascular graft and its associated endothelium.** Because of this ability to preserve, DuraGraft is associated with better clinical outcomes when compared to saline or blood-based solutions.***

My belief is that DuraGraft's beneficial effects on SVG endothelial function can enhance the quality of care and improve outcomes in CABG patients.

– Vladimir Birjiniuk, M.D.
Chief of Cardiothoracic Surgery, Mount Auburn Hospital, Cambridge, MA

Critical to Success

The Value of Preserving the Structure and Function

of the vascular endothelium is unquestionable and critical to successful graft performance, patient outcomes and overall quality of life. DuraGraft uniquely preserves the vascular graft and its associated endothelium.

* Harskamp RE, Alexander JH, et al. Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery. Follow-up From PREVENT IV Randomized Clinical Trial. *JAMA Surg.* 2014; 149(8):798-805.

** Thatte HS, et al. Multi-Photon Microscopic Evaluation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA. *Ann Thorac Surg.* 2003; 75:1145-1152.

*** Data on File.

IAL DAMAGE INHIBITOR

Physiologically Designed

DuraGraft® is a pH, Osmotically and Ionically Balanced

sterile solution containing antioxidants and other components that are pro-endothelial and pro-vasomotor function preserving. DuraGraft is intended for the preservation, storage and flushing of vascular conduits prior to grafting in vascular surgeries.

We found that DuraGraft was better able to preserve the endothelium versus other commonly used holding solutions (e.g. heparinized saline).

*– Miguel Haime, M.D.
Cardiac Surgeon, V.A. Boston Healthcare System, Boston, MA*

Ready To Use

DuraGraft is a Premeasured Solution

which does not interrupt or modify the existing surgical procedure or impact the length of the procedure. The use of DuraGraft mitigates risks associated with the use of standard-of-care solutions and custom-mixed solutions from the hospital pharmacy.

Unmatched Quality

DuraGraft is Manufactured

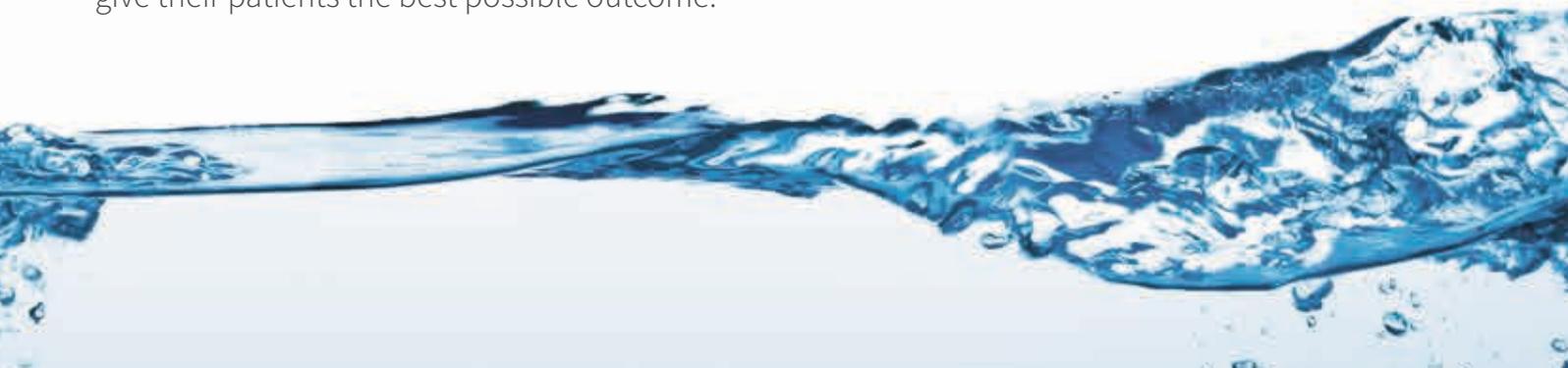
according to the highest quality standards of cGMP and ISO 13485, using only USP/EP grade components, unlike pharmacy and O.R. mixed solutions. This ensures the product will provide maximum patient safety with a desired 2-year shelf life.

A Quality Controlled Product

DuraGraft is aseptically processed and can reduce the risk of infection as compared to custom O.R. mixed and pharmacy compounded solutions. Each lot of DuraGraft is extensively tested and released with a Certificate of Analysis to guarantee a high-quality, consistent product every time.

DuraGraft is the only clinically approved product for the preservation, storage, and flushing of vascular grafts used in coronary artery and peripheral bypass surgeries. DuraGraft reduces the risk associated with errors made during pharmacy and O.R. compounding.

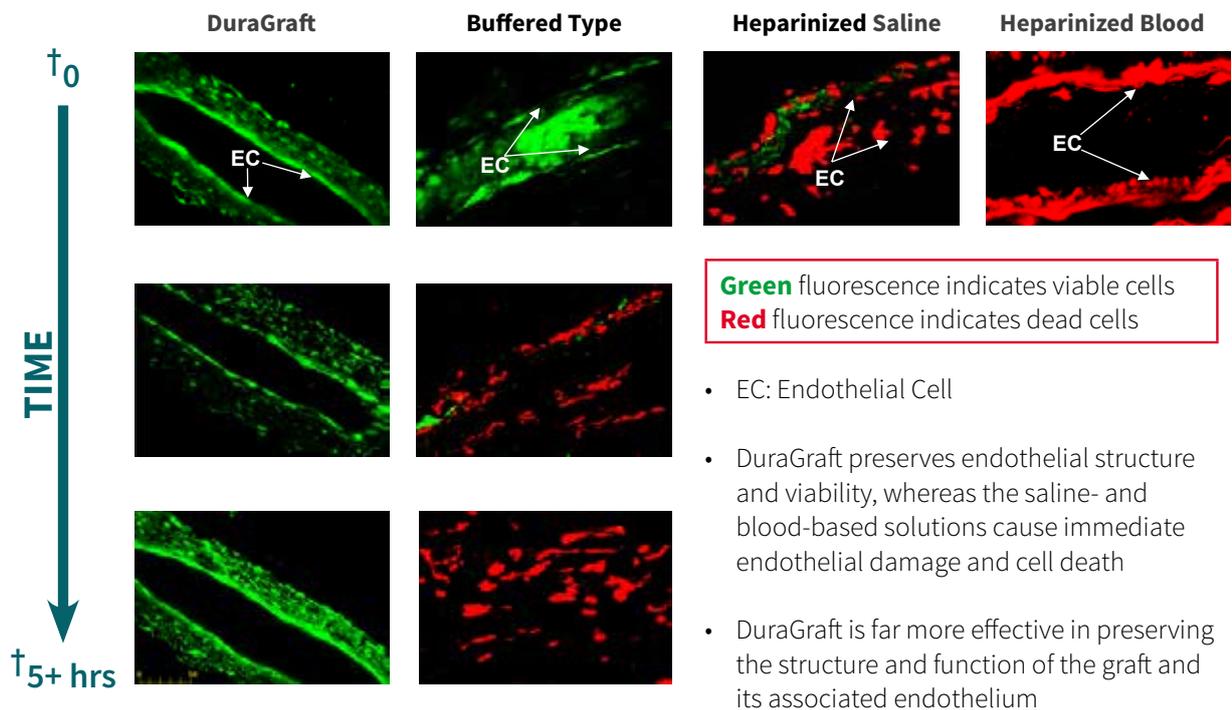
DuraGraft provides surgeons with the confidence and satisfaction that they are doing all they can to give their patients the best possible outcome.



CURRENT SOLUTIONS CA

DURAGRAFT® WAS SHOWN TO OUTPERFORM BUFFERED, HEPARINIZED SALINE AND HEPARINIZED BLOOD IN MINIMIZING VASCULAR ENDOTHELIAL DAMAGE THAT OCCURS DURING THE INTRAOPERATIVE PERIOD.

Changes in Viability and Structural Integrity of Vein Grafts, Following Storage in Various Solutions*



Human saphenous vein grafts stored in DuraGraft were found to maintain viability and structural integrity through extended storage times, while vein grafts stored in saline or blood based solutions were extensively damaged and lost viability almost immediately. Damage exhibited in buffered solutions is not as immediate, however buffered solutions are unable to maintain viability and structural integrity when compared to DuraGraft. Multiphoton microscopy was used to generate images of vein grafts stained using “live/dead” staining technology.

Photo provided with permission of Annals of Thoracic Surgery.

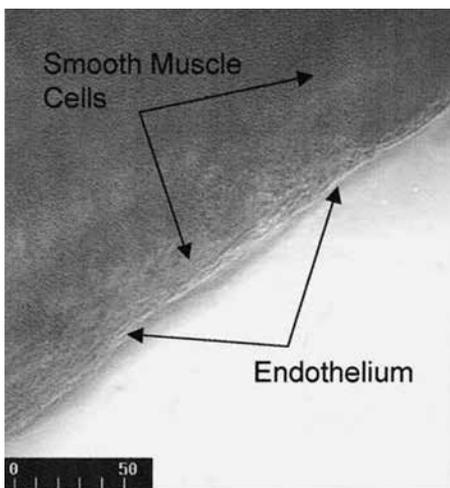
* Thatte HS, et al. Multi-Photon Microscopic Evaluation of Saphenous Vein Endothelium and Its Preservation With a New Solution, GALA. Ann Thorac Surg. 2003; 75:1145-1152.



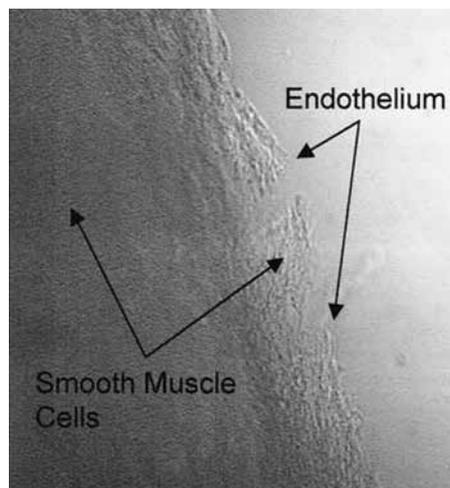
USE IMMEDIATE DAMAGE

ALINE AND HEPARINIZED BLOOD-BASED SOLUTIONS BY INHIBITING THE
ERATIVE STORAGE OF VASCULAR GRAFTS USED IN VASCULAR SURGERIES.

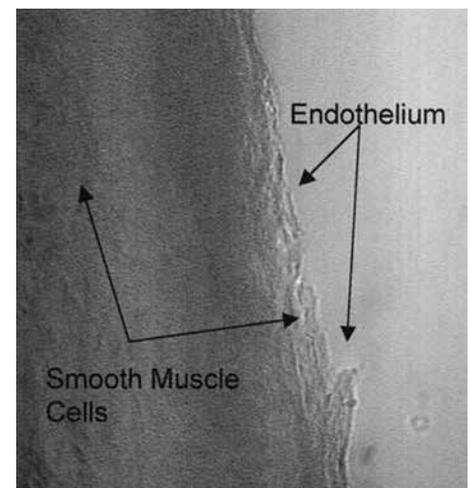
DuraGraft® Maintains the Structural Integrity of Vascular Grafts*



DuraGraft



Heparinized
Saline Solution



Autologous
Heparinized Blood

Multiphoton images of vein grafts stored in DuraGraft demonstrate an uninterrupted vascular endothelium and smooth muscle cells, while grafts stored in heparinized saline and autologous blood present with damaged and disrupted endothelium and smooth muscle cells.

Photo provided with permission of Annals of Thoracic Surgery.

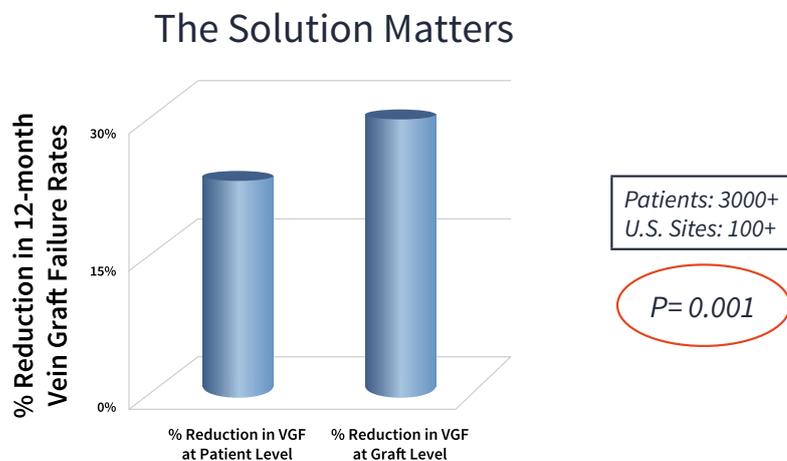
* Thatte HS, et al. Multi-Photon Microscopic Evaluation of Saphenous Vein Endothelium and Its Preservation With a New Solution, *GALA. Ann Thorac Surg.* 2003; 75:1145-1152.



THE SOLUTION MATTERS

Clinical Outcomes

The solutions used to preserve, store and flush the graft have been clinically identified as the most critical intraoperative variable impacting vein graft failure rates.* Researchers from Duke Clinical Research Institute (DCRI) analyzed data from the PREVENT IV trial, which included more than 3,000 patients, a 1-year angiographic follow-up to assess for vein graft failure and 5-year clinical outcomes. They concluded that veins flushed and stored in frequently used saline- and blood-based solutions are associated with the highest vein graft failure rates and the poorest clinical outcomes. According to this analysis, vein graft failure rates were reduced by almost 30% in patients whose vein grafts were not stored and flushed with saline- or blood-based solutions.**



Reduction in 12-month Vein Graft Failure Rates associated with the use of “buffered” graft storage solutions is shown. Both patient-level and graft-level VGF rates were reduced by 22% and 29% respectively as compared to rates associated with the use of both saline and blood-based storage solutions. Both patient and graft level reductions were statistically significant ($p=.001$).

Similarly, a 5-year review of patients undergoing CABG demonstrated that DuraGraft® improved clinical outcomes of repeat revascularization by as much as 48%. Additional improvements were shown in reduced myocardial infarction, mortality and MACE, which may lead to improved quality of life for these patients.***

*Hess CN, Lopes RD, Alexander JH, et al. Saphenous Vein Graft Failure After Coronary Artery Bypass Surgery. Insights from PREVENT IV. *Circulation*. 2014;130:1445-1451.

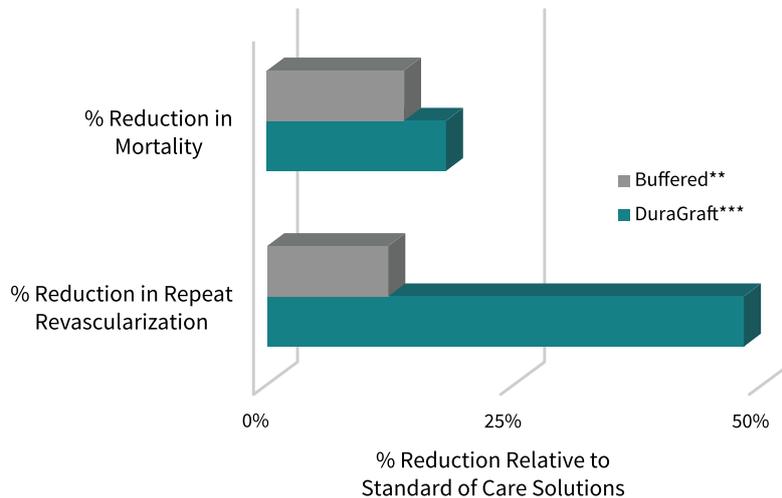
** Harskamp RE, Alexander JH, et al. Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery. Follow-up From PREVENT IV Randomized Clinical Trial. *JAMA Surg*. 2014; 149(8):798-805.

*** Data on File.



CLINICAL PERFORMANCE OF DURAGRAFT®

DuraGraft Reduces MACE Relative to Standard of Care* and Buffered Solutions



* Standard of Care Solutions = Saline- or Autologous Blood-Based

** Harskamp RE, Alexander JH, et al. Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery. Follow-up From PREVENT IV Randomized Clinical Trial. JAMA Surg. 2014; 149(8):798-805.

*** DuraGraft clinical study

The percent reduction in repeat revascularization and mortality relative to standard of care graft storage solutions associated with the use of either DuraGraft or a buffered-type solution is shown. DuraGraft shows clinically significant reductions in repeat revascularization and mortality (and myocardial infarction, not shown) when compared to those rates associated with standard of care and buffered-type graft storage solutions.

DURAGRAFT CAN HELP YOU OPTIMIZE YOUR PATIENTS' OUTCOMES AND PROGNOSIS AND MINIMIZE YOUR INSTITUTION'S EXPOSURE TO RISK. ASK US HOW TO PUT THIS BREAKTHROUGH TECHNOLOGY TO WORK IN YOUR SURGICAL SUITE.

DuraGraft is not available in all markets. Visit somahlution.com/distributors for availability.





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