

PECAlabs®
synthetic cardiovascular devices



PECA Labs in collaboration with
Visionary Medtech Presents

ex-Graft

**A BALLOON DILATABLE
PTFE GRAFT**

exGraft®



exGraft[®]



...is a CE-Marked **Synthetic Vascular Graft**. exGraft fuses the *performance of ePTFE* with the addition of a *novel radiopaque design*. This first-in-class combination enhances the *visibility of graft location and orientation* during surgery and follow-up.

Who We Are

PECA Labs is a spin-off of Carnegie Mellon University and the University of Pittsburgh. Our passion is the development of improved devices for cardiothoracic and vascular surgery.

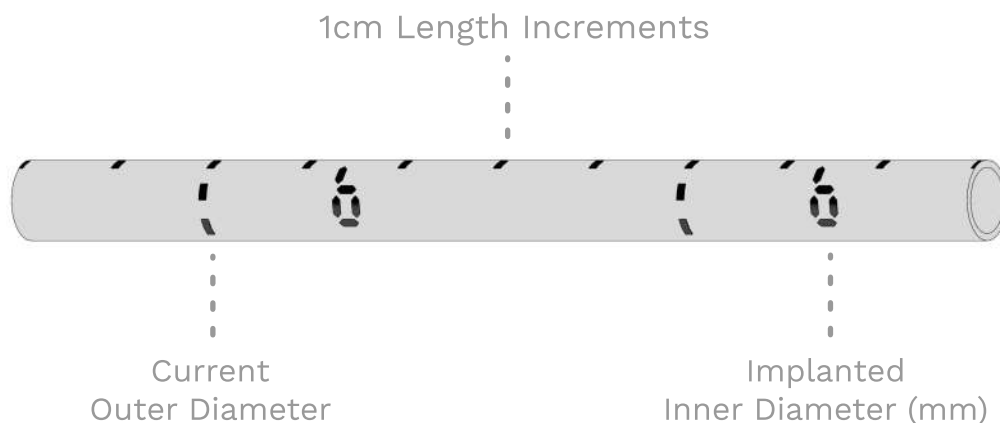
Founded in 2012, PECA's original focus on surgical devices to improve the treatment of congenital heart defects has since broadened into the research and development of an array of cardiovascular surgical devices.

Our model of direct collaboration with surgeons from around the globe is fueling the development of groundbreaking new devices, from expandable vascular conduits to synthetic transcatheter valves.

exGraft[®]



Radiopaque Indicators



exGraft®



exGraft vs Gore-tex

Graft Construction

Product → Feature / Characteristics ↓	PECA Labs		Gore	
	exGraft	exGraft Carbon	Stretch Vascular Graft	Propaten Vascular Graft
Pure ePTFE Vascular Graft*	✓	✓	✓	✓
Radiopaque Markers	✓	✓		
Single Layer Construction**	✓	✓		
Luminal Surface Coating		✓ (Carbon)		✓ (Heparin)

*PECA Labs and Gore Products are both pure expanded polytetrafluoroethylene (ePTFE) grafts but have **different microstructures**.

**PECA Labs grafts have a single layer construction, Gore grafts have an outer wrap. PECA Labs' construction meet and exceed the requirements for water entry pressure, burst pressure, and other strength characteristics without an outer wrap.

IMPORTANT NOTE: PECA Labs' single layer construction will dilate if an oversized balloon is used at high pressures.

Graft Usability Features

Product → Feature / Characteristics ↓	PECA Labs		Gore	
	exGraft	exGraft Carbon	Stretch Vascular Graft	Propaten Vascular Graft
Intra-operative Twisting/Kinking identification	✓	✓	✓	✓
Intra-operative Longitudinal Stretchability			✓	✓
Post-Operative Twisting/Kinking using X-ray / Fluoroscopy	✓	✓		
Post-Operative Size Indicators using X-ray / Fluoroscopy	✓	✓		
Post-Operative Length Indicators using X-ray / Fluoroscopy	✓	✓		

RADIOPAQUE MARKERS

Radiopaque ink on the exGraft is designed for the surgeon, interventionalist, radiologist & the supporting staff.

Surgeons

- Assist pre-op cutting
- Assist pre-op measurements
- Observing twisting during implantation

Interventionists

- Easier conduit identification during angioplasty
- Observing angioplasties effects on outer wall
- Estimating endothelialization using radiopaque rings

Radiologists/Follow-ups

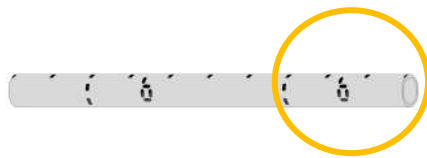
- Visible conduit size at implantation
- Easier conduit identification
- Easier identification of twisting etc.
- Easier identification of conduit patency

Surgical Support Staff

- Double checking size before implant (marked on conduit)

FIGURE 1

exGraft as SANO Shunt for HLHS.



Yellow Circle represents the area of conduit implanted in a new born.

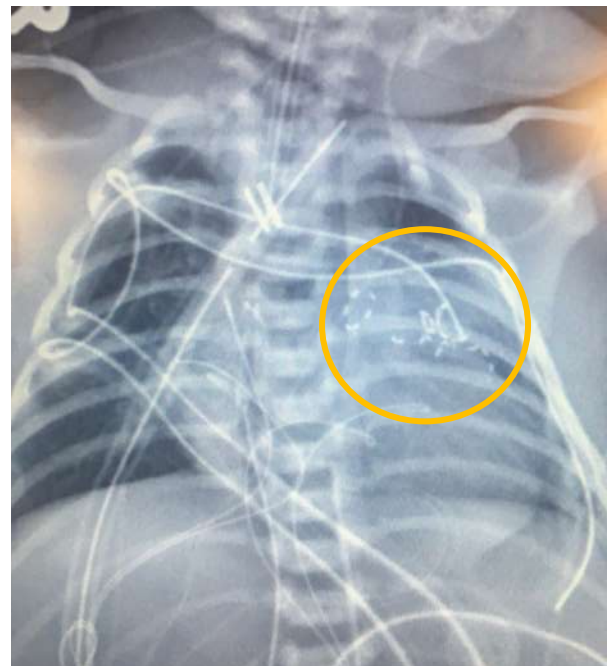


FIGURE 2

exGraft during an interventional procedure in a 5 month old patient with a 6mm Sano shunt implanted soon after birth



Oversized Balloon Precautions

Important Precautions for using oversized balloon:

- Do not use oversized balloon before 5 months post-implantation.
- The operating pressure of balloon should not exceed 4-5 ATM.
- The balloon should not have a burst rating less than 10ATM.
- Never exceed the size of the native vessel the graft is attached to.
- Be cautious of a 20% recoil post-balloon, however, using a covered stent may prevent any recoil.
- Do not inflate fast!
- Do not directly dilate to final diameter if the final diameter is >2mm. Dilations should be sequential – this means only +2mm can be added with each balloon. In case 4mm is being added to original diameter 2 ballooning would be necessary. A +2mm balloon to be introduced at first and then a +4mm balloon subsequently.

The conduit is not approved for >120% oversized balloon so it is upon the interventionalist to make a life saving decision. Also >140% dilation require covered stents, this would also avoid any recoil as well. Each dilation should follow the technique on the next slide.

Precautions during angioplasty:

1. Do not inflating the balloon quickly beyond 2ATM.
2. Wait for at least 2 seconds before proceeding to 3ATM balloon pressure.
3. Do not dilate fast! Increase balloon pressure by 1 ATM at a time and hold 5 seconds until 6ATM pressure is reached, hold for another 5 seconds and subsequently jump from 6 to 8ATM (2ATM jump at end). Having someone to count 5 seconds after each inflation is a cautious measure.
4. Fast inflation of balloon may cause injury to the vessel or the graft. A covered stent may be used with the graft in case of injury.

When a chewing gum is exposed to a sudden force in opposite directions, it breaks.
However, if slow, gentle force is applied, it keeps stretching out.

Available Configurations

All configurations of the exGraft® include the following features:

- Pure ePTFE Conduit
- Radiopaque Indicators
- Procedural Twisting Indicator
- Available Length 25/35 cm

Inner Diameter (mm)	Length (cm)
3	35
3.5	35
4	35
5	35
6	35
8	35
10	35
12*	35
13	35
14*	35
16	35
18*	25
19	25
20*	25
22*	25
24*	25

The First Controllably-Expandable Vascular Graft

Balloon at 2 ATM



Balloon at 6 ATM



Balloon Removed



PECA Labs has developed a synthetic vascular graft that is capable of controlled expansion with a standard angioplasty balloon.

The expandable vascular conduit is capable of providing conduit growth potential of over 250% while maintaining its suture retention strength, burst strength, kink radius, and other critical properties.

The expandable vascular conduit utilizes a bioinert material with well-known clinical performance, and capitalizes on a unique microstructure to provide capabilities beyond any currently marketed vascular graft.

Geometry of the Suture Line

A basic schematic of the suture line at the anastomosis of the vessel (top) and exGraft (bottom) is shown in Figure 4 below.

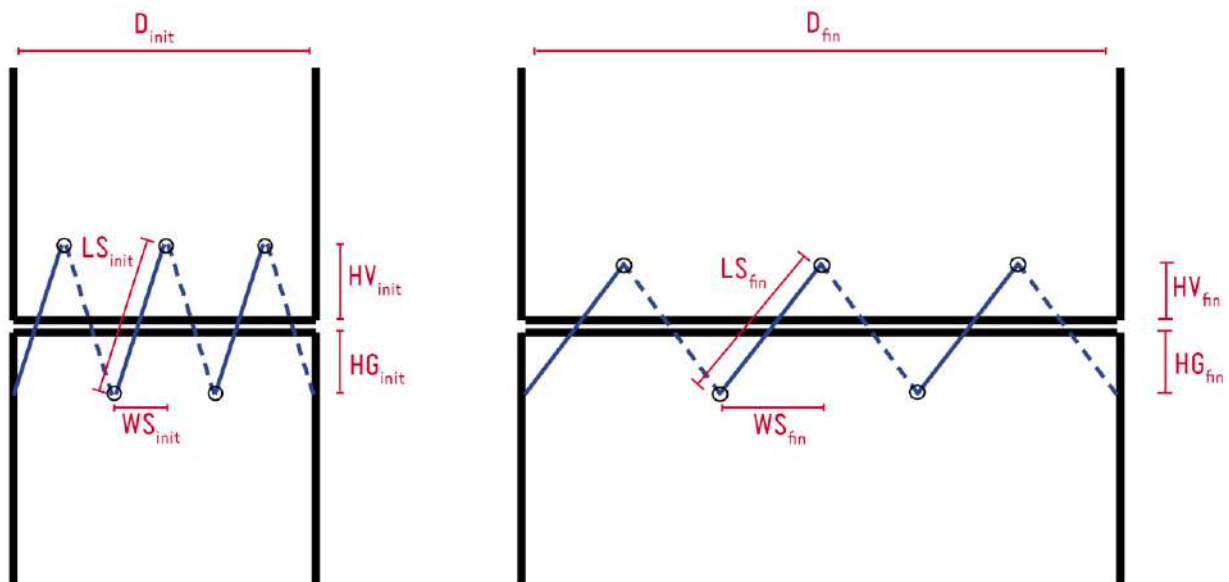


Figure 4. Geometry of the suture line in initial and expanded configurations. D is the diameter of the graft and vessel. LS is the length of a suture between a single pair of holes. WS is the distance in the radial direction between a single pair of suture holes. HV is the depth of suture into the vessel (relative to the original midpoint of the anastomosis, not considering any telescoping). HG is the depth of suture into the graft vessel (relative to the original midpoint of the anastomosis, not considering any telescoping). The subscripts "init" and "fin" describe the initial and expanded states, respectively.

Given these dynamics, the suture line is able to accommodate expansion without deformation or damage to the suture itself. Rather the expansion of the graft is accommodated by the elastic nature of the vessel itself.

List of centers using the exGraft

University of Pittsburgh Medical Center: Children's Hospital of Pittsburgh

Harvard University: Boston Children's Hospital

Children's Hospital Los Angeles: Los Angeles, CA

University of Pennsylvania: Children's Hospital of Philadelphia

Northwestern University: Lurie Children's Hospital

C.S Mott Children's Hospital: Ann Arbor, Michigan

Colombia University: New York Presbyterian Children's Hospital

Cincinnati Children's Hospital Medical Center: Cincinnati Children's

University of Texas Southwestern: Children's Dallas

Anschutz Medical Center: Colorado Children's Hospital

OU Medicine: The Children's Hospital Oklahoma City

Bay Care Health Systems: St Joseph's Children's Hospital

Arkansas Children's Hospital: Little Rock, AR

Advocate Aurora Health: Chicago, IL

Wolfson Children's Hospital: Baptist Medical Center, Jacksonville FL

Loma Linda University Children's Hospital: Loma Linda, CA

University of Maryland: Children's Hospital

Duke University: Durham, NC

Stanford University: Lucile Packard Children's Hospital

The Heart Center: Nationwide Children's Hospital

Methodist Le Bonheur Healthcare: Le Bonheur Children's

Children's Hospital of Wisconsin: Milwaukee Campus

Branch Office:

- ▶ Visionary Medtech Solutions Pvt Ltd, 203, SaiKrupa Bldg, Shiv Vallabh Rd, Nr. Gokul Anand Hotel, Above Platium GYM, Dahisar (East), Mumbai 400068.
- ▶ Visionary Medtech Solutions Pvt Ltd, 544, first floor, New BEL Road, Chikmaranahalli, RMV 2nd Stage, Bangalore 560094
- ▶ Visionary Medtech Solutions Pvt. Ltd. H No. 1-2-597/20, Flat No 402, Fourth Floor, Surya lake View, Lower Tank Bund Road, Damalguda, Hyderabad 500029
- ▶ Visionary Medtech Solutions Pvt Ltd, No. 7/55, A2, First Floor, Vinayagapuram 1st street, 100 feet Road, Arumbakkam, Chennai 600106.

We are also available in:

Delhi, Mangalore, Vijaywada, Kolkota, Chandigarh,
Lucknow, Kochi, Trivandrum and Calicut.

Head Office:

Visionary Health Care.
408, Orange Mall, Nr. Sharda Petrol Pump, Chandkheda,
Ahmedabad 382424.

Website: visionarymedtech.com