

The image features a dark purple background with white line art of a baseball glove. The glove is shown from a side-on perspective, with the fingers and thumb clearly visible. The stitching of the glove is represented by small, repeating 'X' marks. The text 'PECA labs' is centered in the middle of the image. 'PECA' is in a bold, orange, sans-serif font, while 'labs' is in a lighter orange, lowercase, sans-serif font. A registered trademark symbol (®) is positioned to the upper right of the 's' in 'labs'.

PECA labs®

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.

exGraft vs Gore-tex

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

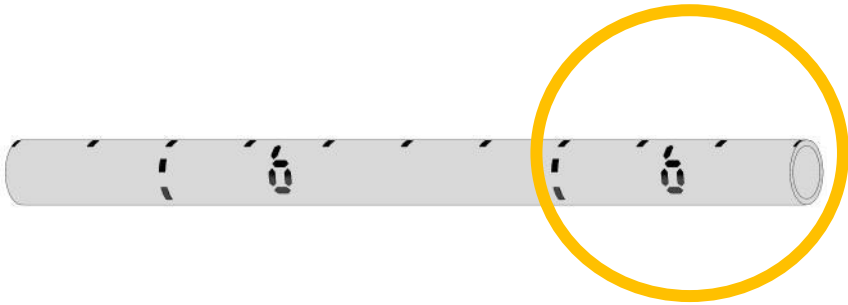
- Visible conduit size at implantation
- Easier conduit identification
- Easier identification of twisting etc.
- **Easier identification of conduit patency**

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 newborn.

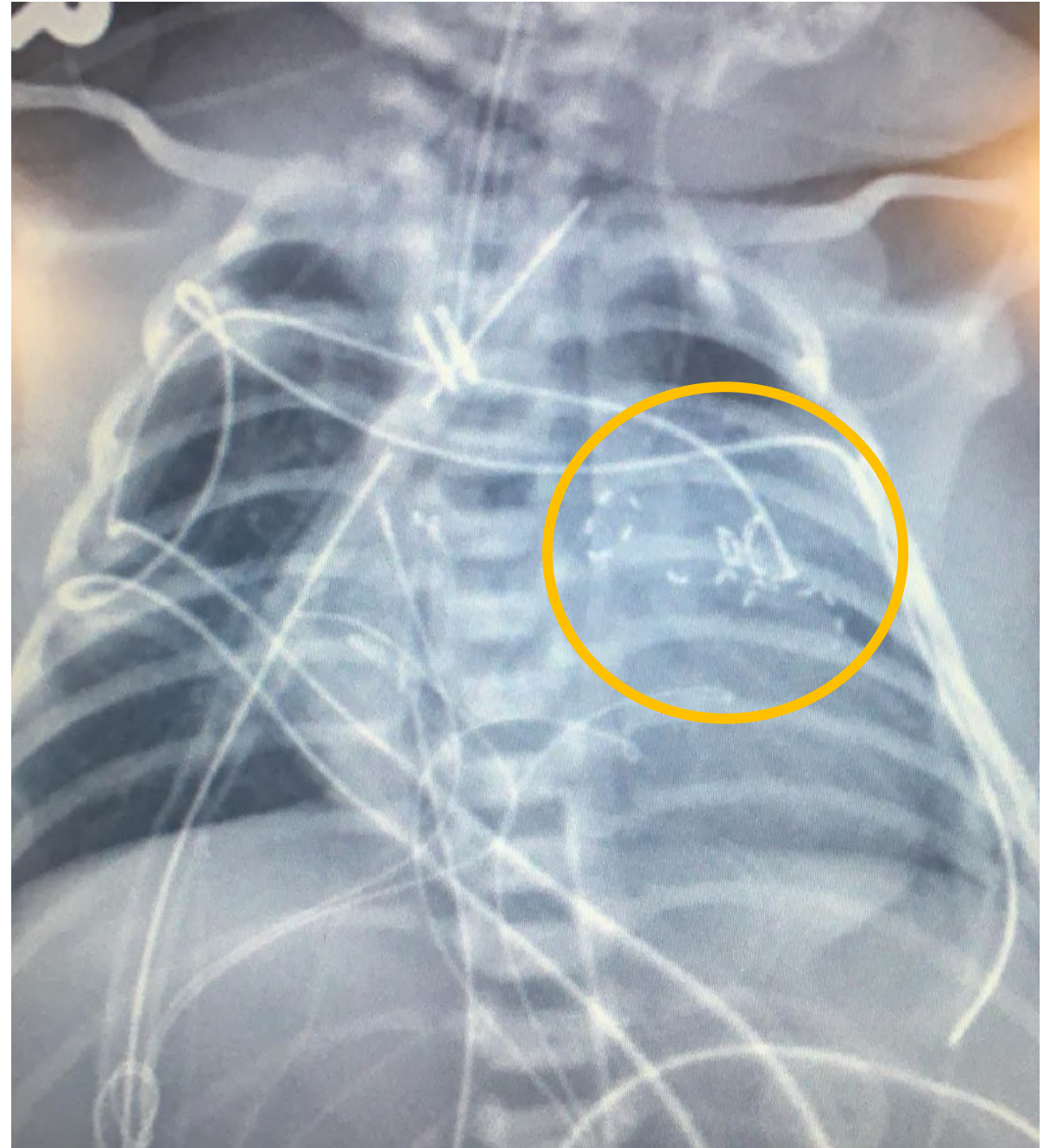
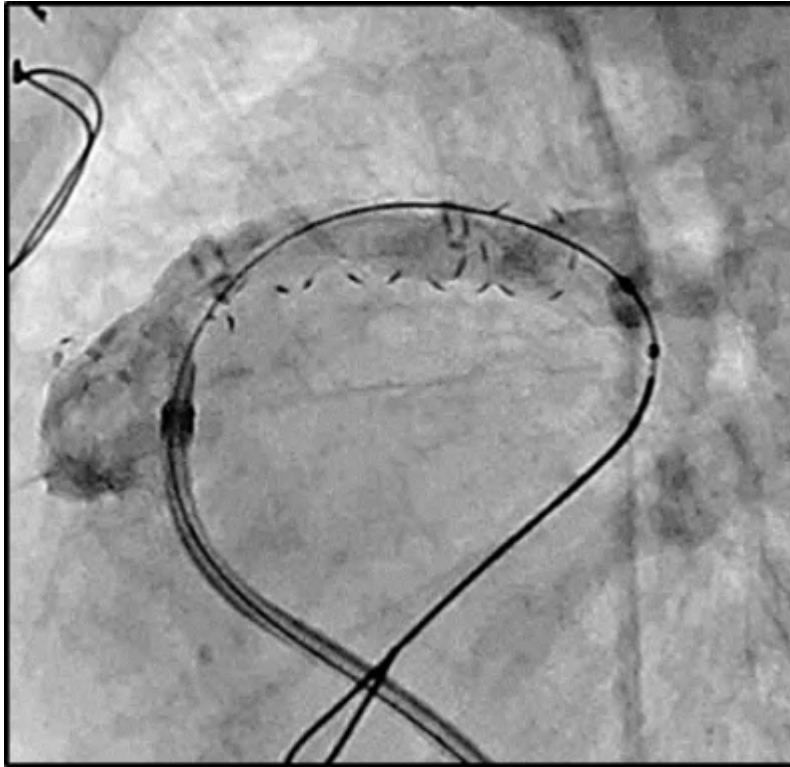


FIGURE 2

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-ballooning, 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.

Oversized Balloon Precautions

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.

FIGURE 3

Ex-vivo X-ray image of an exGraft anastomosed to aortic arch with an intentionally kinked conduit

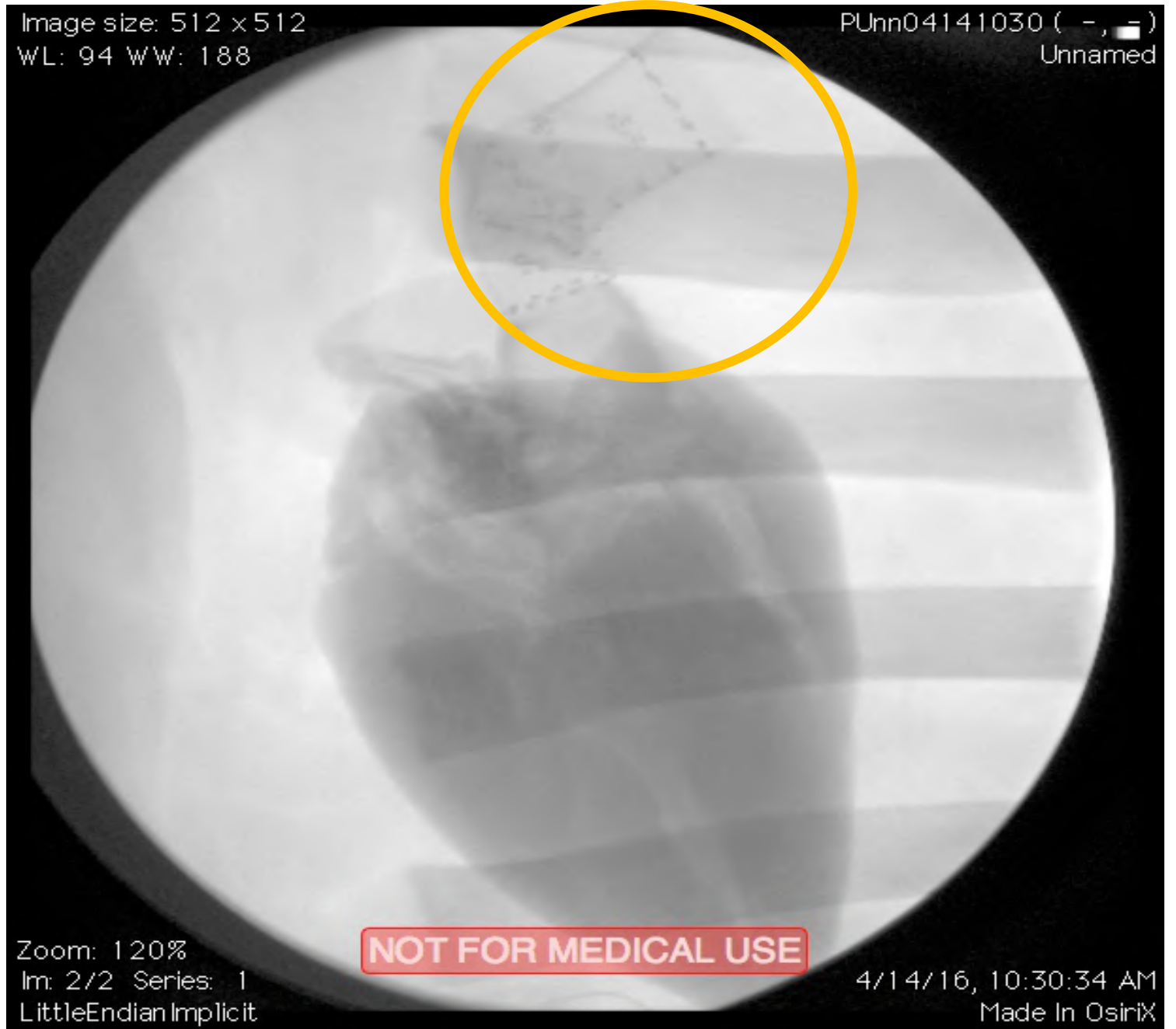
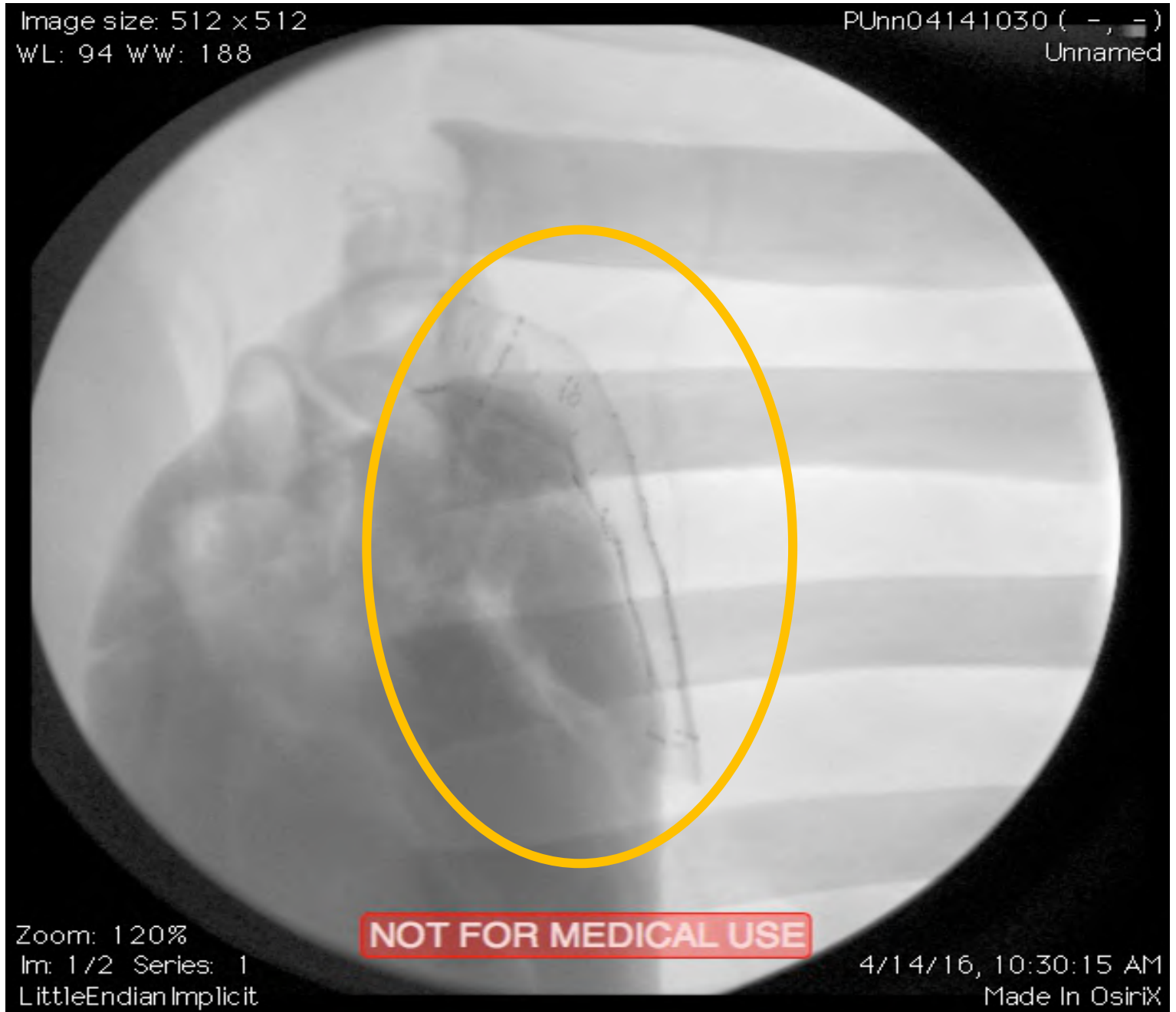


FIGURE 4

Ex-vivo X-ray image of an exGraft anastomosed to the aortic arch with an intentionally compressed conduit





Recent mentions/presentations for PECA Labs exGraft technologies

Carro O C, Giamberti A., Uricchio N.**, Balabushka W., Marianeschi SM.*

*Asst Ospedale Niguarda Milano, * Irccs policlinico San Donato Milano, ** Asst Ospedale papa Giovanni XXIII Bergamo - A new extracardiac conduit in Fontan procedure: the first cases of expandable vascular graft implantation*

*exGraft mentioned while talking about the future of Fontan operation in “Fontan with Lateral Tunnel Is Associated with Improved Survival Compared to Extracardiac Conduit Viktoria H.M. Weixler, David Zurakowski, John Kheir, Alvise Guariento, Jonathan Rhodes, *Christopher W. Baird, *A.K. Kaza, *Pedro J. del Nido, *Sitaram M. Emani” – this was not a direct publication.*

Accepted by Annals of Thoracic Surgery (due for publication): In vivo dilation of exGraft™ conduit in a patient with single ventricle disease Asad Qadir,MD¹; Paul Tannous, MD, PhD¹; Elizabeth H. Stephens, MD, PhD²; Arush Kalra, MBBS³, MS; Joseph M. Forbess, MD, MBA²; Alan Nugent, MBBS¹

exGraft[®]



*exGraft has been successfully implanted &/or is on shelf in 6 countries
including several top hospitals in the US including*

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

Harvard University - Boston Children's Hospital

Stanford University - Lucile Packard Children's Hospital

Northwestern University - Lurie Children's Hospital

University of Texas Southwestern - Children's Dallas

Anschutz Medical Center - Colorado Children's Hospital

The Heart Center - Nationwide Children's Hospital

Cincinnati Children's Hospital Medical Center - Cincinnati Children's

Methodist Le Bonheur Healthcare - Le Bonheur Children's

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

Children's Hospital of Wisconsin - Milwaukee Campus

PECAlabs[®]

exGraft[®]



Currently available Sizes for exGraft

Inner Diameter (mm)	Lengths (cm)
3	15, 25, 35
3.5	15, 25, 35
4	15, 25, 35
5	15, 25, 35
6	15, 25, 35

Inner Diameter (mm)	Lengths (cm)
8	15, 25, 35
10	15, 25, 35
13	15, 25, 35
16	15, 25, 35
19	15, 25

exGraft[®]



Sizes available starting Q1 2020

Inner Diameter (mm)	Lengths (cm)
12*	15, 25, 35
14*	15, 25, 35
18*	15, 25

