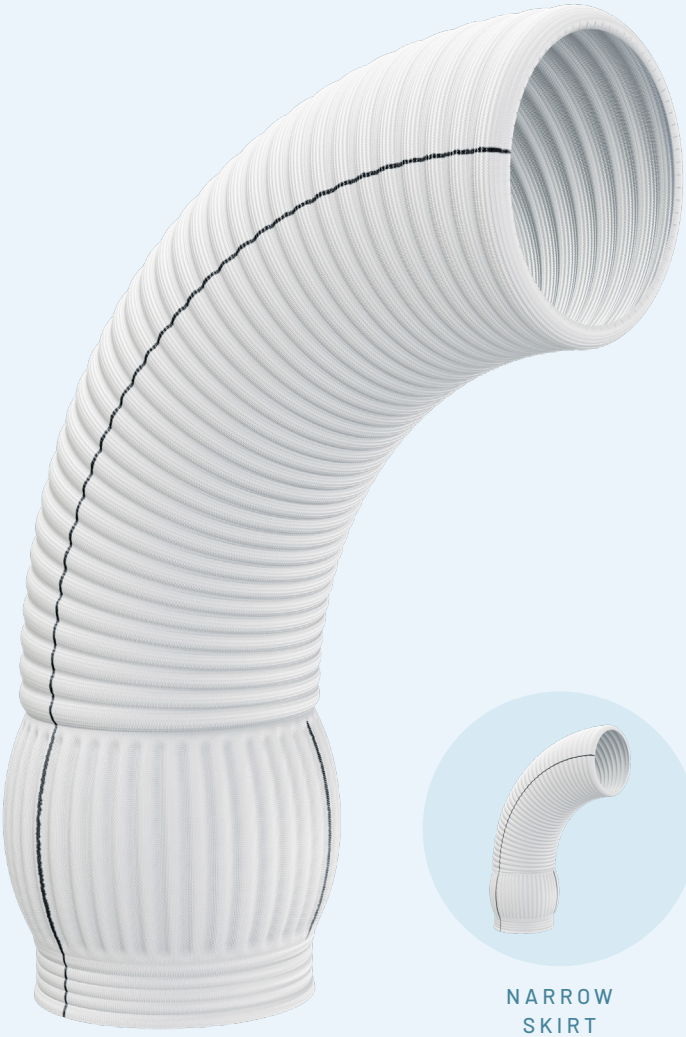
TERUMO AORTIC

USA



ANTE-FLO

ANTE-FLO
SHORT SKIRT

NARROW
SKIRT

SHORT
SKIRT

FLORIDA
SLEEVE

PRODUCT BROCHURE

Gelweave™ Valsalva

Recreating the Space whilst Respecting the Anatomy.

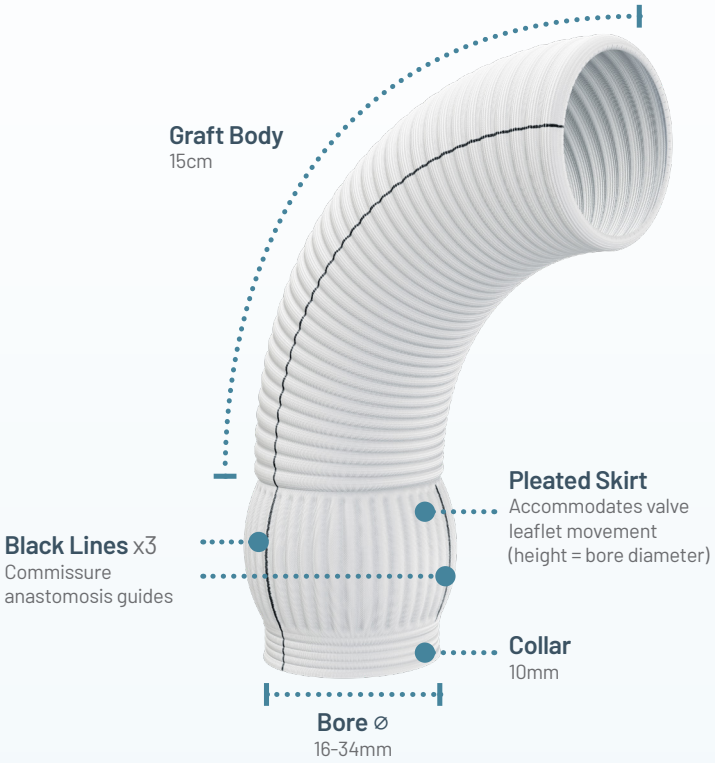
SYGMa

For more information, visit
terumoaortic.com/gelweave

The world's **FIRST** anatomically designed aortic root graft [1]

Engineered for physiological valve leaflet movement and reduced tension on coronary ostia anastomoses.[1]

Why Choose Valsalva?



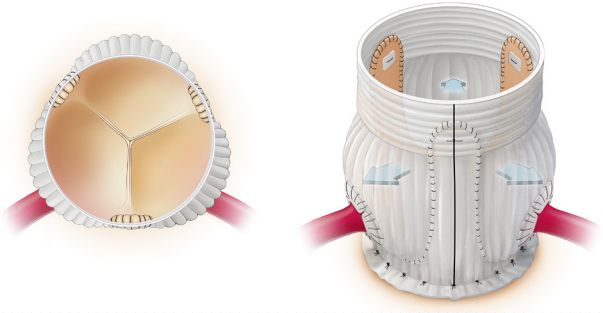
- 20 years clinical experience [2]
- 150,000+ Global Implants**
- Gelatin sealed woven Gelweave™ polyester
- Anatomically mimics the sinus of Valsalva
- Achieve optimal reconstruction of the Aortic Root[2]
- Reduced Aortic Wall Shear Stress[4]

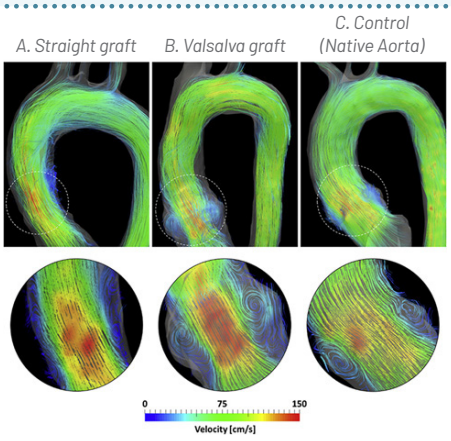
92.2%
+/- 2.1%
Estimated Freedom from recurrent AR*(≥3) @ 20 years [2]
(265 patients)

95.9%
+/- 1.6%
Estimated Freedom from reoperation @ 20 years [2]
(265 patients)

0%
Intraoperative Leakage [3]
(0/400 patients)

"The sinotubular junction and sinuses of Valsalva are crucial for the normal functioning of the valve" [1]





3D Visualization of blood flow at peak systole [4]

* AR = Aortic Regurgitation
** Implants based on Terumo Aortic sales data

Images courtesy of Prof. Ruggero De Paulis, Dept of Cardiac Surgery, European Hospital, Rome, Italy.

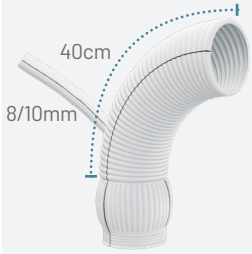
GELWEAVE™ VALSALVA

Made to Order* Options

Graft solutions to meet the evolving surgical needs.

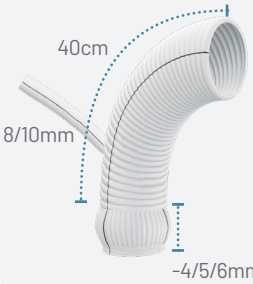
Global Availability

24-34mm bore diameter



Ante-Flo

- **8mm** or **10mm** side branch
- Facilitates antegrade perfusion
- **40cm** body length

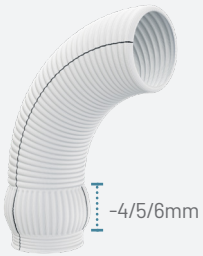


Ante-Flo – Short Skirt

- **8mm** or **10mm** side branch
- Facilitates antegrade perfusion
- **40cm** body length
- Skirt **4-6mm** shorter than bore diameter
- Accommodates shorter commissures

Narrow Skirt

- Skirt **+4mm** wider than bore diameter
  (standard Valsalva skirt is 5-10mm larger)
- Accommodates smaller valves



Short Skirt

- Skirt **4-6mm** shorter than bore diameter
- Accommodates shorter commissures

Florida Sleeve

- **Coronary Ostium** cut-out "keyhole"
- Allows skirt to position around the coronary artery
- Accommodates off-set coronary arteries

2000 (14th February) **First implant**

2002 Launched in the **USA**

2005 Launched in **Japan**

2009 Smaller diameters introduced

2010 **10 year data** (Scientific publication)[5]

2015 Global distribution in >70 countries

2019 Over **100,000** implants**

2020 Marked the **20th year**

2025 Celebrating 25 years of **Gelweave™ Valsalva**

* Made to Order products are pre-existing device configurations and are not part of the custom-made device program. They will be built upon receipt of Purchase Order and are subject to extended lead times.

** Implants based on Terumo Aortic sales data

Biological Bentall Procedures

The Gelweave™ Valsalva Sinus Design:

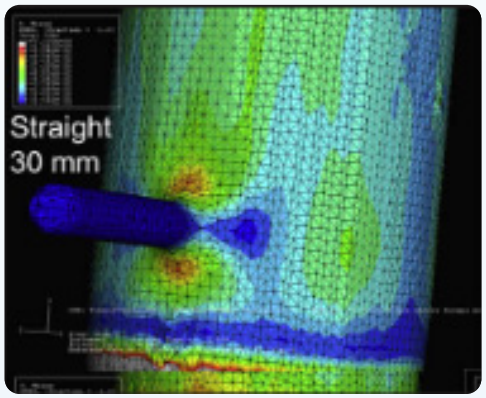
Recreate the Space

- Allows a **space** to be created between stented valve struts and the graft wall **minimizing the potential of coronary button complications** [6]
- Enables stentless and stented biological **valve conduits** to be created [6, 7] resulting in a **more physiologic flow pattern** [9]

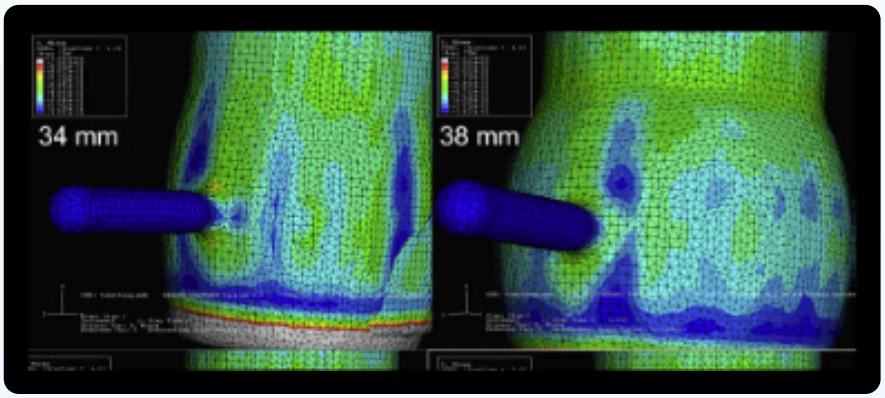
Respect the Anatomy

- Provides the potential to **reduce tension on the coronary buttons** [6,7]
- **Reduces the risk of leaflet contact** with the graft wall during systole [7]
- Potential for **increased valve longevity** [7]

Straight graft

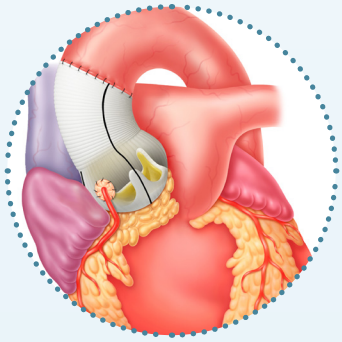


Gelweave™ Valsalva grafts

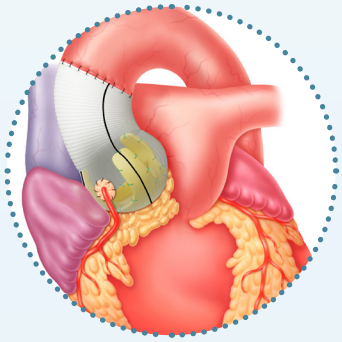


Computer generated 3-D aortic root models showing changes in stress pattern on the annulus and reimplanted coronary arteries depending upon graft shape [8]

Implanted assembled biological valve conduits



Representative image of Gelweave™ Valsalva graft with stented valve added in situ



Representative image of Gelweave™ Valsalva graft with stentless valve added in situ

Images courtesy of Professor Ruggero De Paulis, Dept of Cardiac Surgery, European Hospital, Rome, Italy

Valve-Sparing Procedures

The Gelweave™ Valsalva Sinus Design:

Recreate the Space

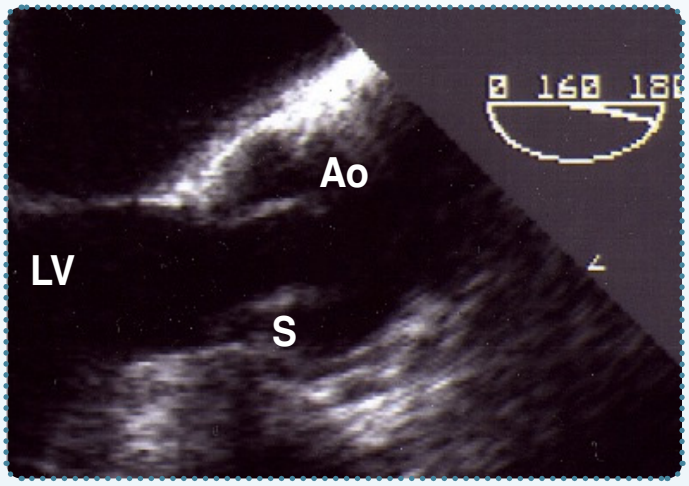
- Closely **matches aortic root anatomy** [1]
- Effectively mimics [9] and **generates the 3 independent sinuses of Valsalva** [5,9]

Respect the Anatomy

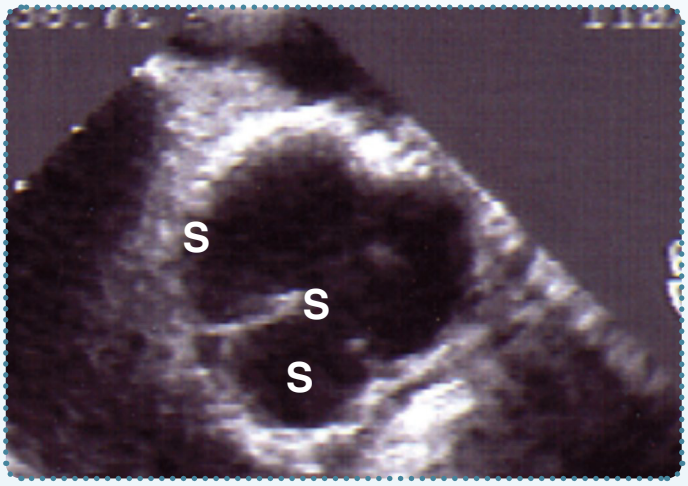
- More **physiologic valve motion** [10,11*] with **potential for increased valve longevity** [12]
- Provides the potential to **reduce tension on the coronary anastomoses** [10]
- Reimplantation with the **Gelweave Valsalva graft maintains annular stability** [13]

Valve-Sparing Reimplantation

Postoperative Gelweave™ Valsalva graft sinus geometry



Long axis view of the aortic root during systole showing sinus geometry and space between the valve leaflets and graft wall. (LV = left ventricle, S = sinus, Ao = aorta)



Short axis view of the sinus region during diastole illustrating the presence of 3 discrete sinuses (S).

* Compared to a "standard" straight polyester graft

Images courtesy of Professor Ruggero De Paulis, Dept of Cardiac Surgery, European Hospital, Rome, Italy

Implantation Guide

(David "reimplantation" technique)

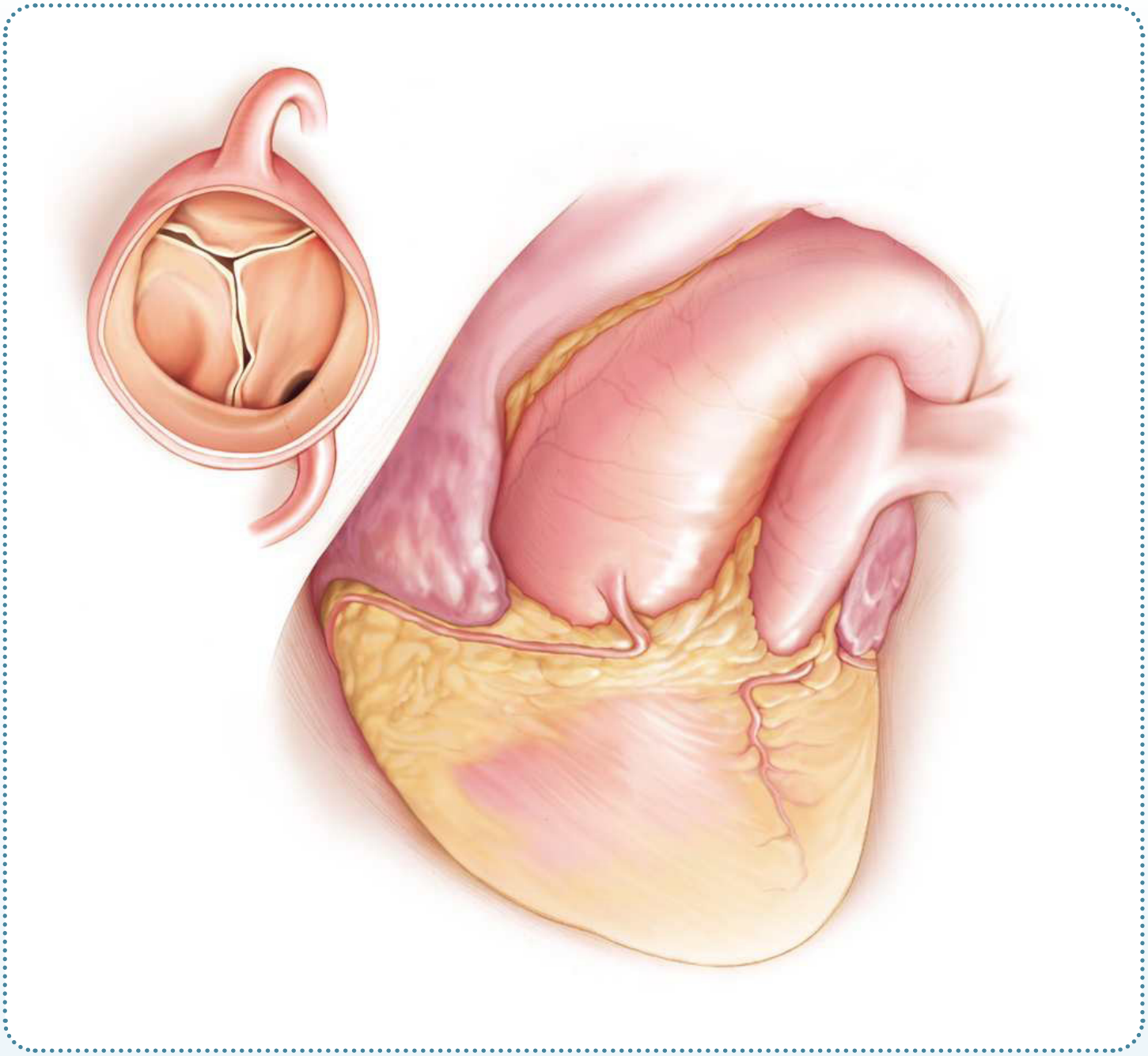


Figure 1: Exposure of the aortic root and valve.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

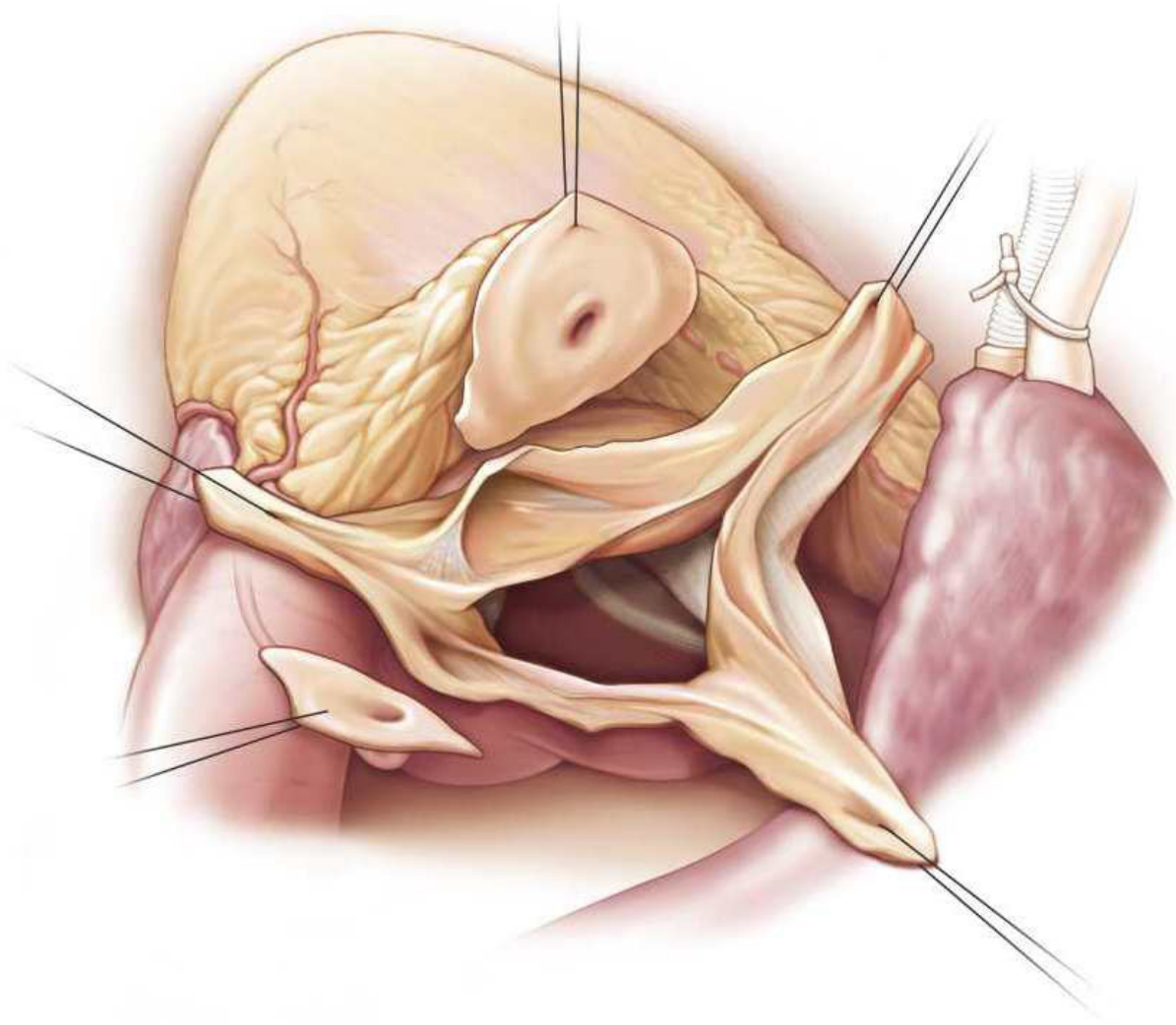


Figure 2: Removal of the diseased tissue and isolation of the 3 commissures and 2 coronary buttons.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

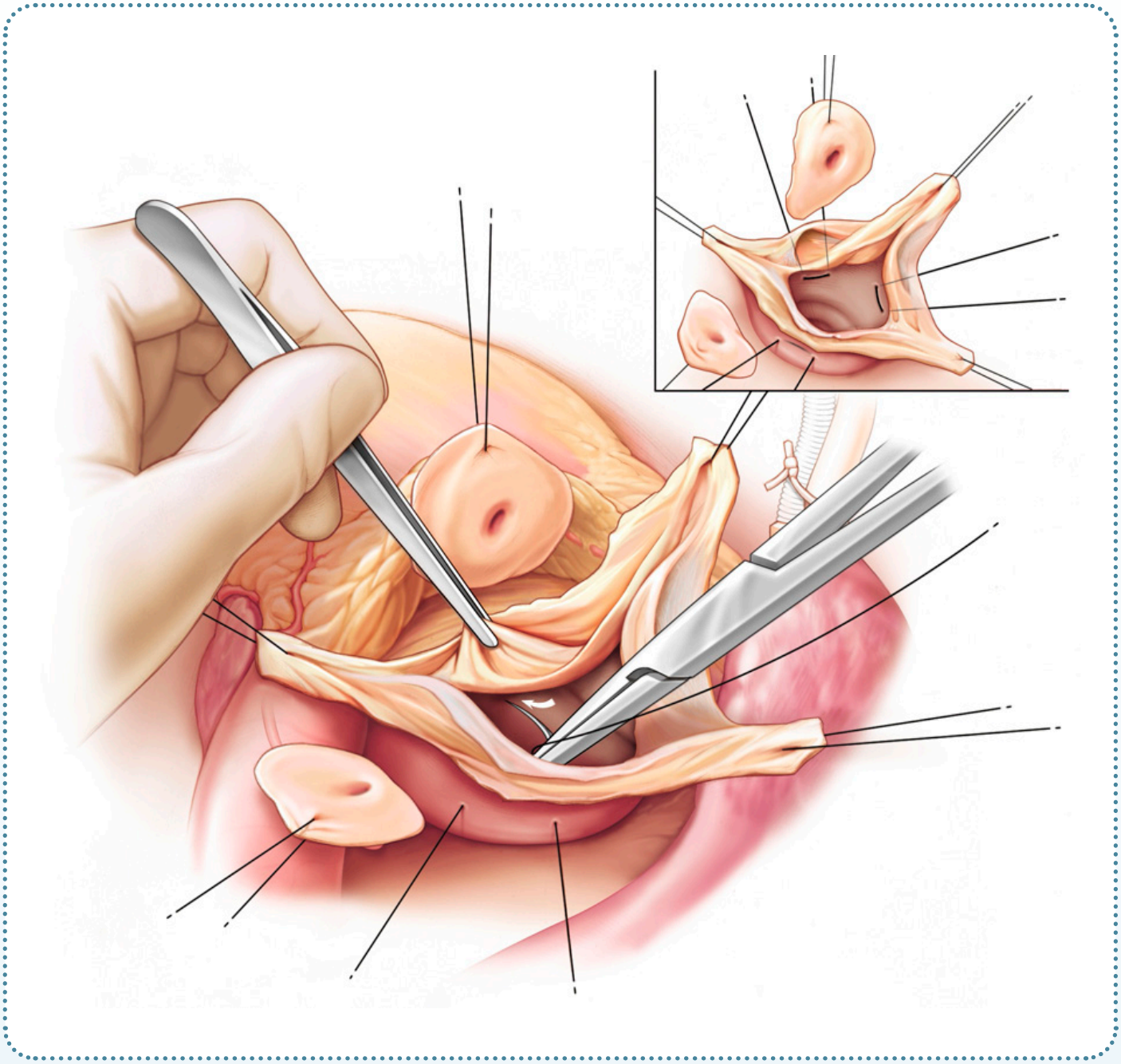


Figure 3: Placement of sub-annular interrupted sutures.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

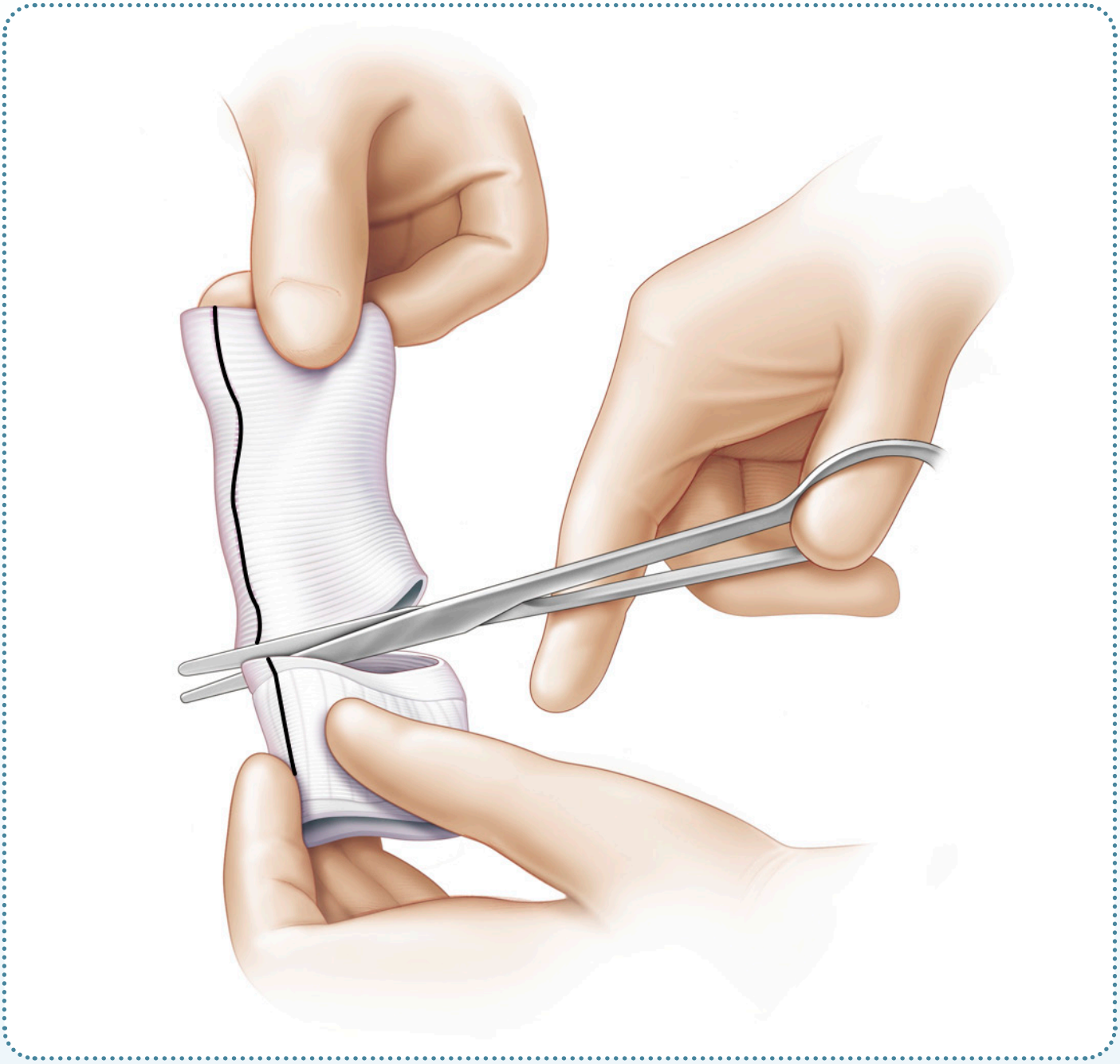


Figure 4: After selecting the required diameter of graft* the collar is trimmed ensuring that the commissures, when the graft is in position, reach the level of the new sinotubular junction. The graft distal to the skirt is then also trimmed.

** Size the graft according to optimal "sinotubular junction" ... usually 30mm.*
(Professor Duke Cameron, Surgery of the Thoracic Aorta, Bologna, Italy 2003)

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

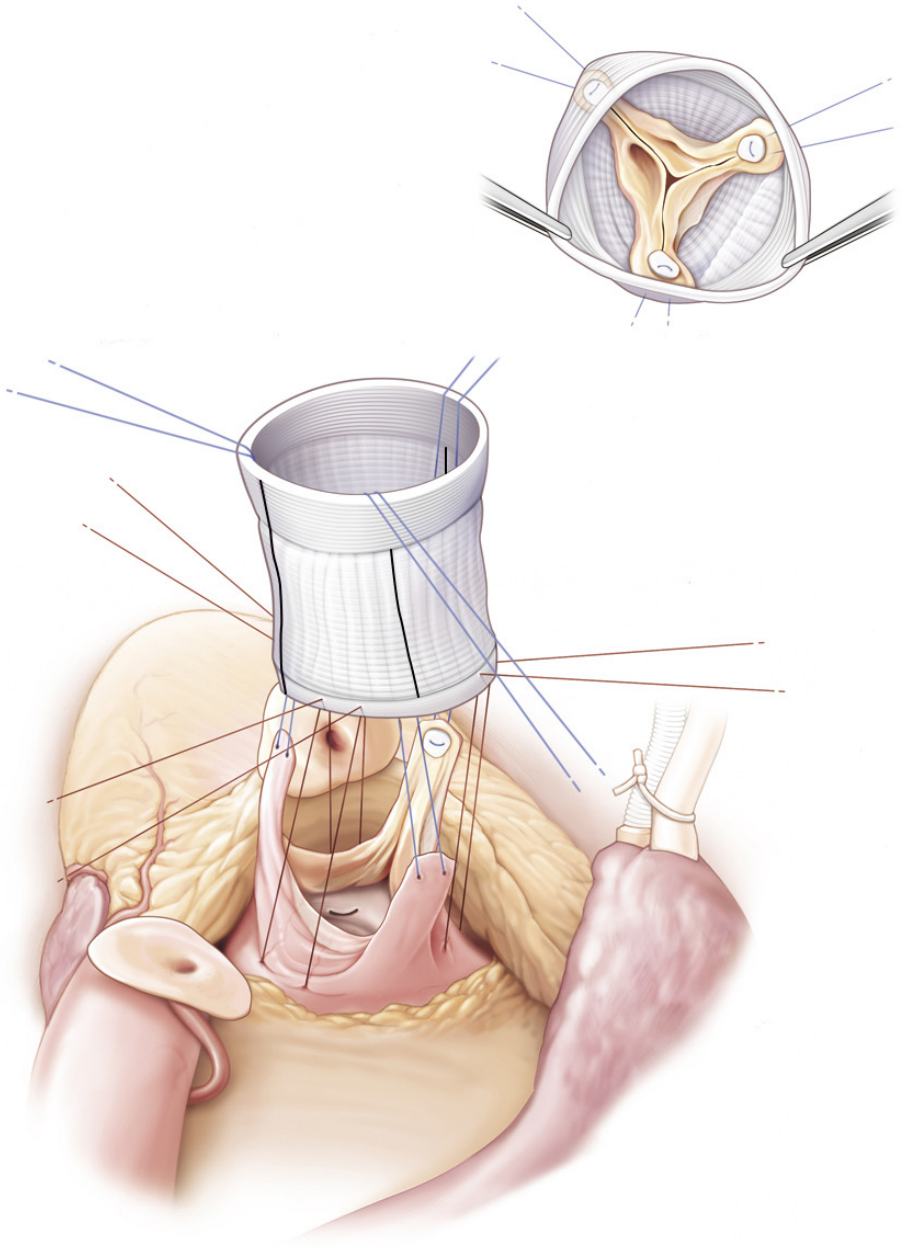


Figure 5: The sub-annular sutures are passed through the graft at the join between the collar and skirt. The graft is then parachuted into position.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

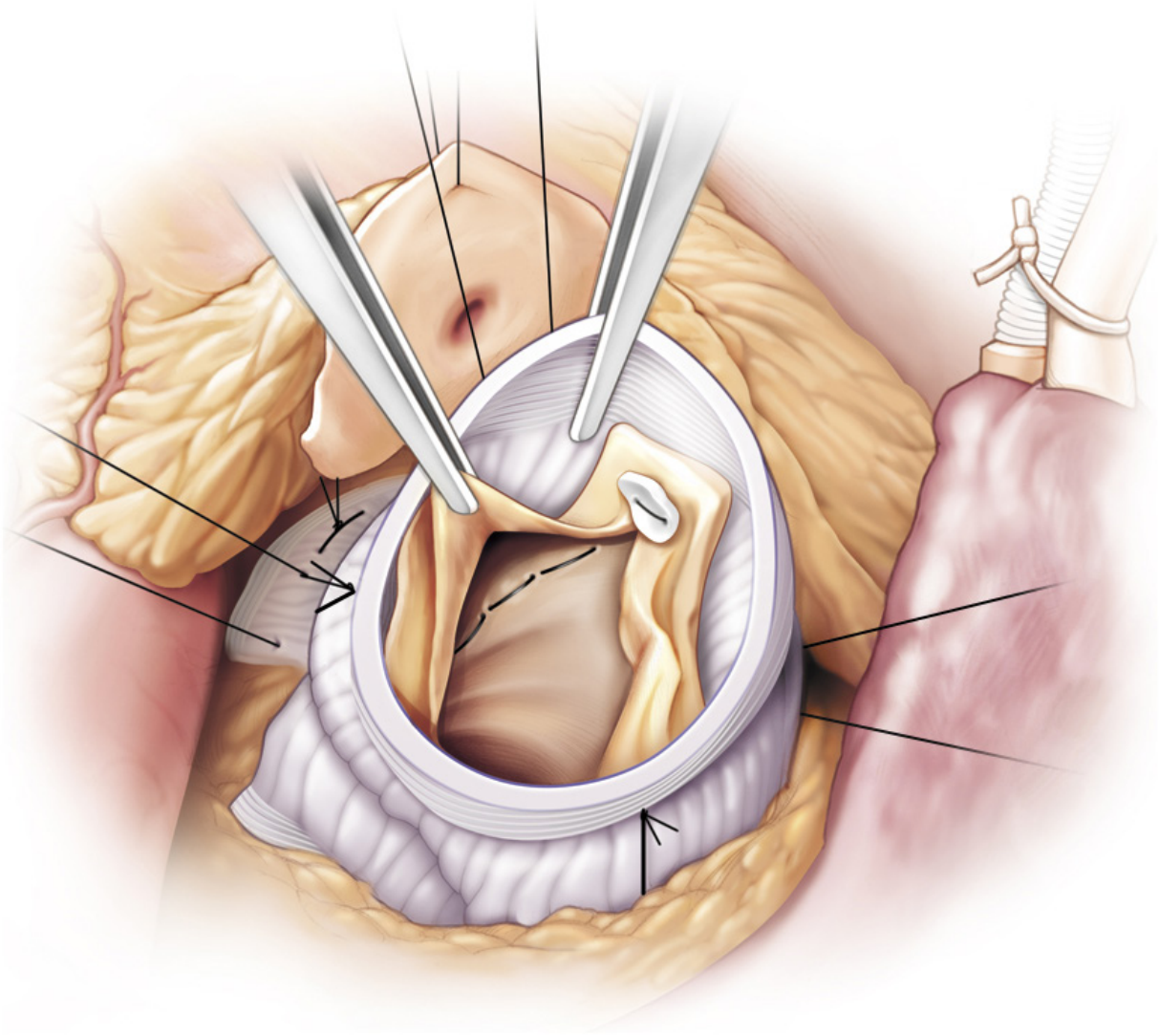


Figure 6: The sub-annular sutures are tied and the top of the commissures secured at the level of the new sinotubular junction.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

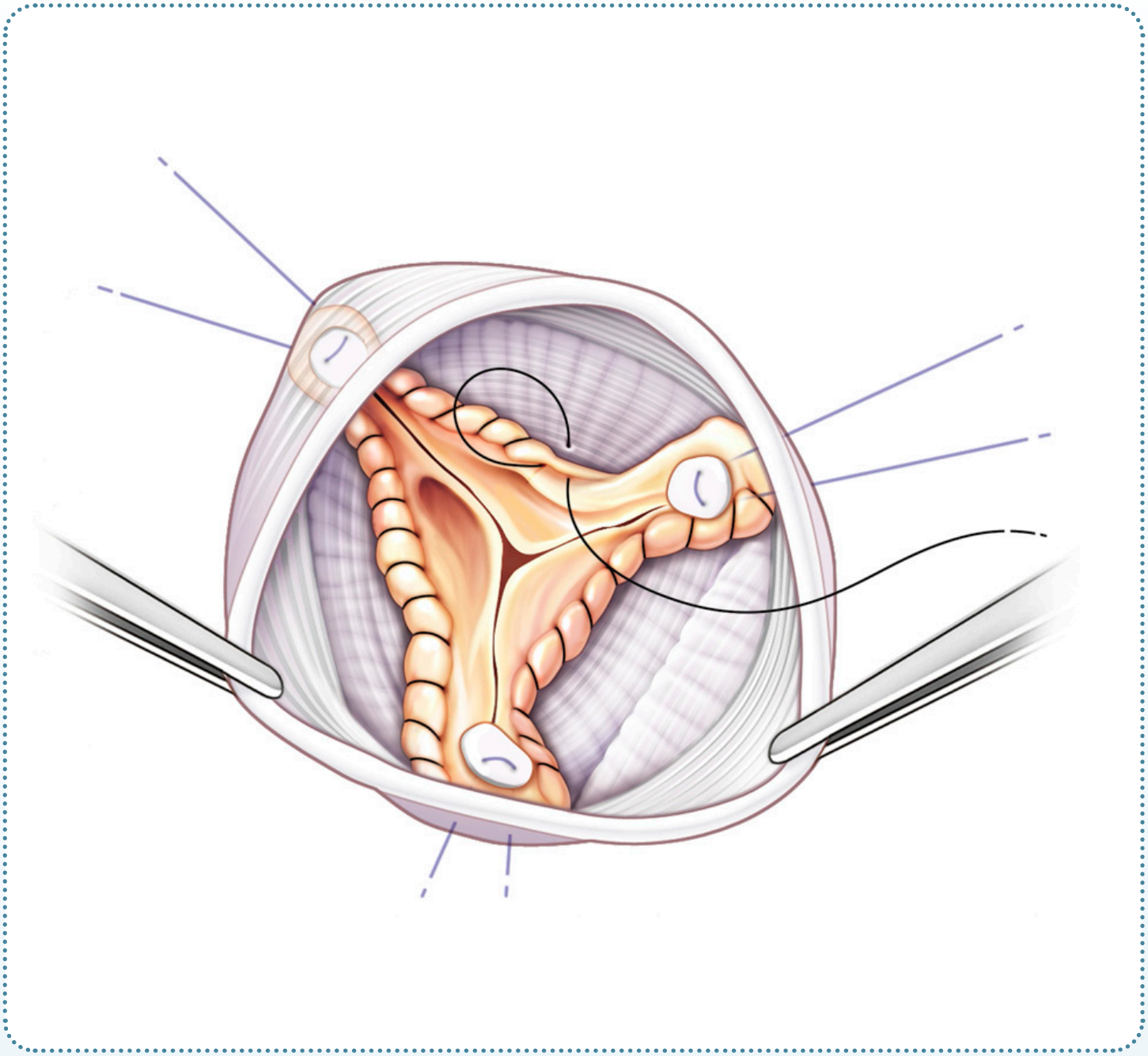


Figure 7: The edges of the commissures are anastomosed to the graft skirt.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

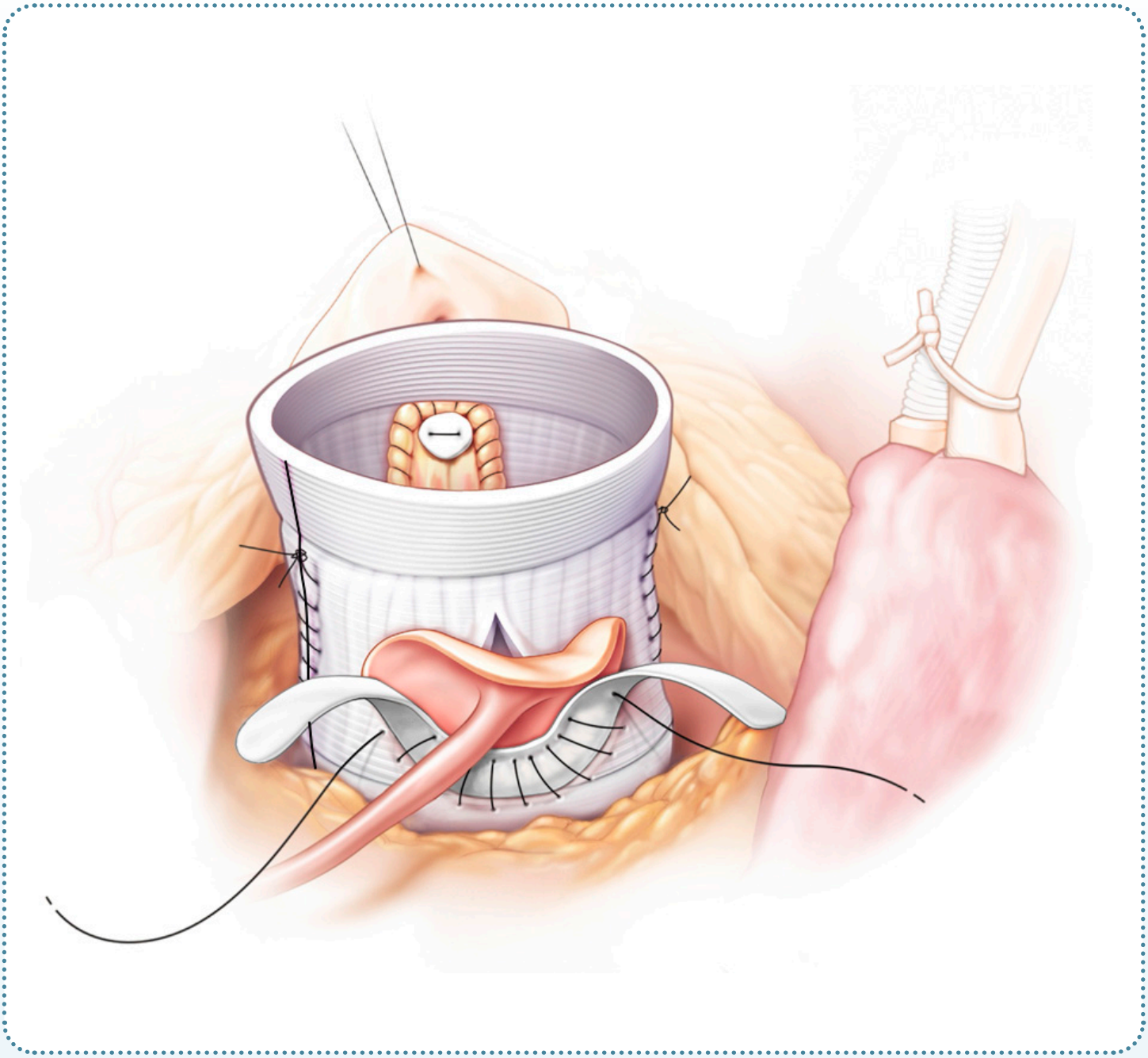


Figure 8: The first coronary button is anastomosed, in a central position, to the graft skirt using ePTFE as a "buttress".

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

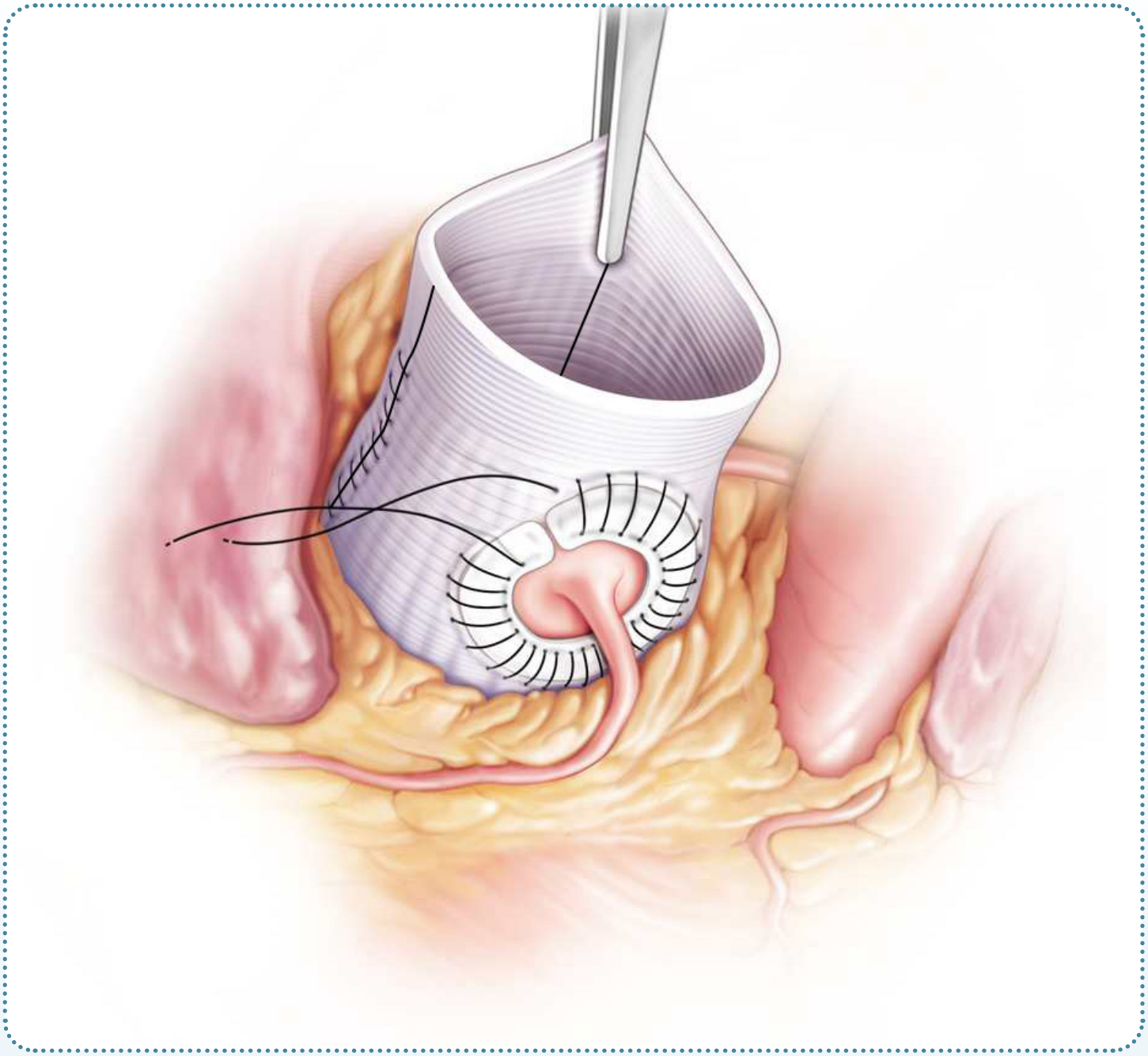


Figure 9: The second coronary button is anastomosed to the graft skirt.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Implantation Guide

(David "reimplantation" technique)

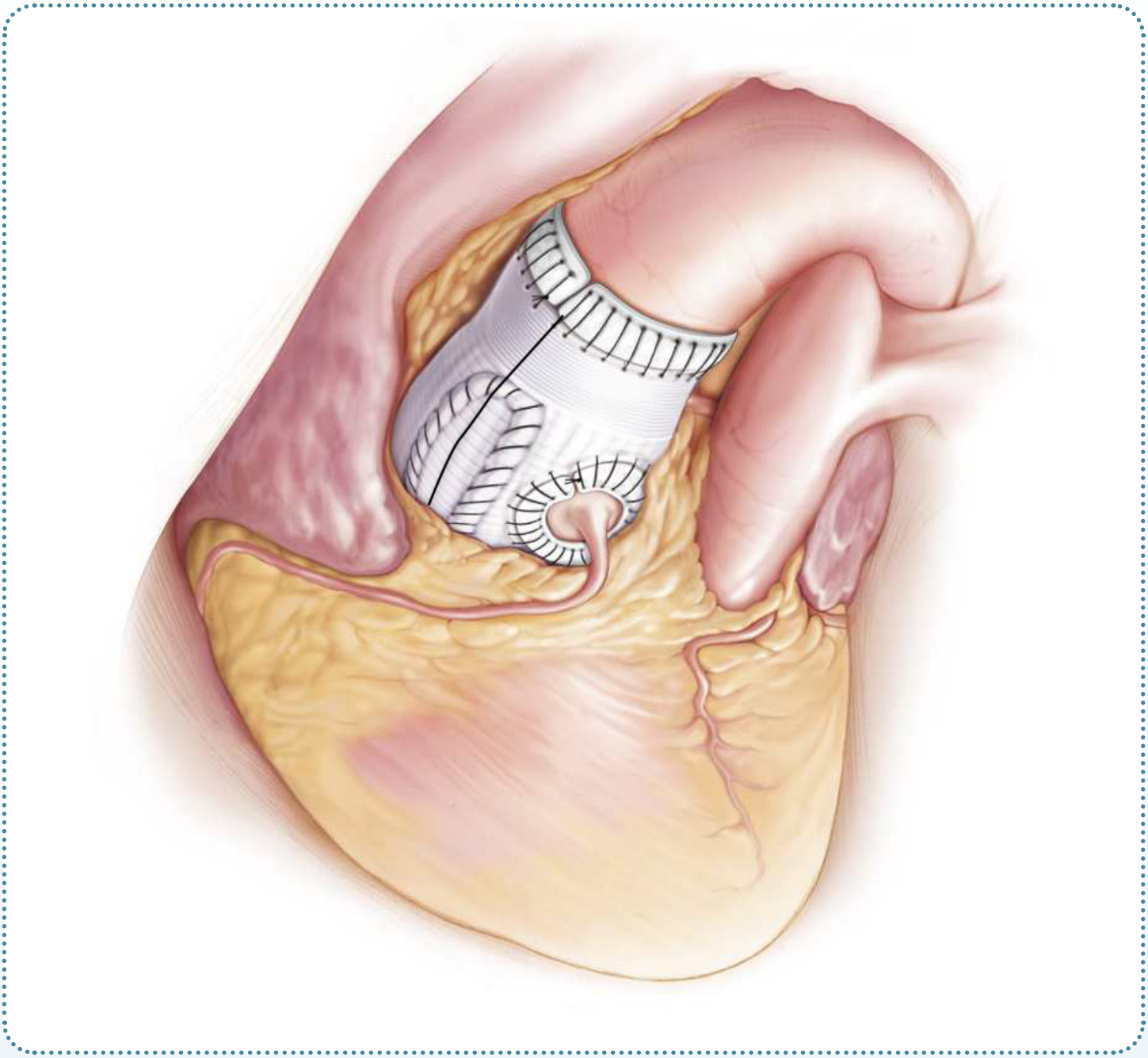


Figure 10: The distal portion of the graft is anastomosed to the ascending aorta.

Images courtesy of Professor Duke Cameron, Johns Hopkins Hospital, Baltimore, USA

Product Ordering Codes

Valsalva graft

Bore Size (mm)	Max Skirt Diameter (mm)	Body Length (cm)	Skirt Length (mm)	Collar Length (mm)	Catalogue Number
16	21	15	16	10	730016ADPE
18	24	15	18	10	730018ADPE
20	26	15	20	10	730020ADPE
22	28	15	22	10	730022ADPE
24	32	15	24	10	730024ADPE
26	34	15	26	10	730026ADPE
28	36	15	28	10	730028ADPE
30	38	15	30	10	730030ADPE
32	42	15	32	10	730032ADPE
34	44	15	34	10	730034ADPE

MADE TO ORDER

Valsalva graft with narrow skirt

Bore Size (mm)	Max Skirt Diameter (mm)	Body Length (cm)	Skirt Length (mm)	Collar Length (mm)	Catalogue Number
24	28	15	24	10	730024ADPSE
26	30	15	26	10	730026ADPSE
28	32	15	28	10	730028ADPSE
30	34	15	30	10	730030ADPSE
32	36	15	32	10	730032ADPSE
34	38	15	34	10	730034ADPSE

MADE TO ORDER

Valsalva graft with short skirt

Bore Size (mm)	Max Skirt Diameter (mm)	Body Length (cm)	Skirt Length (mm)	Collar Length (mm)	Catalogue Number
24	32	15	20	10	730024ADP20E
26	34	15	22	10	730026ADP22E
28	36	15	23	10	730028ADP23E
30	38	15	24	10	730030ADP24E
32	42	15	26	10	730032ADP26E
34	44	15	28	10	730034ADP28E

Made to Stock* Made To Order*

*MTO - "Made to Order" products are pre-existing device configurations and are not part of the custom-made device program. They will be built upon receipt of Purchase Order and are subject to extended lead times.

*MTS – "Made to Stock" products are pre-manufactured and available for immediate shipment. These devices carry a shorter lead time

Product Ordering Codes

MADE TO ORDER

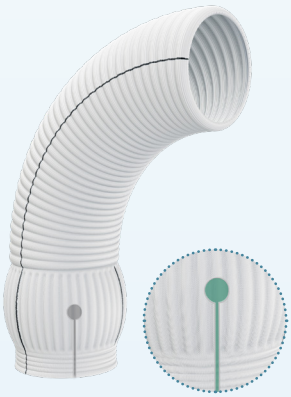
Valsalva Ante-Flo

Bore Size (mm)	Max Skirt Diameter (mm)	Branch Diameter (mm)	Body Length (cm)	Skirt Length (mm)	Collar Length (mm)	Branch Length (cm)	Catalogue Number
24	32	8	40	24	10	15	734024/8ADPE
26	34	8	40	26	10	15	734026/8ADPE
28	36	8	40	28	10	15	734028/8ADPE
30	38	8	40	30	10	15	734030/8ADPE
32	42	8	40	32	10	15	734032/8ADPE
34	44	8	40	34	10	15	734034/8ADPE
24	32	10	40	24	10	15	734024/10ADPE
26	34	10	40	26	10	15	734026/10ADPE
28	36	10	40	28	10	15	734028/10ADPE
30	38	10	40	30	10	15	734030/10ADPE
32	42	10	40	32	10	15	734032/10ADPE
34	44	10	40	34	10	15	734034/10ADPE

MADE TO ORDER

Valsalva Ante-Flo (short)

Bore Size (mm)	Max Skirt Diameter (mm)	Branch Diameter (mm)	Body Length (cm)	Skirt Length (mm)	Collar Length (mm)	Branch Length (cm)	Catalogue Number
24	32	8	40	20	10	15	734024/8ADP20E
26	34	8	40	22	10	15	734026/8ADP22E
28	36	8	40	23	10	15	734028/8ADP23E
30	38	8	40	24	10	15	734030/8ADP24E
32	42	8	40	26	10	15	734032/8ADP26E
34	44	8	40	28	10	15	734034/8ADP28E
24	32	10	40	20	10	15	734024/10ADP20E
26	34	10	40	22	10	15	734026/10ADP22E
28	36	10	40	23	10	15	734028/10ADP23E
30	38	10	40	24	10	15	734030/10ADP24E
32	42	10	40	26	10	15	734032/10ADP26E
34	44	10	40	28	10	15	734034/10ADP28E



MADE TO ORDER

Valsalva Florida sleeve

Bore Size (mm)	Max Skirt Diameter (mm)	Body Length (cm)	Skirt Length (mm)	Collar Length (mm)	Catalogue Number
24	32	15	24	10	730024ADPSLE
26	34	15	26	10	730026ADPSLE
28	36	15	28	10	730028ADPSLE
30	38	15	30	10	730030ADPSLE
32	42	15	32	10	730032ADPSLE
34	44	15	34	10	730034ADPSLE

5mm diameter pre-cut coronary button hole with 1mm diameter slit.

Made to Stock* Made To Order*

*MTO - "Made to Order" products are pre-existing device configurations and are not part of the custom-made device program. They will be built upon receipt of Purchase Order and are subject to extended lead times.

*MTS – "Made to Stock" products are pre-manufactured and available for immediate shipment. These devices carry a shorter lead time

References

1. De Paulis, R. *et al.* (2000) 'A New Aortic Dacron Conduit for Surgical Treatment of Aortic Root Pathology'. *Italian Heart Journal*, 7, pp. 457-463.

2. Chirichilli, I. *et al.* (2023) 'Twenty-year experience of aortic valve reimplantation using the Valsalva graft'. *European Journal of Cardio-thoracic Surgery,* 63(3), pp. 1-10.

3. Terumo Aortic PANTHER Study; Intraoperative Graft Leakage – (Percentages reported out of 649 Gelweave responses, 400 Gelweave Valsalva responses, 397 Gelsoft Plus responses).

4. Gaudino, M. *et al* . (2019) 'Aortic flow after valve sparing root replacement with or without neosinuses reconstruction'. *The Journal of Thoracic and Cardiovascular Surgery*, 157 (2), pp 455-465.

5. De Paulis, R. *et al.*(2010) 'Use of the Valsalva Graft and Long-term Follow Up'. *The Journal of Thoracic and Cardiovascular Surgery*,140(6S), pp. 23-29.

6. Tabata, M. *et al.* (2009) 'Modified Bentall Operation with Bioprosthetic Valved Conduit: Columbia University Experience'. *The Annals of Thoracic Surgery,* 87, pp. 1969-1970.

7. Stewart, A.S. *et al.* (2010) 'Modified Bentall Operation with a Novel Biologic Valved Conduit'. *The Annals of Thoracic Surgery*, 89, pp. 938–942.

8. Weltert, L. *et al.* (2009) 'Re-creation of a sinuslike graft expansion in Bentall procedure reduces stress at the coronary button anastomoses: A finite element study'. *The Journal of Thoracic and Cardiovascular Surgery*,157 (2), pp 455-465.

9. Schoenhoff, F.S. *et al.* (2009) 'The Role of the Sinuses of Valsalva in Aortic Root Flow Dynamics and Aortic Root Surgery: Evaluation by Magnetic Resonance Imaging'. *Journal of Heart Valve Disease*, 18, pp. 380-385.

10. De Paulis, R. *et al.* (2002) 'One-year Appraisal of a New Aortic Root Conduit with Sinuses of Valsalva'. *The Journal of Thoracic and Cardiovascular Surgery*, 123(1), pp. 33-39.

11. De Paulis, R. *et al.* (2001) "Opening and Closing Characteristics of the Aortic Valve After Valve-Sparing Procedures Using a New Aortic Root Conduit". *The Annals of Thoracic Surgery*, 72, pp.487-494.

12. De Paulis, R. *et al.* (2002) 'Analysis of Valve Motion After the Reimplantation Type of Valve-Sparing Procedure (David 1) with a New Aortic Root Conduit'. *The Annals of Thoracic Surgery*, 74, pp. 53-57.

13. Patel, N.D. *et al.* (2006) 'Valve-sparing Aortic Root Replacement: Early Experience with the De Paulis Valsalva Graft in 51 patients'. *The Annals of Thoracic Surgery*, 82, pp. 548-553.

Gianfranco's Story

The first Valsalva Patient operated on for acute dissection in 2000.

What I can tell you is that the quality of my life has been fully preserved. After less than 20 days I was able to re-start working without any medical difficulty. After 1 month I was able to restart my workout, not so intense of course but I was able to recover that important piece of my life. After 6 months roughly, I was back to my normal life.

Initially the requirement for surgery was an 'earthquake' needless to say, but after that event I can tell you my life has dramatically improved because of the value I give to each single day is higher than the value I used to give prior.

You cannot imagine the complexity, the art, the magic which is behind those artifacts (grafts). In my chest there is now a jewel beating somehow, together with my heart. It was wonderful to visit Terumo Aortic and see the sewing team investing so much of their time making the grafts perfect because they can save lives and allow normal life to continue.

In 2020, Gianfranco visited Terumo Aortic in Glasgow, 20 years after undergoing a life changing procedure. Accompanied by his surgeon, Professor Ruggero De Paulis, they reflected on the journey, toured the facility, and had the opportunity to meet some of the associates who contribute to the company's ongoing innovations.

Committed to Aortic Care

Discover solutions for every segment of the aorta

terumoaortic.com

LinkedIn VuMedi X

TERUMO AORTIC

View IFU at eifu.terumoaortic.com for more information on use, indications, contraindications and warnings/precautions.

Product availability subject to local regulatory approval.

PM-09696

For distributor information, visit terumoaortic.com/contact

Vascutek Ltd.
Newmains Avenue, Inchinnan,
Renfrewshire PA4 9RR, United Kingdom