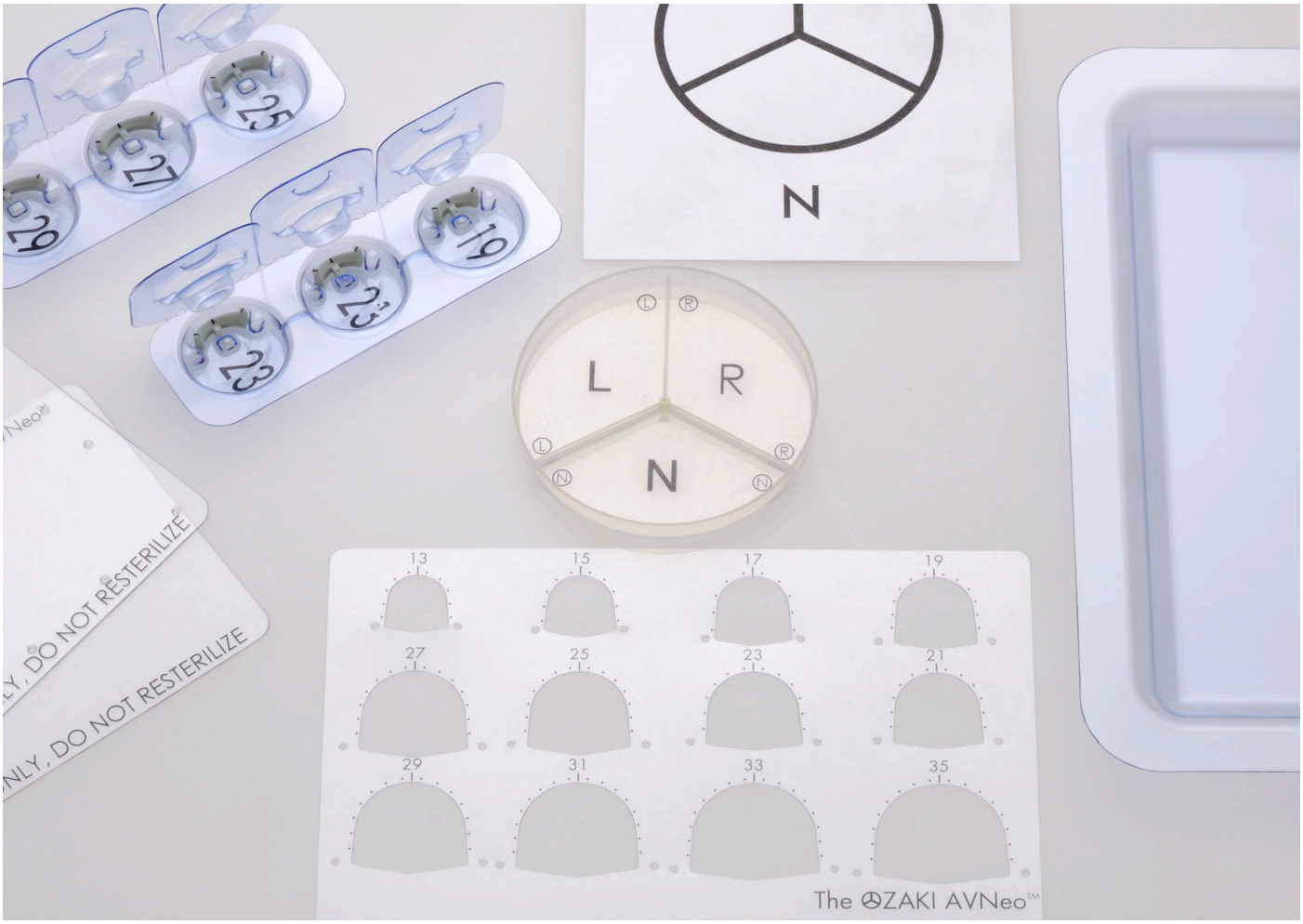
AVNeo

AVNeo™ Sizer System

For Aortic Valve Reconstruction Surgery



Shown: AVNeo™ Common Kit - Single Patient Use

AVNeo™ Sizer System

For Aortic Valve Reconstruction Surgery

The AVNeo™ Sizer System is a single-use device used to perform an aortic valve neocuspidization required for all aortic valve diseases, including aortic stenosis and aortic insufficiency (with or without infective endocarditis). The Sizer System allows surgeons to measure the distance between the native aortic valve commissures to determine the appropriate size of the replacement heart valve leaflets for cardiac valve reconstruction utilizing the patient's autologous pericardium or similar.

Enhanced User-friendliness

The single-use Sizer System is compact and includes necessary tools, such as a glutaraldehyde tray and plate for pericardium treatment and a tri-compartment petri-dish to maintain the treated, trimmed cusps before use. Sizer sets are available in three sizes; Standard (19/21/23/25/27/29 mm), Small (13/15/17 mm) and Large (31/33/35 mm).

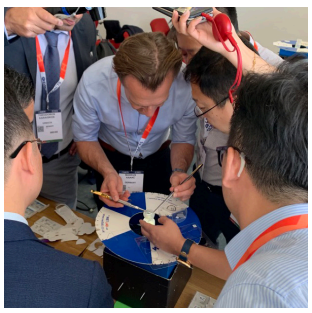
Template for Reproducibility and Precision

The template, which provides for 12 cusp sizes, enables both precise trimming of the cusps and guiding of suturing and commissure reinforcement.

Individual sizers are matched to fit commissure to commissure circumferential distance

Training Process to Perform AVNeo™ Procedure

Stage 1:
Didactic introduction into AVNeo™ procedure



Stage 2:
Hands-on Dry Lab for both tricuspid and bicuspid valves

Stage 3:
Clinical training with designated proctor and direct observation

Stage 4:
Proctor visit to your hospital to assist with your first cases

Please consult your local AVNeo™ representative for further information and registration.

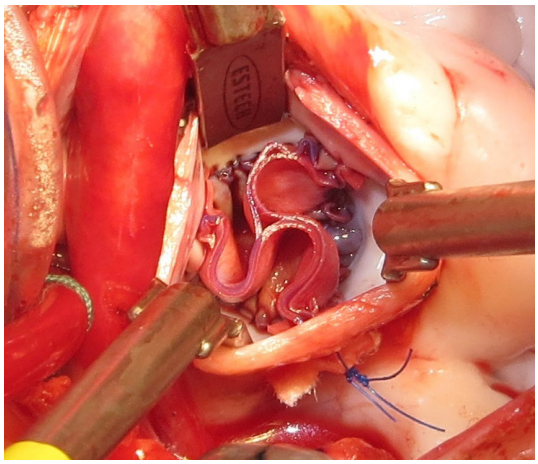
The AVNeo™ Procedure

Perfecting the Art of Natural Aortic Valve Flow

Professor Ozaki began using this highly standardized technique on aortic valve (AV) disease patients in Japan in 2007. Today, the AVNeo™ Procedure is practiced all over the world because of its unique benefits to the patient and its reproducibility. As of March 2020, more than 4,000 patients have been treated using the AVNeo™ Sizer System.

The AVNeo™ Procedure is a suitable solution for all patients suffering from aortic valve diseases who are eligible to undergo open heart surgery, which might be ideal for treating the small annulus and patients who need to avoid anticoagulation therapy.

Retaining the patient's native annulus has been shown to improve the hemodynamic properties of an AVNeo created valve compared to valve replacement with either a bioprostethetic valve or mechanical valve. Effective orifice opening areas and more laminar blood flow may prove to be significant advantages for the AVNeo™ Procedure.



AVNeo™ created valve, implanted into the native annulus using autologous pericardium

Benefits of the AVNeo™ Procedure

FOR PATIENTS
Freedom from anticoagulant therapy*
Preserves natural annular movement
Results in excellent hemodynamics
Uses patient's own tissue

**current protocol post-AVNeo™ is aspirin daily for up to 6-months*

FOR CLINICIANS
Reproducible and consistent results
Expands patient-centric care
Treats for all annular sizes
Effective for tricuspid, bicuspid and unicuspid valves

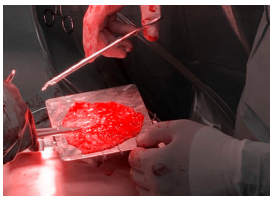
"The AVNeo™ procedure is a very reproducible surgical procedure, for all patient populations, as long as you follow the rules..."

Prof Dr. Markus Krane
AVNeo Proctor
Cardiac Surgeon, Munich, Germany

Step-by-Step Procedure

Ensure precision, every time with the AVNeo™ Sizer System

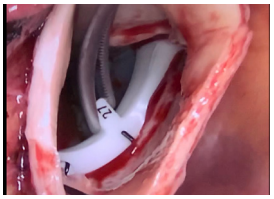
Step 1: Harvest and prepare pericardium. Fix in 0.6% Glutaraldehyde solution and thoroughly rinse in normal saline.



Pericardium is secured to the pericardium plate

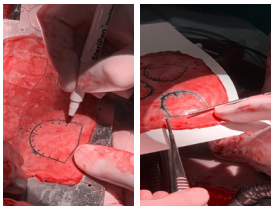
Step 2: Resect native aortic valve.

Step 3: Measure between each commissure, using the AVNeo™ Sizer, to determine the proper leaflet size that will need to implanted into the RCC, LCC, and NCC locations.



Measurements are taken between commissures with AVNeo™ Sizer

Step 4: Use the respective sized AVNeo™ leaflet tracing template to draw and then trim the pericardium to the appropriate size.

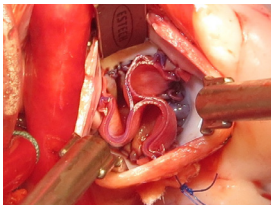


Using the template, trace the leaflets and cut-out

Step 5: After using appropriate AVNeo™ Sizer to determine the nadir of each sinus, begin suturing the 3 new pericardial leaflets to the native annulus following a 9-step implantation technique to create a symmetric tricuspid aortic valve.

Use the standardized sequence to implant the leaflets into the native annulus

Result: New autologous pericardium aortic valve with all three commissures and the distal part of the coaptation zone are on the same level.



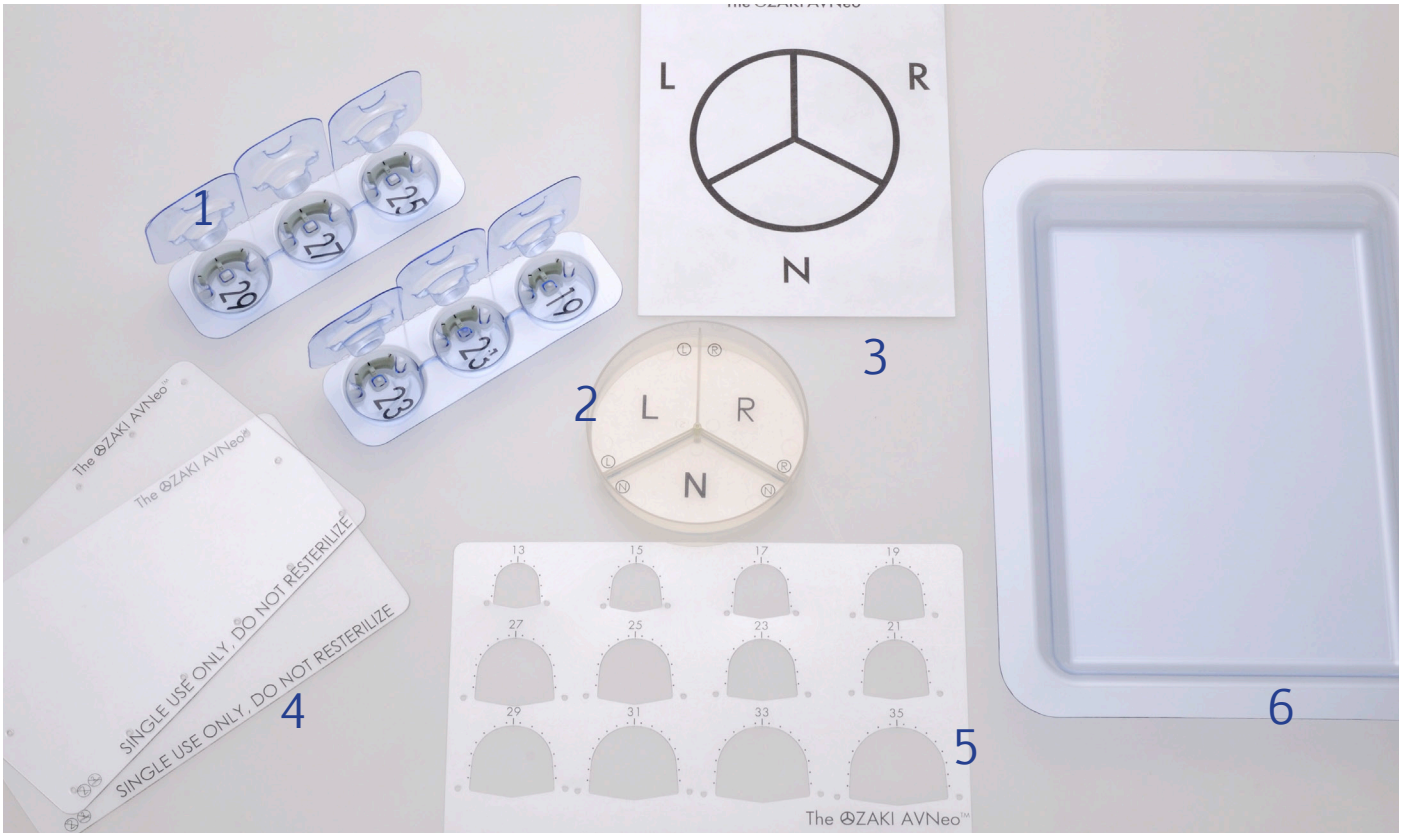
Final result is a new autologous pericardium aortic valve

For complete procedure instructions, please refer to the AVNeo Procedure Manual and AVNeo™ Sizer System Instructions for Use (IFU).

"The post-op results after the AVNeo™ procedure are quite impressive, retaining the native annulus helps improve the hemodynamics..."

Prof Alberto Albertini
AVNeo Proctor, Cardiac Surgeon
Maria Cecilia Hospital, GVM Care & Research
Cotignola, Italy

AVNeo™ Common Kit



1. AVNeo Standard Sizers (19/21/23/25/27/29 mm)

2. Left/right/non-coronary orientation dish

3. Leaflet-size identification sheet

4. Pericardium fixation plates

5. Leaflet tracing template

6. Glutaraldehyde Tray

AVNeo™ Small Sizers (13/15/17mm)

AVNeo™ Large Sizers (31/33/35mm)

References: **1)** Ozaki Procedure: 1,100 patients with up to 12 years of follow-up. Shigeyuki Ozaki, MD; Editorial Comment. Turkish Journal of Thoracic and Cardiovascular Surgery 2019;27(4): 454 **2)** Krane, M, Boehm, J, et al. Excellent hemodynamic performance after aortic valve neocuspidization (AVNeo) using autologous pericardium. The Annals of Thoracic Surgery 2020 (in press). **3)** Ozaki S, et al. Midterm outcomes after aortic valve neocuspidization with glutaraldehyde-treated autologous pericardium. 2018; 155(6): 2379-2387. **4)** Ozaki S, et al. Aortic valve reconstruction using autologous pericardium for aortic stenosis. Circulation Journal. 2015; Vol 79: 1504-1510. **5)** Ozaki, S, et al. Aortic valve reconstruction using autologous pericardium for patients aged less than 60 years. J Thorac Cardiovasc Surg 2014; Vol 148: 934-938. **6)** Ozaki, S, et al. Reconstruction of bicuspid aortic valve with autologous pericardium. Circulation Journal, 2014; Vol 78: 1144-1151. **7)** Hofferberth SC, Baird CW, et al. Mechanical properties of autologous pericardium change with fixation time: implications for valve reconstruction. Seminars in Thoracic and Cardiovascular Surgery, Volume 31, Issue 4, 852 - 854.

AVNeo™ Sizer System

Ordering Information

JD-005-TR3	**AVNeo™ Starter Kit** Includes: · Training with designated proctor · 3 each - AVNeo™ Common Kits · 3 each - Sizers either Large Sizers or Small Sizer (e.g., 2 Large Sizers plus 1 Small Sizers = 3 sets)
JD-005-CK1	**AVNeo™ Common Kit** Includes: AVNeo™ Standard Sizers (19/21/23/25/27/29 mm), left/right/non-coronary orientation dish, leaflet-size identification sheet, pericardium fixation plates, leaflet tracing template, glutaraldehyde tray
JD-005-LS1	**AVNeo™ Large Sizers** *(31/33/35mm)* Intended for large aortic valves. *To be used together with AVNeo™ Common Kit.*
JD-005-SS1	**AVNeo™ Small Sizers** *(13/15/17mm)* Intended for pediatric patients or small valves. *To be used together with AVNeo™ Common Kit.*

Full Training Course and Proctor Support

Components

Packaging

Distributed in the UK and Ireland by:

BVM
— 24 Hours a Day —

BVM House
Trinity Lane, Hinckley
Leicestershire, LE10 0BL

Tel: 01455 614555
Fax: 01455 614546

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