AVNeo™ Sizer System
For Aortic Valve Reconstruction Surgery

Shown: AVNeo™ Common Kit - Single Patient Use
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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.

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.
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 bioprosthetic valve or mechanical valve. Effective orifice opening areas and more laminar blood flow may prove to be significant advantages for the AVNeo™ Procedure.

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

www.avneo.net
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.

**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.

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

**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.

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

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


AVNeo™ Sizer System

Ordering Information

**AVNeo™ Starter Kit**
JD-005-TR3
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 Sizer = 3 sets)

**AVNeo™ Common Kit**
JD-005-CK1
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

**AVNeo™ Large Sizers**
JD-005-LS1
(31/33/35mm)
Intended for large aortic valves.
*To be used together with AVNeo™ Common Kit.*

**AVNeo™ Small Sizers**
JD-005-SS1
(13/15/17mm)
Intended for pediatric patients or small valves.
*To be used together with AVNeo™ Common Kit.*

Distributed in the UK and Ireland by:

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DOC 2020401.2.2

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