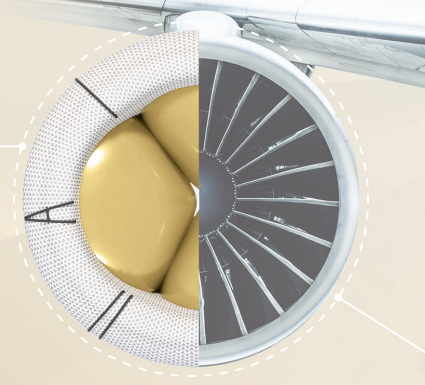


1. Beyond the dimensions: Measurement and calculation of surgical valve sizing parameters



The standardised dimensions aim to simplify comparisons between surgical heart valve models and inform valve selection by providing information on their physical dimensions and haemodynamic performance.¹⁻³ This document provides insights into the methods behind the measurement and calculation of dimensions, demonstrating how they represent the haemodynamic performance of the valve.

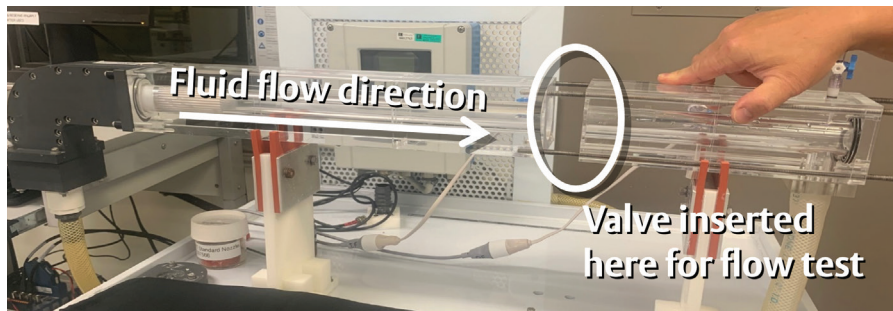
Effective orifice diameter (ID-EFFECTIVE) is an indicator of the size of the flow passage within a valve

The ID-EFFECTIVE is a virtual diameter derived from the effective orifice area (EOA) measured using a validated steady forward-flow test method.³ This method provides a more accurate and reproducible haemodynamic characterisation of a valve than clinical echocardiography.

ID-EFFECTIVE is the only dimension that acts as a haemodynamic performance indicator, thus the most important to compare between valve models.

How is it measured?

1. The Edwards mitral valve is mounted into the testing tube (internal diameter 35 mm)



2. Under steady flow, the pressure gradient is measured across the valve to calculate its EOA using the following formula:

$$EOA = \frac{q_{V_{RMS}}}{51.6 \sqrt{\frac{\Delta p}{\rho}}}$$

3. The EOA is used to calculate the ID-EFFECTIVE using the following formula:

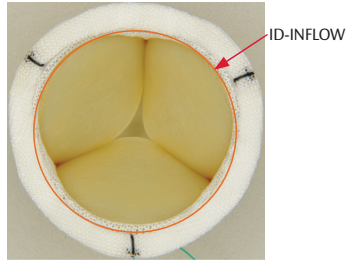
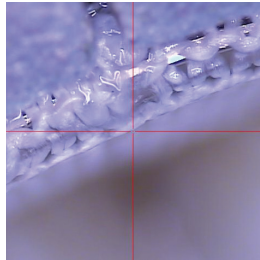
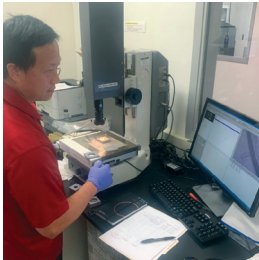
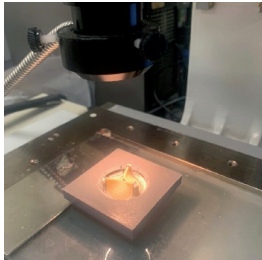
$$ID-EFFECTIVE = 2 \sqrt{\frac{EOA}{\pi}}$$

EOA: effective orifice area (cm²); ID-EFFECTIVE: effective orifice diameter (cm); $q_{V_{RMS}}$: root mean square forward flow (mL/s) during the positive differential flow pressure period; Δp : mean pressure difference (mmHg); ρ : density of the test fluid (g/cm³).

Valve physical dimensions are measured using an optical camera

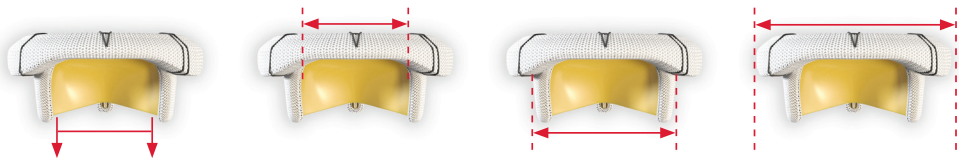
The inflow orifice diameter (ID-INFLOW), valve housing external diameter (OD-HOUSING) and external sewing ring diameter (OD-SEWINGRING) are physical dimensions defined in the diagrams below and precisely measured using an optical camera.

1. The Edwards mitral valve is secured in a holder assembly tailored to the valve design
2. Eight points are selected along a specified boundary between two features (e.g. sewing ring and tissue)
3. The best-fit circle is computed and the relevant diameter measured



MITRIS RESILIA valve key dimensions

When selecting the right valve for a patient, it is important to use the provided sizes, which correspond to the OD-HOUSING and OD-SEWINGRING, instead of the label valve size.



Label valve size, mm	ID-EFFECTIVE (2) 	ID-INFLOW (1)	OD-HOUSING (5) 	OD-SEWINGRING (6)
25	19.5	23.0	27.5	36.5
27	21.0	25.0	29.5	38.5
29	23.0	27.0	31.5	41.0
31	25.0	29.0	33.5	42.5
33	25.0	29.0	33.5	44.5

 : haemodynamic performance indicator;  : affects ease of use; ID-EFFECTIVE: effective orifice diameter; ID-INFLOW: inflow orifice diameter; OD-HOUSING: valve housing external diameter; OD-SEWINGRING: external sewing ring diameter.

References

1. International Organization for Standardization. ISO 5840-2. Cardiovascular implants – Cardiac valve prostheses – Part 2: Surgically implanted heart valve substitutes. Geneva: ISO; 2021.
2. Durko AP et al. *Ann Thorac Surg.* 2021; **111**: 314–26.
3. Wu C et al. *Ann Cardiothorac Surg.* 2024; **13**: 283–90.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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