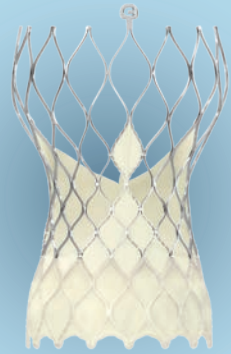


TAVI HEMODYNAMICS

WHAT YOU NEED TO KNOW



Evolut™ TAVI System

Evolut™ Hemodynamic Reference Values¹

Annular Diameter (mm)	≤ 22.3	> 22.3 to ≤ 23.2	> 23.2 to ≤ 24.7	> 24.7 to ≤ 26.2	> 26.2 to ≤ 30.2
Diameter Derived Annular Area (mm ²)	≤ 391	391-423	423-479	479-539	539-716
EOA Ref Data (cm ²)	1.66 ± 0.42 (n = 53)	1.82 ± 0.43 (n = 38)	1.98 ± 0.56 (n = 62)	1.98 ± 0.59 (n = 49)	2.56 ± 0.77 (n = 53)

Patient BSA (m ²)	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8
In Vivo Indexed Effective Orifice Area (iEOA)	1.28	1.19	1.11	1.04	0.98	0.92	0.87	0.83	0.79	0.75	0.72	0.69	0.66	0.64	0.61	0.59
	1.40	1.30	1.21	1.14	1.07	1.01	0.96	0.91	0.87	0.83	0.79	0.76	0.73	0.70	0.67	0.65
	1.52	1.41	1.32	1.24	1.16	1.10	1.04	0.99	0.94	0.90	0.86	0.83	0.79	0.76	0.73	0.71
	1.52	1.41	1.32	1.24	1.16	1.10	1.04	0.99	0.94	0.90	0.86	0.83	0.79	0.76	0.73	0.71
	1.97	1.83	1.71	1.60	1.51	1.42	1.35	1.28	1.22	1.16	1.11	1.07	1.02	0.98	0.95	0.91

Patient BSA (m²)

In Vivo Indexed Effective Orifice Area (iEOA)

Sapien3™ Hemodynamic Reference Values¹

Area Derived Annular Diameter (mm)	≤ 22.1	> 22.2 to ≤ 23.64	> 23.64 to ≤ 24.9	> 24.9 to ≤ 26.2	> 26.2 to ≤ 29.4
Annular Area (mm ²)	248-384	385-439	440-488	489-537	538-678
EOA Ref Data (cm ²)	1.41 ± 0.27 (n = 189)	1.58 ± 0.33 (n = 191)	1.73 ± 0.36 (n = 192)	1.79 ± 0.35 (n = 191)	1.91 ± 0.42 (n = 188)

Patient BSA (m ²)	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8
In Vivo Indexed Effective Orifice Area (iEOA)	1.08	1.01	0.94	0.88	0.83	0.78	0.74	0.71	0.67	0.64	0.61	0.59	0.56	0.54	0.52	0.50
	1.22	1.13	1.05	0.99	0.93	0.88	0.83	0.79	0.75	0.72	0.69	0.66	0.63	0.61	0.59	0.56
	1.33	1.24	1.15	1.08	1.02	0.96	0.91	0.87	0.82	0.79	0.75	0.72	0.69	0.67	0.64	0.62
	1.38	1.28	1.19	1.12	1.05	0.99	0.94	0.90	0.85	0.81	0.78	0.75	0.72	0.69	0.66	0.64
	1.47	1.36	1.27	1.19	1.12	1.06	1.01	0.96	0.91	0.87	0.83	0.80	0.76	0.73	0.71	0.68

Patient BSA (m²)

In Vivo Indexed Effective Orifice Area (iEOA)

The analysis provided above assesses data from separate clinical studies.

These charts are not intended to be a direct comparison of these devices as there is no head-to-head clinical study, but rather are intended to illustrate an analysis of similar trials. Multiple factors, including the use of different echo corelabs, contribute to clinical study outcomes and need to be considered in making any assessments across different studies. Where measurements are derived, conversions assume circularity.

References

- Hahn RT, Leipsic J, Douglas PS, et al. Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. *JACC Cardiovasc Imaging*. Published online June 8, 2018.
- Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *Eur Heart J*. October 2012;33(19):2403-2418

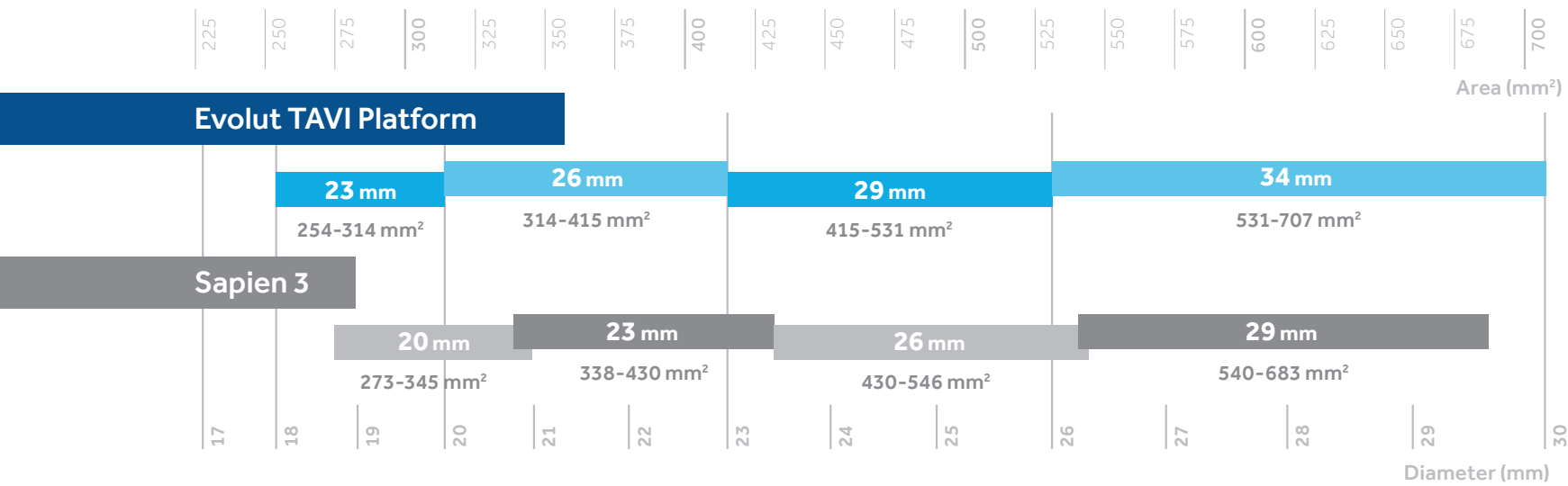
Indexed Effective Orifice Area (iEOA) = EOA/BSA²

iEOA > 0.85 cm ² /m ²	mild
iEOA ≤ 0.85 cm ² /m ²	moderate
iEOA ≤ 0.65 cm ² /m ²	severe

To Aid Patient-Prosthesis Matching²

- First determine patient's body surface area (BSA).
- Second, using the chart, select a valve size with iEOA > 0.65 to avoid moderate PPM.

Medtronic
Further, Together



SIZING COMPARISONS EVOLUT™ TAV vs. SAPIEN™* 3 TAV

Sources: Evolut PRO IFU (M970312A001 Rev. 1C), Sapien 3 IFU (10001354006 A)
Area values for reference only. For Evolut Platform valve sizing always refer to the IFU.
Sizing conversion assumes circularity.

Please reference the CoreValve Evolut R and CoreValve Evolut PRO Instructions for Use for more information regarding indications, warnings, precautions, and potential adverse events.

The commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System.

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