

# CLINICAL CONFIDENCE AND TRUST PROVEN OVER TIME

The Regent valve delivers outstanding clinical performance in a wide therapeutic INR range. Abbott mechanical valves are the most implanted on Earth due to the trust they deliver through clinical performance.

2,800,000  
global implants  
Abbott mechanical heart valves<sup>3</sup>



260,000  
global implants - On-X<sup>4</sup>

Information contained herein for DISTRIBUTION in Europe, Middle East and Africa ONLY.  
Check the regulatory status of the device in areas where CE marking is not the regulation in force.

#### INDICATIONS FOR USE

The SJM Regent™ Mechanical Heart Valve is intended for use as a replacement valve in patients with a diseased, damaged, or malfunctioning aortic valve. This device may also be used to replace a previously implanted aortic prosthetic heart valve.

See Important Safety Information referenced within.

#### References

1. Koertke, Heinrich, et al. "Efficacy and safety of very low-dose self-management of oral anticoagulation in patients with mechanical heart valve replacement." *The Annals of thoracic surgery* 90.5 (2010): 1487-1493.
2. Puskas, John, et al. "Reduced anticoagulation after mechanical aortic valve replacement: interim results from the prospective randomized on-X valve anticoagulation clinical trial randomized Food and Drug Administration investigational device exemption trial." *The Journal of thoracic and cardiovascular surgery* 147.4 (2014): 1202-1211.
3. Abbott. Data on File. Includes all past and present Abbott MHVs.
4. On-X Website. Accessed 11/1/2018. <https://www.cryolife.com/products/on-x-heart-valves/>
5. On-X IFU.
6. Regent IFU.
7. Abbott Internal Specifications Document .
8. Regent PMA Supplement .
9. Suh, Young Joo, et al. "Measurement of opening and closing angles of aortic valve prostheses in vivo using dual-source computed tomography: comparison with those of manufacturers' in 10 different types." *Korean journal of radiology* 16.5 (2015): 1012-1023.
10. Liu, Xiaoli, et al. "Blood compatible materials: state of the art." *Journal of Materials Chemistry B* 2.35 (2014): 5718-5738.

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**CAUTION:** This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at [eifu.abbottvascular.com](http://eifu.abbottvascular.com) or at [medical.abbott/manuals](http://medical.abbott/manuals) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs.

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REGENT VALVE

VS.



ON-X VALVE

## OPERATE WITH THE FACTS IMPLANT CONFIDENTLY

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# OPERATE WITH THE FACTS MAJOR EVENTS\*

## ABBOTT MHV<sub>s</sub>

## ON-X<sup>†</sup>

ESCAT III Study<sup>1</sup>

PROACT Study<sup>2</sup>

0% /pt-yr\*\*  
0.58%/pt-yr\*\*\*

Thromboembolism

1.18%/pt-yr

1.07% /pt-yr\*\*  
0.58%/pt-yr\*\*\*

Bleeding

1.48%/pt-yr

1.6 - 2.1

Target INR

1.5 - 2.0

Study Parameters

Randomized

Randomized

1137

Study Size

375

\*Results from different clinical trials are not directly comparable. Information provided for educational purposes only. Events reported for ESCAT III are grade III events. Events reported for PROACT include major bleeding, ischemic stroke with death or long-term disability, peripheral thromboembolism, and valve thrombosis.

\*\*Test Group VL1 within ESCAT III Study self-monitored INR once weekly

\*\*\*Test Group VL2 within ESCAT III Study self-monitored INR twice weekly

## REGENT IS INDICATED AT A WIDE RANGE OF INRS.

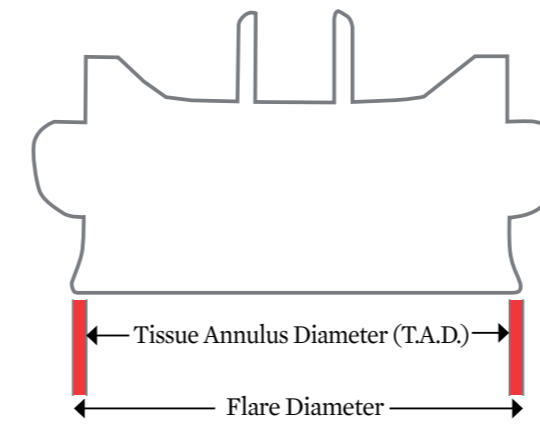
THE ESCAT III STUDY, WITH MORE THAN THREE TIMES THE NUMBER OF SUBJECTS EVALUATED IN A COMPARABLE INR THERAPEUTIC TREATMENT RANGE AS THE PROACT STUDY, SHOWS ABBOTT MECHANICAL HEART VALVES DEMONSTRATE EXCEPTIONAL LOW RATES OF THROMBOEMBOLISM AND BLEEDING.

# OPERATE WITH THE FACTS: IMPLANTABILITY

THE REGENT™ VALVE OFFERS SURGEON-FRIENDLY IMPLANTABILITY, BRINGING CONFIDENCE TO THE TABLE.

## DON'T LET AN INLET FLARE INTERFERE WITH YOUR SUCCESS.

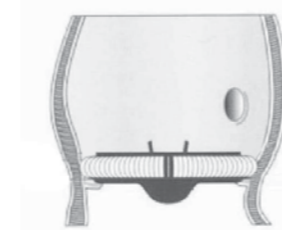
On-X's inlet flare diameter exceeds tissue annulus diameters<sup>5</sup>, which may require resizing the valve. Pressure gradients are lower at higher valve sizes. With Regent, you don't have to choose between better hemodynamics or a straightforward implant.



FLARE DIAMETER EXCEEDS TISSUE ANNULUS DIAMETER

## A LOWER OVERALL OPEN HEIGHT FACILITATES IMPLANTABILITY.

A lower overall open height allows you to confidently avoid interference with the coronary ostia. For example, for a 21 mm valve, Regent's overall open height is 13.0 mm whereas On-X's is 14.7 mm.<sup>5,6</sup>



REGENT

## ONE SIZE DOES NOT FIT ALL.

IDs at Various Sizes (mm)<sup>5,7</sup>

REGENT™



25 mm



27 mm

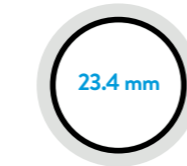


29 mm

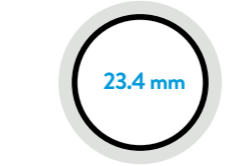
ON-X<sup>†</sup>



25 mm



27 mm

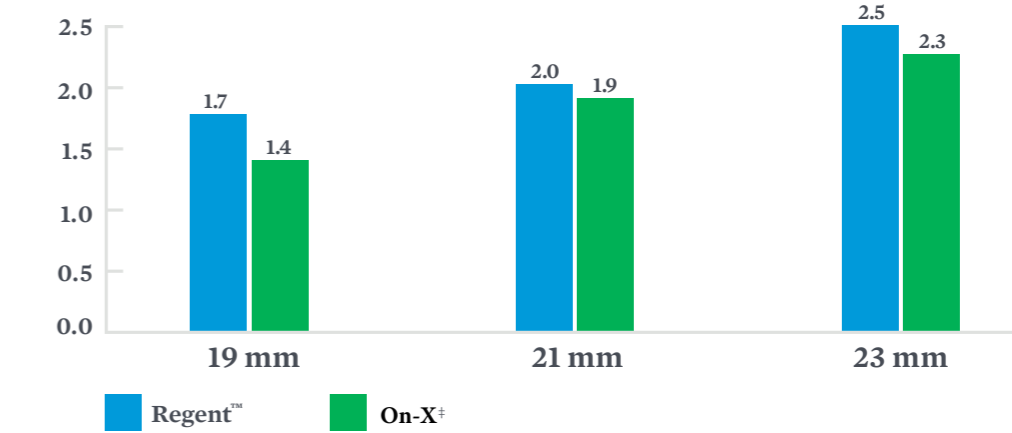


29 mm

The On-X valve's inner diameter does not increase for valve sizes 25mm and larger. Regent's inner diameter increases, allowing for an optimized size choice.

# OPERATE WITH THE FACTS: HEMODYNAMIC PERFORMANCE\*<sup>5,8</sup>

In Vivo Effective Orifice Area (cm<sup>2</sup>)



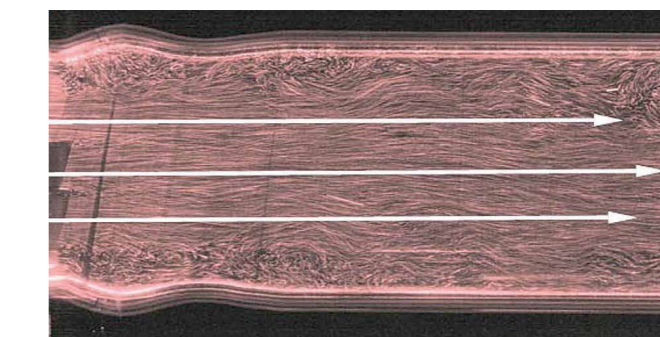
Regent's design allows it to maximize effective orifice area at each valve size.

\*Results from different clinical trials are not directly comparable. Information provided for educational purposes only.

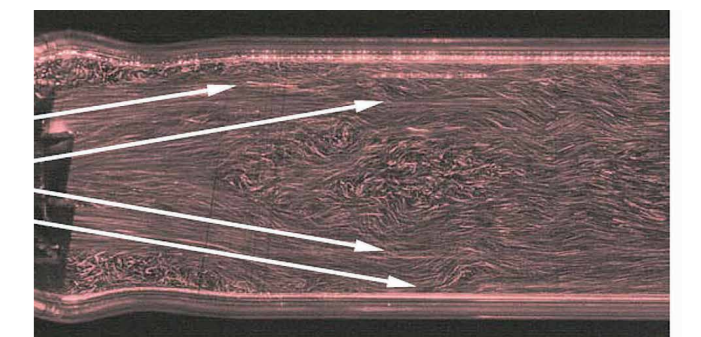
## OPENING ANGLES: 84° IS FURTHER OPEN THAN 79°.

While On-X specifies a 90° opening angle to Regent's 85° opening angle, an *in vivo* study points to an average Regent opening angle of 84.1° versus On-X's 79°.° Opening angle has important implications for ensuring that flow stays laminar, affecting thrombogenicity.

21 MM REGENT



21 MM ON-X



## A PLATELET CAN'T TELL THE DIFFERENCE.

Both pure carbon (On-X Valve) and silicon carbide strengthened carbon (Regent Valve) fall within a very similar roughness range, meaning that there is no advantage to pure pyrolytic carbon when it comes to suppressing thrombus formation.<sup>10</sup>