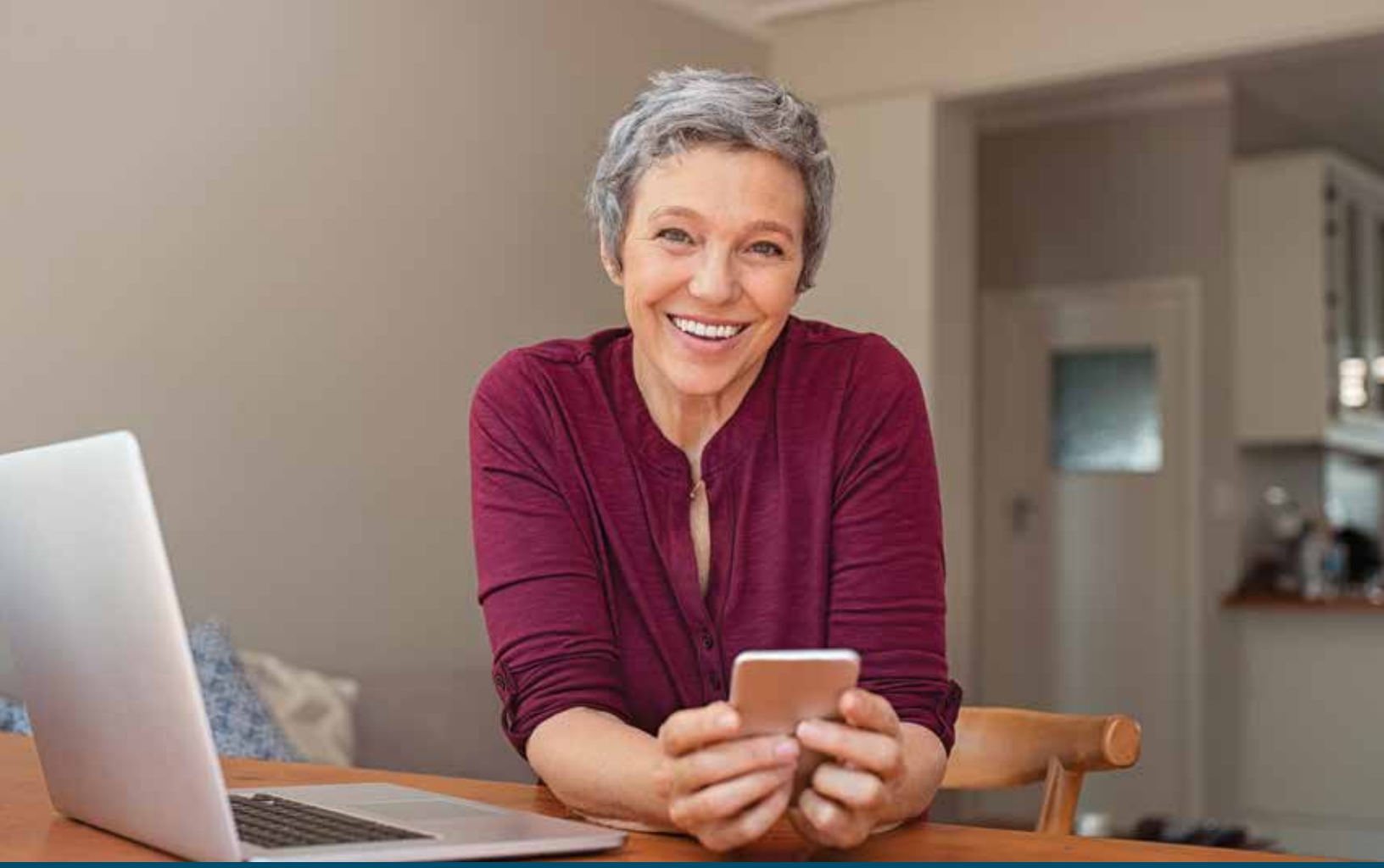


# ABBOTT MECHANICAL HEART VALVES AND REMOTE INR MONITORING WITH ACELIS CONNECTED HEALTH

## ENABLING FREEDOM FOR LIFE

Acelis Connected Health

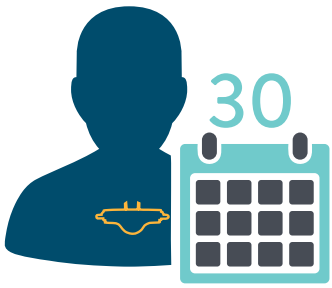
Abbott

# FREEDOM

## TO LIVE YOUR FULLEST LIFE

### RELIABLE AND TRUSTED.

Over 40 years of clinical experience and more than 1,000 published papers[3] have proven Abbott's mechanical heart valve (MHV) is a therapy designed to last your lifetime.




### EXCELLENT DURABILITY.

A study showed 98% freedom from replacement re-operation over a 25 year period[1]

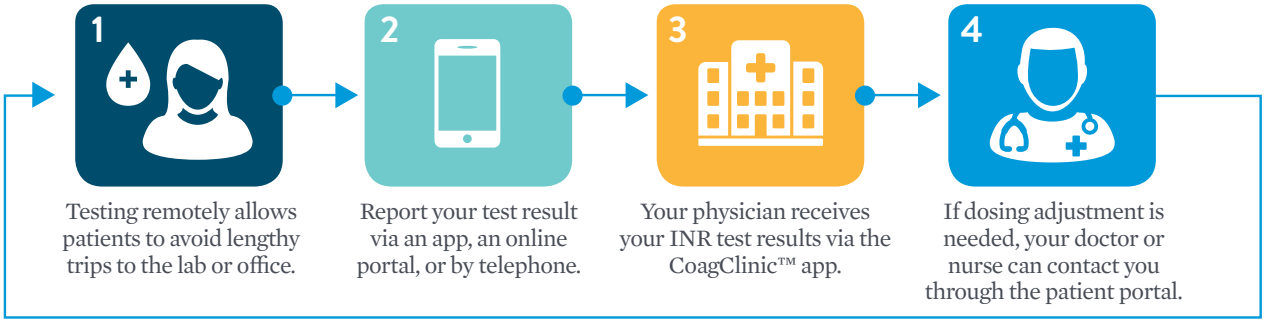
### PROVEN EFFICACY.

Introduced in 1979, Abbott's bileaflet design has revolutionized MHV therapy, lowering the risk of thrombogenic complications and providing exceptional performance.

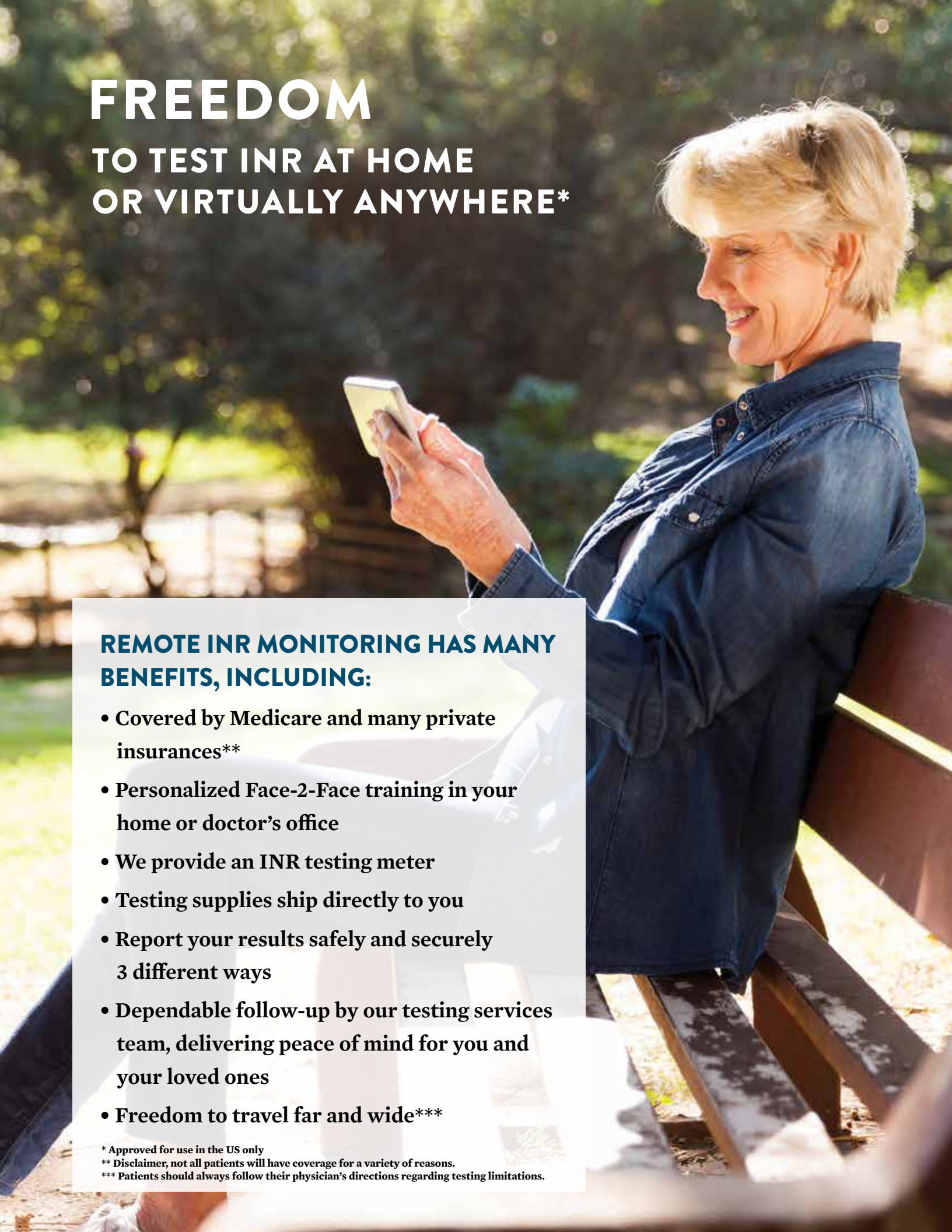

### YOU'RE IN GOOD COMPANY.

Nearly 3 million patients treated with Abbott mechanical heart valves worldwide.[3]

## HOW ACELIS CONNECTED HEALTH REMOTE INR MONITORING WORKS




See Important Safety Information referenced within



# FREEDOM

## TO TEST INR AT HOME OR VIRTUALLY ANYWHERE*

### REMOTE INR MONITORING HAS MANY BENEFITS, INCLUDING:

- Covered by Medicare and many private insurances**
- Personalized Face-2-Face training in your home or doctor's office
- We provide an INR testing meter
- Testing supplies ship directly to you
- Report your results safely and securely 3 different ways
- Dependable follow-up by our testing services team, delivering peace of mind for you and your loved ones
- Freedom to travel far and wide***

* Approved for use in the US only
** Disclaimer, not all patients will have coverage for a variety of reasons.
*** Patients should always follow their physician's directions regarding testing limitations.

# A LEADING PROVIDER OF REMOTE INR MONITORING

With over 100,000 patients on service, Acelis Connected Health Remote INR Monitoring received a superior ranking for home-based INR testing.

## SATISFIED PATIENTS

Nearly all current patients are extremely or very satisfied with Acelis Connected Health Remote INR monitoring[2]*

**95%**

**EASE OF USE/CONVENIENCE**

**94%**

**PROVIDING PEACE OF MIND**

*2018 opinion survey conducted by Kalan & Associates of 307 active Acelis Connected Health customers

# Acelis Connected Health Home INR Monitoring *Customer Information Form*

## Customer Information

First Name, M.I., Last Name | Date of Birth | Gender ☐ Female ☐ Male

Mailing Address | City | State | Zip

Primary Phone Number | Alternate Phone Number | Email

Physician Name | Physician phone

**Please complete the following to allow an alternate contact person to discuss customer care with Acelis Connected Health. If the customer is physically or mentally unable to sign, this document can be signed by a representative of the customer.**

Alternate Contact Person | Relationship to Customer

Mailing Address ☐ SAME AS CUSTOMER | Primary Phone Number

## Insurance Information

Insurance Name | Insurance Phone Number

Insurance Address | City | State | Zip

Insurance Policy or Member Number | Insurance Effective Date

Insurance Group Number | Insurance Expiration Date

## Acknowledgement Of Benefits

Please complete the following Acknowledgment of Benefits from Acelis Connected Health

Customer or Representative please read and initial the following:

_____ I acknowledge the Acelis Connected Health Notice of Privacy Practices available in the Welcome Book and online at acelis.com.

_____ I authorize the release of any minimally necessary medical information to verify benefits, process claims, or provide appropriate care or related services provided by Acelis Connected Health or its Agents.

_____ I authorize Medicare and/or any other insurance plans under which I am covered to make payment to Acelis Connected Health or its Assignee of authorized benefits on my behalf, for products or services furnished to me. I understand charges will not occur until I have reviewed expected out-of-pocket costs and given my consent to move forward. At that point I will accept financial responsibility for any deductible, co-insurance and non-covered charges.

By signing below I acknowledge I have read and accept the statements listed above.

**CUSTOMER OR REPRESENTATIVE SIGNATURE:** _____ Date _____

Print Name _____ Relationship _____

Fax completed form to 1.925.606.6978 or Mail to:

Acelis Connected Health Services • 6465 National Drive • Livermore, CA 94550

Questions? Call Acelis Connected Health at 1.877.262.4669, Option 1 • ptinr.com

Acelis Connected Health

A/C # ABTTSH



PN:1611232-03 01/19

**Acelis Connected Health will verify your benefits, provide you with equipment and supplies for use and support you with continued care—starting from our enrollment process through every test you take.**

**To determine if remote INR monitoring is right for you, talk to your doctor or call us at 1.877.262.4669 or visit the PTINR.com website to learn more about remote INR monitoring.**

## INDICATIONS AND IMPORTANT SAFETY INFORMATION

℞ ONLY

INDICATIONS AND USAGE 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. CONTRAINDICATIONS The SJM Regent™ Mechanical Heart Valve is contraindicated for individuals unable to tolerate anticoagulation therapy. WARNINGS • For single use only. Attempts to reuse the valve may result in valve malfunction, inadequate sterilization, or patient harm. • Do not use if: The valve has been dropped, damaged, or mishandled in any way. The expiration date has elapsed. The tamper-evident container seal or inner/outer tray seals are damaged, broken or missing. • Remove any residual tissue that may impair valve size selection, correct seating of the valve, rotation of the valve, or leaflet motion. • Proper valve size selection is crucial. Do not oversize the valve. If the native annulus measurement falls between two SJM Regent™ Mechanical Heart Valve sizes, use the smaller size SJM Regent™ Mechanical Heart Valve. • Use only St. Jude Medical™ mechanical heart valve sizers. • The outer tray is not sterile, and should not be placed in the sterile field. • To minimize direct handling of the valve during implantation, do not remove the holder/rotator until the valve has been seated in the annulus. • Do not use hard or rigid instruments to test leaflet mobility, as this may result in structural damage to the valve or thromboembolic complications. Use a St. Jude Medical™ leaflet tester to gently test valve leaflet mobility. • Do not use cutting edge needles in the sewing cuff. If use of these needles is necessary, placement of sutures in the outer half of the sewing cuff is imperative. • Never apply force to the valve leaflets. Force may cause structural damage to the valve. • Use only the valve holder/rotator packaged with the SJM Regent™ Mechanical Heart Valve to perform valve rotation. Use of other instruments could result in structural damage. The valve holder/ rotator is intended for single use only and should be discarded after surgery. • The two retention sutures on the valve holder/rotator must be cut and removed before the SJM Regent™ Mechanical Heart Valve can be rotated. • Do not pass catheters or other instruments through St. Jude Medical™ mechanical heart valves. This could result in scratched or damaged valve components, or leaflet fracture or dislodgment. • Cut suture ends short, especially in the vicinity of the pivot guards, to prevent leaflet impingement. PRECAUTIONS • Do not touch the prosthetic valve unnecessarily, even with gloved hands. This may cause scratches or surface imperfections that may lead to thrombus formation. • Be careful not to cut or tear the valve sewing cuff when removing the identification tag and the holder/rotator from the SJM Regent™ Mechanical Heart Valve. • Before placing sutures in the valve cuff, verify that the valve is mounted correctly on the valve holder/rotator. • To avoid structural damage, the valve must be rotated in the fully closed position. • To minimize rotational torque, verify that the valve holder/rotator is properly seated in the valve, and that the valve holder handle is perpendicular to the valve (Figures 15a and 15b). • Remove any loose suture or thread, which may be a source of thrombus or thromboembolism. POTENTIAL ADVERSE EVENTS Complications associated with replacement mechanical heart valves include, but are not limited to: hemolysis; infections; thrombus; or thromboembolism; valve dehiscence; unacceptable hemodynamic performance; hemorrhagic complications secondary to anticoagulation therapy; prosthetic failure; and heart failure or death. Any of these complications may require reoperation or explantation of the device.

INDICATIONS AND USAGE The SJM™ Masters Series Mechanical Heart Valve is intended for use as a replacement valve in patients with a diseased, damaged, or malfunctioning mitral or aortic heart valve. This device may also be used to replace a previously implanted mitral or aortic prosthetic heart valve. The sizer model 905-15 is indicated to confirm size selection of the 15AHPJ-505 and 15MHPJ-505 valves. CONTRAINDICATIONS The SJM™ Masters Series Mechanical Heart Valve is contraindicated for individuals unable to tolerate anticoagulation therapy. The sizer model 905-15 is contraindicated for use with any devices other than the 15 AHPJ-505 and 15MHPJ-505 valves. Any sizer sterilization method other than steam is contraindicated. WARNINGS Valve • For single use only. Attempts to reuse the valve may result in valve malfunction, inadequate sterilization, or patient harm. • Use only St. Jude Medical™ mechanical heart valve sizers. • Do not use if: The valve has been dropped, damaged, or mishandled in anyway. The expiration date has elapsed. The tamper-evident container seal or inner/ outer tray seals are damaged, broken, or missing. • Remove any residual tissue that may impair valve size selection, correct seating of the valve, rotation of the valve, or leaflet motion. • Proper valve size selection is crucial. Do not oversize the valve. If the native annulus measurement falls between two SJM™ Masters Series Mechanical Heart Valve sizes, use the smaller prosthetic valve size. • The outer tray is not sterile, and should not be placed in the sterile field. • To minimize direct handling of the valve during implantation, do not remove the holder/rotator until the valve has been seated in the annulus. • Do not use hard or rigid instruments to test leaflet mobility, as this may result in structural damage to the valve or thromboembolic complications. Use a St. Jude Medical™ leaflet tester to gently test valve leaflet mobility. • Place sutures in the outer half of the valve sewing cuff. • Never apply force to the valve leaflets. Force may cause structural damage to the valve. • Use only SJM™ Valve Holder/Rotators to perform valve rotation. Use of other instruments could result in structural damage. The valve holder/rotator is intended for single use only and should be discarded after surgery. • The two retention sutures on the valve holder/rotator must be cut and removed before the valve can be rotated. • Do not pass catheters or other instruments through St. Jude Medical™ mechanical heart valves. This could result in scratched or damaged valve components, leaflet fracture, or dislodgment. • Cut suture ends short, especially in the vicinity of the pivot guards, to prevent leaflet impingement. PRECAUTIONS Valve • Do not touch the prosthetic valve unnecessarily, even with gloved hands. This may cause scratches or surface imperfections that may lead to thrombus formation. • Be careful not to cut or tear the valve sewing cuff when removing the identification tag and the holder/ rotator from the valve. • Before placing sutures in the valve sewing cuff, verify that the valve is mounted correctly on the valve holder/rotator. • To avoid structural damage, the valve must be rotated in the fully open position. • To minimize rotational torque, verify that the valve holder/rotator is properly seated in the valve, and that the valve holder handle is perpendicular to the valve. • Remove any loose suture or thread, which may be a source of thrombus or thromboembolism. • Implantation of a prosthetic valve too large for the annulus may result in increased risk of damage to the conductive system, obstruction of the left ventricular outflow tract, impairment of valve mobility, damage to the left circumflex artery, and damage to surrounding tissues or cardiac structures including obstruction and/or distortion of adjacent cardiac structures. • NOTE: PROSPECTIVE DATA TO SUPPORT SAFETY AND EFFECTIVENESS OF THE 15-mm HP VALVE IMPLANTED IN THE AORTIC POSITION ARE NOT CURRENTLY AVAILABLE. Sizer • Instruments must be cleaned and sterilized prior to use. • Do not use cracked, deformed, discolored/rusted, or damaged instruments. • Improper cleaning may result in an immunological or toxic reaction. • Instrument sterilization temperature must not exceed 280°F (138°C). • Do not bend flexible instrument handles beyond a 90° angle. • Instruments must be sterilized in a tray or container that is permeable to steam. • Do not expose instruments to cleaning or rinse agents that are not compatible with polysulfone or polyphenylsulfone. POTENTIAL ADVERSE EVENTS Complications associated with replacement mechanical heart valves include, but are not limited to, hemolysis, infections, thrombus, or thromboembolism, valve dehiscence, unacceptable hemodynamic performance, hemorrhagic complications secondary to anticoagulation therapy, arrhythm, heart block requiring pacemaker implant, prosthetic failure, adjacent cardiac structure interference, heart failure, stroke, myocardial infarction, or death. Any of these complications may require reoperation or explantation of the device.

## REFERENCES


1. Emery et al. The St. Jude Medical Cardiac Valve Prosthesis: A 25-Year Experience With Single Valve Replacement, The Society of Thoracic Surgeons, 2005:79:776-83
2. Data on file. Current users of AHM INR Monitoring services. N=307.
3. Internal data on file


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


**Abbott**
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1 800 227 9902
www.Vascular.Abbott




Abbott