Abbott

Mechanical Heart Valves

LESS SURGERY. MORE LIVING.

One trusted therapy that gets you back to your life.

Take the first steps toward understanding and treating your heart valve disease

Did you know that more than five million people in the U.S. are diagnosed with heart valve disease each year?[1] As one of those many people, you may be wondering what is it, what the symptoms are and how it is treated. This guide can help you learn more about the condition and treatment options, so you feel more confident in making decisions with your doctor.

WHAT IS HEART VALVE DISEASE?

Heart valve disease refers to a condition in which at least one valve of the heart does not function properly. Heart valves can be impaired due to defects at birth, damage from infection, age-related issues or other diseases. The results are either a rigid valve with a decreased opening which restricts blood flow (called a stenotic valve) or a valve that does not close properly allowing blood to leak and flow backward (called a regurgitant valve).

WHAT ARE THE SYMPTOMS?

The "leaky" or "stiff" valve affects the hearts ability to pump properly, so it has to work harder to deliver oxygen-rich blood to the other organs and tissues. The overworked heart can begin to fail, causing these symptoms:

Shortness of Breath | Dizziness | Chest Pain | Fatigue | Fluid Retention

For U.S. audience, see Important Safety Information referenced within. For audiences outside of the U.S., always check the regulatory status of the device in your region.

HOW IS IT TREATED?

Based on diagnostic tests and a risk assessment, you and your doctor can determine a treatment that is right for you. There are several treatment options including medication, surgical repair, surgical valve replacement, transcatheter valve repair or transcatheter valve replacement.

WHAT IS A SURGICAL VALVE REPLACEMENT?

If your aortic or mitral valve cannot be repaired, your doctor may recommend a replacement with an artificial (prosthetic) valve. Two types are available — a mechanical valve or a tissue valve — and each offers different benefits depending on your specific needs. To determine what type of valve is best for you, your doctor will take many factors into consideration, such as your age, overall health and medication requirements.[2]

MECHANICAL VALVES VS. TISSUE VALVES

Made of strong, long-lasting materials such as pyrolytic carbon, **mechanical valves** are designed to last for the rest of your life. Daily blood-thinning medication will be required to help prevent blood clots.[2,3]

Made from pig or cow heart tissue, **tissue valves** may not last the remainder of your entire life. When they wear out, another procedure will be required. Daily blood-thinning medication is not usually required in the long-term.[2,3]

REPLACEMENT HEART VALVE RISKS

Potential adverse events that may occur during or after implantation of a mechanical heart valve may include — excessive bleeding related to use of blood thinners; failure of the valve; heart failure; death. For a full list of potential risks see page 12.

WHO ARE MECHANICAL VALVES RECOMMENDED FOR?

A mechanical valve might be right for you if your doctor thinks it fits your condition, if you're comfortable taking blood-thinning medicine and if you'd prefer a one-time procedure that can help you feel better for many years.

For people 60 years old and younger, a recent, large, multi-center study showed that mechanical heart valves lead to:

BETTER SURVIVAL[4]

FEWER REOPERATIONS[5]

THE MOST IMPLANTED MECHANICAL HEART VALVES IN THE WORLD[6]

45+ YEARS[6] **of trusted use**

3.5+ MILLION[6] **lives changed**

THE POWER OF ONE

Lasting longer than tissue heart valves, one single procedure with a mechanical heart valve is proven for durability and reduced risk of another procedure.[5] A majority of mechanical heart valve patients only need one valve replacement surgery for their lifetime.

That is the power of one.

- **97% FREEDOM** from reoperation for aortic valve replacement at **20 YEARS**[7]
- **96% FREEDOM** from reoperation for mitral valve replacement at **20 YEARS**[7]

FEEL LIKE YOU AGAIN

Mechanical heart valve therapy improves the blood flow in your heart, reducing your symptoms, so you can feel like you again and return to the life you love.[8,9]

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FREQUENTLY ASKED QUESTIONS

Here is an overview of what next steps could look like including the surgery, recovery, medication and testing.

WHAT HAPPENS DURING THE SURGERY?

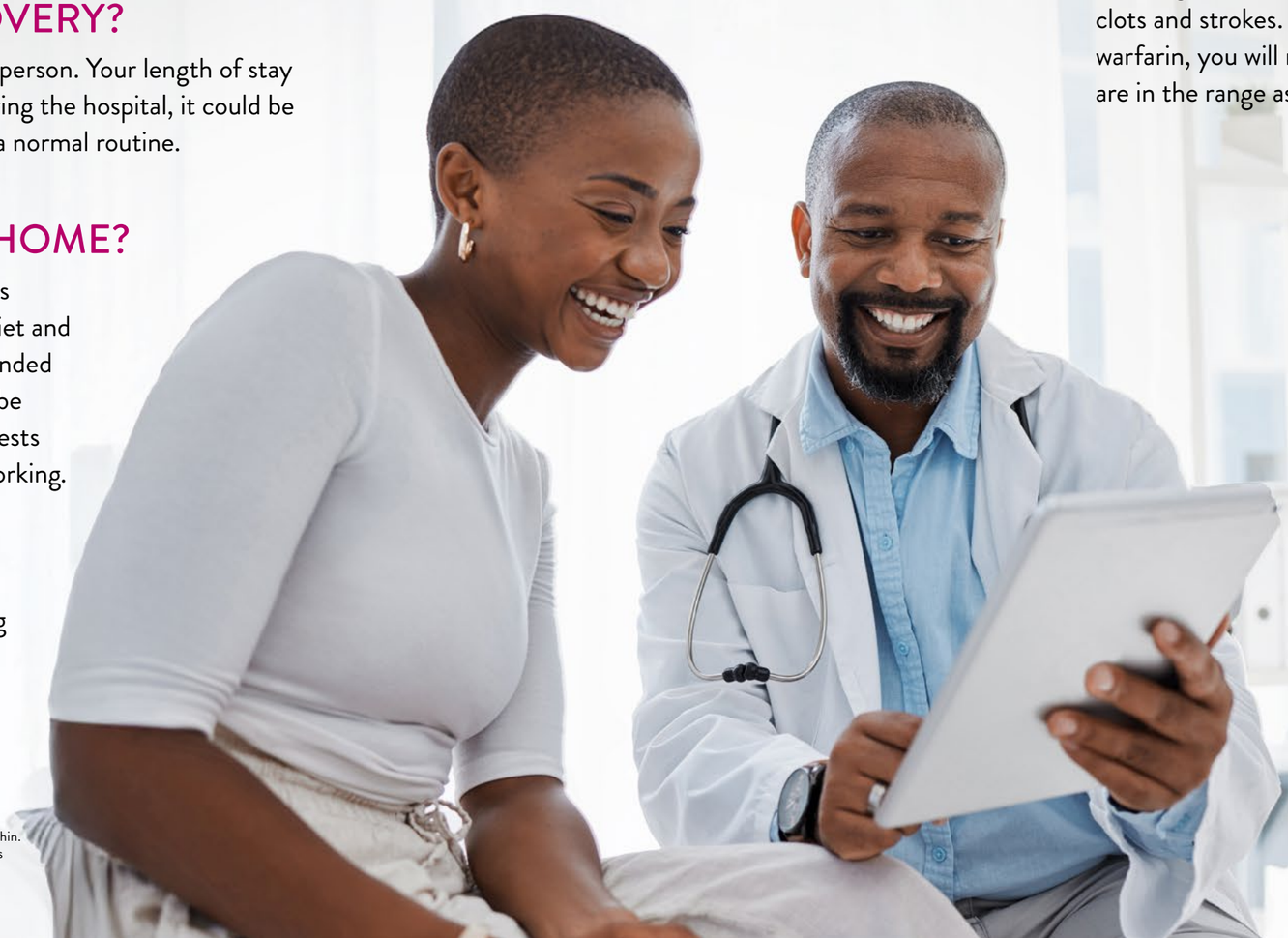
Your surgeon will remove the diseased valve and determine the correct size for your replacement valve. The new valve will be positioned in the original valve location and firmly sewn into place.

HOW LONG IS RECOVERY?

Recovery time is different for each person. Your length of stay could be several days, but upon leaving the hospital, it could be several weeks before you return to a normal routine.

WHAT HAPPENS AT HOME?

Continue to take your medication as prescribed, follow a heart-healthy diet and maintain activity levels as recommended by your doctor. A follow-up should be scheduled with your doctor where tests will evaluate how the new valve is working. You will need to be prescribed an anticoagulant like warfarin, and bloodwork and International Normalized Ratio (INR) Monitoring management will start.



WHAT IS WARFARIN?

It is a medication used to help decrease the clotting ability of your blood. It is prescribed for those at risk to prevent stroke. While taking warfarin, it is important to inform your doctor about any other prescriptions or over-the-counter medications you will be taking with it including pain relievers, cold medicines and herbal supplements. You must also pay attention to what you eat while taking warfarin, as some foods and beverages can alter its effectiveness.

WHAT IS INTERNATIONAL NORMALIZED RATIO?

INR measures how quickly blood clots. It is important for mechanical heart valve recipients to maintain stable levels of anticoagulation as recommended by a doctor to prevent blood clots and strokes. When taking anti-clotting medicines like warfarin, you will need your blood tested regularly to ensure you are in the range as prescribed by your doctor.

HOW DOES INR TESTING WORK?

At first, you will have your blood drawn at a lab or doctor's office. Eventually, with a prescription and the support of your doctor, you may have the option to self-monitor at home to eliminate the need to travel to a lab or to see your healthcare provider for routine testing. See the next page for more information on this.

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CONVENIENTLY MANAGE YOUR INR

The Acelis Connected Health, CoaguChek‡ XS, and Coag-Sense‡ PT2 are systems* that can support you long after surgery with at-home INR monitoring for mechanical heart valve patients. Talk to your doctor about a prescription for INR monitoring.

To help prevent blood clotting, you will be prescribed a medication like warfarin that will require your doctor to monitor its effectiveness by testing your INR in a lab. After 90 days, you may be able to start monitoring your INR at home or wherever it's convenient for you with your doctor's approval. By providing weekly data in near real time, you can feel confident that both you and your doctor are always connected on your INR meter through alerts and reports.

Your enrollment may begin with simple steps guided by a customer service team, followed by one-on-one instructions from specialized trainers.

Travel without missing a test. Your INR meter is designed to be portable and packable, no matter where you go. Whether you are traveling for the day or a month, you'll never have to miss a test or try to find a local lab when you are part of at home INR testing.

Receive reminders to report your results. Depending on at-home monitoring system, if you or your loved one doesn't report your test results according to the testing schedule prescribed by your doctor, you may be contacted by the Testing Services Team to remind you.

Have confidence in dedicated support. From questions about the fingerstick process to queries about how to post results, experienced support representatives are available to help by contacting your specific at-home monitoring system's Customer Support Department.

*At-home INR monitoring systems may not be available in all geographies

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IT'S EASY TO GET STARTED

MOBILE APP

May provide an easy way to access your INR testing history, order supplies and even pay your bill all in one place.

FACE-TO-FACE TRAINING

Depending on your at-home INR system you may learn from specialized trainers or tutorial videos on how to use the INR meter and report results.

REPORTING OPTIONS

Results may be sent from the at-home INR monitoring device, a smartphone, tablet, laptop or telephone.

HAVE A CONVERSATION WITH YOUR DOCTOR

Here is a guide of questions you and your loved one should walk through when talking to your doctor about mechanical heart valves.

What are the benefits and risks of mechanical heart valves?

How does it compare with a tissue heart valve?

How long will I be in the hospital?

What are recovery instructions?

What medication do you expect I will need to take after the surgery?

Will this change my current medications?

Does the hospital have a local community support group for those navigating heart conditions?

Additional notes:

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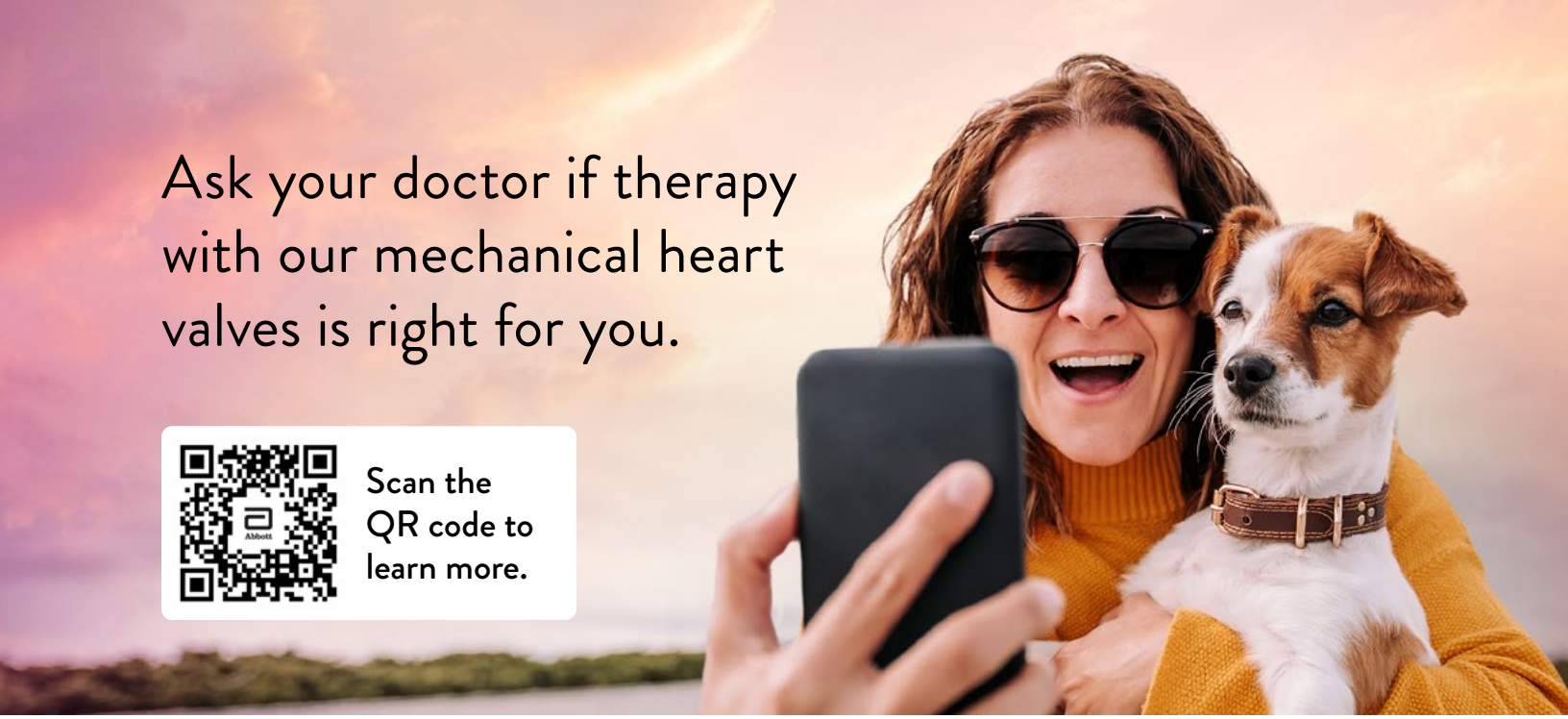
Ask your doctor if therapy with our mechanical heart valves is right for you.



Scan the QR code to learn more.

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FOR U.S. AUDIENCE ONLY

Rx Only
Important Safety Information

REGENT™ MECHANICAL HEART VALVE

What is the Regent™ Mechanical Heart Valve approved for?
The Regent™ Mechanical Heart Valve is for use in replacement of a native (natural) aortic heart valve that is diseased, damaged, or does not function properly. It may also be used to replace a previously implanted prosthetic aortic heart valve.

Who should not receive the Regent™ Mechanical Heart Valve?
Patients who are unable to take aspirin or other blood-thinning medication should not receive the Regent™ Mechanical Heart Valve.

What are the possible complications associated with the Regent™ Mechanical Heart Valve?
Potential adverse events that may occur during or after implantation of the Regent™ Mechanical Heart Valve include, but are not limited to: destruction of red blood cells; infections; blood clot that forms in a vein or blocks a vessel; breakdown of sutures that connect the valve to the heart; poor blood flow; excessive bleeding related to use of blood thinners; failure of the valve; failure of the heart to pump enough blood for the body's needs; death.

It is possible that these complications could lead to reoperation or surgical removal of the valve?
Talk to your doctor to learn more about the risks associated with use of the Regent™ Mechanical Heart Valve.

Rx Only
Important Safety Information

MASTERS SERIES MECHANICAL HEART VALVE

What is the SJM™ Masters Series Mechanical Heart Valve approved for?
The SJM™ Masters Series Mechanical Heart Valve is for use in replacement of a native (natural) aortic or mitral heart valve that is diseased, damaged, or does not function properly. It may also be used to replace a previously implanted prosthetic aortic or mitral heart valve.

Who should not receive the SJM™ Masters Series Mechanical Heart Valve?
Patients who are unable to tolerate blood-thinning medication should not receive the SJM™ Masters Series Mechanical Heart Valve.

What are the possible complications associated with the SJM™ Masters Series Mechanical Heart Valve?
Potential adverse events that may occur during or after implantation of the SJM™ Masters Series Mechanical Heart Valve include, but are not limited to: destruction of red blood cells; infections; blood clot that forms in a vein or blocks a vessel; breakdown of sutures that connect the valve to the heart; poor blood flow; excessive bleeding related to use of blood thinners; failure of the valve; heart failure; death.

It is possible that these complications could lead to reoperation or surgical removal of the valve?
Talk to your doctor to learn more about the risks associated with use of the SJM™ Masters Series Mechanical Heart Valve.

CAUTION: Product(s) 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 www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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