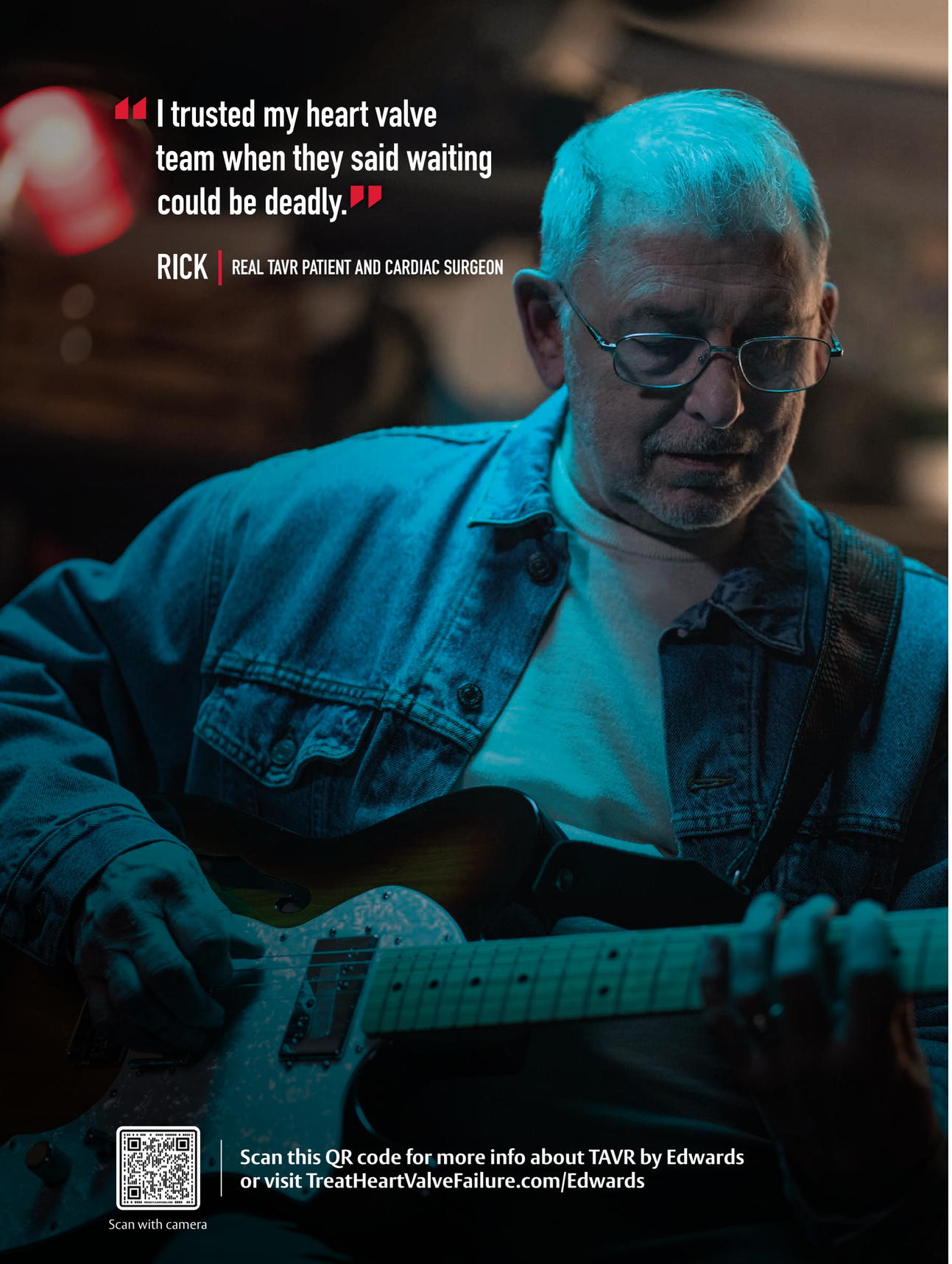
TAVR Procedure Guide

Your guide to TAVR (transcatheter aortic valve replacement) – from treatment through recovery for patients with severe aortic stenosis (heart valve failure).

Edwards Lifesciences



Introduction

All heart valve failure patients are eligible for a TAVR (transcatheter aortic valve replacement). Don't let fixable become fatal, especially when there's TAVR.

This guide is designed to help you and your caregiver understand what to expect before, during, and after your TAVR by Edwards procedure, so you can get back to the life you want.

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What is TAVR?

TAVR is a minimally invasive way to replace a failing aortic heart valve compared to open heart surgery, also known as SAVR (surgical aortic valve replacement). TAVR doesn't involve opening up the chest and on average takes 1 hour vs 4 hours with open heart surgery. There's a reason TAVR is the preferred treatment for people with heart valve failure.

Many people who get TAVR:

Are up and walking in a few hours

Have a short recovery time and go home the next day

Are back to feeling like themselves in as little as 30 days*

Experience long-lasting durability of up to 5 years, similar to SAVR†

*At 1 year, open heart surgery has been shown to have similar quality of life outcomes as TAVR.

† The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and re-hospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

PARTNER 3 Trial 5-Year Results in low-risk patients – Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.1% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

Every week counts. By delaying treatment, you're putting your life at risk

Heart valve failure is a serious condition that can progress rapidly and unpredictably—which can lead to hospitalization, stroke, or even death.

1 in 10 people with heart valve failure who are experiencing symptoms may die within 5 weeks while waiting for their aortic valve replacement.

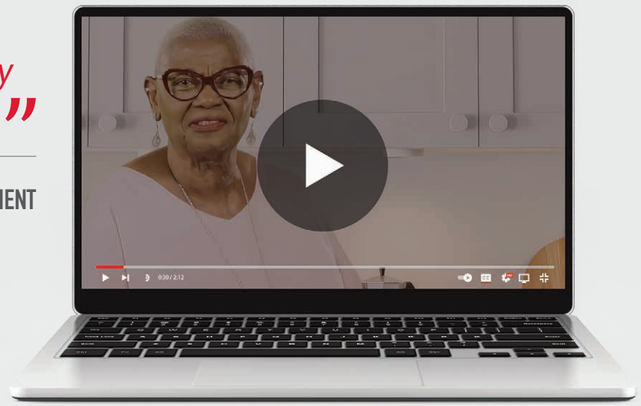
Patients who get TAVR by Edwards before symptoms show up have better outcomes than those who take the "wait and see" approach. All patients diagnosed with heart valve failure should ask to be evaluated for TAVR right away.

Hear real TAVR stories

Joy wasn't about to wait around while her heart valve failure symptoms got in the way of doing what she loved. She decided to take back her life with TAVR.

"I don't wait for anything. Especially heart valve failure."

JOY | REAL TAVR PATIENT

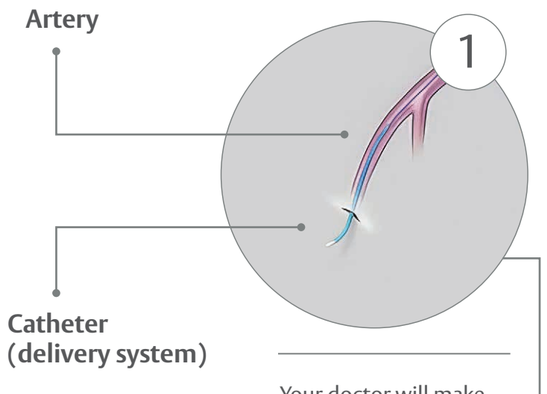


Scan with camera

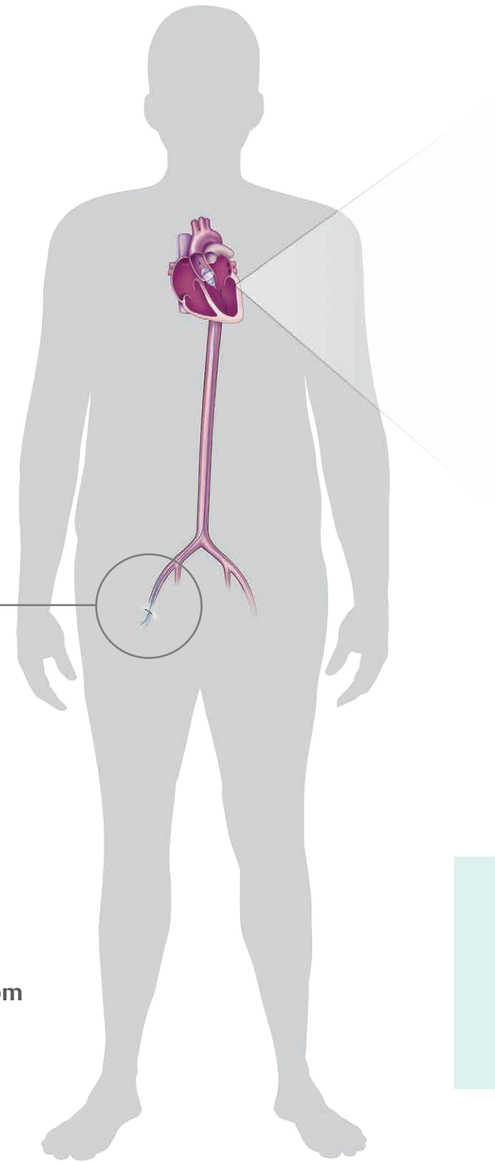
Hear Joy's story. Scan this QR code or visit TreatHeartValveFailure.com

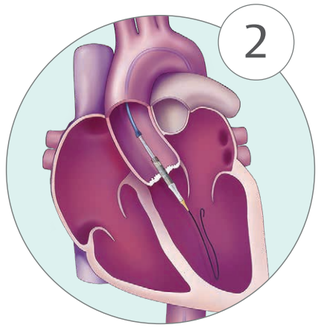
How is TAVR performed?

The TAVR procedure involves using a catheter, or narrow tube, to deliver your new valve to your heart. Most commonly, the catheter is inserted through a small incision (cut) in the leg, near the groin. This is called the transfemoral approach.

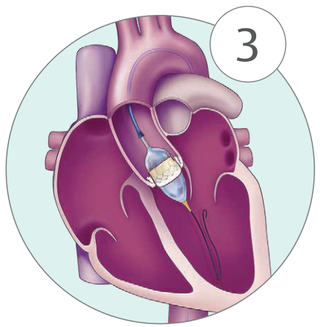


Your doctor will make an incision in your leg and insert a thin tube called a catheter into the artery.

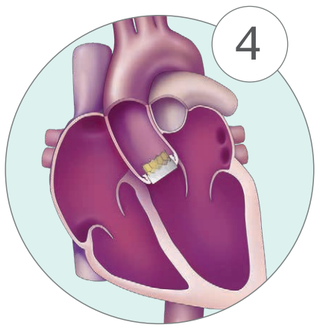




They will then guide the catheter, which is carrying the new valve on a balloon, up to the heart.



The balloon is inflated to expand and fix the new valve into place.



Your existing valve holds the new valve in place, and the balloon is deflated and removed. The new valve will open and close as a normal aortic valve should.

Scan with camera

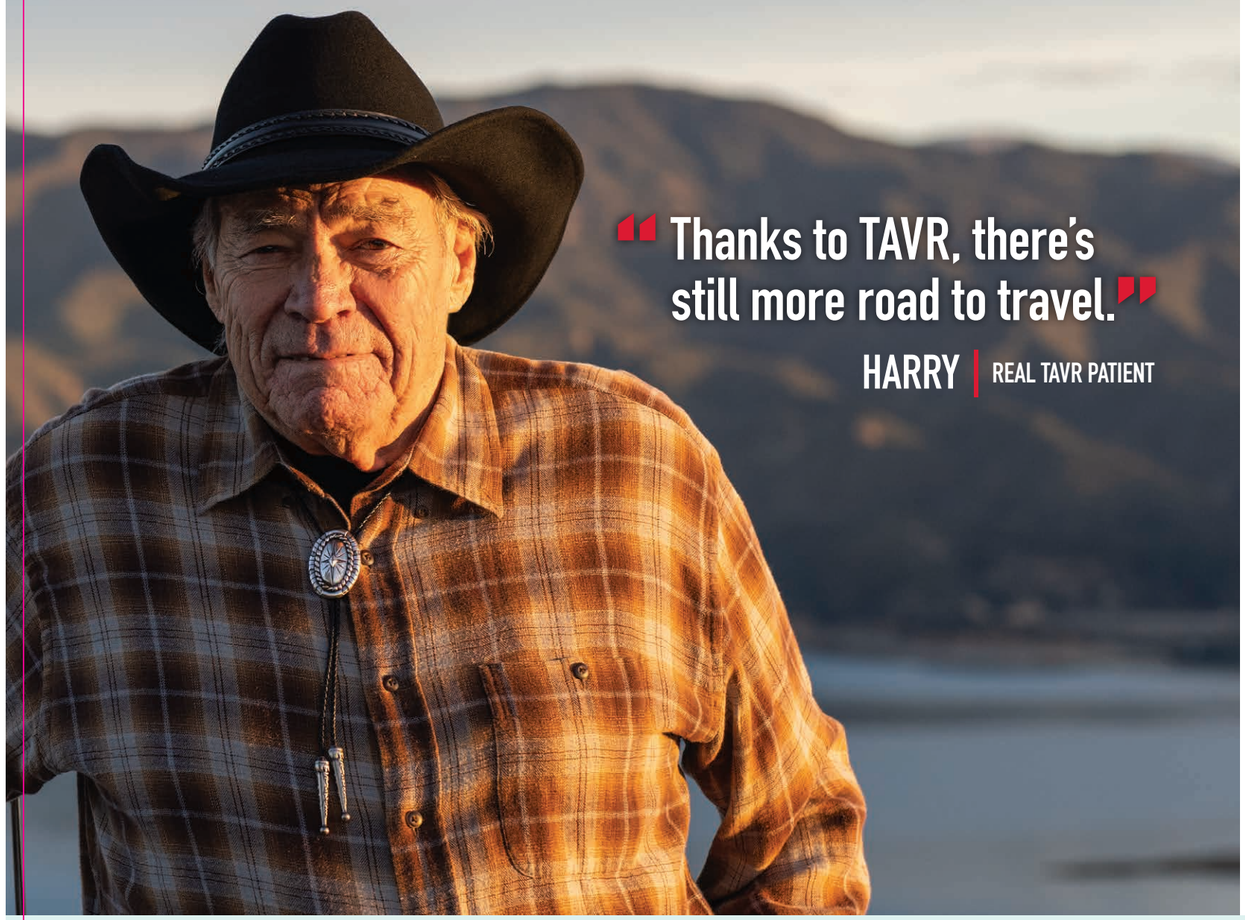
To watch a video of the TAVR procedure, scan this QR code or visit TreatHeartValveFailure.com

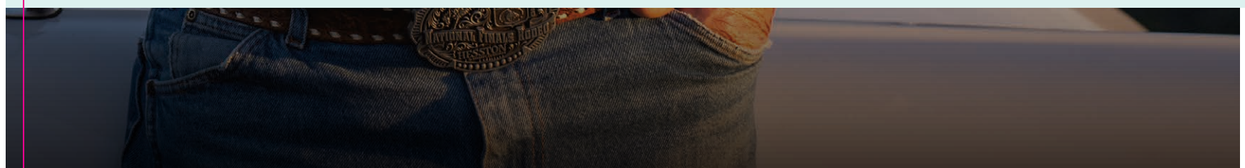
1 hour

The TAVR procedure takes around 1 hour. Most patients go home the next day.

Your choice of heart valve matters

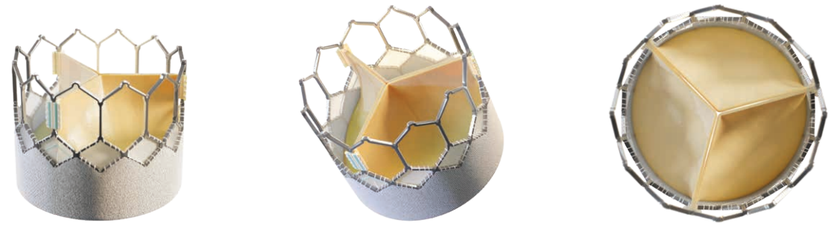
It's been clinically tested and shown that patients who received TAVR by Edwards before they felt any symptoms of heart valve failure maintained their current lifestyle and had fewer hospitalizations compared to patients who waited to have TAVR. After symptoms started, patients also showed improvements in quality of life at 30 days.





Over 1 million people worldwide have received TAVR by Edwards.

TAVR by Edwards is the #1 choice in transcatheter heart valve replacement in the US



- The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves
- The SAPIEN 3 Ultra RESILIA valve is made of cow heart tissue that uses advanced technology to block the buildup of calcium. This RESILIA tissue treatment could potentially allow the valve to last longer*†

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Edwards SAPIEN 3 TAVR valves are not one-size-fits-all. They come in 4 sizes to meet the individual needs of each patient.

Edwards TAVR valves provide:

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- Low rates of needing valve replacement a second time
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Now is the time to talk to your doctor to see if an Edwards TAVR valve is right for you.

*RESILIA tissue has not been studied for long-term results in patients.

†RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng W, et al. *J Thorac Cardiovasc Surg.* 2015;149(1):340-345.

Scan with camera

To learn more about the benefits of Edwards TAVR valves, scan this QR code or visit **TreatHeartValveFailure.com/Edwards**

Preparing for TAVR by Edwards

Make sure to get your TAVR prep information from your doctor or Valve Clinic Coordinator (VCC) and review it with your caregiver. Follow all of the directions you're given.

Here are a few things you will need to do leading up to your procedure:

- Get a dental clearance to ensure any infections present in your mouth or teeth don't spread to your heart valve
- Talk to your doctor about how much activity or exercise you should be doing (and let them know about any new or worsening symptoms)
- Go over any medicine you are taking with your doctor. Consult with your doctor to determine which medications you should or should not take leading up to and on the day of your procedure
- Talk to your doctor about which foods are recommended and when you should stop eating or drinking prior to your procedure
- Make sure you have someone to drive you to and from the hospital the day of your procedure
- Go over this information and any instructions you receive with your caregiver so you both know what to expect and can prepare

Questions and notes

Write down any additional questions to ask your doctor or instructions they give you.

What to expect the day of your procedure

Most people who have TAVR go to the hospital the morning of the procedure. Some people may be asked to go to the hospital the night before. Your doctor or care team will let you know when to arrive.

- 1 hour — The TAVR procedure usually takes about an hour. Most patients have a short recovery time and go home the next day
- Your TAVR doctor will decide what type of anesthesia is best for you. You may be asleep or awake and medicated while your valve is replaced
- Your loved one(s) will be told how the procedure went and how you're doing
- You'll be able to have visitors after the anesthesia wears off
- Nurses will encourage you to start sitting up and moving around soon after the procedure
- You'll learn how to care for yourself once you're home, including caring for your incision, doing breathing exercises, managing pain, and taking recommended medication

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Life after TAVR by Edwards

While you're still in the hospital, you'll want to make sure you know what to do once you're home. Here's a checklist of things the Heart Valve Team may cover with you in the hospital:

- **Pain control** – you may experience some pain or discomfort and receive pain medicine if needed
- **Daily activities** – be patient and follow the advice of your doctor. You may need help when you first go home. It's best to plan ahead so you have the help you need
- **Breathing** – you may be given breathing exercises to help keep your lungs clear
- **Incision care** – your incision dressing will need to be changed to prevent infection
- **Medication** – your doctor may prescribe medication, including blood thinners
- **Your new valve** – you may be given an echocardiogram to see images of your new valve before you leave the hospital

Questions and notes

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Here are some steps that you – and your caregiver – can take to help you recover

Some people may notice improvements in their energy level and quality of life right away. Others may find it takes a few days or weeks. Discuss your activity goals with your doctor.

As you become more active, remember your body may need time to adjust. Try to go easy on yourself and rest when needed.

- **Arrange to have help around the house** for the first few days after your procedure and possibly longer
- **Talk with your loved one or caregiver** about what you need and how they can best help you
- **Continue to care for your incision** as instructed in the hospital
- **Perform any breathing exercises** you learned at the hospital until your doctor says it's OK to stop
- **Keep your pain under control,** as directed by your doctor, to help you stay active while recovering
- **Take all medication as prescribed** and don't stop taking any without talking to your doctor
- **Attend all follow-up appointments** with your doctor

Questions and notes

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Follow-up appointments

It's very important to attend all of your follow-up appointments so your doctor can check your progress. Ask questions or share any concerns with your doctor.

Your follow-up visits may include:

- Blood tests to see how your medication is working
- Tests to check how well your heart and new valve are working

Your doctor will recommend a schedule that's best for you.

In the first 30 days after TAVR

- In the first 24 hours up to the first few days after release from the hospital, you may receive a follow-up phone call from your doctor to check in on your symptoms, medication, and well-being
- You may be asked to see your primary care provider around 5 to 7 days after release from the hospital

In the months after TAVR

- Your TAVR doctor will eventually transfer your care back to either your general cardiologist or primary doctor

Every year after TAVR

- You should schedule a follow-up appointment with your cardiologist to check your heart valve, which may include getting an echocardiogram

Be sure to **inform all healthcare professionals that you have a transcatheter replacement valve** and **share your TAVR Valve Implant Card** with them.

A few additional things to know

- Tell your dentist that you have had a heart valve replacement. You will likely need to take an antibiotic before undergoing any new procedure, including a cleaning, to reduce the risk of getting an infection in your new heart valve
- An MRI scan will not affect your transcatheter heart valve. However, there's important information your doctor needs to know before you undergo an MRI scan. Refer your doctor or the MRI lab staff to **edwards.com/mri-safety** for more detailed information

Questions and notes

Write down any additional questions to ask your doctor or instructions they give you.

Support and resources

Taking control of your health can help you get the care you need. Free resources are available below for you and your loved ones to better understand heart valve failure and the TAVR procedure.

American Heart Association

For information and resources on heart health, visit **heart.org/heartvalves**

Heart Valve Voice

Find in-depth education, resources, and patient stories focused on heart valve disease at **heartvalvevoice.com**

Support for women's heart health

Join the movement to improve the lives of women with or at risk for heart disease – and to promote equity in care. Visit **womenheart.org**

Caregiver resources

For caregiver support, visit the Family Caregiver Alliance at **caregiver.org**

Financial resources

If you need free professional assistance to help navigate insurance and reimbursement, **visit structuralheart.pafcareline.org** or call **1-800-532-5274**

Patient support line

Figuring out the next steps in treating heart valve failure may feel overwhelming. The Edwards Patient Team is here to support you. For more information, please call **1-888-713-1564**

Edwards TAVR Community

You will receive a transcatheter valve temporary ID card when you leave the hospital. A TAVR Valve Implant Card will be mailed to your home within 6 to 8 weeks of your procedure.

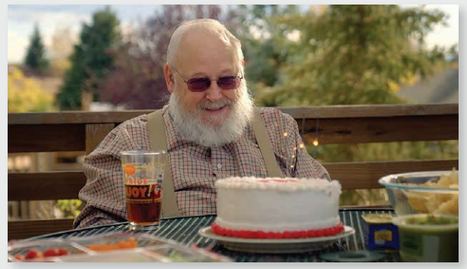
Please call 1-888-713-1564 if you need a replacement card. Keep this card with you at all times and show it to all your healthcare providers.

Here's how to join the Edwards TAVR Community

After you've received your ID card, you'll be invited to join the Edwards community. There, you'll find helpful information, updates by mail and email, and support during your first year after TAVR. It's up to you if you'd like to participate and connect with Edwards and the patient community during your journey to heart valve health.

Patient stories: Hear from people who decided to do something about their heart valve failure

Millions of Americans have been diagnosed with heart valve failure. Watch patients describe their experiences from diagnosis and treatment through recovery.



"Now, years later, I'm feeling great and I've been doing things actively ever since."

THOM | REAL TAVR PATIENT

Scan with camera

Watch Thom's story.
Scan this QR code or visit TreatHeartValveFailure.com

Get answers to frequently asked questions below

How many people have had the TAVR procedure?

Over 1 million patients worldwide and counting.

How long is the TAVR procedure?

The TAVR procedure usually takes about an hour. Most patients have a short recovery time and go home the next day.

Are there different types of transcatheter heart valves, and can I ask for a specific valve?

Transcatheter heart valves are made by different manufacturers. You can check which valves are available at your hospital. Although you can ask for a specific valve, your TAVR Doctor will recommend the best valve for you. Learn more about Edwards transcatheter heart valves at **TreatHeartValveFailure.com/Edwards**.

What is TAVI, and is it different from TAVR?

TAVI stands for transcatheter aortic valve implantation. The procedure is the same as TAVR. Your doctor may use the terms interchangeably when discussing treatment options.

Does my heart have to be stopped for TAVR?

No, unlike open heart surgery, TAVR does not require stopping the heart.

What does life after TAVR look like?

Research has shown patients' health improves within 30 days, including the ability to take care of themselves and participate in everyday activities.

How long does a transcatheter heart valve last?

TAVR by Edwards has better outcomes than open heart surgery in low-risk patients at 1 year – and was proven equally effective at 5 years.*

*The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

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What happens if my transcatheter heart valve fails?

TAVR by Edwards provides excellent durability and performance in all types of people.

Over 98% of TAVR recipients did not require valve reintervention after 10 years of receiving their valve.*

You should schedule a follow-up appointment with your cardiologist every year after TAVR to check that your heart valve is working properly. If your cardiologist discovers that your valve is no longer working the way it should, they will determine the next steps and decide if you need an evaluation for reintervention.

If you're like many patients with coronary artery disease, an Edwards TAVR valve means your physicians may have better access to your coronary arteries, should you ever need another procedure.

*Based on Medicare claims data which may underestimate the actual event rate.

Is TAVR by Edwards for everyone?

Edwards TAVR valves have been studied in patients of varying ages, sexes, and ethnicities across multiple clinical trials and have shown excellent survival out to 5 years.

Edwards valves are available in 4 sizes to fit patients with unique anatomy, including those with smaller or larger needs: 20, 23, 26, and 29 mm in diameter.

What are the risks of TAVR?

The most serious risks of TAVR include death, stroke, serious damage to the arteries, or serious bleeding.

Scan with camera

TAVR might not be for everyone. Only a TAVR doctor can determine if TAVR is right for you. For more information or to find a TAVR Hospital near you, scan this QR code or visit TreatHeartValveFailure.com

Learn more about the Edwards Lifesciences difference and your transcatheter heart valve

With more than 60 years of experience, Edwards Lifesciences has developed innovative support tools to help patients like you.

Call toll-free in the USA

For TAVR inquiries: 1-888-713-1564

Email

Patient_Support@edwards.com

Mail

Edwards Lifesciences
One Edwards Way
Irvine, California 92614

Online

www.TreatHeartValveFailure.com
www.Edwards.com

Please see accompanying Important Risk Information in pocket.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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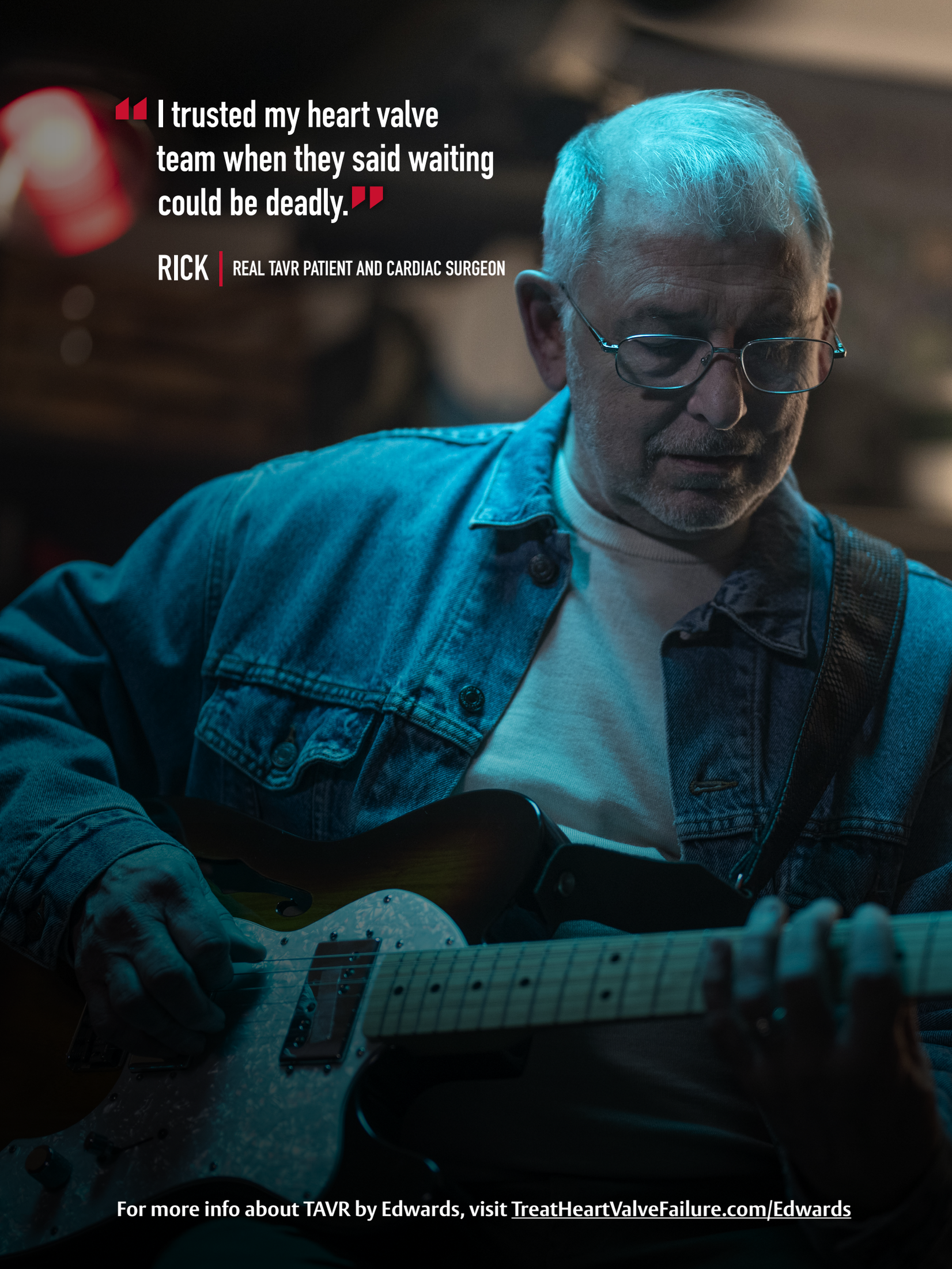
“I trusted my heart valve team when they said waiting could be deadly.”
RICK | REAL TAVR PATIENT AND CARDIAC SURGEON
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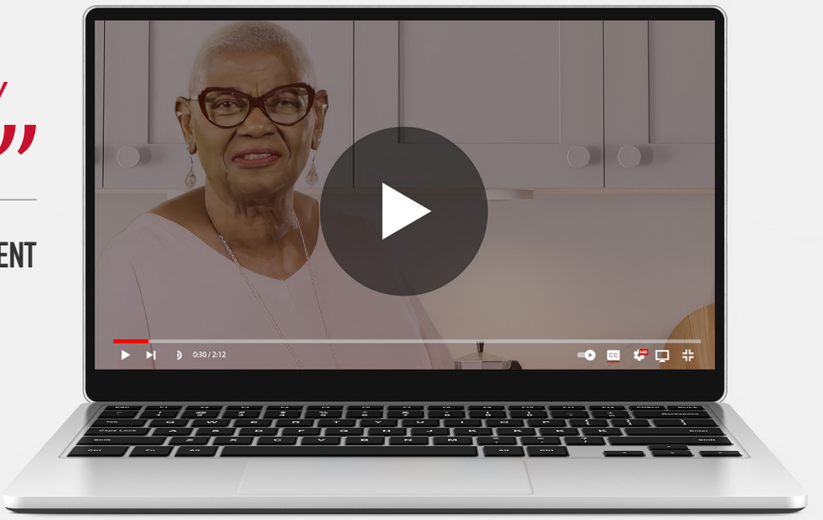

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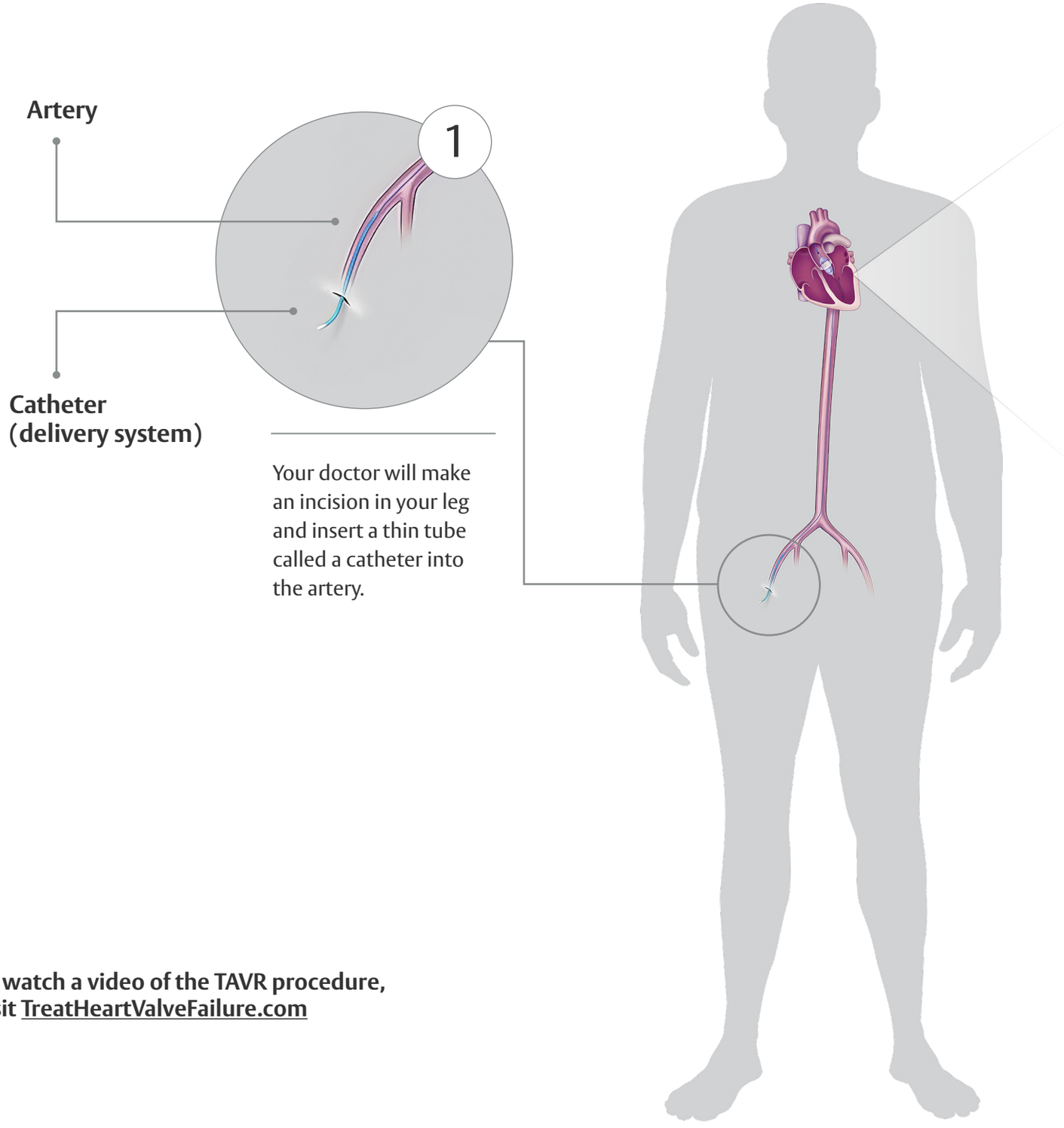

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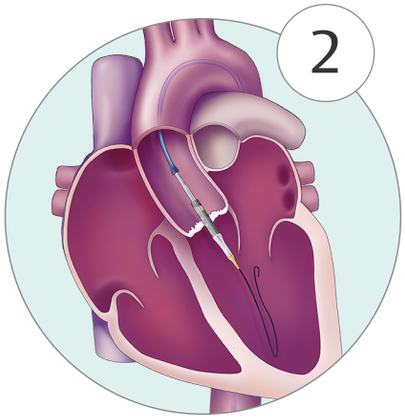

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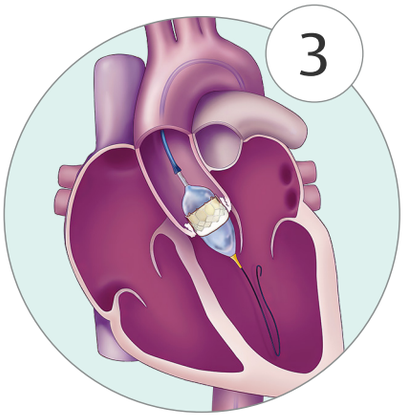

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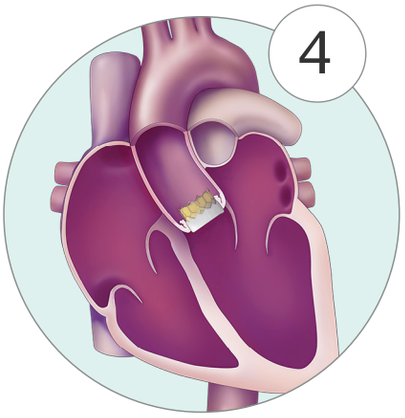

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1 hour

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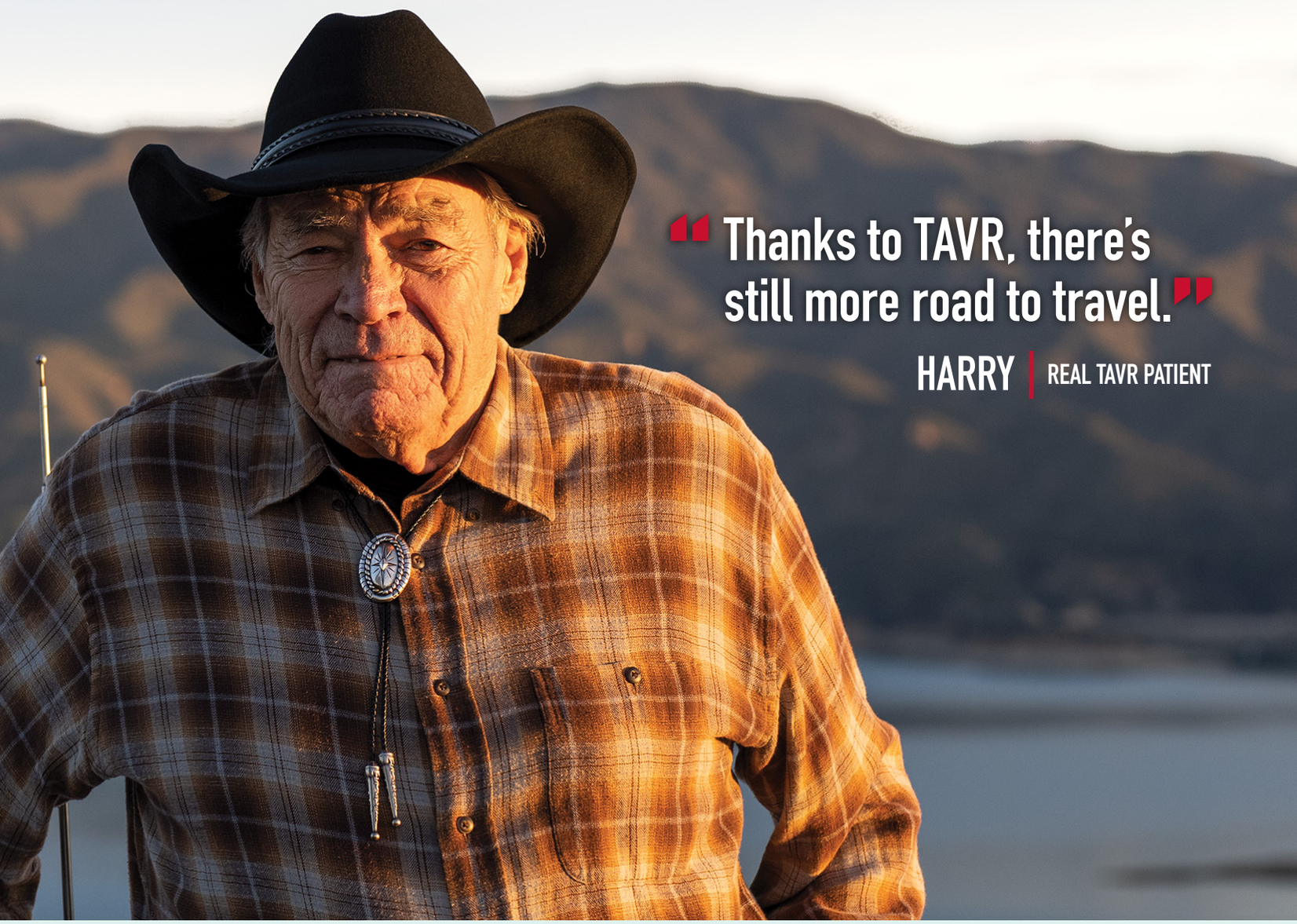

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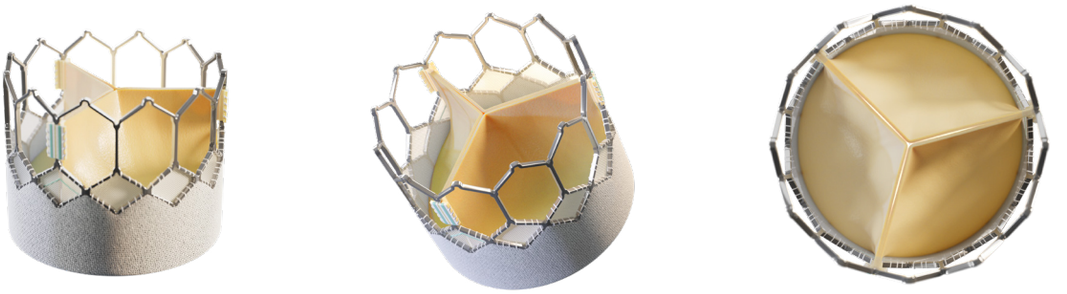

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Now is the time to talk to your doctor to see if an Edwards TAVR valve is right for you.

*RESILIA tissue has not been studied for long-term results in patients.

†RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model. Flameng W, et al. *J Thorac Cardiovasc Surg*. 2015;149(1):340-345.

To learn more about the benefits of Edwards TAVR valves, visit TreatHeartValveFailure.com/Edwards

Preparing for TAVR by Edwards

Make sure to get your TAVR prep information from your doctor or Valve Clinic Coordinator (VCC) and review it with your caregiver. Follow all of the directions you're given.

Here are a few things you will need to do leading up to your procedure:

Get a dental clearance to ensure any infections present in your mouth or teeth don't spread to your heart valve

Talk to your doctor about how much activity or exercise you should be doing (and let them know about any new or worsening symptoms)

Go over any medicine you are taking with your doctor. Consult with your doctor to determine which medications you should or should not take leading up to and on the day of your procedure

Talk to your doctor about which foods are recommended and when you should stop eating or drinking prior to your procedure

Make sure you have someone to drive you to and from the hospital the day of your procedure

Go over this information and any instructions you receive with your caregiver so you both know what to expect and can prepare

What to expect the day of your procedure

Most people who have TAVR go to the hospital the morning of the procedure. Some people may be asked to go to the hospital the night before. Your doctor or care team will let you know when to arrive.

1 hour	The TAVR procedure usually takes about an hour. Most patients have a short recovery time and go home the next day
	Your TAVR doctor will decide what type of anesthesia is best for you. You may be asleep or awake and medicated while your valve is replaced
	Your loved one(s) will be told how the procedure went and how you're doing
	You'll be able to have visitors after the anesthesia wears off
	Nurses will encourage you to start sitting up and moving around soon after the procedure
	You'll learn how to care for yourself once you're home, including caring for your incision, doing breathing exercises, managing pain, and taking recommended medication

Life after TAVR by Edwards

While you're still in the hospital, you'll want to make sure you know what to do once you're home. Here's a checklist of things the Heart Valve Team may cover with you in the hospital:

- **Pain control** – you may experience some pain or discomfort and receive pain medicine if needed
- **Daily activities** – be patient and follow the advice of your doctor. You may need help when you first go home. It's best to plan ahead so you have the help you need
- **Breathing** – you may be given breathing exercises to help keep your lungs clear
- **Incision care** – your incision dressing will need to be changed to prevent infection
- **Medication** – your doctor may prescribe medication, including blood thinners
- **Your new valve** – you may be given an echocardiogram to see images of your new valve before you leave the hospital

Here are some steps that you – and your caregiver – can take to help you recover

Some people may notice improvements in their energy level and quality of life right away. Others may find it takes a few days or weeks. Discuss your activity goals with your doctor.

As you become more active, remember your body may need time to adjust. Try to go easy on yourself and rest when needed.

- **Arrange to have help around the house** for the first few days after your procedure and possibly longer
- **Talk with your loved one or caregiver** about what you need and how they can best help you
- **Continue to care for your incision** as instructed in the hospital
- **Perform any breathing exercises** you learned at the hospital until your doctor says it's OK to stop
- **Keep your pain under control,** as directed by your doctor, to help you stay active while recovering
- **Take all medication as prescribed** and don't stop taking any without talking to your doctor
- **Attend all follow-up appointments** with your doctor

Follow-up appointments

It's very important to attend all of your follow-up appointments so your doctor can check your progress. Ask questions or share any concerns with your doctor.

Your follow-up visits may include:

- Blood tests to see how your medication is working
- Tests to check how well your heart and new valve are working

Your doctor will recommend a schedule that's best for you.

In the first 30 days after TAVR

- In the first 24 hours up to the first few days after release from the hospital, you may receive a follow-up phone call from your doctor to check in on your symptoms, medication, and well-being
- You may be asked to see your primary care provider around 5 to 7 days after release from the hospital

In the months after TAVR

- Your TAVR doctor will eventually transfer your care back to either your general cardiologist or primary doctor

Every year after TAVR

- You should schedule a follow-up appointment with your cardiologist to check your heart valve, which may include getting an echocardiogram

Be sure to **inform all healthcare professionals that you have a transcatheter replacement valve** and **share your TAVR Valve Implant Card** with them.

A few additional things to know

- Tell your dentist that you have had a heart valve replacement. You will likely need to take an antibiotic before undergoing any new procedure, including a cleaning, to reduce the risk of getting an infection in your new heart valve
- An MRI scan will not affect your transcatheter heart valve. However, there's important information your doctor needs to know before you undergo an MRI scan. Refer your doctor or the MRI lab staff to **edwards.com/mri-safety** for more detailed information

Support and resources

Taking control of your health can help you get the care you need. Free resources are available below for you and your loved ones to better understand heart valve failure and the TAVR procedure.

American Heart Association

For information and resources on heart health, visit **heart.org/heartvalves**

Heart Valve Voice

Find in-depth education, resources, and patient stories focused on heart valve disease at **heartvalvevoice.com**

Support for women's heart health

Join the movement to improve the lives of women with or at risk for heart disease – and to promote equity in care. Visit **womenheart.org**

Caregiver resources

For caregiver support, visit the Family Caregiver Alliance at **caregiver.org**

Financial resources

If you need free professional assistance to help navigate insurance and reimbursement, visit **structuralheart.pafcareline.org** or call **1-800-532-5274**

Patient support line

Figuring out the next steps in treating heart valve failure may feel overwhelming. The Edwards Patient Team is here to support you. For more information, please call **1-888-713-1564**

Edwards TAVR Community

You will receive a transcatheter valve temporary ID card when you leave the hospital. A TAVR Valve Implant Card will be mailed to your home within 6 to 8 weeks of your procedure.

Please call 1-888-713-1564 if you need a replacement card. Keep this card with you at all times and show it to all your healthcare providers.

Here's how to join the Edwards TAVR Community

After you've received your ID card, you'll be invited to join the Edwards community. There, you'll find helpful information, updates by mail and email, and support during your first year after TAVR. It’s up to you if you’d like to participate and connect with Edwards and the patient community during your journey to heart valve health.

Patient stories: Hear from people who decided to do something about their heart valve failure

Millions of Americans have been diagnosed with heart valve failure. Watch patients describe their experiences from diagnosis and treatment through recovery.

“Now, years later, I'm feeling great and I've been doing things actively ever since.”

THOM | REAL TAVR PATIENT

Watch Thom's story. Visit TreatHeartValveFailure.com

Get answers to frequently asked questions below

How many people have had the TAVR procedure?

Over 1 million patients worldwide and counting.

How long is the TAVR procedure?

The TAVR procedure usually takes about an hour. Most patients have a short recovery time and go home the next day.

Are there different types of transcatheter heart valves, and can I ask for a specific valve?

Transcatheter heart valves are made by different manufacturers. You can check which valves are available at your hospital. Although you can ask for a specific valve, your TAVR Doctor will recommend the best valve for you. Learn more about Edwards transcatheter heart valves at **TreatHeartValveFailure.com/Edwards**.

What is TAVI, and is it different from TAVR?

TAVI stands for transcatheter aortic valve implantation. The procedure is the same as TAVR. Your doctor may use the terms interchangeably when discussing treatment options.

Does my heart have to be stopped for TAVR?

No, unlike open heart surgery, TAVR does not require stopping the heart.

What does life after TAVR look like?

Research has shown patients' health improves within 30 days, including the ability to take care of themselves and participate in everyday activities.

How long does a transcatheter heart valve last?

TAVR by Edwards has better outcomes than open heart surgery in low-risk patients at 1 year – and was proven equally effective at 5 years.*

*The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

PARTNER 3 Trial 5-Year Results in low-risk patients – Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.1% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

What happens if my transcatheter heart valve fails?

TAVR by Edwards provides excellent durability and performance in all types of people.

Over 98% of TAVR recipients did not require valve reintervention after 10 years of receiving their valve.*

You should schedule a follow-up appointment with your cardiologist every year after TAVR to check that your heart valve is working properly. If your cardiologist discovers that your valve is no longer working the way it should, they will determine the next steps and decide if you need an evaluation for reintervention.

If you're like many patients with coronary artery disease, an Edwards TAVR valve means your physicians may have better access to your coronary arteries, should you ever need another procedure.

*Based on Medicare claims data which may underestimate the actual event rate.

Is TAVR by Edwards for everyone?

Edwards TAVR valves have been studied in patients of varying ages, sexes, and ethnicities across multiple clinical trials and have shown excellent survival out to 5 years.

Edwards valves are available in 4 sizes to fit patients with unique anatomy, including those with smaller or larger needs: 20, 23, 26, and 29 mm in diameter.

What are the risks of TAVR?

The most serious risks of TAVR include death, stroke, serious damage to the arteries, or serious bleeding.

TAVR might not be for everyone. Only a TAVR doctor can determine if TAVR is right for you. For more information or to find a TAVR Hospital near you, visit TreatHeartValveFailure.com

Learn more about the Edwards Lifesciences difference and your transcatheter heart valve

With more than 60 years of experience, Edwards Lifesciences has developed innovative support tools to help patients like you.

Call toll-free in the USA

For TAVR inquiries: 1-888-713-1564

Email

Patient_Support@edwards.com

Mail

Edwards Lifesciences
One Edwards Way
Irvine, California 92614

Online

www.TreatHeartValveFailure.com
www.Edwards.com

See Important Risk Information on the next page.

Important Risk Information

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Indications:
The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated to reduce the risks associated with progression from asymptomatic to symptomatic severe native calcific aortic stenosis in patients who are judged by a heart team to be appropriate for transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to a failing (stenosed, insufficient, or combined) surgical or transcatheter bioprosthetic aortic valve, or a native mitral valve with an annuloplasty ring who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to a failing (stenosed, insufficient, or combined) surgical bioprosthetic mitral valve who are judged by a heart team, including a cardiac surgeon, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 4% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use):
The Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System should not be used in patients who:
- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.
- Have a mitral ring that is damaged and can no longer support the valve.

Warnings:
- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to anesthesia, contrast media, cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- The Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Patient's creatinine level should be measured prior to the procedure.
- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).
- Transcatheter valve replacement is not recommended in previous mitral valve rings that are damaged or have become too rigid.

Precautions:
The long-term durability of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing.

Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. A patient's anatomical characteristics should be considered by their physicians when using the valve in this patient population. In addition, patient age should be considered as long-term durability of the valve has not been established. Data on TAVR in patients with asymptomatic severe aortic stenosis are based on study of predominantly low surgical risk patients. Limited clinical data to inform benefit-risk considerations are available for TAVR in patients with asymptomatic severe aortic stenosis who are deemed to be at intermediate or greater surgical risk. Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics. Patients should be treated post-procedure for heart infection as a precaution.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:
- An aortic heart valve that is not calcified, contains only one leaflet, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Who have a prosthetic ring in the tricuspid position.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal, or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for the delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- Whose previously implanted artificial valve or ring is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching.

Potential risks associated with the procedure include:
- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, sudden loss of heart function, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, dizziness, buildup of fluid in or around the lungs, weakness, or inability to exercise.
- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin, serious damage to the arteries, severe bleeding in the heart or in the body that could require a transfusion or surgery.
- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection, or bleeding at incision sites, or swelling.

Additional potential risks specifically associated with the use of the heart valves include:
- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery or emergency heart surgery and possible removal of the Edwards SAPIEN 3 Ultra, SAPIEN 3 Ultra RESILIA and SAPIEN 3 valves, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), valve issues not related to structure (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage) or mechanical failure of the delivery system and/or accessories.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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