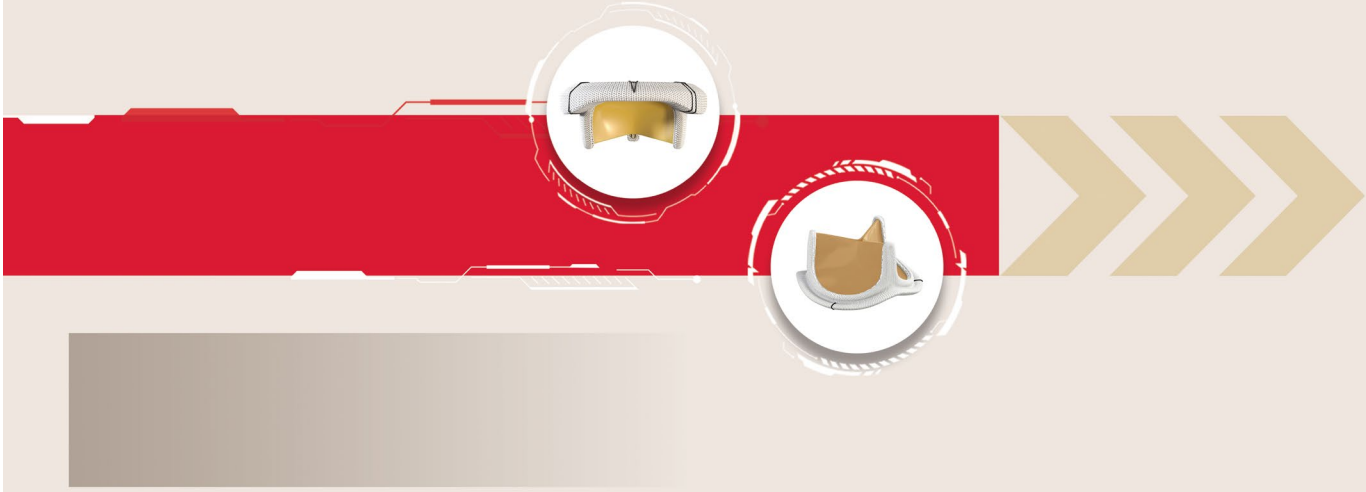
The RESILIA Tissue Insider

The INSPIRIS RESILIA valve:

The world's most implanted surgical aortic tissue valve, leading the way in innovation



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Edwards

In this issue

We hope you enjoy this issue of *The RESILIA Tissue Insider*.

Learn more about our growing RESILIA tissue valve portfolio:
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Introduction

Welcome to this special edition of *The RESILIA Tissue Insider*, specially compiled for the 38th European Association for Cardio-Thoracic Surgery (EACTS) Annual Meeting, taking place on 9–12 October 2024 in Lisbon, Portugal. The 2024 EACTS meeting is focused on 'Navigating New Horizons' – with themes of innovation, discovery and education.

Since 2017, RESILIA tissue has helped treat patients with innovative tissue technology; the INSPIRIS RESILIA valve is now the world's most implanted surgical aortic tissue valve.

In this issue we bring you some key insights and experiences from cardiac surgeons who have been using the INSPIRIS RESILIA valve and/or the MITRIS RESILIA valve in their practice. On page 2, Professor Olaf Wendler, the first surgeon who implanted the INSPIRIS RESILIA valve, describes how the story began and his ongoing commitment to the valve. On page 3, Dr Rafael Sádaba discusses the data-driven evidence behind the RESILIA tissue innovation and Dr Reuben Jeganathan recounts his experience with the MITRIS RESILIA valve on page 4. Continuing from this, on pages 5–6, Professor Kazimierz Widenka and Professor Diane Reser consider how Edwards' commitment to innovation with RESILIA tissue is driving progress in cardiac surgery.

Next, Professors Hendrik Treede and Augusto D'Onofrio examine how the features of the INSPIRIS RESILIA valve allow for lifetime management, while potentially reducing the need for future surgical reintervention, on pages 7–8. Finally, on pages 9–10, we hear from Mr Giovanni Mariscalco and Dr Sergio Cánovas on how RESILIA tissue has benefited their patients.

Read on to learn the experiences, patient feedback and strategies for lifetime management from the experts!

INSPIRIS RESILIA is the world's most implanted surgical tissue valve, with more than 300,000 patients treated

From the beginning: The first implantation of the INSPIRIS RESILIA valve

Professor Olaf Wendler is a consultant cardiothoracic surgeon at King's College Hospital, London, UK and is Chair of the Heart, Vascular and Thoracic Institute at Cleveland Clinic London.

He has extensive experience in complex heart procedures and innovative heart valve disease treatments, and performed the very first implantation of the INSPIRIS RESILIA valve in 2017.

2017: The first patient with an INSPIRIS RESILIA valve

In 2017, I saw a young, recently married woman who wanted to have a baby. However, she had unicuspid aortic valve disease, with a very heavily calcified aortic valve. I was aware of RESILIA tissue and thought that an INSPIRIS RESILIA valve would be ideal for her, avoiding a Ross procedure. She had the surgery, and she now has three children! Her mean valve gradients remain low (12 mmHg) and she is symptom free.

I have gone onto treat other inspiring patients with an INSPIRIS RESILIA valve: women who thought their valve disease was a barrier to their dream family have now gone on to have babies. Also, many of my patients love sport and have gone onto participate in triathlons and marathons after receiving the INSPIRIS RESILIA valve.

2017–2024: Adoption of the INSPIRIS RESILIA valve

Since 2017, I have carried on implanting the INSPIRIS RESILIA valve, performing 60–70 bioprosthetic aortic valve replacements annually, almost always through minimally invasive techniques.

When deciding which prosthesis to use, patients themselves have a great deal of influence. They are well-informed and want to avoid anticoagulation, especially now that better treatment options for potential bioprosthetic valve failure exist.

Patients are also often well informed about alternative surgical procedures, such as the Ross procedure. Nevertheless, the fact that this involves surgery on two heart valves, and that aortic root dilatation – which many of these younger patients suffer from – is a negative predictor for long-term outcomes makes them opt for minimally-invasive biological aortic valve replacements with the INSPIRIS RESILIA valve.

Furthermore, cardiologists are aware of the rise of transcatheter aortic valve implantation (TAVI) for treating bioprosthetic degeneration and so discuss bioprosthetic valves with younger patients. The demonstrated long-term history of the Carpentier-Edwards PERIMOUNT valve, alongside the potential calcification delay of RESILIA tissue appeals to patients. This enables us, as a patient–surgeon team, to identify the best prosthetic valve for them.

Looking to the future

The community is very much looking forward to the long-term outcomes of the INSPIRIS RESILIA valve. My advice to surgeons who may be future users of the valve is to implant big enough valves to enable good long-term outcomes and the potential of valve-in-valve implantation (ViV). Also, be careful to avoid patient–prosthesis mismatch and complications such as paravalvular leak and pacemaker implantation. The low complication rate is a strength of surgical intervention compared with TAVI , and surgeons are the guardians of these qualities.

INSPIRIS RESILIA valve: The importance of strong literature evidence and data transparency

Dr Rafael Sádaba is Chief of Cardiac Surgery at Navarra University Hospital, Spain, and Associate Professor of Surgery at the Public University of Navarra in Pamplona, Spain. His research interests focus on the surgical pathology of heart valves.

Edwards Lifesciences has built my trust in its bioprostheses by supporting them with strong, long-term evidence from the literature and registries. Importantly, Edwards makes this evidence available quickly to physicians, building a good relationship of trust.

INSPIRIS RESILIA valve: A bioprosthetic valve innovation

The RESILIA tissue portfolio was an innovation in the field of bioprosthesis development. I began using the INSPIRIS RESILIA valve for three main reasons:

1. The **preclinical studies** allowed me to see the potential of this valve for younger patients
2. The INSPIRIS RESILIA valve is **similar in design to the Carpentier-Edwards PERIMOUNT Magna Ease valve**, with which we have vast experience, allowing for easy adoption
3. The possibility of **ViV procedures** in the future gave me reassurance that a second procedure would be easier than with a conventional bioprosthesis

The INSPIRIS RESILIA valve has allowed us to offer a bioprosthetic valve to patients on the younger side of the recommended age range (i.e. in their early 60s). This is due to the potential resistance to structural valve deterioration, and potential for ViV procedures of the INSPIRIS RESILIA valve.

INSPIRIS RESILIA valve and the BioBentall procedure

The INSPIRIS RESILIA valve is my valve of choice for a BioBentall procedure, where both the aortic valve and root require replacement. During this procedure, the bioprosthetic valve is inserted into an aortic graft; therefore, if the valve fails, it is complex to resolve. As such, I use the INSPIRIS RESILIA valve because of the potential for reduced structural valve deterioration and increased durability over conventional valves.

Advice to other cardiac surgeons

My advice is to read the literature and data on outcomes and durability of the INSPIRIS RESILIA valve – I think they are convincing. Also, get hold of an INSPIRIS RESILA valve and see how it is similar to traditional valves in terms of ease of implantation – you can make your own conclusions from there.

'Innovation is fundamental to ensure that we give our patients the best possible treatment'

RESILIA tissue: An innovation in both aortic and mitral positions

Dr Reuben Jeganathan is a consultant cardiac surgeon and Clinical Director for Specialist Surgery at the Royal Victoria Hospital, Belfast, UK. His areas of interest are mitral reconstructive surgery, transcatheter mitral valve implantation in mitral annular calcification and aortic valve surgery, including major aortic surgery and transcatheter aortic valve implantation.

RESILIA tissue: Giving patients a choice

The advent of TAVI has catapulted surgical valve innovation forward – as transcatheter valves advance, surgical valves are also progressing in order to keep pace with this new technology.

Edwards dedicates itself to innovation; their products, including surgical valves, are constantly evolving. Now, we have RESILIA tissue to address the biggest challenge in valve technology: durability. As well as new tissue technology, which we hope increases valve durability, the INSPIRIS RESILIA valve also brings the possibility for ViV procedures.

Almost all of my patients over 60 years of age will receive a bioprosthetic valve. The challenge is with patients between 50 and 60 years of age or younger who may want to avoid anticoagulation. After an informed discussion, these patients are pleased to know there is an option available with potential durability. It is important to ensure appropriate valve sizing, especially in younger patients, to avoid patient–prosthesis mismatch and to facilitate potential future ViV procedures if appropriate.

'With RESILIA tissue, younger patients are pleased to know that there is an option for a bioprosthetic valve with potential durability'

MITRIS RESILIA: Innovation in the mitral position

In Europe, most patients over 60 years of age needing an aortic valve replacement will get a bioprosthetic valve. However, in the mitral position, surgeons are still using mechanical valves in patients beyond the age of 70 years. This is mainly because tissue valves tend to have a high-profile design and in the complex anatomical space there is a risk of left ventricular outfow tract (LVOT) obstruction or strut perforation. The MITRIS RESILIA valve is a low-profile valve and has markers for implantation, which aids orientation, and therefore allows the surgeon to position the struts to avoid LVOT obstruction and concerns of strut protrusion. This is in addition to the potential durability benefits of RESILIA tissue.

If the MITRIS RESILIA valve does demonstrate increased durability, a mitral valve replacement may have advantages over risking a very complex repair with a subsequent mitral regurgitation reoccurence in high-risk patients. Also, a tissue valve in the mitral position might facilitate potential future ViV procedures, provided a reasonable size valve was implanted in the index procedure, as demonstrated in registry data. Recently, a patient was admitted to my practice in heart failure with significant comorbidities. I opted to implant a MITRIS RESILIA valve rather than expose the patient to a complex repair, due to the underlying mitral pathology and, importantly, taking into account the patient's longevity.

RESILIA tissue: At the cutting edge of innovation

Professor Kazimierz Widenka is Head of the Cardiac Surgery Department at the University of Rzeszów and Provincial Hospital No. 2. Saint Queen Jadwiga, Poland. He is interested in minimally invasive techniques, for both mitral and aortic valve replacement.

Over the years, I have witnessed mitral valve repair and minimally invasive techniques revolutionise cardiac surgery. They have made the field significantly more engaging for me as a surgeon and incredibly beneficial for our patients.

The INSPIRIS RESILIA valve: An advancement in cardiac surgery

The INSPIRIS RESILIA valve is part of the continuous development in cardiac surgery, offering innovative tissue technology with promising results in preclinical studies. This continuous development in tissue processing is poised to be advantageous in patient care.

'The INSPIRIS RESILIA valve represents evolution, not revolution, enhancing existing techniques for improved outcomes'

Nowadays, more and more patients prefer to have a bioprosthetic valve fitted as it benefits their lifestyle. Patients who are 50–55 years old want to ride a bicycle or go hiking and that is very important to them. While they need to be informed of the potential for bioprosthetic valve deterioration, the potential for ViV procedures alongside the innovative tissue processing of RESILIA tissue, means that with experience, we hopefully will be able to recommend bioprosthetic valves in younger patients.

In 2024, we were the first centre in Poland to implant a MITRIS RESILIA valve. I have also performed over 100 procedures using the INSPIRIS RESILIA valve with remarkable success. **Not a single valve has needed to be explanted, underscoring the valve's exceptional performance and design.** The combination of advanced tissue processing and robust mechanical design, like the struts and annulus, has resulted in high satisfaction among me and my team.

Trust in Edwards Lifesciences

Having started using Edwards products shortly after their European launch, I found the transition from PERIMOUNT valves to the newer RESILIA tissue products to be seamless. My experience with these products has fostered a strong trust in Edwards valves, primarily due to the company's commitment to research and development.

Professor Diana Reser is a consultant cardiac surgeon at the Heart Clinic, Hirslanden Hospital Zurich, Switzerland. Professor Reser is a board member of 'Medical Women Switzerland' and 'Women in Cardiothoracic Surgery' by EACTS and in 2024, she became the first female cardiac surgeon to receive the titular professorship at a Swiss University.

A history of performance

Edwards has a long and successful history of valve development. I work in a Heart Team centre of excellence, and I have trusted the PERIMOUNT valve for decades. Therefore, it was logical to switch to the INSPIRIS RESILIA valve.

INSPIRIS RESILIA valve: An innovation in cardiac surgery

I now use the INSPIRIS RESILIA valve in all my aortic valve replacements, because I believe it is the most innovative valve on the market. The age limit for a bioprosthesis has decreased in the past years of our clinical practice, and I hope that the INSPIRIS RESILIA valve will help to ensure minimal long-term valve deterioration and avoid future redo surgeries in these younger patients.

I am currently very positive about the durability of INSPIRIS RESILIA valve, and if deterioration does occur in the absence of endocarditis, TAVI should be the first line therapy rather than redo SAVR.

'It is easy to trust Edwards because of the company's experience and achievements since the beginning of heart surgery in the 1950s'

Looking to the future: Lifetime management and valve-in-valve technology

Professor Hendrik Treede is the Chief of the Department of Cardiac and Vascular Surgery at University Hospital Mainz, Germany. Since 2021, he has performed more than 500 surgeries using INSPIRIS RESILIA aortic valves.

I have worked with Edwards since the very beginning of my career. Edwards has always been a key player with a great product portfolio in heart valve surgery, for both aortic and mitral valve technologies.

'The choice of valve is driven by the patient and the future that we foresee for them'

Selecting a prosthetic valve

The emergence of TAVI has changed the landscape of aortic valve surgery, with most older patients now opting for TAVI. Now we focus on lifetime management and providing our patients with the best long-term results by prioritising tissue quality and durability, haemodynamics and future ViV procedures when selecting the best valve for our patients. The INSPIRIS RESILIA valve combines these factors in a very good way.

Lifetime management includes prioritising:

- Durability
- Haemodynamics
- ViV procedures

Most patients I see do not want to take anticoagulants for the rest of their lives, and they love the option of a durable biological valve that is a good target for potential future ViV procedures to avoid reoperation.

Traditionally, if a patient with aortic regurgitation, who is usually younger than an aortic stenosis patient, needed a valve replacement, we implanted mechanical valves – however now that the INSPIRIS RESILIA valve is available, it allows for us and our patients to choose a biological valve.

Why should cardiac surgeons choose an INSPIRIS RESILIA valve?

We must offer our patients the best future perspectives possible. If we do implant valves surgically, they must be very good valves. For me, the INSPIRIS RESILIA valve is one of these – it has a **proper stent design and sewing ring, and is very easy to implant.**

The valve hasn't been out long enough to know the long-term results, but if these are good as well, you would be doing your patients a big favour by starting to use INSPIRIS RESILIA valves.

'You don't need to change your practice in any way to use the INSPIRIS RESILIA valve, you just change the valve and then you will see that things are better with the INSPIRIS RESILIA valve'

Professor Augusto D'Onofrio is an Associate Professor and the Interim Chief of Cardiac Surgery at Tor Vergata, University of Rome, Italy. His primary interests include the treatment of the aortic valve, root and arch, and the ascending aorta. Additionally, he is a strong advocate for the concept of micro-invasive cardiac surgery.

'It's all about a lifetime management of aortic valve disease, shared between the surgeon and patient'

Choosing to start using a new device is always challenging, however the animal and *in vitro* data for the new RESILIA tissue, alongside the INSPIRIS valve design, convinced me that this valve has the potential to deliver consistent performance.

This valve is very similar to the well-established Magna Ease valve, but includes VFit technology, enabling stent enlargement ViV procedures, potentially avoiding patient–prosthesis mismatch. **The ability to perform micro-invasive ViV means that with one SAVR and one ViV, we can cover up to 20–25 years of a patient's lifespan.** In younger patients, one SAVR, a redo SAVR and then ViV means that we can cover 35 years without oral anticoagulation.

At the 2022 EACTS annual meeting, my previous group in Padua demonstrated that the haemodynamic performance of the INSPRIS RESILIA valve showed similar excellent performance to the rapid-deployment EDWARDS INTUITY valve, with single-digit mean gradients for most sizes.[1]

VFit technology is designed to allow a controlled and predictable expansion during valve-in-valve deployment

'I'd recommend INSPIRIS RESILIA valve for relatively young patients with a long life expectancy'

Implanting the INSPIRIS RESILIA valve: A spotlight on patients

Mr Giovanni Mariscalco is Head of Service for cardiac surgery and Lead Clinician for complex aortic surgery at Glenfield Hospital, Leicester, UK. His practice focuses on surgery of the aortic root and thoracic aorta. Mr Mariscalco's areas of expertise include bypass surgery, complex aortic valve repairs and replacement, as well as mitral valve repair and replacement.

*'Edwards has a **strong worldwide reputation** built over 20–30 years'*

I have been using Edwards Lifesciences' valves since my residency in Italy in 2006. I started as an academic, analysing the long-term results of various valves; the strong reputation that Edwards has gained from these studies makes choosing its products easy because of their consistent outcomes.

I was one of the first in the UK to the implant the INSPIRIS RESILIA valve, and I now use it for all my patients who choose a tissue valve. The valve has excellent outcomes, ViV technology and comes ready to use thanks to the dry packaging – making it an easy choice for a surgeon. **I have implanted over 200 INSPIRIS RESILIA valves, and I haven't had any unsatisfied patients** – they can get back to active life quickly, playing golf, cycling and running.

Valve selection: A patient-centred approach

I use two main criteria when choosing a valve: the guidelines and patient choice. Patient choice is the priority. Once the patient is well informed, they make the final choice; most prefer a bioprosthetic valve, such as the INSPIRIS RESILIA valve, because of the proven results and lack of anticoagulation treatment. The potential for increased durability and VFit technology with the INSPIRIS RESILIA valve also have an impact.

Patient story

I implanted the INSPIRIS RESILIA valve in a young woman, around 32 years old. She specifically requested the INSPIRIS RESILIA valve as she was participating in the qualification stages of the Olympic Games as a **professional dressage rider.** She was keen to have a valve with promising durability. The patient was very happy and went straight back to practising for the Games.

'I have implanted over 200 INSPIRIS RESILIA valves, and I haven't had any unsatisfied patients'

Dr Sergio Cánovas is the head of the Cardiac Surgery Service at the Virgin of Arrixaca University Hospital, Murcia, Spain. He is also Associate Professor of Surgery at the Faculty of Medicine of Murcia and the current Vice President of the Spanish Society of Cardiovascular and Endovascular Surgery. His interests include minimally invasive cardiac surgery.

'I was asking for the INSPIRIS RESILIA valve before it was even available'

I've been partnering with Edwards Lifesciences for about 25 years. The experience has been great: the products are excellent, and they continue to evolve.

When evaluating the best treatment for my patients, two valve characteristics are key:

1. **Durability**
2. **Haemodynamic results**

If a patient asked me what valve I would choose for myself at this moment of my life, I would say the INSPIRIS RESILIA valve. It has promising long-term results and good haemodynamics. Also, the VFit technology, which enables potential ViV procedures in the future, is an important feature to me.

'The INSPIRIS RESILIA valve is one of the best on the market, from a trusted company with good long-term results'*

Patient stories

Long-term durability

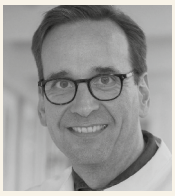
I knew that RESILIA tissue was innovative so **I was asking for the product before it was even on the market.** Specifically, I had a very young female patient who was hoping to have children in the future; she didn't like the idea of having a mechanical prosthesis. **We were both waiting especially for the INSPIRIS RESILIA valve.**

If Edwards says that the INSPIRIS RESILIA valve is going to work, **I truly trust them.** This young woman is doing fine now – she goes to the gym, and she's very happy she received an INSPIRIS RESILIA valve because her life has returned to normal.

Minimally invasive surgery

Another of my patients required a redo operation, which I carried out via minimally invasive surgery using the INSPIRIS RESILIA valve. I felt comfortable with this procedure, because **the valve is very similar in design to the Magna Ease valve and just as easy to implant** through a small incision. So, if you are used to doing minimally invasive surgery, I recommend trying it with the **INSPIRIS RESILIA valve.**

*Expert opinion.



A patient story from Professor Hendrik Treede

A 75-year gentleman was adamant he wanted a TAVI procedure to replace his aortic valve. However, he had a bicuspid valve with a calcified raphe and therefore was at high risk of procedural problems with TAVI. We discussed how I would operate via minimally invasive access, with a great tissue valve that potentially could outlive TAVI valves from today.*

We also discussed the future possibility of a ViV operation using VFit technology if required.

This convinced the patient to agree to surgery and he received a large INSPIRIS RESILIA valve via transaxillary access. He went home after a week and when I saw him again 3 months later, he was playing tennis and golf! He was so happy that he forgot about his previous misgivings about surgery – I think he was very happy with his decision.

*Expert opinion.

References:

1. D'Onofrio A, Cibin G, Lorenzoni G *et al*. Multicentre, large scale, propensity-weighted comparison of three aortic bioprostheses: Conventional stented, new-generation stented and rapid deployment. 36th Annual Meeting of the European Association for Cardio Thoracic Surgery, 5–8 October 2022, Milan, Italy.

Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

Refer to device 'Instructions for Use' for important warnings related to VFit technology. These features have not been evaluated in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures. VFit technology is available on sizes 19–25 mm.

Use of the EDWARDS INTUITY Elite valve system may be associated with new or worsened conduction disturbances, which may require a permanent cardiac pacemaker implant (PPI). The rate of PPI for the EDWARDS INTUITY Elite valve is within the range reported in the literature for various rapid deployment valves, but higher than that reported for surgical aortic valves. Physicians should assess the benefits and risks of the EDWARDS INTUITY Elite valve prior to implantation. See instructions for use for additional information.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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