



# Medical Device Alert

MDA/2020/019

Issued: 06 July 2020 at 10:00

Abbott Trifecta / Trifecta GT bioprosthetic aortic heart valves: cases of structural valve deterioration (SVD).

## Summary

Manufactured by Abbott – cases of valvular insufficiency and early revision.

## Action

- Read Abbott's Technical Bulletin, dated 13 January 2020, on the Trifecta/Trifecta GT bioprosthetic surgical aortic heart valve (Appendix A).
- Note precautions regarding proper valve sizing and handling in accordance with the instructions for use (IFU):
  - implantation of an inappropriately large bioprosthesis may result in stent deformation, valvular incompetence, and/or damage to the surrounding tissue
  - do not oversize the valve
  - do not bend the titanium valve stent. The titanium valve stent is not designed as a flexible stent.
- Identify those patients implanted with a 1<sup>st</sup> generation Trifecta valve and consider implementing enhanced follow-up.

**Due to delays caused by the recent COVID-19 healthcare crisis, we are aware that follow-up and assessments may not take place at normal frequency or in the usual manner. Follow-up recommendations should be risk assessed and completed as soon as possible.**

- Report suspected or actual adverse events involving all heart valves through your local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#). You should also report directly to manufacturers if your local or national systems do not.

### Action by

Cardiothoracic surgeons / cardiologists

### Deadlines for actions

Actions underway: 03 August 2020

Actions complete: 28 September 2020

**Medical Device Safety Officers** (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

## Device details

Abbott Tripecta Valve:

Models TF-19A, TF-21A, TF-23A, TF-25A, TF-27A, TF-29A

Abbott Tripecta Valve with Glide Technology (GT):

Models TFGT-19A, TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, TFGT-29A

- 1<sup>st</sup> generation Tripecta aortic surgical replacement valve, originally manufactured by St. Jude Medical, (now Abbott <sup>+</sup>), was first CE marked (market approval) in March 2010
- An 'improved' Tripecta valve became available from August 2015
- The Tripecta GT valve was CE marked in February 2016

Model number	Description	GTIN
TF-19A	TRIFECTA VALVE, 19MM	05414734052016
TF-21A	TRIFECTA VALVE, 21MM	05414734052023
TF-23A	TRIFECTA VALVE, 23MM	05414734052030
TF-25A	TRIFECTA VALVE, 25MM	05414734052047
TF-27A	TRIFECTA VALVE, 27MM	05414734052054
TF-29A	TRIFECTA VALVE, 29MM	05414734052061
TFGT-19A	19mm Tripecta GT Final Package - WR	05415067018205
TFGT-21A	21mm Tripecta GT Final Package - WR	05415067018212
TFGT-23A	23mm Tripecta GT Final Package - WR	05415067018229
TFGT-25A	25mm Tripecta GT Final Package - WR	05415067018236
TFGT-27A	27mm Tripecta GT Final Package - WR	05415067018243
TFGT-29A	29mm Tripecta GT Final Package - WR	05415067018250

<sup>+</sup>Abbott purchased St. Jude Medical in January 2017.

## Problem / background

Since 2010, the MHRA has received 65 UK adverse incident reports relating to 1<sup>st</sup> generation Tripecta and 'improved' Tripecta valves; 5 relate to the Tripecta GT valve.

Most of these reports (57) relate to revision (explant or valve-in-valve repair) due to some form of structural valve deterioration (SVD). The most common reported problems were leaflet damage and/or valvular insufficiency along with a range of other associated concerns. Time to failure, where known, ranged from perioperative to 8 years, with approximately half occurring between 2 to 3 years post implant. Data from our reports does not appear to show any increased tendency for early degeneration associated with valve size **See Appendix B for more information on these reports.**

The MHRA has been monitoring the frequency and nature of these reports over time and working with the manufacturer to understand the factors and mechanism of these potential complications.

Data accumulated by Abbott through their Tripecta long-term (10 year) follow-up and durability studies conclude acceptable clinical outcomes. However, the manufacturer acknowledges that the design of the 1<sup>st</sup> generation Tripecta valve may increase the likelihood of early degeneration. Specifically, the SVD seen may be a result of having a valve design with externally mounted leaflets, in combination with a stent that may be deformed during implant. Improvements to the valve leaflets and reinforcement of the stent which were implemented in later designs, are expected to reduce this risk (**see Appendix B**).

Abbott has cited important factors that may influence the risk of SVD in these valves, including implant technique (in their technical bulletin) together with other precautions listed in the associated IFU.

As well as creating abnormal stress and strain to the valve, oversizing the Trifecta/Trifecta GT valve could also result in direct contact between the stent post and the aortic wall, which may result in decreased valve durability due to abrasion or fusion of the posts with the aortic wall.

Recently published independent case report studies and articles (though not RCTs - see Appendix B for more information), have also helped to draw attention to this issue. One new significant paper based on data from the Finnish National Database (FinnValve registry), reports a SVD rate disparity between Trifecta and a comparator valve. Abbott confirm that all 13 Trifecta revision events reported in this paper, relate to the 1<sup>st</sup> generation Trifecta valve.

It is likely that most cases of early valve failure such as those outlined above, will be detected either during routine patient surveillance or hospital admission. However, MHRA is recommending that patients who received the 1<sup>st</sup> generation Trifecta valves are identified and considered for more frequent (enhanced) follow-up\*. This advice is due to the potential increased risk of valve deformation during implant, as well as accumulating signals from published case report studies and articles. The form and extent of this follow-up (above the standard annual) should be determined locally on a case-by-case basis.

2017 was the last year that the 1<sup>st</sup> generation Trifecta was sold in the U.K. Their manufacturing dates range from 09 December 2014 to 15 June 2015, with a shelf life of 4 years. Hence the last valves would have expired in June 2019

The MHRA encourages cardiothoracic surgeons and cardiologists to continue to report all adverse incident reports, including early events of SVD / NSVD (non-structural valve deterioration), to both the manufacturer and the MHRA.

**\* Due to delays caused by the recent COVID-19 healthcare crisis, we are aware that follow-up and assessments may not take place at normal frequency or in the usual manner. Follow-up recommendations should be risk assessed and completed as soon as possible.**

## Manufacturer contacts

Name: Luke Gilbertson – Quality Assurance and Regulatory Compliance Specialist (UK & Ireland)  
Tel: 01213060482  
Email: [michael.gilbertson@abbott.com](mailto:michael.gilbertson@abbott.com)

## Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

### Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors

- Coronary care departments
- Coronary care nurses
- Medical directors

### General Practice

For onward distribution to all relevant staff including GPs, Practice Managers and Practice Nurses.

**Note:** We are sending this alert to GPs for information only, in case patients ask them about the contents of this notice.

GPs do not need to take any action.

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: [safetyalerts@mhra.gov.uk](mailto:safetyalerts@mhra.gov.uk) and requesting this facility.

## Enquiries

### England

Send enquiries about this notice to MHRA, quoting reference number MDA/2020/019 or 2019/003/019/468/002

#### Technical aspects

Alexander McLaren, MHRA

Tel: 020 3080 6000

Email: [DSS-TM@mhra.gov.uk](mailto:DSS-TM@mhra.gov.uk)

#### Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

To report an adverse incident involving a medical device in England use the [Yellow Card reporting page](#)

### Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto:niaic@health-ni.gov.uk)

To report an adverse incident involving a medical device in Northern Ireland use the [forms on the website](#).

Alerts in Northern Ireland are distributed via the [NICAS system](#).

### Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

To report an adverse incident involving a medical device in Scotland, [email IRIC](#) to request a webform account.

For more information, or if you can't access the webform, visit the website: [how to report an adverse incident](#)

### **Wales**

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: [Haz-Aic@gov.wales](mailto:Haz-Aic@gov.wales)

To report an adverse incident involving a medical device in Wales, use the [Yellow Card reporting page](#) and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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Addressees may take copies for distribution within their own organisations

## APPENDIX A



## Technical Bulletin

Trifecta Valve (Models TF-19A, TF-21A, TF23A, TF25A, TF-27A, and TF-29A) and  
 Trifecta Valve with Glide Technology (Models TFGT-19A, TFGT-21A, TFGT-23A, TFGT-25A, TFGT-27A, and TFGT-29A)

13 January 2020

Dear Clinician,

This Technical Bulletin is intended to summarize the key design changes made to the Trifecta valve from the first-generation Trifecta valve to the second-generation valve reflecting Abbott's commitment to the quality and continuous improvement of our medical devices. In addition, this Technical Bulletin provides a summary of the clinical outcomes achieved at 10 years post-implant for the first-generation Trifecta valve.

The first-generation Trifecta valve was introduced into clinical use in 2007, designed for supra-annular implantation and excellent hemodynamic performance<sup>1</sup>. To ease the implant procedure and provide added handling protection to the stent and leaflets, a second-generation Trifecta valve with Glide Technology (Trifecta GT) was introduced in 2016<sup>2</sup>.

The Trifecta GT valve has the following enhancements<sup>2, 3</sup>.

- 1) A streamlined holder with legs positioned in front of the leaflets for added protection during valve insertion and knot tying;
- 2) Internal backstops within the holder to protect the stent posts from deforming during valve insertion;
- 3) A softer sewing cuff that conforms more easily to the annulus and which minimizes suture drag;
- 4) An additional titanium band that protects the stent base geometry and provides enhanced fluoroscopic visibility;
- 5) Optimized leaflet suturing process along the stent post to reduce leaflet stress;
- 6) Increased leaflet tissue tensile strength achieved by using a collagen fiber alignment technology, which ensures circumferential fiber alignment to resist fatigue related leaflet tissue degradation

At the same time the Trifecta GT valve was being developed, an improved version of the first-generation Trifecta valve was produced which included the same manufacturing processes utilized on Trifecta GT to improve the leaflet suturing pattern along the stent post, and the leaflet collagen fiber alignment. These two improvements, which are listed as items #5 and #6 above, were introduced to both Trifecta and Trifecta GT to enhance the durability of the leaflet tissue when combined with appropriate valve sizing and handling.

To further ease the implant procedure and improve access to the sewing cuff while suturing, a new holder is being introduced to the Trifecta GT valve in early 2020. The new holder has legs with a narrower footprint to permit easier access to the sewing cuff during placement of sutures while retaining the same protective features of the original Trifecta GT holder. The following figures illustrate (1) the evolution of the Trifecta valve timeline; and (2) the specific enhancements introduced with Trifecta GT.

Figure 1: The evolution of the Trifecta valve timeline

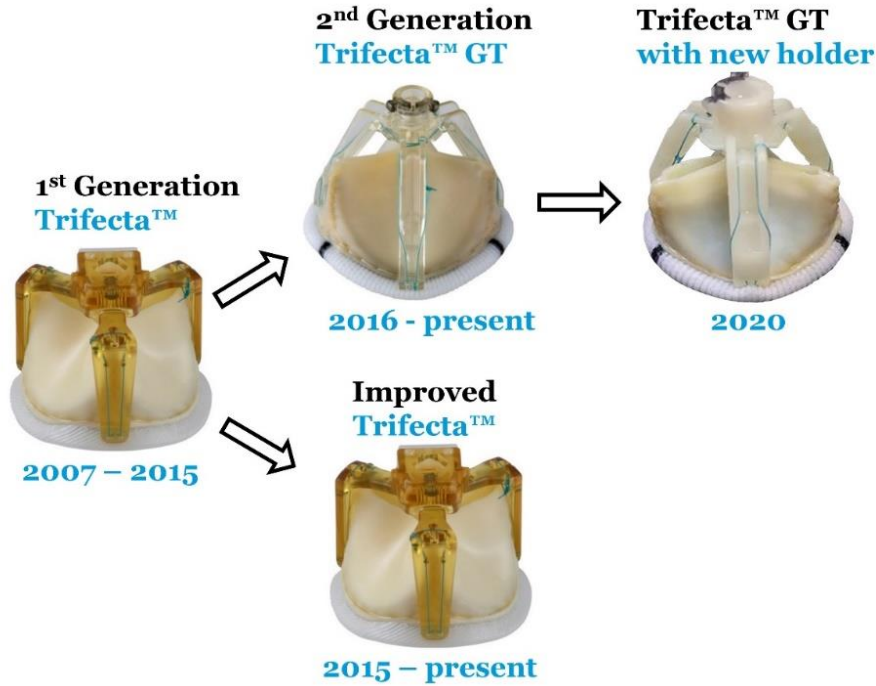
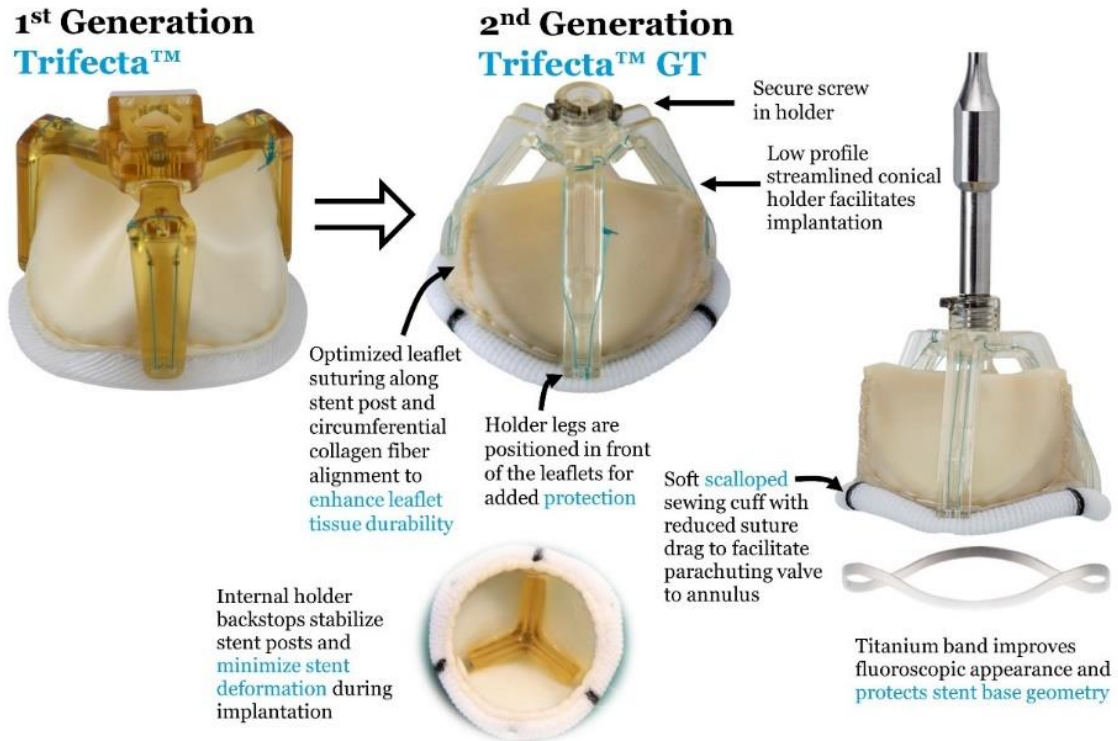


Figure 2: The specific enhancements introduced with Trifecta GT



Bioprosthetic heart valves have a potential for developing either non-structural valve dysfunction (NSVD<sup>4</sup>) or structural valve deterioration (SVD<sup>4</sup>) over the lifetime of the valve. NSVD is characterized as any abnormality not intrinsic to the

valve itself (such as entrapment by pannus, tissue, or suture; paravalvular leak; and inappropriate sizing or positioning) that may result in stenosis or regurgitation of the operated valve or hemolysis. SVD is characterized as changes intrinsic to the valve itself (such as calcification, leaflet fibrosis, leaflet tear, or flail leaflet) that may result in stenosis or regurgitation due to irreversible valve degeneration. NSVD may commonly be attributed to technical factors encountered at the time of valve implant, while SVD may commonly be attributed to biological factors and mechanical stress which develop over a longer implant duration.

To assess the long-term clinical outcomes of the first-generation Trifecta valve, Abbott conducted a Long-Term Follow-Study<sup>5</sup>. The 10-year follow-up from this study was recently completed and demonstrated excellent hemodynamic performance at 10-years (mean transvalvular gradient of 15.6 mmHg). At 10 years post implant, the freedom from all-cause mortality was 70%, the freedom from surgical explant due to SVD was 87%, and the freedom from any reintervention (surgical explant or transcatheter valve-in-valve intervention) due to SVD was 75%. The freedom from any reintervention and all-cause mortality at 10 years post-implant was 51%, which is consistent with the rate reported for other bioprosthetic aortic valves<sup>6,7</sup>. In choosing a bioprosthetic aortic valve, the potential for SVD should be balanced against the potential hemodynamic and survival benefits of the Trifecta valve. In comparison to the first-generation Trifecta valve, the Trifecta GT valve has additional features that make the valve easier to implant and potentially reduce the occurrence of NSVD and SVD over the lifetime of the valve.

In summary, the Trifecta and Trifecta GT valves have been designed and continuously improved with the aim to optimize performance by easing valve implantation and minimizing leaflet tissue damage. These design characteristics, in combination with proper valve sizing and handling in accordance with the IFU (e.g., oversizing, excessive force used during insertion, and handling of the leaflets with surgical instruments which are noted as precautions in the IFU), minimize the potential for developing NSVD and SVD, leading to the best clinical outcomes.

If you have any questions about this communication, please contact your local Abbott representative.

Sincerely,

Kara Carter  
Divisional Vice President, Quality Structural  
Heart

#### References

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2. Goldman, Scott. 'Bigger valve size is not always better.' *The Journal of thoracic and cardiovascular surgery* 154, no. 3 (2017): 820-821.
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4. Capodanno, Davide, Anna S. Petronio, Bernard Prendergast, Helene Eltchaninoff, Alec Vahanian, Thomas Modine, Patrizio Lancellotti et al. 'Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS).' *European journal of cardio-thoracic surgery* 52, no. 3 (2017): 408-417.
5. Long Term Follow Up Study of the St. Jude Medical Trifecta Valve – ClinicalTrials.gov Identifier: NCT01593917 - <https://clinicaltrials.gov/ct2/show/NCT01593917>.
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## APPENDIX B: Background information

### A. Summary of reports received by MHRA

It is important to recognise that the numbers recorded by the MHRA has limitations. Though manufacturers are legally required to submit serious reports of this type to the MHRA, with regards to clinicians and members of the public, it is a passive (voluntary) system. It is recognised that there will inevitably be under-reporting. Though the system cannot provide an accurate UK total number of events, or a precise calculation of the incidence or prevalence rate, it does serve to act as an indicator to undertake further exploration.

Further details of the 65 reports given below:

1. Reported Problem (note more than one problem could be cited per report):

- 34 comment on leaflet damage, terms used include, 'torn', 'loose', 'dehiscence', 'perforation', 'sheared', 'folded', 'retracted', 'pinned', 'prolapsed', 'deterioration', and 'degeneration'
- 31 reports reference some form of regurgitation (transvalvular leak) or insufficiency.
- 19 reports refer to calcification, and or fibrous / pannus thickening.
- 12 cite stenosis / obstruction to blood flow or high gradient.
- 8 remark on deformed / distorted (valve / stent post) or a faulty valve with leaflets not coapting.
- 1 references the stent post being 'fused' to the aortic wall.

2. Implant duration:

Unknown	12
Peri-operative	6
1 to 24 months	6
2 to 3 years	27
4 to 7 years	10
over 7 years	4

### B. Summary of event data provided by Abbott Vascular

The manufacturer has assisted the MHRA and shared information on the numbers of Trifecta reports associated with structural valve deterioration (SVD), fibrous-calcific structural valve deterioration (FCSVD), non-calcific leaflet tear (NCLT), as well as non-structural valve deterioration (dysfunction) (NSVD).

**Note: the SVD rate is the FCSVD and NCLT rates combined.**

	1 year		3 years		4* / 5+ years		8 years	
<b>Trifecta (1<sup>st</sup> Gen.)</b>	FCSVD	0.01%	FCSVD	0.06%	FCSVD	0.21%	FCSVD	0.83%
	NCLT	0.00%	NCLT	0.08%	NCLT	0.26%	NCLT	0.49%
	SVD	0.01%	SVD	0.14%	SVD	0.47%	SVD	1.32%
	NSVD	0.04%	NSVD	0.06%	NSVD	0.06%	NSVD	0.08%
<b>Trifecta "improved"</b>	FCSVD	0.01%	FCSVD	0.07%	* FCSVD	0.16%	N/A	N/A
	NCLT	0.01%	NCLT	0.13%	* NCLT	0.22%	N/A	N/A
	SVD	0.01%	SVD	0.19%	* SVD	0.38%	N/A	N/A
	NSVD	0.01%	NSVD	0.03%	* NSVD	0.03%	N/A	N/A
<b>Trifecta GT</b>	FCSVD	0.00%	FCSVD	0.02%	*FCSVD	0.03%	N/A	N/A
	NCLT	0.00%	NCLT	0.12%	*NCLT	0.18%	N/A	N/A
	SVD	0.01%	SVD	0.13%	*SVD	0.21%	N/A	N/A
	NSVD	0.02%	NSVD	0.02%	*NSVD	0.02%	N/A	N/A

\* data available for reporting out to 4.0 years post-implant

+data available for reporting out to 4.5 years post-implant

The table represents cumulative annual event rates through 31 March 2020 and derived as described in Abbott's response dated 04May2020

## SVD / NSVD<sup>1,2,3</sup>

Structural valve deterioration (SVD) can be defined as changes intrinsic to the valve itself (such as calcification, leaflet fibrosis, leaflet tear, or flail leaflet) that may result in stenosis or regurgitation due to irreversible valve degeneration. Two known modes of SVD observed with tissue heart valves are fibrous-calcific structural valve deterioration (FCSVD) and a non-calcific leaflet tear (NCLT).

FCSVD is characterized by fibrous thickening of the leaflet tissue and/or infiltration of the leaflet tissue with calcium deposits resulting in decreased leaflet mobility (aortic stenosis). Echocardiography demonstrates an elevated transvalvular gradient but may sometimes also show aortic insufficiency secondary to incomplete leaflet coaptation due to leaflet stiffening.

NCLT is characterized by thinning of the leaflet tissue with loss and disruption of collagen fibers at the tear site with absence of leaflet fibrosis and calcification. Echocardiography demonstrates aortic insufficiency without an elevated transvalvular gradient.

Non-structural valve deterioration (dysfunction) (NSVD) is characterized as any abnormality not intrinsic to the valve itself (such as entrapment by pannus, tissue, or suture; paravalvular leak; and inappropriate sizing or positioning) that may result in stenosis or regurgitation of the operated valve or haemolysis.

<sup>1</sup> Capodanno, Davide, Anna S. Petronio, Bernard Prendergast, Helene Eltchaninoff, Alec Vahanian, Thomas Modine, Patrizio Lancellotti et al. 'Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS).' European heart journal 38, no. 45 (2017): 3382-3390.

<sup>2</sup> Edmunds Jr, L. Henry, Richard E. Clark, Lawrence H. Cohn, Gary L. Grunkemeier, D. Craig Miller, and Richard D. Weisel. 'Guidelines for reporting morbidity and mortality after cardiac valvular operations.' (1996): 126-129.

<sup>3</sup> Akins, Cary W., D. Craig Miller, Marko I. Turina, Nicholas T. Kouchoukos, Eugene H. Blackstone, Gary L. Grunkemeier, Johanna JM Takkenberg et al. 'Guidelines for reporting mortality and morbidity after cardiac valve interventions.' European journal of cardio-thoracic surgery 33, no. 4 (2008): 523-528.

### C. Modifications to manufacturing

Abbott have conducted 'primary factor modifications' to the manufacturing sewing process (with the aim of reducing leaflet stress) implemented in July 2015. Similarly, adjustments have been made to reduce tissue variation and improve collagen fibre alignment consistency in order to improve tensile strength and enhance resistance to fatigue. These changes are applicable to both the 'improved' Trifecta and the Trifecta GT valves. Deformation of the Trifecta valve stent base also has the potential to result in acute valvular regurgitation from inadequate leaflet coaptation (rather than leaflet tear). The design of the Trifecta GT valve has been further supplemented with a 'titanium band'.

### D. Literature

Fausto Biancari., MD, PhD, Antti Valtola, MD, Tatu Juvonen, MD, PhD, Annastiina Husso, MD, PhD, Sebastian Dahlbacka, MD, PhD, Teemu Laakso, MD, Maina P. Jalava, MD, Tuomas Tauriainen, MD, PhD, Tuomas Ahvenvaara, MD, Eeva-Maija Kinnunen, MD, PhD, Matti Niemelä, MD, PhD, Timo Mäkikallio, MD, PhD, Markku Eskola, MD, PhD, Marko P.O. Virtanen, MD, Pasi Maaranen, MD, Stefano Rosato, MSc, Vesa Anttila, MD, PhD, Antti Vento, MD, PhD, Juhani Airaksinen, MD, PhD, Peter Raivio, MD, PhD. Trifecta versus Perimount Magna Ease Aortic Valve Prostheses. *Ann Thorac Surg*. 2020 Feb 12;S0003-4975(20)30194-6. doi: 10.1016/j.athoracsur.2019.12.071.

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