Executive Summary

Medtronic Contegra® Pulmonary Valved Conduit
Models 200 (unsupported) and 200S (supported)

H020003

Prepared by the Center for Devices and Radiological Health
for the November 13, 2025 Pediatric Advisory Committee Meeting

INTRODUCTION

In accordance with the Pediatric Medical Device Safety and Improvement Act, this document provides the Pediatric Advisory Committee (PAC) with post-marketing safety information to support its annual review of the Contegra® Pulmonary Valved Conduit ("Contegra"). The purpose of this annual review is to (1) ensure that the Humanitarian Device Exemption (HDE) for this device remains appropriate for the pediatric population for which it was granted, and (2) provide the PAC an opportunity to advise FDA about any new safety concerns it has about the use of this device in pediatric patients.

This document summarizes the safety data the FDA reviewed in the year following our 2024 report to the PAC. It includes data from the manufacturer's annual report, post-market medical device reports (MDR) of adverse events, and peer-reviewed literature.

BRIEF DEVICE DESCRIPTION

Contegra is a glutaraldehyde-crosslinked, heterologous bovine jugular vein with a competent tri-leaflet venous valve. The device is available in 6 sizes in even increments between 12 and 22 mm inside diameter, measured at the inflow end. The device is available in two models (Figure 1): one without external ring support (Model 200), and one with ring support modification (Model 200S).

Figure 1. Contegra 200 and 200S (ring-supported) Models

INDICATIONS FOR USE

Contegra is indicated for correction or reconstruction of the right ventricular outflow tract (RVOT) in patients aged less than 18 years with any of the following congenital heart malformations:

- Pulmonary Stenosis
- Tetralogy of Fallot
- Truncus Arteriosus
- Transposition with Ventricular Septal Defect (VSD)
- Pulmonary Atresia

Contegra is also indicated for the replacement of previously implanted, but dysfunctional, pulmonary homografts or valved conduits.

REGULATORY HISTORY

April 24, 2002:	Granting of Humanitarian Use Device (HUD) designation for Contegra (HUD #020003)
November 21, 2003:	Approval of Contegra HDE (H020003)
April 11, 2013:	Approval to profit on the sale of Contegra

DEVICE DISTRIBUTION DATA

Section 520(m)(6)(A)(ii) of The Food, Drug, and Cosmetic Act (FD&C) allows HDEs indicated for pediatric use to be sold for profit as long as the number of devices distributed in any calendar year does not exceed the annual distribution number (ADN). On December 13, 2016, the 21st Century Cures Act (Pub. L. No. 114-255) updated the definition of ADN to be the number of devices "reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States." Based on this definition, FDA calculates the ADN to be 8,000 multiplied by the number of devices reasonably necessary to treat an individual. However, it is to be noted that unless the sponsor requests to update their ADN based on the 21st Century Cures Act, the ADN will still be based on the previously approved ADN of 4,000. The approved ADN for Contegra is 4,000 devices total per year. Since the last PAC review, a total of 335 devices were sold in the U.S., and 215 devices were implanted. At least 119 of the devices were implanted in pediatric (<22 years) patients. For 94 out of the 215 devices implanted, patient age is unknown.

MEDICAL DEVICE REPORT (MDR) REVIEW

Overview of MDR Database

The medical device reports (MDRs) database is one of several important post-market surveillance data sources used by the FDA. Each year, the FDA receives several hundred thousand MDRs for suspected device-associated deaths, serious injuries, and device malfunctions. The MDR database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as health care professionals, patients, and consumers. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. MDR reports can be used effectively to:

- Establish a qualitative snapshot of adverse events for a specific device or device type
- Detect actual or potential device problems in a "real world" setting/environment, including:
    - rare, serious, or unexpected adverse events
    - adverse events that occur during long-term device use
    - adverse events associated with vulnerable populations
    - off-label use
    - use error

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important post-market surveillance data sources. Other limitations of MDRs include, but are not necessarily limited to:

- MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time, or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
- Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
- MDR data is subjected to reporting bias, attributable to potential causes such as reporting practice, increased media attention, and/or other agency regulatory actions.
- MDR data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.

There were 61 MDRs regarding Contegra identified in the FDA's MDR database between May 1, 2024 and March 31, 2025*. Of the 61 MDRs, 2 MDRs were unrelated to patient outcomes, 14 MDRs were sourced from journal articles, and 3 MDRs were voluntary reports that have 3 identical reports submitted for these events by the manufacturer. The 14 MDRs related to journal articles are excluded from the MDR data analysis for this year's review since these MDRs described events reported in literature that were either presented to the PAC previously (prior years) or are discussed in the Literature Review section of this

document. Therefore, the MDR analysis is based on the review of 42 unique MDRs, 39 submitted by the manufacturer and 3 submitted voluntarily.

** Please note that the reporting period for this year's analysis is 11 months due to the need to perform the MDR analysis and literature review prior to the 12-month reporting period date. Next year's analysis will be from 04/01/25 – 3/31/26 to account for this adjustment.*

Patient Demographic Data

Of the 42 MDRs, 40 (95%) were received from the United States. Patient sex information was included in 38 MDRs; 22 involved males and 16 involved females. Patient age was included in 40 MDRs; 33 were pediatric patients and 7 were adults. Table 1 summarizes this information.

Table 1: Patient Demographic Data (Total 42 MDRs; involve 33 pediatric patients)

Demographic Data		Percentage	Number of MDRs containing the demographic
Reporting Country	US : OUS	95% : 5%	40 : 2 (42 Total)
Patient Sex	Male : Female	58% : 42%	22 : 16 (38 Total)
Patient Age	Pediatric : Adult	83% : 17%	33 : 7 (40 Total)
Pediatric Only: Age Range: 3 months –18 years; Average Age: 9.7 ± 9.3 years			

Primary Reported Events

The 42 MDRs were individually reviewed and analyzed to determine the primary reported events. Additionally, the "time to event occurrence" (TTEO) was either obtained from MDR event text or calculated as the period between the Date of Implant and the Date of Event. The primary reported event by patient age group, as well as the associated TTEO ranges and means are outlined in Table 2 below.

Table 2: Primary Reported Event by Patient Age and TTEO for 2025 PAC Review

Primary Reported Event	Total MDR Count	Patient Age (year)		TTEO (month)*	
		Pediatric (<22)	Adult (≥22)	Range	Mean
Stenosis	**14**	12	2	2 – 180	81
Device replaced (reason not provided)	**9**	7	2	0.2 – 193	50
Arrhythmia	**6**	3	3	0.2 – 196	66
Endocarditis/Infection**	**6**	6	0	0.2 - 32	8
Valve regurgitation	**5**	5	0	0 – 72	21
Degeneration	**1**	1	0	104	-
Thrombus	**1**	1	0	0	-
Grand Total	**42**	35	7		

*TTEO: "Time to event occurrence" was obtained from MDR event text or calculated as the period between the Date of Implant and the Date of Event.

**Two (2) MDRs indicating endocarditis/infection did not include patient age.

A comparison of the primary events reported in the MDRs for the current analysis period with those from 2022, 2023, and 2024 PAC MDR analyses are shown in Table 3 below. The types of primary reported events are consistent, with "stenosis" and "device replacement" remaining as the most frequently reported events for the past 4 years. Please note that confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated. For a comparison of events reported from 2017-2025 please see Appendix A.

Table 3: Comparison of Primary Reported Events for Contegra MDRs in 2022, 2023, 2024 & 2025

Primary Reported Event	2022 PAC MDR Count (%)	2023 PAC MDR Count (%)	2024 PAC MDR Count (%)	2025 PAC MDR Count (%)
Device replaced (reason not provided)	21 (50%)	34 (55.8%)	17 (44%)	9 (21.4%)
Stenosis	13 (31%)	15 (25%)	11 (28%)	14 (33.3%)
Valve regurgitation/ insufficiency	3 (7%)	1 (1.6%)	4 (10%)	5 (11.9%)
Inadequate size for patient	1 (2.3%)	3 (5%)	3 (8%)	0
Thrombus	0	1 (1.6%)	2 (5%)	1 (2.4%)
Arrhythmia	1 (2.3%)	0	1 (2.5%)	6 (14.3%)
Infection/endocarditis/sepsis	1 (2.3%)	5 (8%)	1 (2.5%)	6 (14.3%)
Conduit dilation/aneurysm	2 (5%)	2 (3%)	0	0
Degeneration	0	0	0	1 (2.4%)
Total	**60**	**42**	**61**	**42**

The primary events reported in the 42 MDRs involving 42 injuries are summarized below.

Stenosis (n=14 MDRs; 12 pediatric patients)

Stenosis of conduit or pulmonary artery was the most frequently reported event. In these 14 reports, stenosis (in conjunction with calcification, obstruction, pulmonary regurgitation or insufficiency, and/or elevated pressure gradients) was identified in patients between 2 and 180 months post implant.

Of the stenosis reports, all (13 MDRs involving 11 pediatric patients) but 1 event reflected late events of stenosis (greater than one-year post implant) and the patients required interventions between 2 to 15 years post implant without additional adverse effects reported.

Overall, the interventions required for the 13 patients with late events of stenosis included transcatheter pulmonary valve (TPV) implantations conducted as valve-in-valve (3), surgical replacement of the pulmonary valve (7), balloon dilation (1), and stents with balloon dilation (2).

The one (1) MDR indicating an early event of stenosis in a 5-month-old child reported 2 months post implant of a 12mm conduit, the patient had developed progressive bilateral branch pulmonary artery stenosis with elevated right ventricle pressure. Cardiac catheterization was performed including stent angioplasty of the left pulmonary artery and balloon angioplasty of the right pulmonary artery.

Device replacement* – reason for replacement not reported (n=9 MDRs; 7 pediatric patients)

Nine (9) MDRs indicate that Contegra was replaced, 7 involving pediatric patients. Although the reasons for the device replacement were not reported in the MDRs, 5 of the 9 reports described that the valved conduit was replaced with a conduit of the same size and model between 0.2 and 98 months post Contegra implant. One (1) of the reports described that the conduit was replaced with a larger sized conduit of a different model. One (1) of the reports described that the conduit was replaced with a homograft. In the remaining 2 MDRs, no information was available regarding the reason for device replacement and the device was not returned to the manufacturer for analysis. However, all 2 of these MDRs included transcatheter pulmonary valve (TPV) implantations conducted as valve-in-valve procedures.

**"Replacement" is defined as the intervention taken to replace or substitute the function of Contegra device, including replacing the Contegra valved conduit surgically or via a transcatheter valve-in-valve procedure, without removing the Contegra device.*

Arrhythmia (n=6 MDRs; 3 pediatric patients)

Three (3) MDRs reported defibrillators were implanted in patients between 5 days and 16 years post-implant of the conduit. Two (2) of the three (3) reports describe the reason for defibrillator replacement was due to battery depletion of the previous defibrillator. The initial defibrillators were implanted due to history of sustained ventricular tachycardia for one patient and cardiomyopathy for the other. Two (2) MDRs reported permanent pacemakers were implanted in patients between 1 month and 2.5 years post-implant. Both events of permanent pacemaker implantation were due to incomplete atrioventricular block. One (1) MDR describes a patient who experienced transient heart block, tachycardia, 1st degree atrioventricular block, right bundle branch block and episodes of complete heart block seven years and seven months post- implant.

Endocarditis/Infection (n=6 MDRs; 6 pediatric patients)

Four (4) MDRs reported endocarditis in patients. Three of the four MDRs reported endocarditis in patients between 7 and 15 days post implant. The fourth MDR reported endocarditis in a patient with unknown time to event. In summary, patients experienced fever, inflammation, irritability, and tachypnea. One patient was positive for staphylococcus epidermidis and aggregetibacter aphrophilus. One patient had a polymerase chain reaction test reveal a common oral pathogen. No other pathogens were identified in the MDR narratives. All patients were reported to have been treated with antibiotics.

Two (2) MDRs reported infection in patients. One of the two MDRs describes a patient with an unspecified infection after an unknown duration post-implant of the conduit. The patient was hospitalized for irritability and low-grade fevers. Blood cultures were pending and antibiotics were administered. The second MDR reports a patient experiencing fever 2 years and 8 months post-implant of the Contegra device. Blood cultures were positive for streptococcus constellatus. The valve was explanted and replaced with a handmade PTFE valve.

Valve Regurgitation (n=5 MDRs; 5 pediatric patients)

Five (5) MDRs reported mild to severe pulmonary regurgitation in patients between post-implant and 6 years post-procedure. One (1) of the reports described that six-years post-implant, the patient presented

with pulmonary regurgitation, high gradient, and a possible calcified, frozen leaflet. A balloon valvuloplasty was performed, two stents were placed, and a transcatheter pulmonary bioprosthetic valve (TPBV) was implanted via valve-in-valve procedure. Three (3) MDRs reported events post-procedure of mild to moderate pulmonary regurgitation. No intervention or additional adverse patient effects were reported. One (1) MDR described an event 2 years and 11 months post-implant of mild to moderate pulmonary regurgitation. Five months later, the regurgitation increased to severe regurgitation. The patient was asymptomatic and no intervention or additional patient effects were noted.

Degeneration (n=1 MDR; 1 pediatric patient)

One (1) MDR indicated the Contegra device was explanted and replaced with a larger bioprosthetic valve 8 years and 8 months post-implant. The reason for explant was degeneration of the prosthesis. There were no additional patient effects reported.

Thrombus (n=1 MDR; 1 pediatric patient)

One (1) MDR indicated post-implant of the Contegra device there was "clot burden around the heart." The MDR reports the patient was brought to the operating room and a mediastinal washout was performed. Thrombus was noted throughout the mediastinum. There were no additional patient effects reported.

Conclusions Based on the MDR Review

- The MDRs received in this reporting period reflect peri-operative or late term events which are known complications. These events were likely associated with the procedure or patient underlying conditions and have been addressed in the device IFU.

- No new safety issues were identified based on the MDR review for this reporting period. The rates and types of events identified for this reporting period are similar to those in the previous reporting periods.

CONTEGRA LITERATURE REVIEW

Purpose
The objective of this systematic literature review is to provide an update on the safety of the Contegra bovine jugular vein conduit (BJV) device when used in pediatric patients.

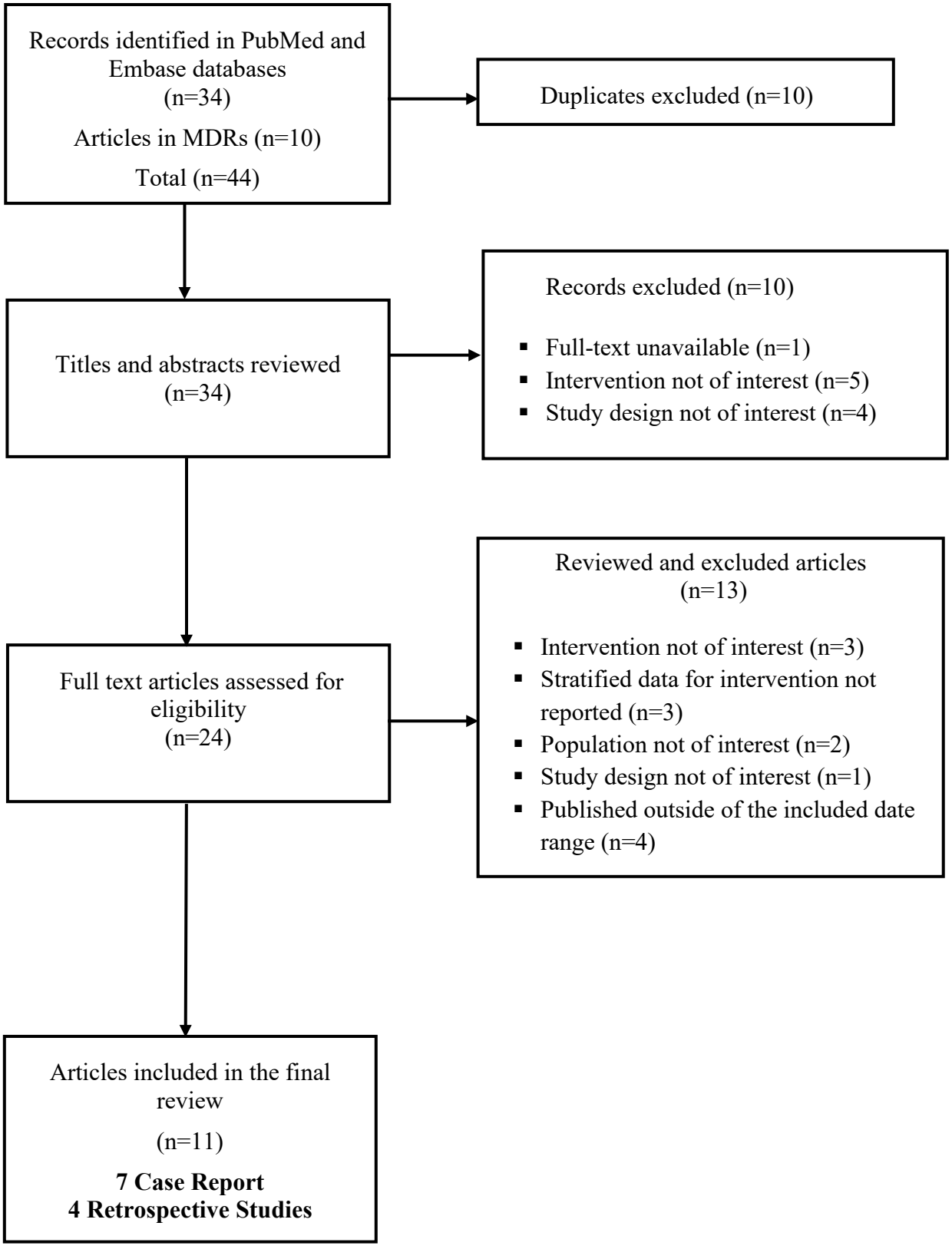
Methods
A search of the PubMed and EMBASE databases were conducted for published literature using the search terms: "Contegra" OR "Bovine Jugular Vein" OR "Pulmonary Valved Conduit," which were the same terms used in the 2024 literature review. The search was limited to articles published in English from 05/01/2024 through 03/31/2025.

Figure 2 depicts the article retrieval and selection process including the criteria for exclusion. A total of 34 (4 PubMed; 30 EMBASE) articles were retrieved. Of note, in addition to the 34 articles retrieved from PubMed and EMBASE databases, there were 10 unique publications identified through the review of the device manufacturer's adverse event reports submitted through the MedWatch system (MDR reports) added to the screening. Ten articles were duplicates. The remaining 34 articles were subjected to review of titles

and abstracts. Ten (10) articles were excluded from full-text review for reasons listed: Five (5) did not address the intervention of interest (i.e. did not include Contegra implants), four (4) did not include study designs of interest, and one (1) did not have full-text available. Twenty-four (24) full-text articles were retrieved and screened. Of these 24 articles, 13 were excluded from further review for reasons listed: Four (4) articles were published outside the included date range, three (3) had no intervention of interest, three (3) had stratified data for intervention not reported, two (2) had no population of interest, and one (1) did not have a study design of interest.

A total of 11 articles were included in this systematic literature review.

Figure 2. Article retrieval and selection process



Characteristics of Publications Included in Evidence Assessment (n=11)

There were four retrospective studies [1-4] and seven case reports[5-11] in this literature review. Two of the case reports included systematic reviews in addition to the case description; however, both systematic reviews included studies published prior to May 1, 2024, and therefore are not included in this review.

Of the four retrospective studies, three were conducted in the U.S.[1-3] and one was conducted in Germany.[4] All seven case reports were conducted outside the U.S. These case reports were from Italy (N = 1),[7] Switzerland (N = 1),[8] France (N = 1),[9] Denmark (N = 1),[11] Turkey (N = 1),[10] Oman (N = 1),[5] and Qatar (N = 1).[6]

A total of 238 pediatric patients were involved in two of the four retrospective studies and seven case reports that focused on pediatric populations, and 40 of those patients were treated with the Contegra device. One retrospective study included 315 adult and pediatric patients, of which 30 adult and 4 pediatric patients were treated with Contegra.[4] One retrospective pediatric study reported the infective endocarditis events in 14 patients, of which four patients received Contegra.[3]

Follow-up durations were provided in three of the four retrospective studies. Abeln et al. (2024) reported a median follow-up of 11 years,[4] while Singh et al. (2024) reported a total follow-up period of 8.6 years.[2] Mastropietro et al. (2025) did not report the overall follow-up duration but noted a maximum follow-up exceeding 10 years and a median follow-up of 19 days (range: 0-79 days) when postoperative echocardiograms were reviewed.[1] Nagiub et al. (2024) did not report follow-up duration.[3] Of the case reports, four cases were followed up in the short term (<90 days; range: immediate post-operative to 3 months)[5,8-10], two were followed for 6 months to 7.5 months[6,7] and one case reported results after 4 years post-surgery.[11]

The age of patients in the included retrospective studies ranged from a median age of 23 days to less than 18 years.[1,3,4] Nagiub et al. (2024) included patients less than 25 years of age; however, all four patients included in the Contegra subgroup were <18 years of age.[3] The age of patients in the case reports ranged from 6 months to 10 years[8,10]. Sex distribution for patients receiving Contegra was reported in one retrospective study, with 45.4% identified as male.[1] Among the case reports, sex was reported in six out of the seven case reports: four involved male patients [5-8], while two involved female patients.[9,10] Table 5 in Appendix B contains more details on the study and patient population characteristics.

Safety Results Discussions

All-cause mortality

Perioperative Mortality (≤90 days post-procedure)

Perioperative mortality (occurring less than 90 days post-procedure) was reported in one retrospective study[1] and two case reports.[8,10] In the retrospective study by Mastropietro et al. (2025), two of 33 patients (6%) experienced postoperative all-cause mortality, though the median time to death and overall follow-up duration were not reported.[1] The two case reports each described one postoperative death, occurring at 2 weeks[8] and 4 weeks[10], respectively.

Mastropietro et al. (2025) conducted a retrospective observational study in the US to assess the relationship between branch pulmonary artery (PA) size and the need for conduit reoperation following

repair of truncus arteriosus.[1] Among the 33 patients examined, 32 (97%) received a Contegra conduit (median size 12 mm), and one received an aortic homograft. While the study reported outcomes for the entire cohort and did not provide results specific to the Contegra subgroup, the study was included in this review as all but one patient was treated with Contegra, and available literature was limited.[1] The median age at surgery was 23 days (range 3–34 days). Postoperative all-cause mortality was reported in two out of 33 patients (6%), and the median time to death and follow-up period for these patients were not specified.[1] Both patients suffered cardiac arrest necessitating extracorporeal cardiopulmonary resuscitation (CPR) with consequent severe anoxic brain injury.[1] The type of conduit received by the patients who died was not specified, and it is unclear if both deaths occurred in the Contegra group.[1] Therefore, based on the limited information provided in the article, it is unknown whether the deaths were related to the Contegra device.

Gonzalez-Calle et al. (2024) described a case involving a 10-year-old male child from Switzerland with complex congenital heart disease, including double-outlet right ventricle (DORV), severe PA stenosis, an atrial septal defect (ASD), and a committed restrictive muscular VSD, accompanied by hypoxemia.[8] The patient underwent a ventricular switch procedure utilizing a one-and-a-half ventricle repair strategy.[8] This included a hemi-Mustard procedure with preservation of the superior cavopulmonary connection, VSD closure, division and closure of the pulmonary trunk, and a Contegra conduit of 14 mm diameter connecting the left ventricle (LV) to the PA.[8] Two weeks postoperatively, the patient developed chest discomfort, followed by sudden cardiac arrest unresponsive to resuscitation, resulting in death.[8] Autopsy revealed a massive myocardial infarction of the hypertrophied systemic right ventricle, along with subendocardial fibrotic lesions.[8] The coronary arteries, venous pathways, and the Contegra conduit were found to be unobstructed.[8]

Ilhan et al. (2024) reported a case from Turkey involving a 6-month-old female patient diagnosed with Townes–Brocks syndrome (TBS) and absent pulmonary valve syndrome with TOF, accompanied by dilated PAs.[10] Surgical repair was performed on the 85th day of life, and the Contegra conduit of 12 mm diameter was sutured between the pulmonary bifurcation and the RVOT.[10] However, the patient passed away 29 days postoperatively due to pneumonia and sepsis. [10] Although the publication does not explicitly identify the cause of death, it is noted that the patient had been intubated preoperatively due to respiratory distress and was placed on mechanical ventilation by day 60 of life. [10] Following surgery, extubation was not possible until postoperative day 29, due to persistently high ventilation pressures. [10] The authors suggested that in patients with TBS and absent pulmonary valve syndrome with TOF, the need for preoperative mechanical ventilation within the first few months of life may lead to prolonged postoperative intubation and potentially increase the risk of mortality. [10]

Long-term Mortality (>90 days post-procedure)

Long-term mortality (occurring more than 90 days post-procedure) was reported in one retrospective study.[1] Mastropietro et al. (2025) reported that one of 33 patients (3%) died 355 days after surgery. As described above, 32 (97%) of the 33 patients included in this study received a Contegra conduit (median size 12 mm), while one patient received an aortic homograft. The type of conduit received by the patient who died was not specified, and it is possible the patient did not receive the Contegra conduit.

No case report described long-term mortality.

Adverse events

Short-term Adverse Events (AEs) (≤90 days post-procedure)

Two case reports[7,9] described short-term AEs in patients who received the Contegra conduit. Additionally, two case reports mentioned the absence of short-term AEs.[5,6] One retrospective study reported short-term AEs and documented several postoperative interventions, including reoperations, extracorporeal membrane oxygenation (ECMO) support, CPR, administration of inhaled nitric oxide, and truncal valve interventions. The specific follow-up duration for these interventions was not reported.[1] The AEs reported by the case reports included moderate to severe tricuspid valve regurgitation (TVR)[7] at 45 days after surgery and a complete conduit thrombosis[9] after six days of surgery, leading to conduit replacement. The AE reported by the retrospective study included more than mild stenosis in at least one PA branch in 57.6% of patients, and severe stenosis in at least one PA branch in 24.2% of patients at a median follow-up of 19 days after surgery.[1]

Tricuspid Valve Regurgitation

Cetera et al. (2024) reported a case of Abiotrophia defectiva infective endocarditis (IE) in a 3-year-old male with congenital aortic stenosis, who had previously undergone neonatal surgical valvuloplasty.[7] To treat the IE, the child underwent an emergency Ross–Konno procedure, during which the pulmonary trunk was replaced with a 20 mm Contegra conduit. On the night following surgery, due to progressive signs of right ventricular failure, the sternum was reopened. Clinical improvement and hemodynamic stabilization allowed for successful sternal closure on postoperative day five. Given the persistent complete atrioventricular (AV) block, a permanent pacemaker was also implanted at that time. At 45 days post-surgery, transthoracic echocardiography (TTE) revealed moderate to severe TVR, though without clinical consequences. At the six-month follow-up, TVR remained stable with an estimated systolic pulmonary artery pressure of 35 mmHg. The child was asymptomatic and maintained on medical therapy, including a diuretic, beta-blocker, and aldosterone antagonist.

Conduit Thrombosis

Haddad et al. (2024) described a case of complete conduit thrombosis in a 6-year-old girl (18 kg, 120 cm) who developed severe native aortic valve insufficiency following a delayed diagnosis of Methicillin-sensitive Staphylococcus aureus endocarditis from France.[9] She underwent an urgent Ross procedure, during which an 18 mm Contegra VenPro conduit was placed between the right ventricle and the pulmonary artery (RV–PA). After the surgery, the patient developed LV akinesia, requiring central veno-arterial ECMO with full support, and a transmitral LV decompression cannula. Despite therapeutic anticoagulation and adequate monitoring of activated clotting time, the patient developed complete thrombosis of the RV–PA conduit on postoperative day 4. Small clots were detected in the ECMO circuit, and the circuit was replaced. By postoperative day 6, the right ventricle was severely dilated, and no anterograde flow was observed through the conduit. A cardiac Computed Tomography (CCT) scan confirmed complete conduit thrombosis, and a concurrent head scan showed no evidence of active bleeding. An urgent cardiac catheterization was performed to restore RV–PA flow. Angiography confirmed complete occlusion of the conduit, and thromboaspiration using the Indigo aspiration system was successfully performed to remove the thrombus and re-establish flow. The patient was gradually weaned off ECMO support, and the conduit was replaced on postoperative day 10 (replacement details not reported). Follow-up at three months post-thromboaspiration indicated favorable outcomes.

PA stenosis

Mastropietro et al. (2025) reported that more than mild stenosis in at least one PA branch was observed

in 19 of 33 patients (57.6%), while severe stenosis in at least one PA branch was noted in 8 patients (24.2%) during a median follow-up of 19 days post-surgery (range: 0-79 days).[1] Postoperative TTEs closest to hospital discharge were reviewed, and PA branch stenoses were assessed based on elevated intravascular flow velocities. The severity of stenosis was classified as mild, moderate, or severe using standard diagnostic cutoff values. As described above, it is unclear in this study if the affected patients included the one patient who received an aortic homograft rather than 32 (97%) patients who received the Contegra conduit.

Postoperative procedures

Mastropietro et al. (2025) reported that six (18%) of 33 patients underwent postoperative reoperation due to bleeding, while one (3%) patient underwent reoperation for other reasons (details are not reported).[1] Additionally, eight (24%) patients required postoperative ECMO support, nine (27%) received postoperative CPR, and 24 (73%) were administered inhaled nitric oxide postoperatively. Truncal valve intervention was performed in one patient (3%). The study reported that postoperative echocardiograms were reviewed at a median follow-up of 19 days (range: 0–79 days). Of note, among the 33 patients examined, 32 (97%) received a Contegra conduit (median size 12 mm), and one received an aortic homograft. While the study reported outcomes for the entire cohort, stratified data specific to the Contegra subgroup were not provided.

No postoperative AEs

Two case reports[5,6] noted no postoperative AEs. Al Kindi et al. (2024) described a 1-year-old male from Oman with a double-outlet right atrium and separate atrioventricular junctions, surgically repaired using a 16 mm Contegra conduit.[5] Postoperative transesophageal echocardiography (TEE) showed good mitral inflow and no tricuspid valve stenosis or regurgitation.[5] Similarly, Boudjemline et al. (2024) reported a 2-year-old male from Qatar with complex congenital heart defects, including hypoplastic left heart syndrome, mitral atresia, partial anomalous pulmonary venous return, VSDs, and interrupted aortic arch.[6] This was initially palliated by atrial and vertical vein stenting and later by repair of the tricuspid valve and transcatheter Fontan, which was completed by creating an extracardiac Fontan.[6] Postoperative TEE showed a well-repaired tricuspid valve, no stenosis on the inferior vena cava (IVC) anastomosis, and the patency of the large unobstructed fenestration.[6] At 7.5-month follow-up, the child remained complication-free, with no arrhythmias.[6] No special antibiotic therapy was started for the Contegra conduit except regular antibiotic prophylaxis before interventions or surgery.[6]

Infective Endocarditis

Three retrospective studies[1,3,4] and one case report[11] described cases of IE associated with Contegra conduits. In the retrospective study from Germany, IE occurred in two out of four pediatric Contegra patients (50%) at a mean follow-up of 6.2 years (SD = 3.4 years) post-surgery.[4] The U.S.-based retrospective study included 14 patients with confirmed IE, 10 of whom had prosthetic valve IE involving RV–PA conduits.[3] Among these, the Contegra conduit was used in four patients. The other U.S.-based retrospective study reported that IE occurred in one out of 33 patients (3.0%).[1] The case report described a rare instance of Salmonella enteritidis endocarditis occurring 4 years after Contegra implantation.[11]

Abeln et al. (2024) presented long-term outcomes of RVOT conduits—pulmonary homograft, stentless xenograft, and Contegra—in patients undergoing the Ross procedure in a retrospective observational study from Germany.[4] Among the 314 patients studied, only four were <18 years of age and received Contegra. Two of these four patients developed IE at a mean follow-up of 6.2 years (SD = 3.4 years) post-surgery.[4]

Nagiub et al. (2024) evaluated the role of CCT in diagnosing IE in children and young adults with congenital heart disease in the United States.[3] The retrospective observational study included 14 patients with confirmed IE, 10 of whom had RV–PA conduit-associated endocarditis, classified as prosthetic valve IE. Among these 10 cases, the Contegra conduit was used in four patients (follow-up period NR). The other conduits were an aortic homograft in two patients, percutaneously implanted Melody valves in two patients, a Hancock bioprosthetic valved conduit in one patient, and a Carpentier-Edwards Magna Ease bovine pericardial bioprosthesis in one patient. No other specific clinical outcomes were reported for the Contegra group.

Mastropietro et al. (2025) reported that IE occurred in one out of 33 patients (3.0%) (follow-up period NR for IE outcome).[1] The type of conduit received by the IE patient was not specified, though 97% of patients in this study received the Contegra conduit.[1]

Sultan et al. (2024) reported a case of Salmonella enteritidis endocarditis in an immunocompetent 8-year-old child from Denmark with a history of complex congenital heart disease.[11] The patient was born with truncus arteriosus and underwent multiple surgical interventions, including VSD closure and implantation of an RV–PA Contegra graft at one month of age. This was followed by truncal valvuloplasty at two months, and at four years of age, the patient received a mechanical aortic valve (MAV) along with an upsizing of the RV–PA Contegra graft. Additional interventions included the right PA stenting and multiple bilateral percutaneous balloon pulmonary angioplasty procedures. At 8 years of age, the patient was diagnosed with S. enteritidis infective endocarditis. The publication does not explicitly identify the cause of infection; however, TEE revealed a multiloculated abscess surrounding the MAV annulus, valvular vegetation, and a pseudoaneurysm at the aortic root, while the RV–PA conduit appeared unaffected.

Conduit Replacement and Reintervention

Three retrospective studies[1,2,4] described conduit replacement[1], and freedom from reintervention[2,4] associated with Contegra conduits. No case report described these adverse events in the long term (more than 90 days post-procedure). Mastropietro et al. (2025) found that 19 of 33 patients (57.6%) had conduit replacement, with a median time to replacement of 1.6 years.[1] Abeln et al. (2024) reported that the probability of freedom from reintervention at five years post-operation in the Contegra group was 83%.[4] In the study by Singh et al. (2024), the patient remained free of severe aortic insufficiency and did not require reintervention after 8.6 years of follow-up.[2]

Replacement

Mastropietro et al. (2025) conducted a retrospective observational study in the U.S. to evaluate the relationship between branch PA size and the need for conduit reoperation following repair of truncus arteriosus.[1] Of the 33 patients, 32 (97%) received a Contegra conduit (median size 12 mm), while one received an aortic homograft.[1] The median age at the time of surgery was 23 days (range: 3–34 days). Conduit replacement was done in 19 of 33 patients (57.6%), with a median time to replacement of 1.6 years (range: 0.04–10.4 years). The primary indications for replacement included distal conduit stenosis in 10 patients (52.6%), conduit contracture and degeneration in 8 patients (42.1%), and endocarditis in one patient (5.3%). Notably, patients with distal conduit stenosis underwent reoperation significantly earlier, at a median of 0.6 years (range: 0.4–6.7 years), compared to those replaced for degeneration or endocarditis, who had a median time to replacement of 4.7 years (range: 1.6–10.4 years; $p = 0.005$).

Two anatomical and procedural factors were significantly associated with an increased hazard of conduit

reoperation.[1] Patients with truncus arteriosus type A2 or A3 anatomy, characterized by the absence of a distinct main PA segment, had a higher risk of reoperation (HR = 3.52; 95% CI: 1.14–10.94; p = 0.029). Additionally, patients with postoperative conduit-to-PA diameter ratios greater than or equal to four also had a significantly increased hazard of reoperation (HR = 4.94; 95% CI: 1.63–14.97; p = 0.005).

Freedom from Reintervention

Abeln et al. (2024) presented long-term outcomes of RVOT conduits—pulmonary homograft, stentless xenograft, and Contegra—in patients undergoing the Ross procedure in Germany.[4] Among the 314 patients studied, 24 were pediatric patients (under 18 years of age); of these, 18 received a pulmonary homograft, four received a Contegra, and two received a stentless xenograft. At 5 years post-operation, the probability of freedom from reintervention in the Contegra group was 83%. When compared across conduit types in pediatric patients, including homograft (N=18), Contegra (N=4), and xenograft (N=2), the reported freedom from reintervention rates at 5 years were 83%, 75%, and 100%, respectively (p = 0.697), indicating no statistically significant difference across conduits.

Singh et al. (2024) examined the impact of preoperative balloon aortic valvuloplasty (BAV) for AS on long-term autograft durability following the Ross procedure in a retrospective U.S.-based study of 198 patients.[2] Only one patient received a Contegra conduit. This 8-year-old child with AS underwent the Ross procedure (without prior BAV), during which an 18-mm Contegra conduit was used for annuloplasty. After 8.6 years of follow-up, the patient had no severe aortic insufficiency and did not require reintervention.

No case reports described conduit deterioration, reintervention, or replacement outcomes. See Table 5 for more details on outcomes.

Evidence Assessment

Overall, there were no new safety events identified, and/or change in their incidence or severity. The current systematic literature review reflects the post-market reported safety data of the Contegra device for use in pediatric patients.

This systematic literature review summarizes the safety data for the Contegra device in pediatric patients published between May 1, 2024, and March 31, 2025. The assessed evidence adds to the prior reports on AEs associated with the use of the Contegra pulmonary conduit in pediatric populations. Similar to the 2024 review, infective endocarditis was the most common adverse event reported across publications. The other AEs reported were conduit thrombosis, PA stenosis, and TV regurgitation. Conduit replacements and reinterventions were also discussed, as well as perioperative and long-term mortality.

The studies' limitations included the lack of randomization, retrospective study designs, differential follow-up, combined pediatric and adult patient populations, and limited evaluation of other AEs. Validity and generalizability are also limited. With a wide range of follow-up times, these retrospective studies are subject to bias due to confounding resulting from the length of follow-up and potential changes in therapy or demographics over time. For the studies with short follow-up times, longer-term outcomes for the Contegra conduit were not observable. Additionally, generalizability is limited because all four retrospective studies were conducted at a single site. Generalizability can vary by local regions due to underlying differences in the baseline prevalence of CHD, disease management, resource allocation, and differences in patient and physician characteristics.

Commercial or manufacturer-related funding and conflicts were not prominent across the included studies. Of the 11 included articles reviewed, 10 declared no conflicts of interest. These include retrospective studies and individual case reports, spanning multiple countries and institutions. One study—Singh et al. (2024)—reported a potential conflict of interest, noting that one author disclosed industry relationships, including serving as a speaker for Terumo, consultant for Artivion and Edwards, and receiving a research grant from the Rudin Foundation; all other authors in that study reported no conflicts[2]. Regarding funding disclosures, five articles[1,3,5,7,11] explicitly stated they received no funding or specific grant support for the research, authorship, or publication. Five other articles[2,4,6,8,9] did not report any information regarding funding status. One article (Ilhan et al., 2024) acknowledged receiving support from research grants (e.g., MINECO/FEDER, Severo Ochoa Excellence Program, UbiCODE, and UBIRed), without any industry sponsorship[10].

Finally, the search terms used have been consistent for every year of literature update for this PAC. There is the possibility that other descriptive search terms for the device may have resulted in different publications, which could cause unintended missed articles. However, this is in part mitigated by the cross-referencing of our search results with the citations provided identifying adverse events in literature searches conducted by the device manufacturer. These are sent to us as a Medical Device Report.

Conclusions Based on the Literature Review

Review of the literature published between 05/01/24 and 03/31/25 revealed the following observations:

- Perioperative mortality (≤90 days post-procedure) was reported in one retrospective study[1] and two case reports.[8,10] Mastropietro et al. (2024) noted a 6% all-cause postoperative (exact time to event was not reported) mortality in a cohort of 33 patients due to cardiac arrest followed by severe anoxic brain injury. However, Contegra conduit-specific mortality data were not reported, and one of 33 patients did not receive the Contegra conduit.[1] Two case reports described perioperative deaths occurring at two[8] and four weeks[10] post-Contegra implantation, attributed to myocardial infarction[8] and postoperative pneumonia with sepsis,[10] respectively.
- Long-term mortality (>90 days post-procedure) was reported in the Mastropietro et al. (2024) retrospective study,[1] with one death occurring 355 days post-surgery (3% of the cohort), again without clarification on conduit type.[1]
- Short-term AEs (≤90 days post-procedure) were described in two case reports[7,9], while two other case reports mentioned the absence of short-term AEs.[5,6] The specific short-term AEs reported by the case reports included moderate to severe tricuspid valve regurgitation[7] at 45 days after surgery, and a complete conduit thrombosis[9] after 6 days of surgery, leading to conduit replacement. One retrospective study reported mild stenosis in at least one PA branch in 58% of patients, and severe stenosis occurred in 24% of patients over a median follow-up of 19 days (range: 0-79 days).[1] The study also documented several postoperative procedures, including reoperation, extracorporeal membrane oxygenation (ECMO) support, CPR, administration of inhaled nitric oxide, and truncal valve interventions. The specific follow-up duration for these outcomes was not reported.[1]
- Infective endocarditis was reported in three retrospective studies[1,3,4] and one case report.[11] The rate of IE varied from 5.3% to 50% across studies.[1,4] In the retrospective study from Germany, IE occurred in two out of four pediatric Contegra patients (50%) at a mean follow-up of 6.2 years (SD = 3.4 years) post-surgery.[4] The U.S.-based retrospective study reported that IE occurred in one out

of 33 patients (3.03%).[1] The other U.S.-based retrospective study included 14 patients with confirmed IE, 10 of whom had prosthetic valve IE involving RV–PA conduits.[3] Among these 10 patients, the Contegra conduit was used in four patients. The case report described an instance of Salmonella enteritidis endocarditis occurring four years after Contegra implantation.[11] However, the RV-PA conduit itself was unaffected in TEE.[11]

- Conduit replacement and reintervention were prominent themes in three retrospective studies.[1,2,4] Mastropietro et al. found that 58% of patients underwent conduit replacement, most commonly due to distal conduit stenosis or conduit contracture/degeneration, with the median time to replacement of 1.6 years.[1] Anatomical features (truncus type A2/A3) and conduit-to-PA diameter ratio ≥4 were statistically significantly associated with increased reoperation risk.[1]
- Abeln et al. reported an 83% freedom from reintervention at five years for Contegra conduits,[4] while Singh et al. (2024) found no need for reintervention over 8.6 years in a single patient[2]. When compared across conduit types in pediatric patients—homograft (N=18), Contegra (N=4), and xenograft (N=2)—freedom from reintervention rates at 5 years were 83%, 75%, and 100%, respectively ($p = 0.697$), indicating no statistically significant difference.[4]

SUMMARY

The FDA did not identify any new unexpected risks during this review of the MDRs received and the literature published since our last report to the PAC. The FDA believes that the HDE for this device remains appropriate for the pediatric population for which it was granted.

The FDA recommends continued routine surveillance and will report the following to the PAC in 2026:

- Annual distribution number
- MDR review and
- Literature review

REFERENCES

1. Mastropietro CW, Rodenbarger A, Herrmann JL. Conduit Size, Branch Pulmonary Artery Size, and Reoperation in Patients With Truncus Arteriosus. Article in Press. World Journal for Pediatric and Congenital Heart Surgery. 2025;doi:10.1177/21501351251314381
2. Singh SK, Bouhout I, Nguyen S, et al. Aortic insufficiency following balloon aortic valvuloplasty does not impact long-term autograft durability after the Ross procedure. Article. Journal of Thoracic and Cardiovascular Surgery. 2024;168(5):1301-1309.e2. doi:10.1016/j.jtcvs.2024.01.024
3. Nagiub M, Fares M, Ganigara M, et al. Value of Time-Resolved Cardiac CT in Children and Young Adults with Congenital Heart Disease and Infective Endocarditis. Article. Pediatric Cardiology. 2024;45(6):1267-1274. doi:10.1007/s00246-022-03069-7
4. Abeln KB, Froede L, Giebels C, Schäfers HJ. Durability of right ventricular conduits in the Ross procedure. Article in Press. Journal of Thoracic and Cardiovascular Surgery. 2024;doi:10.1016/j.jtcvs.2024.10.023
5. Al Kindi H, Abolwafa A, Al Hashmi H, Al-Maskari S, Maddali MM, Anderson RH. An Unusual Presentation of Double-Outlet Right Atrium. Article. World Journal for Pediatric and Congenital Heart Surgery. 2024;15(4):510-514. doi:10.1177/21501351241237956
6. Boudjemline Y, Hijazi ZM, Sallehuddin A, Ghez O. Transcatheter Fontan completion: Creation of an extracardiac Fontan. Article. Catheterization and Cardiovascular Interventions. 2024;104(2):264-271. doi:10.1002/ccd.31131
7. Cetera V, Cantinotti M, Barberi E, Pak V. Huge, invasive, and destructive Abiotrophia defectiva endocarditis of the aortic valve and the aortic wall: a case report of an emergency but successful Ross–Konno operation in a child. Article. European Heart Journal - Case Reports. 2024;8(8)doi:10.1093/ehjcr/ytae356
8. Gonzalez-Calle A, Adsuar-Gomez A, Rodriguez-Mora F, Hosseinpour AR. Ventricular switch as an alternative to single-ventricle palliation: An attractive strategy but with certain pitfalls. Article. JTCVS Techniques. 2024;24:171-173. doi:10.1016/j.xjtc.2024.01.005
9. Haddad RN, Gaudin R, Bonnet D, Malekzadeh-Milani S. Postoperative catheter thrombaspiration to open an occluded right ventricle-to-pulmonary artery conduit in child. Article. European Journal of Cardio-thoracic Surgery. 2024;65(2)doi:10.1093/ejcts/ezae055
10. Ilhan O, Gumus E, Hakan N, et al. A Genotyped Case of Townes-Brocks Syndrome with Absent Pulmonary Valve Syndrome from Turkey. Review. *Journal of Pediatric Genetics*. 2024;13(2):139-143. doi:10.1055/s-0041-1740371
11. Sultan T, Moser C, Smerup MH, Idorn L. Salmonella endocarditis in an immunocompetent 8-year-old with a mechanical aortic valve: A case report and literature review. Article. *Progress in Pediatric Cardiology*. 2024;74doi:10.1016/j.ppedcard.2024.101739

Appendix A: Supplemental Table

Table 4. Comparison of Primary Reported Events for Contegra MDRs from 2017 – 2025

	MDR Count (%)								
Primary Reported Event	**2017 PAC**	**2018 PAC**	**2019 PAC**	**2020 PAC**	**2021 PAC**	**2022 PAC**	**2023 PAC**	**2024 PAC**	**2025 PAC**
Stenosis	37 (44%)	33 (63%)	51 (48%)	36 (39%)	20 (33.3%)	13 (31%)	15 (25%)	11 (28%)	14 (33.3%)
Device replaced (reason not provided)	35 (42%)	12 (23%)	38 (36%)	32 (35%)	35 (58.3%)	21 (50%)	34 (55.8%)	17 (44%)	9 (21.4%)
Valve regurgitation/insufficiency	5 (6%)	2 (4%)	6 (6%)	7 (8%)	0	3 (7%)	1 (1.6%)	4 (10%)	5 (11.9%)
Inadequate size for patient	0	0	4 (4%)	3 (3.3%)	0	1 (2.3%)	3 (5%)	3 (8%)	0
Arrhythmia	2 (2.3%)	0	2 (2%)	4 (4.4%)	3 (5%)	1 (2.3%)	0	1 (2.5%)	6 (14.3%)
Increased pressure gradient	1 (1.2%)	2 (4%)	2 (2%)	2 (2%)	0	0	0	0	0
Infection/endocarditis/sepsis	1 (1.2%)	1 (2%)	2 (2%)	3 (3.3%)	2 (3.3%)	1 (2.3%)	5 (8%)	1 (2.5%)	6 (14.3%)
Conduit dilation/aneurysm	2 (2.3%)	1 (2%)	1 (1%)	2 (2%)	0	2 (5%)	2 (3%)	0	0
Pulmonary edema/hemorrhage	0	1 (2%)	0	0	0	0	0	0	0
Thrombus	1 (1.2%)	0	0	1 (1%)	0	0	1 (1.6%)	2 (5%)	1 (2.4%)
Adhesions	0	0	0	1 (1%)	0	0	0	0	0
Unknown	0	0	0	1 (1%)*	0	0	0	0	0
Degeneration	0	0	0	0	0	0	0	0	1 (2.4%)
Total	**84**	**52**	**106**	**92**	**60**	**42**	**61**	**39**	**42**

**One MDR indicates that after an unknown during of time following the implant of the Contegra device, the patient died. The cause of death is unknown.*

Appendix B: Supplemental Table

Table 5. Summary of study characteristics and results

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Mastropietro et al., 2025[1] **Country:** US **Study Design:** Retrospective Observational Study **Objective:** To determine the relationship between branch PA size and the need for conduit reoperation following repair of truncus arteriosus. **Funding:** The author(s) received no financial support for this article's research, authorship, and/or publication. **Conflict of interest:** The author(s) declared no potential conflicts of interest.	**Patients (N):** 33 **Note**: 32 of 33 patients (97%) received Contegra, and one received an aortic homograft. Data are reported for all 33 patients. Stratified data were not reported for the Contegra-specific population. **Age Median (range):** 23 days (3 to 34 days) **Sex N (% male):** 15 (45.4%) **Diagnosis:** Truncus arteriosus. **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** Patients who underwent truncus arteriosus repair at Hospital A between January 2009 and December 2022, with follow-up through December 2023. **Exclusion Criteria:** Patients were excluded if they: (1) underwent pulmonary artery (PA) banding prior to truncus arteriosus repair; (2) had postoperative echocardiograms performed exclusively while on ECMO; or (3) lacked reliable PA measurements from postoperative imaging obtained before hospital discharge.	**Intervention:** Bovine jugular vein conduits by Contegra, Medtronic. **Note:** 32 of 33 patients (97%) received Contegra, and one received an aortic homograft. Data reported combined for both. Stratified data not reported for Contegra. **Conduit size, median (IQR):** 12 mm (12 - 12) **Comparator:** NA **Indication for use:** Surgical repair of truncus arteriosus. **Follow-up period:** • Mean/median/total follow-up NR; maximum follow-up over 10 years. • Postoperative echocardiograms were reviewed at: median follow-up of 19 days after surgery (range: 0-79 days).	**Note:** Outcomes reported for all 33 patients who received Contegra (N = 32) and aortic homografts (N = 1). Stratified data were not reported for the Contegra. **All-cause Mortality, N (%):** • Postoperative mortality (follow-up period NR): 2/33 (6%), median time of death NR • Long-term mortality (>90 days post-procedure): 1/33 (3%), died 355 days postoperatively. **Replacement, N (%):** 19/33 (57.6%) **Median time to replacement:** 1.6 years (range: 0.04-10.4). **Indications for conduit replacement:** • Distal conduit stenosis: 10/19 (52.6%) • Conduit contracture and degeneration: 8/19 (42.1%) • Endocarditis: 1 (5.3%) **Note:** Patients with distal conduit stenosis underwent conduit replacement significantly earlier—median 0.6 years (range: 0.4-6.7) after surgery—compared with patients who underwent replacement for conduit contraction/degeneration/ endocarditis—median 4.7 years (range: 1.6-10.4) ($p = 0.005$). **Factors associated with conduit reoperation**: • Hazard for conduit reoperation was significantly higher for patients with truncus arteriosus type A2 or A3

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
			PA anatomy (i.e., no distinct main PA segment): HR = 3.52, 95% CI 1.14 to 10.94, p = 0.029 • Hazard for conduit reoperation was significantly higher for patients with postoperative conduit-to-PA ratios greater than or equal to 4: HR = 4.94, 95% CI 1.63 to 14.97, p = 0.005. **Post-operative AE**: **Stenosis, N (%):** Median follow-up 19 days after surgery (range: 0–79 days) • More than mild stenosis of at least one PA branch: 19/33 (57.6%) • Severe stenosis of at least one PA branch: 8/33 (24.2%) **Postoperative procedures, N (%):** • Reoperation, bleeding: 6/33 (18%), • Reoperation, not for bleeding: 1/33 (3%) • Postoperative ECMO: 8/33 (24%) • Postoperative CPR: 9/33 (27%) • Postoperative inhaled nitric oxide: 24/33 (73%) • Truncal valve intervention: 1/33 (3%)

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Singh et al., 2024[2] **Country:** US **Study Design:** Retrospective Observational Study **Objective:** To investigate the impact of pre-operative BAV for AI on long-term autograft durability after the Ross procedure. **Funding:** NR **Conflict of interest:** Dr Takayama reported being a speaker with Terumo, a consultant with Artivion and Edwards, and receiving a research grant from the Rudin Foundation. All other authors reported no conflicts of interest.	**Patients (N):** A Total of 198 patients; only one patient received Contegra. **Note:** The data provided is for the Contegra patient. **Age:** 8 years **Sex N (%):** NR **Diagnosis:** AS **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** NR **Exclusion Criteria:** NR	**Intervention:** Bovine jugular vein conduits by Contegra **Conduit size**: 18 mm **Comparator:** NA **Indication for use:** Ross procedure (without prior BAV) with external AV annuloplasty was done using Contegra 18 mm. **Follow-up period, total:** 8.6 years (for the patient who received Contegra)	**All-cause Mortality, N (%):** NR **Reintervention**: No reintervention was performed on the patient who received Contegra after a follow-up of 8.6 years. **Severe AI**: No severe AI in the patient who received Contegra after a follow-up of 8.6 years.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Nagiub et al., 2024[3] **Country:** US **Study Design**: Retrospective Observational Study **Objective:** To assess the value of cardiac CT in diagnosing IE in children and young adults with congenital heart disease. **Funding:** This research received no specific grant from public, commercial, or not-for-profit funding agencies. **Conflict of interest:** The authors declare no conflict of interest.	**Patients (N):** Total 14 patients, 4 received Contegra **Note:** The data provided is for the Contegra patients only. **Age Median (range):** NR **Sex N (%):** NR **Diagnosis:** CHD with IE **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** Pediatric patients with CHD and IE diagnosis who underwent CCT. The patients must be under 25 years old at the time of the study and have an IE diagnosis proven by surgical pathology specimens or by receiving complete treatment for IE based upon clinical diagnosis. **Exclusion Criteria:** NR	**Intervention:** Bovine jugular vein conduits by Contegra, Medtronic. **Conduit size**: NR **Comparator:** NA **Indication for use:** NR for Contegra patients separately. **Follow-up period:** NR	**All-cause Mortality, N (%):** NR **Infective Endocarditis, N (%):** Of 14 patients with endocarditis selected in this study, 10 had RV-PA conduit endocarditis (Prosthetic valve IE). Of these 10, the Contegra was used in 4 patients. Other Conduits used were: • Aortic homograft: in 2 patients • Percutaneously implanted Melody valves: in 2 patients • Hancock bioprosthetic valved conduit: in 1 patient • Carpentier-Edwards Magna Ease bovine pericardial bio prosthesis: in 1 patient. No other outcome was reported for Contegra patients.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Abeln et al., 2024[4] **Country:** Germany **Study Design:** Retrospective Observational Study **Objective:** To review the long-term experience with different RV conduits (pulmonary homograft, stentless xenograft, BJV) in the Ross procedure. **Funding:** NR **Conflict of interest:** The authors reported no conflicts of interest.	**Patients (N):** Total 315 patients; 34 received BJV with a mean age of 35 years; 4 patients were <18 years of age and received a BJV conduit (Contegra). **Note:** The data provided is for pediatric Contegra patients only. **Age Median (range):** NR for pediatric patients. **Sex N (%):** NR for pediatric patients. **Diagnosis:** Isolated aortic regurgitation, isolated aortic stenosis, combined disease, and endocarditis (details NR for pediatric patients). **Race/ethnicity N (%):** NR for pediatric patients. **Comorbidities N (%):** NR for pediatric patients. **Inclusion Criteria:** NR for pediatric patients. **Exclusion Criteria:** NR for pediatric patients.	**Intervention:** Bovine jugular vein conduits by Contegra, Medtronic. **Conduit size:** NR for pediatric patients. **Comparator:** Homograft and stentless xenograft. **Indication for use:** Ross Procedure (details NR for pediatric patients). **Follow-up period** (for Contegra subgroup): • **Median (IQR)**: 11 (9-15) years • **Mean (SD)**: 12 (4) years	**All-cause Mortality, N (%):** NR for pediatric patients. **Freedom from reintervention, %:** Probability of freedom from reintervention at 5 years was 83% (Number at risk = 4). **Note**: In pediatric patients, freedom from reintervention at 5 years was similar in the Contegra, homograft, and xenograft groups (83% vs 75% vs. 100%; p = 0.697). **Infective Endocarditis, N (%):** 2/4 (50%) (at a mean follow-up of 6.2 [SD: 3.4] years post-operation). **Additional information (Combined data reported for Contegra, homograft, and xenograft):** • The hazard of reintervention was higher in pediatric patients than adult patients for all 3 RV conduit types: HR = 0.91, 95% CI, 0.87 to 0.95, p<.001 (data NR for pediatric Contegra subgroup). • All the patients who developed early degeneration among all 3 conduit types (within the first 4 years) without reoperation were pediatric or young adults. **Note:** The study included homograft, stentless xenograft, and BJV patients. Contegra was the only BJV conduit used. Only data for patients under 18 years of age who received the Contegra conduit are included in this table.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Al Kindi et al., 2024[5] **Country:** Oman **Study Design:** Case Report **Objective:** To describe an unusual example of a double-outlet right atrium with separate atrioventricular junctions. **Funding:** The author(s) received no financial support for this article's research, authorship, and/or publication. **Conflict of interest:** The author(s) declared no potential conflicts of interest.	**Patients (N):** 1 **Age:** 1 year **Sex:** Male **Diagnosis:** Double-outlet right atrium with separate AV junctions. **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra, Medtronic **Conduit size**: 16 mm **Comparator:** NA **Indication for use:** Surgical repair of double-outlet right atrium with separate AV junctions. **Follow-up period:** NR, post-operative data reported.	**All-cause Mortality**: NR **Post-operative AE**: No AE was reported post-operatively. **Note**: The postoperative TEE showed good inflow across the mitral valve, with the right orifice of the tricuspid valve showing neither stenosis nor regurgitation.
Reference: Boudjemline et al., 2024[6] **Country:** Qatar **Study Design:** Case Report **Objective:** To report an innovative extension of a technique for transcatheter extracardiac Fontan completion that may allow patients to receive an extracardiac Fontan at 2 years/11 kg without additional surgery. **Funding:** NR **Conflict of interest:** The authors declare no conflict of interest.	**Patients (N):** 1 **Age:** 2 years **Sex:** Male **Diagnosis:** Hypoplastic left heart syndrome, mitral atresia, partial anomalous pulmonary venous return, VSDs, and interrupted aortic arch. **Race/ethnicity N (%):** NR **Comorbidities N (%):** The patient's cardiac disease was associated with multiple comorbidities, including severe tracheo-broncho-malacia for which the patient required long-term ventilation, left bronchus stenting with a biodegradable stent, and tracheostomy. The patient later developed severe TVR. **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra, Medtronic **Conduit size**: 16 mm **Comparator:** NA **Indication for use:** Tricuspid valve repair and transcatheter Fontan completion by creating an extracardiac Fontan. **Follow-up period, total:** 7.5 months (mean follow-up NR)	**All-cause Mortality**: NR **Post-operative AE**: No AE was reported post-operatively. **Note**: The postoperative transesophageal echocardiography showed the good repair of the tricuspid valve, the absence of stenosis on the IVC anastomosis, and the patency of the large unobstructed fenestration. **Long-term AE (>90 days post procedure):** • At 7.5-month follow-up, the patient did not experience any complications. • No arrhythmia was recorded **Note:** No special antibiotic therapy was started for the Contegra conduit except regular antibiotic prophylaxis before interventions or surgery.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Cetera al., 2024[7] **Country:** Italy **Study Design:** Case Report **Objective:** To report a rare case of invasive and destructive *A. defectiva* IE of the aortic valve and the aortic wall in a 3-year-old child, in follow-up after surgical valvuloplasty for congenital AS. **Funding:** None declared. **Conflict of interest:** None declared.	**Patients (N):** 1 **Age:** 3 years **Sex:** Male **Diagnosis:** Abiotrophia defectiva IE of the aortic valve and the aortic wall in a child with congenital AS after neonatal surgical valvuloplasty. Note: The child presented with signs of left-sided hemiplegia. **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra, Medtronic **Conduit size**: 20 mm **Comparator:** NA **Indication for use:** Emergency Ross–Konno operation for severe AR (due to a large vegetation extending to the aortic wall up to the aortic arch) and moderate TVR with signs of pulmonary hypertension and pulmonary oedema. **Follow-up period:** Until 6 months after surgery.	**All-cause Mortality**: NR **Post-operative AE**: The night after surgery, due to progressive signs of right ventricular failure, the sternum was reopened. Clinical improvements and hemodynamic stability allowed for successful sternal closure on the fifth post-operative day. At the same time, considering the persisting complete AV block, the permanent pacemaker was implanted. **Tricuspid valve regurgitation:** Within 45 days of surgery, on TTE assessment, residual moderate to severe TVR was revealed, with no clinical consequences. After 6 months of surgery: On TTE assessment, TVR remained stable, with an estimated systolic pulmonary pressure of 35 mmHg. **Note**: TTE within 45 days after surgery confirmed the good surgical results on the neo-aortic valve and good ventricular function. 6 months after surgery, the child was asymptomatic and was on medical therapy (diuretic, beta-blocker, and aldosterone antagonist). The review part of this publication reported on published pediatric cases of A. defectiva endocarditis; however, all the case reports were dated outside the included date range for this update.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Gonzalez-Calle al., 2024[8] **Country:** Switzerland **Study Design:** Case Report **Objective:** To present a case of Ventricular Switch as an alternative to single-ventricle palliation. **Funding:** NR **Conflict of interest:** The author(s) declared no conflicts of interest.	**Patients (N):** 1 **Age:** 10 years **Sex:** Male **Diagnosis:** Double-outlet RV, severe PA stenosis, ASD, and a non-committed restrictive muscular VSD with hypoxemia. **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra, Medtronic **Conduit size**: 14 mm **Comparator:** NA **Indication for use:** Ventricular switch with a one-and-a-half ventricle strategy: hemi-mustard, maintaining the superior cavopulmonary connection, VSD closure, pulmonary trunk division and closure, and implantation of Contegra conduit connecting the LV to the PA. **Follow-up period:** Until the death of the patient, which was two weeks after the operation.	**All-cause Mortality**: The patient died 2 weeks after the operation. The patient developed chest discomfort, followed by cardiac arrest with no response to resuscitation. **Autopsy findings**: Massive myocardial infarction of the hypertrophied systemic RV and subendocardial fibrotic lesions but unobstructed coronary arteries, venous pathways, and Contegra conduit.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Haddad al., 2024[9] **Country:** France **Study Design:** Case Report **Objective:** To describe a case of postoperative catheter thromboaspiration to open an occluded RV-PA conduit in a child. **Funding:** NR **Conflict of interest:** The author(s) declared no potential conflicts of interest.	**Patients (N):** 1 **Age:** 6 years **Sex:** Female **Diagnosis:** Severe native aortic valve insufficiency acquired after a late diagnosis of Methicillin-sensitive Staphylococcus Aureus endocarditis. **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra VenPro, Medtronic **Conduit size**: 18 mm **Comparator:** NA **Indication for use:** Urgent Ross procedure involving the placement of an 18 mm Contegra VenPro conduit from the RV–PA. **Follow-up period:** Immediate post-operative data were reported. The patient was followed up for three months after the postoperative catheter thrombaspiration.	**All-cause Mortality, N (%)**: NR **Post-operative AE**: At the end of the surgery, the patient developed LV akinesia and required central veno-arterial ECMO with full assistance and a transmitral LV decompression cannula. **Conduit thrombosis:** **On postoperative day 4**, small clots in the ECMO circuit were identified despite heparinization, and the circuit was replaced. **On postoperative day 6**, the RV was severely dilated despite the support, and there was no anterograde conduit flow. A cardiac CT scan suggested complete conduit thrombosis, and a head scan showed no active bleeding. The patient had urgent cardiac catheterization to restore the RV–PA flow. Angiography demonstrated complete conduit occlusion. Treatment: Thromboaspiration, IndigoVR aspiration system from PenumbraVR (Alameda, USA) to mechanically dissolve and remove the thrombus, restore flow, gradually wean from extracorporeal support, and replace the conduit after postoperative day 10. **Note**: Three-month follow-up outcomes were reported as good.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Ilhan et. al., 2024[10] **Country:** Turkey **Study Design:** Case Report **Objective:** To report a case of a newborn diagnosed with Townes–Brocks syndrome with absent pulmonary valve and TOF and who was found to carry the most common pathogenic SALL1 gene mutation c.826C > T (p.R276X). **Funding:** R. B. acknowledges funding by grants BFU2017–84653-P (MINECO/FEDER, EU), SEV-2016–0644 (Severo Ochoa Excellence Program), 765445-EU (UbiCODE Program), and SAF2017–90900-REDT (UBIRed Program). **Conflict of interest:** The author(s) declared no potential conflicts of interest.	**Patients (N):** 1 **Age:** 6 months **Sex:** Female **Diagnosis:** Townes–Brocks syndrome with absent pulmonary valve syndrome-TOF **Race/ethnicity N (%):** NR **Comorbidities N (%):** NR **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra, Medtronic **Conduit size**: 12 mm **Comparator:** NA **Indication for use:** Surgical repair of absent pulmonary valve syndrome-TOF and dilated PAs (procedure conducted on the 85th day of life). Note: The Contegra conduit was sutured between the pulmonary bifurcation and the RV outflow tract. **Follow-up period:** Until the death of the patient, which was 29 days after surgery.	**All-cause Mortality, N (%)**: The patient died 29 days after the surgery, at the 6th month of life, due to pneumonia and sepsis. **Autopsy findings**: NR **Note**: The patient could not be extubated until postoperative day 29 due to high ventilation pressures under mechanical ventilation. Due to the extended intubation period, tracheotomy was performed.

Study details	Patient Characteristics	Intervention(s)	Safety Outcomes Assessed for Contegra
Reference: Sultan al., 2024[11] **Country:** Denmark **Study Design:** Case Report **Objective:** To present a rare case report and literature review based on a complicated presentation of *S. enteritidis* endocarditis in an immunocompetent 8-year-old child with a MAV. **Funding:** This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. **Conflict of interest:** The author(s) declared no potential conflicts of interest.	**Patients (N):** 1 **Age:** 8 years **Sex:** NR **Diagnosis:** Congenital truncus arteriosus. **Race/ethnicity N (%):** NR **Comorbidities N (%):** Unilateral kidney agenesis. **Inclusion Criteria:** NA **Exclusion Criteria:** NA	**Intervention:** Bovine jugular vein conduit by Contegra, Medtronic **Conduit size**: NR **Comparator:** NA **Indication for use:** VSD closure and implantation of an RV-PA Contegra graft at the age of one month. Other surgeries: A truncal valvuloplasty at two months of age, and a MAV implantation, accompanied by an upgrade in the size of the RV-PA Contegra graft, at four years of age. In addition, the patient received stenting of the right PA and had undergone multiple bilateral percutaneous balloon pulmonary angioplasty procedures. **Follow-up period:** 4 years (the patient was followed from age 4, when the Contegra conduit was implanted (upsized), through age 8).	**All-cause Mortality, N (%)**: NR **Infective endocarditis (S. enteritidis)**: The patient was diagnosed with IE (*S. enteritidis*) at 8 years of age. A Contegra graft had been implanted at one month of age, and the Contegra conduit was upsized at four years of age. **Note**: The authors did not attribute IE to the Contegra graft. TEE reported a multiloculated abscess surrounding the MAV annulus, a valvular aortic vegetation, and a pseudoaneurysm at the aortic root. The RV-PA conduit was unaffected in TEE. The review part of this publication reported on published pediatric cases of *Salmonella endocarditis*; however, all the case reports were dated outside the included date range for this update.

Abbreviations: AE: Adverse Event; AI: Aortic Insufficiency; AR: Aortic Regurgitation; AS: Aortic Stenosis; AV: Atrioventricular; AVB: Atrioventricular Block; BAV: Balloon Aortic Valvuloplasty; BJV: Bovine Jugular Vein; CHD: Congenital Heart Disease; CI: Confidence Interval; CPR: Cardiopulmonary Resuscitation; CT: Computed Tomography; CCT: Cardiac Computed Tomography; ECMO: Extracorporeal Membrane Oxygenation; HR: Hazard Ratio; IQR: Interquartile Range; IE: Infective Endocarditis; LV: Left Ventricle; MAV: Mechanical Aortic Valve; NA: Not Applicable; NR: Not Reported; PA: Pulmonary Artery; RV: Right Ventricle; RV–PA: Right Ventricle to Pulmonary Artery; SD: Standard Deviation; SLL: SALL1 Gene Mutation (e.g., c.826C > T (p.R276X)); TBS: Townes–Brocks Syndrome; TEE: Transesophageal Echocardiography; TOF: Tetralogy of Fallot; TTE: Transthoracic Echocardiography; TVR: Tricuspid Valve Regurgitation; US: United States; VSD: Ventricular Septal Defect.