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 September 16, 2026 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 2025 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 338 devices were sold in the U.S., and 202 devices were implanted. At least 113 of the devices were implanted in pediatric (<22 years) patients. For 85 out of the 202 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 subject 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 36 MDRs regarding Contegra identified in the FDA's MDR database between April 1, 2025 and February 28, 2026[1]. [1. Please note that the reporting period for this year's analysis is 10 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 03/01/26 – 2/28/27 to account for this adjustment.] Of the 36 MDRs, 3 MDRs were unrelated to patient outcomes and 10 MDRs were

sourced from journal articles. The 10 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 23 MDRs, all submitted by the manufacturer.

Patient Demographic Data

Of the 23 MDRs, 22 (96%) were received from the United States. Patient sex information was included in 22 MDRs; 11 involved males and 11 involved females. Patient age was included in 22 MDRs; 18 were pediatric patients and 4 were adults. Table 1 summarizes this information.

Table 1: Patient Demographic Data (Total 23 MDRs; involve 18 pediatric patients)

Demographic Data		Percentage	Number of MDRs containing the demographic
Reporting Country	US : OUS	96% : 4%	22 : 1 (23 Total)
Patient Sex	Male : Female	50% : 50%	11 : 11 (22 Total)
Patient Age	Pediatric : Adult	82% : 18%	18 : 4 (22 Total)
Pediatric Only: Age Range: 6 months – 21 years; Average Age: 10.8 ± 8.2 years			

Primary Reported Events

The 23 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 2026 PAC Review

		Patient Age (year)		TTEO (month)*	
Primary Reported Event	**Total MDR Count**	**Pediatric (<22)**	**Adult (≥22)**	**Range**	**Mean**
Stenosis**	**9**	6	2	0 – 203	86
Device replaced (reason not provided)	**7**	5	2	0 – 119	32
Arrhythmia	**3**	3	0	47 – 138	93
Endocarditis/Infection	**2**	2	0	0 – 56	28
Valve regurgitation	**2**	2	0	51 – 81	66
Grand Total	**23**	18	4		

*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.

**One (1) MDR indicating stenosis did not include patient age.

A comparison of the primary events reported in the MDRs for the current analysis period with those from 2023, 2024, and 2025 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 2017-2026 please see Appendix A. It should be noted that although there is an increase in the percentage of MDRs describing arrhythmia events this year, this may be a reflection of a smaller amount of total MDRs reported during the reporting period. As shown in Appendix A, the number of arrhythmia events has been generally consistent since 2017.

Table 3: Comparison of Primary Reported Events for Contegra MDRs in 2023, 2024, 2025 & 2026

Primary Reported Event	2023 PAC	2024 PAC	2025 PAC	2026 PAC
	MDR Count (%)	MDR Count (%)	MDR Count (%)	MDR Count (%)
Device replaced (reason not provided)	34 (55.8%)	17 (44%)	9 (21.4%)	7 (30.4%)
Stenosis	15 (25%)	11 (28%)	14 (33.3%)	9 (39.1%)
Valve regurgitation/ Insufficiency	1 (1.6%)	4 (10%)	5 (11.9%)	2 (8.7%)
Inadequate size for patient	3 (5%)	3 (8%)	0	0
Thrombus	1 (1.6%)	2 (5%)	1 (2.4%)	0
Arrhythmia	0	1 (2.5%)	6 (14.3%)	3 (13.1%)
Infection/endocarditis/sepsis	5 (8%)	1 (2.5%)	6 (14.3%)	2 (8.7%)
Conduit dilation/aneurysm	2 (3%)	0	0	0
Degeneration	0	0	1 (2.4%)	0
Total	**42**	**61**	**42**	**23**

The primary events reported in the 23 MDRs involving 23 injuries are summarized below.

Stenosis (n=9 MDRs; 6 pediatric patients)

Stenosis of conduit or pulmonary artery was the most frequently reported event. In these 9 reports, stenosis (in conjunction with calcification, obstruction, pulmonary regurgitation or insufficiency, and/or elevated pressure gradients) was identified in patients between day of implant and 17 years post implant.

Of the stenosis reports, all (9 MDRs involving 6 pediatric patients) but 2 events reflected late events of stenosis (greater than one-year post implant) and the patients required interventions between 4 to 17 years post implant without additional adverse effects reported.

Overall, the interventions required for the 7 patients with late events of stenosis included transcatheter pulmonary valve (TPV) implantations conducted as valve-in-valve (4) and surgical replacement of the pulmonary valve (3).

Two (2) MDRs reflected early events of stenosis. One (1) MDR indicated an early event of stenosis in a 5-month-old child reported 7 months post implant of a 12mm conduit. The patient had developed focal narrowing of the right pulmonary artery (RPA). The patient underwent a cardiac catheterization and stent angioplasty of the RPA. One (1) MDR indicated that post implant of an 18mm Contegra conduit,

the patient experienced stenosis and mild regurgitation.

Device replacement[2]– reason for replacement not reported (n=7 MDRs; 5 pediatric patients)

[2."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.]

Seven (7) MDRs indicate that Contegra was replaced, 5 involving pediatric patients. Although the reasons for the device replacement were not reported in the MDRs, 2 of the 5 reports described that the valved conduit was replaced with a larger conduit of the same model between 11 and 17 months post Contegra implant. Device replacement with a larger conduit may be due to patient outgrowth but was not specifically stated in these MDR reports. One (1) of the reports described that the conduit was replaced with a same sized conduit of a different model 8 days post-implant of Contegra. One (1) of the reports described that the conduit was replaced with a homograft 6 years post implant. One (1) MDR reported a Contegra conduit was explanted and replaced with a same sized Contegra conduit 9 years and 11 months post implant. 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.

Arrhythmia (n=3 MDRs; 3 pediatric patients)

Two (2) MDRs reported permanent pacemakers were implanted in two patients between 3 years and 8 years post-implant of the conduit. One event was due to complete heart block, and the other event was due to incomplete atrioventricular block. One (1) MDR describes a patient who was implanted with a defibrillator. The reason for the defibrillator implant was history of sustained ventricular tachycardia, atrial arrhythmias, atrial fibrillation, and atrial flutter.

Endocarditis/Infection (n=2 MDRs; 2 pediatric patients)

One (1) MDR reported endocarditis and stenosis in a patient 4 years and 8 months post-implant of the conduit. The conduit was explanted and replaced with a larger conduit of the same model. One (1) MDR reported fever in a patient the same day as implant of the Contegra device. The patient's antibiotic regimen was adjusted.

Valve Regurgitation (n=2 MDRs; 2 pediatric patients)

One (1) MDR reported that 4 years and 3 months post implant of Contegra the patient demonstrated moderate conduit regurgitation. The patient was being evaluated for physical outgrowth of the conduit. A cardiac catheterization to balloon or stent the conduit is planned. One (1) MDR described a patient who had a valve-in-valve replacement due to severe pulmonary central regurgitation. The central regurgitation was noted 6 years and 9 months post-implant of the original conduit.

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

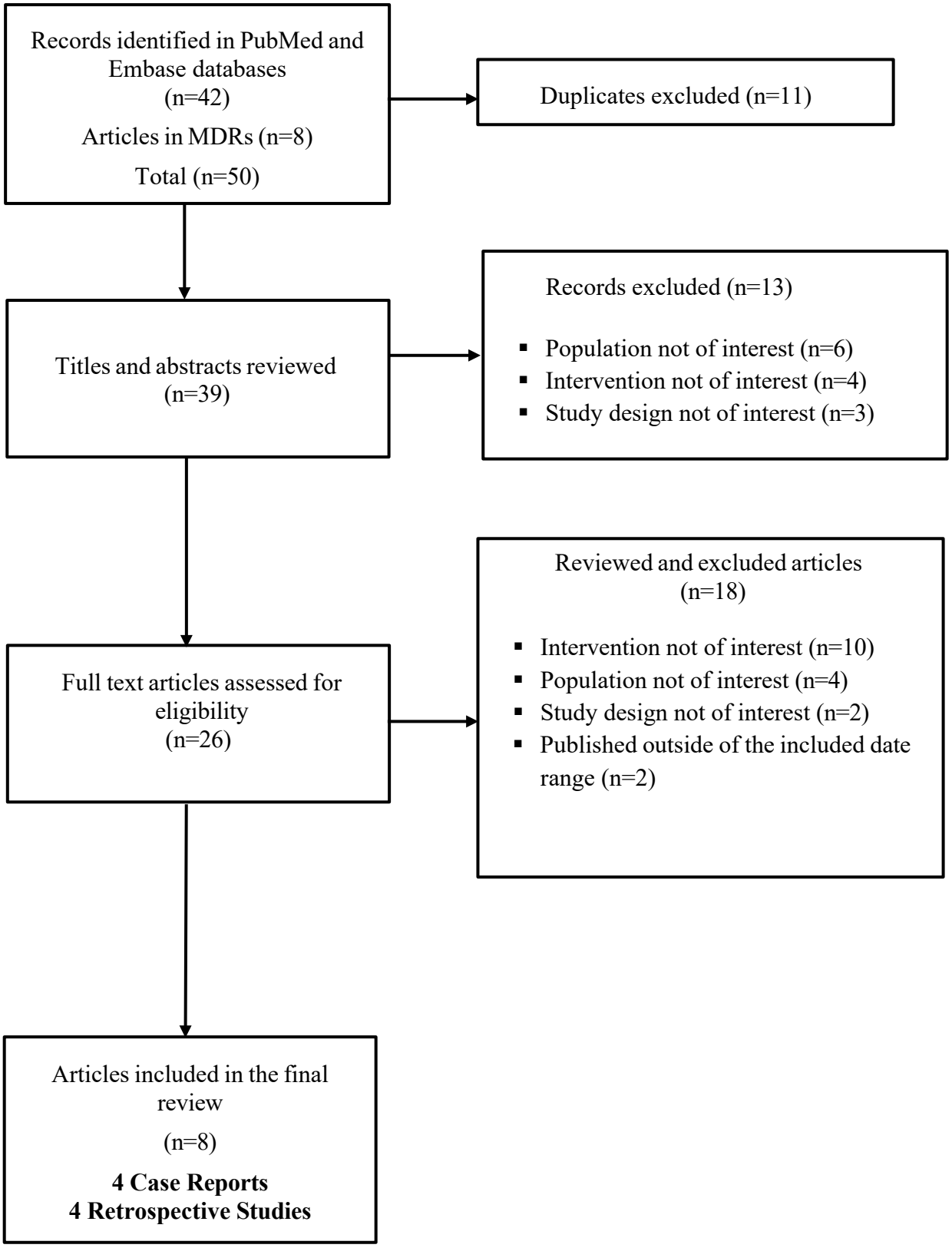
Purpose
The objective of this systematic literature review is to provide an update on the safety of the Contegra bovine jugular vein conduit (BJV) device when used in pediatric patients.

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 2025 literature review. The search was limited to articles published in English from 04/01/2025 through 02/28/2026.

Figure 2 depicts the article retrieval and selection process including the criteria for exclusion. A total of 42 (7 PubMed; 35 EMBASE) articles were retrieved. Of note, in addition to the 42 articles retrieved from PubMed and EMBASE databases, there were 8 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. Eleven articles were duplicates. The remaining 39 articles were subjected to review of titles and abstracts. Thirteen (13) articles were excluded from full-text review for reasons listed: Four (4) did not address the intervention of interest (i.e. did not include Contegra implants), three (3) did not include study designs of interest, and six (6) had no population of interest. Twenty-six (26) full-text articles were retrieved and screened. Of these 26 articles, 18 were excluded from further review for reasons listed: Two (2) articles were published outside the included date range, ten (10) had no intervention of interest, four (4) had no population of interest, and two (2) did not have a study design of interest.

A total of 8 articles were included in this systematic literature review.

Figure 2. Article retrieval and selection process



Characteristics of Publications Included in Evidence Assessment (n=8)

There were four case reports[1-4], three retrospective cohort studies[5-7] and one retrospective case series in this literature review.[8] Of the three retrospective cohort studies, one was conducted in the U.S.[7], one was conducted in Turkey[5] and one conducted in Sweden.[6] All four case reports were conducted outside the U.S. These case reports were from Iran (N = 1),[1] Australia (N = 1),[2] Japan (N = 1),[3] and Germany (N = 1).[4] The retrospective case series was conducted in Turkey[8].

Aside from the four case reports and one case series, the three cohort studies had a sample size that ranged from 50 patients to 487 patients total, and the number of pediatric patients who received the Contegra Pulmonary Valved Conduit ranged from 20 to 235 cases. In Temur et al., 2026[5], a total of 44 pediatric patients were treated with either a Contegra or Biointegral device. Among the 44 patients, six (13.6%) were lost to follow-up, and 20 patients in the Contegra group were assessed. In Lewis et al., 2025[6], a total of 487 patients or 686 cases of pulmonary valve implantation were included. Among the 686 cases, 235 were conducted using the Contegra valved conduit. Although the number of patients lost to follow-up was not reported for the Contegra group, the overall number of patients lost to follow-up was 20 (4.1%). In Samayoa et al., 2025[7], a total of 226 patients who underwent transcatheter pulmonary valve replacements was included. Among these patients, 37 (16.4%) received the Contegra valved conduit, but the study did not report the number of patients lost to follow-up.

The follow-up duration was reported in all studies. All three retrospective cohort studies had a long-term follow-up period, with all studies reporting mean or median follow-up durations greater than 3 years. Temur et al., 2026[5] had a follow-up duration of median (range) 68 (4.8 to 143.7) months. Samayoa et al., 2025[7] had a slightly shorter follow-up duration but was still considered to be long, with a median (range) of 38 (0.0 to 164.0) months. Lastly, Lewis et al., 2025[6] had the longest follow-up duration amongst the three cohort studies, with a mean follow-up duration of 8.5 years. The follow-up duration of the case reports and series varied considerably from 5 days to 3 years. Among the five studies, only one[4] case report reported a follow-up duration beyond 6 months.

Among the three retrospective cohort studies, two[5,6] provided patient age. Samayoa et al., 2025 did not provide the age of the 37 pediatric patients who received the Contegra implant separately from the total sample, which included adult patients. Temur et al, 2026[5] reported a median (range) patient age of 19 (3.0 to 36.0) months. Lewis et al., 2025[6] had a slightly higher patient age, with a mean (SD) patient age of 5.1 (8.8) years. The patient age in the case reports and series was also low and ranged from 2.5 months to 15 months old.

Additionally, among the three retrospective cohort studies, two[5,6] provide the sex distribution of patients who received Contegra implants. Both studies reported that the majority of included patients were male, with one[5] study reporting 14 (70.0%) male patients and the other[6] reporting 120 (51.1%) male patients. Samayoa et al., 2025[7] did not provide patient characteristics separately for the pediatric patients who received the Contegra implant. Across the seven patients included in five case studies, five (71.4%) patients were female. 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 was reported in two[5,8] studies. Temur et al., 2026[5] was a retrospective cohort study that included 20 patients who received the Contegra implant. The study reported that no (0.0%) patients had died at a median (range) in-hospital duration of 19.5 (5.0 to 63.0) days. Istar and Harmandar, 2025[8] was a case series that included three patients who received the Contegra implant. The study reported that one (33.3%) patient died due to ventricular failure despite extracorporeal membrane oxygenation (ECMO) support after 5 days of follow-up.

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

Long-term mortality (> 90 days post-procedure) was reported in two[5,8] studies. Temur et al., 2026[5], a retrospective cohort study, reported one (5.0%) patient who died at a median (range) follow-up of 68 (4.8 to 143.7) months. The study also conducted a Kaplan-Meier survival analysis of patients and reported that 20 (100.0%) patients survived at 1 year, 18 (90.0%) patients survived at 5 years, and 18 (90.0%) patients survived at 10 years. Istar and Harmandar, 2025[8], a retrospective case series, also reported one (33.3%) patient who died after 6 months of follow-up due to multiple complications related to long-term ICU admission.

No case report described long-term mortality.

Adverse events

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

In total, five[1,3-5,8] studies reported short-term adverse events defined as any complication that occurred ≤ 90 days post-procedure. These five studies included three[1,3,4] case reports, a retrospective cohort study[5], and the retrospective case series[8].

Temur et al., 2026[5] was a retrospective cohort study that had 44 patients allocated to either a Contegra valved conduit or a Biointegral valve. The study did not provide the specific complications that the patients experienced but only provided the number of patients with an unspecified complication. At the median (range) follow-up of 19.5 (5.0 to 63.0) days, Temur et al., 2026[5] reported four (20.0%) patients with unspecified complications.

Istar and Harmandar, 2025[8] was a retrospective case series that followed three patients after a Contegra valved conduit implant. In the study, all three patients reported short-term complications that occurred ≤ 90 days post-procedure. Among the three patients, one (Case 1) reported no (0.0%) unspecified postoperative complication at 12 days of follow-up. Another patient (Case 2) had a bronchospasm requiring mechanical respiratory support and obstructive effects of secretion after 24 hours post-operatively. Lastly, ventricular dysfunction was observed 5 days after the procedure in the last patient (Case 3).

In total, three[1,3,4] case reports provided short-term complication outcomes in pediatric patients who received a Contegra valved conduit. Jalali et al., 2026[1] described a patient who received a Contegra valved conduit and reported a right ventricular pressure that was less than 70% of the left ventricular pressure

after 1 week of follow-up. In Takao et al., 2025[3], the patient was weaned from the bypass uneventfully, and the study observed no signs of pulmonary stenosis, baffle leakage, or pressure gradient across the left ventricle to the aortic valve after 3 months of follow-up. Lastly, Linnenbank et al., 2025[4] reported one patient with mild congestion of the hepatic veins and restricted right ventricle (RV) function 1 day post-operatively. Additionally, after 3 months of follow-up, the patient assessment revealed acute right heart decompensation with increasing dilation, functional impairment of the RV, moderate to severe tricuspid valve (TV) insufficiency, and dilation of the right ventricle-pulmonary artery (RV-PA) conduit. The patient also had pulmonary valve insufficiency due to an impaired pocket coaptation. Severe bifurcation stenosis and low-grade mitral valve insufficiency were complications that were all identified after 3 months of follow-up. However, no signs of pleural or pericardial effusion were observed for this patient[4].

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

Long-term complications were reported in two case reports. In Konstantinov E., 2025, the patient had trivial truncal valve insufficiency after 5 months of follow-up. However, the study also noted that during the post-operative period, the patient had excellent biventricular function and was asymptomatic at 5 months. Linnenbank et al., 2025[4] followed the patient for 36 months. It is important to note that after the initial Contegra implant, the patient underwent a tricuspid reconstruction via cleft closure, bifurcation of the peripheral pulmonary arteries, and replacement of the initial conduit with the same valve. After 9 months of follow-up from the initial Contegra implant procedure, and 5 months after the replacement, the patient was diagnosed with a moderate TV insufficiency, a grade I mitral valve insufficiency, a functional TV impairment, a global mural dysfunction and dilation, a ventricular wall thinning, and a significant dilation of the right atrium. However, the conduit valve showed adequate function with mild insufficiency, but stenosis was not observed. Lastly, Linnenbank et al., 2025[4] reported a severe right pulmonary artery branch stenosis at 33 months of follow-up from the initial Contegra implant and 18 months after the implant replacement. The branch stenosis was followed by a severe functional impairment of the dilated RV with an ejection fraction of 11%. However, after reoperation, the patient's RV function and dilation improved significantly. At 36 months of follow-up from the initial implant (21 months after the implant replacement), the patient reported good general condition with no signs of reduced exercise tolerance.

Infective Endocarditis

Among the eight included studies, infective endocarditis was reported in two[6,7] retrospective cohort studies. Lewis et al., 2025[6] included 487 patients who underwent 686 cases of valve implant due to congenital heart disease. Among the 686 cases, 235 utilized the Contegra valved conduit implant. The study had a mean follow-up duration of 8.5 years and reported the number of cases with prosthetic pulmonary valve infective endocarditis (PPVIE), annualized incidence of PPVIE, freedom from PPVIE, and the hazard ratio of the Contegra valved conduit as a risk factor for PPVIE. Samayoa et al., 2025[7] included 226 patients, of whom 37 underwent Contegra valved conduit implantation.

Samayoa et al., 2025[7] reported that among the 37 patients who received Contegra implants, 5 (13.5%) developed infective endocarditis at a median (range) follow-up of 38 (0.0 to 164.0) months. Lewis et al., 2025[6] reported that 21 (8.9%) of the 235 cases receiving Contegra implant procedures reported PPVIE at a mean follow-up of 8.5 years. The study also reported that the annualized incidence rate of PPVIE was 1.05% for patients who received the Contegra implant. Freedom from PPVIE analysis showed that, among the cases who received the Contegra implant, the 5-year, 10-year, and 21.2-year freedom from PPVIE proportions were 94.3%, 89.9%, and 74.1%, respectively. The study used the aorta homograft as the reference cohort in the risk factor analysis. In the univariate Cox regression analysis, Lewis et al.,

2025[6] reported that, as a pulmonary valve type, patients receiving Contegra valved conduits had an estimated hazard ratio (HR) (95% confidence interval (CI) of 14.51 (3.14 to 67.09), $p < 0.0001$ for PPVIE compared to the aorta homograft group, suggesting that the Contegra device was associated with statistically significantly increased risk of PPVIE. Similarly, in the univariate analysis considering Contegra as a conduit type, the Contegra device was also significantly associated with increased PPVIE risk, with an estimated HR (95% CI) of 9.47 (2.68 to 33.51), $p < 0.001$, compared to aorta homograft treatment. Similar findings were observed after multivariable adjustment, where Contegra as a pulmonary valve type showed a similar estimated HR (95% CI) of 12.47 (2.66 to 58.44), $p = 0.001$, suggesting that the Contegra device was a statistically significant risk factor for PPVIE.

Conduit Replacement and Reintervention

Two[4,5] studies reported replacement or reintervention outcomes in pediatric patients who received the Contegra valved conduit implant. Temur et al., 2026[5] was a retrospective cohort study that included 20 patients who received Contegra implants. The study had a median (range) follow-up duration of 68 (4.8 to 143.7) months. Linnenbank et al., 2025[4] was a case report that followed a patient for three years.

Replacement

Two[4,5] studies reported replacement of the Contegra valved conduit during the post-operative follow-up period. In Temur et al., 2026[5], one (5%) patient had a previously implanted Contegra conduit valve replaced at a median (range) follow-up duration of 68 (4.8 to 143.7) months. In Linnenbank et al., 2025[4], 3 months after the initial Contegra valved conduit replacement, the patient underwent a replacement of the valve at the age of 1.5 years. Prior to the Contegra valved conduit replacement, the patient had a severe stenosis of the peripheral pulmonary arteries in the area of the distal anastomosis.

Reintervention

Two[4,5] studies reported reintervention in patients who received a Contegra valved conduit implant. Temur et al., 2026[5] reported one (5%) patient who underwent transcatheter pulmonary valve replacement and reported another (5%) patient who underwent conduit balloon angioplasty after Contegra valved conduit implant at a median (range) follow-up duration of 68 (4.8 to 143.7) months. The study noted that the reason for reintervention of the conduit was either due to stenosis or regurgitation. Additionally, unlike the patients who received the Biointegral valves, no (0.0%) patients underwent conduit stenting after the initial Contegra valved conduit implant procedure. In Linnenbank et al., 2025[4], the patient underwent stent implant due to a dilated RV with severe functional impairment at 33 months after the initial Contegra implant, 18 months after the replacement surgery. Furthermore, Temur et al., 2026[5] conducted a freedom from reintervention analysis of patients who received the Contegra valved conduit implant. The study reported that the freedom from reintervention proportions at 1 year, 5 years, and 10 years were 100.0%, 94.1%, and 47.1%, respectively. The study noted that the difference in freedom from reintervention was significantly improved in the Contegra cohort compared to the Biointegral cohort, with a p-value of 0.024. The authors concluded that Contegra is a valuable alternative to homografts that showed significantly better survival and freedom from reintervention outcome when compared to Biointegral treatment.

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 April 1, 2025, and February 28, 2026. 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 2025 review, infective endocarditis was the most common adverse event reported across publications. Reported infective endocarditis rates in the two publications are consistent with rates reported in prior years and are actively being monitored. The other AEs reported were acute right heart decompensation with increasing dilation, functional impairment of the RV, dilation of the RV-PA conduit, severe bifurcation stenosis, obstructive effects of secretion, bronchospasm requiring mechanical respiratory support, ventricular dysfunction, moderate TV insufficiency, and mitral valve insufficiency. Conduit replacements and reinterventions were also discussed, as well as perioperative and long-term mortality.

Among the included studies, three[5-7] were retrospective cohort studies that had sample sizes ranging from 50 to 487 patients, though the subgroup of patients treated with Contegra valved conduits was smaller, ranging from 20 to 235 patients. A limitation noted in one of the retrospective cohort studies is that it did not provide the age of the pediatric patients who received the Contegra implant separately from the total sample, which included adult patients. Age-disaggregated data are important for pediatric studies and should be encouraged to be reported in future studies. The majority of the studies were case studies, which included four[1-4] case reports that followed a single patient and one[8] case series that followed three patients. All of the included studies were observational designs, which imply potential weaknesses in internal and external validity that are inherent to these study designs. Specifically, unmeasurable confounding variables, selection bias, the lack of a control group, and the lack of blinding of researchers, patients, and outcome assessors were aspects of the studies included in this review that impact internal validity and warrant consideration. Regarding external validity, only one[7] study was conducted in the U.S.; thus, the findings may not be applicable to the U.S. population overall. On the other hand, the studies included in this review appeared to be very similar to the target population in terms of the indications for pediatric patients who received Contegra valved conduit implants, enhancing generalizability of the study findings to the indicated patient population.

The Newcastle-Ottawa Scale was applied to three[5-7] retrospective cohort studies, given that this scale applies to cohort and case-control study designs. Overall, the quality of the three studies was high, with an assessment of a Fair to Good rating. Temur et al., 2026[5] received 9/9 stars and received a good rating. However, Lewis et al., 2025[6] received 7/9 stars and received a fair rating. The study received no stars in the comparability criteria, as the two cohorts had significant differences in mean age, and the p-values for the other patient characteristics were not provided. Samayoa et al., 2025[7] also received a good rating with 8/9 stars. The study lost one star for the follow-up criteria, as it did not provide information regarding patients that were lost to follow-up. Given the characteristics described above, the overall body of evidence in this report was rated as moderate quality.

Commercial or manufacturer-related funding and conflicts were not prominent across the included studies. Among the eight studies, only one[2] did not report funding information. Six[1,3,4,6-8] studies reported not receiving any funding to conduct the studies. One[5] study reported receiving funding from the Scientific and Technological Research Council of Türkiye research foundation. Regarding conflicts of interest (COI), one[2] study did not report COI information for the authors, while the other seven studies declared no COIs.

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.

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 2027:

- Annual distribution number
- MDR review and
- Literature review

REFERENCES

1. Jalali A, Mahdavi M, Ganjifard M, et al. An extremely rare tetralogy of Fallot with absent pulmonary valve and unilateral absence of the pulmonary artery: a rare report of De Bucket Syndrome. Article. *Egyptian Heart Journal*. 2026;78(1). doi:10.1186/s43044-025-00712-5
2. Konstantinov IE. Redo truncal valve surgery: Repair or replacement? Article. *Journal of Thoracic and Cardiovascular Surgery*. 2025;170(5):e111-e115. doi:10.1016/j.jtcvs.2025.07.002
3. Takao H, Hoashi T, Nabeshima T, Suzuki T. Utility of Three-Dimensional Holographic Workstation for Preoperative Simulation of Complex Congenital Heart Surgery. Article. *Interdisciplinary Cardiovascular and Thoracic Surgery*. 2025;40(11). doi:10.1093/icvts/ivaf258
4. Linnenbank P, Biermann D, Schneider EP, et al. A Staged Biventricular Approach Combining the Starnes and Cone Procedures in Ebstein's Anomaly: A Case Report and Literature Review. Review. *Children*. 2025;12(6). doi:10.3390/children12060782
5. Temur B, Gokce I, Tire Y, et al. Outcomes of Bovine Jugular Vein Versus Porcine Valved Conduits for Right Ventricle to Pulmonary Artery Connection. *Pediatr Cardiol*. Mar 2026;47(3):1135-1141. doi:10.1007/s00246-025-03885-7
6. Lewis MJ, Malm T, Hallbergson A, Odermarsky M, Liuba P. Prosthetic pulmonary valve infectious endocarditis in paediatric congenital heart disease patients. *Interdiscip Cardiovasc Thorac Surg*. Jun 4 2025;40(6). doi:10.1093/icvts/ivaf102
7. Samayoa JC, Carlozzi L, Choi C, et al. Serial Changes in Right Ventricular Outflow Tract Gradient and Endocarditis Risk After Transcatheter Pulmonary Valve Replacement. *Catheter Cardiovasc Interv*. Sep 2025;106(3):2026-2036. doi:10.1002/ccd.70027
8. İştar H, Harmandar B. Tetralogy of Fallot with Absent Pulmonary Valve Syndrome: A Case Series. Article. *Duzce Medical Journal*. 2025;27(2):219-222. doi:10.18678/dtfd.1614737

Appendix A: Supplemental Table

Table 4. Comparison of Primary Reported Events for Contegra MDRs from 2017 – 2026

	MDR Count (%)									
Primary Reported Event	**2017 PAC**	**2018 PAC**	**2019 PAC**	**2020 PAC**	**2021 PAC**	**2022 PAC**	**2023 PAC**	**2024 PAC**	**2025 PAC**	**2026 PAC**
Stenosis	37 (44%)	33 (63%)	51 (48%)	36 (39%)	20 (33.3%)	13 (31%)	15 (25%)	11 (28%)	14 (33.3%)	9 (39.1%)
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%)	7 (30.4%)
Valve regurgitation/ insufficiency	5 (6%)	2 (4%)	6 (6%)	7 (8%)	0	3 (7%)	1 (1.6%)	4 (10%)	5 (11.9%)	2 (8.7%)
Inadequate size for patient	0	0	4 (4%)	3 (3.3%)	0	1 (2.3%)	3 (5%)	3 (8%)	0	0
Arrhythmia	2 (2.3%)	0	2 (2%)	4 (4.4%)	3 (5%)	1 (2.3%)	0	1 (2.5%)	6 (14.3%)	3 (13.1%)
Increased pressure gradient	1 (1.2%)	2 (4%)	2 (2%)	2 (2%)	0	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%)	2 (8.7%)
Conduit dilation/aneurysm	2 (2.3%)	1 (2%)	1 (1%)	2 (2%)	0	2 (5%)	2 (3%)	0	0	0
Pulmonary edema/hemorrhage	0	1 (2%)	0	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%)	0
Adhesions	0	0	0	1 (1%)	0	0	0	0	0	0
Unknown	0	0	0	1 (1%)*	0	0	0	0	0	0
Degeneration	0	0	0	0	0	0	0	0	1 (2.4%)	0
Total	**84**	**52**	**106**	**92**	**60**	**42**	**61**	**39**	**42**	**23**

**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)	Outcome
Reference: Jalali et al., 2026[1] **Country**: Iran **Study Design:** Case report **Objective:** To describe an extremely rare case of OTF with both APV and absent PA in a 1-year old girl. **Funding**: The authors declare no funding. **Conflict of interest**: The authors declare no competing interests.	**Sample size, (N)**: 1 patient **Lost to follow-up, n (%)**: 0 (0.0) **Age**: 12 months **Sex, n (%)**: Female: 1 (100.0) **Diagnosis, n (%)**: Subaortic VSD: 1 (100.0) Absent PV: 1 (100.0) Absent pulmonary artery: 1 (100.0) Stenotic right pulmonary artery ostium: 1 (100.0) TOF: 1 (100.0) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: Bronchomalacia: 1 (100.0) **Inclusion Criteria**: NA **Exclusion Criteria**: NA	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: 14 mm **Comparator**: NA **Indication for use**: Prevention of future airway compression and pulmonary valve insufficiency **Follow-up period**: 1 week	**Mortality, n (%)**: NR **Safety, n (%)**: **RV pressure less than 70% of left ventricular pressure at 1 week**: 1 (100.0) *Patient's oxygen saturation improved from 90% to 100%, and was discharged from the ICU after 1 week.

Study Details	Patient Characteristics	Intervention(s)	Outcome
Reference: Temur et al., 2026[5] **Country**: Turkey **Study Design:** Retrospective cohort study **Objective:** To analyze the outcomes of patients with bovine jugular vein conduit (Contegra) and porcine valved conduit (Biointegral) in terms of survival and reintervention rate. **Funding**: Open access funding provided by the Scientific and Technological Research Council of Türkiye (TÜBİTAK). **Conflict of interest**: The authors declare no competing interests.	**Sample size, (N)**: 44 patients Contegra arm: 20 patients **Lost to follow-up, n (%)**: 6 (13.6%) **Age, median (range)**: 19 (3.0 to 36.0) months **Sex, n (%)**: Male: 14 (70.0) Female: 6 (30.0) **Diagnosis, n (%)**: TGA-VSD-PS: 4 (20.0) VSD-PA: 16 (80.0) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: Previous intervention: 18 (90.0) **Inclusion Criteria**: Patients were included if they underwent RV-PA conduit implantation during CHD repair between 2012 and 2023. **Exclusion Criteria**: Patients who underwent TA repair, unifocalization, Ross, and Yasui procedures were excluded from the study for uniformity of the patients. *Data from the Biointegral arm and associated p-values against the Contegra arm were not extracted.	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size, median (range)**: 18 (16.0 to 20.0) mm **Comparator**: Porcine valved conduit (Biointegral, Biointegral Surgical Inc, Ontario, Canada) **Indication for use**: Repair of CHD **Follow-up period, median (range)**: 68 (4.8 to 143.7) months	**Mortality, n (%)**: **In-hospital mortality at median (range) FU of 19.5 (5.0 to 63.0) days**: 0 (0.0) **Long-term morality at median (range) FU of 68 (4.8 to 143.7) months**: 4 (20.0) **Survival analysis**: 1-year: 20 (100.0) 5-years: 18 (90.0) 10-years: 18 (90.0) **Safety, n (%)**: **Unspecified complication at median (range) FU of 19.5 (5.0 to 63.0) days**: 0 (0.0) **Freedom from reintervention analysis**: 1 year: 20 (100.0) 5 years: 19 (94.1) 10 years: 9 (47.1) **Reoperation at median (range) FU of 68 (4.8 to 143.7) months**: Conduit replacement: 1 (5.9) **Reintervention at median (range) FU of 68 (4.8 to 143.7) months**: Transcatheter PV replacement: 1 (5.9) Conduit ballon angioplasty: 1 (5.9) Conduit stenting: 0 (0.0) *Data from the Biointegral arm and associated p-values against the Contegra arm were not extracted.
Reference: Istar and Harmandar, 2025[8] **Country**: Turkey **Study Design:** Retrospective case series	**Sample size, (N)**: 3 patients **Lost to follow-up, n (%)**: 0 (0.0) **Age**: Case 1: 11 months Case 2: 2.5 months	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: NR **Comparator**: NA	**Mortality, n (%)**: **Case 1**: NR **Case 2**: Death due to

Study Details	Patient Characteristics	Intervention(s)	Outcome
Objective: To present the short and mid-term outcomes following surgical repair of three TOF-APVS patients. **Funding**: The authors declare no funding. **Conflict of interest**: The authors declare no competing interests.	Case 3: 9 months **Sex, n (%)**: Case 1: Male: 1 (100.0) Case 2: Female: 1 (100.0) Case 3: Female: 1 (100.0) **Diagnosis, n (%)**: Case 1: TOF: 1 (100.0) APVS: 1 (100.0) Aneurysmal pulmonary branches: 1 (100.0) TV insufficiency: 1 (100.0) Case 2: TOF: 1 (100.0) APVS: 1 (100.0) Aneurysmal pulmonary branches: 1 (100.0) Case 3: TOF: 1 (100.0) APVS: 1 (100.0) Aneurysmal pulmonary branches: 1 (100.0) Perimembranous malalignment: 1 (100.0) VSD: 1 (100.0) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: Case 1: Recurrent pulmonary infection: 1 (100.0) Medical history of hospitalization due to infection: 1 (100.0) Progressive enlargement of the pulmonary artery: 1 (100.0) Case 2: History of severe respiratory problem: 1 (100.0) Pulmonary infection: 1 (100.0) Townes-Brock syndrome: 1 (100.0) Case 3: Recurrent pulmonary infection: 1 (100.0) Severe pulmonary edema: 1 (100.0) **Inclusion Criteria**: Patients diagnosed with TOF-APVS who were operated on by the same surgeon in Mugla Sitki Kocman University Medical Faculty, Department of Cardiovascular Surgery, using data collected from the hospital database between 2018 and 2024. **Exclusion Criteria**: NR	**Indication for use**: Surgical repair of TOF with absent pulmonary valve syndrome **Follow-up period**: Case 1: 12 days Case 2: 6 months Case 3: 5 days	multiple complications of long-term ICU admission at 6 months: 1 (100.0) **Case 3**: Death due to ventricular failure despite ECMO support at 5 days: 1 (100.0) **Safety, n (%)**: **Case 1**: Postoperative complication at 12 days: 0 (0.0) **Case2**: Bronchospasm requiring mechanical respiratory support at 24 hours: 1 (100.0) Obstructive effects of secretion at 24 hours: 1 (100.0) **Case 3**: Ventricular dysfunction at 5 days: 1 (100.0)

Study Details	Patient Characteristics	Intervention(s)	Outcome
Reference: Konstantinov E., 2025[2] **Country**: Australia **Study Design:** Case report **Objective:** To discuss the surgical management of severe truncal valve insufficiency after neonatal repair of a quadricuspid truncal valve in a child. **Funding**: NR **Conflict of interest**: NR	**Sample size, (N)**: 1 patient **Lost to follow-up, n (%)**: 0 (0.0) **Age**: 6 years **Sex, n (%)**: Female: 1 (100.0) **Diagnosis, n (%)**: Severe truncal valve insufficiency: 1 (100.0) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: Prior history of neonatal TA repair: 1 (100.0) Prior history of neonatal quadricuspid truncal valve repair: 1 (100.0) **Inclusion Criteria**: NA **Exclusion Criteria**: NA	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: 20 mm **Comparator**: NA **Indication for use**: Truncal valve repair **Follow-up period**: 5 months	**Mortality, n (%)**: NR **Safety, n (%)**: **Trivial truncal valve insufficiency at 5 months**: 1 (100.0) *Patient had an uneventful postoperative hospital stay with excellent exercise tolerance after 5-months of follow-up.
Reference: Lewis et al., 2025[6] **Country**: Sweden **Study Design:** Retrospective cohort study **Objective:** To evaluate the rate of PPVIE between these two modes of intervention. **Funding**: The authors declare no funding. **Conflict of interest**: The authors declare no competing interests.	**Sample size, (N), cases**: 686 (487 patients) Contegra: 235 **Lost to follow-up, n (%), patients**: 20 (4.1%) **Age, mean (SD)**: 5.1 (8.8) years **Sex, n (%), cases**: Male: 120 (51.1) Female: 115 (48.9) **Diagnosis, n (%), cases**: VSD-PA: 75 (31.9) TOF: 39 (16.6) TA: 52 (22.1) TGA-VSD-PS: 22 (9.4) PVS-PVI-PAIVS: 13 (5.5) AVI-AVS: 7 (3.0) Unspecified: 27 (11.5) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: NR **Inclusion Criteria**: All patients who underwent PV implantation between Jan 1 1993 to Dec 31 2022, using a surgical valved homograft conduit, surgical BJV conduits, or percutaneously implanted biologic PV at the pediatric heart center in Lund, Sweden, who were younger than 18 years of age at the time of valve implantation. **Exclusion Criteria**: Patients who did not receive a homograft conduit, surgical BJV conduit, or percutaneously implanted biologic PV were excluded. *Data from aortic homograft, pulmonary homograft, and Melody valve groups were not extracted.	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: NR **Comparator**: Aortic and pulmonary homografts (Tissue Bank, Lund, Sweden) **Indication for use**: Percutaneous and surgical pulmonary valve implantation **Follow-up period, mean**: 8.5 years	**Mortality, n (%)**: NR **Safety, n (%)**: **PPVIE at mean FU of 8.5 years**: 21 (8.9) **Annualized incidence of PPVIE at mean FU of 8.5 years**: 2.5 (1.05) **Freedom from PPVIE analysis**: 5 years: 222 (94.3) 10 years: 211 (89.9) 21.2 years: 174 (74.1) **Univariate analysis - Risk factor for PPVIE (Reference: Aorta homograft), HR (95% CI), p-value**: PV type – Contegra: 14.51 (3.14 to 67.09), $p < 0.0001$ Conduit type – Contegra: 9.47 (2.68 to 33.51), $p < 0.001$ **Multivariate analysis - Risk factor for PPVIE (Reference: Aorta homograft), HR (95% CI), p-value**: PV type – Contegra: 12.47 (2.66 to 58.44), $p = 0.001$

Study Details	Patient Characteristics	Intervention(s)	Outcome
			*Data from aortic homograft, pulmonary homograft, and Melody valve groups were not extracted.
Reference: Linnenbank et al., 2025[4] **Country**: Germany **Study Design:** Case report **Objective:** To illustrate the institutional experience with the two-stage treatment using the Starnes and Cone procedure in patients with Ebstein's anomaly. **Funding**: The authors declare no funding. **Conflict of interest**: The authors declare no competing interests.	**Sample size, (N)**: 1 patient **Lost to follow-up, n (%)**: 0 (0.0) **Age**: 15 months **Sex, n (%)**: Male: 1 (100.0) **Diagnosis, n (%)**: Membranous pulmonary atresia: 1 (100.0) Hypoplastic pulmonary arteries: 1 (100.0) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: Ebstein's anomaly: 1 (100.0) **Inclusion Criteria**: NA **Exclusion Criteria**: NA	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: 12 mm **Comparator**: NA **Indication for use**: Biventricular correction with cone-shaped reconstruction of the tricuspid valve and right ventricle-to-pulmonary artery valved conduit placement **Follow-up period**: 3 years	**Mortality, n (%)**: NR **Safety, n (%)**: **At 1 day of FU**: Mild congestion of the hepatic veins: 1 (100.0) Restricted RV function: 1 (100.0) **At 3 months of FU**: Acute right heart decompensation with increasing dilation: 1 (100.0) Functional impairment of the RV: 1 (100.0) Moderate to severe TV insufficiency: 1 (100.0) Dilation of the RV-PA conduit: 1 (100.0) PV insufficiency due to impaired pocket coaptation: 1 (100.0) Severe bifurcation stenosis: 1 (100.0) Low-grade mitral valve insufficiency: 1 (100.0) Pleural effusion: 0 (0.0) Pericardial effusion: 0 (0.0) Replacement of Contegra valve with another Contegra valve: 1 (100.0) **At 9 months of FU (5 months after replacement)**: Moderate TV insufficiency: 1 (100.0) Grade I mitral valve insufficiency: 1 (100.0) Functional TV impairment: 1

Study Details	Patient Characteristics	Intervention(s)	Outcome
			(100.0) Global mural dysfunction and dilation: 1 (100.0) Ventricular wall thinning: 1 (100.0) Significant dilation of right atrium: 1 (100.0) Mild insufficiency: 1 (100.0) Stenosis: 0 (0.0) **At 33 months of FU (18 months after replacement)**: Severe RPA branch stenosis: 1 (100.0) Dilated RV with severe function impairment requiring stent implantation: 1 (100.0) **At 36 months of FU (21 months after replacement)**: Reduced exercise tolerance: 0 (0.0) *At the last follow-up at three years of age, the patient was in good general condition with no obvious signs of reduced exercise tolerance.
Reference: Samayoa et al., 2025[7] **Country**: US **Study Design:** Retrospective cohort study **Objective:** To compare the progressive echocardiographic performance of percutaneous implanted PV before the development of infective endocarditis. **Funding**: The authors declare no funding. **Conflict of interest**: The authors declare no competing interests.	**Sample size, (N)**: 226 patients Contegra: 37 patients **Lost to follow-up, n (%)**: NR **Age, mean (range)**: NR **Sex, n (%)**: NR **Diagnosis, n (%)**: NR **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: NR **Inclusion Criteria**: Patients who underwent TPVR between 2009 and 2021 at Seattle Children's Hospital and the University of Washington Medical Center. Patients who underwent a TPVR in circumferential bioprosthetic conduits (homograft or Contegra), bioprosthetic valves, native RVOT, or previous transcatheter PVs were included. **Exclusion Criteria**: Patients who went to the lab during the study period but did not undergo TPVR were excluded.	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: NR **Comparator**: Homograft (NR); Melody (Medtronic Inc., Minneapolis, MN, US); Sapien (Edwards Lifesciences, Irvine, CA, US) **Indication for use**: Transcatheter pulmonary valve replacement **Follow-up period, median (range)**: 38 (0 to 164) months	**<u>Mortality, n (%)</u>**: NR **<u>Safety, n (%)</u>**: **Infective endocarditis at median (range) FU of 38 (0 to 164) months**: 5 (13.5) *Across the five patients, IE occurred per patient at 17, 26, 30, 85, and 102 months.

Study Details	Patient Characteristics	Intervention(s)	Outcome
Reference: Takao et al., 2025[3] **Country**: Japan **Study Design:** Case report **Objective:** To report the use of a holographic workstation for preoperative surgical simulation in a case of primary biventricular repair for a false Taussig-Bing anomaly with a non-committed VSD, PS, and AVSD with an intact atrial septum. **Funding**: The authors declare no funding. **Conflict of interest**: The authors declare no competing interests.	**Sample size, (N)**: 1 patient **Lost to follow-up, n (%)**: 0 (0.0) **Age**: 7 months **Sex, n (%)**: Female: 1 (100.0) **Diagnosis, n (%)**: False Taussig-Bing anomaly: 1 (100.0) VSD: 1 (100.0) **Race/ethnicity, n (%)**: NR **Comorbidities, n (%)**: NR **Inclusion Criteria**: NA **Exclusion Criteria**: NA	**Intervention**: BJV (Contegra, Medtronic, MN, US) **Conduit size**: 14 mm **Comparator**: NA **Indication for use**: Primary biventricular repair **Follow-up period**: 3 months	**Mortality, n (%)**: NR **Safety, n (%)**: **Pulmonary stenosis at 3 months**: 0 (0.0) **Baffle leakage at 3 months**: 0 (0.0) **Pressure gradient across the left ventricle to aortic valve at 3 months**: 0 (0.0) *The patient weaned from bypass uneventfully.

Abbreviations: APVS: absent pulmonary valve syndrome; AVI: Aortic valve insufficiency; AVS: aortic valve stenosis; AR: aortic regurgitation; BJV: bovine jugular vein; CHD: congenital heart disease; CI: confidence interval; CT: computed tomography; ECMO: extracorporeal membrane oxygenation; HR: hazard ratio; IE: infective endocarditis; LV: left ventricle; NA: not applicable; NR: not reported; PA: pulmonary atresia; PAIVS: pulmonary atresia with intact ventricular septum; PS: pulmonary stenosis; PV: pulmonary valve; PVI: pulmonary valve insufficiency; PVS: pulmonary valve stenosis; RV: right ventricle; RV–PA: right ventricle to pulmonary artery; SD: standard deviation; TA: truncus arteriosus; TGA: transposition of the great arteries; TOF: Tetralogy of Fallot; TV: tricuspid valve; US: United States; VSD: ventricular septal defect.