FDA Executive Summary

Prepared for the
Fall 2024 Review by the
FDA's Pediatric Advisory Committee

Medtronic Contegra® Pulmonary Valved Conduit Models 200 (unsupported) and 200S (supported) (H020003)

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I. 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 2023 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.

II. 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.

III. 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

IV. 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

V. 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 445 devices were sold in the U.S., and 222 devices were implanted. At least 124 of the devices were implanted in pediatric (<22 years) patients. For 92 out of the 222 devices implanted, patient age is unknown.

VI. 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 49 MDRs regarding Contegra identified in the FDA's MDR database between May 1, 2023 and April 30, 2024. Of the 49 MDRs, 2 MDRs were unrelated to patient outcomes and 8 MDRs were sourced from journal articles. The 8 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 39 unique MDRs, all submitted by the manufacturer.

Patient Demographic Data

Of the 39 MDRs, 37 (95%) were received from the United States. Patient gender information was included in 38 MDRs; 18 involved males and 20 involved females. Patient age was included in 38 MDRs; 34 were pediatric patients and 4 were adults. Table 1 summarizes this information.

Table 1: Patient Demographic Data (Total 38 MDRs; involve 34 pediatric patients)

Demographic Data		Percentage	Number of MDRs containing the demographic
Reporting Country	US : OUS	95% : 5%	37 : 2 (39 Total)
Patient Gender	Male : Female	47% : 53%	18 : 20 (38 Total)
Patient Age	Pediatric : Adult	89% : 11%	34 : 4 (38 Total)
Pediatric Only: Age Range: 6 months – 18 years; Average Age: 8.6 ± 5.3 years			

Primary Reported Events

The 39 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 2024 PAC Review

Primary Reported Event	Total MDR Count	Patient Age (year)		TTEO (month)*	
		Pediatric (<22)	Adult (≥22)	Range	Mean
Device replaced (reason not provided)	**17**	16	1	4 - 154	60
Stenosis	**11**	10	1	26 - 182	93
Valve regurgitation	**4**	3	1	11 - 129	67
Inadequate size for patient**	**3**	1	1	20 - 92	56
Thrombus	**2**	2	0	0.2 - 30	15
Arrhythmia	**1**	1	0	0.03	-
Endocarditis	**1**	1	0	2	-
Grand Total	**39**	34	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 inadequate size valve for the patient did not include patient age.

A comparison of the primary events reported in the MDRs for the current analysis period with those from 2021, 2022, and 2023 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 2017-2024 please see Appendix A.

Table 3: Comparison of Primary Reported Events for Contegra MDRs in 2021, 2022, 2023 & 2024

Primary Reported Event	2021 PAC	2022 PAC	2023 PAC	2024 PAC
	MDR Count (%)	MDR Count (%)	MDR Count (%)	MDR Count (%)
Device replaced (reason not provided)	35 (58.3%)	21 (50%)	34 (55.8%)	17 (44%)
Stenosis	20 (33.3%)	13 (31%)	15 (25%)	11 (28%)
Valve regurgitation/ insufficiency	0	3 (7%)	1 (1.6%)	4 (10%)
Inadequate size for patient	0	1 (2.3%)	3 (5%)	3 (8%)

Thrombus	0	0	1 (1.6%)	2 (5%)
Arrhythmia	3 (5%)	1 (2.3%)	0	1 (2.5%)
Infection/endocarditis/sepsis	2 (3.3%)	1 (2.3%)	5 (8%)	1 (2.5%)
Conduit dilation/aneurysm	0	2 (5%)	2 (3%)	0
Total	**60**	**42**	**61**	**39**

The primary events reported in the 39 MDRs involving 39 injuries are summarized below.

Device replacement[1] – reason for replacement not reported (n=17 MDRs; 16 pediatric patients)

Seventeen (17) MDRs indicate that Contegra was replaced, 16 involving pediatric patients. Although the reasons for the device replacement were not reported in the MDRs, 8 of the 17 reports described that the valved conduit was replaced with a larger size device between 6 and 154 months post Contegra implant. Three (3) of the reports described that the conduit was replaced with a conduit of the same size and model. One (1) of the reports described that the conduit was replaced with a smaller conduit of the same model. In the remaining 5 MDRs, no information was available regarding the reason for device replacement and the device was not returned to the manufacturer for analysis. However, all 5 of these MDRs included transcatheter pulmonary valve (TPV) implantations conducted as valve-in-valve procedures.

Stenosis (n=11 MDRs; 10 pediatric patients)

Stenosis of conduit or pulmonary artery was the second most frequently reported event. In these 11 reports, stenosis (in conjunction with calcification, obstruction, pulmonary regurgitation or insufficiency, patient outgrowth and/or elevated pressure gradients) was identified in patients between 26 and 182 months post implant.

Of the stenosis reports, all events (11 MDRs involving 10 pediatric patients) reflected late events of stenosis (greater than one-year post implant) and the patients required interventions between 2 to 16 years post implant without additional adverse effects reported.

Overall, the interventions required for the 11 patients with late events of stenosis included transcatheter pulmonary valve (TPV) implantations conducted as valve-in-valve (8) and surgical replacement of the pulmonary valve (3).

Valve Regurgitation (n=4 MDRs; 3 pediatric patients)

Four (4) MDRs (involving 3 pediatric patients) reported mild to severe pulmonary regurgitation in patients between 11 months and 11 years post Contegra implant. One (1) of the reports described a transcatheter pulmonary valve (TPV) implanted via valve-in-valve procedure. One (1) MDR described the conduit being explanted and replaced with a conduit of the same model and size, and two (2) MDRs described occurrence of valve regurgitation but no planned intervention as of the report submission.

Inadequate size for patient (n=3 MDR; 1 pediatric patient)

1 "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.

Two (2) MDRs indicated the Contegra device required re-intervention due to the conduit being an inadequate size for the patient due to somatic outgrowth. One (1) MDR reported approximately 1 year and 8 months post-implant, a TPV was implanted valve-in-valve. One (1) MDR indicated that 7 years and 8 months post-implant of the Contegra device in a 4-year-old patient, a TPV was implanted valve-in-valve due to somatic outgrowth of the original conduit resulting in pulmonary regurgitation. One (1) MDR reported a patient underwent a redo surgery during the same admission due to incorrect conduit sizing which led to increased gradient.

Thrombus (n=2 MDR; 2 pediatric patients)

Two (2) MDRs indicated thrombosis of the Contegra device. In one (1) MDR reported six days post implant of the conduit, an echocardiogram indicated the presence of a thrombus on one of the conduit leaflets. Anticoagulant medication was initiated and twelve days later the thrombus was no longer visible, and the medication was discontinued. One (1) MDR indicated that 2 years and 6 months post implant of the conduit, it was explanted and replaced with a larger conduit of the same model due to pulmonary stenosis and a thrombus on the conduit.

Arrhythmia (n=1 MDR; 1 pediatric patient)

In an 8-year-old patient, a permanent pacemaker was implanted one day post implant of the Contegra device due to complete heart block. No additional adverse events were reported.

Endocarditis (n=1 MDR; 1 pediatric patient)

One (1) MDR reported the Contegra device was explanted and replaced with an unknown device due to endocarditis. The device was explanted and replaced two months post-implant of the conduit in a then 2-year-old patient. Cultures confirmed the presence of aspergillus spp. as the endocarditis-causing pathogen.

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.

VII. 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 2023 literature review. The search was limited to articles published in English from 05/01/2023 through 04/30/2024.

Figure 2 depicts the article retrieval and selection process including the criteria for exclusion. A total of 41 (5 PubMed; 36 EMBASE) articles were retrieved. Four articles were duplicates. The remaining 37 articles were subjected to review of titles and abstracts. Fourteen (14) articles were excluded from full-text review for reasons listed: Eight (8) were off-topic and did not address adverse events associated with Contegra, five (5) did not address the intervention of interest (i.e., did not include Contegra implants), and one (1) was not a study design of interest (i.e., the article was a commentary). Twenty-three (23) full-text articles were retrieved and screened. Of these 23 articles, 12 were excluded from further review for reasons listed: Four (4) had no intervention of interest, five (5) had no outcomes of interest, two (2) had no population of interest, and one (1) did not have a study design of interest (i.e., the study was a non-systematic review). A total of 11 articles were retained for inclusion in the final review.

Of note, in addition to the articles retrieved from PubMed and EMBASE databases, there were 4 unique publications identified through the review of the device manufacturer’s adverse event reports submitted through the MedWatch system (MDR reports). Three of the articles mentioned in the MDRs were also identified during this literature search. The remaining article was reviewed to determine if it should be included in the final literature review but did not fit the inclusion criteria.

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

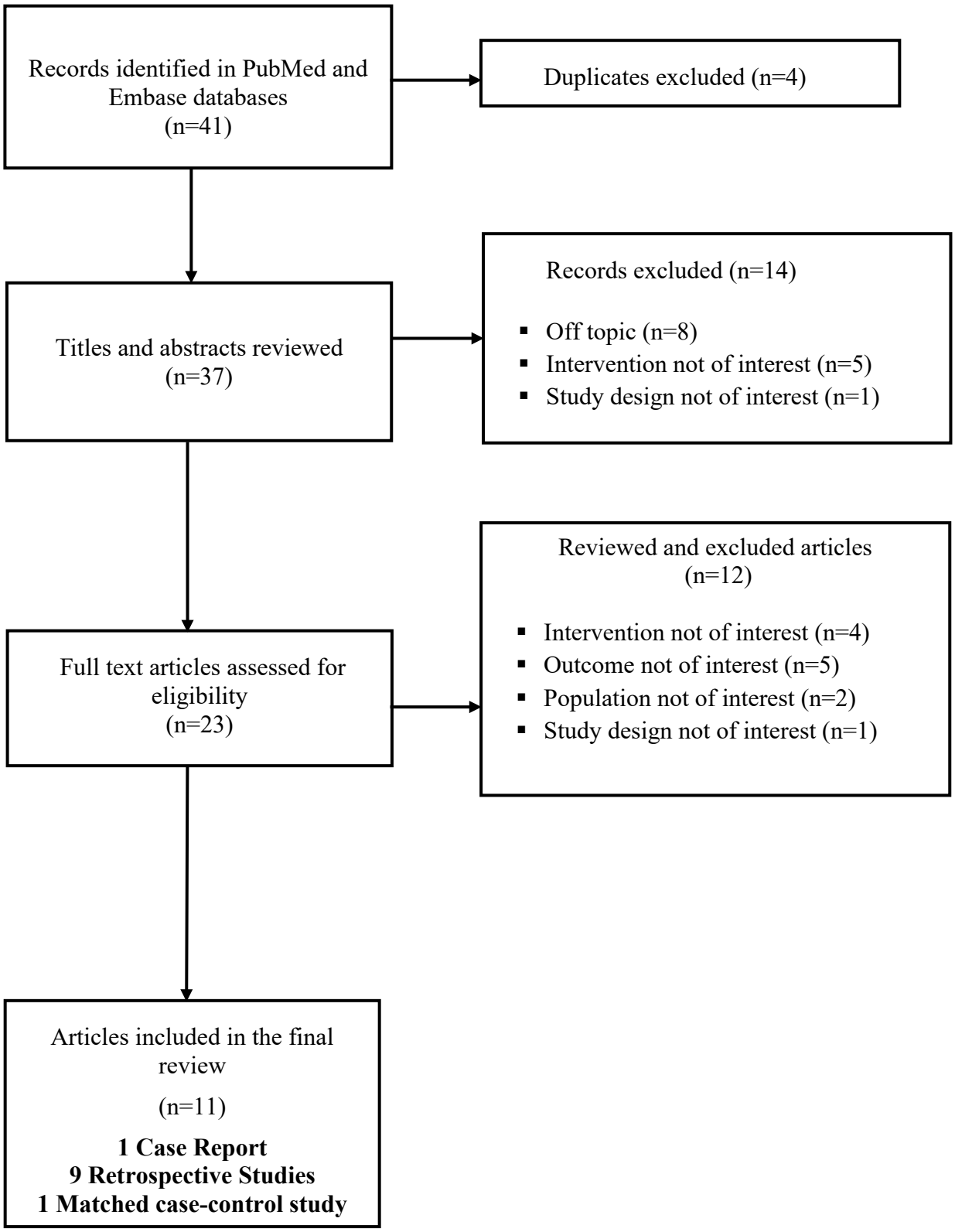

Figure 2. Article retrieval and selection process

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

There were nine retrospective studies [1-9], one matched case-control study[10] and one case report[11] in this literature review. No systematic literature reviews were identified in this search.

Of the included studies, one was conducted in the U.S. (n=1)[1] and the remaining 10 were from outside the U.S. These included studies from Slovakia (n=2)[2,3] and one each from Denmark[4], Egypt[5], Germany[10] (matched case-control study), Poland[6], Saudi Arabia[7], Spain[11] (case report), Sweden[8], and Switzerland[9].

A total of 6,708 patients were involved in nine retrospective studies, one matched case-control study and one case report, with a total of 1,275 Contegra devices implanted in these studies. The mean age of patients in the included studies ranged from 4.5 months to 15.3 years. The percentage of males included in the studies ranged from 53% to 67.1%. The mean duration of follow-up across studies ranged from 2.07 to 8.6 years. The median duration of follow-up ranged from 7 to 10.4 years. Appendix B contains more details on study and patient population characteristics.

Safety Results Discussions

All-cause mortality

Perioperative mortality rates (occurring less than 90 days post-procedure) were reported in four studies.[2,3,6,7] Further, two studies reported overall mortality rates.[5,10]

Helal et al. (2024) compared graft-related events (infective endocarditis, transcatheter pulmonary valve replacement (PVR), transcatheter conduit dilatation, surgical conduit replacement, and transcatheter pulmonary branch intervention for RV-PA reconstruction using BJV, aortic homograft, and porcine-valved conduits among pediatric patients with underlying congenital heart disease (CHD) (tetralogy of Fallot, pulmonary atresia, transposition of great arteries, truncus arteriosus and left sided lesions).[7] Patients received either the BJV (Contegra) (Group 1) (n=153), aortic homograft (Group 2)(n=29), or porcine valved conduit (Group 3) (n=11). The median duration of patient follow-up was 84 months (IQR: 33–127 months). Perioperative mortality occurred in 13 patients, but there was no statistical difference between patients with BJV conduit (12 deaths (7.84%)) and patients with porcine-valved conduit (1 death (9.09%)) (p=0.351). No mortality was reported in patients with aortic homograft. Univariable analysis revealed that male gender [odds ratio (OR): 10.04; 95% confidence interval (CI): 1.28–78.86; p=0.028] and smaller conduit size (OR: 0.78; 95% CI: 0.61–0.99; p=0.048) were associated with increased operative mortality.

Sabateen et al. (2023) compared the outcomes of cryopreserved homografts (n=38) with BJV conduits (n=32) in children under 2 years of age with right ventricular outflow tract (RVOT) reconstruction.[2] The mean duration of patient follow-up was 6.2 years (SD: 5.6 years). A total of 63 patients (70 conduits) were included in the study. Overall, 12 (17.1%) patients died during follow-up (including 30-day mortality): 9 (23.6%) patients in the homograft group, and 3 (9.3%) patients in the BJV conduit group, (p = 0.10). The 30-day mortality was 4/28 (10.5%) in the homograft group and 0/32 (0.0%) in the BJV conduit group, (p = 0.058).

In a similar study, Sabateen et al. (2023) compared the outcomes of cryopreserved homografts, BJV conduits, and decellularized Matrix P Plus N conduits in 173 patients undergoing RVOT reconstruction at a single center.[3] Patients either received the BJV conduit with a competent tri-leaflet venous valve (Contegra pulmonary valve conduit) (n=45 conduits), homografts (n=129 conduits), or the Matrix P Plus N conduit (n=25 conduits). The mean duration of patient follow-up was 8.6 years (SD:5.8 years). Overall,

20 (11.5%) patients died during follow-up (including 30-day mortality): 16 (12.4%) patients in the homograft group, 3 (6.6%) patients in the BVJ group, and 1 (4.0%) in the Matrix P Plus N group (p = 0.78). The 30-day mortality was 3.1% in the homograft group, 0% in the BJV conduit group and 4% in the Matrix P Plus N group (p = 0.5). No deaths were related to the structural failure of the conduit.

In a retrospective cohort study, Wasiak et al. (2023) reported early and late outcomes among 224 children with tetralogy of Fallot (ToF) who underwent repair with a transannular Contegra monocuspid patch.[6] The median duration of patient follow-up was 111 months. A total of 7 patients (3.1%) died during their hospital stay. Further, late-death (six months) occurred in one patient due to sudden cardiac arrest.

Bobylev et al. (2023) presented a matched comparison of bovine jugular vein (BJV) conduits (n=319) and decellularized homografts (n=319) considering patient age, type of congenital heart defect (CHD), and the number of previous heart operations.[10] Matching was performed on the patient's age category at implantation, the type of CHD, the number of previous operations, and the number of previous pulmonary valve replacements (PVRs). The mean follow-up of the study was 6.3 (SD:4.3) years. The 5-year and 10-year freedom from death was 97% vs. 98.1% (p=0.45) and 97% vs. 98.1% (p=0.45) respectively. No statistically significant differences were reported.

In a retrospective study by Ali et al. (2023), 33 patients with underlying CHD were implanted with either a Contegra conduit (n=17) or other conduits (Non-Contegra group: Goretex (polytetrafuoroethylene conduit)) (n=5), Neocore (porcine aortic valve mounted in a bovine pericardial tube) (n=4), Carpentier Edwards (porcine valved conduit) (n=3), Hancock (porcine valved conduit)(n=2), or Biointegral (bovine) (n=1)).[5] The mean duration of patient follow-up was 2.07 years (SD: 2.36 years). The study reported overall survival between two groups. No statistically significant differences were seen in median survival between the two groups without the need to redo surgery for conduit replacement. The median survival without the need for surgical reintervention was 2.5 years for the non-Contegra subgroup vs. 3 years for the Contegra subgroup (p= 0.59). However, the survival without reintervention proportion of both groups at 3 years of follow-up was 21.8% for the non-Contegra subgroup versus 49.9% for the Contegra subgroup.

Perioperative mortality was reported in four studies.[2,3,6,7] The overall perioperative mortality was low and differences did not reach statistical significance between device types (e.g., Contegra vs. homografts). Two studies reported overall mortality rates at longer timepoints (>2 years).[5,10] These studies also did not show statistically significant differences between Contegra and other conduits.

Adverse events

Short-term adverse events (occurring less than 90 days post-procedure) were reported in one study.[1] Stefanescu Schmidt et al. (2024) reported outcomes among 280 pediatric patients with CHD who underwent transcatheter pulmonary valve placement within a previously implanted Contegra conduit.[1] The main outcomes of the study were acute success and adverse events. Acute success was defined as the implanted TPV remaining in place for >24 hours. An MAE outcome was derived as a composite of procedural death or cardiac arrest, urgent surgery or procedure because of a complication of the catheterization, vascular complications requiring treatment, device malposition or thrombosis, coronary artery compression caused by the procedure (excluding temporary occlusion during coronary compression testing), a hemodynamically significant conduit or pulmonary artery rupture, unplanned need for left ventricular assist device or extracorporeal membrane oxygenation (ECMO), or pacemaker implantation. Adverse events were compared to those of patients who underwent implantation with homografts. No follow-up duration was reported in the study, but the primary outcome reported analyzing outcomes as acute success (within 24 hr.). Overall, adverse events (AEs) were reported in 2.4% of patients and were significantly less common in patients with a bioprosthetic valve (BPV) (1.4%) than in those with a

homograft (2.9%) or a native/patched RVOT (3.4%) (p= 0.004). Compared to the homograft, the Contegra conduit had a comparable number of major adverse events (OR: 0.74, 95% CI: 0.28-1.91, p=0.53) (1.4% vs. 2.9%). Key adverse events reported among the Contegra group included: device embolization (0.1%), clinical coronary artery compression (n=1), and hemodynamic/therapeutic tear (n=2). Device embolization requiring retrieval was very rare but was more common in patients with a native RVOT than other RVOT types (1.5% in native RVOT vs 0.5% in homografts and 0.1% in BPVs (Contegra); p < 0.001) and in patients who received a SAPIEN valve (0.9% vs 0.3%; p= 0.019).

One retrospective study reported late adverse events.[7]

Helal et al. (2024) compared graft-related events (infective endocarditis, transcatheter pulmonary valve replacement (PVR), transcatheter conduit dilatation, surgical conduit replacement, and transcatheter pulmonary branch intervention for RV-PA reconstruction using BJV, aortic homograft, and porcine-valved conduits) among pediatric patients with underlying CHD (tetralogy of Fallot, pulmonary atresia, transposition of great arteries, truncus arteriosus and left sided lesions).[7] Patients received either the BJV (Contegra) (Group 1) (n=153), aortic homograft (Group 2)(n=29), or porcine valved conduit (Group 3) (n=11).[7] The median duration of patient follow-up was 84 months (IQR: 33–127 months). At least one graft-related event was reported in 85 conduits: 69 with BJVs, 12 with homografts, and 4 with porcine-valved conduits (p=0.919). Freedom from graft-related events in 2, 5, and 10 years was 76%, 67%, and 52% in Group 1 (Contegra), 86%, 74%, and 36% in Group 2 (homograft), and 89%, 53%, and 53% in Group 3 (porcine valved conduit), respectively.

Short-term adverse events were reported in one study.[1] Stefanescu Schmidt et al. (2024) reported no differences in AEs between Contegra and homografts (OR: 0.74, 95% CI: 0.28-1.91, p=0.53) (1.4% vs. 2.9%).[1] Overall adverse events were reported in one study. Helal et al. (2024) reported higher numbers of adverse events (not statistically significant) among BJVs compared to homografts or porcine-valve conduits.[7]

Infective Endocarditis

Infective endocarditis (IE) was the most common adverse event and was reported in eight studies[2,4,6-11] including a case report[10].

Groning et al. reported the use of the Contegra conduit among 90 patients with double outlet right ventricle of Fallot type.[4] The median duration of patient follow-up was 10.4 years (IQR: 3.6-16.5 years). The prevalence of endocarditis in this cohort was 8.5% (n=4).

Helal et al. (2024) compared graft-related events (infective endocarditis, transcatheter pulmonary valve replacement (PVR), transcatheter conduit dilatation, surgical conduit replacement, and transcatheter pulmonary branch intervention for RV-PA reconstruction using BJV, aortic homograft, and porcine-valved conduits among pediatric patients with underlying CHD (tetralogy of Fallot, pulmonary atresia, transposition of great arteries, truncus arteriosus and left sided lesions).[7] Patients received either the BJV (Contegra) (Group 1) (n=153), aortic homograft (Group 2)(n=29), or porcine valved conduit (Group 3) (n=11).[7] The median duration of patient follow-up was 84 months (IQR: 33–127 months).[7] Infective endocarditis of the graft occurred in 9 patients: 8 with BJVs (Contegra) and 1 with an aortic homograft (p=0.817).

Sabateen et al. (2023) compared the outcomes of cryopreserved homografts (n=38) with BJV conduits (n=32) in children under 2 years of age with right ventricular outflow tract (RVOT) reconstruction.[2] The mean duration of patient follow-up was 6.2 years (SD:5.6 years). Endocarditis was reported in 2 out of 23 patients in the Contegra group.

In a study by Lewis et al. (2023), authors compared incidence of infective endocarditis across three groups of conduits.[8] The median duration of patient follow-up was 8.7 years (IQR:4.3-13.3 years). The report identified prevalence of infective endocarditis as follows: pulmonary homografts n=4 (1.4%), aortic homografts n=5 (3.4%), and BJV n=9 (4.8%). There was a significant difference between rates of endocarditis in pulmonary homografts and BJV grafts (p-value=0.04).

Schuler et al. (2023) evaluated the underlying cause of infective endocarditis among 69 pediatric patients.[9] No follow-up duration was reported in the study. The authors determined that 14 patients had a history of implantation with the Contegra conduit.

In the study by Wasiak et al. (2023), 224 patients with underlying ToF underwent repair using the BJV (Contegra conduit).[6] The median duration of patient follow-up was 111 months. Infective endocarditis was reported in 2 (0.9%) patients.

In a matched case-control study, Bobylev et al. (2023) compared outcomes of 638 patients with an underlying diagnosis of CHD.[10] Patients treated with a BJV (Contegra) conduit (n=319) were matched to patients who used homografts by patient's age category at implantation, the type of congenital heart defect, the number of previous operations, and the number of previous PVR (n=319). The mean duration of patient follow-up was 6.3 years (SD:4.3 years). The rate of freedom from endocarditis was significantly lower for BJV patients (87.1 vs. 96.5%, p=0.006). The 5-year and 10-year freedom from endocarditis rates for BJV vs. homografts were 93.7% vs 98.5% (p=0.006) and 87.1% vs. 96.5% (p=0.006) respectively.

In a case report by Huguet et al., (2024), an 8-year-old male pediatric patient diagnosed with CHD with ventricular septal defect (VSD) and pulmonary artery stenosis was treated with a Contegra conduit.[11] No follow-up duration was reported in the study. The patient was admitted post-operatively and diagnosed with infective endocarditis (possible Q fever). A 7x10 mm vegetation at the prosthetic valve without significant valvular dysfunction, mild pulmonary regurgitation, and mild pulmonary stenosis were found on examination.

Infective endocarditis was reported in eight publications, although rates varied across studies.[2,4,6-11] However, when compared to homografts, Bobylev et al. identified a higher prevalence of endocarditis among patients using the Contegra conduits.[10] The rate of freedom from endocarditis was significantly lower for BJV patients (87.1 vs. 96.5%, p=0.006). The 5-year and 10-year freedom endocarditis for BJV vs. homografts was 93.7% vs. 98.5% (p=0.006) and 87.1% vs. 96.5% (p=0.006), respectively. Overall, these rates are consistent with previously reported rates of infective endocarditis associated with Contegra in the literature.

Conduit deterioration, reintervention and replacement, and stenosis and regurgitation

Conduit Deterioration

No studies reported on conduit deterioration.

Conduit Reintervention and Replacement

Seven studies reported on the prevalence of conduit reintervention and replacement.[2-4,6-8,10]

In a study conducted by Groning et al. (2024), 90 pediatric patients with RVOT obstruction were treated with a BJV (Contegra) conduit.[4] The median duration of follow-up reported in the study was 10.4 years (IQR: 3.6-16.5 years). The cumulative incidence of conduit replacement after 10 years was 47%.

Helal et al. (2024) compared graft-related events (infective endocarditis, transcatheter pulmonary valve replacement (PVR), transcatheter conduit dilatation, surgical conduit replacement, and transcatheter pulmonary branch intervention for RV-PA reconstruction using BJV, aortic homograft, and porcine-valved conduits among pediatric patients with underlying CHD (tetralogy of Fallot, pulmonary atresia, transposition of great arteries, truncus arteriosus and left sided lesions).[13] Patients received either the BJV (Contegra) (Group 1) (n=153), aortic homograft (Group 2) (n=29), or porcine valved conduit (Group 3) (n=11).[13] The median duration of patient follow-up was 84 months (IQR: 33–127 months). Transcatheter PVR was required in 8 patients: 7 with BJV conduits and 1 with porcine-valved conduit (p=0.275). In addition, transcatheter conduit dilatation was performed in 10 patients: 7 with BJVs and 3 with homografts (p=0.266). Thirty-eight patients had conduit replacement: 29 with BJVs, 8 with homografts, and 1 with porcine-valved conduit (p=0.549). Freedom from conduit replacement at 2, 5, and 10 years was 94%, 86%, and 78% in Group 1 (Contegra), 97%, 85%, and 45% in Group 2 (homograft), and 89%, 89%, and 89% in Group 3 (porcine valved conduit), respectively. In addition, peripheral pulmonary branch interventions were needed in 46 patients: 40 with BJVs, 4 with homografts and 2 with porcine-valved conduits (p=0.345). Balloon dilatation of pulmonary branches was performed in 7 patients (17.50%) with BJVs, 2 with homografts (50%), and 2 with porcine-valved conduit (100%). Freedom from peripheral pulmonary branch interventions at 2, 5, and 10 years was 80%, 67%, and 68% in Group 1 (Contegra), 96%, 92%, and 73% in Group 2 (homografts), and 100%, 75%, and 75% in Group 3 (porcine-valved conduit), respectively. Finally, stenting of the peripheral pulmonary artery branches was performed in 33 patients (82.50%) with BJVs and 2 with aortic homografts (50%) (p=0.012).

In a matched case-control study, Bobylev et al. (2023) compared outcomes of 638 patients with underlying diagnosis of CHD.[10] Patients treated with BJV conduit (Contegra) (n=319) were matched to patients who used homografts (n=319) by the patient's age category at implantation, the type of congenital heart defect, the number of previous operations, and the number of previous PVR. The mean duration of patient follow-up was 6.3 years (SD:4.3 years). Freedom from explantation was significantly lower for the BJV group at 10 years (81.7 vs. 95.5%, p=0.001). The 5-year and 10-year freedom from explantation for the BJV vs. homograft groups were 91.3% vs. 98% (p=0.001) and 81.7% vs. 95.5% (p=0.001), respectively.

Lewis et al. (2023) compared outcomes among pediatric patients with congenital heart disease (CHD) who received the BJV conduits (Contegra) (n=192) vs. pulmonary (n=288) or aortic homografts (n=185).[8] The median duration of patient follow-up was 8.7 years (IQR:4.3–13.3 years). For BJV grafts, 10- and 19-year freedom from conduit replacement was 68.1% and 46.0%, respectively. Further, freedom from reintervention was 54.9% at 28 years for pulmonary homografts, 17.6% at 30 years for aortic homografts, and 26.6% at 17 years for BJV grafts (p <0.05)).

Sabateen et al. (2023) compared the outcomes of cryopreserved homografts (n=38) with BJV conduits (n=32) in children under 2 years of age with right ventricular outflow tract (RVOT) reconstruction.[2] The mean duration of patient follow-up was 6.2 years (SD:5.6 years). Transcatheter reinterventions were performed in 25 (35.7%) conduits: 16 conduits in the homograft group (balloon valvuloplasty, n = 12, stent implantation, n = 4), and 9 conduits in the BJV conduit group (balloon valvuloplasty, n = 9). The indication was conduit stenosis across all

cases. Overall freedom from transcatheter reintervention at 5, 10, and 15 years was 56.9%, 37.5%, and 31.2%, respectively. Freedom from transcatheter reintervention in the homograft group at 5, 10, and 15 years was 55.3%, 27.1%, and 27.1%, respectively. Freedom from catheter reintervention in the BJV conduit group at 5 and 10 years was 66.2% and 35.3%, respectively (p=0.32). Freedom from reoperation in the homograft group at 5, 10, and 15 years was 64.4%, 35.4%, and 21.2%, respectively. Freedom from reoperation in the bovine jugular vein conduit (BJVC) group at 5, 10, and 12.5 years was 71%, 59.3%, and 59.3%, respectively (p=0.23).

In a similar study, Sabateen et al. (2023) compared the outcomes of cryopreserved homografts, BJV conduits, and decellularized Matrix P Plus N conduits in 173 patients undergoing RVOT reconstruction at a single center.[3] Patients either received the BJV conduit with a competent tri-leaflet venous valve (Contegra pulmonary valve conduit) (n=45 conduits), homografts (n=129 conduits), or the Matrix P Plus N conduit (n=25 conduits). The mean duration of follow-up of the patients was 8.6 years (SD:5.8 years). A total of 44 conduits (22.1%) underwent catheter reintervention, with an incidence of 28 (21.7%), 9 (20.0%), and 7 (28.0%) in the homograft, BJV and Matrix P Plus N conduits, respectively. Initial catheter reintervention was required in 28 conduits in the homograft group (balloon valvuloplasty, n = 21; stent implantation, n = 4; PPVI, n = 3), 9 in the BJVC group (balloon valvuloplasty, n = 9) and 7 in the Matrix P Plus N group (balloon valvuloplasty, n = 6; PPVI, n = 1). The indications for catheter reintervention were severe conduit stenosis among 40 (90.9%) patients and severe regurgitation among 4 (9.1%) patients. Further, freedom from first catheter reintervention in the homograft group at 5, 10 and 20 years was 87.9%, 77.3%, and 70.0%, respectively. Freedom from first catheter reintervention in the BJVC group at 5 and 10 years was 71.2% and 38%, respectively, and freedom from first catheter reintervention in the Matrix P Plus N group at 5 and 9 years was 75% and 64.3%, respectively. The catheter reintervention rate was significantly different among the 3 groups (p = 0.021). Freedom from reoperation in the homograft group at 5, 10 and 20 years was 88%, 81.7% and 69.7%, respectively. Freedom from reoperation in the BJVC group at 5 and 10 years was 75.7% and 63%, respectively, and freedom from reoperation in the Matrix P Plus N group at 5 and 9 years was 91.3% and 83%, respectively. No statistically significant difference regarding the reoperation rate was seen among the 3 groups (p= 0.23).

In a study by Wasiak et al. (2023), authors aimed to evaluate the early and late outcomes of ToF repair with a transannular Contegra monocuspid patch in a single center.[6] A total of 224 patients with underlying ToF were evaluated. The median duration of patient follow-up was 111 months. The authors reported that two patients (0.9%) underwent a reoperation. Further, graft replacement was reported in 30 patients (14.1%). The event-free survival rate was 85.4% (181 of 212 patients) during the study period, with event-free survival rates of 94.7%, 84.1%, and 73.4% after 5, 10, and 15 years, respectively. The main indications for late reoperations were severe pulmonary insufficiency (n=14) and trunk or branch pulmonary stenosis with moderate pulmonary insufficiency (n=13), RVOT obstruction (n =2) and infective endocarditis (n=1).

Stenosis and Regurgitation

Four studies reported on the prevalence of stenosis/regurgitation among pediatric patients who used Contegra conduits.[2,4,6,10]

In a study conducted by Groning et al. (2024), 90 pediatric patients with RVOT were treated

with BJV (Contegra) conduits.[4] The median duration of follow-up reported was 10.4 years (IQR: 3.6-16.5 years). Of the 90 patients treated with BJV (Contegra) conduits, 48 (53%) exhibited an indication for replacement (4 exhibited endocarditis; 36 developed pulmonary stenosis; 2 showed pulmonary regurgitation; 1 had combined stenosis/regurgitation; and 5 had unknown causes). The timing of these events was not reported.

In a matched case-control study, Bobylev et al. (2023) compared outcomes of 638 patients with an underlying diagnosis of CHD.[10] Patients treated with BJV (Contegra) conduit (n=319) were matched to patients who used homografts (n=319) by the patient's age category at implantation, the type of congenital heart defect, the number of previous operations, and the number of previous PVR. The mean duration of patient follow-up was 6.3 years (SD:4.3 years). The 5-year and 10-year freedom from stenosis for the BJV vs. homograft groups were as follows: 70.2% vs. 85.3% (p=0.001) and 56.8% vs. 82.1% (p<0.001). Similarly, the 5-year and 10-year freedom from regurgitation (>=moderate) were as follows: 82% vs. 87% (p=0.13) and 61.4 vs. 74.3% (p=0.13), respectively. The combined 5-year and 10-year freedom from degeneration (stenosis and regurgitation combined was: 59.65% vs 78% (p<0.001) and 39.6% vs. 65.5% (p<0.001), respectively.

Sabateen et al. (2023) compared the outcomes of cryopreserved homografts (n=38) with BJV conduits (n=32) in children under 2 years of age with right ventricular outflow tract (RVOT) reconstruction.[2] The mean duration of patient follow-up was 6.2 years (SD: 5.6 years). Development of stenosis occurred in 25 patients total; 16 (42.1%) were reported in the homografts group and 9 (28.1%) were reported in patients using Contegra. The mean times between initial implantation and reintervention due to stenosis in the homograft and Contegra groups were 3.6 years (range 2.3–4.9 years) and 3.1 years (range 2–4.2 years), respectively (p = 0.58). Overall freedom from reintervention at 5 and 10 years among homograft patients was 56.9% and 37.5%, respectively. Overall freedom from reintervention at 5 and 10 years among Contegra patients was 66.2% and 35.3% respectively; the reintervention rate was not statistically significantly different between the homograft and Contegra groups (p=0.32).

In a study reported by Wasiak et al. (2023), 224 patients with underlying ToF underwent repair with BJV (Contegra) conduit.[6] The median duration of follow-up after Contegra patch repair was 111 months. Two patients (0.9%) required early reoperation (one for residual ventricular septal defect and moderate pulmonary regurgitation; one due to thrombus in the pulmonary valve). By postoperative echocardiography, 147 (65.6%) patients had mild or no pulmonary insufficiency and 77 (34.4%) patients had moderate pulmonary insufficiency.

Stenosis and regurgitation were reported in four studies.[2,4,6,10] In a matched case-control study by Bobylev et al., the authors reported a higher prevalence of stenosis among patients using BJVs vs homografts with no differences in the prevalence of regurgitation.[10] Across the other three studies, stenosis and regurgitation events varied, with lower rates reported among patients using Contegra conduit compared to homografts.[2,4,6] No studies reported on conduit deterioration. Rates of reintervention and reoperation varied across seven studies and increased with the length of follow up.[2-4,6-8,10]

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 reported safety data of the Contegra device for use in pediatric patients published between May 1, 2023, and April 30, 2024. We continue to add evidence to prior reports on AEs associated with the use of a pulmonary conduit (Contegra). Infective endocarditis continues to remain the most common AE across studies, followed by stenosis and regurgitation.

In general, limitations of these studies include lack of randomization, retrospective study designs, differential follow up, and limited evaluation of other AEs. 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. Also, generalizability is limited due to underlying differences in baseline prevalence of CHD, disease management, and resource allocation, and differences in patient and physician characteristics among local regions.

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 05/01/23 and 04/30/24 revealed the following observations:

- Perioperative mortality was reported in four studies.[2,3,6,7] The overall perioperative mortality was low, and differences did not reach statistical significance between device types (e.g., Contegra vs. homografts). Two studies reported overall mortality rates at longer timepoints (>2 years).[5,10] These studies also did not show statistically significant differences between Contegra and other conduits.
- Infective endocarditis was reported in eight publications, although rates varied across studies.[2,4,6-11] However, when compared to homografts, Bobylev et al. identified a higher prevalence of endocarditis among patients using the Contegra conduits.[10] The rate of freedom from endocarditis was significantly lower for BJV patients (87.1 vs. 96.5%, p=0.006). The 5-year and 10-year freedom endocarditis for BJV vs. homografts was 93.7% vs. 98.5% (p=0.006) and 87.1% vs. 96.5% (p=0.006), respectively. Overall, these rates are consistent with previously reported rates of infective endocarditis associated with Contegra in the literature.
- Short-term adverse events were reported in one study.[1] Stefanescu Schmidt et al. (2024)

reported no differences in AEs between Contegra and homografts (OR: 0.74, 95% CI: 0.28-1.91, p=0.53) (1.4% vs. 2.9%).[1]

- Overall adverse events were reported in one study. Helal et al. (2024) reported higher numbers of adverse events (not statistically significant) among BJVs compared to homografts or porcine-valve conduits.[7]
- Stenosis and regurgitation were reported in four studies.[2,4,6,10] In a matched case-control study by Bobylev et al., the authors reported a higher prevalence of stenosis among patients using BJVs vs homografts with no differences in the prevalence of regurgitation.[10] Across the other three studies, stenosis and regurgitation events varied, with lower rates reported among patients using Contegra conduit compared to homografts.[2,4,6]
- No studies reported on conduit deterioration.
- Rates of reintervention and reoperation varied across seven studies and increased with the length of follow up.[2-4,6-8,10]

VIII. 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 2025:

- Annual distribution number
- MDR review
- Literature review

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Appendix A: Supplemental Table

Table 4. Comparison of Primary Reported Events for Contegra MDRs from 2017 – 2024

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

**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 Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
Reference: Groning et al. (2024)[4] **Study Design:** Retrospective Cohort study. **Purpose:** This study sought to assess temporal trends in PVR procedural volume and BPV durability in a nationwide, retrospective TOF cohort. **Length of follow-up (Median):** 10.4 years (IQR: 3.6-16.5 years) **Funding Source:** This study was funded by the Danish Heart Foundation, Copenhagen, Denmark, and the Novo Nordisk Foundation, Hellerup, Denmark. **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Denmark	**Patients (N):** 384 patients (546 pulmonary valve replacements) **Age Mean (SD):** 8 (9) years **Sex (% male):** NR **Diagnosis:** ToF **Inclusion criteria:** Patients with double outlet right ventricle of Fallot type were included in the cohort. **Exclusion criteria:** Patients with an atrioventricular septal defect, absent pulmonary valve syndrome, and pulmonary atresia with a ventricular septal defect and major aortopulmonary collateral arteries were excluded. **Setting:** Hospital	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=90) **Comparator:** NA **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** NR **Perioperative Mortality (<90 days post-procedure):** NR **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** **Infective endocarditis N (%):**4 (8.5%) **Conduit deterioration:** NR **Reintervention:** NR **Replacement:** Cumulative incidence of replacement after 10 years was 47%. (HR: 4.00, 95% CI: 1.76-9.76, p<0.001) **Stenosis:** 36 (75%) **Regurgitation:** 2 (4%) **Combined stenosis/ regurgitation:** 1 (2%)
Reference: Helal et al. (2024)[7] **Study Design:** Retrospective Cohort study. **Purpose:** The study aimed to compare graft-related events (infective endocarditis, transcatheter pulmonary valve replacement (PVR), transcatheter conduit dilatation, surgical conduit replacement, and transcatheter pulmonary branch intervention for RV-PA reconstruction using bovine jugular vein, aortic homograft, and porcine-valved conduits	**Patients (N):**155 patients (193 procedures) **Age Mean (Range):** 21 (8–45) months **Sex (% male):** 88 (57.52) **Diagnosis:** ToF (n=30), Pulmonary atresia (n=72), TGA (n=17), TA (n=26) and left sided lesion (n=7), additional lesion (n=14) **Inclusion criteria:** All patients had both orthotopic and heterotopic conduit implantation and biventricular repair. **Exclusion criteria:** Patients with RV-PA reconstruction using synthetic conduits	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (Group 1) (n=153) **Comparator:** Aortic homograft (Group 2) (n=29) and porcine valved conduit (Group 3) (n=11) **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** NR **Perioperative Mortality (<90 days post-procedure):** Operative mortality occurred in 13 patients: 12 (7.84%) with BJV conduit and 1 (9.09%) with porcine-valved conduit (P=0.351) **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure: NR** **Other AE:** At least one graft-related event

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
Length of follow-up: 84 months (IQR: 33–127 months). **Funding Source:** None **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous (Contegra Pulmonary Valved Conduit) **Country:** Saudi Arabia	and those with the univentricular repair were excluded. **Setting:** Hospital		was reported in 85 conduits, 69 with BJVs, 12 with homografts, and 4 with porcine-valved conduits (P=0.919). Freedom from graft related events at 2, 5, and 10 years was 76%, 67%, and 52% in Group 1, 86%, 74%, and 36% in Group 2, and 89%, 53%, and 53% in Group 3 **Infective endocarditis N (%):** Infective endocarditis of the graft occurred in 9 patients: 8 with BJVs and 1 with an aortic homograft (P=0.817) **Conduit deterioration:** NR **Reintervention:** Transcatheter PVR was needed in 8 patients: 7 with BJVs conduits and 1 with porcine-valved conduit (P=0.275) Transcatheter conduit dilatation was performed in 10 patients: 7 with BJVs and 3 with homografts (P=0.266) Peripheral pulmonary branch interventions were needed in 46 patients: 40 with BJVs, 4 with homografts and 2 with porcine-valved conduit (P=0.345). Balloon dilatation of pulmonary branches was performed in 7 patients (17.50%) with BJVs, 2 with homografts (50%), and 2 with porcine-valved conduit (100%). Stenting of the peripheral pulmonary artery branches was performed in 33 patients (82.50%) with BJVs, 2 with aortic homografts (50%) (P=0.012). Freedom from peripheral pulmonary branch interventions at 2, 5, and 10 years was 80%, 67%, and 68%

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
			in Group 1, 96%, 92%, and 73% in Group 2, and 100%, 75%, and 75% in Group 3. **Replacement:** Thirty-eight patients had conduit replacement: 29 with BJVs, 8 with homografts, and 1 with porcine-valved conduits (P=0.549). Freedom from conduit replacement at 2, 5, and 10 years was 94%, 86%, and 78% in Group 1, 97%, 85%, and 45% in Group 2, and 89%, 89%, and 89% in Group 3 **Stenosis:** NR **Regurgitation:** NR
Reference: Huguet et al., (2024)[11] **Study Design:** Case Study **Purpose:** NR **Length of follow-up:** NR **Funding Source:** None **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Spain	**Patients (N):**1 **Age:** 8 years **Sex (% male):** 1 (100%) **Diagnosis:** CHD with VSD and Pulmonary artery stenosis. **Inclusion criteria:** NA **Exclusion criteria:** NA **Setting:** Hospital	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Comparator:** NA **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** NR **Perioperative Mortality (<90 days post-procedure):** NR **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** NR **Infective endocarditis N (%):** 1 (100%). A 7x10mm vegetation at the prosthetic valve without significant valvular dysfunction, mild pulmonary regurgitation, and mild pulmonary stenosis **Conduit deterioration:** NR **Reintervention:** NR **Replacement:** NR **Stenosis:** NR **Regurgitation:** NR
Reference: Stefanescu Schmidt et al. (2024)[1]	**Patients (N):** 4,513 **Age Mean (Range):** 13	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous	**Outcomes:** **Mortality (all-cause):** NR

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
Study Design: Retrospective Cohort study. **Purpose:** This study sought to characterize real-world practice, including patient selection, procedural outcomes, complications, and off-label usage **Length of follow-up:** NR **Funding Source:** A portion of this work was supported by the National Institutes of Health (T32HL007604) to Dr Stefanescu Schmidt. **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** U.S.	(11-16.5) years **Sex (% male):** 159 (57%) **Diagnosis:** CHD **Inclusion criteria:** Patients in whom a device was not deployed, who were treated with a self-expanding TPV during the same procedure, or who had no data entered for the valve type were excluded. **Exclusion criteria:** Patients in whom a device was not deployed, who were treated with a self-expanding TPV during the same procedure, or who had no data entered for the valve type were excluded. **Setting:** Hospital	valve (Contegra Pulmonary Valved Conduit) (n=280) **Comparator:** Homograft **Outcomes:** Adverse Events post procedure (acute success and AEs)	**Perioperative Mortality (<90 days post-procedure):** NR **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** NR **Infective endocarditis N (%):** **Conduit deterioration:** NR **Reintervention:** NR **Replacement:** NR **Other AEs:** Compared to homograft, Contegra conduit was not associated with any significant difference in the major adverse event (OR: 0.74, 95% CI: 0.28-1.91, p=0.53) (1.4% vs. 2.9%) Device embolization (n)= 1 Hemodynamic/therapeutic tear (n)=2 Clinical coronary artery compression (n)=1
Reference: Ali et al. (2023)[5] **Study Design:** Retrospective Cohort study. **Purpose:** We aim to describe the outcomes of patients with CHD who had surgical placement of right ventricle to pulmonary artery conduits with a focus on the risk factors for redo-surgery **Length of follow-up:** 2.07 ± 2.36 years **Funding Source:** NR **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra	**Patients (N):** 33 **Age Mean (SD):** 8.28 (4.70 years) **Sex (% male):** 18 (55%) **Diagnosis:** Congenital heart diseases **Inclusion criteria:** All patients who had RV to PA conduit were included. Verbal and written consent were taken from our patients' guardians. **Exclusion criteria:** NR **Setting:** Hospital	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=21) **Comparator:** Non-Contegra group: Goretex (polytetrafuor oethylene conduit) (n=5), Neocore (porcine aortic valve mounted in a bovine pericardial tube) (n=2), Carpentier Edwards (porcine valved conduit) (n=3), Hancock (porcine valved conduit) (n=2), Biointegral (bovine) (n=1) **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** There was no significant difference between the 2 subgroups as regards the median survival without the need for redo surgery for conduit replacement. The median survival without the need for surgical reintervention was 2.5 years for the non-contegra subgroup versus 3 years for the contegra subgroup (P = 0.59). However, the survival without reintervention proportion of both groups at 3 years of follow-up was 21.8% for the non-contegra subgroup versus 49.9% for the contegra subgroup. **Perioperative Mortality (<90**

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
Pulmonary Valved Conduit) **Country:** Egypt			**days post-procedure):**NR **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** NR **Infective endocarditis N (%):** NR **Conduit deterioration:** NR **Reintervention:** NR **Replacement:** NR **Stenosis:** NR **Regurgitation**: NR
Reference: Bobylev et al. (2023)[10] **Study Design:** Matched case control study (Matching was performed based on the patient's age category at implantation, the type of congenital heart defect, the number of previous operations, and the number of previous PVR) **Purpose:** The aim of this study is a matched comparison of bovine jugular vein conduits and decellularized homografts considering patient age, type of congenital heart defect, and the number of previous heart operations. **Length of follow-up (Mean, SD):** 6.3 (4.3) years **Funding Source:** This study was supported by a grant from the European Union's Seventh Framework Program for Research, Technological Development and Demonstration under Grant Agreement No. 278453 **Device (Manufacturer):** Bovine jugular vein conduit	**Patients (N):** 638 **Age Mean (SD):** 15.3 (9.5) **Sex (% male):** 369 (53%) **Diagnosis:** TOF/ ROSS/ PA/TAC/TGA/DORV **Inclusion criteria:** Patients who had received a decellularized pulmonary homograft (DPH) were recruited from the ESPOIR Registry. The registry aims to provide follow-up on all patients receiving DPH processed by corlife oHG (www.corlife.eu), a Hannover-based biotechnology company which provides decellularization as a service to tissue establishments (Comparator group) BJV patients for matching were chosen from the updated RVOT Conduit Registry (Intervention) **Exclusion criteria:** NR **Setting:** Hospital	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=319) **Comparator:** Decellularized homografts **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** BJV (Contegra) vs DPH (Comparator): Freedom from (%) At 5 years/ 10 years: Death: 97% vs 98.1% (p=0.45)/97% vs 98.1% (p=0.45) **Perioperative Mortality (<90 days post-procedure):** **Mortality (>90 days post-procedure):** **Adverse events (<90 days post procedure):** **Infective endocarditis:** The rate of freedom from endocarditis was significantly lower for BJV patients (87.1 vs. 96.5%, p=0.006). BJV (Contegra) vs DPH (Comparator): Freedom from (%) At 5 years/ 10 years: Endocarditis:93.7% vs 98.5% (p=0.006)/87.1% vs. 96.5% (p=0.006) **Conduit deterioration:** NR

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Germany			**Reintervention:** NR **Replacement:** NR **Stenosis:** BJV (Contegra) vs DPH (Comparator): Freedom from (%) At 5 years/ 10 years: Stenosis: 70.2% vs. 85.3% (p=0.001), 56.8% vs.82.1% (p<0.001) **Regurgitation:** BJV (Contegra) vs DPH (Comparator): Freedom from (%) At 5 years/ 10 years: Regurgitation (>=moderate): 82% vs 87% (p=0.13)/ 61.4 vs. 74.3% (p=0.13) **Other AEs:** Freedom from explantation was also significantly lower for BJV at 10 years (81.7 vs. 95.5%, p=0.001) BJV (Contegra) vs DPH (Comparator): Freedom from (%) At 5 years/ 10 years: Explantation: 91.3% vs 98% (p=0.001)/ 81.7% vs 95.5% (p=0.001) Degeneration (Stenosis and regurgitation): 59.65% vs 78% (p<0.001), 39.6% vs.65.5% (p<0.001)
Reference: Lewis et al., (2023)[8] **Study Design:** Retrospective cohort study. **Purpose:** The aim of this study is to evaluate the long-term performance of the three types of conduits we have used and assess risk factors for conduit failure **Length of follow-up:**	**Patients (N):** 455 patients (625 RV-PA conduits) **Age: NR** **Sex (% male):NR** **Diagnosis:** TOF (26.6%), (PA/VSD, 23.3%), and truncus arteriosus (TA, 16.9%). **Inclusion criteria:** All patients who received an RV-to-PA conduit were retrospectively reviewed for	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=192, 30.7%) **Comparator:** Pulmonary homografts (n=288, 46.1%) and aortic homografts (n=145,23.2%) **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** NR **Perioperative Mortality (<90 days post-procedure):** NR **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days (about 3 months) post procedure):** NR **Infective endocarditis N**

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
8.7 years (IQR: 4.3–13.3 years). **Funding Source:** Open access funding provided by Lund University **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Sweden	January 1, 1990, to December 31, 2019. Patients with a two-ventricle circulation were included. **Exclusion criteria:** Patients with single-ventricle physiology were excluded. Additionally, patients were excluded from the study if it was not possible to accurately find any of the study endpoints. **Setting:** Hospital		**(%): Pulmonary** homografts (n=4, 1.4%), aortic homografts (n=5,3.4%) and BJV (n=9,4.8%). There was a significant difference between rates of endocarditis in pulmonary homografts and BJV grafts (P-value=0.04) **Conduit deterioration:** NR **Reintervention:** Freedom from reintervention (FFR) for all patients was 37.8% at 30 years: 54.9% at 28 years for pulmonary homografts, 17.6% at 30 years for aortic homografts, and 26.6% at 17 years for BJV grafts (P-value <0.05) **Replacement:** Freedom from replacement (FCR): For pulmonary homografts, 10-, 20-, and 28-year FCR (P-value < 0.05) was 79.6%, 68.6%, and 66.0%, respectively. For aortic homografts, 10-, 20-, and 30-year FCR was 49.8%, 31.5%, and 23.0%, respectively. For BJV grafts, 10- and 19-year FCR was 68.1% and 46.0%, respectively. **Stenosis:** NR **Regurgitation:** NR **Other AEs:** NR
Reference: Sabateen et al., (2023)[2] **Study Design:** Retrospective cohort. **Purpose:** This study compares the outcomes of cryopreserved homografts with bovine jugular vein conduits (BJVC) in children < 2 years of age with RVOT reconstruction **Length of follow-up (Mean, SD):** 6.2(5.6) years	**Patients (N):** 63 patients (70 conduits) **Age (Mean, Range):** 4 (2 days to 23.5 months) **Sex (% male):** 14 (43.8%) **Diagnosis:** CAT (43.7%), TOF (9.3%), PA (9.3%), aortic valve disease (18.7%), ccTGA (12.5%), other (IAA, HLHC, DORV) (6.5%) **Inclusion criteria:**	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=32,45.7%) **Comparator:** Pulmonary (n=31,44.2%) and aortic homografts (n=7,10.1%). **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** Overall, 12 (17.1 %) patients died during follow-up (including 30-day mortality), 9 (23.6 %) patients in the homograft group, and 3 (9.3 %) patients in the BVJC group, (p = 0.10) **Perioperative Mortality (<90 days post-procedure):** The 30-day mortality was 10.5 % (4/38) in the homograft group and 0 % (0/32) in the BJVC

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
Funding Source: NR **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Slovakia	Inclusion criteria were patients below 2 years of age with congenital heart disease that required RVOT reconstruction using RV-to-PA conduits, who received a cryopreserved homograft, or BJVC (Contegra) **Exclusion criteria:** Exclusion criteria were patients whose operative notes could not be retrieved, and patients receiving another valve and conduit types. **Setting:** Hospital		group, but the difference was not significant (p = 0.058). **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** NR **Infective endocarditis N (%):** 2 (6.2%) and 0 in homografts **Conduit deterioration:** NR **Reintervention:** Transcatheter reinterventions were performed in 25 (35.7 %) conduits. It was needed in 16 conduits in the homograft group (balloon valvuloplasty, n= 12, stent implantation, n = 4), and 9 conduits in BJVC group (balloon valvuloplasty, n = 9). Indication was conduit stenosis across all cases. Overall freedom from transcatheter reintervention at 5, 10, and 15 years was 56.9 %, 37.5 %, and 31.2 %, respectively. Freedom from transcatheter reintervention at 5, 10, and 15 years was 55.3 %, 27.1 %, and 27.1 % in the homograft group, respectively. Freedom from catheter reintervention at 5, 10 years was 66.2 % and 35.3 %, in the BJVC group, respectively (p=0.32) Freedom from reoperation at 5, 10, and 15 years was 64.4 %, 35.4 %, and 21.2 % in the homograft group, respectively. Freedom from reoperation at 5, 10, and 12.5 years was 71 %, 59.3 %, and 59.3 %, in the BJVC group, respectively (p=0.23). The mean interval between initial implantation and reoperation in the homograft group and BVJC group was 5.1 ± 5.3 years and 3.7 ± 3.8 years, respectively (p = 0.21).

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
			Replacement: NR **Stenosis:** 25 (16 in homografts vs.9 in BJV group) **Regurgitation:** NR **Other AEs:** NR
Reference: Sabateen et al., (2023)[3] **Study Design:** Retrospective cohort. **Purpose:** The purpose of this study is to evaluate the outcomes of cryopreserved homografts, bovine jugular vein conduits and decellularized Matrix P Plus N conduits in patients undergoing RVOT reconstruction at a single center **Length of follow-up:** 8.6 ± 5.8 years **Funding Source:** NR **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Slovakia	**Patients** (N):173 (199 conduits) **Age (Median, Range):** 1 (0.005–14.5) years **Sex (% male):** 25 (55.6%) **Diagnosis:** CAT (16%), TOF (30.6%), DORV (3.1%) PAS (8.6%). Aortic valve disease (23.6%). ccTGA (8.6%). Others (9.5%) **Inclusion criteria:** Patients with congenital heart defects receiving cryopreserved homografts, BJVC (Contegra) or Matrix P Plus N conduits at the time of primary repair or reoperation were included. **Exclusion criteria:** Exclusion criteria included patients whose medical records or operative notes were not retrievable and those who had an RV–PA conduit implanted and underwent heart transplantation due to myocardial dysfunction. Additionally, all other conduit types were excluded. **Setting:** Hospital	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=45) **Comparator:** homografts (n=129) (aortic=14, pulmonic=114), and Matrix P Plus N (n=25) **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** The survival rate at 1, 10, 15 and 20 years was 92.9%, 91%, 87% and 83%, respectively. Overall, 20 (11.5%) patients died during follow-up (including 30-day mortality), 16 (12.4%) patients in the homograft group, 3 (6.6%) patients in the BVJC group and 1 (4%) in the Matrix P Plus N group (P = 0.78) **Perioperative Mortality (<90 days post-procedure):** The 30-day mortality was 3.1% in the homograft group, 0% in the BJVC group and 4% in the Matrix P Plus N group (P = 0.5). No deaths were related to the structural failure of the conduit. **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** NR **Infective endocarditis N (%):** NR **Conduit deterioration:** NR **Reintervention:** During the study period, 44 conduits (22.1%) underwent at least 1 catheter reintervention, with an incidence of 28 (21.7%), 9 (20%) and 7 (28%) in homograft, BJV and Matrix P Plus N conduits, respectively. Initial catheter reintervention was required in 28 conduits in

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
			the homograft group (balloon valvuloplasty, n = 21; stent implantation, n = 4; PPVI, n = 3), 9 in the BJVC group (balloon valvuloplasty, n = 9) and 7 in the Matrix P Plus N group (balloon valvuloplasty, n = 6; PPVI, n = 1). The indications for catheter reintervention were severe conduit stenosis (n = 40; 90.9%), with a mean gradient of 62 mmHg, and severe regurgitation (n = 4; 9.1%). Freedom from first catheter reintervention at 5, 10 and 20 years was 87.9%, 77.3% and 70% in the homograft group, respectively. Freedom from first catheter reintervention at 5 and 10 years was 71.2% and 38%, in the BJVC group, respectively, and freedom from first catheter reintervention at 5 and 9 years was 75% and 64.3% in the Matrix P Plus N group, respectively. The catheter reintervention rate was significantly different among the 3 groups (P = 0.021). Freedom from reoperation at 5, 10 and 20 years was 88%, 81.7% and 69.7% in the homograft group, respectively. Freedom from reoperation at 5 and 10 years was 75.7% and 63% in the BJVC group, respectively, and freedom from reoperation at 5 and 9 years was 91.3% and 83% in the Matrix P Plus N group, respectively. No statistically significant difference regarding the reoperation rate was observed among the 3 groups (P = 0.23). **Replacement:** NR **Stenosis:** NR **Regurgitation:** NR **Other AEs:** NR
Reference: Schuler et al., (2023)[9]	**Patients** (N):69 (with IE)	**Intervention:** Bovine jugular vein conduit with a	**Outcomes:**

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
Study Design: Retrospective cohort. **Purpose:** To optimally prepare for the launch of the SERPIE, we conducted the analysis based on national retrospective data on pediatric IE presented here **Length of follow-up:** NR **Funding Source:** NR **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Switzerland	**Age (Median, Range):** 6.4 years (IQR 0.8–12.6) **Sex (% male):** 42 (61%) **Diagnosis:** CHD **Inclusion criteria:** This study was designed as a retrospective nationwide multicenter analysis including cases of pediatric infective endocarditis in children under 18 years of age treated in Switzerland between 2011 and 2020. Only patients fulfilling the modified Duke criteria for definite or possible IE were included. **Exclusion criteria:** NR **Setting:** Hospital	competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit (n=18) **Comparator:** NA **Outcomes:** Adverse Events	**Mortality (all-cause):** NR **Perioperative Mortality (<90 days post-procedure):** NR **Mortality (>90 days post-procedure):** NR **Adverse events (<90 days post procedure):** NR **Infective endocarditis N:** 14 (with Contegra) **Conduit deterioration:** NR **Reintervention:** NR **Replacement:** NR **Stenosis:** NR **Regurgitation:** NR **Other AEs:** Implanted foreign material: Contegra valve (n=5)
Reference: Wasiak et.al (2023)[6] **Study Design:** Retrospective Cohort study. **Purpose:** This study aimed to evaluate the early and late outcomes of ToF repair with a transannular Contegra® monocuspid patch in a single center **Length of follow-up (Median):** 111 months **Funding Source:** NA **Device (Manufacturer):** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) **Country:** Poland	**Patients (N):** 224 **Age Median (Range):** 13.3 (range, 2-106) months **Sex (% male):** 126 (56.25%) **Diagnosis:** Tetralogy of Fallot (ToF) (n=197) and TOF with cardiac abnormalities (n=27) (CAVSD, aberrant subclavian artery, PAPVD, left atrial isomerism, pentalogy of Cantrell, aortopulmonary window) **Inclusion criteria:** The inclusion criterion for transannular patch repair was pulmonary valve annulus hypoplasia, defined based on preoperative echocardiography if the z-score was below −3. **Exclusion criteria:** NR **Setting:** Hospital	**Intervention:** Bovine jugular vein conduit with a competent tri-leaflet venous valve (Contegra Pulmonary Valved Conduit) (n=224) **Comparator:** NA **Outcomes:** Adverse Events	**Outcomes:** **Mortality (all-cause):** NR **Perioperative Mortality (<90 days post-procedure):** Hospital mortality: 7 (3.1%) **Mortality (>90 days post-procedure):** N=1 **Adverse events (<90 days post procedure):** NR **Infective endocarditis N (%):**2 (0.9%) **Conduit deterioration:** NR **Reintervention:** 2 (0.9%) **Replacement:** 30 (14.1%) **Stenosis:** NR **Regurgitation:** N=35 (16.5%). Freedom from more than moderate pulmonary valve insufficiency rates were 92.2%, 84.1%, and 72.2% after 5, 10, and 15 years, respectively.

Study Characteristics	Patient Characteristics	Intervention(s)	Study Outcomes
			Other AEs: The event-free survival rate was 85.4% (181 of 212 patients), with event-free survival rates of 94.7%, 84.1%, and 73.4% after 5, 10, and 15 years, respectively. The main indications for late reoperations were severe pulmonary insufficiency (n=14) and trunk or branch pulmonary stenosis with moderate pulmonary insufficiency (n=13). Other reoperations were for RVOT obstruction (n =2) and infective endocarditis (n=1)

Abbreviations: BJV: Bovine jugular vein; TOF: tetralogy of Fallot, PDA: Patent ductus arteriosus; RVOT: right ventricular outflow tract, NA: not applicable, NR: Not reported, CHD: Congenital heart diseases, VSD: Ventricular septal defect, BJVC: Bovine Jugular vein conduit, TGA: transposition of great arteries, TA: truncus arteriosus, RV: right ventricle, PA: pulmonary artery, DCH: Decentralized homografts, PVR: pulmonary valve replacement, BVP: bioprosthetic pulmonary valve TPV: transcatheter pulmonary value, MAE: Major adverse event; D-TGA dextro-transposition of great arteries, DORV double outlet RV; ccTGA – Congenitally corrected Transposition of Grate Arteries, PAS – Pulmonary atresia, HLHC – Hypoplastic left heart complex, IAA – Interruption of aortic arch, CAT – Common arterial trunk, CAVSD, complete atrioventricular septal defect; PAPVD, partial anomalous pulmonary venous drainage