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Horizon scanning prioritising summary

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Contegra® pulmonary valved conduit: for the correction or reconstruction of the outflow tract of the right ventricle in congenital heart malformations in patients aged under 18.

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Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This *Horizon scanning prioritising summary* was prepared by Adriana Parrella and Tracy Merlin from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Department of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005.

PRIORITISING SUMMARY

REGISTER ID: **0000077**

NAME OF TECHNOLOGY: **CONTEGRA® PULMONARY VALVED CONDUIT**

PURPOSE AND TARGET GROUP: **CORRECTION OR RECONSTRUCTION OF THE OUTFLOW TRACT OF THE RIGHT VENTRICLE IN CONGENITAL HEART MALFORMATIONS IN PATIENTS AGED UNDER 18**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Experimental	☐	Established
☐	Investigational	☐	Established *but* changed indication or modification of technique
☐	Nearly established	☐	Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Greece	✓		
Italy	✓		
Germany	✓		
Netherlands	✓		
Belgium	✓		

IMPACT SUMMARY

Medtronic provides the Contegra® Pulmonary Valved Conduit for the repair of the right ventricular outflow tract in patients with congenital heart disease. It is not available commercially in Australia and is not listed on the TGA however two implant procedures have occurred in Australia and New Zealand during the previous 12 months. The device is available for implantation on an individual basis. The cost of the device is $5,600. The device is available on an individual request basis in Australia (Medtronic Australia). Marketing approval was issued in the U.S. in November, 2003.

The Contegra® Pulmonary Valved Conduit is a biprosthetic heart valve made from a segment of bovine jugular vein. The conduit is treated with preservatives to keep it durable, flexible and sterilised for human implantation. The vein contains a venous valve with three leaflets (trileaflet) that open to allow the forward flow of blood from the right ventricle into the pulmonary artery and close to prevent the backward flow of blood. The device works with the three other existing heart valves, (tricuspid, aortic and mitral) to control the direction of blood flow through the chambers of the heart.

The Contegra® Pulmonary Valved Conduit 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
- Pulmonary atresia

In addition the conduit is indicated for the replacement of previously implanted pulmonary homograft, xenograft or valved conduits.

Different techniques for surgical correction include implantation of bioprostheses fixed in woven Dacron tubes as supportive housing, glutaraldehyde fixed porcine or bovine pericardial valves, glutaraldehyde fixed porcine aortic or pulmonary roots, non-valved conduits, homografts or valvuloplasties (Breymann 2002). Homografts (human valves), often used by paediatric cardiovascular surgeons for this type of reconstruction, are limited by the availability of donated human organs, particularly in small sizes, lack of growth of the graft, early degeneration and calcification in young patients (Bottio et.al 2003, Breymann et.al. 2002).

The results of a retrospective cohort study (level III-2 evidence) comparing RVOT reconstruction using either a Contegra® conduit in 41 patients or a size-reduced pulmonary homograft in 36 patients showed comparable clinical outcomes, with two deaths in the homograft group compared to one in the Contegra group (Bove et.al 2002). The study focussed on the early haemodynamic performance of the Contegra conduit. There were no conduit-related complications in either group. Early echocardiographic assessment showed only trivial to mild regurgitation in 9 homografts versus 17 Contegra conduits.

A phase I clinical trial studies 71 Contegra® patients who were compared retrospectively with 52 patients who had previously received a homograft and 30 who had previously received a porcine xenograft. Data were extracted within equal observation periods for all three groups and mortality, reoperation, echocardiographic assessment, valve incompetence, conduit dilation, survival, freedom from explantation and reoperation rate were compared. There were no device-related adverse events (follow-up maximum 27 months) in the Contegra® group compared to 14% of the homograft and 75% of the porcine xenografts that needed to be explanted (Breymann et al. 2002) within the same observation period. However, the results need to be interpreted cautiously as follow-up was short-term and did not include all patients.

A prospective, multicentre case series study (level IV evidence) is currently being undertaken by the manufacturer, with 237 patients implanted at sixteen centres (Contegra Clinical Report 2003). The intermediate data shows 9% early deaths, 88% freedom from death at one year, 92% freedom from reoperation, 12 % catheter intervention. A total of 28 deaths were reported: 22 deaths in the early post-operative period (within 30 days or prior to hospital discharge) and six deaths in the late post-operative period (after 30 days following hospital discharge). Of the 22 early deaths, two deaths were device-related and two were unexplained. Of the six late deaths, five were device-related and one death was unexplained. The American FDA has compared mortality and morbidity data from this study with historical data from homograft clinical studies undertaken since 1993. This low level of evidence indicated that the Contegra® performed favourably in mortality and freedom from re-operation.

In 2001-2 there were 1023 hospital separations for Congenital Heart Disease (AR-DRG code F68Z). They include (not exclusively) the indications mentioned above (AIHW, 2004). The MBS fee for an intraventricular baffle or conduit (MBS code 38754) for congenital heart disease is currently $2,220.50.

CONCLUSION:

The available level III-2 evidence indicates this technology is potentially safe and effective in the short term, although there is uncertainty regarding its safety and effectiveness in the long-term. The target group for this technology in Australia is small.

HEALTHPACT ACTION:

It is therefore recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Bove, T., Demanet, H. et al (2002). 'Early results of valved bovine jugular vein conduit versus bicuspid homograft for right ventricular outflow tract reconstruction', *Ann Thorac Surg,* 74 (2), 536-541; discussion 541.

Breymann, T., Thies, W. R. et al (2002). 'Bovine valved venous xenografts for RVOT reconstruction: results after 71 implantations', *Eur J Cardiothorac Surg,* 21 (4), 703-710; discussion 710.

Carrel, T., Berdat, P. et al (2002). 'The bovine jugular vein: a totally integrated valved conduit to repair the right ventricular outflow', *J Heart Valve Dis,* 11 (4), 552-556.

Chatzis, A. C., Giannopoulos, N. M. et al (2003). 'New xenograft valved conduit (contegra) for right ventricular outflow tract reconstruction', *Heart Surg Forum,* 6 (5), 396-398.

Corno, A.F., Hurni, M. et al (2002). 'Bovine jugular vein as right ventricle-to-pulmonary artery valved conduit', *J Heart Valve Dis,* 11 (2), 242-247.

SEARCH CRITERIA TO BE USED

Aneurysm/ surgery
Pulmonary Artery/ surgery
Tetralogy of Fallot/complications/ surgery
Transplantation, Heterologous
Ventricular Outflow Obstruction/complications/ surgery
Cardiac Surgical Procedures
Hemodynamic Processes
Jugular Veins/ transplantation
Heart Valve Prosthesis
Heart Valve Prosthesis Implantation
Mitral Valve/ transplantation
Ventricular Outflow Obstruction/ surgery/ultrasonography