



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **Carillon Mitral Contour System for Mitral Regurgitation**



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Australian  
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# PRIORITISING SUMMARY

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**REGISTER ID** S000118

**NAME OF TECHNOLOGY** CARILLON™ MITRAL CONTOUR SYSTEM™

**PURPOSE AND TARGET GROUP** THE CARILLON MITRAL CONTOUR SYSTEM IS FOR PATIENTS WITH FUNCTIONAL MITRAL REGURGITATION

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes  
 No  
 Not applicable

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Germany	✓		
Poland	✓		

## IMPACT SUMMARY

The Carillon™ Mitral Contour System™ (Cardiac Dimensions®, Washington USA) is a contouring device indicated for patients with mitral (valve) regurgitation. The device is positioned around the mitral valve via percutaneous access through the jugular vein (Schofer et al 2009). The Carillon Mitral Contour System (CMCS) provides an alternative, non-invasive intervention for patients classed as unfit for open heart surgery due to co-morbidities (Bach 2009). The CMCS is implanted by a cardiologist under general anaesthesia.

## BACKGROUND

Mitral regurgitation (also known as functional mitral regurgitation (FMR)) is the backflow of blood from the left ventricle into the left atrium due to the incomplete

closure of the mitral valve within the heart (Heart Failure Society of America (HFSA), 2010). MR occurs whilst the left ventricle contracts (systole), in order to pump blood into the systemic circulation. Deformities in the mitral valve, resulting in MR, can arise from a number of causes including mitral valve prolapse, damaged chordae tendineae, deterioration of the valve with age, prior heart attack (myocardial infarction), endocarditis (infection), congenital heart defects and rheumatic fever (Bach 2009, Mayo Clinic 2010). MR is a degenerative disorder and contributes to decreased heart function and therefore congestive heart failure (CHF).

Failure to medically or surgically correct MR can lead to chronic long term congestive heart failure (HFSA 2010). In contrast, acute MR (via sudden rupture of the chordae tendineae or papillary muscle) requires immediate attention and can result in cardiovascular collapse (shock) and death (HFSA 2010). Symptoms of chronic MR include shortness of breath, pulmonary oedema (fluid in the lungs), orthopnea (shortness of breath when lying down) and exercise intolerance (Mayo Clinic 2010).

The clinical implications of MR can be divided into two categories, namely, haemodynamic or functional. Haemodynamic parameters quantify the severity of MR via ECG (Helmcke et al 1987, Schofer et al 2009). Functional parameters for measuring the severity of MR include the New York Heart Association (NYHA) Classification of MR (see Table 1), six minute walk distance (6MWD) test and the Kansas City Cardiomyopathy Questionnaire (Bach 2009, Schofer et al 2009). All measure the overall impact of decreased heart function on quality of life, exercise tolerance and clinical symptoms of MR.

**Table 1: NYHA Classification of MR Severity**

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.
Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

Traditional treatment for MR consists of medical (pharmacological) treatment (with diuretics, ACE inhibitors/angiotensin two receptor blockers and/or beta blockers) as well as surgical replacement of the mitral valve with a prosthesis, or placement of an annuloplasty ring (Bach 2009, e-Medicine 2010). Surgically placed annuloplasty rings aim to decrease the diameter of the mitral valve, in an attempt to increase the probability of complete closure of the mitral valve (during systole) (Bach 2009). However, significant co-morbidities prevent surgical intervention (open heart surgery) in a large proportion of patients with MR (Bach 2009, HFSA 2010, Mayo Clinic 2010). As a result, percutaneous (non-surgical) interventions have been developed and include percutaneous transvenous mitral annuloplasty (PTMA) as well as the Carillon Mitral Contour System.

Percutaneous therapies may also be used as an adjuvant therapy to conventional medical (pharmacological) intervention.

The CMCS is a metal contouring system designed to decrease the annular diameter of the mitral valve (Cardiac Dimensions 2010). It functions in a similar manner to an annuloplasty ring, as decreased mitral diameter increases the probability of complete closure of the valve during systole. Placement of the CMCS is achieved via percutaneous access through the jugular vein to the mitral valve. The metal contour system is then anchored proximally and distally in order to decrease the diameter of the mitral valve. The procedure is performed by a Cardiologist under general anaesthesia. Possible complications include death, myocardial infarction (MI), cardiac perforation necessitating catheter based or surgical intervention, device embolisation, or device failure.

#### **CLINICAL NEED AND BURDEN OF DISEASE**

According to the AIHW 2007-08 data there were 2,826 principle diagnoses of non-rheumatic mitral valve disorders (including mitral insufficiency, mitral prolapse and mitral stenosis). The current prevalence of MR within Australia is estimated to be 11203 people (Hanson 2010, Australian Bureau of Statistics 2010). In addition, patients with dilated cardiomyopathy and congestive heart failure may also possess mitral valve deformities, however; specific data indicating the prevalence of MR within these patient populations was not available. In the Framingham Study (USA) conducted in 1999 the prevalence of MR increased from 0.3% to 11.2% in men and 0% to 2.3% in women from age groups 40 to 83 years of age (Singh et al 1999).

#### **DIFFUSION**

The Carillon Contour System (CMCS) received the CE Mark of approval on the 26<sup>th</sup> January 2009 (Bloomberg.com). The Carillon Contour System has not received Food and Drug Administration (FDA) or Therapeutic Goods Administration (TGA) approval (FDA 2010, TGA 2010).

#### **COMPARATORS**

Comparators include

- Prosthetic mitral valves such as the **Carpentier-Edwards® Perimount Magna Mitral Pericardial Bioprosthesis™** (Edwards Life Sciences®, USA), **Starr-Edwards Silastic ball valve™** (Baxter International Inc®, USA), **Medtronic Hall mitral valve™** (Medtronic Inc®, USA) and others (e-Medicine, 2010).
- Annuloplasty rings include the **Rigid Saddle Ring with EZ Suture™ Cuff** (St. Jude Medical®, USA), **Adjustable Annuloplasty Ring™** (MitralSolutions®, USA), **Memo 3D Annuloplasty Ring™** (Sorin Group®, USA) and others.
- Two percutaneous devices are currently available are the **PTMA™** (Percutaneous Transvenous Mitral Annuloplasty) (Viacor®, USA) and the **MitraClip™** (Abbott Laboratories®, USA) previously examined in Horizon Scanning Prioritising Summary 2006.

## **SAFETY AND EFFECTIVENESS ISSUES**

### *Study description*

Two case series were identified for inclusion, namely, Schofer et al (2009) and Jerzykowska et al (2010).

Schofer et al (2009) enrolled 48 patients (18 years of age and over) with FMR and moderate heart failure (it is unclear if the study was performed prospectively). Based on intent-to-treat analysis 30 of 46 received the device. The mean age of the patients implanted with the device was 64 (SD 9) years and included 26 males and 4 females. Patients were recruited. Haemodynamic baseline characteristics included a mean left-ventricle end diastolic diameter (LVEDD) of  $6.7\pm 0.75$ cm, mitral annular diameter (MAD) of  $4.2\pm 0.4$ cm and left-ventricle ejection fraction (LVEF) of  $30\pm 8\%$ . Functional baseline characteristics included a mean 6 minute walking distance (6MWD) of  $307\pm 87$  metres and NYHA class of between II and IV. In addition, there had been a mean number of 1.2 (SD 1.5) hospital admissions for heart failure (HF) per patient. All patients' medication regimen was optimised throughout the study.

Prior to implantation an ECG was conducted to rule out significant organic mitral valve pathology and to quantify MR, according to ventricular size and left ventricular ejection fraction. Semi-quantitative measures were also determined (including VC, ERO, RV and FMR jet area to left atrial area ratio); and an independent ECG core laboratory reviewed all screening ECGs to qualify patients.

Safety was evaluated by the 30-day rate of major adverse events (AEs). Major AEs were defined as the composite end point of death, myocardial infarction (MI), cardiac perforation necessitating catheter based or surgical intervention, device embolisation, or the occurrence of surgery or percutaneous coronary intervention (PCI) related to device failure.

Assessment of effectiveness was divided into haemodynamic and clinical outcomes. Haemodynamic outcomes were measured using ECG and clinical outcomes included functional improvements (NYHA class, 6-minute walk distance and Kansas City Cardiomyopathy Questionnaire). Secondary outcomes included chest x-ray, ECG, cardiac enzymes and concurrent medications; and baseline variables were reassessed at one and 6 months.

Jerzykowska et al (2010) reports the outcomes of nine consecutive patients enrolled between July 2006 and June 2007, including eight men and one woman (mean age  $58.56\pm 6.3$  years, range 48-67 years). All patients had been diagnosed with dilated cardiomyopathy (DCM), were classified as NYHA class III and class IV and seven patients had previous history of MI. In addition, the PISA method was used to determine the severity of MR and all patients had at least grade 2 MR. Baseline haemodynamic characteristics were determined by ECG prior to device implantation (see Table 2) and include semiquantitative measures of MR (VC, MR jet area to left atrial area ratio, ERO

and RV). Functional outcomes of Carillon device implantation were measured using the NYHA classification system and 6MWD test at one month follow up.

### *Safety*

Implantation was not attempted in five of the 18 (28%) patients who did not receive the Carillon device. Reasons included coronary sinus (CS) access-related dissection/perforation (n=3) and screen failure (n=2). In addition, the implant was recaptured in 13 patients, 3 of which experienced slipping of the distal anchor, precluding device delivery. Following this early experience the apex of the device was modified (twisted) to improve structural rigidity and anchoring. Only 1 patient was implanted with the original design. There were two major reasons for device recapture in the 10 patients who initially experienced successful deployment, namely, insufficient FMR reduction and coronary artery compromise. There was no evidence of late coronary compromise in any of the patients who received a permanent implant. Specifically, there were no hospitalisations for new MI or ECG changes suggestive of chronic device-related coronary compromise. In all 30 patients implanted with the device follow up radiographs were performed and none revealed device movement, loss of integrity or fracture. Two patients withdrew from the study before the 30-day follow up. Six of the 46 (13%) patients (intent-to-treat) experienced a total of 7 major AEs, including one death, a rise in creatine kinase-MB (n=2) and CS perforation or dissection (n=3).

The one death occurred in a 56 year old man with a history of 3-vessel coronary artery disease, chronic renal insufficiency, and chronic obstructive pulmonary disease (COPD). One day after the procedure the patient had a repeat coronary angiogram to evaluate a rise in his creatine kinase-MB level from 6 to 92 U/L. No significant change in the coronary anatomy was identified; however, the patient developed acute renal failure presumed to be due to contrast-induced nephropathy. This patient died of multi-system organ failure 22 days after the index procedure.

The two patients who experienced a rise in creatine kinase-MB (>3 times the upper limit) after the implant procedure had no accompanying ECG changes or clinical symptoms; and their postprocedure clinical course was uncomplicated. In one of the two patients the proximal anchor of the Carillon device was noted to cross the small side branch (<1mm) of the right coronary artery that ran in the atrioventricular groove.

One of the three (33%) patients suffering CS perforation successfully underwent a dissection procedure and the complication resolved without any specific therapy. In one patient in whom the CS was perforated with a stiff guidewire, no therapy was needed, and there were no clinical sequelae with observation. Lastly, the third patient in whom the CS was perforated after advancement of a diagnostic catheter required pericardial drainage. Notably, two of the perforations occurred early in the study (first and fourth patients), and the resulting procedural insights prevented subsequent cases.

Jerzykowska et al (2010) reported that Carillon device implantation was attempted in 15 patients, and successful in 11 (74%) patients; however two were lost to follow up. Attempts to implant the Carillon device were terminated in four (of 15) (27%) patients due to lack of expected reduction in the MR jet (n=2) and unfavourable local coronary

vessel anatomy precluding safe delivery of the device (due to compression of the left circumflex artery) (n=2). In all four patients the device was introduced into the coronary sinus, and the decision to withdraw was assessed by transoesophageal echocardiography (TEE). In two of the four patients device implantation was attempted twice, with a thrombus in the left atrial appendage found during TEE in one patient, and the other patient required initial coronary vessel dilatation and stenting. No further safety data was reported.

*Effectiveness*

Schofer et al (2009) recorded improvements in haemodynamic parameters as outlined in Table 2. Notably, follow up data is not available for six (20%) patients at 6 month follow up as 2 patients died, 1 patient received a transplant and 3 patients declined to return for the follow up visit.

**Table 2: Improvements in haemodynamic properties following implantation of the Carillon device by Schofer et al (2009)**

Haemodynamic parameter	Baseline (n=30)	Follow up (6 months) (n=24)	p-value
MR jet/LA area	47.6	32.3	P<0.001
RV	35.1	24.3	P<0.001
ERO	0.25	0.17	P<0.001
VC	0.71	0.53	P<0.001

MR jet/LA area, mitral regurgitation jet area to left atrial area ratio; RV, regurgitation volume; ERO, effective regurgitation orifice area; VC, vena contracta.

Whilst not statistically significant, a trend toward a reduction in left ventricular end diastolic diameter or volume, left ventricular ejection fraction or mitral annular diameter was observed.

Functional improvements included a reduction in NYHA classification from an average of 2.9 (baseline, n=30) to 1.8 at 6 months (p<0.001, n=24). At baseline 24 of 30 patients (80%) were in class III and class IV, whereas at 6 month follow up 22 of 25 (88%) were in NYHA class I and class II (p<0.001). In addition, the 6MWD improved from a baseline of 307 (SD87) metres to 403 (SD137) metres at 6 months (p<0.001). Finally, the results of the Kansas City Cardiomyopathy Questionnaire Overall Summary Score improved from 47 to 69 between baseline and 6 months (p<0.001).

Jerzykowska et al (2010) reports statistically significant improvements in two haemodynamic properties, namely, VC<sup>1</sup> and MR (see Table 3).

<sup>1</sup> VC, vena contracta; is a measure of MR severity. The cross-sectional area of the vena contracta represents a measure of the effective regurgitant orifice area (ERO), which is the narrowest area of actual flow through the mitral valve (E-chocardiography Journal).

**Table 3: Improvements in haemodynamic parameters following Carillon device implantation in Jerzykowska et al (2010)**

Haemodynamic parameter	Baseline (n=15)	Follow up (1 month) (n=9)	p-value
VC	0.66±0.1	0.35±0.1	P<0.005
MR jet/LA	55±11.2	36±10.2	P<0.005
ERO	0.25±0.1	0.24±0.1	NS
RV	33.1±11.8	32.3±7.8	NS

MR jet/LA area, mitral regurgitation jet area to left atrial area ratio; RV, regurgitation volume; ERO, effective regurgitation orifice area; VC, vena contracta; NS, not statistically significant.

The improvements in VC and MR jet/LA correspond to a reduction of MR severity by one grade according to the PISA method. Patients implanted with the CMCS showed an improvement in the 6MWD from 360 (SD75) metres (baseline) to 422 (SD91) metres at one month follow up. Finally, Jerzykowska et al (2010) reports an improvement in NYHA class for all patients, however does not report the quantitative results.

### **COST IMPACT**

No cost-utility analysis literature was identified for the CMCS. However, if the CMCS is effective in reducing MR without the need for open heart surgery, ongoing medical intervention and in patients with co-morbidities preventing surgical intervention, cost savings may be achieved for the health system.

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified.

### **OTHER ISSUES**

Schofer et al (2009) was funded by Cardiac Dimensions Inc, Kirkland, Washington USA. Schofer et al (2009) conducted further analysis and refinement into the implantation procedure. It was found that there were two main reasons for unsuccessful implantation in the 18 of 30 patients (n=5/18 not attempted; n=13/18 recaptured). Firstly, the device was implanted on average more distal in the coronary sinus/great cardiac vein (CS/GCV). Secondly, during the tensioning process to create tissue plication, the CS anchor was pulled closer toward the CS ostium in the successfully implanted patients. Therefore, it is apparent that further investigation into the implantation methodology is required.

### **SUMMARY OF FINDINGS**

Early peer reviewed literature indicates that the CMCS is feasible, safe and effective for the non-invasive treatment of MR. The complication rate across the two case series ranged from 0% (n=0/9) to 13% (n=6/46). Major complications included death (n=1), a rise in creatine kinase-MB (n=2) and CS perforation or dissection (n=3). Statistically significant improvements in haemodynamic and functional measures of MR severity were also achieved. Schofer et al (2009) reported a reduction in VC, MR jet/LA, ERO and RV (all p<0.001); whilst Jerzykowska et al (2010) observed a reduction in VC and MR jet/LA (both p<0.005). Finally, Schofer et al (2009) demonstrated a functional improvement in NYHA class and 6MWD at 6 month follow up (both p<0.001). Attempts to implant the device were either terminated or abandoned in 5 of 18 (28%) patients

(Schofer et al 2009) and 4 of 15 (27%) patients (Jerzykowska et al 2010). The device recapture rate ranged from 0% to 28% (n=13/46).

#### **HEALTHPACT ASSESSMENT**

Based on the functional improvements experienced by patients implanted with the CMCS and the lack of high-quality evidence comparing these outcomes to those of the gold standard it is recommended that this technology be monitored for 12 months:

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor      | <input type="checkbox"/> Archive                           |

#### **HEALTHPACT ACTION**

#### **NUMBER OF STUDIES INCLUDED**

Total number of studies	2
Level evidence	IV

#### **REFERENCES**

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#### **SOURCES OF FURTHER INFORMATION**

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#### **SEARCH CRITERIA TO BE USED**

Functional Mitral Valve Regurgitation AND Carillon, Mitral Valve Regurgitation AND Carillon, Functional Mitral Valve Regurgitation AND Annuloplasty, Mitral Valve Regurgitation AND Annuloplasty, Carillon AND Annuloplasty, Percutaneous Transvenous Mitral Annuloplasty AND Carillon.

#### **HEALTH PACT DECISION**

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor                 | <input type="checkbox"/> Archive                           |
| <input type="checkbox"/> Refer                   | <input type="checkbox"/> Decision pending                  |

#### **PRIORITY RATING**

- High**                       **Medium**                       **Low**