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**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA  
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# Horizon Scanning Technology Prioritising Summaries

## StarClose™ Vascular Closure System

March 2006



**ASERNIP/S**

**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

**Name of Technology:**

StarClose™ Vascular Closure System (Abbott Vascular Devices, Redwood City, California).

**Purpose and Target Group:**

The StarClose system is a delivery device that facilitates the placement of a nitinol clip to close femoral artery access sites following percutaneous catheterisation procedures in patients undergoing angiographic cardiac procedures. The device achieves an extravascular closure of the arteriotomy site, which promotes primary healing via a 360° tissue apposition (Abbott Vascular Devices 2005).

**Stage of Development (in Australia):**

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use
- Not yet emerged in Australia

The StarClose is registered in the Australian Register of Therapeutic Goods (ARTG number: 71700, Product ID: 146168).

**International Utilisation:**

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States		√	
Europe		√	

**Impact Summary:*****Background***

Femoral artery puncture is a common access where catheters sheaths and guidewires are advanced to the target site to deliver therapies (either drugs or devices).

Haemostasis of the arterial entry site is usually achieved through a period of manual compression with or without the use of adjunctive mechanical compression devices with prolonged immobilisation or bed rest. The compression and bed rest can often be associated with discomfort for the patient and may have economic implications in terms of



time to separation. Various alternative methods to manual compression have been designed to overcome this problem; Arterial puncture closure devices (APCD) include collagen plugs with or without an anchor from inside the artery (Angioseal, Vasoseal). The collagen plugs were developed to seal the entry site by applying discrete pressure against the wall and forming a coagulum (Duda *et al.*, 1999). However, it is unclear whether collagen plugs reduce the time to primary hemostasis and decrease the time to ambulation (Duda *et al.* 1999). Other means of achieving vascular closure include suture type stitches placed around the artery; and balloon-positioning catheters combined with bovine microfibrillar collagen and thrombin (Koreny *et al.* 2004).

The StarClose vascular closure system is designed to deliver an extravascular Nitinol clip to close 6 French puncture sites in the femoral artery following diagnostic and interventional catheterisation procedures. The system consists of the StarClose Clip Applier and a StarClose 6F Exchange System. The implantable nitinol clip is mounted on the Clip Applier, which delivers it via the exchange system for extravascular closure on the access sites. Abbott states that the system can be used with the Introducer Set, which is packaged and sold separately.

### ***Clinical Need and Burden of Disease***

Over 140,000 procedures using vascular access for percutaneous coronary intervention (PCI) and other endovascular access therapies were performed in Australia between June 2003 and June 2005 (Medicare Australia 2006). Procedures involving arterial puncture carry a risk of access site complications in 1% to 5% of procedures ranging from haematomas to significant bleeds requiring transfusion, extended hospital stay or surgical repair (Kussmaul *et al.* 1995).

Vascular access is emerging as a preferred technique for non invasive targeted delivery of drugs and therapeutic devices therefore it is conceivable that the number of these types of procedures will increase.

### ***Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System***

FDA approval for the StarClose vascular closure system was issued in the United States on 21 December 2005. In Europe, StarClose received CE certification in February 2004. The FDA indicates the StarClose has approval for use in Australia (US Food and Drug Administration 2005), although searches of the TGA website failed to retrieve any information. At the time of writing, StarClose is being marketed commercially in Austria, Belgium, Czech Republic, France, Germany, Greece, Hong Kong, Hungary, Ireland, India, Israel, Italy, Kuwait, Lebanon, Malaysia, Netherlands, New Zealand, Norway, Portugal,



Poland, Saudi Arabia, South Africa, Spain, Sweden, Switzerland, Turkey and United Kingdom. Additionally, the StarClose Vascular System has not been withdrawn from marketing for any reason relating to safety and effectiveness (US Food and Drug Administration 2005).

### ***Existing Comparators***

- Manual hand compression
- Vasoseal (Datascope Corp, Montvale New Jersey) – closure device with a collagen plug intended to seal the artery entry site by applying discrete pressure against the wall forming a coagulum (Duda *et al.* 1999).
- Angio-Seal (Sherwood, Davis and Geck, St Louis Missouri) – Similar to Vasoseal with the addition of an intravascular absorbable anchor to facilitate collagen plug apposition (Duda *et al.* 1999).
- Perclose Proglide (Abbott Vascular Devices, Redwood City, California).  
A monofilament suture knot advances to the opening in the artery, facilitating a pre-tied knot to close the access site in the femoral artery (Duda *et al.* 1999).

### ***Estimated Cost Impact***

The cost associated with this device is difficult to determine, as there is no substantial published economic data. The Medicare Benefits Schedule does not list specific reimbursement fees solely for vascular closure.

### ***Efficacy and Safety Issues***

#### **List of Studies Found**

Total number of studies	2
Randomised controlled trials	1
Non-randomised comparative studies	1
Case series studies	0

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data included in this study are drawn from two studies, a nonrandomised-controlled study and a nonrandomised comparative study. These studies were selected as they are the only available clinical results currently available for the StarClose system.

### **Safety**



The FDA safety and efficacy summary describes the results of a prospective multi centre (17 centres) open label randomised study in which 208 diagnostic patients and 275 interventional patients were enrolled. Diagnostic patients were randomised using a 2:1 ratio (StarClose: 136 patients; Standard compression: 72 patients), both groups were analysed on an intention to treat analysis. The primary safety endpoint for this study was the rate of major complication within  $30 \pm 7$  days following the catheterisation procedure, and the secondary safety endpoint, the number of minor complications  $30 \pm 7$  days following the catheterisation procedure.

For the diagnostic patients, no major vascular complications in either the treatment or control groups were reported at 30 days follow-up. Four minor vascular complications were reported, three occurred in the StarClose group (one haematoma  $\geq 6$  cm and two transient access site-related nerve injuries) and one complication was reported in the control group (haematoma  $\geq 6$  cm). The overall rates of minor complications at 30 days follow-up were 2.2% for the StarClose group and 1.4% for the standard compression group (US Food and Drug Administration 2005).

The prospective non-randomised pilot study by Ruygrok *et al.* (2005) involved 25 patients who were treated with the StarClose system at the femoral artery. Minor adverse events were reported as moderate tract ooze in 10/25 (40%) patients, which required adjunctive manual compression, while small haematomas were detected in 11/25 (44%) patients. The authors reported that some patients experienced pain during the procedure, but this was attributed to longer treatment times and diminished effects of anaesthesia, the exact number of patients were not reported.

## **Efficacy**

The primary measure of effectiveness utilised by the FDA was time to haemostasis. The mean time to haemostasis achieved by the StarClose group ( $n=136$ ) was  $1.46 \pm 4.52$  minutes, significantly shorter when compared to the control/standard compression group ( $n=72$ ) which achieved haemostasis at  $15.47 \pm 11.43$  minutes ( $p < 0.001$ ). The secondary effectiveness endpoints were procedural success, device success at discharge, time to ambulation, and time to dischargeability. Both groups achieved a 100% procedural success rate. With regards to device success, the StarClose system was considered successful if final haemostasis using StarClose alone or with adjunctive compression was achieved in  $\leq 5$  minutes and the patient is free from major vascular complications. Based on this definition, StarClose was clinically successful in 94.1% (127/135 patients) of patient who were treated with the device. Device time to ambulation was significantly better in the treatment group ( $162.98 \pm 104.60$  minutes) compared with the control group ( $269.27 \pm 134.76$  minutes) ( $p < 0.001$ ). In addition to this, time to discharge was significantly better in the StarClose group ( $3.53 \pm 2.08$  hours) compared to the control group ( $5.24 \pm 2.12$  hours) ( $p < 0.001$ ) (US Food and Drug Administration 2005).



Ruygok *et al.* reported a procedural success rate of 100%, while the device success rate was 92% (23/25 patients). The two cases of device failure (> 5 minutes to haemostasis or major vascular complication) involved one incident of prolonged time to haemostasis (509 seconds) while the other was due to an error in device delivery technique. The mean clip delivery time was  $42.4 \pm 32.7$  seconds while mean time to ambulation was  $5.9 \pm 3.8$  hours. In addition to this, Ruygok *et al.* (2005) reported patient outcomes 14-days post-procedure using ultrasound analysis. One patient was lost to follow-up while the remaining 24 patients did not report any late events including pain or infection. None of the patients undergoing ultrasound showed evidence of turbulent blood flow, vascular obstruction, pseudoaneurysm or retroperitoneal bleeding.

The FDA safety and efficacy summary reported on 2 smaller studies from Venezuela and Germany. The Venezuelan study reported that mean time to haemostasis was lower in the StarClose group (n=11, 2.1 minutes) compared with the control group (n=10, 33 minutes). Additionally, mean time to ambulation was lower in the treatment group (n=11, 103 minutes.) compared with the treatment group (n=9, 328 minutes) (US Food and Drug Administration 2005).

The German feasibility study enrolled 31 patients with results available for 28 patients. The mean clip delivery time was 1 minute while mean time to ambulation was 120 minutes (one patient ambulated at 14 hours). Adverse events reported were bruising/haematoma (n=2), and AV fistula (n= 1). The report also stated there were 2 failures to deliver the clip, one was attributed to training and the other due to a manufacturing fault (US Food and Drug Administration 2005).

### ***Ethical Issues***

No issues were identified from the retrieved material.

### ***Cultural or Religious Considerations***

No issues were identified from the retrieved material.

### ***Other Issues***

The majority of safety and efficacy data has been undertaken by company sponsored investigators.

Personal communication with a TGA representative indicated that the StarClose Vascular Closure Device was currently not approved for use in the Australian marketplace; however a conclusive statement has not been received.



### Recommendation:

Inadequate haemostasis following endovascular procedures is a significant risk. Limited evidence exists on the safety and efficacy of the StarClose® Vascular Closure System. The evidence currently available is not based on properly randomised controlled trials and most of the published data on the device originates from the development team.

Effectiveness of this device against other medical devices performing this function is uncertain and has not been assessed. It is likely that a clinician will choose an appropriate device which is TGA listed instead. The StarClose® would only replace existing closure devices if it was found to be more effective.

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

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### Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in February 2006.

Search terms used were: StarClose, Vascular closure, Vascular Closure System

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