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Australia and New Zealand Horizon Scanning Network

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# **National Horizon Scanning Unit**

## **Horizon scanning prioritising summary**

**Volume 15, Number 7**

**Activecare DVT<sup>®</sup> for the prevention of deep  
vein thrombosis**

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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.

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# PRIORITISING SUMMARY

**REGISTER ID:** 000290

**NAME OF TECHNOLOGY:** ACTIVECARE DVT®

**PURPOSE AND TARGET GROUP:** PREVENTION OF DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM IN HIGH RISK PATIENTS

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |  |   |
|--|---|
| <input 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 checked="" type="checkbox"/> Nearly established |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |             |       |
|---|-------------|-------|
| <input checked="" type="checkbox"/> Yes | ARTG number | 99454 |
| <input type="checkbox"/> No             |             |       |
| <input type="checkbox"/> Not applicable |             |       |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States		✓	
Europe		✓	
Australia		✓	

## IMPACT SUMMARY:

This prioritising summary investigates the safety and effectiveness of the ActiveCare DVT®, a device designed for the prevention of deep vein thrombosis in high risk patients.

## BACKGROUND

Deep vein thrombosis (DVT) refers to the formation of a blood clot (thrombus) in a deep vein, typically in the lower leg or thigh. Depending on its size, a thrombus can interfere with blood circulation, causing sudden swelling and pain in the affected area. If a thrombus breaks free, it can travel through the blood stream (embolise) and lodge itself in the lungs, a condition known as pulmonary embolism (PE). PE is associated with chest pain, shortness of breath and circulatory collapse and in severe cases, can be rapidly fatal (Kroegel & Reissig 2003). The risk of developing DVT and PE is greatly elevated following surgery, particularly in patients who have undergone knee or hip arthroplasty (O'Reilly et al 2005). Unfortunately, both DVT and PE often produce few specific symptoms and clinical diagnosis can be unreliable (Geerts et al

2001). Often the diagnosis cannot be established until a large PE has occurred or until autopsy. As a result, physicians have relied on prophylactic techniques for patients following surgery in order to prevent the onset of DVT and PE.

A variety of prophylactic treatments have been used to prevent the development of DVT and PE. Anticoagulant medicines are one of the more common treatment options. Agents such as low molecular weight heparin and warfarin are routinely administered both during and following orthopaedic surgery. Although these agents have been shown to be effective in preventing the formation of blood clots, they carry a risk of increased bleeding and other soft-tissue side effects. In patients with a high risk of bleeding or with contraindications to anticoagulants, mechanical prophylaxis may be preferred. Intermittent pneumatic compression devices (IPCDs) prevent DVT and PE by increasing femoral venous blood flow and venous emptying, and can be safely used either during or after surgery (Dai et al 1999). IPCDs have also been demonstrated to decrease DVT formation through fibrinolysis (Salvati et al 2000). IPCDs consist of sleeves that wrap around the legs or feet and are attached to a pump. The pump inflates and deflates the sleeve, squeezing the muscles and increasing blood flow. To be effective however, IPCDs require continuous usage. A major limitation of IPCDs is their size and weight, and the need for them to be connected to an external power source at all times. Given the restriction in patient movement imposed by IPCDs, compliance by both patients and nursing staff remains a significant problem for these devices (Cornwell et al 2002).

In an attempt to overcome the side-effects of anticoagulant therapy and the compliance issues associated with existing ICD systems, Medical Compression Systems DBN-Ltd (Israel) have developed the first portable pneumatic compression device for the prevention of DVT. The ActiveCare DVT<sup>®</sup> is a miniature, lightweight (690 grams), battery-operated pneumatic compression device that can be used before, during and after surgery without the need for removal. It is therefore the first pneumatic compression device capable of providing continuous therapy throughout the course of surgery. The system is equipped with calf, thigh and foot sleeves that can be used on one or two legs concurrently. The foot compression program provides a pressure pulse of 130mmHg to the single celled foot sleeve, whereas the calf and thigh programs provide 50mmHg of pressure to the three-celled calf and thigh sleeves. The ActiveCare DVT<sup>®</sup> automatically identifies the combination of sleeves being used by the patient and selects the appropriate pressure algorithm.

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

The incidence of DVT and PE has been estimated to be approximately one case per 1000 population per year (Heit et al 2001). In 2004-2005, a total of 8,275 Australians were diagnosed with DVT in public hospitals, the condition associated with an average length of hospital stay of 6.3 days. A further 7,734 Australians were

diagnosed with PE in 2004-2005, with an average length of hospital stay of 7.2 days (AIHW 2006). However, given the often silent nature of the condition and the lack of information on private hospital separations, these figures are likely to underestimate the extent of DVT and PE in the Australian population.

The ActiveCare DVT<sup>®</sup> is designed to prevent the onset of DVT and PE in high risk patients, most notably patients undergoing knee or hip arthroplasty. In the absence of appropriate prophylaxis, the prevalence of DVT has been reported to be between 45-57 per cent following total hip replacement, and between 40-84 per cent following total knee replacement (O'Reilly et al 2005). In 2004-2005, a total of 26,651 hip arthroplasties and 26,968 knee arthroplasties were performed in Australian public hospitals (AIHW 2006).

A recent Australian study investigated the prevalence of DVT and PE following total hip replacement (THR) and total knee replacement (TKR) in a NSW hospital (O'Reilly et al 2005). A total of 5,999 patients who underwent THR, TKR or bilateral TKR between April 1995 and December 2001 were included in the study. Each patient received mechanical and chemical prophylaxis and was assessed for DVT seven days postoperatively using ultrasonography. The prevalence of DVT following surgery was found to be 8.9, 25.6 and 36.9 per cent for THR, TKR and bilateral TKR respectively. The prevalence of symptomatic non-fatal in-hospital PE was found to be 1.9 per cent (as assessed by ventilation/perfusion scans in patients exhibiting symptoms of PE), while the prevalence of fatal in-hospital PE was found to be 0.05 per cent (3 patients in total).

#### **DIFFUSION**

The ActiveCare DVT<sup>®</sup> was approved by the FDA in March 2006 for the prevention of DVT. In Australia, the system is marketed through Hill-Rom Australia Pty Ltd following recent approval from the TGA (ARTG Number 99454).

#### **COMPARATORS**

As a mechanical prophylactic device, the primary comparator for the ActiveCare DVT<sup>®</sup> is existing stationary IpCDs. Compared to existing IpCDs, the ActiveCare DVT<sup>®</sup> offers advantages in terms of its size and portability. Not requiring an external power source for operation, the ActiveCare DVT<sup>®</sup> is designed to improve compliance by patients and nursing staff, thereby reducing the likelihood of DVT and PE development. A further comparator for the ActiveCare DVT<sup>®</sup> is chemical prophylaxis. Anticoagulant agents including heparin, low molecular weight heparin and warfarin have been used extensively in the prevention of DVT and PE in high risk patients. Unfortunately these agents have been associated with increased bleeding and are inappropriate for patients with contraindications to anticoagulants. Contradictions

include recent bleeding, coagulation defect, recent major trauma, uncontrolled hypertension and endocarditis (Ho et al 2005).

#### **EFFECTIVENESS AND SAFETY ISSUES**

In an early trial into the efficacy of the system, Ben-Galim et al (2004) compared the ActiveCare DVT<sup>®</sup> to a commonly used IpCD (the Kendall SCD, Kendall, Mansfield, USA) in the prevention of DVT. A total of 50 patients who were scheduled to receive THR or TKR were randomised into two groups, one treated with the ActiveCare DVT<sup>®</sup> and the other with the Kendall SCD (level II intervention evidence). In addition to mechanical prophylaxis, both study groups received heparin for six days following surgery. The authors ensured that compliance to mechanical prophylaxis was comparable in the two groups. Six days following surgery, Doppler ultrasonography revealed no cases of DVT in either treatment group. Although the authors concluded that the ActiveCare DVT<sup>®</sup> was as effective as standard IPCDs, it is unclear whether the lack of difference reported in the study should be attributed to the devices or rather attributed to the use of heparin in the period following surgery.

In another study, Murakami et al (2003) investigated levels of compliance with mechanical prophylaxis in a group of 33 adult trauma patients (mean age = 46 years). Patients arriving at an emergency department who met eligibility criteria were randomised to receive prophylaxis using either the ActiveCare DVT<sup>®</sup> or the Kendall SCD (level II intervention evidence). The overall compliance rate for each patient was calculated as the total number of minutes the device was operational divided by the total number of minutes the patient was enrolled in the study. Overall compliance rates were found to be significantly higher in patients using the ActiveCare DVT<sup>®</sup> (77.7% vs. 58.9%,  $p = 0.004$ ). Compliance rates were also higher in the ActiveCare DVT<sup>®</sup> group when the analysis was restricted to the emergency department and nursing ward ( $p = 0.002$  and  $p = 0.008$  respectively), although no difference in compliance rates were reported in the operating room or intensive care unit ( $p = 0.28$  and  $p = 0.99$  respectively).

In a recent randomised trial, Gelfer et al (2006) compared the ActiveCare DVT<sup>®</sup> to low molecular weight heparin in the prevention of DVT and PE in 121 patients undergoing knee or hip arthroplasty (level II intervention evidence). Patients randomised to the low molecular weight heparin group were administered 40mg of enoxaparin once daily following surgery, whereas patients randomised to the ActiveCare DVT<sup>®</sup> received 100mg of aspirin once daily following surgery. DVT was detected in 17 out of 60 patients in the low molecular weight heparin group compared to 4 out of 61 in the ActiveCare DVT<sup>®</sup> group ( $p = 0.002$ ). After controlling for

potential confounders, a logistic regression model revealed an odds ratio of DVT development between the two groups of 6.5 (95% CI: 1.95–21.4). One patient who received low molecular weight heparin developed a clinically significant PE one month after surgery. No cases of PE were reported in patients who used the ActiveCare DVT<sup>®</sup>. Finally, patients in the ActiveCare DVT<sup>®</sup> group recorded significantly shorter hospital stays in comparison to patients receiving low molecular weight heparin (8.8 days vs. 9.9 days,  $p < 0.02$ ).

#### **COST IMPACT**

Gelfer et al (2006) analysed the cost implications of using the ActiveCare DVT<sup>®</sup> following knee or hip arthroplasty as opposed to low molecular weight heparin. In their analysis the authors obtained costs of the ActiveCare DVT<sup>®</sup> and pneumatic sleeves according to prices listed by the manufacturer in the United States. With the shorter hospital stays of patients in the ActiveCare DVT<sup>®</sup> group and the lower incidence of both DVT and PE, a cost saving of \$2628.56 per patient was reported.

In the United States, the ActiveCare DVT<sup>®</sup> is priced at \$1,500 (Gelfer et al 2006). Unfortunately at the time of writing this summary the Australian costs for the device could not be obtained.

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

No issues were identified/raised in the sources examined.

#### **OTHER ISSUES**

The ActiveCare DVT<sup>®</sup> should not be used on patients with pre-existing DVT or PE, leg gangrene, recent skin graft or acute thrombophlebitis (FDA 2006).

#### **CONCLUSION:**

Given the burden of disease associated with PE and DVT in Australian hospitals, new prophylactic techniques capable of reducing the incidence of these conditions may offer large health benefits. The ActiveCare DVT<sup>®</sup> holds promise as a relatively cheap and effective tool for preventing DVT and PE in high risk patients. At this stage however effectiveness data are limited with only a handful of small scale studies being completed. It is also unclear what the cost impact of the technology will be in Australia.

#### **HEALTHPACT ACTION:**

Although Activecare DVT<sup>®</sup> provides advantages in portability, it provides similar clinical benefits to patients already provided for by other DVT preventative measures. It is likely that there will be uptake of Activecare DVT<sup>®</sup> into the Australian health

care system. However, HealthPACT has recommended that further assessment of this technology is no longer warranted.

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

AIHW (2006). *National Hospital Morbidity Database* [Internet]. Australian Institute of Health and Welfare. Available from: <http://www.aihw.gov.au/hospitals/datacubes/index.cfm> [Accessed 12th December 2006].

Ben-Galim, P., Steinberg, E. L. et al (2004). 'A miniature and mobile intermittent pneumatic compression device for the prevention of deep-vein thrombosis after joint replacement', *Acta Orthop Scand*, 75 (5), 584-587.

Dai, G., Gertler, J. P. & Kamm, R. D. (1999). 'The effects of external compression on venous blood flow and tissue deformation in the lower leg', *J Biomech Eng*, 121 (6), 557-564.

FDA (2006). *510(k) Decision Summary: ActiveCare(R)++ System*, Food and Drug Administration.

Geerts, W. H., Heit, J. A. et al (2001). 'Prevention of venous thromboembolism', *Chest*, 119 (1 Suppl), 132S-175S.

Gelfer, Y., Tavor, H. et al (2006). 'Deep vein thrombosis prevention in joint arthroplasties: continuous enhanced circulation therapy vs low molecular weight heparin', *J Arthroplasty*, 21 (2), 206-214.

Heit, J. A., Silverstein, M. D. et al (2001). 'The epidemiology of venous thromboembolism in the community', *Thromb Haemost*, 86 (1), 452-463.

Ho, W. K., Hankey, G. J. et al (2005). 'Venous thromboembolism: diagnosis and management of deep venous thrombosis', *Med J Aust*, 182 (9), 476-481.

Kroegel, C. & Reissig, A. (2003). 'Principle mechanisms underlying venous thromboembolism: epidemiology, risk factors, pathophysiology and pathogenesis', *Respiration*, 70 (1), 7-30.

Murakami, M., McDill, T. L. et al (2003). 'Deep venous thrombosis prophylaxis in trauma: improved compliance with a novel miniaturized pneumatic compression device', *J Vasc Surg*, 38 (5), 923-927.

O'Reilly, R. F., Burgess, I. A. & Zicat, B. (2005). 'The prevalence of venous thromboembolism after hip and knee replacement surgery', *Med J Aust*, 182 (4), 154-159.

Salvati, E. A., Pellegrini, V. D., Jr. et al (2000). 'Recent advances in venous thromboembolic prophylaxis during and after total hip replacement', *J Bone Joint Surg Am*, 82 (2), 252-270.

#### **LIST OF STUDIES INCLUDED**

Total number of studies

Level II evidence

3

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

Venous Thrombosis/\*prevention & control

Intermittent Pneumatic Compression Devices

Arthroplasty, Replacement