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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

Third Eye Retroscope™ for the retrograde viewing of the colon

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AHTA

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PRIORITISING SUMMARY

REGISTER ID: **000395**

NAME OF TECHNOLOGY: **THIRD EYE RETROSCOPE™**

PURPOSE AND TARGET GROUP: **RETROGRADE VIEWING OF THE COLON DURING ROUTINE COLONOSCOPY**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

The Third Eye Retroscope™ system received United States FDA approval in February 2007.

INTERNATIONAL UTILISATION:

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

IMPACT SUMMARY:

Avantis Medical Systems markets the Third Eye Retroscope™ for use during routine colonoscopy. The device allows the retrograde inspection of the colon during the removal of the colonoscope. This may allow visualisation of regions normally missed in standard colonoscopy, which in turn may increase the diagnostic accuracy of colonoscopy.

BACKGROUND

Colorectal cancer (CRC) is a major burden on the Australian health care system. Definitive diagnosis of CRC is pathology analysis of a biopsy taken during colonoscopy. However, colonoscopy may miss suspect lesions due to the configuration and shape of the colon. The Third Eye Retroscope™ is inserted into the colonoscope instrument channel after the colonoscope has been advanced to the

caecum. The Third Eye Retroscope™ emerges at the distal end of the colonoscope and its tip bends through 180 degrees to form a "J" shape. When the colonoscope is withdrawn the Third Eye Retroscope™ allows the retrograde visualisation of the colon. This may enable the visualisation of areas which are particularly difficult to see during normal colonoscopy due to colon structures or orientation of the colonoscope to the colon e.g. at tight turns or around folds in the colon.

CLINICAL NEED AND BURDEN OF DISEASE

In 2004 the age-standardised incidence of CRC in Australia was 12,977, making it the second most common cancer in both men and women. There were 4,113 deaths in Australia caused by CRC in 2005. In gross terms, the incidence of CRC has been increasing for the period of 1993 to 2003, up 27 per cent. When this figure is age adjusted there was a small decrease in incidence of 1.5 per cent over the same time period (AIHW 2007a; AIHW 2007b). It is estimated that the annual costs of treating colorectal cancer is $235 million (AIHW 2005).

Bowel cancer is the most common cancer in New Zealand, with the highest rate of death in the developed world. In 2004, the rate of registration of new bowel cancer cases was 46.1 and 38.9 per 100,000 for men and women respectively, translating to approximately 2,700 new cases annually (National Screening Unit 2008). In New Zealand the mortality rates from CRC are 23.2 and 18.6 per 100,000 for males and females, respectively (year not stated) (Shaw et al 2008). In addition, there are clear inequalities between Maori and non-Maori. Maori are less likely to be diagnosed with CRC, and are therefore less likely to survive CRC due to late-stage diagnosis (National Screening Unit 2008). New Zealand are currently considering implementing a colon cancer screening programme using the faecal occult blood test (Shaw et al 2008).

DIFFUSION

No evidence of diffusion of this technology into Australia was found.

COMPARATORS

In Australia the faecal occult blood test (FOBT) is used as the initial tool to screen for bowel abnormalities. If this is positive, a colonoscopy may then be performed and a biopsy taken if required. Biennial FOBTs may reduce the risk of dying from bowel cancer by one third (DOHA 2007) and may save up to 2,000 lives per year (Macrae 2005). A FOBT followed by colonoscopy has been shown to be a cost effective method for colorectal cancer screening (Gow 1999; Macrae 2005). A recent study used CT colonography to simulate the areas visualised and missed when using a normal colonoscope. Based on data sets from 20 real patients, it was estimated that colonoscopy only visualised 68 ± 5.2 per cent of the total surface area of the colon (East et al 2007). So despite the effectiveness of colonoscopy there exists room for improvement.

SAFETY AND EFFECTIVENESS ISSUES

An initial study with anatomic models of the colon found that normal colonoscopy found 69/78 (88%) of "obvious" polyps and 20/162 (12%) of "non-obvious" polyps. The Third Eye Retroscope™ was able to detect 70/78 (90%) of "obvious" polyps and 131/162 (81%) of "non-obvious" polyps. Non-obvious polyps were situated on the proximal aspects of folds in the models (Triadafilopoulos et al 2007). While not based on real patient trials, this initial study demonstrated the Third Eye Retroscope™'s potential for increased discovery of polyps missed by traditional colonoscopes.

A second study using virtual models of real patient colons, from CT colonography data, showed that, compared to normal (140 degree field of view) and wide-angle (170 degree field of view), the Third Eye Retroscope™ (135 degree retrograde field of view) had the highest surface area of the bowel visualised with 98.7 ± 0.5 per cent being covered. The normal and wide-angle colonoscopes had 86.6 ± 3.3 per cent, and 92.2 ± 3.3 per cent of the total surface area visualised, respectively (East et al 2007) (Level III-2 diagnostic evidence).

A trial to compare the Third Eye Retroscope™ to a normal colonoscope was conducted in 24 consecutively recruited patients. Aims of the study were to investigate the safety of the device and to also investigate whether additional polyps would be detected compare to the normal colonoscopy procedure. During the trial 38 polyps were detected with 34 of these being identified by the normal colonoscopy during antegrade imaging. An additional four polyps were only seen on the retrograde image obtained with the Third Eye Retroscope™. This was an 11.8 per cent increase in the number of polyps found over the normal colonoscopy procedure, indicating the Third Eye Retroscope™ may be a useful tool to decrease the miss rate of colonoscopy due to difficult anatomical structures within the bowel (Triadafilopoulos & Li 2008) (Level III-2 diagnostic evidence).

No safety issues associated with the use of the Third Eye Retroscope™ were reported in the studies included for assessment in this summary.

COST IMPACT

Avantis Medical Systems were contacted regarding pricing and availability in Australia but no correspondence was received by time of publication.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

A multi-institute phase II trial of the Third Eye Retroscope™ is currently being conducted, however there is no further information about this trial available nor an estimated date for the publication of results (Triadafilopoulos et al 2007).

SUMMARY OF FINDINGS

Small scale human trials indicate that the Third Eye Retroscope™ may facilitate a higher detection rate of polyps during colonoscopy. Further larger scale trials are required and one is currently underway.

HEALTHPACT ACTION:

HealthPACT stated that due to the high diagnostic accuracy of the current gold standard, colonoscopy, that the Third Eye Retroscope™ is unlikely to diffuse into the Australian health care system. Therefore HealthPACT has recommended that further assessment of this technology is no longer warranted.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level III-2 diagnostic evidence	2

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SEARCH CRITERIA TO BE USED:

Colonoscopy

Colonic Polyps/ diagnosis