



SASCI
South African
Society of
Cardiovascular
Intervention

Company reg. no. 2003/018540/08
(Association Incorporated Under Section 21)
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1 November 2012

To whom it may concern

Re SASCI Guidance – Aneugraft pericardial covered stent

The Executive Committee of the South African Society for Coronary Intervention has reviewed the data regarding the Aneugraft pericardial covered stent and strongly supports any application for this product to be made available to local practitioners.

There are few situations in the catheterisation laboratory more dangerous to the patient and difficult to manage than rupture of an epicardial coronary artery during coronary intervention. Currently, although we keep PTFE covered stents available in our labs to deal with such events, our experience and that described by others has shown that where they are crucially needed, such stents frequently fail to adequately address a life threatening situation. They are often not the correct size, being very limited in size availability, or, they may not be able to be delivered at the coronary site where they are most needed: they are bulky, and track very poorly down coronary arteries due to their rigidity. The result is that patients with coronary perforation will usually need to be sent for emergency bypass surgery, with expected poor outcomes in the group of high risk patients who may have been declined the procedure in the first place due to their perceived risk. A more flexible, lower profile deliverable physiological solution, with wider size availability, less thrombotic risk and verifiable results, will be welcomed and likely allow us to deal with these very occasional disasters with much better outcomes.

In a similar vein, there are other unusual clinical scenarios where covered stent technology may offer a useful solution to otherwise extremely challenging problems. Coronary aneurysms, though rare, may place patients at high risk of complications, and often present in patients not suitable for surgery. The pericardial covered device appears to offer the best yet solution for such patients, and can be used to effectively exclude the aneurysm with durable results.

In advanced vein graft disease with very high embolic risk, a covered stent may also provide a very useful solution.

SASCI is a Special Interest Group within SA Heart Association

Executive Committee

F Hellig (President), G Cassel (ex-officio President)

S Khan (Vice-President), C Badenhorst (Treasurer), A Horak (Secretary)

Representatives

M Ntsekhe (Academic), C Zambakides, D Kettles, M Abelson, L Steingo, J Vorster



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We anticipate that such stents will not be high volume products: rather they will provide a service to the cardiology community and our patients, bringing new effective solutions at very reasonable prices into small high risk niches in the market. They will likely supercede older, less effective technology that is currently available, but much less useful than desired.

Please assist the importers in making such technology available for our patients

Sincerely

Dr David Kettles, on behalf of SASCI Exco

Contact Person for Further Information –

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