

CLINICAL COMMENTS

Omniflow™ II

Antithrombotic therapy with the Omniflow II vascular prosthesis

The Omniflow II series of vascular prostheses performs well with a wide range of antiplatelet aggregation and anticoagulation therapies. This document discusses some of the considerations on antithrombotic therapy when implanting Omniflow II.

Although not explicitly required, the use of oral or intravenous antiplatelet or anticoagulation therapies in combination with the Omniflow II prosthesis may improve the clinical outcome. Omniflow II performs well together with a range of anti-thrombotic therapies regularly used when implanting autologous or homologous vein grafts and other vascular prostheses.

Heparinising the prosthesis

Heparin binds well to Omniflow II. Pre-implantation preparation with concentrated heparin is one of the important measures in minimising the risk of early occlusions.

According to the *Instructions For Use*, after rinsing with sterile physiological saline, the lumen of the prosthesis is filled with 10 ml of 5,000 IU/ml (i.e. 50 000 IU in total) of sterile heparin (5 ml {25 000 IU} is sufficient for prostheses below 35 cm length). The prosthesis is then allowed to soak in physiological saline for at least 10 minutes.

The heparin is drained from the prosthesis before implantation or, if the heparin solution is used to distend the prosthesis during positioning, before completing the second anastomosis.

Antiplatelet aggregation therapy

Most patients who have peripheral and/or coronary arterial disease are taking some form of oral antiplatelet aggregation medication, most often acetylsalicylic acid (aspirin), dipyridamol, clopidogrel or a combination of these.

Antiplatelet aggregation therapy is used in most centres performing peripheral vascular procedures.

Disclaimer

This document is a discussion paper on clinical treatment in conjunction with the Bio Nova Omniflow II vascular prosthesis. This paper is not an extension to the Instructions For Use document supplied with each prosthesis. The suitability of any treatment suggested in this paper has to be evaluated based on the individual circumstances for each patient.

For patients receiving Omniflow II prostheses the use of antiplatelet aggregation therapy can be determined by the surgeon's customary practice for implantation of vein grafts or other vascular prostheses.

Anticoagulation therapy

There is no requirement to use systemic anticoagulation when implanting Omniflow II, however, if this is common practice for the surgeon during vascular procedures the existing routine protocol may be followed.

Due to its non-porous structure, Omniflow II appears to be well-suited to patients with certain bleeding disorders or for use with various anticoagulation therapies. Omniflow II has been used successfully with a range of anticoagulation therapies, including but not limited to:

- Dextran 40
- heparin and low-molecular weight heparin
- warfarin and other coumarin derivatives

Whilst existing use of oral or parenteral anticoagulants is not a contra-indication to implanting Omniflow II, normal attention should be paid to any bleeding or other side effects when using such therapies, according to the manufacturer's instructions and normal clinical practice.

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