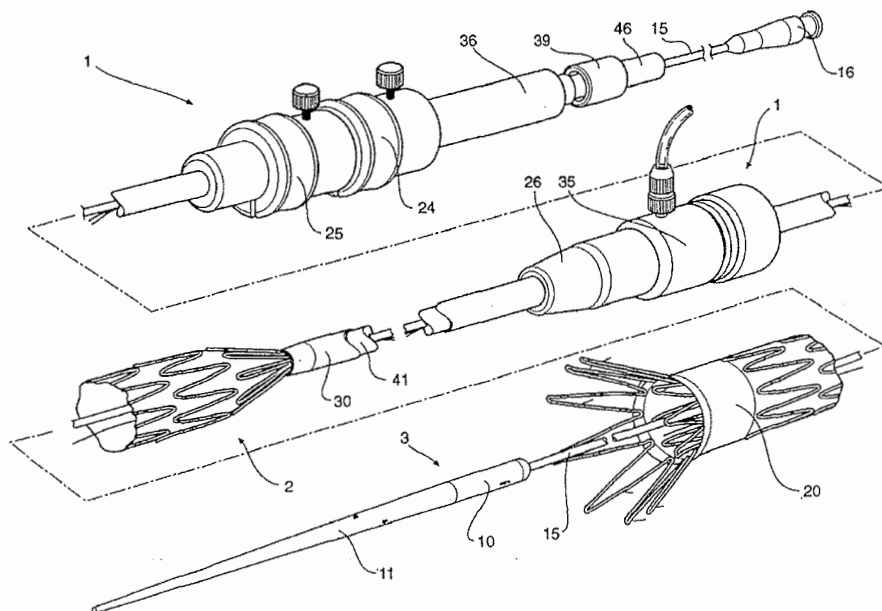




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(21) International Application Number: PCT/AU98/00383 (22) International Filing Date: 25 May 1998 (25.05.98) (30) Priority Data: PO 7008                      26 May 1997 (26.05.97)                      AU (71) Applicant (for all designated States except US): WILLIAM A. COOK AUSTRALIA PTY. LTD. [AU/AU]; 12 Electronics Street, Brisbane Technology Park, Eight Mile Plains, QLD 4113 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): HARTLEY, David [AU/AU]; 2 View Street, Subiaco, W.A. 6008 (AU). LAWRENCE-BROWN, Michael [AU/AU]; 36 Shann Street, Floreat, W.A. 6014 (AU). (74) Agent: COLLISON & CO.; 117 King William Street, Adelaide, S.A. 5000 (AU).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  Published With international search report.	

(54) Title: A PROSTHESIS AND A METHOD AND MEANS OF DEPLOYING A PROSTHESIS



## (57) Abstract

An introducer (1) adapted for the introduction of a self-expanding endovascular prosthesis (20) in a lumen of a patient. The introducer has attachment devices (10, 30) to hold each end of the prosthesis so that each can be moved independently. An end ovascular prosthesitis (20) is also claimed with stents at the proximal and distal ends being within the graft. The remainder of the stents are positioned on the outside of the graft body.

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TITLE: A PROSTHESIS AND A METHOD AND MEANS OF  
DEPLOYING A PROSTHESIS

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FIELD OF INVENTION

This invention relates to a method and means for introducing a expandable intraluminal prosthesis which may be straight, tubular or bifurcated in form and intended for the endovascular repair of diseased or damaged vessels  
1 0 and to a prosthesis which is suitable for such a procedure.

Throughout this specification the terms proximal and proximally are used for a position or direction towards the patient's heart and the terms distal and distally are used for a position or direction away the patient's heart.

BACKGROUND OF THE INVENTION

1 5 The deployment of intraluminal prostheses into the lumen of a patient from a remote location by the use of a deployment device or introducer has been disclosed in a number of earlier patent specifications.

United States Patent No. 4,562,596 in the name of Kornberg proposes the retention of a self expanding graft within a sleeve until it is to be deployed at  
2 0 which time the sleeve is withdrawn and the graft allowed to expand. After the graft has been released there is no possible control of the position of the distal end of the graft. Inadequate placement can render the entire deployment null and void.

United States Patent No. 4,665,918 in the name of Garza et al proposes a  
2 5 system and method for the deployment of a prosthesis in a blood vessel. The prosthesis is positioned between a delivery catheter and an outer sheath and expands outwardly upon removal of the sheath. Once again after the prosthesis has been released by removal of the sheath there is no possible control of the position of the either end of the prosthesis.

3 0 United States Patent No. 4,950,227 in the name of Savia et al proposes the delivery of a stent by mounting the stent to the outside of an inflatable catheter and retaining the ends of an unexpanded stent by fitting sleeve over

either end of the stent. Expansion of the stent is caused by inflation of the catheter between the sleeves so that the ends of the stent are withdrawn from the respective sleeves and the stent released and expanded into position. This system provides very little control over the deployment procedure and in practice would be impractical for intraluminal deployment where accuracy is vital.

European Patent specification No. 472 731 In the name of Inoue proposes an artificial tube prosthesis to be inserted into a human organ in a folded condition retained within a catheter and released to expand within the organ. Deployment is achieved by retention of the proximal end of the prosthesis by wires passing through a tube through the middle of the prosthesis while withdrawing the catheter. A balloon is then used to expand the prosthesis. Once again after the prosthesis has been released by removal of the catheter there is no possible control of the position of the distal end of the prosthesis.

United States Patent No. 5,071,407 in the name of Termin et al proposes the delivery of a stent by retaining the stent in an elastically deformed condition between a catheter and a sheath. The proximal end of the stent is retained at the catheter. The stent is allowed to expand by removal of the sheath and optional balloon expansion. No indication is given of any method for release of the stent from the catheter or how the distal end of the stent can be positioned accurately.

Australian Patent Application No. 669,338 in the name of Chuter proposes a delivery arrangement for transluminally positioning a prosthesis at a particular position on an internal wall of a lumen. The delivery arrangement has an outer sheath to surround the prosthesis and a retention arrangement to hold the prosthesis in a selected position during removal of the sheath before final release.

Australian Patent Application No. 671,910 in the name of Endovascular Technologies, Inc. proposes a delivery arrangement for positioning a prosthesis within a lumen. It has capsules which retain each end of the prosthesis and a balloon arrangement to expand the prosthesis when the capsules have been retracted to release the prosthesis. A sheath is used to protect the prosthesis during insertion. Once the capsules have been withdrawn there is no method provided to ensure that the ends of the

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prosthesis are correctly positioned.

It is the object of this invention to provide a graft and a method and apparatus to deploy the graft prosthesis which will overcome at least some of the problems discussed above or at least provide an alternative arrangement to the prior art systems described above.

#### BRIEF DESCRIPTION OF THE INVENTION

According to one aspect of the present invention there is provided an introducer for positioning an expandable endovascular prosthesis in a lumen of a patient, the prosthesis having a proximal portion and a distal portion, the introducer comprising a prosthesis positioning mechanism selectively releasable from the prosthesis when the prosthesis is positioned at a desired site in the lumen of a patient, a first control member controlling at least the longitudinal position of the proximal portion of the prosthesis; and a second control member controlling at least the longitudinal position of the distal portion of the prosthesis. The prosthesis positioning mechanism can include a distal attachment region and/or a proximal attachment region. The distal attachment region can include a distal attachment device. The proximal attachment region can include a proximal attachment device. The prosthesis positioning mechanism can preferably include a control arrangement for controlling the length of the prosthesis. The prosthesis positioning mechanism can also preferably include a rotational arrangement by which the relative angular orientation of the proximal and distal portions of the prosthesis can be adjusted. This prosthesis positioning mechanism can singly or in combination also adjust the angular orientation of the prosthesis. The introducer can also preferably comprise an expansion control mechanism for controlling expansion of the prosthesis when the prosthesis is positioned at the desired site in the lumen of the patient.

According to another aspect of the present invention therein provides an endovascular arrangement for positioning an expandable prosthesis at a desired location in a lumen of a patient, said arrangement comprising a control section to be maintained external to the patient, and a prosthesis positioning mechanism controllable by the control section for moving and manipulating the prosthesis to a desired location in the lumen, wherein a first member extends from the control section to a proximal region of the

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