

BAXTER HEMOSTASIS

Principal Investigator:

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Sponsor:

Baxter Healthcare Corporation

Study Purpose:

Protocol 550801: Clinical Evaluation of Efficacy and Safety of FS VH S/D 500 S-APR for Hemostasis in Subjects Undergoing Vascular Surgery. The study is intended to compare safety and efficacy of FS VH S/D 500 s-apr versus manual compression in prosthetic ePTFE graft placement, with study results to complement a clinical data package that will be submitted to the FDA to obtain a license for FS VH S/D 500 s-apr in a broad hemostasis indication.

Objective:

The primary objective is to evaluate the efficacy of FS VH S/D 500 s-apr for hemostasis in subjects receiving peripheral vascular ePTFE conduits, as compared to a control arm treated by manual compression with surgical gauze pads.

Inclusion Criteria:

- Undergoing vascular surgery (ie. Conduit placement with an ePTFE graft), including arterio-arterial bypasses, including:
 - Axillo-femoral
 - Axillo-bifemoral
 - Aorto-bifemoral
 - Ilio-femoral
 - Ilio-popliteal
 - Femoro-popliteal (including below knee)
 - Femoro-tibial vessel bypass
 - Arteriovenous shunting for dialysis access in the upper or lower extremity
- If female of childbearing potential, subject presents with a negative serum or urine pregnancy test and agrees to employ adequate birth control measures for the duration of the study.

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Intraoperative Inclusion Criteria:

- Suture line bleeding eligible for study treatment is present after surgical hemostasis (ie. Suturing)

Exclusion Criteria:

- Other vascular procedures during the same surgical session (stenting and/or endarterectomy of the same artery are allowed)
- Congenital coagulation disorders
- Prior kidney transplantation
- Heparin-induced thrombocytopenia
- Known hypersensitivity to heparin
- Known hypersensitivity to aprotinin or other components of the product
- Known severe congenital or acquired immunodeficiency (eg. HIV infection or long-term treatment with immunosuppressive drugs (eg. Organ transplantation patients)
- Prior radiation therapy to the operating field
- Severe local inflammation at the operating field
- If female, subject is pregnant or lactating at the time of study enrollment
- Subject has participated in another clinical study involving an IP or device within 30 days prior to study enrollment or is scheduled to participate in another clinical study involving an IP or device during the course of this study.
- Subject has previously participated in this study (Protocol No.: 550801), is, each subject can only be enrolled once.

Intraoperative Exclusion Criteria:

- Major intraoperative complications that require resuscitation or deviation from the planned surgical procedure.
- Intraoperative change in planned surgical procedure, which results in subject no longer meeting preoperative inclusion and/or exclusion criteria, (eg. Abandonment of ePTFE graft placement)

Status:

Active enrollment

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If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.