Safe and Timely Antithrombotic Removal - Ticagrelor (STAR-T)

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Male or female 18 years of age or older, with documented full, written informed consent 2. Requiring cardiothoracic (CT) surgery with cardiopulmonary bypass (CPB) within two days of ticagrelor discontinuation (day of last dose = day 0)

Exclusion Criteria:

1. CT surgery occurring 3 days or greater following ticagrelor discontinuation 2. Heart-lung transplant procedures 3. Procedures for ventricular assist device (implant/revision of LVAD or RVAD) 4. Pre-existing conditions that pose a known risk for bleeding (i.e., HITT, perioperative platelet count < 50,000u/L, hemophilia, and INR >1.5) 5. Prohibited concomitant antithrombotic medications as defined in the study protocol 6. Acute sickle cell crisis 7. Known allergy to device components 8. Active (untreated) systemic infection 9. History of major organ transplantation and those currently receiving immunosuppressive medication or who are profoundly immune suppressed 10. Women with positive pregnancy test during current admission or who are breast-feeding 11. Life expectancy <30 days 12. Inability to comply with requirements of the study protocol 13. Treatment with investigational drug or device within 30 days of current surgery 14. Previous enrollment in this trial

Conditions & Interventions

Interventions:
Device: DrugSorb-ATR system, Device: Sham comparator
Conditions:
Hemorrhage, Surgical, Blood Loss, Surgical, Blood Loss, Postoperative, Hemorrhage Postoperative

More Information

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Principal Investigator:
Phase: N/A
IRB
Number:
System ID: NCT04976530
