TP-013, Rev 03 PROTOCOL SYNOPSIS FOR CLINICALTRIALS.GOV

HHC-IRB NUMBER: HHC-2020-0086

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TITLE	Dislodgment Infiltration Phlebitis Prevention Eliminating Restarts (DIPPER)
SPONSOR	Lineus Medical
FUNDING ORGANIZATION	Lineus Medical
STUDY START DATE	June 2020
RATIONALE	Accidental IV catheter dislodgement and other mechanical complications (e.g., infiltration, phlebitis, infection, and occlusion) in hospitalized patients are very common. IV catheter mechanical complications increase costs and put patients at increased risk. SafeBreak Vascular is designed to separate into two pieces when a certain threshold of force is applied to an IV administration line. The purpose of this medical device investigation is to determine SafeBreak Vascular's impact on clinical care (e.g., delay of therapy) and its' impact on other IV catheter mechanical complications when compared to a control group of patients not using the device.
STUDY DESIGN	Prospective randomized clinical trial
PRIMARY OBJECTIVE	The primary objective of this study is to determine if the use of SafeBreak Vascular results in a delay in therapy that is non-inferior to the delay in therapy for the control group, and if so, if SafeBreak Vascular is superior.
SECONDARY OBJECTIVES	The secondary objective is to estimate the reduction of other peripheral IV (PIV) catheter mechanical complications including dislodgement, infection, phlebitis, infiltration, occlusion, as well as blood/fluid spillage and PIV restarts when compared to the control group.
NUMBER OF SUBJECTS	Up to 146 total (73 in each arm). This sample size allows for 10% of the subjects to abandon therapy before the normal completion of treatment.
SUBJECT SELECTION CRITERIA	<u>Inclusion Criteria</u>: • All patients admitted into the hospital to one of the following units: Neuro, Neuro/Step Down Epilepsy Pulmonary, Cardiothoraci, Surgery/Step Down; Medicine/Step Down, Vascular Thoracic

	Surgery/Step Down, B8- Surgery, B7E – Medicine/Step Down, B5-Vascular Thoracic Surgery • Patients of any gender may participate • Participants able to provide informed consent or have a legally authorized representative or Next of Kin immediately available to provide informed consent • Patients must have peripheral IV catheter access or need and are planned to have peripheral IV catheter access placed that is anticipated to last a minimum of 24 hours. • Patients must be receiving intermittent or continuous infusion, or have immediate plans to begin an intermittent or continuous infusion • The patients must be at least 18 years of age with no upper age limit. <u>Exclusion Criteria</u>: • Unable to obtain informed consent or without an available LAR or Next of Kin to provide surrogate informed consent • Age less than or equal to 17 • Patient on comfort care only • Predicted to have an IV infusion that lasts less than 24 hours. • Patient admitted from ED refuses to have new PIV catheter placed by IV team. • Patient has two or more peripheral IV catheters at the same time • Patient enrolled in a subject drug or device study at the time of enrollment • Investigator discretion that patient is not suitable for the study • Patient is COVID-19 positive • Patient is receiving an IV infusion with gravity tubing
SUBJECT DEVICE / INTENDED USE	SafeBreak is intended to stop fluid flow and prevent blood loss or fluid spillage in the event of excessive tension (4 ±1 lbs of force) occurs across a peripheral IV

	administration line in adults and adolescent populations eighteen (18) years of age or older. SafeBreak Vascular may be used only with electronic pumps for intermittent infusion or continuous infusion.
CONTROL GROUP	*Participants with current standard of care for peripheral IVs.*
DURATION OF SUBJECT PARTICIPATION AND DURATION OF STUDY	**Study Participation Duration:** Subjects in both groups will be followed for up to 7 days, or until the patient is discharged, or until IV access is discontinued. **Duration of the Study:** The study is expected to last at least two and up to three months.
EFFICACY EVALUATIONS	The primary and secondary objectives address the efficacy of the SafeBreak device.
PRIMARY ENDPOINTS	The primary endpoint is the time to re-start therapy following a mechanical complication with the catheter.
SECONDARY ENDPOINTS	Comparison of occurrence of mechanical complications (e.g., dislodgement, infection, infiltration, phlebitis, occlusion) as well as blood loss, fluid spillage and PIV restarts
SAFETY EVALUATIONS	The research team will evaluate all enrolled subjects at least twice daily for all adverse events and safety concerns and will document and communicate any concerns to the Investigator.