TP-013, Rev 03 STAT PLAN SYNOPSIS FOR CLINICALTRIALS.GOV

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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 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.*
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.
STATISTICAL ANALYSIS	**Primary Objective Test:** To demonstrate that the *average time per 24 hours* that therapy is delayed due to PIV mechanical complications is non-inferior with SafeBreak Vascular to that of the standard of care. The secondary objective does not include a hypothesis test; estimation techniques will be used.

	To test the Primary Objective: a. Of non-inferiority, the 24-hour delay of therapy due to PIV mechanical complications, SafeBreak Separations, and SafeBreak device failures of the SafeBreak group and PIV mechanical complications in the Control group will be compared with a non-inferiority Wilcoxon Rank-Sum test; b. Of inequality, the mean delay of therapy due to PIV mechanical complications, SafeBreak Separations, and SafeBreak device failures of the SafeBreak group and PIV mechanical complications in the Control group will be compared with a standard (inequality) Wilcoxon Rank-Sum test. To analyze Secondary Objective: a . The proportion of patients who experience PIV mechanical complications during the course of therapy will be estimated using a Kaplan-Meier time-to-event analysis. The proportions and counts of total mechanical complications will be compared between groups using a Chi-square analysis, Fisher's Exact Test, or Poisson regression as appropriate. b. Secondary endpoints include rates of IV restarts, blood/fluid spillage, dislodgement, infiltration, phlebitis, occlusion, and infection. The analysis population will be the Per Protocol population; the analysis method permits censoring at the time the patient exits or completes the study if this is prior to 7 days. Missing data that is not endpoint data will be ignored in reporting.
RATIONALE FOR NUMBER OF SUBJECTS	**Sample size rationale**: A total of 66 patients per group will provide 80% power at α=0.05 to demonstrate non-inferiority of SafeBreak An additional 10% will be enrolled to accommodate drop-out prior to therapy completion, for a total of 146 subjects.