B. Braun Medical Inc.

FINAL, CLINICAL STUDY PROTOCOL

Protocol Number: US-N-H-1801

Amendment 1

Assessment of the Effect of B. Braun Peripheral Advantage Program on Complications, Indwell Time and First Stick Success of PIVC Therapy

Name of Products:	Peripheral Advantage Program
Device Classification:	Christie VeinViewer® Vision2 Introcan Safety® IV Catheters – II STEADYCare™ Smallbore Extension Set with Wedge™ Catheter Stabilizer- II
Phase of Development:	4 (post-marketing study)
Study Indication:	NA
Sponsor Contact:	Christopher R. Curtin Manager Clinical Development, Medical Affairs B. Braun Medical Inc. 901 Marcon Blvd. Allentown, PA 18109 Tel: +1 610-596-2726 e-mail: chris.curtin@bbraunusa.com
Protocol Version:	2.0 Final
Protocol Date:	03 February 2021

SPONSOR APPROVAL PAGE

Product name: **Peripheral Advantage Program**

B. Braun protocol number: **US-N-H-1801**

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Wes Cetnarowski MD (Feb 5, 2021 10:44 PST)

Date: Feb 5, 2021

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Angela Karpf, MD (Feb 5, 2021 13:48 EST)

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Date: Feb 5, 2021

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INVESTIGATOR PROTOCOL AGREEMENT PAGE

Product name: **Peripheral Advantage Program**

B. Braun protocol number: **US-N-H-1801 Amendment 1**

I agree:

- To assume responsibility for the proper conduct of the study at this site.
- To conduct the study in compliance with this protocol, any future amendments, and with any other study conduct procedures provided by B. Braun Medical Inc.
- Not to implement any changes to the protocol without written agreement from B. Braun Medical and prior review and written approval from the Institutional Review Board (IRB) except where necessary to eliminate an immediate hazard to patients.
- That I am thoroughly familiar with the appropriate use of the study devices, as described in this protocol and any other information provided by B. Braun Medical.
- That I am aware of, and will comply with, good clinical practices (GCP) and all applicable regulatory requirements.
- To ensure that all persons assisting me with the study are adequately informed about the B. Braun Medical study devices and of their study-related duties and functions as described in the protocol.

Signature: _____ Date: _____

Name (print): _____
Principal Investigator

CONTACT LIST

Name:	B. Braun Medical Inc. 901 Marcon Blvd. Allentown, PA 18109
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PROTOCOL AMENDMENTS

Original Protocol issued 11 July 2019
Amendments are listed beginning with the most recent amendment.

*In this summary document new text is **bolded** and **underlined** where as the deleted text is ~~struck through~~ for easy identification.*

Amendment 1: 03 February 2021

Amendment 1: List of Changes

The overall reason for the amendment: The overall reason for this substantial amendment is to allow multiple study sites, to allow for enrollment from the Emergency Department, to allow for consenting by subject's Legally Authorized Representative (LAR), to clarify text regarding the definitions of a Study Completer and to clarify text regarding re-enrollment.

Applicable Section(s)	Text Changes (new text in **bold/underlined**, deleted text in ~~strikeout~~)	Description of change / Rationale for Change
Throughout the document, minor typographical errors, misspellings and minor formatting issues have been resolved. These minor changes are not listed in this summary.		
Sponsor Approval	**Angela Karpf, MD** **Corporate Vice President, Scientific Affairs**	Added new approver Other B. Braun personnel contact and/or Title information was updated.
Synopsis: Investigators/Study Sites	~~A single~~ **A multi-center study to include individual** hospital**s** or multiple hospital locations within a ~~single~~ hospital network.	Clarification of the number of hospitals allowed to participate in the study.
Synopsis: Study Design	The study will be conducted in the **Emergency Department (ED) and/or M**~~m~~edical **S**~~s~~urgical **(MS)** floor(s)/unit(s) ~~of~~ **in multiple hospitals** ~~the hospital/hospital network~~.	Clarification of the number of hospitals allowed to participate in the study.

Synopsis: Study Population	Registered Nurses: RNs from the **ED or MS** ~~medical surgical~~ unit(s)/**department(s)** of the hospital~~/hospital network~~ can be on any shift and will not be required to have a minimum level of clinical experience. **Any RNs from the participating floors or the hospital ED are eligible to participate in Stage 1 of the study, After completion of protocol training and any required site specific training (GCP, consent process, etc.), they are considered a Study RN.** ~~All RNs within the unit may complete the B. Braun protocol required trainings.~~ Those **Study** RNs who have not completed all of the **required training in the B. Braun Peripheral Advantage Program** ~~protocol required training~~ in Stage 2 cannot continue on to Stages 3 and 4 and thus will be removed from participation in the study. ~~Study RNs should not be currently using the~~ **The** B. Braun Introcan Safety® IV Catheters and/or the STEADYCare™ Smallbore Extension Set utilized in this study **cannot currently be in use in any of the participating units/departments at the time of initiating the study.** **The sites participating in the study cannot be currently using the** ~~The~~ B. Braun Introcan Safety® IV Catheters **or** ~~and.or~~ the STEADYCare™ Smallbore Extension Set **or the Christie VeinViewer** utilized in this study ~~cannot currently be used~~ in any of the participating units/departments at the time of initiating the study.	Updated to allow for enrollment from the Emergency Department
	Subjects: Subjects **or his/her Legally Authorized Representative (if appropriate)** will be consented by Study RNs before participating in Stage 1 and/or Stage 4 ……	Allowing for LARs.
Synopsis: Selection of Patients: Inclusion Criteria Section 4.1: Inclusion Criteria	Inclusion Criteria #2: **The subject or the subject's LAR voluntarily agrees that the subject will participate in this study and is able** ~~Able~~ to understand and sign the Informed Consent Form (ICF); Inclusion Criteria #3: Have a medical condition that requires a PIVC **anticipated to** last~~ing~~ for at least 48 hours	Allowing for LARs Clarification of the requirements for the 48 hour PIVC duration to be "anticipated".
Synopsis: Selection of Patients: Exclusion Criteria Section 4.2: Exclusion Criteria	Exclusion Criteria #3: **The subject or his/her LAR is**~~Are~~ an employee of the Investigator or study center or the sponsor…… Exclusion Criteria #5: 5. Patient has an existing **non study related** IV. ~~in one arm and has a medical condition prohibiting contralateral PIVC insertion.~~	Allowing for LARs.
Synopsis: Planned Sample Size	**The number of PIVC insertion attempts will be recorded.**	Clarifying to record PIVC insertion attempts
Synopsis: Components of the B. Braun Peripheral Advantage Program	**The devices in the B. Braun PA Program are all cleared for marketing or exempt from clearance by the FDA. There will be no study specific product labels**	Indicating all B. Braun products are FDA approved or exempted.

Synopsis: Criteria for Evaluation	Stage 1: **Any RNs from the participating floors or the hospital ED are eligible to participate in Stage 1 of the study. After completion of protocol training and any required site specific training (GCP, consent process, etc.), they are considered a Study RN.** …… Subjects **or their LAR (if appropriate)** will ~~be consented~~ **provide consent** and they must meet all inclusion and none of the exclusion criteria prior to the RN performing a study related PIVC procedure and collection of data.	Updated to allow for enrollment from the Emergency Department and allowing for LARs.
	Stage 2: The Intervention Stage will be conducted after the completion of the Baseline Stage. **Note: an RN may join the study in Stage 2 provided they have completed the site's required research training and protocol specific training before participating in Stage 2.** All ~~participating~~ **Study** RNs ~~from the medical surgical unit(s) of the hospital/hospital network~~ may take part in this Stage for education and skill assessment/perception to assess **the change in** their confidence and knowledge ~~with~~ **after learning…….**	Indicating a new RN can join in Stage 2.
	Stage 3: Only ~~Study~~ RNs **who have completed Stage 2** may participate in this Stage of the study **and will be considered a Study RN**.	Indicating an RN must complete stage 2 to go to Stage 3.
	Stage 4: Subjects **or his/her LAR (if appropriate)** will ~~be consented~~ **provide consent** and they must meet all inclusion and none of the exclusion criteria ……..	Allowing for LARs.
Synopsis: Study Endpoints	The primary endpoint for this study is the rate/percentage of ~~catheter removals due~~ to complications….. •Indwell time for catheters ~~with and without complications~~ (measured in hours)	Clarifying Primary Endpoint is the overall rate/percentage of complications.
Synopsis: Safety Analyses	Events may include, but are not limited to: minor and major complications **such as**, infection **or**, thromb~~us~~ **o**phlebitis, ~~, and~~ device failures (i.e., disconnection, twisted port hub, leakage, and failure of the safety feature) **and needlestick injuries**.	Minor text changes.

Section 3.1: Study Design	The study will be conducted in the medical surgical ~~floor~~ **department**(s)/unit(s) of **multiple hospitals** ~~the hospital/hospital network~~. **Patients from the Emergency Department (ED) are also eligible to be enrolled.** ~~All~~ **Any** RNs from these floors **or the hospital ED** ~~may~~ **are eligible to** participate in Stage 1 ~~and Stage 2~~ of the study. **After completion of protocol training and any required site specific training (GCP, consent process, etc.) the RNs will be considered Study RNs. The Study RNs from Stage 1 and any other RNs from the medical surgical floor(s)/unit(s) or the hospital ED who complete protocol training may participate in the intervention (Stage 2).** ~~A core group of RNs (~~**The** Study RNs~~)~~ on all shifts who have completed the protocol training/intervention (Stage 2) will participate in Stage 3 and Stage 4 of the study. ~~These~~ **All** Study RNs will be responsible for PIVC insertions and ~~monitoring~~ **catheter examinations.** Non-Study RNs should not perform any study related procedures (i.e., catheter insertion, **insertion** site **examinations** ~~evaluations~~ including documentation of both positive and negative findings, and catheter removal). In the event all RNs from the participating **department**(s)/unit(s) **and ED** are not able to participate in the study……..	Indication that multiple hospitals are allowed and that the Emergency Department can be used.
Section 3.2.1: Registered Nurses	Only Study RNs from the medical surgical unit(s) **or within the ED** of the hospital~~/hospital network~~ will perform study-related procedures…….. Years of experience and other demographic information will be collected from the **Study** RNs in Stage 1 and ~~the Study~~ **any** RNs **who join the study** in Stage ~~3~~ **2**~~and Stage 4~~. **Study** RNs participating in Stage 1 **or joining the study in Stage 2** should not be currently using the B. Braun Introcan Safety® IV Catheters and/or the STEADYCare™ Smallbore Extension Set utilized in this study.	Adding the allowance of the Emergency Department and of some Study RN requirements.
Section 3.2.2: Subjects	Subjects **or his/her LAR (if appropriate)** will ~~be consented~~ **provide consent** before participating in Stage 1 …… A subject who previously or currently has a catheter inserted due to medical need may participate in the study if he/she **or his/her LAR (if appropriate)** provides consent.	Allowing for LARs.
	Subjects will be classified as 1 or more of the following based on their individual participation in the study: • **Screen Failure: Any subject who signed the Informed Consent or who's LAR provided consent and then the subject failed to meet the inclusion and or exclusion criteria.** • **Enrolled: Any subject who signed the**	Clarification of the definitions of: Screen Failure, Enrolled, Early Withdrawal and Study Completer

	Informed Consent or who's LAR provided consent and then the subject met all of the inclusion and exclusion criteria, • **Early Termination: Any subject who was Enrolled but never had an attempted PIVC insertion or who was Enrolled and did not have a successful PIVC insertion by a study RN,** • **Early Withdrawal: Any subject who was Enrolled, but who voluntarily withdrew their consent or was withdrawn by their LAR or was withdrawn by the PI,** • **Study Completer: Any Enrolled Subject who had a successful PIVC insertion by a Study RN and had the PIVC removed for any reason** ~~Subjects must meet all of the inclusion criteria and none of the exclusion criteria before enrollment in the study.~~	
Section 4.3: Interruption or Discontinuation of Treatment	A subject may also be withdrawn by **his/her LAR or by** the Investigator or B. Braun due to a serious protocol violation or if it is determined it is in the best interest of the subject. In the event a subject **withdraws** ~~has or was withdrawn~~ from the study before **the first attempt of a PIVC insertion or has no successful stick by a Study RN**, ~~completing all requirements of the Stage in which he/she is participating,~~ he/she will be considered **an Early Termination from the study**. **In the event a subject or his/her LAR withdraws consent or the PI removes the subject from the study for any reason, the subject will be considered an Early Withdrawal.** ~~a non-study completer and will be replaced to ensure there are at least 316 successful PIVC placements in Stage 1 and at least 316 successful PIVC placements in Stage 4.~~	Clarification on an "Early Termination" subject. Allowing for LARs.
Section 5: INVESTIGATINAL DEVICE: DETAILS OF STUDY PRODUCT	**The devices in the B. Braun PA Program are all cleared for marketing or exempt from clearance by the FDA. There will be no study specific product labels.**	Indicating that the B. Braun products are FDA approved or exempt.
Section 5.2: Product Handling and Accountability	Only study related supplies provided by B. Braun will be used by Study RNs **on patients/subjects** ~~in~~ participating ~~medical/surgical unit(s)~~ in Stages 3 and 4. …… **During Stages 3 and 4, Study RNs will only utilize** ~~All PIVC insertions completed by these Study RNs in this unit(s) will utilize~~ the B. Braun **Peripheral Advantage** products**.** ~~for patients in Stage 3 (Run-In) and patients who consent to be study subjects for Stage 4 (Post-Intervention).~~ …….B. Braun products supplied for this study ~~cannot~~ **are not to** be used for patients outside of the	Clarification regarding who should use B. Braun study supplies.

	~~selected medical/surgical~~ unit/**department**(s) **where** this study **is being conducted**. **In the event any** ~~Use of the~~ B. Braun PIVC devices **are inadvertently used** by Study RNs for non-study patients in the participating **ED** or medical/surgical **department(s)**/unit(s) ~~is allowed; however,~~ no study related information will be recorded. Unused Introcan Safety® IV Catheters and unused STEADYCare™ Smallbore Extension Sets will be retained **or destroyed** by the study site **per their internal policies**.	
Section 5.3: Product Storage	The Christie VeinViewer® Vision2 is to be stored/retained ~~on~~ **in** the ~~medical/surgical floor~~ **unit/department(s)** ~~at~~ **where** the study is being conducted. The Introcan Safety® IV Catheters and the STEADYCare™ Smallbore Extension Set are also to be stored ~~on~~ **in** the ~~medical/surgical floor~~ **unit/department(s)** ~~at which~~ **in which** the study is being conducted.	Clarification on the restrictive use of the B.Braun products.
Section 6: STUDY VISITS ANSD ASSESSMENTS	This study will be conducted in the ~~medical surgical floor/unit(s) of multiple individual hospitals and or multiple hospitals within a the Hospital/Hospital Network~~ **ED or medical surgical unit/departments.** Only **participating** Study RNs ~~from the participating unit/department~~ will perform study related procedures.	Text allowing for multiple study sites.
	Subjects must have a medical condition requiring IV treatment through a PIVC **anticipated to** last~~ing~~ for at least 48 hours.	Clarification of the requirements for the 48 hour PIVC duration to be "anticipated".
	The Study Flow Diagram was updated and replaced.	Flow Diagram updated to current Terminology, no new study procedures were added.
Section 6.1: Stage 1: Baseline	**Any RNs from the participating floors or the hospital ED are eligible to participate in Stage 1 of the study and after completion of protocol training and any required site specific training (GCP, consent process, etc.) will be considered Study RNs.** ~~Only Study RNs will participate in this Stage.~~ Subjects **or their LARs** who are consented by **a Study** RN ~~who has received protocol training (Study RN)~~ and who meet all the inclusion and none of the exclusion criteria will be able to participate in this Stage……..During this Stage, ~~all~~ Study RNs will continue with their routine standard-of-care with regard to PIVC insertion technique and continue	Requirements for Study RNs.

	using the Institution's standard **PIVC** product ~~type~~. The ~~product type~~ **catheter brand**, ~~catheter~~ insertion **site** location, characteristics, number of attempts, dressing condition, complications and removal information (length of indwell time in hours and reason for removal) will be recorded in the ~~Case Report Form (CRF) or~~ electronic Case Report Form (eCRF) **for each insertion attempt**. In addition, the catheter and site of insertion will be examined daily and any relevant clinical findings will be recorded in the ~~CRF/~~eCRF. The subject's baseline demographic data (age, gender) will be collected. **If the attempts fail and the subject requires a different catheter, such a PICC, Midline or Central Catheter, or a PIVC form a different manufacturer will be recorded in the eCRF.**	
Section 6.2: Stage 2: Intervention	After completion of the Baseline Stage, ~~all~~ **Study** RNs ~~are permitted to~~ **will** take part in the Intervention which includes protocol training, if needed, and education on the use of B. Braun PA. **Note: an RN may join the study in Stage 2 provided they have completed the site's required research training and protocol specific training before participating in Stage 2.** Before the Intervention begins, the **Study** RNs will ~~take part in various~~ **complete the** skill assessment tools to ~~assess~~ **evaluate** their confidence and knowledge with respect to catheter insertion. These assessments are located in Appendix 1: PIVC Insertion Confidence Assessment and Appendix 2: PIVC Knowledge Assessment. The **Study** RNs will then receive **the full** training on how to use B. Braun PA Program, which consists of the PA Education Program Curriculum, **and in-service on the use of** the Christie VeinViewer® Vision2, Introcan Safety® IV Catheters and STEADYCare™ Smallbore Extension Set. …… After completion of the Intervention, the **Study** RNs will take part in skill assessments of their **PIVC therapy** confidence and knowledge ~~with respect to B. Braun PA~~…..	Requirements for Study RNs.
Section 6.3: Stage 3: Run-In	Only Study RNs ~~from~~ **that completed** Stage 2 will participate in this Stage. After the successful completion of the Intervention, it is anticipated that all current PIVC catheters and extension sets will be collected from the **department(s)**/unit(s) and only B. Braun PA products will be available ~~in the medical surgical unit(sdepartment or unit)~~. If this cannot be accomplished, the Investigator or designee will take reasonable measures to ensure that all Study RNs use only B. Braun **and Christie Medical** study products on their patients. These Study RNs will use the B. Braun devices for	Requirements for Study RNs.

	all **their patients** requiring PIVC ~~patients~~ from this point forward.	
Section 6.4: Stage 4: Post-Interventional	Study subjects **or their LARs** will be consented by Study RNs and must meet all inclusion and none of the exclusion criteria prior to any study related procedures~~,. including the use of B. Braun PA of products~~. The Study RNs should use the B. Braun devices for all of their PIVC study subjects. **Study RNs will use their standard procedures and supplies for PIVC dressing.** The catheter insertion **site** ~~location~~, characteristics, number of attempts, dressing condition, complications and removal information (length of indwell time in hours and reason for removal) will be recorded in the ~~CRF/~~eCRF **for each attempt**. The subject's demographic data (age, gender) will be collected. ~~In addition, t~~**T**he catheter and site of insertion will be examined daily and any relevant clinical findings will be recorded in the ~~CRF/~~eCRF……**If the attempts fail and the subject requires a different catheter, such a PICC, Midline or Central Catheter, or a PIVC form a different manufacturer will be recorded in the eCRF.** ~~At the completion of the Post-Interventional Stage Study RNs will assess their perception of B. Braun PA in the clinical setting using a Likert scale questionnaire.~~ **After completion of the study, the RNs will re-take the skill assessments of their confidence and knowledge with respect to B. Braun PA. These assessments are located in Appendix 1: PIVC Insertion Confidence Assessment and Appendix 2: PIVC Knowledge Assessment.** **Minor editorial changes to Table 1**	Clarifying the appropriate assessment tools.
Section 7: Skill Performance Assessments	The Study RNs will take skill/performance assessments (PIVC Insertion Confidence Assessment and PIVC Knowledge Assessment) before and after completion of the RN Intervention and ~~will record their perceptions of the PA Education Curriculum~~ **again** after the completion of the Post-Interventional Stage ~~in a Likert scale questionnaire~~.	Clarification of when the RN Assessments will be conducted.
Section 8: DEVICE REMOVAL	It is expected that the Study RNs will evaluate the catheter site before ~~they remove~~ the catheter **is removed**. ~~Once the catheter is removed by the Study RN, s~~**S**tandard facility protocols will be followed for **catheter removal and** the dressing of the IV site. ~~This~~ **The** dressing of the IV site may be performed by a non-study nurse**, however the date and time of removal and the reason for removal must be**	Clarification of catheter removal.

	recorded. A catheter may be removed at the end of a subject's medical treatment **requiring PIVC therapy**, as a result of complications or for any other reason determined by the treating clinician. ~~If a subjects is withdrawn before reaching at least 48 hours with the current PIVC insertion, he/she will be considered a non study completer and will be replaced to ensure there will be at least 316 successful PIVC placements in Stage 1 and at least 316 successful PIVC placements in Stage 4~~	
Section 8: DEVICE REMOVAL Section 12.4: Determination of Sample Size; Subjects	If the PIVC was removed as a result of treatment completions (i.e., subject no longer requires a PIVC) **he/she will be considered a Study Completer.** ~~and~~ **In addition, if** he/she was **subsequently** discharged from the facility, then he/she may re-enter the study in the same or different Stage if a re-admission for any reason is required.	Clarification of a Study Completer and potential for re-enrollment.
Section 8.1: Catheter Removal Due to Complication	~~Section 8.1: Catheter Removal Due to Complication~~	Deletion of unnecessary Section header
Section 8.1: Catheter Removal Due to Complication Section 12.4 Determination of Sample Size: Subjects	If the PIVC was removed as a result of treatment completion (i.e., subject no longer requires a PIVC) **he/she will be considered a Study Completer. In addition, if he/she was subsequently discharged from the facility,** then he/she may re-enter the study in the same or different Stage if a re-admission **for any reason** is required.	Clarification of a Study Completer and potential for re-enrollment.
Section 10: STUDY PROCEDURES	**Replace Table 2: Schedule of Events** There is no required routine collection of vital signs, physical examinations **(other than the catheter site)** or clinical laboratory evaluations.	Table 2: Schedule of Events was revised for clarification of procedures.
Section 11.1: Adverse Events	AE collection for each subject will begin after the ICF is signed and will continue until the completion of all study procedures or **until the** subject withdrawals **consent or is withdrawn** from the study. **An Adverse Device Effect (ADE) is an AE determined to be related to the use of the investigational device.**	Clarificati0n of the collection interval for AE's. Defining an Adverse Device Event.
Section 11.3:~~Serious Adverse~~ Event Reporting	**All events related to both the standard-of-care products used in the hospital and the B. Braun Peripheral Advantage Program devices and any required procedures will be evaluated by the Investigator for determination as AEs, SAEs, ADEs and documented on the electronic case report form (eCRF). AE collection for each**	Section was restructured and new text added for clarification of events and reporting information.

	subject will begin after the informed consent form is signed and will continue until the completion of all study procedures or subject withdrawal from the study. **All SAEs will be followed until the Investigator and Sponsor agree the event is satisfactorily resolved (i.e., resolved, stabilized or returned to baseline). Preliminary reports of SAEs must be followed by detailed descriptions later on, including clear and anonymized photocopies of hospital case reports, consultant reports, autopsy reports, and other documents when requested and applicable. SAE reports must be made whether or not the Investigator considers the event to be related to the study device.** ~~For adverse device effects and device malfunctions, notification can be made as described in the following paragraphs:~~ ~~1. Contact the study safety team to inform them that you are reporting an adverse device effect or device malfunction using a Form FDA 3500 MedWatch. If you are unable to speak with a live safety associate, leave a message with the name of the Investigator, your name, the telephone number where you can be reached, and the protocol number and title.~~ ~~2~~ **In the event of an adverse device effect or device malfunction, form FDA 3500 MedWatch must be completed.** ~~Fax or e-mail the~~ **E-mail** Form FDA 3500 MedWatch and any supporting documentation ~~to the study safety team~~ **as instructed below** within 24 hours of becoming aware of the event. ~~Verify successful transmission by obtaining a Fax Confirmation Report; this confirmation page should be kept with the SAE report in case future monitoring is required.~~ **a. During Stage 1 of the protocol, notification shall be made by email to chris.curtin@bbraunusa.com and diana.valencia@bbraunusa.com.** **b. During Stage 4 of the protocol, notification shall be made to the Sponsor's Medical Affairs Department either by phone call: 800-854-6851 or email to medinfo.us@bbraunusa.com.**	
Section 12.1: Statistical Analyses for Primary Endpoint	The statistical analysis will compare the rate/percentage of ~~catheter removals due to~~ complications between B. Braun PA and hospital's current standard of care PIVC utilizing a binomial test (such as Fisher's Exact Test). The source data are the evaluations of catheter placements, i.e., **were there any complications? (Yes/No)**, was there removal of the catheter due to complications?	Clarification of primary assessment will be overall complications and not associated with or without catheter removal.

	(Yes/No) (e.g., due to phlebitis, occlusion, infection, dislodgement, infiltration, etc.).	
Section 12.2: Statistical analyses for Secondary Endpoint	**In the event the subject or his/her LAR withdraws consent or is withdrawn by the PI, for any reason, and the catheter is still in place, the date and time of withdrawal will be used as a surrogate for the date and time of removal.**	Clarification of the documentation of date and time of IV removal in the event of an early withdrawal.
Section 12.4: Determination of Sample Size	Only RNs from the **hospital's ED or** medical surgical ~~unit(s)~~ **departments/unit** ~~of the hospital/hospital network~~ will participate.	RN's can now come from the Emergency Department
	Subjects **or their LAR** will be consented before participating in Stage 1 and/or Stage 4……..If the PIVC was removed as a result of treatment completions (i.e., subject no longer requires a PIVC) **he/she will be considered a Study Completer. In addition, if he/she was subsequently discharged from the facility,** then he/she may re-enter the study in the same or different Stage if a re admission **for any reason** is required.	Clarifying that a Study Completer due to no longer needing the IV can re-enroll. Allowing for LARs.
Section 13.1: Informed Consent	Each subject **or his/her LAR (if appropriate)** must be informed that participation in the study is voluntary,…….	Allowing for LARs.
	The subject **or his/her LAR (if appropriate)** should read and consider the statement before signing and dating it, and he/she should be given a copy of the signed document. No subject can enter Stage 1 and/or Stage 4 of the study or have any study related procedures performed before informed consent has been obtained from him/her **or his/her LAR (if appropriate)**.	Allowing for LARs.
	In the event a subject re-enrolls in the study, he/she or his/her LAR (if appropriate) must sign another Informed Consent.	Clarification regarding re-signing the consent in the event of a re-enrollment.
Section 13.2: Data Handling	In the event a subject **with a successful PIVC insertion** drops out or is withdrawn from the study, B. Braun or its designee will be informed in a timely manner **and the date and time of withdrawal will be recorded**. In the event a subject has or was withdrawn from the study before **a PIVC insertion attempt or a successful PIVC insertion by a Study RN,** ~~completing all requirements of the Stage he/she is participating,~~ he/she will be considered **an Early Termination from the study. In the event a subject or his/her LAR (if appropriate) withdraws consent or the PI removes the subject from the study for any reason, the subject will be consider as an Early Withdrawal.**~~a non-study completer and will be replaced to ensure that there are at least 316~~	Clarification on an "Early Termination" subject.

	~~successful PIVC placements in Stage 1 and at least 316 successful PIVC placements in Stage 4.~~ **In the event of a subject's withdrawal of consent or any other early withdrawal that also did not result in the IV being removed, the date and time of that withdrawal will be used as a surrogate for the date and time of removal of the IV and the subject's data will be treated in the same manner as a study completer. In this case, the subjects will not be allowed to re-enroll in to the study.** ……If the PIVC was removed as a result of treatment completions (i.e., subject no longer requires a PIVC) **he/she will be considered a Study Completer. In addition, if he/she was subsequently** ~~and he/she was~~ discharged from the facility, then he/she may re- enter the study in the same or different Stage if a re-admission for any reason is required.	Clarification of a Study Completer and potential for re-enrollment.
Section 13.6 Monitoring	During the study, B. Braun (and/or designee) may visit the site regularly **or remotely** to evaluate the completeness of study records, the accuracy of entries on the ~~CRF/~~eCRF, the adherence to the protocol and ICH-GCP guidelines, and the progress of enrollment, and to ensure that B. Braun PA is being stored, dispensed and accounted for according to specifications. **Remote monitoring and/or source data verification will be performed if a site has imposed, or is subject to, travel and/or visit restrictions for in-person visits due to circumstances such as those related to the Covid-19 pandemic or if the monitor is subject to travel restrictions.**	Text to allow for the requirements for remote monitoring and source data verification.

SYNOPSIS

Title of Study:	Assessment of the Effect of B. Braun Peripheral Advantage Program on Complications, Indwell Time and First Stick Success of PIVC Therapy
Protocol Number:	US-N-H-1801
Investigators/Study Sites:	A multi-center study to include individual hospitals or multiple hospital locations within a hospital network.
Phase of Development:	4 (post-marketing device study)
Objectives:	**Primary Objective** The primary objective of this study is to evaluate the impact of B. Braun Peripheral Advantage (PA) Program on the incidence of complications associated with PIVC use. **Secondary Objective** The secondary objectives of this study are to evaluate the effect of B. Braun PA on catheter indwell time, first attempt success rates (first stick success), and aggregate costs associated with catheter insertion.
Study Design:	Single sequence clinical study designed to evaluate the effectiveness of B. Braun PA on improved clinical outcomes, indwell time and first stick success of PIVC using B. Braun PA by Registered Nurses (RNs). The study will be divided into 4 Stages: 3 Clinical Stages and 1 Interventional (Educational) Stage. These 4 Stages are: Baseline (Stage 1), Intervention (Stage 2, education), Run-In (Stage 3), and Post-Interventional (Stage 4). The 3 clinical Stages require patient care which includes daily follow-up care for the catheter (Baseline, Run-In, and Post-Interventional). The Intervention (education) Stage is for the RNs to be trained in B. Braun PA and thus will not involve any patients. The study will be conducted in the Emergency Department (ED) and/or Medical Surgical (MS) floor(s)/unit(s) in multiple hospitals. A core group of RNs on all shifts who have completed the protocol required training (Study RNs) will participate in the study. In the event all RNs from the participating Unit are not able to participate in the study, the Investigator will take reasonable measures to ensure all specifically study related procedures are performed by the Study RNs.
Study Population	**Registered Nurses:** RNs from the ED or MS unit(s)/department(s) of the hospital can be on any shift and will not be required to have a minimum level of clinical experience. Any RNs from the participating floors or the hospital ED are eligible to participate in Stage 1 of the study. After completion of protocol training and any required site specific training (GCP, consent process, etc.), they are considered a Study RN. Those Study RNs who have not completed all of the required training in the B. Braun Peripheral Advantage Program in Stage 2 cannot continue on to Stages 3 and 4 and thus will be removed from participation in the study. The sites participating in the study cannot be currently using the B. Braun Introcan Safety® IV Catheters or the STEADYCare™ Smallbore Extension Set or the Christie VeinViewer utilized in this study in any of the participating units/departments at the time of initiating the study. **Subjects:** At least 632 PIVC successful placements are to be performed in the medical surgical unit running the study (Stage 1, at least 316 successful PIVC placements and Stage 4, at least 316 successful PIVC placements). Subjects or his/her Legally Authorized Representative (if appropriate) will be consented by Study RNs before participating in Stage 1 and/or Stage 4 and may participate in either, or both, of those stages. Subjects consented for Stage 1 may participate as patients in Stage 3 (Run-In).
Selection of Patients:	**Inclusion Criteria** RNs must complete all of the required B. Braun trainings in Stage 2 in order to participate in Stages 3 and 4. Subjects must meet all of the following Inclusion Criteria:

	1. Male or female aged ≥18 years; 2. The subject or the subject's LAR voluntarily agrees that the subject will participate in this study and is able to understand and sign the Informed Consent Form (ICF); 3. Have a medical condition that requires a PIVC anticipated to last for at least 48 hours; 4. Have intact skin at the site of insertion; 5. If the patient has an existing IV in one arm he/she must have a viable contralateral arm for additional PIVC insertion. **Exclusion Criteria** Subjects must not meet any of the following Exclusion Criteria: 1. Are currently participating in another medical device or pharmaceutical study; 2. In the opinion of the Investigator, would not be suitable candidates for this study; 3. The subject or his/her LAR is an employee of the Investigator or study center, or the sponsor, or have direct involvement in the study or other studies under the direction of that Investigator or study center, or are a family member of the employees or the Investigator; 4. Have a laboratory confirmed bloodstream infection within 48 hours prior to participation in the study. The assessment is based on clinical observations and not routine for all subjects; 5. Patient has an existing non study related IV 6. Was removed from any Stage of the study due to an AE associated with the PIVC.
Planned Sample Size:	At least 632 successful PIVC placements (316 successful PIVC placements in Stage 1 and 316 successful PIVC placements in Stage 4) are required to complete the study. The number of PIVC insertion attempts will be recorded.
B. Braun Peripheral Advantage Program:	Education Curriculum, Christie VeinViewer® Vision2, Introcan Safety® IV Catheters, and STEADYCare™ Smallbore Extension Set
Components of the B. Braun Peripheral Advantage Program:	PA Education Curriculum – developed and delivered by B. Braun Medical Inc. Christie VeinViewer® Vision2 – manufacturer Christie Medical Holdings Inc Introcan Safety® IV Catheters – manufacturer B. Braun Medical Inc. STEADYCare™ Smallbore Extension Set with Wedge™ Catheter Stabilizer – manufacturer B. Braun Medical Inc. The devices in the B. Braun PA Program are all cleared for marketing or exempt from clearance by the FDA. There will be no study specific product labels.
Criteria for Evaluation:	Subjects must have a medical condition that requires the insertion of a PIVC anticipated to be at least 48 hours for their medical treatment. There will be 3 Clinical Stages and 1 Educational Stage to this study: Baseline (Stage 1), Intervention (Stage 2, education), Run-In (Stage 3), and Post-Interventional (Stage 4). The 3 Clinical Stages require patient care including daily follow-up care for the catheter (Baseline, Run-In, and Post-Interventional). The Intervention (Education) Stage is only for the RNs to be trained in B. Braun PA and thus will not involve any patients. **Stage 1:** Any RNs from the participating floors or the hospital ED are eligible to participate in Stage 1 of the study. After completion of protocol training and any required site specific training (GCP, consent process, etc.), they are considered a Study RN. During the Baseline Stage, the RNs will continue with their routine standard-of-care with regards to PIVC insertion technique used and Institution's PIVC type. Subjects or their LAR (if appropriate) will provide consent and they must meet all inclusion and none of the exclusion criteria prior to the RN performing a study related PIVC procedure and collection of data. **Stage 2:** The Intervention Stage will be conducted after the completion of the Baseline Stage. Note: an RN may join the study in Stage 2 provided they have

	completed the site's required research training and protocol specific training before participating in Stage 2. All Study RNs may take part in this Stage for education and skill assessment/perception to assess the change in their confidence and knowledge after learning the PA Curriculum. B. Braun PA Program includes: Christie VeinViewer® Vision2, Introcan Safety® IV Catheters, STEADYCare™ Smallbore Extension Set, and the PA Curriculum. The PA Education Curriculum consists of approximately 2 hours of individual self-paced on-line training and approximately 2 hours of live classroom training and practice. **Stage 3:** Only RNs who have completed Stage 2 may participate in this Stage of the study and will be considered a Study RN. The Run-In Stage will last approximately 3 weeks and serves to familiarize the Study RNs with the B. Braun devices in a clinical setting. The Study RNs will use the B. Braun devices for all their PIVC insertions from this point forward, when feasible. **Stage 4:** Only Study RNs may participate in this Stage of the study. The Post-Interventional Stage will be conducted after the conclusion of the Run-In Stage and will assess the effectiveness of B. Braun PA in a clinical setting. Subjects or his/her LAR (if appropriate) will provide consent and they must meet all inclusion and none of the exclusion criteria prior to the Study RN performing a study related PIVC procedure and collection of data. B. Braun devices will continue to be used during this Stage.
Study Endpoints:	Data obtained from the use of the current standard-of-care (Stage 1) and B. Braun PA (Stage 4) will be used in the assessment of the Primary and Secondary Endpoints. **Primary Endpoint** The primary endpoint for this study is the rate/percentage of complications (e.g., phlebitis/thrombophlebitis, occlusion, infection (localized or Catheter Related Bloodstream Infection [CRBSI]), dislodgement or infiltration, extravasation, accidental removal, etc.). **Secondary Endpoints** • Indwell time for catheters (measured in hours) • First attempt insertion success rate (first stick success) for PIVC • Rate of insertion of a Peripherally Inserted Central Catheter (PICC) or Midline Catheter due to inability to insert the PIVC or removal of the initial PIVC due to complications (rescue PICC or rescue Midline) • Healthcare costs associated with PIVC use in a clinical setting.
Statistical Methods and Planned Analyses:	Standard statistical methods will be utilized in this study to analyze all data. Endpoints that measure rates (e.g., primary endpoint of rate of complications) will be tested for significance using a binomial test (such as Fisher's exact test). Continuous endpoints will be tested for significance using standard parametric tests (such as Student's t-test), or non-parametric equivalent (such as Wilcoxon signed rank test) if parametric methods are found to be inappropriate. Two interim analyses are planned for the purpose of sample size re-estimation. Using the method of Pocock & Mehta, the sample size can be either held constant or increased – it cannot be reduced based on the results of the re-estimation. **Interim Data Analysis Stage 1:** Upon successful completion of approximately 70% of the originally planned PIVC placements in Stage 1, an interim analysis of the primary endpoint on raw (uncleaned) data will be performed. If the observed complication rate is statistically significantly greater than 50%, the sample size will not be modified. If the observed complication rate is not statistically significantly greater than 50%, the sample size may be re-estimated (increased). **Interim Data Analysis Stage 4:** Upon successful completion of approximately 50% of the initial sample size in Stage 4, another interim analysis on raw (uncleaned) data for the complications will be performed. This sample size re-estimation will follow the method of Pocock and Mehta to calculate the conditional power of the study to conclude that the complication rate in Stage 4 is lower than the complication rate in Stage 1, given the observed complication rates at the interim analysis.

	In the event the conditional power is found to be in the Favorable or Unfavorable zone, the study will continue to the originally planned sample size in Stage 4. In the event the conditional power is in the Promising zone, the total study sample size may be increased to the required sample size to achieve conditional power of 90% at the completion of the study. Additional details on the statistical analyses will be describe in the separate Statistical Analysiss Plan (SAP).
Safety Analyses:	All adverse events reported over the course of the study will be categorized based on MedDRA coding system and tabulated by system organ class, and preferred term within the system organ class. Events may include, but are not limited to: minor and major complications such as infection or thrombophlebitis, device failures (i.e., disconnection, twisted port hub, leakage, and failure of the safety feature) and needlestick injuries.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
ABS	Acrylonitrile-butadiene-styrene
AE	Adverse Event
ADE	Adverse Device Event
B. Braun	B. Braun Medical Inc.
CFR	Code of Federal Regulations
DVD	Digital Versatile Disc
eCRF	Electronic Case Report Form
EEC	European Ethics Committee
ED	Emergency Department
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRB	Institutional Review Board
IV	Intravenous
LAR	Legally Authorized Representative
PA	Peripheral Advantage
PICC	Peripherally Inserted Central Catheter
PIVC	Peripheral Intravenous Catheter
PUR	Polyurethane
RN	Registered Nurse
SAE	Serious Adverse Event
SIN	Subject Identification Number
SOP	Standard Operating Procedure
US	United States
USADE	Unanticipated Serious Adverse Device Effect

1 INTRODUCTION

B. Braun Medical Inc. (B. Braun) is committed to enhancing clinical outcomes while managing workflow efficiencies. B. Braun leads the way in developing infusion therapy and pain management products and services that meet the highest standards for quality, safety, efficiency and sustainability.

Peripheral intravenous catheters (PIVCs) are used to deliver medication and fluids directly into the bloodstream. The placement of PIVCs is the most common invasive hospital procedure. In the United States (US) alone, more than 300 million PIVCs are sold each year and 60% to 90% of hospitalized patients require an IV catheter (Helm, 2015). Despite the large medical demand for PIVCs, there is a high failure rate and large cost associated with replacing the catheter due to complications, not counting the need to perform unnecessary PIVC insertions.

The Centers for Disease Control and Prevention (CDC) recommends rotating the PIVC site at 72 to 96-hour intervals to reduce the risk of infection and patient discomfort associated with phlebitis (O'Grady, 2002). However, typical catheter dwell times range from only 1.9 to 2.5 days (Powell, 2008; Royer, 2003; Sheppard, 1999). Failures, which occur in anywhere from 35% to 70% of PIVCs, take the forms of phlebitis, infiltration, occlusion/mechanical failure, dislodgment, and infection (Helm, 2015; Maki, 1991; Shears, 2006). A PIVC failure is considered to have occurred when the PIVC stops working safely before the end of the 72 to 96-hour limit or before the end of its intended dwell time (PIVC is no longer needed). These failures are associated with many factors, including the products used and the expertise of the clinician inserting and maintaining the PIVC, and add to the costs of intravenous (IV) therapy (Helm, 2015).

While the initial cost of inserting a PIVC in the US is roughly between $28 and $35 for "first-stick" insertions, the costs of identifying, inserting, and removing a PIVC is repeated each time a failed catheter is replaced (Helm, 2015; Rickard, 2012; Webster, 2008). Additional costs come from treating the PIVC complications such as bleeding, hematoma formation, infusate extravasation, thrombophlebitis, and catheter-related bloodstream infection (Smith, 1998; Greig, 2002; Doellman, 2009; Hollenbeak, 2012).

Numerous clinician PIVC knowledge and insertion skill deficits have been identified including patient assessment, insertion site selection, catheter selection and insertion, catheter securement, dwell time, complication identification and treatment, and compliance with best practice guidelines (Hadaway, 2012; Frey, 1998; Palefski, 2001; Abbas, 2007; Cicolini, 2014). Keleekai et al. (2016) reported significant improvements in nurses' PIVC insertion knowledge, confidence, and skills in a simulated environment as a result of participation in a simulation-based, blended learning program. In addition, while not statistically significant, the intervention group demonstrated increased PIVC first stick success by 28 percentage points (from 53% to 81%) during the study period, which represented a 53% increase in first stick success for this population of medical/surgical bedside nurses, average age 39.9 years (standard deviation [SD] = 12.6). For these reasons, there is a need to develop effective strategies to prevent the potential problems associated with vascular access that Registered Nurses (RNs) experience in clinical settings (Vinograd et.al, 2017).

This study is designed to assess the effect of the B. Braun Peripheral Advantage (PA) Program that includes clinician education and specific B. Braun peripheral intravenous (PIV) therapy products designed to improve the clinical outcomes associated with a PIVC.

The study will be conducted in compliance with Food and Drug Administration (FDA) regulations, the ethical principles of the Declaration of Helsinki (Edinburgh, Scotland; 2000), the International Conference on Harmonization (ICH) – Good Clinical Practice (GCP) Guidelines as currently amended, and all applicable Standard Operating Procedures (SOPs) of the study site.

1.1 Rationale for the Study

The placement of PIVCs is the most common invasive hospital procedure. In the US alone, 60% to 90% of hospitalized patients require an IV catheter (Helm, 2015). Despite this large medical demand for PIVCs, there is a high failure rate and large cost associated with replacing the catheter due to complications.

The use of B. Braun PA, which includes PA Education Curriculum, Christie VeinViewer® Vision2, Introcan Safety® IV Catheters, and STEADYCare™ Smallbore Extension Set may improve patient care at the bed side and decrease PIVC associated complications, resulting in increased catheter indwell time and improved financial outcomes.

2 STUDY OBJECTIVES AND ENDPOINTS

2.1 Study Objectives

2.1.1 Primary Objective

The primary objective of this study is to evaluate the impact of B. Braun PA on the incidence of complications associated with PIVC use.

2.1.2 Secondary Objective

The secondary objectives of this study are to evaluate the effect of B. Braun PA on catheter indwell time, first stick success rates (first stick success), and aggregate costs associated with catheter insertion.

2.2 Study Endpoints

Data obtained from the use of the current standard-of-care (Stage 1) and of B. Braun PA (Stage 4) will be used in the assessment of the Primary and Secondary Endpoints.

2.2.1 Primary Endpoint

The primary endpoint for this study is the rate/percentage of complications (e.g., phlebitis/thrombophlebitis, occlusion, infection (localized or Catheter Related Bloodstream Infection (CRBSI), dislodgement or infiltration, extravasation, accidental removal, etc.).

2.2.2 Secondary Endpoint

The secondary endpoints for this study are:

- Indwell time for catheters with and without complications (measured in hours)

- First attempt insertion success rate (first stick success) for PIVC
- Rate of insertion of a Peripherally Inserted Central Catheter (PICC) or Midline Catheter due to inability to insert the PIVC or removal of the initial PIVC due to complications (rescue PICC or rescue Midline)
- Impact of using B. Braun PA on the healthcare costs associated with PIVC use in a clinical setting.

3 INVESTIGATIONAL PLAN

3.1 Study Design

This is a single sequence study to evaluate the effectiveness of B. Braun PA on improved clinical outcomes by decreasing PIVC complications, increasing PIVC indwell time, improving first PIVC stick success and improving estimated aggregated costs utilizing B. Braun PA.

The study will be divided into 4 Stages: 3 Clinical Stages and 1 Interventional (Educational) Stage. These 4 Stages are: Baseline (Stage 1), Intervention (Stage 2, education), Run-In (Stage 3), and Post-Interventional (Stage 4). The 3 clinical Stages (Baseline, Run-In, and Post-Interventional) require patient care which includes daily follow-up care for the catheter. The Intervention (education) Stage (Stage 2) may include all RNs from the medical surgical floor(s)/unit(s) of the hospital/hospital network. This training in B. Braun PA will not involve any patients.

The study will be conducted in the medical surgical floor(s)/unit(s) of multiple individual hospitals. Patients from the Emergency Department (ED) are also eligible to be enrolled. Any RNs from these floors or the hospital ED are eligible to participate in Stage 1 of the study. After completion of protocol training and any required site specific training (GCP, consent process, etc.) to the RNs will be considered Study RNs. The Study RNs from Stage 1 and any other RNs from the medical surgical floor(s)/unit(s) or the hospital ED who complete protocol training may participate in the intervention (Stage 2). The Study RNs on all shifts who have completed the protocol training/intervention (Stage 2) will participate in Stage 3 and Stage 4 of the study. All Study RNs will be responsible for PIVC insertions and catheter examinations. Non-Study RNs should not perform any study related procedures (i.e., catheter insertion, insertion site examinations including documentation of both positive and negative findings, and catheter removal). In the event all RNs from the participating department(s)/unit(s) and ED are not able to participate in the study, the Investigator will take reasonable measures to ensure all study-related procedures are performed by the Study RNs.

A minimum of 632 successful PIVC placements are required to complete the study (316 successful PIVC placements in Stage 1 and 316 successful PIVC placements in Stage 4). Each study Stage must be completed before proceeding to the next study Stage. The final sample sizes of Stage 1 and Stage 4 will be determined by the 2 interim analyses.

The study will be conducted in compliance with this protocol, GCP, and any other applicable regulatory requirements.

3.2 Study Population: Registered Nurses and Subjects

Data obtained from all subjects who enroll in any Stage of the study and from the Study RNs will be included in analysis of safety and the study endpoints.

3.2.1 Registered Nurses

Only Study RNs from the medical surgical unit(s) or within the ED of the hospital will perform study-related procedures. Registered nurses can be on any shift(s) and will not be required to have a minimum level of clinical experience. Any Study RN who does not complete all of the B. Braun trainings in Stage 2 cannot continue on to Stages 3 and 4 and thus is removed from participation in the study. Years of experience and other demographic information will be collected from the Study RNs in Stage 1 and any RNs who join the study in Stage 2. Study RNs participating in Stage 1 or joining the study in Stage 2 should not be currently using the B. Braun Introcan Safety® IV Catheters and/or the STEADYCare™ Smallbore Extension Set utilized in this study.

3.2.2 Subjects

Subjects will be enrolled into the study to ensure there are at least 632 successful PIVC placements, with at least 316 successful PIVC placements in Stage 1 and 316 successful PIVC placements in Stage 4. In Stage 3, Study RNs will familiarize themselves with B. Braun devices in a clinical setting by using them exclusively as standard-of-care for PIVC patients. Stage 3 does not require a statistically defined number of PIVC placements and will run for about 3 weeks. During this time it is anticipated that each Study RN will perform approximately 10 insertions (Reznek 2002).

Subjects or his/her LAR (if appropriate) will provide consent before participating in Stage 1 (Baseline) and Stage 4 (Post-Interventional) and may participate in one, or both, of those stages. Subjects consented for Stage 1 may participate as patients in Stage 3 (Run-In). A subject who previously or currently has a catheter inserted due to medical need may participate in the study if he/she or his/her LAR (if appropriate) provides consent. However, consent must be given before any study-related procedures including the replacement of a catheter utilizing the hospital's standard-of-care (Baseline Stage 1) or B. Braun PA (Post-Intervention Stage 4). The replacement catheter must be inserted in a different arm (see Exclusion criteria 5 below).

Subjects will be classified as 1 or more of the following based on their individual participation in the study:

- Screen Failure: Any subject who signed the Informed Consent or who's LAR provided consent and then the subject failed to meet the inclusion and or exclusion criteria,
- Enrolled: Any subject who signed the Informed Consent or who's LAR provided consent and then the subject met all of the inclusion and exclusion criteria,
- Early Termination: Any subject who was Enrolled but never had an attempted PIVC insertion or who was Enrolled and did not have a successful PIVC insertion by a study RN,

- Early Withdrawal: Any subject who was Enrolled, but who voluntarily withdrew their consent or was withdrawn by their LAR or was withdrawn by the PI,
- Study Completer: Any Enrolled Subject who had a successful PIVC insertion by a Study RN and had the PIVC removed for any reason

4 SELECTION AND DISCONTINUATION OF TREATMENT

RNs must complete all of the required B. Braun trainings in Stage 2 in order to participate in Stages 3 and 4.

4.1 Inclusion Criteria

Subjects must meet all of the following Inclusion Criteria:

1. Male or female aged ≥18 years;
2. The subject or the subject's LAR voluntarily agrees that the subject will participate in this study and is able to understand and sign the Informed Consent Form (ICF);
3. Have a medical condition that requires a PIVC anticipated to last for at least 48 hours;
4. Have intact skin at the site of insertion;
5. If the patient has an existing IV in one arm he/she must have a viable contralateral arm for additional PIVC insertion.

4.2 Exclusion Criteria

Subjects must not meet any of the following Exclusion Criteria:

1. Are currently participating in another medical device or pharmaceutical study;
2. In the opinion of the Investigator, would not be suitable candidates for this study;
3. The subject or his/her LAR is an employee of the Investigator or study center or sponsor, have direct involvement in the study or other studies under the direction of that Investigator or study center, or are a family member of the employees or the Investigator;
4. Have a laboratory confirmed bloodstream infection within 48 hours prior to participation in the study. The assessment is based on clinical observations and not routine for all subjects;
5. Patient has an existing non study related IV;
6. Was removed from any Stage of the study due to an AE associated with the PIVC.

4.3 Interruption or Discontinuation of Treatment

In accordance with legal requirements and ICH-GCP guidelines, every subject has the right to refuse further participation in the study at any time and without providing a reason. A subject may also be withdrawn by his/her LAR or by the Investigator or B. Braun due to a serious protocol violation or if it is determined it is in the best interest of the subject. In the event a subject withdraws from the study before the first attempt of a PIVC insertion or has no successful stick by a Study RN, he/she will be considered as an Early Termination from the study. In the event a subject or his/her LAR withdraws consent or the PI removes the subject from the study for any reason, the subject will be considered an Early Withdrawal.

5 INVESTIGATIONAL DEVICE: DETAILS OF STUDY PRODUCT

The devices in the B. Braun PA Program are all cleared for marketing or exempt from clearance by the FDA. There will be no study specific product labels.

Manufacturers of Components of B. Braun Peripheral Advantage Program:

- PIVC Education Curriculum – developed and delivered by B. Braun Medical Inc.
- Christie VeinViewer® Vision2 – manufacturer Christie Medical Holdings Inc
- Introcan Safety® IV Catheters – manufacturer B. Braun Medical Inc.
- STEADYCare™ Smallbore Extension Set with Wedge™ Catheter Stabilizer – manufacturer B. Braun Medical Inc.

5.1 Description of B. Braun Peripheral Advantage Program Components

Christie VeinViewer® Vision2

The adjustable head can be positioned over any part of the anatomy, leaving the clinician's hands free to perform the procedure, using the trademarked Eyes of Patient (EOP™) technique. The Christie VeinViewer® Vision2 unit contains the following: optical head assembly, arm, battery, battery compartment door, power module, arm lock, power cord, handle, basket, cart, cart base, wheel lock, wheel, cart base counterweight, cable clips, user guide, software (compact disc [CD]) and training video (digital versatile disc [DVD]), and universal serial bus (USB) cable. This study will utilize the optional Stability Mount (S-Mount) which allows Christie VeinViewer® Vision2 to be positioned over any part of the anatomy, leaving the clinician's hands free to perform the procedure. The Christie VeinViewer® Vision2 should be stored between -10°F to +140°F (-23°C to +60°C) and operate between +60°F to +86°F (+16°C to +30°C).

Introcan Safety® IV Catheters

The Introcan Safety® IV Catheters is designed to minimize needlestick injuries and has been available in the US since 2002. This device is made of polyurethane (PUR), polypropylene (PP), acrylonitrile-butadiene-styrene (ABS), chrome-nickel steel or fluorinated ethylene propylene (FEP). This sterile device is for single use only. The specific gauges and lengths to be supplied will be appropriate for the study facility.

STEADYCare™ Smallbore Extension Set with Wedge™ Catheter Stabilizer

The STEADYCare™ Smallbore Extension set is comprised of the STEADYCare™ Smallbore Extension Set with Wedge™ Catheter Stabilizer, Female Luer Lock Connector, and Spin-Lock® Connector. This sterile device is for single use only.

5.2 Product Handling and Accountability

Only study related supplies provided by B. Braun will be used by Study RNs on patients/subjects participating in Stages 3 and 4. These Study RNs will be the only personnel tasked with study related PIVC insertions/removals and assessing for complications on their associated units. During Stages 3 and 4, Study RNs will only utilize the B. Braun Peripheral Advantage products. In the event that standard-of care products are still available alongside B. Braun study-related supplies in this unit(s), the Investigator or designee will take appropriate measures to ensure study subjects receive only the B. Braun devices. B. Braun products supplied for this study are not to be used for patients outside of the unit/department(s) in which this study is being conducted. Study related supplies must be stored as per Hospital/Hospital Network SOP's and guidelines as well as the conditions specified on B. Braun PA labels.

The Investigator or a designee must maintain a complete record of the shipment and receipt of B. Braun PA in an accountability log. This log must be kept current and should contain at least the date and amount received, lot number (s), and expiration date(s). Whenever a B. Braun PIVC device is used for a study subject in Stage 4, the use will be recorded in the eCRF and on the accountability log. In the event any B. Braun PIVC devices are inadvertently used by Study RNs for non-study patients in the participating ED or medical/surgical department(s)unit(s), no study related information will be recorded. The use of B. Braun PA for non-study patient standard-of-care will be recorded in the accountability log.

During the course of the study, the used Introcan Safety® IV Catheters and the used STEADYCare™ Smallbore Extension Set must be disposed of in accordance with hospital policy and local regulations governing the disposal of medical and/or hazardous waste. If a device fails at any point during the study, it must be returned to B. Braun in accordance with B. Braun SOPs for device malfunction/return. The Christie VeinViewer® Vision2 will be returned to B. Braun at the conclusion of the study, unless otherwise agreed upon in writing. Unused Introcan Safety® IV Catheters and unused STEADYCare™ Smallbore Extension Sets will be retained or destroyed by the study site per their internal policies.

When requested in writing by B. Braun, unused study related supplies must be destroyed by the Investigator, provided such disposition does not expose humans to risks. Records shall be maintained by the Principal Investigator of any such alternative disposition of the investigational devices. These records must show the identification and quantity of each unit disposed of, the method of destruction (taking into account the requirements of local law), and the person who disposed of the study related supplies. Such records will be maintained in the Study File.

5.3 Product Storage

The Christie VeinViewer® Vision2 is to be stored/retained in the unit/department(s) where the study is being conducted.

The Introcan Safety® IV Catheters and the STEADYCare™ Smallbore Extension Set are also to be stored in the unit/department(s) in which the study is being conducted. If there is insufficient space on this floor to store all the IV associated products received, it is acceptable to store the remaining IV associated supplies in a limited access/secure area separate from the study floor. These materials must be clearly identified as to be used only for B. Braun study US-N-H-1801.

The Introcan Safety® IV Catheters and the STEADYCare™ Smallbore Extension Set must be used prior to the expiration dates noted on the package labels.

To assure that only the Study RNs complete the subject PIVC insertions using the Introcan Safety® IV Catheters, the STEADYCare™ Smallbore Extension Set and the Christie VeinViewer® Vision2, these products will be stored in a separate locked area. Access to this restricted area will be provided only to the appropriate study staff. Use of study related products will be documented on the accountability log and, for consented subject, in the eCRF.

The Sponsor will provide product with a shelf life of approximately one (1) year.

5.4 Package Labeling

The devices in the B. Braun PA Program are all currently cleared for marketing or exempt from clearance by the FDA. There will be no study specific product labels.

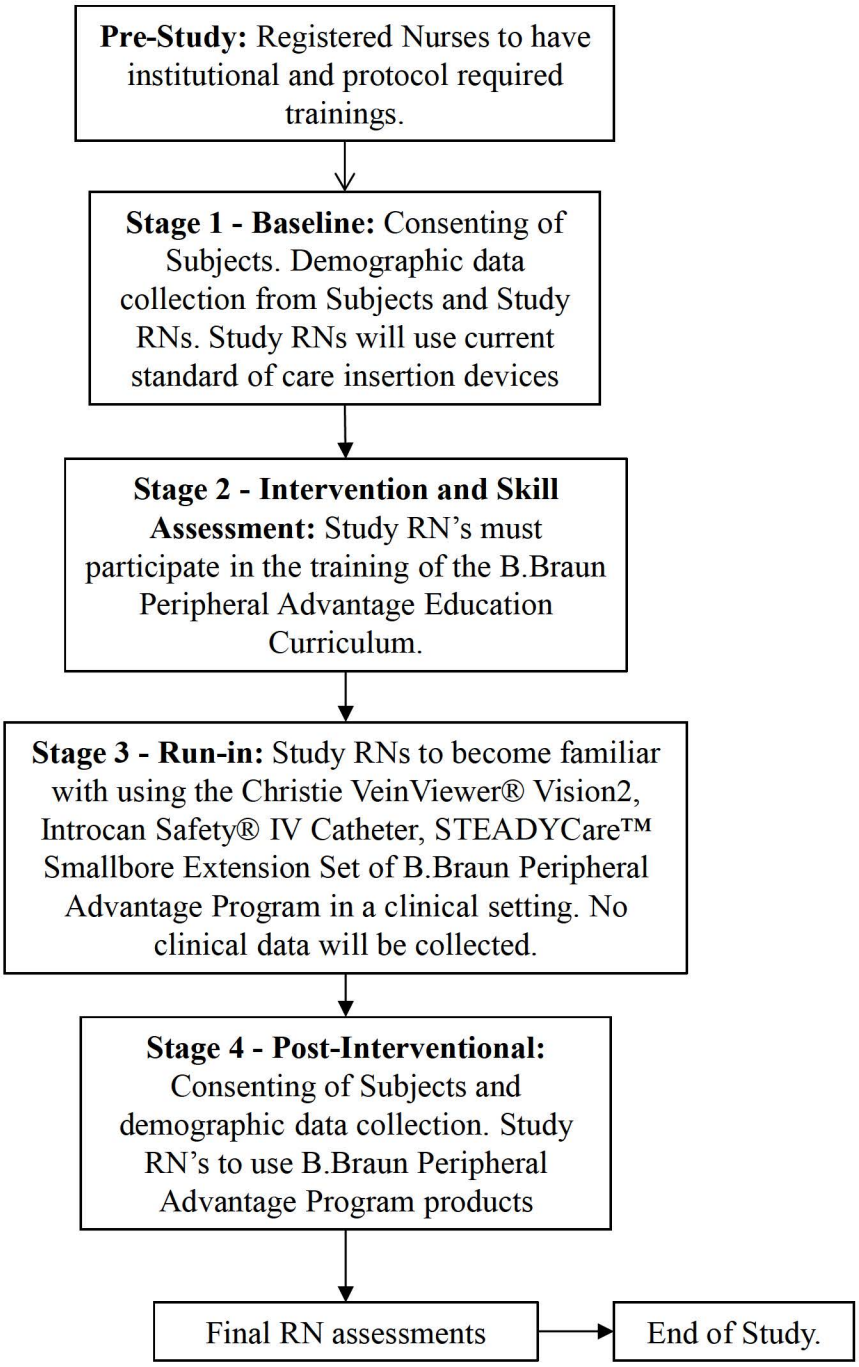
6 STUDY VISIT AND ASSESSMENTS

This study will be conducted in the ED or medical surgical unit/departments. Only participating Study RNs will perform study related procedures. Baseline demographic/clinical experience information from RNs will be obtained. This information will include age, gender, title/function, shift, and years of clinical experience.

Subjects must have a medical condition requiring IV treatment through a PIVC anticipated to last for at least 48 hours. A subject may participate in one or more of the 3 Stages that require patient care (Baseline, Run-In, and Post-Interventional).

A study flow diagram outlining the main study procedures is shown in Figure 1.

Figure 1 **Study Flow Diagram**



6.1 Stage 1: Baseline

Any RNs from the participating floors or the hospital ED are eligible to participate in Stage 1 of the study and after completion of protocol training and any required site specific training (GCP, consent process, etc.) will be considered Study RNs.

Subjects or their LAR who are consented by a Study RN and who meet all the inclusion and none of the exclusion criteria will be able to participate in this Stage. At least 316 successful PIVC placements are required in the Baseline Stage. During this Stage, Study RNs will continue with their routine standard-of-care with regard to PIVC insertion technique and continue using the Institution's standard PIVC product. The catheter brand, insertion site location, characteristics, number of attempts, dressing condition, complications and removal information (length of indwell time in hours and reason for removal) will be recorded in the electronic Case Report Form (eCRF) for each insertion attempt. In addition, the catheter and site of insertion will be examined daily and any relevant clinical findings will be recorded in the eCRF. The subject's baseline demographic data (age, gender) will be collected. If the attempts fail and the subject requires a different catheter, such a PICC, Midline or Central Catheter, or a PIVC form a different manufacturer will be recorded in the eCRF.

6.2 Stage 2: Intervention

After completion of the Baseline Stage, Study RNs will take part in the Intervention which includes protocol training, if needed, and education on the use of B. Braun PA. Note: an RN may join the study in Stage 2 provided they have completed the sites required research training and protocol specific training before participating in Stage 2. Before the Intervention begins, the Study RNs will complete the skill assessment tools to evaluate their confidence and knowledge with respect to catheter insertion. These assessments are located in Appendix 1: PIVC Insertion Confidence Assessment and Appendix 2: PIVC Knowledge Assessment. The Study RNs will then receive the full training on how to use B. Braun PA Program, which consists of the PA Education Program Curriculum, and in-service on the use of the Christie VeinViewer® Vision2, Introcan Safety® IV Catheters and STEADYCare™ Smallbore Extension Set. The PA Education Curriculum consists of approximately 2 hours of individual, self-paced on-line training and approximately 2 hours of live classroom training and practice.

After completion of the Intervention, the Study RNs will take part in skill assessments of their PIVC therapy confidence and knowledge. These assessments are located in Appendix 1: PIVC Insertion Confidence Assessment and Appendix 2: PIVC Knowledge Assessment.

This Stage does not include subjects and must be completed before proceeding to the Run-In Stage of the study.

6.3 Stage 3: Run-In

Only Study RNs that completed Stage 2 will participate in this Stage. After the successful completion of the Intervention, it is expected that all current PIVC catheters and extension sets will be collected from the department(s)/unit(s) and only B. Braun PA products will be available. If this cannot be accomplished, the Investigator or designee will take reasonable

measures to ensure that all Study RNs use only B. Braun and Christie Medical study products on their patients.

This Stage will last approximately 3 weeks in order for the Study RNs to become familiar with the B. Braun devices in a clinical setting. It is anticipated that each Study RN will perform approximately 10 insertions during this 3 week time period (Reznek, 2002).

These Study RNs will use the B. Braun devices for all their patients requiring PIVC from this point forward. There is no minimum number of patients required to complete this Stage, and clinical data on these patients will not be collected.

6.4 Stage 4: Post-Interventional

Only Study RNs will participate in this Stage. Upon completion of the Run-In Stage, the Post-Interventional Stage will begin. At least 316 successful PIVC placements are required in this Stage. Study subjects or their LAR will be consented by Study RNs and must meet all inclusion and none of the exclusion criteria prior to any study related procedures. The Study RNs should use the B. Braun devices for all of their PIVC study subjects. Study RNs will use their standard procedures and supplies for PIVC dressing. The catheter insertion site, characteristics, number of attempts, dressing condition, complications and removal information (length of indwell time in hours and reason for removal) will be recorded in the eCRF for each attempt. The subject's demographic data (age, gender) will be collected. The catheter and site of insertion will be examined daily and any relevant clinical findings will be recorded in the eCRF. At the time of catheter removal the reason for removal of the catheter will be documented. If the attempts fail and the subject requires a different catheter, such a PICC, Midline or Central Catheter, or a PIVC form a different manufacturer will be recorded in the eCRF.

After completion of the study, the Study RNs will re-take the skill assessments of their confidence and knowledge with respect to B. Braun PA. These assessments are located in Appendix 1: PIVC Insertion Confidence Assessment and Appendix 2: PIVC Knowledge Assessment.

A summary of the study Stage name, Stage number, number of subjects/patients and product training used or Intervention is displayed in Table 1.

Table 1: Summary of Stage name, Stage number, number of subjects and product used or Intervention

Stage Identification	# Subjects/Duration	Product/Intervention
Baseline (Stage 1)	316 successful PIVC placements	Hospital PIVC Standard-of-Care
Intervention (Stage 2, Education)	RNs only/ training [a]	B. Braun Peripheral Advantage Education Curriculum [a] + product training
Run-In (Stage 3)	~ 3 weeks	B. Braun Supplies [b]
Post-Interventional (Stage 4)	316 successful PIVC placements	B. Braun Peripheral Advantage Supplies [b]

[a] B. Braun Peripheral Advantage Education Curriculum = Approximately 2 hours of self-paced on-line training followed by approximately 2 hours live/hands on class room training on the use of the PA products
[b] B. Braun Peripheral Advantage supplies = Christie VeinViewer® Vision2, Introcan Safety® IV Catheters, and

7 SKILL PERFORMANCE ASSESSMENTS

The Study RNs will take skill/performance assessments (PIVC Insertion Confidence Assessment and PIVC Knowledge Assessment) before and after completion of the RN Intervention and again after the completion of the Post-Interventional Stage. The skill/performance assessments (PIVC Insertion Confidence Assessment and PIVC Knowledge Assessment) are presented in Appendix 1: PIVC Insertion Confidence Assessment and Appendix 2: PIVC Knowledge Assessment.

8 DEVICE REMOVAL

It is expected that the Study RNs will evaluate the catheter site before the catheter is removed. Once the catheter is removed by the Study RN, Standard facility protocols will be followed for catheter removal and the dressing of the IV site. The dressing of the IV site may be performed by a non-study nurse, however the date and time of removal and the reason for removal must be recorded.

A catheter may be removed at the end of a subject's medical treatment, as a result of complications or for any other reason determined by the treating clinician. If PIVC therapy is still required after catheter removal, the subject may continue to receive PIVCs in accordance with his/her treating physician. If the PIVC was removed as a result of complications, the subject may not continue in or re-enter the study and will be considered a Study Completer. Complications will be assessed as potential Adverse Events (AEs) as described in Section 11. If the PIVC was removed as a result of treatment completion (i.e., subject no longer requires a PIVC) he/she will be considered a Study Completer. In addition, if he/she was subsequently discharged from the facility, then he/she may re-enter the study in the same or different Stage if a re-admission for any reason is required.

The Study RN or designee will record in the eCRF if the PIVC was removed at any time due to any of the following complications: phlebitis/thrombophlebitis, occlusion, infection (localized or Catheter Related Bloodstream Infection [CRBSI]), dislodgement or infiltration, extravasation, or accidental removal. If it is medically appropriate for the subject, the PIVC may also be removed due to other conditions(s). The subject may continue to receive PIVC catheters in accordance with his/her medical treatment. If the PIVC was removed for a complication, then the subject may not continue or re-enter into the study and he/she is considered a Study Completer. Complications will be assessed as potential AEs as described in Section 11.

If the PIVC was removed as a result of treatment completion (i.e., subject no longer requires a PIVC) he/she will be considered a Study Completer. In addition, if he/she was subsequently discharged from the facility, then he/she may re-enter the study in the same or different Stage if a re-admission for any reason is required.

9 PROTOCOL INCIDENTS/DEVIATIONS

Procedures and forms for reporting clinical study incidents and deviations will be reviewed during the site initiation prior to study execution. All incidents and deviations will be recorded in the eCRF.

9.1 Incidents

A Study Incident is defined as any problem involving any of the study devices, reference methods, procedures, equipment, and human subjects as a result of execution of this protocol. Study Incidents may adversely (or potentially adversely) affect human safety, the integrity of the evaluation data, and/or the operation of devices or systems. Any incident which affects the health, safety, and welfare of human subjects will be reported as an Adverse Event (AE) (See Section 11). In the event an Incident results in an injury to a Study RN, the incident will be evaluated by the Investigator to determine the severity (mild, moderate, severe) and relationship to B. Braun PA (none, unlikely, possible, probable, or definite).

Examples of Study Incidents that are not AEs may be mislabeling or adulteration of the investigational device, device malfunctions that do not contribute to or cause an AE, or damage to devices caused by shipping or handling. Device malfunctions are defined as failure of an investigational medical device to perform in accordance with its intended purpose when used in accordance with the instructions for use or clinical investigational protocol. Incidents resulting in an AE or protocol deviation will be documented in the EDC.

9.2 Protocol deviation

Deviations from the protocol should not occur. If deviations occur, the Investigator must inform B. Braun or its designee and the site's clinical research coordinator. The implications of the deviation will be reviewed and discussed.

Any deviation must be documented, including a description of the deviation, why the deviation occurred, the date of occurrence, the action taken, and the impact, if any, to the subject, clinician and/or the study.

Major Deviation Reports should be completed and forwarded to B. Braun or its designee no later than 5 working days after becoming aware of the deviation.

10 STUDY PROCEDURES

Table 2 outlines the timing of assessments to be performed throughout the study. See Section 6 for additional details of study procedures.

Table 2: Schedule of Events

	Stage of the study				
Procedures	**Pre- Study**	**1 - Baseline**	**2 - Intervention and Skill Assessments**	**3 - Run-in**	**4 - Post-Interventional**
Registered Nurses[a]	**RN's**	**Study RN's**	**Study RN's**	**Study RN's**	**Study RN's**
Required Site Specific Training (ie, GCP, consent process, etc)	X				
B. Braun Protocol Training	X				
Demographics		X	X[b]		
Standard PIVC insertion		X			
B. Braun Education and Peripheral Advantage Product Training			X		
PIVC Insertion Confidence Assessment and PIVC Knowledge Assessment			X[c]		X[c]
B. Braun Peripheral Advantage Product Insertion				X	X
Subjects					
Demographics		X			X
Informed Consent		X			X
Inclusion, Exclusion Criteria		X			X
Daily catheter monitoring		X			X
Adverse Events	--continuous--				

[a] All RN's may participate in Stages 1 and 2. However, only B. Braun Peripheral Advantage-trained Study RN's will participate in Stages 3 and 4.

[b] Demographic information to be obtained only if a new Study RN enters the study in Stage 2.

[c] To be performed before and after the Intervention (Stage 2) and again at the completion of the study (Stage 4).

The Investigator or designee will explain the nature of the study, the study procedures, and the potential risks to each patient. Before any study-related procedures occur, the patient must voluntarily sign the ICF.

There is no required routine collection of vital signs, physical examinations (other than the catheter site) or clinical laboratory evaluations. Safety assessments will comprise the collection, review and documentation of AEs, Serious Adverse Events (SAEs) and Adverse Device Events (ADEs).

11 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

11.1 Adverse Events

Study safety will be evaluated by assessment of AEs.

The Study RNs in this study are subjected to minimal health risk from the use of the devices and are anticipated to be experienced users of PIVC devices. The subjects enrolled in this study may be exposed to the standard health risks associated with PIVC insertion. All events

related to both the standard-of-care products used in the hospital and the B. Braun PA and any required procedures will be evaluated for determination as AEs and documented on the eCRFs.

An AE is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the investigational device. AEs may include, but are not limited to, premature device removal, minor and major complications, infection, thrombophlebitis, accidental needlestick injuries, and device failures (i.e., disconnection, twisted port hub, leakage, or failure of safety feature). AE collection for each subject will begin after the ICF is signed and will continue until the completion of all study procedures or until the subject withdraws consent or is withdrawn from the study.

AEs will be reported by the Investigator and the Sponsor will use the reported AE term to determine the MedDRA system organ class and preferred term. The investigator will also report the AE severity (mild, moderate, severe) and relationship of the AE to either the standard-of-care products used in the hospital or the B. Braun PA.

No exposure hazard is expected. The investigational devices were manufactured according to Good Manufacturing Practices (GMPs).

Specific guidelines for classifying AEs by intensity are provided in Table 3.

Table 3: Classification of Adverse Events by Severity

Mild: An event that is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.
Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities.
Severe: An event that prevents normal everyday activities.

When changes in the severity of an AE occur more frequently than once a day, the maximum severity for the event should be noted. If the severity category changes over a number of days, then those changes should be recorded separately (with distinct onset dates).

An Adverse Device Effect (ADE) is an AE determined to be related to the use of the investigational device.

Specific guidelines for classifying AEs by relationship are provided below:

Definite – The adverse event is clearly related to the study device: the event has a temporal relationship to the study device, follows a known pattern of response, or is otherwise logically related to the study device, and no alternative cause is present.

Probable – The adverse event is likely related to the study device: the event has a temporal relationship to the study device, follows a known or suspected pattern of response, or is otherwise logically related to the study device, but an alternative cause may be present.

Possible – The adverse event is unlikely related to the study device: the event does not follow a clear temporal relationship to the study device or does not follow a

known pattern of response, or is otherwise possibly to be due to the subject's clinical state or other modes of therapy.

In some cases, the adverse event may not be adequately assessed because information is insufficient or contradictory and/or the data cannot be verified or supplemented. Maximum effort will be made to define and categorize the event and avoid these situations. If relatedness remains uncertain, then classify the event as "possible".

Unlikely – The adverse event can be reasonably explained by another cause and/or the relationship with the use of the device seems not relevant, but additional information may be obtained.

Not Related – The adverse event is clearly not related to the study device: the event has no temporal or other relationship to the administration of the investigational device follows no known or suspected pattern of response, and an alternative cause is present.

11.2 Serious Adverse Events and Serious Adverse Device Effects

An AE is considered "serious" if in the view of either the Investigator or Sponsor, it meets 1 or more of the following criteria:

- led to death,
- led to serious deterioration in the health of the subject, that either resulted in
- a life-threatening illness or injury, or
- a permanent impairment of a body structure or a body function, or
- in-patient or prolonged hospitalization, or
- medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, or
- led to fetal distress, fetal death or a congenital abnormality or birth defect

A serious ADE is an Adverse Device Effect that has resulted in any of the consequences characteristic of an SAE.

11.3 Event Reporting

All events related to both the standard-of-care products used in the hospital and the B. Braun Peripheral Advantage Program devices and any required procedures will be evaluated by the Investigator for determination as AEs, SAEs, ADEs and documented on the electronic case report form (eCRF). AE collection for each subject will begin after the informed consent form is signed and will continue until the completion of all study procedures or subject withdrawal from the study.

All SAEs will be followed until the Investigator and Sponsor agree the event is satisfactorily resolved (i.e., resolved, stabilized or returned to baseline). Preliminary reports of SAEs must be followed by detailed descriptions later on, including clear and anonymized photocopies of hospital case reports, consultant reports, autopsy reports, and other documents when

requested and applicable. SAE reports must be made whether or not the Investigator considers the event to be related to the study device.

An SAE occurring during the study must be reported to the Sponsor or designee. Any such SAE due to any cause, whether or not related to the study devices, must be reported within 24 hours of occurrence or when the Investigator becomes aware of the event.

Appropriate remedial measures should be taken to treat the SAE, and the response should be recorded. Clinical, laboratory, and diagnostic measures should be employed as needed in order to determine the etiology of the problem. All SAEs will be followed until the Investigator and Sponsor agree the event is satisfactorily resolved. The Sponsor will report SAEs to the FDA as required.

In the event of an adverse device effect or device malfunction, form FDA 3500 MedWatch must be completed. E-mail Form FDA 3500 MedWatch and any supporting documentation as instructed below within 24 hours of becoming aware of the event.

a. During Stage 1 of the protocol, notification shall be made by email to chris.curtin@bbraunusa.com and diana.valencia@bbraunusa.com.
b. During Stage 4 of the protocol, notification shall be made to the Sponsor's Medical Affairs Department either by phone call: 800-854-6851 or email to medinfo.us@bbraunusa.com.

Unanticipated Serious Adverse Device Effects (USADEs) are serious adverse device effects which by nature, incidence, severity or outcome have not been identified in the current version of the risk analysis report. SAEs which are attributed by the Investigator to the patient's underlying medical condition and unrelated to the study device will not be reported as USADEs. The Sponsor is responsible for expedited reporting of USADEs to the FDA.

The Investigator is responsible for notifying the Institutional Review Board (IRB).

11.4 Reporting responsibility and procedures

A needlestick-related event reportable under 21 CFR Part 803 includes any death, serious injury, or malfunction for either the standard-of-care products used in the hospital or the B. Braun PA products as detailed below:

A death report should be submitted by a user facility, importer, and manufacturer if the device may have caused or contributed to the death of an individual.

A serious injury report (Form FDA 3500 MedWatch) should be submitted by a user facility, importer, and manufacturer if the device resulted in an injury to an individual and the injury was life-threatening, resulted in permanent impairment of a body function or permanent damage to a body structure, or necessitated medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

A device malfunction report (Form FDA 3500 MedWatch) should be submitted by an importer and manufacturer if the device failed to perform as intended and would be likely to cause or contribute to a death or serious injury if the needlestick event reoccurred. B. Braun should also be notified of SAEs and of any follow-up information in writing using the Form FDA 3500 MedWatch, as is practical, and depending on local regulations (Needlesticks, 2002).

12 STATISTICAL ANALYSIS

The statistical evaluation will be performed using the Statistical Analysis Software (SAS®) Version 9.2 or higher (SAS Institute, Cary, NC). All data will be summarized using descriptive statistics, and where necessary, data will also be listed either by subject or by event, as appropriate. For continuous variables, data will be summarized with the number of subjects (N), mean, standard deviation (SD), median, minimum, and maximum. For categorical variables, data will be tabulated with the number and proportion of subjects for each category. Where appropriate, 95% two-sided confidence intervals may be presented. If the observed data are found not to follow a normal distribution, appropriate non-parametric methods may be employed. Two interim analyses are planned.

All hypothesis tests will be two-sided and performed at the alpha=0.05 level. No adjustments to the alpha level will be made for the number of significance tests performed.

Data obtained from all subjects who enroll in any Stage(s) of the study and data obtained from the RN's participating in the study will be included in analysis of safety and the study endpoints.

Additional data driven subgroup analyses may be performed. Additional details on the statistical analyses will be describe in the separate Statistical Analyses Plan (SAP).

12.1 Statistical Analyses for Primary Endpoint

Incidence of Complications Associated with PIVC Use

The statistical analysis will compare the rate/percentage of complications between B. Braun PA and hospital's current standard-of-care PIVC utilizing a binomial test (such as Fisher's Exact Test). The source data are the evaluations of catheter placements, i.e., were there any complications? (Yes/No), was there removal of the catheter due to complications? (Yes/No) (e.g., due to phlebitis, occlusion, infection, dislodgement, infiltration, etc.).

12.2 Statistical Analyses for Secondary Endpoints

Standard statistical methods will be utilized in this study to analyze all data. Secondary endpoints that measure rates (e.g., first stick success) will be tested for significance using a binomial test (such as Fisher's exact test). Continuous endpoints will be tested for significance using standard parametric tests (such as Student's t-test), or non-parametric equivalent (such as Wilcoxon signed rank test) if parametric methods are found to be inappropriate.

Indwell Times: The source data are the indwell times measured for all catheters (e.g., catheter withdrawn due to complications, end of medical treatment, routine catheter change, end of treatment or voluntary withdrawal of subject from study). The indwell time is calculated from the time of catheter insertion until the time of catheter removal for any reason. In the event the subject or his/her LAR withdraws consent or is withdrawn by the PI, for any reason, and the catheter is still in place, the date and time of withdrawal will be used as a surrogate for the date and time of removal.

A survival analysis will be performed to further understand the difference in indwell times. A catheter will be considered to have been a failure/event if it is removed due to any

complication or failure of the unit. It will be considered censored/non-event if it is removed as it is no longer needed, i.e., the condition improves or the subject is discharged from the hospital.

12.3 Safety Analyses

Adverse events will be summarized as an overall incidence of at least one event, incidence within system organ class only, and incidence by system organ class and preferred term. Events may include, but are not limited to: minor and major complications, infection, thrombus, phlebitis, accidental needle sticks, and device failures (i.e., disconnection, twisted port hub, leakage, and failure of the safety feature). Section 11 of this protocol details AE definitions and relationship classifications.

A Statistical Analysis Plan (SAP) will be prepared after the protocol and eCRF are approved. This document will provide further details regarding the definition of analysis variables and analysis methodology to address all study objectives. The SAP will serve as a complement to the protocol and supersedes it in the case of any differences.

12.4 Determination of Sample Size

Based on initial study design assumptions, at least 316 successful PIVC insertions are necessary to complete Stage 1 and at least 316 successful PICV insertions are necessary to complete Stage 4 in order to detect a statistically significant difference between the current standard-of-care and B. Braun PA at 90% power and two-sided confidence level of 5.0%. The estimated complication rate in Stage 1 is 50% and the estimated complication rate in Stage 4 is 35%. (Helm, 2015)

Two interim analyses are planned, solely for the purpose of sample size re-estimation. Using the method of Pocock & Mehta, the sample size can be either held constant or increased – it cannot be reduced based on the results of the re-estimation.

Interim Data Analysis Stage 1
Upon successful completion of approximately 70% of the originally planned PICV placements in Stage 1, an interim analysis of the primary endpoint on raw (uncleaned) data will be performed. The observed complication rate in Stage 1, utilizing actual data collected in the study up to this point, will be compared to the originally estimated complication rate of 50%. If the observed complication rate is statistically significantly greater than 50%, the sample size will not be modified, and Stage 1 enrollment will continue to the original sample size of at least 316 successful PIVC insertions. If the observed complication rate is not statistically significantly greater than 50%, the sample size may be re-estimated with the assumed Stage 1 complication rate equal to the observed interim analysis complication rate, with other assumptions held constant.

Interim Data Analysis Stage 4
The final sample size in Stage 1 (based on the results of the sample size re-estimation in Stage 1) will be used as the initial sample size for Stage 4. Upon successful completion of approximately 50% of the initial sample size in Stage 4 (which is determined at the interim analysis in Stage 1), another interim analysis on raw (uncleaned) data for the complications will be performed. This sample size re-estimation will follow the method of Mehta and

Pocock to calculate the conditional power of the study to conclude that the complication rate in Stage 4 is lower than the complication rate in Stage 1, given the observed complication rates at the interim analysis. The conditional power (CP) will be categorized into one of the three following zones:

- Favorable: CP $\geq$ 90%
- Promising: 41% $\leq$ CP < 90%
- Unfavorable: CP < 41%

In the event the conditional power is found to be in the Favorable or Unfavorable zone, the study will continue to the originally planned sample size in Stage 4 (i.e., final sample size in Stage 1). In the event the conditional power is in the Promising zone, the total study sample size may be increased to the required sample size to achieve conditional power of 90% at the completion of the study. Note that only the sample size in Stage 4 can be increased at this time, as the data collection in Stage 1 has been completed.

Registered nurses: Only RNs from the hospital's ED or medical surgical departments/unit will participate. Registered nurses can be on any shift and will not be required to have a minimum level of clinical experience. There is no minimum number of RNs required.

Subjects: Subjects or their LAR will be consented before participating in Stage 1 and/or Stage 4 and may participate in either, or both, of those stages. Subjects consented for Stage 1 may participate as patients in Stage 3 (Run-In). If the PIVC was removed for a complication, then the subject may not continue or re-enter into the study and he/she is considered a Study Completer. If the PIVC was removed as a result of treatment completion (i.e., subject no longer requires a PIVC) he/she will be considered a Study Completer. In addition, if he/she was subsequently discharged from the facility, then he/she may re-enter the study in the same or different Stage if a re-admission for any reason is required. Subjects who participate in more than one stage, or more than once in a single stage, will be considered independent for all analyses.

12.5 B. Braun Peripheral Advantage Program /Visit Compliance

Any deviations from the protocol will be documented, evaluated and subsequently described in the final study report. A protocol amendment may be required depending on the nature of the deviation.

12.6 Demographic and Baseline Characteristics

Descriptive statistics will be used to summarize demographic/clinical experience information including age, gender, title/function, shift, and years of clinical experience for the RN population. Demographic information including age and gender will be collected from the subject population. No statistical testing to compare the two populations (RNs and Subjects) will be performed.

Demographic and baseline information will be summarized in tables using descriptive statistics.

13 STUDY MANAGEMENT

The Investigator must conduct the study in accordance with the laws and regulations of the country in which the study is conducted and in accordance with the accepted version of the Declaration of Helsinki and/or all relevant federal regulations, as set forth in Parts 50, 56, 312, Subpart D, of Title 21 of the Code of Federal Regulations (CFR), and in compliance with good clinical practice (GCP) guidelines.

Conduct of the study must be approved by an appropriately constituted IRB. Approval is required for the study protocol, any protocol amendments, and ICFs.

13.1 Informed Consent

The Investigator or designee must explain to each subject participating in Stage 1 and Stage 4 the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits involved, and any discomfort it may entail. Each subject or his/her LAR (if appropriate) must be informed that participation in the study is voluntary, that he/she may withdraw or be withdrawn from the study at any time, and that withdrawal of consent will not affect his/her relationship with the treating physician.

The informed consent should be given by means of a standard written statement, written in non-technical language. The subject or his/her LAR (if appropriate) should read and consider the statement before signing and dating it, and he/she should be given a copy of the signed document. No subject can enter Stage 1 and/or Stage 4 of the study or have any study related procedures performed before informed consent has been obtained from him/her or his/her LAR (if appropriate). A subject may participate in one or more of the 3 Stages that require patient care (Baseline, Run-In, or Post-Interventional). However, subjects must be consented for Stage 1 and/or Stage 4 of the study. In the event a subject re-enrolls in the study, he/she or his/her LAR (if appropriate) must sign another Informed Consent.

The Investigator will provide B. Braun or its representative with a copy of the Institutional Review Board (IRB) approved ICF prior to the start of the study.

13.2 Data Handling

In the event a subject with a successful PIVC insertion drops out or is withdrawn from the study, B. Braun or its designee will be informed in a timely manner and the date and time of withdrawal will be recorded. In the event a subject has or was withdrawn from the study before a PIVC insertion attempt or a successful PIVC insertion by a Study RN, he/she will be considered as an Early Termination from the study. In the event a subject or his/her LAR (if appropriate) withdraws consent or the PI removes the subject from the study for any reason, the subject will be consider as an Early Withdrawal. In the event of a subject's withdrawal of consent or any other early withdrawal that also did not result in the IV being removed, the date and time of that withdrawal will be used as a surrogate for the date and time of removal of the IV and the subject's data will be treated in the same manner as a study completer. In this case, the subjects will not be allowed to re-enroll in the study.

If the PIVC was removed for a complication, then the subject may not continue or re-enter into the study and he/she is consider a Study Completer. If the PIVC was removed as a result of treatment completions (i.e., subject no longer requires a PIVC) he/she will be considered a

Study Completer. In addition, if he/she was subsequently discharged from the facility, then he/she may re-enter the study in the same or different Stage if a re-admission for any reason is required.

Any data to be recorded directly on the eCRFs (to be considered as source data) will be identified at the start of the study. Data reported on the eCRF that are derived from source documents should be consistent with the source documents, or the discrepancies must be explained.

Clinical data will be entered on eCRFs for transmission to the Sponsor. Data on eCRFs transmitted via the web-based data system must correspond to and be supported by source documentation maintained at the study site, unless the study site makes direct data entry to the databases for which no other original or source documentation is maintained. In such cases, the study site should document which eCRFs are subject to direct data entry and should have in place procedures to obtain and retain copies of the information submitted by direct data entry (such as diaries). All study forms and records transmitted to the Sponsor must carry only coded identifiers such that personally identifying information is not transmitted. The primary method of data transmittal is via the secure, internet-based EDC system maintained by the Contract Research Organization. Access to the EDC system is available to authorized users via the study's Internet web site, where an assigned username and password are required for access.

Any changes made to data after collection will be made through the use of electronic data clarification forms/queries. eCRFs will be considered complete when all missing and/or incorrect data have been resolved.

13.3 Source Documents

Source documents are considered to be all information in original records and certified copies of original records of clinical findings, observations, data or other activities in a clinical study necessary for the reconstruction and evaluation of the study.

13.4 Recording of data

Case Report Forms or eCRFs will be designed to identify each subject by a unique Subject Identification Number (SIN), B. Braun PA being evaluated, and the results observed. All entries to the eCRFs must be made according to appropriate SOPs. Data collected on eCRFs during the study will be documented in an anonymous fashion, and the subject will only be identified by the SIN. If, as an exception, it is necessary for safety or regulatory reasons to identify the subject, both B. Braun and the Investigator are bound to keep this information confidential.

The Investigator must sign the designated page(s) of the eCRFs, thereby stating that he/she takes responsibility for the accuracy of the data in the entire eCRF. All records will be kept in conformance to applicable national laws and regulations.

Any changes made to data after collection will be made through the use of electronic data clarification forms/queries. Case Report Forms/eCRFs will be considered complete when all missing and/or incorrect data have been resolved and or source verified.

The original signed ICF will be saved with each subject's file. When the study is completed, the ICF will be kept in the appropriate file folder; otherwise a note indicating where the records are located will be saved in the study file.

13.5 Record Retention

Study records and source documents will be maintained per Hospital policy and local regulations.

The Investigator agrees to comply with all applicable federal, state, and local laws and regulations relating to the privacy of patient health information, including, but not limited to, the Standards for Individually Identifiable Health Information, 45 CFR, Parts 160 and 164 (the Health Insurance Portability and Accountability Act of 1996 [HIPAA] Privacy Regulation). The Investigator shall ensure that study patients authorize the use and disclosure of protected health information in accordance with HIPAA Privacy Regulation and in a form satisfactory to the Sponsor.

Storage of all source documents will be maintained for at least 2 years by the study site. Database management activities can be found in the Data Management Plan (DMP).

13.6 Monitoring

During the study, B. Braun (and/or designee) may visit the site regularly or remotely to evaluate the completeness of study records, the accuracy of entries on the eCRF, the adherence to the protocol and ICH-GCP guidelines, and the progress of enrollment, and to ensure that B. Braun PA is being stored, dispensed and accounted for according to specifications. Remote monitoring and/or source data verification will be performed if the site has imposed, or is subject to, travel and/or visit restrictions for in-person visits due to circumstances such as those related to the Covid-19 pandemic or if the monitor is subject to travel restrictions. Key study personnel will be available to assist the monitor during these visits.

The data required by the protocol must be recorded on the appropriate eCRFs. The eCRFs and any source documents will be available to the study monitor who may perform a 100% source document verification (comparison of the data recorded in the eCRF with those in the source documents). The eCRFs and source data will also be available for an audit by B. Braun or the FDA at any time.

The Investigator will give the monitor access to relevant clinical records to confirm their consistency with the eCRF entries. No information in these records about the identity of the clinicians will leave the study center. Additional checks of the consistency of the source data with the eCRFs are performed according to the study-specific monitoring plan.

13.7 Quality Control and Quality Assurance

The Sponsor or its designee will perform the quality assurance and quality control activities of this study; however, responsibility for the accuracy, completeness, and reliability of the study data presented to the Sponsor lies with the Investigator generating the data.

The Sponsor may arrange audits as part of the implementation of quality assurance to ensure that the study is being conducted in compliance with the protocol, standard operating

procedures, GCP, and all applicable regulatory requirements. Audits will be independent of, and separate from, the routine monitoring and quality control functions. Quality assurance procedures will be performed at study sites and during data management to assure that safety and efficacy data are adequate and well documented.

14 STUDY-SPECIFIC MATERIALS

The Sponsor will supply B. Braun PA Program for this study which consists of the following items:

1. PA Education Curriculum
2. Christie VeinViewer® Vision2
3. Introcan Safety® IV Catheters
4. STEADYCare™ Smallbore Extension Set

15 PROTOCOL AMENDMENT AND PROTOCOL DEVIATION

15.1 Protocol Amendment

Changes to the protocol that entail corrections of typographical errors, clarifications of confusing wording, changes in study personnel, and minor modifications that have no impact on the safety of patients or the conduct of the study will be classed as administrative or non-substantial amendments and will be submitted to the IRBs for information only. B. Braun or its designee will ensure that acknowledgement is received and filed.

Any changes or additions to this clinical study protocol that are classed as substantial amendments (having a direct impact on the safety, physical or mental integrity of the subject, or the scientific value of the trial, or the conduct or management of the trial, or the quality or safety of any study device used in the trial) requires a written protocol amendment that must first be approved by B. Braun unless there is a safety concern that requires immediate action. In the event a substantial amendment is required, B. Braun will make a determination if the Study will need to be put on hold until the amendment is approved. Amendments classed as substantial amendments must be submitted to the IRBs for approval.

15.2 Protocol Deviations

Deviations from the planned study conduct are not permitted. Should a protocol deviation occur, the Sponsor or its designee must be informed as soon as possible and the deviation must be documented in the Study File/Trial Master File and summarized in the final study report. Protocol deviations and the reasons they occurred will be included in the clinical study report. Reporting of protocol deviations to the IRB and in accordance with applicable FDA mandates is an Investigator responsibility.

16 ETHICAL CONSIDERATIONS

This study must be carried out in compliance with the protocol and in accordance with appropriate SOPs. These are designed to ensure adherence to GCP guidelines, as described in:

- ICH Harmonized Tripartite Guidelines for GCP 1996. Directive 91/507/European Ethics Committee (EEC), The Rules Governing Medicinal Products in the European Community.
- US 21 Code of Federal Regulations (CFR) dealing with clinical studies (including parts 50 concerning informed consent regulations).
- Declaration of Helsinki, concerning medical research in humans (Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects, Helsinki 1964 and amendments).

The Investigator agrees, when signing the protocol, to adhere to the instructions and procedures described in it and thereby to adhere to the principles of GCP that it conforms to.

17 FINANCING AND INSURANCE

Prior to the study commencing, the Sponsor or its designee and the Investigator (or the institution, as applicable) will agree on costs necessary to perform the study. This agreement will be documented in a financial agreement that will be signed by the Investigator (or the institution signatory) and the Sponsor or its designee.

The Investigator is required to have adequate current insurance to cover claims for negligence and/or malpractice. The Sponsor will provide insurance coverage for the clinical study as required by national regulations.

18 TERMINATION OR SUSPENSION OF STUDY

Both B. Braun and the Investigator reserve the right to terminate or suspend the study at any time. If early study termination is necessary, study procedures will be completed on an individual subject basis after review and consultation by both B. Braun and the Investigator. In terminating the study, B. Braun and the Investigator will ensure that adequate consideration will be given regarding the protection of the subjects' interests.

19 CONFIDENTIALITY AND PUBLICATION POLICIES

19.1 Disclosure and confidentiality

By signing the protocol, the Investigator agrees to keep all information provided by B. Braun in strict confidence and to request similar confidentiality from his/her staff. Study documents provided by B. Braun or its designee (e.g., protocol, eCRFs and other material) will be stored appropriately to ensure their confidentiality. The information provided by B. Braun or its designee to the Investigator may not be disclosed to others without direct written authorization from B. Braun or its designee, except to the extent necessary to obtain informed consent from subjects or his/her LAR (if appropriate) who wish to participate in the study.

19.2 Publication Policy

Both the use of data and the publication policy are detailed within the clinical study agreement. Intellectual property rights (and related matters) generated by the Investigator and others performing the clinical study will be subject to the terms of a clinical study

agreement that will be agreed between the Institution and the Sponsor or its designee. With respect to such rights, the Sponsor will solely own all rights and interests in any materials, data, and intellectual property rights developed by Investigators and others performing the clinical study described in this protocol, subject to the terms of any such agreement. In order to facilitate such ownership, Investigators will be required to assign all such inventions either to their Institution or directly to the Sponsor or its designee, as will be set forth in the clinical study agreement.

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APPENDICES

Appendix 1: PIVC Insertion Confidence Assessment

Peripheral Intravenous Catheter (PIVC) Insertion Confidence Assessment

Protocol No. US-N-H-1801

RN Identification_____**Date**_____

This assessment is to be taken both **BEFORE** and **AFTER** training on B. Braun Peripheral Advantage Education Curriculum.

Circle one of the following.

Stage 2 Pre-Training; Stage 2 Post-Training; Stage 4 End of Study

1=strongly disagree; 2=disagree; 3=neither disagree nor agree; 4=agree; 5=strongly agree

Using the scale above, please rate your agreement with each of the following statements:

I am confident I can,

	Strongly disagree - Strongly agree
1) start an IV within 1 or 2 attempts.	1 2 3 4 5
2) select the most appropriate catheter for the prescribed treatment plan.	1 2 3 4 5
3) assist my peers with difficult IV starts.	1 2 3 4 5
4) select an ideal site and vein for peripheral IV access using patient landmarks.	1 2 3 4 5
5) prepare the insertion site.	1 2 3 4 5
6) insert Catheter correctly.	1 2 3 4 5
7) advance the IV catheter correctly.	1 2 3 4 5
8) remove the needle/stylet with minimal blood exposure.	1 2 3 4 5
9) stabilize the IV catheter.	1 2 3 4 5
10) dress and secure the IV catheter and tubing.	1 2 3 4 5
11) document my peripheral IV insertion.	1 2 3 4 5
12) recognize and document the complications associated with a catheter.	1 2 3 4 5

Appendix 2: PIVC Knowledge Assessment

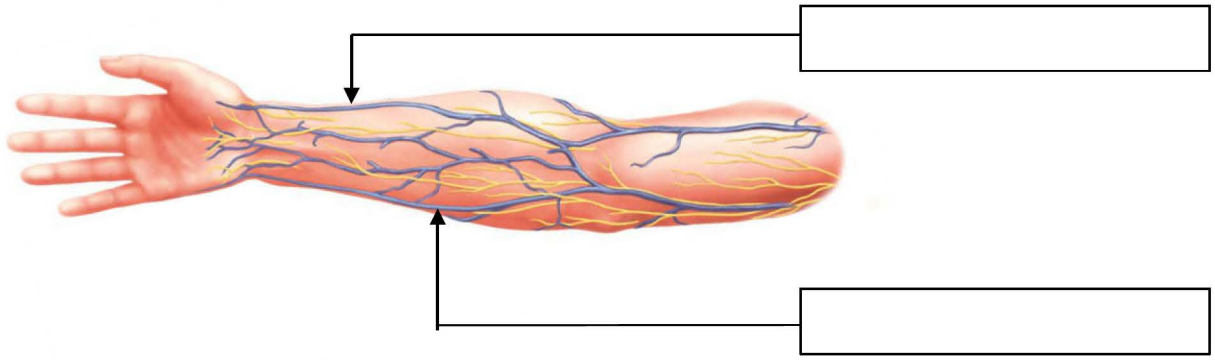
PIVC Knowledge Assessment
RN Identification_____ **Date**_____

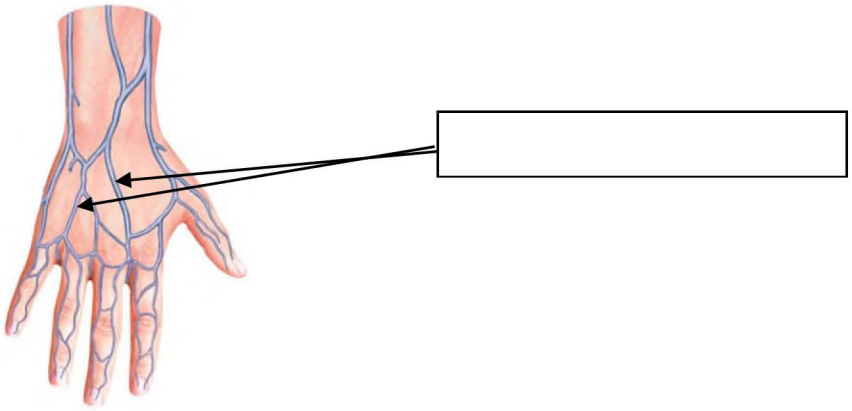
This assessment is to be taken both **BEFORE** and **AFTER** training on B. Braun Peripheral Advantage Education Curriculum.

Circle one of the following:
Stage 2 Pre-Training; Stage 2 Post-Training; Stage 4 End of Study

1. Identify the veins on the following images by writing the name of the vein in each of the blanks provided, select from the list of vein names below.

• Metacarpal	• Digital
• Dorsal venous arch	• Cephalic
• Median	• Ancillary





2. Indicate whether the veins below are appropriate or not appropriate for routine peripheral IV catheter placement in the adult patient with an **"A" or an "N"** where:

A = Appropriate
N = Not appropriate

_____Veins of the wrist
_____Mid-forearm basilic vein
_____Great saphenous vein
_____Mid-forearm cephalic vein
_____Veins in areas of joint flexure
_____Antecubital fossa cephalic vein
_____Veins without bifurcations
_____Veins of the lower extremities

3. What is the purpose of using a tourniquet in the process of placing a PIVC?
   a. To promote vascular distention in preparation for peripheral venipuncture
   b. To impair circulatory flow until peripheral IV catheter is placed
   c. To stabilize veins and prevent veins from rolling
   d. To distract from pain sensation

4. Which peripheral IV complication is the result of inflammation of the vein?
   a. Phlebitis
   b. Infiltration
   c. Extravasation

d. Infection

5. Which peripheral IV complication is the result of a vesicant solution entering into tissue surrounding the vein?

a. Phlebitis

b. Infiltration

c. Extravasation

d. Infection

6. The peripheral IV complication commonly associated with swelling, blanching, coolness to touch and alteration in flow rate is:

   a. Phlebitis

   b. Infiltration

   c. Extravasation

   d. Infection

7. Place the following venipuncture steps in correct order from start to finish.

   a. Occlude blood vessel _____

   b. Wash hands _____

   c. Remove stylet _____

   d. Thread catheter _____

   e. Release tourniquet _____

   f. Stabilize vein _____

   g. Connect to an IV administration set or saline lock _____

   h. Insert needle and catheter _____

   i. Don gloves _____

8. During insertion, what does the presence of blood in the flashback chamber of a peripheral IV catheter indicate?

   a. The catheter is in the vein

   b. Both the catheter and the needle are in the vein

   c. The needle bevel has punctured the back wall of the vein

   d. The needle bevel has entered the vein

9. From the following examples, select the most appropriate documentation for a peripheral IV catheter insertion procedure?

a.

01/17/2014 11:00
22- Gauge peripheral IV Catheter placed in left arm per MD orders on 2nd attempt. Flushed with 5mL 0.9% NS. Pt tolerated procedure well. No redness or swelling at site. Site dressed per protocol.
V. Eni RN

b.

01/17/2014 11:00
22-Gauge 1 inch PIVC inserted into right cephalic vein, midpoint of forearm on first attempt. Flushed easily with 5mL 0.9% NS. Site without indication of complications. Dressed and secured per protocol. Patient states, "That wasn't bad."

c.

01/17/2014 11:00
20-Gauge 1-inch PIVC inserted into right mid forearm on first attempt. Patient understood procedure and tolerated well. Site without sign or symptom of complications. Dressed and secured per protocol. IV therapy initiated.

d.

01/17/2014 11:00
20-Gauge IV Catheter was placed in right metacarpal vein on 2nd attempt. Flushed easily with 5mL 0.9% NS, saline lock in place. Patient states, "I have difficult veins, most nurses try 3 or 4 times before getting it in."
V. Eni RN

10. During an attempt to insert an IV catheter, the patient expresses feeling an electric shock-like sensation down his arm, what is the most likely reason?

    a. Anxiety due to fear of needles
    b. The needle passed through the back wall of the vein
    c. Direct needle contact with the nerve
    d. Catheter shearing

For questions 11 through 13 refer to the following scenario:

Mrs. Smith is an 85 year old patient with pneumonia transferred to your unit, after spending 6 hours in the ED, for IV antibiotics and continuous IV fluids. The current IV is an 18g in the right lateral antecubital vein. Mrs. Smith complains of discomfort at the site, and the IV pump intermittently alarms occlusion. You assess that the site is red and tender to touch and determine that this current IV device and site has to be changed.

11. Based on your assessment of the right antecubital access site, this would most likely be a sign of which complication?
    a. Infiltration
    b. Extravasation
    c. Phlebitis
    d. Infection

12. After removal and dressing the right antecubital access site, the best nursing intervention care for this site would be to…
    a. Apply cool compress and document intervention and assessment
    b. Apply a warm compress and document intervention and assessment
    c. Apply an arm splint and elevated extremity, document intervention and assessment
    d. Apply a topical antihistamine and notify physician of assessment

13. From the list below select the most appropriate site and catheter combination to use for restarting the IV.
    a. Left mid-forearm vein; 22g, 1-inch catheter
    b. Left median antecubital Vein; 20g, l.25-inch catheter
    c. Vein in back of left hand; 18g, 1-inch catheter
    d. Vein in back of right hand; 22g, 1.5-inch catheter

14. As a general guideline, what type of IV catheter should be selected when considering routine peripheral venous access?

    a. The largest gauge and shortest length catheter the vein will accommodate to deliver prescribed therapy

    b. The largest gauge and longest length catheter the vein will accommodate to deliver prescribed therapy

    c. The smallest gauge and longest length catheter the vein will accommodate to deliver prescribed therapy

    d. The smallest gauge and shortest length catheter the vein will accommodate to deliver prescribed therapy

LAST PAGE