The in vivo evaluation of the flushing efficiency of the Neutron™ needlefree catheter patency device compared to two other connectors commonly used on central and PICC lines

PURPOSE
This study was designed to determine how much fluid volume of saline is required to flush a connector completely free of blood or blood constituents. For the purposes of the study, three different types of connectors that are most commonly used on central and PICC lines were chosen—two positive needlefree IV pressure connectors (CareFusion MaxPlus® and B. Braun ULTRASITE®) and one anti-reflux needlefree IV connector (ICU Medical Neutron™).

MATERIALS AND METHODS
Three separate sheep were used in this analysis, with repeated blood samples obtained through indwelling catheters placed percutaneously and remaining indwelling for three days, allowing each needlefree connector to be accessed over several days. A baseline blood sample was drawn to determine the CBC: Red Blood cells/uL (RBC-s), Hematocrit (Hct), Hemoglobin (Hgb). The connectors were then pulled free of the bandage and the samples were collected as follows:

- Flush each connector with 5 mL normal saline to ensure patency.
- Disinfect each needlefree connector and attach a sterile 3 mL syringe.
- Aspirate 3 mL of blood from lumen and discard.
- Remove blood-saturated connector from catheter lumen port, place a new connector onto the catheter lumen port, and proceed to flush the removed blood-saturated connector as follows:
  - Attach 12 mL syringe filled with 10.0 mL 0.9% sterile saline to needlefree connector.
  - Infuse 0.5 mL increment of saline through connector into uniquely labeled flush capture vessels.
- Analyze each flush capture for hemoglobin concentration.

Two connector types (ULTRASITE and Neutron) were flush tested five times, whereas the third connector (MaxPlus) clotted and was only flush tested four times. An accurate sample flush volume was ensured by weighing the capture vessel while empty and following the addition of 0.5 mL of flush volume.

Samples that contained appreciable amounts of blood (visible to the naked eye) were run at the BioSurg Clinical Pathology Laboratory on an Advia clinical analyzer. The range of reliable and reproducible detection for hemoglobin by the Advia unit is 0.5 g/dL (500 mg/dL). In addition to the hemoglobin, each sample was analyzed for total erythrocyte count and hematocrit. All samples below the 0.5 g/dL threshold were sent to Equine Laboratories (Houston, TX) for analysis. Equine Laboratories employs a spectrophotometric method (TMB method) to determine total hemoglobin concentration and is reproducible and sensitive to 0.05 mg/dL.

RESULTS
The ICU Medical Neutron needlefree catheter patency device was blood free after 4.0 mL of flush volume. Initial flushes of the Neutron were also found to contain lesser blood components when compared to the other connectors tested. By contrast, all of the CareFusion MaxPlus devices tested showed residual blood after 10 mL of saline flush, as did four out of the five B. Braun ULTRASITE connectors.
TABLE

Raw data of the samples. Measured hemoglobin in mg/dL. Blue indicates values measured on the Advia 120 clinical analyzer. All others measured by Equine Labs by spectrophotometry using a proven TMB colorimetric assay.

### Hemoglobin retention (mg/dL):
Considered blood free at less than 1.0 mg/dL.

<table>
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<tr>
<th>Flush Vol (mL)</th>
<th>ICU Medical Neutron®</th>
<th>CareFusion MaxPlus®</th>
<th>B. Braun ULTRASITE®</th>
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CONCLUSION

In summary, the ICU Medical Neutron needlefree catheter patency device is superior to the positive displacement CareFusion MaxPlus and B. Braun ULTRASITE connectors as determined by the total flush volume needed to clear the connectors of blood elements. In addition, the flush volume to clear the Neutron had a much narrower range of variability across flush volume increments.

Previous studies have demonstrated that the more proteinaceous material (including small blood clots) that resides in the connector hub, the greater the chance of infection. Infection is a major concern in the hospital environment and especially so given the issues of antibiotic resistance and hospital-acquired infection. Prevention of such issues is of great concern. The Neutron shows a definite advantage in this environment compared to the other two tested.

A second potential negative consequence of blood retention within a connector is the loss of catheter patency as occurred with the MaxPlus connector prior to the final test flush. A compromised catheter necessitates placement of a new catheter, resulting in additional expense and discomfort for the patient.

References