



SKYDANCE
VASCULAR INC.

CLINICAL EXPERIENCE
FOCUS GROUP

A focus group was held on 6/10/21 in a simulated use environment to elicit clinician feedback relating to the user experience and potential clinical adoption of a novel pre-market medical device known as the OspreyIV Peripheral Intravenous Catheter (PIVC).



The OspreyIV is the only PIVC delivery system that simplifies initial access using a bevel only technique, protects the catheter with skin avoidance technology and protects the clinician with passive needle retraction technology.

RECRUITMENT

Recruitment was directed at diversity within type of healthcare setting (Outpatient / Inpatient, Acute / LTAC, Home Health) and average PIVC placements per month (10-20, 21-30, 31-40, 41+)

No participants had previous affiliations with SkyDance Vascular, Inc nor any training on the OspreyIV Intravenous Catheter prior to this focus group. The 6/10/2021 focus group represented this group's first exposure to the device.

TRAINING

The 10 selected clinician participants were trained on the OspreyIV Peripheral Intravenous Device in a 4-step process

- Didactic
- Instructor Demonstration
- Proctored Return Demonstration
- Independent Return Demonstration

OspreyIV was compared side by side with another widely used commercially available PIVC during the proctored clinician insertion for size and dimension acceptability.



SURVEY

After the participants completed the independent return demonstration, they were asked to complete an eight-question survey.

1. The ergonomic design of the OspreyIV promotes comfort and ease of use for the clinician.

9 – Strongly Agree

1 – Agree

0 – Disagree

0 – Strongly Disagree

2. The "bevel only" access approach has the potential to positively affect first stick success rates.

8 – Strongly Agree

2 – Agree

0 – Disagree

0 – Strongly Disagree

3. Describe your ability to visualize a blood return (flash) during the initial venipuncture.

7 – Unmistakable

3 – Easy

0 – Able

0 – Unable

4. Describe the advancement of catheter advancement once vessel has been accessed.

7 – Effortless

3 – Easy

0 – Difficult

0 – Unable

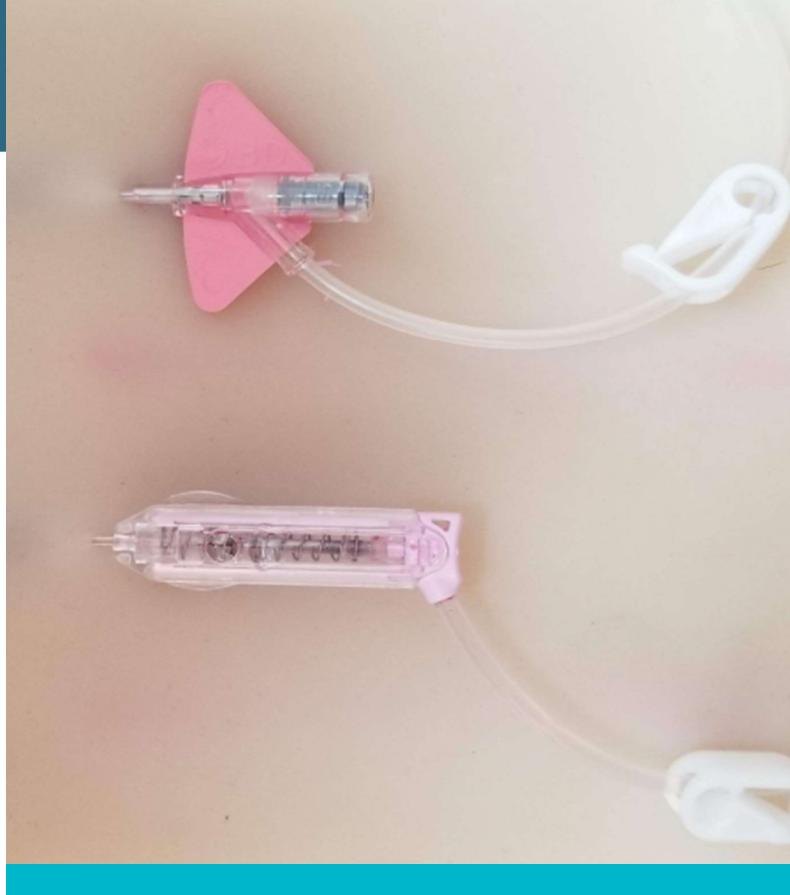
5. The passive integrated needle retraction safety feature is clinically acceptable.

5. 8 – Strongly Agree

6. 2 – Agree

7. 0 – Disagree

8. 0 – Strongly Disagree



6. The OspreyIV housing dimensions promote stability and comfort.

8 – Strongly Agree

2 – Agree

0 – Disagree

0 – Strongly Disagree

7. The OspreyIV is an easy-to-use and easy-to-teach vascular access device.

6 – Strongly Agree

4 – Agree

0 – Disagree

0 – Strongly Disagree

8. The OspreyIV is a clinically acceptable vascular access device.

9 – Strongly Agree

1 – Agree

0 – Disagree

0 – Strongly Disagree

SUMMARY AND CONCLUSION

This focus group came to an overwhelming agreement that the OspreyIV Intravenous Catheter was a clinically acceptable device. Additionally, these clinicians were in strong agreement this device would positively affect first stick success rates and offer a higher level of safety and comfort for the patient as well as the clinician. The level of training was surveyed as highly appropriate for the successful use of the OspreyIV Intravenous.

In summary, the OspreyIV Intravenous Catheter focus group demonstrated a high propensity for usability and clinical acceptability.

ADDITIONAL COMMENTS

"This set up would seem to lay down better on the skin when the dressing is applied because it is flatter – it would be more comfortable to the patient – it would not make divots on the patient's skin after a few hours – no padding necessary. The built-in extension tube would prevent movement of the catheter itself when drawing blood or attaching IV fluids. The extension tubing is just skinny enough to not be so bulky when wrapping with coban."

Clinician 1

"The magnifying glass on the catheter makes it so easy to visualize the initial blood return. The device is light weight and ergonomic. The size is perfect for various clinical uses and will be comfortable on patient's skin. I feel comfortable that the needle remains in the device so that the risks for needle stick injuries are reduced."

Clinician 3

"Great ease of needle retraction. Love that there is nothing to pull back and needle remains in housing. Like the extension tubing with clamp attached to catheter. Smooth surface in contact with patient's skin. Anxious for other sizes to be released."

Clinician 5

"Very well researched. Comfortable to use and feels very safe for both clinical person and patient. Thank you for involving me in this presentation. Looking forward to see it in use in the future."

Clinician 7

"Device is extremely user friendly while minimizing risk to the provider. Excited to see this product in routine use."

Clinician 8

"Great invention. I think it will do very well. Can't wait to have it our practice. Fabulous vein preservation tool."

Clinician 10