



Case Report

Improving the Way Catheterizations Are Performed From the Neck

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Abstract

Background: A focus on patient protection is a priority for all physicians when patients need to be treated using ionizing radiation. Countless publications report on these risks. **Aims:** What about our intervention lists; they are exposed and work tirelessly without concern for what they are enduring to care and protect their patient. How can we improve their longevity and exposure? **Methods:** Discussions with Radux to modify the Stand Tall allowing use in pediatrics. Once approved these were added to procedures at Children's Wisconsin. Attachment to the sheath that were placed in the neck and or the groin to evaluate. **Results:** Improved physician positioning and posture results in improved wellbeing along with improving care for patients with sterility of neck access. **Conclusions:** Standing up straighter, further from the scatter, secured to table for patient protection, and improved sterility for jugular access are all possible with the Stand Tall added to the access site(s). Customizable too many scenarios without increased risk to the patient.

Keywords: Internal Jugular; Stand Tall; Congenital heart disease; Cardiac catheterizations; Ergonomics

Introduction/Background:

Pediatric interventional cardiology is a rapidly expanding field of medicine. In the last 40 years the specialty has grown at a rapid pace allowing for increasingly more cardiac interventions to occur outside the operating room. But interventional cardiology is not without its risks. A portion of those risks are to the patients, and a section to the providers. Recently the risks to the provider have become more of a concern, with these procedures being performed using ionizing radiation, for cancer and other medical issues. The focus has moved from just having the patients survive to minimizing the complications, and this ethos now also needs to extend to the provider, to minimize the complications from the work that is done.

In order to perform the procedures that are needed on the patients, access into the artery and/or vein is needed. This can be achieved via the femoral vessels on most occasions. But over time these vessels can become occluded, or for certain procedures

other vessels like the right internal jugular (RIJ) vein or carotid artery might be the preferred approach. There are times when patients need femoral and RIJ access. Internal jugular access has been used to place septal occluders in the atrial septum [1, 2] and even to perform pulmonary valvuloplasty in small patients [3, 4]. Maintaining a sterile field with access into the neck can be complicated by not having a sterile field beyond the patients head and anesthesia checking on the patient from time to time. Additionally when you are working from the RIJ, the provider stands at the head of the bed where there is no protection from the radiation and also the position is not favorable ergonomically and puts unnecessary strain on the lumbar spine. When the provider stands at the normal table position, they are protected by lead shields that significantly reduce the exposure, and the table is positioned for better posture.

The company at Radux Devices was founded by an interventional radiologist who experienced these ergonomic pitfalls while he performed treatments on his patients. He set out to improve how he felt after doing procedures all day. Feeling the woes in his body the Stand Tall was created.

The goal was to improve his body positioning during procedures but in working on this goal he was also able to move himself back from the radiation source. Being further from the source of ionizing radiation had a two-fold impact in radiation reduction which the operator endured. Recent reports [5,6] show that doctors who reach the age of 50 are experiencing tumors in their brains, and extremities having squamous cell and basal cell carcinomas. Interventionalist have an inevitable exposure and increased risk of cumulative cancer.

The Stand Tall is a secured sheath extender that attaches to the hub of the sheath that is in the vessel. It has an 8.3Fr inner lumen allowing it to attach to any sheath up to 8Fr. Its benefits to the provider are that it moves them further away from the radiation, allows the provider when working from the neck to have the sheath and catheters in the normal position at the foot of the patient, which is desired for the provider in the cath lab. Protectively this position has shields that cover the lower and upper body of the provider. The second area that the StandTall benefits is the providers' position. It is common that the provider will be having to stretch over the bed and can put strain on the back, the StandTall allows for a more neutral position by placing the sheath closer to the physician without the need for stretching.

Material/Methods

Radux Stand Tall Device comes in three lengths which are 10cm, 15cm, and 25 cm. StandTall device description taken directly from the instructions for use provided from Radux Device Company:

The Stand Tall is a sterile, disposable device that is used during the introduction of catheters and other devices into the vasculature. It is designed to hold an introducer sheath or other interventional devices in the desired, secured position and to

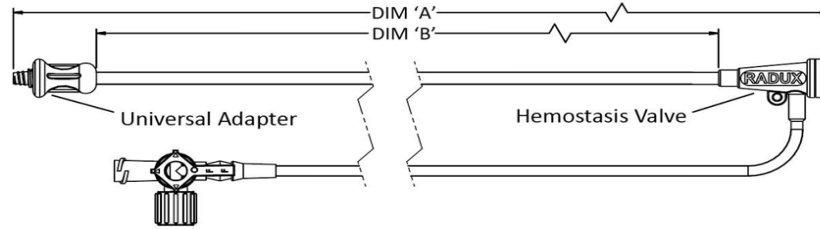
facilitate alignment and introduction of interventional devices during percutaneous procedures. It consists of a sheath extender adapter and a securement clasp.

Stand Tall Sheath Extender is comprised of a:

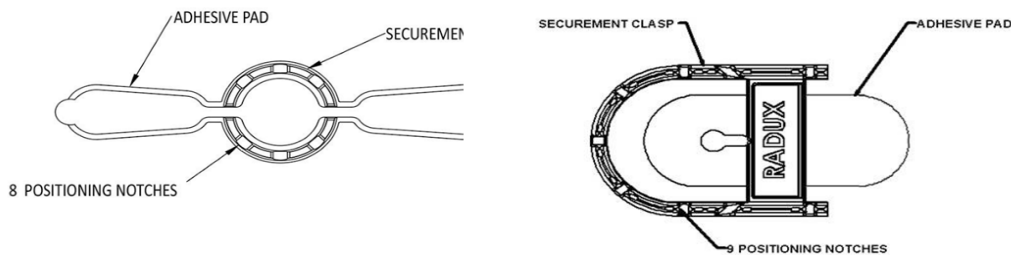
- Sheath hub adapter,
- Malleable, lubricious, intermediary sheath, and
- A proximal hemostasis valve having side-arm flush tubing with a three-way stopcock for aspiration or infusion.
- The Sheath Extender is offered in multiple lengths as follows and shown in Figure 1A. The sheath extender is 8.3 Fr internal diameter (2.7mm ID). It is designed to connect to 5-8 Fr introducer sheaths through the use of the universal hub adapter. Following attachment of the sheath extender to a previously placed introducer sheath, the sheath extender is attached to the securement clasp, which is then attached via its adhesive strip to the patient's skin, a drape, or another object associated with the patient.

Stand Tall Securement Clasp is designed to hold the sheath extender or other interventional devices in the desired, secured position. There are two version as shown in Figure 1B. The Securement Clasp is a plastic base with a medical grade adhesive pad used to secure the plastic base to the patient, drape, or another object associated with the patient. The securement clasp has positioning notches (Figure 1C) that allow for positioning and securement by friction fitting the sheath 300088-001 REV E Page 3 of 16 extender or interventional devices into the positioning notches. The notches are 0.13 inches wide and 0.14 inches deep, and therefore the Securement Clasp is compatible with devices of approximately 9 Fr (3 mm) outer diameter.

A: Stand Tall Sheath Extender



B: Securement Clasp Options



C: Stand Tall showing Adjustable Positioning

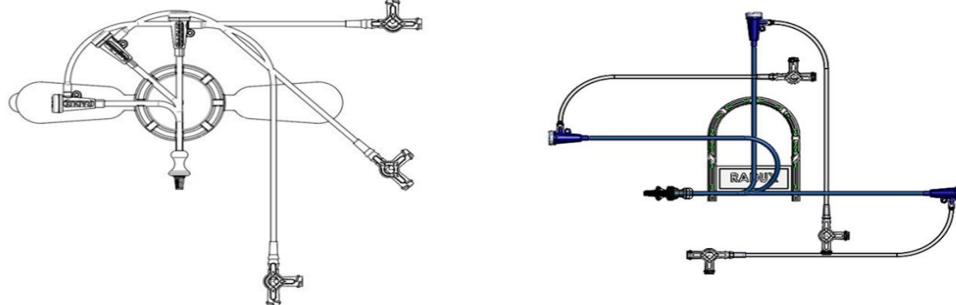


Figure 1A-C: Stand Tall Sheath.

The sheath extenders were placed on IJ access and secured to the anterior lateral chest. This allowed for the interventionalist to return to the standard cath position on the patients left side. The sheath extenders were placed on the groin access sites and the interventionalist was able to step further from the direct x-ray beam and stand without having to lean over.

Results

Successful attachment to sheaths placed for cardiac catheterization as seen in (Figure 2-3). The added length was

beneficial for interventionalists to be able to move their hands out of the direct x-ray beam. Allowed for access to be obtained in the neck and return to the standard procedure position with lower concerns for contamination of the sterile field, reduced operator exposure, and better ergonomically positioned for the entire procedure. The securement of the Stand Tall allowed for placement in plenty of locations to achieve good workflow and not too complex of angles with the many positioning notches on the securement.

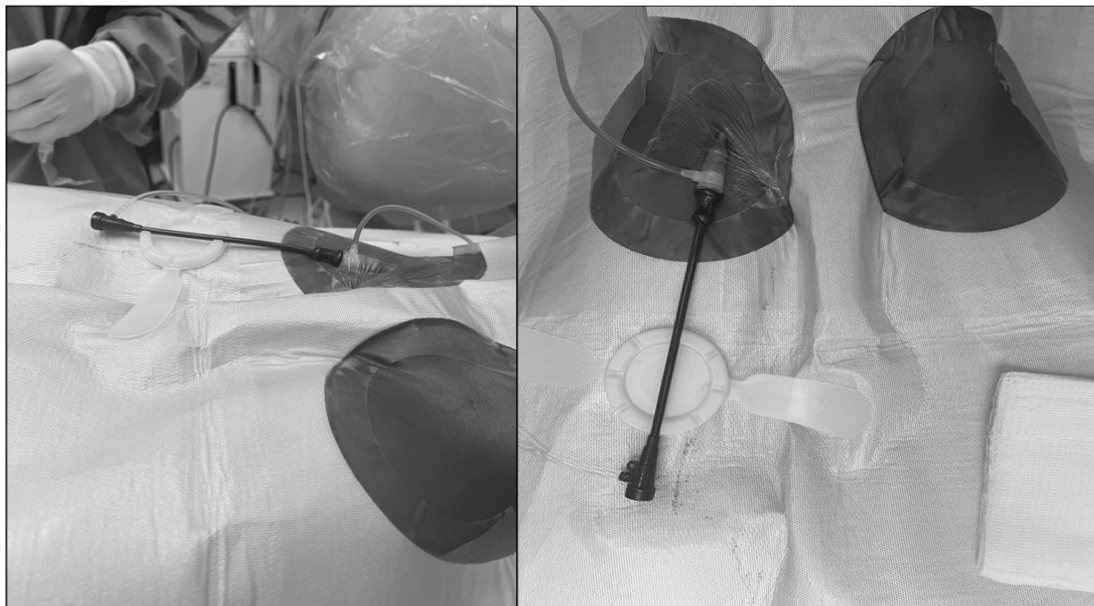
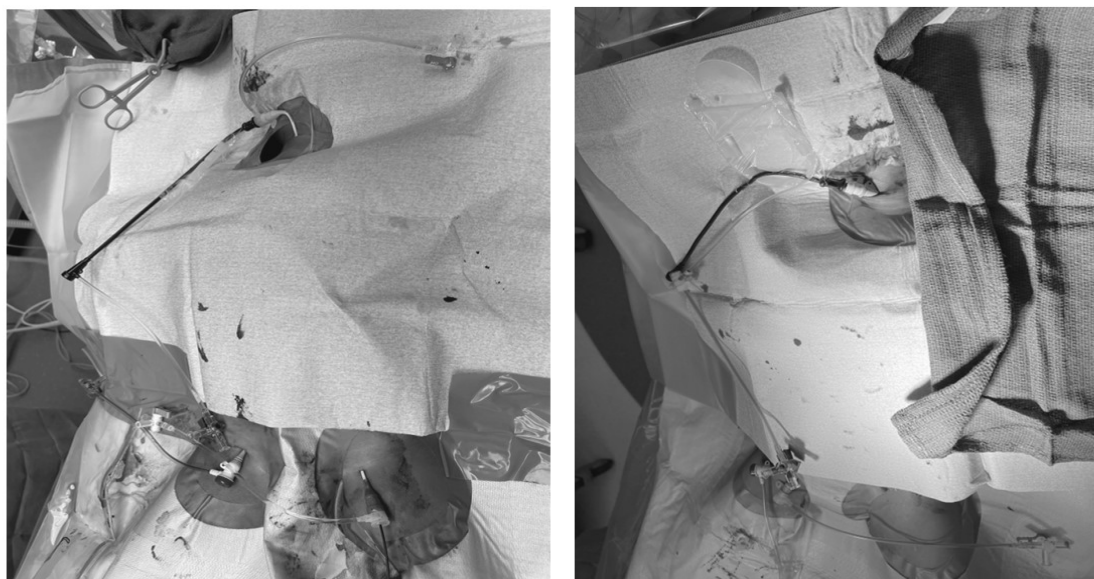


Figure 2: Groin Access with 10cm Stand Tall.



Left image: Right internal jugular access.

Right image: Left internal jugular access.

Figure 3: Both with groin access and the sheath extender securement on jugular access.

Many cases have now been performed without obvious additional time to the case. There were no clots noted in the StandTall when drawback was performed throughout the case.

Discussion

Can this be helpful in the setting of pediatric congenital heart patients or is just another thing that increase the cost of doing procedures? The challenge we all see is that congenital heart disease affects patients of all ages. The adaptability of providers and equipment becomes necessary to improve workflows, ergonomics, and safety for our patients. The length of 10-25cm improves challenges in pediatrics however raises a question if a longer extension would be better for neck access. Heparinized saline is flushed through the extension thus the length doesn't cause increased incidence of clot formation. While there is a cost to the Stand Tall it can improve the sterility of wires and catheters going in and out of jugular access. The length of the procedure table allows for normal positioning of patients on the table and a larger sterile field. This also keeps physicians further from the scattered radiation given they perform a multitude of procedures daily.

Does use of StandTall reduce procedural time and therefore reduce patient dose and physician dose? Adding the extension is not likely to reduce the length of the procedure unless you are having to move back and forth from the patient's right side and neck. In single ventricle patient access in the internal jugular is necessary to evaluate the palliated connections and collaterals. It is known that radiation exposure is inversely related to the distance from the beam. The dose to physicians is reduced more the greater the distance from the x-ray. The table has built in lead shields to reduce the exposure to the physicians but that is only if they can stand behind the shields. Time, distance, and shielding are the best and most effective way of reducing the risks from ionizing radiation [7, 8].

Does StandTall provide access stability by having the horseshoe clasp help absorb insertion and extraction forces therefore increasing both procedure and patient safety? When we think about smaller pediatric patients it may not be possible to use the horseshoe clasp at the connection but rather placing a tegaderm over the access site and connection to the StandTall. Placing the horseshoe connection around the shoulder to redirect access towards the groin and not over the center of the chest. This will allow for easier and more sterile movements throughout the procedure.

Does the StandTall create an issue of hubbing the catheter? While we have seen this with some of the groin access; there is a document on their website (<https://raduxdevices.com/products/>) that provides guidance of catheters and the StandTall correlation to patient's height. The reference document was created for radial access however can aid in preventing this occurrence in our dynamic population.

Conclusion

A myriad of benefits come from the use of StandTall including reduction in physician dose of radiation, improving wire management and control, improves sterility particularly for neck access, and ergonomically it helps to improve posture and back strain. These benefits out way the added cost of the Stand Tall.

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Conflict of Interest statement covering ALL authors: There are no conflicts of interest for the authors and were not proved any compensation.

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