

Product Description:

Gus Gear's Central Line Vest is a wearable catheter securement system. The device uses an adjustable strap system to secure the catheter by absorbing the force of pulls on the catheter. The Central Line Vest is designed for double- or single-lumen tunneled central catheters and accessed ports and can be adjusted to fit many diameters of catheters and infusion tubing.

Expected Clinical Benefits:

- Protection of entire central line against accidental pulling, tugging, and twisting
- Reduction in risk of central line trauma (fracture, fissures, dislodgement)
- Reduction in risk of central line infection

Intended Use:

The Central Line Vest is intended for comprehensive catheter securement (exit to hub) in:

- Short or long-term securement of percutaneous indwelling tunneled catheters for intravenous use
- Short or long-term securement of accessed ports for intravenous use

Warnings and Precautions:**Warnings:**

- Intended for **Single Patient Use only**. May be re-used in the same patient for an extended time.
- This product contains nylon, spandex, polyester, polyethylene, polyurethane, and calcium carbonate. Do not use in patients with known or suspected allergy to any of these components.
- Do not use if any Safe Strip securement strap is missing, damaged or not properly securing the catheter(s) in place for any reason.
- Contact your doctor immediately if the catheter is damaged or dislodged.
- Do not use if patient's body size is too small or too large to fit appropriately into the standard size range of the vest
- Do not use if patient's skin is unable to tolerate the minimal pressure associated with wearing the Vest

Precautions:

- Read and follow all instructions prior to use, including care instructions.
- Vest must be properly fitted and utilized according to the instructions to secure catheter.
- DO NOT remove Safe Strip while catheter is attached. To remove Safe Strip, first unfasten Safe Strip strap(s), releasing catheter.
- DO NOT place Safe Strip edge in contact with catheter or damage may occur.
- DO NOT use hot water to wash. DO NOT place in a dryer. (Please refer to care instructions.)
- Vest should be replaced if hook and loop closures (Velcro) no longer adequately secure adjustment straps and front flap.
- Patient breast development may hinder the vest's ability to perform.
- Device is NOT sterile.

Possible Complications:

The potential exists for complications including the following:

- If the product is not used within guidelines provided, damage to the catheter can occur.
- Contact your doctor immediately if the catheter is damaged or dislodged.

MRI Information:

- This product does not contain any metal and is composed entirely of materials that are electrically non-conductive, non-metallic, and non-magnetic.
- This product is considered **MR Safe** but has not been tested for safety with MRI.

Preparation for Use:

- Examine the Vest carefully to determine that all parts are present and in working order
- Do not use if product is damaged or missing parts
- Product can be re-used for the same patient after washing. (Refer to care instructions.)

Application & Removal:






- Refer to detailed instructions.

Exit Site Visualization:

- The catheter exit site can be visualized **without** removing the Vest.
- For exit site high on the chest, completely open one **shoulder** strap to visualize.
- For exit site lower on the chest, completely open one **torso** strap to visualize.
- Refer to instructions for details.

Product Tracing:

- Product can be traced based upon a Lot number (Batch Code) located on the Safe Strip adjustable strap.

	Single Patient, Multi-Use
	Refer to IFU for more information
	Not made with Natural Rubber Latex
	Batch Code
	MR Safe

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