INSTRUCTIONS FOR USE

MEDWRAP™

(Part No. Q15682)

These Instructions for Use (IFU) show how to apply the MEDWRAP™.

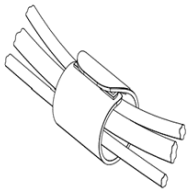
Intended Use: The MEDWRAP™ tool is intended to secure intravenous (IV), hemodynamic and vital sign monitor cords for patients during transportations, ambulation, or in stationary settings where there is potential for IV line and cord entanglement.

Figure 1. Outer Layer

Figure 2. Inner Layer

Figure3. Side View

Figure 4. Wraped View



Administration Instructions:

1. Remove the MEDWRAP™ from packaging. If damaged or soiled, discard.
2. Apply MEDWRAP™ to a small grouping of IV lines and cords. The IV lines and cords should be able to slide through the MEDWRAP™ without resistance. If this resistance occurs, reduce the number of IV lines or cords grouped.
3. Organize groupings of IV lines and monitor cords separately. You may need to use more than one MEDWRAP™ per patient.
4. Discard when not in use, damaged, or visibly soiled. MEDWRAP™ is single patient use.

Storage Instructions

Ambient room temperature (15-30C), away from direct sunlight and heat and in original packaging.

Disposal Instructions

Discard when soiled. Single patient use.

Additional Information

1. MEDWRAP™ may remain connected to IV lines and cords when patient is not in transport. Refer to your organization's policy for changing disposable medical equipment.
2. Do not group IV lines together originating from opposite sides of the patient's body.

3. Do not attach MEDWRAP™ containing IV lines or monitor cords to a stationary surface (e.g., bedrail or IV pole).
4. Do not attach MEDWRAP™ containing IV lines or monitor cords to the patient.
5. Do not reuse. Do not clean, should be discarded if soiled.

The MedWrap™ is US FDA Class I, 510(k) exempt; Product Code PUK, Regulation 21CFR880.5210

Contact Jill Amoroso at jamoroso@assureinnovations.com or 602-791-6311 for further questions or concerns.

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