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Corporate Quality Assurance/Regulatory Affairs

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SAFETY AND EFFECTIVENESS SUMMARY

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Device Name:	Protective Restraint, Vest Wheelchair Accessory, Vest Restraint
Proprietary:	Medline Safety Vest, Medline Economy Vest, Medline Tie-Back Vest, Medline Security Vest
Common:	Vest Restraint
Classification:	Protective Restraint Wheelchair Accessory

These devices have been legally marketed prior to the date of this submission, and, in fact, prior to 1976. The intended use and claims, technological features, materials and physical and mechanical specifications have not been changed.

1.0 General Description

Medline's Safety Vests are intended to be utilized as a patient safety device when physical restraint of the patient is deemed necessary.

The four types of vests are described as follows:

A. Security Vest - Criss-Cross vest with waist belt that ties out of reach. Shoulder loops may be used with extra straps (provided) to help prevent patient from sliding down or sitting up in bed. All straps are intended to be tied to the bed frame or to the wheelchair kick spurs utilizing an overhand knot and magnus hitch. Vest criss-crosses in front through a sewn in web loop. See tab C (labeling page 5A) for illustration of appropriate tie methods and directions. Reference Attachment A for a pictorial of this device. This vest is manufactured of "Koolnit" material which is a polyester mesh.

B. Economy Vest - Criss-Cross vest with waist belt that ties out of reach. All straps are intended to be tied to the bed frame or to the wheelchair kick spurs utilizing an overhand knot and magnus hitch. Vest criss-crosses in front through a sewn in web

loop. See tab C (labeling page 5A) for illustration of appropriate tie methods and directions. Reference Attachment A for a pictorial of this device.

C. Safety Vest - Criss-Cross vest with waist belt that ties out of reach. This vest differs from the Security Vest and Economy in that there are no shoulder loops and there is a sewn slot in the front of the vest which the material passes through, as opposed to a sewn web loop. All straps are intended to be tied to the bed frame or to the wheelchair kick spurs utilizing an overhand knot and magnus hitch. See tab C (labeling page 5A) for illustration of appropriate tie methods and directions. Reference Attachment A for a pictorial of this device.

D. Tie-Back Vest - Vest crosses and ties in back, making it more difficult for the patient to remove. Shoulder loops may be used with extra straps (provided) to help prevent patient from sliding down or sitting up in bed. Corset buckles are used to secure straps to bed frame or wheel-chair kick spurs. See tab C (labeling page 5A) for illustration of appropriate tie methods and directions. Reference Attachment A for a pictorial of this device.

INTENDED USE

Vest Restraints may be used either in a bed or wheelchair. They are intended for use with patients or residents that need a "gentle reminder" for the patient to stay in their bed or wheelchair. These products are designed for use with a carefully defined medical treatment program which addresses (but is not limited to) restorative nursing, patient release, and pressure sore prevention. Aggressive, agitated or restless patients require increased monitoring and a systematic review and evaluation of both their physical and psychological status.

Medline Patient Safety Products are intended to be used for those patients suffering from temporary medical related cognitive deficits, for agitated patients, or to help patients feel safer in a bed or wheelchair.

Medline Vest Restraints are not intended for use with stretchers, on toilets or shower chairs or in the shower or tub, and should always be secured to the movable portion of the bed frame, never to the side rails. Vest restraints may get tight over the chest, possibly compromising breathing, in which case the patient may require a safety product with a pelvic portion between the legs.

Medline Patient Safety Products are not intended for use in a motorized vehicle., as they are not designed to withstand the force of a crash.

Medline Patient Safety Products are not intended for home use.

These devices are for use in hospitals and/or nursing homes to help maximize patient safety and are not intended to preclude good nursing care and common sense.

A reasonable search of all information known or otherwise presently available to Medline Industries, Inc. has been conducted. Such a search is defined as examining articles in medical literature, FDA literature, and company documents concerning safety and effectiveness information for safety restraints. Following is a summary of and citation to the safety and effectiveness data found in that search.

Specific safety and effectiveness data outlined in the literature include actual as well as potential complications which may occur and are summarized as follows:

Emotional desolation, agitation, fractures, chafing, burns, nerve damage, circulatory impairment, decubitus ulcers, death, and strangulation attributed to incorrect supervision, handling or application of protective restraint devices by medical or paramedical personnel. These incidences seem to be the result of inappropriate patient selection (physically restraining a patient for whom physical restraint is contraindicated), incorrect restraint selection, errors in correctly applying the device, and/or inadequate monitoring of patients when restrained.

When used correctly and for indicated circumstances, protective restraints provide benefits to many patients, such as precluding patients with temporary medical related cognitive deficits from impairing the resolution of their physical problems by involuntarily discontinuing life-support or other needed medical interventions, temporarily reducing the mobility of agitated patients, or helping patients feel safer in a bed or wheelchair.

Medline Industries, Inc. offers a variety of additional materials to help insure the safe and proper use of its patient safety products, including posters and videos. Medline Industries, Inc. stresses the importance of patient monitoring, and that these products should only be used upon advice of a physician or other trained, licensed healthcare professional.

A total of thirteen articles were reviewed for this 510(k) submission. The articles listed in the citation contained pertinent data for establishing the safety and efficacy of protective restraints.

CITATION

Physical Restraints: An FDA Update, American Journal of Nursing From FDA Nurses 1992; 74: November 1992, Mary D. Weick, RN, MSN.

Potential Hazards With Protective Restraint Devices; FDA Medical Alert, dated November 14, 1991; MDA91-3

The Misuse of Physical Restraints in the Confused Patient; This paper was presented by Ms. Barbara Fitzgerald, Ward Sister, Geriatric Unit, St. James Hospital Dublin at the INO Nursing Association for the Elderly Day Conference in April, 1986.

Federal Register/Vol. 57, No. 119/Friday, June 19, 1992/ Proposed Rules

Potential Hazards with Physical Restraint Devices; FDA Safety Alert, dated July 15, 1992

Restraint and Seclusion; Journal of Psychosocial Nursing, June 1985, Vol. 23, No. 6, Janice M. Roper, RN, MS, Adam Courtts, MS Janet Sather, RN, and Rosella Taylor, RN.