



Medline Industries, Inc.

One Medline Place
Mundelein, Illinois 60060.4486

1.847.949.3109
1.800.950.0128
Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

SAFETY AND EFFECTIVENESS SUMMARY

K963569

Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Phone #: (847) 949-2639
Fax #: (847) 949-2643
Lara N. Simmons
Corporate Regulatory Affairs Manager

OCT 18 1996

August 29, 1996

Device Name: Wheelchair Accessory, Wheelchair Safety Belt
Proprietary: Medline Wheelchair Safety Belt, Medline Two-Piece
Safety Soft Belt, Medline Wheelchair Belt, Medline
Wheelchair Lock Belt
Common: Wheelchair Belt
Classification: Wheelchair Accessory

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

1.0 General Description

Medline's Wheelchair Safety Belts are intended to be utilized as a "gentle reminder" for patients to stay in their wheelchair or not to attempt to stand without assistance. They are intended to help the patient feel safer or more secure in their wheelchair. Two of the items are designed to be able to be released by the patient.

The first two items are not designed to be released by the wearer:

A. Wheelchair Waist Belt

Made of 2" nylon web. Belt circles patient's waist and passes through a slid buckle in front for individual fit. Belt criss-crosses in back and attaches to kick spurs at rear of wheelchair.

B. Economy Wheelchair Belt

Made of 2" nylon web. Similar to the Wheelchair Waist Belt except this item does not have the slide buckle in front. Belt goes around wearer's waist and attaches to the kick spurs using an adjustable loop.

The following three items are designed to be released by the wearer:

C. Two-Piece Safety Soft Belt

Hook and Loop (Velcro) closure enables the wearer to release the belt by themselves as required by the O.B.R.A. regulations. Padded belt made of blue knit material for extra comfort.

D. Wheelchair Belt with Buckle

Made of 2" nylon web. Quick release buckle enables the wearer to release the belt by themselves as required by the O.B.R.A. regulations.

E. Wheelchair Belt with Hook & Loop

Made of 2" nylon web. Hook and Loop closure in the front enables the wearer to release the belt by themselves as required by the O.B.R.A. regulations.

INTENDED USE

Medline Wheelchair Safety Belt Restraints are intended for use with patients or residents that need a "gentle reminder" for the patient to stay in their wheelchair or to remind them to seek assistance before standing. These products are also intended to help prevent falls or to help the patient feel safer in their wheelchair. Several of the designs are intended to enable the user to release them, per O.B.R.A. regulations. 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, for patients that are at risk for a life threatening fall or fall that may cause serious injury or re-injury, or to help patients feel safer in wheelchair.

Medline Wheelchair Safety Belt Restraints are not intended for use with stretchers, on toilets or shower chairs or in the shower or tub.

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.