



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

K 963404

**SAFETY AND EFFECTIVENESS SUMMARY**

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

10/11/96

OCT 18 1996

August 26, 1996

Device Name: Protective Restraint, Pelvic Holder  
Proprietary: Medline Pelvic Holder  
Common: Pelvic Holder  
Classification: Protective Restraint

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 Pelvic Holders are designed for use with either a bed or wheelchair. They are used to help hold the patient upright and help prevent sliding in a wheelchair, or to help prevent the patient from sliding down in bed. They may be used alone or in combination with a vest restraint. They are made of cotton flannel and are secured by polyester web straps.

**INTENDED USE**

Medline Pelvic Holders may be used either in a bed or wheelchair. They are intended to be used to help keep the patient upright and to help prevent them from sliding down in a wheelchair or for use in a bed to help prevent the patient from sliding down. They may be used alone or in tandem with a vest restraint.

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, to help patients maintain position or to help prevent them from sliding down in a bed or wheelchair, or they may be used to help patients feel safer in a bed or wheelchair.**

**Medline Pelvic Holders 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.**

**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, helping patients maintain an upright position in a wheelchair, helping to prevent patients from sliding down in a bed or wheelchair, 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.**