

Morrison Medical Products
Stretcher/Cot and Backboard Restraints

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

Morrison Medical Products
610 W. Town Street
Columbus, OH 43215-4446

Contact Person

Joseph S. Tokarz; Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048
Ph: (847)680-2849, Fax: (847)918-3860

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2. Name of Device:

Morrison Medical Stretcher/Cot and Backboard Restraints

3. Name of Predicate Device(s)

Morrison Medical Stretcher/Cot and Backboard Restraints

4. Description of Device

The Morrison Medical Stretcher/Cot and Backboard Restraints are intended to be used by qualified and properly trained personnel to help secure a patient's body to a stretcher, cot or backboard.

The Morrison Medical Stretcher/Cot and Backboard restraints connect to or wrap around a stretcher, cot or backboard. The restraints are constructed by combining various webbing, buckles/closures and end styles. The webbing is available in nylon, polypropylene and vinyl coated polyester materials. The webbing that is used is dependent on user preference. The Morrison Medical Stretcher/Cot and Backboard Restraints are available as a reusable or disposable (series 139x) restraint. The restraint is available in either a one-piece length or two-piece lengths depending on user preference. The one-piece restraint wraps around a patient and the stretcher, cot or backboard and is secured with a buckle. The two-piece restraint is connected to the frame on both sides of the stretcher, cot or backboard with an end-style (end-style description below) and is secured together with a buckle/closure. (See chart below for a detailed description of the one- and two-piece length presentation)

The buckles are available in six different styles (see chart below) depending once again on user preference. On the end of the two-piece restraint webbing is an end style. The

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end style is the component of the restraint that connects to the stretcher, cot or backboard. There are four different end styles available (see chart below), depending on whether the restraint will be used with a stretcher, cot or backboard and depending on user preference.

One-Piece and Two-Piece Webbing and Strap Length Presentation:

Length/No. of Straps	Description
Five foot section; two piece strap	The two sections of webbing are connected to each other by the preferred buckle to form a five foot section. At the end of each section is the preferred end style that connects to the stretcher/cot or backboard frame.
Seven foot section; two piece strap	The two sections of webbing are connected to each other by the preferred buckle to form a seven foot section. At the end of each section is the preferred end style that connects to the stretcher/cot or backboard frame.
Seven foot section; one piece strap	The restraint is constructed with the preferred webbing and buckle of choice. One component of the buckle is secured to each end of the seven foot strap.
Nine foot section; one piece strap	The restraint is constructed with the preferred webbing and buckle of choice. One component of the buckle is secured to each end of the nine foot strap.

Restraint Buckles/Closures

The buckle/closure that connects the webbing material is intended to close together to secure the patient while he/she is lying on the stretcher/cot or backboard. The style of buckle/closure that is used is based on user preference. All the buckles/closures perform the same basic function, closing together to secure the patient onto the stretcher/cot or backboard.

On the following page is a chart that provides the name and description of each buckle/closure style.

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Name of buckle/closure	Description
Metal Push Button (auto)	Similar to an auto seat belt. Push ends together to secure; push button to release.
Plastic side release	Polypropylene quick release closure. Push ends together to secure; squeeze sides together to release
Metal Cam (friction) Plastic Cam (friction)	Metal Buckle. Thread webbing through back of buckle and press buckle lever down to secure; pull buckle lever up and unthread webbing to release
Metal Roller Buckle (friction)	Metal Roller Buckle. Thread webbing through buckle and move sliding bar to roller bar to secure; move sliding bar off roller bar and unthread webbing to release
Metal Double D-Ring	2" Metal Double D-Rings. Thread webbing through Double D-Ring to secure; unthread webbing to release

End Styles

The end style is the component of the restraint that connects to the stretcher/cot or backboard. There are four different end styles available depending on whether the restraints will to be used with a stretcher/cot or backboard and depending on user preference. Below is a chart which shows the name and description of each end style.

Name	Description
Loop-Lok™ End	Loop-Lok ends can be used with stretchers/cots and backboards. Webbing wraps around stretcher frame or backboard hand hold and through end of webbing where loop is sewn. Unthread loop to release
Non-Swivel Speed Clip	Non-Swivel Speed Clips are to be used with specially designed backboards containing speed clip pins only. Clips onto backboard pin and locks shut. Does not swivel. Push lock in to release.
Metal Swivel Speed Clip Plastic Swivel Speed Clip	Swivel Speed Clips are to be used with specially designed backboards containing speed clip pins only. Clips onto backboard pin and locks shut. Push lock in to release.

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5. Statement of Intended Use

Morrison Medical Stretcher/Cot and Backboard Restraints are intended to help secure a patient's body to a stretcher, cot or backboard.

6. Statement of Technological Characteristics of the Device

The Morrison Medical Stretcher/Cot and Backboard restraints connect to or wrap around a stretcher, cot or backboard. The restraints are constructed by combining various types of webbing materials, buckles/closures and end styles.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility Assessment

The subject devices are identical in component materials to the predicate devices. Morrison Medical Products is not aware of any reports or complaints of skin irritation associated with the materials used in these devices. A biocompatibility review of these materials indicated little potential to evoke an adverse reaction.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Morrison Medical Stretcher/Cot and Backboard restraints are safe and effective for their intended use and are substantially equivalent to the predicate devices.