Posey Company

5635 Peck Road
Arcadia, CA 91006-0020 USA
Toll Free: (800) 44-POSEY or (800) 447-6739
Web: www.posey.com

FAQ No.:	28
FAQ:	What are the FDA requirements for labels on protective restraints **?**

The protective restraint itself should have a label on it, displaying the following information:

- The manufacturer's name and product identification;
- On vest, jackets and other upper torso restraints (e.g. body holders) a position label noting the orientation of the device on the patient (e.g. top/bottom, front/back inside/outside);
- The common size (e.g. small, medium, large) plus body measurements and weight ranges;
- A cleaning instruction label, if appropriate;
- Specific warnings related to incorrect placement, wrong size, improper application to the "vehicle", knots preventing quick release and the use of restraints in damaged/poor condition;
- Pictorials illustrating hazards (e.g. proper/improper placement) to the patient, when appropriate;
- Cautionary information about the need for frequent patient monitoring and device flammability; and
- The most important application steps, whenever possible;

The package label and the instructions must include the "Prescription Legend" that states:

- "Caution: Federal law restricts this device to sale by or on the order of a Physician."

- Note: Posey protective restraints meet these requirements.

References:

(1) 21 CFR §801.109 Prescription Devices
(2) FDA document titled "Guidance on the Content of Premarket Notification (510K) Submissions for Protective Restraints" dated December 1999**,** starting on Page 9, section 2 Parts a & b, entitled Device Labels.

For more information contact Richard J. Cain at J.T. Posey Company (800) 447-6739 Ext. 122.