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FAQ No.: 03

FAQ: Can Restraints Be Used At Home

We are not aware of any law or regulation that specifically states that restraints cannot be used at home.

However, the **FDA issued a letter to Manufacturers in February, 1992**, stating that Restraints are "Prescription Devices" that must bear a prescription label "Caution: Federal law restricts this device to sale by or on the order of a Physician."

In addition, the FDA published a **Final Rule, 21 CFR Parts 880 and 890 in the Federal Register / Vol. 61, No. 43/ Monday, March 4, 1996 Rules and Regulations**. These Rules and Regulations state among other things:

"FDA believes the use of restraints should be limited to those circumstances when they are clearly clinically indicated, and that they should be used only for a strictly defined period of time and under the supervision of a licensed health care provider."

These Rules and Regulations also state:

"FDA strongly encourages that after restraints are prescribed by a licensed health care practitioner, they be applied only by adequately trained personnel, in accordance with State licensure and Federal certification requirements for facilities."

Therefore, **The Posey Safety Instructions for the Use of Posey Torso and Wrist Restrictive Products (item #15) states:**

"Posey Torso and Wrist restrictive products should NOT be used at home without constant supervision of a licensed healthcare provider, Physician's order and Individualized Care Plan."

For home use of the Posey Bed Enclosure Safety System, see the instruction manual M5080.

For complete cleaning and use instructions for all Posey products, please refer to package insert instructions accompanying each product. Copies of all package insert instructions are available on the Posey website at www.posey.com.

We hope that this answers your questions. If you have any further questions, please feel free to call Posey Customer Service at (800) 44-Posey or (800) 447-6739.