



# Posey Company

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**FAQ No.:** 23

**FAQ:** Is the Posey Bed Canopy System Considered a Restraint?

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Yes. The Posey Bed Canopy System is considered a restraint by The Centers for Medicare & Medicaid Services (CMS), and the applicable regulations, policies, and procedures for restraints must be followed.

CMS and the FDA each define medical devices in accordance with its own statutory authorities. These differences in definition do not compromise the ability of the agencies to enforce their own regulatory requirements. Medical device manufacturers must comply with FDA requirements. Medicare and Medicaid providers must comply with CMS requirements in order to become, or remain certified.

#### **FDA-MANUFACTURER**

The Posey Bed Canopy System is considered a medical device. Posey as the manufacturer must comply with the FDA regulations. Therefore The Posey Bed Canopy System is listed with the FDA under 21CFR 880.5100 –Accessory for AC Powered Hospital Bed.

#### **CMS-MEDICARE AND MEDICAID SUPPLIERS**

CMS defines a restraint in 42CFR 482.13.e.1

A physical restraint is any manual method, or physical, or mechanical device, material, or equipment, attached or adjacent to the patient's body that he or she cannot easily remove, that restricts freedom of movement or normal access to one's body. Therefore, since the patient cannot remove him or herself from the Bed Canopy system on their own, it is considered a restraint under CMS regulations. The same is also true for JCAHO Regulations, and requires implementation of the facility's restraint policies and procedures.

#### **PRESCRIPTION DEVICE**

The Posey Company has declared the Posey Bed Canopy System to be a prescription device. The Posey Bed Canopy System is labeled with the FDA legend: "**CAUTION: Federal law (USA) restricts this device to sale by or on order of a physician**". Therefore, you must have a Physician order to use the Bed Canopy System.

The Posey Bed Canopy should be considered as a less restrictive device, and can be tried before more restrictive products are ordered or utilized. The Bed Canopy allows full mobility and range-of-motion within the bed while providing safety, security and patient well-being.

For Safety, Application, and Cleaning 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](http://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.