Urgent Field Safety Notice

Epidural Positioning Device (EPD)
FSCA Reference: RA 5652 CAPA 110

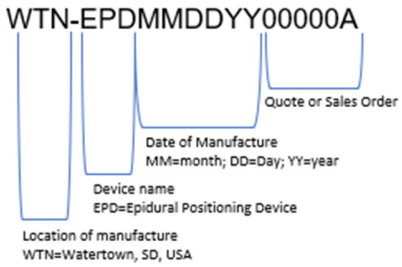
Device Advice and Device Modification

2019-08-27

Attention: Owners and Users of the Epidural Positioning Device (EPD)

Details on affected devices:
The Epidural Positioning Device, EPD, is a support tray that is rolled in front of a patient to assist in the positioning of a patient for an epidural, or during other spinal anesthetic procedures. Epidural Positioning Devices sold prior to 01 July 2019 are affected. The date of manufacture can be found in the serial label as indicated below:

Format of Serial Label:



An image of the EPD can be found in Appendix 1.

Description of the problem:
Two of the corners on the bottom edge of the Foot Rest Tray were found to be sharp. See Appendix 1 for the location of the hazard on the device. There is a possible risk that a patient could be cut if a moving foot or leg were to contact the bottom of the Foot Rest Tray. In normal use it is not expected that such contact would occur as the Foot Rest Tray is intended to be positioned below the level of a patient's foot before rolling the device in front of a patient. However, if the Foot Rest Tray ends up above the level of a patient's foot or leg and unexpected patient movement occurs, unexpected contact with EPD device could occur. The risk increases with patients with limited mobility, or where a patient does not have full control of their limbs.

Advice on action to be taken by the user:

Users of the Epidural Positioning Device should obtain and review the Safety and Operation sections of the updated User / Service Manual. Users should also contact Pivotal Health Solutions, and can request a corner protector kit that contains adhesive and corner protectors that can be easily attached to the frame and prevent contact with the sharp corner of the Foot Rest Tray.

Transmission of this Field Safety Notice:

This notice should be passed on to all those who need to be aware in your organization, or to any organization where the potentially affected devices have been transferred.

Contact reference person:

Julee Driver
Quality Director
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The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

Sincerely,

Julee Driver

Appendix 1. Image of the Epidural Positioning Device and location of the affected portion of the Foot Tray.

Location on bottom of Foot Tray where two sharp corners have been identified.

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