


## Urgent Safety Communication

### Urgent Recall of Mac Pin Non-Cannulated Screw Manufactured by Amendia, Inc (is now Spinal Elements, Inc.)

<b>Device/ Product Name:</b>	Mac Pin Non-Cannulated Screw
<b>Lot numbers/Serials:</b>	Mac Pin Non-Cannulated Screw, 6.5 x 60mm Model #85-6560-1, Lot #132117
<b>Manufacturer:</b>	Amendia, Inc ( is now Spinal Elements, Inc.)
<b>Problem:</b>	Saudi FDA would like to bring to your attention that Amendia, Inc. ( is now Spinal Elements, Inc.) has removed one lot from Mac Pin Non-Cannulated Screw, 6.5 x 60mm Model #85-6560-1 due to Incorrect labeling for the lot of MAC Pins. Although the pins are laser as 460 mm in length, the pins are 60 mm in length.
<b>Recommendation/Actions:</b>	Examine inventory and quarantine affected products.
<b>Devices/Products photo:</b>	

For further information, please see the recall by [Click Here](#).

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

**National Center for Medical Devices Reporting.**

Medical Devices Sector

Saudi Food and Drug Authority

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Sincerely,  
NCMDR Team