

SPINE SAFETY ALERT:

**Information for Healthcare Professionals:
Mizuho OSI Modular Table Systems:
Class I Recall - Reports of Patient Injury**

SOURCE: FDA MedWatch

AUDIENCE: Risk Managers, Surgery, Orthopedics

ISSUE: FDA notified health professionals of a Class I Recall of Mizuho OSI Modular Table Systems because of reports of patient injury related incidents. The incorrect removal of the T-pins that support the bottom base, instead of the T-pins that support the top, may result in patients falling to the floor. Another potential concern is unexpected movement/tilting of the table which may result in unanticipated movement and/or patient falls during surgery. Patient falls or unanticipated movement may result in serious injury or death.

BACKGROUND: Mizuho OSI Modular Table Systems are used for patient positioning during a diverse set of orthopedic trauma, thoracic, and spinal surgery procedures.

RECOMMENDATION: On July 29, 2011, Mizuho issued a Field Advisory Notice to Hospital Risk Management, Operating Room Directors, Operating Room Technicians, Physicians, Nurses, Anesthesiologists and any personnel involved in the use and/or set up of the OSI Modular Table Systems. The Field Advisory Notice provided warnings and recommendations for safe use of the Mizuho OSI Modular Table Systems including performing a verification count of all the T-pins to confirm the stability of the table top.

Questions should be directed to Mizuho on their toll-free hotline at 1-800-777-4674, Monday through Friday from 9:00 am to 5 pm, Pacific Time.

Read the MedWatch safety alert, including a link to the Recall Notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicinalProducts/ucm279266.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.