

SPINE SAFETY WARNING:

Information for Healthcare Professionals:

Stryker Operating Room System II Surgical Navigation System:

Recall due to potential for the navigation PC SPC-1 component to stop working

According to MedWatch, Stryker and FDA notified healthcare professionals of a recall of 23 Operating Room System II Surgical Navigation Systems because there is a potential for the navigation PC SPC-1 component to stop working which could result in the screen freezing, the system updating at a slow rate, or not responding at all. The Navigation System II is a computer aided surgery platform that surgeons can use to perform Hip, Knee, Spine, Neuro and ENT surgical procedures and contains a computer workstation with the navigation System II software and various components necessary to run the system. The potential harms associated with this failure are: delay in surgery, reschedule of the procedure resulting in an additional surgery, risk of infection, increased morbidity, potential neurological deficits, or injury due to the surgeon operating in an area where they did not intend to operate. Depending on the type of surgery, these failures could potentially lead to serious adverse health consequences, including death. Hospitals that have product that corresponds to the catalog numbers above should immediately quarantine the product, label it as a recalled product and stop using the product.

Read the complete MedWatch 2009 Safety summary including a link to the firm press release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm192105.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.