

Model Number AFFIX SP PLATE Device Problems Break; Detachment Of Device Component Event Date 10/13/2009 Event Type Malfunction Event Description The pt's surgery consisted of an xlif procedure at l3-l4 followed by placement of 35 mm affix plate at l3-l4 and 45 mm affix plate at l4-l5. The affix plate lock mechanism at l3-l4 separated from the plate intraoperatively. At the time, the plate appeared to be locked despite the lock mechanism having separated. The surgeon elected to leave the plate in place at the time of initial surgery. A decision to replace the plate assembly was made a short time later. Revision surgery was completed on (b)(6) 2009 and proceeded without incident.

Manufacturer Narrative The device was returned to nuvasive and is currently being analyzed. Instructions for use indicate that "care should be taken to ensure that all components are ideally fixated prior to closure. " although the root cause of this failure is unk at this time, in the event that additional relevant info becomes available, a subsequent report will be filed.

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