stryker®
Craniomaxillofacial

Risk of Needlestick Injury in Oral and Maxillofacial Surgery

Introducing SMARTLock Hybrid MMF

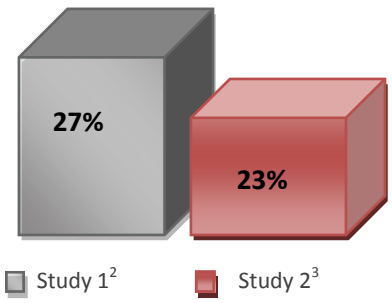
A revolutionary, patented product designed to combine the strength and rigidity of arch bars with the safety and efficiency of MMF screws. With nine potential points of fixation along the plate, posterior fixation and vector control are enhanced when compared to traditional MMF screws. The self-drilling, locking technology of the screws allows for purchase into both the bone and the plate for additional stability. The plate and screw combination omits the need for interdental wiring that is required with arch bars, and thereby reduces the chance of wire stick injuries for health care providers. It can be removed under local anesthesia in the office setting, thereby eliminating non-reimbursable OR based removals.

Risk of Needlestick Injury

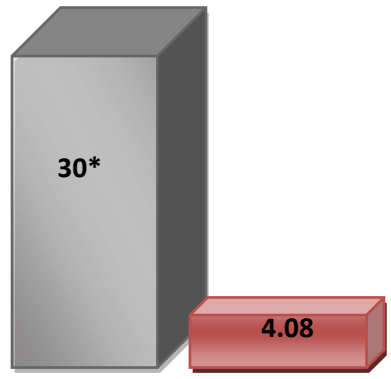
A general concern in the healthcare industry involves the high risk of needlestick injuries among surgeons. These injuries can potentially cause bloodborne infections such as HIV, Hepatitis B and Hepatitis C[2]. The Centers for Disease Control have estimated that 600k-800k needlestick injuries and other percutaneous injuries occur annually[1] and the risk of these injuries has been shown to be higher in oral and maxillofacial surgeries[2]. Findings have shown the prevalence of HCV and HCB in oral surgeons was tenfold higher[2] and 3 times higher[2] than other surgical specialties. In addition, most maxillofacial surgeons sustain 3 needlestick injuries a year[2].

Intermaxillary fixation (IMF) involves a time consuming continuous use of sharps, including wires, cutters, and sharp instruments. Multiple passes of wire are required around the teeth, followed by tightening and cutting of the wires. Limited access to the oral cavity and the frequency of how often the procedure is performed as an emergency protocol are other reasons for higher risk. A recent study looked at the incidence and patterns of needlestick injuries during IMF. A total of 172 IMF procedures (101 placements and 71 removals) were recorded during the one-year survey, with 40 needlestick injuries (23%)[2]. Another study found a rate of percutaneous injury of 27% using arch bars and wires for IMF[3]. The SMARTLock Hybrid MMF System can potentially reduce the number of wires required to achieve IMF. During our early product surveillance (EPS), the average number of wires used per case with the SMARTLock Hybrid MMF System was 4.08[4]. Typically, an arch bar is wired around each tooth neck with additional wires being used to bind the maxilla and mandible together whereas The SMARTLock Hybrid MMF plates are fixated with screws into the alveolar bone. The SMARTLock Hybrid MMF System can potentially reduce the number of wires required to achieve IMF, thus reducing prolonged OR time, high risk of wire stick injuries, and pain and discomfort to the patient.

Rate of Needlestick Injury During IMF



Average Number of Wires/Case to Achieve IMF



* 30 wires is an estimation based off of the standard 32 teeth anatomy

9410-400-395 Rev. None
US Pat. 8,118,850

1. Centers for Disease Control. Updates US Public Health Service guidelines for the management of occupational exposures to HBV, HCV, HIV. MMWR, 2001
2. R Bali et al. Incidence and patters of needlestick injuries during intermaxillary fixation. British Journal of Oral and Maxillofacial Surgery, Volume 49, Issue 3, Pages 221-224, 2010
3. A Ayoub and J Rowson. Comparative assessment of two methods used for interdental immobilization. Journal of Craniomaxillofacial Surgery, Volume 31, Issue 3, Pages 159-161, 2003
4. Early Product Surveillance data on file at Stryker