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. The Centers for Disease Control have estimated that 600k-800k needlestick injuries and other percutaneous injuries occur annually and the risk of these injuries has been shown to be higher in oral and maxillofacial surgeries. Findings have shown the prevalence of HCV and HCB in oral surgeons was tenfold higher and 3 times higher than other surgical specialties. In addition, most maxillofacial surgeons sustain 3 needlestick injuries a year.

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%) from IMF. Another study found a rate of percutaneous injury of 27% using arch bars and wires for IMF. 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. 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

![Graph showing rate of needlestick injury during IMF]

27% Study 1
23% Study 2

Average Number of Wires/Case to Achieve IMF

![Graph showing average number of wires/ case to achieve IMF]

30* Arch Bars
4.08 SMARTLock Hybrid MMF

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

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

4. Early Product Surveillance data on file at Stryker

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery. The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.