

**Clinical Information**  
**on the Vitek TMJ Interpositional (IPI) Implant**  
**and the Vitek-Kent (VK) and Vitek-Kent I (VK-1)**  
**TMJ Implants**

**The Interpositional Implant**

The Vitek Interpositional Implant (IPI) has been demonstrated to significantly-wear, migrate, tear, fragment, delaminate, and perforate. When this type of failure occurs, a significant amount of wear particles are produced. These particles have been reported to migrate to regional lymph nodes, as well as the adjacent tissue. In the immediate anatomical area of the TMJ, the particulate, including the failed prosthesis itself, initiates a foreign body response that causes progressive bone degeneration (including the glenoid fossa and the mandibular condyle). This degeneration can result in permanent hearing damage, chronic pain, permanent loss of functional masticatory function, and reduced range of motion of the mandible. An additional report has described bone erosion into the cranial space resulting in an open communication to the brain.

Due to the uncertainty of the actual number of implants placed in the TMJ, failure rates on the total patient population cannot be calculated. However, retrospective studies (1-7) have been conducted that provide the respective failure rates and failure modes experienced. In addition, numerous case studies have been published that demonstrate individual experiences with the IPI.

The Department of Oral and Maxillofacial Surgery at the University of Iowa retrospectively evaluated patients who had the IPI implanted at its medical center from 1983-86. The study demonstrated that of the 51 IPI's available for follow-up examination, 73% had been removed due to fragmentation, (the sheeting material separated into small particles due to wear), perforation (the sheeting material developed holes), and/or foreign body reaction that resulted in progressive bone degeneration.

In addition, 19 implants in 15 patients were initially determined to be successful, that is, there was no clinical evidence of temporomandibular disease or symptoms. However, radiographic analysis demonstrated that 65% of these implants had been displaced, 50% had fractured or been perforated, and that significant progressive bone degeneration was occurring around all implants. The studies demonstrate that patients with symptoms and, more importantly, patients without symptoms are extremely likely to experience failure of the IPI.

An inability to open the mouth fully, joint clicking, and pain immediate to the TMJ are common symptoms associated with a failed IPI. However, it is extremely important to recognize that an asymptomatic patient may still be undergoing progressive bone degeneration.

The Vitek Interpositional Implant (IPI) was distributed between 1973 and 1988. The actual number of IPIs implanted has not been confirmed; however, at least 26,000 were distributed between 1983 and 1988 in the United States.

### **The Vitek-Kent and Vitek-Kent I**

The Vitek-Kent I (VK-I) has been demonstrated to wear significantly, fragment, and perforate. When this type of failure occurs, a significant amount of wear particles are produced. This failure mode is very similar to that of the IPI failure mode. Many of the same complications that lead to failure in the IPI have also been observed. In the immediate anatomical area of the TMJ, the particulate, including the failed prosthesis itself, initiates a foreign body response that causes progressive bone degeneration. These particles, when produced in IPI failure, have been reported to migrate to regional lymph nodes, as well as the adjacent tissue. This degeneration can result in chronic pain, permanent loss of functional masticatory function, and reduced range of motion of the mandible.

Due to the ever-changing design of the VK TMJ implant system and the lack of FDA clearance for the implant (thus not having reliable sources of when each design was marketed), it is impossible to determine the actual number of implants that were marketed. Therefore, failure rates on the total patient population cannot be calculated. However, a retrospective study (9,10) has been conducted that provides the failure rates and failure modes experienced at an individual clinical site. In addition, reports have been provided to the FDA that convey individual experiences with the Vitek-Kent (VK) and VK-I.

The Department of Oral and Maxillofacial Surgery at Louisiana State University (LSU) Medical School has reported its experience with the VK-I (10). The retrospective study evaluated patients who had the VK-I used for both partial and total TMJ reconstruction. These implants were placed between 1982-1986. The study demonstrated that of 39 implants used in partial TMJ reconstruction 16 (41.03%) had failed. The resulting cumulative success rate was 42.4%. In total TMJ reconstruction, 29 of 85 implants failed (34.12%). The resulting cumulative success rate was 57.95%. In this study, similar physiological and anatomical effects were observed (e.g., pain, progressive bone resorption, etc.). An inability to open the mouth fully, joint clicking, and pain immediate to the TMJ are common symptoms associated with a failed VK-I. Although, the LSU study did not look at asymptomatic patients in particular, the lessons learned with the IPI warrant monitoring all patients with the VK or VK-I.

The history of the development of VK and VK-I glenoid fossa and condylar implants is not well known. The first indication of clinical use of the V-K glenoid fossa is in 1981(8). This device was composed of Proplast I (interfacing the glenoid fossa), a middle layer of Teflon/ FEP embedded with a polyamid or metallic mesh, and an articulating surface of Teflon reinforced with graphite. This device was used alone or with a condylar prosthesis until 1982. From 1982 through 1984, numerous changes were made to the implant resulting in a bilaminate structure for the glenoid fossa prosthesis. The resulting material composition of this implant is Proplast II (interfacing the glenoid fossa) and a Teflon/FEP (articulating with a condylar prosthesis) articulating surface with a polyamid mesh embedded in the Teflon/FEP. Later in the development of additional TMJ implants (e.g., VK-II), it appears that the VK was renamed VK-I. Oral Surgery Marketing Inc. (OSMI) is the manufacturer that currently markets the V -II (formerly known as the VK-II) implant. The VK, VK-I and VK II (V-II) have not been cleared for marketing in the United States or for exportation to foreign countries.

On the basis of the clinical information described in the LSU and Iowa studies and the experience derived from the IPI failures, the following actions are recommended:

- All patients (symptomatic or asymptomatic) should undergo routine radiographic evaluation. This evaluation must include CT or MRI scans to evaluate the implant, as well as the adjacent anatomical structures.
- If progressive bone degeneration or implant disruption is demonstrated in these evaluations, the IPI, YK or VK-I should be removed.
- If pain or occlusal changes persists six months or longer, the IPI, VK or VK-I should be removed.
- If bone degeneration is not revealed, the patient should still undergo routine (annual) radiographic evaluations (CT or MRI) for the life of the IPI, and radiographic evaluations for the life of the VK or VK-I implants.
- Further implantation of the IPI, VK, VK-I, and VK-II should not occur.

Please contact Barry E. Sands at 301-427-1230 for further information pertaining to this clinical risk paper.

### **Recommendations**