



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

September 1991

**PUBLIC HEALTH ADVISORY  
FROM  
THE U.S. FOOD AND DRUG ADMINISTRATION  
ON  
VITEK PROPLAST TEMPOROMANDIBULAR JOINT IMPLANTS**

Dear Health Professional and Vitek Consignee:

The United States Food and Drug Administration (FDA) requests that you notify all patients of the problems associated with the following temporomandibular joint (TMJ) interpositional implants manufactured by Vitek, Inc., Houston, Texas:

- TMJ interpositional implant (IPI)
- VK (glenoid fossa)
- VK-I (condylar head, glenoid fossa)

The concerns about the IPI were expressed in FDA's December 28, 1990 Safety Alert (copy enclosed).

The Vitek implants were distributed in the United States between 1973 and 1990. The implants present a hazard to the health of patients. Additionally, some of the implants were marketed without appropriate FDA clearance.

FDA has determined that masticatory forces may lead to damage of these implants. The devices contain layers of Teflon, Proplast, or various combinations of these materials which may deteriorate, flake and migrate within the body, eventually resulting in a foreign body giant-cell tumor response and bone deterioration. Patients may experience symptoms of intense pain or limited joint function, but may be asymptomatic even though active bone deterioration is occurring.

FDA has data which indicate that not all patients who have these implants have been notified of the need to be examined for bone deterioration. An MRI or CT scan will detect whether a foreign body giant-cell tumor response or bone deterioration has occurred. If the examination shows that implant integrity has been lost or progressive bone deterioration is occurring, explanting the implant may decrease further damage. The decision whether to explant should be reached after consultation with the oral

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maxillofacial surgeon. Postponing the examination or explantation may result in additional deterioration and pain for the patient. Asymptomatic patients should be re-evaluated annually.

We ask that you contact your patients as soon as possible. To assist you, we have enclosed questions and answers that are commonly asked by patients and practitioners. Because the manufacturer, Vitek Inc., is bankrupt, FDA is notifying both the domestic and foreign community of the problems so that measures can be taken to protect patients from unreasonable risks.

I would also like to alert you to the existence of problems associated with the VK-II implant. This device was initially marketed by Vitek in 1988 and subsequently by Oral Surgery Marketing, Inc., (OSMI), a successor corporation to Vitek. The VK-II has not been cleared by the FDA for commercial distribution. Safety and effectiveness data have not been submitted to the FDA. The VK-II is identical to the VK-I, with the following exceptions: the material interfacing with the fossa is Proplast hydroxylapatite (Proplast-HA), and the material on the articulating side is ultra high molecular weight polyethylene.

Because of the history of other implants containing Proplast, which often begin to exhibit problems within 24 to 36 months after implantation, I am advising you to closely monitor symptomatic and asymptomatic patients with the VK-II implant. The CT or MRI examinations are recommended to detect bone degeneration and soft tissue destruction. If the MRI is contraindicated, the CT examination is suggested. You should not continue to implant this device.

Because of the symptoms patients have experienced, they have frequently consulted practitioners such as general dentists, physical therapists specializing in facial pain, chiropractors, physicians specializing in chronic pain conditions, and plastic surgeons. Therefore, we ask that you share this information with other practitioners who may treat these patients.

The FDA has asked the Medic Alert Foundation, a nonprofit organization, to establish a centralized independent tracking system for future communications with all patients who have the Vitek TMJ implants. All information provided to Medic Alert is confidential and will be maintained in the Implant Registry. If you have questions about this Registry, please direct your inquiries to:

Medic Alert Foundation  
2323 Colorado Avenue  
Turlock, California 95380 U.S.A.

Telephone 1-209-668-1111

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Patients will be requested to pay a one-time enrollment fee of \$20.00 for the Registry. An additional \$10.00 renewal fee will be charged on the anniversary date of patient enrollment. This fee will cover the cost of routinely updating the information in the registry file. Patients who choose not to enroll in the registry will not be tracked.

The FDA has some concerns about other load-bearing devices composed of Proplast, e.g., material used for alveolar ridge augmentation, the ulnar ridge head, and the trapezium. If you encounter problems related to this material used in these circumstances, I encourage you to report them to the FDA's Problem Reporting Program by calling 1-301-881-0256. The data provided in these reports allow the FDA to identify problems and take needed corrective actions.

We appreciate your cooperation in this important public health issue.

Sincerely yours,



Ronald M. Johnson  
Director  
Office of Compliance and  
Surveillance  
Center for Devices and  
Radiological Health

Enclosures