DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 1991

Route to: OR
Medical Records
Purchasing
Risk Manager

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

Dear Health Professional:

In December 1990, the Food and Drug Administration (FDA) issued a special Safety Alert letter to oral and maxillofacial surgeons (copy enclosed), urging that they contact patients implanted with Vitek temporomandibular joint interpositional implants (TMJ/IPI). FDA is now expanding this public health advisory to include the VK and VK-I implants which are also used in the TMJ joint. These implants may pose a significant health risk, and we ask that patients be notified and then examined to monitor the condition of the implant.

Despite FDA's Safety Alert, investigation has shown that many patients were not notified about problems with the TMJ/IPI. **We are again requesting that you contact these patients if you have not already done so.** In addition, we are asking you to contact patients with the VK, VK-I and VK-II implants.

Should further investigation show that patients have not been notified, we may invoke Section 518 of the Food, Drug and Cosmetic Act. **Under this provision, health professionals may be required to notify patients.**

Here is what we are asking you to do at this time:

- If you have **not** had patients with the Vitek TMJ/IPI, VK, VK-I or VK-II:

  Respond on the enclosed form within 30 days of receipt of this letter informing us that you have not had such patients in your practice or institution.

- If you **have** had patients with the Vitek TMJ/IPI, VK, VK-I or VK-II:

  1. **Conduct clinical followup of your Vitek TMJ patients.** Screening radiography (limited skull radiography and tomograms) may be needed to detect the presence of metal associated with some of the implants. For nonmetallic

implants, MRI is the most efficient method to detect signs of foreign body giant-cell tumor response, implant deterioration, and destruction in bone and/or soft tissue. A CT scan may be used under special circumstances or when an MRI is contraindicated. The patient should be reexamined annually for as long as the implant remains in place.

If the evaluation demonstrates progressive bone degeneration or implant disruption, or if the patient demonstrates pain or occlusal changes for a period of six months or longer, the implant should be removed.

2. **Contact each of these patients** and arrange for a specialized radiological examination (i.e., **MRI** or **CT** scan) to determine whether a foreign body giant cell tumor response or implant deterioration has occurred. It is critical that proper imaging is used and sufficient views are taken to detect pathology. The MRI is recommended. If MRI is contraindicated, the CT examination can be used. If the examination shows that the implant integrity has been lost or that progressive bone deterioration is occurring, explanation of the implant should be considered.

3. **Respond on the enclosed form within 30 days of receipt of this letter informing FDA, through Medic Alert, of what actions you have taken to notify your patients.**

4. **Complete the enclosed form** with information for each of the Vitek/OSMI implant patients you have or may have had.

In order to establish a centralized independent tracking system for future communications, the names that you provide will be sent directly to the Medic Alert Implant Registry. Medic Alert will send an information packet to each patient whose name you provide. The packet includes a form that will enable patients to enroll in the Registry at a cost of $20 initially and $10 for each annual renewal. All information is confidential. The Medic Alert Foundation is a non-profit organization that was asked by FDA to maintain a registry of all patients who have the Vitek IPI, VK, VK-I and VK- II. The major benefit to you is that the registry will make it easier for the FDA to provide you and your patient with the latest medical information about these implants as soon as it becomes available.

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 for review.

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. In other devices containing Proplast material the incidence of problems often begins to appear within 24 to 36 months.

Because of the history associated with the other implants containing Proplast, I am advising you to closely monitor symptomatic and asymptomatic patients with the VK-II implant. The MRI examination is recommended as the best procedure to detect bone degeneration. However, if the MRI is contraindicated, the CT examination can be used. I urge you, do not continue to implant this device.

The FDA has some concerns about other load bearing devices composed of Proplast, e.g., material used for alveolar ridge augmentation, 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 FDA's Problem Reporting Program by calling the toll-free number 1-800-638-6725. The data provided in these reports allow the FDA to identify problems and take needed corrective actions.

We also ask that you share this information with other health care professionals, including primary care physicians or dentists, who may be caring for these patients.

To further assure that patients are notified of the potentially serious problems associated with Vitek implants, **we will be making news media announcements in the near future.** FDA will urge patients with these implants to contact their practitioners to discuss the risks involved and to avail themselves of followup care including enrollment in the Implant Registry. To assist you in these consultations we have enclosed some questions that patients may ask and suggested replies you may wish to use. The media announcements will encourage any patient or doctor wishing to receive information packets to call a toll-free telephone number established for this notification program. The toll-free telephone number, effective in September, will be 1-800-554-5297. If you have questions concerning this request you may call Mary-Lou Davis at 1-301-427-1122.

Sincerely yours,

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

Enclosures