



September 1991

**PUBLIC HEALTH NOTICE
ON
VITEK PROPLAST TEMPOROMANDIBULAR JOINT IMPLANTS**

Dear TMJ Patient:

This letter contains important health information for persons who have or have had jaw implants manufactured by Vitek. These include the temporomandibular joint (TMJ) interpositional implant (IPI), VK, and VK-I. The information contained in this letter also applies to individuals with a VK-II TMJ implant manufactured by Oral Surgery Marketing, Inc., (OSMI), a successor corporation of Vitek.

This letter describes:

- a special program for all Vitek TMJ implant patients; and
- important health-related information about your implant.

You can determine whether you have or had a Vitek implant by contacting your implanting surgeon or hospital for the name of your implant. If you were reimbursed by your insurance company, you can contact them for the information about your implant, but be sure to give them the date of your implant surgery.

THE MEDIC ALERT SPECIAL PROGRAM FOR VITEK TMJ PATIENTS

At the request of the Food and Drug Administration (FDA), Medic Alert Foundation has established a special registration program for all Vitek TMJ patients. The Registry is a service which maintains current addresses and certain health information about its members. The information maintained by the Medic Alert Registry is confidential. We urge you to join this Registry.

The benefits of joining this registry are:

- to receive the latest medical information about your implant as soon as it becomes available, as well as future information about any persisting symptoms and their treatment after the implant has been removed.
- to inform you and your doctor of news about other devices that may serve you better if they become available.
- to ensure that you receive continuing information in the event your present doctor is no longer available to you.
- to assist the FDA in locating you and your doctor should we need to contact you in the future. Neither the FDA nor the manufacturer knows who or how many individuals received these implants.

The initial enrollment fee you will be requested to pay will be \$20.00. On your enrollment anniversary date (12 months after you first joined) there will be an annual \$10.00 renewal charge to compensate for the cost of updating the information in your registry file.

Enclosed is additional information about the Registry and the benefits of joining.

To join Medic Alert's International Implant Registry, fill out and return the enclosed form. If you wish more information about the registry, call toll-free, 24 hours a day, 7 days a week: 1-800-554-5297.

IMPORTANT HEALTH-RELATED INFORMATION ABOUT YOUR VITEK TMJ IMPLANT

Your Vitek implant replaces parts of your temporomandibular joint (TMJ). Just as your TMJ no longer functions because of disease or trauma, the implant can also break apart and not function properly. The forces from chewing can cause the material to fragment. This can cause the bone to deteriorate, resulting in a variety of symptoms which are described in the question and answer enclosure.

Recent studies of the Vitek TMJ/IPI implant show that of 51 implants, 37 (73%) were removed because the implant had fragmented. Additional studies show a similar pattern with the other Vitek TMJ implants. Because your implant can fail, sometimes without any symptoms, FDA urges you to contact your doctor to be examined with a special type of x-ray. The VK-II implant contains some of the same material found in the implants manufactured by Vitek, and was sold without permission of the FDA. If you have a VK-II implant, I encourage you to follow the advice contained in this letter.

We know you will have many questions about this letter and what it means to you. Your doctor knows your specific medical/dental situation and can best answer your questions. You may wish to use the enclosed questions and answers as a basis for discussing your implant with your dentist or surgeon.

It is very important that you discuss any questions you may have with your surgeon and/or dentist. Please do not direct your medical questions to Medic Alert.

The FDA has clinical information available for all dentists and other health professionals. This information has been given to Medic Alert to send to your doctor at no charge if he or she calls 1-800-554-5297.

FDA would like to evaluate the success of this patient notification program. Because the Medic Alert Foundation is very strict about patient confidentiality, it is necessary that you give Medic Alert permission to provide your name and address to the FDA. This will enable the FDA to contact you in the future to ask a few questions about the program. FDA will also keep your identity confidential.

To enroll in the Registry and give Medic Alert permission to release your name and address to the FDA requires two signatures:

- Sign in the space in item number 7 of the enrollment form to enroll in the Registry;
- Sign the permission line found in the box at the bottom of the Registry enrollment form to allow FDA to contact you.

You should know that granting permission to Medic Alert to provide the FDA with your name and address does not automatically enroll you in the International Implant Registry.

Again, we urge you to:

1. Consider enrolling in Medic Alert's International Implant Registry set up for Vittek implant patients.
2. Contact your surgeon or dentist for a clinical examination and a CT or MRI evaluation.
3. Discuss the information in this letter with your surgeon or dentist.
4. Consider granting permission to the Medic Alert Foundation to provide the FDA with your name and address for program evaluation.

Sincerely yours,

A handwritten signature in black ink that reads "James S. Benson". The signature is written in a cursive style with a large, looped initial "J".

James S. Benson
Director
Center for Devices and
Radiological Health

Enclosure

Sample Questions and Answers about TMJ Implants

How can I find out what kind of implant I have?

Contact your implanting surgeon and/or hospital for the name of the implant. If you were reimbursed by your health insurance company, they should also have the information.

What should I do if I have a Vitek TMJ Implant?

Contact your implanting surgeon or another oral maxillofacial surgeon to schedule a clinical examination and have an MRI or CT examination if you have not had one within the last six months.

What is the problem with the Vitek TMJ Implants?

Vitek implants are composed of Proplast and other materials. These materials have been shown to either break apart or fail to function because of the forces caused by chewing.

Because the materials break apart (fragment), it may be very difficult to remove all particles and some symptoms may persist after surgical removal of the implant. Additional medical treatment may be required.

What are the common symptoms associated with the Vitek TMJ Implants?

Symptoms may vary widely, and in some cases, may mimic sinus infections, ear infections, and/or loss of hearing. *In some cases there are no symptoms even though the implant is failing.*

The most common symptoms are:

- pains near the ear on the side where the implant has been placed and/or headaches;
- limited lower jaw movement along with a change in the bite or the way the teeth meet;
- joint noise in the jaw;
- nausea, dizziness, or ringing in the ear; and,
- increased sensitivity in the head, neck and shoulder.

If I don't have any problems with the implant, should I still make an appointment?

Yes. Changes, such as bone loss, can occur even without symptoms. These changes can only be found through careful medical evaluation.

What should I do if I have the symptoms described earlier?

Contact your implanting surgeon or the surgeon who now treats you. Schedule an appointment for a clinical examination and a CT or MRI examination. Screening radiography (limited skull radiography and tomograms) may be needed to determine if metal was used with some of the implants. For nonmetallic implants (those without metal), MRI will help to discover if there are signs of foreign body giant cell tumor response, implant break down, and/or destruction in bone and/or soft tissue. A CT scan may be used under special circumstances or when an MRI is not advisable. Depending on the results of these examinations, it may be necessary to remove the implant as soon as possible. *Speedy removal will prevent further damage.*

What if I'm not having symptoms, should I have the implant removed now to avoid future problems?

Not necessarily, but you should be followed routinely. However, if there is evidence that the implant is breaking up, the implant should be removed if possible, even if you have no symptoms. If you are experiencing pain or a change in your bite, this may be a sign that the implant is breaking up and removal should be considered. Contact your implanting surgeon or the surgeon who now treats you.

What alternatives to the Vitek TMJ implants are currently available?

The use of the patient's own bone grafts have shown success in certain cases. There are other options available, but for the best option for you, please consult with your implanting or oral maxillofacial surgeon.

If I've had my implant removed, should I still make an appointment with my physician?

No, but if you experience any of the symptoms, make an appointment.

If I've had my Implant removed, do I need to enroll in the registry?

Yes, enroll in the registry. There may be situations where because of the difficulty in removing all the particles, soft or bone tissue changes may still occur. The registry will allow you to receive additional information should it become available.

What is the cost of joining the registry?

There is an enrollment fee of \$20. On your enrollment anniversary date (12 months after you first join the registry), there is a \$10 renewal charge to maintain your records.

Why do I have to pay the registry fee?

Ordinarily, Vitek, the manufacturer of these TMJ devices, would be responsible for the patient notification program. However, the company has declared bankruptcy and has been unable to finance this program.

How can I find an oral surgeon for consultation?

Call your local or State dental society or a major medical or dental school in your area.

Where do I sign on the enrollment form?

There are two places for your signature on the form:

- To grant permission to Medic Alert to release your name to the FDA, sign in the box at the bottom of the registry form.
- To enroll in the International Implant Registry (IIR), sign in the space under item number 7.

You should know that granting permission to Medic Alert to provide the FDA with your name and address does not automatically enroll you in the International Implant Registry (IIR).

I don't know about others, but I was never sent one of these Q & A's.

Clinical Information on the Vitek TMJ Interpositional (IPI) Implant and the Vitek-Kent (VK) and Vitek-Kent I (VK-I) 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 followup 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.

Recommendations

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, VK 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.

References

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10. Kent, J.N., and Block, M.S., "Comparison of FEP and UPE Glenoid Fossa Prosthesis," Abstract, International Association of Dental Research, 1991.