

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.