

TMJ Implants

A Consumer Information Update

April 2001

Dear Reader:

This is an updated introductory letter from the current 1999 TMJ implant consumer handbook entitled, "TMJ Implants – A Consumer Informational Update -- 1999." While the Food and Drug Administration (FDA) is in the process of updating the handbook, we want to provide you with some new updates and the current information.

Background:

The FDA's regulation of new medical devices entering the market began with the 1976 Medical Device Amendments. Temporomandibular Joint (TMJ) implants are pre-Amendments devices, meaning they entered the market before 1976. This allowed sale of TMJ implants marketed before May 28, 1976 to continue without demonstrating safety and effectiveness. These devices introduced after 1976 required FDA clearance. In 1993, the Dental Products Advisory Panel reclassified them into Class III – the highest risk category. This means that all manufacturers of TMJ devices would be required to submit a Premarket Approval Application (PMA) – demonstrating safety and effectiveness – when called for by the FDA. On December 30, 1998, the FDA called for PMAs from all manufacturers of TMJ implants.

- On May 11, 1999, the Dental Products Advisory Panel evaluated PMAs for two TMJ implants.
- On July 2, 1999 TMJ Concepts total TMJ Prosthesis received FDA Premarket approval (PMA). It is indicated for reconstruction of the temporomandibular joint for use in patients with one or more of the following conditions: inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment; recurrent fibrous and/or bony ankylosis not responsive to other modalities of treatment; failed tissue graft; failed alloplastic joint reconstruction; and loss of vertical mandibular height and/or occlusal relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion. Further information is available at: <http://www.fda.gov/cdrh/pdf/p980052.html>.

New Information:

- The TMJ Implants, Inc. TMJ Fossa-Eminence/Condylar Prosthesis System received FDA Premarket (PMA) approval on January 5, 2001. This device is indicated for reconstruction of the natural temporomandibular joint (TMJ). The device is indicated if patients have one of more of the following conditions: inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment; recurrent fibrous and/or bony ankylosis

not responsive to other modalities of treatment; failed tissue graft; failed alloplastic joint reconstruction; loss of vertical mandibular height and/or occlusal relationship due to resorption, trauma, developmental relationship due to bone resorption, trauma, developmental abnormality, or pathologic lesion. Further information is available at: <http://www.fda.gov/cdrh/mda/docs/p000023.html>.

- On October 6, 2000, the Dental Products Panel met to evaluate the PMA for a Fossa-Eminence/Prosthesis by TMJ Implants Inc. which is indicated for the partial joint reconstruction under very specific restrictions.
- TMJ Implants, Inc. TMJ Replacement Prostheses Fossa-Eminence/Prosthesis received FDA Premarket Approval (PMA) on February 27, 2001. The Fossa-Eminence Prosthesis is indicated for use in treatment of severe temporomandibular joint disease due to: inflammatory arthritis involving the temporomandibular joint not responsive to other modalities of treatment; recurrent fibrosis and/or bony ankylosis not responsive to other modalities of treatment; failed tissue graft; failed alloplastic joint reconstruction; and internal derangement confirmed to be pathologic in origin by both clinical observation and radiographic findings, where the patient has moderate to severe pain and/or disabling dysfunction and has not responded to less invasive conventional therapy. Further information is available at: <http://www.fda.gov/cdrh/mda/docs/p000035.html>.

The Handbook:

The handbook contains information about TMJ implants to assist you in making an informed decision when considering the use of these devices. It includes topics such as availability of TMJ implants, potential risks, answers to the most frequently asked questions by consumers, reporting of serious problems, chronology of FDA activities related to TMJ implants, and TMJ implant resource groups.

The Consumer Affairs Staff of the Office of Health and Industry Programs (OHIP) is responsible for answering TMJ implant calls and distributing the TMJ implant handbook. The TMJ implant handbook may also be obtained by visiting FDA's web site at <http://www.fda.gov/cdrh/consumer/tmjupdate.html>.

The Consumer Affairs Staff at OHIP is available Monday through Friday, 8:00am to 4:30pm Eastern Standard Time (EST). To contact a Consumer Affairs Specialist, use one of the following options:

- Call 301-827-3990.

To speak to a Consumer Affairs Specialist during business hours, press 2, press 2, and then press 4.

•Call 1-888-463-6332.

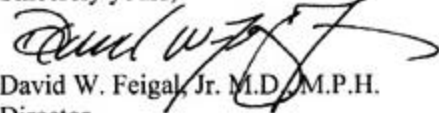
When prompted, press 1, press 3, press 2, press 4, and press 1. Then, to speak to a Consumer Affairs Specialist during business hours, press 5, or to request information outside of business hours, press 4 and leave a message.

•Fax 301-443-9535.

•Email DSMA@cdrh.fda.gov

We hope this information will be helpful to you. You may duplicate it for further distribution without permission. If you have any comments regarding the TMJ implant handbook, please write to us at FDA, Office of Device Evaluation, Division of Dental, Infection Control, and General Hospital Devices, 9200 Corporate Boulevard, HFZ-480, Rockville, MD 20850.

Sincerely yours,

A handwritten signature in black ink, appearing to read "David W. Feigal, Jr.", written in a cursive style.

David W. Feigal, Jr. M.D./M.P.H.
Director

Center for Devices and Radiological Health

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BACKGROUND

The Food and Drug Administration (FDA) was given the responsibility for regulating medical devices, such as Temporomandibular Joint (TMJ) implants, under a law called the Medical Device Amendments of 1976. The law requires manufacturers of new medical devices to first show that they are safe, effective and properly labeled before the devices are allowed on the market.

Devices in use before the 1976 law, including TMJ implants, were allowed to stay on the market. Under the law, manufacturers can inform FDA that a product they plan to market is substantially equivalent in safety and effectiveness to a product that is already legally marketed via the premarket notification [510(k)] process. Applicants submit descriptive data and, when necessary, performance data to show that their device is substantially equivalent to the legally marketed device.

The law also directed that eventually FDA would require scientific evidence of the safety and effectiveness of many of these pre-1976 devices. TMJ implants were among the products allowed to remain on the market until FDA called for safety and effectiveness data. (See page 13 for a chronology of FDA activities.)

AVAILABILITY OF IMPLANTS

What is the current status of TMJ implants presently on the market?

Presently there are three TMJ implants on the market: the Morgan and the Christensen, which were on the market prior to the enactment of the medical device law in 1976, and the Anspach Total Temporomandibular Implant (formerly known as the Techmedica Implant, and now distributed through TMJ Concepts), which received premarket notification (510(k) clearance on July 17, 1996.

On August 29, 1993, FDA's Device Tracking regulation became effective. Therefore, the Anspach 510(k) clearance required device tracking and postmarketing surveillance. The tracking provision is intended to ensure that manufacturers can quickly remove potentially dangerous or defective devices from the market and/or notify patients of significant device problems. Manufacturers of certain devices, including TMJ implants, must establish tracking systems, which will enable them to promptly locate devices in distribution.

What does the FDA know about the safety of TMJ devices that are on the market?

FDA has taken the necessary steps to require manufacturers to provide data in order to evaluate the device's overall safety and effectiveness. In December of 1994 the agency classified TMJ implants into Class III.¹ Class III is the class of devices which presents the most risks, and FDA requires clinical data and in depth review for approval. The purpose of classifying a device into Class III is to require each manufacturer of the device to submit data in support of its safety and effectiveness in a premarket approval application (PMA) to the FDA. Each application must include sufficient scientific evidence to provide reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in its proposed labeling. This information must include clinical data.

On December 30, 1998 FDA published a final regulation in the *Federal Register* that requires manufacturers of all TMJ implants that want to remain in or enter the marketplace to submit PMA's with data showing the safety and effectiveness of the implants. The PMA's must be submitted no later than 90 days after the date of publication in the *Federal Register*.

INFORMATION

Medical Condition

Temporomandibular disorders (TMD) refer to a medical and dental condition in which pain and discomfort affect the temporomandibular joint (TMJ) and/or the muscles, as well as contiguous tissue components. For some patients this pain is severe and unrelenting. The symptoms include clicking or popping of the jaw joints, pain in or around the jaw joints, locking or limited opening of the mouth, headaches, pain behind the eyes, dizziness, earaches or ringing in the ears, clenching or grinding of the teeth, neck, shoulder or back pain, and numbness, or tingling of the fingers. Although epidemiological data are inadequate, the total number of TMD sufferers in this country can be roughly estimated at more than 10 million. It is a complex medical condition which is very difficult to treat. Vigilance by both patients and health professionals is necessary in its treatment. At the Technology Assessment Conference at the National Institutes of Health held April 29-May 1, 1996, it was stated that "concern about safety and efficacy of the care provided to patients with TMD requires that both clinicians and patients achieve a better understanding of these health problems. The absence of clear, valid, and reliable guidelines for

¹ FDA has three regulatory categories for medical devices. Class I and Class II are for devices whose safety and effectiveness is well-established. Class I devices are simple devices whose risks can be controlled by the manufacturing process; class II devices require additional measures, called "special controls," to control risks. Special controls may include performance standards, postmarket surveillance studies, user education or other measures. If there is a lack of information about what makes a device safe and effective, it is put into class III and the highest level of premarket review is required. Class III devices include innovative, medical breakthrough and new technology devices, as well as devices with poorly established or questionable safety and effectiveness.

diagnosis and the dearth of proven rationales for a full range of treatment methods means that potentially many patients and practitioners may attempt therapy with approaches that have not been adequately tested in scientifically-based research studies.”

Total joint replacement should never be the first line of treatment for TMD. FDA does, however, recognize that there is a population of patients for whom non-surgical treatment of diagnosed temporomandibular disorders is not a viable option. This subset of patients has had a variety of previous nonsurgical treatments and has also had at least one previous surgical procedure. These surgeries may have resulted in failed Teflon\Proplast or other types of alloplastic joint reconstruction, or failed autogenous bone graft reconstruction. Often these patients have experienced numerous surgeries to one or both joints. The original presenting complaint is often clouded because numerous surgical procedures have complicated the diagnostic picture. Inflammatory and/or immunological responses in some of these patients may preclude further reconstruction with bone from the patient. These patients often present with severe pain and extremely limited function. The population in need of surgical reconstruction may also include patients with severe trauma to the temporomandibular joint, neoplasms (tumors), congenital deformities, ankylosis or arthritis involving the TMJ, rendering it dysfunctional.

The Implant

Total Joint IPI

Over time a variety of artificial materials have been used to reconstruct the TMJ, including plastics, teflon, silicone, various types of metals, and some combination materials. The implant may take many different forms. Some implants are intended to replace the temporomandibular joint disc, and other implants are intended to replace the entire joint. If an implant is intended to replace the entire joint, it will attach to the bottom jaw (mandible) and the skull. The purpose of these types of implants is to restore the patient’s functioning. This includes opening and closing the mouth, and chewing. Implants, however, are not ideal and all of the movements of a normal joint may not be possible with an artificial joint.

Although an artificial joint may be able to restore much of the joint function, it may not always address the pain which is the chief complaint of many patients. The reasons that pain may not be reduced are complex. There appears to be a direct relationship between the number of surgeries that a patient has had and the pain that is experienced. In other words, with more surgeries there is more pain. It is therefore important for patients to understand the limitations of joint replacement surgery.

TMJ implants that are intended to replace the entire joint are typically made from a metal or a combination of metals. These include cobalt, chrome and titanium. In addition to the metal portions, the joint may also have a plastic portion that is composed of acrylic or of ultra high molecular weight polyethylene.

The designs of implant vary depending on the manufacturer. The joint may be entirely composed of metal or have the “plastic” portion on the condylar head or in the fossa portion of the implant.

All implant materials degenerate over time. The challenge to the research community is to develop the most functional device from materials that are biocompatible and durable. Future research will include ways to develop biological alternatives, such as implanting cells that will grow new bone and or cartilage.

THE SURGERY

The Procedure

The surgical procedure to place a total TMJ prosthesis typically involves admission to a hospital and surgery under general anesthesia. Several different incisions may be made to access the area of the TMJ. The incisions are commonly just in front of the ear and under the lower jawbone.

In total joint replacement surgery the condylar head from the natural joint is removed and the artificial joint is attached to the lower jaw with screws. The fossa portion of the implant is also attached with screws to the portion of the skull that is just in front of the internal bony portion of the ear. (See diagram on Page 3.)

Recovery

Recovery time varies depending on individual patient factors. Following surgery, the surgeon will probably recommend a specific diet and series of exercises to help regain function. It is very important for the patient to work closely with the surgeon to achieve optimal results.

Post Surgery Expectations

Patients may have unrealistic expectations for total joint replacement surgery. The results of such surgery vary considerably and as stated previously, the outcome of surgery is often directly related to the number of previous surgical procedures that a patient has experienced. The desired outcome from surgery is generally increased function and decreased pain. The surgery itself is just the first step to recovery. Patients may need further pain management and physical therapy to achieve improved results.

What questions should patients consider asking when discussing TMJ surgery with the surgeon?

Patients should discuss with the oral surgeon the risks and benefits before implanting any device. Some questions patients may want to ask include:

- How long has this device been on the market?
- Does the labeling on the device indicate that this is a temporary or permanent implant?
- If temporary, how long is the implant intended to remain functional?
- What are the possible complications of having the device implanted?
- What are the advantages of having the device implanted?
- Are there alternatives to surgery? What are they?
- Is this the right implant for me and why?
- What kind of problems have been reported with this device?
- Who should I tell if I have a problem?
- What kind of records should I keep?
- Are there changes in my appearance that I should know about?
- What are the advantages and disadvantages to surgery?
- Given my condition, am I a candidate for alternative therapies?
- What effect does MY medical history have on the outcome of this surgery?
- Does my insurance cover this kind of surgery and implant?

REPORTING SERIOUS PROBLEMS TO FDA

Should a patient experiencing a problem report it?

If you believe that you have experienced a serious adverse reaction related to your TMJ implant, you should report to the FDA. Although we encourage consumers to report their problem through their health care providers, you may report directly to FDA through the MedWatch voluntary reporting system. For more information on MedWatch and how to file a report, see page 26.

How many reports of adverse reactions (problems) has FDA received?

From 1984 through June 15, 1998, FDA has received 434 adverse event reports or Medical Device Reporting (MDR's) for TMJ implants. Of these reports, 58% are associated with patient injuries, 28% are associated with device malfunctions, 14% are uncoded or coded as "other," and no reports are associated with patient deaths. Over 75 per cent of the 434 MDR's are reports citing two manufacturers, Dow Corning and Vitek, and both companies no longer manufacture TMJ implants. TMJ Implants, Inc., a firm currently manufacturing TMJ implants, is cited in 14% of the MDR's.

Most of the MDR's received on TMJ implants (74%) were received between 1992 and 1995. Thirty percent of all reports were received in 1994; since then, the number of TMJ implant reports received has declined dramatically, with only 15% of all reports being received since January of 1996.

The most frequent patient problems reported in MDR's received since January 1996 include surgery to remove implants, pain, foreign body reactions, and loss of range of motion. Most device problem coding (58%) of this same group of reports cites removal or explantation of implant and/or reaction.

Several graphs on pages 24-25 help illustrate the above information.

QUESTIONS FREQUENTLY ASKED BY PATIENTS WITH TMJ IMPLANTS

What is FDA's role in regulating devices such as jaw implants?

The FDA is a regulatory agency charged with helping to ensure the safety and effectiveness of drugs and medical devices. FDA's primary authority in the medical area is over the manufacturers of medical products. FDA assesses new drugs and devices before they are marketed and monitors their subsequent performance, taking action when problems are discovered.

However, the FDA does **NOT**:

- have direct authority over medical practice issues;
- recommend types of treatment or recommend a doctor;
- have authority over lawyers or legal practice issues;
- have authority over reimbursement policies of insurance companies.

What can a patient do if his or her surgeon dismisses complaints or will no longer treat the patient?

Patients can write their state dental association or the American Association of Oral and Maxillofacial Surgeons (AAOMS), explaining the circumstances.

The address for AAOMS is:

American Association of Oral and Maxillofacial Surgeons
9700 West Bryn Mawr Avenue
Rosemont, Illinois 60018-5701
Website: <http://www.aaoms.org>

Resource organizations are listed on page 18 for further information. To find out how your name can be placed on a mailing list, call or write to one of these organizations.

If a patient cannot find a surgeon who will accept him or her for treatment, what recourse do patients have?

Patients can contact the dental school at a university or call their state dental association.

Will FDA send information to patients?

Yes. Although FDA does not maintain a mailing list, you may contact FDA to receive updated information by calling 1-888-463-6332 or writing:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs
Division of Small Manufacturers Assistance
Consumer Staff, HFZ-210
1350 Piccard Drive
Rockville, MD 20850
Website: <http://www.fda.gov/cdrh/consumer/tmjupdate.html>

What is being done to make it easier for patients who will be receiving implants in the future to be notified of device problems?

FDA's Device Tracking Regulation became effective on August 29, 1993. The regulation requires manufacturers, distributors, and hospitals to establish systems to track those medical devices, including jaw implants that are subject to the regulation. Manufacturers should be able to locate patients who receive jaw implants through these tracking systems. Patients should notify their doctors or the manufacturer of any changes in their residency in order to facilitate location and notification by manufacturers.

QUESTIONS FREQUENTLY ASKED BY PATIENTS WITH VITEK IMPLANTS

How did Vitek devices get on the market?

As mentioned earlier, FDA was given the authority to regulate medical devices including TMJ implants in 1976. Devices on the market before 1976, including some TMJ implants, were allowed to remain on the market. Under the law, manufacturers can inform FDA that a product they plan to market is substantially equivalent to a product that was on the market before 1976. If FDA decides that the new device is equivalent, it can be marketed.

In March 1983, Vitek notified FDA that it was planning to market the Interpositional Implant (IPI) to treat TMJ problems. The firm claimed that it was substantially equivalent to an existing product, silicone sheeting, which was also used as a TMJ implant. FDA agreed with the manufacturer's claim of equivalence and the IPI device was allowed to be marketed.

What were the Vitek products composed of?

The products were composed of a combination of materials with the composition changing over time. To determine the composition of a patient's implant, the patient may need to investigate hospital and doctor records.

<u>Product</u>	<u>Composition</u>
Proplast I,II or HA Sheeting or blocks	Composite of Polytetrafluoroethylene (PTFE) Aluminum Oxide (II) or Hydroxylapatite (HA) from which various devices were formed by surgeons
IPI (interpositional implant)	Proplast I or II with polyamide or polyester fiber and teflon or silicone or fluorinated ethylene propylene copolymer
VK	Proplast I or II with polyamide or metallic mesh. Layer 1 composed of Proplast I or II with polyamide or metallic mesh laminated with nonporous Polytetrafluoroethylene (PTFE). Layer 2 composed of nonporous PTFE or teflon or fluorinated ethylene-propylene copolymer
VKI or V-I	Condyle: Cobalt-Chromium Molybdenum alloy with proplast on the condyle Fossa: Polyamide fiber and teflon or fluorinated ethylene-propylene copolymer
VK-II or V-II	Condyle: Cobalt Chromium- Molybdenum alloy with proplast on the condyle Fossa: Proplast HA with ultra high molecular weight polyethylene (UHMWPE)

What are the problems and symptoms patients are reporting with Vitek Proplast devices?

Patients are experiencing a variety of problems. These problems include:

- severe pain around the ear and in the jaw area;
- radiographic evidence of severe bone loss to the condyle and glenoid fossa;
- limited lower jaw movement;
- bone degeneration/soft tissue deterioration;
- joint noise in the jaw;
- nausea, dizziness or ringing in the ear;
- fragmentation and/or displacement of the implant;
- infection; and
- vision and hearing problems.

What should patients do who are not having a problem with the Vitek implant? Should they consult with their doctor on a regular basis?

At this time, it appears likely that all of the implants will experience some disintegration (breaking down). It is strongly recommended that patients schedule semi-annual appointments to be examined clinically and have an appropriate MRI or CT scan (if the implant contains metal) conducted annually. If there are indications of device failure, the device should be removed.

If patients have had the device removed and continue to have problems, what should they do?

A number of patients have continued to experience problems after the device has been removed due to device fragmentation and small particles remaining in the jaw or surrounding tissue. Patients who are experiencing problems should continue to be monitored closely by their oral surgeon and other professionals.

Is there long term harm from Proplast fragments in the body?

More research is needed to determine whether there are long term health effects as a result of small particles of Proplast remaining in the body for long periods of time.

The National Institute of Dental and Craniofacial Research (NIDCR) is conducting a study of patients with failed implants to help find the answer. No additional patients are being enrolled at this time. Please contact them for information on the study at (301) 496-4261 or at www.nidr.nih.gov.

In April 1994 FDA, in collaboration with the NIDCR, held an international workshop on Temporomandibular Disorders and Related Pain Conditions. The Proceedings from the meeting have been published in a book available from the International Association for the Study of Pain (IASP) Press at:

International Association for the Study of Pain
909 Northeast 43rd Street, Suite 306
Seattle, Washington 98105
206-547-6409
Website: <http://www.halcyon.com/iasp> (under publications)

In addition, FDA has participated in the following conferences:

Satellite Workshop to the International Workshop on the TMD's and Related Pain Conditions (TMJ Alloplastic Implants and Local and Systemic Response)
September 12-13, 1994.

NIH Workshop - Biomaterials and Medical Implant Science:
"Present and Future Perspectives October 16-17, 1995."

NIH Technology Assessment Conference: "Management of Temporomandibular Disorders" April 29-May 1, 1996.

These conferences sought the basic science research agenda and treatment methodology questions that should be addressed.

In the past FDA sent a notice about Vitek to physicians. Is there new information on this notice?

No, there is no new information. On December 28, 1990 FDA issued the first safety alert to all oral and maxillofacial surgeons warning them of serious problems. On July 15, 1994 FDA sent a letter to physicians who treat TMJ patients and informed them of problems with TMJ implants. The letter went to orthopedic surgeons, otolaryngologists, and plastic and reconstructive surgeons because these physicians may treat TMJ implant patients. FDA wanted to make sure these physicians were aware of problems with TMJ implants so they may be able to better treat a TMJ patient.

Silastic

QUESTIONS FREQUENTLY ASKED BY PATIENTS WITH SILASTIC TMJ IMPLANTS

How did Silastic get on the market?

Silastic sheeting was on the market prior to 1976 when FDA received authority to regulate medical devices and thus was allowed to stay on the market.

What is the problem with Silastic?

Reports indicate that Silastic breaks apart when it is placed under a load. A load could be biting pressure or grinding of the teeth.

What problems and symptoms are patients reporting with Silastic?

Patients have reported the following problems:

- necrosis (localized death of living tissue);
- chronic pain;
- various blood disorders;
- foreign body reaction and immune inflammatory response;
- bone and tissue deterioration; tissue granulation (tissue made up of blood bearing cells which form grainy - like projections on the surface of a healing wound, ulcer, or inflamed tissue surface); and
- facial numbness.

There are no long term studies or data to demonstrate safety or effectiveness in these products when used in the TMJ Implant.

What should patients with Silastic implants do if they are having problems?

Patients should make an appointment with their oral surgeons for an immediate evaluation which may include an MRI, or if the device contains metal, a CT scan. There is the possibility that the implant may have to be removed.

If patients are not experiencing problems, should they do anything?

Even if patients are not experiencing problems, they should consult with their oral surgeons on a regular basis.

Will all patients have problems with their Silastic implants?

It is unknown at this time if all patients will have problems. Many factors play a role in this issue, including: length of time an implant is in place; the anatomical configuration of the patient's joint; and how force is applied in the jaw area by actions such as chewing.

Is there a connection between the kind of silicone used in jaw implants and connective tissue diseases and immune-related disorders?

There has been some concern that silicone gel of the type used in breast implants may have been used in the manufacture of TMJ implants and thus may be connected with certain conditions such as connective tissue diseases and immune-related disorders. Silicone gel was not used in jaw implants.

Scientific knowledge is incomplete concerning all of the potential health consequences associated with TMJ implant failure.

Are Dow Corning Silastic implants still on the market?

No. On June 15, 1993 Dow Corning discontinued the marketing of H.P. sheeting, Silastic TMJ implants, and medical grade sheeting and block material.

Other manufacturers are marketing silicone sheeting that is indicated for a variety of uses. FDA is presently working with manufacturers to appropriately label silicone sheeting with warnings against its use in the TMJ implant.

CHRONOLOGY OF FDA ACTIVITIES RELATED TO TMJ IMPLANTS

- May 28, 1976 -The Medical Device Amendments were enacted giving FDA authority to regulate medical devices, such as TMJ implants, which were already on the market.
- March 1983 - Vitek, Inc. notified FDA that it was planning to market the Interpositional Implant (IPI) to treat TMJ problems. The firm claimed that it was substantially equivalent to an existing product, silicone sheeting, which was also used as a TMJ implant. FDA agreed with the manufacturer's claim of equivalence and the IPI device was allowed to be marketed.*
- 1988 - FDA became aware of complaints about the IPI implants and explants showing bone resorption, implant fragmentation and delamination.
- October 1989 - FDA issued Vitek, Inc., a regulatory letter for medical device reporting (MDR) and good manufacturing practices (GMP) violations.
- January 26, 1990 - FDA issued a letter to Vitek, Inc. advising them to warn all oral surgeons of record against implanting further devices and monitoring their patients until further clinical data was evaluated demonstrating long term safety and effectiveness.
- March 23, 1990 - Vitek, Inc., issued a "Dear Doctor" letter informing doctors of the hazards associated with the IPI product and advising them to closely monitor all patients by clinical and radiographic examination. FDA classified this action as a voluntary safety alert.
- June 1990 - Vitek, Inc., filed for bankruptcy. Oral Surgery Marketing, Inc. (OSMI) and Novamed, Inc., were created.
- July 27, 1990 - FDA issued Vitek, Inc., a letter informing it that its voluntary safety alert was ineffective. An audit check of the safety alert disclosed that some consignees were never notified.

* FDA was given the authority under the Federal Food, Drug and Cosmetic Act to regulate medical devices in 1976, including TMJ implants. Devices on the market before 1976 were "grandfathered"; that is, they were allowed to remain on the market. Under the law, manufacturers can inform FDA that a product they plan to market is substantially equivalent to a product that was on the market before 1976. FDA must then make the final decision about the equivalence. If FDA decides that the new device is equivalent, it can be marketed.

- December 28, 1990 – FDA reclassified Vitek, Inc.’s voluntary safety alert to a Class I recall and issued a safety alert to all oral and maxillofacial surgeons warning of serious problems with proplast-coated TMJ implants manufactured by Vitek, Inc. and Oral Surgery Marketing, Inc. The FDA alert urged surgeons to refrain from using the device and to return all unused devices to the bankruptcy trustee for Vitek, Inc. The alert also advised surgeons to monitor all patients on a regular basis for possible loss of implant integrity and/or progressive bone degeneration.
- January 7, 1991 - FDA issued a press release announcing a recall of Vitek Inc.’s jaw implants, describing the possible health hazard associated with the product. The release encouraged all people with implants to contact their implanting dentist and urged all dentists to reexamine their patients to see if the implants should be replaced. It also directed oral surgeons to return all unused implant to the bankruptcy trustee.
- March 1991 – FDA received a Public Citizen/Health Research Group petition requesting that all patients with TMJ implants be alerted of associated risks.
- March 1991 – FDA conducted a mass seizure of all OSMI/Novamed articles and devices composed of proplast. A Federal judge subsequently ruled in favor of FDA. The seized articles were forfeited to FDA.
- October 1991 – FDA initiated the Patient Notification Program for Vitek’s IPI implant. This involved a mass media campaign to publicize problems associated with proplast devices. This effort included press and video news releases, notification to professional and consumer journals and magazines, and letters to oral surgeons and related health care professionals.
- June 1992 - FDA ordered Novamed, Inc., and Oral Surgery Marketing, Inc., (subsidiaries of Vitek then defunct) to immediately notify all customers to cease distribution and use of replacement devices for the TMJ joint, VK, VK-1, and VK-11, and blocks and sheets of proplast used in weight-bearing positions in the body. The firms were also ordered to contact all health professionals and device user facilities currently in possession of the devices and inform them of FDA’s order concerning the devices and instruct them to cease use of these devices in the TMJ joint. FDA determined that the firms made an inadequate effort to comply with this order.
- June 29, 1992 - FDA/CDRH staff met with representatives of AAOMS to discuss patient abandonment, reimbursement issues, and recommendations for patient follow-up and future research efforts. AAOMS agreed to distribute a "TMJ Implant Advisory" to more than 6,000 AAOMS members and to publish the "Advisory" in their Journal.
- July 7, 1992 - FDA/CDRH staff met with representatives of the Health Insurance Association of America to discuss insurance coverage for TMJ-related disorders.
- September 1, 1992 - FDA published a proposed regulation classifying the IPI, condylar and fossa prostheses into Class III.

- September 18, 1992 - FDA published a proposal in the *Federal Register* to reclassify TMJ Implants and components including interpositional use, from Class II to Class III devices.
- October 1992 - At FDA's request, the Medic Alert International Implant Registry established an 800 number for patients and physicians to request information about Vitek TMJ implants and to join a registry.
- October 30, 1992 - FDA participated in NIDR workshop to develop a surveillance instrument for assessing the frequency, cost, and effects of TMJ surgery in the U.S.
- November 28, 1992 - "FDA Needs Your Help" was exhibited at the Greater New York Dental Meeting. This exhibit alerted doctors to the need to notify patients with Vitek implants to call Medic Alert and enroll in the registry.
- December 2, 1992 - FDA notified Dr. Christensen that the Christensen Fossa and Condylar prostheses have pre-Amendment status.
- December 7, 1992 - FDA Inspection of Dow was requested due to consumer reports of problems associated with the Wilkes design and Silastic sheeting (35 MDR/PRP reports).
- December 29, 1992 - FDA notified all six TMJ manufacturers that two TMJ devices are pre-Amendments devices, which allows the other four companies to market their devices through the premarket notification [510(k)] process instead of the more rigorous premarket approval (PMA) process.
- February 11, 1993 - The Dental Devices Panel met and reaffirmed FDA's position to reclassify TMJ implants as Class III devices.
- April 4, 1993 - FDA issued a warning letter to Dow citing the need for the submission of 510 (k)s for the Silastic HP sheeting, Medical Grade Sheeting and Wilkes design. Dow responds that, effective March 31, 1993, they discontinued marketing all implant-grade silicone.
- June 9, 1993 - FDA notified Dr. Morgan that his TMJ implants have pre-Amendments status.
- June 18, 1993 - A 510(k) for a TMJ implant was received from Osteomed.
- Summer 1993 - FDA's Office of Compliance authorized "urgent use" of the Techmedica TMJ implant in 12 patients.
- August 29, 1993 - Tracking requirements of the Safe Medical Devices Act became effective. Manufacturers of certain devices, including TMJ implants, must establish tracking systems, which will enable them to promptly locate devices in distribution. Newly marketed devices subject to tracking are also subject to postmarket surveillance studies.
- September 10, 1993 - FDA learned that Dr. Homsey was attempting to market Proplast TMJ products in Europe and FDA wrote a letter to WHO citing Agency concerns.

- October 12, 1993 - FDA staff met with representatives of Dow to discuss an increase in the number of problem reports associated with the Wilkes IPI and Silastic sheeting used in TMJ. Dow agreed to send an advisory to its consignees.
- October 29, 1993 - FDA developed a 510(k) guidance document for manufacturers of TMJ implants advising them how to set up protocols for evaluations of their products. The guidance addressed the length of time required to conduct studies and follow-up of their products.
- October 29, 1993 - FDA sent letters to Techmedica and Osteomed requesting additional information on their TMJ implants. This resulted in withdrawal of both 510(k)s. FDA would expedite the processing of new applications received.
- December 8, 1993 - Dow issues letter to consignees regarding Silastic sheeting and the Wilkes IPI.
- February 14, 1994 - A draft classification regulation to re-propose the fossa and condylar prostheses into Class III was published.
- April 17 - 20, 1994 - FDA co-sponsored a conference with National Institute of Dental Research entitled, "Management Requirements for a National Implant Data System." The planning conference served to accelerate the process of producing a unified approach to the study of biological host and implant response performances of various biomaterials and devices in human clinical use.
- July 15, 1994 - FDA sent a "Dear Doctor" letter to all U.S. plastic and reconstructive surgeons, orthopedic surgeons and otolaryngologists concerning problems with Proplast TMJ implants.
- September 1994 - FDA revised its "TMJ Implants: A Consumer Information Update."
- September 12-13, 1994 - FDA sponsored an "International Satellite Workshop on the TMJ and Related Pain Conditions."
- September 14, 1994 - FDA sent a letter to Japan, Italy, Switzerland, Canada, Mexico, Australia, New Zealand and the Director General of EC in Belgium to inform regulatory bodies about the Proplast TMJ experience in the U.S.
- November 17, 1994 - FDA sent a letter to all TMJ implant patients in the Medic Alert International Implant Registry (IIR) informing them that the IIR will no longer continue its operation. FDA will continue to inform the medical and dental community and TMJ resource organizations of any problems related to Vitek TMJ implants.
- December 20, 1994 - A final rule to classify the IPI, total joint, fossa, and condylar prostheses into Class III devices was published in the *Federal Register*.
- October 16-17, 1995 - FDA participated in the NIH Workshop "Biomaterials and Medical Implant Science: Present and Future Perspectives."

- April 29-May 1, 1996 - NIH convened the Technology Assessment Conference: “Management of Temporomandibular Disorders.”
- July 17, 1996 - The Anspach Total Temporomandibular Implant (formerly known as the Techmedica Implant, and now distributed through TMJ Concepts) received premarket notification 510(k) clearance which will require device tracking and postmarket surveillance.
- August 2, 1996 - FDA issued letters stating the agency’s intention to rescind the determinations of substantial equivalence (SE) for nine 510(k)s Proplast devices which are used in loaded situations, (for example in joints.)
- June 19, 1998 - FDA rescinded the determinations of SE for four of the nine 510(k)s and the remaining five are being reviewed.
- December 30, 1998 - FDA published a final 515(b) regulation in the Federal Register that requires manufacturers of TMJ implants to submit PMAs with data showing the safety and effectiveness of the implants.

May 10-11, 1999 - FDA's Dental Products Panel met to discuss two premarket approval applications submitted by TMJ Concepts and TMJ Implants, Inc. The Panel recommended to the agency that both applications were approvable with conditions. For a transcript of the meeting, write to the FDA, Freedom of Information Staff (HFI-35), at the address on page 23.

TMJ IMPLANT RESOURCE GROUPS

The following list provides sources of information and organizations involved in the TMJ implant issue. The list is provided for information purposes only and does not constitute an endorsement by the Food and Drug Administration of the information or recommendations they may provide.

MANUFACTURERS: TMJ Implants

BIOMET

AIRPORT INDUSTRIAL PARK
P.O. BOX 587
WARSAW, IN 46581
1-800-348-9500

ENDOTECH

20 VALLEY STREET
SOUTH ORANGE, NJ 07079
201-762-0095

TMJ CONCEPTS

4750 CALLE QUETZAL
CAMARILLO, CA 93012
1-800-504-9527

TMJ IMPLANTS, INC.

17301 W. COLFAX AVE, SUITE 135
GOLDEN, CO 80401
303-277-1338
www.tmj.com

TEMPOROMANDIBULAR JOINT

RESEARCH FOUNDATION

3043 FOOTHILL BOULEVARD, SUITE 8
LA CRESCENTA, CA 91214
(714) 761-8825

HEALTH PROFESSIONAL GROUPS

AMERICAN DENTAL ASSOCIATION (ADA)

211 EAST CHICAGO AVENUE
CHICAGO, IL 60611
(312) 440-2500
www.ada.org

AMERICAN ASSOCIATION OF ORAL AND MAXILLOFACIAL SURGEONS (AAOMS)

9700 WEST BRYN MAWR AVE.
ROSEMONT ILLINOIS, 60018-5701
1-800-822-6637
www.aaoms.org

CONSUMER AND PATIENT INFORMATION

The TMJ Association, Ltd.

P.O. Box 26770
Milwaukee, Wisconsin 53226-0770
(262) 432-0350
www.tmj.org

National Oral Health Information Clearinghouse

1 NOH1C
Bethesda, MD 20892-3500
(301) 402-7364
FAX (301) 907-8830
www.aerie.com

National Women's Health Network

514 Tenth Street, NW, Suite 400
Washington, D.C. 20004
(202) 347-1140
www.womenshealthnetwork.org

Society for the Advancement for Women's Health Research

1828 L Street, N.W., Suite 625
Washington, D.C. 20036
(202) 223-8224
www.womenshealth.org

FEDERAL GOVERNMENT

U.S. Food and Drug Administration

Center for Devices and Radiological Health
Office of Health and Industry Programs
Division of Small Manufacturers Assistance
Consumer Staff, HFZ-210
1350 Piccard Drive
Rockville, MD 20850

www.fda.gov/cdrh/consumer/tmjupdate.html

National Institutes of Health

National Institute of Dental & Craniofacial
Research

7550 Wisconsin Avenue
Bethesda, MD 20892
(301) 496-4261

www.nidr.nih.gov

U.S. Food and Drug Administration

Office of Women's Health
5600 Fishers Lane, Rm. 14-62
Rockville, MD 20857

FDA REGIONAL OFFICES

The Public Affairs Specialists may provide information about local resources as well as FDA's role in regulating TMJ implants.

Northeast Region

Connecticut, Maine	P. Fairfield (ext. 184), J. Raulinaitis (ext. 186) S. Small (ext.185)
Massachusetts, New Hampshire Rhode Island, Vermont	(781) 279-1675, Fax (781) 279-1687
New York City, Long Island Westchester Co., Rockland Co.	D. Granville (ext. 5043), V. Zuberko (ext 5755) (718) 340-7000; Fax (718) 340-7057
New York (except Metro area)	D. Monaco (ext 3118), D. Dathe (ext 3101) (716) 551-4461; Fax (716) 551-3845

Central Region

New Jersey	J. Lytle (973) 331-2926; Fax (973) 331-2969
Delaware, Pennsylvania	A. Brown (215) 597-4390; Fax (215) 597-6649
Maryland, West Virginia	J. Prego
Virginia, Washington D.C.	(410) 962-3731; Fax (410) 962-2307
Kentucky, Ohio	M. Zipkes (ext. 110) (513) 679-2700; Fax (513) 684-2905 R. Weisheit (330) 273-1038; Fax (330) 225-7477
Illinois	D. Bailey (ext. 187), K. Phillips (ext 186) (312) 353-5863; Fax (312) 886-3280
Michigan	E. DeNike (ext. 149) (313) 226-6158; Fax (313) 226-3076
Indiana	J. LeClair (ext.13), C. Gallagher (ext.31) (317) 226-6500; Fax (317) 226-6506
Minnesota, North Dakota	D. Aird (ext.129)
South Dakota	(612) 334-4100; Fax (612) 334-4134
Wisconsin	S. Davis (ext.19), K. Rozewicz (ext.20) (414) 771-7167; Fax (414) 771-7512

Southeast Region

Puerto Rico, Virgin Islands	N. Villegas, R. Marcano (787) 729-6852; Fax (787) 729-6847
Georgia	J. Pittman (ext. 5340)
South Carolina	(404) 253-1272; Fax (404) 347-1912
North Carolina	M. Lewis (ext. 17) (919) 856-4456; Fax (919) 856-4776
Northern Florida	L. Isaacs (ext. 202), F. Fronner (ext.203), F. Goodwin (ext.221) (407) 475-4704; Fax (407)475-4769
South Florida	E. Niella-Brown (ext. 937) (305) 526-2800; Fax (305)526-2693
Alabama, Tennessee	S. Baxter (ext.122), M. Davis (ext.147) (615) 781-5372; Fax (615) 781-5383
Louisiana, Mississippi	D. Tollestrup (ext.121) (225) 589-2420/2421; Fax (225) 589-6360
Southwest Region	
Texas (Dallas/Ft. Worth)	M. Velasco (ext.308), H. Monda (ext 303) (214) 655-5315; Fax (214) 655-5331
Oklahoma	
Texas (Houston, Eastern)	S. Lunnon-Baylor (ext. 15)
Arkansas	(713) 802-9095; Fax (713) 802-0906
Texas (South Central)	Vacant (ext. 13) (210) 308-4531; Fax (210) 308-4548
Kansas, Nebraska	
Montana, Northwest Missouri	(913) 752-2141; Fax (913) 752-2111
Southeast Missouri	M. Richardson (ext. 123)
Iowa	(314) 645-1167; Fax (314) 645-2969
Colorado, New Mexico	V. Walker (303) 236-3018, D. Koontz (303) 236-3020
Utah, Wyoming	Fax: (303) 236-3551
Pacific Region	
Northern California	J. McDonald (510) 337-6845, M. Taylor (510) 337-6888
Nevada, (Pacific Rim Territories)	Fax: (510) 337-6708
Southern California	R. Vior (714)798-7607, L. Eu (714) 798-7609 Fax: (714) 798-7715
Arizona	G. Meza (ext. 225) (602) 829-7396; Fax (602) 829-7677
Washington, Alaska	S. Hutchcroft (425) 483-4953; Fax (425) 483-4996
Oregon, Idaho, Montana	A. Bennett (ext. 22) (503) 671-9322; Fax (503) 671-9445

CURRENT BIBLIOGRAPHIES IN MEDICINE

The National Library of Medicine (NLM) offers publications in its *Current Bibliographies in Medicine* (CBM) series free-of-charge through the World Wide Web. Bibliographies in the CBM series are produced by staff of NLM's Reference Section in collaboration with subject specialists from the National Institutes of Health and elsewhere. Each bibliography is prepared by searching a variety of online databases and covers a separate topic of current interest. The result is a subject-categorized list of citations in the recent literature, primarily journal articles and books. CBM's may be retrieved from the Library's Web site at <http://www.nlm.nih.gov/pubs/resources.html>.

The most recent publications in the CBM series include:

- [96-2 Management of Temporomandibular Disorders, 917 citations from January 1990 through 1995.](#)
- [Prepared in support of the National Institutes of Health, Technology Assessment Conference on Management of Temporomandibular Disorders, NIH Technol Statement Online 1996, April 29-May 1, 1996.](#)

NLM began putting CBMs on its Web site in mid-1992. Please visit this site at the address given above to see a complete list of those bibliographies available and to make a copy of any of those desired. If you do not have Internet access, paper copies of bibliographies previous to 1997 may be obtained from a local medical library or Federal depository library. Beginning in 1997, NLM made all of these bibliographies available only through the Web; the U.S. Government Printing Office offers for sale paper copies of those bibliographies which have been prepared in support of National Institute of Health Consensus Development Conferences.

Questions of the CBM series may be answered by calling 1-888-FINDNLM or by sending an email to ref~nlm.nih.gov.

FDA FREEDOM OF INFORMATION

We sincerely hope that the information in this packet has been of help to you. If you need more technical information, a written request to the FDA Freedom of Information Staff should be submitted.

The Freedom of Information Act allows anyone to request FDA records.

Your letter should include your name, address and telephone number and a statement of the records being sought, identified as specifically as possible. A request for specific information releasable to the public can be processed much more quickly than a request for "all information" on a particular subject. There is a charge of 10 cents per page. You are billed after your request for information has been filled.

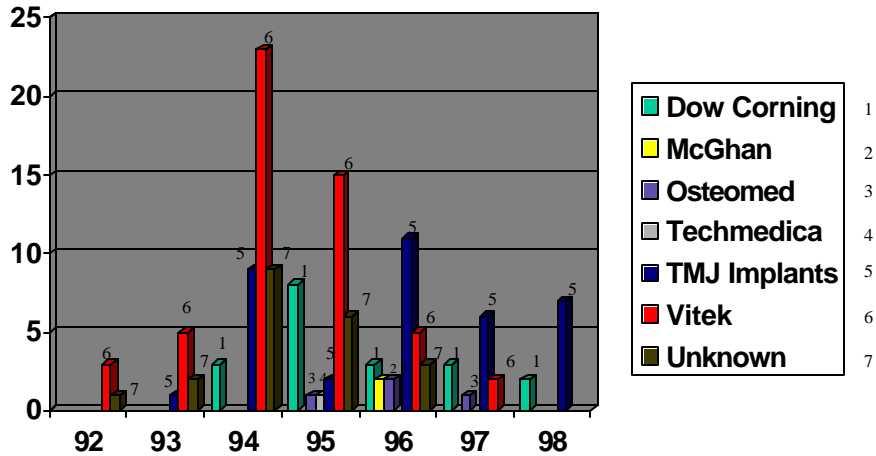
Agency documents regarding TMJ implants are available from FDA and may be obtained by submitting a written request to the following address:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857
FAX: 301-443-1726
Voice Mail Message: 301-827-6500

If you have submitted a Freedom of Information request and have questions relating to the status, please write to:

Freedom of Information Office (HFZ-82)
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road
Rockville, MD 20850
Fax 301-594-4792

MAUDE MDR* Reports on TMJ Implants Received from 1992 - 1998**



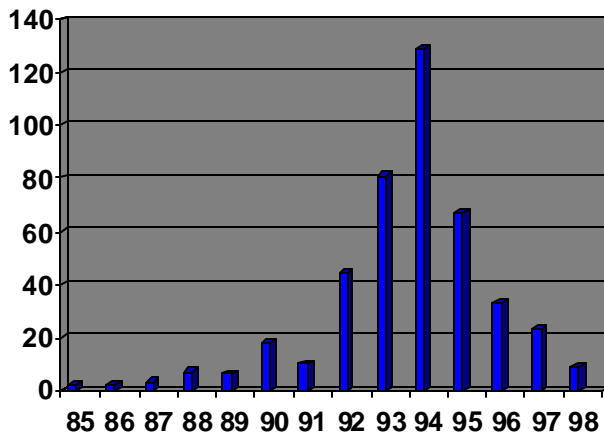
*Manufacturer and User Facility Device Experience (MAUDE)

*Medical Device Reporting (MDR)

** MDR reports received through June 15, 1998

CXP/OSB

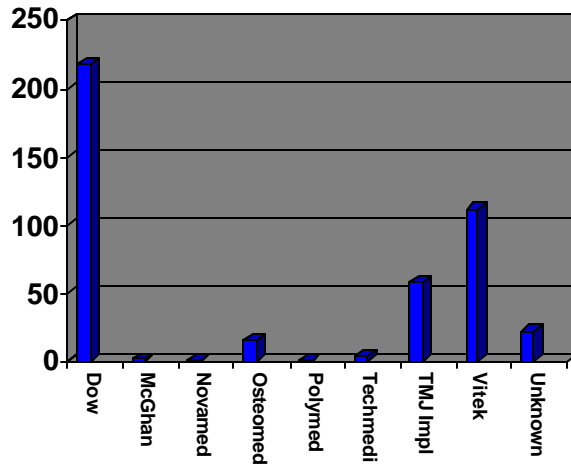
MDR Reports of TMJ Implants by Year from 1984 - 1998*



* MDR reports received through June 15, 1998

CXP/OSB

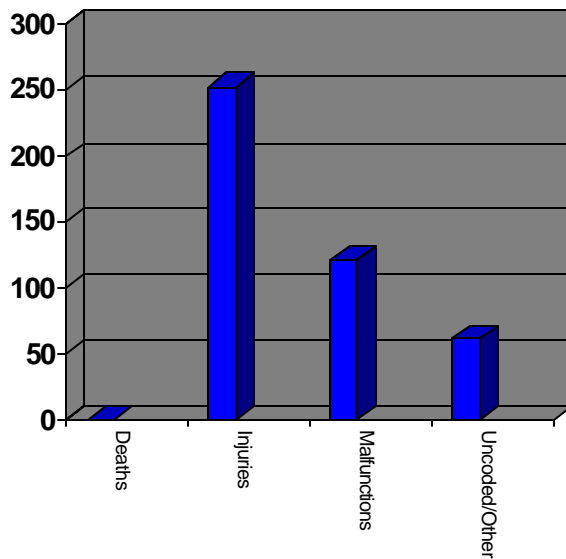
MDR Reports of TMJ Implants by Manufacturer 1984 - 1998*



* MDR reports received through June 15, 1998

CXP/OSB

MDR Reports of TMJ Implants by Report Type 1984 - 1998*



* MDR reports received through June 15, 1998

CXP/OSB

MEDWATCH:

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Reporting Problems with Implants to FDA: A Right and Responsibility

Patients and their health care providers can report problems or adverse events with TMJ implants through **MEDWATCH**. An adverse event is any undesirable experience associated with the use of a drug or medical product in a patient. The event is serious and should be reported when the patient outcome is:

Death: Report if the patient's death is suspected as being a **direct** outcome of an adverse event.

Life-threatening injury or illness: Report if patient was at substantial risk of dying at the time of the adverse event or **it is** suspected that the use or continued use of the product would result in the patient's death.

Hospitalization initial or prolonged: Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event.

Disability: Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life.

Congenital anomaly: Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child.

Medical or surgical intervention: Report if you suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient.

To report, use [MEDWATCH form 3500](#) (included at the end of this information package). If you are a consumer, call 1-888-463-6332 from 10:00 a.m. - 4:00 p.m. Eastern Standard Time Monday through Friday to receive an additional FDA MedWatch Package.

If you are a health care professional, to receive a form or to report by phone, call 1-800-332-1088. The form may be mailed to MedWatch, The FDA Medical Products Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852-9787, faxed to 1-800-332-1088, or sent by modem to 1-800-332-7737. A [form with instructions](#) for completion and definitions of serious adverse reactions are at the end of this package.