DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

Important Information About TMJ Implants

To: Orthopedic Surgeons
Otolaryngologists
Plastic and Reconstructive Surgeons

July 15, 1994

The Food and Drug Administration (FDA) is aware that you may see patients who have received temporomandibular joint (TMJ) implants. We are writing to inform you about the potential problems with these implants.

Enclosed is a copy of the 1990 FDA Safety Alert sent to all U.S. oral and maxillofacial surgeons urging them to re-examine their patients with Proplast®-coated TMJ implants. This Alert describes the signs and symptoms of problems associated with Proplast®-coated TMJ implants and provides recommendations for management of patients. We request that you follow the recommendations in the Alert in evaluating your patients with these types of implants. In addition, the American Academy of Oral and Maxillofacial Surgeons (AAOMS) published recommendations for management of patients with TMJ implants in its professional journal in October 1993.[1] These recommendations address the management of patients with the following three types of alloplastic TMJ implants: Teflon-Proplast® interpositional implants, total joint prosthesis with a Teflon-Proplast® fossa, and Silastic® TMJ implants.

Practitioners who become aware of device-related deaths, serious illnesses and/or serious injuries are asked to notify FDA. Please submit reports to MedWatch, Medical Product Reporting Program, by phone at 1-800-FDA-1088 (same number to obtain MedWatch information); by FAX at 1-800-FDA-0178; by modem at 1-800-FDA-7737; or by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane (HF-2), Rockville, MD 20857.

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other facilities to report deaths, serious illnesses and injuries associated with the use of medical devices. You should follow the procedures established by your facility for such mandatory reporting. Practitioners who become aware of any medical device-related adverse event or product problem/malfunction should report these events to their Medical Device User Facility Reporting person. If the event or problem is not reportable under the SMDA, it may be reported directly to MedWatch.

If you have any questions regarding this letter, please contact Cathy Backinger, Ph.D., Office of Surveillance and Biometrics, Center for Devices and Radiological Health, FDA by FAX at 301-594-2968 or by mail at 5600 Fishers Lane (HFZ-510), Rockville, MD 20857.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

Enclosure

1. American Academy of Oral and Maxillofacial Surgeons. Recommendations for management of patients with temporomandibular joint implants. J Oral Maxillofacial Surg 1993; 51:1164-1172.

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FDA SAFETY ALERT

SERIOUS PROBLEMS WITH PROPLAST®-COATED TMJ IMPLANT

To Oral and Maxillofacial Surgeons: December 28, 1990

This is to urge you to re-examine all of your patients who have received temporomandibular joint (TMJ) interpositional implants which were manufactured or marketed by either Vitek Inc. or Oral Surgery Marketing, Inc. (both of Houston, Texas). These implants were distributed between February 1983 and June 1988 and were the subject of Vitek's March 23, 1990 safety alert. The patent for this medical device is currently held by Hadaco, Ltd. (British Virgin Islands). Any remaining implants should not be used and should be returned to:

Bonham, Carrington, and Fox
Bankruptcy Trustee for Vitek, Inc.
400 One Shell Plaza
Houston, Texas 77002
Attention: Mr. Ben Floyd

PROBLEM:
These implants, all of which are made of Proplast® (Teflon®-carbon or Teflon®-aluminum oxide fiber composite), have been associated with implant perforation, fragmentation and/or a foreign body response which may result in progressive bone degeneration of the mandibular condyle and/or the glenoid fossa (1-3). If bone degeneration continues unchecked, patients may experience intense pain and severely limited joint function. One study found that all patients with Proplast® coated TMJ interpositional implants who experienced complications demonstrated progressive bone degeneration in as little as one to two years (1). In a second study, implant failure and bone degeneration occurred in both symptomatic and asymptomatic patients (2).

RECOMMENDATIONS:
Because asymptomatic patients may experience bone degeneration, FDA recommends that all patients with these implants who have not had a radiograph taken in the past six months undergo immediate and appropriate radiographic examination. The examination will assist in determining if loss of implant integrity has occurred or if progressive bone degeneration is occurring.

- If loss of implant integrity or progressive bone degeneration is not occurring, regular radiographic examinations of the implant should be performed every six months for as long as it remains in the jaw.

- If either loss of implant integrity or progressive bone degeneration is found, explantation may be appropriate. If explantation is chosen, patients should be evaluated to determine what alternative procedures might be appropriate, e.g., a non-Proplast® coated implant, an autologous bone graft, or no replacement (symptomatic management).

FDA SAFETY ALERT
SERIOUS PROBLEMS WITH
PROPLAST® COATED TMJ IMPLANT

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Rockville, Maryland 20857

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
HFZ-250

I would appreciate your sharing the information in this Safety Alert with other practitioners who might find it useful. If you have questions concerning the Alert, please contact: Gregory Singleton, D.D.S., Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Drive, HFZ-250, Rockville, Maryland 20850.

Sincerely,

Walter E. Gundaker
Acting Director
Center for Devices and
Radiological Health

References:

1. Primely, Donald, Jr., "Histological and Radiographic Evaluation of the Proplast-Teflon Interpositional Implant in Temporomandibular Joint Reconstruction Following Meniscectomy", Thesis, Masters Degree in Oral Maxillofacial Surgery, May 1987. University of Iowa.

2. Westlund, Kurt J., "An Evaluation Using Computerized Tomography of Clinically Asymptomatic Patients Following Meniscectomy and Temporomandibular Joint Reconstruction Using the Proplast-Teflon Interpositional Implant", Thesis, Masters Degree in Oral and Maxillofacial Surgery, May 1989. University of Iowa.

3. Wagner, J. D., and Mosby, E. L., "Assessment of Proplast-Teflon Disc Replacements", J. Oral Max. Surg. 48:1140-1144 (1990).