U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

"Getting More Information"

Because the following document was developed a number of years ago, the contact information is no longer accurate. If you wish to contact the agency with questions, please use the following:

Mail: Office of Surveillance and Biometrics (HFZ 510)
1350 Piccard Drive
Rockville, MD 20850

FAX: 240-276-3356

Phone: 240-276-3357

Email: mailto:phann@cdrh.fda.gov

FDA SAFETY ALERT
SERIOUS PROBLEMS WITH PROPLAST^{R} –COATED TMJ IMPLANT

To Oral and Maxillofical 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^{R} (Teflon^{R} -carbon or Teflon^{R} – 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 will Proplast^{R} 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^{R} coated implant, an autologous bone graft, or no replacement (symptomatic management).

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, MD 20850.

Sincerely yours,

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 Maxillofical 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 Maxillofical 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).