IMPORTANT REMINDER ABOUT SILASTIC TMJ IMPLANTS AND MEDICAL GRADE OR HP SILICONE SHEETING

Dear Customer:

We are writing to you as a former customer of our SILASTIC® Temporomandibular Joint Implant (Wilkes Design) or our Medical Grade or HP silicone sheeting to bring to your attention important information. As you are aware, we voluntarily discontinued sales of our temporomandibular joint (TMJ) implant and silicone sheeting products in January 1993.

Dow Corning is aware of continuing debate within the medical community regarding the use of alloplastic materials in the TMJ. Dow Corning is also aware of the general recommendations from the American Academy of Oral and Maxillofacial Surgeons (AAOMS) that permanent placement of silicone as an interpositional material in the TMJ should no longer be done. It is also recommended that patients who have received a silicone implant and who have returned to the original surgeon or another practitioner for care be advised of the risks and benefits of retaining/removing the implant. Those patients who Choose to retain the implant should be followed on a regular basis, and such follow up should include appropriate radiographic imaging and evaluation of clinical symptoms such as pain and function.

We also wish to remind you that the Wilkes Design TMJ is a temporary device (to be implanted up to four months) and these devices should have been removed from patients by this time. We also request your diligence in monitoring, per the AAOMS guidelines, patients with silicone sheeting used in custom TMJs. We recommend you consider consulting with AAOMS regarding the recommendations for management of temporomandibular joint (TMJ) implants.

As SILASTIC® Temporemandibular Joint Implant (Wilkes Design), Medical Grade and HP silicone sheeting have been discontinued, we request that any remaining inventory not be used and returned for full refund. Please contact Mr. Barnard Howard at Dow Corning Corporation, (517) 496-4668, and he will advise as to where to send the units and to obtain your refund. If you have sold or distributed any of these products to others, we urge you to provide copies of this letter to those customers. If you would like us to provide you with copies for mailing or to mail the letters for you, contact Mr. Howard at the above telephone number.

If you have any questions, please feel free to contact me. Any patient questions can be directed to our Implant Information Center at (800) 442-5442.

Sincerely,

Richard H. Hoeyer

General Manager

Performance Materials Business

TFI FPHONE: (517) 496-4000