

## **Scar Management Device Medical Device Report Summary**

There are about 75 Scar Management Devices on the market. We searched medical device reports data base for the device adverse events. The following two adverse events were found:

The first adverse event reported in January 1998 was a significant blistering caused shortly after using gel sheeting followed by full thickness skin necrosis due to secondary infection. The blistering was not at the site of gel sheeting application, but in the areas nearby. It was determined by the reporting physician that the event was unrelated to the device but, we could not rule out the possibility that the device was involved.

The other adverse event reported in June 2001 was an allergic reaction following the use of silicone sheeting. Following 39 hours of continuous use, the patient developed a severe red rash and flaky rough skin. This was determined as an isolated event and not likely that it was due to the use of the device. Some possible causes for the reported incident may be a reaction to the tape used to hold the sheeting in place or moisture created under the silicone sheeting after wearing the product for such an extended period of time.