Breaking News
INTERGEL Withdrawn from Market by Company
As posted on the IAS website 17 April 2003 at: www.adhesions.org/whatsnew.htm

GYNECARE
WORLDWIDE
a division of ETHICON, Inc.
a Johnson & Johnson company

URGENT VOLUNTARY MARKET WITHDRAWAL
OF
GYNECARE INTERGEL*
ADHESION PREVENTION SOLUTION

March 28, 2003

Dear Doctor:

GYNECARE is conducting an urgent, voluntary global withdrawal of GYNECARE INTERGEL* Adhesion Prevention Solution, a device indicated for use in patients undergoing open, conservative gynecologic surgery as an adjunct to good surgical technique to reduce post-surgical adhesions. **You should immediately discontinue use of the device.**

GYNECARE is conducting this voluntary withdrawal in order to complete an assessment of information obtained during post-marketing experience with the device, including adverse events associated with off-label use in laparoscopy and non-conservative surgical procedures (such as hysterectomy).

GYNECARE has received post-market reports of late-onset, post-operative pain, and repeat surgeries following the onset of pain, non-infectious foreign body reactions, and tissue adherence. In some patients, a residual material was observed during the surgery. The post-operative pain could be suggestive of other, serious complications and physicians should be aware of this in managing patients in the post-operative period.

GYNECARE is withdrawing the device from the market while we conduct a full and thorough assessment of technical issues, surgical techniques and circumstances associated with the post-market events. From the launch of this device in 1998 to February 2003, the overall complaint rate worldwide is low.

Your GYNECARE sales representative is available to answer any questions you may have, or you can contact our toll free customer support center at 1-877-ETHICON.

The U.S. Food and Drug Administration has been notified of this action.

Sincerely,
GYNECARE

*Trademark of Ethicon, Inc.

Gynecare (division of Johnson & Johnson) have voluntarily withdrawn the anti-adhesion product - INTERGEL - from the market pending an investigation into the circumstances surrounding some adverse events including post-operative pain and inflammatory reaction. There were also two deaths where the product had been used after the accidental puncture of the bowel. The relationship between the product and these events is not certain, but the company are investigating it.

WHAT TO DO IF YOU THINK YOU HAVE HAD SIMILAR REACTIONS

The IAS has been contacted by a number of patients who have asked us what to do if they believe they have had a reaction to Intergel. Gynecare (a division of Johnson & Johnson - the marketers of the product) have kindly provided us with the following announcement:

"If you have had Intergel used during a surgical procedure and have any questions about it or believe you have had a reaction to it, you may contact Gynecare directly by dialing 877-384-4266, option 1. This number will connect you with a Registered Nurse who is trained to respond to your call."

Source: IAS