

For Immediate Release:

Unique Breast Implant Advancement Receives Patent

The invention relates to the field of prostheses or implants for cosmetic and reconstructive surgery, such as a breast implant containing a microencapsulated biologically compatible chemical indicator for early detection of rupture of the implant.

Deerfield Beach, Florida – July 26, 2010 – Barry H. Schwibner, M.D., Chief Medical Officer of TONABA HealthScience, LLC and co-inventor has announced that the Company has been issued a patent covering its innovative concept for detecting the compromise or rupture of breast implants.

The rupture of an implant has been defined as the development of a tear or a hole in the envelope or shell of the prosthesis. Types of rupture that have been described in the medical literature range from very small holes to larger physical tears with complete destruction of the prosthesis envelope or shell.

Current breast implants utilize the newer cohesive silicone gel. Different from the silicone gel used in the past, cohesive silicone gel tends not to leak out from the shell of the implant upon rupture. However, when the implant shell ruptures the patient's tissues are in contact with the cohesive silicone gel, an issue causing continued concerns.

TONABA's invention provides for an *immediate* indication of a breast implant rupture. It proposes the incorporation of an additional indicator lumen or compartment as the most exterior component of an implant which contains the biologically compatible chemical indicator encapsulated in a sustained release delivery vehicle.

Upon rupture of the implant shell, even a minor asymptomatic or so-called *silent rupture*, the sustained release delivery vehicle upon exiting the implant gradually releases the indicator which is absorbed and subsequently excreted through the kidneys, dramatically changing the color of the urine to a bright reddish-orange. This color change of the urine induced by the rupture indicator is the signal or *early warning* to the patient of a rupture or impending rupture of an implant, alerting the patient to seek medical attention.

Providing a microencapsulated delivery vehicle provides several important features in terms of maintaining stability of the chemical indicator throughout the life of the implant and furnishing a sustained release capability, which provides a prolonged signal or warning period for the patient, giving her ample time to notice the change in urine color.

Citing from the *FDA NEWS RELEASE* upon the approval of silicone gel-filled breast implants on November 17th of 2006, referring to breast implant package and patient labeling mandated by the FDA:

“The patient labeling outlines some of the important factors women should consider when deciding whether to get silicone gel-filled breast implants. Some of these factors are: breast implants are not lifetime devices and a woman will likely need additional surgeries on her breast at least once over her lifetime; many of the changes to a woman’s breast following implantation are irreversible; rupture of a silicone gel-filled breast implant is most often silent, which means that usually neither the woman nor her surgeon will know that her implants have ruptured; and a woman will need regular screening MRI examinations over her lifetime to determine if silent rupture has occurred. The device labeling states that a woman should have her first MRI three years after her initial implant surgery and then every two years thereafter. The cost of MRI screening over a woman’s lifetime may exceed the cost of her initial surgery and may not be covered by medical insurance. The labeling also states that if implant rupture is noted on an MRI, the implant should be removed and replaced, if needed.”

How many women actually comply with the above FDA recommendation for “regular screening MRI examinations over their lifetime to determine if silent rupture has occurred” is not known at this time. “However, Schwibner states, we believe that our rupture indicator concept could eliminate the need for periodic MRI screenings and that an MRI would only be required should a woman note a color change to her urine, thereby signaling a rupture or impending rupture of her implant.”

TONABA HealthScience, LLC according to Schwibner, “is an emerging medical technology company with additional implant technologies in the “pipeline”. We see a need for improved implants with built-in safeguards and we believe that the awarding of this patent is a significant step in that direction.”

Contact:

Barry H. Schwibner, M.D.
Chief Medical Officer
[TONABA HealthScience, LLC](#)
Phone: 561-756-1100 (direct)
###