

Exhibit I

Safety of Silicone Breast Implants
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SAFETY OF SILICONE BREAST IMPLANTS

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logo by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Detection of Rupture of Gel-Filled Implants

As noted above, intracapsular rupture of gel implants can go unrecognized. There may be no patient complaints and no physical diagnostic findings. The sensitivity of commonly used imaging technologies, such as film mammography, is reported to be around 50%, and some report a sensitivity as low as 15–20% (Ahn et al., 1994a; Bassett and Brenner, 1992; Robinson et al., 1995; Samuels et al., 1995), although there are some who claim it is much higher (Cohen et al., 1997; also see Chapter 12). Ultrasound may detect more ruptures. Magnetic resonance imaging is generally reported to have a sensitivity of around 90% in experienced hands, but this technology is currently too costly and time-consuming for routine screening. Physical diagnosis of extracapsular rupture, when the shape or feel of the gel mass has changed, is much easier, although occasionally such changes can escape detection (Edmond and Versaci, 1980). The changed contour of the gel is also observed on film mammography, although contour irregularities may be secondary to accommodation of an unruptured implant to, or herniation through, a capsulotomy defect. Presence of gel is reported outside the capsule in about 12–26% of ruptures (Ahn et al., 1994a; Berg, et al. 1995; Frankel et al., 1995; Gorczyca et al., 1994a; Middleton, 1998b). It has been as high as 35% in selected series (Andersen et al., 1989). These figures generally refer to more fragile second generation implants and come from case series of patients who present because of problems and, therefore, may overstate complications. There are also reports of series of 19 or 30 instances in which there has been implant rupture without any extracapsular movement of gel (Beekman et al., 1997a; Malata et al., 1994a) or a low proportion of extracapsular movement, e.g., 5.7% of ruptured implants (Peters et al., 1997). Extracapsular rupture is also more easily detected on ultrasound and MRI.

The diagnosis of rupture of a gel implant is important because the release of silicone gel and fluid into the tissues may result in local complications. An intracapsular rupture may become extracapsular, and both are generally, but not always (Hardt, IOM Scientific Workshop, 1998), agreed to be an indication for explantation (Young, 1998). Moreover, rupture should be anticipated at some point since implants have a finite life span, although what this might be with current models is not certain. Careful explantation and direct visual examination are the standard for diagnosis of silicone gel-filled implant rupture, both unsuspected or silent, and for confirmation of rupture. Explantation allows only a retrospective or confirmatory diagnosis. It is not a prospective means of resolving the question of presence or timing of rupture in an individual patient.