

## **MENTOR STATEMENT ON PIP BREAST IMPLANTS**

At Mentor, our primary concern is always for the health and safety of our patients. Recent news reports have highlighted the safety of breast implants of one specific manufacturer, Poly Implant Prothèse, known as PIP. We realize that these reports may have led to concerns among clinicians and patients about the quality of all breast implants. Mentor's silicone gel-filled and saline implant products are not associated with PIP and have a long, proven history of high quality with rigorous testing during the manufacturing process. Our products are manufactured with medical grade materials, in regulated facilities and are designed to meet all quality and safety requirements.

In March of 2010, the French company PIP was ordered by AFSSAPS, the French Regulatory Authority, to withdraw and suspend marketing, distribution, and exportation of their implants. On December 23, 2011, AFSSAPS recommended that women with PIP implants have them removed by their surgeons as a "preventative measure not of an urgent measure". This recommendation by AFSSAPS is limited to breast implants manufactured by PIP only.

To the best of our knowledge, PIP silicone gel-filled implants were never approved for use in the United States and patients would need to have been implanted outside the United States to have received the implants of concern. PIP is neither a subsidiary nor an affiliate of Mentor, Prouse Plastique, or any of their affiliates within the Johnson & Johnson family of companies. Also, neither Mentor, Prouse Plastique nor any of their Johnson & Johnson affiliates distribute PIP implants.

Mentor only uses medical-grade silicone in our gel-filled implants and our adherence to strict quality manufacturing requirements has resulted in silicone shells that have been tested and shown to possess excellent strength, resilience and elasticity. Mentor also conducts extensive bio-compatibility testing on all its breast implants as described in the U.S. Food and Drug Administration's Summary of Safety and Effectiveness Data. This is why we believe Mentor Worldwide LLC is recognized as a leading global manufacturer of high quality breast implants. Our longevity in this market has provided a wealth of experience and a global reputation for integrity. Our manufacturing expertise and safety record are unsurpassed and are a tremendous source of pride for our 1,200 employee associates worldwide.