



### Physician Safety Statement:

The Motiva SmoothSilk® Round and SmoothSilk Ergonomix® Silicone Gel Breast Implants are indicated for breast augmentation for women of at least 22 years old. Breast augmentation includes primary breast surgery to increase the breast size, as well as revision surgery to correct or improve the result of an original primary breast augmentation surgery (i.e., revision-augmentation). Breast Implant surgery is contraindicated in women with active infection anywhere in their bodies, with existing cancer or pre-cancer of their breast who have not received sufficient treatment for those conditions, or who are currently pregnant or nursing. Prior to use, plastic surgeons should review all risk information with women who are considering breast implant surgery. This risk information can be found in the Directions for Use which is provided with each device and found on [www.motivausa.com](http://www.motivausa.com). Plastic surgeons should advise patients of the key complications that have been historically associated with breast implant surgery and implantation of silicone gel breast implants, including, but not limited to, capsular contracture, implant removal, reoperation, infection, and rupture. Plastic surgeons should also advise patients that breast implants are not lifetime devices and patients should follow-up with them, as recommended. The Directions for Use and detailed information regarding the risks and benefits of Motiva SmoothSilk® Round and SmoothSilk Ergonomix® Silicone Gel Breast implants can be found at: [www.motivausa.com](http://www.motivausa.com) or by calling Motiva at 1-800- 924-5072.

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Establishment Labs® and Motiva® USA. Federal (USA) Law restricts this device to sale by or on the order of a physician.