



Important Safety Information for Patients:

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. Adequate studies have not been performed to confirm the safety of breast implant surgery in women with these conditions or under these circumstances; therefore, if you have any of the conditions or circumstances listed above, breast augmentation surgery with implants should not be performed at this time. Failure to take into consideration these contraindications may increase the risks involved with breast implant surgery and have the potential to cause harm. Patients should be advised that key complications have historically been associated with silicone gel breast surgery and implantation of silicone gel breast implants including, but not limited to, capsular contracture, implant removal, reoperation, infection, and rupture. Further, breast implants are not lifetime devices and patients should visit their healthcare professional, as recommended. For more detailed information about the benefits and risks of Motiva SmoothSilk® Round and SmoothSilk Ergonomix® Silicone Gel Breast Implants, please visit: www.motivausa.com or call 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.