Patient Compensation for the Safety and Effectiveness Study of the Motiva Implants®
For patients undergoing augmentation or revision augmenation surgery

Thank you for participating in the clinical study. Here we provide you with some information regarding the compensation we are offering to subjects participating in this clinical study. We are committed to supporting you throughout the full 10 year's of the study. We thank you in advance for completing all of the scheduled follow-up visits.

The breast implants to be used in the clinical study are investigational devices and are not FDA approved. They are CE Marked, which means they comply with European Union regulations. These implants are already being used in more than 60 countries, including the UK, Sweden, Germany, Switzerland, Austria, Japan, Australia and South Korea and in each one of these countries the implants are registered according to the requirements of the local Health Authorities.

The two families of implants included in this study are SmoothSilk Round ProgressiveGel™ Plus (Round Plus) and SmoothSilk Ergonomix® Round ProgressiveGel™ Ultima® (Motiva Ergonomix®).

Motiva Implants® are intended to be used in women who are considering undergoing the following procedures:

- Primary Breast Augmentation: First time surgery, indicated to increase breast size as an aesthetic procedure for patients age 22 and over.

- Revision Augmentation Surgery: Secondary surgery for removal or replacement of breast implants to correct or improve the results of a first-time breast augmentation for aesthetic reasons.

- Primary Breast Reconstruction: First time surgery due to breast tissue that has been removed due to cancer, prophylactic mastectomy, breast trauma or that has failed to develop properly due to a severe breast anomaly.

- Revision Reconstruction Surgery: Secondary surgery for removal or replacement of breast implants to correct or improve the results of first time reconstruction surgery due to cancer, prophylactic mastectomy, breast trauma or that has failed to develop properly due to a severe breast anomaly.

Compensation for subjects in this clinical trial includes:

1. **Breast Implants at no cost**

On the day of surgery, one pair of Motiva Implants® will be provided at no cost.

2. **Compensation for all follow-up visits**

All the subjects participating in the clinical trial will be compensated for follow-up study visits with their study surgeon. Aditionally, they will receive a cash bonus as described in the table below, to be paid to the Patient after each follow-up visit for a total amount of US $2,150 over the 10 years.

APPOINTMENT	CASH BONUS
Year 1	$200
Year 2	$250
Year 3	$250
Year 4	$200
Year 5	$200

APPOINTMENT	CASH BONUS
Year 6	$200
Year 7	$150
Year 8	$250
Year 9	$150
Year 10	$300

3. **Trust fund**

After your first annual follow up visit (Year 1), we will deposit into a trust fund the full amount of $750 , corresponding to the total of all trust fund installments noted in the table below. With every annual follow up visit you will vest the corresponding amount in the table below into your trust and will receive the total amount after completing the 10 year follow-up.

APPOINTMENT	TRUST FUND INSTALMENTS
Year 1	$100
Year 2	$100
Year 3	$100
Year 4	$100
Year 5	$100

APPOINTMENT	TRUST FUND INSTALMENTS
Year 6	$50
Year 7	$50
Year 8	$50
Year 9	$50
Year 10	$50

Important Considerations

If a subject drops out of the Study before completion of all 10 year follow up visits, the total of $750 corresponding to her trust fund will be divided equally among the patients that finish the study. Additionally, any patient who misses two consecutive annual visits will be considered lost to follow-up and will only keep the implants and cash payments received for study visits attended. Only patients that complete all of the 10-year follow-up visits will receive the total of the trust fund installments.

Both, cash bonuses and the total of the Trust Fund Installments, will be paid directly to the subject.

If you have any questions regarding your participacion or compensation for the study, please contact your surgeon. We thank you again for your commitment and participation in this study.