

# **Skin Tightening/Fat Reduction - Radio Frequency Assisted Liposuction Clinical Trial Inclusion & Exclusion Criteria. Please Read Carefully**

## **Inclusion Criteria**

- **Healthy males and females 21 to 60 years of age**
- **Presence of excessive fat and loose skin localized to the face regions**
- **For female candidates only - post menopausal or surgically sterilized, or using a medically acceptable form of birth control at least 3 months prior to enrollment and during the entire course of the study**
- **Willingness to follow the treatment and follow-up schedule and post treatment care & Willing to sign informed consent**

## **Exclusion Criteria**

- **Current or history of cancer**
- **Pacemaker or internal defibrillator**
- **Significant systemic illness or occult systemic illness**
- **Illness, infection or skin diseases localized in the area of treatment**
- **Breastfeeding, pregnant, or planning to become pregnant during the study**
- **Impaired immune system due to immunosuppressive diseases such as AIDS and HIV**
- **Poorly controlled endocrine disorders, such as diabetes or hypo- or hyper-thyroidism**
- **Recent surgery in the treatment area within the past 6 months**
- **History of thrombophlebitis**
- **Any acute infection**
- **Heart failure**
- **Allergy to lidocaine or other anesthesia**
- **Participation in a study of another device or drug within 3 months prior to enrollment**
- **Experienced weight loss or gain of more than 15lbs or had a significant change in diet or exercise within the last 3 months**
- **History of Herpes Simplex or Zoster**
- **Known anticoagulative or thromboembolic condition or use of anticoagulants like aspirin**