

## VII. TREATMENT OF WRINKLES DESCRIPTION AND USE

The Ellman Pellevé Generator can be used for non-ablative treatment of mild to moderate facial wrinkles and rhytids. To treat wrinkles and rhytids, the Pellevé® S5 generator should only be used in conjunction with Pellevé® Wrinkle Treatment Handpieces and Pellevé® Treatment Gel.

**WARNING: Wrinkle treatment procedures are dependent upon ongoing patient feedback. Local, oral and systemic anesthetic agents must not be used prior to or during wrinkle treatment.**

Refer to the Sections 4 and 5 for instructions on connection of the Neutral Plate and Handpiece; the setting of the power levels; and general operation of the generator.

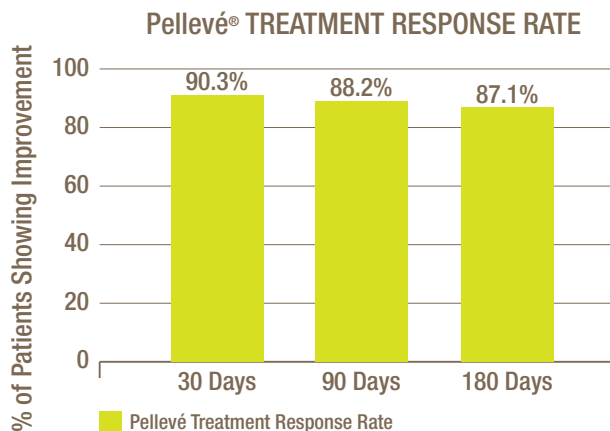
### 7.0 CLINICAL DATA

Six month follow-up on patients treated with the Ellman wrinkle treatment handpieces demonstrates that this system is associated with statistically significant improvements in mild to moderate facial wrinkles ( $p < 0.01$ ) at all time points compared to pretreatment baseline. The 510(k) submission to the US Food and Drug Administration (FDA) was supported by data from the study presented by Rusciani et al<sup>1</sup> in the "Journal of Drugs in Dermatology" with extended data analysis conducted on the study's raw data.

Ninety-three consecutive patients with mild to moderate facial wrinkles were treated with the Ellman Surgitron® Dual RF™ and Ellman wrinkle treatment handpieces. Each patient received a single treatment and was followed for six months post treatment. Evaluation photographs were scored by three independent evaluators, blinded to time interval post treatment, per the following scale

- 0: Less than 25% improvement
- 1: 25 - 50% improvement
- 2: 51 – 75% improvement
- 3: Greater than 75% improvement

The correlation between the three independent evaluators was statistically significant ( $p < 0.01$ ) with 90.3% of patients receiving an average score of 1.0 or higher at 30 days, 88.2% at 90 days, and 87.1% at 180 days. The mean score across all patients and evaluators is shown below.



#### Percentage of patients showing improvement of mild to moderate facial wrinkles across 93 patients vs. Time post treatment.

There were no serious adverse affects. Two patients experienced small abrasions that healed in 3 days. Three patients experienced mild asymmetries.

<sup>1</sup>Rusciani, A. et al. "Nonsurgical Tightening of Skin Laxity: A New Radiofrequency Approach." Journal of Drugs in Dermatology. April 2007. Pgs. 377-382.