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Elegance through science.

**Pelleve Procedure Protocol**  
(10mm handpiece)



## Pelleve Procedure Protocol (10mm handpiece)

The intended use for the SURGITRON® DUAL RF™ S5 with the Pelleve handpiece is non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I–IV.

### WARNINGS

- High frequency surgical equipment should be used only by persons having adequate training and familiarity with high frequency surgical equipment and related techniques. A thorough understanding of the use of high frequency surgical equipment is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical equipment. Consult medical literature relative to related techniques, complications, and hazards prior to use of high frequency surgical equipment.
- Never increase the power settings without first checking both the active electrode and the neutral plate.
- Corneal Eye Shields must be used for any radiofrequency surgical procedure involving the eyelid and the immediate surrounding areas.
- Treatment of wrinkles is dependent upon ongoing patient feedback. Local, oral and systemic anesthetic agents must not be used prior to or during wrinkle treatment.
- Patients with nerve insensitivity to heat anywhere in the treatment area should not be treated for wrinkles. Treatment of patients with nerve insensitivity may lead to patient burns or injury.
- Use only with Ellman accessories including Ellman handpieces, neutral plates, cables, electrodes and gels.

### PRECAUTIONS

#### Treatment of Wrinkles

- Removing the tip when activated or touching the skin after activating the tip may result in the patient feeling an electric shock similar to a static discharge in a dry environment.
- Do not treat wrinkles on cut, wounded or infected skin.
- All jewelry and makeup, including lotions, eyeliner and eyeshadow should be removed from the treatment area.
- Only Pelleve Treatment Gel should be applied to the surface of the patient's skin prior to or during treatment.
- Remove beard stubble thoroughly prior to treatment.
- Treatment of wrinkles using the SURGITRON® DUAL RF™ S5 is unstudied and unknown for the following populations: pregnant patients, patients with autoimmune disease, diabetes, herpes simplex, and patients with recently applied fillers to the treatment area.

## ADVERSE REACTIONS OBSERVED WITH TREATMENT OF WRINKLES USING THE SURGITRON® DUAL RF™ S5

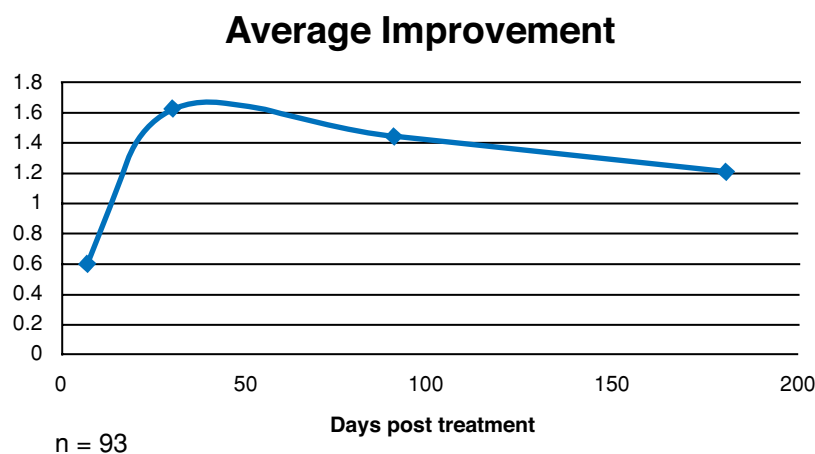
- Mild discomfort during treatment may be experienced by the patient. Typically, the discomfort is temporary during the procedure and localized within the treatment area. Adjust power setting to maintain acceptable levels of patient discomfort.
- Mild swelling (edema) and redness may occur which typically resolves within 3 to 5 days, but can persist up to several weeks.

## 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™ S5 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.



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

## WRINKLE TREATMENT HANDPIECE

Use the Pellevé Wrinkle Treatment Handpiece to efficiently treat facial wrinkles. Ellman provides the following recommendation; however, physicians may have individual preferences.

### 3-Button Fingerswitch Activated Wrinkle Treatment Handpiece



**D110FSHP** The recommended initial power output intensity setting for most patients should be at approximately 15.

This handpiece is ideal for less confined areas to ensure contact with all tissue in the treatment areas; such as crow's feet, perioral, forehead and chin.

## PRE-TREATMENT OF WRINKLES PRACTICE

SURGITRON® DUAL RF™ S5 can be used to treat wrinkles in the facial region. Move to the Cut mode. A Pellevé Wrinkle Treatment Handpiece is used to treat wrinkles. Prior to performing wrinkle treatment, the tissue should be wiped clean of any lotions or makeup. Pellevé Treatment Gel should be applied liberally to the surface of the tissue.

## PROCEDURAL INSTRUCTIONS

- Set up the system with a Pellevé Wrinkle Treatment Handpiece.
- The SURGITRON® DUAL RF™ S5 generator should be in the “CUT” mode for all wrinkle treatments.
- The power settings for the treatment should be based on the verbal feedback from the patient. If the patient experiences any discomfort from the treatment, immediately turn the setting on the SURGITRON® DUAL RF™ S5 generator down to a comfortable setting for the patient.
- The patient is typically relaxing in an examining chair or on an examining table with the physician positioned close to the patient's head. The Neutral Plate is placed under the patient's shoulders or back, but always making full contact.
- Pellevé Treatment Gel is applied to the skin of the treatment area of the face. The gel should be applied as a thin, even layer. The Pellevé handpiece should only be activated on skin that is coated with gel. The gel should be applied liberally to the treatment area throughout the procedure.
- After application of gel to the treatment area, the handpiece is placed on the treated skin and is activated by pressing either the yellow “CUT” foot pedal connected to the generator or the yellow “CUT” button on the probe handpiece. The handpiece must be in contact with the skin prior to the activation of the generator and the generator must be deactivated prior to removing the handpiece from the treatment area. The audible “beep” sound is the signal that the generator is active.



The activated handpiece, in contact with the skin, is continuously moving in small circular overlapping patterns (2-5 cm diameter) in the gel-coated treatment area for 3 to 5 minutes.

It is important to have the patient's feedback on the temperature of the treatment. If the patient feels that the temperature is too hot, turn the setting on the SURGITRON® DUAL RF™ S5 generator down by approximately 10% and then ask them how it feels. The treatment should be warm to the patient but without a burning sensation. If the temperature is slightly warm, slowly turn up the settings until the patient feels warm and the physician can see contraction of the collagen or firming of the skin. The skin temperature should be approximately 42° C during ideal treatment.

- An ice pack can be applied to the skin for approximately 10-15 seconds to relieve and cool the skin after treating an area for approximately 5 minutes. The skin may redden or darken slightly due to the treatment.
- Mild swelling (edema) and redness may occur which typically resolves within 3 to 5 days, but can persist up to several weeks.
- A regimen to moisturize and soothe skin for one week post-treatment is recommended.



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