The Aviva procedure is based on RF thermal coagulation of subcutaneous tissue. This Handpiece is ideal for performing focal treatments of small areas. The small size of the Handpiece allows performance of the treatment with a minimal incision port and minimal downtime.

INDICATIONS

The system is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. The result is heating of the fibrous septa and reticular dermis, resulting in collagen contraction.

TREATMENT AREAS

- Typical treatment depth for Vulvar Area is 5-10mm
- Working superficially on hair-bearing areas may cause hair loss.
- Treatment zone size is ~4x4cm (do not operate closer than 2cm from the incision port)

TREATMENT TECHNIQUES

- Heating on Withdrawal technique – Insert cannula forward without RF then apply RF on withdrawal only.
- Stamping technique – Used ONLY on very small treatment areas where moving is limited and Heating on Withdrawal Technique is impossible. Insert the cannula, apply RF for a couple seconds, release footswitch, reposition the canula, apply RF. Use caution when operating with this technique.

TYPICAL TREATMENT PARAMETERS

Treatment Area	Treatment Depth	Hand Piece	External Cut-off Temperature	Internal Cut-off Temperature	Energy Total Per Zone
Mons Pubis	5-10mm	Aviva	35-38°C	50-65°C	1.0 – 1.5 kJ max
Labia Majora	5-10mm	Aviva	35-38°C	50-65°C	1.0 – 1.5 kJ max per side
Labia Minora	5-10mm	Aviva	38°C	50-58°C	0.25 – 0.5 kJ max per side
Clitoral Hood	5-8mm	Aviva	38°C	50-58°C	0.1 – 0.3 kJ max

- RF power is automatically adjusted to reach and maintain the temperature.
- Maximal safety is achieved when External cut-off is monitored and best end point when Internal cut-off is achieved uniformly in the treatment zone.
- Higher temperature cutoffs and energy for lateral, larger structures. Lower temperature cutoffs and energy for medial, smaller and mucosal tissues.
- Treatment time is a safety feature, requiring footswitch reactivation after time elapses if endpoint has not been reached. Passes are made until proper cut-off temperatures and skin responses are achieved.

PRE-TREATMENT

- Prophylactic antivirals should be prescribed in all patients with a history of Herpes.
- Anticoagulants should be stopped 10 days before treatment, if medically permitted.
- Review patient intake and consider all contraindications for RF.
- Mark treatment zones.
- Select incision/access ports, considering accessibility and curvature, avoid treating over Clitoris Base line, stay 2cm above and 2 cm below Clitoris Base line to avoid Dorsal Nerve of Clitoris injury.
- **Do not treat Clitoris or Urethra.**
- The Handpiece is gamma-sterilized for a single use only and CANNOT be autoclaved or re-sterilized by any other technology. The Handpiece should be inspected for and damage before use.

TREATMENT PROCEDURE

- Make a small incision, using 16G or 18G needle or with a scalpel away from the treatment area border.
- Anesthesia - Infiltrate tumescent to the sub-dermal plane with syringe and spinal needle or infiltrating cannula until tissue is firm. Wait for 20min. IV sedation may also be used for sensitive patients or multiple zone treatment.
- Before activating the RF energy, confirm your depth and ascertain a sense of internal characteristics.

- Apply sterile ultrasound gel and introduce the cannula through the incision port.
- Insert the cannula into subcutaneous layer parallel to tissue surface.
- To avoid external and internal burns in the treatment area, avoid treating too superficially and too deep near delicate structures like the base of clitoris.
- Ensure complete contact between external electrode and the tissue to avoid hot spots.
- Use free hand to flatten the tissue and direct the cannula, especially on curved areas.
- Touch STANDBY on the screen to enter READY mode then press the footswitch to apply RF.
- Use ***Heating on Withdrawal*** technique for treatment of Labia Majora, Labia Minora, Mons Pubis.
- Use ***Stamping*** technique with caution for treatment of Clitoral Hood if ***Heating on Withdrawal*** is not possible.
- Keep moving the cannula slowly while foot switch is pressed.
- Treat the zone in a sequential fanning motion avoiding continuous heating of the same line and avoid applying RF too close to the access port.
- After time elapses, release the footswitch and press again if cut-off temperature has not been reached.
- If cut-off temperature is reached before time elapses, stop and move to next zone or finish the treatment.
- Release the footswitch and stop RF at least 1.5-2.0cm from the access port before removing the cannula.
- Avoid treating more than 2 minutes continuously through the same access port. Alternate access ports or allow the access port to cool down for about 1-2 min using sterile cold compresses.
- Typical energy applied is about 1.0kJ for each side of Labia Majora, 1.0-1.5kJ for Mons Pubis, 0.25 – 0.5 kJ max per side for Labia Minora.
- Always stop when there is excessive response such as dark erythema or nodule. Cool the area and avoid heating that area further. Cool the access ports after completing treatment of each zone.
- Avoid treatment in the areas above superficial nerves. Ensure enough tumescent infiltration in this area to minimize heat expansion.
- Aspiration of fat in Mons Pubis area should be done if more than 50cc of tissue per area is coagulated.

POST-TREATMENT

- Immediate cooling of the tissue with saline-soaked gauze can reduce discomfort and excessive skin response.
- Suture access ports or leave open, depending on the incision port size.
- Dressing should be applied for 24 hours.
- Drainage of fluids out the incision ports may continue for 1-3 days and dressing should be changed daily.
- Discomfort can be reduced by the prescription of oral analgesia.
- Prophylactic oral and topical antibiotics for the incision ports may be prescribed as per the physician discretion. It may start the day of treatment and continued for 5-7 days to minimize risk of infection.
- Compression garment should be applied upon physician discretion: For Mons Pubis – 3-4 full days and 1-2 weeks night only.
- Ecchymosis may last for 7-10 days or more.
- Substantial edema may last for 1-3 weeks.
- Numbness, tingling, itching and tenderness to touch may be present in the treated areas and gradually regained after 4-16 weeks or occasionally longer. Burning or heat sensation may also be experienced in the treatment areas as well.
- Patient should avoid intercourse for 2 weeks post procedure.

RESULTS

- Edema and a tightening effect from the edema and immediate collagen shrinkage should be seen during and post treatment.
- Improvement of contour may be seen immediately, but all effects improve gradually over 3-12 months.

TIPS

- Cooling measures, preferably sterile, should be ready if needed.
- Avoid applying RF over superficial injected areas with natural fillers. It is better to inject after RF treatment, but treatment over deep natural fillers is possible immediately. Wait for ~6 months or more to treat over superficial natural fillers. Treating over synthetic fillers, like silicon, is contraindicated.
- For optimal healing of access ports, apply sterile cold compresses to access port after treating each zone.