INSTRUCTIONS FOR USE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

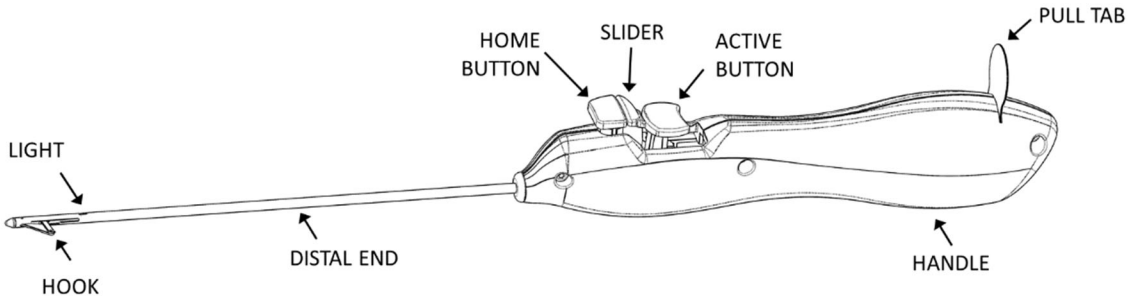
INDICATIONS FOR USE

The Avéli® Precision Cellulite Release Device is indicated for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating treatment benefits through one year of observation. Avéli is also indicated for soft tissue dissection during general and plastic surgical procedures.

DEVICE DESCRIPTION

Avéli® is a device intended for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating treatment benefits through one year of observation. Avéli is also indicated for soft tissue dissection during general and plastic surgical procedures. Avéli consists of a Handle and a Distal End. The Handle houses the Slider, Home Button, and Active Button used to actuate the moving parts at the distal end of the device. The device incorporates a Light to provide transillumination for navigation; transillumination through the skin allows the user to identify and track the location of the Hook. The Pull Tab is removed prior to use to activate the Light.

Figure 1 - The Avéli Precision Cellulite Release Device



CONTRAINDICATIONS

Avéli should not be used on patients who have (or who are):

- Coagulant disorders / on anticoagulant medications
- Diabetic
- Had recent surgery (6 weeks)
- Pregnant
- Severe anemia
- Skin infections/ open lesions
- Tumors
- Uncontrolled hypertension
- Varicose veins (in the area of treatment)

WARNINGS

- Failure to carefully follow all applicable instructions may result in injury to the patient, user, or attendants and may have an adverse effect on procedural outcomes.
- Avéli is for single use only. Do NOT re-use or re-sterilize. Re-sterilization of the device or components may result in a risk of device malfunction and/or contamination due to residual fluids/tissue in the device.
- Avéli contains sharp areas. Handle with caution and dispose of in appropriate sharps containers per standard practice.
- Prior to use, inspect device and packaging for damage or breach of sterile packaging seals. Do NOT use product if there is any evidence of damage or breach.

PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.
- Avéli is intended for use by trained users.
- Prior to using the device, the user must thoroughly read and understand the Instructions for Use.
- Inspect device prior to use for damage. If damage is found, set device aside and use another. Pay close attention to the Hook during inspection.
- Do not drop Avéli. If dropped it should be inspected for damage and its function checked. If dropped and any part of the device leaves the sterile field, the device should be considered non-sterile and removed from use.
- The Handle contains electrical components. Do NOT expose the Handle to fluids.

ADDITIONAL WARNINGS AND PRECAUTIONS

Additional warnings and precautions are provided within the **Instructions for Use** section for specific procedural steps.

RISKS

Potential adverse events related to the Avéli device or procedure include the following:

- Abnormal or burning sensation
- Bleeding
- Ecchymosis / bruising
- Edema
- Fainting
- Fat necrosis
- Fluid collection
- Fluid discharge
- Hematoma
- Hemosiderin stain
- Hyper/hypo pigmentation
- Incision site complication
- Induration
- Infection
- Inflammation / swelling
- Irritation, itch
- Laceration
- Numbness / Tingling / Hypersensitive skin
- Pain / Stinging / Tenderness / Discomfort
- Scar
- Seroma
- Skin discoloration
- Skin indentation, depression or other irregularity
- Skin necrosis
- Toxic, allergic, or other reaction from the anesthetic

PROCEDURE OVERVIEW

Avéli is a sterile, single-use manual instrument that releases fibrous tissue (septa) beneath cellulite for long-term reduction in the appearance of cellulite in the buttocks and thigh areas of adult females. Avéli also dissects soft tissue in general and plastic surgical procedures. The device consists of a Handle and a Distal End. The Handle houses components used to actuate the moving parts at the distal end of the device. The Distal End is advanced into subcutaneous tissue through a small incision to a procedure location. An integrated light source provides illumination and allows the user to track and advance to the procedure location. The Distal End contains a Blade and a Blocker forming a Hook. When the Handle is moved in a retrograde fashion, the Hook captures the nearby septa or other soft tissue resulting in tugging. The user feels the resistance, confirming that septa under a cellulite depression or other treatment area have been identified and then exposes the Blade at the Distal End. The user pushes the skin distally with the free hand while maintaining the device stable or applies additional retrograde motion with the device to release the soft tissue. The user then retracts the Blade and the Blocker into the device, allowing removal without further tissue engagement. The user can verify all appropriate soft tissue has been released by passing through the area again with the Hook. The step is repeated for each visible cellulite depression or other surgical area.

PRE-PROCEDURE

If the patient is a good candidate for the procedure, the following are recommended:

- Patients should discontinue, if medically feasible, any drugs or dietary supplements that could prolong bleeding at least 14 days prior to the procedure.
- Review the patient's medical history for evidence of disease, condition, or drug use and compare to the contraindications which may compromise the results of the procedure.

Cellulite depressions disappear in the prone position; therefore, the depression locations should be marked with a surgical marker while the patient is standing relaxed. With the targeted skin depressions marked, procedural planning can occur. The choice of access sites, bilateral or unilateral, and how many marked locations will be at the discretion of the user. Attention should be paid to the size of marked locations.

ANESTHESIA DELIVERY

The procedure is performed under anesthesia. The type of anesthesia is at the discretion of the physician.

PACKAGING

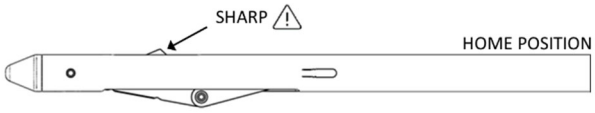
Avéli is provided sterile and has a limited shelf life. The device must be used on or before the "Use by Date" provided on the package.

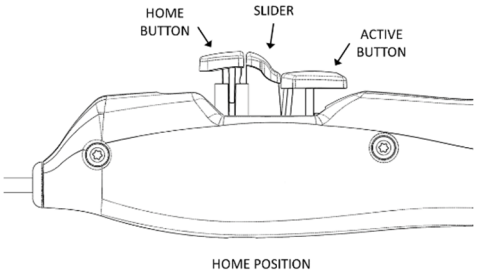
INSTRUCTIONS FOR USE

Device Positions

Avéli can be placed in three positions: Home Position, Open Position, and Active Position.

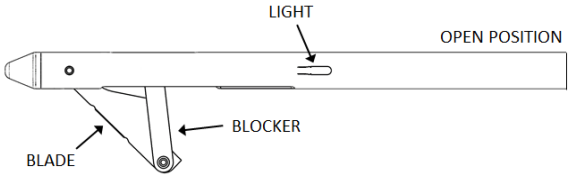
Figure 2 - Home Position

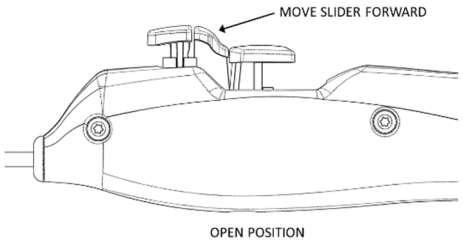




In Home Position the Slider is retracted, and the distal mechanism is drawn into the Distal End.

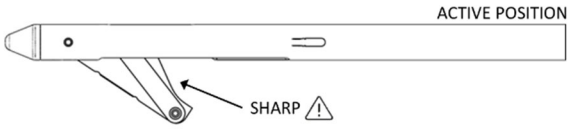
Figure 3 - Open Position

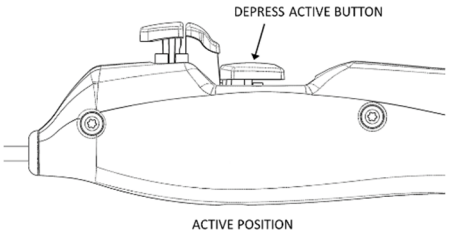




The Slider is moved forward to deploy the Hook into Open Position. When the Slider is fully forward the Hook will lock into position until the Home Button is depressed to return to Home Position.

Figure 4 - Active Position





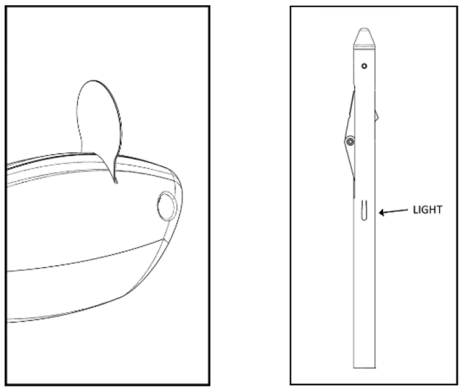
With the device in Open Position, the Active Button is pressed and held to expose the Blade. The hook shape is maintained while the Active Button is depressed. By releasing the Active Button, the device is returned to Open Position.

Device Set Up

Activate the Light by removing the Pull Tab. Once removed, confirm light is illuminating from the distal end of the device.

If during use the Light dims or turns off, remove device safely and complete procedure with new device.

CAUTION: DO NOT stare directly at the Light after the Pull Tab has been removed.



Device Use

With the device illuminated and in Home Position, advance the Distal End through the entry incision toward the procedure area with the Light facing up. Using the Light, track the device as it approaches the marked cellulite depression location or general surgical area. The Light size and brightness can aid in ensuring the tip is at the appropriate depth.

Once aligned with the marked depression location, move the Slider forward to place the device into Open Position. With the Hook deployed, pull the Handle back to engage septa or soft tissue intended for dissection. Once resistance is felt, continue to pull back until visible tension is seen in the skin.

CAUTION: DO NOT use excessive force.

CAUTION: DO NOT rotate device in Open Position.

If the created cellulite depression is outside the target location, or if the soft tissue engaged is not intended for dissection, disengage the tissue by advancing the device forward. Place the device into Home Position by pressing the Home Button. The device can then be repositioned, and septa or soft tissue engagement can be attempted again. Once the skin tension aligns with the marked location, press and hold the Active Button to expose the Blade. With the Active Button pressed, push the skin distally with the free hand while maintaining the device stable or continue pulling the Handle back to release the septa or soft tissue while using the free hand to stabilize the skin. Stop pulling once the target septa or other soft tissue is released.

CAUTION: DO NOT rotate device in the Active Position.

CAUTION: DO NOT press on patient's skin near the Blade to avoid laceration.

CAUTION: DO NOT treat between marked locations.

Verify all intended soft tissue has been released by passing through the area again in the Open Position. If it is not possible to engage septa and create a depression in the intended area, press the Home Button to return to Home Position. Repeat the Device Use steps for other marked depressions or procedure locations.

CAUTION: DO NOT move device to a new treatment area or remove with device in Open or Active Positions.

Whenever the device is withdrawn from the incision, clean the Blocker and Blade as necessary. If unexpected resistance is felt, remove the device, and inspect the distal mechanism for any tissue or damage.

DEVICE DISPOSAL

Dispose of device according to Federal, state, and local regulations, and appropriate environmental health safety guidelines. The device should be disposed of in a biohazard sharps disposal container. Device contains lithium battery. Do NOT incinerate except for disposal in a controlled incinerator.

POST-TREATMENT EXPECTATIONS

- Discomfort or pain may occur during the first days of the postoperative period and can be controlled with common analgesics. Areas may be painful with pressure for the first month.
- Compressive clothing can be worn during the first 2 weeks post treatment as desired.
- Light physical activity is allowed in the first 14 days, but extreme physical activity should be avoided during healing. Strenuous activity may increase symptoms.
- Ecchymosis and some hemosiderosis are expected.
- Palpable areas of firmness (or softness) are expected. Patients are usually reassured when they are told that these areas are reported to be desirable for correcting the depressions that previously existed. If the areas are slow to improve, patients can be asked to perform firm massage with their fingertips for a few minutes a day until resolved.

CLINICAL DATA SUMMARY

The *in vivo* performance of the Avéli Precision Cellulite Release Device was evaluated in a pivotal clinical study. A prospective, non-randomized, multi-center study was conducted to evaluate the safety and effectiveness of Avéli for the treatment of cellulite in the buttock and thigh areas of 74 participants across nine (9) investigational sites in the US and Australia. All participants served as their own control and underwent a single treatment with Avéli. Participants underwent follow-up assessments at 1 day (virtual), 7 days (virtual or clinic), 30 days, 3 months, 6 months, and one year post-treatment.

The participant inclusion/exclusion criteria limited inclusion to females between the ages of 21 and 55 with moderate to severe cellulite in the thighs and/or buttocks and a body mass index (BMI) less than 30. The enrolled study population included females between the ages of 26 and 54 with moderate to severe cellulite and BMI between 19 and 29.8. In addition, participants were excluded that smoked or had recently quit smoking (within the last 6 months). The participants were asked to rate their pain and satisfaction with their appearance. Photographs were taken under standardized conditions in accordance with study photography manual at baseline and each follow-up visit. Outcomes were assessed by three, independent blinded reviewers using photographs before treatment, at 3 months, 6 months, and one year post-treatment to verify the effectiveness of the procedure. The one year results demonstrate safety and durability through one year.

No Unanticipated Adverse Device Effects (UADE), related Serious Adverse Events (SAE) nor severe adverse events occurred in the study. The primary safety endpoint for the study was achieved with no device related SAEs at 30 days. Any undesirable medical occurrence was considered an adverse event. There were three adverse device effects (ADEs) that occurred in two participants: 1) an extended incision to facilitate removal of device in Hook Position, 2) a skin laceration (~1mm), and 3) a small scar from the skin laceration. The types and rates of the observed events are typical of this mechanism of action and were generally mild, transient, and only four events involved interventions to resolve: (1) aeration of ~2x1cm discreet subcutaneous mass, (2) seroma requiring aspiration, (3) hematoma requiring aspiration, and (4) stitching an extended device entry incision. The most common AEs were ecchymosis (86.8%), tenderness (51.5%), pain (38.2%), induration (36.8%), and numbness (17.6%). Ecchymosis had a median duration of 27 days, tenderness a median duration of 21 days, induration a median of 172 days, and numbness a median of 58 days. Many participants (83.8%, 57/68) experienced tenderness or pain within the first 24 hours. Some participants (13/68, 19.1%) could return to normal activities the day of the procedure, and most (63/68, 92.6%) within a week. Of the most common adverse events reported, induration had the longest mean duration. Generally, the induration was described as small areas of firmness, not visible or painful, and not associated with the incision site. A small proportion of adverse events (6.0%) were ongoing at study exit (one year) and included induration, numbness, skin hyperpigmentation, skin dysaesthesia, and skin indentation (also described as a depression or other irregularity). The skin indentations (2/68, 2.9%) presented at 3 months and 6 months, respectively. No medical intervention was required.

In the clinical study, effectiveness was evaluated with an improvement assessment by independent physician evaluation of participant photographs. Participants were overall satisfied with their cellulite procedure results. The participant photo evaluation was conducted by an independent firm in accordance with the study protocol whereby the evaluators were disclosed nothing about the sponsor, the investigational device, or the clinical investigators. A total of three independent physician evaluators were selected, individually trained, and monitored throughout the evaluation. In the evaluation, blinded before (baseline) and after photographs were provided side by side in randomized orientation (L-R) and the

physician evaluators were asked to identify the baseline and after photographs and rate the overall improvement according to a Global Aesthetic Improvement Scale GAIS and the Cellulite Severity Scale (CSS)[1]. All reliability and repeatability measures were met at 3 months and validated the methodology.

The overall study success criterion was achievement of a safe and clinically significant improvement in the appearance of cellulite in the treated subjects. The primary effectiveness endpoint was to demonstrate that the mean change (improvement) in the Cellulite Severity Score (CSS) is more than 1 for the study population, as determined by the independent, blinded physician evaluators comparing baseline and 3-month photos. The primary effectiveness endpoint was achieved. The CSS evaluations at 6 and 12 months demonstrated durability through one year.

In conclusion, the study primary endpoints were achieved, and results were sustained at one year. The *in vivo* performance data collected in the pivotal study demonstrates that Avéli is both safe and effective for treating cellulite in the buttock and thigh locations.

[1] CSS = CSS-A (Number of Evident Depressions) + CSS-B (Average Depth of Depressions) – 1, as assessed and averaged by three blinded, independent physicians.

GRAPHIC SYMBOLS CONTAINED ON DEVICE LABELING

	Consult Instructions for Use
	Lot Number
	Model Number
	Sterilization with Ethylene Oxide
	Do Not Reuse
	Manufacturer
	Manufacture Date
	Use By
	Type BF Applied Parts
	Temperature Range
	Humidity Symbol
	Medical devices — Indicates a medical device that should not be used if the package has been damaged or opened.

SPECIFICATIONS

Weight	58 Grams
Working Length	159mm
Light Source	620 - 630 nm
Activation Time	60 Minutes
Battery Type	Lithium Manganese Dioxide, CR2, 3V
Power Source	Internally Powered
LED Output	65000 mcd, typ.
Mode of Operation	Continuous
Operating Temperature Range	15° to 31° C (59° to 88° F)
Operating Humidity Range	30%-75% RH Non-Condensing
Transport Temperature Range	-30° to 60° C
Storage Temperature	0° to 40° C
Storage and Transport Humidity Range	15% to 90% RH Non-Condensing
Altitude (Operating)	<3000m (9800 ft.)
Complies with medical safety standards	AAMI/IEC 60601-1, IEC60601-1-6/62366

ELECTROMAGNETIC COMPATIBILITY (EMC)

Avéli complies with the requirements of IEC 60601-1-2:2014. The system was tested to the following standards.

Emissions (Class A, Group 1)	CISPR 11:2016 (Radiated Emissions)
Immunity	IEC 61000-4-2:2008 – ESD
	IEC 61000-4-3:2010 – Radiated
	IEC 61000-4-8:2009 – Magnetic

The limits are designed to provide reasonable protection against harmful interference in a typical hospital/medical installation. This equipment generates, uses, and can radiate radio frequency energy, and if not used in accordance with the manufacturer's instructions may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular circumstance.

To maintain proper functioning of Avéli as it pertains to EMC, all the instructions in this manual should be followed throughout the useful life of the product.

Interference from electronic sources may result in loss of illumination.

The operator should be aware of the following; however, they do not pose hazards to the patient or operator.

If this equipment causes interference with other devices or if other equipment is causing interference with this equipment, which may be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment (minimum 30cm is recommended)
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Replace un-shielded cables with shielded ones.
- Consult the manufacturer or field service technician for help.

Manufacturer

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