INSTRUCTIONS FOR USE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

1. INTENDED USE

The Celluleaf is intended for subcutaneous blunt release of fibrous septae in soft tissues.

2. DEVICE DESCRIPTION

Celluleaf is a sterile, single-use medical device for subcutaneous blunt release of fibrous septae. The handheld device consists of a handle and a cannula fitted with a deployable wire (Figure 1). The deployable wire (called the "leaf") is used to engage the fibrous septae. The operator-controlled slider button positioned on top of the handle is used to deploy/retract the leaf. Once the leaf is deployed, the manipulation of the septae is done manually by the operator.

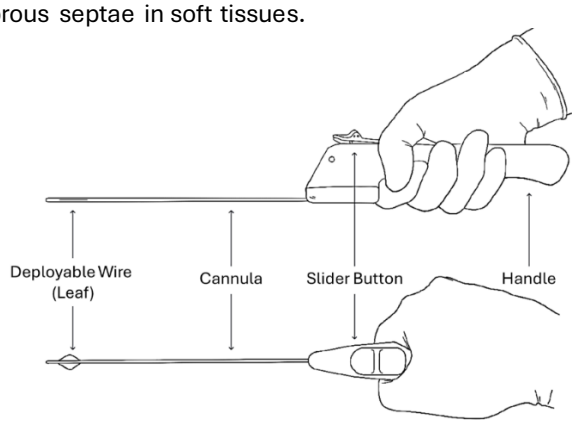

Figure 1. Annotated schematic of the Celluleaf device.

The device has two configurations based on the position of the slider button: deployed leaf configuration (Figure 2A, slider button pushed to front and latched) and closed leaf configuration (Figure 2B, slider button unlatched and pulled back).

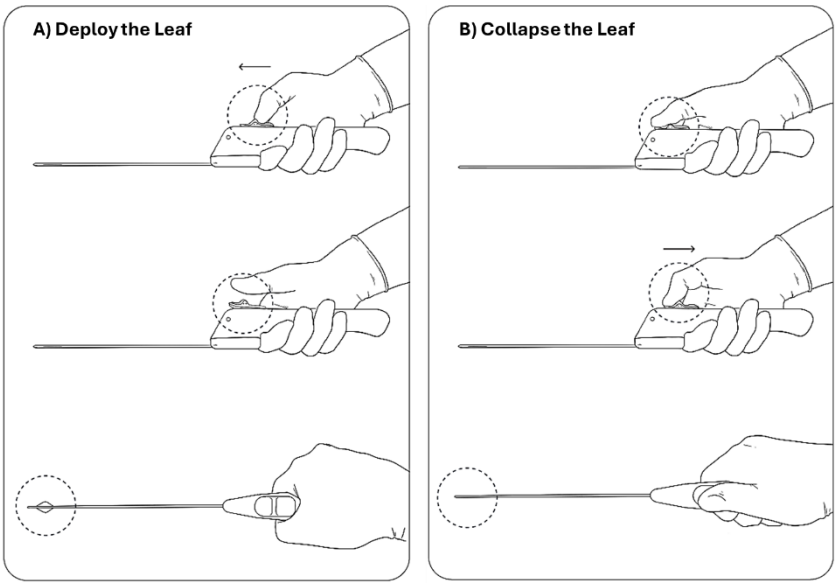

Figure 2. Celluleaf configurations.

3. INSTRUCTIONS FOR USE

Prior to inserting the device into the tissue, a skin incision must be made and anesthesia provided at the discretion of the physician. Celluleaf is delivered in the deployed leaf configuration. To begin the procedure, remove the device from its protective packaging, press down on the slider button and pull it backward into the closed configuration (Figure 2B) to collapse the leaf inside the cannula. Whilst in collapsed configuration, insert the Celluleaf cannula through the pre-made skin entry incision and guide it toward the treatment area. Using the handle, position the cannula under the skin surface, ensuring the tip of the cannula extends slightly beyond the targeted septae (Figure 3, Step 1). To fully deploy the leaf, push the slider button fully forward and latch it (Figure 3, Step 2). When latched, the button elevates slightly. Once the leaf is deployed, initiate the mechanical blunt dissection of fibrous septae by pulling the handle backward. Continue pulling to gently release the fibrous septae in the targeted area (Figure 3, Step 3). After the release is completed collapse the leaf into the cannula by pressing the slider button down and pulling it backward to the retracted position (Figure 3, Step 4).

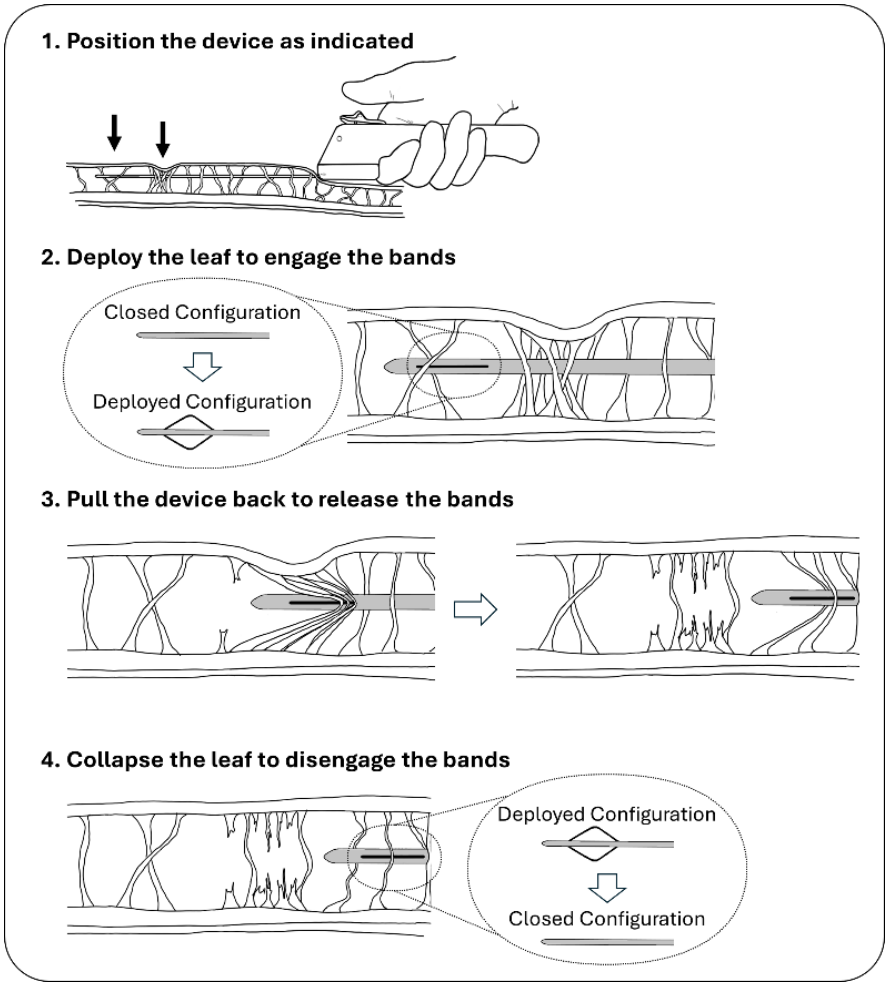

Figure 3. Stepwise instructions for using Celluleaf.

CAUTION: DO NOT push the device forward in the deployed leaf configuration as it could damage the leaf.

CAUTION: DO NOT use excessive force when using the device.

CAUTION: DO NOT pull the wires of the leaf apart with fingers as it could damage the leaf.

CAUTION: DO NOT rotate the device in the deployed leaf configuration within the tissue as it could damage the leaf.

CAUTION: DO NOT deploy/collapse the leaf for more than 400 cycles in total per individual device.

WARNING: If UNEXPECTED RESISTANCE is felt during use, collapse the leaf, remove the device, and inspect the cannula and the leaf.

At the discretion of the user, the release can be repeated based on the remaining resistance of the septae. To treat a new area, draw back and reposition the device in the closed configuration within the tissue (Figure 3, Step 1), then repeat the leaf deployment, followed by mechanical blunt septae release (Figure 3, Steps 2-4). Once finished, remove the device whilst in the closed configuration through the incision.

CAUTION: DO NOT withdraw the device from the incision in the deployed leaf configuration to avoid unintended dissection.

4. CONTRAINDICATIONS

Celluleaf shall not be used on patients who have (or who are):

- Coagulant disorders
- On anticoagulant medications

- Diabetic
- Had recent surgery (6 weeks)
- Pregnant
- Skin infections/ open lesions
- Tumors
- Uncontrolled hypertension
- Allergy/ hypersensitivity to nickel or titanium
- Varicose veins (in the area of treatment)

5. WARNINGS

- Failure to carefully follow all instructions may result in injury to the patient, physician, user, or attendants and may have an adverse effect on procedural outcomes.
- Celluleaf is for single use only. Do NOT reuse or resterilize. Resterilization of the device or components may result in a risk of device malfunction and/or contamination due to residual fluids/tissue in the device.
- Prior to use, inspect device and packaging for damage or breach of sterile packaging seals. Do NOT use the product if there is any evidence of damage or breach.
- The device must be used on or before the "Use-by Date" provided on the label located on the carton and the pouch.
- Dispose of device according to Federal, state, and local regulations, and appropriate environmental health safety guidelines.
- The device contains 304 stainless steel and nitinol (an alloy of nickel and titanium). People with allergies or hypersensitivities to these metals may suffer an allergic reaction to this device. Prior to use, patients shall be counseled on this.
- Additional Warnings are provided within the Instructions for Use above.

6. PRECAUTIONS

- Federal law restricts this device to sale by or on the order of a physician (RX only).
- Celluleaf is intended for users trained by profession.
- Prior to using the device, the user must thoroughly read and understand the Instructions for Use.
- Inspect device prior to use for damage. Pay close attention to the sterile barrier system and the deployable leaf unit. If damage is found, do not use the device.
- Do not drop the Celluleaf. If dropped it must be inspected for damage and its function checked. If dropped and any part of the device leaves the sterile field, the device must be considered non-sterile and removed from use.
- Do not repeatedly deploy/collapse the leaf outside the tissue as it may cause malfunction and damage to the device.

7. RISKS

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

- Abnormal or burning sensation
- Bleeding
- Ecchymosis, bruising
- Edema
- Fainting
- Fluid collection
- Fluid discharge
- Hematoma
- Hemosiderin stain
- Hyper-, hypopigmentation
- Incision site complication
- Induration
- Infection
- Inflammation, swelling
- Irritation, itch
- Laceration
- Necrosis of fat or skin
- Numbness, tingling, hypersensitive skin
- Pain, stinging, tenderness, discomfort
- Scar
- Seroma
- Skin discoloration
- Skin indentation, depression or other irregularity
- Toxic, allergic, or other reaction from the anesthetic

8. REPORTING COMPLAINTS AND INCIDENTS

All complaints and serious incidents associated with the use of this device shall be reported to Aliform B.V. through info@aliformsurgical.com or through the contact form on https://www.aliformsurgical.com/en/contact-us.

9. SPECIFICATIONS

Weight	63 g
Working Length	177 mm
Transport Temperature Range	-30°C to 60°C (-22°F to 140°F)
Transport Humidity Range	15 to 90% RH, Non-Condensing
Storage Temperature	15°C to 25°C (59°F to 77°F)
Storage Humidity Range	15% to 60% RH, Non-Condensing

10. GRAPHIC SYMBOLS CONTAINED ON DEVICE LABELLING

	Consult Instructions for Use
	Caution
LOT	Batch Code
REF	Catalogue number
STERILE R	Sterilization using irradiation
	Single sterile barrier system with protective packaging inside
	Do Not Reuse
	Do not use if package is damaged and consult instructions for use

	Do not resterilize
	Manufacturer
	Importer
	Date of Manufacture
	Use-By Date
	Temperature Range
	Humidity Range
UDI	Unique Device Identifier

Manufacturer
Aliform B.V.
Oxfordlaan 55
6229 EV Maastricht
Netherlands
www.aliformsurgical.com
Email: info@aliformsurgical.com

Importer
RAF Solutions, Inc.
10124 NW 53rd St
Sunrise, FL 33351
United States
www.rafsolutions.net