Instructions for Use
Sono-Instrument Kits

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CE 0051

SPIRECUT

Sono Instruments

EN

1. General Info

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These IFU refer to any article labelled with: "IFU/Label Reference: **SIKITS**" reported on device label.

Every user is required to read these instructions carefully before using the devices. Keep these instructions accessible to all users at all times. Non-compliance with these instructions may lead to users/patients' injuries and/or other risks. Use the devices only for the described purposes. Using them for different purposes may cause damage or failure, or may cause injuries to the patients or even their death.

Each residual risk, side-effect, contra-indication, warning, precaution, measure, recommendation and/or any other safety info is preceded by dedicated symbols.

2. Device Description

SPIRECUT has developed two different Sono-Instrument Kits (SI), one for carpal tunnel release (CT-SI), and the other for trigger finger/thumb (TF-SI) surgical procedures. Both SI are composed by a Sono-Instrument and a probe. The Sono-Instrument is made out of a handle connected to an elongated rod. The handle is designed to allow holding, orientation and manipulation of the Sono-Instrument by the physician. The SI has markings designed to be distinguishable under sonography and a marking on the handle to manage the orientation. There are two similar models of SI, differing by their size and by the shape of the rod. The larger variant is adapted to the treatment of the adult carpal tunnel (CT-SI), and the smaller variant to the treatment of the adult trigger finger/thumb (TF-SI). The probe is used to identify the tissues to be released, to dissect and make surgical space for the Sono-Instrument, and, at the end of the operation, to make sure that the release is complete.

Recommendation: The patient must be informed about any residual risk, side-effect, contraindication, warning, precaution, measure, recommendation and/or any other safety info.

Recommendation: During surgical procedure follow the orientation of SI by mean of sonographer.

2.1 Intended Use

The SI are single-use medical devices intended for mini-invasive hand surgery under sonography.

2.1.1 Indications for Use

The Sono-Instruments are intended to be used for adult common upper extremity affections:

- *Carpal tunnel syndrome* (percutaneous release of the transverse carpal ligament or flexor retinaculum);
- *Trigger finger/thumb* (percutaneous release of annular pulley(s), in particular the A1 pulley, with or without adjacent ganglion).

The probes are used to dissect the tissues and, at the end of the procedure, to make sure that the surgical release is complete.

2.1.2 Patient Target Population

- Gender: Not relevant
- Age Range: Adult population only
- Weight: Not relevant
- Nationality: Not relevant

2.1.3 Patient Selection Criteria

The practitioner is responsible and has the appropriate skills to define criteria for patient selection depending on clinical conditions. The device shall be selected and used on the defined patient following the manufacturer intended use, indications for use, contra-indications and target population.

2.2 Contra-indications

Contraindications:
Do not use SI:
- in direct contact with Central Circulatory System,
- in direct contact with Central Nervous System,
- in children, dwarf patients or in case of small size hand/carpal tunnel/finger-thumb,
- if there is a history of a previous infection, as the infection could have caused fibrosis, or as the operation can re-activate the infection, causing delayed healing and/or severe complications,
- in case of active or past infections, because the infection may be spread to healthy tissues and made worse by the operation,
- in conditions that tend to limit the patient's ability or willingness to understand per or postoperative recommendations during the healing period,
- for surgeries other than those indicated or at another anatomical location,
- in case of known allergic reaction to metals,
- in case of known clinical risks associated to the use of SI outweighing the expected clinical benefits,
- in case of anatomical abnormalities affecting the flexor digital sheath, digital nerves/vessels, median nerve, median nerve artery, flexor tendons, wrist bones or in case of local tumors or other conditions increasing the risk of an iatrogenic lesion; a trigger finger of long evolution, with stiffness of the proximal interphalangeal joint, constitutes a relative contra-indication as it could be better treated by open surgery with removal of a superficialis tendon slip,
- in case of an alteration of the coagulation with significant risk of per/postoperative bleeding,
- in case of any contra-indication to anesthesia, whether local, regional or general,
- in case of insufficient sonographic identification of the operated tissues or insufficient experience of the user in sonography,
- in case of neuro-vascular structures in the zone of intended release, like may be seen in anatomical variations or vessel dilatation like seen in case of an arterio-venous fistula,
- in case the physician has insufficient experience in hand surgery and particularly deficient knowledge of hand anatomy, including anatomical variants,
- in case of tissue adhesions which may potentially compromise the safe and precise introduction of the probe and then of the Sono-Instrument,
- in case of a previous attempt to treat the condition, for example a persistent disease after previous open, endoscopic or percutaneous procedure, or a recurrence of the condition with persistent or recurrent symptoms,
- in case of a previous fracture or dislocation in the operated area or any affection causing malalignment or distortion of the local skeleton, due to trauma, arthritis or other causes,
- for the carpal tunnel syndrome, in case of severe median nerve dysfunction requiring microsurgical epineurotomy, or if the nerve dysfunction has another cause that an idiopathic compression syndrome, like a canalar mass (ganglion, tumor, foreign body, or other space-occupying disesases);
- in case of the devices are plastically deformed, broken or fall down. If the event happens throughout surgical procedure, remove the instrument and all the fragments immediately.

In general, all other contra-indications mentioned for endoscopic release of carpal tunnel or trigger finger/thumb are valid for percutaneous release using Spirecut's SI.

2.2.1 Other Residual Risks and/or Side Effects

Adverse Effects:
- Postoperative bleeding and/or haematoma after the release,
- Infection both deep and superficial,
- Allergic reaction to metals,
- Incomplete release with persistent symptoms,
- Risk of iatrogenic lesion in case of poor recognition of the tissues to be released,
- Classical complications of hand surgery occur also after percutaneous release, including decreased strength, stiffness, CRPS, PIP extension lag after trigger finger release, pillar pain after carpal tunnel release.

2.2.2 Special Considerations

The device neither contains nor incorporates medicinal substances, including human blood or plasma derivative, human or animal tissues, cells and derivatives.

2.3 Intended User and Use Environment

The SI device may only be used by professional users in accordance with its indications. Users must have demonstrated technical knowledge, experience and education concerning hand anatomy, hand surgery, the use of the device and hand sonography. They must attend specific training courses before using the SI in patients, as these instructions contain only a limited amount of information. The devices must be managed in aseptic environments and under strict sterile conditions.

Precaution: SPIRECUT assumes that professional users have experience and knowledge of standard protocols regarding hand surgery and particularly in percutaneous release procedures under sonography. Furthermore, SPIRECUT declines any responsibility if the users have not followed lab manual-skills training with associated instrumentation prior the procedure. Surgeons are advised to review the product specific surgical technique prior to performing any surgery. SPIRECUT provides detailed surgical technique in print and in video. Training courses are also organized. Contact the distributor representative for more information.

Precaution: In case of any doubt in identification of the anatomical structures or poor visibility of the SI during the operation, always convert to open surgery (or stop the surgery).

Precaution: The cutting extremity of the SI is sharp. The user should be quite careful to limit the release to the transvers carpal ligament (carpal tunnel) or the flexor annular pulley (trigger finger/thumb), and not to cut neither the superficial tissues nor the skin. In case of skin laceration, in addition to the non-desired skin opening, there is a danger to perforate the sterile sheath of the sonographic probe, causing contamination of the operative field and possibly an infection.

Rx only | US Federal Law restricts this device to sale by or on the order of a physician only.

3. Surgical Techniques

Surgical techniques are available on SPIRECUT webpage at following link:
https://spirecut.com/surgical-procedure/

4. Accessories and Device Combination

The SI kits contain a Sono-Instrument and a probe. The devices are intended to be used under sonography guidance. The ultrasound scanner must provide good B-mode imaging of relatively superficial tissues which usually implies the use of an imaging device allowing high ultrasound frequencies. Doppler mode can be useful to better visualize the neighboring vascular structures. It is necessary to use sterile sonography gel and a sterile, transparent cover for the probe.

⚠ | *Recommendations:* The device may only be used in combination with original products provided by manufacturer or on behalf of him.

5. Device Performances / Expected Clinical Benefit

The following clinical benefits are associated with SI application:

- efficient treatment of trigger finger/thumb without surgical incision and related complications (instead, simple puncture wound),
- for the trigger finger, simultaneous treatment of associated tendon sheath ganglion, if present,
- for the trigger finger, preoperative understanding of the location of tendon blockade, with more efficient release and peroperative confirmation, after the release, of adequate flexor tendon gliding,
- postoperative improvement with diminution or disappearance of paraesthesiae after carpal tunnel release.

Therefore, a positive impact is expected on the health of the treated patients. Furthermore, no adverse clinical outcomes are expected if the instructions for use and surgical technique are strictly followed by experienced physicians. However, the usual clinical sequels of trigger finger and carpal tunnel surgery seen after open or endoscopic surgery may also be observed after percutaneous technique, including finger stiffness, proximal interphalangeal joint extension deficit after trigger finger surgery, decreased hand strength, pillar pain. Occasionally, CRPS may be observed. Overall, the patient's life quality is improved.

⚠ | *Precautions:* Do not force the SI and probe in case of difficulties to insert it. This may lead to device deformation and/or breakage that can cause unforeseeable injuries.

6. Clinical Info / Technical Knowledge

A Clinical Investigation has been carried out on SPIRECUT' Sono-Instrument Kits.
Results are available on the European Database for Medical Devices (EUDAMED).

7. Delivery Conditions

⚠ | *Precaution:* The SI are fragile, and their cutting extremity is sharp. The instruments should be handled with care during transportation and handling procedures, including when opening their sterile pack.

STERILE R | SI are delivered in sterile state. Sterilization is achieved by irradiation.

Re-Sterilization is absolutely forbidden.

Do not use the sterile devices after expiration date

Check the integrity of the packaging before use. SI must not be used and shall be disposed pursuant to these IFU if the packaging is open or damaged and consequently, sterility and/or device may be jeopardized.

SI is for single use only and must not be used in more than one trigger finger/carpal tunnel surgical procedure. Re-use may pose health and/or safety risks to the patient that can include but are not limited to cross-infections, compromised mechanical and cutting performances due to wear, lack of or no function, no guarantee of proper cleaning or sterilization of the device. In case of bilateral disease, or in case of several trigger fingers, use a new SI for each release.

8. Transport, Storage and Handling Conditions

SI must be transported, stored and managed with care. The transport conditions and the storage room have to be dust-free, with low microbiological contamination, dark and free of temperature fluctuations.

Keep the devices away from sunlight.

Keep the devices in dry area.

+35 / +5 | Indicates the maximum (+35°) and minimum (+5°) temperature limits at which the item shall be stored, transported or used.

9. Disposal

The products are to be disposed according to the local laws and regulations.

10. Quality and Warranty

All SPIRECUT products are designed and manufactured to the highest quality standards. SPIRECUT excludes all warranty claims and takes no responsibility for direct or subsequent damage resulting from:

- Use for the wrong indication or anatomical location,
- Improper use, application or handling,
- Lack of training;
- Repeated use;
- Combination with foreign products;
- Disregard of the IFUs.

11. Notice

Serious incidents and/or relevant harms related to the use of SPIRECUT devices are not expected. Nevertheless, SPIRECUT kindly asks users/patients and/or third parties to promptly inform in case of any incident that has occurred in relation to the use of its devices.

12. Used Symbols Explanation

The following symbols may have been used in this or in a connected labelling:

Symbol	Description
	Symbol for "Manufacturer"
	Symbol for "Consults the Instruction for Use"
MD	Symbol for "Medical Device"
REF	Symbol for "Article Number"
LOT	Symbol for "Batch Code"
STERILE R	Symbol for "Sterilized by Irradiation"
	Symbol for "Do not use whether packaging is open or damaged"
	Symbol for "Use by"
	Symbol for "Keep away from sunlight"
	Symbol for "Keep dry"
+35 / +5	Symbol for "Temperature Limits"
	Symbol for "Do not Re-sterilize"
	Symbol for "Do not-Reuse"
	Symbol for "Caution, consult accompanying documents"
UDI	Symbol for "UDI"
Rx only	Symbol for "US Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner"
EC REP	Symbol for "Authorized European Representative"
CE 0051	Symbol for "European conformity to the essential requirements with notified body number"