	ISO 15223-1:2016 5.1.6	**Catalogue or Model Number/** Indicates the manufacturer's catalogue number so that the medical device can be identified.
	IEC 60601-1:2012 Table D.2, Symbol 10	**Follow Instructions for Use** / Refer to instruction manual/booklet.
	ISO 15223-1:2016 5.4.2	**Single Use only** / Indicates medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1:2016 5.4.4	**Attention, see Instructions For Use /** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions.

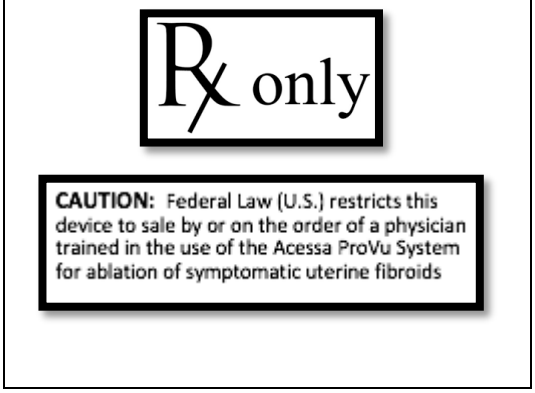
MANUFACTURED FOR: Acessa Health Inc.
317 Grace Ln, Suite 200
Austin, TX 78746 USA

www.acessaprocedure.com
Telephone: 877.412.3828
Fax: 925.605.0327

acessa ProVu

Acessa ProVu Handpiece (7300)

Instructions for Use



Product description:
The Acessa ProVu Handpiece is an RF ablation device to be connected to the Acessa ProVu System. The Acessa ProVu Handpiece is designed to function with or without tracking. The Acessa ProVu Handpiece is equipped with a slider knob to control the deployment and retraction of the needle array.

The Acessa ProVu Handpiece (7300) is part of the Acessa ProVu System.

Indications for use:
The Acessa ProVu Handpiece is an accessory to the Acessa ProVu System (Model 7100) for use during the Acessa procedure. See the Acessa ProVu System User's Guide (PI-01-0040) for additional information.

Contraindication:
- The tracking feature may not be used to guide the tip of the Acessa ProVu Handpiece once the tip has penetrated the uterine serosa. Ultrasound visualization must be used for fibroid penetration and treatment
- The Acessa ProVu Handpiece is not intended for any type of diagnostic use.
- Patients who are not candidates for laparoscopic surgery (e.g. patients with known or suspected intra-abdominal adhesions that would interfere with safe use of the Acessa ProVu Handpiece).
- Uterus adherent to pelvic tissue or viscera.
- Non-uterine pelvic mass.

Warnings:
- The safety and effectiveness of the tracking feature to guide the tip of the Acessa ProVu Handpiece has not been evaluated in clinical trials. Therefore, tracking should only be used until the device has penetrated the uterine serosa.
- Prior to use, refer to the Acessa ProVu User's Guide (PL-01-0040) for complete information.
- For single patient use only! Re-use of the electrosurgical Acessa ProVu Handpiece may result in its failure as well as post-operative infection.
- Caution, Sharp Distal tip.
- The Acessa ProVu Handpiece should be used only by physicians and medical staff who have been trained and have a thorough understanding of the system.
- The Acessa ProVu Handpiece's guidance capability has an accuracy of ±10 mm.
- The Acessa ProVu Handpiece is shipped sterile. DO NOT ATTEMPT TO RE-STERILIZE as doing so will result in product damage and may cause injury to patient or physician.
- When using the device in situations where vision may be limited, burns may result if the device is activated outside the field of view.
- Do not touch the Acessa ProVu Handpiece tip of the coagulating electrode and Dispersive Electrode at the same time especially when operating the system, as capacitive coupling may lead to burns.
- Do not use product after its expiration date (see packaging label)
- Always verify that the needles are fully retracted before positioning, advancing, or withdrawing the Acessa ProVu Handpiece.
- To avoid damage to the needles, maintain stability of the uterus position and do no rotate the Acessa ProVu Handpiece handle/shaft when needles are deployed in tissue.
- Excessive bending or kinking of Acessa ProVu Handpiece shaft may damage internal mechanicals rendering the device inoperable.
- When deploying the Acessa ProVu Handpiece needles, observe the force applied to the slider knob. Stop deployment if excessive resistance is felt. In all cases deployment should be accomplished with one hand while grasping the Acessa ProVu Handpiece. Higher resistance may indicate dense tissue; see Acessa ProVu User Guide for suggestions in treatment.
- During Coag mode, the user may experience char on the tip. A sterile disposable wipe moistened with 70/30 isopropyl alcohol may be used to clean the trocar tip. Dry the Trocar or allow it to evaporate before use. Before Acessa ProVu Handpiece insertion into peritoneal cavity, deploy needle array and inspect.
- After use, this product is potentially a biohazard. Handle and dispose of, in accordance with accepted medical practice and with applicable laws and regulations.

Precautions:
- Prior to use, refer to the Acessa ProVu User's Guide (PL-01-0040) for complete information.
- The Acessa ProVu Handpiece is used with products manufactured by Acessa Health Inc. under the Acessa family of devices.
- The Acessa ProVu Handpiece cannot be used with any other radiofrequency generator. It can only be used with the Acessa ProVu System.
- The safety of electrosurgery will be greatly enhanced by a thorough knowledge of the medical literature on the subject. Study of specific information on the hazards and complications of the procedure in question is especially recommended. All packaging should be inspected prior to use.
- Do not use if the sterile barrier has been breached.
- Do not use if the packaging or product is damaged in any way.
- Do not use if product has been dropped.
- Once the Acessa ProVu Handpiece tip is visible in the ultrasound, within the area where the fibroid is located, the physician reverts to standard laparoscopic ultrasound imaging to place the tip within the fibroid. Tracking is no longer necessary at this point.

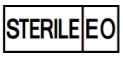
Potential Complications:
Potential complications of RF ablations may include, but are not limited to:
- Unintended Burns
- Bleeding
- Pain
- Local and/or Systemic Infections
- Hematoma at entry side
- Tissue Nerve Damage

Device Preparation and Operation:
1. Store in a dry place.
2. Remove package and place Acessa ProVu Handpiece in sterile field.
3. Attach the Acessa ProVu Handpiece to the Acessa ProVu Handpiece Cable.
4. Ensure that there are 6 thermocouple temperatures registering on the User Interface screen.
5. Deploy the needles once in the air and then retract before inserting the Acessa ProVu Handpiece into the site.
6. Placement and deployment of the Acessa ProVu Handpiece shaft must be done with ultrasound guidance.
7. Needle deployment and retraction is done with the slider knob as shown in the image below.

8. Retraction of the needles must be done before Acessa ProVu Handpiece removal or Coag is used.

Warranty: Acessa warrants the original purchase of the Acessa ProVu Handpiece shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use. The obligation of Acessa under this warranty shall be limited to a replacement, at no charge, if examination shall disclose to the satisfaction of Acessa that the Acessa ProVu Handpiece does not meet this warranty.

Glossary of Symbols

Symbol	Standard Reference	Symbol Title/Description
	US 21 CFR 801.109	**Prescription Only** / Device restricted to use by or on the order of a physician.
	ISO 15223-1:2016 5.1.5	**Lot Identification** / Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1:2016 5.1.1	**Manufacturer** / Indicates the medical device manufacturer.
	ISO 15223-1:2016 5.2.3	**Sterilized Using Ethylene Oxide** / Indicates medical device has been sterilized using ethylene oxide.
	ISO 15223-1:2016 5.1.4	**Use by** / Indicates date after which medical device is not to be used (YYYY-MM-DD).