Table 3. Recommended Sterilization Cycles (V-PRO®)

STERILIZATION METHOD	PREPARATION*	STERIS V-PRO® STERILIZER & CYCLE TYPE
Low-temperature Hydrogen Peroxide Gas Plasma Technology	Place into STERIS Sterilization Tray and wrap with H600 OneStep wrap	V-PRO® 1 – Standard Cycle.
		V-PRO® 1 Plus – Lumen and Non-Lumen Cycles
		V-PRO® maX – Lumen, Non-Lumen & Flexible Cycles
		V-PRO® maX 2 – Lumen, Non-Lumen, Flexible and Fast Non-Lumen Cycles
		V-PRO® 60 – Lumen, Non-Lumen and Flexible Cycles
		V-PRO® s2 – Lumen, Non-Lumen, Flexible and Fast Cycles

**Device preparation is based on the Acessa validated process. Reference appropriate V-PRO® model instructions for additional information or guidance.*

No toxic residues are left after STERRAD® or V-PRO® sterilization. No aeration is needed for devices sterilized using the STERRAD® or V-PRO® Systems.

Specific sterilization questions should be made directly either to Advanced Sterilization Products at: http://www.aspjj.com/,
Or STERIS Corporation at: http://www.steris.com/.

Glossary of Symbols

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE/DESCRIPTION
Rx only	US 21 CFR 801.109	**Prescription Only** / Device restricted to use by or on the order of a physician.
LOT	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.
REF	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.
NON STERILE	ISO 15223-1:2016 5.2.7	**Non-sterile** / Sterilize Prior to Use (manufacturer does not provide this device sterile)

MANUFACTURER: 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 Cable (Model Number 7400)

Instructions for Use

Rx only

CAUTION: Federal Law (U.S) restricts this device to sale by or on the order of a physician trained in the use of the Acessa ProVu System for ablation of symptomatic uterine fibroids

Product Description:
The Acessa ProVu Handpiece Cable provides connectivity of the Acessa ProVu Handpiece to the Acessa ProVu System.

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

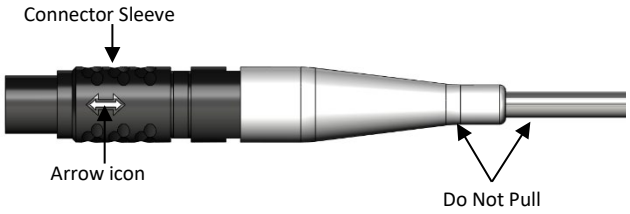
Contraindication:
The Acessa ProVu Handpiece Cable is contraindicated for use any time use of the Acessa System is contraindicated.

Warnings:
- The Acessa ProVu Handpiece Cable should be used only by physicians and medical staff who have been trained and have a thorough understanding of both the Acessa ProVu System.
- The Acessa ProVu Handpiece Cable is shipped non-sterile.

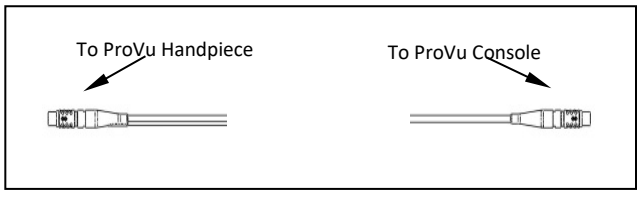
Precautions:
- Do not use if the product is damaged in any way.
- Refer to the Acessa ProVu System User's Guide (PL-01-0040) for additional information on the set-up and use of the Acessa ProVu System.
- The Acessa ProVu Handpiece Cable has not been validated for more than 20 uses.

Preparation and Operation:
1. Remove the Acessa ProVu Handpiece Cable from its packaging.
2. Inspect cable for damage. Do not use if it appears to be damaged.
3. CLEAN & STERILIZE THE CABLE PRIOR TO EVERY USE.
4. Ensure that the cable & interconnections are completely dry prior to use.
5. See diagram below: Connect one end to the Acessa ProVu Handpiece and the other end to the Acessa ProVu Console with this icon:

6. Ensure that there is a tactile feel when the connector latches or listen to the engaging click of the connector. Do the same for the Acessa ProVu Handpiece connector.
7. Follow any other instructions pertinent to the Acessa ProVu Handpiece being used.
8. To disconnect the cable, pull straight back on the connector sleeve (see Arrow icon) and then disconnect. DO NOT PULL ON CABLE.



9. Store cable in a dry location.
10. See figure below for connections to the system.



Recommended Cleaning and Sterilization
Acessa Health recommends the following cleaning and sterilization steps as outlined below. Clean and sterilize the Acessa Handpiece Cable before first and every use. Acessa Handpiece Cables must be thoroughly cleaned, rinsed and dried according to the process described in this section before proceeding with sterilization of the device. Thorough cleaning and rinsing are the first and most important steps in the reprocessing of any reusable medical device. Without thorough cleaning and rinsing, it is not possible to achieve effective sterilization of the device.

Cleaning
Rinse contact area of cable thoroughly with running water for two (2) minutes at 40°C (104°F), making sure all foreign matter, blood, mucus, etc. are removed with a debris removal tool. (ex. soft bristle brush, lint free cloth, sponge, etc.).
Immerse device in an Enzymatic Cleaner with water at approximately 43°C (110°F) for three (3) minutes, while wiping and scrubbing cable and connectors with a debris removal tool.
Follow the detergent manufacturer's instructions for concentration and other conditions.
Rinse with water for four (4) minutes at 40°C (104°F).
Dry with a lint free cloth.
Thoroughly examine all surfaces that have been cleaned and visually inspect the entire device to make sure it is clean.

Table 1. Recommended Manual Cleaning Durations

TREATMENT	TIME(MM:SS)	CLEANING SOLUTION
Rinse under running water with a with a debris removal tool ensuring all soil has been removed	02:00	Water 40°C (104°F)
Immerse device while wiping and scrubbing cable and connector with a debris removal tool.	03:00	Enzymatic Cleaner 43°C (110°F)
Rinse	04:00	Water 40°C (104°F)

Sterilization
The Acessa Handpiece Cable is provided non-sterile. The cable is sterilized using low-temperature hydrogen peroxide gas plasma technology, selected for its ability to process heat- and moisture-sensitive medical devices quickly, without producing toxic residues or emissions. The cable has been designed to be compatible with ASP STERRAD® 100NX, NX, and 100S systems, as well as STERIS V-PRO® systems.

NOTE: Only one (1) Acessa Handpiece Cable should be run in a STERRAD® NX, 100S, or V-PRO® load at a time and No more than two (2) Acessa Handpiece Cables should be run in a STERRAD® 100NX load at a time.

The following low-temperature hydrogen peroxide gas plasma sterilization cycles have been validated to result in a SAL of 10^{-6} in accordance with applicable standards, including AAMI TIR12:

Table 2. Recommended Sterilization Cycles (STERRAD®)

STERILIZATION METHOD	PREPARATION*	STERRAD® STERILIZATION SYSTEM & CYCLE TYPE
Low-temperature Hydrogen Peroxide Gas Plasma Technology	Double wrap utilizing (inner wrap 500 grade, outer wrap 600 grade) FDA cleared Sterilization Wrap	STERRAD® Model 100NX Standard Cycle.
	Place into APTIMAX® Instrument Tray, PC:13837	STERRAD® Model NX Standard Cycle.
	Double wrap with H400 Sterilization Wrap, Halyard Health, PC:68248	STERRAD® Model 100S Short and Long Cycles.

**Device preparation is based on the Acessa validated process. Reference appropriate STERRAD® model instructions for additional information or guidance.*