Glossary of Symbols

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
LOT	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	EN ISO 15223-1, 5.2.6 ISO 7000, 2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	EN ISO 15223-1, 5.4.2 ISO 7000, 1051 IEC 60601-1, Table D.1, 28	Do not re-use	Indicates a medical device that is intended for one single use only.
	EN ISO 15223-1, 5.2.8 ISO 7000, 2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	ISO 7010 ISO 3864-2, M002	Follow instructions for use	To signify that the instruction manual/booklet must be read.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3079	Open here	To identify the location where the package can be opened and to indicate the method of opening it.
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
Rx ONLY	FDA 21 CFR 801.109	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
STERILE EO	EN ISO 15223-1, 5.2.3 ISO 7000, 2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	IEC 60601-1, Table D.1, 20 IEC 60417, 5333	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1
	EN ISO 15223-1, 5.1.4 ISO 7000, 2607	Use-by date	Indicates the date after which the medical device is not to be used.

acessa®

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Acessa Handpiece (7300) Instructions for Use

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

The Acessa Handpiece (7300) is part of the Acessa procedure.

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

Contraindication:
- The tracking feature may not be used to guide the tip of the Acessa Handpiece once the tip has penetrated the uterine serosa. Ultrasound visualization must be used for fibroid penetration and treatment
- The Acessa 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 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 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 System User's Guide (PL-01-0040) for complete information.
- For single patient use only! Re-use of the electrosurgical Acessa Handpiece may result in its failure as well as post-operative infection.
- Caution, Sharp Distal tip.
- The Acessa Handpiece should be used only by physicians and medical staff who have been trained and have a thorough understanding of the system.
- The Acessa Handpiece's guidance capability has an accuracy of ±10 mm. The Acessa 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 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 Handpiece.
- To avoid damage to the needles, maintain stability of the uterus position and do no rotate the Acessa Handpiece handle/shaft when needles are deployed in tissue.
- Excessive bending or kinking of Acessa Handpiece shaft may damage internal mechanicals rendering the device inoperable.
- When deploying the Acessa 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 Handpiece. Higher resistance may indicate dense tissue; see Acessa System 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 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 System User's Guide (PL-01-0040) for complete information.
- The Acessa Handpiece is used with products manufactured by Hologic Inc. under the Acessa family of devices.
- The Acessa Handpiece cannot be used with any other radiofrequency generator. It can only be used with the Acessa Procedure.
- 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 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 Handpiece in sterile field.
3. Attach the Acessa Handpiece to the Acessa 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 Handpiece into the site.
6. Placement and deployment of the Acessa 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.

DEPLOYED ◄——► RETRACTED

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

Warrenty: Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d). designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

FOR MORE INFORMATION
For Technical Support or reorder information in the United States, please contact:

Hologic Inc.
250 Campus Drive
Marlborough, MA 01752 USA
www.hologic.com
Telephone: 800-442-9892 • Fax.: 855.511.6540
Email: GSSTechSupport2@Hologic.com