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, 5.2.8 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.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
	EN ISO 15223-1, 5.2.7 ISO 7000, 2609	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	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.
	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.


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acessa®

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

Acessa Handpiece Cable (Model Number 7400) Instructions for Use

PL-01-0041 Rev. 005 05/2022

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

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

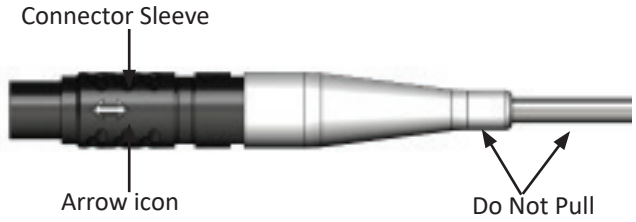
Contraindication:
The Acessa Handpiece Cable is contraindicated any time when the use of the Acessa procedure is contraindicated.

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

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

Preparation and Operation:
1. Remove the Acessa 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 Handpiece and the other end to the Acessa 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 Handpiece connector.
7. Follow any other instructions pertinent to the Acessa 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
Hologic, Inc. 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 approximately 43°C (110°F), making sure all foreign matter, blood, mucus, etc. are removed with a soft bristle brush.
Immerse device in Prolystica Enzymatic Cleaner, at a concentration of 1/2 ounce cleaner to 1 gallon water, at approximately 43°C (110°F) for three (3) minutes, while wiping and scrubbing cable and connectors with an Endozime Sponge.
Follow the detergent manufacturer's instructions for concentration and other conditions.
Rinse with deionized water for one minute.
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 43°C (110°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	Deionized Water

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, V-PRO® or 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 Steriliation 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® modelinstructions for additional information or guidance.*

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/.