



October 23, 2009

To whom it may concern:

The following are the tested and recommended methods of cleaning the Hemostatix Thermal Scalpel Handles including:

REF #	DESCRIPTION
7013-5050	5050 HANDLE FOR MODELS 150 & 600D CONTROLLER
7013-6050	6050 HANDLE FOR MODELS 2400Z CONTROLLER
7013-8050	8050 HANDLE FOR MODELS P8400 CONTROLLER

HANDLE / CABLE CLEANING

- **DO NOT** immerse the handle in liquid of ANY KIND. The handle contains electronic contacts and a printed circuit board which will be damaged and fail to function if immersed in liquids of any kind.
- **DO NOT** allow any solution to penetrate to the interior of the handle.
- **DO NOT** use ultrasonic cleaning. Manual cleaning is the recommended (and tested) method of cleaning for the Model P8400 handle and cable.

Since the devices cannot be immersed, it is important to adhere to the following instructions: Cleaning should begin as soon as possible following a procedure. Prepare an enzyme solution (e.g., Klenzyme™) and a detergent solution (e.g., Manu-Klenz™) as recommended by the manufacturer. An enzyme is not a cleaner. An enzyme is intended to break down blood and bodily fluids (i.e., protein), and thus facilitate cleaning. Detergents contain wetting and emulsifying agents that suspend soil and prevent the formation of insoluble compounds on the device or on the surface of the cleaning solution. Gently wipe the surface of the device with a sponge or towel that has been moistened with the enzyme solution. Rinse the blade receptacle of the handle thoroughly with the enzyme solution and use a soft bristle brush to remove any gross soil paying attention to crevices and other hard-to-clean areas. The use of pipe cleaners or cotton swabs should be avoided since they tend to fray, leaving behind particles inside the blade receptacle. Carefully examine the device for any adherent visible soil (e.g., blood, protein). Enzymes are themselves protein substances and must be thoroughly removed with a detergent. Repeat the steps of wiping the surface of the device and cleaning the blade receptacle with a soft bristle brush and the detergent solution. Rinsing with lukewarm water is necessary to remove all traces of detergents and extraneous debris. Following cleaning, shake the device to remove excess water and wipe the handle and cable with a dry cloth.

- **NOTE:** Electrical contacts in the handle will wear and become oxidized with repeated use. When handle contacts have degraded, the handle will no longer function properly and should be replaced with a new one. **USE OF A HANDLE WITH DEGRADED CONTACTS CAN RESULT IN BLADES RUNNING HOTTER OR COOLER THAN THE 'TEMPERATURE SETTING' VALUE INDICATED BY THE CONTROLLER UNIT AND MAY ADVERSELY AFFECT SURGICAL PERFORMANCE.**
- **NOTE:** Hemostatix Thermal Scalpel handles are limited-use, reusable devices intended to be replaced after no more than 10 uses. The Model P8400 controller is designed to count the number of times a particular handle has been energized. Beginning with the 5th time, the controller will display the number of uses. Once the number of uses has reached the maximum number of recommended uses (10), the controller will display a message indicating that the number of recommended uses has been reached. If the same handle is used again, the display will alert the user that the maximum number of recommended uses has been exceeded and the handle should be replaced.



October 23, 2009

To whom it may concern:

The following are the tested and recommended method(s) of sterilizing the Hemostatix Thermal Scalpel Handles including:

REF #	DESCRIPTION
7013-5050	5050 HANDLE FOR MODELS 150 & 600D CONTROLLER
7013-6050	6050 HANDLE FOR MODELS 2400Z CONTROLLER
7013-8050	8050 HANDLE FOR MODELS P8400 CONTROLLER

NOTE: DO NOT STERILIZE THE HANDLE USING THE STERRAD® METHOD OF STERILIZATION. THIS STERILIZATION METHOD HAS NOT BEEN VALIDATED FOR THIS PRODUCT AND THE SENSITIVE ELECTRICAL COMPONENTS WITHIN THE HANDLE ARE DAMAGED BY THE PROCESS.

HANDLE / CABLE STERILIZATION – Before re-sterilization, inspect to ensure there are not breaks in the cable and no foreign material in the blade receptacle or the handle / cable connectors. Ensure that the handle On/Off switch is in the ON or OFF position (not in between). Loop the cable cord assembly into approximately seven inch diameter circles and place in appropriate packaging material for the type of sterilization to be performed. The Hemostatix Thermal Scalpel handle and/or cable can be sterilized using the following methods:

STEAM AUTOCLAVE PARAMETERS FOR HEMOSTATAIX HANDLES AND CABLES

- NOTE:** Repeated exposures to steam autoclave temperatures of 132° C (270° F) and above in an unwrapped" for "flash" steam autoclave cycle may result in discoloration and/or deformation of the handle parts, cable, or connectors; thereby, reducing the life of the devices. If steam autoclaving is the chosen method of sterilization, the handles are to be "wrapped" and the recommended parameters used as follows:

Gravity Displacement Cycle 1
 Temperature: 132° C (270° F)
 Exposure Time: 15 Minutes
 Drying Time: 30 Minutes

Gravity Displacement Cycle 2
 Temperature: 121° C (250° F)
 Exposure Time: 30 Minutes
 Drying Time: 30 Minutes

Pre-vacuum Cycle
 Temperature: 132° C (270° F)
 Exposure Time: 4 Minutes
 Drying Time: 30 Minutes

- NOTE:** A complete drying cycle should be performed to reduce/prevent eventual corrosion of the electrical contacts within the handle from the steam sterilization process.
- NOTE:** Electrical contacts in the handle will wear and become oxidized with repeated use. When handle contacts have degraded, the handle will no longer function properly and should be replaced with a new one. **USE OF A HANDLE WITH DEGRADED CONTACTS CAN RESULT IN BLADES RUNNING HOTTER OR COOLER THAN THE 'TEMPERATURE SETTING' VALUE INDICATED BY THE CONTROLLER UNIT AND MAY ADVERSELY AFFECT SURGICAL PERFORMANCE.**
- NOTE:** Hemostatix Thermal Scalpel handles are limited-use, reusable devices intended to be replaced after no more than 10 uses. The Model P8400 controller is designed to count the number of times a particular handle has been energized. Beginning with the 5th time, the controller will display the number of uses. Once the number of uses has reached the maximum number of recommended uses (10), the controller will display a message indicating that the number of recommended uses has been reached. If the same handle is used again, the display will alert the user that the maximum number of recommended uses has been exceeded and the handle should be replaced.