

Essential Product Information

ULTRACISION[®] HARMONIC SCALPEL[®] 5 mm Instruments

Important	This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.
Product Codes	SHS05 HDH05 HC325 HBC05
Indications	The ULTRACISION HARMONIC SCALPEL 5 mm Instruments are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, gynecologic, and thoracic surgery, including mobilization of the Internal Mammary Artery (IMA).
Contra-indications	<ul style="list-style-type: none"> • The instruments are not indicated for incising bone. • The instruments are not intended for contraceptive tubal occlusion.
Warnings and Precautions	<ul style="list-style-type: none"> • Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure. • Minimally invasive instruments may vary from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure. • A thorough understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed. • Audible high-pitched tones, resonating from the blade or hand piece, are an abnormal condition and an indicator that the blade or hand piece is not operating properly. The tones may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high sheath temperatures and user or patient injury. • Do not use the ULTRACISION HARMONIC SCALPEL blades without the proper adaptor. Failure to use the proper adaptor as described in the device description may result in user or patient burn injury. • The blade has been designed to meet the international safety standard EN60601-1 based on an intermittent operation of 15 second on/off intervals. For activation time of longer duration and under certain fault conditions, the blade sheath may become hot. To prevent burn injury, avoid direct tissue contact with the blade sheath or take preventative measures to protect tissue that comes in contact with the sheath. • Blood and tissue buildup between the blade and sheath may result in abnormally high temperatures at the distal end of the sheath. To prevent burn injury, remove any visible tissue buildup at the distal end of the sheath.

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Warnings and Precautions (continued)	<ul style="list-style-type: none">• As with all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.• In case of system failure, ensure the availability of the appropriate backup equipment relevant to the specific procedure.• Do not attempt to bend, sharpen or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.• To avoid user or patient injury in the event that accidental activation occurs, the instrument blades should not be in contact with the patient, drapes or flammable materials while not in use. During prolonged activation in tissue, the instrument blades may become hot. Avoid unintended blade contact with tissue, drapes, surgical gowns, or other unintended sites after activation.• Use only the ULTRACISION HARMONIC SCALPEL Foot Switch, Hand Piece, blade accessories, and power cord to ensure that they are compatible with the Generator.• Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery, Inc. may not be compatible with the ULTRACISION HARMONIC SCALPEL System. Use of such products may lead to unanticipated results and possible injury to the user or patient.• After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.• Instruments or devices which comes into contact with bodily fluids may require special disposal handling to prevent biological contamination.• Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips, or other instruments while the instrument is activated may result in cracked or broken blades which may be identified by generator solid tone or instrument error.
	<ul style="list-style-type: none">• This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness or death. Cleaning and resterilization of single patient use ULTRACISION HARMONIC SCALPEL 5 mm Instruments can also result in abnormally high sheath temperatures and burn injury to user or patient when the blade is activated. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.