

syllable[™]

Ultrasonic Surgical Debridement System



"A superior wound healing method going beyond just 'cleaning' the wound bed."

Syllable™ Ultrasonic Surgical Debridement System

A Gamechanger Device Offering Better Results

- ✓ Decreasing bioburden,
- ✓ Preserving healthy tissue,
- ✓ Enhancing the wound healing process.

Mechanism of Action

Syllable™ Ultrasonic Surgical Debridement System uses ultrasonic technology in the form of a debridement system that ensures the secure and efficient removal of soft nonviable tissues excisional or sharp-edge debridement of wounds while safe preservation of healthy structures. Ultrasonic waves are utilized with Sterile Saline in order to remove debris and particulate matter from the wound bed which results in the proliferation phase.

1) Decreasing bioburden:

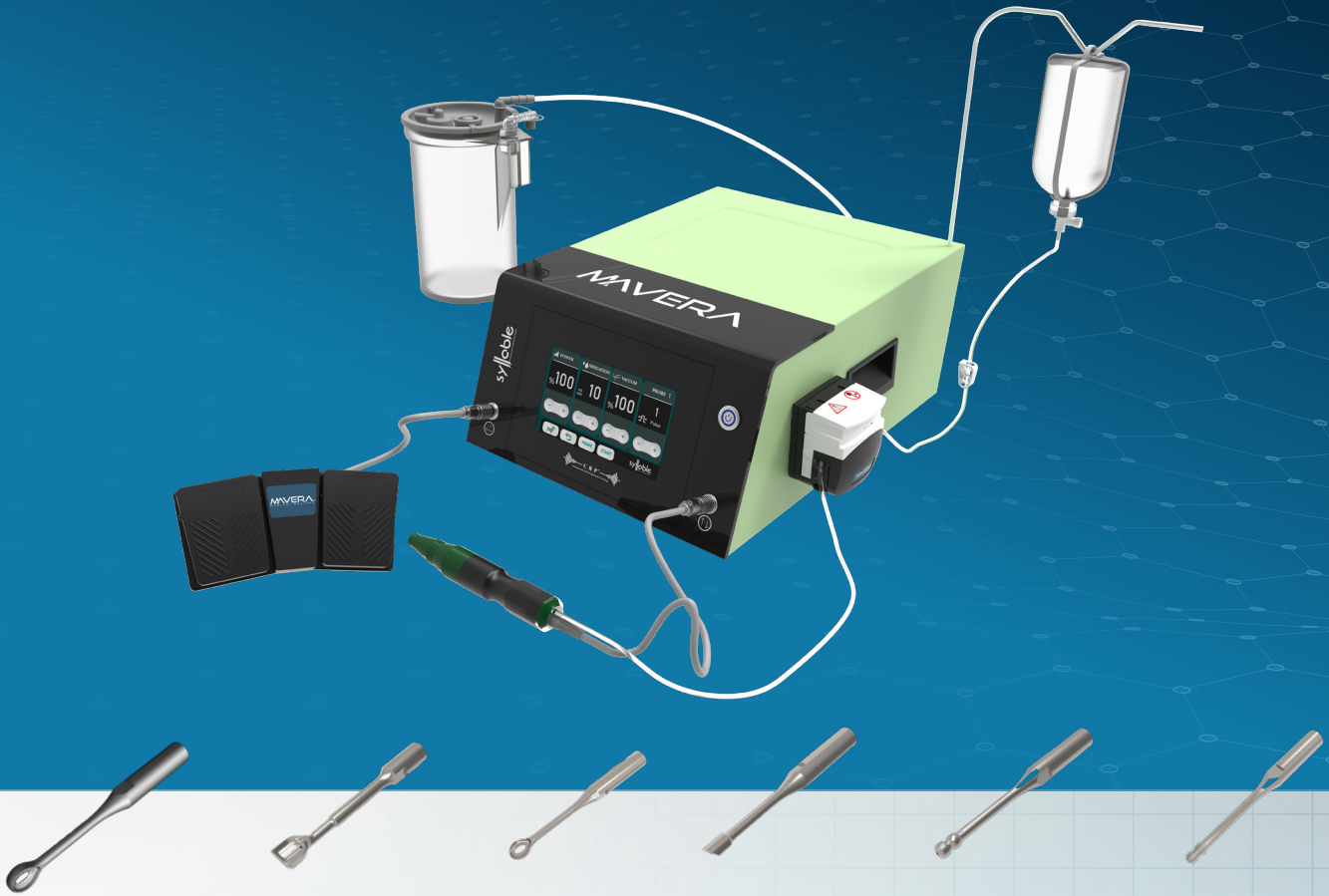
It was proved that UAW is effective in the cleaning the wound bed by destroying the extracellular substances. It influences the biofilm slime building capacity of bacteria left at wound site.¹ The gas-filled bubbles that is created by Ultrasonic Surgical Debridement System, expand rapidly after collapse. The microbubbles implosion releases energy which causes debridement thereby decreasing bioburden by fragmenting biofilms and bacteria.

2) Preserving healthy tissue:

Ultrasonic Surgical Debridement System uses cavitation effect to debride wound selectively. Cavitation is caused by the vibrations of the transducer at an ultrasonic frequency of 40kHz in an irrigation solution. An ultrasonic generator and Piezo-crystals transform the electrical energy into this mechanical vibratory motion that results in oscillations in tissue molecules that consists of a linear movement of macromolecules and ions around the stationary structure of the cells. This cavitation removes devitalized tissue from the wound bed while healthy tissue membranes move with oscillation.²

Indications

Ultrasonic Surgical Debridement System is indicated for using in selectively fragmentation, emulsification, resection, irrigation and aspiration of nonviable tissues excisional or sharp-edge debridement of wounds and, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site.



Product Overview

PRODUCT LIST	REF NO
Ultrasonic Generator Integrated with a Peristaltic Pump (Non-Sterile, Reusable)	SYL-GN01-N
Foot Switch (Non-Sterile, Reusable)	SYL-SHA01-N
Serum Hanger (Non-Sterile, Reusable)	SYL-FW01-N
Ultrasonic Handle (Non-Sterile, Re-Sterilizabile)	SYL-HL01-N
Surgical Probe SPR (Non-Sterile, Re-Sterilizabile)	SYL-SPR-N
Probe Torque Tool (Non-Sterile, Re-Sterilizabile)	SYL-PTTRQ-N
Sterilization Case (Non-Sterile, Re-Sterilizabile)	SYL-STE01-N
Surgical Probe SPI (Sterile, Single-Use)	SYL-SPI-S
Surgical Probe SPII (Sterile, Single-Use)	SYL-SPII-S
Surgical Probe SPIII (Sterile, Single-Use)	SYL-SPIII-S
Surgical Probe SPIV (Sterile, Single-Use)	SYL-SPIV-S
Surgical Probe SPV (Sterile, Single-Use)	SYL-SPV-S
Irrigation Tubing (Sterile, Single-Use)	SYL-IRT-S

References

¹Yarets, Y. (2017). Effective biofilm removal and changes in bacterial biofilm building capacity after wound debridement with low-frequency ultrasound as part of wound bed preparation before skin grafting. *Chronic Wound Care Management and Research*, Volume 4, 55-64. doi:10.2147/cwcmr.s127874

²Nyborg, W.L. Ultrasonic microstreaming and related phenomena. *Br J Cancer*. 1982; 45: 156-160.

J. Vanable Integumentary potentials and wound healing R. Borgens (Ed.), *Electric Fields in Vertebrate Repair*, Alan Liss Inc., New York (1989), pp. 171-224

The Syllable™ Ultrasonic Surgical Debridement System is intended to be used in selectively fragmentation, emulsification, resection, irrigation and aspiration of soft nonviable tissues excisional or sharp-edge debridement of wounds. Indications, contraindications and instructions for use can be found on the product labeling supplied with each device.

Syllable™ Ultrasonic Surgical Debridement System should be used by surgeons who have received the appropriate training.

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BEYOND FROM WITHIN™

Disclaimer

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Maveria Medical Devices Inc. guarantees that the products are designed, manufactured and packaged on application of the EN ISO 13485 certified quality management with all possible care, using the most suitable state-of-the-art processes and applying the principle of integrating safety into its design and manufacture. This system is designed to guarantee the safe use of device when it is employed under condition and for the purposes for which it is intended, in accordance with precautions described in the operator's manual and/or instructions for use and to minimize the risks associated with the use of the device as far as possible, although they cannot be totally eliminated. The device must only be used under the responsibility of specialist medical personnel, taking account of the unavoidable risks and the possible side effects and complications of the treatment for which, it is designed, including those referred to in other sections of these instructions for use.

U.S. and foreign patents pending

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