CLEAN
Medical Products

DISPOSABLE PULSED LAVAGE SYSTEM

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Science for health

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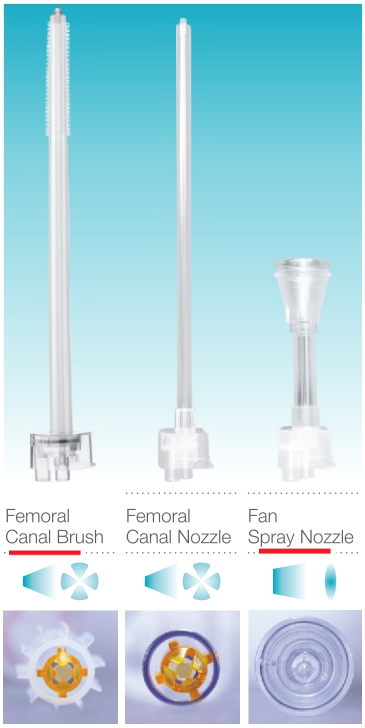
General Introduction

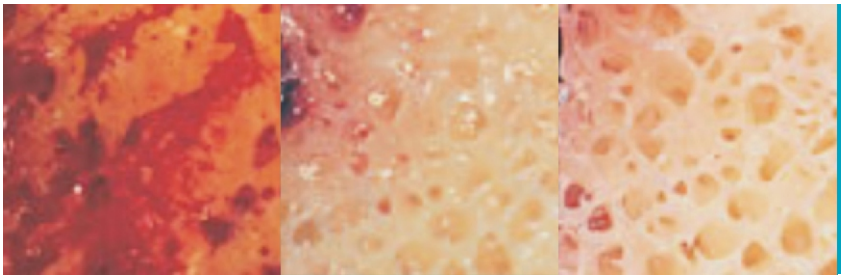
The application of Pulsed Lavage has been clinically proven to be essential for both orthopaedic procedures and wound debridement. In arthroplasty, bone bed cleaning with a Pulsed Lavage is a key aspect to the long-term survival of the prosthesis. In wound debridement, it effectively removes more than 90% of the necrotic tissues, contaminant and bacteria, consequently reduces infections rates. The CLEANEST Pulsed Lavage System is designed accordingly to fulfill these functions. This ergonomic, low noise, lightweight system offers both a powerful gear for orthopaedic applications and a gentle gear for soft tissue debridement. Concurrent suction and irrigation efficiently does its job without flooding the field. The system is delivered sterile and fully disposable.



Arthroplasty

For use in Total Joint Procedures, cemented, press-fit or revision

Fan Spray Nozzle, Femoral Canal Nozzle and Femoral Canal Brush are indicated respectively for Knee, Hip and Revision Hip procedures. It effectively prepares bone bed for cementation by thoroughly cleaning the cancellous bone, removing blood and debris, optimizing the interface between bone and cement and greatly reducing revision rate. The use of Pulsed Lavage has also been proven to reduce the risk of fat embolisms and cardiorespiratory complications following bone cementation.



Comparison of cancellous bone before and after pulsed irrigation

Clinical Report

"The routine use of pulsed or pressurized lavage appears to be the single most important factor in preparing the bone bed. It is essential in achieving adequate and uniform penetration of bone cement and a sound cement-bone interface."

"after pressurized lavage, the cement-bone composite layer was 50% to 75% as strong as the bone cement and always stronger than the adjacent cancellous bone. This situation would seem to offer the best chance of maintaining a stable mechanical environment and allowing osseointegration to take place."

"Since initial fixation strength is considered a key to long-term survival of the implants, the use of pulsed lavage should be regarded as a mandatory preparation step when cementing tibial components."

References

R.S. Majokowski, A.W. Miles, O.C. Bannister J. Perkins, G.J.S. Taylor Bone Surface Preparation in Cemented Joint Replacement. The Journal of Bone and Joint Surgery, Vol 75-B, Nr.3, May 1993.

Ulf J. Schlegel, Jan Siewe, Karl S. Deland, Peer Eysel, Klaus Pueschel, Michael M. Morlock, Anne Gebert de Uhlenbrock Pulsed Lavage Improves Fixation Strength of Cemented Tibial Components. International Orthopaedics (SICOT) (2011)35:1165-1169

Trauma and Wound Care

Indicated for trauma, burns, diabetic and pressure ulcers, chronic and infected wound debridement

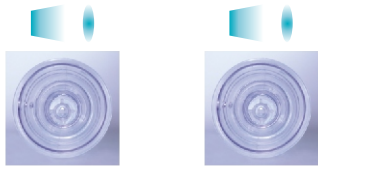
- Efficient removal of necrotic tissue, debris and contaminants.
- Concurrent irrigation and suction prevents flooding the field.
- Adjustable irrigation pressure, avoids secondary damage to surrounding tissue.
- Substantially reduces the risk of infection compared to conventional wound debridement.

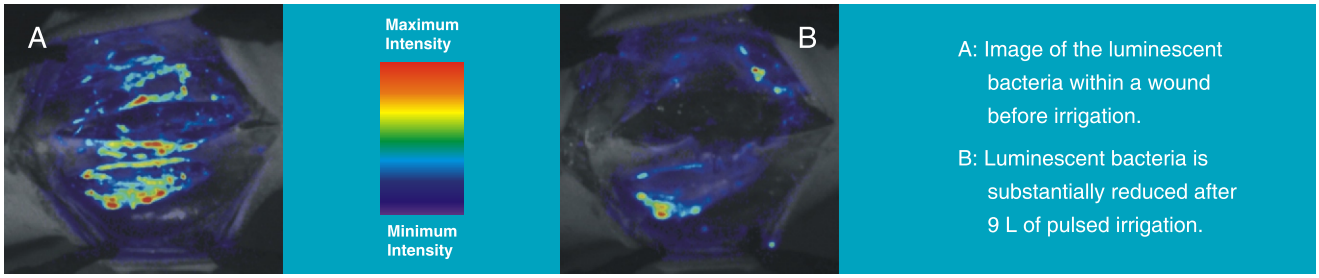
Facilitates rapid healing of wounds

- Pressure ulcers, diabetic ulcers, non-healing wounds and wound infections are major challenges to today' s health care. Not only does it add to the burden of expensive health care costs, it also impacts patient' s morbidity and mortality.
- Severe diabetic ulcers and infections are leading causes to limb amputation.

Fan
Spray Nozzle

Fan Spray Nozzle
with 12cm Splash Shield





A: Image of the luminescent bacteria within a wound before irrigation.

B: Luminescent bacteria is substantially reduced after 9 L of pulsed irrigation.

Clinical Report

The United States Army Institute of Surgical Research, after performing an experiment on a Bioluminescent Musculoskeletal Wound Model, concludes that "Irrigation with pulsed lavage is more effective than irrigation with a bulb syringe in this large-animal model of a complex, contaminated musculoskeletal wound and may allow smaller volumes of irrigant to be used."

References

Major Steven J. Svoboda, MD; Terry G. Bice, MS; Heather A. Gooden, BS; Daniel E. Brooks, BS; Darryl B. Thomas, MD; Joseph C. Wenke, PhD Comparison of Bulb Syringe and Pulsed Lavage Irrigation with Use of a Bioluminescent Musculoskeletal Wound Model.
The Journal of Bone & Joint Surgery. 2006; 88:2167-2174 doi:10.2106/JBJS.E.00248

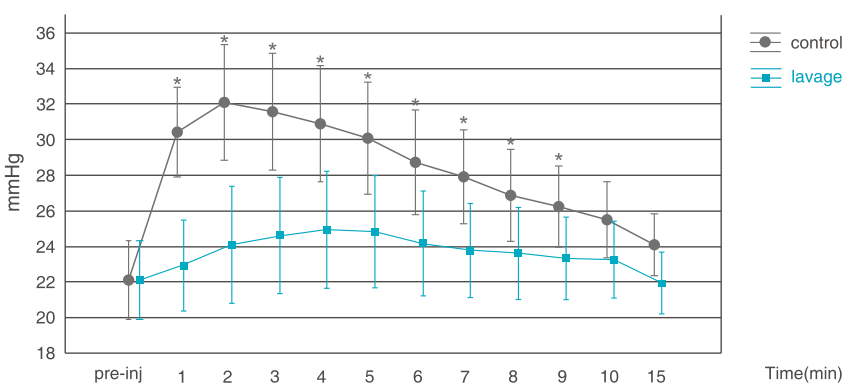
Spine

For use in various spinal procedures

The Shower Spray Nozzle is designed to irrigate complex structures of the spine with gentle pressure. Concurrent suction and irrigation clears up the view of surgical field from extensive bleeding and removes debris and contaminants, in turn reducing surgery time and infection rate.

Clinical Report

"In conclusion, lavage of the vertebral bodies resulted in a significant reduction of the embolic load and thus prevented the increase in pulmonary arterial pressure after PMMA injection, even though significantly more cement was injected into the lavaged vertebrae potentially displacing more bone marrow fat into the venous system. Vertebral lavage for removing intravertebral fat prior to cement injection for multilevel vertebroplasty may be useful for preventing potentially life threatening complications in patients with impaired cardiopulmonary function."



Shower
Spray Nozzle (Spinal) A

References

Lorin M. Benneker, Jorg Krebs, Vanessa Boner, Andreas Boger, Simon Hoerstrup, Paul F. Heini, and Armando Gisep Cardiovascular Changes After PMMA Vertebroplasty in Sheep: the Effect of Bone Marrow Removal Using Pulsed Jet-Lavage. Eur Spine J. 2010 November; 19(11): 1913 – 1920.

Mean pulmonary arterial pressure after cement injection (pooled data). Asterisk indicates a significant (P<0.02) difference from the pre-injection value.

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Product Features

Simple set-up and convenient battery recycling

Integrated tubings prevent

Powerful irrigation and durable battery life

Easy nozzle exchange and locking mechanism

Delivered double packed and sterile

Ordering Information

Product No.	Product Description	
W-203-00(EC)	Disposable Pulsed Lavage System [Handpiece Only]	
W-203-A(EC)	Disposable Pulsed Lavage System [Handpiece, Fan Spray Nozzle (Short Nozzle)]	
W-203-B(EC)	Disposable Pulsed Lavage System [Handpiece (Knee Nozzle) ,Femoral Canal Nozzle (Long Nozzle)]	
W-203-C(EC)	Disposable Pulsed Lavage System [Handpiece, Femoral Canal Nozzle (Long Nozzle)]	Box of 10 (50x37x42cm) Each double packed with blister and sterile pouch
W-203-D(EC)	Disposable Pulsed Lavage System [Handpiece, Shower Spray Nozzle (Spine Nozzle)]	
W-203-E(EC)	Disposable Pulsed Lavage System [Handpiece, Femoral Canal Brush (Brush Nozzle)]	
W-202-P3(EC)	Femoral Canal Brush [For use with Disposable Pulsed Lavage System]	Box of 50 (45x42x35cm) Each double packed with blister and sterile pouch
W-202-P11(EC)	Large Splash Shield [5″ (12cm)] [For use with Disposable Pulsed Lavage System]	Box of 40 (45x42x35cm) Each packed with sterile pouch
W-202-P4(EC)	Shower Spray Nozzle (Spine Nozzle) [For use with Disposable Pulsed Lavage System]	Box of 50 (45x42x35cm) Each packed with sterile pouch

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