



WOUND-
MANAGEMENT



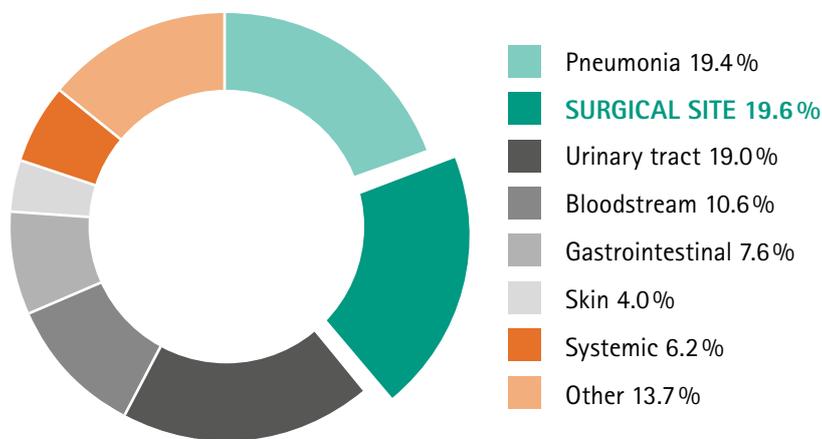
LavaSurge[®]

STERILE READY TO USE SOLUTION
FOR SURGICAL IRRIGATION AND INFECTION PREVENTION

CHALLENGE – SURGICAL SITE INFECTIONS

Surgical site infections (SSIs) are one of the most important parts of procedure related healthcare associated infections (HCAIs) and remain a severe complication after a surgery.¹

Percentage of healthcare-associated infections by infection type, 2011-12



Every surgical site infection leads to economic and human burden:

- SSI can double the length of time a patient stays in hospital³
- Additional costs attributable to SSI
- Tragedy for each patient with enormous psychosocial stress

In Europe the incidence for SSI is 157 cases per 100'000 population with an estimate of 800'000 cases per year⁴ which generate est. costs of up to 19 Bio EUR⁵ to the health care system.

Risk categories for complications after surgical treatment can be classified either according to the severity of consequences of SSI's or according to their incidence rate². The higher the risk/incidence the more preventive measures are recommended:

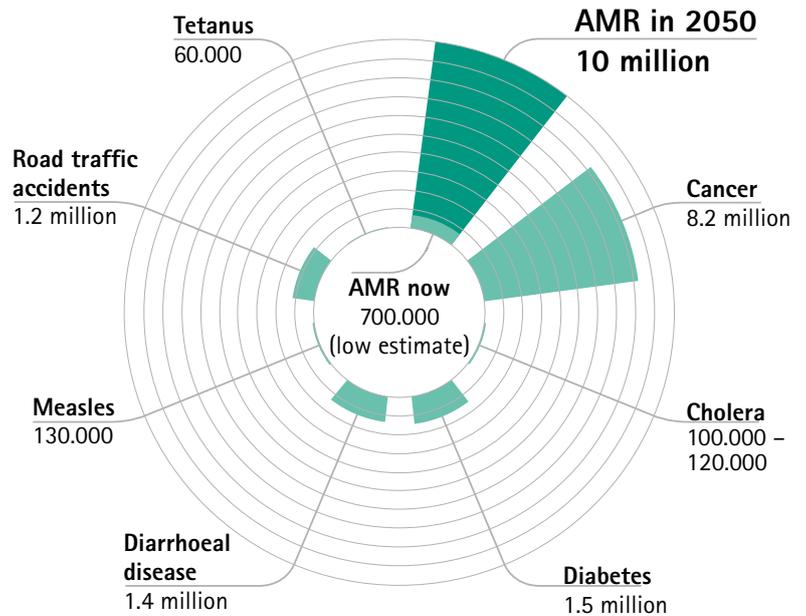
Risks and consequences of surgical site complications of closed incisions	
Severity of consequence(s) of surgical site complications	<p>Higher severity</p> <ul style="list-style-type: none"> ▪ Primary arthroplasty ▪ Implant surgery – e.g. replacement heart valve, breast ▪ Coronary artery bypass graft ▪ Vascular surgery with aortic and limb graft insertion ▪ Abdominal wall repair for congenital open abdomen (gastroschisis, omphalocele) ▪ Maxillofacial and craniofacial paediatric plastic surgery ▪ Complex multi-staged urethroplastic procedures
	<p>Lower consequences severity/lower incidence</p> <ul style="list-style-type: none"> ▪ Inguinal hernia ▪ Thyroidectomy ▪ Carpal tunnel surgery ▪ Mole/elective lesion surgery ▪ Elective breast augmentation ▪ Liposuction/other elective cosmetic surgery
	<p>Higher consequence severity/higher incidence</p> <ul style="list-style-type: none"> ▪ Complex surgery – e.g. major colorectal surgery, oesophagogastronomy, extensive combined procedures which include a long skin-to-skin time especially in redo or multiple redo procedures ▪ Heart, lung or heart-lung transplant ▪ Arthroplasty revision ▪ Liver transplant in children ▪ Major oncological procedures in children ▪ After radiotherapy
	<ul style="list-style-type: none"> ▪ Caesarean section in a patient with chorioamnionitis ▪ Planned caesarean section (high BMI) ▪ Colorectal surgery ▪ Pilonidal sinus ▪ Peripheral vascular surgery ▪ Paediatrics – site of implanted pacemaker/defibrillator ▪ Reducion mammoplasty
Lower incidence	Higher incidence
Incidence of SSI/surgical site complications	

N.B. The classification of procedures in this figure are highly generalised, and the procedures given here are examples and do not comprise a complete list. In reality, level of severity and incidence exist as continuous scales. In addition, individual patients undergoing the same procedure may experience different levels of risk and severity of consequences of surgical site complications as a result of variation in the presence of other risk factors. Higher severity consequences include failure of surgery, life-changing implications for the patient, and death

CHALLENGE – ANTIMICROBIAL RESISTANCE (AMR)

Antimicrobial resistance continues to rise and is a major cause of death⁶. Alternatives to reduce the use of antibiotics should be considered.

Continued rise in resistance by 2050 would lead to 10 million people dying every year and a reduction of 2% to 3.5% in Gross Domestic Product (GDP). It would cost the world up to 100 trillion USD.



SOLUTION

LavaSurge® is targeted to be used as an adjuvant preventive measure to avoid SSIs. It's a sterile, ready to use liquid medical device and is based on Ringer solution with 0.04% of Polyhexanide as antimicrobial agent to prevent growth of microorganism. It's aimed to be used as surgical irrigation replacing or supporting the use of standard ringer or saline solutions.

POSSIBLE APPLICATIONS

- Primary Total Hip & Knee Arthroplasty
- Revision Hip & Knee Arthroplasty
- Total Shoulder Arthroplasty
- Breast reconstruction

CONTRAINDICATIONS

- If patient is known to be allergic to one of the ingredients of the product
- On the CNS or the meninges
- In the middle or inner ear
- In the eyes
- On hyaline cartilage
- In combination with anionic tensides, cleansing soaps, ointments, oils, enzymes, etc
- For peritoneal lavage or rinsing



LavaSurge®

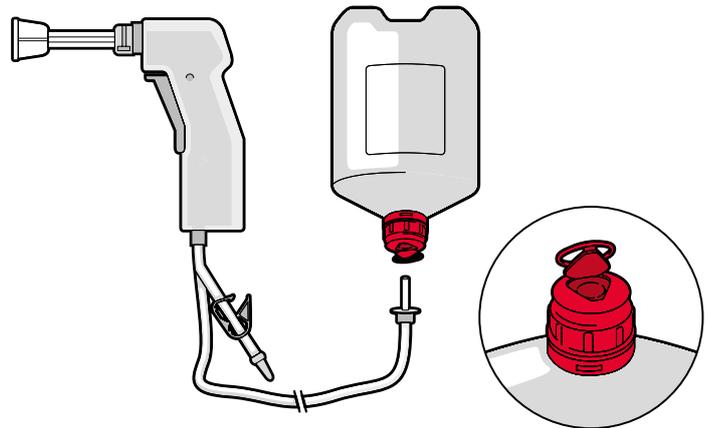
STERILE READY TO USE SOLUTION
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HANDLING INSTRUCTIONS

Manual



With Pulse Lavage



ORDER INFORMATION

Item no.	Description
19901	LavaSurge® 250 ml
19902	LavaSurge® 1000 ml

Composition:

1 Liter contains:

Polyhexanidium 0.40 g

Macrogolum 0.02 g

Ringer solution

Shelf Life after opening: 6 weeks

This international brochure contains information which is targeted to a wide range of audiences and could contain product details or information otherwise not accessible or valid in your country.

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1) WHO. Report on the burden of endemic Health Care-Associated Infection Worldwide. WHO. 2011 | 2) WUWHS Consensus Document. Closed surgical Incision Management: understanding the role of NPWT, Wounds International 2016 | 3) National Institute for Health and Clinical Excellence. Guidance. Surgical Site Infection: Prevention and Treatment of Surgical Site Infection. London: RCOG Press; 2008 Oct. | 4) Cassini A, Plachouras D, Eckmanns T, Abu Sin M, Blank H-P, Ducombe T, et al. (2016), Burden of Six Healthcare-Associated Infections on European Population Health: Estimating Incidence- Based Disability-Adjusted Life Years through a Population Prevalence-Based Modelling Study. PLoS Med 13(10): e1002150. doi:10.1371/journal.pmed.1002150 | 5) Source WHO, Global Guidelines for the prevention of surgical site infection | 6) AMR review. Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations Chaired by Jim O'Neill. December 2014 Igenis etus dolent aliquate res net