



SURGICAL SITE INFECTIONS

RISK PREVENTION BY SURGICAL GLOVING

SURGICAL SITE INFECTIONS

INTRODUCTION

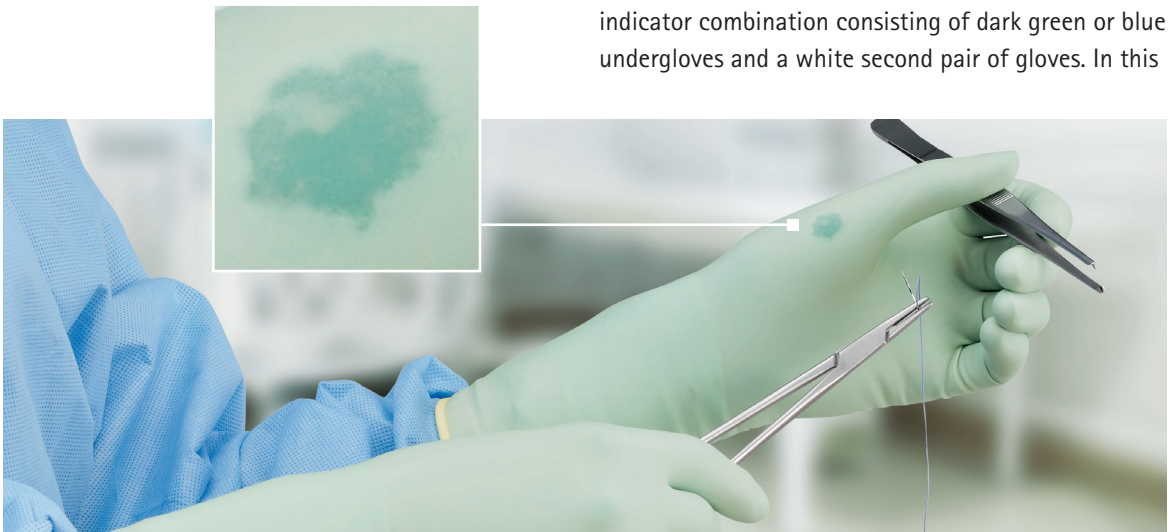
CONTENT

Introduction	2
Definition of Risks	4
Causes for Risks	6
Consequences	10
Preventive Strategies	14
Risk Prevention	18
Literature	20
Mandatory Information	23

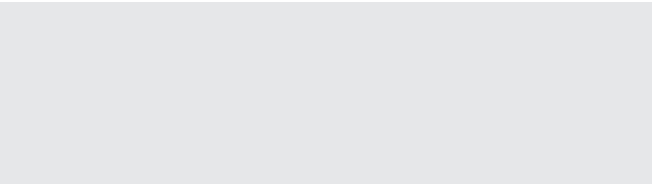
INTRODUCTION

During surgery there is a high risk of pathogen transmission from surgical staff to patients and vice versa. Surgical gloves provide an important protective barrier between patient and surgeon. Wearing surgical gloves is an effective and safe measure to prevent pathogen transmission and to reduce the risk of surgical site infections and therefore contributes to the safety of healthcare workers and patients.

In surgical practice, different gloving methods are used. It is common to either wear single standard surgical gloves, single special gloves with lower wall thickness in micro-surgery or with higher wall thickness mainly used in orthopedic surgery. In high risk procedures, double gloving has been established, either wearing two pairs of standard gloves or wearing an indicator combination consisting of dark green or blue undergloves and a white second pair of gloves. In this



Double gloving with a darker underglove for easy detection of perforation of the outer glove to increase personal protection



case perforations of the outer gloves can be easily detected through a dark dot between the glove layers.

Perforations in surgical gloves may be due to pre-existing leaks, pinholes due to sharps and bony surfaces and due to shear forces. A high percentage of perforations remain unnoticed.

The quality of gloves and the gloving method including the policy of glove changing can affect the overall perforation rate and the risk of surgical site infections (SSI). Besides gloving standard procedures, main factors to influence the risk and incidence of SSI are the experience of operators and surgical staff, surveys and training of surgical staff. The topic is considered important enough that meanwhile two COCHRANE-Reviews evaluating the scientific evidence in this field have been published, the first in 2009 and the second in 2014.^{1,2}



Double gloving with B. Braun Vasco® OP Underglove and Vasco® OP Sensitive

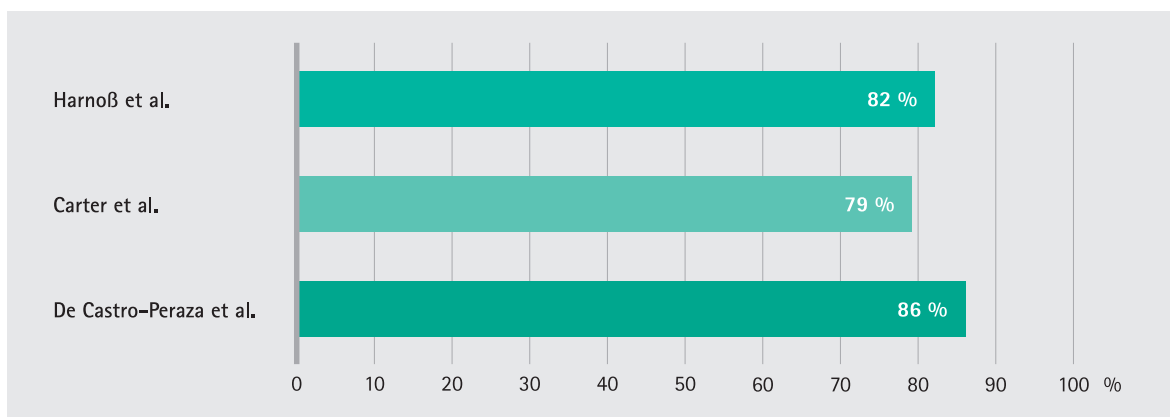


Figure 1: Reported percentage of non-detected glove perforations^{3,4,5}

SURGICAL SITE INFECTIONS

DEFINITION RISKS

Definition

Transmission of causative pathogens for SSI (bacterial and fungal origin)

SSI belong to the "procedure-related" or "medical device-related" infection types. They can be caused by the transmission of pathogenic microorganisms in the same environment, between patients and between patients and medical staff.

Due to the invasive procedures in surgery and exposure to blood, body fluids and tissue, there is a high risk of transmission of pathogens, closely related to conditions around the operation field and the patient, the surgical team and the type of surgical intervention. At the end SSI may also cause a contamination of surgical wounds.

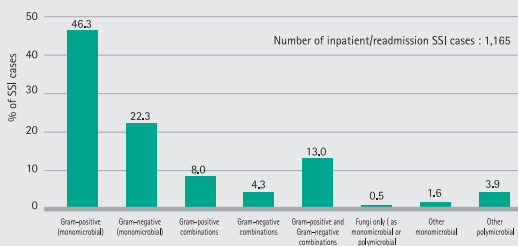


Figure 2: Distribution of monomicrobial and polymicrobial SSI cases¹⁰

SSI are considered to be the most frequent complication in surgical patients, being responsible for 38 % of all infections. The patient's risk to develop an SSI is particularly dependent on the status of the immune system and its response to microorganisms that contaminate the patient's operated area. "SSI are considered to reflect the quality of care, as they are potentially preventable complications directly linked to surgery."^{6,7} Guidelines for prevention of surgical site infections have been presented already since 1999.^{7,8,9}

Trends of key microorganisms that cause SSI in patients reported by NHS between 2004 and 2014 show a strong decrease of *Staphylococcus aureus* in general, mainly due to the decrease of MRSA, while Enterobacteriaceae representing mostly multi-resistant, gram-negative germs show a marked increase.

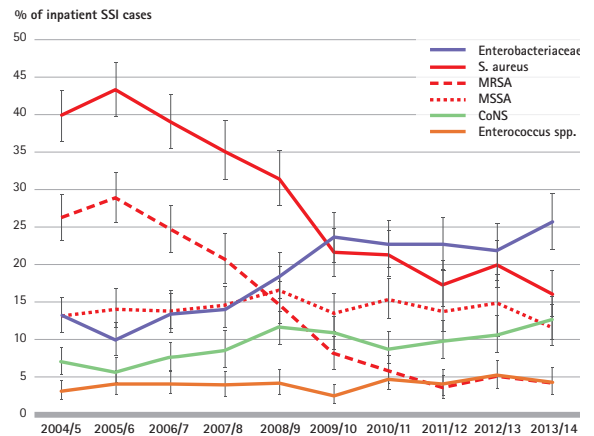
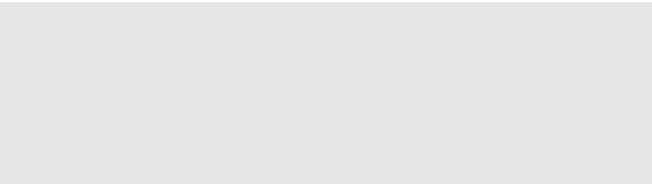


Figure 3: Trends in key microorganisms reported as causing SSI (inpatient), all surgical categories*, NHS hospitals in England¹¹
* excludes breast, cranial, cardiac (non-CABG) and cranial surgery

The reasons for the described decrease of MRSA and its lower occurrence in 2013/14 is reflecting the impact of infection control initiatives directed at controlling MRSA.



While SSI in patients are mostly of bacterial provenience, surgical staff infections are more often of viral origin. 26 different viruses have been described to be responsible for occupational pathogen transmission.¹² The risk of bloodborne infections such as Hepatitis B (HBV), Hepatitis C (HCV) and the Human Immunodeficiency Virus (HIV) is highest in the operating room environment and is closely related to work practices. Compliance with standard precautions is crucial for prevention of percutaneous injuries.¹³ Surgeons and laboratory assistants have been identified with the highest risk of percutaneous injuries.^{14,15,16} Without post-exposition prophylaxis or adequate vaccination, the risk of HBV infection is estimated to reach up to 30 % after percutaneous injuries in HCWs.¹⁷

The guideline for "Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus" of the Society for Healthcare Epidemiology of America SHEA categorizes the level of risk for bloodborne pathogen transmission in three risk categories, where open and extensive surgery are described to be at highest risk. SHEA argues for comprehensive education concerning bloodborne pathogens for all healthcare workers.¹⁹

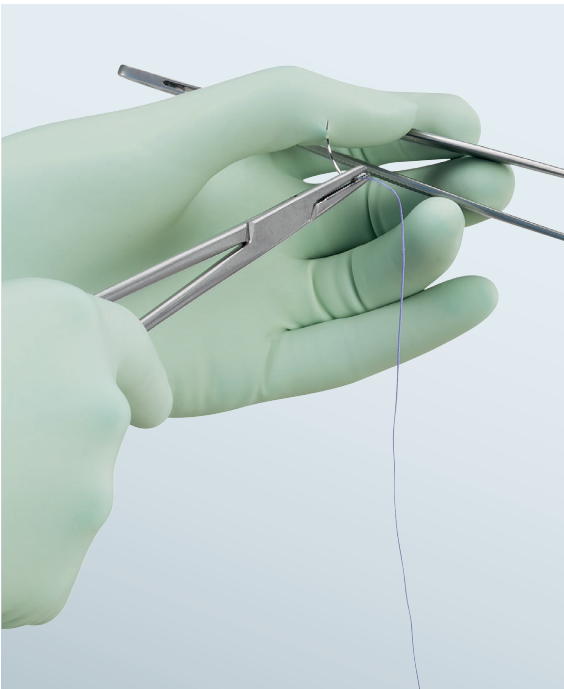
Risk factors are summarized in the right hand column, highlighting skills as well as barriers like reinforced or double gloves as main issues for healthcare providers.

"Issues for the Hospital Epidemiologist and the Expert Review Panel to Consider When Providing Advice to Infected Healthcare Providers Regarding the Performance of Various Procedures.

1. The precise procedures for which permission is sought, the historical risks for provider-to-patient bloodborne pathogen transmission associated with these procedures, the provider's experience with such procedures, and the likelihood of patient exposure to provider blood during these procedures
2. Gather evidence of the infected provider's skills, practices, and adherence to the institutional infection control plan (particularly with respect to standard precautions)
3. Investigate and discuss with the provider the availability of safer devices that will reduce the risk for patient exposures (eg, spring-loaded retractable needles, guards that shield dangerous tips, and blunted surgical needles)
4. Investigate and discuss the availability of barriers that will reduce the risks for exposures (eg, reinforced gloves, double gloves, gloves constructed of monofilament polymers or other materials resistant to tears, glove-liners, and other devices or materials to protect the provider's hands)
5. Discuss work process controls, such as the "hands free" technique in the operating room
6. Emphasize the need and ethical obligation to notify the hospital epidemiologist, immediate supervisor, or other individual, as detailed (or identified) in the contract, should a breach and/or patient exposure occur
7. Emphasize a detailed description of the process to be used in the event of breach of infection control procedures or a patient exposure" (quoted from SHEA¹⁹)

SURGICAL SITE INFECTIONS

RISKS CAUSES



Perforation of a Vasco® OP Sensitive glove (with a surgical needle), worn over a Vasco® OP Underglove

CAUSES FOR RISKS

In a very recent publication by the CDC it is stated that despite the fact that "...advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis, SSIs remain a substantial cause of morbidity, prolonged hospitalization, and death. SSI is associated with a mortality rate of 3 %, and 75 % of SSI-associated deaths are directly attributable to the SSI..."²⁰

On the patient side, surgical site infections have been identified to depend on the type of surgery.¹¹ In the cardiac field, for non-CABG (coronary artery bypass grafting) surgery the risk of SSI is highest in younger patients (age < 45 years) whereas in e.g. bile duct/liver/pancreatic, CABG, gastric or for spinal surgery the risk is being observed to be higher in older patients. In knee prosthesis the risk is comparable in all age categories. The risk causes of patient infection are classified by score-based classification-systems e.g. the ASA-score, wound class-score or the BMI of the patient.

SSIs in patients have been reported to correlate with individual risk factors, such as diabetes, cigarette smoking and its interference with wound healing, obesity (in association with diabetes), and coincident remote site infections or colonization.^{21,22}



Apart from standard gloving procedures and awareness regarding the detection of unnoticed glove perforations, main risk factors of occupational pathogen transmission are the experience of operators and surgical staff, their adherence and degree of compliance with standard procedures and to regular trainings as well as a feedback-culture between experienced seniors and e.g. students.

The incidence of surgical cross infection is directly proportional to surgical gloves perforation and also directly related to the duration of the surgical procedure.²³ The risk of acquiring glove perforations strongly depends on the type of surgery performed, and varies from 3.58 % in total hip arthroplasty²⁴ up to 91.1 % in orthognathic surgery.²⁵ According to a study by Partecke et al.²⁶ cardio-thoracic surgeries show a risk of 32.3 %, followed by vascular surgeries with 22.3 %, abdominal surgeries (minor, moderate, major) with between 12.3 % and 20.3 % of punctuation and laparoscopic interventions with 15.3 %. "Compared to other clinical fields, orthopedic surgery poses a higher risk of perforation due to the frequent manipulation of surgical instruments and the presence of sharp bones during operative treatment."²⁷

Perforation incidence reports from different studies is summarized in the table to the right.

Author	Type of Surgical Procedure/ Perforation Rate
Partecke et al. ²⁶	15.3 % Laparoscopic 17.3 % Minor abdominal 12.3 % Moderate abdominal 20.3 % Major abdominal 22.3 % Vascular 32.3 % Cardiothoracic
Demircay et al. ²⁸	Hip and knee arthroplasty 18.4 % Outer gloves 8.4 % Inner gloves
Feng et al. ²⁹	Urology: 29.0 % in all cases 15.2 % Endoscopy 25.0 % Laparoscopic cases 30.6 % Open surgical cases
Dhar ³⁰	15.0 % Elective orthopedic surgery
Carter et al. ⁴	Arthroplasty (primary/revision total hip, total knee) 3.7 % Outer gloves, primary 8.9 % Outer gloves, revision
Kuroyanagi et al. ²⁵	Oral and maxillofacial surgery: 91.1 % Orthognathic surgery 55.0 % Cleft lip and palate surgery 54.5 % Excision of oral soft tumour 50.0 % Dental implantation
Beldame et al. ²⁴	3.58 % Total hip arthroplasty ("all ... unnoticed")
Witzke et al. ³¹	18.5 % Cardiac surgery (2.5 % "Inner indicator glove" 4.0 % Inner "standard double gloves")
Han et al. ²⁷	4.3 % Total knee arthroplasty (TKA) 3.4 % Inner gloves 5.2 % Outer gloves

Table 1: Glove perforation incidence in different surgical procedures

SURGICAL SITE INFECTIONS

RISKS CAUSES

Most studies investigating glove perforation show that within the surgical teams surgeons' gloves are at highest risk for perforations. However, as shown in the table below there are also studies that identified (scrub) nurses at highest risk for glove perforation during surgical procedures.^{25,31}

Author	Surgeon	(Scrub-) Nurse	Assistant
Partecke et al. ²⁶	23.0 %	20.5 %	1 st 19.0 % 2 nd 10.9 % 3 rd 15.4 %
Shimantani et al. ³²	17.4 %	14.7 %	10.5 %
de Castro-Peraza ⁵	9.85 %	6.91 %	4.04 %
Dhar ³⁰	11.1 %	0.40 %	3.40 %
Kabling ²³	5.0 %	--	1 st 4.73 % 2 nd 3.06 %
Beldame et al. ²⁴	67.8 %	14.3 %	17.8 %
Carter et al. ⁴	4.0 % (inner 1.5 %, outer 5.5 %)	--	--
Kuroyanagi et al. ²⁵	44.4 %	63.4 %	16.3 %
Witzke et al. ³¹	10.5 %	45.0 %	23.0 %
Han et al. ²⁷	13.6 %	1.8 %	1 st 1.4 % 2 nd 0.4 %

Table 2: Glove perforation incidence in surgical teams

The perforated locations at both hands of the surgeons have been quantified in different studies, on average the highest frequency of perforation has been identified at the index finger of the non dominant hand – as shown in the alongside table and corresponding figure of gloved hands right and left with average puncture-frequency.^{24,25,26,28,33}

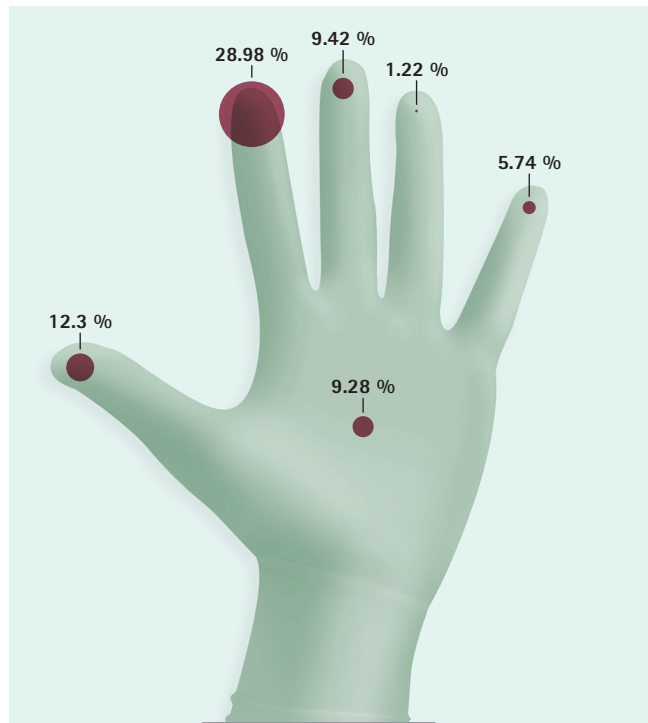
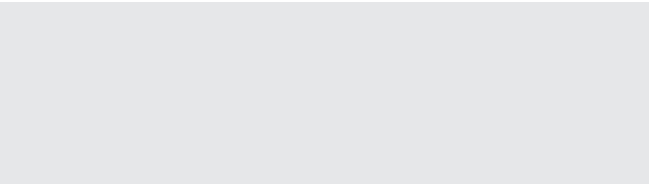


Figure 4: Average distribution of glove microperforations on the hands of

	non-dominant hand					
	thumb	index	middle	ring	little	palm
Partecke ²⁶	8.2	32.2	9.4	2.9	1.8	12.3
Kuroyanagi ²⁵	16.9	46.2	2.3	1.5	0.8	1.5
Demircay ^{**28}	10.6	25.6	8.3	1.7	1.1	8.9
Beldame ^{*24}	17.8	14.5	21.4	0.0	25.0	21.4
Timler ³³	8.0	26.4	5.7	0.0	0.0	2.3
Average	12.3	28.98	9.42	1.22	5.74	9.28

Table 3: Overall distribution of glove microperforations on the hands of
 * no side differentiation, data doubled into left and right
 ** dorsum and palm differentiated – in table summarized

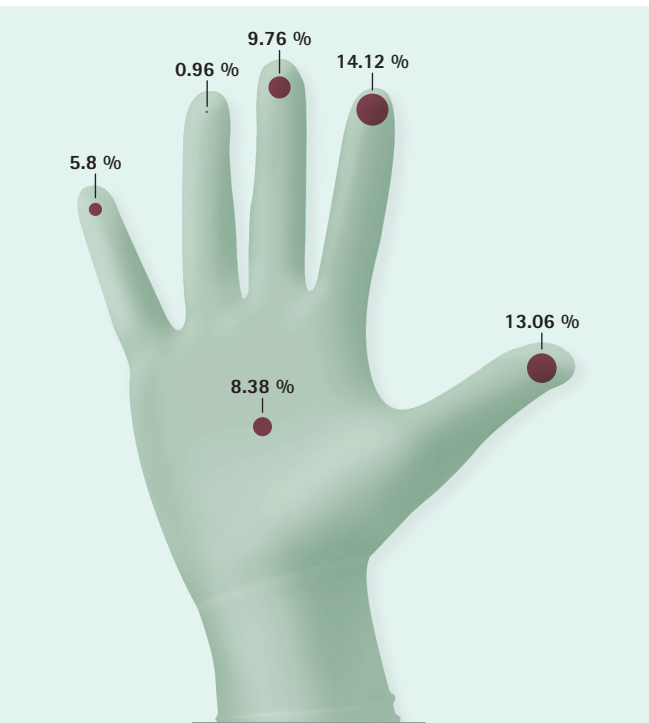


Besides sharps puncture and mechanical stress, inadequate gloving procedures may be the cause of glove perforation. The majority of glove perforations remains undetected, see figure 1 page 3. In a study investigating a total amount of 1,537 gloves after 113 operations 121 perforations were detected, and only 7 of them were noticed during the surgical procedure.⁵

When double gloving is performed, the relative risk of glove perforations from inner to outer glove has been shown to increase from 4.5 % to 14.1 %.³²

In an investigation on glove perforation on a total of 3,863 gloves collected from 58 primary and 36 revision of total joint arthroplasty (TJA) cases, surgeons had a 3.7 % outer-glove perforation rate in primary TJA compared with 8.9 % in revision TJA. When both gloves were perforated, the outer-glove perforation was recognized intraoperatively 100 % of the time, and the inner-glove perforation was noted only 19 % of the time.⁴

According to the "Basel SSI Cohort study"⁶ glove perforation in the absence of surgical antimicrobial prophylaxis increased the risk of SSI significantly. Therefore a routine change of gloves or double gloving is recommended in the absence of antimicrobial prophylaxis.



glove wearers

dominant hand					
thumb	index	middle	ring	little	palm
7.0	6.4	11.7	1.8	1.8	4.7
9.2	7.7	6.2	0.8	0.0	4.6
8.3	13.3	6.1	2.2	2.2	8.9
17.8	14.5	21.4	0.0	25.0	21.4
23.0	28.7	3.4	0.0	0.0	2.3
13.06	14.12	9.76	0.96	5.8	8.38

glove wearers (in %)

SURGICAL SITE INFECTIONS

CONSEQUENCES

CONSEQUENCES

Transmission of pathogens during surgery may lead to severe illness, both for patients and health care workers. In patients, surgical site infections are most frequently caused by bacteria, in less cases also by fungi. These microorganisms are leading to surgical wound infections which may develop severe and life-threatening complications. Multi-drug resistance may restrict options of therapies.

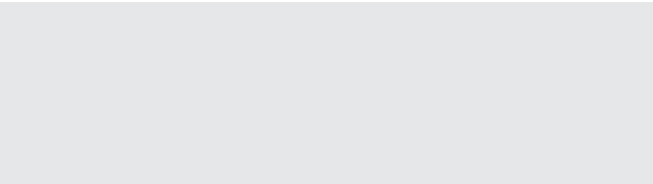
As a result, the hospital stay will be prolonged after surgery, depending on the severity of infection, therapies and additionally necessary surgical procedures.

Cost analysis have been conducted in many studies. The Centers of Disease Control and Prevention CDC is estimating 300,000 SSIs per year in the US with 3 % mortality, 7-10 additional postoperative hospital days and up to \$ 10 billion annual costs.⁹ Detecting SSI is challenging due to an increasing number of outpatient surgeries and shorter inpatient stay. Total annual costs may therefore be even higher.

According to the latest CDC National and State HAI Progress Report, between 2008 and 2013 acute care hospitals experienced a 19 % reduction in SSIs.³⁴

Direct costs	Indirect costs
Prolonged hospitalization and re-admission	Lost productivity (patient and family members)
Outpatient and emergency care visits	Temporary or permanent impairment of functional and mental capacity
Additional surgical procedures	Decreased patient satisfaction
Incision and drainage	Decreased referrals
Staged re-implantation	Increased litigation
Prolonged antibiotic therapy	
Increased use of ancillary services	
Home health visits	
Radiology and laboratory tests	
Drug costs	
Durable medical equipment	

Table 4: Costs associated with SSI³⁵



Depending on surgical procedures and patient risk factors, the estimated cost per SSI reflecting data of the 1990s may vary from less than \$ 400 to more than \$ 30,000.³⁵ A more recent publication reviewing data of 14 studies between the years 2000 and 2009 is stating additional costs between \$ 3,859 (mean) and \$ 40,559 (median) per SSI.³⁶

Little information is available about SSI follow up after hospital discharge, including frequency of re-hospitalization, outpatient treatments and long-term disabilities. Post discharge surveillance other than re-admission surveillance is especially important for evaluation of short postoperative stay.

A study on SSI after hospital discharge using patient questionnaires reports an incidence of 1.9 % of 4,571 procedures. Average total cost during 8 weeks after discharge for patients with SSI was \$ 5,155 compared to \$ 1,773 for controls.³⁷

In healthcare workers, pathogen transmission during surgery happens after sharps injuries. Safety campaigns have decreased sharps injuries in the US by 31.6 % during 2001-2006 but injuries in surgical settings increased in the same period by 6.5 %. The highest risk of percutaneous injury in surgery is associated with the use of suture needles as shown in the figure below.³⁸

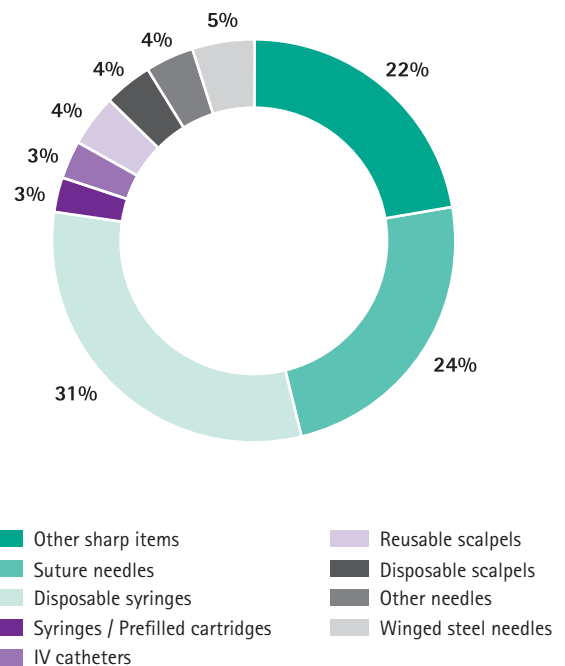


Figure 5: Risk of percutaneous injury in surgery³⁸

SURGICAL SITE INFECTIONS

CONSEQUENCES

Sharps injuries can cause a number of direct and indirect costs for the health care facility, including:

- Loss of employee time
- Investigation related to the injury
- Laboratory testing
- Treatment for infected staff
- Replacement of staff

Affected workers and their families usually suffer of enormous anxiety during test periods and distress due to treatment and consequences of potential infection.

Various studies have estimated the financial impact of NSIs. As an example of short-term direct costs, Hatcher described that a single NSI would cost the healthcare facility \$ 2,234 to \$ 3,832.³⁹

In the case of a transferred bloodborne disease after a NSI, the overall long-term financial cost has been calculated to be as high as € 922,000.⁴⁰

FINANCIAL IMPACT

Each NSI without infection costs employers between \$ 2,234 and \$ 3,832.^{39,41}

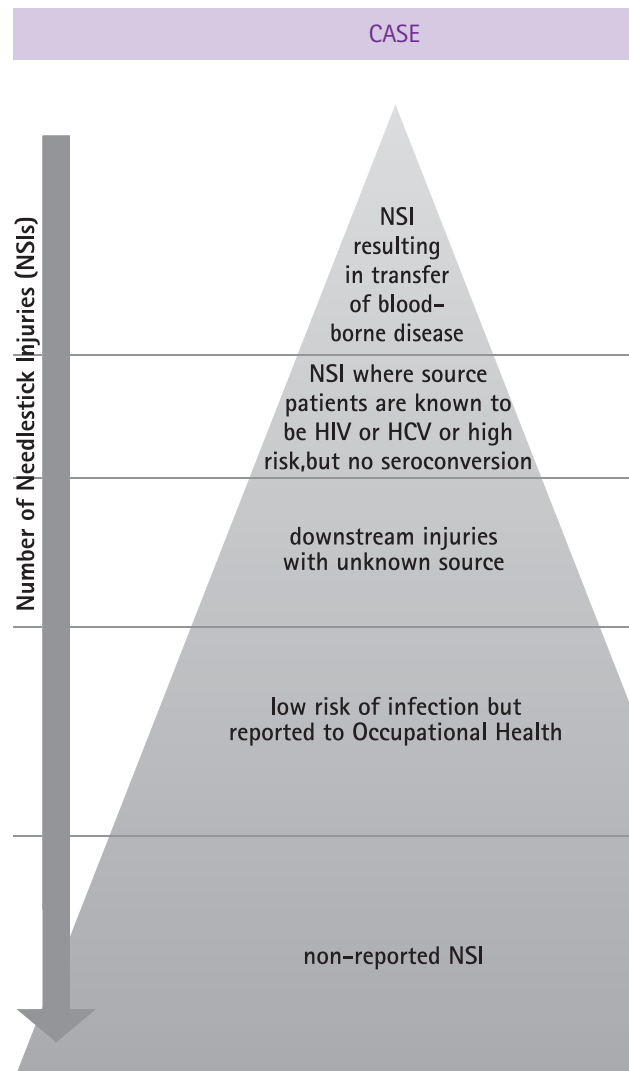


Figure 6: Costs associated with NSIs. The costs are segregated into five



COST LEVEL	MEASURE	COST PER CASE
LEVEL 1	<ul style="list-style-type: none"> ▪ Long-term treatment ▪ Disability payments 	£ 10,000 – £ 620,000
	+	
LEVEL 2	<ul style="list-style-type: none"> ▪ Immunoglobulin and/or PEP treatment 	£ 3,000 – £ 5,000
	+	
LEVEL 3	<ul style="list-style-type: none"> ▪ Follow up blood test ▪ Counseling ▪ Certified medical absence ▪ Sourcing of temporary replacement staff 	£ 1,000 – £ 2,000
	+	
LEVEL 4	<ul style="list-style-type: none"> ▪ Time to report the injury to manager, Occupational Health/A&E ▪ Completion of accident form ▪ Occupational Health assessment of infection risk ▪ Blood test ▪ Involvement of Phlebotomy and Pathology ▪ Administrative effort 	£ 50 – £ 100
	+	
LEVEL 5	<ul style="list-style-type: none"> ▪ Time for self-help measures: <ul style="list-style-type: none"> - make the wound bleed under water - wash with soap/water + wash with 70% alcohol - dry and apply waterproof dressing 	up to £ 10

levels and number of NSIs increases from level 1 to level 5. Compensation claims are not explicitly included and have to be added individually.⁴²

SURGICAL SITE INFECTIONS



PREVENTIVE STRATEGIES

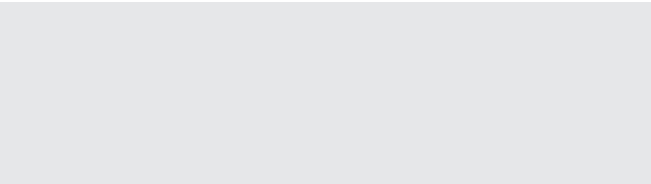
PREVENTIVE STRATEGIES

Optimizing and standardizing gloving procedures together with protective wear are basic means in surgical risk prevention strategy.^{42,43}

The "Basel SSI Cohort Study" states that SSI account for 14 - 16 % of all nosocomial infections in hospitalized patients thereby representing the most frequent hospital-associated infection in surgery. SSI are considered to be preventable complications after surgery and may well reflect performance and quality of care in the clinical institutions. Introduction of double gloving procedures as well as surgical training are recommended to reduce the SSI incidence.⁶

Additionally, a standardized pre-operative decolonization treatment to prevent MDRO (Multi-Drug Resistant Organisms) colonization in the nose, on the skin and in the oropharynx prior to elective interventions can contribute to minimize the risk for infection.^{44,45,46}

A number of patient-related factors do exist for which correlations to SSIs have been suggested, e.g. diabetes, cigarette smoking, obesity, coincident remote site infections or colonization.²¹ So, as to "preventive strategies", the patients themselves would be able to contribute to a prevention – they should be enabled and encouraged to try to reduce these risk factors and in parallel become aware of their own responsibility towards their health, nowadays called "patient empowerment".



Surveillance is an important strategic tool to fight against infections like SSI, with feedback of appropriate data to surgeons to reduce or minimize the corresponding risk.²⁰ A new CDC and Healthcare Infection Control Practices Advisory Committee guideline for the prevention of surgical site infection has been announced, based on the results of a successfully introduced surveillance program²⁰, replacing the previous "Guideline for Prevention of Surgical Site Infection" by Mangram et al. 1999.⁷

During surgical procedures, microperforations have been shown to increase over time and remain mostly unnoticed. It is therefore advisable to implement glove changing standards according to risk evaluation with respect to different surgical interventions.

In general, glove changing after at least 90 minutes is recommended.^{3,26,30}

In a simulation model it was shown that when double gloving is used, only 17 % of the blood is transferred through the gloves compared to single glove layers.⁴⁷ An enzyme contamination assay proved double glove layers to be more puncture-resistant and able to remove more enzyme contaminant from a solid cutting suture needle compared with an equivalently thick single layer.⁴⁸ During removal of protective wear after surgery, an experimental study reported a significantly lower virus transfer to hands after double gloving compared to single gloving.⁴⁹



The dark-colored Vasco® OP Undergloves are ideally suited for double gloving with bright surgical gloves like Vasco® OP Sensitive



For better detection of a perforation of the outer glove Vasco® OP Sensitive surgical gloves should be worn above dark-colored gloves like Vasco® OP Undergloves

SURGICAL SITE INFECTIONS

PREVENTIVE STRATEGIES

In a clinical study, in four out of five cases the inner glove remained intact when the outer glove was inadvertently perforated. "Surgical teams must balance the improved safety of double gloving with the possible discomfort and reduced sensitivity".⁵

In contrast to this statement, various studies have shown, that double gloving does not have a substantial impact on manual dexterity or tactile sensitivity when compared to no gloves or single gloving.^{2,27,50}

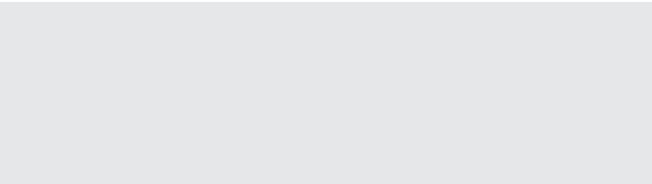
A double gloving indicator system of dark-colored undergloves and a white second pair of gloves helps detecting perforations of the outer gloves layer. In case of liquid entrance through the outer glove, a

dark spot becomes immediately visible between the glove layers and the gloves can be changed instantly. The use of indicator glove systems reduces the frequency of unnoticed glove perforations and risk of intra operative cross-infection.³¹

It is significantly more effective than single gloving in reducing glove perforations and provides also more protection than standard double gloving.¹ "Evidence supports the use of double gloving and double gloving with an indicator glove system to decrease the risk of percutaneous injury and therefore double gloving is an effective barrier to bloodborne pathogen exposure."⁵¹



Comparative demonstration between double gloving with a green underglove (indicator system) and two white surgical gloves



Double gloving is not only recommended to be introduced as a routine practice for surgeons but has also been shown to be effective in protecting operating room nurses against bloodborne pathogen exposure.⁵² In laryngoscopy and intubation it was shown that when anesthesiologists wear 2 sets of gloves and remove the outer set immediately after intubation, the contamination of the intra-operative environment is significantly reduced.⁵³

The recent literature review by the Cochrane Collaboration Group identified until June 2013 34 assessable studies covering altogether 6,890 surgical procedures and in particular 17 studies investigating double standard gloves. The authors conclude "There is moderate-quality evidence that double gloving compared to single gloving during surgery reduce perforations and blood stains on skin, indicating a decrease in percutaneous exposure incidents. (...) The preventive effect of double gloves on percutaneous incidents in surgery does not need further research."²

Today, double gloving is recommended by various professional organizations, including the Centers for Disease Control and Prevention (CDC), the Association of periOperative Registered Nurses (AORN), the American Academy of Orthopedic Surgeons (AAOS), the American College of Surgeons (ACS) and the WHO Patient Safety initiative to create a safer working environment. Checklists and tools have been developed to increase compliance and safety, such as SSI Toolkits by US Department of Health or by the CDC.⁹

In addition, recommendations of the German Association for the Control of Viral Diseases (DW) e.V. and the Society for Virology (GfV) e.V. are given for HIV-positive Healthcare Workers (HCW):

"With a permanent viral burden of less than or equal to 50 copies/mL, HIV-positive HCWs are allowed to perform any surgery and any invasive procedure, as long as the infected HCW uses double gloving, undergoes follow-up routinely by occupational medicine professionals, undergoes a quarterly examination of viral burden, and has a regular medical examination by a physician who has expertise in the management of HIV."⁵⁴

IN CONCLUSION, THERE IS A NEED FOR HIGHLY DURABLE SURGICAL GLOVES.

Evidence is provided that the use of double gloves and regular changing of gloves within integrative infection prevention strategies is an effective tool contributing to patient safety and HCW personal protection.

"Perioperative managers and educators should develop educational methods to support double gloving compliance; monitor and conduct periodic audits to evaluate compliance; and review and revise quality improvement strategies as necessary to protect surgical employees from percutaneous injuries."⁵¹

SURGICAL SITE INFECTIONS

RISK PREVENTION



Prontoderm®

Preoperative cleansing and decolonization

- Ready-to-use colorless solution for antimicrobial cleansing of the whole body, MDRO (in particular MRSA) decolonization
- Based on surfactants and polihexanide (polyaminopropylbiguanide): high skin and mucous membrane tolerability
- No rinsing of the skin required after treatment antimicrobial barrier effect for up to 24h



Softa-Man® / Softalind®

Hand disinfection for sensitive skin

- Combination of alcohols as active ingredients, free of colorants
- Spectrum of activity for hygienic and surgical hand disinfection
- Effective against bacteria (incl. MRSA, TbB), fungi, enveloped viruses (incl. HBV, HCV, HIV) and rotavirus
- Active ingredients see page 22

Alternative product: **Promanum® pure** with special moisturizing system.

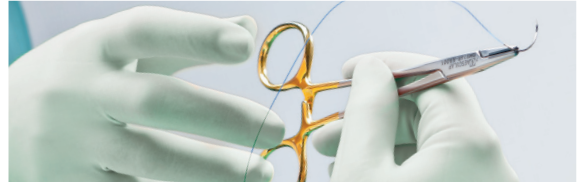
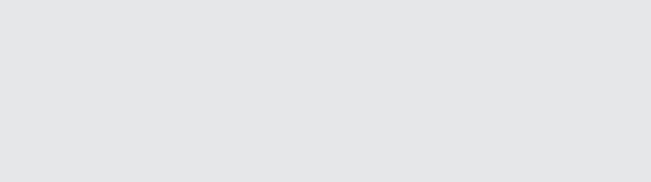


Vasco® OP Underglove, Vasco® OP Sensitive, Vasco® OP Grip

Double gloving / surgical gloves

- High quality fully anatomical surgical gloves
- Made from natural rubber latex
- Powder-free
- Latex-free inner polymer coating
- Double gloving indicator system: Vasco® OP Underglove plus Vasco® OP Sensitive / Grip for a quick detection of perforations





Braunol®

Preoperative skin disinfection

- Aqueous povidone-iodine solution for antiseptic treatment of skin, mucous membranes and wounds
- Povidone-iodine is effective against bacteria incl. MRSA, spores, fungi, yeasts, protozoa and numerous viruses
- Active ingredients see page 23

Alternative product: **Braunoderm®** – an alcoholic PVP-Iodine solution.



Askina® DresSil Border

Wound dressing

- Self adherent foam dressing with silicone adhesive on one side and vapour permeable waterproof film on the other side
- Additional 1.5 cm large adhesive border for more security during wear and protection against external contamination
- Silicone adhesive allows safe adhesion that respects fragile skin and repositioning for control
- Capacity to absorb residual exudate
- Hypoallergenic



Medibox®

Sharps disposal containers

- No-touch, twist-off and insertion inlets for all kinds of used luer and luer-lock needles as well as pen needles
- Large opening to ease the insertion of various medical sharps
- Easy to use temporary closure
- Irreversible final lock mechanism
- Overfill warning by maximum fill line



SURGICAL SITE INFECTIONS

LITERATURE

- [1] Tanner J et Parkinson H. Double gloving to reduce surgical cross-infection (Review). *The Cochrane Library* 2009, Issue 4.
- [2] Mischke C, Verbeek JH, Saarto A, Lavoie M-C, Pahwa M & Ijaz S. Gloves, extra gloves or special types of gloves for preventing percutaneous exposure injuries in healthcare personnel (Review). *The Cochrane Database of Systematic Reviews* 2014, Issue 3, Art. No.: CD009573. DOI: 10.1002/14651858.CD009573.pub2.
- [3] Harnob J-C, Partecke LI, Heidecke C-D, Hübner N-O, Kramer A & Assadian O. Concentration of bacteria passing through puncture holes in surgical gloves. *Am J Infect Control* 2010;38:154-8.
- [4] Carter AH, Casper DS, Parvizi J, Austin MS. A prospective analysis of glove perforation in primary and revision total hip and total knee arthroplasty. *Journal of Arthroplasty* (2012) 27:7 (1271-1275).
- [5] De Castro-Peraza ME, Garzon-Rodriguez E, Rodriguez-Perez V, Sosa-Alvarez I, Gutierrez-Hernandez J & Asiain-Ugarte C. Glove perforation in surgery and protective effect of double gloves. *Enfermeria Clinica* (2010) 20:2 (73-79).
- [6] Junker T, Mujagic E, Hoffmann H, Rosenthal R, Misteli H, Zwahlen M, Oertli D, Tschudin-Sutter S, Widmer AF, Marti WR & Weber WP. Prevention and control of surgical site infections: review of the Basel SSI Cohort Study. *Swiss medical weekly* (2012) 142 (w13616).
- [7] Mangram AJ, Horan TC, Pearson ML, Silver LC & Jarvis WR. Hospital Infection Control Practices Advisory Committee. Guideline for prevention of surgical site infection. *Infect Control Hosp Epidemiol* 1999;20:247-78.
- [8] NICE, National Institute for Health and Care Excellence, UK. Surgical Site Infections: prevention and treatment. NICE guidelines [CG74]. Published date: October 2008. <https://www.nice.org.uk/guidance/cg74> (Accessed Nov., 05, 2015)
- [9] Berrios-Torres SI. Surgical Site Infection (SSI) Toolkit. Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention (CDC), Department of Health & Human Services USA, 2009. http://www.cdc.gov/HAI/pdfs/toolkits/SSI_toolkit021710SIBT_revised.pdf (Accessed Nov., 05, 2015)
- [10] Public Health England, Dec. 2013. Surveillance of Surgical Site Infections in NHS Hospitals in England 2012/13. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/364319/SSI_annual_report_2012_to_13_final.pdf (Accessed: Nov, 11, 2015)
- [11] Public Health England, Dec. 2014. Surveillance of Surgical Site Infections in NHS Hospitals in England: 2013 to 2014. <https://www.gov.uk/government/publications/surgical-site-infections-ssi-surveillance-nhs-hospitals-in-england> (Accessed Nov., 05, 2015)
- [12] Tarantola A, Abiteboul D & Rachline A. Infection risks following accidental exposure to blood or body fluids in health care workers: a review of pathogens transmitted in published cases. *Am J Infect Control* 2006;34:367-75.
- [13] Deuffic-Burban S, Delarocque-Astagneau D, Abiteboul D, Bouvet E & Yazdanpanah Y. Blood-borne viruses in health care workers: Prevention and management. *J. of Clinical Virology*, Vol. 52, Issue 1, 4-10, Sept. 2011.
- [14] FitzSimons D, Francois G, De Carli G, Shouval D, Pruss-Ustun A, Puro V et al. Hepatitis B virus, hepatitis C virus and other blood-borne infections in health-care workers: guidelines for prevention and management in industrialised countries. *Occup Environ Med* 2008;65:446-51.
- [15] Wicker S, Jung J, Allwinn R, Gottschalk R & Rabenau HF. Prevalence and prevention of needlestick injuries among health care workers in a German university hospital. *Int Arch Occup Environ Health* 2008;81:347-54.
- [16] Alamgir H, Cvitkovich Y, Astrakianakis G, Yu S & Yassi A. Needlestick and other potential blood and body fluid exposures among health care workers in British Columbia, Canada. *Am J Infect Control* 2008;36:12-21.
- [17] Hofmann F, Kralj N & Beie M. Needle stick injuries in health care—frequency, causes and preventive strategies. *Gesundheitswesen* 2002;64:259-66.
- [18] Deisenhammer S, Radon K, Nowak D & Reichert J. Needlestick injuries during medical training. *J Hosp Infect* 2006;63:263-7.
- [19] Henderson DK, Demby L, Fishman NO, Grady C, Lundstrom T, Palmore TN, Sepkowitz KA, Weber DJ for the Society for Healthcare Epidemiology of America. SHEA Guideline for Management of Healthcare Workers Who Are Infected with Hepatitis B Virus, Hepatitis C Virus, and/or Human Immunodeficiency Virus. *Infect Control Hosp Epidemiol* 2010, Vol. 31, No. 3:203-32.
- [20] Centers for Disease Control and Prevention (CDC), April 2015. <http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSICurrent.pdf> (Accessed Nov., 05, 2015)
- [21] Reichman DE & Greenberg JA. Reducing surgical site infections: A Review. *Rev Obstet Gynecol* 2009; 2(4):212-221.
- [22] Rajvir Singh, Pooja Singla & Uma Chaudhary. Review Article - Surgical Site Infections: Classification, Risk factors, Pathogenesis and Preventive Management. *International Journal of Pharma Research and Health Sciences* Volume 2 (3), 2014, Page-203-214, e-ISSN: 2348-64652014.



- [23] Kabiling CS. Intraoperative glove perforation and incidence of surgical site infection. *Colorectal Disease* (2011) 13 SUPPL. 5 (59).
- [24] Beldame J, Lagrave B, Lievain L, Lefebvre B, Frebourg N & Dujardin F. Surgical glove bacterial contamination and perforation during total hip arthroplasty implantation: When gloves should be changed. *Orthopaedics and Traumatology: Surgery and Research* (2012) 98:4 (432-440).
- [25] Kuroyanagi N, Nagao T, Sakuma H, Miyachi H, Ochiai S, Kimura Y, Fukano H & Shimozato K. Risk of surgical glove perforation in oral and maxillofacial surgery. *International Journal of Oral and Maxillofacial Surgery* (2012) 41:8 (1014-1019).
- [26] Partecke LI, Goerdts A-M, Langner I, Jaeger B, Assadian O, Heidecke C-D, Kramer A, Huebner N-O. Incidence of Microperforation for Surgical Gloves Depends on Duration of Wear. *Infection Control and Hospital Epidemiology*, Vol. 30, No. 5 (May 2009), pp. 409-414.
- [27] Han CD, Kim J, Moon SH, Lee BH, Kwon HM & Park KK. A Randomized Prospective Study of Glove Perforation in Orthopaedic Surgery: Is a Thick Glove More Effective? *Journal of Arthroplasty* (2013) 28:10 (1878-1881).
- [28] Demircay E, Unay K, Bilgili MG & Alataca G. Glove perforation in hip and knee arthroplasty. *Journal of Orthopaedic Science* (2010) 15:6 (790-794).
- [29] Feng T, Yohannan J, Gupta A, Hyndman ME & Allaf M. Microperforations of surgical gloves in urology: minimally invasive versus open surgeries. *The Canadian Journal of Urology* (2011) 18:2 (5615-5618).
- [30] Dhar D. Occult glove perforation during adult elective orthopaedic surgery. *Macedonian Journal of Medical Sciences* (2011) 4:4 (399-402).
- [31] Witzke HJ, Fuchs S, Schmitz E, Wittmann A, Kralj N, Vetter HO. Surgical glove perforation-Raising the bar for safety during cardiac surgery. *Thoracic and Cardiovascular Surgeon* (2012) 60 SUPPL. 1.
- [32] Shimantani M, Matsui Y, Sakakibara K, Iwase T & Yano K. Investigation of the rate of glove perforations in orthopedic procedures with an indicator underglove system (IUS) in a Japanese hospital. *American Journal of Infection Control* (2009) 37:5 (E117-E118).
- [33] Timler D, Bończak O, Jończyk J, Ilchev P, Śliwczyński A & Marczak M. Risk assessment of accidental exposure of surgeons to blood during orthopedic surgery. Are we safe in surgical gloves? *Annals of Agricultural and Environmental Medicine* 2014, Vol 21, No 1, 212-216.
- [34] Centers for Disease Control and Prevention (CDC), 2015. Healthcare-associated Infections (HAI) Progress Report. <http://www.cdc.gov/hai/progress-report/index.html> (Accessed Nov., 05, 2015)
- [35] Urban JA. Cost Analysis of Surgical Site Infections. *Surgical Infections*, Vol. 7, Suppl. 1, S19-S22, 2006.
- [36] Graf K, Ott E, Vonberg R-P, Kuehn C, Schilling T, Haverich A & Chaberny, IF. Surgical site infections – economic consequences for the health care system. *Langenbecks Arch Surg* (2011), 396: 453-459.
- [37] Perencevich EN, Sands KE, Cosgrove SE, Guadagnoli E, Meara E & Platt R. Health and economic impact of surgical site infections diagnosed after hospital discharge. *Emerg Infect Dis*. 2003 Feb; 9(2):196-203.
- [38] Centers for Disease Control and Prevention (CDC), June 2013. The National Institute for Occupational Safety and Health (NIOSH). STOP STICKS CAMPAIGN. <http://www.cdc.gov/niosh/stopsticks/sharpsinjuries.html> (Accessed Nov., 05, 2015)
- [39] Hatcher IB. Reducing Sharps Injuries Among Health Care Workers: A Sharps Container Quality Improvement Project. *Jt Comm J Qual Improv* 2002;28(7):410-414.
- [40] National Health Service for Scotland (NHS Scotland). Needlestick Injuries: Sharpen Your Awareness. Report of the Short Life Working Group on Needlestick Injuries in the NHS Scotland. Edinburgh: National Health Services for Scotland:2001.
- [41] Tan L, Hawk JC, Sterling ML. Report of the Council Scientific Affairs: Preventing Needlestick Injuries in Health Care Settings. *Arch Intern Med* 2001;161(7):929-936.
- [42] Jain R, Kralovic SM, Evans ME, Ambrose M, Simbartl LA, Obrosky DS, Render ML, Freyberg RW, Jernigan JA, Muder RR, Miller LJ & Roselle GA. Veterans Affairs Initiative to Prevent Methicillin-Resistant Staphylococcus aureus Infections. *N Engl J Med* 2011; 364:1419-30.
- [43] Harris AD, Pineles L, Belton B, Johnson K, Shardell M, Loeb M, Newhouse R, Dembry, L, Braun B, Perencevich EN, Hall KK, Morgan DJ and the Benefits of Universal Glove and Gown (BUGG) investigators. Universal Glove and Gown Use and Acquisition of Antibiotic resistant bacteria in the ICU: A Randomized Trial. *JAMA*. 2013 October 16; 310(15): 1571-1580. doi:10.1001/jama.2013.277815.
- [44] Schweizer M, Chiang H, Septimus E, Moody J, Braun B, Hafner J, et al. Association of a bundled intervention with surgical site infections among patients undergoing cardiac, hip, or knee surgery. The "STOP SSI"-Study. *JAMA*. 2015;313:2162-71.
- [45] Lepelletier D, Saliou P, Lefebvre A, Lucet J, Grandbastien B, Bruyère F, et al. Preoperative risk management: strategy for Staphylococcus aureus preoperative decolonization" (2013 update). *Med Mal Infect*. 2013;44:261-7.

SURGICAL SITE INFECTIONS

LITERATURE

[46] Bode L, Kluytmans J, Wertheim H, Bogaers D, Vandembroucke-Grauls C & Roosendaal R, et al. Preventing surgical-site infections in nasal carriers of *Staphylococcus aureus*. *N Engl J Med*. 2010;362;1:9-17.

[47] Wittmann A, Kralj N, Kover J, Gasthaus K & Hofmann F. Study of blood contact in simulated surgical needlestick injuries with single or double latex gloving. *Infection Control and Hospital Epidemiology* (2009) 30:1 (53-56).

[48] Din SU & Tidley MG. Needlestick fluid transmission through surgical gloves of the same thickness. *Occupational Medicine* (2014) 64:1 (39-44).

[49] Casanova LM, Rutala WA, Weber DJ, Sobsey MD. Effect of single- Versus double-gloving on virus transfer to health care workers' skin and clothing during removal of personal protective equipment. *American Journal of Infection Control* (2012) 40:4 (369-374).

[50] Fry DE, Harris WE, Kohnke EN & Twomey CL. Influence of Double-Gloving on Manual Dexterity and Tactile Sensation of Surgeons. *Journal of the American College of Surgeons* (2010) 210:3 (325-330).

[51] Childs T. Use of Double Gloving to Reduce Surgical Personnel's Risk of Exposure to Bloodborne Pathogens: An Integrative Review. *AORN Journal* (2013) 98:6 (585-593).

[52] Guo YP, Wong PM, Li Y & Or PPL. Is double-gloving really protective? A comparison between the glove perforation rate among perioperative nurses with single and double gloves during surgery. *American Journal of Surgery* 2012 204:2 (210-215).

[53] Birnbach DJ, Rosen LF, Fitzpatrick M, Carling P, Arheart KL & Munoz-Price LS. Double gloves: A randomized trial to evaluate a simple strategy to reduce contamination in the operating room. *Anesthesia and Analgesia* (2014).

[54] Rabenau HF, Gottschalk R, Gürtler L, Haberl AE, Hamouda O, Himmelreich H, Korn K, Mertens T, Schmidt KW, Schmiedel S, Spickhoff A, Wirz G, Wutzler P & Wicker S. Prävention der nosokomialen Übertragung von humanem Immunschwächevirus (HIV) durch HIV-positive Mitarbeiterinnen und Mitarbeiter im Gesundheitswesen Empfehlungen der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und der Gesellschaft für Virologie (GfV) e.V. *Bundesgesundheitsbl* 2012 · 55:937-943 - DOI 10.1007/s00103-012-1546-8.

Softa-Man®

COMPOSITION:

100 ml solution contain: Active substances: 45 g ethanol (100%), 18 g propanol. *Other ingredients:* purified water, diisopropyl adipate, macrogol 6 glycerol caprylocaprate (Ph. Eur.), dexpanthenol, bisabolol, allantoin, fragrance (contains limonene, linalool)

THERAPEUTIC INDICATIONS:

Hygienic and surgical hand disinfection.

CONTRAINDICATIONS:

Hypersensitivity (allergy) to ethanol, propanol or any of the other ingredients.

POSSIBLE SIDE EFFECTS:

Contact allergy. Skin irritation symptoms (e.g. itching, redness), especially after frequent application.

WARNINGS:

Flammable.

Keep container tightly closed.

Keep away from sources of ignition - No smoking!

Avoid contact with eyes. Do not use on damaged skin or mucous membranes.

For external use only.

Flash point 21°C per DIN 51755.

MARKETING AUTHORIZATION HOLDER:

B. Braun Melsungen AG

34209 Melsungen

Germany

(02/2012)

Promanum® pure

COMPOSITION:

100 g solution contain: Active substances: 73.4 g ethanol (100 %), 10.0 g isopropyl alcohol. *Other ingredients:* Purified Water, Isopropyl Myristate, Butanone, Sorbitol, Cetearyl Ethylhexanoate, Povidone.

THERAPEUTIC INDICATIONS:

Hygienic and surgical hand disinfection.

CONTRAINDICATIONS:

Hypersensitivity (allergy) to ethanol, isopropyl alcohol or any of the other ingredients.

POSSIBLE SIDE EFFECTS:

Contact allergy. Skin irritation symptoms (e.g. itching, redness), especially after frequent application.

WARNINGS:

Highly flammable.

Keep container tightly closed.

Keep away from sources of ignition - No smoking!

Avoid contact with eyes. Do not use on damaged skin or mucous membranes.

For external use only.

Flash point 14°C per DIN 51755.

MARKETING AUTHORIZATION HOLDER:

B. Braun Melsungen AG

34209 Melsungen

Germany

(03/2012)

MANDATORY INFORMATION



Braunol®

Active ingredient: Povidone iodine

COMPOSITION:

100 g solution contain 7.5 g povidone iodine with a content of 10 % available iodine.
Other ingredients: sodium dihydrogen phosphate dihydrate, sodium iodate, macrogol lauryl ether 9 E0 (Ph. Eur), sodium hydroxide, purified water.

THERAPEUTIC INDICATIONS:

For single application:

Disinfection of intact external skin and mucous membrane antiseptics, e.g. before surgery, biopsies, injections, punctures, blood sampling and catheterisations.

For repeated application, limited in time:

Antiseptic treatment of wounds (e.g. pressure sores, leg ulcers), burns, infected skin diseases.

Hygienic and surgical hand disinfection.

CONTRAINDICATIONS:

Hypersensitivity to povidone iodine or any of the other ingredients, hyperthyroidism or other present thyroid diseases, skin disease dermatitis herpetiformis, planned or administered radioiodine therapy (until the end of treatment), very low birth weight infants (birth weight <1,500 g) due to iodine absorption.

SIDE EFFECTS:

Very rare: Cutaneous reactions due to hypersensitivity (allergy), e.g. contact allergy reactions of the late type in the form of itching, redness, blisters etc.

Very rare: Acute reactions of the immune system (anaphylactic reactions) with the involvement of other organs (e.g. skin, respiratory tract, circulatory system).

At the beginning of the treatment a temporary local burning sensation may occur (uncommon).

A significant level of iodine intake can result from the long-term application of Braunol to extensive wounds and burns. Very rarely, in predisposed patients iodine-induced hyperthyroidism can occur, sometimes with symptoms like increased pulse rate or restlessness.

Following resorption of large quantities of povidone iodine (e.g. in treatment of burns) disturbance in electrolyte- and serum osmolarity, renal failure and metabolic acidosis have been described.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment with phosphate-containing eye drops.

MARKETING AUTHORIZATION HOLDER:

B. Braun Melsungen AG
34209 Melsungen
Germany
(05/2013)

Braunoderm® / Braunoderm® Colored

COMPOSITION:

100 g solution contain: Active substances: 50.0 g isopropyl alcohol and 1.0 g povidone iodine with a content of 10 % available iodine.
Other ingredients: Purified water, potassium iodide (0.4 g, stabiliser), sodium dihydrogen phosphate dihydrate, (Braunoderm® colored also contains dyes C.I. 15985 [E 110], C.I. 16255 [E 124] and C.I. 28440 [E 151]).

THERAPEUTIC INDICATIONS:

Skin disinfection before surgical procedures, injections, punctures, catheterizations, taking of blood samples, vaccinations.

CONTRAINDICATIONS:

Hyperthyroidism or other present thyroid diseases, skin disease dermatitis herpetiformis, planned or administered radioiodine therapy (until the end of treatment), hypersensitivity (allergy) to iodine, isopropyl alcohol or any of the other ingredients.

POSSIBLE SIDE EFFECTS:

Very rare: Cutaneous reactions due to hypersensitivity (allergy), e.g. contact allergy reactions of the late type in the form of itching, redness, blisters etc.

Very rare: Acute reactions of the immune system (anaphylactic reactions) with the involvement of other organs (e.g. skin, respiratory tract, circulatory system).

Uncommon: Local alcohol-induced dryness and irritation symptoms of the skin (e.g. redness, tension, itching).

WARNINGS:

Flammable.

Keep container tightly closed.

Keep away from sources of ignition - No smoking!

Avoid contact with eyes. Do not use on damaged skin or mucous membranes.

For external use only.

Flash point 21-22°C per DIN 51755.

MARKETING AUTHORIZATION HOLDER:

B. Braun Melsungen AG
34209 Melsungen
Germany
(05/2011)

NOTE:

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.



The summarized scientific information in this document has been prepared for healthcare professionals. It is based on an analysis of public literature and guidelines. The intention is to give an introduction to the risks commonly associated with clinical procedures and to increase the awareness of healthcare workers to these kinds of problems. Due to its summary nature, this text is limited to an overview and does not take into account all types of local conditions. B. Braun does not assume responsibility for any consequences that may result from therapeutical interventions based on this overview.

B. Braun Melsungen AG | OPM | 34209 Melsungen | Germany
Tel. +49 5661 71-33 99 | www.bbraun.com