Contamination risk

-using reusable cuffs

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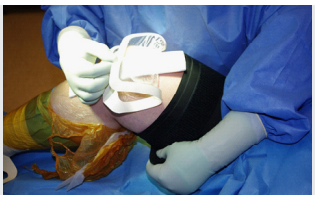
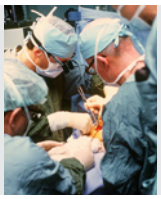



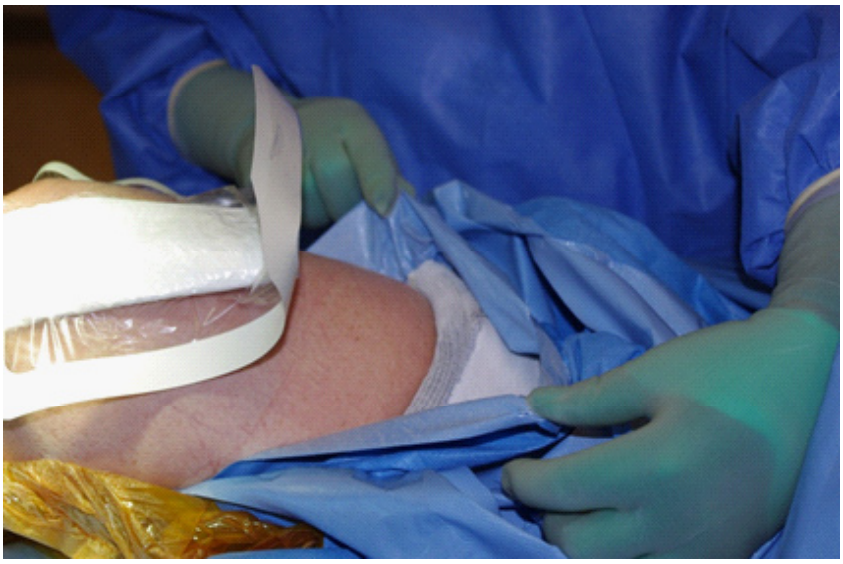
Contamination risk using reusable cuffs

Surgery of extremity in bloodless field

Many orthopedic procedures, such as knee replacement surgery and anterior cruciate ligament reconstruction, etc., is usually preformed in a so called ”bloodless field”. Bloodless field, in this type of surgery, is created by use of a Tourniquet-system. This system creates and maintains the surgery site bloodless by use of a pressure cuff. In Sweden are reusable cuffs most often used, which are available both as single and double cuffs.

After each operation, the cuffs are wiped with alcohol, coiled and stored on a shelf in a room near the operating theatre until the next surgery.

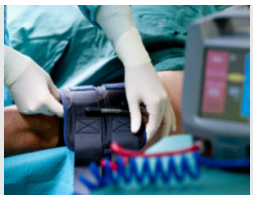
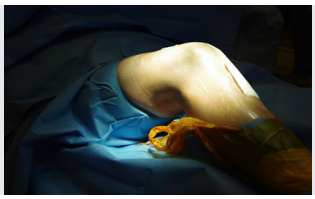
When a patient is prepared for surgery, the cuff is placed proximal on, for example the thigh, then the surgical site is washed sterile. This means, that sterile wash only is made up to the cuff but not under. The sterile drape is pasted into two separate layers. At a knee operation, this means that the non-sterile cuff is applied very close to the surgical site.



Bloodless field during surgery is also used in fracture surgery, nerve exposure, tendon interposition arthroplasty and arthroscopy, and even in this type of surgery there are high demands for sterility. For example, during fracture surgery, there are even requirements for bloodless field to repair and fix the fracture and often, the cuff has to be placed very close to the surgical site. At a fracture there is a considerable tissue damage that increases the risk of infection. Arthroscopy of knee and ankle are usually performed in bloodless field and, again, the cuff is placed very close to the surgical site.

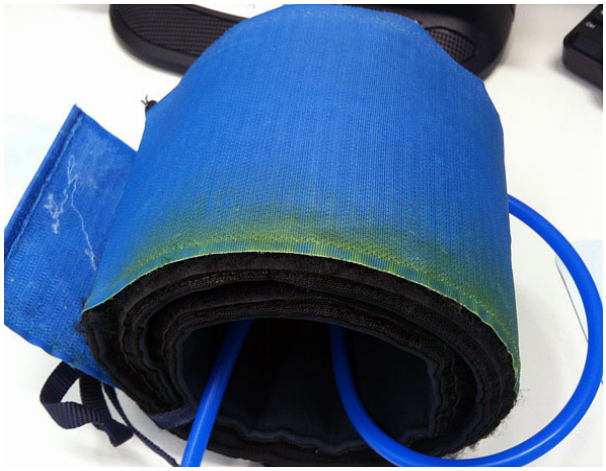
An infected joint, after for example a joint replacement surgery, involves great suffering for the patient and also high costs for health care. The patient may be treated with antibiotics for months, perhaps for life. A revision surgery may then be necessary, which means that the old prosthesis is removed and temporarily replaced with a so called ”spacer”, and after a couple of month a new prosthesis is implanted. There are special hospital wards for post-operative care of prosthesis patients and strict hygiene routines, so by using disposable cuffs the risk off surgical site infections would decrese further in orthopedic surgery.

The most common routine for cleaning of reusable cuffs, with disinfectant, are not satisfactory. A bacterial culture, made under standardized forms of Department of Laboratory Medicine, Clincal Microbiology Section, Örebro University Hospital[1], of reusable cuffs shows a strong growth of Gram-positive cocci and rods and even mold (see Appentix 1).

Time consuming, but more correctly, cleaning of reusable cuffs

If the cuff is autoclavable it should be sterilized and autoclaved between each patient. The reusable cuff shall be cleaned properly between each surgical procedure in lukewarm water and an approved disinfectant. Scrub with a soft brush if necessary. The cuff should then be rinsed thoroughly because cleaning solution residue may cause skin irritation. All tubing should be cleaned, rinsed, and dried between patients and before storage, water in the ports contributes to microbial growth. The bladder should be thoroughly dried to avoid that water causes damage to the Tourniquet during deflation of the cuff. The cleaned cuff and tubing should be allowed to drip dry at room temperature[2].

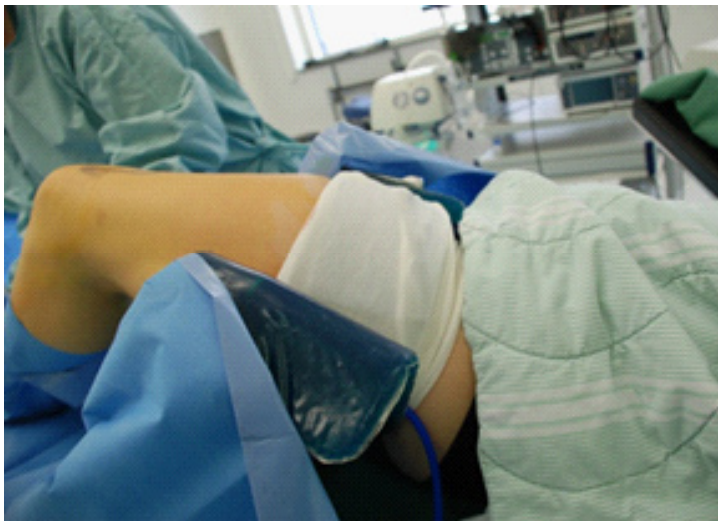


Background

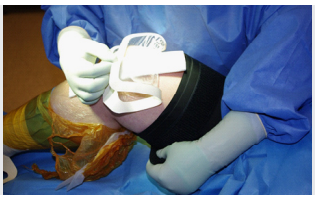
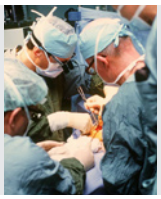
Hygiene has always been an important part of healthcare far back. Health care services are constantly working to reduce the healthcare-associated infections (HAIs) that are associated with, for example surgery. In modern medicine today, there are many developed procedures, regulations and guidelines of hygiene within health care. The technical knowledge has increased, leading to more and more advanced surgical procedures, which also increases the risk for more HAIs. Additionally, has the increased use of antibiotics led to an increase in the proliferation of multi-resistant bacteria. This compared to an increasing pace and demands for cost effectiveness makes it even more important than ever to prevent the spread of infection in a surgical unit.

For the past decade, the health care community has been inundated with announcements from governmental agencies and consumer watchdog groups reporting that tens of thousands of lives are lost each year as a result of avoidable incidents in US hospitals. Reports from around the world show a similar trend as well. Wrong site surgery and surgical site infections (SSIs) have been highlighted in many of these reports. SSIs are a subset of a larger group of infections known as healthcare-associated infections (HAIs). SSIs affect many thousands of patients each year and contribute greatly to the morbidity and mortality associated with surgery.[3] Respiratory tract infections and urinary tract infections account for the majority of HAIs, closely followed by SSI:s. Despite that the SSI is not the most abundant, it is the most costly.[4]

Infections may be caused by endogenous (e.g., bacteria on the patient's skin) or exogenous sources (e.g., personnel, the environment or materials used for surgery). The most common microorganisms causing surgical site infection are Staphylococcus aureus (20 percent), Coagulase negative staphylococcus (14 percent) and enterococcus (12 percent).[5]



In order to treat infections caused by bacteria, we use antibiotics. Excessive and inappropriate use is causes of bacteria becoming resistant to antibiotics. This is a growing public health problem that causes increased morbidity and mortality. It also causes cost for medical care in terms of prolonged hospital stays and more expensive medicines. A resistant bacterium jeopardizes the treatment of severe bacterial infections. Our modern healthcare depends on effective antibiotics in such activities, which carries an increased risk of infection e.g. surgical operations.[6]

Infection prevention practices during surgery

There are routines for both pre- and intraoperative care to prevent postoperative SSIs.
In any surgical practice, policies and procedures should be in place, pertaining to the making of a surgical incision and the prevention of infection. This policies and procedures should govern the following: skin disinfection and hand washing practices of the operating team, preoperative preparation of the patient's skin (e.g., hair removal and use of antiseptics), the use of prophylactic antibiotics, techniques for preparation of the operative site, dressings, standards of behavior and practice for the operating team (e.g., the use of gown, mask and gloves) and sterilization and disinfection of instruments.[7]

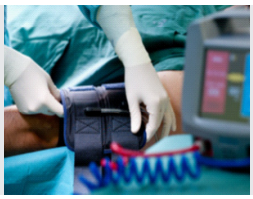
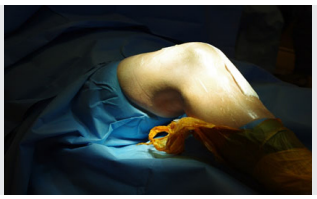
The operating theater is equipped with special ventilation. To reduce the bacterial content in the air, and thus the risk of airborne infection, it is generally recommended that the air in the operating theater is exchanged 17-20 times per hour. Such so-called mixing ventilation reduces the concentration of bacteria-carrying particles in the air to 50-100 cfu/m3. More efficient ventilation system based on the delivery of a so-called laminar (non-turbulent) flow of sterile filtered air, is the laminar air flow or LAF system. These Systems reduce the bacterial flora of the air to isolated cfu/m3 at the surgical site and instruments. Such systems have been shown to have SSI-preventive effect of, for example, hip- and knee arthroplasty.[8]

Summary

Healthcare-associated infections, HAIs, are a serious threat in all health care worldwide. In Europe alone, are approximately five million people per year affected by HAIs. Of these, about 50 000 (1%) leads to death and a further 135 000 (2.7%) is a contributing cause of death.[9] In the United States suffer an estimated 2 million patients annually by HAIs, and of those estimated approximately 90 000 to be fatal.[10] Besides the human suffering are HAIs a huge economic burden on the health care worldwide.

There are clear hygiene routines for both pre-, intra-and postoperative care, despite this fact, suffers patients from SSIs. In orthopedic surgery today in so-called bloodless field is, in many cases, a non-sterile reusable cuff, often inadequately cleaned between operations, is used. To clean a cuff more properly is both a time consuming and costly process. After have sent some used reusable cuffs for analyze to Department of Laboratory Medicine, Clincal Microbiology Section, Örebro University Hospital[1], showed that they were anything but clean, and much less suitable for use in surgery (see Appendix 1). Consequently, a non-sterile, contaminated reusable cuff is applied on the patient's limb near the surgical site. On the market today, there are sterile, disposable cuffs. These could help reduce the risk of SSIs and futhermore, spare much suffering, money and time, in other words, by using disposable cuffs a further important step is taken in the fight against HAI and SSI.

The chain is never stronger than its weakest link!

Appendix 1

Örebro University Hospital
Department of Laboratory Medicine
Örebro County Council
Clinical Microbiology Section

SWEDAC ACKREDITERING 1351 ISO 15189

RAPPORT
utfärdad av ackrediterat laboratorium
REPORT issued by an Accredited Laboratory

Date: 2012-01-02 Page 1 of 1

To Scandinavian Medical Systems AB
Västberga Allé 36 B
126 30 Hägersten

To

Your ref: Peter Westrin

Your ref:

VIABLE COUNT REPORT

Date of arrival: 2011-12-15 Access no: 11544-00575

Product:

Manufacturer	
Name of product	Smal manschett / Single cuff
Product no	
Lot no	
Ster no/date	
Exp date	
No of item	1

Method (according to SS-EN ISO 11737-1): The sample was aseptically divided and after that rinsed through shaking in 1000 ml 0,1% buffered peptone water for 30 minutes. Approx. 500 ml were passed through a membrane filter 0,45 µm. The filter was divided in equal parts and placed on tryptic soy agar medium - incubated at 30°C and Saboraud agar medium- incubated at 22°C. Approx. 500 ml were passed through a membrane filter 0,45µm and this was divided in equal parts and placed on tryptic soy agar medium - incubated at 22°C and enriched blood agar medium - incubated at 30°C anaerobic atmosphere. All media were incubated for 12 days.
Using a spread agar technique 0,5 mL were spread on Saboraud agar- incubated at 22°C and 0,5 mL were spread on Drigalski agar- incubated at 35°C for 7 days.

Result:

Yttertyg / Outer shell	Overgrowth of Grampositive rods Growth of Gramnegative rods, non fermentative, 4 CFU Growth of molds, 6 CFU No growth of anaerobic bacteria
Silikonblåsa / Silicone bladder	Growth of Grampositive rods, 4 x 10^2 CFU Growth of Grampositive cocci, Staphylococcus aureus excluded, 2 x 10^2 CFU Growth of yeasts, 4 CFU No growth of anaerobic bacteria
Slangar / Hoses	Growth of Grampositive rods, 5 x 10^2 CFU Growth of Grampositive cocci, Staphylococcus aureus excluded, 1 x 10^2 CFU Growth of molds, 12 CFU No growth of anaerobic bacteria

Comments:

Torbjörn Norén, MD/Ulrika Getzmann
Dept of Laboratory Medicine, Microbiology

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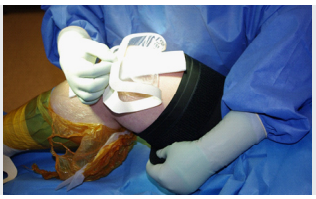
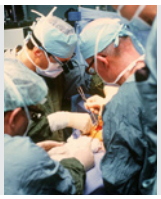
INTERNET www.orebroll.se/uso/mikrobiol

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Department of Laboratory Medicine
ÖREBRO COUNTY COUNCIL
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RAPPORT
utfärdad av ackrediterat laboratorium
REPORT issued by an Accredited Laboratory

Date: 2012-01-02

To Scandinavian Medical Systems AB
Västberga Allé 36 B
126 30 Hägersten

To

Your ref: Peter Westrin

Your ref:

VIABLE COUNT REPORT

Date of arrival:	2011-12-15	Access no:	11544-00576
Product:			
Manufacturer			
Name of product	Bred manschett/ Double cuff		
Product no			
Lot no			
Ster no/date			
Exp date			
No of item	1		

Method (according to SS-EN ISO 11737-1):

The sample was aseptically divided and after that rinsed through shaking in 1000 ml 0,1% buffered peptone water for 30 minutes. Approx. 500 ml were passed through a membrane filter 0,45 µm. The filter was divided in equal parts and placed on tryptic soy agar medium - incubated at 30°C and Saboraud agar medium- incubated at 22°C. Approx. 500 ml were passed through a membrane filter 0,45µm and this was divided in equal parts and placed on tryptic soy agar medium - incubated at 22°C and enriched blood agar medium - incubated at 30°C anaerobic atmosphere. All media were incubated for 12 days.
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Result:		
	Yttertyg / Outer shell	Overgrowth of Grampositive rods Growth of Grampositive cocci, Staphylococcus aureus excluded, 40 CFU Growth of molds, 8 CFU No growth of anaerobic bacteria
	Silikonblåsa / Silicone bladder	Overgrowth of Grampositive rods Overgrowth of molds No growth of anaerobic bacteria
	Slangar / Hoses	Growth of Grampositive rods, 6 x 10^2 CFU Growth of Grampositive cocci, Staphylococcus aureus excluded, 2 x 10^2 CFU No growth of anaerobic bacteria

Comments:

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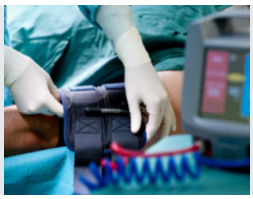
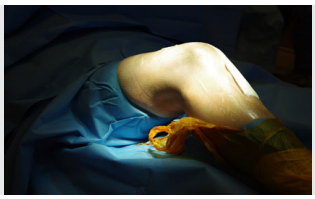

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