

VACUETTE®
one step ahead ▶


greiner bio-one



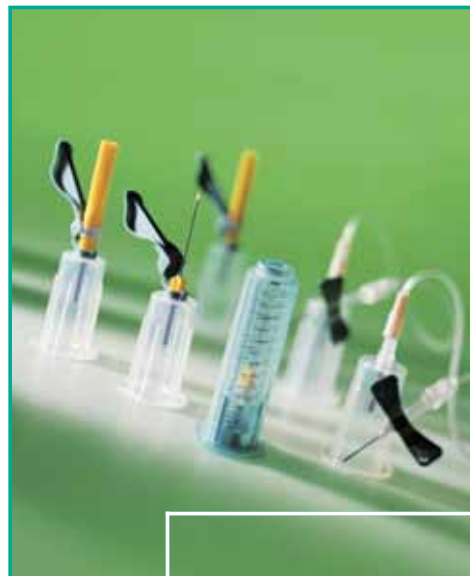

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VACUETTE®
Safety Brochure



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VACUETTE[®]

Specimen Collection System

Our Innovations
for Your Safety

Foreword

"Ouch!"
"Never mind, it's just a drop of blood, surely nothing will have happened!"

"We've still got such a lot to do, so put a plaster on and carry on!"

Do you ever talk to yourself like this? Does it have a familiar ring?

In the medical field, the terms "needlestick injury" and "sharps injury" mean a percutaneous injury from a sharp or pointed object, which was previously exposed to blood or serum from a patient. The problem is not the "harmless" injury to the skin, rather, the possible incorporation of infectious agents. This exposure is often trivialised, even by medical personnel, as the risk of blood transmitted infections is underestimated, or even forgotten about. This is only human, as there is a lack of personal experience with infections that occur so rarely. However, it is fatal, since we are dealing with life threatening diseases such as hepatitis C, hepatitis B or HIV/AIDS.

Protective measures consist,

above all, of prevention: anticipate danger, use the right material, dispose of correctly and immediately. Prevention also applies to purposeful, prompt behaviour directly after a needlestick injury: rinse out any material that has entered, disinfect, check risk, administer post-exposition prophylaxis, document as occupational accident.

Only those who know how to react after a needlestick injury, will be able to apply the appropriate risk reducing measures within the relatively brief time frame. In the interests of self-protection, everybody should acquire the basic knowledge required to be able to do this. As a result of this, he or she will deal with "sharps" so carefully, that danger to self or others will be minimised. Only when you know what you are doing and - more importantly - what you should not do, will you be able to act accordingly.

You've already got the right information in your hands - succinct yet comprehensive. Use this reading material, and you and your colleagues will profit from it!



Dr. med. Martin Thieves Darmstadt
Consultant for Hygiene and
Environmental Medicine

Recommendations on Avoiding Blood Transmitted Infections



Potential source of danger: Glass breakage

Become Aware of the Dangers!

The purpose of this brochure is to inform you of the injury risks that you could be exposed to through the handling and disposal of sharp or pointed objects, as an employee in the healthcare branch.

Unfortunately, there are many sources of danger that are not noticed, or not taken seriously enough. Those affected by potential sources of danger often do not realise it, view injury by a contaminated object as a minor accident or just as a hazard of the job.

However, the psychological strain after a needlestick injury can be enormous for the person affected and those close to him/her. The consequences are tragic, and the effects far-reaching. An infection may lead to occupational invalidity along with all the social and financial consequences.

It is essential that the dangers be explained, and how to deal with them professionally. In our everyday hectic working lives and the continual pressure of time, accidents resulting from contact with

Which Pathogens Can Lead to an Infection in Case of a Needlestick Injury?

contaminated objects cannot be ruled out. The cause of the accident is not necessarily negligent behaviour or lack of care, but ever increasing stress and consequent lack of concentration in risky situations. There are enough opportunities to ensure adequate protection in such situations.

The main sources of danger are blood transmitted pathogens such as hepatitis B (HBV), hepatitis C (HCV) and HIV.

The risks resulting from these three pathogens vary greatly when evaluated. The probability of coming into contact with an HIV pathogen is the smallest since the total number of infected persons in the entire population is the least. The probability of coming into contact with hepatitis C is 10 times higher, and the chances of coming into contact with the hepatitis B pathogen is 30 times higher.

Proportion of Persons Affected By Most Significant Pathogens to Entire Population (Prevalence)

Please note: The prevalence rate in a hospital is often significantly higher than the population average.

	Europe	Africa	South-East Asia	America	Worldwide
HBV	< 2.0 %	> 8.0 %	> 8.0 %	< 2.0 %	n.a.
HCV	1.0 %	5.3 %	2.2 %	1.7 %	3.1 %
HIV	0.3 %	8.4 %*	0.6 %	0.6 %	1.2 %

* Regional in central and southern Africa > 50%

HCV is subject to an internationally increasing trend, whilst HBV tends to remain constant in the developed regions due to the immunisation availability in the medical branch and a WHO immunisation project for children and adolescents. The development of HIV varies greatly in the individual regions.

Sources:
HCV: M. Schreier M. Höhne: Bundesgesundheitsbl. - Gesundheitsforsch. - Gesundheitsschutz 2001 44:554-561 Springer Verlag 2001
HBV: Graphische Verteilung von chronischen HBV Infektionen: <http://biosun.bio.tu-darmstadt.de/viro/HBV/sld005.htm>
HIV: Regionale HIV-/Aids - Statistik, Status: end of 2001 UNAIDS/WHO 2001:3

If a Pathogen Is Present, Will It Be Passed on Every Time There Is an Injury?

The frequency of pathogen transmission subsequent to an injury with contaminated material (rate of seroconversion) varies amongst the pathogens. Whilst the chance of transmitting HIV is very low, the chance of HBV transmission is very high.

Transmission after a needlestick injury:

HBV 300 out of 1000
HCV 30 out of 1000
HIV 3 out of 1000

What Is the Known Infection Risk?

The risk is determined from the prevalence rate and the rate of seroconversion.

The greater the amount of infectious material transferred in case of a needlestick, the greater the risk of an infection.



Potential source of danger: Overfilling disposal boxes

HBV - Protect Yourself with Sufficient Immunisation

By far the greatest risk of transmission is with HBV. However, the health risks resulting from an HBV infection are not viewed as seriously as those resulting from an HCV or HIV infection. Furthermore, far-reaching protection is made possible by immunisation, although transmission of this pathogen caused by occupational incidents still occurs time after time, with dramatic consequences for those affected.

This is the result of a large amount of persons working in the healthcare branch, who are not immunised. These are persons who do not belong to a risk group; persons who refuse to be immunised, non or low responders; persons who either do not react or react insufficiently to vaccination; and persons who do not have enough antibodies present due to missing a booster.

HCV Is Viewed as the Current Biggest Risk for Healthcare Employees

The transmission risk relating to HCV is not quite as high as HBV, but the health risks are far more serious, and for the foreseeable future, immunisation is not possible. Whilst HBV infections remain between constant and slightly declining, the rate of registered HCV cases increase year by year. This is further aggravated by the high rate of spontaneous mutations of the hepatitis C-virus, which causes problems for the endogenic immune system.

HIV - No Vaccine in the Foreseeable Future

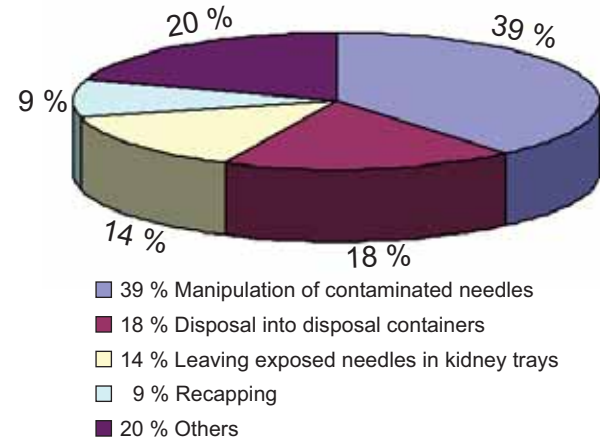
There is no vaccine against Human Immunodeficiency Virus (HIV). In spite of extremely intensified research, it is not expected that a vaccine will become available in the foreseeable future. The consequences of an infection are fatal, not to forget the enormous personal suffering of the infected person.

What Are the Chances of Recovery From a Disease?

	Recovery	Chronic liver infections	Liver cirrhosis	Cancer of the liver
HBV	90 %	5 - 10 %	2 %	0.60 %
HCV	15 - 20 %	75 - 85 %	10 - 15 %	1 - 5 %
HIV	0 %	Varying course of the disease		

Where Do the Risks Lurk?

- ▶ Most incidents occur when handling and disposing of contaminated objects



Source: Clinicum special issue, May 2002, Needlestick injuries, Vienna

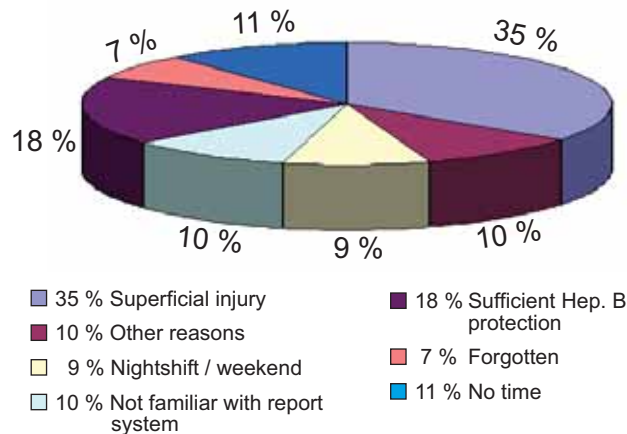
- ▶ 66% of accidents leading to injuries occur in the patient's room, 9% in the operating room or intensive care ward and 6% in the laboratory

Source: SAFETY FIRST Kooperative, Bundesverband der Unfallkassen

Learn to Appraise the Risks Correctly

The mentality "Nothing can happen to me", is reflected directly in the total of registered injuries with risk potential. The report rate lies around 15%. Report rates amongst nursing staff are higher than amongst medical staff. Clearly these two occupational groups evaluate the risks differently.

The reasons for not reporting incidents were given as follows:



Source: Hasselborn, Hofmann et al Needlestick injuries in hospital

► **Of those affected by injuries, 60% are nursing staff, 25% medical staff and 11% laboratory staff**

Source: SAFETY FIRST Kooperative, Bundesverband der Unfallkassen

How Do I Protect Myself?

Ignorance is the biggest safety risk. Take risks and warnings seriously. Do not think that it cannot happen to you, but do not let this make you feel insecure. If you follow recommended safety measures and if you work using safe product solutions, then you already have the best strategy for preventing an accident.

- ⊕ Take time to inform yourself sufficiently of risks and potential ways of protection against accidents. Take advantage of training materials and information provided by your employer.
- ⊕ Vaccination against HBV is urgently recommended for all exposed occupational groups.
- ⊕ Observe recommendations regarding organisation given by your employer and behave appropriately. Avoid dangerous working methods and do not take any unnecessary risks.
- ⊕ Never use a standard product, when a safer alternative is available.
- ⊕ Always dispose of dangerous objects in suitable containers.
- ⊕ Get involved when safety products are being selected and evaluated.



Potential source of danger: Needles lying around

For Your Personal Protection You Should Avoid the Following Dangerous Working Procedures

- ❌ Recapping used needles
- ❌ Use of unsuitable disposal containers
- ❌ Overfilling disposal containers
- ❌ Injecting blood into containers (e.g. blood culture bottles)
- ❌ Manual removal of a needle from a syringe
- ❌ Manual removal of a needle from blood collection system holder without a suitable technical aid
- ❌ Transfer of blood from a syringe into a specimen container
- ❌ Carelessly handing over used instruments / devices
- ❌ Leaving contaminated objects lying around in patients' rooms
- ❌ Open transport of contaminated objects
- ❌ Disposal of dangerous objects in unsuitable, or disposal simply in rubbish bags
- ❌ Use of glass instead of safe plastic products

Sources: Safety First Cooperative, Medical Laboratory Observer Vol. 35 No2 Feb 2003;
Richard Fairfax of OSHA talks about the Bloodborne Pathogen Standard

Stand Up for Your Own Personal Protection



**Potential source of danger:
Passing on used needles**

By using safety products, needlestick injuries can be avoided. According to different investigations using various safety products, 88% of needlestick injuries could be avoided.

- ▶ **"62% - 88% of the estimated annual needlestick injuries could be avoided if safety products were used."** Quote

Source: Jim Chamblee; Blue Print for Health: www.blueprint.bluecrossmn.com

- ▶ **"By taking technical measures to protect against infection and introducing organisational improvements, the total of accidents with sharp and pointed objects can be reduced by up to 70%."** Quote

Source: PD Dr. med. Nenad Kralj, Bergische Universität - Gesamthochschule Wuppertal, Department of Safety Techniques

- ▶ **By using safety products, you can reduce your personal risk very effectively.**

In application studies using various safety products, significantly fewer needlestick injuries were registered:

66% fewer injuries when using blood collection holders with integrated needle safety shield,

76% fewer injuries when using safety blood collection sets.

Source: CDC Centers for Disease Control and Prevention; Morbidity and Mortality Weekly Report, January 17, 1997/Vol. 46/Nº. 2

Greiner Bio-One Has the Perfect Product for Every Application in Order to Protect YOUR Health

VACUETTE® QUICKSHIELD
Especially suited for daily blood collection procedures

- Activation with the aid of a stable surface
- Particularly user-friendly due to activation with one hand
- Especially safe, as the fingers never move forward to contaminated needle tip during activation
- As it is attached to holder, the safety shield always remains in the same position during the blood collection procedure
- The safety shield is attached directly to the holder - no danger of being accidentally removed - and corresponds to the specially oriented needles.



VACUETTE® TIPGUARD*
The best health protection due to unique technology

- Complete security due to automatic needle withdrawal directly from the vein
- Maximum comfort with simple-to-activate safety mechanism
- No changes to venipuncture technique necessary
- Especially suitable for risk patients (HIV, HCV, HBV)
- For exclusive use with **VACUETTE®** blood collection needles with oriented needle tips



VACUETTE® Safety Blood Collection Set
Specially developed for patients with difficult vein conditions



- Even simpler handling with new improved activation mechanism
- Visual venipuncture control enabled by transparent material (viewing window)
- Available with different needle gauges and tubing lengths
- Available with pre-attached holder
- Flexible tubing that does not roll up (no memory effect)
- Simple handling and disposal
- Complete activation signified by audible "click"

VACUETTE® PREMIUM Tube with Safety Twist Cap*

- Easy manual opening with just a half turn of the new twist cap
- Unbreakable
- No danger of blood splashes when opening
- Aerosol effect is minimised due to controlled opening movement
- Absolute safety during transport, as cap remains firmly attached
- Improved visual control of sample material due to transparent plastic label



Safety Closure for VACUETTE® Blood Collection Tubes



- Blood contact when opening tube is prevented by plastic cap
- Deep recess - prevention of contact to blood residue on puncture channel
- Blood repellent rubber material keeps the inner part of the cap largely free of blood

What Should You Do if You Still Injure Yourself in Spite of All Precautionary Measures?

► If you incur a prick or cut injury:

Sustain the blood flow so that the wound can bleed sufficiently by immediately applying pressure for as long as possible.

Following this, disinfect the wound with a skin disinfection solution containing alcohol for at least 30 seconds, regardless of pain.

► If your skin becomes contaminated:

Rinse the affected area of skin immediately under running water. Wash thoroughly with liquid soap and dry off with a disposable towel. Then disinfect with a skin disinfection solution containing alcohol for at least 30 seconds.

► If the mucous membrane gets contaminated:

In case of contamination in the mouth or eye, wash out immediately and thoroughly with a saline solution. Then disinfect carefully with a suitable disinfection solution for mucosa.

Always Report an Accident Straight Away. An Accident Report Is Important for Various Reasons:

- ⊕ Laboratory tests can provide certainty and emotional relief.
- ⊕ Insurance protection is guaranteed.
- ⊕ By reporting the accident, you are making a contribution to increased awareness of problems, to improved understanding of risk factors and to improved precautions.
- ⊕ Your report will be treated confidentially.

Source: Handbuch für Gesundheitsberufe, Empfehlung zur Verhütung von blutübertragenen Infektionen: Arge hiv / pflege, 1. Auflage Vienna 2000

What Can You Expect After a Needlestick Injury?

- Your employer reports the accident to the accident insurance company.
- The laboratory determines your HIV serology and prepares a hepatitis diagnosis for the patient.
- The laboratory determines your HIV serology and prepares the hepatitis antibody diagnosis.
- If you have an infection, an anti-retroviral post-exposure prophylaxis (PEP) will be administered and the side effects of a PEP will be explained. The Robert Koch Institute (www.rki.de) provides information on which medication is most appropriate according to current medical information.
- If hepatitis C incorporation is suspected, then attention must be paid to the seroconversion. Anti-viral therapy with interferons is then indicated.



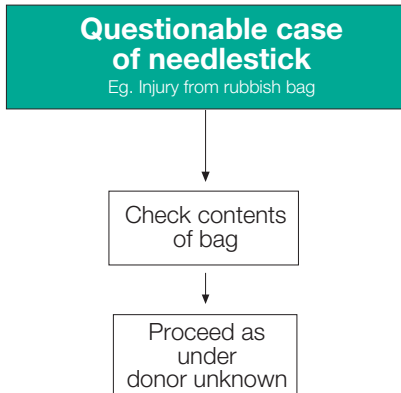
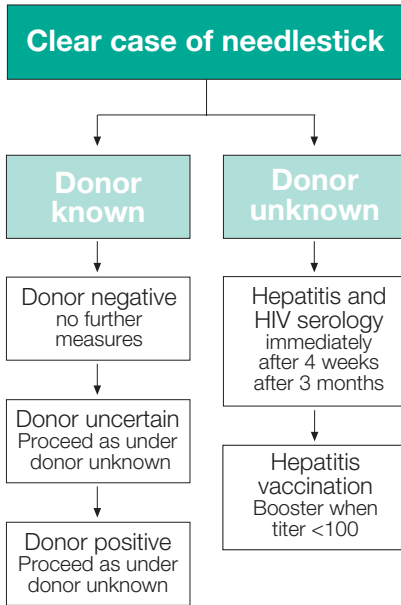
**Potential source of danger:
Injecting blood from syringes
into specimen containers**



**Potential source of danger:
Recapping needles**

Procedure Following a Needlestick Injury

Needlestick Prophylaxis from the Economic Point of View



Source: Drüen Bernhard; ARGE Arbeitssicherheit, Neufarn

Based purely on statistics, 0.66 needlestick injuries occur per year per exposed employee.
In an average hospital with 340 exposed employees, this amounts to 225 needlestick injuries per year. Approximately 15% of these, i.e. 34 injuries, are reported and lead to costs.

The costs for determining a needlestick injury amount approximately to a minimum of EUR 750 and a maximum of EUR 2,000 (laboratory tests, examinations, counselling, medication etc. without consideration of lost working hours).

Source: HFM Magazine: Innovative new equipment lowers risk of needlesticks www.hospitalconnect.com

► **This results in costs of 34 x EUR 750 = EUR 25,000 per year**

If report rates are higher, the total of determinations to make and the costs are correspondingly higher.

Out of 34 reported needlestick injuries, a post-exposure prophylaxis (PEP) is necessary for 0.8% of cases. This amounts to 0.3 PEPs per year. A PEP costs around EUR 5,000.

Source: Drüen, Bernhard, Neufarn, ARGE Arbeitssicherheit

► **The resultant annual costs are approximately EUR 1,500**

► **Consequently, an average hospital has the following costs to bear:**

Costs for determinations approx. EUR 25,500 per year
Costs for PEP approx. EUR 1,500 per year

► **The sum of directly attributable costs is approx. EUR 27,000 per year**

The following was not taken into account for the model calculation:

- ▶ The costs of working hours lost due to report, determination, diagnosis
- ▶ 6 weeks of salary to be paid in case of infection
- ▶ Insurance contributions which indirectly cover the resulting costs of an infection

Model calculation:

An average hospital pays: EUR 27,000 per year

By using precautionary technology, 62-88% could be prevented ¹⁾

Over a year this amounts to: EUR 16,800 - EUR 24,000

Investment costs per year for precautionary technology amount to²⁾:

EUR 10,000 - EUR 12,000

Savings per year: EUR 6,800 - EUR 12,000

1) Source: Chamblee, Jim: Blue Print for Health: www.blueprint.bluecrossmn.com (\$=EUR)
2) Source: Garwin, Michael: University of Iowa Hospitals and Clinics, Iowa City: www.hospitalconnect.com (\$=EUR)

▶ **Get involved in using safety products for your own protection.**

▶ **The use of safety products is also economically advantageous for your employer.**

How Can the Problem of Infection Protection Against Blood Transmitted Pathogens Be Solved Internationally?

- ▶ Awareness of this problem is far more advanced in the USA where the report rate is over 45%. In order to examine all these cases, the costs are three times higher than in, for example, many west European countries with report rates of approx. 15%. Therefore, it is far more economical to apply the precautionary technology that has become standard work practices in many hospitals in the USA. The main driver for the increased use of safety products has been the introduction of the Needlestick Safety and Prevention Act, which was signed into law in November 2000.
- ▶ The situation in France is similar. The use of precautionary technology is strongly encouraged there. It is clear that it does not just have financial advantages to prevent infection risks, but it also provides affected healthcare employees with more personal safety in dealing with their patients, and improved quality of life. 10 years ago, WHO started up an international program for immunising neonates against hepatitis B. This provides children and adolescents with protection to a large extent.

Literature

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