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VACUETTE[®] Safety Brochure



Our Innovations
for Your Safety

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VACUETTE® Safety Products

VACUETTE® Safety Products

**Our Innovations
for Your Safety**

Recommendations on Avoiding Blood Transmitted Infections.



Potential source of danger: Recapping a used needle

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, or view injury by a contaminated object as a minor accident of no further significance.

However, the psychological strain after a needlestick injury can be enormous for the person affected and those close to him/her. The consequences may be tragic, and the effects on both career and private-life far-reaching. In many cases, an infection leads to occupational invalidity or even be excluded from working again in the health-care sector, along with all the social and financial consequences.

Because of the drastic consequences, it is essential that the dangers are explained, as well as how to deal with them professionally. In the everyday hectic of working life and the continual time pressure, accidents resulting from contact with contaminated objects cannot be ruled out. The cause of the accident is not necessarily negligent behaviour or lack of care, but ever increasing strain and consequent lack of concentration in risky situations. However, there are enough opportunities to ensure adequate protection even in such situations.

In certain countries, the difficulties are already reflected in the legislation, as appropriate guidelines and laws have already been decreed, which must now be put into practice. However, this can only be successful if all persons involved are familiar with the new rules, and in a position to observe them, adapting their behaviour correspondingly.

Which Pathogens Are Most Dangerous?

The main sources of danger are blood transmitted viruses. Hepatitis B, C and HIV pathogens.

The infection risk resulting from these pathogens is dependent on two factors: the rate of seroconversion and the prevalence.

The prevalence is the proportion of infected persons in the general population, and differs according to region. For example:

	Europe	Africa	South East Asia	America	Worldwide
HBV	< 2.0 %	> 8.0 %	> 8.0 %	< 2.0 %	5.0 %
HCV	1.0 %	5.3 %	2.2 %	1.7 %	1-2 %
HIV	0.3 %	8.4 %*	0.6 %	0.6 %	1.2 %

* regional in Central and South Africa > 50 %

For employees in the healthcare sector, the number of infectious patients being treated in the affected institution is far more significant. Many studies prove, that the proportion of virus carriers in a hospital is considerably higher than in the general population.

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 transmissions per 1000 needlesticks
HCV 30 transmissions per 1000 needlesticks
HIV 3 transmissions per 1000 needlesticks

The greater the amount infectious material transmitted per needlestick, the more likely an infection will occur.

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/ro/HBV/sld005.htm>
HIV: Regionale HIF-/Aids - Statistik, Stand Ende 2001 UNAIDS/WHO 2001:3

What Is the Known Infection Risk?

In 2002, for example, in Germany alone the following suspected cases of infection after an occupational risk were reported:

170 HBV cases
254 HCV cases
9 HIV cases

These figures lead to the conclusion that in countries where the immunisation rate against hepatitis is very high, as it is in Germany, the risk of contracting an HBV infection at work can be reduced considerably. On the other hand, the actual risks involved with HCV and HIV exceed by far the purely mathematical figures based on the rate of seroconversion and prevalence.



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 so high, 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 reported HCV cases increase year by year. This is further aggravated by the high rate of spontaneous mutations of the HC virus, which causes problems for the endogenous immune system.

HIV – The Sources of Danger Are Generally Known.

There is less risk of transmission with HIV. HIV patients are usually known in clinics. The risks can therefore be catered for. Immunisation in this case is also not available. 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		

Which Occupational Group Is Most at Risk?

- ⌂ Nursing staff 55,6 %
- ⌂ Medical staff 29,3 %
- ⌂ All others 15,1 %



Which Objects Cause Injuries?

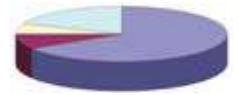
- ⌂ Syringes and needles 69,9 %
- ⌂ Surgical instruments 24,9 %
- ⌂ Glass 1,6 %
- ⌂ All others 3,6 %



Source: SAFETY FIRST Kooperative, Bundesverband der Unfallkassen

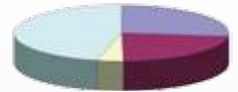
Where Do the Accidents Occur?

- ⌂ Patient's room 66 %
- ⌂ Operat. theatre/intensive care 9 %
- ⌂ Laboratory 6 %
- ⌂ Other reasons 19 %



Which Activities Cause the Most Injuries?

- ⌂ Disposal 27,0 %
- ⌂ Whilst applying object as intended 22,6 %
- ⌂ Recapping 3,9 %
- ⌂ All other activities 46,5 %



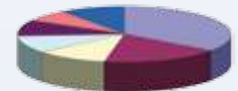
Needlesticks Are Not Trivial Incidents.

As shown in 23 studies from throughout the world, an employee suffers a needlestick or cut injury with a sharp object every 1 – 2 years.

The mentality "Nothing can happen to me", is reflected directly in the total of registered injuries with risk potential. The report rate lies between 10% and 50%. 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:

- ⌂ Superficial injury 35 %
- ⌂ Sufficient Hepatitis immunisation 18 %
- ⌂ No time to make a report 11 %
- ⌂ Not familiar with report system 10 %
- ⌂ Nightshift/weekend duty 9 %
- ⌂ Forgotten 7 %
- ⌂ Other reasons 10 %



Source: Hasselborn, Hofmann et al Needlestick injuries in hospital

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 are able to correctly take stock of the situation, and if you work using safe product solutions, then you already have the best strategy for avoiding 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. Frequent checks of protection level are imperative.

+ Observe suggestions regarding organisation given by your employer and behave appropriately. Avoid dangerous working methods and do not take any unnecessary risks.

+ Use safety products.

+ Always dispose of dangerous objects in suitable containers.



Potential source of danger: Needles lying around

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



! Recapping a used needle



! 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 holder

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



- ! Transfer of blood from a syringe into a specimen container



- ! Carelessly handing over used devices



- ! Letting used contaminated objects lie around in patients' rooms



- ! Disposal of dangerous objects in unsuitable containers 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

Application of Safety Products Significantly Reduces the Risk of Needlesticks.

As shown in various studies, needlestick injuries are considerably less, when safety products are used:

Three studies in USA: 62 – 88 % reduction of needlestick injuries
One study in Germany: 72.5 % reduction of needlestick injuries

How Can Legislation Protect Employees in the Healthcare Sector?

In some countries, the application of instruments with a needle protection mechanism is obligatory and legally binding.

USA

As far back as November 2000, the Needlestick Prevention and Safety Act was introduced in the USA as a judicial basis for avoiding needlestick injuries. The "US Department of Labor" has developed a foundation for the practical application with the "OSHA Standards". These and other similar standards are applied in the USA today for avoiding dangerous injuries. This includes a broad range of accident avoidance strategies, as well as the use of safety products.

EU

The existing European legislation is not enough to guarantee sufficient protection. This is the conclusion of the responsible committee of the European Parliament. On 6th July 2006, the committee was given the task of finding a suggestion to change the law so as provide effective protection against needlestick injuries for workers in the healthcare sector.

France

In France the application of safety technology has been encouraged for several years. The financing for safety products is supported to a large extent, so the application of this kind of product has been widespread throughout the country for a while now.

Germany

On 14th February 2008 the last amendment to the “Technischen Regeln für biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege – TRBA 250 (Technical Laws for Working with Biological Materials in Healthcare)” came into power. Regarding prevention of needlestick injuries, the following applies:

“To protect employees from injuries when working with pointed or sharp medical instruments, these instruments must – as far as technically possible – be replaced with suitable safe work instruments, which provide no risk or virtually no risk of needlestick and cut injuries.”

With this regulation, Germany is ahead of the EU legislation. The ruling is currently in the process of being put into practice.



Potential source of danger: Use of unsuitable disposal containers

Greiner Bio-One Can Offer You Optimal Products for Your Safety, in Particular for Blood Collection.

Greiner Bio-One Safety Products fulfil all international regulations for protection from needlesticks. Furthermore, **VACUETTE®** products have other characteristics which simplify application and increase safety.

VACUETTE® QUICKSHIELD Safety Tube Holder

For daily blood collection procedures

The **VACUETTE®**

QUICKSHIELD Safety Tube Holder is especially suitable for routine blood collection. There is no change to usual collection technique, and the safety shield is activated one-handed with the aid of solid surface. This product can provide the user with the simplest handling and reliable infection protection. Once activated it is not possible to unthread the used needle, thereby additionally preventing injuries on the backend of the needle sleeve.



Also available as a combination product with a pre-attached **VACUETTE®** VISIO PLUS or a **VACUETTE®** Standard Needle, making the **VACUETTE®** QUICKSHIELD Safety Tube Holder the ideal product for safe blood collection. The **VACUETTE®** VISIO PLUS Needle with optical venipuncture control makes blood collection a lot easier for the user. With the transparent view window in the needle hub, blood flow is visible immediately on correct venipuncture.

VACUETTE® TIPGUARD Safety Tube Holder

In case of increased infection risk

Comfort and safety are the features of the **VACUETTE®** TIPGUARD Safety Tube Holder. After blood collection the needle is automatically withdrawn by pressing the two blue buttons on the top of the holder. The used needle is kept safe within the holder for subsequent disposal.



VACUETTE® PREMIUM Safety Needle System

Maximum safety for high-risk cases

The latest product development from the Preanalytics division is the **VACUETTE® PREMIUM** Safety Needle System. This is ideal for use on high-risk patients. The safety needle is already integrated into the blood collection holder. The new product is absolute simplicity, as there is no need



Left: "Tube-Touch" (TT) Right: "Skin-Touch" (ST)

for the blood collection staff to manually activate the safety mechanism. The safety engineered designs represent true passive safety. The visual indicator on the safety shield provides the user additional assistance in identifying the position of the needle in the vein.

There are two product variations to choose from (available 2009):

Activation via tube insertion - "Tube-Touch" (TT)

When the user pushes in the tube, the pressure of the tube onto the back end of the needle triggers the safety mechanism automatically.

Activation via skin penetration - "Skin-Touch" (ST)

The safety mechanism is activated automatically when pressed against the skin.

The safety shield can then move freely, enclosing the needle via the spring mechanism as it is withdrawn from the vein. Features of the system are extreme comfort and maximum safety, with the additional advantage that the user can collect blood samples as usual and has no additional handling steps.

VACUETTE® Safety Blood Collection Set

Especially for difficult vein conditions

The **VACUETTE®** Safety Blood Collection Set has been especially developed for patients with difficult vein conditions. As the protection mechanism is activated whilst still in the vein, a high level of safety is ensured. Correct activation is indicated via an acoustic signal. With the transparent view window, visual control of blood flow is possible, thus increasing venipuncture safety.



MiniCollect® Safety Lancets

Maximum safety even for capillary puncture

The handling of the **MiniCollect®** Safety Lancets could not be easier, making them extremely safe. Slight pressure on the button of the colour-coded lancet casing activates the blade, upon which the blade is automatically withdrawn into the plastic casing. Once activated, the safety mechanism cannot be reversed.

The **MiniCollect®** Safety Lancets for Capillary Blood Collection are available in various puncture depths, which is easily identifiable with the colour code: pink 1.0mm, green 1.5mm, blue 2.0mm.



Disposal Containers

For the routine disposal of sharp and pointed objects

Disposal containers increase safety considerably. They are applied in practically all areas of the clinic. Our product line includes different disposal containers for a range of disposal situations. The capacity volumes are between 0.5 and 50 litres. The containers are non-penetrable and once closed cannot be re-opened.



VACUETTE® PREMIUM Tube

Optimal protection even when opening sample tubes in the laboratory

The **VACUETTE®** PREMIUM Tube with Safety Twist Cap provides even laboratory staff with far-reaching infection protection, when used as component of the **VACUETTE®** Blood Collection System, in particular when opening the tube. Just a half-twist

of the protective cap is enough to open the tube. This controlled opening movement prevents blood splashes and aerosols. The tube is manufactured from shatterproof PET. The firm hold of the cap provides the highest level of transport safety.



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

All measures must be taken after an injury.

If You Incur a Prick or Cut Injury:

Sustain the blood flow so that the wound can bleed sufficiently by immediately applying pressure for at least 1 to 2 minutes, in order to remove as much foreign matter as possible.

Following this, disinfect the wound with a skin disinfection solution containing alcohol for at least 30 seconds regardless of pain to ensure long-lasting effectiveness. The disinfection lasts for 4 to 5 minutes.

The effectiveness of the disinfection causes some pain. Only when the pain is great, is the disinfection successful.

When finished, the wound is protected with a sterile bandage soaked in ethanol.

If Your Skin Becomes Contaminated:

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

If the Mucous Membrane Gets Contaminated:

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



Potential source of danger: recapping needles

Always Report an Accident Straight Away to the Staff Doctor. An Accident Report Is Important for Various Reasons:

- Laboratory tests are carried out on you as well as the source of infection – if known – and 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 improved precautions.
- Your employer reports the incident to the insurance company. All costs that occur are covered by the insurance.
- Your report will be treated confidentially.

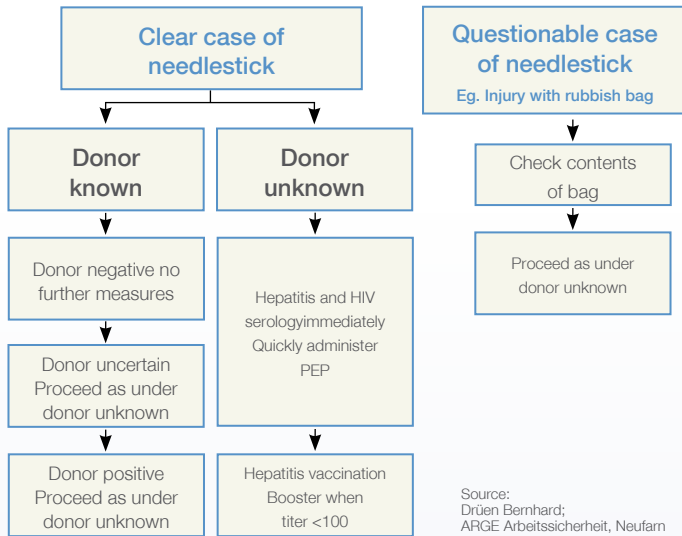
Which Prophylaxis Is Necessary After a Needlestick Injury?

- Both blood samples are sent quickly to the laboratory.
- 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 too.
- If indicated by the laboratory results, an antiretroviral post-exposure prophylaxis (PEP) must be administered.
- If a hepatitis B immunisation is required, it must be given within 48 hours of the accident
- A PEP for HIV must be given as soon as possible, maximum 24 hours after the accident. A HIV-PEP is useless 72 hours after inoculation.
- You will be informed of the PEP side-effects.
- Prophylaxis with drugs can save your life.



Potential source of danger: injecting blood into containers

Procedure Following a Needlestick Injury



Every prophylaxis is just a belated attempt to prevent an infection and thus a life-threatening illness. There is no guarantee that it will succeed. The best prophylaxis is prevention.

What Does Effective Infection Protection Cost?

Needlestick injuries cause high costs. Various studies have calculated costs ranging from EUR 356 to EUR 3465 for a needlestick. On average the costs are round EUR 500, according to reliable calculations made by occupational health practitioners in Wuppertal. The costs incurred due to work stoppage are not included.

For around 50,000 reported needlestick injuries in Germany, for example, costs of approx. 25 million euros arise. If the costs for the needlestick injuries that go unreported are added, then economic damages amount to about 47 million euros in Germany alone.

Over the past 4 years the costs for safety products have decreased.

Today protection of employees from dangerous infections in the healthcare sector is virtually **self-financing** with safe devices, thus ensuring staff increased personal safety when dealing with patients, and improving life quality.

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For further informations please visit our website www.gbo.com/preanalytics or contact us:

Austria

Greiner Bio-One GmbH
Phone (+43) 75 83 67 91-0
Fax (+43) 75 83 63 18
E-Mail office@at.gbo.com

Brazil

Greiner Bio-One Brasil
Phone (+55) 19 34 68 96 00
Fax (+55) 19 34 68 96 21
E-Mail office@br.gbo.com

Egypt

Greiner Bio-One Middle East
Phone (+20) 26 21 87 06
Fax (+20) 26 21 87 08
E-Mail hisham.ouda@gbo.com

France

Greiner Bio-One SAS
Phone (+33) 1 69 86 25 50
Fax (+33) 1 69 86 25 36
E-Mail office@fr.gbo.com

Germany

Greiner Bio-One GmbH
Phone (+49) 2 01 86 18 6-0
Fax (+49) 2 01 86 18 61-2
E-Mail office@de.gbo.com

Great Britain

Greiner Bio-One Ltd.
Phone (+44) 14 53 82 52 55
Fax (+44) 14 53 82 62 66
E-Mail info@uk.gbo.com

Hungary

Greiner Müanyagtechnika Kft.
Phone (+36) 96 21 30 88
Fax (+36) 96 21 31 98
E-Mail office@hu.gbo.com

Spain

VACUETTE Espana S.A.
Phone (+34) 91 652 77 07
Fax (+34) 91 652 33 35
E-Mail info@vacuette.es

Switzerland

Greiner Bio-One VACUETTE
Schweiz GmbH
Phone (+41) 7 12 28 55 22
Fax (+41) 7 12 28 55 21
E-Mail office@ch.gbo.com

Thailand

Greiner Bio-One Thailand Ltd
Phone (+66) 3 84 65 63-30
Fax (+66) 3 84 65 63-6
E-Mail office@th.gbo.com

The Netherlands

Greiner Bio-One B.V.
Phone (+31) 1 72 42 09 00
Fax (+31) 1 72 44 38 01
E-Mail info@nl.gbo.com

USA

Greiner Bio-One North America Inc.
Phone (+1) 70 42 61 78 00
Fax (+1) 70 42 61 78 99
E-Mail office@us.gbo.com