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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 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 healthcare 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 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 under these kind of circumstances.

In certain countries, the difficulties are already reflected through the legislation, and for EU countries, a council directive on prevention of sharp injuries in hospitals and healthcare was published in May 2010 which must come into effect in all EU countries by 11th May 2013. 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 of material transmitted per needlestick, the more likely an infection will occur.

Sources:

HCV: M. Schreier M. Höhne: Bundesgesundheitsbl. - Gesundheitsforsch.-
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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 the purely mathematical figures based on the rate of seroconversion and prevalence.

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 health-care 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 respond or respond 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.

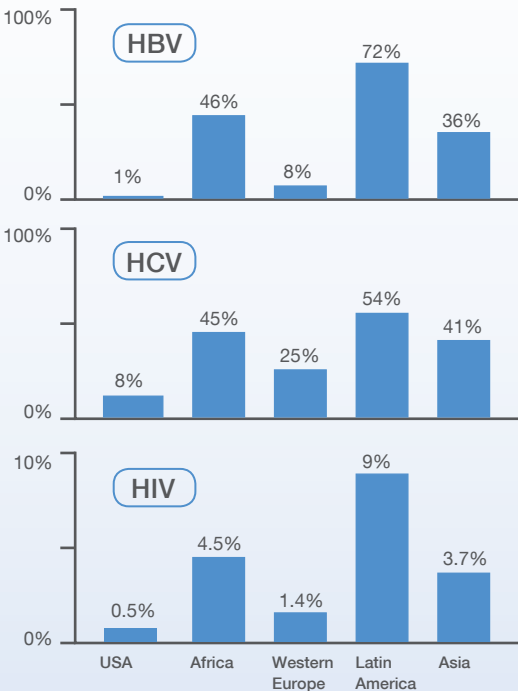
The transmission risk relating to HCV is not quite so high as HBV, but the health risks are far more serious, and for the foreseeable future, immunisation is not possible. Whilst HBV infections remain between constant and slightly declining, the rate of reported HCV cases increase year after year. This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

The Risk of Infection on an International Scale

If an employee in the healthcare sector becomes infected by HBV, HCV or HIV, the cause is often due to an injury with a sharp, contaminated object, but there are enormous differences throughout the world. In regions where there are trained professionals, the risk awareness is high and safety products tend to be used. For example, in North America the total of infection incidents is very low. In regions where the risk awareness is low, and safety products are seldom applied, the total of infection incidents is high.



The share as a percentage of HBV, HCV and HIV infections amongst healthcare workers, caused by injuries with sharp contaminated objects.

Study by Roland Berger Strategy Consultants



Potential source of danger: overfilling disposal containers.

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
- ☞ Medical staff
- ☞ All others

- 55,6 %
- 29,3 %
- 15,1 %



Which Objects Cause Injuries?

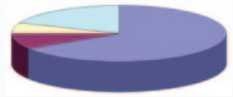
➤ Syringes and needles	69,9 %
➤ Surgical instruments	24,9 %
➤ Glass	1,6 %
➤ All others	3,6 %



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 unjuries in hospital



Potential source of danger: needles lying around

How Do I Protect Myself?

The biggest safety risk is the lack of education. 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 systems, 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. 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.

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



Recapping a used needle



How to do it correctly: Use safety products with needle protection!
(e.g. **VACUETTE**[®] QUICKSHIELD Safety Tube Holder)



Use of unsuitable disposal containers



How to do it correctly: Only use disposal containers, which have been classified for disposal!



Overfilling disposal containers



How to do it correctly: Never overfill a disposal container, observe the maximum fill line!

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



Injecting blood from a syringe into the blood culture bottle



How to do it correctly: Use special blood culture collection adapters!



Manual removal of a needle from a syringe



How to do it correctly: Never remove a needle from a syringe. Use only safety products with a needle protection cap!



Manual removal of a needle from blood collection holder



How to do it correctly: Never remove the needle from the holder, use safety tube holders such as the **VACUETTE® QUICKSHIELD**.

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



Transferring blood from a syringe into a specimen container



How to do it correctly: Use a blood collection system that fills the blood sample tube directly!



Carelessly handing over used devices



How to do it correctly: Never pass on used devices to somebody. Dispose of them correctly!



Letting used contaminated objects lie around in patients' rooms



How to do it correctly: Never leave a contaminated object lying around in a patient's room!

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



Disposal of dangerous objects in unsuitable containers or disposal of open containers in rubbish bags



How to do it correctly: Always dispose of dangerous objects in a disposal container. Even safety products must always be disposed of in a disposal container! Always be sure to close the disposal container correctly before disposing.



Using products made out of glass



How to do it correctly: Use shatter-proof plastic products!

Source: 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

Experts confirm that when safety products are introduced, needlestick injuries can be reduced by at least 85%.

How Can Legislation Protect Employees in the Healthcare Sector?

In some countries, the application of devices 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 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 today for avoiding dangerous injuries. This includes a broad range of accident prevention strategies, as well as the use of safety products. The success of the measures is indicated by the significant reduction of needlestick injuries.

EU

The European Federation of Public Service Unions (EPSU) and the European Hospital and Healthcare Employers' Association (HOSPEEM) signed a "Framework Agreement on Prevention of Sharp Injuries in the Hospital and Healthcare Sector"* on 17th July 2009. The framework agreement was accepted as a directive in EU law

in March 2010. The directive has to be implemented in the member states by 11th May 2013 at latest. The goal is to create the safest possible working environment for workers in hospitals and the 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 is widespread throughout the country.

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)" was implemented. 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 devices, which provide no risk or virtually no risk of needlestick and cut injuries."

With this regulation, Germany is ahead of the EU legislation.



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 either one-handed with the aid of solid surface or with the thumb. 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 complete product with a preassembled **VACUETTE®** VISIO PLUS 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 much easier for the user. With the transparent view window in the needle hub, blood flow is visible immediately upon correct vein penetration.

SAFETY Blood Collection Set

Especially for difficult vein conditions

The SAFETY Blood Collection Set has been especially developed for patients with difficult vein conditions.

As the protection mechanism is activated whilst the needle is 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 successful vein penetration is possible, thus increasing venipuncture safety.

The SAFETY Blood Collection Set is available in three versions:

- SAFETY Blood Collection/Infusion Set (without Luer Adapter); are particularly suitable for short-term infusion procedures
- SAFETY Blood Collection Set with Luer Adapter
- SAFETY Blood Collection Set with Holder



VACUETTE® PREMIUM Safety Needle System Tube-Touch

Maximum safety

The latest product development from the Preanalytics division is the **VACUETTE®** PREMIUM Safety Needle System Tube-Touch. The safety needle is already integrated into the blood collection holder. The new product is absolute



simplicity, as there is no need for the blood collection staff to manually activate the safety mechanism. The safety engineered design represents automatic safety. The visual indicator on the safety shield provides the user additional assistance in identifying the depth of the needle in the skin.

Tube-Touch - Activation:

When the user pushes in the tube, the pressure of the tube onto the back end of the needle releases the safety shield, automatically covering the needle which moves forward lightly resting against patient's skin.

Due to the spring mechanism, the safety shield can move freely allowing for repositioning when necessary, as well as automatically covering the needle when removed 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.

HOLDEX® Single-Use Holder

Used in combination with Hypodermic Needle-Pro® Needle with Needle Protection Device*

The practical Luer system for attaching the HOLDEX® Single-Use Holder with a safety hypodermic needle makes daily routine procedures easier. The occasionally time-consuming



process of threading in the double-ended multiple use drawing needle is no longer necessary. The HOLDEX® Single-Use Holder features an eccentric (offcentre) Luer adapter. This special design of the holder provides a more comfortable flat angle for venipuncture.

When used in combination with the Needle-Pro® Needle, the HOLDEX® Single-Use Holder ensures safe blood collection. The safety protection cap is activated immediately after blood collection with the aid of solid surface.

MiniCollect® Safety Lancets

Maximum safety even for capillary puncture

The handling of the **MiniCollect®** Safety Lancets could not be easier contributing to a safer working procedure. Slight pressure on the button of the colour-coded lancet casing activates the puncture, after which the lancet is automatically withdrawn into the casing. Once activated, the safety mechanism cannot be reversed. The **MiniCollect®** Safety Lancets for Capillary Blood Collection are available in various puncture depths and needle and blade versions, which is easily identifiable with the colour code:



- **MiniCollect®** Safety Lancets with blade:
pink 1.0 mm, green 1.5 mm, blue 2.0 mm
- **MiniCollect®** Safety Lancets with needle:
lavender 1.25 mm / 28G, orange 2.25 mm / 23G

Sharps Disposal Containers

For disposal of sharp and pointed objects

Disposal containers increase safety considerably. They are used in practically all clinical areas. Our product line covers different disposal containers for varying disposal situations. The capacity volumes range from 0.6 litres to 50 litres. The containers are non-penetrable and once they have been closed, they cannot be re-opened.



Certification: British Standard, UN, AFNOR

VACUETTE® PREMIUM Tube

Optimum protection when opening sample tubes in the laboratory

The **VACUETTE®** PREMIUM Tube with Safety Twist Cap as component of the **VACUETTE®** Blood Collection System provides laboratory staff a high level of protection, especially when opening the tube. Just a half twist is necessary to open the safety cap. This controlled opening movement helps prevent blood splashes and aerosols. The firm fit of the cap enables absolute 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

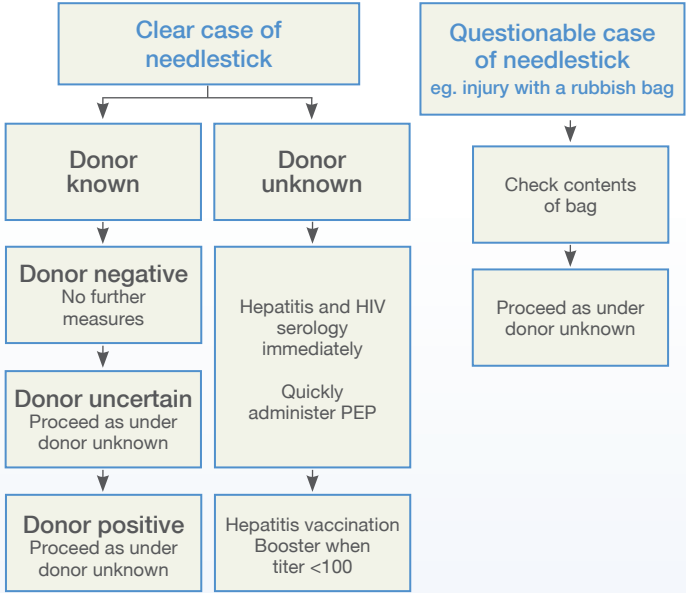
Always Report an Accident Straight Away to the Staff Doctor. An Accident Report Is Important for Various Reasons:

- 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 the needlestick injury.
- You will be informed of the PEP side-effects.
- Prophylaxis with drugs can save your life.

Procedure Following a Needlestick Injury



Source: Drüen Bernhard; ARGE Arbeitssicherheit, Neufarn

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.



Potential source of danger: injecting blood into containers

What Does Effective Infection Protection Cost?

Needlestick injuries cause varying high costs. Several studies carried out in Switzerland determined the following costs for a needlestick injury.

EUR 356,- if source is negative

EUR 682,- if source is HCV positive

EUR 3.465,- if source is HIV positive

In areas with high prevalence of HCV or HIV, then higher average costs are to be expected. A high HBV vaccination rate reduces the average costs. In West Europe the average costs, depending on the extent of HBV mass vaccination, are approximately EUR 450,- to EUR 635,- calculated by occupational medical specialists in Wuppertal.

For approx. 50,000 registered needlestick injuries, e.g. in Germany, the costs for hospitals and insurance companies amount to 24 million euros. If the costs for the unregistered needlestick injuries are added to the costs, this amounts to more than 47 million euros of economic damages annually in Germany alone. Furthermore this total does not include the subsequent costs of infectious diseases after a needlestick injury, i.e. in the form of treatment costs, loss of earnings, pensions etc.

Over the past 4 years the costs for safety products have decreased by 25%.

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 quality of life.

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