

Translation of Relevant Section 4.2.4 of TRBA 250

4.2.4 In order to protect employees from injuries while working with pointed or sharp medical instruments, such instruments are to be replaced - to the extent technically possible - under the measures of the following numbers 1 through 7 by suitable safer implements in which there is no risk or less risk of puncture or cut injuries.

1. Safer implements must be utilized in the following activities and in the following areas with relatively high risk of infection or accident:
 - treatment and care of patients known to be infected with pathogens of risk group 3 (including 3**) or higher
 - treatment of patients who pose a risk for others
 - activities in emergency medical services and in the emergency room
 - activities in prison hospitals
2. As a matter of principle, safer implements are to be used supplementally to No. 1 in activities in which body fluids can be transmitted in quantities relevant for infectious purposes. Specifically included in these activities are
 - the drawing of blood
 - other punctures for the purpose of drawing body fluids
3. In deviation from No. 2, conventional implements may continue to be employed if in the framework of the risk assessment that is to be prepared with the participation of the company physician, work processes are established that minimize the risk of injury or if a low risk of infection is determined.

The risk of infection is minimized, for example, through

- established work processes that are not circumvented even in emergency situations and
- training and annual instruction of the employees and
- a tested disposal system for used instruments (see section 4.1.2.8)

There is a low risk of infection if the infectious status of the patient is HIV, HBV and HCV-negative.

The results of this portion of the risk assessment must be separately documented.

4. The selection of the safer implements must be made in relation to the application, including with respect to ease of handling and acceptance by the employees. Work processes are to be adapted in terms of the use of safer systems.

5. It must be ensured that employees are able to properly use safer implements. For this it is necessary to provide information on safer implements and to convey the handling of safer implements.
6. The effectiveness of the measures instituted is to be monitored.
7. Safer implements for the prevention of puncture wounds and cuts must not endanger patients.
They must also have the following properties:
 - The safety mechanism is a component of the system and is compatible with other accessories.
 - Its activation must be possible with one hand.
 - Its activation must be possible immediately after use.
 - The safety mechanism excludes the possibility of reuse.
 - The safety product does not require any change in application technique.
 - The safety mechanism must be identified by a clear signal (tactile or audible).

On equal footing with the utilization of safer implements are also procedures with which needles can be safely retracted into the protective sheath, for example [in] local anesthesia in dentistry or in the case of the injection of medications (pen).