



#### Sterilization and Disinfection of Patient Care Items

Sterilization and disinfection of patient care items is a critical component to all medical and dental facilities. Understanding that there are different types of patient care items can help your company know how to best keep your patients and staff safe from cross contamination. Medical and dental instruments/devices are labeled by the manufacturer as either reusable or single use. Reusable devices have instructions from the manufacturer for cleaning, disinfection, or sterilization. Single-use devices do not have instructions for reprocessing and should be properly discarded after every use.

The Spaulding classification is the traditional way to reprocess medical and dental devices. EH Spaulding states that how an instrument or device is processed depends on how that instrument is used. The approach is based upon the degree of risk for transmitting infections if the device is contaminated at the time of use. There are three classifications of instruments: Critical, Semi-critical, and Non-critical.

Critical instruments are those that enter sterile tissue or the vascular system. They penetrate soft tissue, teeth, or bone and have the

greatest risk of transmitting infection. Medical items that are classified as critical are surgical instruments. Dental instruments that are classified as critical are hygiene scalers and burs. These are a few examples but remember that any device/instrument that enters sterile tissue is classified as critical. The CDC states that all critical instruments should be cleaned and sterilized by heat before use. If they cannot be heat sterilized, they are considered single use items.

Semi-Critical instruments contact mucous membranes or non-intact skin. They DO touch mucous membranes but don't enter the vascular system. Semi-critical instruments have a lower risk of transmitting infection. If a Semi-critical instrument is heat stable, it should be heat sterilized before use. If it is not heat stable, at a minimum it would require high-level disinfection. Many dental Semi-critical items are heat tolerant; therefore, they would be cleaned, and heat sterilized between uses

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and before use on another patient. Examples include mouth mirrors and handpieces. Medical devices that are deemed semi-critical are endoscopes. Flexible endoscopes are not heat tolerant and therefore would undergo a cleaning process and high-level disinfection. There are rigid endoscopes which are heat tolerant and available, these should be autoclaved. When a Semi-critical instrument cannot be heat sterilized or high-level disinfected, they are considered single use items.

Non-critical is the last in the classification approach. Non-critical items are those that contact intact skin but not mucous membranes. These pose the least risk of transmitting infection. Non-critical items should be low or intermediate level disinfected between use. Whether to use low or intermediate level disinfection would depend on the nature and degree of contamination. If the item is visibly soiled with blood or other potentially infectious material, the item is cleaned, and an EPA-registered hospital disinfectant is adequate. Examples of Non-critical items include a blood pressure cuff, pulse oximeter, or radiograph tube head.

To reiterate: all Critical and Semi-critical instruments should be cleaned to remove all blood and other potentially infectious material, packaged, and, when possible, heat sterilized between use. They should remain packaged until point of use. Semi-critical instruments that cannot be heat sterilized should be high-level disinfected.

Medical and dental devices are sterilized or high-level disinfected utilizing FDA-cleared sterilant or high-level disinfectants and EPA-registered disinfectants. Manufacturer's instructions must be followed when utilizing the disinfectants. Practices should follow the directions regarding concentrations and exposure time for disinfection.

Some key recommendations for cleaning, disinfection, and sterilization of devices are as follows:

- Ensure that reusable devices/instruments are cleaned and reprocessed prior to use on another patient.
- Reusable devices should be cleaned, reprocessed, and maintained according to manufacturer's instructions for use.
- Health care personnel (HCP) should be trained prior to being assigned responsibilities in instrument processing. The training should be hands-on with step-by-step guidance.
- Manufacturer's instructions should be available and followed.
- Assure HCP wear and have access to appropriate personal protective equipment when handling and reprocessing contaminated instruments.

Sterilization and disinfection of medical devices, instruments, and equipment should be a top priority for all healthcare facilities. This will keep both your patients and employees safe. If your company needs help with Infection Control, TMC is proud to announce that we are rolling out an Infection Control Program to help you with all your needs. Be on the lookout for our emails and information about this exciting new program!

#### It's Your Call - June 2024

### OSHA/Infection Control: Can you refuse to use a safety device for a sharp instrument on the basis that it costs too much?

By law, you must review your sharps (any device that cuts or punctures the skin) every year. Any new safety devices that have the potential to be safer than what you are using must be evaluated by the personnel who would be using it. Cost can never be the basis for not using a better device. The only reasons that OSHA would accept for not using the new device are as follows:

- The device is more likely to cause harm to the employee.
- Using the device for the procedure would put the patient at greater risk.

Either reason must be well documented.

#### HIPAA: Can a subpoena be ignored if we feel it will cause harm to the patient?

A subpoena, whether it is from a judge or an attorney, can never be ignored but it can be fought. If the provider (and only the provider) feels that to release the information required would likely cause harm to someone in the provider's professional judgement they can go before a judge and make their case.

The judge can rule in several ways:

- The subpoena is blocked.
- The subpoena must be answered.
- The information will be released only to the judge.

You should consult an attorney immediately to guide you through this process. REMEMBER: An attorney representing the practice in this situation would be considered a business associate and you should sign a Business Associate Agreement with them.

## HIPAA, Battling Parents, and Minor's Health Records

Dealing with a minor's health records can be a minefield when a child is from a blended family, or the parents have a contentious divorce ongoing. This gets especially sticky when you add in stepparents, grandparents, and situations where a minor controls all or a portion of their own records. Reviewing the basics can help your practice stay ahead of a potential costly HIPAA violation.

**Custody versus Parental Rights:** Don't confuse custody with parental rights. Both parents of a minor have access rights to a minor's record unless the minor can consent to their own treatment. If one parent wants to block the other parent from the records, there is only one way to do it. The parent being blocked has to have their "parental rights" removed by the court. Your practice must be presented with a judge-signed order designating this.

Custody of the child is different. One parent can have full custody but as long as the parental rights of the other parent haven't been revoked by the courts then both parents can view and get copies of the healthcare records of the child.

**Extended Family:** Either parent can sign an authorization for a stepparent, grandparent or another person to have a copy of the child's records or discuss the records with someone at the practice. It is a parental right, and the other parent can't block that without legal documentation. However, state law on custody can influence this issue. Depending on custody arrangements, it may take both parents to agree. As a practice, you don't have access to the custody agreement and its implications. When you are presented with a conflict, take the stance of restricting the release until you are presented with an agreement between the parents or a legal document. You do not have to be put in the middle of a parental dispute. Consult your own lawyer if needed. Without permission from one of the parents, stepparents and grandparents do not have any rights beyond the same "to the extent they are involved in the care" standard that applies to anyone.

**Adoptive Parents:** In order for someone to adopt a child, one or both parents have to give up their parental rights. For example, if a single mother marries a man who is not the father of her child, and her husband adopts her child, then he becomes the father, and the birth father no longer has any rights to the records.

**Legal Guardians**: A legal guardian is granted **parental rights** by court order. If someone is designated a legal guardian, parental rights are not automatically removed from the parents. That would take an extra step and, again, your practice must be presented with the court order stating the parental rights have been removed.

**State Custody:** When the state has custody of a minor and the child has been removed from the home, the state assumes legal guardianship of the child and the same rules apply. The social worker in charge of the case is granted parental rights but this does not remove the rights of the parents. Note that the social worker is the legal guardian, not the caregiver. Parent Information: Care should be taken when sharing information about one parent to the other. This especially concerns location, credit card numbers, and insurance numbers. If possible, that information should not be included in the minor's medical record. If this is not possible, and

**Minor Control:** Some minors have control of their own records. In general, HIPAA says that if the minor can consent to their own treatment then the minor <u>alone</u> has access rights. State law determines when a minor can consent to their own treatment.

one parent has concerns, they should consult with an attorney on how to legally revoke this

Familiarity with the basics of parental rights as it pertains to contentious custody arrangements is critical in avoiding a hefty fine from HIPAA. If you have questions, do not hesitate to contact Client Services or your personal consultant. TMC is here and eager to help you. With our decades of experience, we are equipped to find the solutions for your compliance issues.

# THEADYSOR MONTHLY COMPLIANCE COMMUNICATOR

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1			Print and post newsletter in	
2			office for staff review. Each	
3.			member should sign thi	
4.			form when completed Keep on file as proof o	
5.			training on these topics	
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