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Supplies for Sterile Compounding: Tools of the Trade

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Sterile compounding is a unique and critical skill of both pharmacists and pharmacy technicians. In order to become proficient in such skills, it is crucial to have a thorough understanding of the supplies and materials utilized when compounding sterile products. Not every pharmacist responsible for compounding sterile products or overseeing the sterile compounding process may have the necessary level of foundational knowledge or experience needed, thus a foundational review of compounding supplies will be beneficial to those who find themselves in these roles. Similarly, many pharmacy technicians responsible for compounding sterile products but are who inexperienced in this area will likely benefit from a thorough review of available compounding supplies. This activity is designed to introduce the learner to the some of the supplies used to compound sterile products. It will provide thorough descriptions of these supplies and aid the learner in understanding how to both select and use the appropriate supplies when engaging in sterile compounding activities. Additionally, it will address pertinent safety concerns that arise when working with such supplies.

Learning Objectives

Pharmacist

1. Describe supplies used to compound sterile products
2. Recognize if supplies have been appropriately selected and used to compound sterile products
3. Describe appropriate safety measures to take when working with supplies used to compound sterile products

Pharmacy Technician

1. Describe supplies used to compound sterile products
2. Recognize the appropriate selection and use of sterile compounding supplies
3. Identify safety measures for working with supplies used to compound sterile products

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Pharmacists, Pharmacy Technicians, Nurses

Universal Activity Number

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Key Abbreviations

API	active pharmaceutical ingredient
CSP	compounded sterile preparation
IPA	isopropyl alcohol
IV	intravenous
MDV	multidose vial
PVC	polyvinyl choride
SDV	single dose vial
USP	United States Pharmacopeial Convention

Key Definitions

Coring	the process which occurs when a needle shears out or “cores” a piece of the rubber stopper of a vial
Critical Site	a location that includes any component or fluid pathway surfaces or openings exposed and at risk of direct contact with air, moisture, or touch contamination
Lyophilized	freeze-dried
Reconstitution	adding fluid to a powdered drug to result in a desired concentration

Introduction

Compounding personnel includes both pharmacists and pharmacy technicians. These individuals have the unique and critical obligation to prepare compounded sterile preparations (CSPs) for patients in a variety of health care settings. Numerous organizations have assisted in developing standards and guidelines to optimize the effectiveness and safety of the sterile compounding process. One of these is the United States Pharmacopeial Convention (USP), an independent, not-for-profit organization whose mission is to ensure the quality and safety of medications.[1] USP develops standards for drug substances, products, and excipients and publishes these within the United States Pharmacopeia and National Formulary (USP-NF).[1] USP-NF is composed of a number of general chapters, including USP Chapter <797> Pharmaceutical Compounding: Sterile Preparations. This chapter details the minimum practices and quality standards to utilize when compounding sterile products. The objective of USP <797> is to describe conditions and practices needed to prevent harm that may result from issues such as microbial contamination and variability in the intended strength of ingredients used for sterile compounding.[2]

Per USP <797>, all compounding personnel have the responsibility to make sure CSPs are accurately measured, diluted, and mixed, in addition to being properly packaged and labeled.[2] One key to ensuring these tasks are carried out in an appropriate manner is a thorough understanding and correct utilization of compounding supplies. For each type of supply, there is an array of available options from which to choose, and selecting the correct supplies assists compounding personnel in accurately compounding sterile preparations. Firm knowledge of these supplies is crucial, as working with incorrect supplies may lead to errors in measurement and potential loss of time and product.

The following review describes some of the supplies commonly used in the preparation of CSPs:

- Container systems (vials, ampules, bottles, and bags)
- Supplies used to transfer medications to and from containers (needles and syringes)
- Miscellaneous supplies (isopropyl alcohol, caps, IVA seals, stickers, light protective bags, and sharps containers)

Containers

The sterile compounding process involves the use of basic containers, including vials, ampules, bottles, and bags. The role of containers is to house various products, including diluents and active pharmaceutical ingredients (APIs). Compounding personnel may also utilize empty sterile containers, into which solutions can be transferred. These are useful for containing abnormal volumes and concentrations of drugs.[3] Vials account for approximately 50% of all small-volume injectable packaging, while ampules account for 10%, and bags and bottles together account for 10%.[4] Considerations for selection of containers includes their compatibility with the product as well as their ability to maintain sterility of the product throughout its shelf life.[4]

Vials

Vials are the most common container utilized for both liquid and lyophilized (freeze-dried) injectable products.[4] They may contain single or multiple doses of medications and are available in sizes ranging from 1 mL to 100 mL.[5] Vials are made of glass or in some instances, plastic, and have a rubber stopper secured to the top with a metal ring. While glass vials are typically clear or colorless, those that contain light-sensitive APIs must be made of amber glass to prevent decomposition of the product.

The parts of a vial include the head, neck, and body (Figure 1). The head consists of a plastic cap or aluminum cover and a rubber stopper. The plastic cap prevents the rubber stopper from being accidentally being punctured.[3] It does not guarantee sterility of the vial contents and should be removed prior to entering into the vial with a needle.[3] The rubber stopper is accessed by a needle to either add or remove fluid and prevents air and fluid from freely passing in and out of the vial.[3] The rubber stopper is considered a critical site and must be disinfected with sterile 70% isopropyl alcohol (IPA) prior to withdrawing contents from the vial. To be properly disinfected, the rubber stopper should be wetted with an alcohol pad. The alcohol should remain wet for 10 seconds and allowed to dry completely before being pierced with a needle.[5] The neck of the vial is an indentation below the head and the body contains the vial contents and is the area on which the vial label is located.

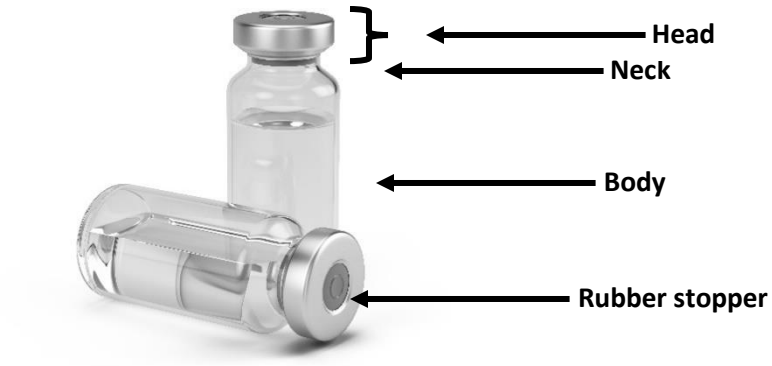

Figure 1: Parts of a Vial

Vials are available in single dose and multidose forms. Single dose vials (SDVs) should be used for only one compounding session.[3] Per current USP <797> guidelines, SDVs may be used for up to 6 hours once punctured with a needle in appropriate compounding environment.[2] SDVs are important when compounding preparations for neonatal patients, in addition to products intended for epidural or intrathecal administration, as they do not contain unnecessary preservatives. Use of preservatives in these types of preparations may lead to patient harm.[6] In contrast to SDVs, multidose vials (MDVs) allow for vial contents to be accessed more than once. These vials contain preservatives which assist with slowing bacterial growth, though they do not ensure sterility of the vial contents.[6] MDVs should be dated and stored according to manufacturer requirements. If these are not available, current USP <797> guidelines recommended a 28 day beyond-use date (BUD) for MDVs once punctured with a needle.[2] It is important to always date MDVs with the appropriate BUD. Insulin is an example of a product available as an MDV.

Working with Vials

When selecting a vial for use during the compounding process, personnel should consider the size of the vial. In general, working with vials of smaller sizes presents numerous benefits. These include a reduction in waste and prevention of SDVs from accidentally being reused.[7] Additionally, compounding personnel are less likely to make errors calculating the amount of solution to draw up when the vial size chosen best accommodates the dose of medication needed.[7] Vials of larger sizes may be selected when preparing multiples doses of the same product.

What advantages do multidose vials have over single dose vials? Disadvantages?

When compounding personnel access the rubber stopper of a vial with a needle, the "non-coring" method should be utilized. This technique prevents coring of the rubber stopper, which could result in rubber fragments being present in the final preparation.[5] When employing the non-coring method, the needle should be angled at 45 degrees with the bevel facing up as the needle is inserted into the vial.[5]

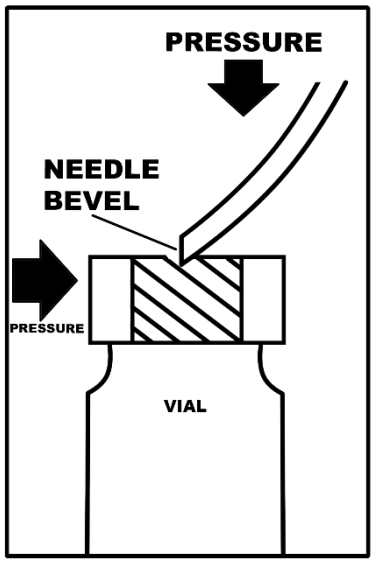

Figure 2: Non-coring Method

Vials are considered closed-system containers as air and fluid cannot freely pass in and out of them.[5] If air or fluid is added to a vial, this will cause positive pressure to develop within the vial which can lead to leakage or spraying of fluid.[5] Removing air or fluid from a vial causes negative pressure to develop, creating a vacuum inside the vial that makes it challenging to remove the contents.[5] When withdrawing liquid contents from a vial, it is important to equalize the pressure within the vial. To accomplish this, the amount of fluid to be withdrawn from the vial should be replaced with an approximately equal amount air before the contents are removed.[5] Steps to withdraw liquid from a vial are detailed below.

Steps to Withdraw Liquid from a Vial[7]

1. Attach the needle to a syringe.
2. Remove the plastic vial cap, swab the rubber stopper with an alcohol pad, and allow the alcohol to dry.
3. Remove the needle cap.
4. Draw up a volume of air equal to the amount of fluid needed to be removed from the vial.
5. Insert the needle into the rubber stopper at a 45-degree angle with the bevel side up and push the needle through.
6. Inject the air into the vial.
7. Invert the syringe and vial and release the plunger.
8. If required, pull back on the syringe without touching the plunger until the correct amount of solution is obtained.
9. Gently tap the syringe to remove any air bubbles.
10. Expel any air or excess volume.
11. Withdraw the needle from the vial.

What problems does a vial with positive pressure pose for compounding? How is this complicated when working with hazardous drugs?

Vials containing medication in a powdered or lyophilized form require reconstitution in order to create a solution. The vial label or medication package insert will contain information regarding the recommended amount of diluent to add to the vial for reconstitution. To prevent spraying of vial contents after the diluent has been added, an equal volume of air should be removed from the vial.[5] Compounding personnel should refer to the vial label or package insert to determine how to appropriately mix the diluent with the vial contents, for example shaking vs. rolling or swirling the vial in order to dissolve the lyophilized powder.[5]

Ampules

Ampules are sealed, glass containers that contain sterile injectable solutions.[6] These containers provide advantages over vials in that they are made entirely of glass, as opposed to plastic and rubber, and are thus associated with a decreased potential for interactions between themselves and the drug products they contain.[4] Two disadvantages associated with ampules are the potential for glass

fragments to enter the solution when the ampule is broken and the risk of compounding personnel cutting themselves when accessing ampule contents.[3]

Ampules range in size from 1 mL to 50 mL.[3] The parts of an ampule include the head, neck, shoulder, and body (Figure 3). The head is the portion broken off to access the contents of the ampule and the neck is the critical site of the ampule where breaking occurs.[3] The shoulder designates the point beyond which the ampule can accommodate no further volume, and the body is the portion that holds the medication and on which the ampule label is found.[3]

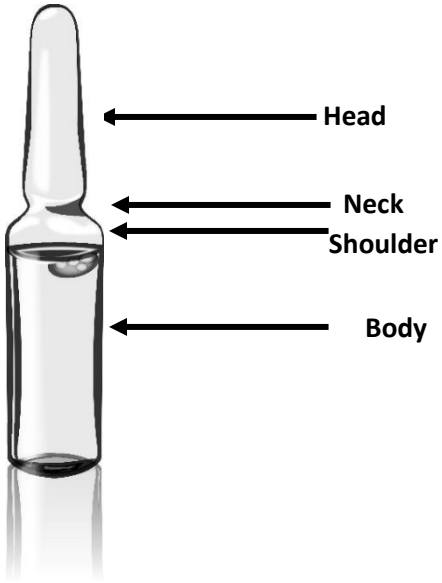

Figure 3: Parts of an Ampule

Working with Ampules

Prior to accessing an ampule, personnel should visually verify that the entire contents are contained within the body. If solution is located within the head, it may be gently tapped with a finger to move the contents into the body.[5] The neck of the ampule should then be disinfected. This can be done by wrapping an alcohol pad around the neck and cleaning all surfaces using a twisting motion. The neck should be allowed to dry for 10 seconds before being broken.[5] Compounding personnel by choose to break the neck by wrapping an alcohol pad around the neck to protect themselves from cuts. They may also use an ampule breaker, which is a round piece of plastic that is placed over the head of the ampule to assist with the breaking process.[3] To note, ampule breakers are not sterile and must be completely disinfected prior to use.[5] Many ampules have a scored or weak point in the neck, which assists with easily breaking the ampule open. The following procedure can be used to break open an ampule.

Procedure to Break an Ampule Open[5]

Note: Caution should be taken to avoid opening the ampule toward the HEPA filter or other sterile products located in the work area

1. Hold the head of the ampule between the thumb and index finger of one hand.
2. Hold the body of the ampule with the thumb and index finger of the other hand.
3. Using both thumbs to exert pressure, push away from yourself in a quick motion to snap the ampule open at the neck.
4. Discard the ampule head into a sharps container.

Once the neck is broken, a filter needle should be used to withdraw the contents of the ampule.[8] After removal of contents, the ampule should be discarded into a sharps container. Ampules should not be reused or saved at any time during the preparation of a CSP.[8] Once opened ampules are considered open-system containers. This means no pressure differential is present that requires the addition of air prior to removal of fluid, such as with a vial.[5] The following procedure can be followed to remove contents from an ampule.

Procedure to Remove Ampule Contents[7]

1. Attach a needle to a syringe.
2. Hold the ampule upright and gently tap the head or invert the ampule quickly to ensure all solution is in the body of the ampule.
3. Swab the neck of the ampule with an alcohol swab.
4. Grip the head with the thumb and fingers of one hand and the body of the ampule with the thumb and fingers of the other hand.
5. Bend the neck until it cracks, and the head is separated from the body of the ampule.
6. Tilt the ampule and insert the bevel of the needle into upper corner space or shoulder near the opening. (**Note:** surface tension will keep the contents of the ampule from spilling out.)
7. Withdraw the solution of the ampule by pulling back on the syringe.
8. Remove any air bubbles by tapping the syringe or moving the bubbles to the top and expelling additional fluid.
9. Change needles.

Bottles and Bags

Bottles are prefilled, sterile glass or plastic containers that are used to hold medication solutions (Figure 4). They are typically 100 mL or larger in size and are the preferred containers for large-volume solutions.[4] While glass bottles have an associated risk of breaking, they are particularly useful for storing medications that have adsorption concerns when stored in plastic, which could lead to loss of product. Examples of medications commonly stored in glass bottles include nitroglycerin and propofol.

Figure 4: Glass Bottle of Nitroglycerin

Bags are sterile empty or pre-filled containers made of plastic (most commonly PVC plastic). They are used to administer both small- and large-volume intravenous (IV) medications. Bag sizes typically range in size from 25 mL to greater than 1000 mL and typically have a 10 percent overfill, depending on the manufacturer and specific product.[4] Bags have several advantages over glass bottles including being lighter in weight, easier to see through in order to detect possible contamination or incompatibilities, less easily broken, and less expensive.[6] Bags are also easier to dispose of and can be frozen if needed.[6] The parts of a bag include the injection port, which is an opening used to inject additives and as a critical site should be

disinfected prior to being accessed. Other parts include an administration set port, which is used to connect to the patient's main IV line, and an eyehole or hanging loop, which is used to hang the bag on an IV pole when needed. Bags come contained in a protective outer wrap which should be removed and discarded before placing the bag in the work area.[5]

Some bags have vial adapters in place of the injection port, which allows for vials to be directly attached to the bag.[5] The vial is attached to the adapter under sterile conditions, and the seal between the bag and the vial is later broken and contents mixed prior to administration of the product.[5]

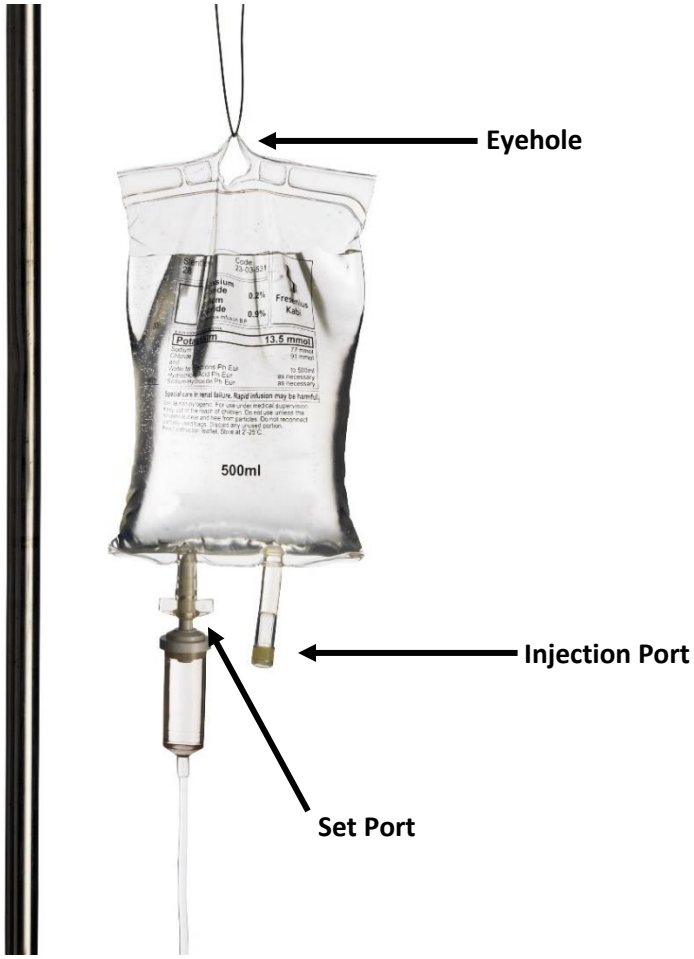

Figure 5: IV Bag

Needles and Syringes

Needles and syringes are essential to the sterile compounding process. These supplies are used in tandem to assist in manipulating and transferring ingredients to accurately prepare the final CSP. There are various types of needles and syringes from which to choose and they are available in a wide variety of sizes. The different characteristics of these supplies lend to the individual functionality of each type. The process utilized to prepare each CSP will determine the specific types and sizes of needles and syringes to be used.[6] For example, compounding a CSP using a 10 mL ampule will require a different combination of needles and syringes than preparing a CSP using a 2 mL vial.

Needles

Needles are disposable devices made of either stainless steel or aluminum (Figure 6). They are attached to syringes and used to enter medication containers such as vials and ampules.[6] Needles arrive from the manufacturer individually packaged in either a plastic or paper overwrap. As long as needles remain within this protective covering, they are considered sterile until the manufacturer's expiration date is exceeded.[6] However, once the packaging has been opened or somehow compromised, the sterility of the needle can no longer be guaranteed.[6] Appropriate handling of needles begins with removing them correctly from this packaging. To appropriately unpackage a needle, compounding personnel should peel back the overwrap and then carefully remove the needle. Needles should never be accessed by pushing them through the overwrap.

A needle has five basic components (hub, shaft, lumen, bevel, and cap), which are defined in Table 1. Compounding personnel should be familiar with each part of the needle, including the critical sites.

Table 1: Parts of a Needle[6]

Component	Description
Hub	The base of the needle that attaches to the syringe
Shaft	The long, slender stem of the needle that comes to a point at one end
Lumen	The inner portion of the needle through which fluid moves
Bevel	The slanted portion that exposes the opening of the needle
Bevel Tip	The sharp, pointed end of needle that enters the vial or other container
Bevel Heel	The short end of the bevel opposite the bevel tip
Cap	The covering of the needle

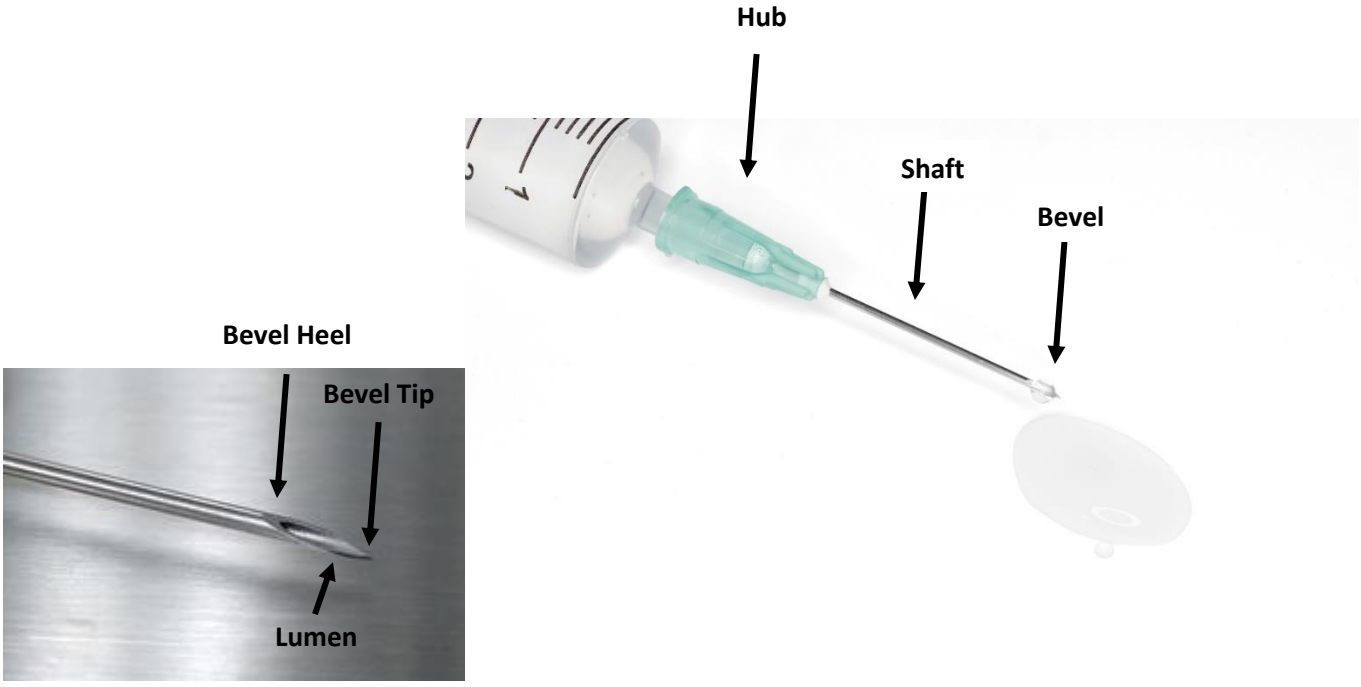

Figure 6: Parts of a Needle

Except for the cap, all parts of the needle are considered critical sites. The protective overwrap must be disinfected with a product that does not leave a residue, such as sterile 70% IPA, before placing the needles into the work area.[5] However, needles themselves do not require disinfection prior to use. Attempting to disinfect the shaft of a needle by cleaning it with alcohol may cause the removal of its silicone coating, which can make it challenging to enter into containers.[6] Should any part of the needle become contaminated during the compounding process, compounding personnel should safely discard the needle and select a new needle for use.

Needle Sizes

Needles are available in a wide variety of sizes and selecting the correct needle size is important. There are two considerations of size: needle length and needle gauge. Needle length is a measure of the distance from the hub of the needle to the tip of the needle, and it is measured in inches.[6] Common needle lengths range between 3/8 inch to 3 inches.[5] Needle gauge is a measure of the diameter of the needle lumen.[4] Typical gauge sizes range from 13 to 31. The larger the needle gauge, the smaller the diameter of the needle lumen. For example, a 16-gauge needle has a larger lumen diameter than a 27-gauge needle. Needle hubs are color-coded based on gauge size. For example, 18-gauge needles have hubs that are pink in color. Needle size is specified by specific labeling. Needles are labeled with a number, followed by the letter G, followed by a second number.[6] The first number refers to the gauge and the second number refers to the length of the needle in inches. For example, a needle labeled “20G1/2” is a 20-gauge needle that is half an inch in length.[6]

Sixteen-gauge and 18-gauge needles are commonly used during the sterile compounding process. Needles with smaller gauge sizes, such as 27-gauge, can be used when withdrawing solutions from MDVs, as this will help to prevent leakage caused by multiple reentries into the vial.[3] The type of solution that will be transferred during compounding can dictate the needle gauge selected. When working with a thick or viscous solution, compounding personnel should select a needle with a smaller gauge (i.e. 19-gauge or 20-gauge).[6] The type of vial closure should also be considered when selecting a needle. A needle with a smaller gauge size will aid in penetrating thick rubber vial stoppers.[6]

Types of Needles

Depending on the compounding task, personnel can choose many types of needles with which to work. These include filter needles, double-ended needles, and vented needles. Filter needles have a filter embedded into the hub. They are longer than regular 18-gauge needles and essential when working with ampules.[3] It is critical to remember that filter needles should only be used one time and in one direction. Using the same filter needle to both withdraw and expel a solution may cause the glass particles trapped in the filter to be expelled into the final preparation.[6] This can lead to serious patient harm and potentially death when the solution is infused into the patient.[6] Once the solution has been drawn from the ampule into the syringe, the filter needle should be replaced with a regular needle prior to injecting the solution into the next container. When the compounding task is complete, the cap that covers the filter needle hub can be safely discarded while the cap covering the shaft end of the needle should be kept for the verification process. [3]

Figure 7: Filter Needle

A second type of needle is a double-ended needle. Double-ended needles are two needles joined by a plastic hub, and they cannot be attached to a syringe. [3] Because no syringe is utilized, it is not possible to measure the volume of the contents that are transferred between two containers, so this type of needle should only be used when transferring the entire contents of one container into another. Compounding personnel should be cautious to touch only the center hub of the double-ended needle; touching the metal portion will result in contamination. [6] A double-ended needle can be utilized by first inserting one end of the needle into a container. The other end is then inserted a second container, with the container the solution is being transferred into kept on the bottom.[6]

Figure 8: Double-ended Needle

A third type of needle is a vented needle. Vented needles are plastic spikes thicker than typical needles in diameter, and they are useful for situations in which there are concerns related to the pressure within a vial, such as when working with multidose vials. [3] These needles have features that include a large lumen diameter, an opening in the needle shaft which helps to relieve pressure, and a razor-like tip, heel, and bevel. [3] Vented needles prevent pressure differences from occurring when withdrawing solutions from vials and minimize spraying and foaming during reconstitution. [6]

Figure 9: Vented Needle

Working with Needles

When would it be appropriate to use a filter needle? A double-ended needle? A vented needle?

Needles should be reused no more than three times during the compounding process. The outer coating of the needle will become worn when used multiple times. This can not only make it challenging to insert the needle into a vial, but also increases the risk of coring. [3]

Syringes

Syringes are sterile, single-use supplies whose purpose is to house solutions that will be transferred from one container to another (Figure 11). [6] Almost all syringes are made of plastic, though glass syringes may be used when compounding for a patient with an allergy to plastic or when compounding a medication that is directly incompatible with plastic. [6] Plastic syringes are typically preferred as they are disposable, less expensive, and less likely to break. [5] Similar to needles, syringes are packaged individually and remain sterile as long as they are contained within their original packaging.

Compounding personnel should be familiar with the various parts of a syringe, including all critical sites. These components are described in Table 2. The main parts of a syringe are the barrel and plunger. The plunger is the inner component of the syringe that fits inside the barrel, and it is composed of the flange (which is shaped like a flat disk), the ribs, and the piston, which is made of rubber or silicone. The tip of the syringe is where the needle attaches. [5] Critical sites of the syringe include the tip, ribs, and piston. As is the case with needles, the critical sites of a syringe do not require disinfection prior to use. However, if the syringe becomes contaminated at any point during the compounding process, it should be discarded appropriately, and a new syringe should be used to make the preparation. Contamination can be avoided by taking caution not to touch or shadow critical sites while compounding.

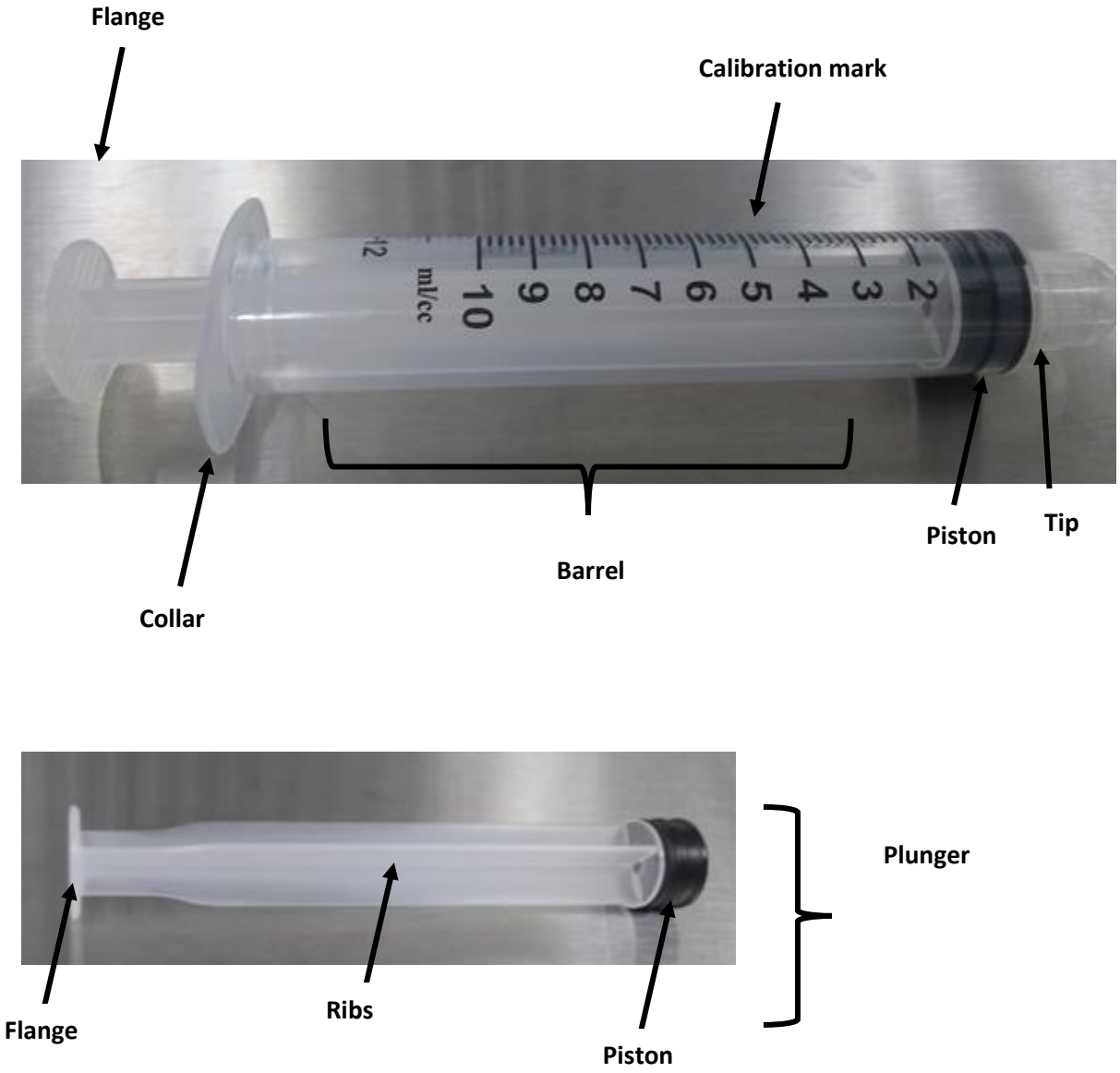

Figure 11: Parts of a Syringe

Table 2: Parts of a Syringe[6]

Component	Description
Barrel	Holds the solution to be transferred
Plunger	Piston-type rod with a cone-shaped top that passes the point of attachment for a needle
Piston	Comes in direct contact with solution being transferred and is used to measure syringe contents
Ribs	Located between flange and tip and comes into contact with the inside of the barrel when the plunger is fully pushed in
Flange	Flat end of plunger that facilitates manipulation of the syringe
Tip	Pointed end of syringe where the needle attaches
Calibration marks	Mark the volume of solution inside the syringe

Two types of syringes are luer-lock and slip tip. Luer-lock syringes are the most common type and have tips that are threaded to accept a needle. This design minimizes leaks and maintains a secure attachment to the needle. [3] In contrast, slip tip syringes have a smooth surface which utilizes friction to help the needle to stay in place. Slip tip syringes are more likely to cause the needle to disengage if not assembled appropriately and are more commonly used for processes including irrigation.[3] For medical safety purposes, traditional slip tip syringes intended for the addition of a needle should NEVER be used to dispense oral medications due to the potential for accidental injection. Special oral syringes should be used that are designed not to accommodate the attachment of a needle.

Syringe Sizes

The volume of a syringe can range anywhere from 0.5 mL to 60 mL, and the length and diameter of the syringe will increase as the volume of the syringe increases.[3] Compounding personnel generally use the following syringe sizes when compounding sterile preparations: 1 mL, 3 mL, 5 mL, 10 mL, 20 mL, 30 mL, and 60

mL. The barrel of the syringe is marked in increments called calibration (or graduation) marks that increase as the size of the syringe increases.[5] Different sizes of syringes are calibrated differently. For example, the calibration marks on a 3 mL syringe represent one tenth of a milliliter. The marks on 5 mL and 10 mL syringes reflect every two tenths (for example, 3.2 mL, 3.4 mL). Twenty milliliter, 30 mL, and 60 mL syringes are marked in whole numbers, with lines representing 1 mL increments (1 mL, 2 mL, etc.).[5]

During the compounding process, it is important to take into consideration the accuracy of the chosen syringe to ensure the final preparation is made correctly. To determine accuracy of a syringe, the smallest increment of its calibration marks is divided in half. [6] For example, a syringe calibrated in 1 mL increments is accurate up to 0.5 mL. In some instances, it may be necessary to use two syringes of appropriate sizes when compounding very small doses. [3] A study by Erstad and colleagues investigated the accuracy of small-volume injections using syringes of various sizes. The authors determined that as the syringe size increased from 1 mL to 5 mL, the accuracy of measuring 0.5 mL of volume decreased.[9]

Working with Syringes

There are a few general rules to be followed when working with syringes. First, compounding personnel should select the smallest syringe that will accommodate the volume needed to be measured.[3] For example, if measuring 4 mL of a solution, a 5 mL syringe should be selected. Using a smaller or larger syringe may cause errors in measurement and increases the possibility that more or less solution will be withdrawn. Second, the syringe should never be filled to capacity, as the plunger could dislodge, leading to loss of product. [5] Finally, the volume measured into a syringe should be at least 20% of the syringe's normal capacity. [6] For example, if a 1 mL syringe is being used, 0.2 mL is the smallest volume that could be accurately measured (1 mL x 20% = 0.2 mL).

To appropriately measure a solution into a syringe, compounding personnel should line up the final edge of the plunger piston to the desired calibration mark on the barrel.[5] Before injecting the contents of the syringe into a container, personnel should ensure that all air bubbles have been removed. Air bubbles take up space within a syringe, and the presence of air bubbles indicates that the full volume required for the preparation has not been measured accurately. This may lead to

large errors in dosing, especially when compounding products for certain populations like neonates. In order to remove air bubbles from a syringe, the following procedure can be used. [6]

Procedure to Remove Air Bubbles from a Syringe[6]

1. Hold the syringe in a vertical position
2. Pull back the plunger a short distance
3. Firmly tap the barrel of the syringe
4. Expel all the air in the syringe

Compounding personnel can utilize the following steps to appropriately attach a needle to the syringe.[7]

Procedure to Attach a Needle to a Syringe[7]

1. Remove the syringe from packaging, being careful not to touch any critical sites
2. If the syringe has a protective cap, remove this carefully
3. Hold the syringe by the barrel to avoid contamination
4. Remove the needle carefully from the outer wrap
5. Insert the tip of syringe into the needle hub
6. Twist to secure the needle
7. Leave the plastic cover on the needle until use

Miscellaneous Supplies

Isopropyl Alcohol

Sterile isopropyl alcohol in a strength of 70% is commonly used for disinfecting purposes during the compounding process. This product is not only used to clean the work surface prior to compounding but to disinfect the critical sites of vials, ampules, and bags. [3] Sterile isopropyl alcohol swabs are presoaked 1x1 sheets often used for disinfecting critical sites. [3] Sterile gauze (typically 4x4 in size) can also soaked with isopropyl alcohol and used to disinfect the workspace and items used for compounding. [3] It should be noted that not all alcohol wipes are sterile. It is important to check the labeling before proceeding.

Caps

In some instances, a compounded preparation will be administered to as patient via the intramuscular, subcutaneous, or intradermal route. In these cases, a syringe may be transported to the patient without an attached needle and thus must be sealed with a syringe cap. [3] This keeps the contents of the syringe sterile. [3] There are two types of syringe caps that may be used for this purpose. The first is a rubber cap, which is pushed down onto the syringe tip. The second is a plastic cap, which is twisted on the end of the syringe and locked into place. [3]

Figure 13: Syringe Caps

IV Admixture (IVA) Seals

IVA seals are coverings that can be placed over the critical sites of vials, syringes, and bags during transfer in order to keep their contents sterile. Vial IVA seals are round with a white dot on the underside and are placed over the rubber stopper of the vial until later use.[3] IVA seals used for syringes are thin and long with a white dot on the underside. They are placed over the end of a syringe cap.[3]

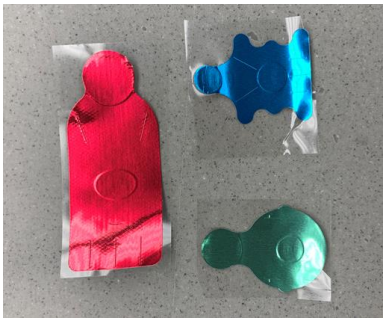

Figure 14: IVA Seals

Stickers

Auxiliary stickers may be placed on the patient label of CSPs to provide information such as storage conditions and administration warnings. Examples include “Protect from Light”, “Refrigerate”, and “Chemotherapy”. Triplicate stickers are placed on large volume solutions. They include three rows of stickers with the name of a high alert drug. The individual who administers the medication will place one sticker on the patient label, one on the end of the patient’s tube set, and one on the back of the fluid bag.[3]

Figure 15: Sticker

Light Protective Bags

Light-protective bags (available in brown, green and black plastic) are placed over compounded preparations that require protection from light sources, such as morphine. These bags are tinted dark, which protects the product from light and prevents a decrease in potency of the medication to be administered. [3]

Figure 16: Light Protective Bag

Sharps Containers

Sharps containers are typically red, plastic bins with a cover that prevents someone from accessing the contents of the bin. [3] They are a type of disposal equipment for any items considered to be "sharps". These include needles (and anything attached to them), ampules, and any other glass materials. Syringes, vials, and other non-glass items can be disposed of in regular trash bins.

Figure 17: Sharps Container

Safety Considerations

All compounding personnel must take appropriate steps to ensure the safe use of needles when preparing CSPs. As many go unreported, the exact number of needlestick injuries that occur during sterile compounding is unknown. Fortunately the majority of injuries are preventable.[10] While the risk is low, there is the potential for the transmission of bloodborne pathogens whenever compounding personnel are working with needles.[6] Additionally, if a needlestick injury occurs while compounding a chemotherapy preparation, there is a risk of pain, ulceration, and potential tissue death.[11] A number of factors may increase the risk of needlestick injuries including failure to adopt universal precautions, not following an established safety protocol, and using needles that lack safety features.[11]

Should a needlestick injury occur, the affected personnel should follow the associated institution's policies and procedures regarding such injuries. In general, the injured individual should first attend to the injury.[11] Next, the compounding

area should be cleaned and disinfected, and any product that may have been compromised at the time of the injury should be discarded.[11] Finally, the incident should be reported and recorded per the institution's policy. An investigation into the cause of the injury may also be warranted and action steps taken, such as additional training, in order to prevent future injuries.[11]

There are several steps compounding personnel can take in order to reduce the risk of needlestick injuries. The first is with regard to recapping needles. In general, recapping needles is an unnecessary task that may introduce the unnecessary risk of needlestick injury. Thus, it is recommended to not recap needles prior to disposal in an appropriate container.[5] However, if a needle needs to be recapped, compounding personnel should avoid recapping the needle using two hands, as this greatly increases the risk of injury. Instead, the "scoop method" should be employed. This method involves laying the needle flat on the surface of the work area and picking up the cap with one hand. The compounder then places the cap onto the tip of the needle using a scooping motion. The cap can then be "clicked" down firmly over the needle and the entire device disposed of appropriately.

What are some advantages of safety syringes? Disadvantages in sterile compounding?

Compounding personnel can also consider utilizing safety needles and syringes, as these devices aid in the prevention of needlestick injuries. Safety needles have plastic covers that can slide and lock over the end of the needle once the compounding task has been completed. These types of needles prevent the need for recapping.[3] One type of available safety syringe inactivates the plunger of the syringe once it is fully depressed. This prevents compounding personnel from reusing the syringe. A second type of safety syringe shields the needle by retracting it into the syringe barrel when the plunger is depressed.[6]

Conclusion

Sterile compounding is a unique and critical skill of both pharmacists and pharmacy technicians. In order to become proficient in such skills, it is crucial to have a thorough understanding of the supplies utilized when compounding sterile products. A foundational understanding of commonly used compounding supplies will assist those who find themselves in these roles.

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Supplies for Sterile Compounding: Tools of the Trade

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Describe supplies used to compound sterile products	YES	NO
Recognize the appropriate selection and use of sterile compounding supplies	YES	NO
Identify safety measures for working with supplies used to compound sterile products	YES	NO

2. Was the program independent & non-commercial? YES NO

3. Relevance of topic Low Relevance 1 2 3 4 5 6 7 Very Relevant

4. What did you like MOST about this lesson? _____

_____

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1. Which of the following is a critical site that must be disinfected during the sterile compounding process?
    a. The body of a vial
    b. The shaft of a needle
    c. The tip of a syringe
    d. The neck of an ampule

2. Which of the following requires disposal within a sharps container?
    a. An empty vial
    b. A broken ampule
    c. A syringe without an attached needle
    d. A used alcohol swab

3. Which of the following parts of a needle attaches to the syringe?
    a. Lumen
    b. Hub
    c. Shaft
    d. Cap
4. Which of the following is the correct label for a needle with a 27-gauge diameter and length of 1/2 inch?
    a. 27G1/2
    b. 1/2G27
    c. 271/2G
    d. G271/2

5. Which of the following is a safety consideration when working with needles and syringes?
    a. Compounding personnel should always recap needles after use
    b. Compounding personnel should avoid use of the “scoop method” when recapping needles
    c. Compounding personnel should utilize safety needles and syringes when available
    d. Compounding personnel should only report needlestick injuries when compounding chemotherapy products

6. Which of the following types of needles should be used when compounding a sterile preparation involving an ampule?
    a. Insulin needle
    b. Vented needle
    c. Filter needle
    d. Double-ended needle

7. Which of the following parts of a syringe is considered a critical site?
    a. Barrel
    b. Calibration marks
    c. Tip
    d. Flange

8. Which of the following syringe sizes should be used to withdraw 2 mL of solution from a vial?
    a. 1 mL syringe
    b. 3 mL syringe
    c. 5 mL syringe
    d. 10 mL syringe

9. Which of the following needles is the smallest in diameter?
    a. 18G
    b. 20G
    c. 25G
    d. 27G

10. Which of the following is considered a best practice when working with needles and syringes?
    a. Do not reuse needles more than six times during the sterile compounding process
    b. Always disinfect the shaft of the needle prior to use
    c. Select the largest syringe size that will accommodate the volume you need to withdraw
    d. Never fill the syringe to capacity in order to avoid dislodging the plunger