Aseptic Technique:

Sterile Product Preparation for Non-Pharmacy Personnel

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Objectives

- Describe the importance of accuracy and use of proper aseptic technique when preparing IV medications.
- Identify the critical areas of a syringe.
- List the steps involved in aseptically preparing an IV medication from either a vial or ampule.
- Describe the difference between “single-dose” and “multiple-dose” vials.
- Perform common IV medication calculations.

What is USP 797?

- USP Chapter <797> is a document published by the United States Pharmacopea that provides procedures and requirements for preparing sterile products.
- These procedures are generally viewed as "best practices" for sterile product preparation and storage.
- USP Chapter <797> is intended to be applicable to any area where compounded sterile preparations are prepared, stored, or dispensed, including:
  - Pharmacies
  - Hospitals
  - Physician Practice Facilities

Am J Health-Syst Pharm 2004(61):1928-38.

Why is USP 797 Important?

- Improperly prepared sterile products may cause serious consequences to patients, including infection, embolization, occlusion, and death.
- The intent of USP Chapter <797> is to reduce the risk of harm from:
  - Microbial contamination (i.e. non-sterility)
  - Bacterial endotoxins
  - Unintended bacterial or physical contaminants
  - Variability in ingredient strength

Ref: http://www.usp.org/pdf/EN/USPNF/PF797.pdf,
Am J Health-Syst Pharm 2004(61):1928-38.

Why is USP 797 Important?

- Regulatory agencies (such as JCAHO) may inspect for complicity with USP 797 Standards.
- "No patient should have to give up their right to an accurate, safe, sterile dose no matter where that dose is prepared or who prepares it." (USP Statement on applicability of USP Chapter <797>)

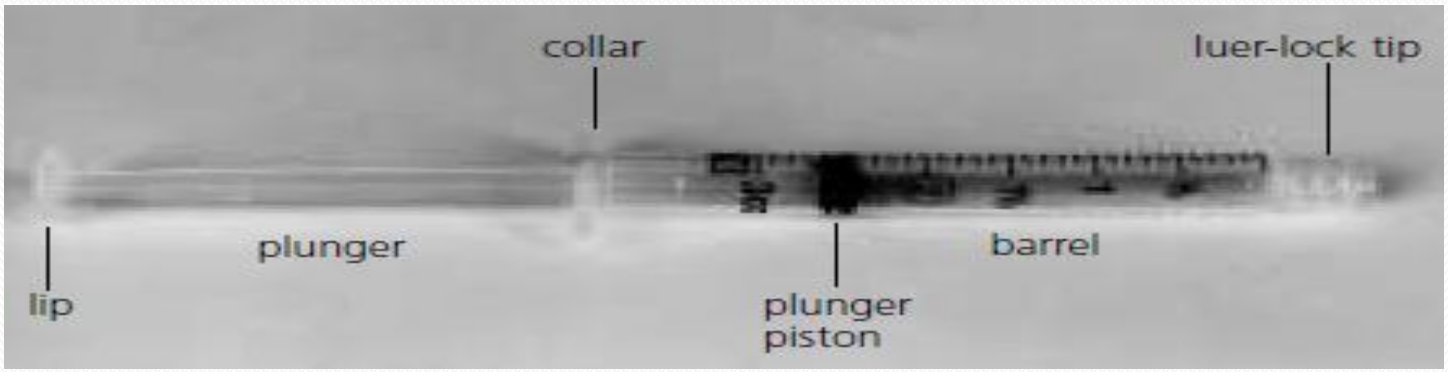
http://www.usp.org/audiences/pharmacist/797FAQs.html
Am J Health-Syst Pharm 2004(61):1928-38.

Definitions

- Aseptic Technique
  - A procedure designed to prevent contamination of drugs, packaging, equipment or supplies with microorganisms during their preparation.
- Critical Site
  - Any area where the sterile product and the environment (or any surface) may come in contact.
  - Critical sites are areas that should never be touched while preparing a sterile product.

Definitions - Syringe Areas

- Critical areas of a syringe include the tip, the plunger, and the plunger piston. These areas should **not** be touched.
- Non-Critical areas of a syringe include the barrel, collar, and lip. These areas may be touched.



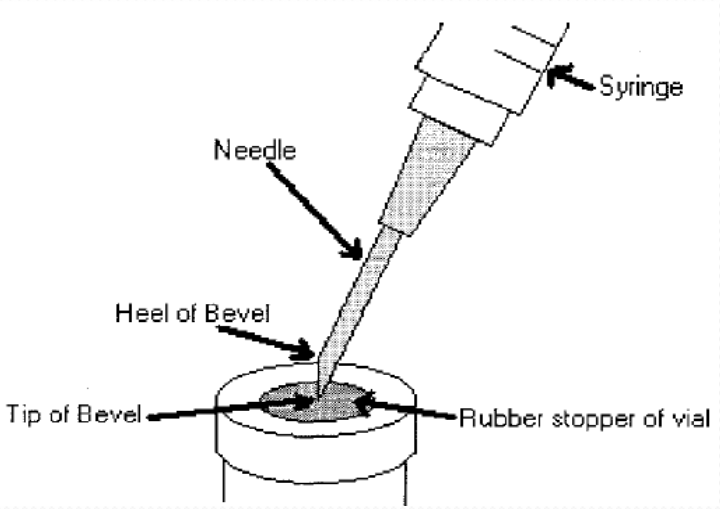
Ref: http://www.pharmacists.ca/content/hcp/Resource_Centre/Practice_Resources/pdf/chapter.pdf

Aseptic Technique Checklist

- For sterile products prepared outside of the pharmacy for "immediate use" (begin using within 1 hour of preparation):
  - Assemble the materials that you will need near a designated area for sterile product preparation.
  - Prepare only 1 product at a time (for safety reasons)
  - Perform any necessary pharmaceutical calculations and double-check your math with a colleague.
  - Remove all jewelry from hands and wrists.
  - Wash your hands and arms with a hospital-approved disinfectant.
  - Clean the designated workspace with 70% isopropyl alcohol and allow the area to dry.
  - Disinfect all rubber surfaces (vial tops and additive ports of IV solutions) and glass ampule necks with alcohol swabs prior to using. Allow the alcohol to dry completely.

Aseptic Technique for Vials

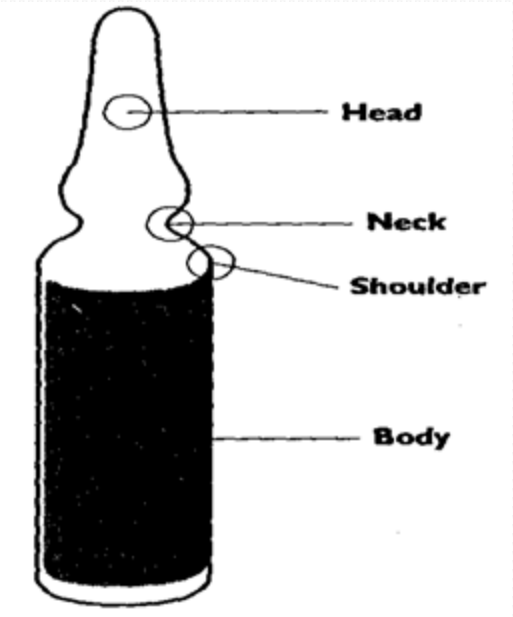
- Swab the rubber closure with 70% isopropyl alcohol and allow the alcohol to dry.
- To prevent coring, insert the needle in the rubber stopper at the same point with both the tip and heel of the needle bevel.



Aseptic Technique for Vials

- To prevent vacuum formation, inject air into the vial equal to the volume to be withdrawn.
- When reconstituting a powdered drug, withdraw a volume of air equal to the amount of the diluent to be added. This will prevent positive pressure from developing inside the vial.

Aseptic Technique for Ampules



- To break ampule
  - Clean ampule neck with alcohol swab
  - Leave swab in place
  - Grasp ampule neck with thumb and index finger
  - Use quick, firm, snapping motion away from body

http://www.hosp.uky.edu/pharmacy/resources/USP797/Theoretical%20Principles%20and%20Practicle%20Skills%20of%20Aseptic%20Manipulations.ppt

Aseptic Technique for Ampules

- To withdraw medication from ampule
  - Tilt ampule
  - Place needle bevel in corner space near opening
  - Pull back syringe plunger
- To avoid glass contamination of ampule solution
  - Use a 5 micron filter needle to filter any broken glass out of the solution.
  - A filter needle can only be used in one direction, otherwise glass particles originally filtered are reintroduced. You must change needles.

http://www.hosp.uky.edu/pharmacy/resources/USP797/Theoretical%20Principles%20and%20Practicle%20Skills%20of%20Aseptic%20Manipulations.ppt

Aseptic Technique Checklist

- Once the proper amount of drug is removed from the vial or ampule, the medication may either be administered or further diluted in a carrier solution, using aseptic technique, as appropriate for the drug.

Aseptic Technique "Do's"

- Do use a filter needle to withdraw solution from glass ampules and change the needle before adding the product to a solution.
- Do check containers for cracks, punctures, and solution clarity before using the product you have prepared.
- Do properly label the finished product with the drug name, dose, carrier solution name and volume, the date/time prepared, the date/time of product expiration (infusion to begin within 1 hour), and your initials. Use a "Medication Added" sticker if necessary.
- Do properly record your initials and the date and time of expiration for any multi-dose vials that are not entirely used. Also include the final strength of any reconstituted powders in multi-dose vials.
- Do promptly discard any vials that are labeled as "single-dose" or not specifically noted to be multi-dose vials.

Aseptic Technique “Don’ts”

- Do not cough, sneeze or talk in the direction of the sterile product you are preparing.
- Do not touch or otherwise contaminate any sterile area of the syringe or needle.
- Do not eat, or drink while preparing a sterile product.

“Immediate Use” Category

- Sterile products produced from simple aseptic measuring and transferring.
- May involve up to three stopper penetrations (including the penetration of the IV bag) of non-hazardous drugs.
- No contact contamination of ingredients or critical sites.
- Administration must begin within 1 hour after the start of preparation or the dose must be discarded (no storing, no recycling).

Trissel LA. Revisions to USP Chapter <797> Examining Sterile Compounding Practices. Presented as an Exhibitor Theater at the 42nd ASHP Midyear Clinical Meeting December 3, 2007.

“Immediate Use” Category

- Examples of where “immediate use” sterile product preparation may be used:
  - Ambulance
  - Emergency Room
  - Code situations
  - Patient bedside

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“Immediate Use” Category

- Proprietary Bag/Vial Systems
  - Mini-Bag Plus®
  - ADD-Vantage®
  - Vial-Mate® Adaptors
  - Add-a-Vial®.
- Products are FDA-Approved - follow manufacturer’s instructions for handling and storing.

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"Immediate Use" Category

- Single-Dose Vials:
  - Are not designed for entry on multiple occasions.
  - Must be used within 1-hour or discarded.
- Ampules:
  - Must be discarded after opening and not stored for any period of time.
- Multi-Dose Vials:
  - Contain one or more antimicrobial preservatives and are designed for entry on multiple occasions.
  - Discard within 28 days of initial entry, unless otherwise specified by the manufacturer.

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