Proper Aseptic Technique for Ampule Vials

What Is an Ampule?
An ampule is a glass storage device within which a sterile medication or solution is stored, to keep it protected from air and contaminants. The ampule consists of the following parts: the head, neck, shoulder and body. They come in different sizes and colors but have a similar shape. Ampules have a colored stripe around the neck if they are pre-scored to indicate the neck has been weakened by the manufacturer to facilitate opening. Some ampules are not pre-scored by the manufacturer, and the neck must first be weakened (scored) with a fine file.2

To get the solution out of the ampule, the ampule must be broken at the “neck”. This could cause what is called glass particle contamination (GPC) to occur in which microscopic pieces of glass from the broken ampule can contaminate the solution.

Parts of the Ampule
The use of a filter needle is required when drawing up medication or solution from a glass ampule. This allows any glass particles to be filtered out of the solution before using that solution in a patient or final product. A filter needle looks like a standard needle but contains a filter in its base (usually 5 micron). Filter needles are in sterile packaging until they are opened, not to be autoclaved after use, and should only be used once before they are properly discarded.
Before You Break the Ampule
Medications should be drawn up in a designated clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. Water can splash or spread as droplets more than a meter from a sink. In addition, any item that could have come in contact with blood or body fluids, such as soiled equipment used in a procedure, should not be in the medication preparation area. Examples of contaminated items that should not be placed in or near the medication preparation area include used equipment such as syringes, needles, IV tubing, blood collection tubes, or needle holders (e.g., Vacutainer® holder).

The medication preparation area should be cleaned and disinfected on a regular basis and any time there is evidence of soiling. In addition, there should be ready access to necessary supplies (such as alcohol-based hand rub, needles and syringes in their sterile packaging, and alcohol wipes) in the medication preparation area to ensure that staff can adhere to aseptic technique.¹

From an infection control perspective, the safest practice is to prepare an injection as close as possible to the time of administration to the patient. This is to prevent compromised sterility (i.e., microbial contamination or proliferation) or compromised physical and chemical stability (e.g., loss of potency, adsorption to the container) of the medication when it is transferred outside of its original container and stored for a period of time before administration.

Proper Technique for Breaking the Ampule
Proper hand hygiene should be performed before handling medications and the neck of the ampule should be disinfected with 70% isopropyl alcohol prior to breaking and allow the alcohol to dry. It is best to wear gloves when breaking open an ampule.

1. Hold the ampule upright and tap the top to remove solution from the head space.
2. Swab the neck of the ampule with an alcohol swab.
3. Wrap the neck with an alcohol pad or gauze and grasp the top with the thumb and index finger of one hand. With the other hand, grasp the bottom of the ampule.
4. Quickly snap the ampule moving your hands away and out from you. If the ampule does not snap easily, rotate it slightly and try again. Do not force the ampule to break, it should break easily.
5. Inspect the opened ampule for any particles of glass that might have fallen inside.²
Withdrawing Solution from the Ampule
After breaking the ampule open, there is a chance of glass particle contaminants to have contaminated the solution. The following steps for drawing the solution from the ampule with a filter needle will ensure no glass particles will be in the final solution.

1. Attach a 5 micron filter needle to a syringe.
2. Tilt the ampule to about a 20 degree angle.
3. Insert the needle into the ampule without touching the broken edges of the ampule neck.
4. Place the beveled edge of the needle facing down in the bottom corner of the ampule. This will avoid pulling glass particles into the needle. Another method is to turn the ampule upside down (a vacuum seal will form at the neck of the ampule) and the solution can be withdrawn that way.
5. Pull back plunger to withdraw solution but keep needle submerged to avoid withdrawing air into the syringe.
6. The filter needle should then be removed and replaced the needle you would use to inject into the final destination (does not have to be a filter needle). A filter needle can only be used in one direction, otherwise glass particles which were originally filtered could be reintroduced. It is crucial to remove the filter needle once the solution is withdrawn from the ampule.

Reminders
- Protect your hands from injury by wearing gloves and using a swab or towel on the neck of the ampule before breaking it.
- Discard all pieces of the ampule and needles in a Sharps container.
- The contents of an ampule should be for immediate use and should not be stored once opened.
- Always use a filter-needle when drawing a medication or solution from an ampule.
- Do not use the medication if the ampule shatters.

References