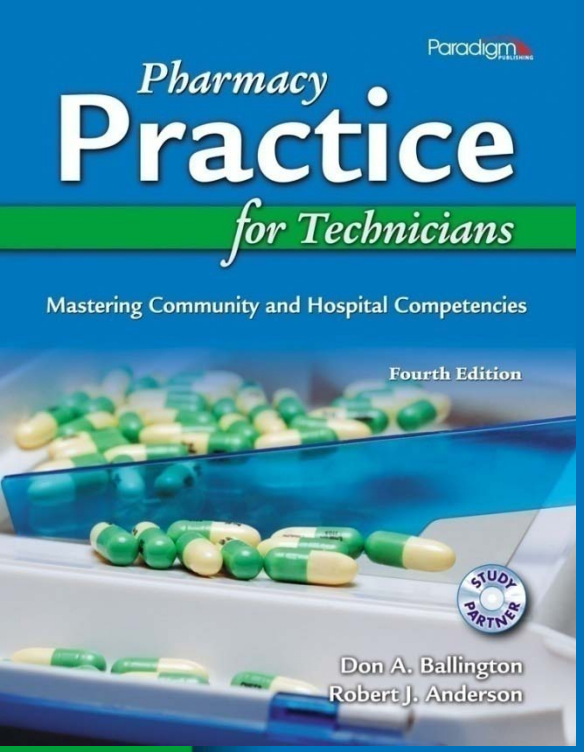


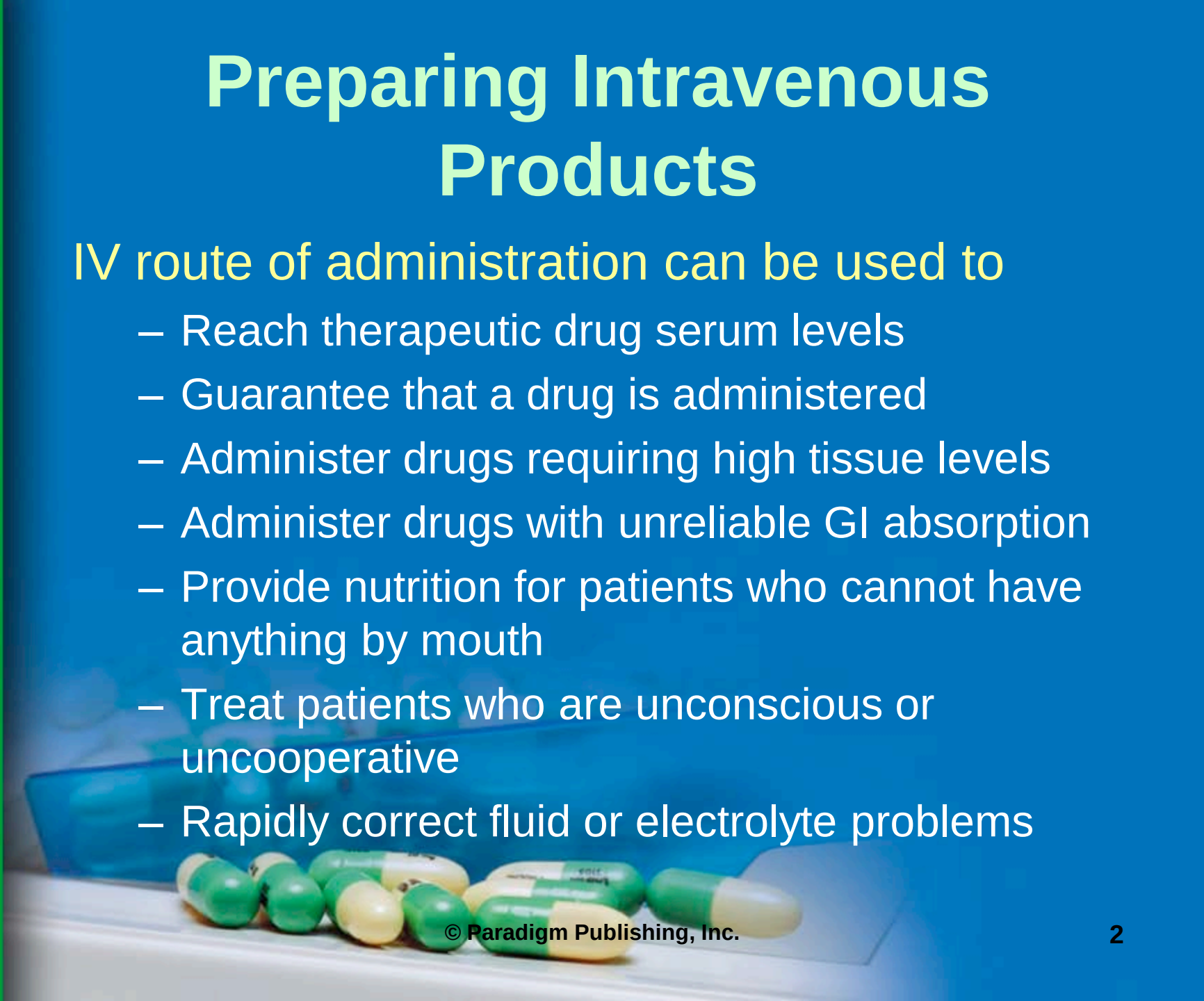
Chapter 11

Preparing and Handling Sterile Products and Hazardous Drugs

Preparing Intravenous Products

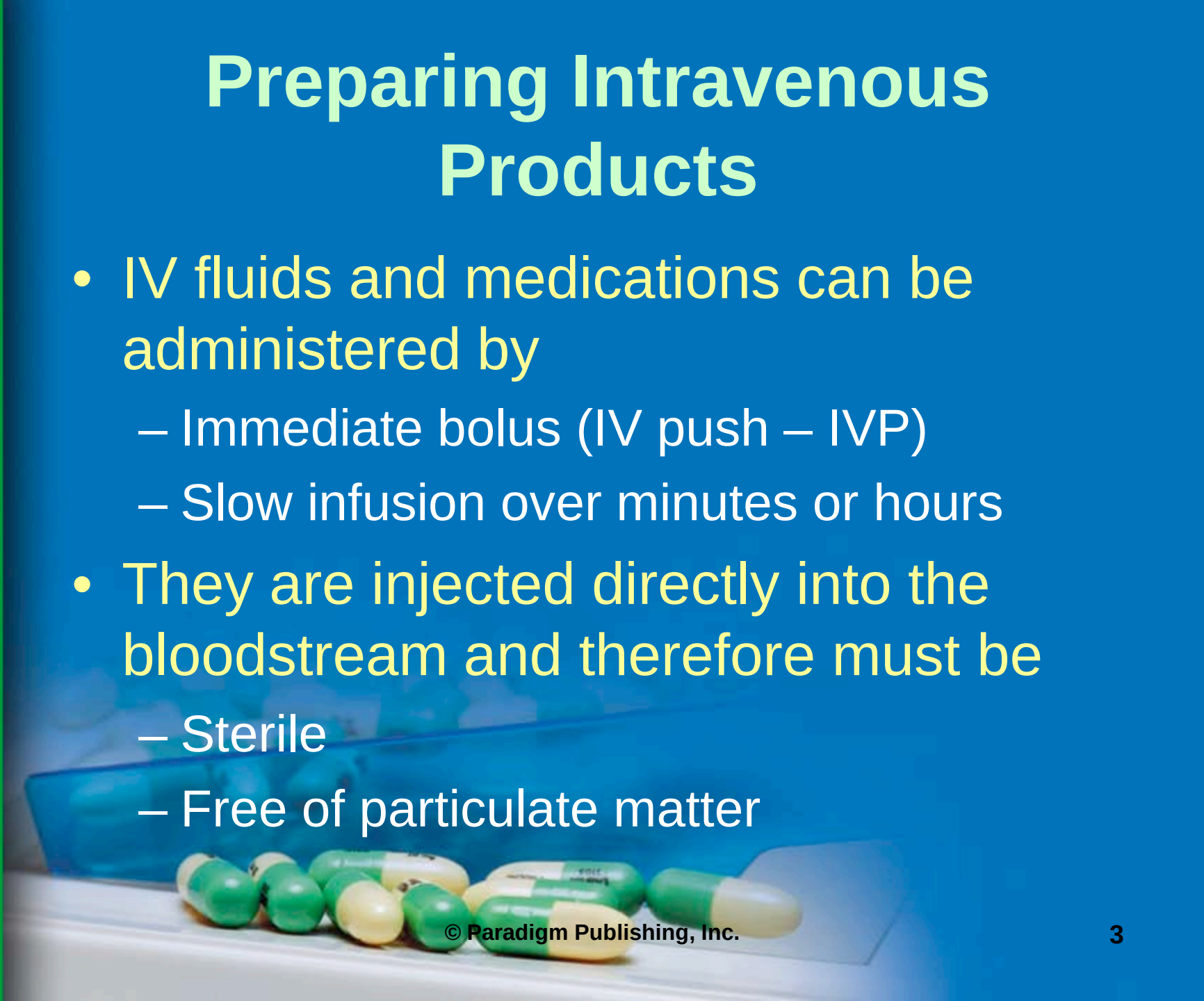
IV route of administration can be used to

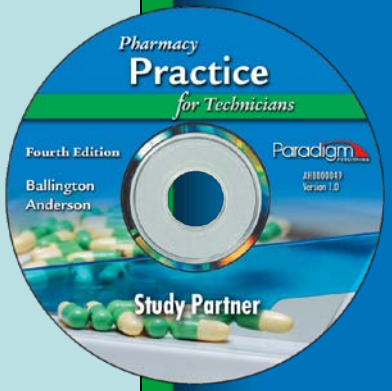
- Reach therapeutic drug serum levels
- Guarantee that a drug is administered
- Administer drugs requiring high tissue levels
- Administer drugs with unreliable GI absorption
- Provide nutrition for patients who cannot have anything by mouth
- Treat patients who are unconscious or uncooperative
- Rapidly correct fluid or electrolyte problems



Preparing Intravenous Products

- IV fluids and medications can be administered by
  - Immediate bolus (IV push – IVP)
  - Slow infusion over minutes or hours
- They are injected directly into the bloodstream and therefore must be
  - Sterile
  - Free of particulate matter





Terms to Remember

IV push (IVP)

the rapid injection of a medication in a syringe into an IV line or catheter in the patient's arm; also called bolus injection

Preparing Intravenous Products

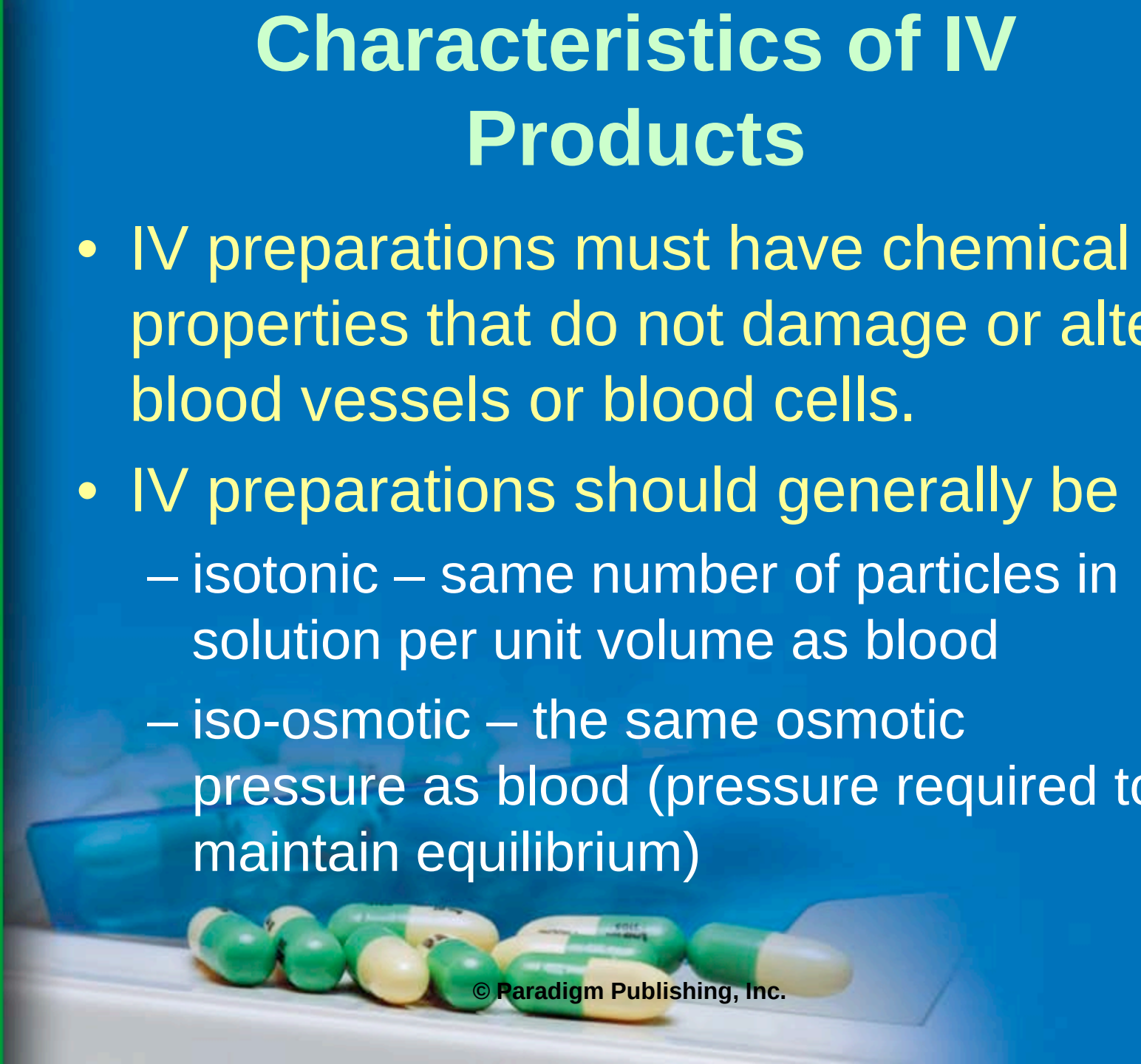
- Characteristics of IV products
- IV solutions
- Aseptic technique
- Preparing a label for an IV admixture
- Final inspection and delivery to the patient care unit
- CSP returns

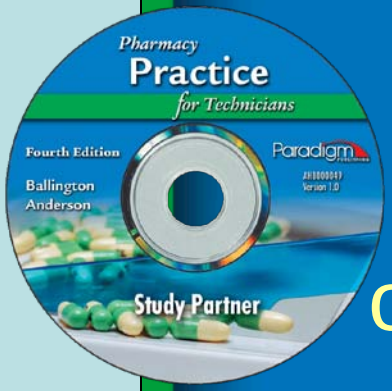
Characteristics of IV Products

- IV preparations are solutions in which ingredients are dissolved or emulsified.
- Most IV preparations are based on a sterile water medium.
- Some preparations may be oleaginous (oily), such as a fat emulsion for supplying extra calories.

Characteristics of IV Products

- IV preparations must have chemical properties that do not damage or alter blood vessels or blood cells.
- IV preparations should generally be
  - isotonic – same number of particles in solution per unit volume as blood
  - iso-osmotic – the same osmotic pressure as blood (pressure required to maintain equilibrium)





Terms to Remember

osmotic pressure

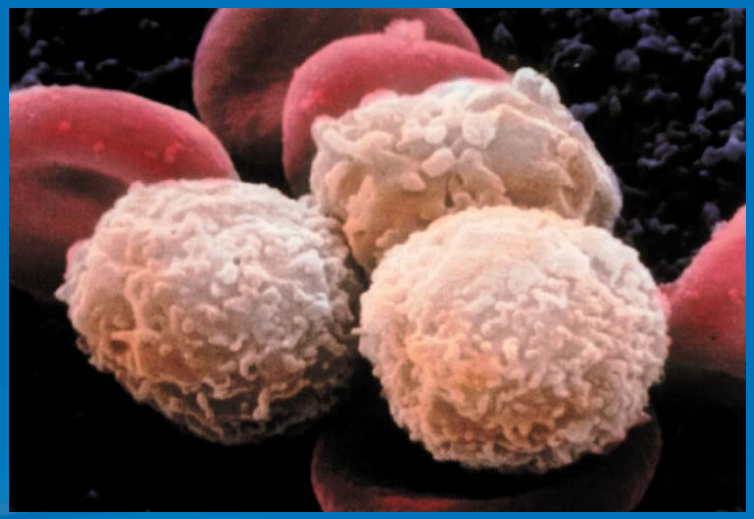
the pressure required to maintain an equilibrium, with no net movement of solvent

osmolarity

a measure of the milliosmoles of solute per liter of solution (mOsm/L); for example, the osmolarity of blood is 285 mOsm/L; often referred to as tonicity for IV solutions

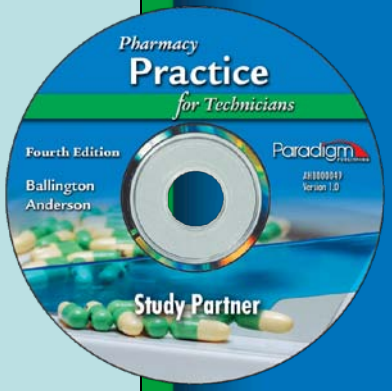
Characteristics of IV Products

- Osmolarity (or tonicity) is a measure of the milliosmoles of solute per liter of solution.
- Osmolarity of blood is about 285 mOsm/L.
- Isotonic solution has the same osmolarity as blood (e.g., 0.9% normal saline).



Characteristics of IV Products

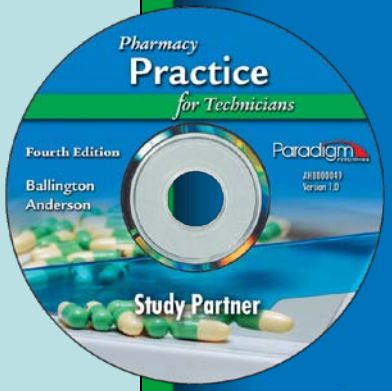
- Hypertonic solution has a greater osmolarity than blood (e.g., 50% dextrose or 3% sodium chloride):
  - Must be administered slowly and cautiously
  - Must be administered in a large vein to be sufficiently diluted by blood
- Hypotonic solution has a lower osmolarity than blood (e.g., 0.45% normal saline).



Terms to Remember

isotonic solution

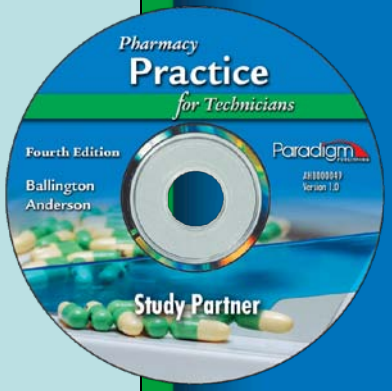
a parenteral solution with an equal number of particles as blood cells (285 mOsm/L); 0.9% normal saline is isotonic



Terms to Remember

hypertonic solution

a parenteral solution with a greater number of particles than the number of particles found in blood (greater than 285 mOsm/L); also called hyperosmolar, as in a TPN solution



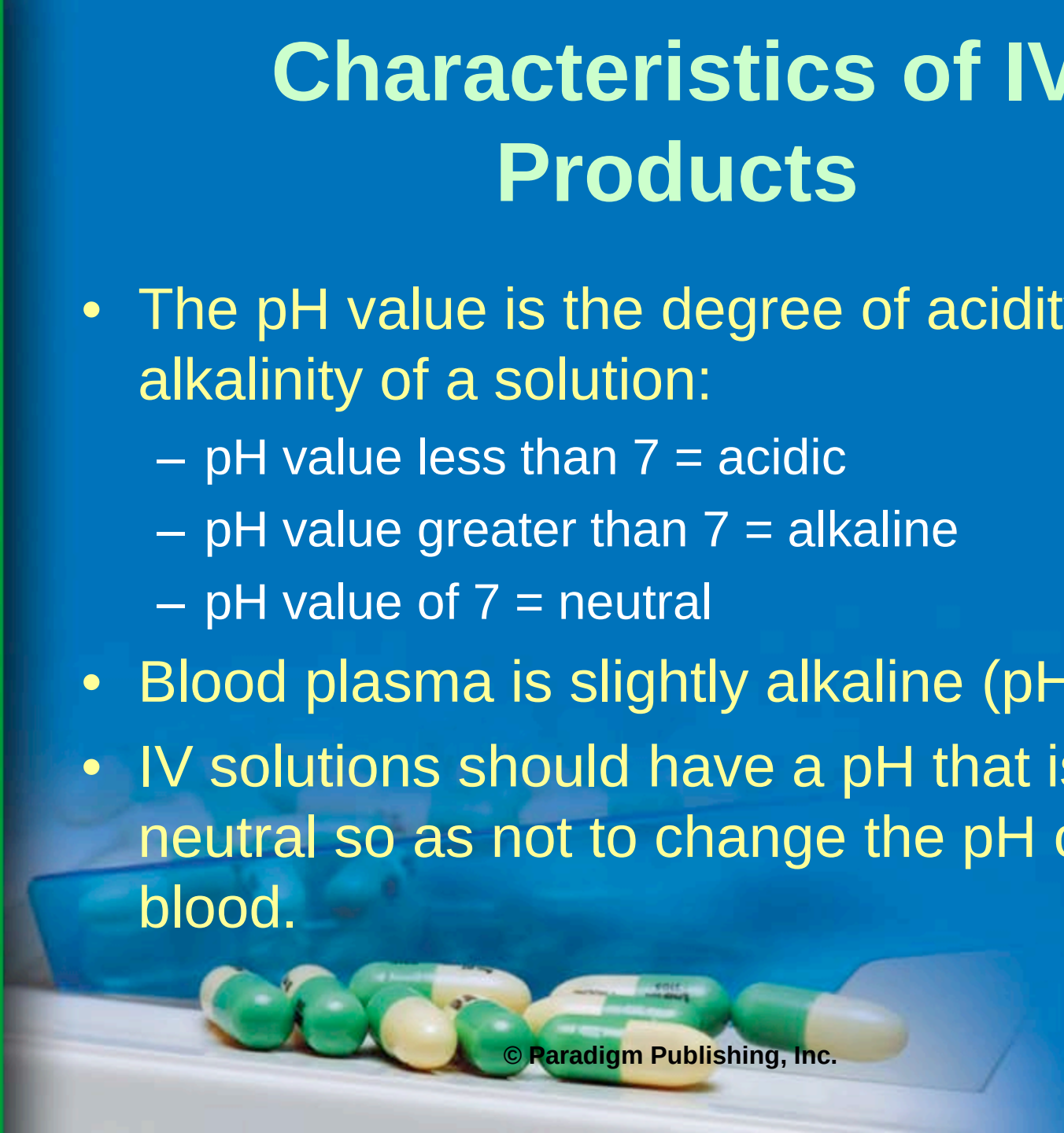
Terms to Remember

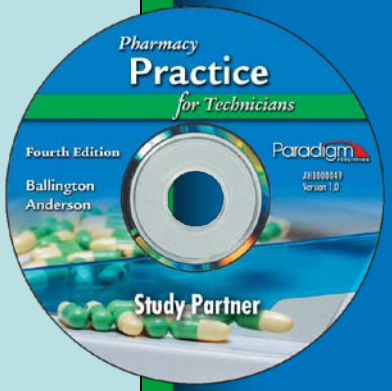
hypotonic solution

a parenteral solution with a fewer number of particles than the number of particles found in blood (less than 285 mOsm/L); also called hypoosmolar

Characteristics of IV Products

- The pH value is the degree of acidity or alkalinity of a solution:
  - pH value less than 7 = acidic
  - pH value greater than 7 = alkaline
  - pH value of 7 = neutral
- Blood plasma is slightly alkaline (pH of 7.4).
- IV solutions should have a pH that is neutral so as not to change the pH of the blood.





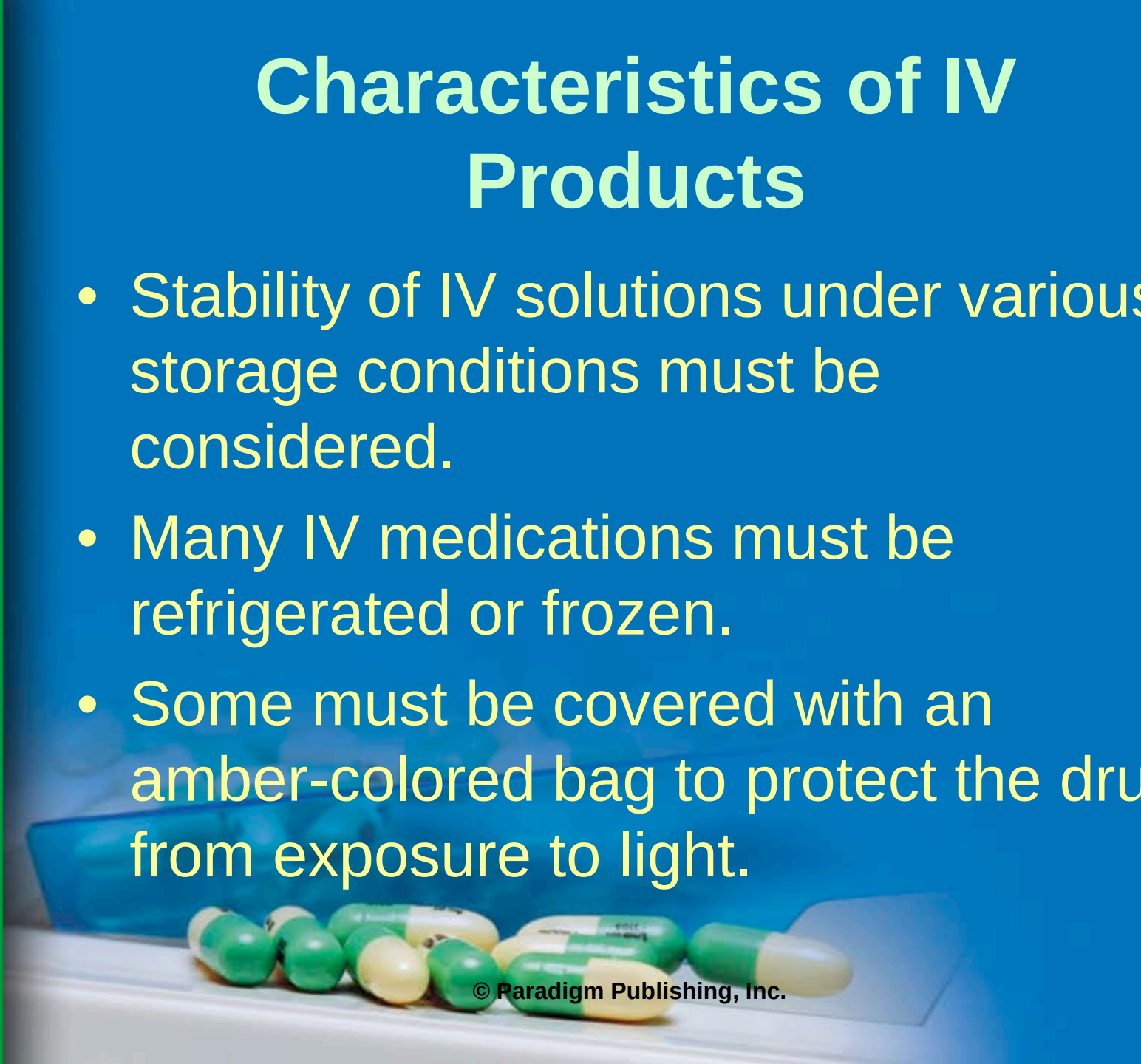
Terms to Remember

pH value

the degree of acidity or alkalinity of a solution; less than 7 is acidic and more than 7 is alkaline; the pH of blood is 7.4

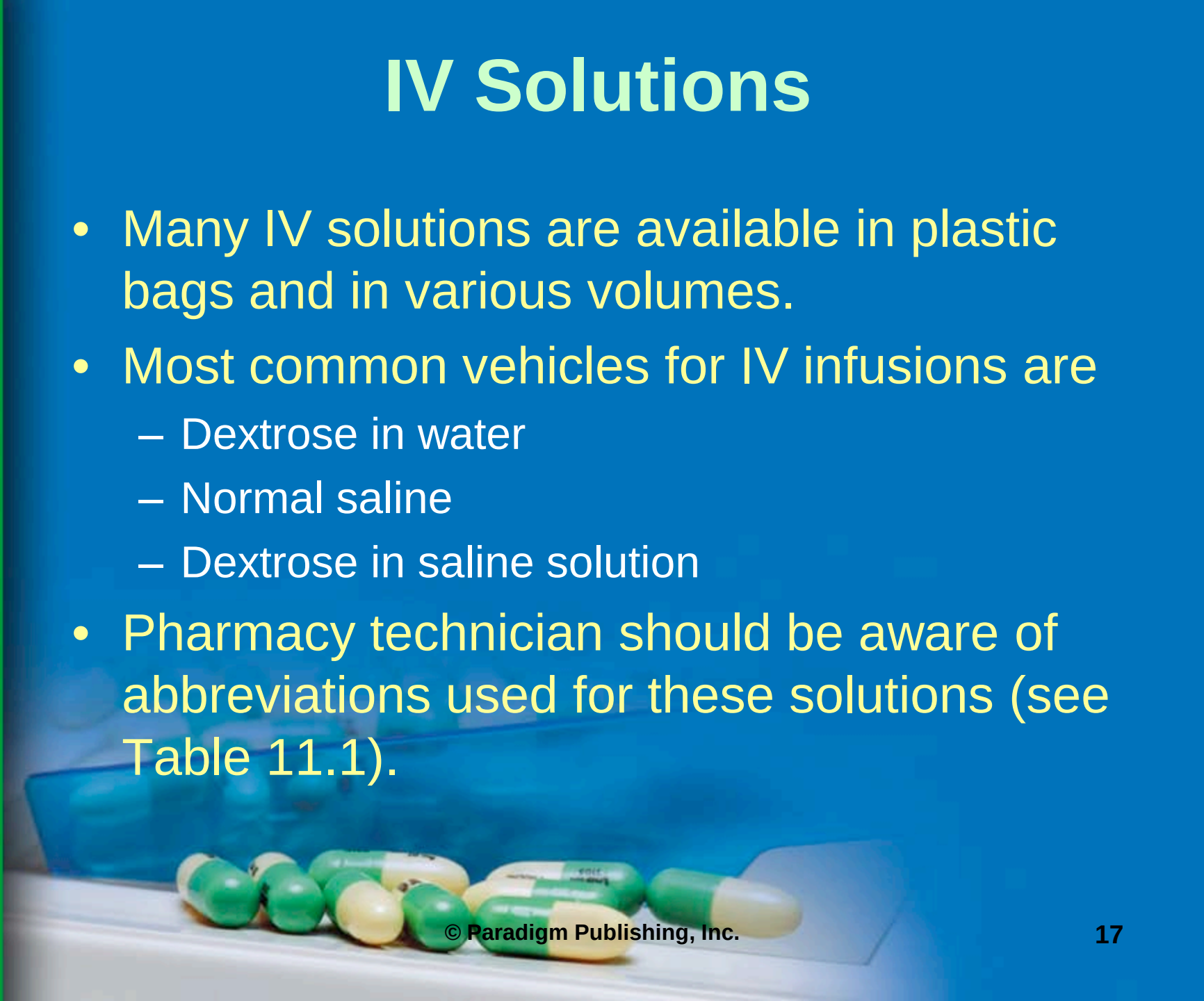
Characteristics of IV Products

- Stability of IV solutions under various storage conditions must be considered.
- Many IV medications must be refrigerated or frozen.
- Some must be covered with an amber-colored bag to protect the drug from exposure to light.



IV Solutions

- Many IV solutions are available in plastic bags and in various volumes.
- Most common vehicles for IV infusions are
  - Dextrose in water
  - Normal saline
  - Dextrose in saline solution
- Pharmacy technician should be aware of abbreviations used for these solutions (see Table 11.1).



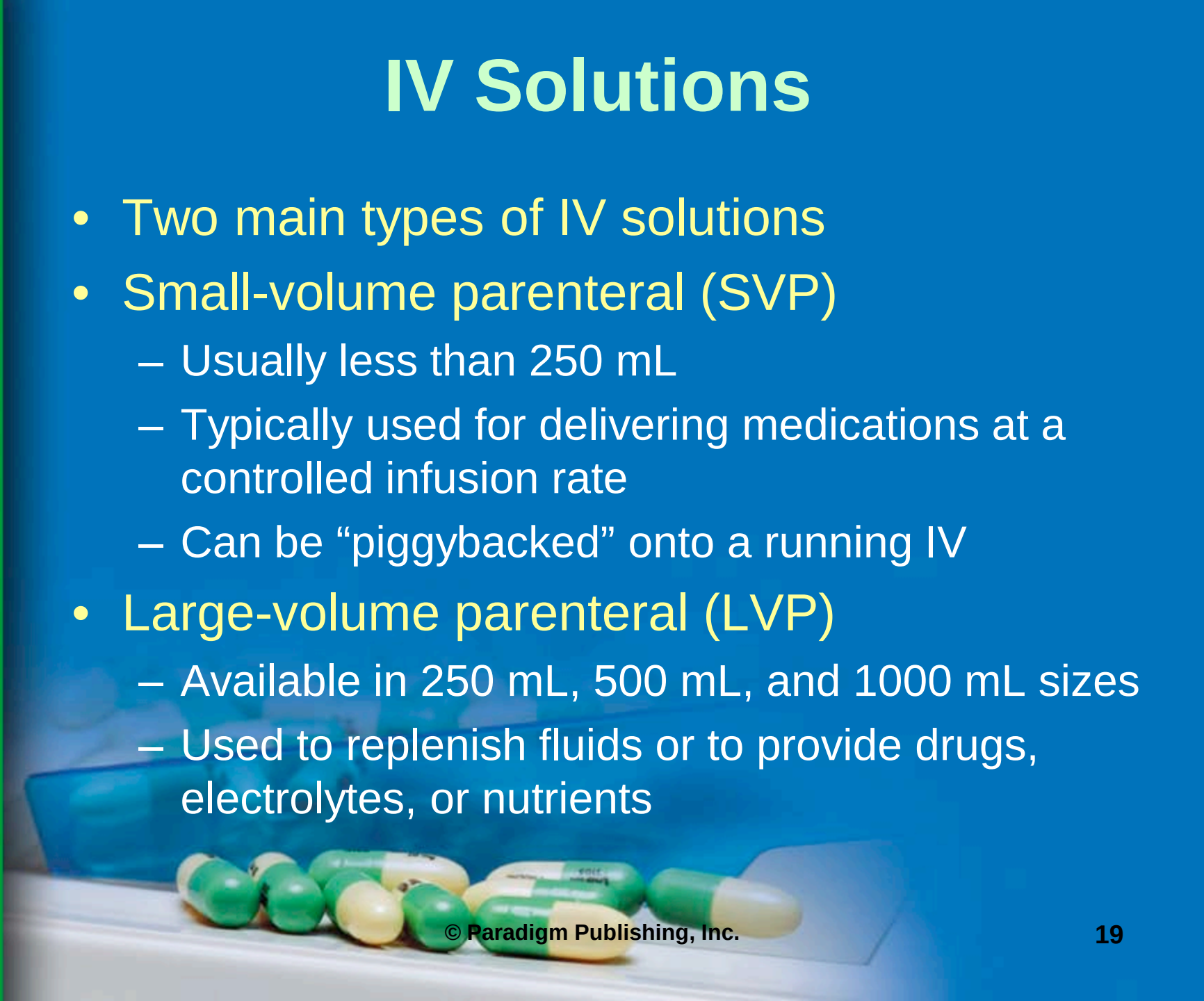
IV Solutions

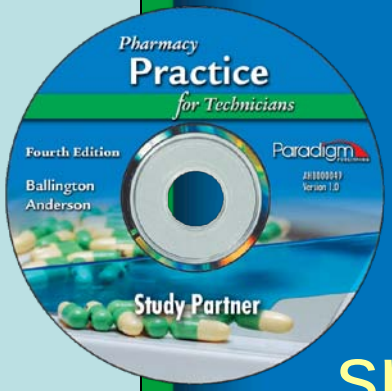
TABLE 11.1 Commonly Used IV Products and Abbreviations

Component		Abbreviation
Fluids	2.5% dextrose in water	$D_{2.5}W$
	5% dextrose in water	D_5W
	5% dextrose and lactated Ringer's solution	D_5RL or D_5LR
	10% dextrose in water	$D_{10}W$
	5% dextrose and normal saline	D_5NS
	2.5% dextrose and 0.45% normal saline	$D_{2.5}$½NS
	5% dextrose and 0.45% normal saline	D_5½NS
	normal saline	NS
	0.45% normal saline	0.45% NS or ½NS
	lactated Ringer's solution	RL or LR
	sterile water for injection	SW for injection or SWFI
	bacteriostatic water for injection	BW for injection or BWFI
	sterile water for irrigation	SW for irrigation
	normal saline for irrigation	NS for irrigation
Electrolytes	potassium chloride	KCl
	potassium phosphate	K phos or KPO_4
	potassium acetate	K acet
	sodium phosphate	Na phos or $NaPO_4$
	sodium chloride	NaCl
Additives	multivitamin for injection	MVI
	trace elements (combinations of essential trace elements such as chromium, manganese, and copper)	TE
	zinc (a trace element)	Zn
	selenium (a trace element)	Se

IV Solutions

- Two main types of IV solutions
- Small-volume parenteral (SVP)
  - Usually less than 250 mL
  - Typically used for delivering medications at a controlled infusion rate
  - Can be “piggybacked” onto a running IV
- Large-volume parenteral (LVP)
  - Available in 250 mL, 500 mL, and 1000 mL sizes
  - Used to replenish fluids or to provide drugs, electrolytes, or nutrients





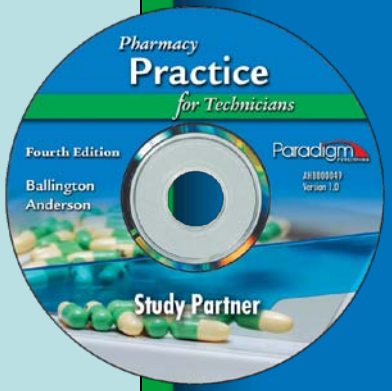
Terms to Remember

small-volume parenteral (SVP)

an IV fluid of 250 mL or less commonly used for infusion of drugs; with medication, also called an IV piggyback

IV piggyback (IVPB)

a small-volume IV infusion (50 mL, 100 mL, 250 mL) containing medications



Terms to Remember

large-volume parenteral (LVP)

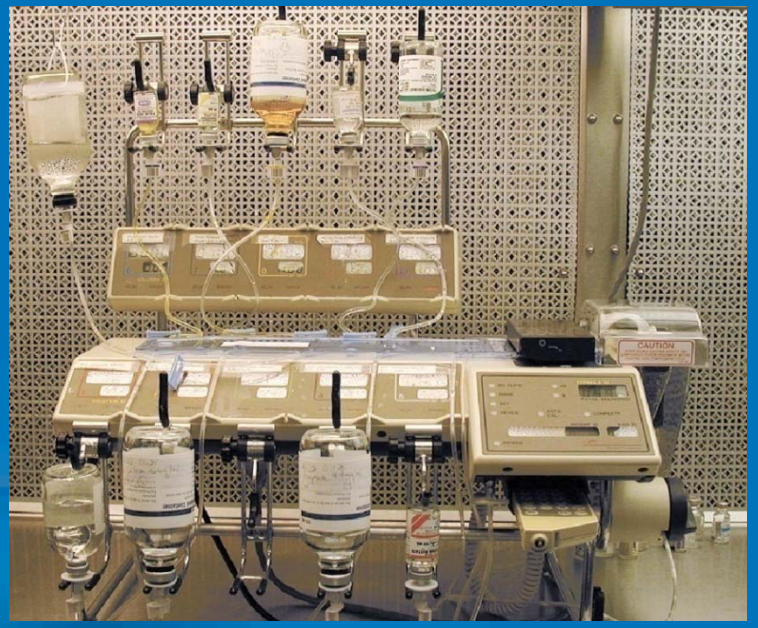
an IV fluid of more than 250 mL that may contain drugs, nutrients, or electrolytes

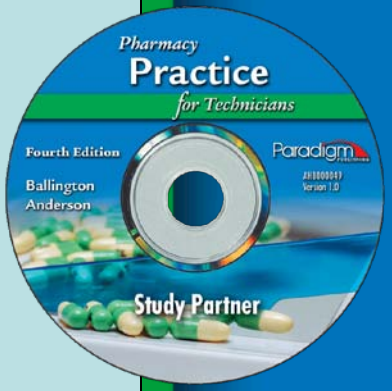
IV Solutions

- A special type of IV admixture is total parenteral nutrition (TPN).
- A TPN provides nutrition for patients who can have nothing by mouth (NPO).
- A TPN often contains more than 50 components, including
  - Protein and amino acids
  - Carbohydrates
  - Electrolytes, vitamins, and minerals
  - Medication

IV Solutions

- TPN solutions are often prepared using an automated compounding device (ACD).
- ACDs handle multiple ingredients and reduce medication errors and contamination.





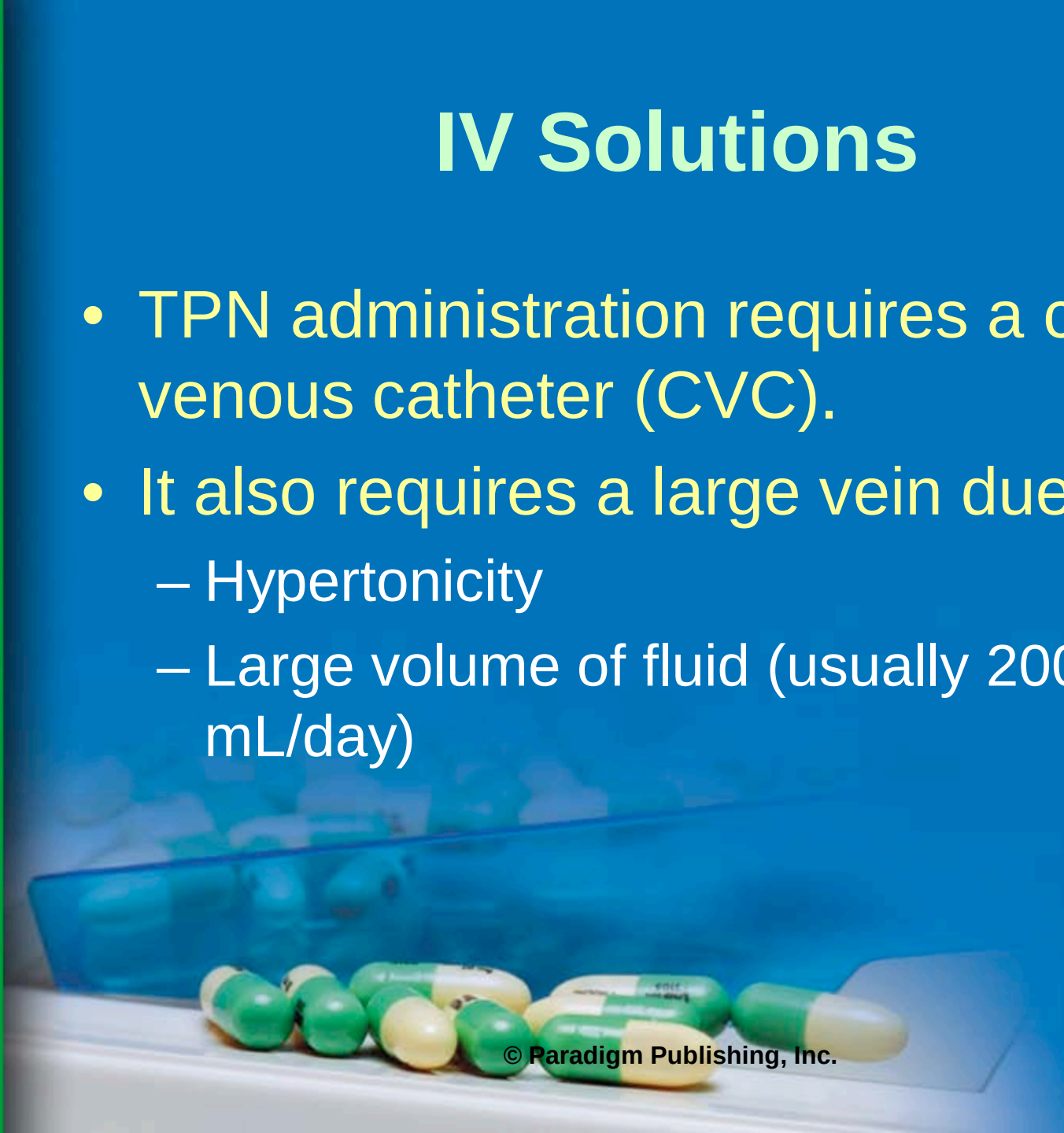
Terms to Remember

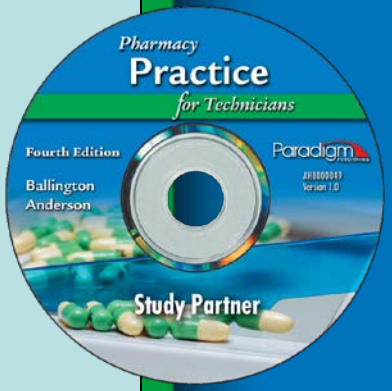
automated compounding device (ACD)

- a programmable, automated device to make complex IV preparations such as TPNs

IV Solutions

- TPN administration requires a central venous catheter (CVC).
- It also requires a large vein due to
  - Hypertonicity
  - Large volume of fluid (usually 2000 mL/day)





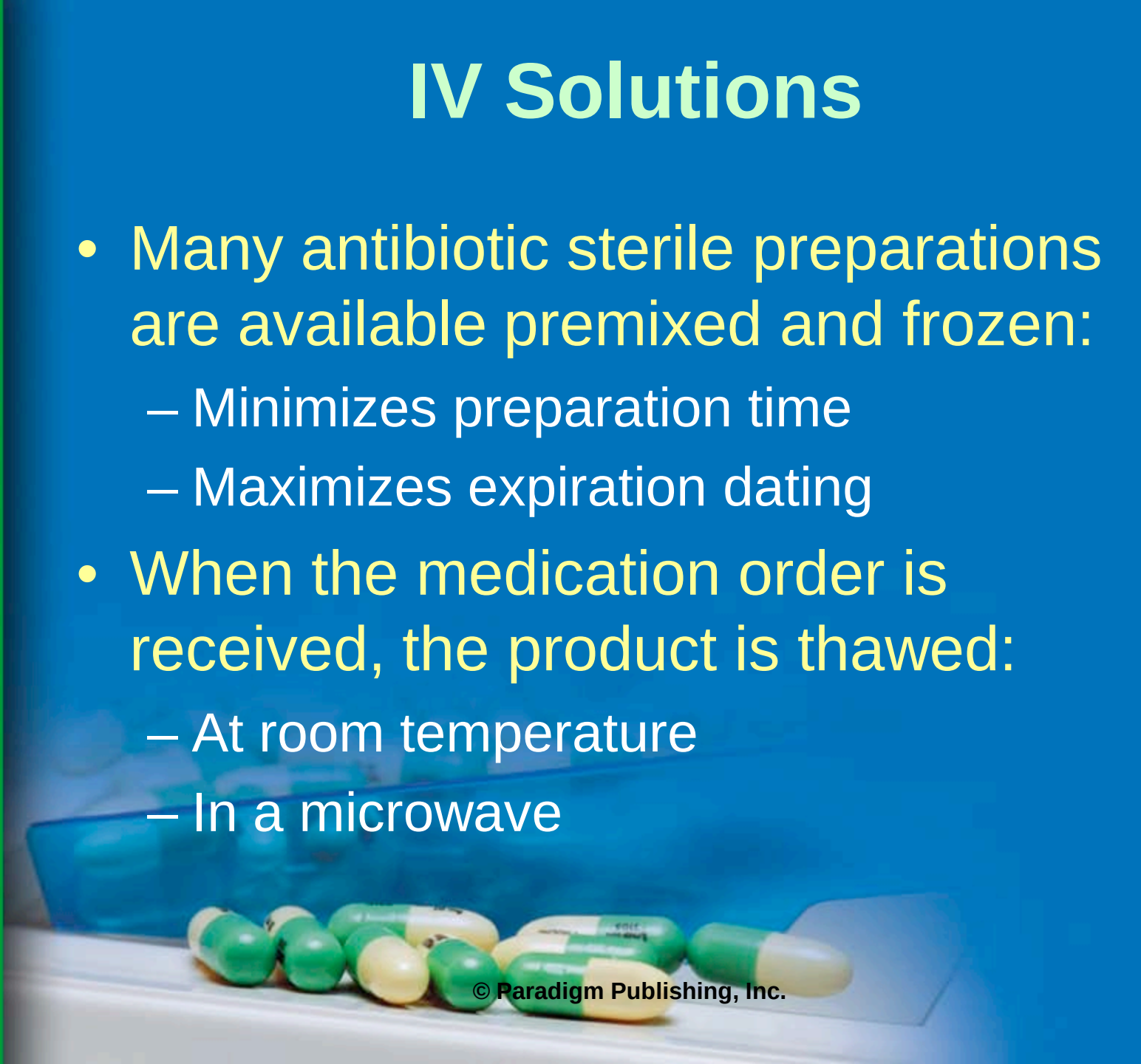
Terms to Remember

central venous catheter (CVC)

a catheter placed into a large vein deep into the body; also called a central line

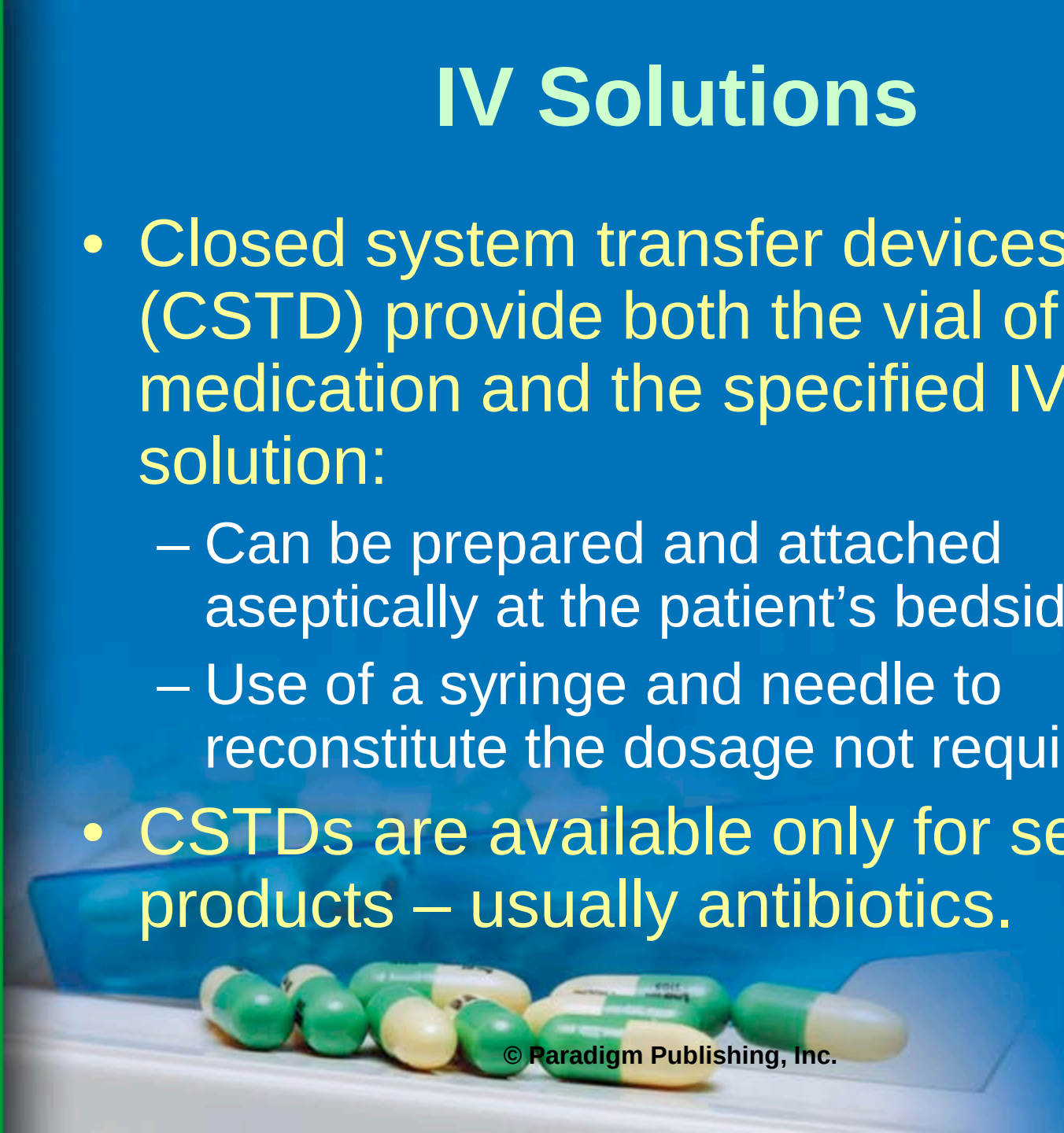
IV Solutions

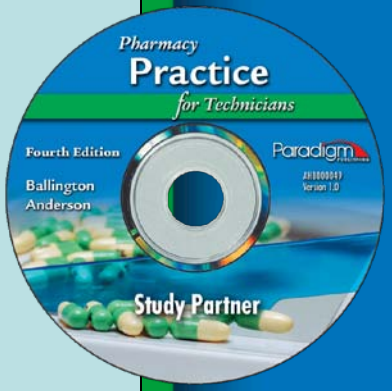
- Many antibiotic sterile preparations are available premixed and frozen:
  - Minimizes preparation time
  - Maximizes expiration dating
- When the medication order is received, the product is thawed:
  - At room temperature
  - In a microwave



IV Solutions

- Closed system transfer devices (CSTD) provide both the vial of medication and the specified IV solution:
  - Can be prepared and attached aseptically at the patient's bedside
  - Use of a syringe and needle to reconstitute the dosage not required
- CSTDs are available only for selected products – usually antibiotics.





Terms to Remember

closed system transfer device (CSTD)

a needleless delivery system by which medications are aseptically activated and added to an IV minibag at patient's bedside

IV Solutions

- Pharmacy technician is responsible for assembling the CSTD with proper labeling and expiration dating.
- CSTDs are more efficient:
  - Doses are premeasured for rapid reconstitution.
  - There is no need for freezing, thawing, or refrigeration.

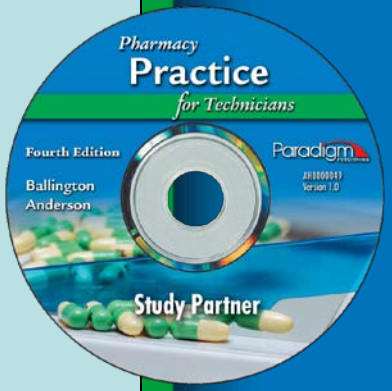
IV Solutions

Other advantages of CSTDs

- Admixing errors are minimized.
- Doses are standardized.
- Labeling and barcoding is enhanced.
- Contamination is minimized.

Aseptic Technique

- Aseptic technique is used to handle sterile preparations and devices so as to avoid introducing disease-causing microorganisms.
- Proper technique is an essential skill for the pharmacy technician.
- Pharmacy technicians prepare CSPs on a laminar airflow workbench (LAFW).



Terms to Remember

aseptic technique

the manipulation of sterile products and devices in such a way as to avoid disease-causing organisms

Aseptic Technique

Safety Note

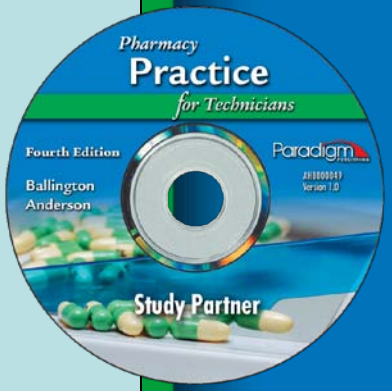
Wear appropriate sterile gear when working in the pharmacy clean room. This includes shoe covers, face mask, full head covering, scrubs or gown with back closure, and gloves. Eye protection should be used if preparing hazardous drugs.

Aseptic Technique

- In preparing CSPs, the pharmacy technician must often transfer medication from vials to IV bags.
- The rubber stopper on the vial must be cleaned with 70% isopropyl alcohol.

Aseptic Technique

- Needle tip must not be touched.
- Needle must be inserted into the vial properly to avoid coring (see Table 11.3).
- Beyond-use dating on the vial must be checked carefully.



Terms to Remember

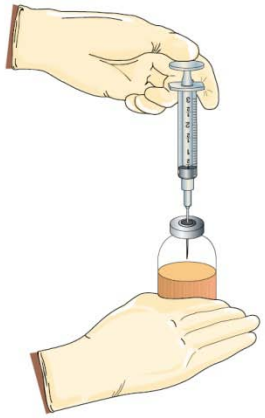
coring

the act of introducing a small chunk of the rubber closure into the solution while removing medication from a vial

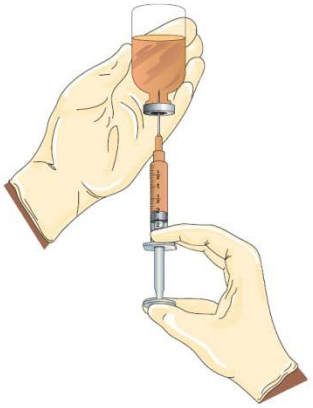
Aseptic Technique

TABLE 11.3 Using a Syringe to Draw Liquid from a Vial

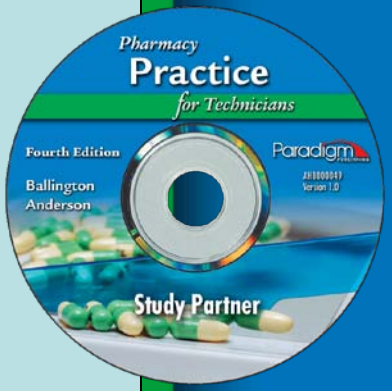
1. Choose the smallest-gauge needle appropriate for the task. The smaller the needle, the less the chance of coring the rubber top of the vial and thus introducing particulate into the liquid within it.
2. Attach the needle to the syringe.
3. Draw into the syringe an amount of air equal to the amount of drug to be drawn from the vial.
4. Swab or spray the top of the vial with alcohol beforehand; allow the alcohol to dry. Puncture the rubber top of the vial with the needle bevel up. Then bring the syringe and needle straight up, penetrate the stopper, and depress the plunger of the syringe, emptying the air into the vial (Figure 11.3, *a*). Check for coring.
5. Invert the vial with the syringe still inserted.
6. Draw up from the vial the amount of liquid required (Figure 11.3, *b*).
7. Withdraw the needle from the vial. In the case of a multiple-dose vial, the rubber cap closes, sealing the contents of the vial.
8. The majority of liquids drawn up from a vial are added to an IV solution. In these cases, capping of the empty syringe is discouraged to avoid needlesticks. In the rarer cases in which an actual syringe is dispensed, remove and properly dispose of the needle, and then cap the syringe with a sterile syringe cap. If a capped syringe is sent to the patient care unit, then a new needle is attached at the time of injection into a patient.



(a) Inject an amount of air into the vial equal to the volume of liquid needed.



(b) Withdraw the desired amount of medication into the syringe from the inverted vial.



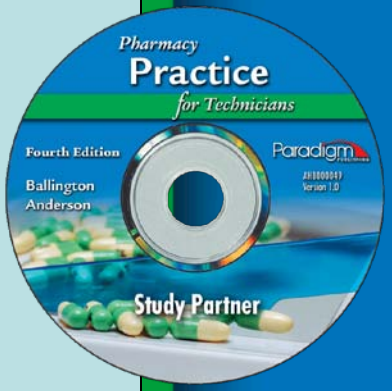
Terms to Remember

diluent

a sterile fluid added to a powder to reconstitute, dilute, or dissolve a medication

Aseptic Technique

- Some medications come in glass ampules:
  - Single dose
  - No preservatives
- Any fluid in the top of the ampule must be moved to the bottom:
  - Quickly swirl, invert, and return the ampule to the upright position.
  - Tap the top of the ampule.



Terms to Remember

ampule

a single-dose-only drug container; contains no preservative

Aseptic Technique

- Ampule neck must be cleaned with alcohol.
- A quick motion is used to snap off the top.
- A needle with a filter should be used to withdraw medication (to screen out any particles).

Preparing a Label for an IV Admixture

When making an IV admixture, the pharmacy technician must also prepare a medication label containing

- Patient name, identification number, and room number
- Fluid and amount
- Drug name and strength
- Infusion period and flow rate
- Beyond-use dating or expiration date and time
- Any additional required information

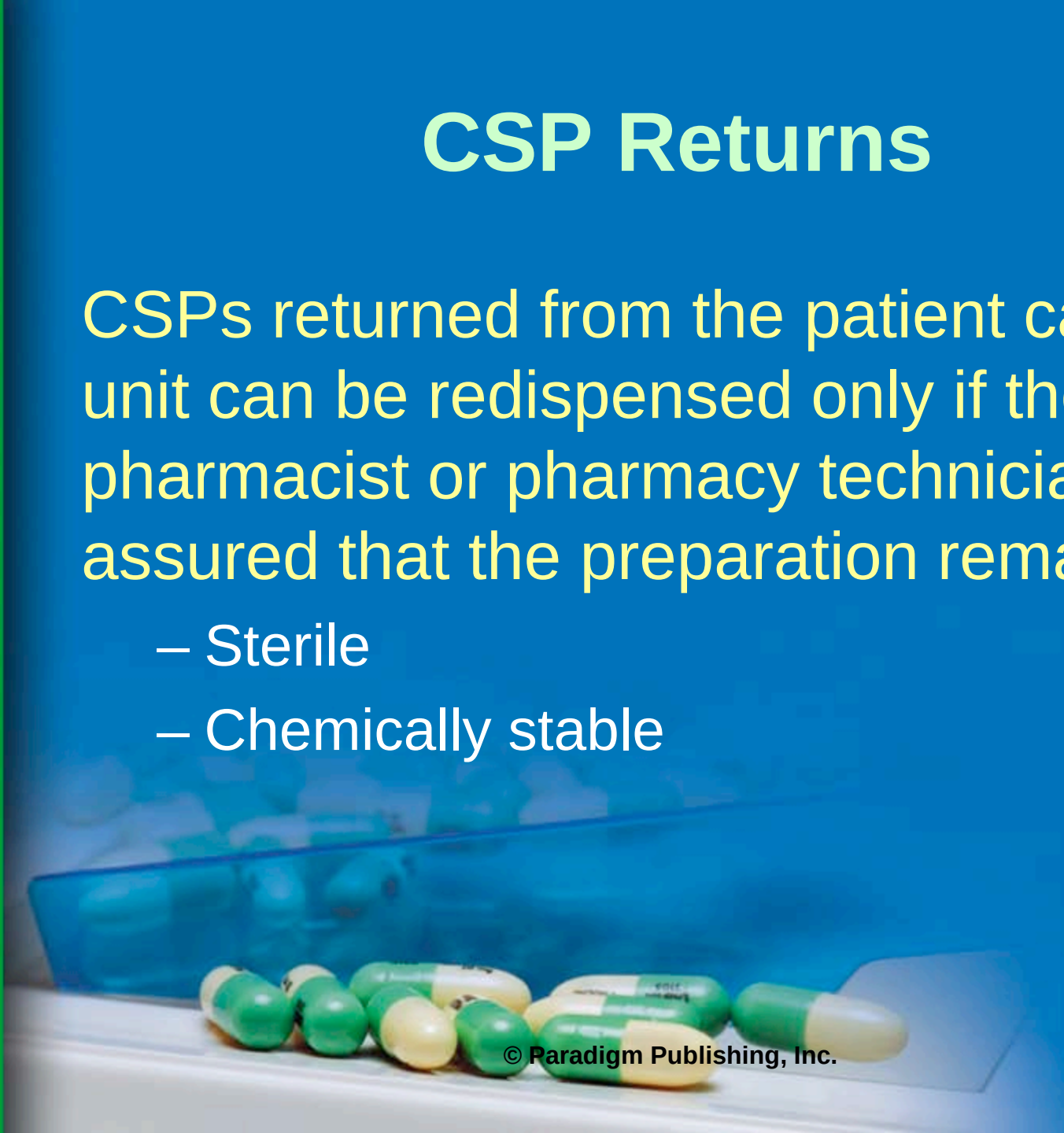
Final Inspection and Delivery to the Patient Care Unit

- All materials used to make a CSP must be inspected by the pharmacist.
- Inspection should include
  - Accuracy in identification and amount of ingredients
  - Aseptic mixing and sterilization
  - Packaging and labeling
  - Physical appearance

CSP Returns

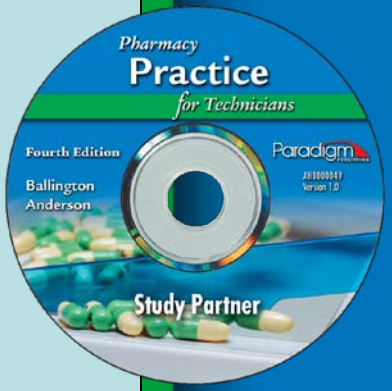
CSPs returned from the patient care unit can be redispensed only if the pharmacist or pharmacy technician is assured that the preparation remained

- Sterile
- Chemically stable



Equipment Used in IV Drug Preparation

- A wide variety of sterile devices are used to prepare and administer IV medications.
- Most are plastic and disposable.



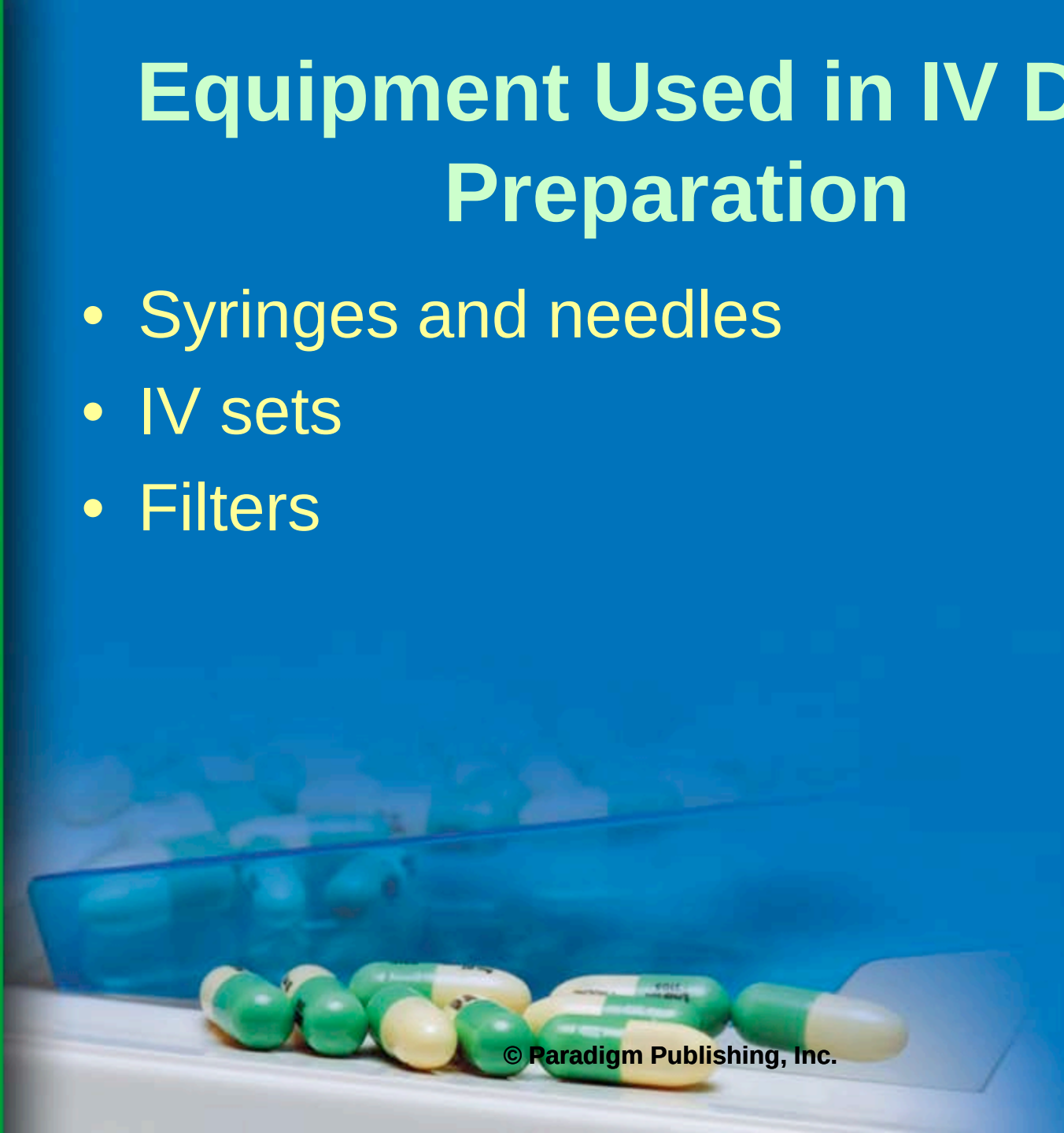
Terms to Remember

catheter

a device inserted into a vein for direct access to the blood vascular system

Equipment Used in IV Drug Preparation

- Syringes and needles
- IV sets
- Filters

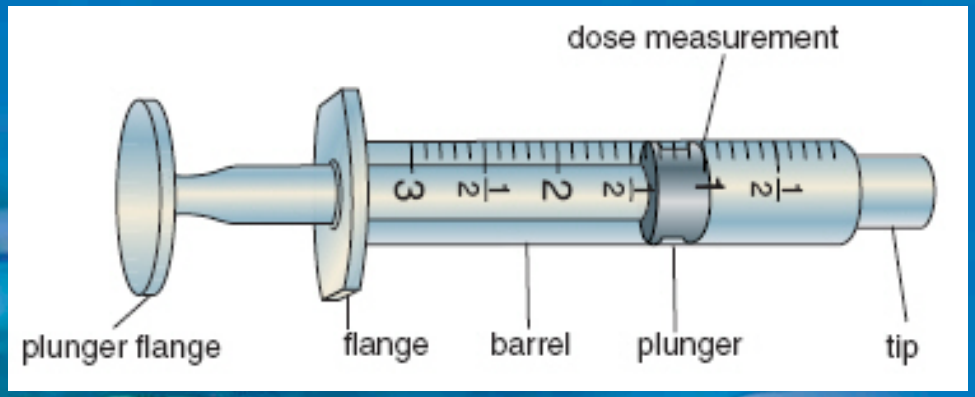


Syringes and Needles

- Syringes can be made of glass or plastic.
- Glass syringes are more expensive and are used mainly with medications that may be absorbed by plastic.
- Plastic syringes are less expensive and disposable, and they come in sterile packaging.

Syringes and Needles

- The plunger and the tip of the syringe are sterile and should not be touched.
- For greatest accuracy, use the smallest syringe that is able to hold the desired amount of solution.



Syringes and Needles

Safety Note

Remember that the plunger and the tip of the syringe are sterile and must not be touched.

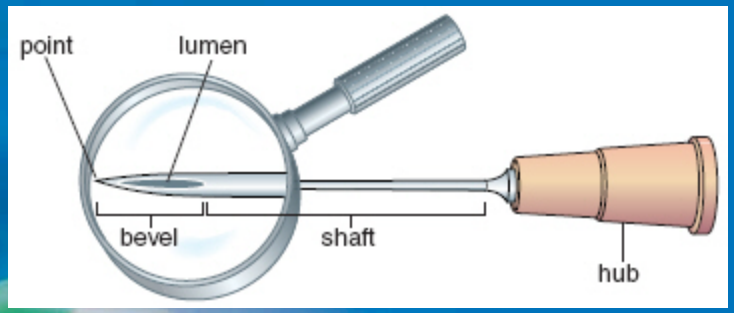
Syringes and Needles

Safety Note

After use, needles must be discarded in a designated sharps container.

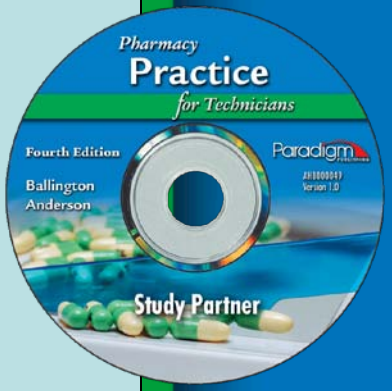
Syringes and Needles

- Needles used to prepare solutions consist of two parts:
  - Cannula (shaft)
  - Hub (the part that attaches to the syringe)
- Needles are made of stainless steel or aluminum:
  - Range in length from ⅜ inch to 6 inches
  - Range in width from 31 gauge (smallest) to 13 gauge (biggest)



IV Sets

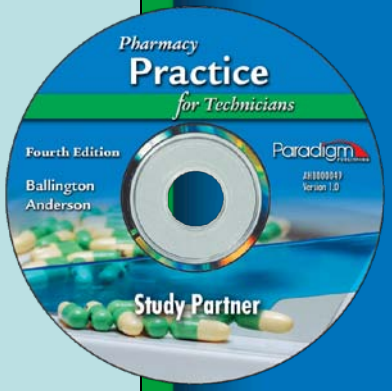
- A sterile, nonpyrogenic disposable device used to deliver IV fluids and medications to patients
- Pharmacy personnel need a thorough understanding of IV sets in order to
  - Select set optimal to prevent drug or fluid incompatibilities
  - Calculate dosages and drip rates in emergency situations
  - Check and change IV lines
  - Provide in-service training to nurses
  - Transfer fluids from container to container
  - Prime tubing for medication administration



Terms to Remember

IV administration set

a sterile, pyrogen-free disposable device used to deliver IV fluids to patients



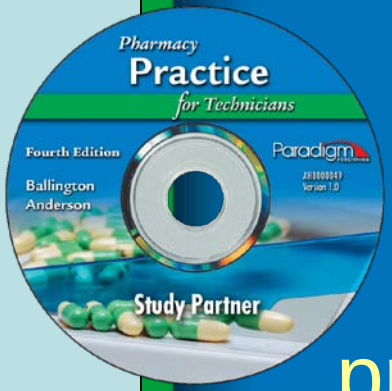
Terms to Remember

nonpyrogenic

the state of being free from microorganisms; a description of a packaged IV set

IV Sets

- Most of the length of IV tubing and IV bags is molded from PVC.
- Some sets are made from other materials to accommodate solutions and medications that are absorbed by PVC:
  - Nitroglycerin
  - Fat emulsions
- IV lines may need to be primed, or flushed with fluid, to remove particles and displace air.



Terms to Remember

priming

the act of flushing out the small particles in the tubing's interior lumen prior to medication administration and letting fluid run through the tubing so that all of the air is flushed out

IV Sets

Safety Note

Do not use PVC IV sets for nitroglycerin or fat emulsions.

IV Sets

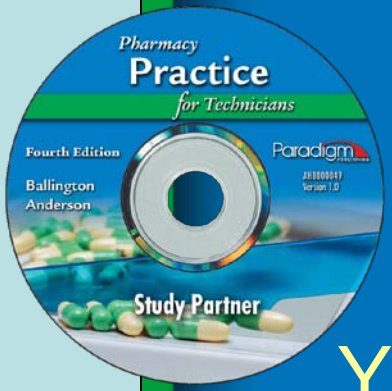
Basic components

- Spike – to pierce the rubber stopper on the IV container
- Drip chamber – to trap air and allow viewing of the drops per minute
- Control clamp – to adjust or stop the flow
- Flexible tubing – to deliver the fluid
- Adapter – to attach a needle or catheter

IV Sets

Other components

- Y-site – resealable port for adding medication to the IV
- Vent – to allow filtered air to enter the bag as fluid flows out



Terms to Remember

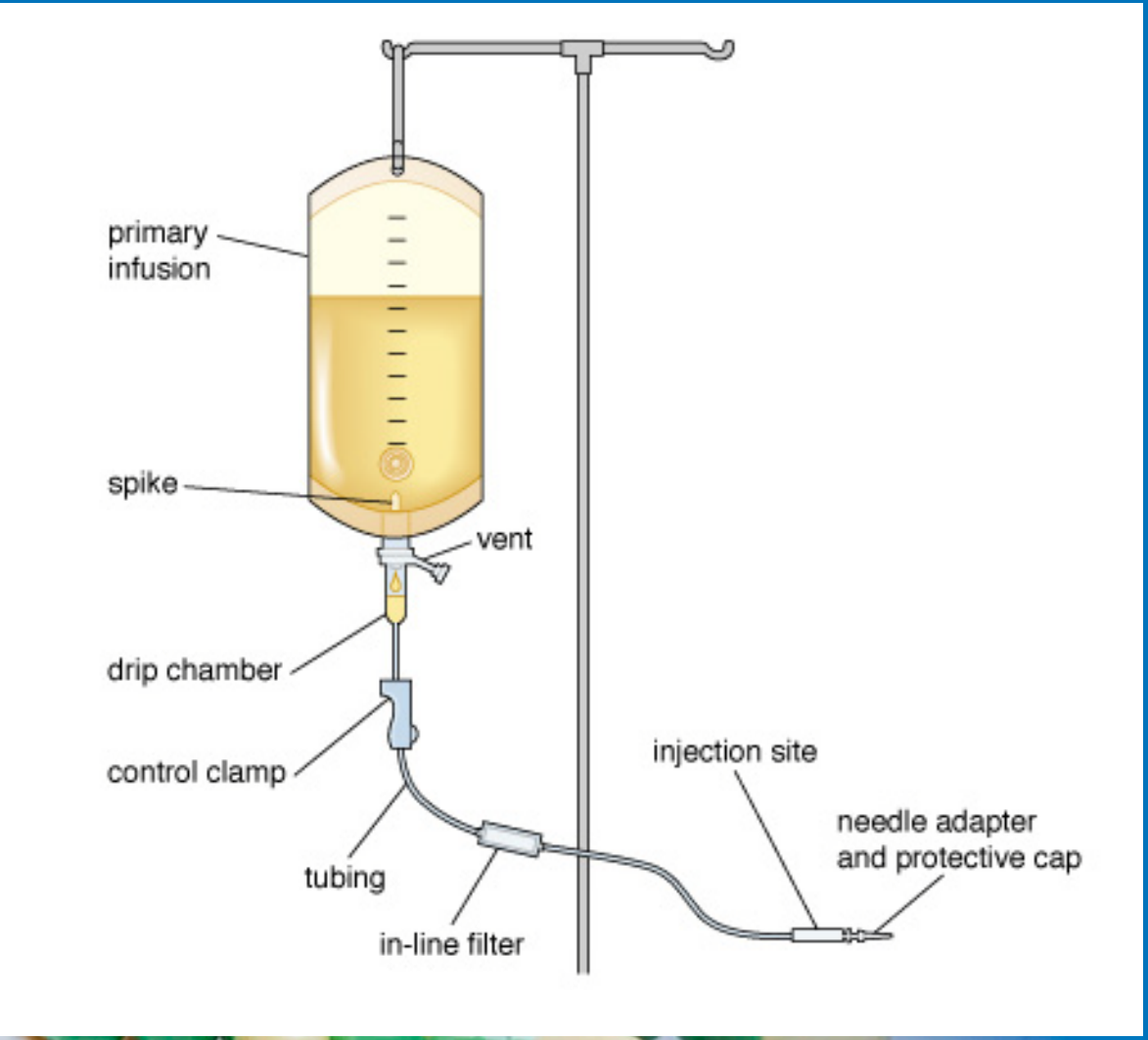
Y-site

a rigid piece of plastic with one arm terminating in a resealable port that is used for adding medication to the IV

spike

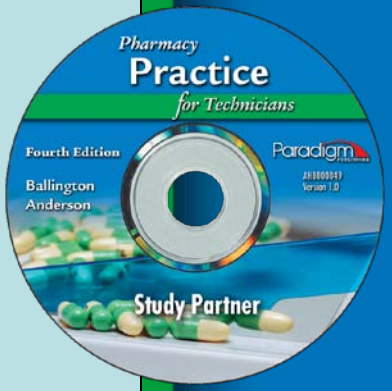
the sharp plastic end of IV tubing that is attached to an IV bag of fluid

IV Sets



IV Sets

- Sets are identified by drop set – the number of drops it takes to make 1 mL.
- Common drop sets are 10, 15, 20, and 60 (gtt/mL).
- Nurse administering the IV counts drops and adjusts as necessary.

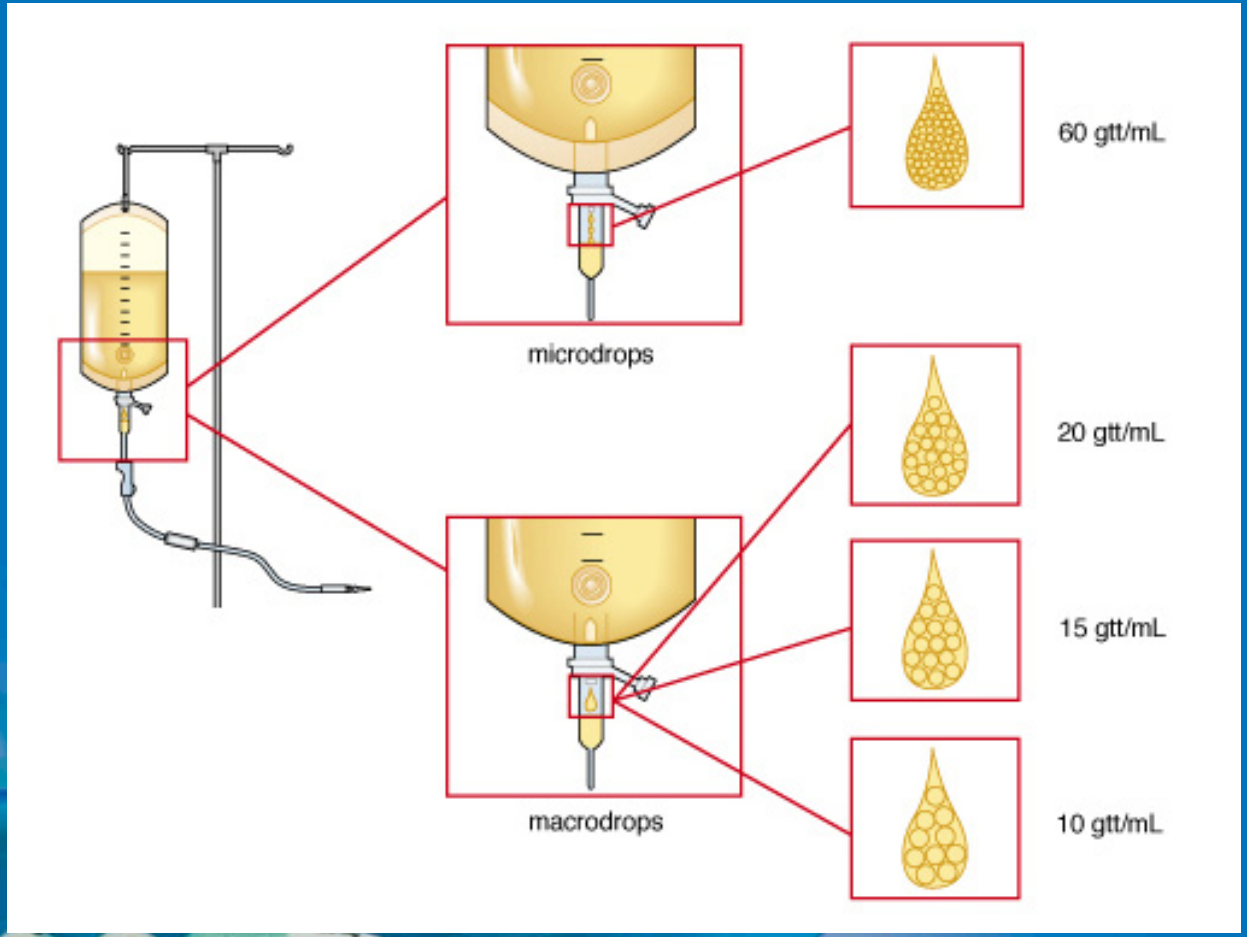


Terms to Remember

drop set

the calibration in drops per milliliter on IV sets

IV Sets

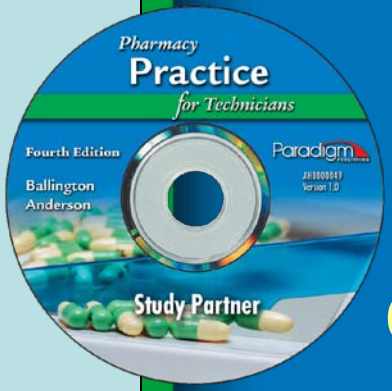


IV Sets

- Clamps are used to adjust or shut down the flow.
- Three types of clamps are common:
  - Slide clamp – used primarily for shutting off flow
  - Screw clamp – thumbscrew can be tightened or loosened to adjust flow
  - Roller clamp – can be rolled up or down IV tubing to compress it and adjust flow

IV Sets

- Two factors affect clamp accuracy: creep and cold flow.
- Creep is the tendency of PVC tubing to return to its previous shape or position; tubing can return to its original state when clamped or unclamped.
- Cold flow is the tendency of some clamps to slowly return to a more open position with increased fluid flow.



Terms to Remember

creep

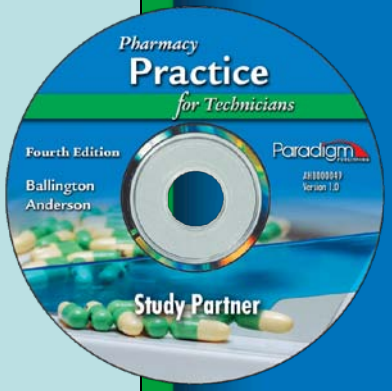
the tendency of a clamp on an IV administration set to return to its previous position

cold flow

the tendency of a clamp on an IV administration set to return slowly to a more open position, with an increase in fluid flow

Filters

- Included in many IV sets
- Used to remove contaminants such as
  - Glass
  - Paint
  - Fibers
  - Rubber cores
  - Bacteria



Terms to Remember

filter

a device used to remove contaminants such as glass, paint, fibers, rubber cores, and bacteria from IV fluids

Filters

- Final filtration should protect patient from
  - Particulate matter
  - Bacteria
  - Air emboli
  - Phlebitis
- Common filter sizes
  - 5.0 microns – removes large particulate matter
  - 0.45 microns – used in in-line IV filters
  - 0.22 microns – removes bacteria and produces a sterile solution

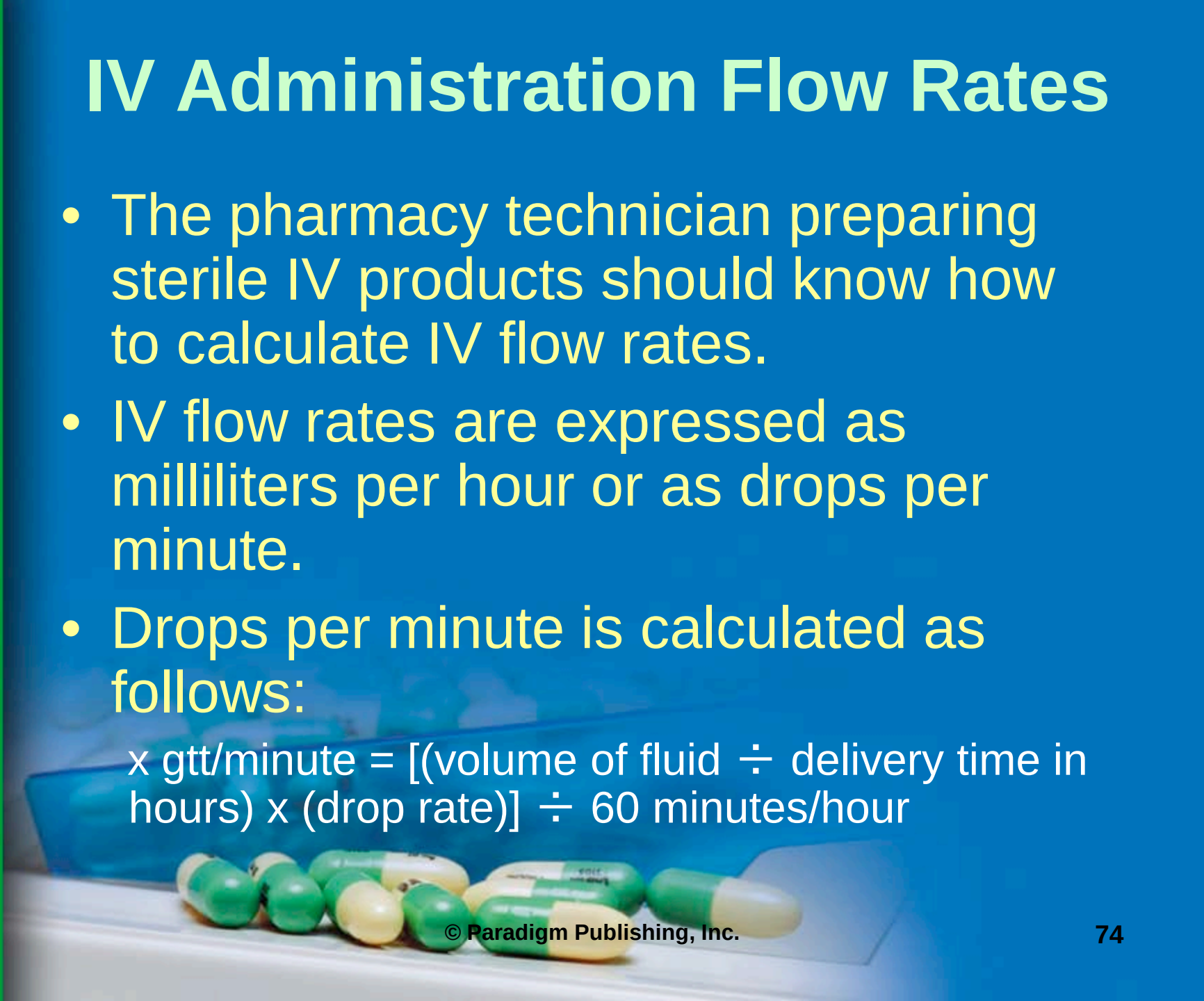
Calculations in the Hospital Pharmacy

- IV administration flow rates
- Electrolytes

IV Administration Flow Rates

- The pharmacy technician preparing sterile IV products should know how to calculate IV flow rates.
- IV flow rates are expressed as milliliters per hour or as drops per minute.
- Drops per minute is calculated as follows:

  x gtt/minute = [(volume of fluid ÷ delivery time in hours) x (drop rate)] ÷ 60 minutes/hour



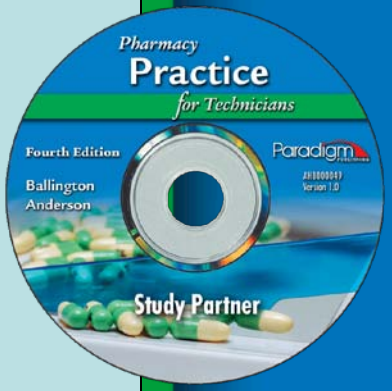
IV Administration Flow Rates

Safety Note

Always carefully check and double-check all calculations.

Electrolytes

- Many IV fluids contain electrolytes (dissolved mineral salts).
- Electrolyte solutions are measured in standard metric units and also in milliequivalents (mEq), which are related to molecular weight.
- To add a milliequivalent amount of electrolyte solution, set up a proportion using known and unknown ratios and solve using the ratio-proportion method.



Terms to Remember

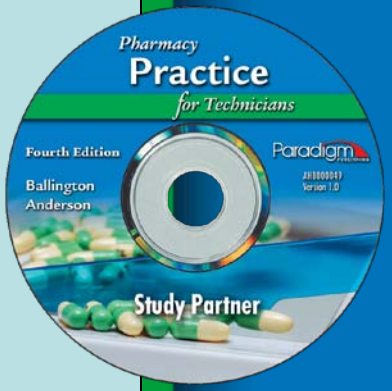
electrolyte

a dissolved mineral salt, commonly found in IV fluids

Hazardous Agents

Pharmacy personnel often come into contact with hazardous agents, such as cytotoxic drugs used in

- Cancer chemotherapy
- Antiviral treatment for HIV patients
- Biological hormones
- Bioengineered drugs
- Radioactive pharmaceuticals



Terms to Remember

cytotoxic drug

a hazardous drug that must be handled and prepared with extra precaution; can be a drug used in cancer chemotherapy, an antiviral drug for a patient with HIV, a biological hormone, a bioengineered drug, or a radioactive pharmaceutical

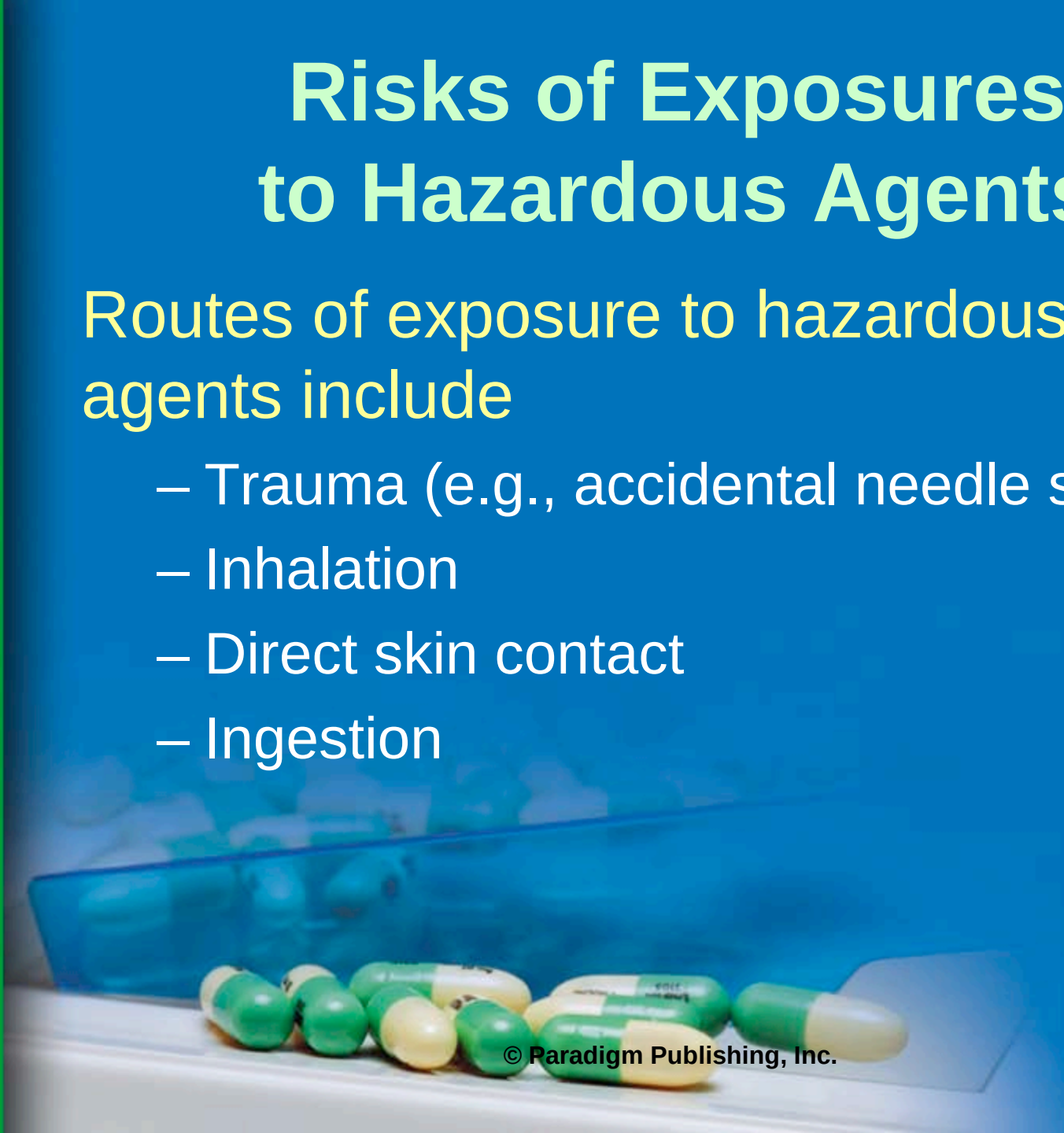
Hazardous Agents

- Risks of exposures to hazardous agents
- Receipt and storage of hazardous agents
- Protective clothing
- Handling and preparation of hazardous agents
- Hazardous agent spills
- Procedures in case of exposure

Risks of Exposures to Hazardous Agents

Routes of exposure to hazardous agents include

- Trauma (e.g., accidental needle sticks)
- Inhalation
- Direct skin contact
- Ingestion



Risks of Exposures to Hazardous Agents

- Exposure to hazardous agents can cause acute, chronic, and/or long-term health risks.
- Acute risks may be from contact resulting in skin rashes, allergic reactions, or hair loss.

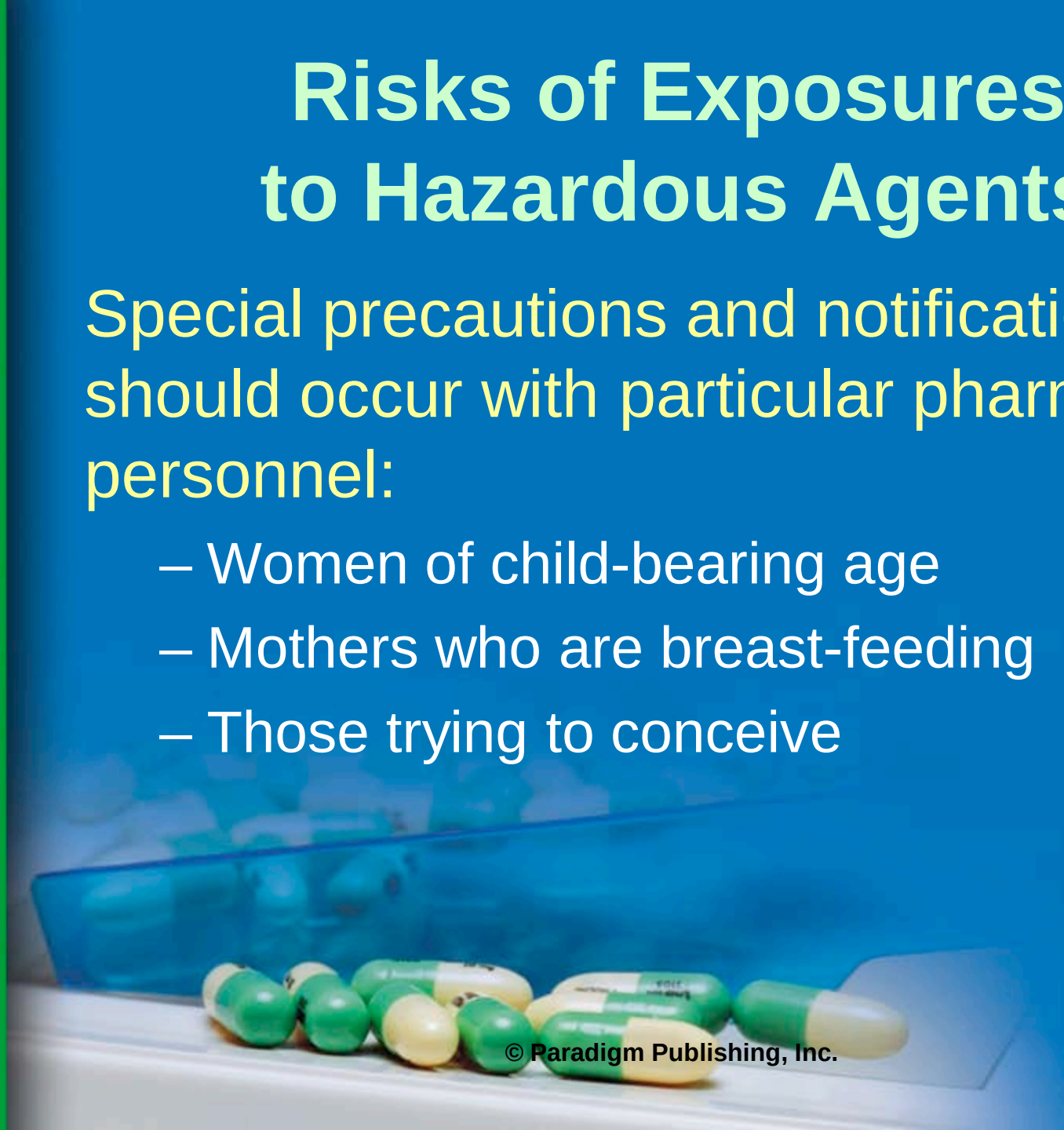
Risks of Exposures to Hazardous Agents

- Chronic exposure can result in infertility, spontaneous abortions, low-birth-weight infants, or congenital malformations.
- Long-term risks can include higher risk for certain cancers.

Risks of Exposures to Hazardous Agents

Special precautions and notifications should occur with particular pharmacy personnel:

- Women of child-bearing age
- Mothers who are breast-feeding
- Those trying to conceive

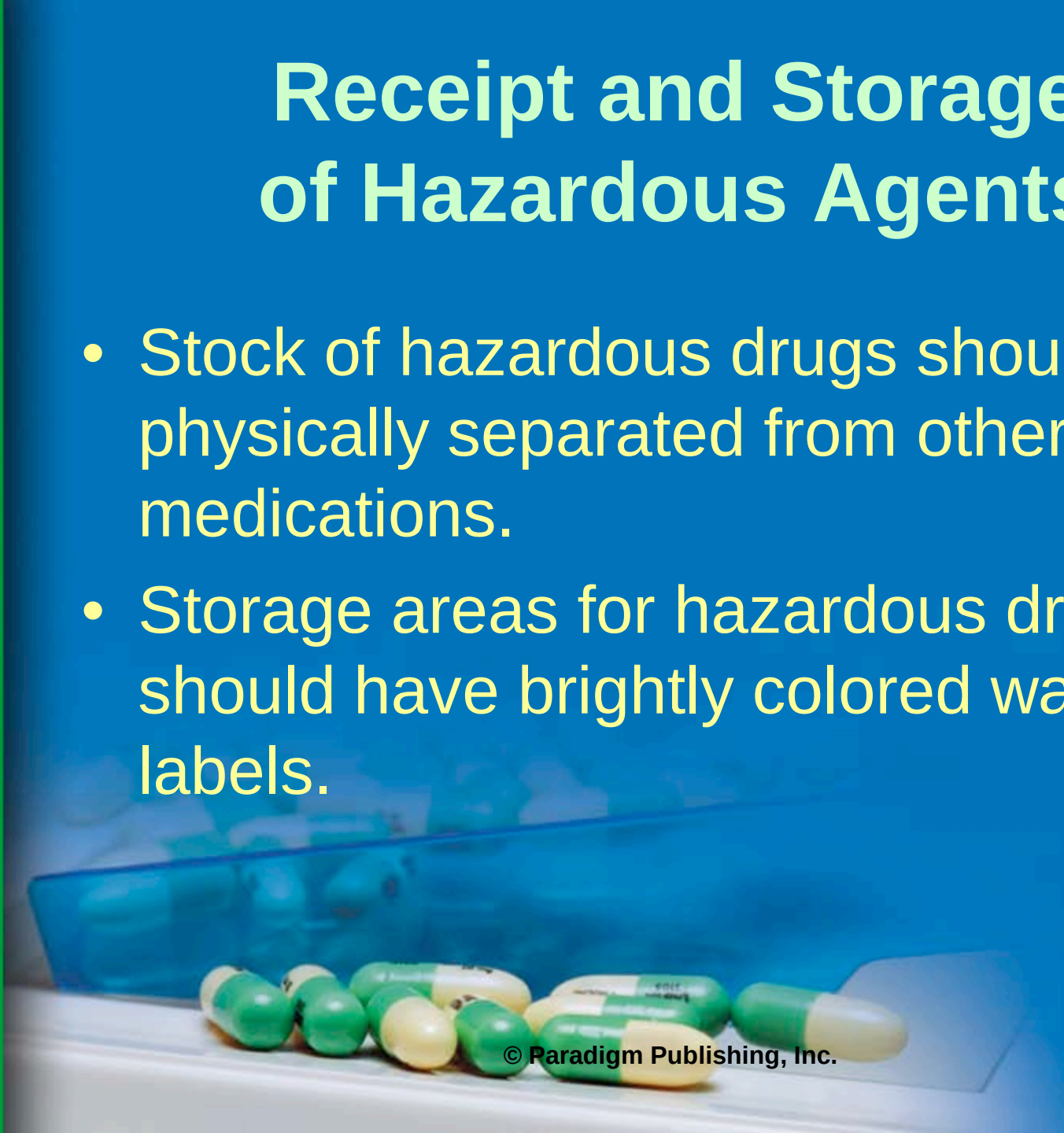


Receipt and Storage of Hazardous Agents

- Pharmacy technician must wear gloves when working with hazardous agents (includes receiving, stocking, inventorying, disposing and preparing).
- Hazardous drugs should be delivered directly to the storage area and inventoried.

Receipt and Storage of Hazardous Agents

- Stock of hazardous drugs should be physically separated from other medications.
- Storage areas for hazardous drugs should have brightly colored warning labels.



Protective Clothing

Working with cytotoxic drugs requires additional protective clothing:

- Disposable gown with cuffed sleeves
- Hair and shoe covers
- Eye protection and mask
- Double latex gloves

Protective Clothing

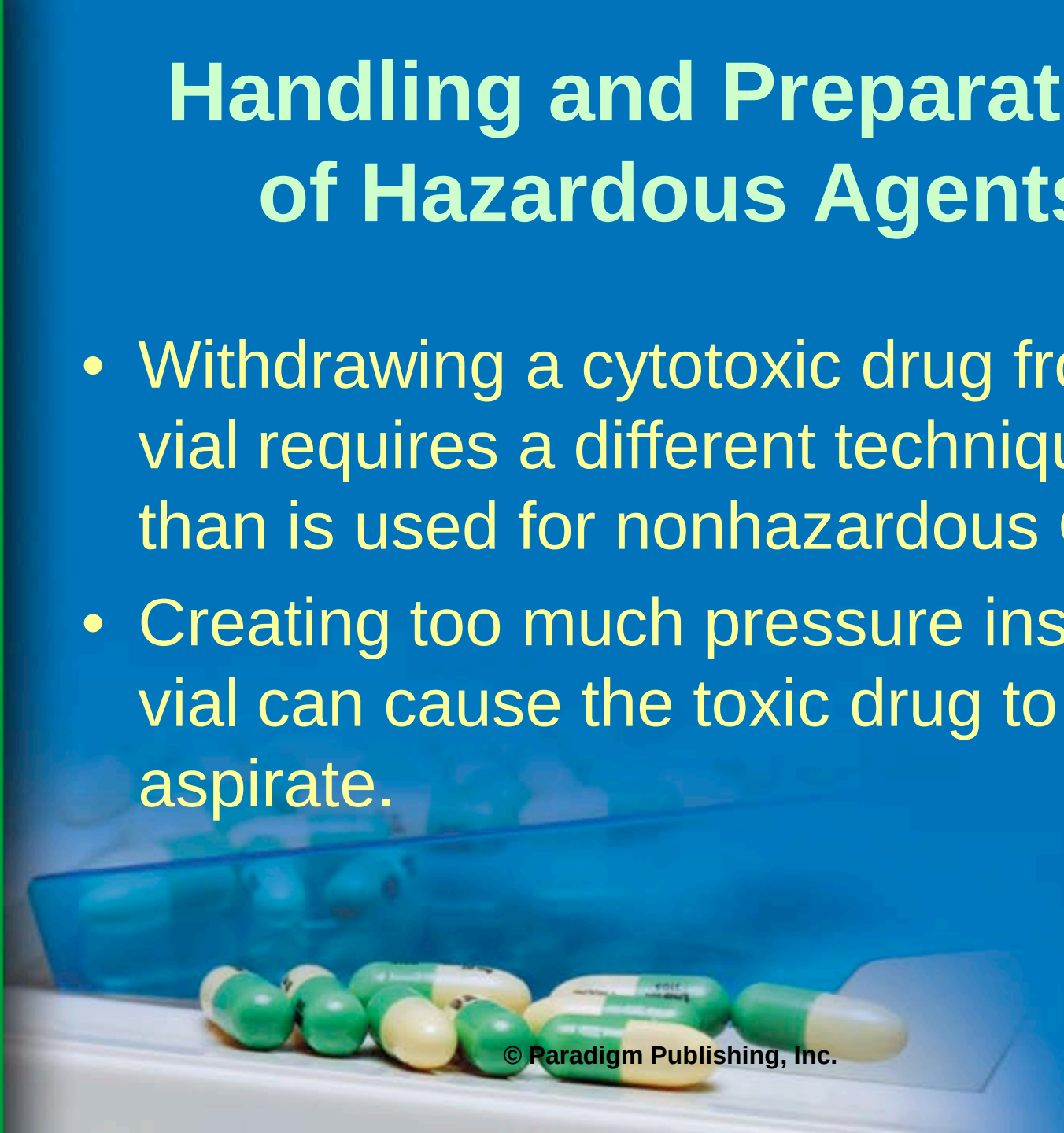
- Gloved hands should be washed to remove powder particles.
- Gloves should be
  - Changed every 20 to 30 minutes of continuous use
  - Turned inside out as they are removed
  - Disposed of in designated hazardous waste containers

Handling and Preparation of Hazardous Agents

- A closed system transfer device (CSTD) is the safest way to deliver hazardous agents.
- Hazardous agents are not always available in a CSTD due to stability or other concerns.
- The pharmacy technician must prepare these agents manually.

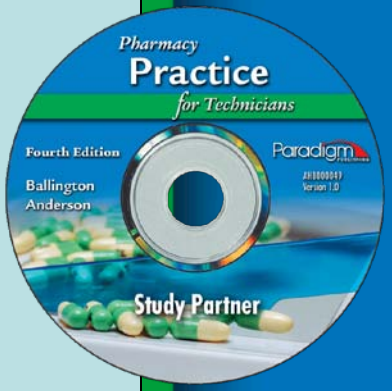
Handling and Preparation of Hazardous Agents

- Withdrawing a cytotoxic drug from a vial requires a different technique than is used for nonhazardous CSPs.
- Creating too much pressure inside the vial can cause the toxic drug to aspirate.



Handling and Preparation of Hazardous Agents

- The pharmacy technician should introduce an amount of air equal to only about 75% of the solution volume.
- A chemo venting pin can also be used to equalize the air pressure in the vial.



Terms to Remember

chemo venting pin

a device used to equalize pressure in the preparation of hazardous drugs

Handling and Preparation of Hazardous Agents

Safety Note

With hazardous drugs, inject a volume of air that is no more than 75% of the amount of drug to be withdrawn.

Handling and Preparation of Hazardous Agents

- Preparation of IV sets containing cytotoxic drugs should done under a vertical laminar airflow workbench (LAFW).
- Priming of the IV tubing should also be done under the vertical LAFW.
- Garb used in preparation and administration should be disposed of in a hazardous waste container.

Handling and Preparation of Hazardous Agents

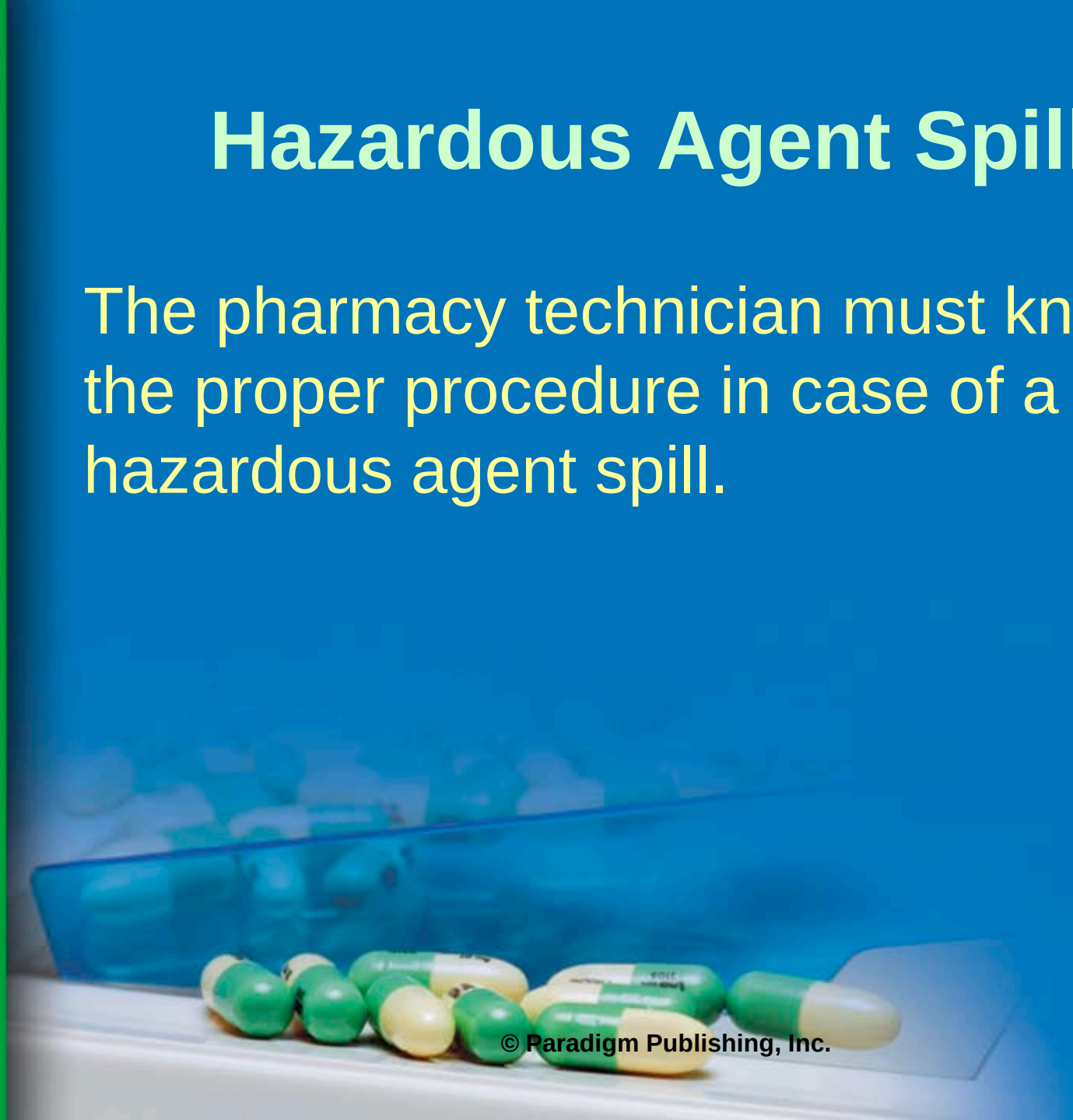
- Special care should be taken in handling hazardous oral medications.
- Workers should wear gloves, gown, and a respirator.

Handling and Preparation of Hazardous Agents

- Equipment should be immediately cleaned and rinsed.
- Automated counting and packaging machines should not be used.

Hazardous Agent Spills

The pharmacy technician must know the proper procedure in case of a hazardous agent spill.



Hazardous Agent Spills

All spills must be cleaned up immediately with a commercial spill kit or one assembled with the following:

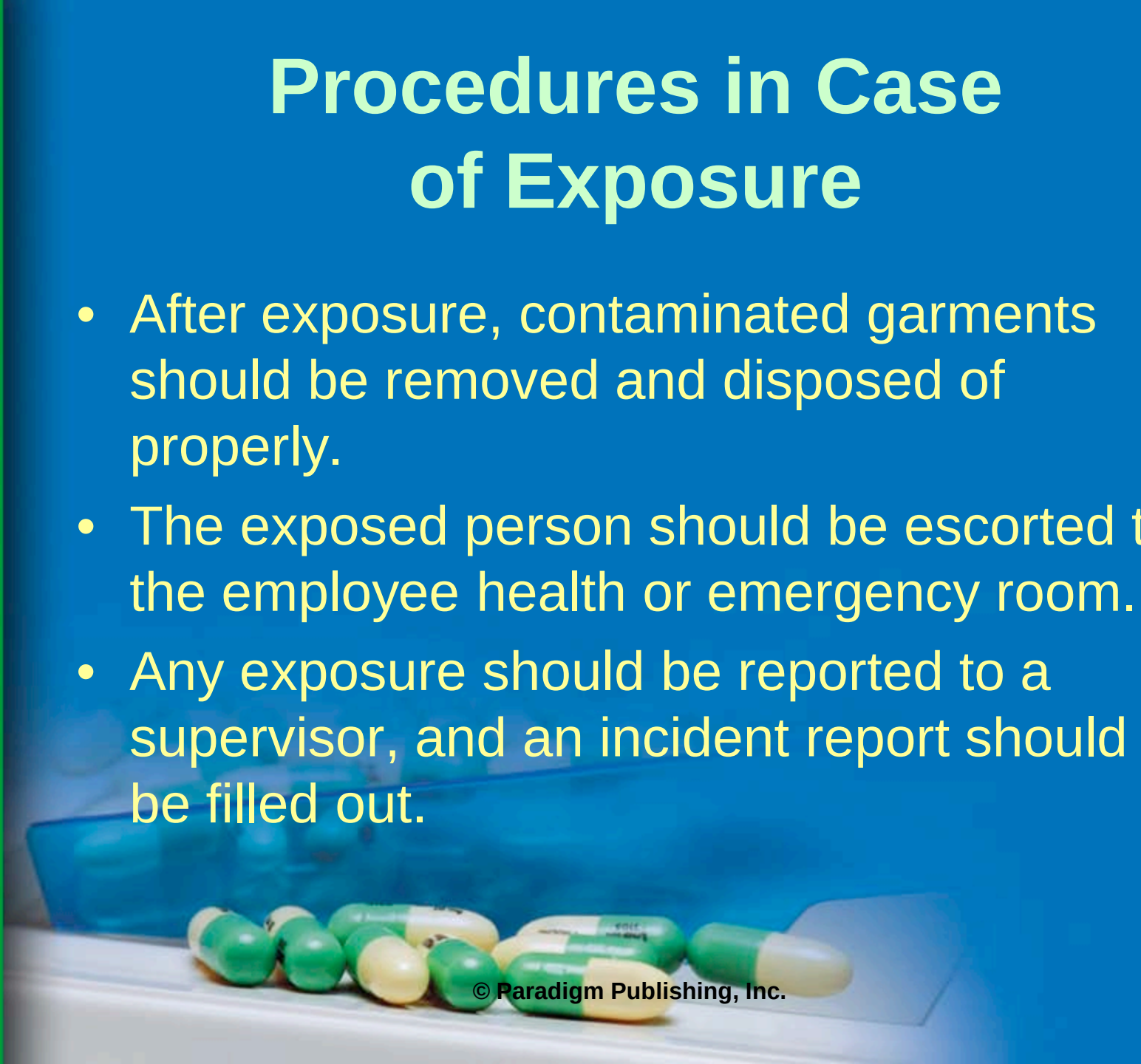
- Nonabsorbent gown and gloves (2 pairs)
- Respirator mask and goggles
- Absorbent towels and spill control pillows
- Scoop and brush
- Plastic disposal bags labeled “Chemo Waste”
- Chemo hazard labels and a sign reading “CAUTION: Chemo Spill”

Procedures in Case of Exposure

- All hazardous materials have a Material Safety Data Sheet (MSDS) with instructions on how to handle an exposure.
- Exposed skin should be flooded with water immediately and cleaned with soap and water.
- Eyes should be flushed with large amounts of water (or use an eye flush kit).

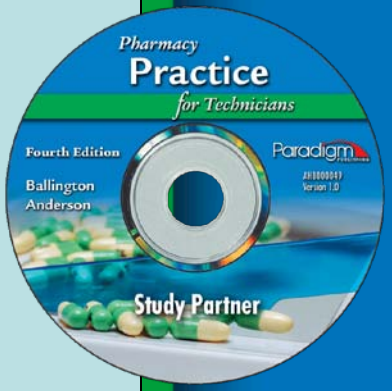
Procedures in Case of Exposure

- After exposure, contaminated garments should be removed and disposed of properly.
- The exposed person should be escorted to the employee health or emergency room.
- Any exposure should be reported to a supervisor, and an incident report should be filled out.



Quality Assurance

- All hospital pharmacies must have a quality assurance (QA) plan.
- QA programs are not to assign blame, but rather are to fix systems.



Terms to Remember

quality assurance (QA) program

a feedback system to improve care by identifying and correcting the cause of a medication error or improper technique

Quality Assurance

- Pharmacy should have a procedure for environmental monitoring of clean room, LAFW, buffer area, and ante area.
- Sampling of air, work surfaces, and glove tips should be done routinely.

Quality Assurance

- All hospital personnel must have training in dealing with hazardous agents.
- Pharmacy personnel must be trained in aseptic technique.
- Training must be documented and repeated yearly.