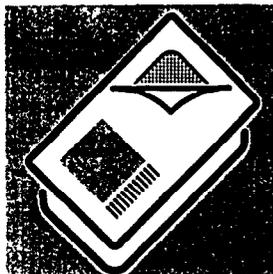


Document type: SPECIFICATION	Document No.: RM-H3201B	Issue Date:	Previous Date:	Origination Office: DIS	Revision:	Page:
Product name: IV Start Pak	Description: Unit Label	Catalog No.: 386144	Authorized Change Notice #:	Initiator Signature and Date		

PRINT CARD

Color: PMS 272 Violet

REF 386144



IV Start Pak™

I.V. Site Prep Kit
 Equipo de preparación del lugar de punción I.V.
 Kit de prep. de local I.V.
 Trousse de préparation pour ponction intraveineuse
 Desinfektionsset
 Kit per la preparazione del punto I.V.
 Voorbehandelingsset voor I.V. punctieplaats
 Preparationsutrustning för IV-stället
 Kit for klargöring af I.V. område
 静注部位プレップキット
 I.V.部位小箱



Becton Dickinson Infusion Therapy Systems Inc.
 Sandy, UT 84070, Packaged in Mexico
 Gloves from Canada.

H3201B (4-00)



STERILE EO



4.875"

7.000"



REF 442001



BD BACTEC™
Blood Culture Procedural Tray 2

- BACTEC™ Standard 18 Aerobuck Bottle
- BACTEC™ Standard Anaerobuck Bottle
- PERSIST™ Iodine Prep
- SAFETY-LOC™ Blood Collection Set
- Stretch Tourniquet (Latex Free)
- Alcohol Prep Pad (2)
- VACUTAINER™ Brand Holder
- Gloves (Latex Free)
- Elastic Bandage (Latex Free)
- Gauze Pads (2)
- Instruction Sheet
- Specimen Collection Bag

The Product Contains Dry Natural Rubber
Caution: This Product Contains
Natural Rubber Latex Which May Cause
An Allergic Reaction.

BD, BD Logo, BACTEC, PERSIST,
SAFETY-LOC, and VACUTAINER are
trademarks of Becton, Dickinson
and Company

Becton, Dickinson and
Company, Sparks, MD 21152



IVD

in vitro Diagnostic



Drug Facts	
Active Ingredient Isopropyl Alcohol, 70% w/v	Purposes Antiseptic
Use • For the preparation of skin prior to an injection to decrease germs in minor cuts and scrapes	
Warnings • For external use only	
Keep out of the reach of children. If swallowed, get medical help or contact a poison control center immediately	
Caution. Do not apply to irritated skin.	
Do not use in the eyes, or on mucous membranes In case of deep or puncture wounds, consult a doctor.	
Directions: Wipe injection site vigorously.	
Other information: Store at room temperature.	
Inactive ingredient: Water	



Drug Facts	
Active Ingredients Povidone-iodine 10% (w/v) Ethyl Alcohol 70% (v/v)	Purposes Antiseptic Antiseptic
Uses • As a patient preoperative skin preparation: Helps to reduce bacteria that potentially can cause skin infection • to cleanse the skin prior to percutaneous procedure or injection • Follow-up site care	
Warnings • For external uses only • Contains alcohol which is flammable until dry • Do not use with electrocautery procedure	
Do not use: • if you are allergic to povidone iodine or ethyl alcohol • to treat wounds or burns • in eyes, mucous membranes • on broken skin	
Stop use and ask a doctor if site becomes: • red • irritated • swollen • painful • infected	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions • Apply with friction • Allow to air dry • Do not blot or wipe away	
Inactive ingredients acrylates copolymer, ethyl acetate, isopropyl myristate, urea, water	

L001785 (C)

Notes: Color band at top is PMS Process Yellow and PMS Process Blue
All other color is PMS 2755 Blue
Lot and Expiry to be printed online at time of manufacture.

TOP WEB PRINT AREA

BOTTOM WEB PRINT AREA

 **BD Persist™** Site Prep REF 38XXXX

Drug Facts

Active Ingredients	Purposes
Povidone-Iodine 10% (w/v)	Antiseptic
Ethyl Alcohol 70% (v/v)	Antiseptic

Uses • As a patient preoperative skin preparation: Helps to reduce bacteria that potentially can cause skin infection • To cleanse the skin prior to percutaneous procedures or injection • Follow-up site care

Warnings • For external uses only • Contains alcohol which is flammable until dry • Do not use with electrocautery procedure ▼

Drug Facts (continued)

Do not use • if you are allergic to povidone iodine or ethyl alcohol • To treat wounds or burns • In eyes, mucus membranes • on broken skin

Stop use and ask a doctor if site becomes: • red • irritated • swollen • painful • infected

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions • Apply with friction • Allow to air dry • Do not blot or wipe away

Inactive ingredients: acrylates copolymer, ethyl acetate, isopropyl myristate, urea, water

One Swab Stick • DIN 02213362
Becton Dickinson Infusion Therapy Systems Inc., Sandy, Utah 84070 USA. XXXXX (6-01)

5 Point Condensed Type

REF 386411



.....TEAR.....

Persist™
Protective Barrier
With Chlorhexidine
In Alcohol



XC214A (4-97)

Manufactured by:
Becton Dickinson Infusion
Therapy Systems Inc.
Sandy, UT 84070
Distributed in Canada by:
Becton Dickinson Canada Inc.
Mississauga, Ontario L5J 2M8

Contains 1% Chlorhexidine Gluconate
with 75% Ethanol. Protective Barrier has
minimum 4% Chlorhexidine Gluconate.
DIRECTIONS: Apply to intended catheter
insertion site. Allow to dry to form protec-

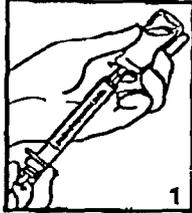
tive barrier.
Warnings: Keep this product out of the reach of chil-
dren. Keep out of eyes and ears. In case of ocular
injury, seek professional assistance or contact a
Poison Control Center immediately. Contains Alcohol
which is flammable until dry. For external use only.
Store at room temperature.

Drug Facts	
Active ingredient	Purpose
Chlorhexidine gluconate 1% w/w	Antiseptic
Ethyl alcohol 75% v/v	Antiseptic
Uses	
<ul style="list-style-type: none"> • To form a barrier between the skin and device to prevent Catheter Related Bloodstream Infections; to prevent localized site infection; and to reduce skin recolonization • To disinfect the skin prior to vascular or non-vascular procedures • To protect the skin from irritating effects of adhesives and dressings • For follow-up site management 	
Warnings	
<ul style="list-style-type: none"> • For external use only. • Contains alcohol which is flammable until dry • Flammable, keep away from fire or flame • Do not use with electrocautery procedures 	
Do not use	
<ul style="list-style-type: none"> • In children less than 27 weeks gestational age because of potential for excessive skin irritation and increased drug absorption • if you are allergic to Chlorhexidine gluconate or ethyl alcohol • to treat wounds or burns • in eyes, ears, mucus membranes • on broken skin • directly on meninges 	
Stop use and ask a doctor if site becomes:	
<ul style="list-style-type: none"> • red • swollen • painful • infected 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Apply with friction. • Allow to dry. Do not blot or wipe away. 	
Other information Avoid storage temperature above 40°C (104°F).	
Inactive ingredients colorants, ethyl cellulose, fragrance, poloxamers, USP purified water	
Questions? 1.888.237.2762 Weekdays (8 AM to 4:30 PM Mountain Time)	

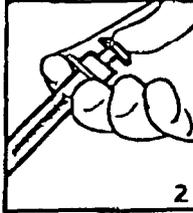
Device Label - Syringe Directions for Use

DIRECTIONS FOR USE:

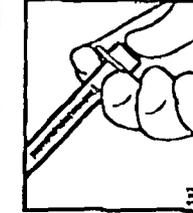
Do NOT use this product to draw blood or for venipuncture.



1. Draw up medication in accordance with established protocol.



2. Administer medication in accordance with established protocols, making sure that all medication has been dispensed.



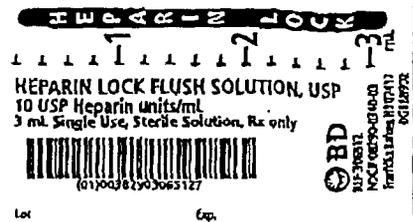
3. Push to activate the safety mechanism. Depress the plunger until you sense two "clicks." The needle will disappear into the syringe and the plunger will be recessed into the barrel when activation is complete.

4. Discard after single use in an approved sharps container in accordance with applicable regulations and institutional policy.

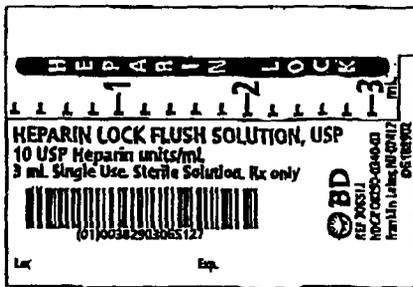
CAUTION: If you must transport the filled syringe to the point of administration, use a safe, passive recapping technique to cover the needle before transporting. OSHA standards require that such recapping must be accomplished using a one-handed technique. DO NOT hold the needle shield during the recapping process.

NOTE: 1. This syringe is designed to allow for activation with the needle outside the patient or inside the patient, based on your Institutional protocol.
2. Activation of the device outside the patient may cause minimal splatter. For greatest safety, activate the device away from self and others.
3. When activating the device inside the patient, do not advance the needle further into the patient as the plunger is being depressed.

CURRENT REV	
Rev. #	Descriptio
01	Initial R
02	Add US



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FULL SIZE REPRESENTATION

FOR REFERENCE

GRAPHICS FI

DRAWING SIZE:	N/A
TOLERANCES:	N/A
SCALE:	FULL

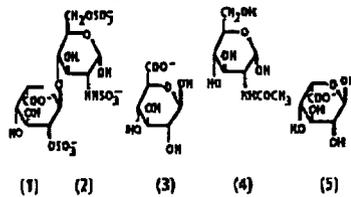
This controlled

Heparin Lock Flush Solution, USP

BD Pre-Filled Heparin Lock Flush Syringe

DESCRIPTION:

Heparin is a heterogeneous group of straight-chain anionic mucopolysaccharides, called glycosaminoglycans, having anticoagulant properties. Although others may be present, the main sugars occurring in heparin are: (1) α -L-iduronic acid 2-sulfate, (2) 2-deoxy-2-sulfamino- α -D-glucose 6-sulfate, (3) β -D-glucuronic acid, (4) 2-acetamido-2-deoxy- α -D-glucose, and (5) α -L-iduronic acid. These sugars are present in decreasing amounts, usually in the order (2)>(1)>(4)>(3)>(5), and are joined by glycosidic linkages, forming polymers of varying sizes. Heparin is usually acidic because of its content of covalently linked sulfate and carboxylic acid groups. In heparin sodium, the acidic protons of the sulfate units are partially replaced by sodium ions. Its structural formula (representative subunits) is as follows:



Heparin Lock Flush Solution, USP, is a sterile solution of heparin sodium derived from porcine intestinal mucosa. It is provided in either 10 or 100 USP Heparin Units/mL concentrations in 0.9% Sodium Chloride Injection, USP (isotonic) packaged in a plastic, disposable, single use, latex free syringe. Solution pH is 5.0-7.5. BD Pre-Filled Heparin Lock Flush Syringes contain trace amounts of the preservatives methylparaben and propylparaben.

CLINICAL PHARMACOLOGY:

Heparin inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*. Heparin acts at multiple sites in the normal coagulation system. Small amounts of heparin in combination with antithrombin III (heparin cofactor) can inhibit thrombosis by inactivating activated Factor X and inhibiting the conversion of prothrombin to thrombin. Once active thrombosis has developed, larger amounts of heparin can inhibit further coagulation by inactivating thrombin and preventing the conversion of fibrinogen to fibrin. Heparin also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor. Bleeding time is usually unaffected by heparin. Clotting time is prolonged by full therapeutic doses of heparin; in most cases, it is not measurably affected by low doses of heparin. Patients over 60 years of age, following similar doses of heparin, may have higher plasma levels of heparin and longer activated prothrombin times (APTTs) compared with patients under 60 years of age.

INDICATIONS AND USAGE:

BD Pre-Filled Heparin Lock Flush Syringes are intended for maintenance of patency of vascular access devices only. They are not to be used for anticoagulant therapy.

CONTRAINDICATIONS:

Heparin sodium should NOT be used in patients with an uncontrollable active bleeding state (see WARNINGS) except when this is due to disseminated intravascular coagulation.

WARNINGS:

Heparin Lock Flush Solution should be used with caution in infants with disease states in which there is an increased danger of hemorrhage. Neonatologists do not advise the use of the 100 units/mL concentration because of the risk of bleeding, especially in low birth weight infants. Heparin is not intended for intramuscular use.

Hypersensitivity. Patients with documented hypersensitivity to heparin should be given the

drug only in clearly life-threatening situations. (see ADVERSE REACTIONS).

Thrombocytopenia. Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0% to 30%. Mild thrombocytopenia (count greater than 100,000/mm³) may remain stable or reverse even if heparin is continued. However, thrombocytopenia of any degree should be monitored closely. If the count falls below 100,000/mm³ or if recurrent thrombosis develops (see White Clot Syndrome, PRECAUTIONS), the heparin product should be discontinued. If continued heparin therapy is essential, administration of heparin from a different organ source can be reinstated with caution.

Miscellaneous. BD Pre-Filled heparin Lock Flush Syringes contain trace amounts of the preservatives methylparaben and propylparaben.

PRECAUTIONS:

Do not use if: package is not intact, syringe is damaged, syringe exhibits any evidence of leakage, or syringe tip cap is improperly affixed or dislodged from syringe tip. Caution must be exercised to avoid the pharmacological effects of heparin. Consideration should be given to the cumulative amounts of heparin received from the frequent administration of Heparin Lock Flush Solution during a 24-hour period, especially in infants and the elderly. Heparin Lock Flush Solution should be used with caution in patients receiving drugs such as aspirin, dextran, phenylbutazone, ibuprofen, indomethacin, dipyridamole, hydroxychloroquine, and others that interfere with platelet reactions (the main hemostatic defense of heparinized patients). The drugs may induce bleeding in patients receiving heparin. Patients over 60 years of age may require lower doses of heparin. **Laboratory tests:** Periodic platelet counts, hematocrits and tests for occult blood in stool are commended during the entire period of use of Heparin Lock Flush Solution.

White Clot Syndrome

It has been reported that patients on heparin may develop new thrombus formation in association with thrombocytopenia resulting from irreversible aggregation of platelets induced by heparin, the so-called "white clot syndrome." The process may lead to severe thromboembolic complications like skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke, and possibly death. Therefore, heparin administration should be promptly discontinued if a patient develops new thrombosis in association with thrombocytopenia. Precautions must be exercised when drugs which are incompatible with heparin are administered through an indwelling intravenous catheter containing Heparin Lock Flush Solution. (see DOSAGE AND ADMINISTRATION).

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term studies in animals have been performed to evaluate the carcinogenic potential of heparin. Also, no reproduction studies in animals have been performed concerning mutagenesis or impairment of fertility.

Pregnancy

Pregnancy Category C

Teratogenic Effects: Animal reproduction studies have not been conducted with heparin sodium. It is also not known whether heparin sodium can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Heparin sodium should be given to a pregnant woman only if clearly needed.

Nonteratogenic Effects: Heparin does not cross the placental barrier.

Nursing Mothers

Heparin is not excreted in human milk.

ADVERSE REACTIONS:

Hemorrhage

Hemorrhage is the chief complication that may result from heparin. An overly prolonged clotting time or minor bleeding during therapy can usually be controlled by withdrawing the drug (See OVERDOSAGE).

Hypersensitivity

Generalized hypersensitivity reactions have been reported, with chills, fever, and urticaria as the most usual manifestations, and asthma, rhinitis, lacrimation, headache, nausea and vomiting, and anaphylactoid reactions, including shock, occurring more rarely. Itching and burning, especially on the plantar side of the feet, may occur.

Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of 0% to 30%. While often mild and of no obvious clinical significance, such thrombocytopenia can be accompanied by severe thromboembolic complications such as skin necrosis, gangrene of the extremities that may lead to amputation, myocardial infarction, pulmonary embolism, stroke, and possibly death. (See WARNINGS and PRECAUTIONS). Certain episodes of painful, ischemic, and cyanosed limbs have in the past been attributed to allergic vasospastic reactions. Whether these are in fact identical to the thrombocytopenia-associated complications remains to be determined.

OVERDOSAGE:

Symptoms. Bleeding is the chief sign of heparin overdosage. Nosebleeds, blood in urine or tarry stools may be noted as the first sign of bleeding. Easy bruising or petechial formations may precede frank bleeding.

Treatment. Neutralization of heparin effect. When clinical circumstances (bleeding) require reversal of heparinization, protamine sulfate (1% Injection) by slow infusion will neutralize heparin sodium. No more than 50 mg should be administered, very slowly, in any 10 minute period. Each mg of protamine sulfate neutralizes approximately 100 USP heparin units. The amount of protamine required decreases over time as heparin is metabolized. Although the metabolism of heparin is complex, it may, for the purpose of choosing a protamine dose, be assumed to have a half-life of about 1/2 hour after intravenous injection. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions often resembling anaphylaxis have been reported, the drug should be given only when resuscitation techniques and treatment of anaphylactoid shock are readily available. For additional information, consult the labeling of Protamine Sulfate Injection, products.

DOSAGE AND ADMINISTRATION:

PARENTERAL DRUG PRODUCTS SHOULD BE INSPECTED VISUALLY FOR PARTICULATE MATTER AND DISCOLORATION PRIOR TO ADMINISTRATION, WHENEVER SOLUTION AND CONTAINER PERMIT. SLIGHT DISCOLORATION DOES NOT ALTER POTENCY.

Heparin Lock Flush Solution, USP is not recommended for use in the neonate.

Clearing Intermittent Infusion (Heparin Lock) Sets

To prevent clot formation in a heparin lock set following its proper insertion, Heparin Lock Flush Solution is injected via the injection hub in a quantity sufficient to fill the entire set to the needle tip. This solution should be replaced each time the heparin lock is used. Aspirate before administering any solution via the lock in order to confirm patency and location of needle or catheter tip. If the drug to be administered is incompatible with heparin, the entire heparin lock set should be flushed with sterile water or normal saline before and after the medication is administered; following the second flush, Heparin Lock Flush Solution may be reinstalled into the set. The set manufacturer's instructions should be consulted for specifics concerning the heparin lock set in use at a given time.

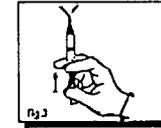
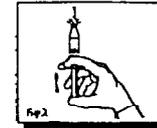
Geriatric Use: Patients over 60 years of age may require lower doses of heparin. The selection of the appropriate concentration of Heparin Lock Flush Solution, USP should be based on current practice standards and institutional policies and procedures. Heparin Lock Flush Solution, USP 100 USP Units/mL, is injected as a single dose into an intravenous injection device using a volume of solution equivalent to that of the indwelling venipuncture device (see catheter manufacturer's instructions labeling for specific catheter lumen volumes). After each use of the indwelling venipuncture device for injection or infusion of medication, or withdrawal of blood samples, another dose (using a volume of solution equivalent to that of the indwelling venipuncture device)- should be injected to restore the effectiveness of the heparin lock. The amount of heparin solution in each single dose is sufficient to prevent clotting within the lumen of indwelling venipuncture devices for up to twenty-four hours. When the drug injection to be administered is incompatible with heparin, a flush of the intravenous access device with 0.9% Sodium Chloride Injection, USP, should precede and follow the use of the Heparin Lock Flush Solution; appropriate literature should be consulted to verify compatibility between the drug injection and sodium chloride injection.

NOTE: Since repeated injections of small doses of heparin can alter tests for activated partial thromboplastin time (APTT), a baseline value for APTT should be obtained prior to insertion of a heparin lock set.

Withdrawal of Blood Samples

Heparin Lock Flush Solution may also be used after each withdrawal of blood for laboratory tests. When heparin (or sodium chloride) would interfere with or alter the results of blood tests, the heparin solution should be cleared from the device by aspirating and discarding it before withdrawing the blood sample.

DIRECTIONS FOR USE:



1. Tear open package and remove syringe.
2. Using aseptic technique, remove the syringe tip cap from the syringe by twisting off (Fig.1).
3. Attach Blunt Plastic Cannula, if required, for flushing a needleless I.V. system with pre-slit septum. For traditional ports, attach a needle with safety engineered feature as required by the OSHA Bloodborne Pathogens Standard.
4. Hold the syringe upright and expel the air in the syringe (Fig. 2).
NOTE: BD™ Blunt Plastic Cannula Utilization - When expelling air/fluid from a syringe, contents exit sideways from the cannula in two separate paths (Fig. 3). Expel air or fluid carefully, directing flow paths away from face or mucous membranes.
5. Attach the syringe to the port, valve or needleless system and flush following institution's policy and indwelling manufacturer's recommendations.
6. Discard used syringe and any unused portion of the solution according to the Institution policy. **DO NOT REUSE.**

We guarantee the solution in our unopened, undamaged syringes to be sterile, non-toxic and non-pyrogenic.

Store at 20°C to 25°C (68-77°F); excursions permitted to 15-30°C (59° F to 86°F); do not freeze. Federal (USA) law restricts this device to sale by or on the order of a physician.

HOW SUPPLIED:

BD™ Pre-Filled Heparin Lock Flush Syringes are available in various fill volumes and syringe sizes. Single syringes and combination packages are available with a standard luer lock fitting or with BD™ Blunt Plastic Cannula.

- Reorder No. 306527 Flush Syringe 2mL USP Heparin Lock Flush Solution fill in 3mL syringe - 10 USP Heparin units/mL
- Reorder No. 306512 Flush Syringe 3mL USP Heparin Lock Flush Solution fill in 3mL syringe - 10 USP Heparin units/mL
- Reorder No. 306511 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 5mL syringe - 10 USP Heparin units/mL
- Reorder No. 306521 Flush Syringe 3mL USP Heparin Lock Flush Solution fill in 10mL syringe - 10 USP Heparin units/mL
- Reorder No. 306510 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 10mL syringe - 10 USP Heparin units/mL
- Reorder No. 306509 Flush Syringe 6mL USP Heparin Lock Flush Solution fill in 10mL syringe - 10 USP Heparin units/mL
- Reorder No. 306525 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 10mL syringe - 10 USP Heparin units/mL with Blunt Plastic Cannula
- Reorder No. 306528 Flush Syringe 2mL USP Heparin Lock Flush Solution fill in 3mL syringe - 100 USP Heparin units/mL
- Reorder No. 306517 Flush Syringe 3mL USP Heparin Lock Flush Solution fill in 3mL syringe - 100 USP Heparin units/mL
- Reorder No. 306516 Flush Syringe 3mL USP Heparin Lock Flush Solution fill in 5mL syringe - 100 USP Heparin units/mL
- Reorder No. 306515 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 5mL syringe - 100 USP Heparin units/mL
- Reorder No. 306529 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 5mL syringe - 100 USP Heparin units/mL with Blunt Plastic Cannula
- Reorder No. 306514 Flush Syringe 3mL USP Heparin Lock Flush Solution fill in 10mL syringe - 100 USP Heparin units/mL
- Reorder No. 306513 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 10mL syringe - 100 USP Heparin units/mL
- Reorder No. 306531 Flush Syringe 5mL USP Heparin Lock Flush Solution fill in 10mL syringe - 100 USP Heparin units/mL with Blunt Plastic Cannula
- Reorder No. 306538 SASH Kit, 3mL fill in 3mL Syringe 10 USP Heparin units/mL
- Reorder No. 306539 SASH Kit, 3mL fill in 5mL Syringe 100 USP Heparin units/mL
- Reorder No. 306537 SASH Kit, 5mL fill in 10mL Syringe 100 USP Heparin units/mL

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