REBOA Catheter Convenience Set

Instructions for Use

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P/N 12-7001 Rev B

REBOA CATHETER CONVENIENCE SET

CAUTION:

- USA Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- Prior to use, read this entire Instructions for Use.
- The below instructions, warnings, precautions, and contraindications have been incorporated from the IFUs of the constituent parts of the REBOA Catheter Convenience Set. Please consult all labeling included in the REBOA Catheter Convenience Set packaging prior to use.

DEVICE DESCRIPTION:

The REBOA Catheter Convenience Set is comprised of components compatible with the Prytime ER-REBOA™, ER-REBOA PLUS™, and pREBOA-PRO™ Catheters. The Convenience Set is utilized for gaining access, placement and fixation of the catheter.

The Convenience Set includes the following sterile items in their original packaging:

Description	Manufacturer	Device Identifier
Access Needle, 18gaX7cm, Echogenic, Sterile	Merit Medical Systems, Inc.	AD18T71W-E
Percutaneous Sheath Introducer Set, 7fr w/.035" short guidewire, Sterile	Arrow International, Inc.	CP-08703
Safety Scalpel, #11, Sterile	Aspen Surgical Products, Inc.	372611
30ml Syringe, Sterile	Becton Dickinson and Company	302832
3/4 Drape, Sterile, Disposable	Halyard Health, Inc.	47628
Cath Clamp, 5fr, Sterile	Arrow International, Inc.	CC-00005
10ml 0.9% Saline Flush, Sterile, SFR	Becton Dickenson	306553
Suture, Nylon, 2-0, Armed, Sterile	J&J Ethicon	585H

The Catheters are sold separately.

INTENDED USE:

The REBOA Catheter Convenience Set is intended to aid in gaining vascular access, placement, and securing the Catheter to the patient. The suture in this kit is intended for temporary securement of the catheter clamp to the patient's skin. The suture and clamp are to be removed immediately after the catheter is withdrawn.

CONTRAINDICATIONS:

None known.

WARNINGS:

- Read all package insert warnings, precautions, and instructions for use. Failure to do so may result in severe patient injury or death.
- The items within the Convenience Set are provided in their own Sterile, Single Use packaging. Do not reuse, reprocess or resterilize. Reuse of the devices creates a potential risk of serious injury and/or infection which may lead to death.

PRECAUTIONS:

- The Arrow Percutaneous Sheath Introducer Set contains DEHP.

INSTRUCTIONS FOR USE:

Use sterile technique.

1. Follow Catheter Instructions for Use for placing the catheter.
2. Catheter Clamp with Fastener:
    a. Spread wings of rubber clamp and position on catheter as required to ensure proper tip location (refer to Fig. 1).

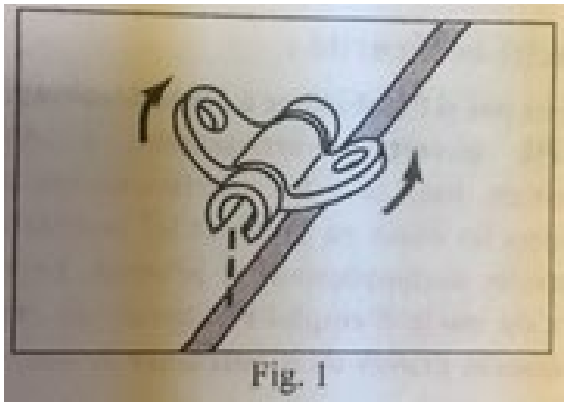
Fig. 1

b. Snap rigid fastener onto catheter clamp (refer to Fig. 2).

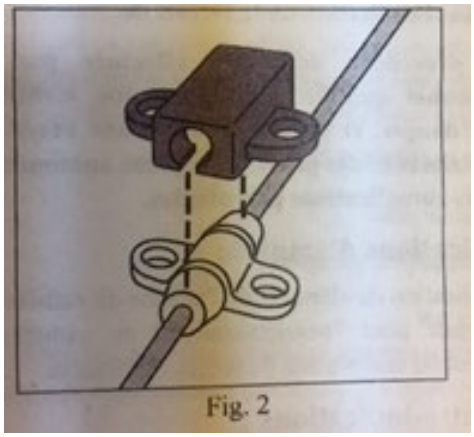

Fig. 2

c. Secure catheter to patient by suturing the catheter clamp with fastener together to the skin, using the side wings to minimize the risk of catheter migration (refer to Fig. 3).

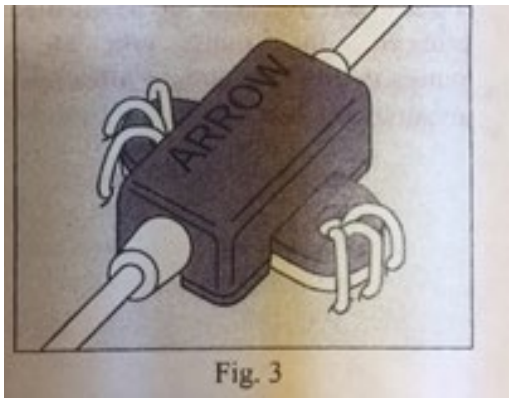

Fig. 3

d. Continue procedure per manufacturer's instructions.

HOW SUPPLIED

Each item within the REBOA Catheter Convenience Set is supplied sterile by the manufacturer. The individual sterile items are placed within a non-sterile over-pack. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

DEFINITIONS

Symbol	
	Read the Instructions for Use before using this product.
	Store the product appropriately in a cool, dry location.
	Do not re-sterilize this product.
	Do not reuse this product.
R_x ONLY	USA Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Inspected Dimensions:
Folded width: 5-1/2" (14 cm)
Folded length: 7-1/2" (19 cm)

Catheter Clamp and Fastener Product

Safety and Efficacy Considerations:

Do not use if package has been previously opened or damaged. Warning: Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.

Do not alter the catheter clamp or fastener during use or removal.

Procedure must be performed by trained personnel well versed in anatomical landmarks, safe technique, and potential complications.

Indications for Use:

The catheter clamp and fastener are indicated for use in securing catheter to patient or as a secondary suture site.

Contraindications:

None known.

Warnings and Precautions:*

1. **Warning: Sterile, Single use: Do not reuse, reprocess or resterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.**

2. **Precaution: Catheter clamp and fastener must not be attached to catheter until spring-wire guide is removed.**

A Suggested Procedure:
Use sterile technique.

1. Follow manufacturer's instructions for placing catheter.

2. After spring-wire guide has been removed and the necessary lines have been connected or locked, spread wings of rubber clamp and position on catheter as required to ensure proper tip location (refer to Fig. 1).

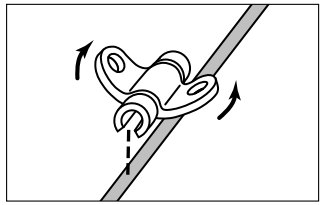

Fig. 1

3. Snap rigid fastener onto catheter clamp (refer to Fig. 2).

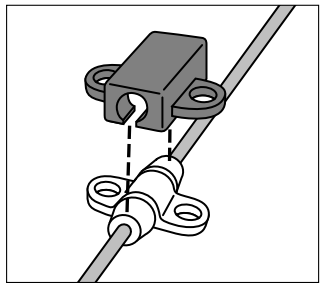

Fig. 2

4. Secure catheter to patient by suturing the catheter clamp and fastener together to the skin, using side wings to minimize the risk of catheter migration (refer to Fig. 3).

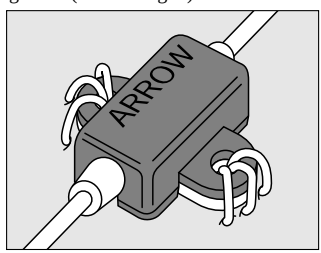

Fig. 3

5. Continue procedure per manufacturer's instructions.

*If you have any questions, please contact Arrow International, Inc.

Clamp et attache de cathéter

Efficacité et sécurité :

N'utilisez pas si l'emballage a été endommagé ou est déjà ouvert. Avertissement : Avant l'utilisation, lisez tous les avertissements ainsi que toutes les mises en garde et les instructions de la notice accompagnant le produit. Le non-respect du mode d'emploi risquerait de causer des blessures graves ou d'entraîner le décès du malade.

N'altérez pas le clamp ou l'attache du cathéter durant l'utilisation ou le retrait du matériel.

La procédure doit être effectuée par un personnel qualifié appliquant une technique sans danger, et faisant preuve d'une excellente connaissance des points de repères anatomiques et des complications potentielles.

Indications d'emploi :

L'utilisation du clamp et de l'attache du cathéter est indiquée pour l'assujettissement du cathéter au patient ou comme site de suture secondaire.

Contre-indications :

Aucune connue.

Avertissements et précautions : *

1. **Avertissement : Stérile, à usage unique : Ne pas réutiliser, retraiter ou restériliser. La réutilisation du produit crée un risque potentiel de blessure et/ou d'infection grave pouvant causer le décès.**
2. **Précaution : Il ne faut pas raccorder le clamp et l'attache du cathéter au cathéter avant d'en avoir retiré le fil de guidage métallisé spiralé.**

Procédure suggérée :
Utilisez la technique stérile.

1. Suivez les instructions du fabricant relatives à la mise en place du cathéter.
2. Après le retrait du fil de guidage métallisé spiralé et le raccordement ou le verrouillage des lignes nécessaires, écartez les ailes du clamp en caoutchouc et positionnez-le sur le cathéter comme cela est requis pour assurer une position correcte de l'extrémité (cf. Fig. 1).
3. Forcez l'attache rigide sur le clamp de cathéter (cf. Fig. 2).
4. Assujettissez le cathéter au patient en suturant ensemble le clamp et l'attache du cathéter à la peau, en utilisant des ailes latérales pour réduire au minimum le risque de migration du cathéter (cf. Fig. 3).
5. Continuez la procédure selon les instructions du fabricant.

* Si vous avez des questions, veuillez entrer en contact avec Arrow International, Inc.

Katheterklemme und Katheterhalter

Hinweise zur Sicherheit und Leistungsfähigkeit:

Nicht verwenden, wenn die Packung offen oder beschädigt ist. Warnung: Vor Gebrauch alle Warnungen, Vorsichtsmaßnahmen und Anleitungen in der Packungsbeilage lesen. Wenn dies nicht getan wird, kann es zu schweren Verletzungen oder zum Tod des Patienten kommen.

An der Katheterklemme und dem Katheterhalter dürfen während der Verwendung oder Entfernung keinerlei Änderungen vorgenommen werden.

Das Verfahren muß von geschultem Personal, das über die anatomischen Verhältnisse, eine sichere Technik und potentielle Komplikationen informiert ist, durchgeführt werden.

Indikationen:

Die Katheterklemme und der Katheterhalter werden zur Fixierung des Katheters am Patienten oder zur Anbringung einer Sekundärnaht verwendet.

Kontraindikationen:

Nicht bekannt.

Warnungen und Vorsichtsmaßnahmen:*

1. **Warnung: Steril, für den Einmalgebrauch: Nicht wiederverwenden, wiederaufbereiten oder erneut sterilisieren. Eine Wiederverwendung der Vorrichtung birgt das potenzielle Risiko einer schweren Verletzung und/oder Infektion, die zum Tod führen kann.**
2. **Vorsichtsmaßnahme: Die Katheterklemme und der Katheterhalter dürfen nicht vor Entfernung des Federführungsdrahtes am Katheter befestigt werden.**

Vorgeschlagenes Vorgehen: Eine sterile Technik verwenden.

1. Befolgen Sie die Anleitungen des Herstellers bei der Plazierung des Katheters.
2. Nach Entfernung des Federführungsdrahtes und Verbindung oder Verschluß der nötigen Leitungen Flügel der Gummiklemme ausbreiten und am Katheter entsprechend plazieren, um eine richtige Plazierung der Spitze sicherzustellen (siehe Abb. 1).
3. Unbiegsamen Halter auf der Katheterklemme einrasten lassen (siehe Abb. 2).
4. Katheter am Patienten durch Annähen der Katheterklemme und des Katheterhalters an der Haut fixieren, wobei die Seitenflügel verwendet werden, um das Risiko einer Kathetermigration auf ein Minimum herabzusetzen (siehe Abb. 3).
5. Verfahren nach den Anleitungen des Hersteller fortsetzen.

* Wenn Sie Fragen haben, wenden Sie sich bitte an Arrow International, Inc.

Morsetto e fermo del catetere

Considerazioni in merito alla sicurezza ed all'efficacia:

Non usare se la confezione è stata aperta o manomessa. Avvertenza: prima dell'uso, leggere tutte le avvertenze, precauzioni e istruzioni stampate nel foglietto illustrativo. La mancata osservanza di tali avvertenze, precauzioni e istruzioni potrebbe comportare gravi lesioni al paziente, e persino provocarne la morte.

Non alterare il morsetto o il fermo del catetere durante l'uso o la rimozione.

La procedura deve essere effettuata da personale addestrato, molto esperto nei punti di riferimento anatomici, sicuro nella tecnica ed in grado di affrontare eventuali complicazioni.

Indicazioni per l'uso:

Il morsetto e il fermo del catetere sono indicati per fissare il catetere al paziente o come sito secondario di sutura.

Controindicazioni:

Nessuna nota.

Avvertenze e precauzioni:*

1. **Avvertenza: Sterile, monouso: non riutilizzare, ricondizionare o risterilizzare. Il riutilizzo del dispositivo crea un rischio potenziale di gravi lesioni e/infezioni che possono risultare fatali.**
2. **Precauzione: collegare il morsetto e il fermo al catetere soltanto dopo aver rimosso la guida metallica a molla.**

Procedura suggerita:
Usare una tecnica sterile.

1. Per inserire correttamente il catetere, attenersi alle istruzioni fornite dalla ditta produttrice.
2. Dopo aver estratto la guida metallica a molla e collegato o bloccato le linee pertinenti, allargare le alette del morsetto in gomma e collocarlo sul catetere come necessario per garantire il corretto posizionamento della punta (fare riferimento alla Fig. 1).
3. Fissare con uno scatto il fermo rigido sul morsetto del catetere (fare riferimento alla Fig. 2).
4. Fissare il catetere al paziente suturando insieme il morsetto e il fermo del catetere alla cute e usando le alette laterali per ridurre al minimo il rischio che possa spostarsi (fare riferimento alla Fig. 3).
5. Continuare la procedura attenendosi alle istruzioni fornite dalla ditta produttrice.

* In caso di quesiti, rivolgersi alla Arrow International, Inc.

Grampo e Fixador do Cateter

Considerações Sobre Segurança e Eficácia:

Não utilizar caso a embalagem tenha sido previamente aberta ou danificada. Aviso: Antes de utilizar, leia todas as advertências, precauções e instruções constantes no folheto acompanhante. Se não o fizer, poderá provocar lesões graves ou mesmo a morte do doente.

Não altere o grampo ou fixador do cateter durante a utilização ou remoção.

O procedimento deve ser realizado por pessoal treinado, bastante conhecedor das referências anatómicas, da técnica mais segura e das suas potenciais complicações.

Indicações para a Utilização:

O grampo e fixador do cateter destina-se a fixar o cateter ao doente ou como um local secundário de sutura.

Contra-indicações:

Desconhecidas.

Advertências e Precauções:*

1. **Aviso: Estéril, utilização única: não reutilizar, reprocessar ou reesterilizar. A reutilização do dispositivo cria um potencial risco de lesões graves e/ou infecção que poderão resultar em morte.**
2. **Precaução: O grampo e fixador do cateter não devem ser colocados no cateter enquanto o fio guia não for removido.**

Procedimento Sugerido: Utilize uma técnica estéril.

1. Siga as instruções do fabricante para a colocação do cateter.
2. Depois de remover o fio guia e ligar ou fixar as linhas necessárias, abra as asas do grampo de borracha e posicione-o no cateter conforme for necessário para garantir a permanência da ponta do cateter no local apropriado (consulte a Fig. 1).
3. Encaixe o fixador rígido no grampo do cateter (consulte a Fig. 2).
4. Fixe o cateter ao doente suturando, em bloco, o grampo e o fixador do cateter à pele, utilizando as asas laterais para minimizar o risco de migração do cateter (consulte a Fig. 3).
5. Continue o procedimento de acordo com as instruções do fabricante.

* Se tiver alguma questão a colocar, por favor contactar a Arrow International, Inc.

Pinza y sujetador del catéter

Consideraciones relativas a la seguridad y la eficacia:

No utilizar si el paquete ha sido previamente abierto o está dañado. Advertencia: Antes de usar el dispositivo, leer todas las advertencias, precauciones e instrucciones incluidas en el paquete. El no hacerlo puede ocasionar lesiones graves o el fallecimiento del paciente.

No alterar la pinza o el sujetador del catéter durante el uso o la extracción.

El procedimiento debe ser realizado por personal especializado con buen conocimiento de los puntos de referencia anatómicos, las técnicas de seguridad y las posibles complicaciones.

Indicaciones de uso:

La pinza y el sujetador del catéter están indicados para sujetar el catéter al paciente o como sitio de sutura secundario.

Contraindicaciones:

No se conoce ninguna.

Advertencias y precauciones:*

1. **Advertencia: Estéril, para un solo uso: no reutilizar, reprocesar ni reesterilizar. La reutilización del dispositivo genera un riesgo potencial de lesiones graves e infección potencialmente mortal.**
2. **Precaución: La pinza y el sujetador no deben acoplarse al catéter hasta después de extraer la guía de alambre flexible.**

Procedimiento sugerido: Utilizar una técnica estéril.

1. Seguir las instrucciones del fabricante para la colocación del catéter.
2. Después de haber extraído la guía de alambre flexible y de haber conectado o cerrado las líneas necesarias, extender las alas de la pinza de goma y colocarla sobre el catéter de forma que la punta quede colocada correctamente (véase la Figura 1).
3. Prender (se oirá un chasquido) el sujetador rígido a la pinza del catéter (véase la Figura 2).
4. Sujetar el catéter al paciente suturando la pinza y el sujetador conjuntamente a la piel, usando las alas laterales para reducir al mínimo el riesgo de migración del catéter (véase la Figura 3).
5. Continuar el procedimiento siguiendo las instrucciones del fabricante.

* En caso de tener alguna pregunta, póngase en contacto con Arrow International, Inc.

Kateterklämma och fäste

Säkerhet och verkan:

Använd ej om förpackningen har öppnats vid ett tidigare tillfälle eller om den är skadad. Varning: Läs före användning varningar, viktiga påpekanden och anvisningar i bipacksedeln. Underlåtenhet att läsa dessa kan eventuellt resultera i allvarlig patientskada eller dödsfall.

Modifiera aldrig kateterklämman eller fästet under användning eller avlägsnande.

Förfarandet måste utföras av utbildad personal, väl bevandrad i anatomiska riktpunkter, säker teknik och eventuella komplikationer.

Indikationer för användning:

Kateterklämman och fästet är indicerade för att fästa en kateter på patienten eller som ett sekundärt sutureringsställe.

Kontraindikationer:

Inga kända.

Varningar och Viktigt:*

1. **Varning: Steril, avsedd för engångsbruk: Får inte återanvändas, ombearbetas eller omsteriliseras. Återanvändning av produkten medför en potentiell risk för allvarlig skada och/eller infektion som kan leda till dödsfall.**
2. **Viktigt: Kateterklämman och fästet får ej monteras på katetern förrän fjädertrådsledaren har avlägsnats.**

En föreslagen procedur:
Använd steril teknik.

1. Följ tillverkarens anvisningar för inplacering av katetern.
2. Efter att fjädertrådsledaren avlägsnats och nödvändiga slangar blivit anslutna eller tillslutna efter behov öppnas gummiklämmans käftar och placeras på katetern så att spetsen säkert ligger på rätt plats (se Fig. 1).
3. Knäpp fast det styva fästet på kateterklämman (se Fig. 2).
4. Fäst katetern på patienten genom att tillsammans suturera fast katetern och klämman i huden och minska risken för att katetern börjar migrera genom att använda sidovingarna (se Fig. 3).
5. Fortsätt proceduren enligt tillverkarens anvisningar.

* Om du har frågor kan du kontakta Arrow International, Inc.

ARROW INTERNATIONAL

2400 Bernville Road
Reading, PA 19605 USA
1-800-523-8446
1-610-378-0131
8 a.m. - 8 p.m. EST

Teleflex Medical EC REP
IDA Business and Technology Park
Athlone, Ireland

STERILE EO

CE 0086

C-00004-132B (3/10)

0.9% Sodium Chloride Injection, USP

BD PosiFlush™ SF Saline Flush Syringe

Description:

BD PosiFlush™ SF Saline Flush Syringes contain sterile, non-toxic, non-pyrogenic, 0.9% Sodium Chloride Injection, USP, packaged in a plastic, disposable, single use syringe that does not contain natural rubber latex or preservatives.

The package contents are sterile. Solution pH is 4.5 - 7.0. The solution osmolarity is 0.308 mOsm/mL (calc.). **Suitable for use on sterile field.**

Intended Use:

BD PosiFlush™ SF Saline Flush Syringes are intended to be used only for the flushing of indwelling vascular access devices.

Contraindications: None.

Cautions:

1. Do not use if package is not intact.
2. Do not use if syringe is damaged in any way that suggests syringe leakage.
3. Do not use if syringe tip cap is improperly affixed to or dislodged from the syringe tip.
4. Visually inspect and do not use if solution is discolored, cloudy or hazy, contains a precipitate or has any type of suspended particulate matter.
5. Do Not Re-Sterilize Before Use.
6. Verify the expiration date on the product label. Do not use if product has expired.
7. Do Not Reuse. For Single Use Only. Discard any unused portion.
8. Avoid contact between this solution and incompatible drug products. Consult appropriate compatibility literature.
9. Federal (USA) law restricts this device to sale by or on the order of a physician.
10. We guarantee the pre-filled syringe in our unopened, undamaged package to be sterile, non-toxic and non-pyrogenic.

Adverse Events: None.

Storage:

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F); do not freeze.

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Rev. 2016-11

Directions For Use:

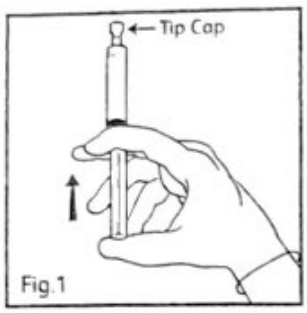

Fig.1

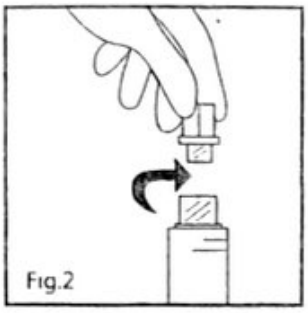
Fig.2

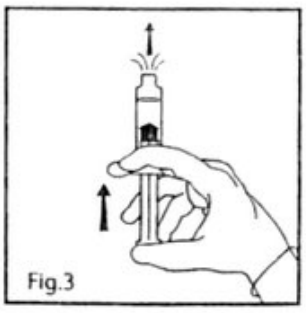
Fig.3

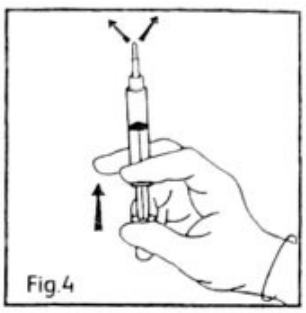
Fig.4

1. **May be used on sterile field using proper aseptic technique**.
2. After removing from package, depress plunger **with tip cap on** to relieve the resistance between the stopper and the barrel. (Fig. 1).
3. Remove the syringe tip cap from the FLUSH syringe by twisting off. (Fig. 2).
4. 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.
5. Hold the syringe upright and expel the air in the syringe. (Fig. 3)
   Note: BD™ Blunt Plastic Cannula Utilization - When expelling air/fluid from a syringe, contents exit sideways from the cannula in two separate paths (Fig. 4). Expel air or fluid carefully, directing flow paths away from face or mucus membranes.
6. Attach the syringe to the port, valve or needleless system and flush following institution's policy and indwelling device manufacturer's recommendations.
7. Discard used syringe and any unused portion of the solution according to institution policy. DO NOT REUSE.

How Supplied:
BD PosiFlush™ SF Saline Flush Syringes are provided in sterile, peel apart packages in shelf cartons of thirty (30) unit packaged syringes, for sterile field procedures.

Reorder No. 306553 - BD PosiFlush™ SF 10 mL saline syringe with regular length plunger rod

BD PosiFlush™ Saline Flush Syringes with sterile solution and fluid path are provided in shelf containers of thirty (30) unit packaged syringes in the following fill volume / syringe size combinations.

Reorder No. 306544 - BD 3 mL syringe
Reorder No. 306545 - BD 5 mL syringe
Reorder No. 306546 - BD 10 mL syringe with regular length plunger rod
Reorder No. 306547 - BD 10 mL syringe
Reorder No. 306549 - BD 3 mL syringe packaged with separate BD Blunt Plastic Cannula
Reorder No. 306550 - BD 5 mL syringe packaged with separate BD Blunt Plastic Cannula
Reorder No. 306551 - BD 10 mL syringe with regular length plunger rod and packaged with separate BD Blunt Plastic Cannula

Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417 USA
Made in Ireland bd.com