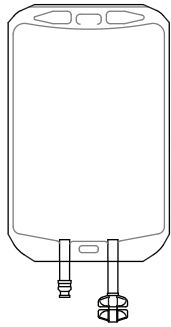


SmartSite Bag DFU - US
11365-370-11
Revision B

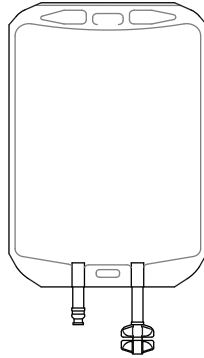
BD SmartSite™ Bag

REF 200100



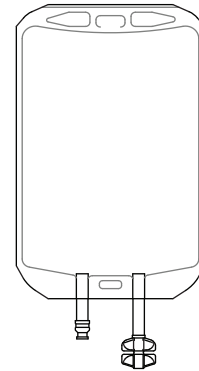
100mL

REF 200250



250mL

REF 200500



500mL

Rx Only

Distributed by: BD Switzerland
Sàrl, Route de Crassier 17,
Business Park Terre-Bonne,
Batiment A4, 1262 Eysins Switzerland
Made in France



Gilero, LLC
635 Davis Dr. Suite 100
Morrisville, NC 27560 USA

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Symbols Glossary
<http://www.bd.com/symbols-glossary>



Do not re-use



Do not use if
package is damaged



Do not resterilize



Non-pyrogenic



Fluid path sterilized
using irradiation



Caution



Catalogue number



Consult instructions
for use



Batch code



Manufacturer



Use-by date



Do not use
needles

INDICATIONS FOR USE

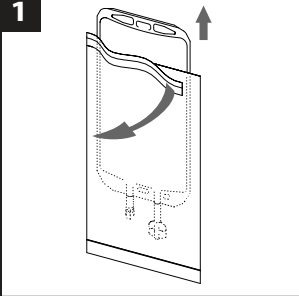
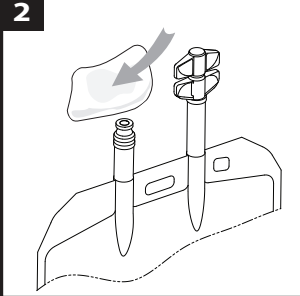
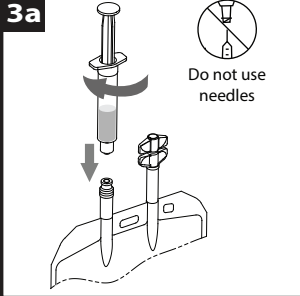
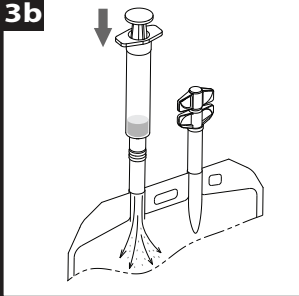
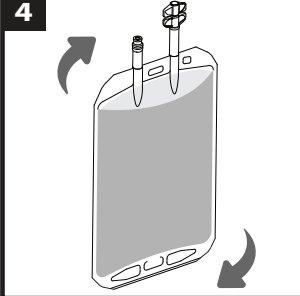
The BD SmartSite™ Bag is an empty container used for administration of intravenous solutions to the patient using an intravascular administration set. Medication transfer in and out of the container is done using aseptic technique.

PRECAUTIONS

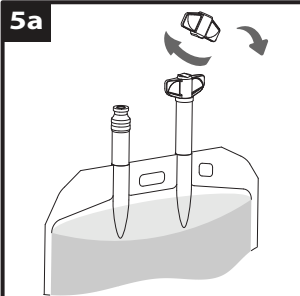
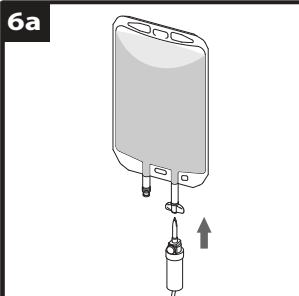
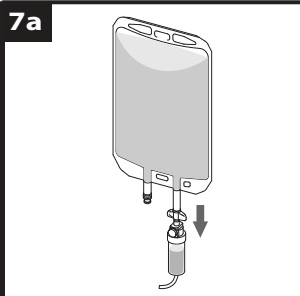
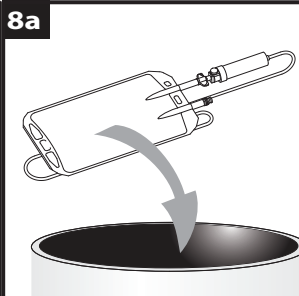
- DO NOT use if the outer package is damaged.
- DO NOT use a needle to inject solution into the SmartSite™ Bag. Using a needle will damage the SmartSite™ Needle-Free Valve, causing it to leak.
- DO NOT fill bag above nominal volume.
- Protect SmartSite™ Bag from freezing.
- DO NOT leave slip luer connectors unattended.
- Use solution within 24 hours of preparation or according to storage requirements in drug package insert or facility protocol, whichever is shorter.

PVC, DEHP or Natural Rubber Latex are not part of the material formulation.

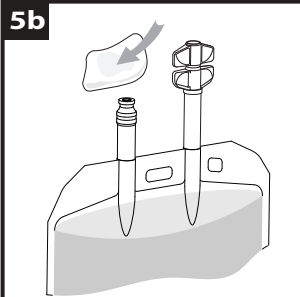
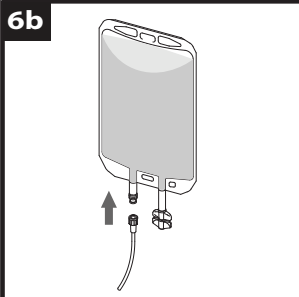
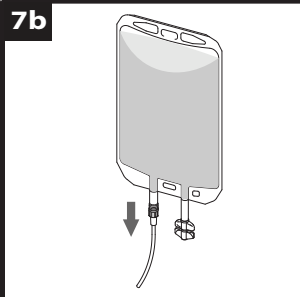
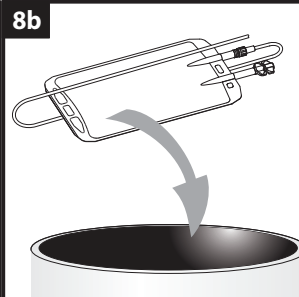
FILLING DIRECTIONS – USE ASEPTIC TECHNIQUE

				
1. Remove SmartSite™ Bag from overwrap packaging by tearing along perforation line.	2. Prior to every access, swab the top of the SmartSite™ Bag Needle-Free Valve with 70% isopropyl alcohol (2-5 seconds) and allow to dry (approximately 30 seconds). Dry time depends on temperature, humidity, and ventilation of the area.	3a. Attach an ISO 594-compatible male luer lock syringe to the SmartSite™ Bag Needle-Free Valve.	3b. Inject solution. Repeat, as needed, to add additional fluid to the SmartSite™ Bag. Dispose of syringe per facility protocol.	4. Mix SmartSite™ Bag contents per facility protocols. Note: The contents of the SmartSite™ Bag may be administered through either the SmartSite™ Needle-Free Valve or the spike port. Proceed to step 5a if administering through the spike port, or step 5b if administering through the SmartSite™ Needle-Free Valve.

SPIKE PORT DELIVERY DIRECTIONS – USE ASEPTIC TECHNIQUE

			
5a. Twist the spike port cap to remove, and dispose per facility protocol.	6a. Insert IV set spike into exposed pierceable septum until a secure connection is achieved.	7a. Administer contents of SmartSite™ Bag per facility protocol.	8a. Once contents of the SmartSite™ Bag have been administered, dispose of SmartSite™ Bag per facility protocol.

SmartSite™ DELIVERY DIRECTIONS – USE ASEPTIC TECHNIQUE

			
5b. Prior to every access, swab the top of the SmartSite™ Bag Needle-Free Valve with 70% isopropyl alcohol (2-5 seconds) and allow to dry (approximately 30 seconds). Dry time depends on temperature, humidity and ventilation of the area.	6b. Attach an ISO 594-compatible male luer lock connector to the SmartSite™ Bag Needle-Free Valve.	7b. Administer contents of SmartSite™ Bag per facility protocol.	8b. Once contents of the SmartSite™ Bag have been administered, dispose of SmartSite™ Bag per facility protocol.