Helping to protect you from exposure to hazardous drugs

Closed system solution: Texium® closed male luer and SmartSite® needle-free valve products

CareFusion

What you can't see can hurt you

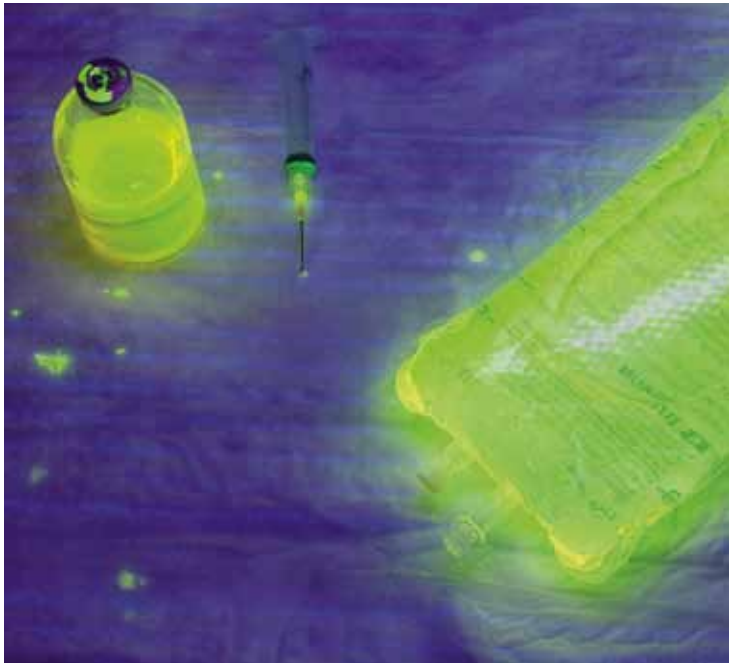
The risks are well documented—and all too common

Pharmacists, nurses, physicians and other caregivers spend every day focused on the health of their patients—often unaware of potential risks to their own physical and reproductive health.

- Traces of the hazardous substances used to treat patients—including chemotherapy, antivirals, antibiotics and hormones—have been detected on chairs and tabletops at the point of care, as well as floors and countertops in hospital pharmacies.[1]
- It's estimated that millions of healthcare workers are exposed to these substances each year, despite the well-established risks.[2] In multiple studies, these substances have been found in the urine of workers who handled them—and even among workers who didn't.[3]
- Harrison (2001) reported that six different drugs (cyclophosphamide, methotrexate, ifosfamide, epirubicin and cisplatin/carboplatin) were detected in the urine of healthcare workers by 13 of 20 investigations.[4]

Exposure risks

Reconstituting, transporting and administering hazardous drugs can put healthcare workers at risk of exposure to these agents via spillage, surface contamination and aerosols. The continued use of needles to draw up and administer medication also presents a major hazard in the healthcare environment.



Closed system solution: Texium® closed male luer and SmartSite® needle-free valve products

Intuitive and easy to use

Safe: Texium closed male luer and SmartSite needle-free valve products partner together to form a closed system, providing leak-free connections and disconnections that help reduce surface contamination and the risk of exposure.

Simple: The luer lock connection of the Texium closed male luer to a SmartSite needle-free valve helps you quickly and easily achieve a closed system, without adding cumbersome steps to your clinical process.

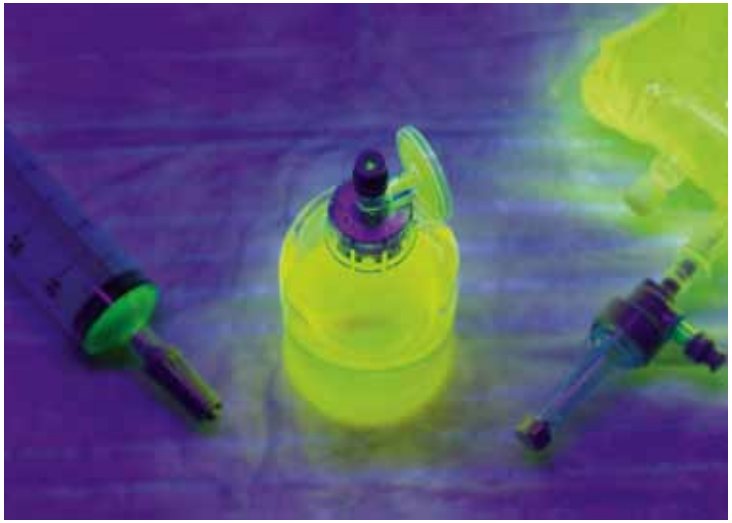
Cost-effective: Our closed system solution makes it possible for any facility to follow NIOSH recommendations for using closed, needle-free systems for the safe handling of hazardous drugs.

Helps to protect healthcare workers from exposure to hazardous drugs

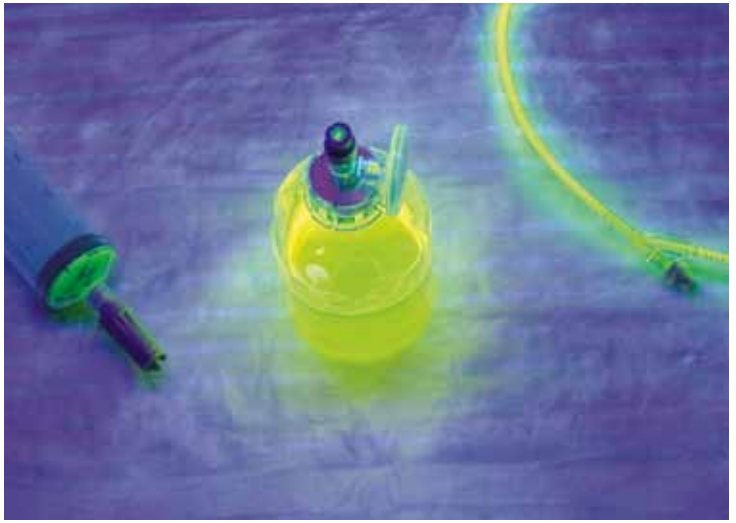
The following are black light photos, using a fluorescent indicator for visibility, showing no visible surface contamination with our products.

* The fluorescent indicator can be seen through the thin seal area of the SmartSite needle-free valve. This fluid is within the SmartSite needle-free valve. There is no fluid on the external surface.

Photos are on file at CareFusion.



Drug preparation with our closed system solution*



IV push with our closed system solution*

Full continuum of care

A complete system of products provide safe handling of hazardous drugs from end-to-end: drug mixing, preparation, transport, delivery and disposal.

In the pharmacy

Reconstitution

How the Texium closed male luer works: The Texium closed male luer is based on a simple luer-lock principle, allowing free flow of the drug when connected, and automatically closing when disconnected. Together, the Texium closed male luer and SmartSite needle-free valve create an automatically closed system that helps eliminate leakage.

The Texium closed male luer partners with any SmartSite needle-free valve product to create an easy-to-use, closed needle-free system. The patented no-drip-tip technology of the Texium closed male luer creates a vacuum mechanism when closing to ensure a drip-free, leak-free disconnection.

The SmartSite vented vial access device: The hydrophobic air inlet filter minimizes aerosols and neutralizes vial pressure, thus reducing the risks of surface contamination.

Preparation

Attach the Texium closed male luer to a SmartSite needle-free valve access port for closed system access to IV bags for adding or removing fluids. The SmartSite needle-free add-on bag access device allows closed system additions of drugs to bags when used with the Texium closed male luer.

Transport

Attach the Texium closed male luer to the end of a syringe. Automatic safety lock prevents accidental discharges from the syringe.

The Texium closed male luer remains sealed when the cap is removed, reducing the risk of spillage from the syringe.

In the patient care area

IV administration

IV push: Safe and easy closed system administration of medication with the Texium closed male luer and SmartSite needle-free valve Y-port on the administration set.

IV infusion: Attach the Texium closed male luer to the distal end of an infusion set and then connect the Texium closed male luer to a SmartSite needle-free valve on patient's intravascular line.

Disposal

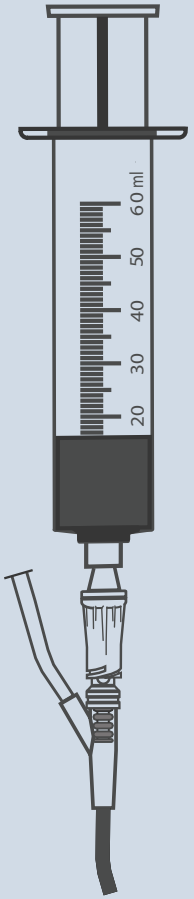
Assuring that drug-contaminated waste is properly contained will protect workers from respiratory exposure to volatile or micro aerosolized drugs.

Connor et al. 2000; Kiffmeyer et al. 2002; Larson et al. 2003[5]

Put safety first

SmartSite needle-free valve

- No needle
- No caps
- No metal
- Reduces the risk of needlestick injuries
- Straight-through non-tortuous fluid path
- High chemical resistance (lipids and alcohol)
- Cost-effective, MRI compatible, latex-free IV administration system
- Partners with Texium closed male luer for delivering safe and convenient IV therapy in closed system



Texium closed male luer

Partners with SmartSite needle-free valve to achieve a closed system.

Feature	Benefit
No-drip-tip technology	• Leak-free transfer of drugs • Reduces surface contamination
Passive safety system	• Closes upon disconnection • Reduces surface contamination • Protects against free-flow
Lock-and-go design	• Fast and easy connection to SmartSite needle-free valve
Automatic safety lock	• Prevents accidental discharges from a syringe
Vacuum technology	• Reduces risk of exposure to hazardous drug when disconnecting from SmartSite needle-free valve

Key performance specifications

Priming volume: Total volume in the male luer when not activated	~ 0.12 mL
Luer flow rate: Test per ISO 8536-4 guidelines	5,948 mL/hr
Internal diameter:	18 gauge
Material:	Latex free, DEHP free and ABS plastic free

SmartSite vented vial access device

Partners with Texium closed male luer for closed system access to drug vials.

Feature	Benefit
SmartSite needle-free	• Allows needle-free access to multiple use vials
0.2 micron hydrophobic air venting filter	• Neutralizes vial pressure, minimizing aerosols and surface contamination • Eases drug extraction • Retains bacteria
Dual pathway spike	• Efficiently transfers fluids for maximum extractable volume

Key performance specifications

Priming volume: Total volume in needle-free valve and spike when not activated	~ 0.14 mL
Residual volume: Quantity of fluid remaining in vial after withdrawing the maximum amount through the access port	0.28 mL
Filter:	0.2 micron hydrophobic
Material:	Latex free, DEHP free and ABS plastic free
Compatibility:	20 mm diameter rubber stoppered vials

SmartSite add-on bag access device

Partners with Texium closed male luer for closed system access to IV bag.

Feature	Benefit
SmartSite needle-free valve bag access port	• Allows direct, needle-free access to IV bags for adding or removing fluids
Universal spike adapter	• Fits any ISO standard spike

Key performance specifications

Priming volume:	
Needle-free valve port	~ 0.16 mL
Fluid channel	~ 0.61 mL
Compatibility:	
Spike adapter	ISO standard spikes
Material:	Latex free and DEHP free

Infusion sets

Our range of SmartSite needle-free primary and secondary sets help achieve a closed system during administration of hazardous drugs when partnered with the Texium closed male luer.

Feature	Benefit
SmartSite needle-free valve partnered with Texium closed male luer	• Allows safe needle-free access for the administration of cytotoxic drugs • Reduces exposure to hazardous drugs • Maintains closed system
Specific designs for Alaris® System infusion devices	• Ensures accuracy • Provides free-flow protection • Enables prevention of medication errors with Guardrails® safety software
DEHP free, PVC free and latex free	• Avoids patient exposure to DEHP plasticizer
Polyethylene-lined sets available	• Prevents drug sorption • Helps prevent leaching of phthalates into fluid pathway, therefore avoiding patient exposure

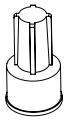
Drug reconstitution products

The Texium closed male luer partners with the SmartSite needle-free valve to deliver an easy-to-use closed system. The SmartSite IV sets and accessories eliminate the need for needles, caps, blunt cannulas and add-on components. Access devices and accessories provide flexibility and additional infusion capabilities to gravity and infusion instrument sets. All access devices are latex free.

Texium closed male luer and SmartSite access device and accessories

Model #: 10012240-0500 **Case quantity: 100** DEHP

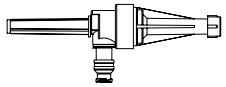
Texium female cap



Model #: 10013365 **Case quantity: 100** DEHP

SmartSite add-on bag access device, spike adapter, with 1 needle-free valve bag access port.

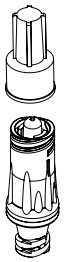
Approximate length:	3.8”	9.6 cm. approx.
Approximate priming volume:	0.61 mL	



Model #: 10012241-0500 **Case quantity: 100** DEHP

Texium closed male luer with female cap

Approximate priming volume: 0.12 mL

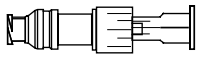


Model #: 2000E **Case quantity: 100** DEHP

SmartSite needle-free valve

Approximate priming volume: 0.11 mL

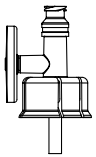
Labeled for use with low pressure power injectors up to 325 psi and maximum flow rate of 10 mL/second.



Model #: 10012392-0500 **Case quantity: 80** DEHP

SmartSite 20 mm vented vial access device, 0.2 micron-hydrophobic air-venting filter.

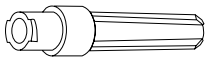
Approximate priming volume: 0.14 mL



Model #: 2201 **Case quantity: 100** DEHP

Single-dose dispensing pin

Approximate priming volume: 0.3 mL

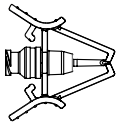


Texium closed male luer and SmartSite access device and accessories (continued)

Model #: 2202E **Case quantity: 100** DEHP

SmartSite needle-free access pin

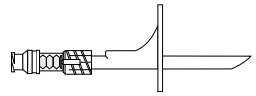
Approximate priming volume: 0.07 mL



Model #: 2300E-0500 **Case quantity: 100** DEHP

SmartSite bag spike

Approximate priming volume: 0.51 mL

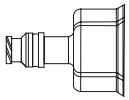


Model #: 2203E **Case quantity: 100** DEHP

SmartSite 13 mm vial access device

Approximate priming volume: 0.07 mL

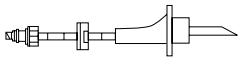
30-day lead time



Model #: 2309E **Case quantity: 100** DEHP

SmartSite bag spike with check valve

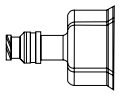
Approximate priming volume: 0.93 mL



Model #: 2205E **Case quantity: 100** DEHP

SmartSite 20 mm vial access device

Approximate priming volume: 0.09 mL



Model #: 2519A **Case quantity: 50** DEHP

Manifold with three 1-way valves

Approximate set length: 6″ 15 cm. approx.

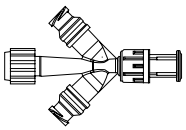
Approximate priming volume: 1.5 mL

30-day lead time

Model #: 20558E **Case quantity: 50** DEHP

SmartSite tri-port connector

Approximate priming volume: 0.46 mL

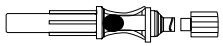


Model #: 19MMPT **Case quantity: 100** DEHP

Vial dispensing pin with vent

Approximate length: 2″ 5 cm. approx.

Approximate priming volume: 0.22 mL



Model #: 10013364 **Case quantity: 100** DEHP

Non-vented secondary set, needle-free valve bag access port, fixed male luer lock and hanger.

Approximate set length:	32″	81 cm. approx.
Approximate priming volume:	12 mL	

Drops: 20

Model #: 10014881 **Case quantity: 100** DEHP

Non-vented low sorbing secondary set, needle-free valve bag access port, fixed male luer lock and hanger.

Approximate set length:	31″	79 cm. approx.
Approximate priming volume:	12 mL	

30-day lead time

Drops: 20

Model #: 11610341 **Case quantity: 100** DEHP

Non-vented secondary set, needle-free valve bag access port, spin male luer lock and hanger.

Approximate set length:	31″	79 cm. approx.
Approximate priming volume:	12 mL	

30-day lead time

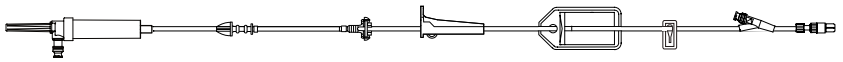
Drops: 20

Model #: 2465-0007 **Case quantity: 20** DEHP

Low sorbing infusion set, non-vented, needle-free bag access port, 0.2 micron (low-protein binding) filter, 1 needle-free valve 6" from 2-piece male luer lock.

Approximate set length:	116"	293 cm. approx.
Approximate priming volume:	26 mL	

30-day lead time

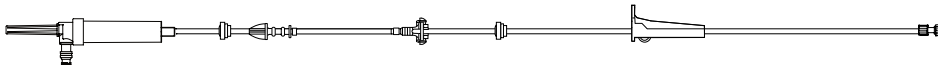


Drops: 20

Model #: 2466-0007 **Case quantity: 20** DEHP

Low sorbing infusion set, non-vented, needle-free bag access port, spin male luer lock.

Approximate set length:	86"	219 cm. approx.
Approximate priming volume:	20 mL	

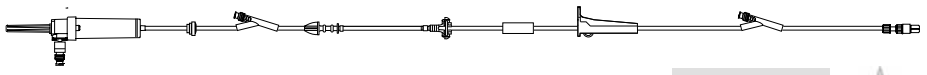


Drops: 20

Model #: 10013361 **Case quantity: 20** DEHP

Infusion set, non-vented, needle-free valve bag access port, check valve, 2 needle-free valves 78" and 6" from 2-piece male luer lock.

Approximate set length:	117"	297 cm. approx.
Approximate priming volume:	25 mL	



Drops: 20

Model #: 10014855 **Case quantity: 20** DEHP

Low sorbing infusion set, non-vented, needle-free valve bag access port, check valve, 2 needle-free valves 95" and 6" from 2-piece male luer lock.

Approximate set length:	116"	295 cm. approx.
Approximate priming volume:	24 mL	

30-day lead time

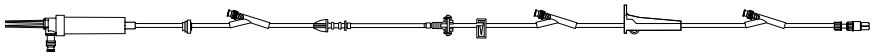
Drops: 20

Model #: 10015861 **Case quantity: 20** DEHP

Low sorbing infusion set, non-vented, needle-free valve bag access port, check valve, 3 needle-free valves 95", 75" and 6" from 2-piece male luer lock.

Approximate set length:	128"	325 cm. approx.
Approximate priming volume:	26 mL	

30-day lead time

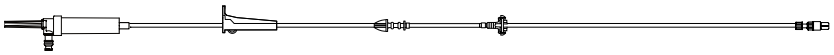


Drops: 20

Model #: 10015862 **Case quantity: 20** DEHP

Low sorbing infusion set, non-vented, needle-free valve bag access port, 2-piece male luer lock.

Approximate set length:	44"	112 cm. approx.
Approximate priming volume:	14 mL	



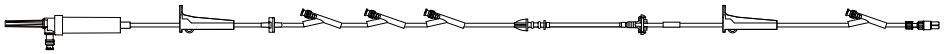
Drops: 20

Model #: 10061661 **Case quantity: 20** DEHP

Low sorbing infusion set, non-vented, needle-free valve bag access port, check valve, 4 needle-free valves 94", 92", 90" and 6" from 2-piece male luer lock.

Approximate set length:	121"	307 cm. approx.
Approximate priming volume:	25 mL	

30-day lead time

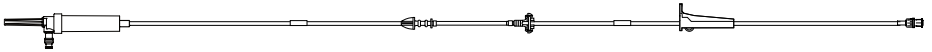


Drops: 20

Model #: 10321213 **Case quantity: 20** DEHP

Infusion set, non-vented, needle-free valve bag access port, fixed male luer lock.

Approximate set length:	106"	269 cm. approx.
Approximate priming volume:	23 mL	



Drops: 20

Model #: 10013363 **Case quantity: 50**

Infusion set, non-vented, needle-free valve bag access port, check valve, 2 needle-free valves 90" and 9" from 2-piece male luer lock.

Approximate set length:	100"	254 cm. approx.
Approximate priming volume:	16 mL	

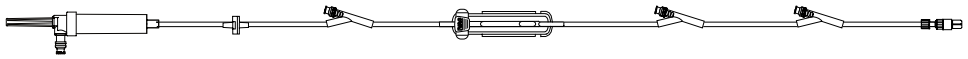
Drops: 20

Model #: 10015863 **Case quantity: 50**

Infusion set, low sorbing tubing segment, non-vented, needle-free valve bag access port, check valve, 3 needle-free valves 83.5", 37.5" and 9" from 2-piece male luer lock.

Approximate set length:	101"	257 cm. approx.
Approximate priming volume:	19 mL	

30-day lead time

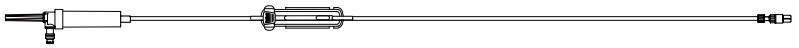


Drops: 20

Model #: 10026645 **Case quantity: 20**

Infusion set, low sorbing tubing segment, non-vented, needle-free valve bag access port, 2-piece male luer.

Approximate set length:	87.5”	222 cm. approx.
Approximate priming volume:	16 mL	



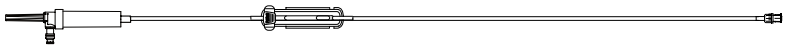
Drops: 20

Model #: 10784614 **Case quantity: 20**

Infusion set, low sorbing tubing segment, non-vented, needle-free valve bag access port, spin male luer.

Approximate set length:	88”	223 cm. approx.
Approximate priming volume:	17 mL	

30-day lead time



Drops: 20

1 Minoia et al. 1998; Connor et al. 1999; Pethran et al. 2003.

2 NIOSH report, 2004.

3 Valanis et al. 1991, 1992; Mahon et al. 1994; Nieweg et al.

4 CDC/NIOSH 2004-165: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings.

5 NIOSH alert, 2004.

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San Diego, CA

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