

Helping to protect you from exposure to hazardous drugs

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





What you can't see can hurt you

The risks are well documented—and all too common

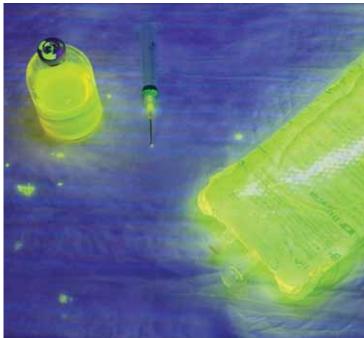
Pharmacists, nurses, physicians and other caregivers spend every day focused on the health of their patients—often unaware of potential risks to their own physical and reproductive health.

- 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, methrotrexate, 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.

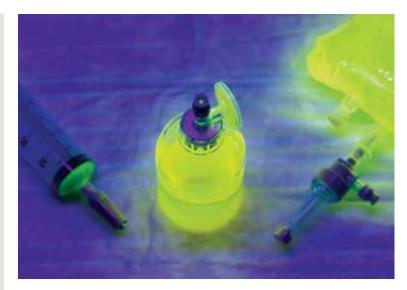


Helps to protect healthcare workers from exposure to hazardous drugs

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 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. 2003⁵



Put safety first



SmartSite® needle-free valve

- No needle
- No caps
- No metal
- Reduces the risk of needle-stick 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 drugsReduces surface contamination
Passive safety system	Closes upon disconnectionReduces surface contaminationProtects 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

P	'n	m	ina	l VO	lui	ne

Total volume in the male luer when not activated

Luer flow rate:

Test per ISO 8536-4 guidelines

Internal diameter:

Material:

~ 0.12 mL

5948 mL/hr

18 gauge

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

0.2 micron hydrophobic air venting filter

Dual pathway spike

- Allows needle-free access to multiple use vials
- Neutralizes vial pressure, minimizing aerosols and surface contamination
- Eases drug extraction
- Retains bacteria
- Efficiently transfers fluids for maximum extractable volume

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 adaptor

 Fits any ISO standard spike

Key performance specifications

Priming volume:

Total volume in needle-free ~ 0.14 mL valve and spike when

not activated

Material:

Residual volume:

Quantity of fluid remaining in vial after withdrawing the maximum amount through

0.28 ml

the access port

Filter: 0.2 micron hydrophobic

Latex free, DEHP-free and ABS plastic free

Compatibility: 20mm diameter

rubber stoppered vials

Key performance specifications

Priming volume:

Needle-free

valve port $\sim 0.16 \text{ mL}$ Fluid channel $\sim 0.61 \text{ mL}$

Compatibility:

Spike adaptor 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



Texium® female cap



Model #: 10013365

Case quantity: 100



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



Texium® closed male luer with female cap

Approximate priming volume:

0.12 mL



Model #: 2000E

Case quantity: 100

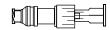


0.11 mL

SmartSite® needle-free valve

Approximate priming volume:

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



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

Approximate priming volume: 0.14 mL



Model #: 2201

Case quantity: 100



Single-dose dispensing pin

Approximate priming volume:

0.03 mL



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

Model #: 2202E

Case quantity: 100



SmartSite® needle-free access pin

Approximate priming volume: 0.05 mL



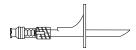
Model #: 2300E-0500

Case quantity: 100



SmartSite® bag spike

Approximate priming volume: 0.47 mL



Model #: 2203E

Case quantity: 100



SmartSite® 13mm vial access device

Approximate priming volume: 0.08 mL

30-day lead time



Model #: 2309E

Case quantity: 100



SmartSite® bag spike with check valve

Approximate priming volume: 0.86 mL



Model #: 2205E

Case quantity: 100



SmartSite® 20mm vial access device

Approximate priming volume: 0.09 mL



Model #: 2519A

Case quantity: 50





Manifold with three 1-way valves

Approximate set length: 5.75" 15 cm. approx.

Approximate priming volume: 1.5 ml

30-day lead time

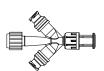
Model #: 20558E

Case quantity: 50



SmartSite® tri-port connector

Approximate priming volume: 0.6 mL



Model #: 19MMPT

Case quantity: 100





Vial dispensing pin

Approximate length: 5 cm. approx.

Approximate priming volume: 0.22 mL

Reconstitution/administration sets

Model #: 10013364

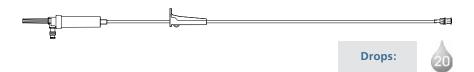
Case quantity: 100



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

Approximate set length: 31" 79 cm. approx.

Approximate priming volume: 7 mL



Model #: 10014881

Case quantity: 100

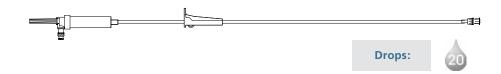


Non-vented low sorbing secondary set, needle-free valve bag access port, fixed male luer lock and hanger.

Approximate set length: 31" 79 cm. approx.

Approximate priming volume: 8 mL

30-day lead time





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



Model #: 2465-0007

Case quantity: 20



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" 295 cm. approx.

Approximate priming volume: 26 mL

30-day lead time



Drops:



Model #: 2466-0007

Case quantity: 20



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

Approximate set length: 86" 218 cm. approx.

Approximate priming volume: 20 mL



Drops:





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: 20 mL



Drops:



Alaris® Pump module administration sets with SmartSite® bag access port (continued)



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: 21 mL

30-day lead time



Drops:

4



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: 127" 323 cm. approx.

Approximate priming volume: 23 mL

30-day lead time



Drops:



Model #: 10015862 Case quantity: 20



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: 10 mL

30-day lead time



Alaris® Pump module administration sets with SmartSite® bag access port (continued)

Model #: 10061661

Case quantity: 20



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: 21 mL

30-day lead time



Drops:





Infusion set, non-vented, needle-free valve bag access port.

Approximate set length: 106" 270 cm. approx.

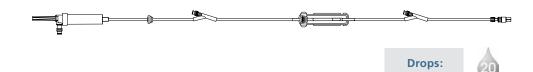
Approximate priming volume: 19 mL



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



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



Alaris® SE Pump administration sets with SmartSite® bag access port (continued)

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:



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

Approximate set length: 88" 223 cm. approx.

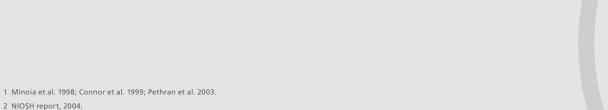
Approximate priming volume: 17 mL

30-day lead time

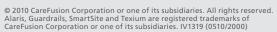


Drops:





- 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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