

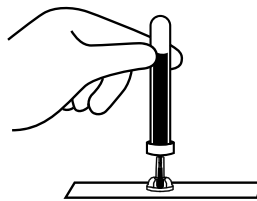
### Intended Use:

SmearSafe™ is an in vitro diagnostic device intended to provide a safe means of obtaining a drop of blood from a closed specimen collection tube without requiring the user to open the tube. It is designed to produce a drop of blood on a sturdy target surface, such as a microscope slide for a manual blood smear or cartridges for point-of-care analyzers. It is a single-use device and is compatible with Vacutainer® and Vacurette® blood collection tubes.

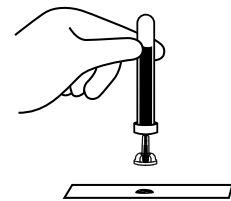
SmearSafe is clear, which allows the user to see the blood drop as it is dispensed. SmearSafe is indicated for use by qualified healthcare professionals. It is intended for use as a blood dispensing accessory in laboratory and near-patient testing environments. SmearSafe is a blood dispensing accessory and does not independently perform diagnostic evaluations, measurements, or provide diagnoses.



1.



2.



3.

1. Hold the specimen tube upright. Point the cannula of the SmearSafe device so that it is aimed at the center of the specimen tube cap. Insert the SmearSafe device into the specimen tube rubber septum until the cannula is no longer visible.
2. Place your target surface (e.g. microscope slide, cartridge, etc.) on a flat surface. Invert the specimen tube and position SmearSafe on the middle of a glass slide or other target surface. Press the tube gently downward until a blood drop forms at the tip of the SmearSafe device.
3. Release the pressure once the drop touches the target surface and lift the tube straight up from the target surface.










**NOTE:** The size of the drop can be controlled based on the speed and pressure applied to the tube. If a larger sample volume is needed, repeat the push and release of the tube until the desired amount has been dispensed.

Discard the SmearSafe device in a sharps medical waste container after use. SmearSafe may be discarded while still in the tube or removed from the tube and discarded separately. If discarded separately, hold the specimen tube cap in place while pulling SmearSafe out.

### CAUTION:

Wear gloves when using SmearSafe. Inspect each SmearSafe before use to ensure no damage has occurred in transport. Use care when handling SmearSafe, as the cannula can cause injury or tear gloves if handled inappropriately. Do not insert SmearSafe when the specimen tube is inverted or positioned upside-down.

For specimen tubes that have been previously opened and recapped, be sure the tube cap is fully seated on the tube to avoid excess blood being dispensed onto the target surface. Any serious incident that has occurred in relation to the device should be reported to Typenex Medical.

Symbol	Description	Standard Reference
	Catalog number	ISO 15223-1 5.1.6
	Batch code	ISO 15223-1 5.1.5
	Sufficient for <n> tests	ISO 15223-1 5.5.5
	Authorized representative in the European Community	ISO 15223-1 5.1.2
	Manufacturer	ISO 15223-1 5.1.1
	Do not reuse	ISO 15223-1 5.4.2
	In vitro diagnostic medical device	ISO 15223-1 5.5.1
	Consult Instructions for Use	ISO 15223-1 5.4.3
	CE marking	EC No. 765/2008

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