

**Expiration**

ViperSlide lubricant is intended for single use only and bag should be disposed of after a single procedure.

The lubricant should be used prior to the Expiration Date indicated on the shelf carton and individual bag labels.

Do not resterilize or reuse.

**Storage**

ViperSlide should not be stored above 25°C (77°F). Do not freeze ViperSlide. If accidentally frozen, discard the bag.

**DISCLAIMER OF WARRANTY**

Cardiovascular Systems, Inc. (CSI) disclaims all warranties whether expressed or implied, written or oral, including but not limited to any warranties of merchantability of fitness for a particular purpose. CSI does not warrant either for a good effect or against any ill effect following use. CSI shall not be liable for any direct, indirect, incidental or consequential loss, damage, or expense arising from or related to the use of this device.

CSI may, at its sole discretion, replace any device that is determined to have been out of specification at the time of shipment.

**Manufactured for:**

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**ViperSlide®****atherectomy lubricant****Instructions for Use**



### Description

ViperSlide® lubricant is an emulsion for use with the Diamondback 360® Orbital Atherectomy System. The ViperSlide lubricant increases the lubricity and reduces friction in the Diamondback 360° shaft and guide wire.

ViperSlide lubricant is composed of Soybean Oil, Egg Yolk Phospholipids, Glycerin, and Water for Injection. In addition, Sodium Hydroxide has been added to adjust the pH so that the final product pH 8. pH range is 6.0 to 8.9.

ViperSlide lubricant is available in a 100 mL bag and is provided sterile and non-pyrogenic. Each bag is intended for single-use only; partially used containers must be discarded and cannot be stored for later use.

Read this document carefully and refer to the Instructions for Use for the Diamondback 360° Orbital Atherectomy System: Controller and Orbital Atherectomy Device.

### Indications for Use

ViperSlide lubricant is indicated for use with the Diamondback 360° Orbital Atherectomy System.

### Contraindications

ViperSlide lubricant is contraindicated in patients with known allergies to the components and ingredients listed above.

### Restrictions

Caution: Federal Law (United States of America) restricts this device to sale by or on the order of a physician.

### Precautions

The emulsion will destabilize under the following conditions:

- Below freezing temperature
- Excessive acidity
- Inappropriate electrolyte content

Careful consideration should be given to additions of divalent cations (Ca<sup>++</sup> and Mg<sup>++</sup>) which have been shown to cause instability.

### Warnings

- Discard if sterility may have been compromised by tears, punctures or leaks in the bag or seal.
- Discard bag if particulates are visible in the suspension or if the solution appears to be non-homogeneous.
- If the Oxalert™ indicator is black the overpouch is damaged and the product should be discarded.



### Instructions

1. The integrity indicator (Oxalert) "A" should be inspected before removing the overpouch. If the indicator is black the overpouch is damaged and the product should be discarded. See Figure 1.

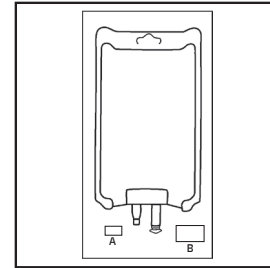


Figure 1.

2. Remove the overwrap by tearing the notch and pulling down along the container. See Figure 2. Dispose of the Oxalert sachet and the oxygen absorber "B". Using sterile aseptic technique, use a syringe to inject ViperSlide lubricant into the saline infusion bag to be used during the atherectomy procedure.

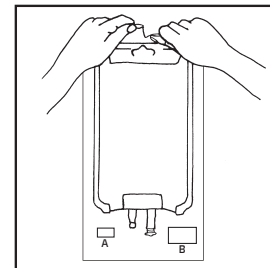


Figure 2

3. Mix at the ratio of 20 mL of ViperSlide lubricant per 1000 mL of saline; discard any unused portion.
4. Mix thoroughly by inverting the bag 3 - 5 times, or until mixture is uniformly opaque. Do not shake. Mixing with caution will prevent the formation of bubbles which are to be avoided.
5. Once mixed, the ViperSlide/Saline mixture is considered an "Immediate-use" compound with a Beyond-Use-Date (BUD) of 1 hour. Administration of the ViperSlide/Saline mixture must begin within 1 hour of mixing. If administration has not begun within 1 hour of preparation, the mixture should be promptly discarded.
6. Follow the instructions for the Diamondback 360° Orbital Atherectomy System to connect the saline infusion bag to the device handle.