

**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, sodium hydroxide, and water; the pH range is 6.0 to 9.0.

ViperSlide lubricant is available in a 20ml vial and is provided sterile and non-pyrogenic. Each vial is intended for single-use only; partly 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 Manual and Orbital Atherectomy Device IFU.

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⁺⁺ and Mg⁺⁺) which have been shown to cause instability.

Warnings:

- Discard if sterility may have been compromised by cracks or leaks in the vial or seal.
- Discard vial if particulates are visible in the suspension or if the solution appears to be non-homogeneous.



Instructions:

1. Using sterile aseptic technique, use a syringe to inject ViperSlide™ lubricant into the saline infusion bag to be used during the atherectomy procedure.
2. Mix at the ratio of 20ml, of ViperSlide lubricant, per 1000ml of saline; discard any unused portion.
3. 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.
4. Follow the instructions for the Diamondback 360® Orbital Atherectomy System to connect the saline infusion bag to the device handle.

Expiration:

ViperSlide lubricant is intended for single use only and vial 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 vial labels.

Do not resterilize or reuse.

Storage:

Store in dry conditions at 20-25°C (68-77°F). Do not freeze.



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

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