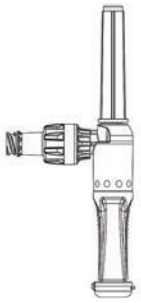
YUKON MEDICAL

# Arisure® Dry Spike Non-Vented

REF **YM064**

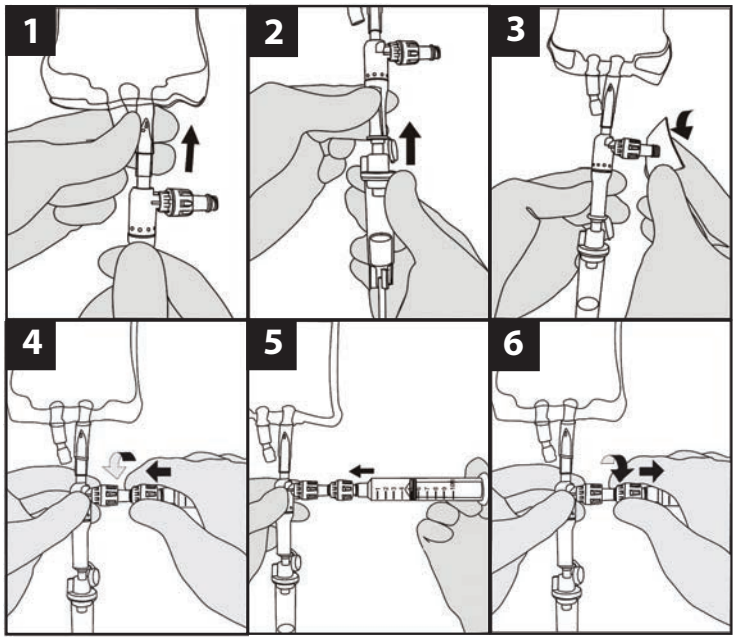


## Indications for Use

The Arisure Dry Spike Non-Vented is intended for use by healthcare professionals in a wide variety of healthcare environments including hospitals, healthcare facilities, and pharmacies for dispensing of medication and as a component of the Arisure Closed System Drug Transfer Device (CSTD). The Arisure Dry Spike Non-Vented allows for the addition of liquid medications to IV containers through a needle-free valve and serves as a connector between an IV container and a standard IV set, while minimizing exposure to hazardous drug aerosols and spills.

## Precautions

- Follow standards of practice and facility policies and protocols for safe handling and disposal of hazardous drugs. The Arisure Dry Spike Non-Vented should be used in concert with personal protective equipment (PPE) and a laminar air flow hood or other enclosure suitable for preparation of hazardous drugs.
- Always use proper aseptic techniques for sterile medication preparation and administration. Follow standards of practice and facility protocols for intravenous (IV) admixture preparation and delivery, including disinfection of IV access ports. Failure to follow disinfection directions may result in unintended device performance.
- Do not spray package with cleaning agents as damage to labeling may occur.
- Do not use if packaging is open or damaged.
- Do not apply alcohol to the body of the Arisure Dry Spike Non-Vented or damage may occur.
- Not designed for use with glass bottles or rigid IV containers.
- Only use Arisure Dry Spike Non-Vented with ISO-compatible IV container access ports and IV administration set spikes, respectively, or unintended device performance may occur.
- Do not grip the Arisure Dry Spike Non-Vented by the needle-free valve when spiking the device into the IV container or damage may occur.
- Once inserted, do not remove the Arisure Dry Spike Non-Vented from the IV container or leaks may occur.
- When prepared in the pharmacy and transported to the care area, the entire IV preparation should be placed in an appropriate secondary container (for example, a labeled, resealable plastic bag). Do not use the IV preparation if the medication has leaked into the secondary transport container.
- Discard the Arisure Dry Spike Non-Vented every 168 hours or after 10 activations with the Arisure Closed Male Luer, whichever comes first.
- The Arisure Dry Spike Non-Vented must be used with the Arisure Closed Male Luer to support a dry disconnection (closed system).
- Do not use needles or blunt cannulae with the needle-free valve or damage to the needle free valve can occur.
- Do not leave slip Luer connections unattended.
- Use aseptic techniques defined by facility protocol.
- After use, dispose the entire IV preparation in accordance with facility protocol and applicable local, state, and federal laws and regulations. Do not disconnect the Arisure Dry Spike Non-Vented from the IV container or IV administration set.
- Arisure devices contain polycarbonate and acrylonitrile-butadiene-styrene (ABS). Do not use these devices with undiluted drug products that are contraindicated for use with polycarbonate and ABS, including those containing concentrated *N,N*-Dimethylacetamide (DMA). For enquiries regarding workflow for specific drugs, please contact Medical Information at Yukon Medical (medaffairs@yukonmedical.com).
- Pharmaceutical products prepared using the Arisure CSTD should be administered as soon as possible. Refer to drug manufacturer's recommendations and USP compounding guidelines for shelf life and sterility information. Use of the Arisure CSTD does not modify, extend, or supersede the manufacturer's label recommendations for drug storage and admixture stability. If desired, it is the responsibility of the compounding pharmacist to establish beyond use dates for compounded sterile preparations.
- This device does not contain Polyvinyl Chloride (PVC).




## Directions

1. Remove the Arisure Dry Spike Non-Vented from the packaging and remove the spike cap. Firmly grip the Arisure Dry Spike Non-Vented while avoiding the needle-free valve, and spike IV container until a secure connection is achieved.
2. Open Arisure Dry Spike Non-Vented handle cover (yellow) and spike with selected IV administration set. Prime the administration set per facility protocols.

   NOTE: If required, the distal end of the administration set may be equipped with a Arisure Closed Male Luer (with Cap).
3. Prior to every access, swab the top of the needle-free valve with 70% isopropyl alcohol (IPA) or 70% IPA/3.5% Chlorhexidine (CHG).
   - Disinfect the valve by thoroughly scrubbing the top of the valve with an alcohol pad for at least 15 seconds using circular motions.
   - Shift to a new area of the pad at least once during the 15 second scrubbing period.
   - Allow to dry (approximately 30 seconds).
4. Attach mating Luer access device to needle-free valve on the Arisure Dry Spike Non-Vented.

   NOTE: Arisure Dry Spike Non-Vented **must** be used with the Arisure Closed Male Luer to support a dry disconnection (closed system).
5. Transfer medication into the IV container per facility protocol. Flush the needle-free valve and syringe multiple times by withdrawing and injecting the contents of the IV container.
6. Disconnect mating Luer access device from needle-free valve on the Arisure Dry Spike Non-Vented.

   NOTE: Grasp the Arisure Closed Male Luer (not the syringe barrel) when disconnecting from the female needle-free valve of the Arisure Dry Spike Non-Vented.
7. Place the drug containing IV bag with pre-primed IV administration set in a secondary container (for example, a resealable bag) and label appropriately for storage or transport. Before transporting the prepared medication and primed IV set, and before connecting and administering to the patient, check that all spike connections are secure and properly attached.
8. After use, dispose of the entire IV administration preparation (without disconnecting any components) in accordance with applicable regulations or facility protocol.

STERILE R | DEHP-FREE | LATEX

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4021 Stirrup Creek Drive
Durham, NC 27703 USA

Rx Only



LBL 251.02 Oct 2021

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| Does not contain DEHP*<br>DEHP-FREE<br>SS-EN 15986:2011* | Indicates the medical device does not contain bis (2-ethylhexyl) phthalate (DEHP). |
| Not made with natural latex rubber<br>LATEX<br>5.4.5 | Indicates dry natural rubber latex is not a material of construction within the medical device or the packaging of a medical device. |
| For prescription use only**<br>Rx Only<br>21CFR801.109** | Caution: Federal Law restricts this device to sale by or on the order of a physician. |
| Non-pyrogenic<br>5.6.3 | Indicates a medical device that is non-pryogenic. |
| Do not use if package is damaged<br>5.2.8 | Indicates a medical device that should not be used if the package has been damaged or opened. |
| Catalog Number<br>REF<br>5.1.6 | Indicates the manufacturer's catalogue number so that the medical device can be identified. |

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| Consult instructions for use<br>5.4.3 | Indicates the need for the user to consult the instructions for use. |
| Do not re-use<br>5.4.2 | Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |
| Use-by date<br>5.1.4 | Indicates the date after which the medical device is not to be used. |
| Batch Code<br>LOT<br>5.1.5 | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
| Sterilized using irradiation<br>STERILE R<br>5.2.4 | Indicates a medical device that has been sterilized using irradiation. |
| Caution<br>5.4.4 | Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |

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| Manufacturer<br>5.1.1 | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC |
| Authorized representative in the European Community<br>EC REP<br>5.1.2 | Indicates the Authorized Representative in the European Community. |

All symbols in these tables are from ***ISO 15223-1:2012 - Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1 General requirements***, except where specifically noted.

*This symbol is from ***SS-EN 15986:2011 - Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates***

**This symbol is from ***21CFR801.109 - Code of Federal Regulations Title 21 Chapter I Subchapter H Part 801 Section 109 Prescription Devices***