



Instructions For Use

Item: CMS-1212

Item Description: Single Use Infiltration Tubing Set

Manufactured by: Custom Assemblies Inc.

Address: 330 East Main St, Pine Level, North Carolina 27568

Country of Origin: United States of America

Intended Use:

To deliver fluid from a bag to patient through a peristaltic pump and either a cannula or needle.

Setup:

1. (**Warning**) Ensure the integrity of the seal has been persevered and that the package is completely sealed.
2. Remove the infiltration set from the sterile barrier.
3. Remove the tape and uncoil the infiltration set.

How to Operate:

1. Insert the silicone pump-header into the peristaltic pump.
2. The fluid being administered through the tubing should flow from left to right.
3. Insert bag spike into the fluid bag.
4. Attach luer lock (opposite end of the spike) to the infiltration cannula or needle.
5. Ensure the connection between luer and cannula/needle is secure and that the threads are compatible.

Troubleshooting:

Problem	Action
Leaking from bag spike	Verify that the spike is secured in the fluid bag.
Leaking from luer lock, needle or cannula	Verify that the luer lock is secured to the device and that the threads are compatible.
Low vacuum	<ol style="list-style-type: none">1. Verify the tubing is devoid of any kinks and that neither of clamps on the set are in a closed position.2. Verify that the rollers on the peristaltic pump are capable of performing their intended use.3. After performing steps 1, 2, increase the pressure using the knob on the peristaltic pump.4. If low vacuum persists, dispose of the set in accordance with the facility's guidelines.

Storage of Product:

The product should be stored at room temperature and in a dry area. Avoid humidity and store with tubing of similar composition in accordance with the facility's guidelines.

Sterilization of Product:

This tubing set is sterilized using Ethylene Oxide via third party. Sterilization Services of Virginia performs the sterilization process at 5674 Eastport Blvd, Henrico, Virginia 23231

Transportation of Product:

The product is safe to be transported through freight and cargo. Avoid humidity and excessive heat.

Maintenance and Disposal:

There is no maintenance of the tubing set. This product is intended to be disposed of after completion of procedure. Dispose of the used tubing in accordance with the facility's operating procedures. Do not reuse.