



Product Warranty and Limitations of Liability:
MED-LOGICS warrants that the Infusion Tubing Set will conform to MED-LOGICS' then current version of the product specifications for such disposable items in all material respects and shall be free from defects in material and/or workmanship for a period equal to the disposables expiration date. MED-LOGICS excludes all other warranties, whether expressed, implied or by operation of law, including but not limited to any implied warranties of merchantability or fitness. MED-LOGICS shall not be liable for any incidental, consequential or exemplary loss, damage or expenses, directly or indirectly resulting from the use of the Infusion Tubing Set even if MED-LOGICS has been advised of the possibility of such loss, damage, or expense.


 Manufactured by:
MED-LOGICS, Inc.®
1627 Enterprise Street, Athens, TX, USA
Tel: +1-949-582-3891, E-mail: info@mlogics.com


 European Representative:
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5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland
Tel: +353-89-225-1951, E-mail: info@ecrep.ie

 UK Representative:
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Tel: +44-7543-672-888, E-mail: info@responsible-person.co.uk

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









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









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Symbols Used on Labeling	
 Catalog Number	 Manufacturer
 LOT Number	 Authorized Representative in the EU
 CE Mark is Self Certifying	 Authorized Representative in the UK
 Caution	 Consult instructions for use
 Do not use if package is damaged	 Do not reuse
 Date of manufacture: (YYYY-MM)	 Sterilized using Ethylene Oxide
 Use by: (YYYY-MM)	

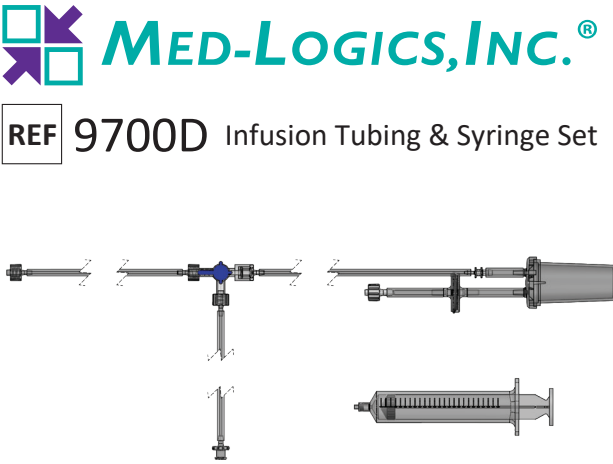
- Warnings:**
- This product is not intended for purpose other than supplying pressure to the AAC and the MED-LOGICS pressure monitoring devices.
 - EtO Sterilization is performed on the pouch and content. Never open pouch until just before use. Do not use if the pouch is broken or expiration date has passed. The part may no longer be sterile and may other deficiencies caused by age.
 - Do not re-sterilize. Additional sterilization can compromise the product, which may result in malfunction.
 - Verify the integrity of the Infusion Tubing Set before use. If the Infusion Tubing Set is damaged or defective, do not use as it may not hold pressure. Please contact MED-LOGICS or an authorized representative.

Storage Conditions:
The disposable products have no special storage conditions, but should be stored under normal warehouse conditions, which includes protection from moisture, extreme cold (less than 5°C), and excessive heat (greater than 40°C).

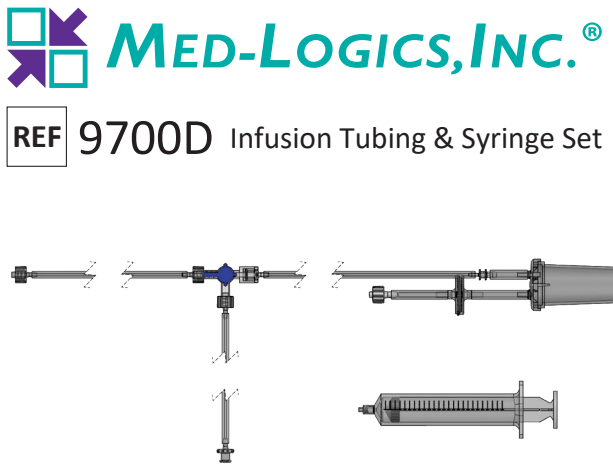
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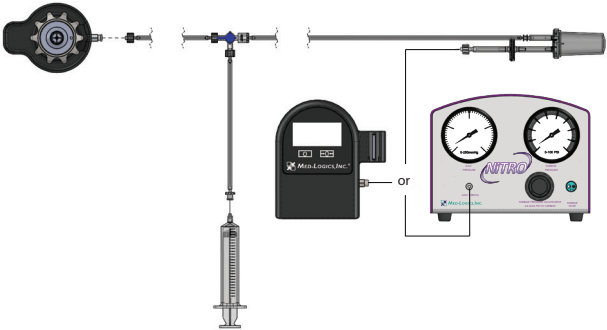
Indication For Use:
The 9700D Infusion Tubing & Syringe Set is a sterile, disposable, and single-use components for use with the MED-LOGICS (Part # 9600D) Digital Pressure Gauge and/or the MED-LOGICS (Part # MLN1900) NiTRO Donor Cornea System Console. The intended use of this component is to connect an artificial anterior chamber (AAC) with a MED-LOGICS pressure monitoring device and be able to deliver positive pressure to the donor cornea tissue using the supplied syringe.



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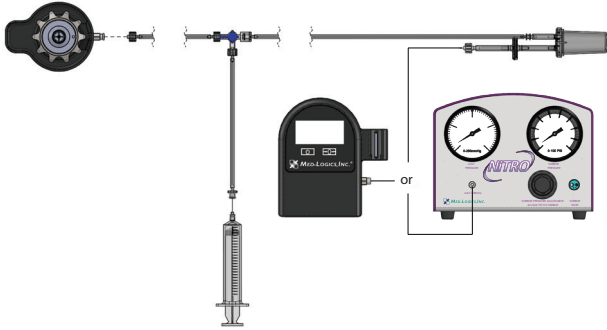
Set Up

- 1. Remove tubing set and syringe from their sterile pouches and place them in a sterile area.
- 2. With a non-sterile hand or with the help from another technician, attach the female luer connector with the filter and collection canister to a MED-LOGICS pressure monitoring device, which is outside the sterile area. **Note: It is advised that the pressure monitoring device be elevated approximately (4 inches / 10 centimeters) above the AAC to maintain a column of air going to the gauge.**
- 3. While sterile, securely attach the female luer connector at the end of the tube to the AAC male connector port (see illustration below).
- 4. While sterile and depending on the centers surgical protocol, fill and securely attach the sterile syringe to the end of the other tubing with the male connector (see illustration below).



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- 3. While sterile, securely attach the female luer connector at the end of the Y tube to the AAC male connector port (see illustration below).
- 4. While sterile and depending on the centers surgical protocol, fill and securely attach the sterile syringe to the available stopcock at the end of one of the Y tube (see illustration below).



Instruction For Use

- Note: The following section is provided as a guide only. Use the facility's established protocol to prepare the cornea for sectioning.**
- 1. Prime the lines by opening the stopcock with the finger positioned at the back of the stopcock or resembling a + sign. Press on the syringe to remove any air from the tubing line going to the AAC.
 - 2. Drape or float the cornea over the meniscus dome. Introducing fluid may be required by pressing the syringe in order to remove any air bubbles from under the cornea during this step.
 - 3. Make sure the cornea is centered and attach the cornea Fixation Cap on top of the cornea making sure the AAC pin mates with the hole on the Fixation Cap. Introduce the threaded ring over the Fixation Cap and securely tighten the ring to the AAC. Wait 15-30 seconds and tighten the threaded ring once again. **Note: This is done to avoid pressure leaks due to tissue compression.**
 - 4. Inflate the cornea by pressing on the syringe while watching the pressure monitor gauge. Recommended pressure to the AAC should be between 125 – 135mmHg. Once the desired pressure is reached, move the finger on the stopcock directly above the connector that is going to the syringe). **Note: It is important to achieve the same pressure level in subsequent procedures in order to establish an accurate nomogram.**
 - 5. Check for leaks, once you have pressurized the cornea and the pressure being displayed is stable. Close the stopcock leading to the AAC (move the finger on the stopcock directly above the connector that is going to the AAC) before cutting the tissue.
 - 6. Retrieve tissue, open stopcock with the finger positioned at the back of the stopcock or resembling a + sign and apply pressure from the syringe during the dismount of the cornea from the AAC.

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Stopcock Settings Reference Chart

Task	Syringe	AAC
Prime Lines	Open	Open
Inflate Cornea	Open	Open
Check For Leaks	Closed	Open
Cut Tissue	Closed	Closed
Retrieve Cornea	Open	Open

After Use

- 1. Carefully remove the luer connectors on the Infusion Tubing from the attached AAC and MED-LOGICS pressure monitoring device . Dispose of the Infusion Tubing and Syringe Set into a medical waste bin. **Note: Use the facility's established protocol for disposable of medical waste.**

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