AngiAssist™

Medical Gas Management and Delivery System

INSTRUCTIONS FOR USE

Manufactured by Robling Medical, Inc.
Youngsville, NC
for
AngioAdvancements, LLC

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Indications for Use

The AngiAssist® is pressure tubing and accessories intended to deliver pressurized medical gases through a designated pathway.
Carefully tighten all fittings prior to use.

This system is designed for a gas pressure of NO MORE THAN 0.6895 bar or 10psi at a fixed setting and should only be used at .6895 bar or 10psi or less. Higher pressures involve a risk of compromising the integrity of the system.

The correct pressure should be checked before connecting to any gas source.

Be certain to read all instructions and observe all Warnings, Precautions, and Indications prior to using this device. Patient complications may occur if this is not done.

⚠ WARNINGS and PRECAUTIONS

- Make sure connections are secure to prevent the introduction of room air into the system.
- Finger-tighten all connections with caution as over-tightening can create cracks and/or leaks.
- Carefully read all instructions prior to use.
- Inspect device and packaging for damage prior to use.
- Do not use product if packaging or product have been damaged in any way.
- Ensure that products not belonging to this set are compatible and read their instructions for use carefully.
- US Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Single-use only. Do not re-use this device. Do not re-sterilize this device.
- Use only sterile techniques when handling this device.
- Be sure all tubing is free from crimps or bends.
- Do not re-use any parts of this system to avoid incompatibilities.
- Discard in accordance with acceptable medical practices and applicable regulations.
- Do not alter this device.
- Use a low-pressure system or regulate to pressure **not exceeding .6895 bar or 10psi.**
- If the syringe fails to draw or deliver properly, check for a crimp in hose, or verify the direction of flow through the valve.
- Be certain gases used in this system have passed validated performance specifications including, for example, accuracy, and sensitivity.
- Do not connect to any source with pressure exceeding .689474 bar or 10psi.

Potential Complications

- None Known

Instruments Required

- Safety Eyewear
- AngiAssist™ Medical Gas Management and Delivery System
- Compatible gas filter

Positioning of the AngiAssist™

- Device should always be operated with the valve toward the "top" and the syringes toward the "bottom", or closest to the operator.

Specifications:

Service: Compatible medical gases.
Temperature & Pressure Limits: Maximum .6895 bar or 10psi @ 100° F (48° C)
Process Connection Incoming Tubing: 1/8" OD Tubing 24" long PVC Tubing with One Way Valve and Female Luer Fitting
Process Connection Outgoing Tubing: 1/8" OD Tubing 36" long PVC Tubing with One Way Valve and Male Luer Fitting
-PVC Tubing Material: 100% Virgin PVC meets ISO 10993-1 Biological Evaluation for Indirect Contact, Limited Exposure.

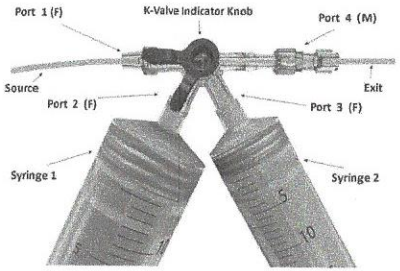
Symbol	Used For	Symbol	Used For
⚠	Caution, consult accompanying documents	REF	Catalog number
	Consult instructions for use	LOT	Batch code
	Do not reuse		Date of manufacture
LATEX	Latex Free		Use by YYYY-MM
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician	STERILE R	Sterilized using irradiation
	Manufacturer		Do Not Use if Opened or Damaged
STERILIZE	Do Not Re-sterilize		Pyrogen Free

Instructions for Use of the AngiAssist™

Examine package integrity and continue ONLY if package if free from damage.
Remove product from package and discard packaging. Remove paper band and discard.

Hand Tighten all fittings and connections, taking care not to over tighten.

Remove **Dust Caps** from **Extension Tubing** by working back and forth, NOT BY TWISTING. Double-check connection of **One-Way Valves** to ensure they did not loosen when **Dust Caps** were removed.



Check the incoming pressure of your gas source to ensure that the pressure does not exceed .689474 bar or 10psi. Connect **Incoming One Way Valve** with attached **Incoming Extension Tubing** securely to the gas source.

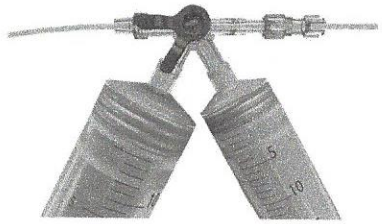
The system should be "purged" at least two times to avoid any room air contamination through the closed system in the lines and/or valves. Complete the following instructions at least twice to "purge" the system before assuming the system is delivering only the gas desired.

With the gas source connected to the **Incoming One Way Check Valve (8a)**, and the **K-Valve** in **Position I**, begin the gas flow. The **60mL Syringe** will begin to fill. Fill to maximum of 60mL, being careful to not overfill beyond capacity.

Once the **60mL Syringe** is full, stop the flow of gas into the system. Turn the **K-Valve** to **Position II** allowing the gas to flow between the **60mL Syringe** and the **30mL Syringe**. Draw up to fill the **30mL Syringe** thus de-pressurizing the gas that may have gotten compressed in the **60mL Syringe**.

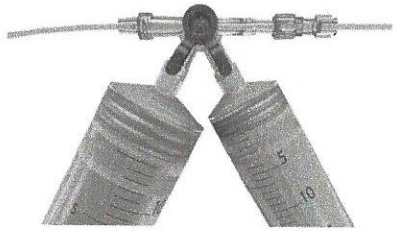
Turn the **K-Valve** to **Position III** and manually push gas supply through the **Exit Tubing** and out through the **Outgoing One Way Check Valve**. With the **K-Valve** in **Position I,** the flow will only move in the direction from ***Port 1*** to ***Port 2***. The **AngiAssist™** comes with the system in **Position I.**

Position I



With the **K-Valve** in **Position II,** the flow will only move in the direction from ***Port 2*** to ***Port 3***.

Position II



With the **K-Valve** in **Position III,** the flow will only move in the direction from ***Port 3*** to ***Port 4***.

Position III

Turn the **K-Valve** Indicator Knob to **Position III** for dispensing. The materials leaving ***Port 4,*** connected to the **K-valve**, exit via **Outgoing One-Way Valve**. The one-way valves at both the source tubing and exit tubing will reduce the likelihood of system contamination.

Item Key	Part Description
1A	24" long Incoming Extension Tubing - 1/8" OD x 1/16" ID
1B	36" long Outgoing Extension Tubing – 1/8" OD x 1/16" ID
2	60ml Syringe w/ luer lock
3	30mil Syringe w/luer lock
4	K-Valve
5	Female Luer Fitting
6	Male Luer Fitting
7	Slide Clamp with Hook
8a	Incoming One Way check valve
8b	Outgoing One Way check valve
9	Dust Cap