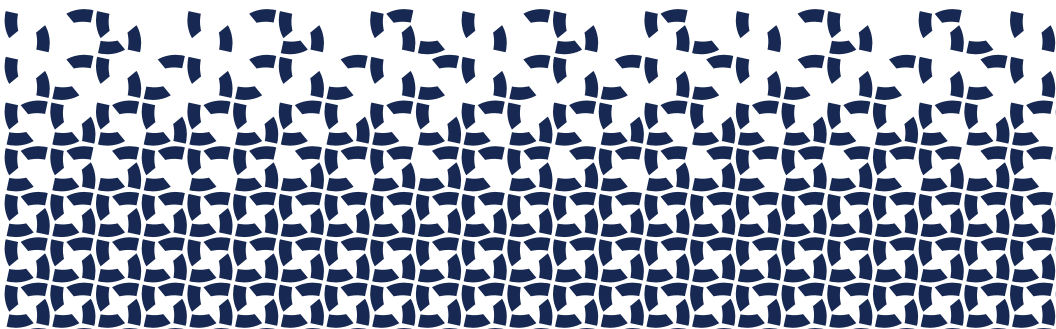
HALYARD*

COOLIEF* COOLED RADIOFREQUENCY KIT

Instructions for Use



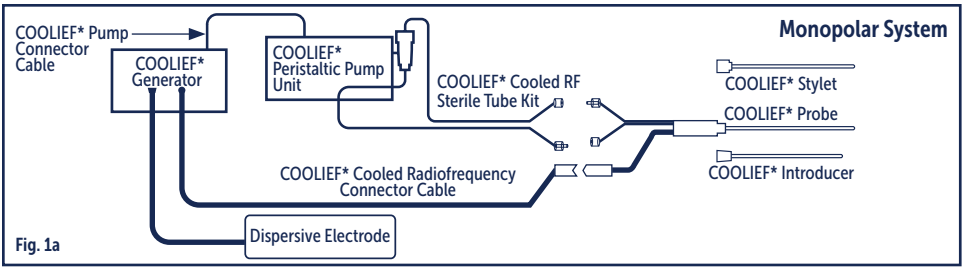


Fig. 1a

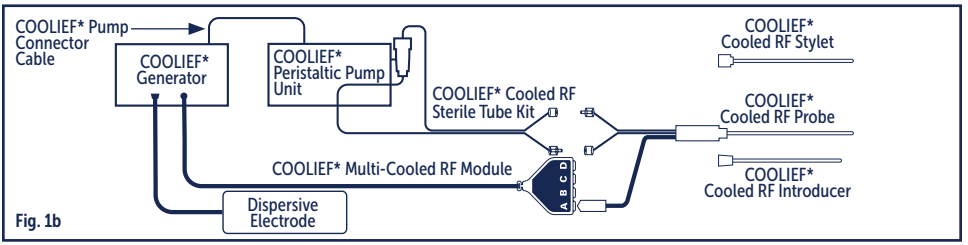


Fig. 1b

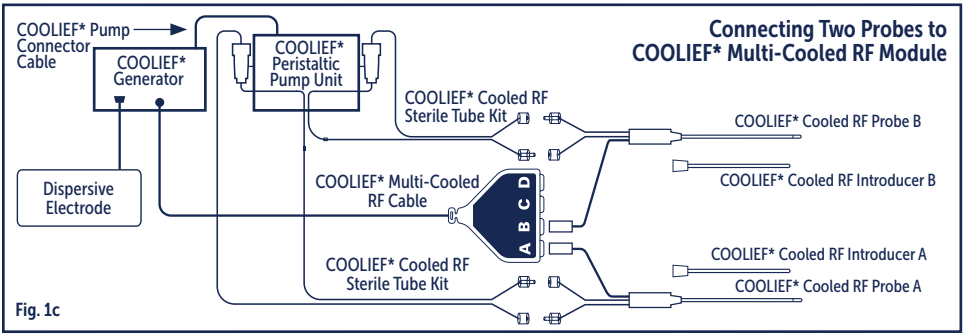


Fig. 1c

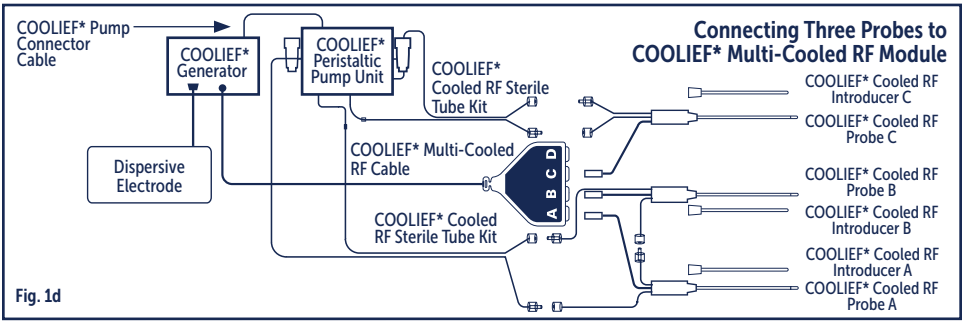


Fig. 1d

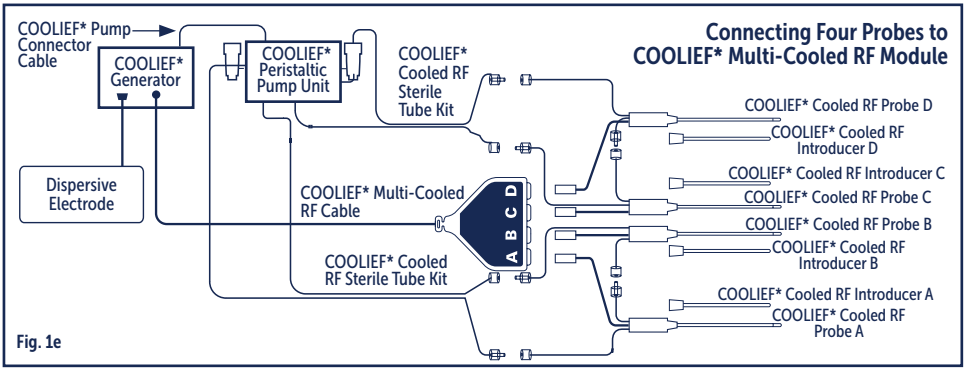


Fig. 1e

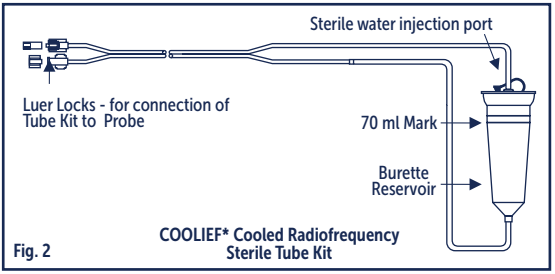


Fig. 2 COOLIEF* Cooled Radiofrequency Sterile Tube Kit

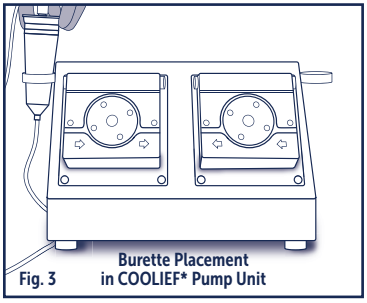


Fig. 3 Burette Placement in COOLIEF* Pump Unit

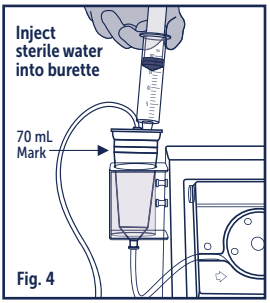


Fig. 4

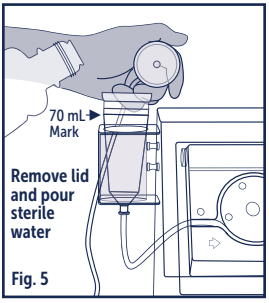


Fig. 5

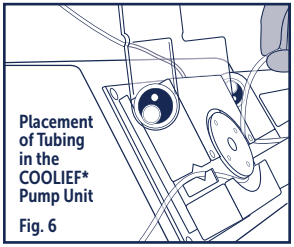


Fig. 6

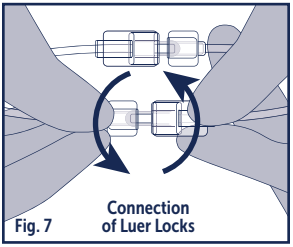


Fig. 7 Connection of Luer Locks

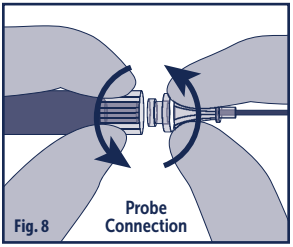


Fig. 8 Probe Connection

Single Use Only	STERILE EO	Rx Only	Do not use if package is damaged
Non-Pyrogenic	Follow instructions for use	Keep away from sunlight	Dispose of properly

EN HALYARD* COOLIEF* Cooled Radiofrequency Kit

Rx Only: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Device Description

HALYARD* COOLIEF* Cooled Radiofrequency Sterile Tube Kit (sterile, single use, non-body contact): It is used for closed-loop circulation of sterile water through a HALYARD* COOLIEF* Cooled Radiofrequency (RF) Probe. It includes a burette and tubing.

HALYARD* COOLIEF* Cooled Radiofrequency Introducer (sterile, single use): It is to be used with the Probes only. The Cooled Radiofrequency Introducer provides a path for the Probe to the nervous tissue.

HALYARD* COOLIEF* Cooled Radiofrequency Probe (sterile, single use): It is inserted through a Introducer into or near nervous tissue. Sterile water circulates internally to cool the Probe while it delivers radiofrequency energy. A thermocouple in the Probe measures cooled electrode temperature throughout the procedure. The "Cooled RF Set Temp" (Default Setting T = 60°C) displayed on the COOLIEF* RF Generator refers to the cooled electrode temperature and does not reflect the immediate surrounding tissue temperature. The heat generated from the radiofrequency energy produces thermal energy with average maximum tissue temperatures greater than 80°C.

Indications For Use

The HALYARD* COOLIEF* Cooled Radiofrequency Kit, in combination with the HALYARD* COOLIEF* Radiofrequency (RF) Generator (PMG-115-TD/PMG-230-TD/PMG-ADVANCED) (formerly Baylis Pain Management Generator or KIMBERLY-CLARK® Pain Management Generator) is indicated for use to create radiofrequency lesions in nervous tissue.

Contraindications

For patients with cardiac pacemakers, a variety of changes can occur during and after the treatment. In sensing mode the pacemaker may interpret the RF signal as a heartbeat and may fail to pace the heart. Contact the pacemaker company to determine if the pacemaker should be converted to a fixed-rate pacing during the radiofrequency procedure. Evaluate the patient's pacing system after the procedure.

Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the COOLIEF* RF Generator.

If the patient has a spinal cord, deep brain, or other stimulator, contact the manufacturer to determine if the stimulator needs to be in the bipolar stimulation mode or in the OFF position.

This procedure should be reconsidered in patients with any prior neurological deficit.

The use of general anesthesia is contraindicated. To allow for patient feedback and response during the procedure, it should be performed under local anesthesia.

Systemic infection or local infection in area of the procedure.

Blood coagulation disorders or anticoagulant use.

⚠Warnings

The Kit contains single-use devices. Do not reuse, reprocess, or resterilize these medical devices. Reuse, reprocessing, or resterilization may 1) adversely affect the known biocompatibility of the device, 2) compromise the structural integrity of the device, 3) lead to the device not performing as intended, or 4) create a risk of contamination and cause the transmission of infectious diseases resulting in a patient injury, illness, or death.

The COOLIEF* Probe must be used with the correct connector cable. Attempts to use it with other connector cables can result in electrocution of the patient or operator.

Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency procedures due to the continuous use of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.

Discontinue use if inaccurate, erratic or sluggish temperature readings are observed. Use of damaged equipment may cause patient injury.

Do not modify HALYARD* Equipment. Any modifications may compromise safety and efficacy of the device.

When the COOLIEF* RF Generator is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment.

The RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the Probes, particularly when operating the device.

During power delivery, the patient should not be allowed to come in contact with grounded metal surfaces.

Do not remove or withdraw the device while energy is being delivered. There is a rare potential for localized skin burn if RF lesion site has insufficient subcutaneous tissue (<15mm) or is near a shallow metal implant.

There is a rare potential for unintended nerve or vascular damage if RF lesion is created over a nerve or vessel:

Ensure proper selection of the appropriate sized active electrode tip to achieve the desired lesion size.		
Active Tip Size	**Lesion Size and Shape (T=60°C)**	**Typical Anatomy Placement**
2 mm	4 – 6 mm, Oblate Spheriod	Cervical Spine
4 mm	10 –12 mm, Spherical	Lumbar Spine, Knee, Hip
5.5 mm	12 mm, Spherical	Thoracic Spine

⚠Precautions

Do not attempt to use the Kit before thoroughly reading the accompanying Instructions for Use and the User's Manual for the COOLIEF* RF Generator and Dispersive Electrode (PMA-GP-BAY).

Apparent low power output or failure of the equipment to function properly at normal settings may indicate: 1) faulty application of the dispersive electrode or 2) power failure to an electrical lead. Do not increase power level before checking for obvious defects or misapplication.

To prevent the risk of ignition, make sure that flammable material is not present in the room during RF power application.

Only physicians familiar with RF lesion techniques should use the COOLIEF* Kit components.

It is the physician's responsibility to determine, assess and communicate to each individual patient all foreseeable risks of the RF lesion procedure.

The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised.

Proper sterile techniques must be used when assembling and filling the Tube Kit. Do not place the lid down on a non-sterile surface.

HALYARD* COOLIEF* Cooled Radiofrequency Sterile Tube Kit

The COOLIEF* Tube Kit is for use with a single Probe.

Care must be taken to ensure all luer fittings are secure to prevent leaking. Do not disconnect luer fittings while the pump is running.

Arrange equipment to minimize tubing tripping hazards.

Do NOT perform cooled RF lesion procedures if water is not circulating through the Tube Kit, water is leaking or air bubbles are seen in the tubing. Immediately stop the procedure and correct circulation before restarting the procedure.

Do NOT pinch the tubing of the Tube Kit.

HALYARD* COOLIEF* Cooled Radiofrequency Introducer

Be careful while handling the COOLIEF* Introducer. The sharp tip can cause injury to the operator if handled carelessly.

Handle the Introducer safely when it is in use due to electric currents.

Do not move the Introducer without the stylet fully inserted.

Choose the properly sized Introducer.

HALYARD* COOLIEF* Cooled Radiofrequency Probe

The Tube Kit should never be disconnected from the Probe when RF delivery is in progress. The lumen of the Tube Kit should not be obstructed in any way during the procedure, as this will stop cooling of the Probe.

Disconnect the Probe by pulling the connector, not the cable.

Handle the Probe safely when it is in use due to electric currents and the hot tip.

While inserting the Probe through the Introducer watch the fluoroscope for any buckling. Do not attempt to further insert the Probe if any buckling is observed or significant resistance is felt.

Do not move the Introducer when the Probe is in it. If repositioning is needed, retract the Probe from the Introducer and then reposition the Introducer with the stylet inserted.

The "Cooled RF Temp" displayed on the COOLIEF* RF Generator refers to the cooled electrode temperature and not the hottest tissue temperature.

Adverse Events

Potential complications associated with the use of this device include but are not limited to: infection, nerve damage, increased pain, visceral injury, failure of technique, paralysis, and death.

Product Specifications

The COOLIEF* Probe is comprised of an electrically insulated shaft with an active tip that functions as an electrode for RF energy delivery, a handle, tubes with luer locks and a cable with a 7-pin connector.

The COOLIEF* Introducer includes an insulated stainless steel cannula and a stylet.

The COOLIEF* Tube Kit is comprised of a burette and flexible tubing fitted with luer locks for connection to the Probe.

The COOLIEF* Probe, Introducer, and Tube Kit are ethylene oxide sterilized and supplied sterile. The devices should be stored in a cool, dry environment.

Note: *Please contact Halyard Health for a list of all model numbers and sizes.*

Inspection Prior To Use

The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been opened or damaged. Do not use the equipment if the packaging has been compromised.

Equipment Required

Procedures should be performed in a specialized clinical setting equipped with a fluoroscopy unit. The equipment required to perform RF procedures include:

- COOLIEF* Cooled Radiofrequency Probe
- COOLIEF* Cooled Radiofrequency Introducer(s)
- COOLIEF* Cooled Radiofrequency Peristaltic Pump Unit and Cable
- COOLIEF* Cooled Radiofrequency Sterile Tube Kit
- COOLIEF* Cooled Radiofrequency Connector Cable (Monopolar System) or COOLIEF* Multi-Cooled Radiofrequency (MCRF) Module (CRX-BAY-MCRF)
- Dispersive Electrode
- COOLIEF* Radiofrequency Generator (PMG-115-TD/PMG-230-TD/ PMG-ADVANCED)

Instructions for Use

Monopolar System (Fig. 1a – 1e)

Assemble all the equipment required for the procedure. Set up the COOLIEF* Radiofrequency Generator (PMG-115-TD/PMG-230-TD/PMG-ADVANCED) and the COOLIEF* Pump Unit (pump), as directed in their Instructions for Use. Connect the COOLIEF* Cooled RF Connector Cable to the RF Generator as described in its Instructions for Use.

Open the package in the sterile field using appropriate sterile techniques. Inspect the devices visually to make sure there is no damage to them. Do NOT perform the procedure with any damaged equipment.

HALYARD* Cooled Radiofrequency Sterile Tube Kit (Fig. 2)

1. Place the burette into the burette holder on the side of the Pump Unit. The side of the burette with two or three ports indicates the top of the burette. **(Fig. 3)**
2. Fill the burette with room temperature sterile water. Use sterile handling techniques. Fill the burette to the 70 mL mark. Burette can be filled by injecting sterile water through a port in the lid, or by temporarily removing the lid and pouring sterile water in.
   ⚠Warning: BE SURE TO FILL THE BURETTE TO THE 70 mL MARK. Not filling the burette to the 70 mL mark will result in an inadequate supply of water for circulation.
   Use ONLY sterile, room temperature water.
   Ensure the lid is snapped back onto the body of the burette after filling. (Figs. 4-5)
   Inject sterile water into burette OR remove lid and pour sterile water.
3. Place the thick-walled tubing coming out of the bottom of the burette into the pumphead of the Pump Unit. Place the tubing in the channels of the L-shaped bracket to ensure that the tubing is not obstructed while closing the pumphead. Close the lid on the pumphead to clamp down on the tubing.
4. Remove the caps on the male and female luer locks. Connect the appropriate luer lock to the corresponding luer lock on the COOLIEF* Probe. Do not over tighten the connection. **(Fig. 6)**
   ⚠Caution: Connect one Tube Kit to one Probe. **(Fig. 7)**
5. At the end of the procedure, discard the Tube Kit appropriately.

HALYARD* COOLIEF* Cooled Radiofrequency Introducer

1. With the stylet in the COOLIEF* Introducer, carefully insert the Introducer into the patient using fluoroscopic guidance to place it at the desired lesion location.
2. Once the Introducer is in the proper position, carefully remove the stylet from the Introducer.
3. Repeat steps 1-2 with a second Introducer if necessary.

HALYARD* COOLIEF* Cooled Radiofrequency Probe

1. Insert the COOLIEF* Probes into the tissue through the Introducer. Never force the Probe in if significant resistance is felt.
2. Connect the Probe to the Introducer using the luer lock on the Probe Handle. **(Fig. 8)**
3. Attach the Dispersive Electrode to the COOLIEF* RF Generator and place the Dispersive Electrode Pad on the patient as directed in the Instructions for Use accompanying the package.
4. Connect the Probe to the Tube Kit.
5. Connect the 14-pin connector of the COOLIEF* Cooled RF Connector Cable into the RF Generator. Connect the Probe to the 7-pin connector on the Cooled RF Connector Cable.
6. Select the Treatment mode in the RF Generator. Set advanced settings and the parameters for RF delivery in the RF Generator as described in the User's Manual.
7. Perform the procedure as described in the RF Generator User's Manual. The procedure comprises pre-cooling, treatment and optional post-cooling stages.
   Note: *Other than reproduction of their usual referred pain or irritation due to probe introduction, monitor the patient for unexpected symptoms that may indicate, for example, spinal cord or nerve root irritation. If these indications are suspected, discontinue energy delivery.*
8. After treatment remove the Probes and the Introducer and discard as biohazards. Remove the Dispersive Electrode from the patient and discard appropriately. Disconnect the Cooled RF Connector Cable from the RF Generator. Follow standard hospital techniques to handle reusable items.

Troubleshooting

The following table is provided to assist the user in diagnosing potential problems.

PROBLEM	TROUBLESHOOTING
No temperature measurement **OR** **Inaccurate, erratic or sluggish temperature reading**	Ensure all connections are made: • COOLIEF* Probe(s) to COOLIEF* Cooled RF Connector Cable • Cooled RF Connector Cable to the COOLIEF* RF Generator • RF Generator to power outlet Check for an error message on the RF Generator Visually inspect the Probe or Cable for damage. Ensure that devices are dry and at room temperature. If problem persists, discontinue use.
Water does not flow through the COOLIEF* Probe and Tube Kit	• Stop the procedure immediately. • Check the luer lock connections to ensure the Tube Kit is connected to the Probe. • Check the Pump to ensure the lid is not open. • Check RF Generator for any error messages.
Probe Connector does not fit in Probe Plug-in	• Check that the connector's keys are lined up in the proper orientation. • Ensure that the Connectors are clean and unobstructed.

PROBLEM	TROUBLESHOOTING
Damage to Insulation on COOLIEF* Probe or Introducer	Do not use. Discard immediately.
Water is not circulating through tubing during pre-cooling, ON and post-cooling states	• Ensure the COOLIEF* Tube Kit is correctly connected to the COOLIEF* Probe. • Ensure the Tube Kit has been correctly placed in the pumphead. • Ensure the burette reservoir has been filled. • Visually inspect the Tube Kit tubing and joints for leaks and occlusions. • Ensure that the float ball in the burette is floating and not occluding the outflow of water from the burette. • Ensure the pump tubing (thick-walled tubing that is coming directly out of the bottom port of the burette) is placed in the pumphead.
Water is not dripping into the burette	Check to see if water is running down the wall of the burette.
Float is stuck on bottom port of the burette	Close the pumphead lid. Gently shake the burette to try and loosen the ball from the bottom of the burette.
The lid of the burette cannot be removed	Inject sterile water through the port of the lid, rather than removing the lid.
COOLIEF* Tube Kit breaks, is leaking or is occluded	Immediately discard the Tube Kit.

Customer Service and Product Return Information

If you have any problems with or questions about HALYARD* Equipment, contact our technical support personnel.

Halyard Health
5405 Windward Parkway
Alpharetta, GA 30004 USA

E-mail: PMPorders@hyh.com

1-844-425-9273 (1-844-HALYARD)

Notes

For further detail on the creation of RF lesions in nervous tissue utilizing the Cooled RF Probe, please contact Customer Service and request to speak with a clinical specialist.

In order to return products under limited warranty you must have a return authorization number before shipping the products back to Halyard Health.

Limited Warranty

Halyard Health warrants that these products are free from defects in original workmanship and materials. If these products prove to be defective in original workmanship or original materials, Halyard Health, in its absolute and sole discretion, will replace or repair any such product, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products that have been used for their normal and intended uses. Halyard Health's limited warranty shall NOT apply to Halyard Health's products which have been repaired, altered or modified in any way and shall NOT apply to Halyard Health's products which have been improperly stored or improperly installed, operated or maintained contrary to Halyard Health's Instructions. The warranty period for HALYARD* RF Probes and RF Generator Connector Cables is 90 days from the date of purchase, unless otherwise stated.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind, which extend beyond the description of the warranties as previously mentioned. Halyard Health disclaims and excludes all warranties, whether express or implied, of merchantability or fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Halyard Health shall not be liable for damages for loss of profits or claims of buyer's customers for any such damages. Halyard Health's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Halyard Health to buyer which give rise to the claim for liability.

The buyer's use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.

www.halyardhealth.com

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