

INSTRUCTIONS FOR USE

Infiniti Medical® Jackson Pratt Drain

CAUTION: U.S federal law restricts this device to sale by or on the order of a veterinarian.

CAUTION: This product is intended for veterinary use only. It is not for human use.

TARGET SPECIES: Canine

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE: FAILURE TO FOLLOW SPECIFIC INSTRUCTIONS WARNINGS AND PRECAUTIONS MAY RESULT IN PROCEDURE COMPLICATIONS. AN ASEPTIC TECHNIQUE IS REQUIRED.

DEVICE DESCRIPTION

Jackson-Pratt Wound Drainage Systems are sterile single-use devices. The wound drainage system consists of a wound drain and a fluid collection reservoir. The wound drain is a radio-opaque section of perforated silicone tubing. The wound drain is surgically placed in a surgical wound site. Blood and body fluids are collected through a wound drain into a fluid collection reservoir.

AVAILABLE SIZES

Size	Total length	Fenestrated length	Bulb capacity
5 mm (w) x 2.5 mm (h)	510 mm	150 mm	100 cc
7 mm (w) x 3.2 mm (h)	510 mm	150 mm	100 cc
10 mm (w) x 3.9 mm (h)	1050 mm	150 mm	100 cc
13 mm (w) x 5.1 mm (h)	1050 mm	150 mm	100 cc

STORAGE

Store in a dry, dark, cool place.

INTENDED USE

The *Infiniti Medical® Jackson Pratt Drains* are closed suction drains that collect bodily fluids from surgical sites. The device consists of an internal drain connected to a grenade-shaped bulb via plastic tubing. The purpose of the drain is to prevent fluid (blood or other) build-up in a closed space. This product is intended for use by veterinarians appropriately trained and knowledgeable in general surgical techniques and the used of surgical drains. It is for veterinary use only.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

This device is intended to be used by veterinarians with surgical training and familiarity with the use of the device.

POTENTIAL ADVERSE EVENTS

- Infection
- Inflammation
- Bleeding
- Organ injury
- Device retention/breakage which may require additional intervention or surgery for removal.
- Death or serious injury related to device placement or anesthesia required for the procedure.

PRECAUTIONS

- Store in a dry, dark, cool place. Inspect all components prior to use. Do not use if package is open or damaged or if the contents appear damaged.
- Use sterile technique when making all connections.
- To facilitate removal, the drain and tubing portions should not be curled, pinched, over-stretched or sutured either internally or externally. Do not suture the drain(s). Drains should be placed and removed carefully by hand only with a slow, steady pressure. Excessive force may result in breakage.
- Be sure that all user assembled connections are secure.
- During placement and removal of the drain, do not nick, cut, tear or otherwise damage the drain as this may lead to breakage.
- The drain must not be allowed to become occluded nor the reservoir to completely fill. If occlusion does occur, the drain can be aspirated by connecting suction or by applying suction directly to the drain. If the reservoir is not emptied when it is full, the likelihood of back contamination increases.
- All drainage holes must be located within the wound site and an air tight seal achieved at the wound exit to maintain vacuum. An air-tight seal must be maintained or the reservoir will fill with air and the likelihood of back contamination increases. Any air leaks must be rectified.
- A drain may be left indwelling for up to 30 days. It should be replaced by another drain if long-term therapy is required.

- While the drain is in place, tissue in-growth may occur around the drain and into the holes. This could cause the drain to break on removal. The patient's rate of healing should be monitored carefully by the surgeon. If tissue in-growth occurs, and the force required to remove is excessive, the drain may need to be removed surgically.
- Do not autoclave or resterilize.
- Do not expose to organic solvents (e.g. alcohol).

NOTICE

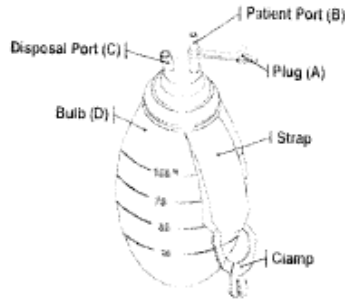
The material contained in this document does not describe the procedure for using this product and is not intended as a reference document for that procedure.

INSTRUCTIONS FOR USE

Use sterile technique

1. Initial Testing of Bulb:
 - Remove Bulb from packaging and test for efficacy as follows:
 - Fully compress Bulb (D).
 - Close Disposal Port (C).
 - Occlude Patient Port (B) and release Bulb (D).
 - If vacuum is effective, Bulb should remain compressed. If Bulb expands, it should be discarded.

**Silicone Bulb
100cc**



2. Initial Activation of System:
 - Place drain in wound site, ensuring that all channels or holes are located *within* the wound site. (Correct placement will ensure an air-tight seal at the wound exit, maintaining vacuum after closed wound draining begins. Air leakage will cause the system to be converted to open drainage and must be rectified accordingly).
 - Attach drain to Patient Port (B).
 - Firmly compress Bulb (D) to evacuate air.
 - Close Disposal Port (C) with Plug (A).
 - Release Bulb (D)
 - The Closed Wound Drain System has commenced.
 - Bulb should be located at patient level or below drain's exit for adequate suction to be maintained.
 - Drainage should be monitored such that Bulb is not filled to excess
3. Emptying Bulb Contents:
 - Raise Bulb above collection basin and tip.
 - Open Disposal Port (C) by releasing Plug (A).
 - Slowly compress Bulb (D).
 - All exudates will be evacuated into collection basin.
 - DO NOT RELEASE BULB!
 - Close Disposal Port (C) with Plug (A).
 - Renewed closed wound drainage will begin.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. The product is intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REUSE PRECAUTION STATEMENT

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

LIMITED WARRANTY

Infiniti Medical warrants to Buyer that products supplied by Infiniti Medical that are sold to Buyer will be free from defects in material and workmanship for six (6) months after delivery to Buyer. Buyer must inspect and notify Infiniti Medical of any such defects within this six (6) month period. Further, notice of a defective product must be given to Infiniti Medical in writing within ten (10) days following the discovery of such defect prior to the expiration of the warranty period in order to recover under the warranty. All returns are subject to the prior authorization of INFINITI, in its discretion.

The warranty does not cover and Infiniti Medical will have no warranty obligation whatsoever with respect to any damage to a product caused by or associated with: (i) usage not in accordance with product instructions or usage for a purpose not indicated on the labeling; (ii) abuse, misuse, neglect, improper maintenance or storage, accident, vandalism, or the negligence of any party other than Infiniti Medical; (iii) external causes, including (but not limited to) natural disasters, acts of God, power failure, cosmetic damage or damage to product packaging; or (iv) use of unauthorized consumables and/or accessories with the product. Infiniti Medical's sole liability under this warranty will be, at Infiniti Medical's sole option, to a) replace; b) repair; or c) refund the purchase price of the defective product(s). This will be Buyer's exclusive remedy for a covered defect. Any oral or written statement concerning the products inconsistent with the limited warranty set forth herein will be of no force or effect.

INFINITI EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OR CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AS WELL AS ANY WARRANTIES ARISING FROM COURSE OF DEALING AND USAGE OF TRADE, AND INFINITI MEDICAL DOES NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET BUYER'S REQUIREMENTS.

RETURNS

Buyer must notify Infiniti Medical within seven (7) calendar days of delivery regarding any products delivered to Buyer that were shipped in error, were damaged in shipping, or were in a shipping package that was damaged in shipping and such damage to the shipping package may have affected the quality of the products inside the shipping package.

Any products which Buyer wishes to return due to a) being shipped in error or damaged in shipping or b) a defect subject to the warranty provisions will be subject to receiving a Return Material Authorization (RMA) from Infiniti Medical. All returns are subject to the prior authorization of Infiniti Medical in its discretion. Only items appearing on an approved RMA are acceptable for return. Product returns will only be accepted from the original Buyer. Product returns will not be accepted from any third parties. Unauthorized returns will be destroyed and no credit issued. All authorized returned products must be shipped freight prepaid to the Infiniti Medical location indicated on the RMA, except Infiniti Medical will pay freight costs for product shipped-in-error or damaged in shipping.

LIMITATIONS OF LIABILITY

In no event shall Infiniti Medical be liable to Buyer for any unforeseen, indirect, incidental, special, punitive or consequential damages (including any loss of use, loss of revenue or damage for lost or anticipated profits), or otherwise arising out of or in connection with furnishing of products or service hereunder, or the performance, use of, or inability to use any products or service, or otherwise, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory. Infiniti Medical's total liability for any claim or action, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory shall not exceed the purchase price of the product or products out of which such claim or action arose, or Ten Thousand Dollars (\$10,000.00), whichever is less.

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