



## DEVICE DESCRIPTION:

The iO-Flex® Irrigation Cannula consists of a rigid, curved, hollow shaft with a proximal luer lock for connection to a standard syringe. The atraumatic distal tip is designed to deliver fluids in the lumbar spinal neural foramen and adjacent spaces. The Gravity flow rate at 1 Meter of Water Infusion Pressure is indicated in **Precautions Section - Table 1**.

## HOW SUPPLIED:

The iO-Flex® Irrigation Cannula is supplied sterile for single-patient use and available in two (2) different configurations:

Order Number	Description	
iO-CC	iO-Flex® Contra Irrigation Cannula for irrigating via an ipsilateral approach	
iO-IC	iO-Flex® Ipsi Irrigation Cannula for irrigating via a contralateral approach	

## INTENDED / INDICATIONS FOR USE:

The iO-Flex Irrigation Cannula is intended for continuous or intermittent preoperative, perioperative or post-operative delivery of local anesthetics and analgesics in the epidural space or near a nerve for regional anesthesia and pain management. May also be used perioperatively during open spinal procedures to irrigate, aspirate, or inject a bolus of fluid or medication.

## CONTRAINDICATIONS:

None known.

## WARNINGS:

- Decompressing L1/L2 with the iO-Flex system is not advised due to the theoretical risk of damage to the conus medullaris and the low incidence of stenosis at this level.

## PRECAUTIONS:

- Read all instructions prior to use.
- Failure to properly follow instructions may result in improper functioning of the device and may lead to patient injury.
- This device should only be used by personnel trained in the use of this device.
- Do not use the product after the "Use By" date.
- Do not use the product if packaging integrity appears compromised, open, or damaged in any way.
- Do not attempt use if any component of the system appears damaged, bent, crushed, or is missing.
- For single patient use only. Do not reuse or resterilize.

- Reuse or attempted resterilization of the device may lead to device failure and subsequent patient injury. Attempted resterilization of the device may create the risk of contamination and patient infection.
- The Gravity flow rate at 1 Meter of Water Infusion Pressure is indicated in **Table 1** below.

	Gravity flow rate (1 Meter of Water Infusion Pressure)
Ipsi Cannula	435 mL/min
Contra Cannula	460 mL/min

**Table 1: Gravity Flow Rate**

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

### ADVERSE EVENTS:

The complication rate using the iO-Flex System devices in commercial use has been demonstrated to be low (<5% device-related). The events listed below are associated with use of the iO-Flex System in order of more to least likely.

- Transient nerve irritation
- Hematoma
- Bone fracture
- Durotomy with or without CSF leakage
- Neuropathy
- Bleeding requiring transfusion
- Infection
- Paralysis
- Bowel/Bladder incontinence










### DIRECTIONS FOR USE:

1. Choose the appropriate device for either an ipsilateral or contralateral access approach.
2. Inspect package for damage. If undamaged, open using sterile technique.
3. Remove assembly from package and inspect for damage.
4. If irrigating, attach a syringe of fluid or medication to the Irrigation Cannula luer. Dispense a small amount of fluid or medication through cannula until visual inspection confirms exit of fluid or medication from distal end.
5. After a standard posterior surgical access to the spinal canal has been achieved, advance the distal end of the Irrigation Cannula over the dura towards the neural foramen.
6. Ensure that the dura and major neural and neurovascular structures remain on the convex side of the Irrigation Cannula, while the tissues in the lateral recess and/or neural foramen that are targeted for removal remain on the concave side of the Cannula.
7. Irrigate as desired. Be certain to follow the prescribed physician labeling that accompanies any fluid/medication to be delivered through the iO-Flex® Irrigation Cannula.
8. Only medications cleared for administration through an epidural cannula/catheter should be used with the Irrigation Cannula.
9. If aspirating,

- a. Attempt to aspirate only fluids with a viscosity comparable to saline. If material is more viscous, dilute with saline if allowed by fluid/medication’s IFU.
- b. Aspirate with a 10mL syringe or smaller.

10. At the completion of the procedure, dispose of used product in accordance with all local government regulations.

**Symbols:**

Symbol	Description
	Manufacturer
	Lot Number
	Model Number
	YYYY-MM-DD
	Sterile - Method of Sterilization Using Irradiation
	Do Not Reuse - Single Patient Use Only
	Do Not Use if Package is Open or Damaged
	Consult Instructions for Use
	Contents
<b>Rx only</b>	Caution – Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured in the USA by:



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