

**DEVICE DESCRIPTION:**

The iO-Flex® Distal Handle is an accessory device for the iO-Flex System, designed to securely terminate and clamp the distal portion of the iO-Flex® Wire.

**HOW SUPPLIED:**

The iO-Flex® Distal Handle is supplied sterile for single-patient use:

Order Number	Description
iO-DH	iO-Flex Distal Handle

**INTENDED / INDICATION FOR USE:**

The iO-Flex® Distal Handle can be used with iO-Flex® Wires, neural localization, cutting and biting devices during spinal surgery.

**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.
- Do not attempt use if any component of the system appears damaged, bent 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.

**CAUTION: Always exercise caution handling the sharp distal tip of the guide wire to prevent needle-stick injuries!**

**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. Inspect package for damage. If undamaged, open using sterile technique.
2. Remove Distal Handle from package and inspect for damage.
3. After the distal wire tip has exited the skin, insert the sharp distal tip into the funnel of the Distal Handle. (See **Figure 1**)
4. Insert Guide Wire tip into Distal Handle.
5. When the sharp end of the iO-Flex Wire exits the skin lateral to the incision, capture it in
  - a. the Distal Handle:
  - b. Depress button with thumb
  - c. Insert Wire into Distal Handle funnel
  - d. Continue feeding iO-Flex Wire into Distal Handle until the barrel end of the wire is contained inside the Probe plunger
- Lay Distal Handle on surgical field and proceed with removing iO-Flex® Probe

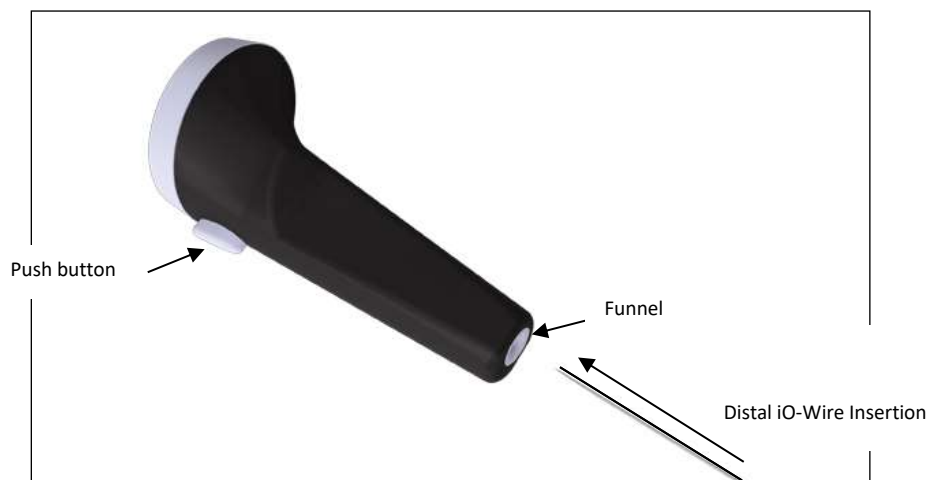
### 6. Two methods to load the Wire into the Distal Handle:

**“One-handed” method:** When sharp end of wire is approximately 1” (2.54 cm) exiting the skin, insert into Distal Handle funnel with push button depressed.

1. Release button and pull approximately 1” (2.54 cm) of wire through skin.
2. Depress button and zero out Distal Handle against skin.
3. Repeat until Wire is contained within the Distal Handle

**“Pull and feed” method:** When sharp end of wire is approximately 1” (2.54 cm) exiting the skin, insert into Distal Handle with push button depressed.

1. Release button and with one fluid motion, pull desired amount of wire through skin.
2. Depress plunger and hold Distal Handle with one hand; feed wire all at once into Distal Handle with other hand.












**Figure 1: Wire insertion**

7. While pressing the release button on the Distal Handle, slide the wire into the handle until there is no visible gap between the bottom of the Distal Handle and the patient’s skin.
8. Be sure to advance the Wire into the Distal Handle until the dark section of the Wire is completely contained within the Distal Handle and only the silver portion of the Wire is exposed.

**CAUTION: Always exercise caution handling the sharp distal tip of the guide wire to prevent needle-stick injuries!**

9. To release the Wire, press and hold the release button while gently pulling on the Wire.
10. At the completion of the procedure, dispose of used product in accordance with all applicable 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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