DEVICE DESCRIPTION:

The iO-Flex® Probe is an accessory of the Amendia iO-Flex® System, which includes the MicroBlade Shaver® device. The iO-Flex Probe is designed to access the neural foramen. It is comprised of an outer stainless steel Cannula, a flexible inner Catheter, a telescoping Handle for deployment of the Catheter, a main Handle and a Stylet.

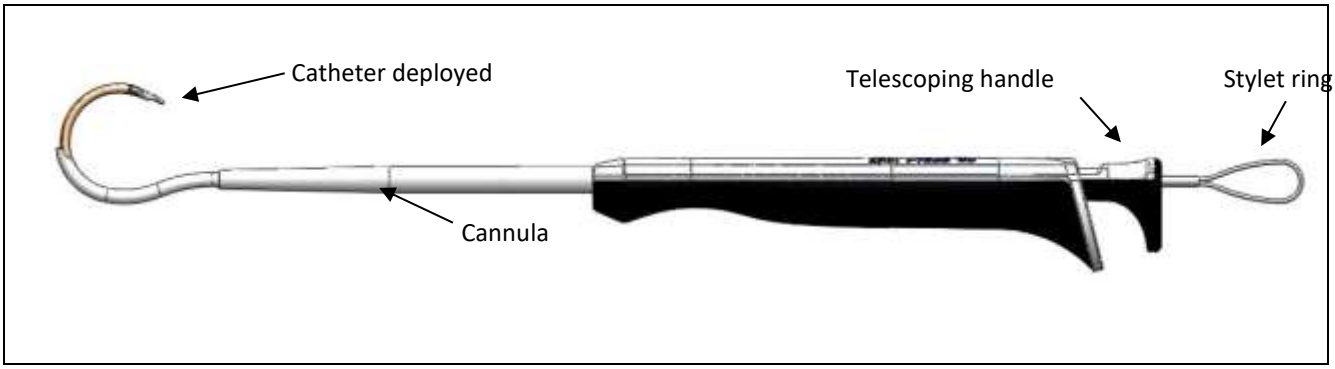

Figure 1: iO-Flex® Ipsi Probe

HOW SUPPLIED:

The iO-Flex Probe is delivered sterile as a single-patient use surgical instrument.

Order Number	Description	Display
iO-IP	iO-Flex Ipsi Probe for ipsilateral access	
iO-IP-TR	iO-Flex Ipsi Probe-TR with tight distal curvature for ipsilateral access	
iO-CP45	iO-Flex Contra Probe 45 for contralateral access	

INTENDED / INDICATION FOR USE:

The iO-Flex MicroBlade Shaver® and Accessories are designed for accessing, cutting and biting soft tissue and bone during surgery involving the spinal column.

CONTRAINDICATIONS:

None known.

WARNINGS:

- Failure to properly follow instructions may result in improper functioning of the device and may lead to patient and/or operator injury.
- For use only with Amendia iO-Flex instruments and accessory devices only.
- Do not use with surgical instruments from other manufacturers.
- 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.
- This device should only be used by personnel trained in the safe 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 cross-infection.

CAUTION: Always exercise caution handling the sharp distal tip of the iO-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® Probe or any iO-Flex System device 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 iO-Flex Probe device for either an ipsilateral (iO-IP or iO-IP-TR) or contralateral access approach.
2. Inspect package for damage. If undamaged, open using sterile technique.
3. Remove iO-Flex Probe from package and look for apparent damage.
4. Return any damaged product to Amendia or your Sales Representative.
5. Ensure smooth movement of the Catheter by plunging and retracting the Catheter using the telescoping handle.
6. Ensure that the Stylet is inserted completely into the Handle by confirming the distal end of the Stylet ring is touching the proximal end of the Handle (**see Figure 1**).
7. Prior to use, retract the Catheter into the Cannula so that only the smooth distal metal tip of the Catheter extends from the distal end of the Cannula.
8. If access is to be provided through a fixed tube, use a minimum 18mm OD tube with no more than 8cm in tube length.

Probe Placement

9. After a standard posterior surgical access to the spinal canal has been achieved, insert the undeployed Probe at the medial wall of the caudal pedicle
10. Advance Probe superior to the caudal pedicle for disc-level passes; inferior to the caudal pedicle for nerve root passes
11. Advance Probe tip into targeted foramen
12. Ensure that the dura and major neural and neurovascular structures remain on the convex side of the 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.

Caution: Positioning the Probe too far cephalad in the foramen could:

- Hook the exiting nerve root
- Endanger lateral vasculature
- Position on IAP rather than SAP
- Disrupt the facet joint

13. Confirm Probe placement in the caudal third of the foramen using lateral fluoroscopy
14. For disc-level passes, rotate Probe 10° cephalad
15. Deploy plunger to 2/3; 4 for L5/S1 or nerve root pass
16. Once placed, advance the Catheter through the Cannula to the desired position by depressing the Telescoping handle.

17. Remove stylet and feed the iO-wire into the plunger until exiting skin laterally (distal sharp tip first).

Probe Removal

18. Once the Guide Wire has been passed and the sharp distal end captured in the Distal Handle
19. Retract (pull up on) Probe plunger **(Fig 2.)**
20. Roll the Probe handle laterally until the handle is parallel with the floor(white side facing the floor) (**Fig. 3)**

Fig 2.: Retract Probe Plunger

Fig 3.: Roll the Probe Handle until It is parallel with the floor.

21. Pull straight up on the handle until the wire is free from the Probe
22. If not using other iO-Flex System instruments and no iO-Wire is in place, re-insert the Stylet fully prior to retracting the Catheter. Visually confirm the stylet does not extend past the Probe tip. (If there is more than one stylet on the scrub table, insert the longest stylet and verify it does not extend past the probe tip. If the longest stylet extends past the probe tip, insert the shortest one.)
23. Retract the Catheter fully into the Cannula before removing the Probe.

CAUTION: **If any resistance is encountered during retraction, determine the cause of resistance before proceeding. Failure to do so can result in damage to the flexible catheter sheath.**

Do not attempt to pull the Probe straight with a deployed or semi-deployed distal catheter portion as depicted in Figure 4.

If it is necessary to remove the iO-Flex Probe in its deployed or semi-deployed state, carefully roll the handle aside as shown in Figure 5 below before removing the Probe.

Figures 4: Do not attempt to remove the Probe straight up in its deployed or semi deployed state!

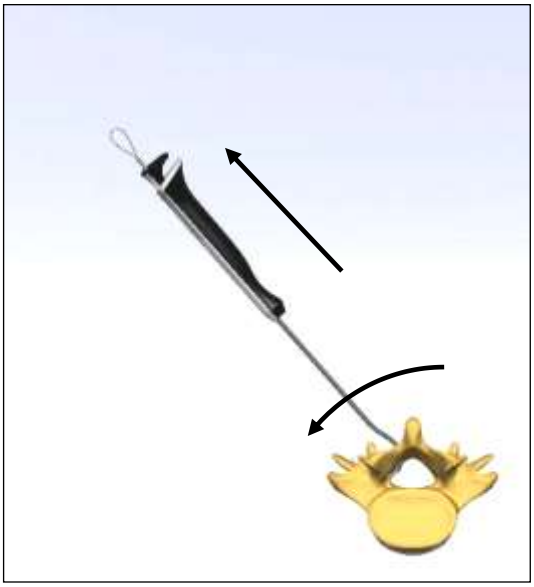

Figure 5 : Removal of Probe in its deployed or semi-deployed state.

24. If the Probe will be used to access a subsequent foramen or repositioned in a foramen, ensure that the Stylet is loaded into the Handle prior to use and retain the iO-Flex Probe within the sterile field. (If there is more than one stylet on the scrub table, insert the longest stylet and verify it does not extend past the probe tip. If the longest stylet extends past the probe tip, insert the shortest one.)

25. At the completion of the procedure, dispose of used product in accordance with local regulations.

Symbols:

Symbol	Description
	Attention! See Instructions for Use
	Manufacturer
	Lot Number
	Model Number
	YYYY-MM-DD
	Sterile - Method of Sterilization Using Irradiation
	Do Not Reuse - Single Use Only
	Do Not Use if Package is Open or Damaged
	Consult Instructions for Use
Rx only	Prescription Labeling Statement Caution – Federal (USA) law restricts this device to sale by or on the order of a physician.
	Contents
	Peel Off Here

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