

DEVICE DESCRIPTION:

The iO-Flex® MicroBlade Shaver® (MBS) device is part of the Amendia iO-Flex® System. The MBS consists of a proximal handle, rigid shaft, and a thin flexible cutting platform (**Figure 1**). The MBS device is used in conjunction with the iO-Flex System instruments and accessories. The iO-Flex Probe and Neuro Check device are available separately.

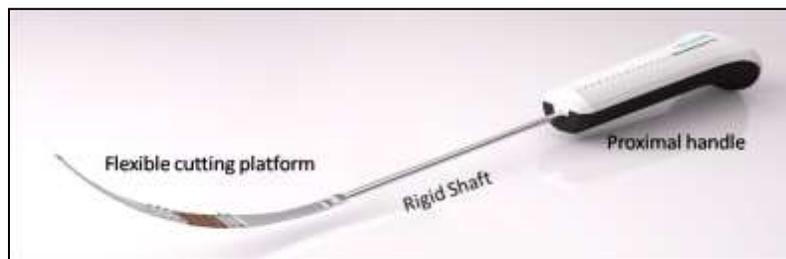


Figure 1: MicroBlade Shaver device
(Note: in this figure, cutting surface is facing up)

HOW SUPPLIED:

The MicroBlade Shaver device is supplied sterile for single-patient use and available in four (4) different configurations:

Order Number	Description
iO-MBS5.5	iO-Flex MicroBlade Shaver with a 5.5mm cutting width
iO-MBS7.5sc	iO-Flex MicroBlade Shaver with a 7.5mm cutting width and side cutters
iO-MBS10sc	iO-Flex MicroBlade Shaver with a 10mm cutting width and side cutters
iO-MBS12sc	iO-Flex MicroBlade Shaver with a 12mm cutting width and side cutters

INTENDED / INDICATION FOR USE:

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:

- For use only with iO-Flex instruments and Accessories. Do not use with instruments from another manufacturer.
- Do not proceed with decompression using the MicroBlade Shaver device unless an acceptable EMG response was achieved with the Neuro Check device.

- Ensure that the MicroBlade Shaver device is advanced/placed dorsal to the surrounding neural structures. Severe neural injury can occur with improper MicroBlade Shaver device advancement and placement.
- The cutting surface of the MicroBlade Shaver device must always face away from the surrounding neural structures.
- Severe neural injury can occur with improper MicroBlade Shaver device advancement and placement.
- 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.
- Use imaging (pre-operative and intraoperative) to help determine the appropriate MicroBlade Shaver® device size.
- Consider patient’s bone density prior to using any surgical instrument that accesses, cuts and bites bony tissue.
- Patients with osteoporosis/ osteopenia may require fewer reciprocations due to decreased bone density.

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

ADVERSE EVENTS:

The complication rate of the iO-Flex MicroBlade Shaver 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.

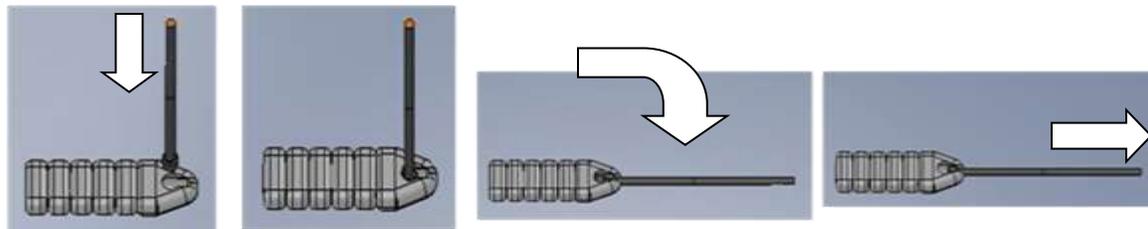
- Transient nerve irritation
- Hematoma
- Bone fracture
- Durotomy with or without CSF leakage
- Neuropathy
- Bleeding requiring transfusion

- Infection
- Paralysis
- Bowel/Bladder incontinence

DIRECTIONS FOR USE:

1. Inspect all packages for damage. Open using sterile technique and inspect for any signs of physical damage to the device and cable. Remove the MicroBlade Shaver device from the package.
2. After access to the posterior spinal canal has been achieved and the neural structures have been identified (either through direct visualization or using the iO-Flex® Neuro Check® device), attach the MicroBlade Shaver device to the proximal end of the Guidewire (**Figure 2**).

Figure 2: Attach guidewire to MicroBlade Shaver® device



(a) Align Guidewire barrel to tip of the MicroBlade Shaver device, (b) insert guidewire barrel into MicroBlade Shaver device tip, (c) rotate guidewire 90 degrees, (d) pull guidewire forward

3. Insert the proximal barrel feature of the guidewire into the distal tip of the MicroBlade Shaver at a right angle (**Figure 2a +2b**). Then rotate the wire for 90 degrees such that it is in line with the MicroBlade Shaver device (**Figures 2c to d**).
4. If access is to be provided through a fixed tube, use a minimum 16mm outer diameter (OD) tube with no more than 8cm in length.
5. If Distal Handle is not already connected to Guidewire, advance the sharp distal end of the Guidewire through the funnel of the Distal Handle to desired location.
6. Pull the Distal Handle to advance the MicroBlade Shaver device to the desired location adjacent to the target tissue, with the cutting elements of the device facing in the direction of the target tissue (dorsal).

CAUTION: Do not pull the Distal Handle such that the distal tip of the MicroBlade Shaver device exits the patient's skin.

7. Position the MicroBlade Shaver platform such that the **most distal cutting blade** is positioned medial to the foramen entrance (**Figure 3b.**)
8. Take a lateral fluoroscopic image to confirm the MicroBlade Shaver most distal cutting blade is at the referenced starting position. (Refer to **Figure 3a and 3b** for fluoroscopic image illustrations).

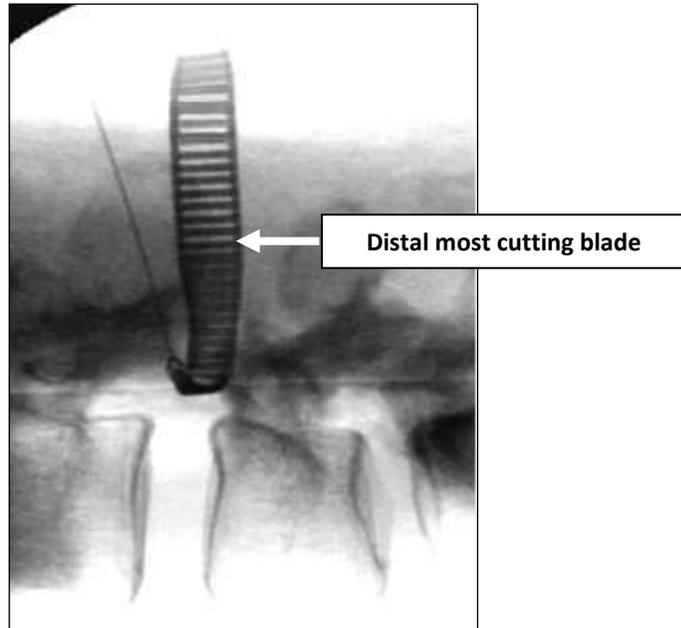


Figure 3a. Most distal cutting blade

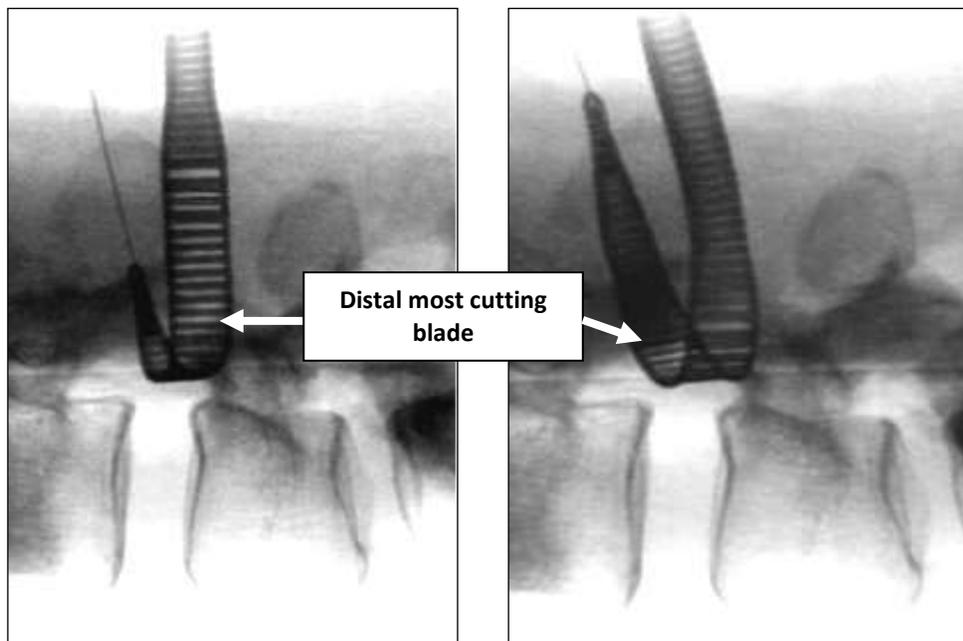


Figure – 3b. Starting position. Distal most cutting blade is medial to foramen entrance.

Figure – 3c. Ending position. Distal most cutting blade has advanced through the foramen to the medial side of the facet joint by approximately 1"/25 mm.

Fluoroscopic images in Figures 3a, 3b & 3c are illustrations and do not represent a particular MicroBlade Shaver size. Images are for reference purpose only.

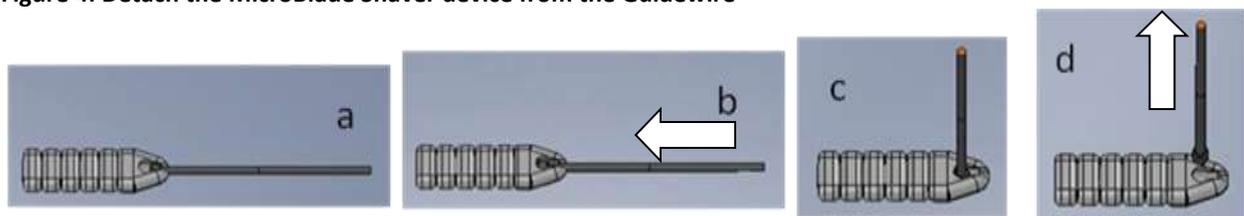
9. Adjust the Distal Handle relative to the Guidewire by depressing the release button on the handle until the funnel end lightly touches the patient's skin.

10. With the MicroBlade Shave device in the desired position, grasp the MicroBlade Shaver device handle (proximal handle) in one hand and the Distal Handle in the other hand. Apply tension to the device by simultaneously pulling up on both the proximal and distal handles.
11. Pull the Distal Handle to advance the MicroBlade Shaver device through the foramen (approximately 1"/25mm) until the proximal most cutting blade is on the medial side of the facet joint. (**See Figure 3c for correct ending position**).
12. Cut targeted tissue by using short bimanual reciprocations of the MicroBlade Shaver device while maintaining an upward tensioning force on both handles of the device.

CAUTION: If excessively high friction is experienced while using the MicroBlade Shaver device or if free movement of the device becomes arrested, avoid twisting the temporarily lodged device. Excessive and/or aggressive twisting of the lodged device can lead to structural failure of the device.

13. Irrigate and aspirate thoroughly after each decompressive pass to remove tissue debris from the epidural and foraminal space using the iO-Flex Cannula device or other appropriate off-the-shelf accessory devices.
14. Irrigation/aspiration devices with an internal lumen diameter (ID) of > 0.035"/0.9 mm/3 French can be positioned in the epidural and foraminal space.
15. After irrigation and aspiration has been performed, injectable hemostatic or therapeutic agents can be delivered (optionally using the same catheter) as necessary.
16. At the completion of tissue removal, unlock and remove the Distal Handle from the Guidewire by depressing the release button while pulling the handle off of the wire. Remove the MicroBlade Shaver device and Guidewire by pulling on the proximal handle. Detach the Guidewire from MicroBlade Shaver Tip (**Figure 4**).

Figure 4: Detach the MicroBlade Shaver device from the Guidewire



(a) Align Guidewire barrel to tip of the MicroBlade Shaver device, (b) push the guidewire in, (c) rotate guidewire 90 degrees and (d) remove the guidewire.

17. Following completion of the procedure, perform a standard surgical closure and dispose consumed devices in accordance with local safety and environmental regulations.

CAUTION: Excessive and/or aggressive use of the MicroBlade Shaver[®] may weaken the Guidewire. Excessive and/or aggressive pull forces can lead to structural failure of the device. Replacement of the Guidewire is recommended after performing two (2) foraminal lumbar spinal decompressions or as needed.

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
Rx only	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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