

ARTICULATION OF THE DISTAL TIP

- Deflecting the Handle results in a corresponding deflection of the Articulating Tip (Fig 5).
- When the Handle is in line with the shaft, the Articulating Tip will be straight.

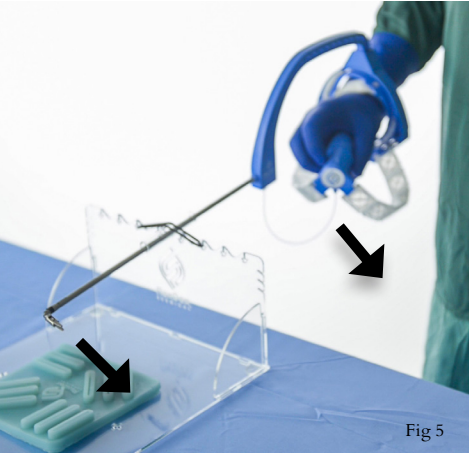


Fig 5

AXIAL ROTATION

- Turning the Rotation Dial causes the Articulating Tip and device to rotate about its axis and can be performed while straight or articulated (Fig 6).

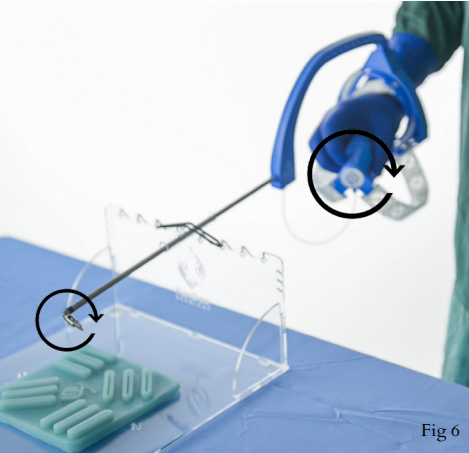


Fig 6

CLOSING, LOCKING AND UNLOCKING THE JAWS

- Squeezing the Handle Lever closes the jaws.
- Releasing the Handle Lever opens the jaws.
- The Jaws are locked by squeezing the Handle Lever until it “clicks”.
- The Jaws are unlocked by squeezing the Handle Lever a second time until it “clicks”.

DISPOSAL

Dispose of used devices as a biohazard.

Symbol	Definition	Symbol	Definition
	BATCH CODE		DO NOT USE IF PACKAGE IS DAMAGED
	CATALOG NUMBER		CAUTION, CONSULT ACCOMPANYING DOCUMENTS
	DO NOT REUSE		CONSULT OPERATING INSTRUCTIONS
	DO NOT RESTERILIZE		STERILIZED USING ETHYLENE OXIDE
	CAUTION: US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN		AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	USE BY DATE		MANUFACTURER
	QUANTITY OF PRODUCT IN PACKAGING		



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# 8MM FLEXDEX NEEDLE DRIVER



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# INSTRUCTIONS FOR USE

## IMPORTANT

Before using product, read the following information thoroughly. These instructions are for the use of this product. No instruction of surgical techniques are provided.

## DESCRIPTION

The FlexDex Needle Driver is a single use device with a 7.5mm nominal diameter for use with an 8mm trocar port. The Needle Driver consists of a Jaw, Articulating Tip, Shaft, Frame, 3-Axis Gimbal, Handle, and a Wrist Cuff. The Wrist Cuff and 3-Axis Gimbal positions the Virtual Center™ at the surgeon's wrist. The Handle allows for direct transmission of the surgeon's hand and wrist motions to the Articulating Tip. The Rotation Dial located on the Handle rotates the device 360 degrees.

The FlexDex Needle Driver can articulate up to 80° and provides 7 degrees of freedom for the purpose of suturing. The device is optimized for the use of needles between the diameter range of 0.4mm and 1.1mm.

## INDICATIONS FOR USE

Intended for single-use in minimally invasive surgical applications involving laparoscopic suturing procedures.

## CONTRAINDICATIONS

- Do not use the FlexDex Needle Driver when minimally invasive procedures are contraindicated.
- Do not use the FlexDex Needle Driver as a grasper or dissector.
- Do not reuse or re-sterilize the FlexDex Needle Driver.

## WARNINGS & CAUTIONS

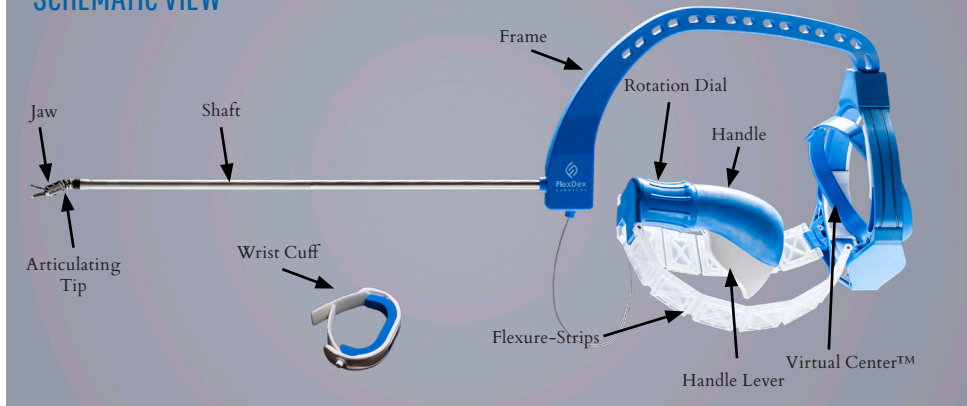
- The design of the FlexDex Needle Driver provides a low barrier to surgical use. However, only trained users or those who have developed adequate skills to perform the tasks associated with each of its features should use the device. Training in the use of the device is provided by FlexDex but does not replace the necessary medical training and experience required to perform laparoscopic surgery. For self-guided training on the functionality of the needle driver, visit FlexDex's website.
- Prior to inserting or removing the device through the trocar, ensure that the instrument Jaws are closed, and the Articulating Tip is straight, otherwise, damage to device or trocar is possible.
- Do not back-drive or flex the Articulating Tip by any means other than the Handle, otherwise, damage may occur.
- Do not use if the package is opened or damaged.
- Care should be taken when working with materials that can be transferred to the device through handling (e.g. latex proteins, disinfecting solutions)
- The Needle Driver can accommodate needles between the diameters of 0.4 and 1.1 mm. Use of needles outside of this range may reduce the device performance.

## KNOWN/POSSIBLE ADVERSE EVENTS

Failure to observe the warnings and precautions associated with this device may result in health consequences, such as, blood loss, infection, biological reaction, perforations, adhesions, or additional medical intervention.



## SCHEMATIC VIEW



## INSTRUCTIONS FOR USE

- Using sterile technique, remove device from packaging by gripping the Frame and deliver all contents into the sterile field.
- Inspect device components for damage and do not use if damage is evident.
- When passing device in and out of the surgical field, hold device by the Frame, otherwise damage may occur.
- Only use the Handle to manipulate the Articulating Tip.
- Do not exert excessive force on Articulating Tip or Flexure-Strips.
- Prior to inserting the device through the trocar, ensure that the instrument Jaws are closed, and the Articulating Tip is straight.

### ERGONOMICS AND TABLE HEIGHT

- Maintain a neutral posture with upper arms relaxed at the side.
- Adjust OR table to ensure a comfortable height.

### POSITIONING OF WRIST CUFF

NOTE: Appropriate use of the Wrist Cuff establishes a fixed position on the user's wrist and is important for the proper use of the FlexDex Needle Driver.

- Select appropriately sized Wrist Cuff, small, medium or large.
- Position between the hand and wrist joint distal to the ulnar styloid process (Fig 1, 2).
- Secure with integrated straps to ensure a snug fit - comfortable but secure.

### ENGAGING AND DISENGAGING FROM THE DEVICE

- While properly wearing the Wrist Cuff, snap top and bottom posts into the two receiving slots of the 3-Axis Gimbal (Fig 3, 4).
- To disengage, snap the posts of the Wrist Cuff out of the receiving slots.



Fig 1

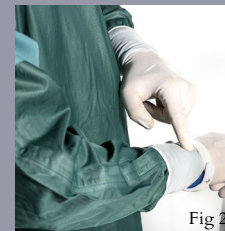


Fig 2

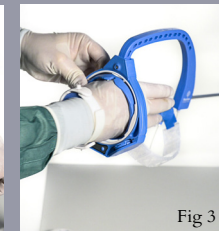


Fig 3



Fig 4