

FlexDex Gastric Bypass and Gastrectomy Kit

IMPORTANT

Before using product, read the following information thoroughly. These instructions are for the use of this product. No instruction of surgical techniques is provided. This device is intended for single use only.

Reuse or reprocessing may lead to device failure.

CONTENTS OF THE FLEXDEX GASTRIC BYPASS AND GASTRECTOMY KIT

1 x FlexDex Needle Driver and either 5 x absorbable sutures and 1 x V-Loc 90 absorbable wound closure device or 6x absorbable sutures (either PDS II or Biosyn).

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 surgeons hand and wrist motions to the Articulating Tip. The Rotation Dial located on the Handle rotates the device 360 degrees.



The Biosyn monofilament synthetic absorbable sutures are prepared from a synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. The Biosyn synthetic absorbable sutures are colored violet to increase visibility. The Biosyn™ synthetic absorbable sutures are indicated for use in general soft tissue approximation and/or ligation including use in ophthalmic surgery, but not for use in cardiovascular or neurological surgery.

The V-Loc absorbable wound closure device consists of a barbed absorbable thread, armed with a surgical needle at one end and a loop end effector at the other. The barb and loop end effector design allow for tissue approximation without the need to tie surgical knots. The V-Loc absorbable wound closure devices are indicated for soft tissue approximation where use of an absorbable suture is appropriate.

PDS II is a sterile synthetic absorbable monofilament suture made from the polyester poly (p-dioxanone). The empirical molecular formula of the polymer is (C₄H₆O₃)_n. Polydioxanone polymer has been found to be non-antigenic, non-pyrogenic and elicits only a slight tissue reaction during absorption. PDS™ II sutures are intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue, in microsurgery and in ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

INDICATIONS FOR USE

Intended for single use in minimally invasive surgical applications for the approximation of soft tissue with sutures.

CONTRAINDICATIONS

- Do not use the FlexDex Needle Driver for any procedures other than laparoscopic suturing.
 - 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 resterilise the FlexDex Needle Driver.
- Do not reuse or resterilise the Biosyn or PDS sutures or the V-Loc wound closure device.

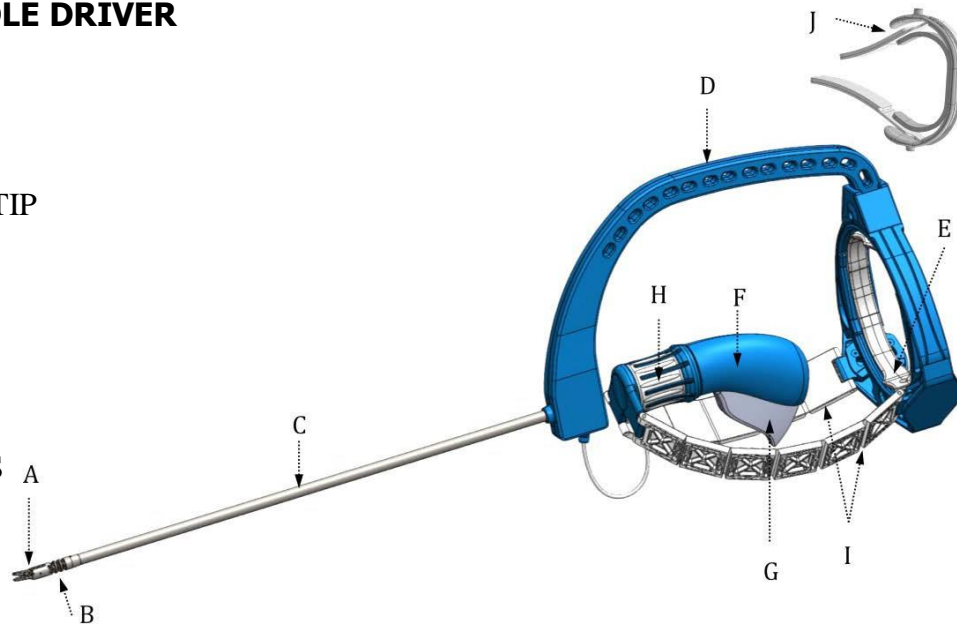
WARNINGS & CAUTIONS

- Only physicians having adequate training should perform laparoscopic procedures.
- Only physicians who have fully read this IFU should use the [FlexDex Gastric Bypass and Gastrectomy Kit](#)
- Prior to inserting the needle driver through the trocar, ensure that the instrument Jaws are closed and the Articulating Tip is straight.
- No modification of the device components is allowed.
- Prior to entering or removing the device from the trocar, ensure the Articulating Tip is straight, otherwise damage to the device or injury to the patient 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.

Manufactured and Distributed by:
Apne Surgical Pty Ltd
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NSW 2088 Australia

SCHEMATIC VIEW of the NEEDLE DRIVER

- ➔ (A) JAW
- ➔ (B) ARTICULATING TIP
- ➔ (C) SHAFT
- ➔ (D) FRAME
- ➔ (E) 3-AXIS GIMBAL
- ➔ (F) HANDLE
- ➔ (G) HANDLE LEVER
- ➔ (H) ROTATION DIAL
- ➔ (I) FLEXURE-STRIPS
- ➔ (J) WRIST CUFF



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.

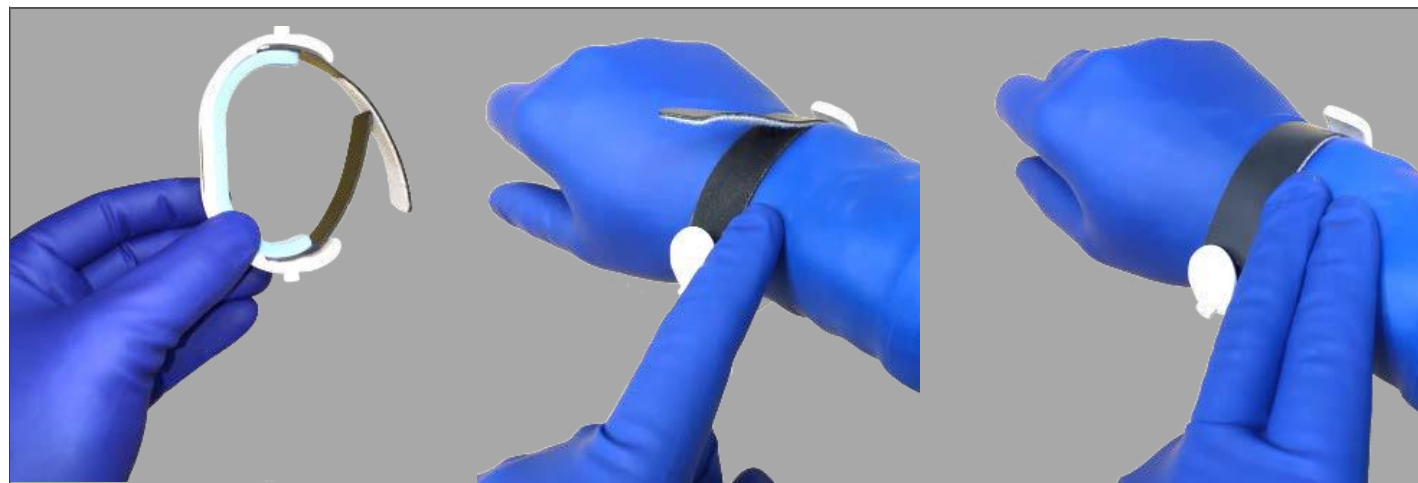
ERGONOMICS AND TABLE HEIGHT

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

POSITIONING OF WRIST CUFF

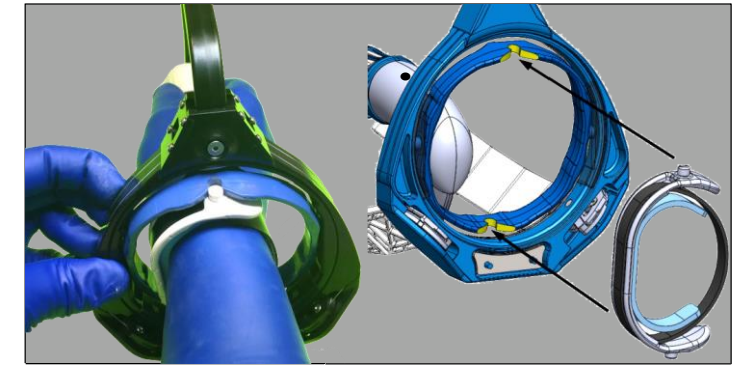
NOTE: Appropriate use of the Wrist Cuff establishes a fixed-position on the user's wrist and is important for the proper use of the FlexDex Needle Driver.

- Select appropriately sized Wrist Cuff, small, medium or large (Fig 1).
- Position between the hand and wrist joint distal to the ulnar styloid process (Fig 2).
- Secure with integrated straps to ensure a snug fit - comfortable but secure (Fig 3).



ENGAGING AND DISENGAGING

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



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.
- Prior to inserting or removal from the trocar, ensure the Articulating Tip is straight and in line with the shaft.

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).

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".
- FlexDex is designed to grasp a suture needle when pushing and pulling a needle through tissue during suturing including the needles of each of the Biosyn and V-Loc and PDS II sutures included in the Kit



DISPOSAL

Dispose of used devices as a biohazard

INSTRUCTIONS FOR USE ONLINE

The instruction for use of each one of the devices included in the Kit can be found online at : www.apne.com.au