Autosture™

DST Series™ EEA™ OrVil™ 21 mm Device

to be used with DST Series™ EEA™ XL 21 Single Use Staplers

DST Series™ EEA™ OrVil™ 25 mm Device

to be used with DST Series™ EEA™ XL 25 Single Use Staplers

10000-32175

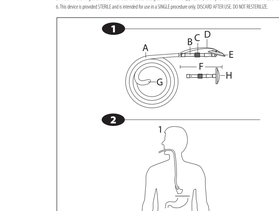
ENGLISH

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!
This booklet is designed to assist in using this product. It is not a reference to surgical techniques.
This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Regenerating and/or sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or sterilize this device.

DESCRIPTION
The DST Series™ EEA™ OrVil™ 21 mm device is a DST Series™ EEA™ 21 mm anvil assembly, and the DST Series™ EEA™ OrVil™ 25 mm device is a DST Series™ EEA™ 25 mm anvil assembly, both with the anvil head shown in the illustration.
The anvil assembly is mounted on a 90cm long PVC delivery tube and is secured to the tube with a suture. When used with the DST Series™ EEA™ XL 21 or 25 mm stapler, a circular, double staggered row of titanium staples is placed. Immediately after staple formation, the stapler also transects the excess tissue, creating a circular anastomosis. The diameter of the staple line is 21 mm or 25 mm, depending on the device selected.
The EEA™ OrVil™ anvil is permanently affixed to the center rod and cannot be removed from the center rod.

INDICATIONS
The Autosture™ EEA™ OrVil™ 21 mm device when used with the DST Series™ EEA™ XL 21 mm stapler and the Autosture™ EEA™ OrVil™ 25 mm device when used with the DST Series™ EEA™ XL 25 mm stapler has applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.

CONTRAINDICATIONS
1. Refer to the Instructions for Use for the EEA™ XL stapler for specific indications, contraindications, warnings, precautions, and operating instructions.

WARNINGS AND PRECAUTIONS:
1. Tissue thickness should be carefully evaluated before firing any stapler. Refer to the DST Series™ EEA™ Instructions for Use <stapler specification chart> and the "tissue compression requirements" section
2. DST Series™ staplers should not be used on tissue that does not meet the specified requirements.
3. The DST Series™ 21 mm and 25 mm devices are compatible with the corresponding diameter EEA™ XL length products ONLY. They are not compatible with the 22 cm long products or any other EEA™ type products.
4. Use of an improperly matched instrument and anvil assembly combination will cause instrument malfunction and/or staple malformation. Malformed staples may compromise the integrity of the staple line, resulting in leakage or disruption.
4. Improper cutting and removal of anvil retaining suture may result in the suture being stapled in the anastomotic site. The delivery tube should be carefully inspected after removal to ensure the anvil retaining suture has been removed with the delivery tube.
5. The anvil retaining suture is not intended for use as a surgical suture or implant. Its only function is to retain the anvil assembly.
6. This device is powder STERILE and is intended for use in a SINGLE procedure only. DISCARD AFTER USE. DO NOT RESTERILIZE.