

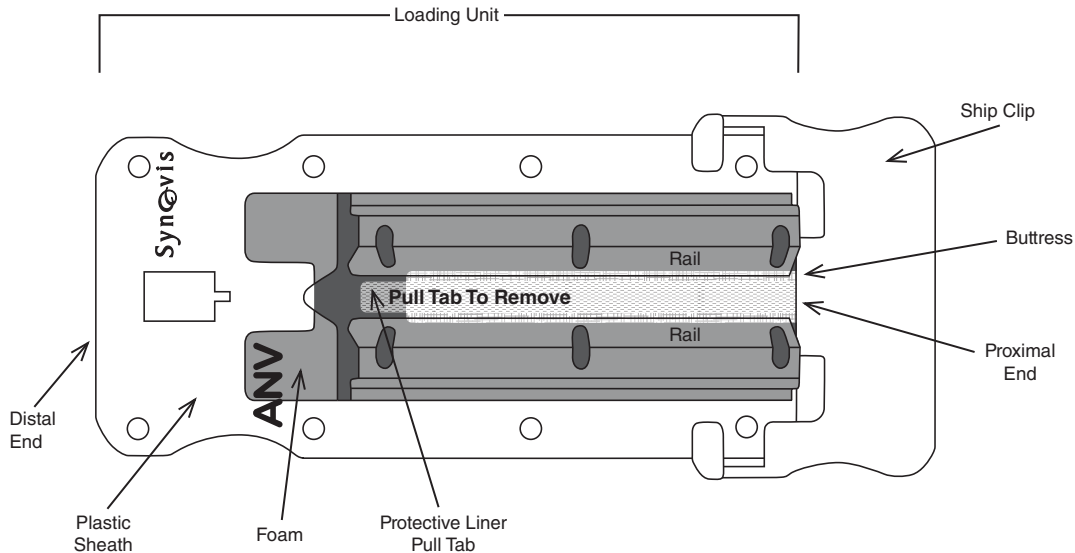
Peri-Strips Dry

Staple Line Reinforcement
with **Veritas** Collagen Matrix
with *Secure Grip* Technology

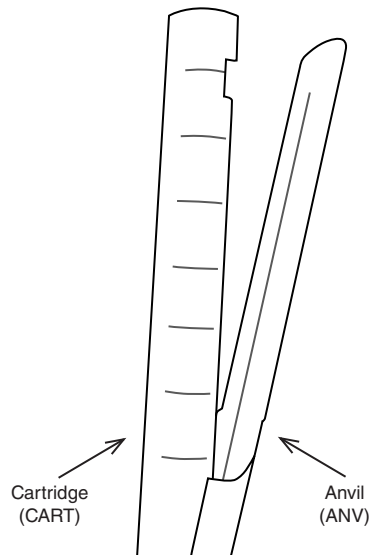
INSTRUCTIONS FOR USE

PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Components Illustration 1

Note: An off-the-shelf grasper may be used to assist in the removal of the stapler jaws from the implanted buttress.

















STAPLER ORIENTATION



Symbols Referenced on Labeling







Symbol Glossary per US FD&C Act:

Standard*	Symbol	Symbol Title	Symbol Meaning	Symbol Number
ISO 15223-1		Manufacturer	Manufacturer	5.1.1
ISO 15223-1		Use-by date	Use-by date	5.1.4
ISO 15223-1		Batch code	Lot number	5.1.5
ISO 15223-1		Catalogue number	Reorder number	5.1.6
ISO 15223-1		Sterilized using ethylene oxide	Sterilized using ethylene oxide	5.2.3
ISO 15223-1		Do not resterilize	Do not resterilize	5.2.6
ISO 15223-1		Do not use if package is damaged	Do not use if the product sterile barrier or its packaging is compromised	5.2.8
ISO 15223-1		Keep away from heat	Keep away from heat. Do not use if heat indicator is red.	5.3.2
ISO 15223-1		Temperature limit	Store at controlled room temperature	5.3.7
ISO 15223-1		Do not re-use	Do not re-use	5.4.2
ISO 15223-1		Consult instructions for use	Consult instructions for use	5.4.3
ISO 15223-1		Caution	Caution: Consult instruction for use for warning and precaution information	5.4.4
			Content	
			Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	

*ISO15223-1 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied- Part 1: General requirements.

Additional symbols on the product labeling that are not required by the US FD&C Act:

en

Symbol	Symbol Meaning
	Made in the USA
	Manufacturer internal code
	Manufacturer part number
	Manufacturer tracking number
	This product is derived from cattle
	Remove before use

DESCRIPTION:

PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology (PSDV-SG) is prepared from dehydrated bovine pericardium procured from cattle under 30 months of age in the United States.

The product consists of a loading unit which includes two (2) buttresses, one for the anvil (**ANV**) and one for the cartridge (**CART**) side of the stapler. Each buttress has acrylic adhesive on one side for attachment to the stapler surfaces. Each PSDV-SG loading unit is packaged sterile in a separate pouch.

PSDV-SG utilizes animal tissue; patient must be informed prior to any procedure. PSDV-SG is MR Safe. See Table 1 for product models and configurations.

Table 1. PSDV-SG Model Numbers and Sizes

Model Number	Size (mm)	Thickness (mm) per Firing	Stapler Compatibility
PSDA45ECH	45	0.45-1.26	Ethicon Echelon 45 ENDOPATH Ethicon Echelon FLEX 45 ENDOPATH
PSDA60ECH	60	0.45-1.26	Ethicon Echelon 60 ENDOPATH Ethicon Echelon FLEX 60 ENDOPATH
PSDA60GIA	60	0.45-1.26	Medtronic Endo GIA Universal Straight 60 Medtronic Endo GIA Universal Reticulator 60 Medtronic Endo GIA Reloads with 60 Tri-Staple Technology Intuitive SureForm 60 Stapler for da Vinci X and Xi

INDICATIONS FOR USE:

PSDV-SG is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

PSDV-SG can be used for reinforcement of staple lines during bariatric, gastric, small bowel, colon, and colorectal procedures.

CONTRAINDICATIONS:

The use of PSDV-SG is contraindicated in patients with known sensitivity to bovine or acrylic material(s).

ADVERSE REACTIONS:

As with any surgical procedure involving implantation of a foreign material, adverse reactions are possible and include but are not limited to: infection, rejection, erosion, and allergic reaction.

WARNINGS:

Do not re-sterilize. Resterilization may cause changes to the tissue and negatively impact functionality of the device.

Discard all open, used, or unused components as sterility is no longer assured.

Do not use product if there is damage to the pouch or seals as sterility may be compromised.

Ensure the staple line is completely covered with the buttress, or it may result in inadequate coverage after firing.

PSDV-SG is not designed, sold, or intended for use except as indicated; doing so may result in surgical complications.

PSDV-SG configurations differ; substitution of one product for another product may reduce product performance.

Do not use PSDV-SG if the product has been submerged in liquids or if heat indicator has been activated.

CAUTIONS:

Use care when removing loading unit components from the stapler to prevent buttress dislodgement.

Do not get the anvil or cartridge buttress wet before applying, or the buttress may not adhere to the stapler properly.

Ensure the anvil and cartridge side of the loading unit are on the corresponding stapler jaws or the buttress may not adhere to the stapler properly.

Final tissue compression, including PSDV-SG, must meet the range specified by the stapler manufacturer; this is especially important if staple firings are overlapped. PSDV-SG increases the total thickness of the area stapled by 0.45 mm–1.26 mm (0.018"–0.049").

Follow Instructions for Use supplied by the stapler manufacturer. Do not use PSDV-SG contrary to the stapler manufacturer's instructions.

The cartridge and anvil sides of the PSDV-SG loading unit differ; substitution of one side for the other may interfere with alignment and adherence of the buttress strips

The use of PSDV-SG has not been studied in lung or bronchus resection.

STORAGE CONDITIONS:

1. Store at controlled room temperature (20°–25°C / 68°–77°F).
2. Do not use the product if the heat indicator has been activated (turns red).

INSTRUCTIONS FOR USE:

NOTE: Each model of PSDV-SG has been designed specifically for the stapler models indicated on the label; verify that the correct model of PSDV-SG has been selected.

NOTE: Loading technique for PSDV-SG varies. Follow the appropriate technique as indicated.

1. Inspect outer pouch. Do not use if pouch integrity is compromised.
2. Open the outer PSDV-SG pouch.
3. Using sterile technique, remove the inner pouch and place in the sterile field.
4. Inspect the pouch. Do not use if the pouch is damaged or if the seals are not intact.
5. Open the inner PSDV-SG pouch and remove the PSDV-SG loading unit by using atraumatic techniques.
6. Ensure that the jaws of the stapler are clean and dry before inserting the PSDV-SG loading unit and between firings. Follow any instructions supplied by the stapler manufacturer with respect to cleaning and drying.

CAUTION: Do not get the anvil or cartridge buttress wet before applying, or the buttress may not adhere to the stapler properly.

CAUTION: Final tissue compression, including PSDV-SG, must meet the range specified by the stapler manufacturer; this is especially important if staple firings are overlapped. PSDV-SG increases the total thickness of the area stapled by 0.45 mm–1.26 mm (0.018"–0.049").

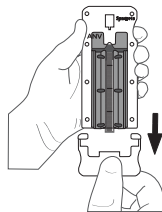


Figure 1

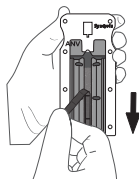


Figure 2

7. Remove ship clip from PSDV-SG loading unit. Discard ship clip (See Figure 1).
8. Grasp protective liner pull tab from distal end of loading unit and carefully peel protective liner to expose adhesive (See Figure 2).
9. Repeat step 8 for opposite side of loading unit. Avoid inadvertent contact with exposed adhesive as buttress alignment could be impacted.

10. Inspect the adhesive surface on both sides of the loading unit to ensure all protective liner has been removed.

11. Identify the anvil (ANV) and cartridge (CART) sides of the PSDV-SG loading unit.

12. Position the open stapler onto the stapler loading unit.

13. Ensure the anvil and cartridge side of the unit are on the corresponding stapler jaws.

14. Advance loading unit onto the stapler jaws until the loading unit cannot advance any further.

CAUTION: The cartridge and anvil sides of the PSDV-SG loading unit differ; substitution of one side for the other may interfere with alignment and adherence of the buttress strips.

NOTE: Keep dry until firing. Do not submerge loaded surgical stapler in fluid prior to use.

NOTE: For Medtronic Endo GIA and Intuitive SureForm stapler models, skip to step 20.

LOADING STAPLER FOR ETHICON ENDOPATH MODELS

15. Close the stapler jaws until the stapler closing handle clicks (See Figure 3).
16. Remove and discard the plastic sheath leaving the foam spacer between the stapler jaws (See Figure 4).
17. Firmly squeeze the stapler heads together at the distal end of the jaws to effectively apply pressure and improve adhesion to the stapler (See Figure 5).
18. Release stapler jaws to remove and discard foam (See Figure 6).

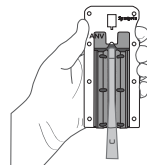


Figure 3

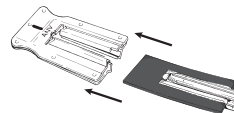


Figure 4



Figure 5

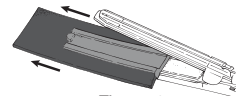


Figure 6

19. Visually inspect each buttress strip to ensure they are on the stapler jaws and cover the staple line. If necessary, manually press the buttress strip to reinforce adherence to the stapler jaws (See Figure 7).

NOTE: Skip to step 24.

LOADING STAPLER FOR MEDTRONIC ENDO GIA AND INTUITIVE SUREFORM MODELS

20. Manually close stapler jaws.
21. Hold both sides of the stapler jaws and remove the plastic sheath leaving the foam spacer between the stapler jaws (See Figure 8). Discard the plastic sheath.
22. Release stapler jaws to remove and discard foam (See Figure 6).
23. Visually inspect each buttress strip to insure they are on the stapler jaws and cover the staple line.

IMPLANTING PSDV-SG INSTRUCTIONS FOR ALL STAPLER MODELS

NOTE: PSDV-SG can be used immediately or allowed to remain between the stapler jaws until surgery.

24. To implant, follow Instructions for Use supplied by the stapler manufacturer.
25. Prior to engaging the surgical stapler, verify that the tissue buttress is in place on the stapler jaws.
26. After engaging the surgical stapler, verify that the stapler jaws have released from the implanted tissue buttress.
27. If necessary, use additional surgical steps (e.g. using a grasper, articulating the stapler or other technique) to assist in the removal of the stapler jaw from the implanted buttress.

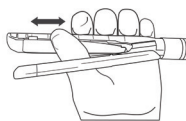


Figure 7

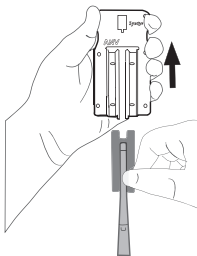


Figure 8



Figure 9

28. If necessary, cut the end of the PSDV-SG buttress to remove the dissected tissue (See Figure 9).

29. Discard any open PSDV-SG pouches. These cannot be re-sterilized or reused.

DISPOSAL

Any packaging or components exposed to human tissue/fluids should be disposed of per hospital protocols. Any open, unused components should be discarded due to compromised sterility.

DISCLAIMER OF WARRANTIES:

Synovis Life Technologies, Inc. (SLT), warrants that reasonable care has been used in the manufacture of this device. As a result of biological differences in individuals, no product is 100% effective under all circumstances.

Because of this fact and since SLT has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration, or its handling after it leaves its possession, SLT does not warrant either a good effect or against an ill effect following its use. SLT will replace any device, which is defective at the time of shipment. No representative of SLT may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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2021-08-19