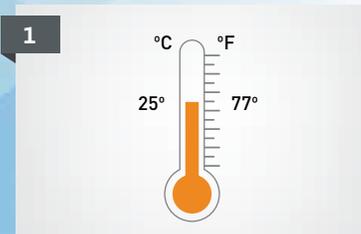


Preparation



1 Remove from box and allow PREVELEAK to reach room temperature prior to use.



2 Open the outer pouch and pass inner sterile pouch into sterile field.



3 Hold the syringe with the cap end upward. Remove the syringe cap by turning it 90° counterclockwise and pulling upwards, using a gentle side-to-side motion.



4 To attach a delivery tip, orient the small alignment tab on the hub end of the delivery tip with the corresponding V-shaped alignment notch on the syringe.



5 Firmly push delivery tip toward the syringe and turn it 90° clockwise to lock the tip in place.

Application



1 Discard the first 0.25 mL of sealant immediately prior to use.



2a Applied to suture line

Apply PREVELEAK to a clamped application site in a slow and steady manner, approximating the suture line with the delivery tip.



2b Applied to synthetic graft



3 Leave the clamps in place for at least 60 seconds before restoring circulation or touching sealant.



Preveleak

SURGICAL SEALANT

INDICATIONS

PREVELEAK Surgical sealant is indicated for use in cardiac, vascular and soft tissue reconstructions.

Cardiac Reconstructions: Aortic root replacement, Aortoplasty, Aortic valve procedures, Valve procedures, Bentall procedure, Composite valve conduit procedure, Mitral Valve replacement, Ross procedure, Proximal and distal coronary anastomoses including coronary artery bypass grafting (CABG) procedures and other reconstruction of coronary arteries, Aortic aneurysm repair, Aortic wall replacement, Ascending aorta repair, Aortic dissection repair, and Cannulation sites.

Peripheral Vascular Reconstructions: Aorto-femoral bypass, Aorto-iliac bypass, Aortic bypass, Aorto-innominate bypass, Carotid bypass, Carotid endarterectomy, Femoral-distal bypass, Femoral-femoral bypass, Femoral-popliteal bypass, Hepatic-renal bypass, Popliteal-dorsalis pedis bypass, Profunda endarterectomy, Renal bypass, Extremity bypass, Renal endarterectomy, Hemodialysis access, Arteriovenous graft.

Soft Tissue Repair Involving Sutures and Staples: Cardiac wound repair, Pancreatic anastomotic leak, Hepatic resection, Splenic bleeding, Biliary leaks, Esophageal repair, Colorectal repair, Stapled gastrojejunostomy and Lymphatic leaks.

Contraindications

- Not for patients with known sensitivity to materials of bovine or shellfish origin.
- Not for intravascular use.
- Not for cerebrovascular repair.

Important Risk Information

Do not use PREVELEAK Surgical sealant as a substitute for sutures or staples.

Avoid exposure of PREVELEAK Surgical sealant to areas of active blood flow, including intraluminal spaces and intracardiac spaces.

Do not use PREVELEAK Surgical sealant intraluminally. Open lumen procedures require protection of the lumen (e.g. use of gauze, occlusion balloon or other suitable approach) prior to applying the sealant to avoid inadvertent intraluminal exposure.

Avoid exposing nerves to PREVELEAK Surgical sealant. Avoid the sinoatrial node, the atrial ventricular node and any other nerve tissue when applying PREVELEAK Surgical sealant to the heart.

Do not use PREVELEAK Surgical sealant in the presence of obvious infection.

PREVELEAK Surgical sealant polymerizes rapidly. After the applicator tip has been primed, use the sealant immediately.

Avoid tissue contact with material expelled from the applicator during priming and in case of contact with eyes, flush with plenty of water and seek medical attention.

ORDERING INFORMATION

PREVELEAK Surgical Sealant	4mL	ADS201812
PREVELEAK Delivery Tips	10pack	ADS201811

Advancing the art of healing