INSTRUCTIONS FOR USE: **LeGoo®**

TO ENSURE PROPER USE OF THIS DEVICE AND TO PREVENT INJURY TO PATIENTS, READ ALL INFORMATION CONTAINED IN THIS INSTRUCTIONS FOR USE.

CAUTION: Federal (U.S.A.) Law limits this device to sale by, or on the order of, a physician.

Device is provided sterile.

PRODUCT DESCRIPTION

LeGoo is comprised of a 20% (weight percent in saline) of purified poloxamer 407, a non-toxic gel which is part of a family of biocompatible, water-soluble polymers that possess reverse, thermo-sensitive properties (i.e. as temperature increases, viscosity increases). Poloxamer 407 dissolves in blood and is excreted in urine.

At room temperature it is a viscous but injectable liquid, and it transitions to a temporary self-forming polymeric plug at body temperature. Because the material undergoes a temperature-induced phase change with no alteration in the product's chemical composition, the material does not "cure" *in situ*.

INDICATIONS FOR USE

LeGoo is indicated for temporary endovascular occlusion of blood vessels below the neck up to 4 mm in diameter.

CONTRAINDICATIONS

- Do not use LeGoo in patients with vascular anatomy or blood flow that precludes cannula placement or proper injection and control of LeGoo.

WARNINGS

- Do not use if package is open or damaged.
- Do not inject LeGoo into a vessel that is not intended to be occluded.
- Always use the minimum volume of LeGoo required to achieve satisfactory occlusion. Use caution when re-administering LeGoo within the same blood vessel. Excessive or prolonged vessel occlusion may result in increased ischemic risks to the patient.

PRECAUTIONS

- LeGoo is a sterile single use device. Discard any unused material after use in a single patient.
- Inject LeGoo quickly into the vessel to avoid premature dissolution in blood.
- The safety and effectiveness of LeGoo in blood vessels in and above the neck, including neurovascular, internal and external carotid, and vertebral vessels, has not been demonstrated
- LeGoo is only meant for temporary blood vessel occlusion. Do not rely on LeGoo for permanent hemostasis. Use a hemostatic agent when necessary.

- The appropriate volume of LeGoo and size of cannula must be chosen based on the vessel size to be treated.
- This device should only be used by physicians properly trained in vascular occlusion techniques.
- Ensure attention to technique during preparation. Inspect syringe before injection to ensure cleanliness of the device and to avoid introducing air bubbles and contaminants.
- LeGoo dissolves naturally, which may cause premature reperfusion of the blood vessel. The user should be prepared to apply additional LeGoo to maintain temporary blood vessel occlusion, if necessary.
- In the Investigative Device Exemption (IDE) trial, one patient in the LeGoo treatment arm died of diffuse intravascular thrombosis that may consistent with Heparin Induced Thrombocytopenia (HIT). Although no link has been described between use of poloxamer compounds such as LeGoo and HIT, LeGoo should be used with caution in patients with a history of hypercoaguability or HIT or known heparin antibodies.

POTENTIAL ADVERSE EFFECTS

Potential complications may include, but may not be limited to:

- Effects of transient occlusion of a blood vessel (e.g. infarction, undesired ischemia).
- Risks associated with the general procedure of clamping a blood vessel (e.g. fibrillation).
- Risks associated with cannulation (e.g. intimal wall injury.)
- Risks associated with application of LeGoo to epicardial or pericardial surfaces (e.g. adhesions)

See "Clinical Study Overview" below for adverse events recorded in a clinical study of the use of LeGoo versus vessel loops during off-pump coronary artery bypass surgery.

CLINICAL STUDY OVERVIEW

Study design

A prospective, randomized multi-center (Canada, France, Germany, Netherlands) clinical study with a minimum target of 110 eligible study subjects (56 treated, 54 control) undergoing Off-Pump Coronary Artery Bypass (OPCAB) was conducted. The purpose of this study was to assess the clinical efficacy (primary endpoint) and safety of LeGoo in comparison to a standard vessel occlusion method (i.e. vessel loops). LeGoo is a device that is intended to be used during surgical procedures to temporarily occlude blood vessels while forming an anastomosis. This study specifically focused on the use of LeGoo in OPCAB as a most sensitive model of adverse changes that may occur at any vascular site.

Clinical Inclusion and Exclusion Criteria

This study included subjects undergoing OPCAB surgery who were judged by the operating surgeon to be low-risk candidates for OPCAB and excluded any subjects meeting high-risk criteria. The inclusion/exclusion criteria were selected as consistent with other known clinical studies of medical devices for cardiovascular surgery.

Clinical Endpoints

The primary efficacy endpoint, satisfactory hemostasis, was determined by surgical observation. The secondary efficacy endpoint, duration of anastomosis, was determined by time measurement. These are appropriate measures of efficacy to support the device claim.

Safety was measured as a composite of four Major Adverse Cardiac Events (MACE).

Primary Efficacy Endpoint

The primary research hypothesis was that surgeons will obtain a bloodless surgical field and achieve satisfactory hemostasis in a larger proportion of anastomoses using LeGoo than using a conventional temporary hemostasis technique. The primary efficacy endpoint, satisfactory hemostasis, was defined by the surgeon who quantified his/her observation about the quality of the surgical field using the following scoring system:

- Excellent hemostasis (no bleeding)
- Minimal bleeding (bleeding does not interfere with suturing)
- Modest bleeding (required intermittent use of another device to control bleeding at the site of the anastomosis)
- Copious bleeding (required continuous use of another device)

"Excellent hemostasis" and "minimal bleeding" were considered "satisfactory hemostasis". Satisfactory hemostasis constituted a treatment success for the purpose of evaluating the primary efficacy endpoint, the proportion of anastomoses in which satisfactory hemostasis was achieved.

Secondary Efficacy Endpoint

The secondary efficacy endpoint was total duration of anastomosis, including the time necessary for ensuring vessel occlusion.

Efficacy Results

The primary efficacy endpoint, satisfactory hemostasis, was determined by surgical observation. The secondary efficacy endpoint, duration of anastomosis, was determined by time measurement. These are appropriate measures of efficacy to support the device claim.

Table 1. Primary Efficacy – Satisfactory Hemostasis per Anastomosis

	LeGoo			**Control**		
	N	**Probability of Satisfactory Hemostasis**		**N**	**Probability of Satisfactory Hemostasis**	**P-Value**
Satisfactory: Intent-to-treat	121	86%		123	61%	<0.0001
Satisfactory: Completed cases	116	87%		116	63%	<0.0001
Satisfactory: As-treated	117	88%		122	61%	<0.0001

Table 2. Secondary Efficacy – Duration of the Anastomosis

	Duration of the anastomosis		P value
	LeGoo N=121	Control N=127	
Duration of anastomosis, total, min	12.8 ± 4.7	15.4 ± 6.1	<0.001
to LAD/diagonal territory, min	12.9 ± 4.9	14.4 ± 5.3	
to marginal/circumflex territory, min	12.2 ± 3.7	16.1 ± 5.6	
to RCA/PDA territory, min	13.8 ± 6.1	17.6 ± 8.2	

Safety Variable

Safety was assessed by comparing a composite of four Major Adverse Cardiac Events: death, graft occlusion, low post-procedure cardiac output and myocardial damage. Myocardial damage was defined per ESC-ACCF-AHA-WHF Guidelines for the Application of the Universal Definition.

Safety Results

The safety assessment was a composite of 4 Major Adverse Cardiac Events (MACE), which were assessed during the in-hospital phase and at a one month follow up visit.

Table 3. Safety Composite Results

	LeGoo		**Control**	
	N	**Frequency**	**N**	**Frequency**
Composite Safety Index	48	6.3% (3)	46	6.5% (3)

Six subjects experienced at least one of the four events within the MACE index: three LeGoo and three Control subjects. One LeGoo subject reported all four elements of the MACE safety composite index. This was the only patient death in the study.

Table 4. Elements of Safety Composite

Safety Element	**LeGoo**	**Control**

	N	Frequency	N	Frequency
Graft Occlusion	55	3	51	0
Myocardial Damage	48	1	46	1
Low post procedure cardiac output	55	1	51	2
Death	55	1	51	0

ADVERSE EVENTS

A summary of all Adverse events (AEs) reported in the clinical study is provided below in Table 5, classified by System Organ Class. Serious Adverse Events (SAEs), reported in Table 6, are a subset of the AEs, that is, Table 6 includes those AEs from Table 5 that were judged by the investigators as meeting the definition of serious, predefined in the study as including: death; life-threatening or permanently disabling events; or those that required hospitalization or prolonged hospitalization.

At least one AE was reported in 43/56 (76.8%) LeGoo and 33/54 (61.1%) control subjects; no AEs were reported in 13/56 (23.2%) LeGoo and 21/54 (38.9%) Control subjects. No unanticipated AEs were reported. There were no device failures or replacements.

At least one SAE was reported in 16/56 (28.6%) LeGoo and 8/54 (14.8%) Control subjects. No SAEs were reported in 40/56 (71.4%) LeGoo and 46/54 (85.2%) Control subjects. The levels and types of SAEs reported in this clinical study were anticipated and are similar to those reported in similar sized studies of major cardiac procedures.

One SAE was recorded as unknown as to whether it was related to the study device.

Table 5. Adverse Events reported including SAEs.

System Organ Class	LeGoo (N=56)		Control (N=54)	
	Events	Patients with Events	Events	Patients with Events
No Adverse Events	-	13 (23.2%)	-	21 (38.9%)
At Least One Adverse Event	139	43 (76.8%)	115	33 (61.1%)
Blood and lymphatic system disorders	5	5 (8.9%)	3	3 (5.6%)
Cardiac disorders	37	29 (51.8%)	21	19 (35.2%)
Endocrine disorders	0	0 (0%)	1	1 (1.9%)
Gastrointestinal disorders	13	9 (16.1%)	6	5 (9.3%)
General disorders and administration site conditions	16	11 (19.6%)	10	9 (16.7%)

System Organ Class	LeGoo (N=56)		Control (N=54)	
	Events	Patients with Events	Events	Patients with Events
Infections and infestations	8	7 (12.5%)	5	5 (9.3%)
Injury, poisoning and procedural complications	11	10 (17.9%)	14	11 (20.4%)
Investigations	2	2 (3.6%)	5	5 (9.3%)
Metabolism and nutrition disorders	4	3 (5.4%)	7	5 (9.3%)
Musculoskeletal and connective tissue disorders	2	2 (3.6%)	0	0 (0%)
Nervous system disorders	5	4 (7.1%)	1	1 (1.9%)
Psychiatric disorders	7	6 (10.7%)	6	6 (11.1%)
Renal and urinary disorders	3	3 (5.4%)	6	4 (7.4%)
Respiratory, thoracic and mediastinal disorders	20	14 (25%)	21	14 (25.9%)
Skin and subcutaneous tissue disorders	3	3 (5.4%)	1	1 (1.9%)
Surgical and medical procedures	0	0 (0%)	1	1 (1.9%)
Vascular disorders	3	2 (3.6%)	7	5 (9.3%)

Table 6 – Serious Adverse Events reported

System Organ Class	LeGoo (N=56)		Control (N=54)	
	Events	Subjects with Events	Events	Subjects with Events
At Least One Serious Adverse Event	19	16 (28.6%)	11	8 (14.8%)
No Adverse Events	0	40 (71.4%)	0	46 (85.2%)
Cardiac disorders	9	9 (16.1%)	3	2 (3.7%)
General disorders and administration site conditions	3	3 (5.4%)	1	1 (1.9%)
Infections and infestations	0	0 (0%)	2	2 (3.7%)
Injury, poisoning and procedural complications	7	6 (10.7%)	3	3 (5.6%)
Investigations	0	0 (0%)	1	1 (1.9%)
Respiratory, thoracic and mediastinal disorders	0	0.(0%)	1	1 (1.9%)

The safety data collected in this clinical study suggests that LeGoo is as safe as traditional vessel loops. The study was done in surgeries of the cardiovascular bed, where adverse events are well known and well documented through an abundance of device studies. Use in the cardiovascular bed also represents a worst case situation to support use for temporary vascular occlusion of below the neck vessels up to and including 4 mm in diameter.

CONCLUSIONS

The data in this application support the reasonable assurance of safety and effectiveness of the device when used in accordance with the indication for use. The clinical evidence demonstrates that LeGoo achieves its intended performance of vessel occlusion to achieve and maintain satisfactory hemostasis during normal conditions of use.

How Supplied
LeGoo is supplied as a sterile, single use, disposable kit.
DO NOT RESTERILIZE.

LeGoo is non-pyrogenic.

Contents of LeGoo Carton

Catalog number	Volume per syringe	Syringes per carton	Cannulae per carton
10-0025	0.25 mL	2	6 (2 each 1.0 x 40 mm, 1.5 x 40 mm & 1.5 x 80 mm)
10-0050	0.5 mL	2	6 (2 each of 1.0 x 40 mm, 1.5 x 40 mm & 1.5 x 80 mm)
10-0100	1.0 mL	2	6 (2 each of 1.5 x 40 mm, 1.5 x 80 mm & 3.0 x 80 mm)
10-0250	2.5 mL	2	2 (1 each 3.0 x 80 mm)

Material needed but not supplied
Sterile, iced saline or sterile ice.

Guide to volume selection
LeGoo is a self-forming plug that occupies space in the vessel and temporarily prevents blood flow. Refer to the table below as a guide to estimate the quantity of LeGoo needed to create the desired plug. Note: vessel inner diameter is inherently variable and the surgeon should use this as a guide only.

Vessel Inner Diameter	Syringe	Volume Proximal [1]	Volume Distal [1,2]
1.5 mm Ø	0.25 mL (10-0025) [3]	0.03 mL	0.01 mL
2 mm Ø	0.25 mL (10-0025) or 0.5 mL (10-0050) [3]	0.06 mL	0.02 mL

3 mm Ø	1.0 mL (10-0100) [3]	0.2 mL	0.07 mL
4 mm Ø	2.5 mL (10-0250) [3]	0.5 mL	0.2 mL

1) Recommended injection volume does not include priming of cannula or LeGoo delivered outside of vessel.
2) Distal injection volume assumes back bleeding at ~1/3 pressure of proximal flow.
3) Volume volume contained in syringe should allow repeat injection if desired.

DIRECTIONS FOR USE

Preparation

- Select the appropriate volume of LeGoo to be injected using the above table as a guide.
- Open the package using aseptic technique. Deliver contents into the sterile field. The oxygen scavenger may be discarded.
- Uncap the syringe and firmly attach the cannula.
- Prime the cannula: Purge air out of the syringe and cannula by advancing the plunger until a drop of LeGoo appears at the tip of the cannula. If air is entrapped within the syringe, cool the syringe until LeGoo becomes a liquid, then hold the tip of the syringe up and purge the air.
- Allow LeGoo to reach its gel phase before injecting into blood vessel.

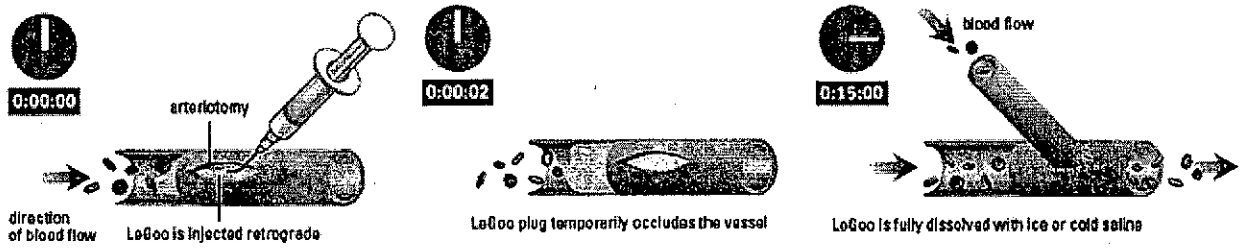
Application

- Insert the cannula into the vessel through the arteriotomy. Rapidly inject the appropriate amount of LeGoo retrograde while slowly withdrawing the cannula. Manual vessel compression may be used, if desired, to slow blood flow during gel deployment
- After a proximal occlusion has been made, a small amount of LeGoo may be injected distal to an arteriotomy and against the flow of blood to prevent back-bleeding.
- Additional LeGoo may be injected if flow resumes earlier than desired.
- Higher volume of LeGoo may be necessary in applications where blood pressure is elevated (e.g., arteriovenous fistula) in order to form a longer plug that resists the higher flow.

WARNING: Always use the minimum volume of LeGoo required to achieve satisfactory hemostasis. Use caution when re-administering LeGoo within the same blood vessel. Excessive or prolonged vessel occlusion may result in increased ischemic risks to the patient.

Removal

- Apply sterile ice to the site or slowly infuse sterile, iced saline intravascularly at a rate of about 1 mL per second to dissolve the plug.



Application

The surgeon creates an arteriotomy in the vessel and injects LeGoo retrograde while withdrawing the cannula.

Occlusion

LeGoo forms a plug that prevents blood flow. LeGoo keeps the vessel cylindrical.

Dissolve after the procedure

As the anastomosis is completed, the plug is dissolved by applying ice to the vessel or via slow infusion of iced saline.

Storage & Handling

LeGoo Internal Vessel Occluder should be stored at room temperature (15-30 °C, 59-86 °F). Dispose of LeGoo according to local, state and federal regulations regarding medical waste. Do not re-sterilize or reuse LeGoo.