DuraGraft®
Vascular Conduit Solution

US

Instructions for Use

Marizyme Inc.
1645 Palm Beach Lakes Blvd, Suite 1200
West Palm Beach, FL 33401, USA

Customer Care Unit: 1-561-320-3929
CustomerCareUnit@Marizyme.com

P/N 300-01010 Rev. 1

INSTRUCTIONS FOR USE

DESCRIPTION

DURAGRAFT® Vascular Conduit Solution is a clear, colorless to slightly yellow, aseptically processed, non-pyrogenic solution for flushing and storage of vascular conduits used during the harvesting and grafting interval in CABG surgeries.

DuraGraft Vascular Conduit Solution is supplied in two separate containers composed of a Solution A (237.5 mL) and a Solution B (12.5 mL-13.5 mL). Solution A is mixed with 12.5 mL of Solution B prior to use. **DuraGraft** Vascular Conduit Solution is stored at Controlled Room Temperature between 20°C-25°C. Composition and molar concentrations of **DuraGraft (mixed solution)** and the solutions A and B are given in **Table 1**, **Table 2** and **Table 3** respectively.

Table 1: Composition of DuraGraft (Mixed Solution)

SOLUTIONS A + B (19:1 ratio)	
Ingredients	**Concentration in mM**
Calcium chloride	0.95
Potassium chloride	5.37
Potassium phosphate monobasic	0.44
Magnesium sulfate	0.41
Magnesium chloride	0.49
Sodium chloride	136.89
Sodium bicarbonate	4.29
Sodium phosphate dibasic	0.19
L-Glutathione	1.01
D-Glucose	5.55
L-Arginine	0.86
L-Ascorbic acid	0.51
pH	7.4
Water For Injection	q.s.

Table 2: Solution A Composition

Vascular Conduit Storage Solution A is 1.05X in Concentration with Respect to DuraGraft	
Ingredients	**Concentration in mM**
Calcium chloride	1.000
Potassium chloride	5.647
Potassium phosphate monobasic	0.463
Magnesium Sulfate	0.426
Magnesium chloride	0.516
Sodium chloride	144.089
Sodium bicarbonate	4.512
Sodium phosphate dibasic	0.197
pH	8.0
Water for injection	q.s.

Table 3: Solution B Composition

Vascular Conduit Storage Solution B is 20X in Concentration with Respect to DuraGraft	
Ingredients	**Concentration in mM**
L- Glutathione	20.174
D-Glucose	111.015
L-Arginine	17.221
L-Ascorbic acid	10.220
pH	3.0
Water for injection	q.s.

DURAGRAFT Vascular Conduit Solution has an osmolality of about 305 mOsmol/kg, viscosity of 1.06 cST, a sodium concentration of 155-160 mEq/L, a potassium concentration of 5.8 mEq/L, and a pH of about 7.4 at room temperature.

Do not freeze. Do not use if obvious particulate matter, precipitates, or contamination are evident in the solution.

Rx Only - Federal (USA) law restricts this device to sale by or on the order of a physician.

MECHANISM OF ACTION

The mechanism of action is through reduction of oxidative damage to maintain the structural and functional integrity of vascular conduits. The salts in DuraGraft are intended for buffering (maintain pH) and to maintain isotonicity and ionic balance with respect to vascular conduits. The organic components are intended to maintain additional buffering capability, osmolality and to provide a non-oxidizing environment to vascular conduits. The organic components are normal constituents of blood and are included for their roles in maintaining the extracellular environment of vascular conduits.

Use of DuraGraft does not change clinical/surgical practice; it replaces solutions currently used for flushing and storage. DuraGraft is not intended to be mixed with any other storage and flushing solution; mixing may reduce the effectiveness of DuraGraft.

Containers for Solution A and Solution B should be at room temperature prior to use. The mixed solution is used to flush and store saphenous veins from harvesting through grafting, including tests for graft leakage.

INDICATION FOR USE

DURAGRAFT Vascular Conduit Solution is a solution indicated for adult patients undergoing Coronary Artery Bypass Grafting Surgeries and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to 4 hours.

CONTRAINDICATIONS

There are no known contraindications when used as directed.

WARNINGS

DuraGraft Vascular Conduit Solution includes a component, L-arginine. L-arginine may cause an allergic reaction in certain patients.

The re-use of this product is hazardous to patient safety and may cause serious infections from contamination of opened product, leading to serious injury or death.

PRECAUTIONS

Not intended for direct injection or intravenous infusion.

To be used only as directed.

Single use device.

Discard any unused product after use.

The performance of this product has not been studied with additives other than heparin.

Do not use saline, blood, or other solutions with DuraGraft as it may decrease the effectiveness of DuraGraft.

ADVERSE EVENTS

There are no known adverse events when used as directed.

PREPARATION AND USE

Prior to use, check each container for leaks by inspecting the closures. If a leak is found, discard the product. Perform a visual inspection of the solution for particulate matter. Do not use the solution if obvious particulate matter, precipitates, or contamination are evident in the solution. Immediately prior to use, perform the following steps:

1. Pour the entire contents of Solution A into a sterile container (e.g., tray, cup, or small basin) where the vascular conduit will be stored after harvesting and prior to grafting.
2. With a sterile syringe, aseptically remove 12.5 mL of Solution B and add it to the container with Solution A.
3. Add heparin as per the standard practice at your center. Up to 12,500 units of heparin has been clinically evaluated with DuraGraft.
4. Mix by gently swirling the container.
5. Approximately 10 mL of DuraGraft may be used for in-situ flushing of the saphenous vein during harvesting and storage in DuraGraft.
6. Approximately 10 mL of DuraGraft may be used to check the distal anastomosis for leaks.
7. Grafts may be stored in DuraGraft for up to four hours

The mixed solution is used to flush and store the saphenous vein grafts from harvesting through grafting, including tests for graft leakage.

DuraGraft Vascular Conduit Solution should be used within 4 hours of preparing the mixed solution as indicated above.

Manufactured by: Marizyme, Inc.
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DuraGraft Preclinical Studies Summary

The following preclinical studies support DuraGraft for use as a Flushing and Storage Solution for vascular conduits.

Table 4. Preclinical Studies Supporting DuraGraft

Publication	Experimental Conditions	Summary and Conclusions
Pachuk et al., 2019[1]	Human saphenous vein (HSV) segments collected from 9 patients undergoing CABG surgery stored for up to 5 hours in DuraGraft or normal saline solution (NSS)	Graft cell viability was maintained in human saphenous vein segments when the segments were flushed and stored in DuraGraft up to 5 hours. Loss of graft cell viability was observed within 15 minutes following flushing and storage in NSS.
	Pig mammary vein segments were flushed and stored with DuraGraft or NSS for 45 minutes and 24 hours.	H&E staining and Immunohistochemistry staining for CD31 and von Willibrand factor (vWF) showed normal morphology by H&E staining and strong immunostaining of endothelial surface markers CD31 and vWF that was continuous across the endothelium at both timepoints for veins stored in DuraGraft. NSS stored veins had normal morphology by H&E staining at 45 minutes but displayed multifocal aggregation of and missing patches of endothelium at 24 hours. CD31 and vWF staining was weaker for NSS stored grafts.
Korkmaz-Icoz et al., 2021	Rat thoracic aortic rings undergoing cold ischemic storage in either DuraGraft or NSS at 4 °C for 24 hours were incubated in an organ bath culture containing 200µM sodium hypochlorite for 30 minutes to induce free radical formation as seen in reperfusion.	Vasoactive physiologic arterial dysfunction was observed when aortic rings were stored in saline.
Aschacher et al., 2021	Radial Artery and HSV segments from 23 patients undergoing CABG surgery were flushed and stored in either DuraGraft or Ringers lactate solution (RL) at room temperature for 60 minutes or times up to 3 hours at room temperature.	DuraGraft treated grafts showed normal endothelial and sub-endothelial structure whereas RL-treated grafts showed damaged endothelial surface and beginning incongruence of intimal structure. DuraGraft treated grafts were associated with a lower level of reactive oxygen species that correlated with a reduction of hypoxic damage and significant increase in oxidation-reduction potential.

DuraGraft Clinical Studies Summary

DuraGraft has been studied in two sponsor initiated clinical trials:

1. DuraGraft Prospective Study: Randomized Controlled Trial of 125 subjects
2. DuraGraft EU Registry: European Post Approval Study of 2964 subjects
3. Propensity Matched Comparison of DuraGraft EU Registry to STS Registry, 2400 subjects

DuraGraft Prospective Randomized Study

The Prospective randomized controlled trial (Perrault 2019) was a prospective, multicenter, randomized trial conducted to evaluate the effects of DuraGraft on graft level anatomic parameters that are early anatomical markers of vein graft disease. The study employed a "within-patient control" design, in which patients received both a control saline-treated saphenous vein graft and a DuraGraft-treated saphenous vein graft, randomly assigned per graft. The initial trial included multi-detector computed tomography (MDCT) evaluation at 1 and 3 months. Follow-up was extended to 1-year with an additional MDCT evaluation in the second protocol requiring re-consenting the patients.

A total of 125 patients were randomized and enrolled from September 2014 to December 2016 at seven investigational sites in Canada, Ireland, and Denmark. 125 grafts were treated with DuraGraft, and 125 grafts treated with saline. Mean Society of Thoracic Surgeons score for mortality was 0.9 ± 0.6 and mean European System for Cardiac Operative Risk Evaluation II score was 1.1 ± 0.6. Grafts were assessed using serial MDCT at 1 month (n=116), 3 months (n=118), and 12 months (n=97), respectively.

Results:
Safety:
The results of the safety endpoint analysis is exhibited below (Table 5). Vein graft occlusions were observed in 7.2% of the DuraGraft treated grafts and 8.8% of the saline treated grafts. According to the Fitzgibbon classification, a stenosis type B (flow limited) or type O (occlusion) was observed in 1.6% of the grafts in the DuraGraft group and 2.4% of the saline group. No MACE events were observed in the DuraGraft group compared to 1 in the saline group and in particular no deaths were observed in either group. The composite event rate was 8.8% for DuraGraft treated grafts and 11.2% for saline treated grafts.

Table 5. Adjudicated safety outcomes after graft treatment by either DuraGraft or saline after a follow-up duration of 110.3 patient-years (1 year follow-up timepoint)

Outcome	DuraGraft (n = 125)	Saline (n = 125)
Major adverse cardiac events†	0	1 (0.8) [0.009]
Composite end point‡	11 (8.8) [0.100]	14 (11.2) [0.127]
Death	0	0
Myocardial infarction	0	1 (0.8) [0.009]
Repeat revascularization	0	0
Increased angina	0	1 (0.8) [0.009]
Increased arrhythmia	0	0
Increased shortness of breath	0	0
Vein graft thrombosis/occlusion	9 (7.2) [0.082]	11 (8.8) [0.100]
Fitzgibbon class B and O	2 (1.6) [0.018]	3 (2.4) [0.027]

Values are n (%) [number of events per patient-year]
†Death, myocardial infarction, or repeat revascularization.
‡Composite of all adverse events
*Perrault et al., JTCVS 2019

Effectiveness:

MDCT analysis revealed that there was no significant difference between the DuraGraft group and the saline group in terms of change in mean wall thickness between 1 and 3 months in the analysis of whole grafts. However, at 12 months, DuraGraft treated SVGs had smaller mean wall thickness versus their saline-treated counterparts 0.12±0.06 mm vs 0.20±0.31 mm (Figure 1) and the change in maximal focal narrowing 0.2 ± 3.8 mm versus 4.7 ± 12.7 mm **(Figure 2).**

Figure 1: Wall thickness analysis by MDCT for whole graft

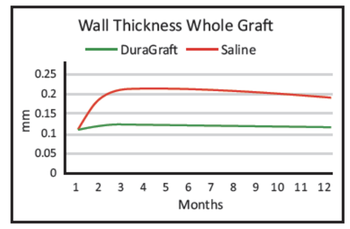
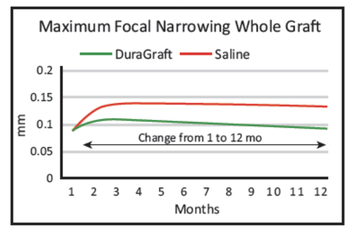


Figure 2: Maximum Focal Narrowing analysis by MDCT for whole graft



DuraGraft EU Registry

The DuraGraft EU Registry is an ongoing European post-market study designed to support an International CABG registry database used to assess patients receiving DuraGraft during CABG surgery and whose free vascular grafts, 4,454 venous grafts and 586 arterial conduits have been treated with DuraGraft. A total of 2,964 patients were enrolled in the Registry, which enrolled patients between December 2016 and August 2019. There were 45 enrolling centers in eight countries: Austria, Germany, Ireland, Italy, Spain, Switzerland, Turkey and United Kingdom. Follow-up data has been completed out to one (1) year and will continue for up to five (5) years.

The subjects have an average age of 67.8 ±9.2 years (range 33 - 90 years). The majority of subjects were males (82.3%, 2438/2964) and were Caucasian (88.3%, n=2610/2956). The majority of subjects had a history of hypertension 84.4% (2486/2946), dyslipidemia 76.9% (2251/2929), and diabetes was present in 43.7% (1294/2962). The overall mean EuroSCORE II (ESII) for all patients is 2.6 ± 3.7 (n=2964). For CABG only patients (n=2532), the mean score is 2.3 ± 3.4 and for CABG +valve patients n=(432) is 4.3±5.0.

Results:

In the total study population, 120 (4.1%) patients experienced a MACE at 30 days and 7.4% at 1 year. The 30-day incidence of death, myocardial infarction and repeat revascularization was 2.7%, 1.6% and 1.1%, respectively for all patients, isolated CABG and CABG + valve cohorts and at 1 year was 5.2%, 2.2% and 2.1%, respectively. In the total population 2.3% of the patients experienced a stroke at 1 year. The 1-year all-cause death rate was 5.2% (148/2964). 30-day and 1-year Kaplan Meir rates for MACE are given in **Table 6**.

In the isolated CABG group, the 30-day MACE rate was 3.5% with all-cause death (2.3%), myocardial infarction (1.3%), and repeat revascularization (1.0%). The 1-year MACE rate was 6.6% with all-cause death (4.4%), myocardial infarction (2.0%), and repeat revascularization (2.2%).

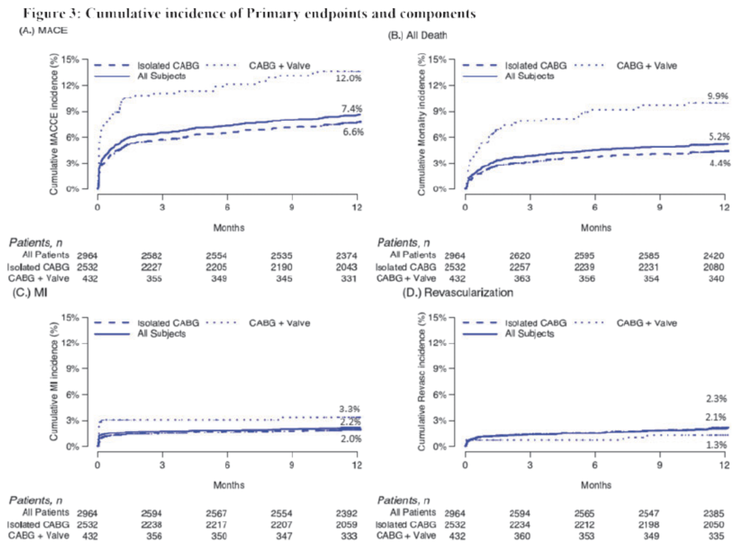
The 30-day MACE rate for the combined CABG + valve groups was 7.5% with rates of death 5.4%, myocardial infarction 3.1% and repeat revascularization 0.7%. The 1-year MACE rate was 12.0% with rates of death 9.9%, myocardial infarction 3.3% and repeat revascularization 1.3% Cumulative incidence of primary endpoints and incidents are shown in **Figure 3**.

Table 6. 30-Day and 1-Year Kaplan Meier rates for MACE

	All patients (n=2964)		Isolated CABG (n=2532)		CABG and valve (n=432)	
	% (No. of events)		*% (No. of events)*		*% (No. of events)*	
	30 days	1 year	30 days	1 year	30 days	1 year
MACE	4.1% (120)	7.4% (210)	3.5% (88)	6.6% (160)	7.5% (32)	12.0% (50)
MACCE	5.2% (153)	8.6% (247)	4.6% (115)	7.8% (190)	8.9% (38)	13.6% (57)
All-Cause Death	2.7% (80)	5.2% (148)	2.3% (57)	4.4% (107)	5.4% (23)	9.9% (41)
Cardiovascular Death	2.7% (80)	4.5% (130)	2.3% (57)	3.8% (92)	5.4% (23)	9.1% (38)
Myocardial Infarction	1.6% (46)	2.2% (63)	1.3% (33)	2.0% (49)	3.1% (13)	3.3% (14)
All Repeat Revascularization	1.1% (31)	2.1% (58)	1.1% (28)	2.2% (53)	0.7% (3)	1.3% (5)
PCI	0.8% (22)	1.8% (48)	0.8% (21)	1.9% (45)	0.2% (1)	0.8% (3)
Re-CABG	0.3% (9)	0.3% (10)	0.3% (7)	0.3% (8)	0.5% (2)	0.5% (2)
Stroke	1.7% (50)	2.3% (65)	1.5% (37)	1.9% (46)	3.1% (13)	4.6% (19)

*Percentages indicate cumulative event rates by Kaplan Meier estimates.
**MACE: major adverse cardiac events; MACCE: major adverse cardiac and cerebrovascular events; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting.

Figure 3: Cumulative incidence of Primary endpoints and components



Cumulative incidence of (A) the primary outcome; Major Adverse Cardiac Events (MACE); and the individual components of the primary outcome (B) all-cause death; (C) myocardial infarction; (D) repeat revascularization, at 1 year.

Propensity Matched Comparison of DuraGraft EU Registry to STS Registry

To compare mortality of patients in the single arm DuraGraft Registry, the Society of Thoracic Surgery (STS) Database was identified and determined suitable for use as a contemporaneous control. 2532 patients underwent isolated CABG surgery in the DuraGraft Registry between December 2016 and August 2019. 294,725 isolated CABG patients were identified in the STS Registry who were operated on between 2016 and 2018 and had at least 1 year mortality data available from linkage to the US National Death Index (NDI), a database maintained by the National Center for Health Statistics (NCHS) which captures all death records for the US and US territories. An analysis was conducted comparing Isolated CABG patients from the DuraGraft Registry to a propensity matched control group from the STS Registry Adult Cardiac Surgery Database2400/2532 patients were matched from the DuraGraft cohort to 2400 patients in the STS Database, matching on 35 prespecified variables, selected to be predictive of mortality risk in the operative, peri-operative, and follow-up periods. These variables included demographics, cardiac risk factors, pre-operative cardiac status, coronary anatomy, and surgical characteristics.

Results:
The propensity matched groups were well balanced on all important demographic, procedural and anatomic characteristic. The cumulative incidence of mortality through 36 months of follow up in the 2,400 propensity matched DuraGraft and STS registry subjects is presented as Kaplan Meier estimates in **Figure 4.** and **Table 7.** At 30 days and 12 months the mortality estimate in DuraGraft was 2.38% [95% CI, 1.84% - 3.07%] and 4.32% [CI, 3.58% - 5.22%] compared to the STS Registry patients 1.96% [95% CI 1.47% - 2.60%] and 4.79% [95% CI 4.01% - 5.72%], respectively. At 36 months the mortality estimate in DuraGraft patients was reduced compared to the STS Registry patients (7.37% [95% CI, 6.36% - 8.53%] vs. 9.65% [95% CI 8.37% - 11.10%]).

Figure 4. Kaplan Meier estimates of all-cause mortality through 36 months in 2400 DuraGraft patients and Kaplan Meier estimates of all-cause mortality through 36 months in 2400 Propensity Matched STS patients

Table 7. Kaplan Meier estimates of all-cause mortality through 36 months in 2400 DuraGraft patients that were Propensity Matched to STS patients. Product Limit (PL) Estimates.

	DuraGraft				STS Registry			
Time Points (days)	*Number at Risk*	*Number Failed*	*Survival Estimate*	*Standard Error*	*Number at Risk*	*Number Failed*	*Survival Estimate*	*Standard Error*
0	2400	1	99.96%	0.04%	2400	1	99.96%	0.04%
30	2341	57	97.62%	0.31%	2353	47	98.04%	0.28%
180	2264	90	96.23%	0.39%	2316	84	96.50%	0.38%
365	2209	103	95.68%	0.42%	2285	115	95.21%	0.44%
725	2024	126	94.63%	0.47%	1552	160	93.04%	0.53%
1085	1729	166	92.63%	0.55%	798	194	90.35%	0.69%

Clinical Outcomes for DuraGraft Registry vs Published Literature:

To gain perspective on the observed outcomes in this single arm registry, we have performed a literature review of published registries. 30-day and 1-year outcomes are evaluated, including all-cause mortality and the components of MACE versus the published literature using EuroSCORE II values for comparison and to gain perspective on the measured outcomes. Values are presented in the table when reported in each study.

The DuraGraft Registry compares favorably for 30-day death rates with contemporary registry studies which reported 30-day and/or in-hospital mortality for patients undergoing isolated CABG surgery as seen in **Table 8.** Additional data is scant as the majority of the registry studies do not always report the individual components of MACE besides death at 30-days and 1-years. The 30-day death rate was 2.3% in the DuraGraft Registry and ranged from 1.1% in Bangalore et al[6] to 3.2% in Adelborg et al[7]. It is notable that the comparative registries mostly reported In-Hospital mortality. If reported at 30 days, it is likely that full 30-day mortality rates would have been even higher in these registries. One-year mortality in real world registry studies ranged from 4.8% in the MAIN COMPARE[8] registry to 10.5% in Biancari et al[9], compared to 4.5% in the DuraGraft Registry.

Table 8. 30-day and 1-Year Comparative MACE Event Rates in Patients Receiving Isolated CABG Surgery – Registry Studies

	European Registries						Non-European Registries		
Study	**DuraGraft Registry[5]**	**Paparella (2014)**	**Biancari (2012)[9]**	**Kieser (2016)**	**Adelborg (2017)[7]**	**Beckman (2019)**	**Bangalore (2015)[6]**	**MAIN-COMPARE (2008)[8]**	**Puskas (2012)**
Number of CABG patients	2,544	2,605	1,027	1,125	47,415	34,224	9,223	542	20,014
EuroSCORE (II)	2.3% ± 3.4		4.5% ± 6.7	1.5%					
Syntax score									
30 days or In-Hospital	**30 days**	**In-hospital**	**30 days**	**In-hospital**	**30 days**	**In hospital**	**30 days + in-hospital**		**30 days**
Death	2.3%	3%	3.7%	3.2%	3.2%	2.7% (3% OPCAB)	1.1%		2.1%
Cardiac death	2.3%				1.4%				
Non cardiovascular	0.0%								
MI	1.3%						0.4%		
Revascularizations	1.3%								
Stroke	1.5%		2.4%				1.2%		
1 year	**1 year**		**1 year**		**1 year**			**1 year**	**1 year**
Death	4.5%		10.5%		6.0%			4.8%	5.4%
MI	2.1%								
Revascularizations	2.5%							1.5%	
Stroke	2.1%								

Symbol Glossary

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD TITLE	STANDARD REFERENCE
REF	Catalog #	Indicates the manufacturer's catalog # so that the medical device can be identified	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.6 FDA Recognition # 5-134 ISO 7000 Reference #2493 FDA Recognition # 5-124
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.5 FDA Recognition # 5-134 ISO 7000 Reference #2492 FDA Recognition # 5-124
	Use-by Date	Indicates the date after which the medical device is not to be used. Date format is YYYY-MM-DD	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.4 FDA Recognition # 5-134 ISO 7000 Reference #2607 FDA Recognition # 5-124
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.3.7 FDA Recognition # 5-134 ISO 7000 Reference #0632 FDA Recognition # 5-124
	Do not re-use	Indicates the medical device is single use	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.2 FDA Recognition # 5-134 ISO 7000 Reference #1051 FDA Recognition # 5-124
	Consult instructions for use	Indicates the need for the user to consult instructions for use	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.3 FDA Recognition # 5-134 ISO 7000 Reference #1641 FDA Recognition # 5-124
Rx only	Labeling – symbol for Prescription Device	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	Guidance for Industry and FDA on Alternative to certain Prescription Device Labeling Requirements	NA
	Do not use if package is damaged	Not to be used if package is damaged or opened	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.8 FDA Recognition # 5-134 ISO 7000 Reference #2606 FDA Recognition # 5-124
	Caution	Warning: Not for IV Infusion or Direct Injection	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.4 FDA Recognition # 5-134 ISO 7000-0434A FDA Recognition # 5-124
STERILE A	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.2 FDA Recognition # 5-134 ISO 7000-2500 FDA Recognition # 5-124

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[6] Bangalore, Sripal, et al. "Everolimus-eluting stents or bypass surgery for multivessel coronary disease." New England Journal of Medicine 372.13 (2015): 1213-1222.
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Revision Number: 1
Date of latest revision: 26-JUN-2025

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