Perclose ProGlide

Suture-Mediated Closure System

DON'T JUST CLOSE.
REPAIR.

TO LEARN MORE, VISIT
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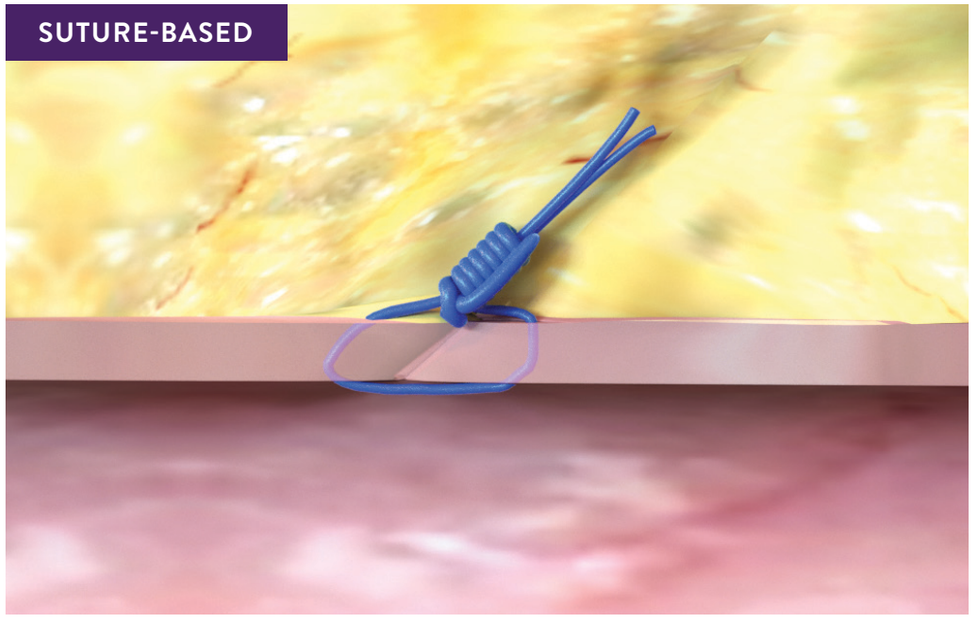
DON'T JUST CLOSE. REPAIR.

Perclose ProGlide provides percutaneous surgical repair with a suture by delivering a secure, non-masking percutaneous repair. Perclose ProGlide promotes primary intention healing[1] with less scarring[2] and reduces time to hemostasis, ambulation, and discharge[3].

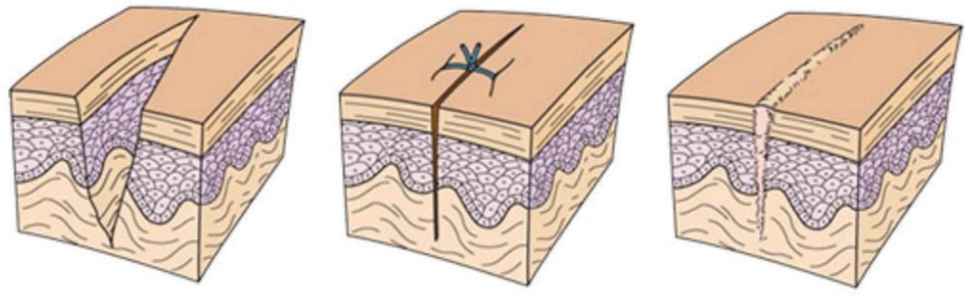
The use of Perclose ProGlide for repair of large-bore arterial access is associated with significantly lower blood transfusions, infections, mortality, and length of stay compared to cutdown[4].

SUTURE-BASED



PRIMARY INTENTION

Primary Wound Healing With Suture Repair

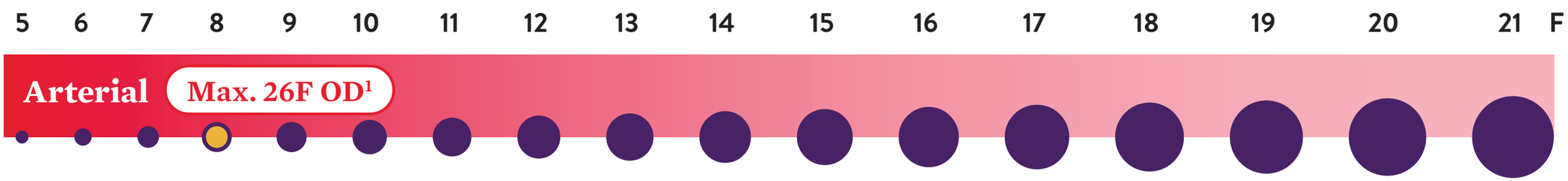


Clean Incision | Early Suture | "Hairline" Scar

1. Primary intention healing occurs where vessel wall edges are brought together, adjacent to each other. This can be achieved with suture, stitches, staples, and clips.
2. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 19 May 2017. Web. March 21, 2018.
3. Bhatt, Deepak L. et al. Successful "Pre-Closure" of 7Fr and 8Fr Femoral Arteriotomies With a 6Fr Suture-Based Device (The Multicenter Interventional Closer Registry). *American Journal of Cardiology* Vol 89. March 2002.
4. Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.

BROADEST INDICATION*

The Perclose ProGlide vascular closure system has the **broadest indication for femoral arterial access**



For Common Femoral Access Sites

		Max. OD[1]
Artery	5-21F[2]	26F

*As compared to Angio-Seal, ExoSeal, FemoSeal, InClosure, MANTA, Mynx, PerQseal, Vascade, Velox CD, X-Seal. Data on file at Abbott.

1. Max. OD 26F/0.340 inches/8.62 mm; Max. OD 29F/0.378 inches/9.59 mm. Tests performed by and data on file at Abbott.
2. For sheath sizes greater than 8F, at least two devices and pre-close technique are required.

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BROADEST INDICATION* FOR FEMORAL ARTERIAL ACCESS

PARALLELS THE SURGICAL GOLD STANDARD

- Associated with significantly lower blood transfusions, infections, mortality, and shorter length of stay compared to surgical cutdown[1]
- Secure repair with pre-tied polypropylene monofilament suture
- Minimal intravascular footprint

PROMOTES VESSEL HEALING

- Minimized inflammatory response[2]
- No re-access restrictions after using Abbott vascular closure devices

GIVES IN-LAB CONFIDENCE

- Low access site-related complication[1], reduces time to hemostasis, ambulation, and discharge[3]
- Suture repair can be challenged and confirmed on the table
- Ability to maintain wire access

*As compared to Angio-Seal, ExoSeal, FemoSeal, InClosure, MANTA, Mynx, PerQseal, Vascade, Velox CD, X-Seal. Data on file at Abbott.

1. Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.
2. Mercandetti, Michael. Wound Healing and Repair. Medscape. WebMD, 19 May 2017. Web. March 21, 2018.
3. Bhatt, Deepak L. et al. Successful "Pre-Closure" of 7Fr and 8Fr Femoral Arteriotomies With a 6Fr Suture-Based Device (The Multicenter Interventional Closer Registry). *American Journal of Cardiology* Vol 89. March 2002.

DEVICE OVERVIEW

PERCLOSE PROGLIDE

Guide Wire Exit Port – Allows for guide wire insertion and removal

Foot – Provides tactile confirmation of correct device position when open

Suture Knot – Biocompatible USP 3-0 Class I monofilament polypropylene suture

Marker Lumen – Provides visual confirmation of correct device positioning

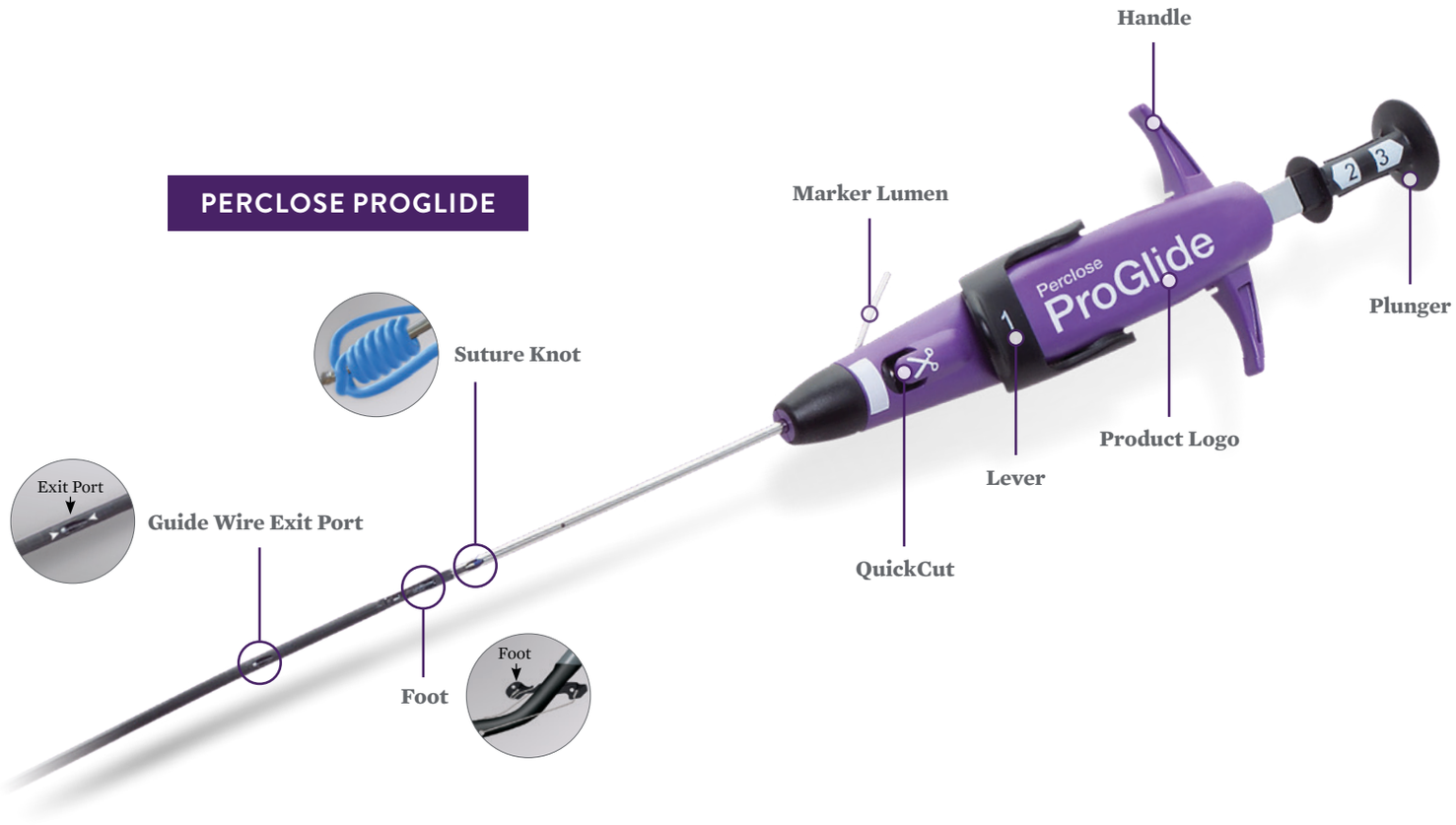
QuickCut – Allows for suture cutting

Lever – Opens and closes the Foot

Product Logo – Indicates suture deployment position

Handle – For device stabilization

Plunger – Deploys the needles and suture



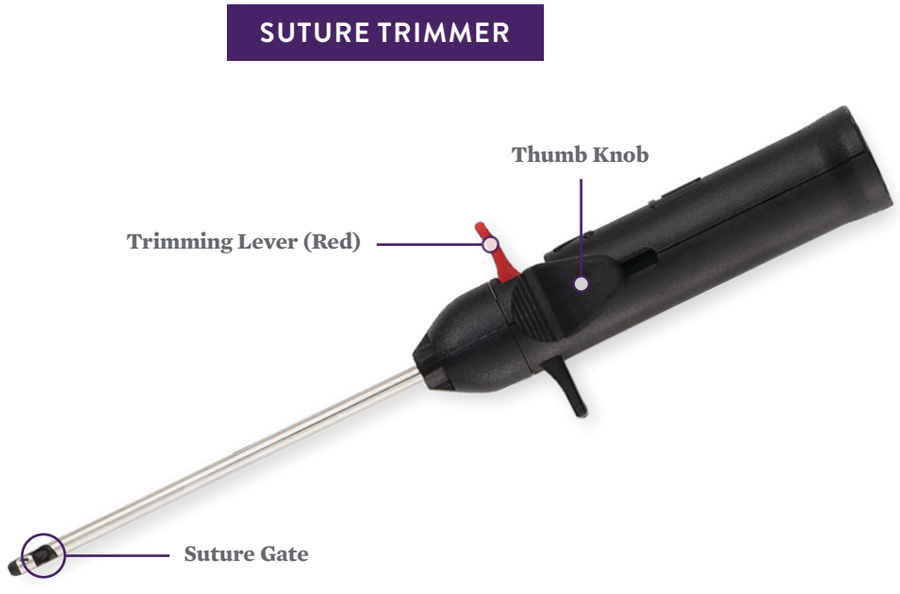
SUTURE TRIMMER

Suture Trimmer – Advances Suture Knot and allows subcutaneous suture trimming

Suture Gate – Open and close to capture suture

Trimming Lever (Red) – Pull to cut suture

Thumb Knob – Slide to open and close Suture Gate

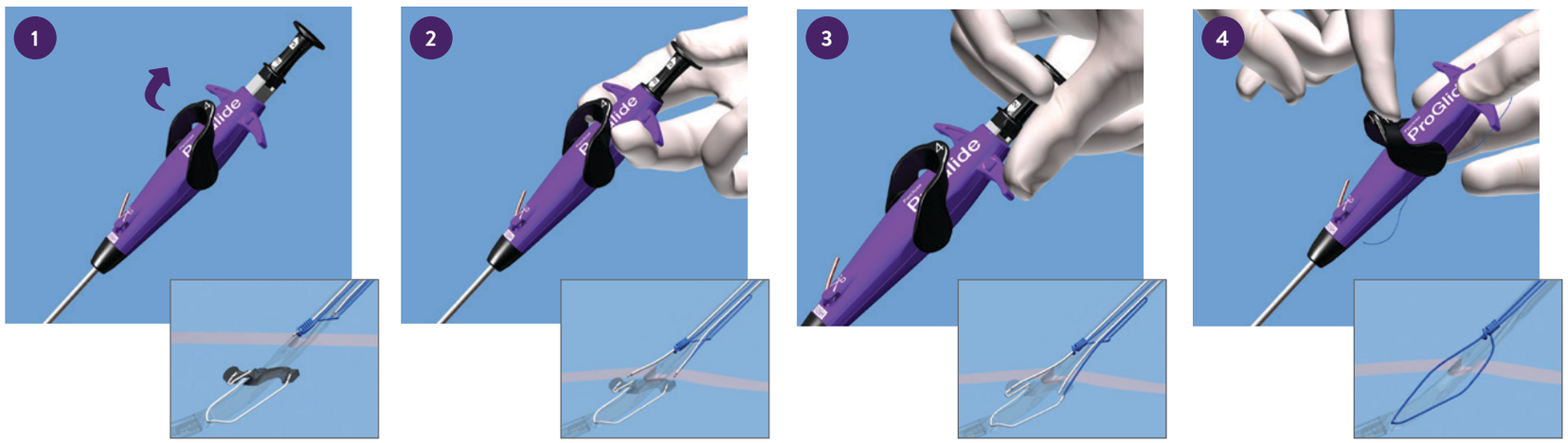


Perclose ProGlide
Suture-Mediated Closure System

DON'T JUST CLOSE. **REPAIR.**

FOUR KEY STEPS TO SUTURE DEPLOYMENT

1. Advance device and lift Lever (open Foot)
2. Maintain retraction and depress Plunger (deploy Needles)
3. Pull back Plunger (deploy Suture)
4. Lower Lever (close Foot)



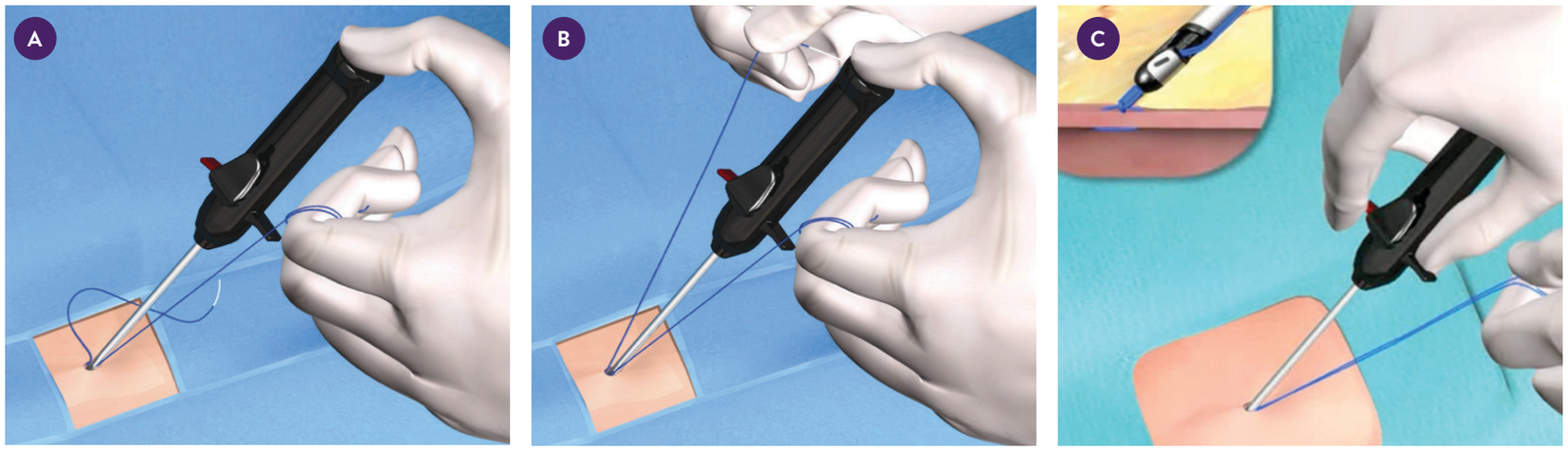
SUTURE MANAGEMENT

Suture Trimmer – Advances Suture Knot and trims Suture

A. Capture blue (rail) suture limb in Suture Gate and advance Suture Knot

B. Lock Suture Knot by pulling white (non-rail) suture limb

C. Trim suture limbs by pulling Trimming Lever



Refer to the **Instructions for Use** for additional information.

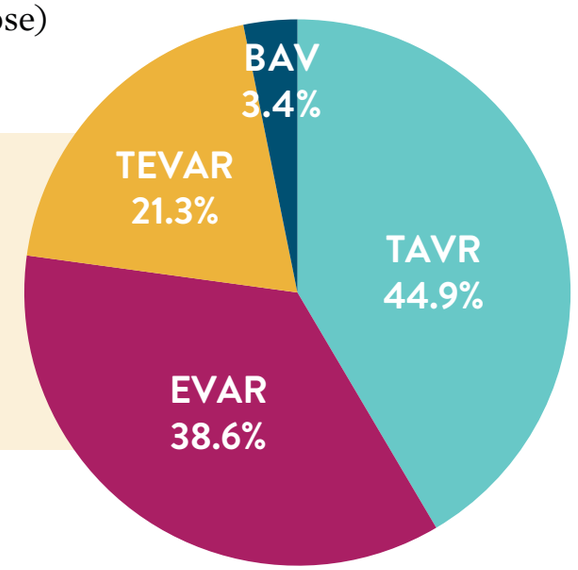
REAL-WORLD EVIDENCE ON REPAIR OF LARGE-BORE ARTERIAL ACCESS

Perclose ProGlide vs. Surgical Cutdown

The Perclose ProGlide vs. Surgical Cutdown retrospective study was designed to compare clinical outcomes and complication rates among patients undergoing closure of large-bore arterial access using Perclose ProGlide (Perclose) vs. Surgical Cutdown (Cutdown) in a real-world setting.

KEY FINDINGS

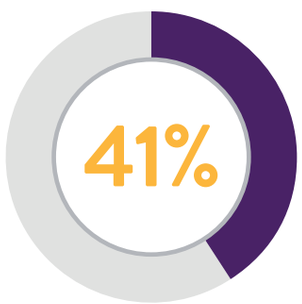
The use of Perclose ProGlide for repair of large-bore arterial access is associated with significantly **lower blood transfusions, infections, mortality, and length of stay compared to Surgical Cutdown**.



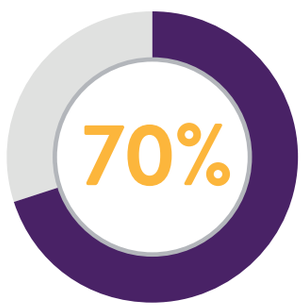
Patients may have had multiple procedures during index admission

PERCLOSE PROGLIDE PATIENTS

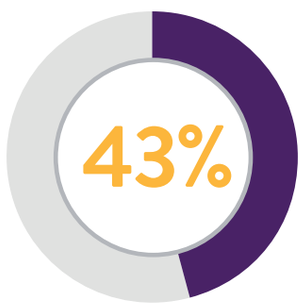
Less likely to require a blood transfusion



Less likely to have an infection



Less likely to die within 30 days post-procedure



Shorter hospital stay

Source: Perclose ProGlide Versus Surgical Closure Outcomes – Real World Evidence. Schneider, Darren B; Krajcer, Zvonimir; et al. LINC 2018.

ORDERING INFORMATION

DESCRIPTION	STOCK NUMBER	UNITS PER PACKAGE	INCLUDES
Perclose ProGlide Suture-Mediated Closure System	12673-05	10	(1) Perclose ProGlide Suture-Mediated Closure Device (1) Suture Trimmer

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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *eifu.abbottvascular.com* or at *manuals.sjm.com* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Information contained herein for **DISTRIBUTION outside of the U.S. ONLY.** Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

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Document# Rev
AP2946185-OUS A

AP2946185-OUS
ProGlide Brochure (arterial only)
A
Effective Date: 7/20/2018

Document #:	**AP2946185-OUS**		**Title:**	ProGlide Brochure (arterial only)	
Current Revision:	A	**Future Revision:**		**Change Type:**	New Release
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Superceded By Doc. # (Supercede only):					
Supporting Documentation Attached?	Yes [ ] No [X]				
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	N/A [X]	Mat'l type:		UOM:	Alt. UOM: Qty: 0
Material Disposition:		On Order:	Rec'g Insp:	Stock:	FU: FS:
		Memo:			
Material Division:					
Associated Products (product name(s) only):		*** NONE *** (N)			

Reference Documents

Document	Location

Approval Signatures

Level	Role / Function	Name	Site	Signature	Date	Comments
1	Doc Control/Labeling	Hu, Grace	CA	Hu, Grace	7/18/2018 11:59:32 AM	
2	Clinical	Piard-Ruster, Karine	CA	Piard-Ruster, Karine	7/18/2018 12:58:20 PM	
2	Clinical Engineer	Stokes, James A	CA	Stokes, James A	7/18/2018 12:03:46 PM	
2	Customer Service	Martinez, Catherine L	CA	Martinez, Catherine L	7/18/2018 12:14:19 PM	
2	Doc Owner (AP2946185-OUS)	Leung, Fiona W	CA	Leung, Fiona W	7/20/2018 5:24:36 PM	
2	Doc Owner (AP2946211-OUS)	Leung, Fiona W	CA	Leung, Fiona W	7/20/2018 5:27:03 PM	
2	Doc Owner (AP2946239-OUS)	Leung, Fiona W	CA	Leung, Fiona W	7/20/2018 5:29:11 PM	
2	HEOR	Hasegawa, James	CA	Hasegawa, James	7/18/2018 4:46:17 PM	
2	Marketing Com	Navarro, Tricia M	CA	Navarro, Tricia M	7/18/2018 12:18:49 PM	
2	Office of Ethics and Compliance	Hu, Grace	CA	Hu, Grace	7/18/2018 12:00:11 PM	
2	Originator	Hu, Grace	CA	Hu, Grace	7/18/2018 11:59:54 AM	
2	R&D	Fortson, Aaron M	CA	Fortson, Aaron M	7/18/2018 3:14:32 PM	
2	RA (A & P)	McFerran, Aurora B	CA	McFerran, Aurora B	7/20/2018 11:51:05 AM	

Revision History

Revision	Date	Description of Change	CO Number	Originator
A	7/20/2018 9:46:13 PM	New Document Purpose: To provide an overview on ProGlide's key features, device components, deployment, and clinical information. Geography: OUS - in countries with arterial indication only. Audience: Sales, marketing, and health care professionals Method of Distribution - Electronic	428448	Hu, Grace

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