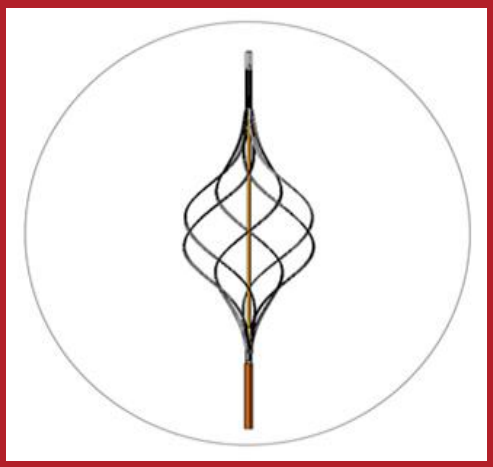
THROMBOLEX™

INNOVATIVE ENDOVASCULAR CATHETERS

Thrombolex provides an innovative line of Endovascular Catheters, which feature a unique combination of mechanical, expandable infusion catheters to infuse physician specified fluids for the treatment of Arterial & Venous Thromboembolic (AVTE) conditions



Value Analysis Packet

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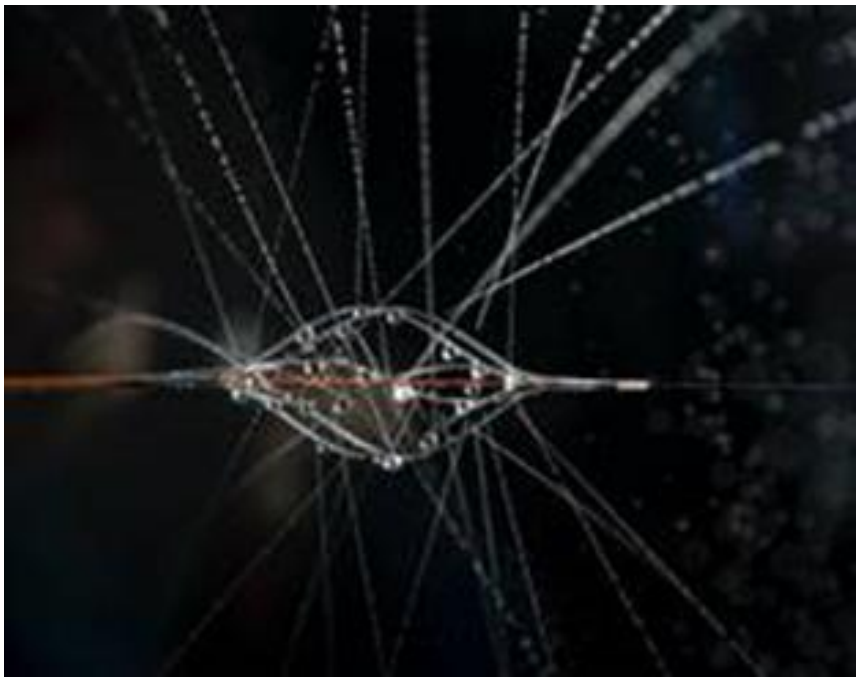
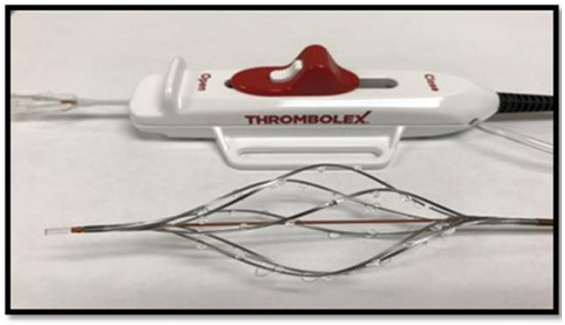
THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS



PRODUCT OVERVIEW

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

BASHIR™
endovascular catheter



THE PROBLEM

Venous thromboembolic (VTE) disease is an under-recognized and under-treated condition. It is the third leading cause of cardiovascular-related death and accounts for 15% of all hospital related deaths.

OUR SOLUTION

BASHIR™ Endovascular Catheter: An innovative CDT‡ technology featuring a unique mechanical function that immediately restores blood flow, while enabling accelerated thrombolysis via its *expandable* infusion basket.

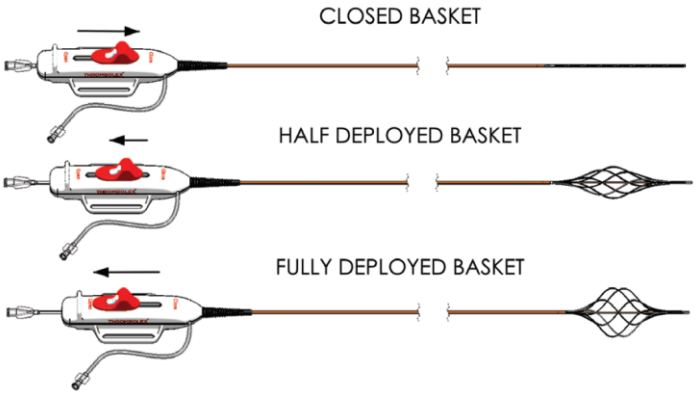
DESIGNED TO ENHANCE OUTCOMES

BASHIR™ Endovascular Catheter is the first interventional catheter to rapidly create multiple channels so the patient's own endogenous lytics can flow into the culprit thrombus. It is the only CDT device that allows clinicians to monitor cardiovascular function and patient vital signs, through the device and during infusion treatment. This helps enable diagnostic and therapeutic decisions to be made earlier, helping to guide clinician treatment decisions for critically ill patients.

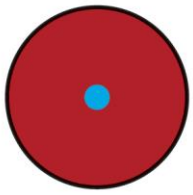
‡ CDT = catheter directed thrombolysis

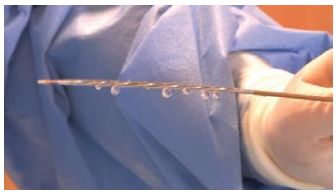
TECHNOLOGY OVERVIEW

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

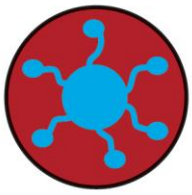


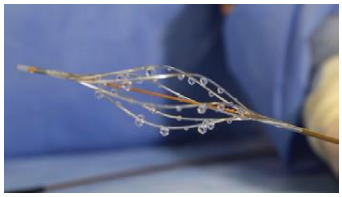
Single channel through thrombus





Multiple channels through thrombus





MODE OF ACTION

Total clot burden reduction

Mechanical expansion of the 6 mini-infusion catheters of the basket in the BASHIR™ family of Endovascular Catheters creates a large central channel which is designed to allow the patient's own blood to flow through the culprit clot immediately. This creates a greater surface area within the clot where the endogenous and exogenous lytics may attach to plasminogen receptors to accelerate lysis, fragmenting the clot and reducing the total clot burden.

SAFETY

The potential to reduce bleeding complications

The patent center lumen of the BASHIR™ Endovascular Catheters uniquely allows the medical team to measure pulmonary artery pressure and mixed venous oxygen saturation during infusion†. This should reduce bleeding complications by helping clinicians assess cardiovascular function data to guide *real time* treatment decisions. This also enables early intervention for critically ill patients, by clinicians, supported by diagnostic and therapeutic decisions.

EASE OF USE & COST-EFFECTIVE CARE

Minimal change to workflow and simple to use

By employing standard interventional techniques used in most cath labs, the BASHIR™ family of Endovascular Catheters are easy to use and do not require the purchase of expensive additional capital equipment. This enables a more cost-effective and efficient approach across the patient care continuum.

† The Bashir™ N-X Endovascular Catheter is the only catheter presently offered by Thrombolex Inc. with an indication for use in the pulmonary artery vasculature. For more information, please refer to Regulatory Information.

MECHANISM OF ACTION

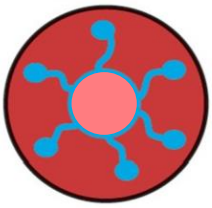
THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

SYNERGISTIC ENDOGENOUS AND EXOGENOUS THROMBOLYSIS

(A unique mechanism that enhances the body's own ability to dissolve blood clots, while improving the therapeutic effect of thrombolytic drugs)

Rapid flow restoration

Established by creating a large central channel through the thrombus by expansion of the catheter basket.

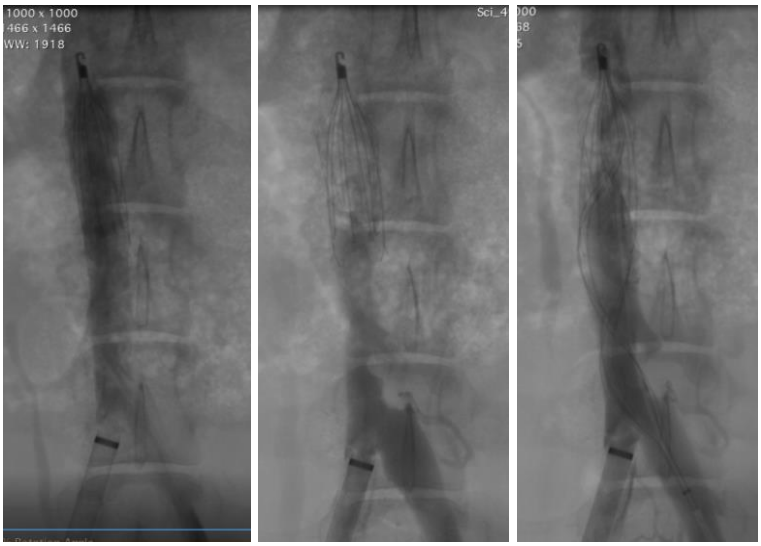


INCREASE Luminal filling and blood velocity

PROMOTE **Endogenous** thrombolysis[i,ii]

This creates a greater surface area within the culprit clot for the endogenous and exogenous lytics to attach to more plasminogen receptors, causing fragmentation and promoting accelerated lysis of the clot burden.

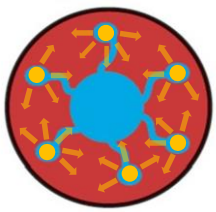
Experimental model of inferior vena cava (IVC) thrombosis



Normal flow in IVC prior to thrombosis | Flow cessation in thrombosed IVC | Flow restored after deployment of basket

Multichannel infusion

Enabled by expansion of the 6 mini sidehole catheters into the thrombus.



INCREASE Surface area and lytic penetration

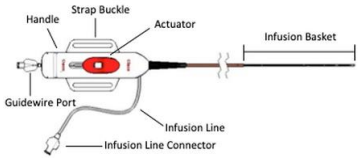
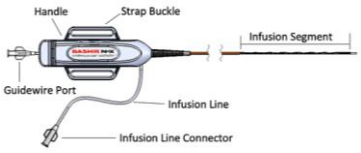
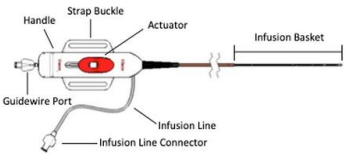
PROMOTE **Exogenous** thrombolysis

Thrombolytic delivery via the expanded mini catheters

References: i) Blinc et al. Thromb Haemost. 1994 Feb;71(2):230-5. ii) Comerota et al. Ann Surg. 1997;226(3):306-314.

PRODUCT SPECIFICATIONS

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

BASHIR™ endovascular catheter	BASHIR™ N-X endovascular catheter	BASHIR™ S-B endovascular catheter
		

KEY DIMENSIONS

French Size	7 F (2.3 mm)		
Effective Length	92.5 cm (36.44 in)		
Infusion Basket Length	12.50 cm (4.94 in)	N/A	10.00 cm (3.94 in)
Infusion Basket Diameter	45 mm max.	N/A	42 mm max.

CHARACTERISTICS

Basket Expansion	Controlled by actuator	N/A	Controlled by actuator
Thrombolytic Infusion	6 mini-infusion catheters with 48 precision laser-drilled holes		
Guidewire Compatibility	0.018”		
Sterilization	Ethylene oxide gas		
Use	Single use		
Shelf Life	2 years		

ORDERING INFORMATION

Product Order Number	7201	7200	7101
Minimum Order Quantity*	Each	Each	Each

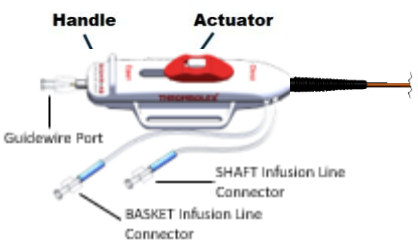
* Suggested initial order quantity of 8 catheters (2 cartons)

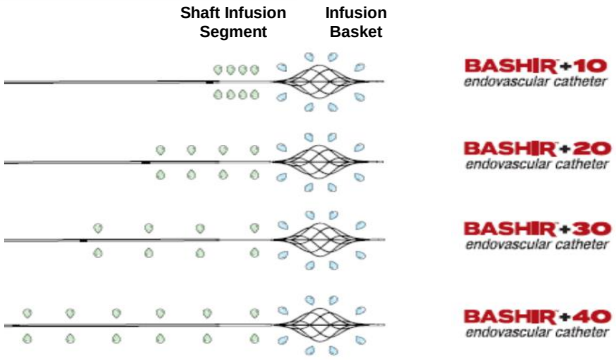
To order or for more information,
contact customer service at 1.844.792.6300
or fax your order to 267.224.4436

PRODUCT SPECIFICATIONS

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

BASHIR™+ endovascular catheter





KEY DIMENSIONS

French Size	7 F (2.3 mm)
Effective Length	92.50 cm (36.44 in)
Infusion Basket Length	12.50 cm (4.94 in)
Infusion Basket Diameter	45 mm max.
Shaft Infusion Additional Treatment Zone Segment Length	10.00 cm (3.94 in) for +10 20.00 cm (7.87 in) for +20 30.00 cm (11.80 in) for +30 40.00 cm (15.75 in) for +40

CHARACTERISTICS

Basket Expansion	Controlled by actuator
Thrombolytic Infusion	6 mini-infusion catheters with 48 precision laser-drilled holes in the infusion basket, and additionally along the shaft: • 42 precision laser-drilled holes for +10, +20, +30 • 56 precision laser-drilled holes for +40
Guidewire Compatibility	0.018”
Sterilization	Ethylene oxide gas
Use	Single use
Shelf Life	2 years

ORDERING INFORMATION

Product Order Number	7210, 7220, 7230, 7240
Minimum Order Quantity*	Each

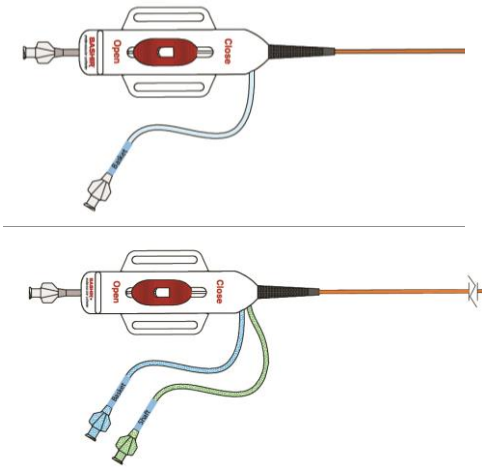
* Suggested initial order quantity of 8 catheters (2 cartons)

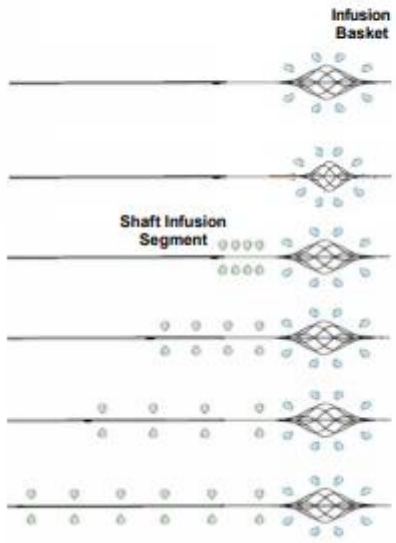
To order or for more information, contact customer service at 1.844.792.6300 or fax your order to 267.224.4436

PRODUCT CATALOG

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Customer Service: 844.792.6300
Customer Service Fax: 267.224.4436
Email Inquiries: INFO@THROMBOLEX.COM
Place Orders: ORDERS@THROMBOLEX.COM
Website: WWW.THROMBOLEX.COM

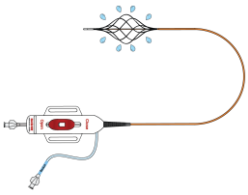
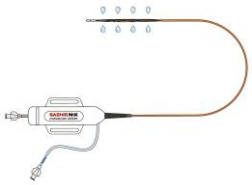
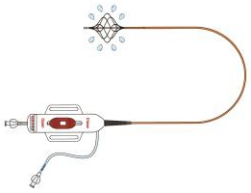
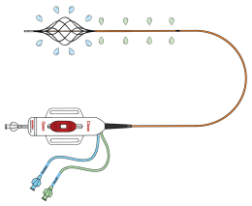




Trade Name	Product No.
BASHIR endovascular catheter	7201
BASHIR S-B endovascular catheter	7101
BASHIR +10 endovascular catheter	7210
BASHIR +20 endovascular catheter	7220
BASHIR +30 endovascular catheter	7230
BASHIR +40 endovascular catheter	7240

REGULATORY INFORMATION

THROMBOLEX
INNOVATIVE ENDOVASCULAR CATHETERS

	BASHIR endovascular catheter	BASHIR N-X endovascular catheter	BASHIR S-B endovascular catheter	BASHIR+ endovascular catheter
				
Intended Use	The Bashir™ Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus.	The Bashir™ N-X Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.	The Bashir™ S-B Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.	The Bashir™ Plus Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus
Trade/Device Name	Bashir™ Endovascular Catheter, Model 7201	Bashir™ N-X Endovascular Catheter, Model 7200	Bashir™ S-B Endovascular Catheter, Model 7101	Bashir™ Plus Endovascular Catheter, Model [7210, 7220, 7230, and 7240]
510(k) Number	K183290 K211061	K183290	K192598	K193071 K211061
Clearance Date	25 February 2019	25 February 2019	17 October 2019	17 December 2019
Classification Name	Continuous Flush Catheter			
Regulation Number	21 CFR 870.1210			
FDA Classification	2			
Product Code	KRA – Continuous Flush Catheter			
Classification Panel	Cardiovascular			
Prescriptive Details	For the most current material and IFU, please visit www.thrombolex.com			

REGULATORY INFORMATION

THROMBOLEX
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ Endovascular Catheter
Bashir™ N-X Endovascular Catheter

FDA U.S. FOOD & DRUG ADMINISTRATION

February 25, 2019

Thrombolex, Inc.
% Diane Horwitz
Regulatory Consultant
Eminence Clinical Research Inc.
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K183290
Trade/Device Name: Bashir Endovascular Catheter Model 7201, Bashir N-X Endovascular Catheter Model 7200
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 31, 2019
Received: January 31, 2019

Dear Ms. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Bashir™ Endovascular Catheter
Bashir™ N-X Endovascular Catheter

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell 2019.02.25 16:29:55 -05'00'

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

REGULATORY INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ Endovascular Catheter
Bashir™ N-X Endovascular Catheter

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183290

Device Name
Bashir™ Endovascular Catheter Model 7201
Bashir™ N-X Endovascular Catheter Model 7200

Indications for Use *(Describe)*
Bashir™ Endovascular Catheter:

The Bashir™ Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Bashir™ N-X Endovascular Catheter:

The Bashir™ N-X Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

REGULATORY INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ Endovascular Catheter
Bashir™ Plus +10, +20, +30, +40 Endovascular Catheter

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number: *K211061*

Device Name
BASHIR™ Endovascular Catheter and BASHIR™ Plus Endovascular Catheters (BASHIR™+10, BASHIR™+20, BASHIR™+30, BASHIR™+40)

Indications for Use *(Describe)*
The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheters (BASHIR™+10, BASHIR™+20, BASHIR™+30, BASHIR™+40) are intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Food and Drug Administration
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FORM FDA 3881 (5/20) Page 1 of 1

REGULATORY INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ S-B Endovascular Catheter

U.S. FOOD & DRUG ADMINISTRATION

October 18, 2019

Thrombolex, Inc.
% Diane Horwitz, PhD
Regulatory Consultant
Eminence Clinical Research, Inc.
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K192598
Trade/Device Name: Bashir™ S-B Endovascular Catheter, Ref. No. 7101
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: September 19, 2019
Received: September 20, 2019

Dear Dr. Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Bashir™ S-B Endovascular Catheter

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Eleni Whatley
Digitally signed by Eleni Whatley
Date: 2019.10.18 09:39:55 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

REGULATORY INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ S-B Endovascular Catheter

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192598

Device Name
Bashir™ S-B Endovascular Catheter, Ref. No. 7101

Indications for Use *(Describe)*
The Bashir™ S-B Endovascular Catheter is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

REGULATORY INFORMATION

THROMBOLEX
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ Plus Endovascular Catheter

FDA U.S. FOOD & DRUG ADMINISTRATION

December 17, 2019

Thrombolex, Inc.
% Diane Horwitz
Regulatory
Eminence Clinical Research Inc.
5 Lake Como Ct.
Greenville, South Carolina 29609

Re: K193071
Trade/Device Name: Bashir Plus Endovascular Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: November 1, 2019
Received: November 4, 2019

Dear Diane Horwitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Bashir™ Plus Endovascular Catheter

2K193071 - Diane Horwitz Page

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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Sincerely,

Gregory W. O'connell -S Digitally signed by Gregory W. O'connell -S Date: 2019.12.17 15:11:09 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

REGULATORY INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Bashir™ Plus Endovascular Catheter

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193071

Device Name
Bashir™ Plus Endovascular Catheter

Indications for Use *(Describe)*
The Bashir™ Plus Endovascular Catheters are intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

CODING INFORMATION

THROMBOLEX
INNOVATIVE ENDOVASCULAR CATHETERS

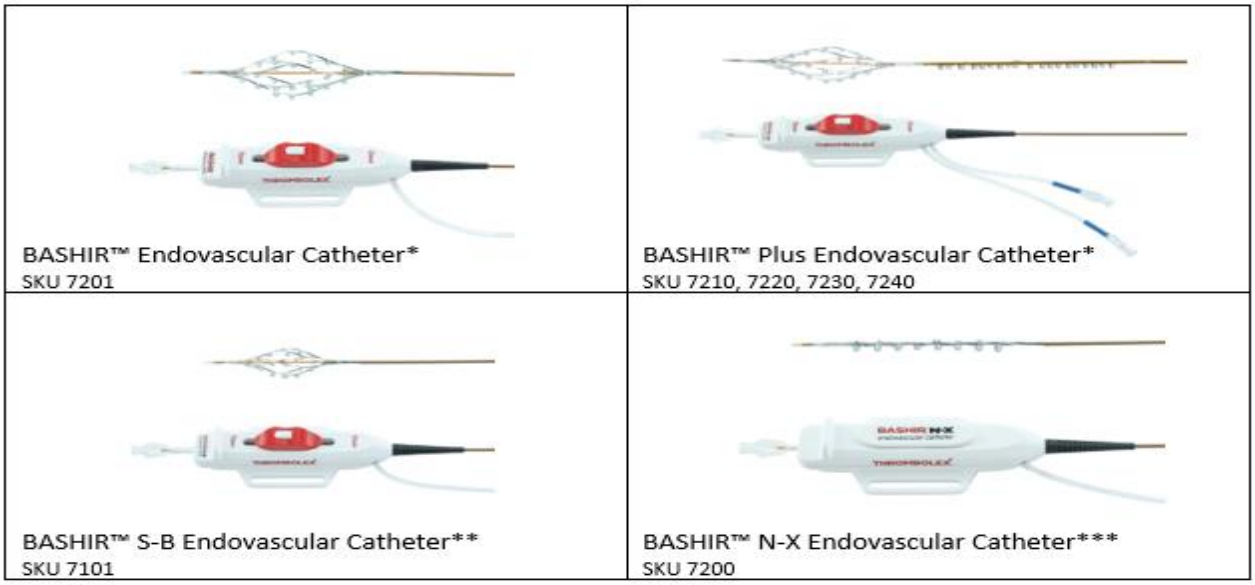
FY 2022 CODING INFORMATION (In effect Oct.1, 2021 thru Sept. 30, 2022)

Thrombolex has received multiple clearances from the FDA for these products:

* **The BASHIR™ Endovascular Catheter and the BASHIR™ Plus Endovascular Catheter** is (are) intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus.

****The BASHIR™ S-B Endovascular Catheter** is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

*****The BASHIR™ N-X Endovascular Catheter** is intended for the controlled and selective infusion of physician-specified fluids into the peripheral and pulmonary artery vasculature.



ICD-10 Diagnosis Code	Description
Pulmonary Vessels	
I26.0	Pulmonary embolism with acute cor pulmonale
I26.9	Pulmonary embolism without acute cor pulmonale
Thoracic Veins	
I82.29	Embolism and thrombosis of other thoracic veins
Peripheral Veins	
I82.4	Acute embolism and thrombosis of deep veins of lower extremity
Peripheral and Other Arteries	
I74.2	Embolism and thrombosis of arteries of the upper extremities
I74.3	Embolism and thrombosis of arteries of the lower extremities
I74.4	Embolism and thrombosis of arteries of extremities, unspecified
I74.5	Embolism and thrombosis of iliac artery
I74.8	Embolism and thrombosis of other arteries
I74.9	Embolism and thrombosis of unspecified artery

CODING INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

CPT Code	Description
37211	Transcatheter therapy, arterial infusion for thrombolysis other than coronary or intracranial, any method, including radiological supervision and interpretation, initial treatment day
37212	Transcatheter therapy, venous infusion for thrombolysis, any method, including radiological supervision and interpretation, initial treatment day

ICD-10 Procedure Code	Description	DRG Assignments
Pulmonary Vessels		
02FP3ZZ	Fragmentation of Pulmonary Trunk, Percutaneous Approach	166, 167, 168
02FQ3ZZ	Fragmentation of Right Pulmonary Artery, Percutaneous Approach	166, 167, 168
02FR3ZZ	Fragmentation of Left Pulmonary Artery, Percutaneous Approach	166, 167, 168
02FS3ZZ	Fragmentation of Right Pulmonary Vein, Percutaneous Approach	166, 167, 168
02FT3ZZ	Fragmentation of Left Pulmonary Vein, Percutaneous Approach	166, 167, 168
Upper Arteries		
03F23ZZ	Fragmentation of Innominate Artery, Percutaneous Approach	166, 167, 168
03F33ZZ	Fragmentation of Right Subclavian Artery, Percutaneous Approach	252, 253, 254
03F43ZZ	Fragmentation of Left Subclavian Artery, Percutaneous Approach	252, 253, 254
03F53ZZ	Fragmentation of Right Axillary Artery, Percutaneous Approach	252, 253, 254
03F63ZZ	Fragmentation of Left Axillary Artery, Percutaneous Approach	252, 253, 254
03F73ZZ	Fragmentation of Right Brachial Artery, Percutaneous Approach	252, 253, 254
03F83ZZ	Fragmentation of Left Brachial Artery, Percutaneous Approach	252, 253, 254
03F93ZZ	Fragmentation of Right Ulnar Artery, Percutaneous Approach	252, 253, 254
03FA3ZZ	Fragmentation of Left Ulnar Artery, Percutaneous Approach	252, 253, 254
03FB3ZZ	Fragmentation of Right Radial Artery, Percutaneous Approach	252, 253, 254
03FC3ZZ	Fragmentation of Left Radial Artery, Percutaneous Approach	252, 253, 254
03FY3ZZ	Fragmentation of Upper Artery, Percutaneous Approach	252, 253, 254
Lower Arteries		
04FC3ZZ	Fragmentation of Right Common Iliac Artery, Percutaneous Approach	252, 253, 254
04FD3ZZ	Fragmentation of Left Common Iliac Artery, Percutaneous Approach	252, 253, 254
04FE3ZZ	Fragmentation of Right Internal Iliac Artery, Percutaneous Approach	252, 253, 254
04FF3ZZ	Fragmentation of Left Internal Iliac Artery, Percutaneous Approach	252, 253, 254
04FH3ZZ	Fragmentation of Right External Iliac Artery, Percutaneous Approach	252, 253, 254
04FJ3ZZ	Fragmentation of Left External Iliac Artery, Percutaneous Approach	252, 253, 254
04FK3ZZ	Fragmentation of Right Femoral Artery, Percutaneous Approach	252, 253, 254
04FL3ZZ	Fragmentation of Left Femoral Artery, Percutaneous Approach	252, 253, 254

CODING INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

04FM3ZZ	Fragmentation of Right Popliteal Artery, Percutaneous Approach	252, 253, 254
04FN3ZZ	Fragmentation of Left Popliteal Artery, Percutaneous Approach	252, 253, 254
04FP3ZZ	Fragmentation of Right Anterior Tibial Artery, Percutaneous Approach	252, 253, 254
04FQ3ZZ	Fragmentation of Left Anterior Tibial Artery, Percutaneous Approach	252, 253, 254
04FR3ZZ	Fragmentation of Right Posterior Tibial Artery, Percutaneous Approach	252, 253, 254
04FS3ZZ	Fragmentation of Left Posterior Tibial Artery, Percutaneous Approach	252, 253, 254
04FT3ZZ	Fragmentation of Right Peroneal Artery, Percutaneous Approach	252, 253, 254
04FU3ZZ	Fragmentation of Left Peroneal Artery, Percutaneous Approach	252, 253, 254
04FY3ZZ	Fragmentation of Lower Artery, Percutaneous Approach	252, 253, 254
Upper Veins		
05F33ZZ	Fragmentation of Right Innominate Vein, Percutaneous Approach	252, 253, 254
05F43ZZ	Fragmentation of Left Innominate Vein, Percutaneous Approach	252, 253, 254
05F53ZZ	Fragmentation of Right Subclavian Vein, Percutaneous Approach	252, 253, 254
05F63ZZ	Fragmentation of Left Subclavian Vein, Percutaneous Approach	252, 253, 254
05F73ZZ	Fragmentation of Right Axillary Vein, Percutaneous Approach	252, 253, 254
05F83ZZ	Fragmentation of Left Axillary Vein, Percutaneous Approach	252, 253, 254
05F93ZZ	Fragmentation of Right Brachial Vein, Percutaneous Approach	252, 253, 254
05FA3ZZ	Fragmentation of Left Brachial Vein, Percutaneous Approach	252, 253, 254
05FB3ZZ	Fragmentation of Right Basilic Vein, Percutaneous Approach	252, 253, 254
05FC3ZZ	Fragmentation of Left Basilic Vein, Percutaneous Approach	252, 253, 254
05FD3ZZ	Fragmentation of Right Cephalic Vein, Percutaneous Approach	252, 253, 254
05FF3ZZ	Fragmentation of Left Cephalic Vein, Percutaneous Approach	252, 253, 254
05FY3ZZ	Fragmentation of Upper Vein, Percutaneous Approach	252, 253, 254
Lower Veins		
06FC3ZZ	Fragmentation of Right Common Iliac Vein, Percutaneous Approach	252, 253, 254
06FD3ZZ	Fragmentation of Left Common Iliac Vein, Percutaneous Approach	252, 253, 254
06FF3ZZ	Fragmentation of Right External Iliac Vein, Percutaneous Approach	252, 253, 254
06FG3ZZ	Fragmentation of Left External Iliac Vein, Percutaneous Approach	252, 253, 254
06FH3ZZ	Fragmentation of Right Hypogastric Vein, Percutaneous Approach	252, 253, 254
06FJ3ZZ	Fragmentation of Left Hypogastric Vein, Percutaneous Approach	252, 253, 254
06FM3ZZ	Fragmentation of Right Femoral Vein, Percutaneous Approach	252, 253, 254
06FN3ZZ	Fragmentation of Left Femoral Vein, Percutaneous Approach	252, 253, 254
06FP3ZZ	Fragmentation of Right Saphenous Vein, Percutaneous Approach	252, 253, 254
06FQ3ZZ	Fragmentation of Left Saphenous Vein, Percutaneous Approach	252, 253, 254
06FY3ZZ	Fragmentation of Lower Vein, Percutaneous Approach	252, 253, 254

CODING INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

DRG	Description
166	OTHER RESP SYSTEM O.R. PROCEDURES W MCC
167	OTHER RESP SYSTEM O.R. PROCEDURES W CC
168	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC/MCC
252	OTHER VASCULAR PROCEDURES W MCC
253	OTHER VASCULAR PROCEDURES W CC
254	OTHER VASCULAR PROCEDURES W/O CC/MCC

The above listing of codes is not exhaustive. There may be other codes for endovascular catheter procedures. There are codes for thrombolysis procedures. CMS defines **"FRAGMENTATION"** as "Breaking solid matter in a body part into pieces. The pieces of solid matter are not taken out."

DISCLAIMER: The materials contained in this document are presented for general informational purposes only, are only effective from October 1, 2021 thru September 30, 2022, and have been gathered from third-party sources, and are subject to change without notice. Nothing in this document is intended to represent, constitute, or may be construed as legal, coding, business, financial, clinical, or consultative advice, recommendation, or instruction. Thrombolex expressly and explicitly disclaims any accuracy, reliability, or completeness and does not promise or guarantee any coverage or reimbursement by any health insurance plan. **The ultimate responsibility for documentation and coding always remains with the healthcare provider.** Healthcare providers should consult their own advisors. Refer to these official sources for further information:

1. ICD-10 diagnosis codes are maintained by the World Health Organization.
2. CPT-4 codes are maintained and copyrighted by the American Medical Association.
3. ICD-10-PCS and DRG codes are maintained by the Centers for Medicare & Medicaid Services of the U.S. Department of Health & Human Services ("CMS").

For prescribing and safety information please see https://www.thrombolex.com.

Thrombolex, Inc.
October 1, 2021

IRS FORM W-9

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

► Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give Form to the requester. Do not send to the IRS.

Print or type. See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

Thrombolex, Inc.

2 Business name/disregarded entity name, if different from above

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☑ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☐ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ► _____

Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is **not** disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ►

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) _____

Exemption from FATCA reporting code (if any) _____

(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.) See instructions.

4416 Route 27, Suite A, PO Box 64

Requester's name and address (optional)

6 City, state, and ZIP code

Kingston, NJ 08528

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your *TIN* in the appropriate box. The *TIN* provided must match the name given on *line 1* to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–			–				

or

Employer identification number

8	1	–	2	8	3	7	9	1	0

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here Signature of U.S. person ► [signature] Date ► 2/14/2020

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

Purpose of Form

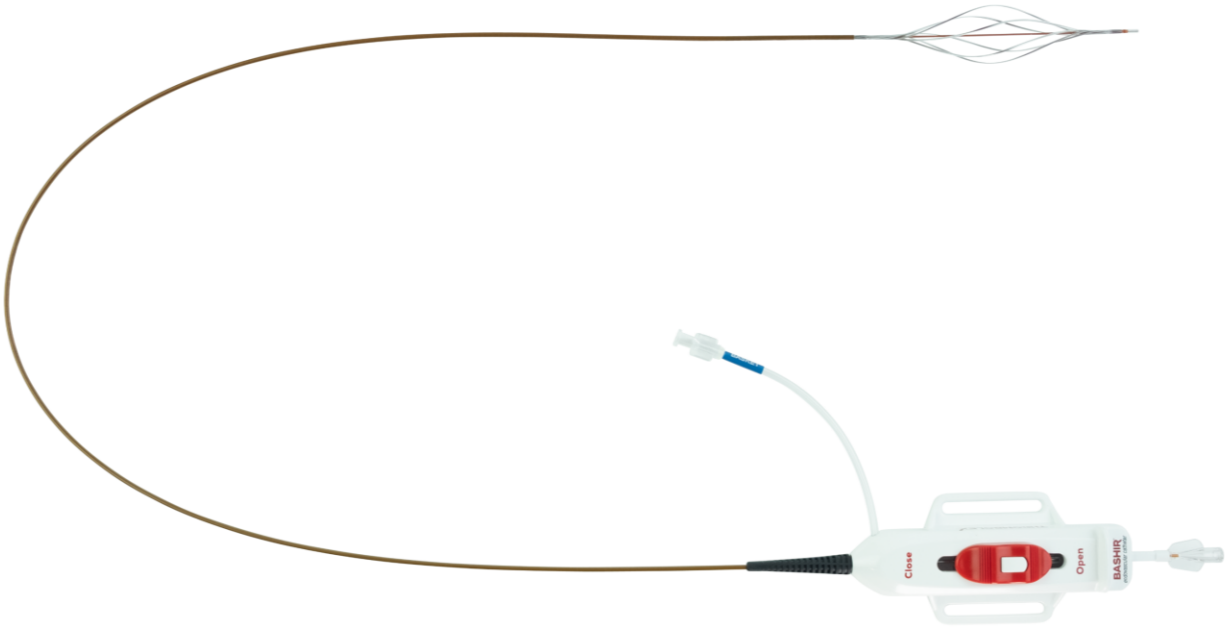
An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, *later.*

Cat. No. 10231X Form **W-9** (Rev. 10-2018)



THROMBOLEX™

INNOVATIVE ENDOVASCULAR CATHETERS

To order or for more information,
contact customer service at 1.844.792.6300
or fax your order to 267.224.4436

75 Britain Drive, New Britain, PA 18901
www.thrombolex.com