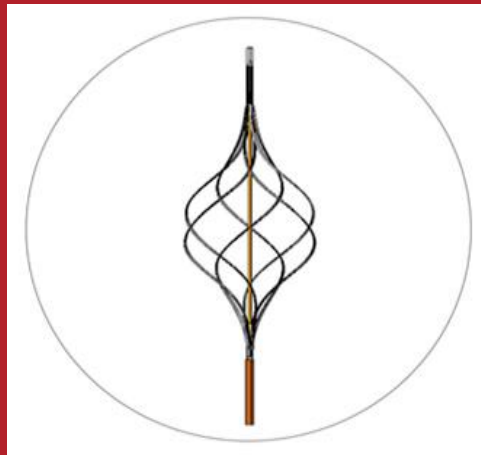


THROMBOLEX™

INNOVATIVE ENDOVASCULAR CATHETERS

Thrombolex provides an innovative line of Endovascular Catheters featuring an expandable infusion basket that allows infusion of physician-specified fluids for the treatment of acute Pulmonary Embolism (PE), as well as Arterial and Venous Thromboembolic (A&VTE) conditions

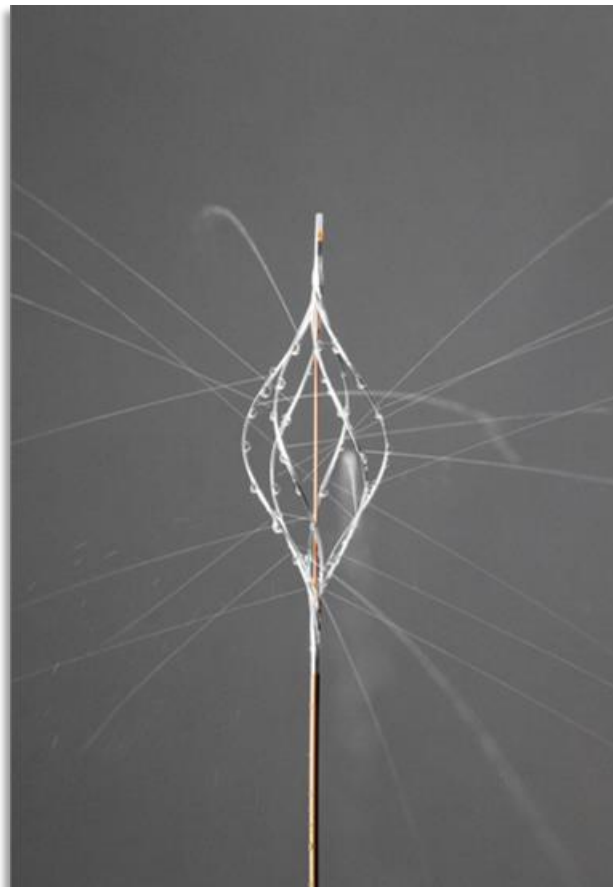


Value Analysis Packet

Thrombolex is committed to providing safe, effective, high quality medical devices that meet physician requirements to care for their patients. We ensure our devices are designed, manufactured, tested and distributed under effective quality systems that meet all regulatory requirements.

TABLE OF CONTENTS

PRODUCT OVERVIEW.....	3
TECHNOLOGY OVERVIEW.....	4
MECHANISM OF ACTION.....	5
PRODUCT SPECIFICATIONS.....	6-8
PRODUCT CATALOG.....	9
REGULATORY INFORMATION.....	10-19
REIMBURSEMENT AND CODING.....	20
FORM W-9.....	24





BASHIR™ *endovascular catheter*



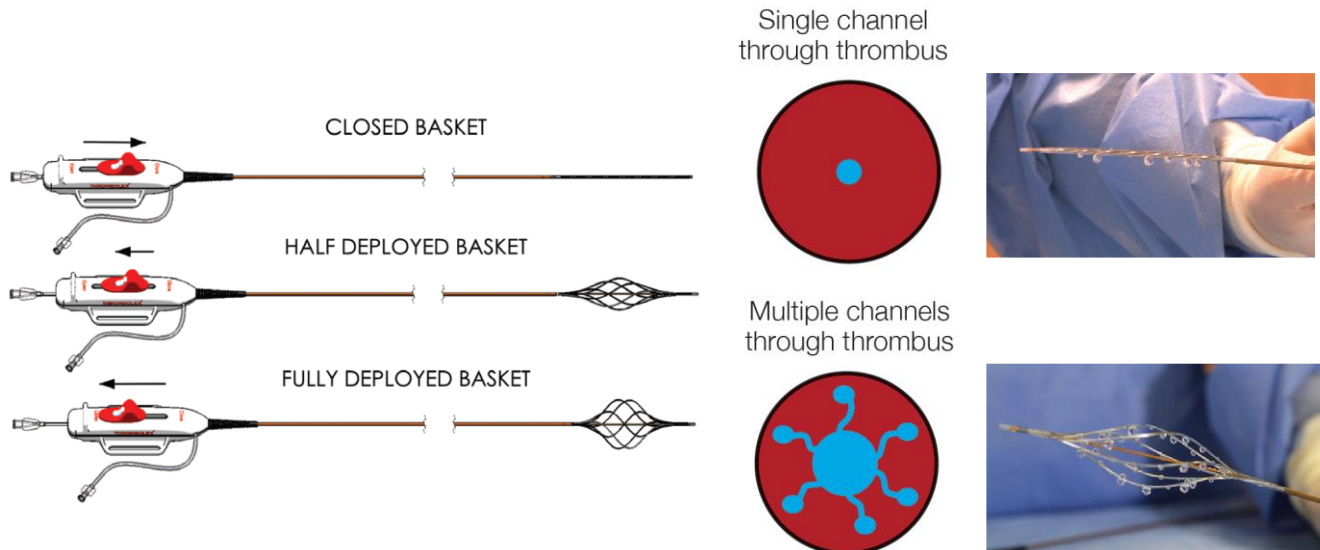
THE PROBLEM

Venous Thromboembolic disease (VTE) is an under-recognized and under-treated condition. VTE includes deep vein thrombosis (DVT) and Pulmonary Embolism (PE). PE is the third leading cause of cardiovascular-related mortality.

OUR SOLUTION

The BASHIR™ and BASHIR™ S-B Endovascular Catheters are designed to enable physicians to effectively treat Pulmonary Embolism (PE) as well as Arterial and Venous Thromboembolic disease (A&VTE) to restore blood flow. For patients with long lesions in peripheral vessels, the BASHIR™ Plus Family of Endovascular Catheters deliver targeted thrombolytics through the expandable infusion basket as well as the distal shaft to achieve optimal clinical results.

The BASHIR™ Family of Endovascular Catheters uses pharmacomechanical lysis (PML) therapy to optimize the resolution of Pulmonary Embolism as well as arterial and venous thrombus. Targeted thrombolytics are delivered through the expandable infusion basket enabling the immediate restoration of blood flow. This allows for the synergistic effect of both endogenous and exogenous thrombolytics to accelerate thrombus lysis more efficiently and safely



MODE OF ACTION

Mechanical expansion of the 6 mini-infusion catheters, each with 8 laser-drilled infusion holes, create fissures and fragments the thrombus. This mechanism of action also increases the surface area where targeted thrombolytics are delivered within the thrombus. The synergistic effect of endogenous and exogenous lytics results in maximum reperfusion.

SAFETY

The BASHIR™ Family of Endovascular Catheters are clinically proven to be safe and effective in treating patients with VTE. The Catheters are low in profile and the mechanism of action reduces the risk of bleeding due to the optimized delivery of thrombolytics for thrombus resolution.

EASE OF USE

The BASHIR™ Family of Endovascular Catheters are easy to use and do not require capital equipment, providing a more cost-effective and efficient therapy when treating VTE patients.

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)

Key insights

Significant reduction in obstruction in each named segmental pulmonary artery. This reduction in pulmonary arteries was based on an independent core lab data analysis of 107 patients from 18 sites in the US with acute intermediate-risk pulmonary embolism.

Clinical Results from NIH-Funded IDE RESCUE Trialⁱⁱ

- PM-CDT therapy using the BASHIR™ Endovascular Catheter to administer r-tPA in small doses (7mg for unilateral and 14 mg for bilateral PE over 5 hours) resulted in a 71.1% (40.5% to 11.7%; $P < 0.0001$) reduction in the number of segmental PA branches with total or subtotal occlusions at 48 hours
- Proximal PA branch total or subtotal occlusions decreased by 61.3% (28.7% to 11.0%; $P < 0.0001$) and the reduction in segmental artery occlusions correlated significantly with the reduction in right ventricular/left ventricular (RV/LV) ratio ($P = 0.0026$)
- Rapid resolution of obstruction in the main and segmental arteries, with a less than 1% major bleeding rate

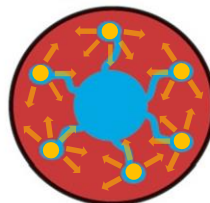
Thrombolytic delivery via the expanded mini-infusion catheters

Rapid flow restoration

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

Multichannel infusion

Cleared by expansion of the 6 mini-infusion catheters into the thrombus.



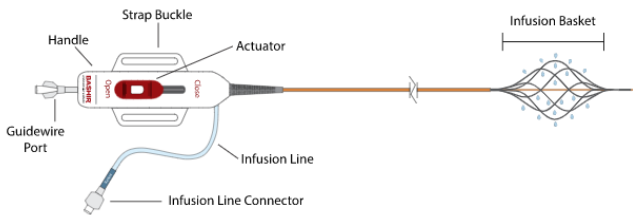
INCREASE

Luminal filling and blood velocity, surface area and lytic penetration

PROMOTE

Endogenous and exogenous thrombolysis Endogenous thrombolysis^{i,ii}

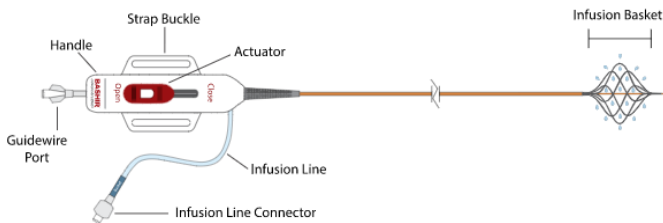
BASHIR™.035 *endovascular catheter*



KEY DIMENSIONS – Product Code 8201

French Size	8 F (2.67 mm)
Effective Length	92.5 cm (36.44 in)
Infusion Basket Length	12.50 cm (4.94 in)
Infusion Basket Diameter	45 mm max.

BASHIR™S-B.035 *endovascular catheter*



KEY DIMENSIONS – Product Code 8101

French Size	8 F (2.67 mm)
Effective Length	92.5 cm (36.44 in)
Infusion Basket Length	10.00 cm (3.94 in)
Infusion Basket Diameter	39 mm max.

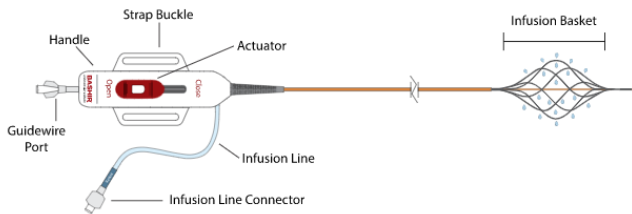
CHARACTERISTICS

Basket Expansion	Controlled by the physician via the actuator (Range: Closed 2.3mm to 39mm or 45mm max.)
Thrombolytic Infusion	6 mini-infusion catheters with 48 precision laser-drilled holes
Guidewire Compatibility	0.035"
Sterilization	Ethylene oxide gas
Use	Single use
Shelf Life	3 years
Unit of Measure*	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

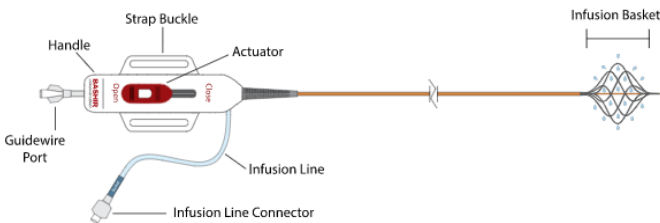
BASHIR™ *endovascular catheter*



KEY DIMENSIONS – Product Code 7201

French Size	7 F (2.3 mm)
Effective Length	92.5 cm (36.44 in)
Infusion Basket Length	12.50 cm (4.94 in)
Infusion Basket Diameter	45 mm max.

BASHIR™ S-B *endovascular catheter*



KEY DIMENSIONS – Product Code 7101

French Size	7 F (2.3 mm)
Effective Length	92.5 cm (36.44 in)
Infusion Basket Length	10.00 cm (3.94 in)
Infusion Basket Diameter	39 mm max.

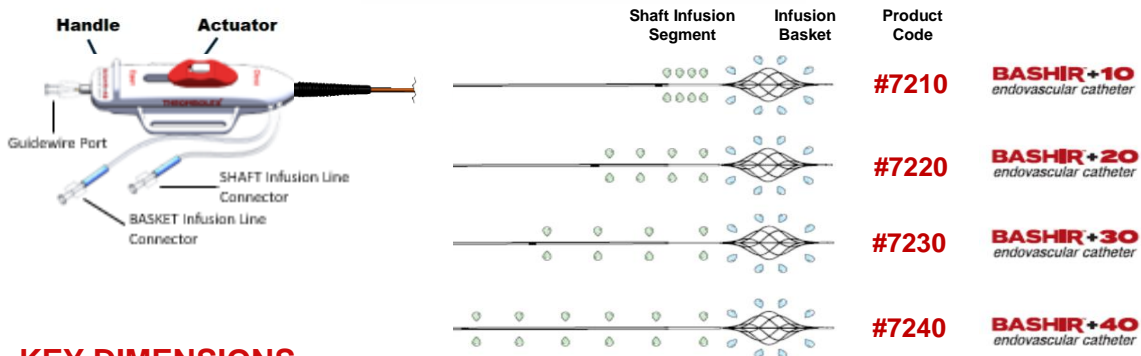
CHARACTERISTICS

Basket Expansion	Controlled by the physician via the actuator (Range: Closed 2.3mm to 39mm or 45mm max.)
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	3 years
Unit of Measure*	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

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 the physician via the actuator (Range: Closed 2.3mm to 45mm max.)
Thrombolytic Infusion	6 mini-infusion catheters with 48 precision laser-drilled holes in the infusion basket, and additionally along the shaft: <ul style="list-style-type: none"> • 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	3 years
Unit of Measure*	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

Size	Product Item #	Device Name	Description
8 F (0.035" guidewire)	8101	BASHIR™ S-B .035 Endovascular Catheter Short Basket	10cm Expandable Infusion Basket
	8201	BASHIR™ .035 Endovascular Catheter	12.5cm Expandable Infusion Basket
7 F (0.018" guidewire)	7101	BASHIR™ S-B Endovascular Catheter Short Basket	10cm Expandable Infusion Basket
	7201	BASHIR™ Endovascular Catheter	12.5cm Expandable Infusion Basket
	7210	BASHIR™ +10 Endovascular Catheter	12.5cm Expandable Infusion Basket & 10cm shaft infusion
	7220	BASHIR™ +20 Endovascular Catheter	12.5cm Expandable Infusion Basket & 20cm shaft infusion
	7230	BASHIR™ +30 Endovascular Catheter	12.5cm Expandable Infusion Basket & 30cm shaft infusion
	7240	BASHIR™ +40 Endovascular Catheter	12.5cm Expandable Infusion Basket & 40cm shaft infusion

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

REGULATORY INFORMATION

THROMBOLEX™
INNOVATIVE ENDOVASCULAR CATHETERS

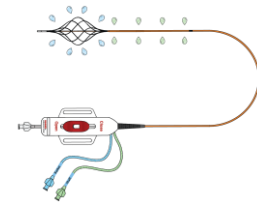
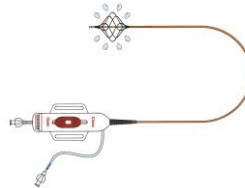
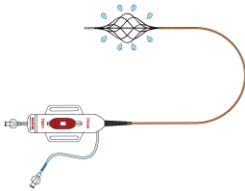
BASHIR™
endovascular catheter

BASHIR™ S-B
endovascular catheter

BASHIR™+
endovascular catheter

BASHIR™.035
endovascular catheter

BASHIR™ S-B.035
endovascular catheter



Intended Use	<p>The BASHIR™ Endovascular Catheter and BASHIR™ S-B Endovascular Catheter and the BASHIR™ .035 Endovascular Catheter and BASHIR™ S-B .035 Endovascular Catheter are mechanical thrombolysis catheters indicated for the:</p> <ul style="list-style-type: none"> Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism. Infusion of physician-specified fluids, including thrombolytics, into the peripheral* vasculature, enabling the restoration of blood flow in patients with venous thrombus 			<p>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</p>
Trade/Device Name	BASHIR™ Endovascular Catheter, Model 7201	BASHIR™ S-B Endovascular Catheter, Model 7101	BASHIR™ .035 Endovascular Catheter , Model 8201 BASHIR™ S-B .035 Endovascular Catheter, Model 8101	BASHIR™ Plus Endovascular Catheter, Model 7210, 7220, 7230, and 7240
510(k) Number	K222095 K211061 K183290	K222095 K192598	K231653	K211061 K193071
Clearance Date	20 April 2023 10 June 2021 25 February 2019	20 April 2023 17 October 2019	03 July 2023	10 June 2021 17 December 2019
Classification Name	Mechanical Thrombolysis Catheter			
Regulation Number	21 CFR 870.5150			
FDA Classification	2			
Product Code	QEY – Mechanical Thrombolysis Catheter; KRA - Continuous Flush Catheter			
Classification Panel	Cardiovascular			
Prescriptive Details	For the most current material and IFU, please visit www.thrombolex.com			

*Veins and Arteries

BASHIR™ Endovascular Catheter BASHIR™ S-B Endovascular Catheter



April 20, 2023

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

Re: K222095

Trade/Device Name: BASHIR™ Endovascular Catheter, Ref. No. 7201
BASHIR™ S-B Endovascular Catheter, Ref. No. 7101

Regulation Number: 21 CFR 870.5150

Regulation Name: Embolectomy catheter

Regulatory Class: Class II

Product Code: QEY, KRA

Dated: March 17, 2023

Received: March 17, 2023

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

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

BASHIR™ Endovascular Catheter **BASHIR™ S-B Endovascular Catheter**

K222095 - Diane Horwitz

Page 2

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,

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

BASHIR™ Endovascular Catheter 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: 06/30/2023 See PRA Statement below.	
510(k) Number (if known) K222095		
Device Name BASHIR™ Endovascular Catheter, Ref. No. 7201 BASHIR™ S-B Endovascular Catheter, Ref. No. 7101		
Indications for Use (Describe) The BASHIR™ Endovascular Catheter and BASHIR™ S-B Endovascular Catheter are mechanical thrombolysis catheters indicated for the: <ul style="list-style-type: none"> • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism. • 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) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> 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 (6/20)	Page 1 of 1	PBC Publishing Services (301) 443-4740 EF

BASHIR™ .035 Endovascular Catheter

BASHIR™ S-B .035 Endovascular Catheter



July 3, 2023

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

Re: K231653

Trade/Device Name: BASHIR™ .035 Endovascular Catheter, BASHIR™ S-B .035 Endovascular Catheter

Regulation Number: 21 CFR 870.5150

Regulation Name: Embolectomy Catheter

Regulatory Class: Class II

Product Code: QEY, KRA

Dated: June 5, 2023

Received: June 6, 2023

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

BASHIR™ .035 Endovascular Catheter **BASHIR™ S-B .035 Endovascular Catheter**

K231653 - Diane Horwitz

Page 2

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,

Gregory W.
O'Connell - S

Digitally signed by
Gregory W. O'Connell -
S
Date: 2023.07.03
11:20:26 -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

BASHIR™ .035 Endovascular Catheter BASHIR™ S-B .035 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.
<hr/> 510(k) Number (if known) K231653	
<hr/> Device Name BASHIR™ .035 Endovascular Catheter BASHIR™ S-B .035 Endovascular Catheter	
<hr/> Indications for Use (Describe) The BASHIR™ .035 Endovascular Catheter and BASHIR™ S-B .035 Endovascular Catheter are mechanical thrombolysis catheters indicated for the: <ul style="list-style-type: none"> • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism. • Infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus. 	
<hr/> Type of Use (Select one or both, as applicable)	
<input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
<hr/> CONTINUE ON A SEPARATE PAGE IF NEEDED. <hr/>	
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 (6/20)	Page 1 of 1
PSC Publishing Services (301) 443-6740 EF	

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



June 10, 2021

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

Re: K211061

Trade/Device Name: BASHIR Endovascular Catheter (Ref. 7201), BASHIR Plus 10 Endovascular Catheter (Ref. 7210), BASHIR Plus 20 Endovascular Catheter (Ref. 7220), BASHIR Plus 30 Endovascular Catheter (Ref. 7230), BASHIR Plus 40 Endovascular Catheter (Ref. 7240)

Regulation Number: 21 CFR 870.1210

Regulation Name: Continuous flush catheter

Regulatory Class: Class II

Product Code: KRA

Dated: April 8, 2021

Received: April 9, 2021

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](#).

BASHIR™ Endovascular Catheter **BASHIR™ Plus +10, +20, +30, +40 Endovascular Catheter**

K211061 - Diane Horwitz

Page 2

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/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,

Gregory W. O'Connell -S

Digitally signed by
Gregory W. O'Connell -S
Date: 2021.06.10
12:43:23 -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



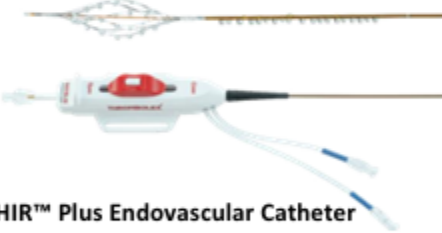
Enclosure

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) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> 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 (6/20)	Page 1 of 1

FY 2025 CODING INFORMATION (In effect Oct. 1, 2024 through Sept. 30, 2025)

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

<p>The BASHIR™ Endovascular Catheter and BASHIR™ S-B Endovascular Catheter and the BASHIR™ .035 Endovascular Catheter and BASHIR™ S-B .035 Endovascular Catheter are mechanical thrombolysis catheters indicated for the:</p> <ul style="list-style-type: none"> Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for treatment of pulmonary embolism. Infusion of physician-specified fluids, including thrombolytics, into the peripheral* vasculature, enabling the restoration of blood flow in patients with venous thrombus <p>*Arteries and veins</p>	 <p>BASHIR™ Endovascular Catheter SKU 7201 BASHIR™ .035 Endovascular Catheter SKU 8201</p>
<p>The BASHIR™ Plus Endovascular Catheters 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</p> <p>*Arteries and veins</p>	 <p>BASHIR™ S-B Endovascular Catheter SKU 7101 BASHIR™ S-B .035 Endovascular Catheter SKU 8101</p>  <p>BASHIR™ Plus Endovascular Catheter SKU 7210, 7220, 7230, 7240</p>

ICD-10 Diagnosis Code	Description
Pulmonary Vessels	
I 26.02	Saddle embolus pulmonary artery with acute cor pulmonale
I 26.09	Other pulmonary embolism with acute cor pulmonale
I 26.92	Saddle embolus pulmonary artery without acute cor pulmonale
I 26.99	Pulmonary embolism without acute cor pulmonale
Thoracic Veins	
I 82.290	Acute embolism and thrombosis of other thoracic veins
Peripheral Veins	

I 82.401	Acute embolism and thrombosis of unspecified deep veins of right lower extremity
I 82.402	Acute embolism and thrombosis of unspecified deep veins of left lower extremity
I 82.403	Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I 82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
Peripheral and Other Arteries	
I 74.2	Embolism and thrombosis of arteries of the upper extremities
I 74.3	Embolism and thrombosis of arteries of the lower extremities
I 74.4	Embolism and thrombosis of arteries of extremities, unspecified
I 74.5	Embolism and thrombosis of iliac artery
I 74.8	Embolism and thrombosis of other arteries
I 74.9	Embolism and thrombosis of unspecified artery
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	MS-DRG Assignments
Pulmonary Vessels		
02FP3ZZ	Fragmentation of Pulmonary Trunk, Percutaneous Approach	173
02FQ3ZZ	Fragmentation of Right Pulmonary Artery, Percutaneous Approach	173
02FR3ZZ	Fragmentation of Left Pulmonary Artery, Percutaneous Approach	173
02FS3ZZ	Fragmentation of Right Pulmonary Vein, Percutaneous Approach	173
02FT3ZZ	Fragmentation of Left Pulmonary Vein, Percutaneous Approach	173
Upper Arteries		
03F23ZZ	Fragmentation of Innominate Artery, Percutaneous Approach	278, 279
03F33ZZ	Fragmentation of Right Subclavian Artery, Percutaneous Approach	278, 279
03F43ZZ	Fragmentation of Left Subclavian Artery, Percutaneous Approach	278, 279
03F53ZZ	Fragmentation of Right Axillary Artery, Percutaneous Approach	278, 279
03F63ZZ	Fragmentation of Left Axillary Artery, Percutaneous Approach	278, 279
03F73ZZ	Fragmentation of Right Brachial Artery, Percutaneous Approach	278, 279
03F83ZZ	Fragmentation of Left Brachial Artery, Percutaneous Approach	278, 279
03F93ZZ	Fragmentation of Right Ulnar Artery, Percutaneous Approach	278, 279
03FA3ZZ	Fragmentation of Left Ulnar Artery, Percutaneous Approach	278, 279
03FB3ZZ	Fragmentation of Right Radial Artery, Percutaneous Approach	278, 279
03FC3ZZ	Fragmentation of Left Radial Artery, Percutaneous Approach	278, 279

CODING INFORMATION

03FY3ZZ	Fragmentation of Upper Artery, Percutaneous Approach	278, 279
Lower Arteries		
04FC3ZZ	Fragmentation of Right Common Iliac Artery, Percutaneous Approach	278, 279
04FD3ZZ	Fragmentation of Left Common Iliac Artery, Percutaneous Approach	278, 279
04FE3ZZ	Fragmentation of Right Internal Iliac Artery, Percutaneous Approach	278, 279
04FF3ZZ	Fragmentation of Left Internal Iliac Artery, Percutaneous Approach	278, 279
04FH3ZZ	Fragmentation of Right External Iliac Artery, Percutaneous Approach	278, 279
04FJ3ZZ	Fragmentation of Left External Iliac Artery, Percutaneous Approach	278, 279
04FK3ZZ	Fragmentation of Right Femoral Artery, Percutaneous Approach	278, 279
04FL3ZZ	Fragmentation of Left Femoral Artery, Percutaneous Approach	278, 279
04FM3ZZ	Fragmentation of Right Popliteal Artery, Percutaneous Approach	278, 279
04FN3ZZ	Fragmentation of Left Popliteal Artery, Percutaneous Approach	278, 279
04FP3ZZ	Fragmentation of Right Anterior Tibial Artery, Percutaneous Approach	278, 279
04FQ3ZZ	Fragmentation of Left Anterior Tibial Artery, Percutaneous Approach	278, 279
04FR3ZZ	Fragmentation of Right Posterior Tibial Artery, Percutaneous Approach	278, 279
04FS3ZZ	Fragmentation of Left Posterior Tibial Artery, Percutaneous Approach	278, 279
04FT3ZZ	Fragmentation of Right Peroneal Artery, Percutaneous Approach	278, 279
04FU3ZZ	Fragmentation of Left Peroneal Artery, Percutaneous Approach	278, 279
04FY3ZZ	Fragmentation of Lower Artery, Percutaneous Approach	278, 279
Upper Veins		
05F33ZZ	Fragmentation of Right Innominate Vein, Percutaneous Approach	278, 279
05F43ZZ	Fragmentation of Left Innominate Vein, Percutaneous Approach	278, 279
05F53ZZ	Fragmentation of Right Subclavian Vein, Percutaneous Approach	278, 279
05F63ZZ	Fragmentation of Left Subclavian Vein, Percutaneous Approach	278, 279
05F73ZZ	Fragmentation of Right Axillary Vein, Percutaneous Approach	278, 279
05F83ZZ	Fragmentation of Left Axillary Vein, Percutaneous Approach	278, 279
05F93ZZ	Fragmentation of Right Brachial Vein, Percutaneous Approach	278, 279
05FA3ZZ	Fragmentation of Left Brachial Vein, Percutaneous Approach	278, 279
05FB3ZZ	Fragmentation of Right Basilic Vein, Percutaneous Approach	278, 279
05FC3ZZ	Fragmentation of Left Basilic Vein, Percutaneous Approach	278, 279
05FD3ZZ	Fragmentation of Right Cephalic Vein, Percutaneous Approach	278, 279
05FF3ZZ	Fragmentation of Left Cephalic Vein, Percutaneous Approach	278, 279
05FY3ZZ	Fragmentation of Upper Vein, Percutaneous Approach	278, 279
Lower Veins		
06FC3ZZ	Fragmentation of Right Common Iliac Vein, Percutaneous Approach	278, 279
06FD3ZZ	Fragmentation of Left Common Iliac Vein, Percutaneous Approach	278, 279
06FF3ZZ	Fragmentation of Right External Iliac Vein, Percutaneous Approach	278, 279
06FG3ZZ	Fragmentation of Left External Iliac Vein, Percutaneous Approach	278, 279
06FH3ZZ	Fragmentation of Right Hypogastric Vein, Percutaneous Approach	278, 279
06FJ3ZZ	Fragmentation of Left Hypogastric Vein, Percutaneous Approach	278, 279
06FM3ZZ	Fragmentation of Right Femoral Vein, Percutaneous Approach	278, 279
06FN3ZZ	Fragmentation of Left Femoral Vein, Percutaneous Approach	278, 279
06FP3ZZ	Fragmentation of Right Saphenous Vein, Percutaneous Approach	278, 279
06FQ3ZZ	Fragmentation of Left Saphenous Vein, Percutaneous Approach	278, 279
06FY3ZZ	Fragmentation of Lower Vein, Percutaneous Approach	278, 279

DRG	Description
173	Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism
278	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC
279	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures without 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."

NOTE: IT IS IMPERATIVE THAT THE APPROPRIATE ICD-10 DIAGNOSIS CODE + THE APPROPRIATE ICD-10 TREATMENT CODE FOR "FRAGMENTATION" ARE USED IN COMBINATION IN ORDER TO MAP TO THE DRGS 173, 278 AND 279, RESPECTIVELY. IF EITHER THE ICD-10 DIAGNOSIS CODES OR ICD-10 TREATMENT CODES ARE NOT ENTERED, MAPPING TO THESE DRGS WILL NOT OCCUR. MAPPING TO DRG 278 WILL ONLY OCCUR IF THERE IS ADDITIONAL CODING FOR MAJOR COMORBIDITIES OR COMPLICATIONS

**FY 2025 DRG REIMBURSEMENT FOR PE AND DVT
EFFECTIVE OCTOBER 1, 2024 TO SEPTEMBER 30, 2025**

DRG 173: FINAL MEDICARE BASE RATE	\$21,899
DRG 278: FINAL MEDICARE BASE RATE	\$35,706
DRG 279: FINAL MEDICARE BASE RATE	\$22,868

DISCLAIMER: The materials contained in this document are presented for general informational purposes only, are only effective from October 1, 2024 through September 30, 2025, 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 CM diagnosis codes are developed and maintained by the National Center for Health Statistics (NCHS) as authorized by the World Health Organization.
2. CPT-4 codes are maintained and copyrighted by the American Medical Association.
3. ICD-10-PCS Codes and MS-DRGs 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 2024.

Form **W-9**
(Rev. December 2014)
Department of the Treasury
Internal Revenue Service

**Request for Taxpayer
Identification Number and Certification**

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

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; 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. For a single-member LLC that is disregarded, do not check LLC; check the appropriate box in the line above for the tax classification of the single-member 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.)
75 Britain Drive

6 City, state, and ZIP code
New Britain, PA 18901

7 List account number(s) here (optional)

Requester's name and address (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 Part I instructions on page 3. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN* on page 3.

Note. If the account is in more than one name, see the instructions for line 1 and the chart on page 4 for guidelines on whose number to enter.

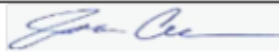
Social security number									
			-				-		
or									
Employer identification number									
8	1	-	2	8	3	7	9	1	0

Part II Certification

Under penalties of perjury, I certify that:

- 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
- 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
- I am a U.S. citizen or other U.S. person (defined below); and
- 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 on page 3.

Sign Here Signature of U.S. person ▶  Date ▶ May 2, 2023

General Instructions

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

Future developments. Information about developments affecting Form W-9 (such as legislation enacted after we release it) is at www.irs.gov/fw9.

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)

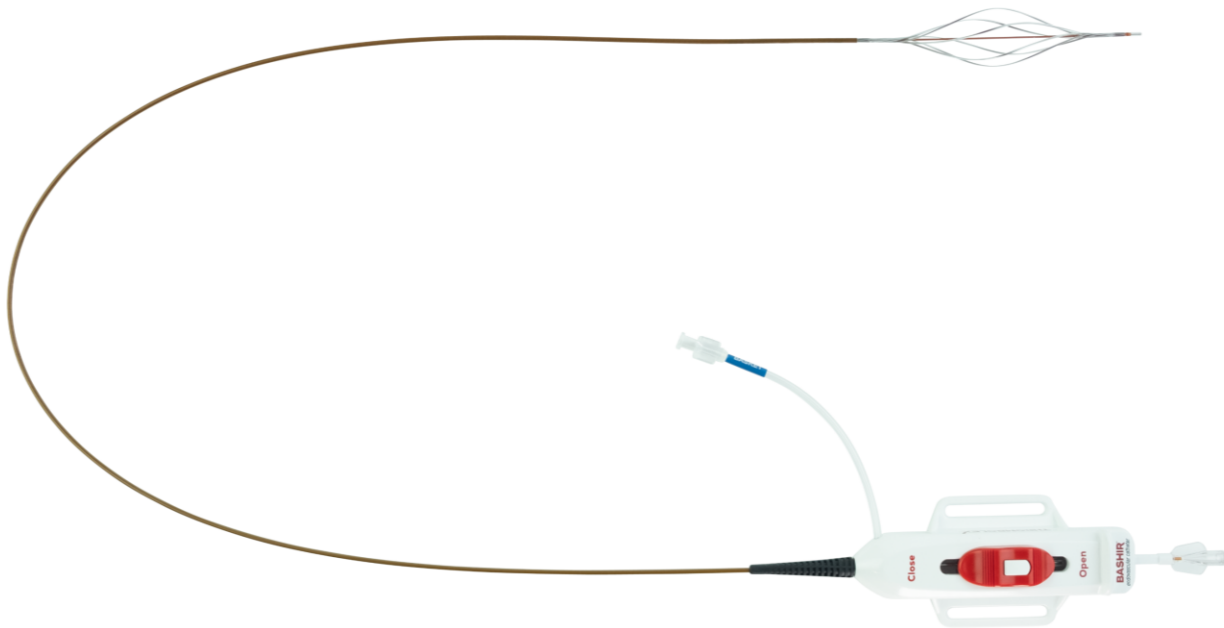
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

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?* on page 2.

By signing the filled-out form, you:

- Certify that the TIN you are giving is correct (or you are waiting for a number to be issued).
- Certify that you are not subject to backup withholding, or
- Claim exemption from backup withholding if you are a U.S. exempt payee. If applicable, you are also certifying that as a U.S. person, your allocable share of any partnership income from a U.S. trade or business is not subject to the withholding tax on foreign partners' share of effectively connected income, and
- Certify that FATCA code(s) entered on this form (if any) indicating that you are exempt from the FATCA reporting, is correct. See *What is FATCA reporting?* on page 2 for further information.



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**

All trademarks are property of their respective owners.
All photographs and images taken by Thrombolex, Inc.

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

© 2024 Thrombolex, Inc. All rights reserved.