

# **FDA Executive Summary**

Prepared for the  
July 31, 2014 Meeting of the  
Gastroenterology-Urology Devices Panel  
Classification of Nephrostomy Catheters

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# 1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the Act), the Food and Drug Administration (FDA) is convening the Gastroenterology-Urology Devices Advisory Panel (the Panel) for the purpose of securing recommendations regarding the classification of nephrostomy catheters, a pre-amendments device type which remains unclassified. Specifically, the FDA will ask the Panel to provide recommendations regarding the regulatory classification of nephrostomy catheters under product code “LJE.”

FDA is holding this panel meeting to obtain input on the risks to health and benefits of nephrostomy catheters. The Panel will discuss whether nephrostomy catheters should be classified into Class III (subject to General Controls and Premarket Approval), Class II (subject to General and Special Controls) or Class I (subject only to General Controls). If the Panel believes that classification into Class II is appropriate for nephrostomy catheters, the Panel will also be asked to discuss appropriate controls that would be necessary to mitigate the risks to health.

## 1.1. Current Regulatory Pathways

Nephrostomy catheters are a pre-amendments, unclassified device type. This means that this device type was marketed prior to the Medical Device Amendments of 1976, but was not classified by the original classification panels. Currently these devices are being regulated through the 510(k) pathway, and are cleared for marketing if their indications for use and technological characteristics are “substantially equivalent” to a legally marketed predicate device.

## 1.2. Device Description

Nephrostomy catheters are regulated under product code LJE as “Catheter, nephrostomy.” Since it is unclassified, there is no regulation associated with the product code.

Nephrostomy catheters include flexible tubular devices that are inserted through the skin into the kidney. The device is used to pass fluids to and from the urinary tract. This generic device type also includes devices used in conjunction with nephrostomy catheters during percutaneous nephrostomy procedures including dilatation balloon catheter, guidewire, sheath, stylet, stiffener, trocar, needle, dilator, retention disc, and cannula.

# 2. Regulatory History

Please refer to Table 1 below for a listing of the manufacturers, device names, and associated 510(k) submission numbers for cleared nephrostomy catheters under product code “LJE”:

Table 1: 510(k) clearances for nephrostomy catheters

510(k) Number	Trade Name	Applicant/Sponsor
K132383	GYRUS ACMI NEPHRO - EZDILATE NEPHROSTOMY BALLOON	GYRUS ACMI, INC.

	DILATION CATHETER	
K121614	NEPHROMAX HIGH PRESSURE NEPHROSTOMY BALOON DILATATION CATHETER	BOSTON SCIENTIFIC CORP.
K111315	MULTIPURPOSE DRAINAGE CATHETER	NAVILYST MEDICAL, INC.
K080944	X-FORCE NEPHROSTOMY BALLOON DILATION CATHETER	C.R. BARD, INC.
K080508	MANDREL GUIDEWIRES OR M-WIRE	LAKE REGION MEDICAL
K063632	X-FORCE N30 NEPHROSTOMY BALLOON DILATION CATHETER	C.R. BARD, INC.
K053245	GP GENERAL PURPOSE DRAINAGE CATHETER; MINI-PIG DRAINAGE CATHETER; NEPHROSTOMY CATHETER; BILIARY CATHETER	URESIL, LLC
K051316	X-FORCE NEPHROSTOMY BALLOON DILATION CATHETER	C.R. BARD, INC.
K033862	BIOTEQ PIGTAIL DRAINAGE CATHETER SET (ONE STEP TYPE) WITH OR WITHOUT SAFETY STRING LOCK	BIOTEQUE CORP.
K024050	COOK NEPHROSTOMY DILATION BALLOON CATHETER SET	COOK UROLOGICAL, INC.
K011121	RUSCH PERCUTANEOUS NEPHROSTOMY CATHETER SETS	RUSCH INTL.
K003753	GP GENERAL PURPOSE DRAINAGE SET, MINI-PIGTAIL DRAINAGE CATHETER WITH LOCKING PIGTAIL, GP GENERAL PURPOSE DRAINAGE CATHE	URESIL CORP.
K000570	BLUE MAX BALLOON DILATATION CATHETER, MAXFORCE BALLOON CATHETER, XXL BALLOON DILATATION CATHATER, SYMMETRY BALLOON DILA	BOSTON SCIENTIFIC CORP.
K990808	PBN DILATORS	MEDICAL DEVICE TECHNOLOGIES, INC.
K990689	ZYNERGY LOCK-SURE SINGLE PASS DRAINAGE CATHETER, Z10005/7/9	ZCV ,INC.
K981344	URESIL PERCUTANEOUS DRAINAGE CATHETERS WITH HYDROPHILIC COATING	URESIL CORP.
K980192	MANAN NEPHROSTOMY DRAINAGE CATHETER	MEDICAL DEVICE TECHNOLOGIES, INC.
K980193	MANAN GENERAL UTILITY DRAINAGE CATHETER	MEDICAL DEVICE TECHNOLOGIES, INC.
K980889	URESIL NEPHRO-URETERAL STENT	URESIL CORP.
K961933	CIRCLE NEPHROSTOMY CATHETER SET	COOK UROLOGICAL, INC.
K953601	MANAN UNIVERSAL SUMP DRAINAGE CATHETER	MANAN MEDICAL PRODUCTS, INC.
K953713	MANAN GENERAL UTILITY DRAINAGE CATHETER	MANAN MEDICAL PRODUCTS, INC.
K953597	NOPROFILE OLBERT CATHETER SYSTEM BALLOON DILATION CATHETER	MEADOX MEDICALS, DIV. BOSTON SCIENTIFIC CORP.
K953547	MANAN NEPHROSTOMY DRAINAGE CATHETER	MANAN MEDICAL PRODUCTS, INC.
K952887	NOPROFILE OLBERT CATHETER SYSTEM BALLOON DILATATION CATHETER	MEADOX MEDICALS, DIV. BOSTON SCIENTIFIC CORP.
K952968	DILATATION CATHETER, BALLOON	BOSTON SCIENTIFIC CORP.
K942688	NEPHRO-URETERAL STENT	URESIL CORP.
K945061	NOPROFILE OLBERT CATHETER SYSTEM	MEADOX SURGIMED, INC.
K943893	PERCUTANEOUS GRAINAGE CATHETER	MENLO CARE, INC.
K915209	MALECOT-NEPHROSTOMY TAMPONADE CATHETER	COOK UROLOGICAL, INC.
K920509	URESIL SUMP DRAINAGE CATHETER	URESIL CORP.
K923097	URESIL NEPHROSTOMY CATHETER	URESIL CORP.
K891406	BALLOON (NEPHROSTOMY TRACT) DILATION CATHETER SET	COOK UROLOGICAL, INC.
K862742	NEPHROSTOMY SET	MEADOX SURGIMED, INC.
K850287	MENTOR PERCUTANEOUS MALECOT NEPHROSTOMY SET	MENTOR CORP.
K850286	MENTOR PERCUTANEOUS COIL NEPHROSTOMY SET	MENTOR CORP.

K845047	NEPHROSTOMY GUIDEWIRE SHEATH	AMERICAN EDWARDS LABORATORIES
K845048	NEPHROSTOMY DRAINAGE CATHETER & STIFFENER	AMERICAN EDWARDS LABORATORIES
K844090	PERCUTANEOUS NEPHROSTOMY TROCAR SYS	AMERICAN EDWARDS LABORATORIES
K842840	CURITY SILICONE NEPHROSTOMY CATHETER	THE KENDAL CO.
K842121	E-Z-EM SINGLE STICK PUNCTURE/DRAINAGE	E-Z-EM, INC.
K842899	CURITY SUPRAPUBIC DRAINAGE SYSTEM	THE KENDAL CO.
K841720	E-Z-EM PERCUTANEOUS NEPHROSTOMY SETS	E-Z-EM, INC.
K833762	PERCUTANEOUS RETROGRADE NEPHROSTOMY	VPI
K834476	NEPHROSTOMY/BILIARY DRAINAGE BAG	VERTEX MEDICAL CORP.
K833008	PERCUTANEOUS NEPHROSTOMY CATHETER	MEDICAL ENGINEERING CORP.
K830803*	URINARY DIVERSION STENT	VAN-TEC, INC.
K830226	SURGITEK PERCUTANEOUS NEPHROSTOMY CATH	MEDICAL ENGINEERING CORP.
K823382	NEPHROSTOMY CATHETER	UMI, INC.
K823418*	HEYER-SCHUTE UNIVERSAL URETERAL STENT	AMERICAN HOSPITAL SUPPLY CORP.
K821776	SURGITEK PERCUTANEOUS NEPHROST. STENT	MEDICAL ENGINEERING CORP.

\*These products likely have been incorrectly assigned the product code “LJE.” FDA intends to correct this administrative error accordingly.

### 3. Indications for Use

The Indications For Use (IFU) statement identifies the condition and patient population for which a device should be appropriately used. Representative indications for use statements for nephrostomy catheters under product code “LJE” cleared in the 510(k)s noted in Table 1 are as follows:

- The device is intended for percutaneous drainage of urine from the kidney.
- The device is intended for temporary or permanent urinary diversion following nephrostomy.
- The device is indicated for nephrostomy drainage, and low pressure tamponade to prevent hemorrhage, following percutaneous stone removal.
- The device is intended for dilation of the nephrostomy tract.
- The device is intended for use in percutaneous nephrostomy procedures to provide a cover for the safety guidewire, maintain secondary access to the kidney, and allow injection of contrast medium into or drainage of fluid from the ureter. It also can serve as a guide for placement of a nephrostomy drainage catheter.
- The device is intended to facilitate the introduction of other diagnostic and treatment devices used in gastroenterology and urology procedures.

### 4. Clinical Background

This section summarizes the history of the use of nephrostomy catheters under product code “LJE.”

#### **4.1. Nephrostomy Catheters**

Nephrostomy catheters are used in percutaneous nephrostomy. Percutaneous nephrostomy is an interventional radiology/surgical procedure in which the renal pelvis is punctured while using imaging as guidance. Images are obtained once an antegrade pyelogram (an injection of contrast), with a fine needle, has been performed. This contrast is used to show calcifications at the renal pelvis. A nephrostomy tube may then be placed to allow drainage.

Currently, nephrostomy catheters are cleared in the US as devices intended for use in percutaneous drainage of urine from the kidney.

#### **4.2. Current Standard of Care**

##### Procedure

The patient lies prone and the renal pelvis is opacified either by intravenous pyelography or alternatively by antegrade pyelography with a needle. The patient is then rotated to a semi-prone position so that his calyces are visualized end on. The needle is then inserted through the renal parenchyma into the renal pelvis. The stylet is removed and a guide wire inserted. The tract is progressively dilated over the guide wire and a Percutaneous Nephrostomy Catheter inserted.

Obstruction in the upper urinary tract is a common condition and can be caused by cancer, congenital malformation, or kidney stones. The nephrostomy catheter is placed in the kidney through the skin. Its function is to secure draining the urine, and this requires a urine bag. The nephrostomy is usually placed under local anesthetic.

Percutaneously placed nephrostomy catheters are utilized in the oncology setting as a temporary, permanent, or palliative procedure to decompress the kidney and alleviate hydronephrosis related to renal compression or urine outflow obstruction.

Indications for a nephrostomy catheter include:

- To remove renal calculi
- To decompress an obstructed system and maintain or improve renal function following ureteric obstruction
- To obtain access to the renal pelvis for radiological procedures

### **5. Literature Survey**

A search was conducted using the Google search engine, restricted to the term “nephrostomy catheter.” The reference (<http://www.surgeryencyclopedia.com/La-Pa/Nephrostomy.html#ixzz33EVd5ltI>) discussed below was discovered in this search.

## **5.1. Complications Associated with Nephrostomy Treatment and Management**

A nephrostomy is an established and generally safe procedure. As with all operations, there is always a risk of allergic reaction to anesthesia, bleeding, and infection. Bruising at the catheter insertion site occurs in about half of people who have a nephrostomy. This is a minor complication. Additional complications include:

- Perforation of the collecting system (< 30%) typically resolves within 48 hours of nephrostomy tube placement, provided that drainage of the collecting system is established (via nephrostomy tube or ureteral catheter)
- Possible complications of the intercostal approach include pleural effusion, hydrothorax, and pneumothorax, possibly requiring chest tube placement (< 13%).
- Acute bleeding requiring transfusion (< 5%)
- Failed access (< 5%)

## **5.2. Rare complications**

- Periorgan injury, including bowel perforation, splenic injury, and liver injury (< 1%)
- Intraperitoneal injury that mandates open exploration (< 1%)
- Infection leading to septicemia (< 1%)
- Significant loss of functioning renal tissue (< 1%)
- Delayed hemorrhage (< 0.5%)
- Emergency arterial embolization of the kidney (< 0.5%) with uncontrollable arterial bleeding
- Nephrectomy (< 0.2%)
- Mortality (< 0.05%)

Patients with uncontrolled hypertension may develop peri-renal hematoma or extensive renal hemorrhage.

# **6. Risks to Health Identified Using “Manufacturer and User Facility Device Experience” (MAUDE) Database**

## **6.1. Overview of MAUDE Database**

The MAUDE database is maintained by the Office of Surveillance and Biometrics at FDA. This database contains adverse events and reportable product problems with medical devices. The database was fully implemented in August 1996, and contains individual adverse event reports submitted by manufacturers, user facilities, importers, and voluntary reporters. Medical device manufacturers are required to report known adverse events as part of the general controls that most medical devices are subject to; patients and consumers are also encouraged to voluntarily report adverse events.

One does need to note the limitations to MDR reporting, including the fact that not all events are captured since there is a voluntary component to the reporting system. In addition, confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report.

## **6.2. MAUDE Search Results: Nephrostomy Catheters**

The FDA conducted a query of the MAUDE database on May 29, 2014 to identify adverse events related to use of nephrostomy catheters. The search was restricted to the period, January 1, 1992 to May 29, 2014, and utilized the parameter of device product code “LJE.” The queries resulted in the identification of 163 Medical Device Reports (MDRs) on nephrostomy catheters.

The reported adverse events fall primarily into the following categories (please note that multiple adverse events may be related to a single MDR):

- Malfunction (n=69)
- Injury (n=84)
- Death (n=2)
- Other (n=5)

The two cases of death were noted, one each associated with bleeding and heart failure. Detailed descriptions of the adverse events are listed in Appendix A.

## **7. Summary**

In light of the information available, the Panel will be asked to comment on whether nephrostomy catheter devices under product code “LJE”:

meet the statutory definition of a Class III device:

- insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of its safety and effectiveness, and
- the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury

or would be more appropriately regulated as Class II, in which:

- general and special controls, which may include performance standards, postmarket surveillance, patient registries and/or development of guidelines, are sufficient to provide reasonable assurance of safety and effectiveness;

or as Class I, in which

- the device is subject only to general controls, which include registration and listing, good manufacturing practices (GMPs), prohibition against adulteration and misbranding, and labeling devices according to FDA regulations.

For the purposes of classification, FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;
2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. The reliability of the device.

### 7.1. Special Controls

FDA believes that special controls, in addition to general controls, can be established to mitigate the risks to health identified, and provide a reasonable assurance of the safety and effectiveness of nephrostomy catheter devices and the balloon dilatation catheters used in conjunction with nephrostomy catheters during percutaneous nephrostomy procedures. Following is a risk/mitigation table, which outlines the identified risks to health for this device type and the recommended controls to mitigate the identified risks:

**Table 2: Risk/mitigation recommendations for nephrostomy catheter**

Identified Risk	Recommended Mitigation Measure
Infection	<ul style="list-style-type: none"> <li>• Labeling</li> <li>• Sterilization</li> </ul>
Bleeding, bruising at percutaneous insertion site	<ul style="list-style-type: none"> <li>• Labeling</li> </ul>
Adverse tissue reaction to device including foreign body reaction, inflammation and granuloma formation	<ul style="list-style-type: none"> <li>• Biocompatibility Testing</li> </ul>
Local tissue injury due to material breakage	<ul style="list-style-type: none"> <li>• Performance Testing – Bench (tensile strength, durability)</li> </ul>
Local tissue injury due to leakage or obstruction of device	<ul style="list-style-type: none"> <li>• Performance Testing – Bench (flow rate)</li> </ul>
Local tissue injury due to incorrect placement or post-placement migration of device	<ul style="list-style-type: none"> <li>• Performance Testing – Bench (mechanical)</li> <li>• Labeling</li> </ul>

*The panel will be asked whether this list is a complete and accurate list of the risks to health presented by Nephrostomy Catheters and whether any other risks should be included in the overall risk assessment of the device type.*

Based on the recommended mitigation measures, FDA believes that the following special controls would provide reasonable assurance of safety and effectiveness for the nephrostomy catheters and balloon dilatation catheters under product code “LJE”:

- a. The labeling must include adequate instructions regarding the proper placement and use of the device.
- b. The device must be demonstrated to be sterile and maintain sterilization over the requested shelf life.
- c. The device must be demonstrated to be biocompatible.
- d. Performance testing must provide a reasonable assurance of safety and effectiveness of the device regarding tensile strength, durability and flow rate. Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use.

*If the panel believes that Class II is appropriate for the nephrostomy catheters and balloon dilatation catheters under product code “LJE,” the panel will be asked whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.*

## **7.2. Overview of Proposed Classification**

Based on the safety and effectiveness information gathered by the FDA, the identified risks to health and recommended mitigation measures, we recommend that nephrostomy catheters indicated for use in urine drainage from the kidney and balloon dilatation catheters used during percutaneous nephrostomy procedures be regulated as Class II devices (special controls). We further recommend that devices used conjunction with a nephrostomy catheter during a percutaneous nephrostomy procedure including a guidewire, sheath, stylet, stiffener, trocar, needle, dilator, retention disc, and cannula be regulated as Class I devices because general controls are sufficient to provide reasonable assurance of their safety and effectiveness.

### **876.XXXX Nephrostomy Catheter and Accessories**

(a) *Identification.* A nephrostomy catheter is a prescription device which consists of a flexible tube that is inserted through the skin into the kidney to pass fluids to and from the urinary tract. This generic device type also includes devices used in conjunction with nephrostomy catheters during percutaneous nephrostomy procedures including dilatation balloon catheter, guidewire, sheath, stylet, stiffener, trocar, needle, dilator, retention disc, and cannula.

(b) *Classification.* Class II (special controls) for the nephrostomy catheter and balloon dilatation catheter used during percutaneous nephrostomy procedures. The special controls for this device are:

- (1) The labeling must include adequate instructions regarding the proper placement and use of the device.
- (2) The device must be demonstrated to be sterile and maintain sterilization over the requested shelf life.
- (3) The device must be demonstrated to be biocompatible.

(4) Performance testing must provide a reasonable assurance of safety and effectiveness of the device regarding tensile strength, durability and flow rate. Mechanical bench testing of material strength must demonstrate the device will withstand forces encountered during use.

(2) Class I for the guidewire, sheath, stylet, stiffener, trocar, needle, dilator, retention disc, and cannula used in conjunction with a nephrostomy catheter during a percutaneous nephrostomy procedure.

***Based on the available scientific evidence, the FDA will ask the Panel for their recommendation on the appropriate classification of the nephrostomy catheters and devices used in conjunction with nephrostomy catheters during a percutaneous nephrostomy procedure under product code "LJE" for use in drainage of urine from the kidney.***

## 8. References

<http://emedicine.medscape.com/article/445893-treatment#a17>

<http://www.surgeryencyclopedia.com/La-Pa/Nephrostomy.html#ixzz33EVd5ltI>

## Appendix A: Public MAUDE Information on Nephrostomy Catheter Medical Device Reports (MDRs)

Report number	Event type	Date FDA received	Event description
(b) (6)	MALFUNCTION	05/13/2009	A COOK 8.5 FRENCH PERCUTANEOUS NEPHROSTOMY CATHETER WAS PLACED SUCCESSFULLY. A MONTH LATER, THE PATIENT WHO WAS 31 5/7 WEEKS PREGNANT EXPERIENCED INCREASED FLANK PAIN AND THE TUBE WAS NOT DRAINING WELL. THE CATHETER HUB WAS CUT AND EXTENSIVE ATTEMPTS WERE MADE TO PASS TWO DIFFERENT WIRE GUIDES THROUGH THE TUBE. WIRE PASSAGE WAS NOT POSSIBLE SECONDARY TO COMPLETE OBSTRUCTION. ATTEMPTS WERE MADE TO REMOVE WITHOUT A WIRE. HOWEVER, THE PIGTAIL WAS COMPLETELY LOCKED IN PLACE. THE PIGTAIL WAS UNABLE TO BE UNLOCKED. A SHEATH WAS PLACED AND THE NEPHROSTOMY TUBE STRAIGHTENED. HOWEVER, THE TUBE WOULD NOT PASS COMPLETELY INTO THE SHEATH. APPROXIMATELY 7MM OF THE DISTAL TIP WOULD NOT PASS INTO THE SHEATH. A DENSITY CONSISTENT WITH SEDIMENT/CALCIFICATION WAS NOTED AT THE CATHETER TIP. DESPITE NUMEROUS ATTEMPTS THE CATHETER TIP WAS UNABLE TO BE REMOVED, AND UPON FINAL TRACTION WITH THE USE OF A HEMOSTAT THE TIP OF THE CATHETER BROKE AND REMAINED IN THE RETROPERITONEAL TISSUE. THE PLAN IS TO REMOVE THE BROKEN TIP OF THE CATHETER LAPAROSCOPICALLY AFTER THE DELIVERY OF THE INFANT.
(b) (6)	MALFUNCTION	04/03/2009	THIS PATIENT HAS HAD NEPHROSTOMY TUBES PLACED AND REPLACED BEGINNING THE EARLY PART OF THIS YEAR. RECENTLY THE TUBE WAS BEING REPLACED AS IT WAS NONFUNCTIONING. THE STRING FIXATION MECHANISM OF THE EXISTING CATHETER WAS UNLOCKED, BUT DID NOT RELEASE. ATTEMPTS AT ADVANCING A WIRE THROUGH THE CATHETER WERE UNSUCCESSFUL. THE CATHETER WAS THEN CUT IN AN ATTEMPT TO RELEASE THE LOCKING MECHANISM. SHEATHS WERE ADVANCED OVER THE TUBING; HOWEVER NONE OF THESE ATTEMPTS WERE SUCCESSFUL AT REMOVING THE CATHETER. THE CATHETER COULD NOT BE REMOVED AND WAS CLAMPED. IT WILL LIKELY NEED TO BE REMOVED SURGICALLY.
(b) (6)	MALFUNCTION	09/24/2011	THE PT WENT TO SPECIAL PROCEDURES FOR PLACEMENT OF A NEPHROSTOMY TUBE. THE PT. RETURNED WITH THE TUBE LEAKING. THE TUBING WAS RECONNECTED AND THE LEAK PERSISTED REQUIRING EXPLANATION.
1018233-2012-01602	MALFUNCTION	10/29/2012	IT WAS REPORTED THAT THE BOTTOM SEAL WAS NEVER SEALED. THE ISSUE WAS FOUND PRIOR TO USE.

Report number	Event type	Date FDA received	Event description
1036710-2010-00023	MALFUNCTION	07/07/2010	INITIALLY AN 8 FR SKATER WAS INSERTED IN THE PT AND WAS THEN REPLACED AS A RESULT OF A PT COMPLAINT STATING PAIN AND CONTINUED DIFFICULTY BREATHING. THERE WAS A KINK FOUND IN THE 8 FR CATHETER. AS A RESULT, THE 8 FR WAS CHANGED TO THE 10 FR IN QUESTION. THE PT STILL CONTINUED TO EXPERIENCE DIFFICULTIES AT WHICH TIME A CARDIOVASCULAR SURGEON WAS CONSULTED. THE SURGEON DOCUMENTED CHANGING A CONNECTOR USING A COOK PNEUMOTHORAX TRAY WHICH SEEMED TO RESOLVE THE COMPLAINTS OF PAIN AND DIFFICULTY BREATHING.
1317056-2013-00022	INJURY	05/30/2013	AS REPORTED, NEPHROSTOMY DRAINAGE CATHETER "DISINTEGRATED" INSIDE THE PATIENT. IT WAS REMOVED BY A PHYSICIAN AND "ABOUT 95%" OF THE DEVICE WAS RETURNED FOR EVALUATION. NAVILYST MEDICAL IS IN THE PROCESS OF OBTAINING ADDITIONAL INFORMATION ON THIS EVENT, INCLUDING THE LENGTH OF TIME THE CATHETER WAS IMPLANTED, THE LOCATION OF THE PLACEMENT, AND THE CURRENT PATIENT CONDITION.
1317056-2013-00025	MALFUNCTION	07/02/2013	AS REPORTED BY NAVILYST MEDICAL'S DISTRIBUTOR IN AUSTRALIA, DURING PREP FOR A CORONARY ANGIOGRAPHY PROCEDURE IT WAS NOTICED THAT THE O-RING OF THE 12ML SYRINGE FURNISHED IN THE HOSPITAL'S CONVENIENCE KIT WAS BROKEN. A FRAGMENT OF THE O-RING WAS FOUND TO BE WITHIN THE SYRINGE BARREL, BELOW THE STOPPER. THE DEVICE WAS NOT USED ON A PATIENT AND THE PROCEDURE WAS COMPLETED WITH ANOTHER SYRINGE. THE USED SYRINGE HAS BEEN RETURNED TO NAVILYST MEDICAL FOR EVALUATION.
1317056-2013-00029	INJURY	07/11/2013	AS REPORTED BY NAVILYST MEDICAL'S DISTRIBUTOR IN KOREA, DURING A PICC PLACEMENT PROCEDURE, THE HANDLES DETACHED FROM A PEEL-AWAY SHEATH WHICH WAS INSERTED INTO THE VESSEL. IT WAS NECESSARY TO UTILIZE A SNARE TO REMOVE THE SHEATH. THE PT'S CONDITION IS REPORTED AS "STABLE." IT WAS STATED THAT THE USED SHEATH WOULD BE RETURNED TO NAVILYST MEDICAL FOR EVALUATION.
1450395-2011-00001	OTHER	07/11/2011	THE PT IS LIVING IN A LONG CARE HEALTH FACILITY. THE PT REGULARLY USES NEPHROSTOMY DRAINAGE CATHETERS FOR DRAINAGE OF URINE FROM THE RENAL PELVIS. IN THIS PARTICULAR EVENT, THE NURSING STAFF NOTED ON 3/9/2011 THAT THE STRAIN RELIEF COLLAR WAS MISSING FROM THE CATHETER. THE PT HAD BEEN PREVIOUSLY SCHEDULED FOR A CATHETER EXCHANGE (UNRELATED TO THIS EVENT), SO THE NURSING STAFF ALERTED THE PT'S PHYSICIAN. USING FLUOROSCOPY ON 3/11/2011, THE PHYSICIAN DETERMINED THAT THE COLLAR WAS IN THE PT'S RENAL PELVIS. IT IS NOT KNOWN HOW THE COMPONENT BECAME POSITIONED IN THIS LOCATION. USING A MINIMALLY INVASIVE INTERVENTIONAL SNARE, THE COMPONENT WAS REMOVED FROM THE PT. THE COMPONENT WAS DISCARDED BY THE END-USER. THE PT SUFFERED NO ILL EFFECTS FROM THIS EVENT.

Report number	Event type	Date FDA received	Event description
1820334-2013-00089	INJURY	02/27/2013	DURING A PERCUTANEOUS NEPHROLITHOTOMY, WHILE PASSING SHEATH OVER BALLOON, THE DOCTOR NOTED THAT THE SHEATH BENT THE BALLOON AND WAS TUNNELING INTO THE TISSUE CAUSING EXCESSIVE BLEEDING. A SECTION OF THE DEVICE DID NOT REMAIN INSIDE THE PATIENT'S BODY. THE PATIENT DID NOT REQUIRE ANY ADDITIONAL PROCEDURES DUE TO THIS OCCURRENCE.
1820334-2014-00007	MALFUNCTION	01/06/2014	THE BALLOON BURST CIRCUMFERENTIALLY BY USE AT THE PATIENT. THEY MADE A PCNL WITH UNBS. NO SECTION OF THE DEVICE REMAINED IN THE PATIENT OR HAD TO BE RETRIEVED. NO ADDITIONAL PROCEDURES WERE REQUIRED DUE TO THIS OCCURRENCE. NO ADVERSE EFFECTS ON THE PATIENT WERE REPORTED TO HAVE OCCURRED DUE TO THIS EVENT.
1825146-2011-00036	INJURY	09/09/2011	DURING INITIAL KIDNEY ACCESS, AN INCISION WAS MADE APPROX 30 FRENCH WITH A #11 BLADE. A FUCHS NEEDLE (#090004) WAS INTRODUCED INTO INCISION. THE 4 PART NEEDLE FROM #080000-S5 WAS INSERTED THROUGH THE FUCHS NEEDLE TO THE KIDNEY. THE POSITION WAS NOT OPTIMAL AND THE 4-PART NEEDLE WITH THE 2 INNER PIECES OUT, WAS EXTRACTED. THE REMAINING CATHETER AND STYLET SEEMED TO "CATCH" ON THE WAY OUT AND WHEN EXTRACTED IT WAS NOTED THAT THE LOWER APPROX 1" OF THE OUTER CATHETER WAS MISSING. ON F/U X-RAY, THE PIECE WAS VISUALIZED BETWEEN THE SKIN AND THE RETROPERITONEUM. NO EXTRACTION OF THE PIECE COULD BE MADE. THE PT WAS MADE AWARE OF THE LEFT BEHIND PIECE.
(b) (6)	INJURY	04/23/2010	THIS PATIENT HAS AN ILEAL CONDUIT AND COMES IN EVERY 2 MONTHS TO HAVE THIS TUBE CHANGED. WE REMOVED THE TUBE OVER A GUIDEWIRE AND PLACED A NEW TUBE. THEN WE EXAMINED THE OLD TUBE AND DISCOVERED THE TIP WAS MISSING. THE TIP IS CLEAR, CONE-SHAPED PLASTIC AND ABOUT THE SIZE OF A PENCIL TIP. WE CHECKED THE STERILE FIELD, THE SURROUNDING LINEN AND THE FLOOR TO NO AVAIL. A RETROGRADE URETEROPYLEOGRAM DID NOT NOTE THE TIP ON X-RAY. THERE WAS NOT ANY FILLING DEFECT IN THE LEFT RENAL PELVIS, COLLECTING SYSTEM AND THE URETER. THE PATIENT WAS ADVISED THAT THE TIP MAY PUSH OUT BY PERISTALSIS TO THE COLLECTING BAG AND TO BRING IT INTO THE UROLOGIST'S OFFICE. PLANS ARE IN THE WORKS FOR A CT SCAN WITHOUT AND WITH CONTRAST TO POSSIBLY LOCATE THE TIP IN THE STENT IN IMAGING STUDIES IN THE NEAR FUTURE.

Report number	Event type	Date FDA received	Event description
2020394-2009-00137	INJURY	04/17/2009	THE PT WAS ADMITTED FOR A PROSTATE AND PRESENTED WITH RT SIDED URETERIC OBSTRUCTION WITH DETERIORATING RENAL FUNCTION. RIGHT KIDNEY WAS NON-FUNCTIONING ON ADMISSION. ON INVESTIGATION, IT WAS APPARENT THAT THE LEFT KIDNEY WAS ALSO OBSTRUCTED. PROCEDURE PERFORMED ON PT: LEFT RENAL PELVIS - USING SELDINGER TECHNIQUE, FLUOROSCOPY, AND AN ACCUSTICK KIT TO GAIN ACCESS, THE PHYSICIAN PLACED A URETERIC STENT, BUT WANTED TO LEAVE THE PT ON EXTERNAL DRAINAGE AS THE PROCEDURE HAD BEEN QUITE DIFFICULT AND THERE WAS A LOT OF BLOOD IN THE RENAL PELVIS. THE NAVARRE DRAIN WAS PLACED TO ALLOW DRAINAGE OF THE BLOOD OF THE LEFT KIDNEY. IT WAS REPORTED THAT THE HUB/LUER WAS TOO TIGHT BETWEEN THE METAL CANNULA AND THE DRAIN. IN TRYING TO RELEASE THE METAL CANNULA FROM THE LUER LOCK OF THE NAVARRE DRAIN, ALLEGEDLY THE WHOLE DRAIN SHOT FORWARD AND PUNCTURED THE KIDNEY - LOSS OF RENAL FUNCTION WAS AS A RESULT OF LACERATION OF THE RENAL PELVIS AND HEMATOMA. SURGICAL INTERVENTION WAS NOT REQUIRED. PT WAS PUT ON DIALYSIS 24 HRS AFTER THE PROCEDURE. PT IS STILL IN HOSP BUT IS NO LONGER ON DIALYSIS. LEFT RENAL FUNCTION IS NOW NORMAL. RIGHT RENAL ALSO NOW HAS SOME OUTPUT.
(b) (6)	MALFUNCTION	11/03/2011	THE INTERVENTIONAL RADIOLOGY TEAM INSERTED A NEPHROURETEROSCOPY TUBE AND IT LEAKED AND HAD TO BE REPLACED.
(b) (6)	MALFUNCTION	01/31/2011	THE PHYSICIAN WAS REMOVING THE NEPHROSTOMY TUBE AND WIRE WHEN HE MET RESISTANCE AND THEN THE WIRE BEGAN TO UNRAVEL. HOWEVER, ALL OF THE WIRE CAME OUT AND THERE WASN'T ANY APPARENT INJURY OR TRAUMA TO THE PT.
3005099803-2009-02186	MALFUNCTION	05/01/2009	THE COMPLAINANT REPORTED THAT ON APRIL 08, 2009, THE CLINICIAN WAS PREPARING TO PERFORM THE IMPLANT OF A PERCUFLEX URINARY DIVERSION STENT ON A PATIENT. DURING THE PREPARATION OF THE DEVICE FOR IMPLANT, A CRACK WAS IDENTIFIED. THE CRACK WAS LOCATED ON THE DEVICE'S SECOND HOLE FROM THE DISTAL END, MAKING IT DIFFICULT TO ADVANCE THE GUIDEWIRE. THE CLINICIAN THEN OBTAINED ANOTHER OF THE SAME DEVICE AND SUCCESSFULLY COMPLETED THE PATIENT PROCEDURE. THERE WAS NO ADVERSE AFFECT ON THE PATIENT AS A RESULT OF THE REPORTED PROBLEM. THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "GOOD".

Report number	Event type	Date FDA received	Event description
3005099803-2009-03138	MALFUNCTION	06/30/2009	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A 20FR MALECOT NEPHROSTOMY DRAINAGE CATHETER WAS USED POST PCNL PROCEDURE. ACCORDING TO THE COMPLAINANT, THE DRAIN WAS KEPT INSITU FOR 2 DAYS POST-OPERATIVELY. DRAINAGE APPEARED NORMAL. HOWEVER, WHEN THE DR. INSERTED THE INNER STYLET OF THE NEPHROSTOMY CATHETER, HE NOTICED DURING WITHDRAWAL OF THE CATHETER THAT THE STYLET PASSED THE CATHETER FLARE THUS NOT STRAIGHTENING THE PROXIMAL FLARED END. THIS CREATED SOME RESISTANCE DURING EXTRACTION/WITHDRAWAL AND CAUSED MINIMAL PAIN AND BLEEDING AS WELL AS DISCOMFORT TO THE PT. THE PHYSICIAN DRESSED THE EXTERIOR WOUND ACCORDING TO STANDARD PROCEDURE AND THE PT WAS DISCHARGED IN A STABLE CONDITION. THE MALECOT CATHETER WAS THEN DISCARDED. INNER STYLET OF MALECOT NEPHROSTOMY CATHETER DID NOT REACH CENTRE POINT OF PROXIMAL FLARED END BUT 'PIERCED' PASSED FLARED ENDS TOWARDS THE EXTERIOR OF THE CATHETER, THUS NOT STRAIGHTENING PROXIMAL END DURING WITHDRAWAL OF THE CATHETER. THE PT IS REPORTED TO BE "FINE".</p>
3005099803-2009-04464	MALFUNCTION	09/23/2009	<p>NOTE: THIS IS ONE OF TWO DEVICES THAT WERE USED DURING THE SAME PROCEDURE. REFER TO ASSOCIATED MANUFACTURERS REPORT# 3005099803-2009-04499 FOR A DESCRIPTION OF THE SECOND DEVICE. IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION, THAT A PERCUFLEX URINARY DIVERSION STENT SET WAS USED DURING A DRAINAGE PROCEDURE. ACCORDING TO THE COMPLAINANT, TWO DEVICES (FROM THE SAME BOX) WERE INSERTED INTO THE BODY PERCUTANEOUSLY (ONE FOR THE LEFT URETER AND ONE FOR THE RIGHT URETER). THE DEVICE WERE ACCESSED FROM THE SAME POINT ON THE BODY SURFACE AND THE PROXIMAL PARTS OUTSIDE THE BODY WERE TIED UP TOGETHER USING A SUTURE. THREE WEEKS AFTER PLACEMENT, THE DEVICES WERE REMOVED, AND FOUND TO BE PARTIALLY MELTED AND ATTACHED TO EACH OTHER AROUND THE INSERTION POINT (ACCESS PART). THERE WERE NO PT COMPLICATIONS REPORTED AS A RESULT OF THIS EVENT. THE PT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "GOOD".</p>

Report number	Event type	Date FDA received	Event description
3005099803-2009-04499	MALFUNCTION	09/23/2009	NOTE: THIS IS ONE OF TWO DEVICES THAT WERE USED DURING THE SAME PROCEDURE. REFER TO ASSOCIATED MANUFACTURERS REPORT# 3005099803-2009-04464 FOR A DESCRIPTION OF THE FIRST DEVICE. IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION, THAT A PERCUFLEX URINARY DIVERSION STENT SET WAS USED DURING A DRAINAGE PROCEDURE. ACCORDING TO THE COMPLAINANT, TWO DEVICES (FROM THE SAME BOX) WERE INSERTED INTO THE BODY PERCUTANEOUSLY (ONE FOR THE LEFT URETER AND ONE FOR THE RIGHT URETER). THE DEVICE WERE ACCESSED FROM THE SAME POINT ON THE BODY SURFACE, AND THE PROXIMAL PARTS OUTSIDE THE BODY WERE TIED UP TOGETHER USING A SUTURE. THREE WEEKS AFTER PLACEMENT, THE DEVICES WERE REMOVED AND FOUND TO BE PARTIALLY MELTED AND ATTACHED TO EACH OTHER AROUND THE INSERTION POINT (ACCESSES PART). THERE WERE NO PT COMPLICATIONS REPORTED AS A RESULT OF THIS EVENT. THE PT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "GOOD".
3005099803-2009-04597	MALFUNCTION	09/30/2009	IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A PERCUFLEX URINARY DIVERSION STENT SET WAS USED DURING A ILEAL CONDUIT PROCEDURE. ACCORDING TO THE COMPLAINANT, THE PIGTAIL WAS FOUND TO BE BENT PRIOR TO INSERTION INTO THE BODY. THE PROCEDURE WAS SUCCESSFULLY COMPLETED WITH ANOTHER PERCUFLEX URINARY STENT. THERE WERE NO PATIENT COMPLICATIONS REPORTED AS A RESULT OF THIS EVENT. THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "GOOD".
3005099803-2009-05480	MALFUNCTION	11/19/2009	IT WAS REPORTED TO BOSTON SCIENTIFIC CORP THAT A PERCUFLEX URINARY DIVERSION STENT SET WAS GOING TO BE USED IN AN UNK PROCEDURE (DATE OF EVENT UNK). ACCORDING TO THE COMPLAINANT, DURING PREPARATION FOR THE PROCEDURE, ONE OF THE KITS IN THIS BOX WAS FOUND TO BE OPEN. THE PT WAS REPORTED TO BE IN "GOOD" CONDITION.
3005099803-2010-01510	MALFUNCTION	04/06/2010	IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A URINARY DIVERSION STENT WAS BEING PREPPED FOR USE IN AN ILEAL CONDUIT PROCEDURE ON A MALE PATIENT (WEIGHT UNKNOWN).  ACCORDING TO THE COMPLAINANT, WHILE LOADING THE STENT ONTO THE GUIDEWIRE, THE GUIDEWIRE POKED THROUGH THE STENT CAUSING THE STENT TO BREAK IN HALF.  THE PROCEDURE WAS SUCCESSFULLY COMPLETED USING A SECOND URINARY DIVERSION STENT. THE PATIENT WAS REPORTED TO BE "FINE" AT THE CONCLUSION OF THE PROCEDURE.

Report number	Event type	Date FDA received	Event description
3005099803-2010-04188	MALFUNCTION	10/11/2010	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT AN LEVEEN INFLATION DEVICE WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY (PERC) PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE INFLATION DEVICE FAILED TO REGISTER ANY CHANGE ON THE PRESSURE GAUGE DESPITE THE BALLOON BEING INFLATED WITH NO ISSUES.</p> <p>THE PROCEDURE WAS COMPLETED WITH ANOTHER LEVEEN INFLATION DEVICE. THERE WERE NO PATIENT COMPLICATIONS AND THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "STABLE".</p>
3005099803-2011-00524	MALFUNCTION	03/01/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX NEPHROSTOMY BALLOON DILATATION CATHETER WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY (PCNL) PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, THE PATIENT WAS BEING TREATED FOR A STONE WITHIN THE RIGHT KIDNEY. A SENSOR GUIDEWIRE AND AN AMPLATZ GUIDEWIRE WERE PLACED WITHIN THE PATIENT'S KIDNEY. THE BALLOON CATHETER WAS INSERTED APPROXIMATELY 5-6 CM THROUGH THE PATIENT'S BACK WHEN THE CATHETER BENT AND COULD NOT BE INSERTED ANY FURTHER. THE BALLOON CATHETER WAS REMOVED FROM THE PATIENT.</p> <p>A SECOND NEPHROMAX NEPHROSTOMY BALLOON DILATATION CATHETER WAS USED WITH THE SAME GUIDEWIRES TO COMPLETE THE PROCEDURE. THERE WERE NO OTHER COMPLICATIONS AND THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "FINE."</p>

Report number	Event type	Date FDA received	Event description
3005099803-2011-01247	INJURY	04/14/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER AND LEVEEN INFLATOR WERE USED DURING A PERCUTANEOUS NEPHROLITHOTOMY PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, WHILE THE PHYSICIAN WAS INFLATING THE BALLOON USING THE LEVEEN INFLATOR, THE WHITE COLLAR WHICH HOLDS THE THREADED SYRINGE PLUNGER IN PLACE BROKE. THE PRESSURE THE BALLOON WAS INFLATED TO WHEN THIS OCCURRED IS UNKNOWN. THE PATIENT THEN BEGAN BLEEDING FROM THE KIDNEY FOR TWELVE MINUTES AND LOST 500 CC'S OF BLOOD. THE PHYSICIAN WAS ABLE TO STOP THE BLEEDING USING A TAMPONADE AND COMPLETING THE DILATATION WITH THE SAME BALLOON AND AN ENCORE INFLATOR.</p> <p>THERE WERE NO OTHER PATIENT COMPLICATIONS AND THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "FINE."</p>
3005099803-2011-01521	MALFUNCTION	05/11/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED WITH AN ENCORE INFLATOR DURING A PERCUTANEOUS NEPHROLITHOTOMY PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE ENCORE INFLATOR GAVE INCORRECT READINGS CAUSING THE BALLOON TO BURST INSIDE THE PATIENT. THE BALLOON WAS CONNECTED TO THE INFLATOR AND INSERTED INTO THE NEPHROSTOMY TRACT. THE PHYSICIAN BEGAN TO INFLATE THE BALLOON AND NOTICED THAT THE PRESSURE GAUGE ON THE INFLATOR WAS NOT MOVING WHILE THE BALLOON WAS INFLATING. THE PHYSICIAN THEN TAPPED ON THE PRESSURE GAUGE AND THE NEEDLE MOVED UP SLIGHTLY, THEN FELL BACK TO ZERO. THE PHYSICIAN CONTINUED TO INFLATE THE BALLOON WHEN IT BURST INSIDE THE PATIENT. IT IS UNKNOWN AT WHAT PRESSURE THE BALLOON BURST. THE BALLOON WAS RETRIEVED FROM THE PATIENT WITH NO PIECES MISSING.</p> <p>THE PHYSICIAN COMPLETED THE PROCEDURE WITH A METAL RIGID RENAL DILATOR SET WITH NO COMPLICATIONS AND THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "STABLE."</p>

Report number	Event type	Date FDA received	Event description
3005099803-2011-02043	MALFUNCTION	06/16/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT UPON UNPACKING A PERCUFLEX URINARY DIVERSION STENT INTENDED TO BE PLACED IN THE PATIENT, IT WAS DISCOVERED THAT ONE OF THE STERILE BAGS HAD ALREADY BEEN OPENED; IT WAS NOT SEALED.</p> <p>THE PROCEDURE WAS SUCCESSFULLY COMPLETED USING ANOTHER PERCUFLEX URINARY DIVERSION STENT, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY ¿GOOD.¿</p> <p>ATTEMPTS TO OBTAIN ADDITIONAL INFORMATION REGARDING THE CIRCUMSTANCES SURROUNDING THIS EVENT HAVE BEEN UNSUCCESSFUL TO DATE. SHOULD ADDITIONAL RELEVANT DETAILS BECOME AVAILABLE, A SUPPLEMENTAL REPORT WILL BE SUBMITTED.</p>
3005099803-2011-02841	MALFUNCTION	08/25/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY PROCEDURE IN AUGUST 2011. THE PATIENT AGE WAS REPORTED TO BE OVER 18 YEARS.</p> <p>ACCORDING TO THE COMPLAINANT, WHILE THE BALLOON WAS BEING INFLATED INSIDE THE PATIENT, THE DISTAL TIP OF THE BALLOON CATHETER KINKED. THE LEVEEN INFLATOR INCLUDED WITH THE BALLOON KIT WAS USED FOR INFLATION. THE KINK MADE IT DIFFICULT TO ADVANCE THE ACCESS SHEATH OVER THE BALLOON TO MAINTAIN DILATATION AND THE PHYSICIAN WAS UNABLE TO SUCCESSFULLY PASS THE SHEATH OVER THE BALLOON. NO DEFECTS WERE NOTED TO THE BALLOON CATHETER WHEN IT WAS REMOVED FROM THE PACKAGE. THE BALLOON WAS REMOVED FROM THE PATIENT.</p> <p>THE PHYSICIAN COMPLETED THE PROCEDURE WITH ANOTHER NEPHROMAX BALLOON AND THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "STABLE."</p>

Report number	Event type	Date FDA received	Event description
3005099803-2011-04080	MALFUNCTION	11/23/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING A PERCUFLEX URINARY DIVERSION URETERAL STENT PLACEMENT PROCEDURE, THE NURSE REPORTED THAT THE STENT HAD A HOLE AND A CREASE.</p> <p>THE PROCEDURE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE, WITH NO COMPLICATIONS TO THE PATIENT.</p> <p>SEVERAL ATTEMPTS HAVE BEEN MADE TO OBTAIN ADDITIONAL PATIENT AND EVENT INFORMATION. HOWEVER, NO FURTHER EVENT DETAILS HAVE BEEN MADE AVAILABLE TO BOSTON SCIENTIFIC TO DATE.</p>
3005099803-2011-04130	MALFUNCTION	12/02/2011	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A URINARY DIVERSION URETERAL STENT WAS USED IN A STENT REPLACEMENT PROCEDURE ON NOVEMBER 04, 2011. TWO DAYS LATER, THE PATIENT REPORTED PAIN. THE STENT WAS CHECKED BY THE NURSE, WHO NOTED THAT THE STENT WAS DETACHING ABOUT 23CM FROM THE PIGTAIL. REPORTEDLY, THE FOLEY CATHETER HAD BEEN TIED TO THE STENT USING SUTURES TO PREVENT THEM FROM SEPARATING. THE PHYSICIAN OPINED THAT IT WAS POSSIBLE THAT THE STENT AND THE FOLEY CATHETER HAD BEEN TIED TIGHTLY WITH SILKEN SUTURES TO FIX THEM. THE DETACHED PORTION OF THE STENT WAS PRESENT OUTSIDE THE BODY. THE PHYSICIAN WITHDREW THE PORTION THAT WAS PRESENT ON THE BODY SURFACE AND THE REST OF THE STENT WAS REMOVED FROM INSIDE THE PATIENT.</p> <p>THE PHYSICIAN REPLACED THE STENT WITH ANOTHER OF THE SAME TYPE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY STABLE.</p>

Report number	Event type	Date FDA received	Event description
3005099803-2012-00976	INJURY	03/13/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY (PCNL) PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE PHYSICIAN ATTEMPTED TO ADVANCE THE DILATATION SHEATH OVER THE BALLOON BUT THE BALLOON ADVANCED INTO THE PATIENT WITH THE SHEATH. THE BALLOON WAS INFLATED TO ABOUT 8 ATM WHEN THE SHEATH WAS PLACED OVER IT. THE BALLOON WAS NEVER INFLATED TO 17 ATM AND AT SOME POINT DURING THE PROCEDURE THE PHYSICIAN ASKED THE TECH TO DEFLATE THE BALLOON.</p> <p>THE PHYSICIAN WAS ABLE TO CONTINUE WITH THE PROCEDURE BUT AT THE END OF IT NOTED THAT THERE WAS EXTRAVASATION WITHIN THE PATIENT'S KIDNEY. THE EXACT NATURE OF THE EXTRAVASATION IS UNKNOWN AND THE PHYSICIAN REPORTED THAT IT MAY HAVE OCCURRED DUE TO THE BALLOON BEING PLACED TOO FAR IN THE PATIENT. THE PHYSICIAN PLACED A NEPHRO-URETERAL MALECOT CATHETER TO DRAIN THE KIDNEY.</p> <p>THE PHYSICIAN COMPLETED THE PROCEDURE WITH THIS DEVICE WITH NO FURTHER COMPLICATIONS. THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "STABLE."</p>
3005099803-2012-01418	MALFUNCTION	04/13/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING PREPARATION TO PLACE A PERCUFLEX URINARY DIVERSION URETERAL STENT, WHEN THE DEVICE WAS UNPACKED AND OPENED, IT WAS DISCOVERED THAT PART OF THE STENT WAS DETACHED.</p> <p>THE PROCEDURE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY <u>GOOD.</u></p>

Report number	Event type	Date FDA received	Event description
3005099803-2012-01819	INJURY	05/16/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY (PCNL) PROCEDURE ON APRIL 23, 2012.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE PHYSICIAN INFLATED THE NEPHROMAX BALLOON IN THE NORMAL MANNER BUT COULD NOT DEFLATE IT, THEREFORE, THE BALLOON GOT STUCK AND HAD TO BE SURGICALLY REMOVED. THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE "STABLE."</p> <p>ATTEMPTS TO OBTAIN ADDITIONAL INFORMATION HAVE BEEN UNSUCCESSFUL TO DATE.</p>
3005099803-2012-02065	MALFUNCTION	05/25/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING PREPARATION TO PLACE A PERCUFLEX URINARY DIVERSION URETERAL STENT, THE GUIDEWIRE COULD NOT BE INSERTED INTO THE STENT DUE TO A 3 CENTIMETER FLATTENING OF THE DEVICE NEAR THE HUB. THE PHYSICIAN CUT AND REMOVED THE FLATTENED PORTION OF THE DEVICE, AND THE PROCEDURE WAS COMPLETED WITH THIS DEVICE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY <i>¿GOOD.¿</i></p>
3005099803-2012-02066	MALFUNCTION	05/25/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING PREPARATION TO PLACE A PERCUFLEX URINARY DIVERSION URETERAL STENT, THE GUIDEWIRE COULD NOT BE INSERTED INTO THE STENT DUE TO A 3 CENTIMETER FLATTENING OF THE DEVICE NEAR THE HUB. THE PHYSICIAN CUT AND REMOVED THE FLATTENED PORTION OF THE DEVICE, AND THE PROCEDURE WAS COMPLETED WITH THIS DEVICE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY <i>¿GOOD.¿</i></p>

Report number	Event type	Date FDA received	Event description
3005099803-2012-02176	MALFUNCTION	06/08/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A DILATATION OF NEPHROSTOMY PROCEDURE ON MARCH 13, 2012. THERE WERE NO COMPLICATIONS DURING THE PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE BALLOON WAS INSERTED INTO THE PATIENT'S RENAL PELVIS. AFTER THE BALLOON WAS INFLATED TO 12 ATMOSPHERIC PRESSURE (ATM) , THEY TRIED TO ADVANCE THE SHEATH, HOWEVER THEY HAD DIFFICULTY ADVANCING THE SHEATH OVER THE BALLOON BECAUSE THE BALLOON INFLATED NON-UNIFORMLY. WITHOUT DEFLATING THE BALLOON, THE PHYSICIAN TRIED THE SECOND TIME TO ADVANCE THE SHEATH OVER THE BALLOON BUT COULD NOT. THE SHEATH WAS DESCRIBED AS STICKING TO THE BALLOON. THE CONDITION OF THE PATIENT FOLLOWING THE PROCEDURE WAS REPORTED AS GOOD.</p> <p>THE EVENT, AS REPORTED, DID NOT REFLECT AN MDR-REPORTABLE SCENARIO; HOWEVER, EVALUATION OF THE RETURNED DEVICE REVEALED AN MDR-REPORTABLE MALFUNCTION OF CATHETER SHAFT KINKED.</p>
3005099803-2012-02365	MALFUNCTION	06/28/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING PREPARATION TO PLACE A PERCUFLEX URINARY DIVERSION URETERAL STENT, WHEN THE DEVICE WAS UNPACKED, IT WAS FOUND TO BE DEFECTIVE. NO FURTHER EVENT DETAILS HAVE BEEN MADE AVAILABLE TO BOSTON SCIENTIFIC TO DATE.</p> <p>THE PROCEDURE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY <u>GOOD.</u></p>

Report number	Event type	Date FDA received	Event description
3005099803-2012-02670	INJURY	07/12/2012	<p>THIS REPORT PERTAINS TO ONE OF TWO DEVICES PLACED DURING THE SAME PROCEDURE ON AN UNKNOWN DATE. ASSOCIATED MANUFACTURER REPORT #3005099803-2012-02706 PERTAINS TO THE OTHER DEVICE.</p> <p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT THE PATIENT VISITED THE HOSPITAL DUE TO A FEVER, AND IT WAS DETERMINED THAT THE INDWELLING PERCUFLEX URINARY DIVERSION URETERAL STENT WAS COMPLETELY OCCLUDED. THE STENT WAS REMOVED AND REPLACED. SINCE THE STENT WAS OCCLUDED, A GUIDEWIRE COULD NOT BE INSERTED INTO THE STENT, SO IT WAS ADVANCED ALONG THE OUTSIDE OF THE STENT INTO THE TARGET LOCATION.</p> <p>THE PHYSICIAN BELIEVED THE STENT BECAME OCCLUDED DUE TO THE PATIENT'S CONDITION. THIS WAS THE EIGHTH STENT REPLACEMENT FOR THIS PATIENT.</p> <p>THE PATIENT'S CONDITION FOLLOWING THE PROCEDURE IS REPORTEDLY <u>GOOD</u>.</p>
3005099803-2012-02671	INJURY	07/09/2012	<p>THE DEVICE HAD BEEN PLACED IN THE PATIENT BODY FOR 29 DAYS. WHEN THE PHYSICIAN TRIED TO REMOVE THE DEVICE FROM THE PATIENT IN ORDER FOR REPLACEMENT, THE DEVICE BROKE AND DETACHED AT THE PIGTAIL AREA. THE DETACHED PIECE WAS APPROXIMATELY 5CM IN LENGTH. ALTHOUGH THE DETACHED PIECE REMAINED IN THE PATIENT BODY, IT WAS REMOVED FROM THE BODY USING URETHROSCOPE.</p> <p>WHEN THE DEVICE WAS VISUALLY CHECKED AFTER REMOVAL, SOME SMALL CRACKS WERE NOTICED AROUND SIDE HOLE OF DETACHED AREA.</p> <p>**THE DRAINAGE STENTS HAD BEEN REPLACED EVERY MONTH, AND THIS WAS THE NINTH REPLACEMENT FOR THIS PATIENT. THE DETACHED FRAGMENT WAS REMOVED, AND THE PATIENT CONDITION WAS REPORTED AS GOOD.</p>

Report number	Event type	Date FDA received	Event description
3005099803-2012-02672	INJURY	07/09/2012	<p>THE DEVICE HAD BEEN PLACED IN THE PATIENT BODY FOR 29 DAYS. WHEN THE PHYSICIAN TRIED TO REMOVE THE DEVICE FROM THE PATIENT IN ORDER FOR REPLACEMENT, THE DEVICE BROKE AND DETACHED AT THE PIGTAIL AREA. THE DETACHED PIECE WAS APPROXIMATELY 5CM IN LENGTH. ALTHOUGH THE DETACHED PIECE REMAINED IN THE PATIENT BODY, IT WAS REMOVED FROM THE BODY USING URETHROSCOPE.</p> <p>WHEN THE DEVICE WAS VISUALLY CHECKED AFTER REMOVAL, SOME SMALL CRACKS WERE NOTICED AROUND SIDE HOLE OF DETACHED AREA.</p> <p>**THE DRAINAGE STENTS HAD BEEN REPLACED EVERY MONTH, AND THIS WAS THE NINTH REPLACEMENT FOR THIS PATIENT. THE DETACHED FRAGMENT WAS REMOVED, AND THE PATIENT CONDITION WAS REPORTED AS GOOD.</p>
3005099803-2012-02706	INJURY	07/12/2012	<p>THIS REPORT PERTAINS TO ONE OF TWO DEVICES PLACED DURING THE SAME PROCEDURE ON AN UNKNOWN DATE. ASSOCIATED MANUFACTURER REPORT #3005099803-2012- 02670 PERTAINS TO THE OTHER DEVICE.</p> <p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT THE PATIENT VISITED THE HOSPITAL DUE TO A FEVER, AND IT WAS DETERMINED THAT THE INDWELLING PERCUFLEX URINARY DIVERSION URETERAL STENT WAS COMPLETELY OCCLUDED. THE STENT WAS REMOVED AND REPLACED. SINCE THE STENT WAS OCCLUDED, A GUIDEWIRE COULD NOT BE INSERTED INTO THE STENT, SO IT WAS ADVANCED ALONG THE OUTSIDE OF THE STENT INTO THE TARGET LOCATION.</p> <p>THE PHYSICIAN BELIEVED THE STENT BECAME OCCLUDED DUE TO THE PATIENT'S CONDITION. THIS WAS THE EIGHTH STENT REPLACEMENT FOR THIS PATIENT.</p> <p>THE PATIENT'S CONDITION FOLLOWING THE PROCEDURE IS REPORTEDLY GOOD.</p>

Report number	Event type	Date FDA received	Event description
3005099803-2012-03172	INJURY	08/02/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A BILATERAL PERCUTANEOUS NEPHROSTOLITHOTOMY (PCNL) PROCEDURE ON JULY 6, 2012.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE PHYSICIAN INFLATED THE BALLOON AND THE BALLOON WAS BANANA SHAPED. DUE TO THE CURVE OF THE BALLOON IT WAS DIFFICULT FOR THE PHYSICIAN TO PLACE THE RENAL SHEATH OVER IT. HE DID NOT ANTICIPATE THIS PROBLEM AND PUNCTURED PART OF THE KIDNEY. THE PROCEDURE WAS COMPLETED WITH THIS DEVICE (ONE ON EACH SIDE). IT WAS REPORTED THAT THERE WERE NO PT COMPLICATIONS AND THE PATIENT WAS FINE AFTER THE PROCEDURE.</p>
3005099803-2012-03938	MALFUNCTION	09/04/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING PREPARATION TO PLACE A PERCUFLEX URINARY DIVERSION URETERAL STENT, IT WAS DISCOVERED THAT THE DISTAL TIP OF THE DEVICE WAS ¿FLATTENED.¿</p> <p>THE PROCEDURE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY ¿GOOD.¿</p>
3005099803-2012-05130	MALFUNCTION	11/16/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A BILATERAL PERCUTANEOUS NEPHROSTOLITHOTOMY (PCNL) PROCEDURE ON AUGUST 27, 2012.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE NEPHROMAX WOULD NOT INFLATE TO ANY PRESSURE LEVEL. THE DIFFICULTY INFLATING OCCURRED DURING THE FIRST ATTEMPT TO INFLATE. IT WAS ALSO NOTED THAT THE CATHETER SHAFT WAS KINKED. UPON REMOVAL OF THE CATHETER THE PHYSICIAN SAW THAT THE BALLOON WAS BENT. THE BALLOON SHAPE WAS KINKED, NOT CURVED LIKE A BANANA. THE CONDITION OF THE PATIENT FOLLOWING THE PROCEDURE WAS REPORTED AS STABLE.</p>

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3005099803-2012-05935	INJURY	12/21/2012	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY (PCNL) PROCEDURE ON NOVEMBER 29, 2012. THE PATIENT AGE WAS REPORTED AS OVER 18 YEARS.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, THE PHYSICIAN INFLATED THE BALLOON TO 17 ATM AND WAITED 30 SECONDS. HE THEN REDUCED THE ATM TO 14 TO ADVANCE THE BALLOON, HOWEVER THE SHEATH WAS NOT SLIDING OVER THE BALLOON. ONCE THE BALLOON WAS DEFLATED TO ALLOW THE SHEATH TO GO OVER THE BALLOON, THE BALLOON HAD DIFFICULTY KEEPING ITS SHAPE. AS THE PHYSICIAN PUT PRESSURE TO SLIDE THE SHEATH OVER THE BALLOON, THE BALLOON WAS WEAKENING AND BOWING CAUSING THE BALLOON TO ADVANCE INTO THE RENAL PELVIS. THERE WAS NO PERFORATION HOWEVER THE BALLOON PUSHED INTO THE URETEROPELVIC JUNCTION (UPJ) CAUSING SIGNIFICANT BLEEDING DURING THE CASE AND EVENTUALLY CAUSED THE PATIENT TO GET A TRANSFUSION POST CASE. THERE WAS DIFFICULTY PLACING THE SHEATH OVER THE BALLOON WHICH CAUSED DIFFICULT ACCESS. THERE WERE NO KINKS NOTED ON THE CATHETER. THE SHEATH DIAMETER MATCHED THE DFU.</p> <p>THE PATIENT WAS ALREADY BOOKED TO STAY A NIGHT IN THE HOSPITAL.</p>
3005099803-2013-00014	DEATH	01/03/2013	<p>NOTE: THIS REPORT IS FOR ONE OF ELEVEN BOSTON SCIENTIFIC CORPORATION (BSC) DEVICES USED DURING THIS PROCEDURE. PLEASE REFERENCE MDR# 3005099803-2012-06224 FOR THE PARENT DEVICE.</p> <p>IT WAS REPORTED TO BSC THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED IN A PERCUTANEOUS NEPHROLITHOTOMY (PCNL) PERFORMED ON DECEMBER 7, 2012. DURING THE PROCEDURE, THE PHYSICIAN NOTED THAT THE PATIENT'S BLOOD PRESSURE DROPPED SUDDENLY. SHE BLED PROFUSELY. THE PATIENT, WHOSE AGE WAS REPORTED TO BE IN HER 50'S, HAD OTHER COMORBIDITIES (SPECIFICS UNKNOWN). SHE DIED THE FOLLOWING DAY, DECEMBER 8, 2012. THERE WERE NO REPORTED DEFECTS OR MALFUNCTIONS WITH THE BSC DEVICE.</p> <p>THE PHYSICIAN HAS NOT RESPONDED TO SEVERAL REQUESTS FOR ADDITIONAL INFORMATION.</p>

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3005099803-2013-01130	MALFUNCTION	03/08/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT DURING PREPARATION FOR A PCNL PROCEDURE, WHEN THE NEPHROMAX DEVICE WAS UNPACKED, THE LABEL OF THE DEVICE WAS NOTICED TO READ A 30FR SIZE, BUT THE DEVICE APPEARED TO BE A 24FR SIZE. REPORTEDLY, THE PHYSICIAN BELIEVED BOTH THE BALLOON AND SHEATH APPEARED SMALLER THAN WHAT WAS LABELED ON THE PACKAGE.</p> <p>THE PROCEDURE WAS COMPLETED WITH THIS DEVICE, WITH NO COMPLICATIONS TO THE PATIENT.</p>
3005099803-2013-01392	MALFUNCTION	03/15/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT THE SHEATH OF THE NEPHROMAX RENAL DILATOR BUCKLED DURING A PERCUTANEOUS NEPHROLITHOTOMY (PCNL) PROCEDURE. REPORTEDLY, THE SHEATH BUCKELED WHILE THE PHYSICIAN WAS ADVANCING THE BALLOON, THAT HAD BEEN INFLATED TO 20ATM. THE PRESSURE OF THE BALLOON WAS REDUCED AND THE PROCEDURE WAS COMPLETED WITH THIS DEVICE, WITH NO COMPLICATIONS TO THE PATIENT, WHOSE CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTEDLY <u>¿ FINE ¿</u>.</p>
3005099803-2013-01535	MALFUNCTION	03/22/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX BALLOON DILATATION CATHETER WAS USED DURING A PROCEDURE ON DECEMBER 4, 2012. THERE WERE NO COMPLICATIONS DURING THE PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE, IT WAS NOTICED THAT THE PRODUCT HAD A MELTED SHEATH, THEREFORE, THEY WERE UNABLE TO USE THE BALLOON. IT IS UNKNOWN IF THE PROBLEM OCCURRED INSIDE OR OUTSIDE THE PATIENT. THE CASE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE WITH NO PATIENT INJURY. THE CONDITION OF THE PATIENT FOLLOWING THE PROCEDURE WAS UNKNOWN.</p> <p>THE EVENT, AS REPORTED, DID NOT REFLECT AN MDR-REPORTABLE SCENARIO; HOWEVER, EVALUATION OF THE RETURNED DEVICE REVEALED AN MDR-REPORTABLE MALFUNCTION OF CATHETER SHAFT KINKED.</p>

Report number	Event type	Date FDA received	Event description
3005099803-2013-03006	MALFUNCTION	04/23/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A PERCUFLEX URINARY DIVERSION STENT SET WAS USED DURING A DEPLOYING STENT (URETEROCUTANEOUS FISTULA) PROCEDURE. ACCORDING TO THE COMPLAINANT, DURING UNPACKING OF THE OUTER PACKAGE OF THE DEVICE, THE CATHETER WHICH WAS CONTAINED IN ONE OF THE BOXES WAS FOUND TO BE DETACHED. THE PROCEDURE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE.</p> <p>THERE WERE NO PATIENT COMPLICATIONS REPORTED AS A RESULT OF THIS EVENT. THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE FINE.</p>
3005099803-2013-11947	MALFUNCTION	10/01/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX WAS USED DURING A PERCUTANEOUS NEPHROLITHOTRIPTY PROCEDURE PERFORMED ON JUNE 21, 2013.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE A GAP WAS NOTED BETWEEN THE BALLOON AND THE SHEATH RESULTING IN DIFFICULTY ADVANCING THE SHEATH OVER THE BALLOON, THUS THE ACCESS SHEATH DID NOT REACH INTO THE KIDNEY. THE PROCEDURE WAS COMPLETED WITH ANOTHER OF THE SAME DEVICE.</p> <p>THERE WERE NO PATIENT COMPLICATIONS REPORTED AS A RESULT OF THIS EVENT. THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE GOOD.</p> <p>NOTE:</p> <p>THE EVENT, AS REPORTED, DOES NOT CONSTITUTE AN MDR REPORTABLE EVENT; HOWEVER, THE RETURNED DEVICE REVEALED AN MDR REPORTABLE EVENT. THE RETURNED DEVICE REVEALED THAT THE SHEATH WAS DAMAGED WITH A SPLIT THAT SPIRALLED FROM TIP TO THE END. SEE H10 FOR FURTHER ADDITIONAL INFORMATION.</p>

Report number	Event type	Date FDA received	Event description
3005099803-2013-13893	INJURY	11/14/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX KIT WAS USED DURING NEPHROSTOLITHOTOMY PROCEDURE PERFORMED ON OCTOBER 22, 2013. ACCORDING TO THE COMPLAINANT, THE SHEATH OF THE NEPHROMAX WOULD NOT ADVANCE OVER THE BALLOON. ADDED FORCE WAS APPLIED TO ADVANCE THE SHEATH WHICH CAUSED THE KIDNEY TO BE TORN. THE PROCEDURE WAS COMPLETED WITH THIS DEVICE.</p> <p>THE PHYSICIAN DID NOT DO ANYTHING TO THE TORN IN THE KIDNEY.THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE STABLE.</p>
3005099803-2013-13894	INJURY	11/14/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX KIT WAS USED DURING NEPHROSTOLITHOTOMY PROCEDURE PERFORMED ON OCTOBER 22, 2013. ACCORDING TO THE COMPLAINANT, THE SHEATH OF THE NEPHROMAX WOULD NOT ADVANCE OVER THE BALLOON. ADDED FORCE WAS APPLIED TO ADVANCE THE SHEATH WHICH CAUSED THE KIDNEY TO BE TORN. THE PROCEDURE WAS COMPLETED WITH THIS DEVICE.</p> <p>THE PHYSICIAN DID NOT DO ANYTHING TO THE TORN IN THE KIDNEY.THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE STABLE.</p>
3005099803-2013-13895	INJURY	11/14/2013	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX KIT WAS USED DURING NEPHROSTOLITHOTOMY PROCEDURE PERFORMED ON OCTOBER 22, 2013. ACCORDING TO THE COMPLAINANT, THE SHEATH OF THE NEPHROMAX WOULD NOT ADVANCE OVER THE BALLOON. ADDED FORCE WAS APPLIED TO ADVANCE THE SHEATH WHICH CAUSED THE KIDNEY TO BE TORN. THE PROCEDURE WAS COMPLETED WITH THIS DEVICE.</p> <p>THE PHYSICIAN DID NOT DO ANYTHING TO THE TORN IN THE KIDNEY.THE PATIENT'S CONDITION AT THE CONCLUSION OF THE PROCEDURE WAS REPORTED TO BE STABLE.</p>

Report number	Event type	Date FDA received	Event description
3005099803-2014-01313	INJURY	02/28/2014	<p>IT WAS REPORTED TO BOSTON SCIENTIFIC CORPORATION THAT A NEPHROMAX KIT WAS USED DURING A PERCUTANEOUS NEPHROLITHOTOMY PROCEDURE.</p> <p>ACCORDING TO THE COMPLAINANT, DURING THE PROCEDURE AFTER THE NEPHROMAX DILATATION BALLOON WAS INFLATED THE PHYSICIAN HAD A HARD TIME INSERTING THE SHEATH OVER THE BALLOON AND HAD TO USE LOT OF FORCE TO GET IT IN. THE PHYSICIAN WAS ABLE TO COMPLETE THE PROCEDURE WITH THIS BALLOON, HOWEVER THE PHYSICIAN STATED THAT WHEN HE PUSHED THE BALLOON IN, THERE WAS SOME TEARING IN THE KIDNEY. DUE TO THE TEAR IN THE KIDNEY, THE PATIENT EXPERIENCED BLEEDING AND CONTRAST GOT INTO THE PATIENT AND CAUSED THE PATIENT TO GET SICK. THE PROCEDURE WAS COMPLETED WITH THIS DEVICE.</p> <p>THE PATIENT'S CONDITIONS WAS REPORTED TO BE FINE POST-PROCEDURE.</p>
(b) (6)	INVALID DATA	05/25/2011	AN EIGHT FRENCH NEPHROSTOMY CATHETER WAS PLACED IN THE RIGHT KIDNEY FOR RENAL CYST SCLEROSING. TWENTY ML OF DEHYDRATED ALCOHOL WAS INJECTED VIA CATHETER. THE PT DEVELOPED PAIN AFTER TEN MINUTES. APPROXIMATELY FIVE ML OF ISOVUE 300 WAS INJECTED VIA CATHETER. THE CATHETER WAS REMOVED. EXAMINATION OF CATHETER REVEALED A SPLIT.
(b) (6)	MALFUNCTION	08/10/2009	PATIENT WAS UNDERGOING ABDOMINAL EXPLORATION FOR REIMPLANTATION OF RIGHT URETER. DURING THE PROCEDURE THE NEPHROSTOMY TUBE TIP FRACTURED.
4100070000-2013-8067	MALFUNCTION	08/13/2013	<p>DURING A LEFT PERCUTANEOUS NEPHROLITHOTOMY, A NEPHROSTOMY BALLOON WAS BEING USED. WHILE INFLATING THE BALLOON WITH DILUTED CONTRAST, THE BALLOON BROKE. THE BALLOON WAS REMOVED AND NO FRAGMENTS WERE SEEN BEHIND BY SURGEON ON FLUOROSCOPIC IMAGING AND ON THE VIDEO MONITOR SCREEN.</p> <p>DEVICE #1 IS THIS A LABORATORY DEVICE OR LABORATORY TEST? NO</p>
(b) (6)	MALFUNCTION	03/12/2009	THIS DRAINAGE CATHETER WAS BEING PLACED IN A PATIENT'S CHEST AND AN AIR LEAK WAS FOUND AT THE TIME OF PLACEMENT. THE CATHETER WAS REPLACED AND THE PATIENT WAS NOT HARMED.
5200980000-2009-8015	MALFUNCTION	03/12/2009	THE CATHETER WAS BEING PLACED AS A NEPHROSTOMY TUBE FOR URINARY DRAINAGE. AFTER FORMING THE PIGTAIL AND LOCKING THE SUTURE, THE HOLE THAT THE SUTURE COMES OUT OF BEGAN TO LEAK. THE TUBE WAS REPLACED AND THE PATIENT WAS NOT HARMED.

Report number	Event type	Date FDA received	Event description
MW5017346	MALFUNCTION	09/03/2010	THE NEPHROSTOMY TUBE WAS FLUSHED AND THE INNER PLASTIC STYLET PUT INTO PLACE. THE TUBE WAS PLACED OVER A GUIDEWIRE INTO THE KIDNEY. DOCTOR WAS TRYING TO REMOVE THE INNER STYLET AND WIRE AND COULD NOT REMOVE IT WITH EASE. HE THEN PROCEEDED TO REMOVE THE STYLET AND WIRE, THE WIRE STARTED TO UNWIND AND THE STYLET WAS STRETCHING. EVENTUALLY THE STYLET AND WIRE WERE REMOVED.
MW5018208	DEATH	11/16/2010	PT TREATED AT ST JOHN HOSPITAL FOR BACTERIAL INFECTION IN UTERUS. EXCESSIVE VAGINAL BLEEDING. BLOOD TRANSFUSION. TUBE WAS PLACED IN BACK TO DRAIN BACTERIA. PT NEEDED TO HAVE TUBE REMOVED BUT PHYSICIANS KEPT PUTTING IT OFF. THEY SAID SHE NEEDED REFERRALS AND THEN HER PHYSICIAN WAS OUT OF TOWN. FLUID BUILT UP IN BACK AND HEART STOPPED ON THE WAY TO HOSPITAL. PT WAS RESUSCITATED TEN TIMES AND HOSPITAL TRIED DIALYSIS, BUT PT DIED. THE MEDICAL EXAMINER SAYS THE CAUSE OF DEATH IS PENDING. SON BELIEVES THE HOSPITAL AND THE PHYSICIANS CAUSED HIS MOTHER'S DEATH.
MW5020464	INJURY	05/02/2011	BALLOON ON NEPHROMAX NEPHROSTOMY CATHETER RUPTURED IN RIGHT URETER DURING PROCEDURE. DILATION HAD BEEN OBTAINED AS DESIRED AND STONE WAS SUCCESSFULLY REMOVED. SURGEON WAS ABLE TO REMOVE ALL REMNANTS AS WELL AS STONE THROUGH ORIGINALLY PLANNED CYSTOSCOPY. 45-0684-2011-003.
MW5020554	MALFUNCTION	05/09/2011	PT HAD DIMINISHED URINE OUTPUT 10 DAYS AFTER IMPLANTATION OF A LEFT NEPHROSTOMY CATHETER. RADIOLOGIC REPORT IDENTIFIED CATHETER HAD BEEN WITHDRAWN FROM ITS EXPECTED POSITION AND A SMALL FRAGMENT WAS IN THE RENAL SPACE. ATTEMPTS WERE MADE TO PERCUTANEOUSLY REMOVE THE FRAGMENT. THE ITEM WAS INTENTIONALLY RETAINED. DATES OF USE: 4/2/2011 - 4/12/2011. DIAGNOSIS OR REASON FOR USE: HYDRONEPHROSIS.
MW5030615	MALFUNCTION	06/17/2013	ACCORDING TO THE RN, THE PT ARRIVED IN THE OPERATING ROOM SUITE WITH THE NEPHROSTOMY TUBE ALREADY PLACED. I SPOKE WITH DR WONG, AND THIS PT HAD A PREVIOUS PERCUTANEOUS NEPHROLITHOTOMY WHEN THIS NEPHROSTOMY TUBE WAS PLACED. DR WONG TRIED TO REMOVE THE TUBE IN THE OFFICE AND WAS NOT SUCCESSFUL. ON JUN 13, 2013 THIS PT WAS BROUGHT BACK TO SURGERY TO REMOVE THE NEPHROSTOMY TUBE AND A SECONDARY LOOK AND SEE PERCUTANEOUS NEPHROLITHOTOMY. WHEN REMOVING THE NEPHROSTOMY TUBE PART OF THE CATHETER BROKE OFF IN THE PT. DR WONG LOOKED FOR THE MISSING PIECE. THIS PT IS MORBIDLY OBESE AND THEY NEED TO BRING HIM BACK TO SURGERY. THIS PRODUCT WAS PLACED ON AN UNK DATE SO NO LOT NUMBER IS AVAILABLE.