B. Braun Medical Inc.
901 Marcon Blvd.
Allentown, PA 18109
Telephone: (610)-266-0500
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July 20, 2018

URGENT MEDICAL DEVICE CORRECTION – RECALL NOTIFICATION

Dear Valued Customer:

B. Braun Melsungen AG (BBMAG), manufacturer of the Perifix Catheter Connector, which is a component of various regional anesthesia convenience kits manufactured and distributed by B. Braun Medical Inc. (BBMI), has notified BBMI that the connector may not remain closed during use. In some cases this has led to leakage or disconnection of the catheter from the Perifix Catheter Connector.

As a result of this issue, B. Braun is issuing a voluntary medical device recall of the Perifix Catheter Connector, which is distributed as a single sterile packaged unit, and bulk non-sterile packaged units, and in various sterile anesthesia procedural trays. **This recall is being executed as a correction and not a product removal**; please read this letter in its entirety as it provides you with important information regarding the continued safe use of this product.

Please reference **Attachment 1** for the full list of affected product that utilized one of the below affected components:

Component Number:	Component Description:	Distribution Date Range:
8451290	PERIFIX CATH.CON. 2.0 G20-G24 YELLOW	Since October 2017
8451699	PERIFIX CATH.CON. 2.0 G19 TRANSLUCENT	
8456216	PERIFIX CATH.CONN. NL 19G TRANSLUCENT	
8456224	PERIFIX CATH.CONN. NL G20-G24 YELLOW	
8455783	CONTIPLEX C SET US, SH, 30°,25Gx7 1/2"	
8455784	CONTIPLEX C SET US, SH,15°,25Gx7 1/2"	

Perifix Catheter Connector is a connection device used by clinicians to provide various anesthetic and fluid administration devices with a single, common access point to a catheter for delivery of anesthetics. The connector is used in conjunction with the catheter for continuous administration of anesthetic fluids.

Reason for the recall:
BBMAG has become aware that Perifix Catheter Connectors may not stay closed during use and in some cases leakage or disconnection of the catheters from the Perifix Catheter Connector has been observed. While no serious injuries to patients, users, or third parties have been reported to date, there is a possibility of contamination of the catheter or delay of anaesthesia of different severity.

Risk to Health:
If the catheter connector leaks or opens and another connector is not readily available as a replacement, the clinician may remove the catheter and convert the analgesia to systemic analgesia or the anesthesia to general anesthesia. This could expose the patients (or fetus in the case of labor/C-section) to the risks associated with the new procedure. In addition, if the catheter disconnects from the connector it may become contaminated, with the possibility of infection. To date there have been no reported serious injuries to patients, users, or third parties associated with the identified issue.

Actions to be taken by the Customer/User:

1. Review this Medical Device Correction Notification in its entirety and ensure that all users of the mentioned products in your organization and other concerned persons are informed about this Medical Device Correction – Recall Notification. If you are a distributor, please forward this recall notification to your customers.
2. For continued safe use of the Perifix Catheter Connector as part, review and follow the instructions described in **Attachment 2**, "Step-by-Step Correction of the Perifix Catheter Connector using Label".
3. For continued safe use of the Perifix Catheter Connector, review and follow the instructions described in **Attachment 3,** "Step-by-Step Correction of the Perifix Catheter Connector using Cloth/Silk Medical Tape". This method can be applied to the Perifix Catheter Connector in **Procedural Trays**.
4. Utilizing the attached "Medical Device Correction – Recall Notification Acknowledgement" form, please acknowledge that you have received and reviewed this information.
5. Return the completed "Medical Device Correction – Recall Notification Acknowledgement" form to B. Braun Medical Inc. Quality Assurance department by faxing or e-mailing the form within two (2) weeks of receipt of this notice. It is important this form is returned so B. Braun Medical Inc. can meet regulatory requirements of the United States Food and Drug Administration.
6. If you have any affected products as identified in attachment 1 that you choose to return instead of following the continued safe use instructions within Attachment 2 and 3, please identify on the "Medical Device Correction – Recall Notification Acknowledgement" form that you will be returning the product and submit the form to BBMI Quality Assurance Department. A BBMI Customer Support Representative will contact you to provide instructions for handling the affected product and arrange for return to BBMI. A credit will be given due to no replacement product at this time.

Actions being taken by B. Braun:
B. Braun is actively working to implement a corrective action that assures secure closure of the Perifix Catheter Connector. BBMI will provide a communication to customers on the status of this corrective action by end of September 2018.

Should you experience any adverse reactions or quality problems with the product, please report the event promptly to BBMI by contacting our Medical Affairs Department at 1-800-854-6851.

Additionally, any adverse reactions or quality problems experienced during the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail** or **Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This voluntary medical device correction is being conducted with knowledge of the U.S. Food and Drug Administration (FDA).

For Canadian customers, any adverse reactions experienced with the use of this product may also be reported to the Health Products and Food Branch Inspectorate at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/md_prob_rep-rap_incident_im-eng.php.

We apologize for the inconvenience to you, your patients and your facility and appreciate your understanding of our commitment to provide safe and effective products for both health care professionals and patients.

Sincerely,

Bridseida Cruz
Director, Quality
B. Braun Medical Inc.

Enclosures:
Attachment 1 - 3
Medical Device Correction Acknowledgement Form

B|BRAUN

ATTACHMENT 1
Affected Items Utilizing Components

Product Catalog Number:	Product Description:
331640	CONTI TUOHY ULTRA 360 2 IN CONT PNB SET
331641	CONTI TUOHY ULTRA 360 4 IN CONT PNB SET
331642	CONTI TUOHY ULTRA 360 6 IN CONT PNB SET
331670	CNBFX350O CONTIPLEX CONT NERVE BLOCK
331672	CNBFX350C CONTIPLEX CONT NERVE BLOCK
331673	CONTIPLEX TUOHY ULTRA 2 IN CONT. PNB SET
331674	CONTIPLEX TUOHY ULTRA 4 IN CNB400TU, LF
331676	CONTIPLEX TUOHY ULTRA 6 IN CNB600TU
331691	CNB200T CONTIPLEX TUOHY SET 2 IN
331693	CONTIPLEX TUOHY SET, 18GX4", 1.3X100MM
331694	CONTIPLEX TUOHY SET, 18GX6", 1.3X150MM
331695	CONTIPLEX TUOHY SET, 18GX11/2X 1,3X40MM
331697	CNB200S CONTIPLEX INSULATED TUOHY NDL
331698	CNB400S 18GA X 4 CONTIPLEX STRAIGHT NDL
331701	CNB200TK CONTIPLEX CONT NERVE BLOCK
331706	CNB400TK CONTIPLEX CONT NERVE BLOCK
331711	CONT FX CNB SET OT W/STYLET 17G X 3.5 IN
331714	CONT FX CNB SET CT W/STYLET 17G X 3.5 IN
331751	CONT STIM FULL KIT W/2 IN INSUL TUOHY
331752	CONT STIM FULL KIT W/4 IN INSUL TUOHY
331754	CONT STIM BASIC KIT W/4 IN INSUL TUOHY
331755	SCNB2TK CONT STIM W/2 INCH INSUL TUOHY
331756	SCNB4TK CONT STIM W/4 INCH INSUL TUOHY
331757	CONT STIM BASIC KIT W/2 IN INSUL TUOHY
331758	CONT STIM BASIC KIT W/4 IN INSUL TUOHY
331761	CONTIPLEX ECHO CT W/2" TUOHY ULTRA SET
331762	CONTIPLEX ECHO OT W/4" TUOHY ULTRA SET
331763	CONTIPLEX ECHO CT W/4" TUOHY ULTRA SET
331764	CONTIPLEX ECHO OT W/2" TUOHY ULTRA SET
331766	CONTI ECHO OT W/4IN TUOHY ULTRA 360 SET
331767	CONTI ECHO CT W/2IN TUOHY ULTRA 360 SET
331768	CONTI ECHO CT W/4IN TUOHY ULTRA 360 SET
331771	CNB350TUEC CONT ECHO CLSD TIP NERVE BLK
332075	CE17TKFCY 17GA SAFETY TUOHY NEEDLE TRAY
332077	CE17TBFC EPIDURAL BASIC TRAY 17G TOUHY
332078	CE17TKFCPS EPIDURAL FULL TRAY
332079	CE17TKFC EPIDURAL TRAY W/ 17GA TUOHY
332080	CE17TKFSA FULL TRAY W/17G TUOHY 19G SPRW
332081	CE18TKST CONT EPID W/SOFT TIP
332082	CE17TKST CONT EPID W/SOFT TIP

Product Catalog Number:	Product Description:
332084	CE18HKST CONT EPID 20G SOFTIP
332086	CE17TKF PERIFIX CONTIN. EPIDURAL TRAY
332087	CE17TKFPS PERIFIX FX CONT. EPID TRAY-LF
332093	CE17TKFSDT EPID TRAY W/17GA FIXED WING
332095	CE17TKFSDTD EPID TRAY W/17GA FIXED WING
332096	CE17TKFMHDT 17 GA X 4 FULL EPID KIT
332097	CE17TKFCS CONT EPID TRAY W/17G TUOHY-LF
332098	CE17TKFS EPIDURAL TRAY
332124	CONTIPLEX CONT. 2" TUOHY ULTRA PNB TRAY
332127	CNB200TKU NON-STIM CATH FULL KIT
332128	CNB400TKU NON-STIM CATH FULL KIT
332129	CONTIPLEX CONT 4 IN TUOHY ULTRA PNB TRAY
332132	CONT FX CNB TRAY, CT W/STYLET
332133	CONT FX CNB TRAY, OT W/STYLET
332142	CONTI CONT 2inTUOHY ULTRA 360 PNB TRAY
332143	CONTI CONT 4inTUOHY ULTRA 360 PNB TRAY
332170	CNB400TU3KUE 18GX4 CONTI THY ULTRA 360
332200	CE18T CONT EPIDURAL SET
332201	CE18TIN CONT EPIDURAL SET LF
332202	CE17T CONT EPIDURAL SET
332204	CE17TO CONT EPIDURAL SET LF
332206	CE18HKCD CONT EPIDURAL TRAY
332209	CE18TKCDLS CONT EPIDURAL TRAY
332210	CE18H CONT EPIDURAL SET
332211	CE18TKCD CONT EPIDURAL TRAY
332212	CE17TKCDLS CONT EPIDURAL TRAY
332215	CE18TKDP CONT EPID/DURAPREP
332216	CE18TKPS CONT EPIDURAL TRAY (LF)
332217	CE18TKCD10L 18GA TUOHY/10CC GLAS
332219	CE18TBLS CONT EPIDURAL TRAY
332220	CE18TK ACCU-BLOC PERIFIX KIT
332221	CE17TK CONT EPIDURALTUOHY
332222	CE18TB CONT EPIDURAL TRAY
332223	CE18HB CONT EPIDURAL HUSTEAD
332224	CE17TB CONT EPIDURAL TUOHY
332229	CE17TKCD CONT EPIDURAL ANESTHESIA KIT
332230	CE18HK ACCU-BLOC PERIFIX KIT
332231	CE18HKPS CONTIN. EPIDURAL TRAY
332233	CE17TKPS CONTINUOUS EPIDURAL ANES TRAY
332234	CE17TF PERIFIX FX CONTIN. EPIDURAL SET
332235	CE17TOD CONT EPIDURAL TRAY LF
332236	CE18TOD CONT EPIDURAL TRAY LF
332238	CE17TFC CONTINUOUS EPID SET W/17G TUOHY
332239	CE18TBPS CONT EPIDURAL TRAY
332242	CE17TB19C CONT EPIDURAL TRAY
332262	CE17TK19CDP CONT EPIDURAL TRAY
332264	CCE18HK10L CONT EPIDURAL TRAY
332266	CE18TKY 18GA SAFETY TUOHY NEEDLE TRAY

Product Catalog Number:	Product Description:
332282	CE18TKO PERIFIX ONE EPIDURAL FULL TRAY
332283	CLAMP STYLE CATHETER CONNECTOR 20GA- LF
332285	CLAMP STYLE CATH. CONNECTOR 18-19 GA- LF
332290	CEP18TKO CONT. EPIDURAL PEDIATRIC KIT
332291	CEP18TO CONT. EPIDURAL PEDIATRIC SET
332292	EPID PAED FULL KIT 24GA CT NG CATH LF
332293	CEP20TO CONT EPID PEDIATRIC SET
332294	CE18TO PERIFIX ONE CONT EPIDURAL SET
332301	18 GA. TUOHY TRAY - NO TEST DOSE
332302	18GA. TUOHY TRAY - NO TEST DOSE CE18HDCD
332303	17GA. TUOHY TRAY - NO TEST DOSE CE17TDFC
332304	CE18TDST WITHOUT TEST DOSE
332305	CE18TKCD10L WITHOUT TEST DOSE
332306	CE17TD WITHOUT TEST DOSE
332307	CE17TDFCS WITHOUT TEST DOSE
332308	CE18TDCDLS WITHOUT TEST DOSE
332309	CE18TDPS WITHOUT TEST DOSE
332600	GOVCE18TK ACCU-BLOC PERIFIX KIT
332602	GOVCE17TKFC EPIDURAL TRAY W/ 17GA TUOHY
332604	GOVCE18TKST CONT EPID W/SOFT TIP
332605	GOVCE18HK ACCU-BLOC PERIFIX KIT
332610	GOVCE17TK CONT EPIDURALTUOHY
332614	GOVES1827K SPINAL/EPIDURAL TRAY (LF)
332615	GOVCE17TKFCS CONT EPID TR W/17G TUOHY-LF
333165	ES1725K SPINAL/EPIDURAL TRAY
333182	ES1827QK ESPOCAN COMBINED 27GA
333192	ES1827K SPINAL/EPIDURAL TRAY (LF)
333193	ESPOCAN SPINAL/EPID TRAY W/ 18G TUOHY
333194	ES1827KDS SPINAL/EPIDURAL FULL KIT
333196	ES1725KFX ESPOCAN SPINAL/EPID. TRAY
333197	NES1727KFX W /17GA TUOHY 19GA SPRW OT
333501	EC19O 19G X 100CM CATHETER OPEN TIP
333511	EC19C 19G X 100CM CATHETER CLOSED
333512	EC19CF 19G X 100CM CATH CLOSED TIP LF
333514	EC19OF SPRINGWOUND 19G EPID CATHETER
333520	EC20O 20G X 100CM CATH OPEN TIP LF
333521	EC20CST 20G CLSD SOFT TIP CATH
333532	EC20CS EPIDURAL CATHETER
333538	EC24CPNG PEDIATRIC CATH CLSD TIP NG-LF
333539	EC20CPNG, 20G NEXT GENERATION PED CATH
333540	EC20C 20G X 100CM CATH CLOSED
333541	EPID. CATH. NG, 20GA. CLOSED TIP-LF
333696	CONTIPLEX C CATHETER SET, 20 GA.
333697	CONTIPLEX C 30 DEGREE
339114	ES1725KFXN ESPOCAN SPINAL/EPID TRY NRFIT
339115	ES1827KN SPINAL/EPIDURAL TRAY NRFIT
339120	EC19CFN 19G X 100CM CATH CLOSE TIP NRFIT
339121	EC20CN 20G X 100CM CATH CLOSED NRFIT

Product Catalog Number:	Product Description:
339163	PCC1900N 19GA CATH CONN NRFIT
339164	PCC2000N 20GA - 24GA CATH CONN NRFIT
339183	CE17TKN CONT EPIDURALTUOHY NRFIT
339184	CE17TKFN PERIFIX CONT EPID TRAY NRFIT
339185	CE17TKFSN EPIDURAL TRAY NRFIT
339186	CE17TKFCN EPID TRAY W/ 17GA TUOHY NRFIT
339187	CE17TKFCSN CON EPI TRAY W/17G TUHY NRFIT
339188	CE18TKN ACCU-BLOC PERIFIX KIT NRFIT
339189	CE18HKN ACCU-BLOC PERIFIX KIT NRFIT
339190	CE18TKON PERIFIX ONE EPID FULL TRY NRFIT
339191	CE18TKSTN CONT EPID W/SOFT TIP NRFIT
339194	CEP20TON CONT EPID PEDIATRIC SET NRFIT
530024	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
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Product Catalog Number:	Product Description:
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552103	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
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Product Catalog Number:	Product Description:
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555091	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555098	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
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555110	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
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555215	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555217	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
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555296	DESIGN OPTIONS® PAIN MANAGEMENT TRAY

Product Catalog Number:	Product Description:
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555325	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555340	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555357	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555374	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555392	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555421	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555422	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555438	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555449	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555450	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555482	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555483	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555484	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555498	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555525	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555551	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555569	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555578	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555579	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555601	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555647	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555660	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555704	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555706	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555757	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555779	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555854	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555857	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555884	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555904	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555931	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555951	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
555987	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570180	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570204	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570205	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570207	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570218	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570222	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570231	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570234	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570241	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570245	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570246	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570249	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570257	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570259	DESIGN OPTIONS® PAIN MANAGEMENT TRAY

Product Catalog Number:	Product Description:
570265	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570269	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570272	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570282	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570283	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570285	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570287	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
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570289	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570290	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570292	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570295	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570297	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
570301	DESIGN OPTIONS® PAIN MANAGEMENT TRAY
8451699N	BULK NONSTERILE PERIFIX CATHETER CONN.

ATTACHMENT 2

Step-by-Step Correction of the Perifix Catheter Connector using Label

1. Ensure the Perifix Catheter Connector is in the fully open position and insert catheter per IFU.

2. Remove one of the labels from the kit as per normal procedure. Instead of placing the label on the catheter or the filter, place the dotted line of the label on the side of the connector. Line the edge of the label with the proximal end of the connector (see figures 1-3).

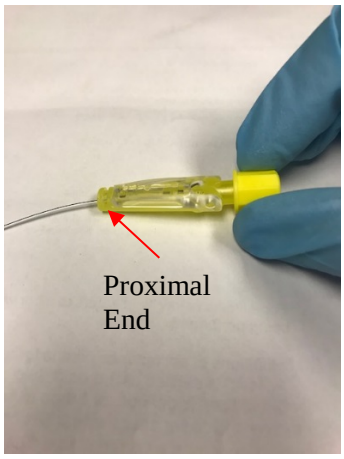

Figure 1

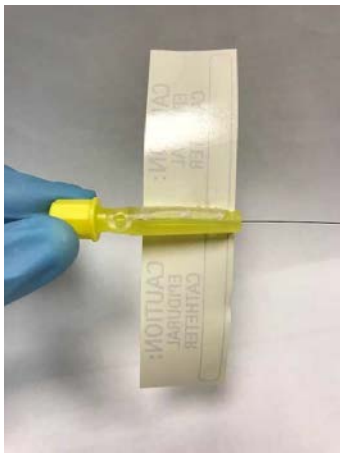

Figure 2

Figure 3

3. Fold the label in half, creating the usual "flag" and secure label onto the connector.

Figure 4

Figure 5

ATTACHMENT 3

Step-by-Step Correction of the Perifix Catheter Connector using Cloth/Silk Medical Tape

1. Ensure the Perifix Catheter Connector is in the fully open position and insert catheter per IFU.

2. Cut a 2.5 inches long piece of cloth/silk medical tape.

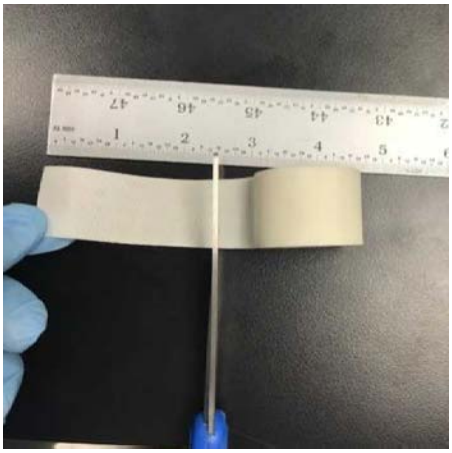

Figure 1

3. Wrap the cut piece of cloth/silk tape around the distal end of the catheter connector. Make sure the cloth tape is secure against the sides of the connector. The 2.5 inches piece of cloth tape should wrap fully around the catheter connecter approximately two times.

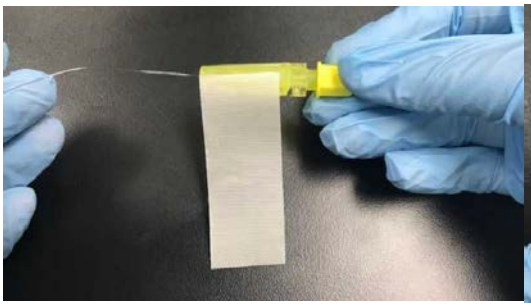

Figure 2

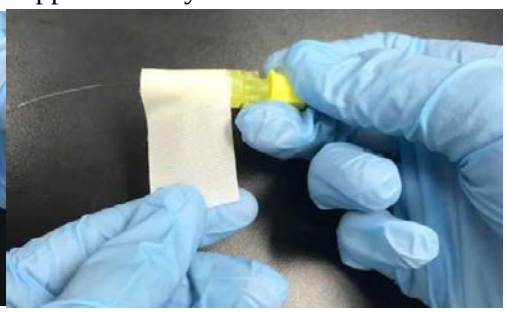

Figure 3

Top View

Figure 4

Bottom View

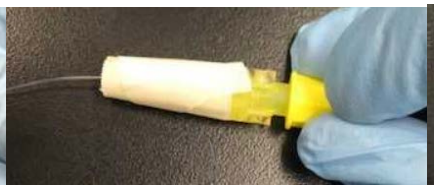

Figure 5

Side View

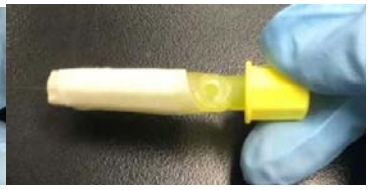

Figure 6

***Note:** This method can be applied to the Perifix Catheter Connector in Procedural Trays.