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SISK HEALTHCARE T A SYNAPSE MEDICAL
5 SANTRY HALL INDUSTRIAL ESTATE
Dublin 11
IE

Contact Category	
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<input type="checkbox"/>	2 nd Contact
<input type="checkbox"/>	3 rd Contact

URGENT VOLUNTARY MEDICAL DEVICE RECALL
IMMEDIATE ACTION REQUIRED
MORPHEUS™ SMART PICC CT

March 11, 2015

AngioDynamics, the manufacturer of Morpheus™ Smart PICC CT Kits is conducting a medical device recall on specific kits/lots of power injectable PICC catheters. Based on a review of complaints, AngioDynamics has determined that the power injectable PICC catheters contained in the kits exhibit a higher than anticipated rate of extension tube fracture or leakage. Use of the PICC catheters that are subject to this recall may have an increased incidence of extension tube fractures or leakage which would require replacement of the PICC catheter.

To date, no patient injuries have been reported to AngioDynamics as a result of this issue. This recall will need to be carried out to the end user level.

AngioDynamics began distributing these specific kits/lots on March 19, 2012.

Our records indicate that your organization has received one or more of the products subject to this recall. Please refer to the Reply Verification Tracking Form, included with this Recall Notification, for the details on the affected product provided to your specific organization. (Product Descriptions, Product Numbers, Ref./Catalog Numbers, Lot/Batch Numbers, Quantity Shipped, Date Shipped, and Sales Order Number)

NOTE: The Ref./Catalog numbers and lot/batch numbers are located on both the lid sealed tray/pouch label and box label. No other products/lots are affected.

1. Actions to be taken:

- Immediately remove the recall product from your inventory (whether in Inventory, Hold Cage, Unprocessed Returns or ANY other location).
- Segregate this product in a secure location for return to AngioDynamics, Inc.
- Prepare a Recall Notification for delivery to any/all locations to which you have distributed affected product.



2. Complete and return the Reply Verification Tracking Form.

- If affected product is located in your institution, please call AngioDynamics, Inc. Customer Service at 1-800-772-6446 between 8:00 a.m. and 7:00 p.m. (Monday – Friday: Eastern Standard Time) to obtain a replacement or credit for your returned product.
- Promptly complete, sign and return the enclosed Reply Verification Tracking Form (even if you do not have any product to return); following the directions on this page and the Reply Verification Form.

Fax Reply Verification Tracking Form:

Attn: Morpheus™ Smart PICC CT Recall Coordinator

Fax number 1-800-782-1357

Email Reply Verification Tracking Form:

rdenino@angiodynamics.com or sbaxter@angiodynamics.com

3. Package and Return the Recalled Product.

- Package any product that is being returned in an appropriate shipping box.
- Affix enclosed shipping label to the outside of the shipping box.
- Please use our FedEx Account Number (460072263) to return this package via second day delivery.
- Write the RMA number on the box(s). (Provided on the Recall Verification Tracking Form)
- Seal the box and return to:

AngioDynamics, Inc.

603 Queensbury Avenue

Queensbury, NY 12804

Attn: Morpheus™ Smart PICC CT Recall Coordinator

We regret any inconvenience that this action may have caused and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from AngioDynamics, Inc. This medical device recall action is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Sincerely,

A handwritten signature in black ink, appearing to read "MD", with a long horizontal flourish extending to the right.

Michael Duerr

Director Quality Compliance

Tel: 1-518-742-4571

Fax: 1-800-782-1357



CUSTOMER ACCOUNT NO: 310071
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 5 SANTRY HALL INDUSTRIAL ESTATE
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Contact Category	
<input checked="" type="checkbox"/>	Initial Contact
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REPLY VERIFICATION TRACKING FORM
URGENT VOLUNTARY MEDICAL DEVICE RECALL
IMMEDIATE ACTION REQUIRED
Morpheus™ Smart PICC CT

Instructions: Complete, Sign and Return:
 Attn: Morpheus™ Smart PICC CT Recall Coordinator
 Fax: **1-800-782-1357**
 Email: rdenino@angiodynamics.com or sbaxter@angiodynamics.com

Return Products via FedEx (Account #460072263 two day delivery) to:
 AngioDynamics, Inc.
 603 Queensbury Avenue
 Queensbury, NY 12804
 Attn: Morpheus™ Smart PICC CT Recall Coordinator

Note: Please Return Immediately Upon Completion
 Only products/lots identified below are affected by this recall action.

Morpheus™ Smart PICC CT							
Product Description	Product No.:	Ref./ Catalog No.:	Batch/ Lot No.	Qty Shipped	Date Shipped	Sales Order Number	Qty to be Returned
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W	H787121028025	12102802	594377	20	6/11/2013	1036596	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W	H787121028025	12102802	590988	5	6/24/2013	1041711	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W	H787121028025	12102802	601006	5	11/4/2013	1097752	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	608521	1	2/12/2014	5011281	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	608914	2	2/12/2014	5011281	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	608914	3	2/28/2014	5011653	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	609436	5	2/28/2014	5011653	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	4745529	4	8/29/2014	5016847	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	4799505	3	9/18/2014	5017396	
MOR 4F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028025	12102802	4815216	3	11/29/2014	5019229	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	574070	15	7/30/2012	903613	

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MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	574677	100	8/30/2012	917033	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	582004	100	11/27/2012	953818	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	591117	150	2/26/2013	991575	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	588079	50	2/26/2013	991575	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	595358	10	7/15/2013	1050314	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	597964	40	8/29/2013	1069286	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	599457	100	8/29/2013	1069286	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	601490	40	11/27/2013	1108158	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W	H787121028035	12102803	605525	60	11/27/2013	1108158	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	609442	1	2/28/2014	5011653	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	610336	9	2/28/2014	5011653	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4718127	14	5/31/2014	5014502	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4725175	10	8/29/2014	5016847	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4770415	10	8/29/2014	5016847	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4726571	9	9/18/2014	5017396	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4743309	1	9/18/2014	5017396	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4743309	15	11/29/2014	5019229	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4778649	3	1/23/2015	5020485	
MOR 5F SINGLE LUMEN CT PICC FULL SHORT W PG	H787121028035	12102803	4778649	10	2/10/2015	5021026	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028055	12102805	582011	5	11/27/2012	953818	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028055	12102805	585748	10	1/16/2013	973510	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028055	12102805	585259	20	2/4/2013	982134	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028055	12102805	589447	170	2/26/2013	991575	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	608930	12	2/28/2014	5011653	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	4770406	6	8/29/2014	5016847	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	4812044	7	11/29/2014	5019229	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	4812046	2	1/7/2015	5020164	

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MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	4815209	2	1/23/2015	5020485	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	4815209	1	2/10/2015	5021026	
MOR 5F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028055	12102805	4834717	1	2/10/2015	5021026	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	571268	95	4/30/2012	850090	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	572095	20	8/30/2012	917033	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	574163	40	8/30/2012	917033	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	579410	30	11/27/2012	953818	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	580583	50	11/27/2012	953818	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	591211	90	2/26/2013	991575	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	588085	90	2/26/2013	991575	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028065	12102806	592778	50	11/27/2013	1108158	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028065	12102806	609434	12	2/28/2014	5011653	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028065	12102806	4782398	4	10/1/2014	5017632	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028065	12102806	4782398	3	11/7/2014	5018662	
MOR 6F DUAL LUMEN CT PICC FULL SHORT WIRE PG	H787121028065	12102806	4782398	4	11/29/2014	5019229	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	574181	10	5/29/2012	878054	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	574236	70	6/28/2012	878054	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	577294	120	7/20/2012	878054	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	585471	65	11/27/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	580118	15	11/28/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	583854	30	11/28/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	587163	10	12/14/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	587163	5	1/16/2013	973510	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	588701	25	1/16/2013	973510	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	589451	20	2/4/2013	982134	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	591524	40	2/26/2013	991575	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	589451	60	2/26/2013	991575	

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MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	592805	150	3/26/2013	991575	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	588701	25	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	589451	20	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	592805	100	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	598284	10	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	597970	15	11/27/2013	1108158	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	600180	50	11/27/2013	1108158	
MOR 7F DUAL LUMEN CT PICC FULL SHORT WIR	H787121028075	12102807	603515	35	11/27/2013	1108158	
MOR 5F SINGLE LUMEN CT PICC FULL LONG WIRE PG	H787121028115	12102811	4768098	4	11/29/2014	5019229	
MOR 6F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028145	12102814	594340	4	11/29/2014	5019229	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	568018	70	3/21/2012	837530	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	568691	50	4/30/2012	864585	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	568691	150	5/29/2012	878054	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	576712	150	7/20/2012	878054	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	576712	50	8/30/2012	917033	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	578492	30	8/30/2012	917033	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	578492	25	11/27/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	580119	110	11/27/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	580882	50	11/27/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	580882	20	11/28/2012	953818	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	590118	125	2/26/2013	991575	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	592806	125	3/26/2013	991575	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	590118	25	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	592806	10	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	592807	50	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	593050	10	8/29/2013	1069286	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	595079	60	8/29/2013	1069286	



MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE	H787121028155	12102815	599465	30	11/27/2013	1108158	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	595079	3	2/12/2014	5011281	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	599465	1	2/12/2014	5011281	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	599465	5	2/28/2014	5011653	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	603516	10	2/28/2014	5011653	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	603968	8	2/28/2014	5011653	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	605540	17	2/28/2014	5011653	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4722458	8	5/31/2014	5014502	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	605540	3	5/31/2014	5014502	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4722458	13	8/29/2014	5016847	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4783018	10	8/29/2014	5016847	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4722458	15	11/29/2014	5019229	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4722458	3	1/7/2015	5020164	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4722458	11	1/23/2015	5020485	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4780792	1	1/23/2015	5020485	
MOR 7F DUAL LUMEN CT PICC FULL LONG WIRE PG	H787121028155	12102815	4780792	10	2/10/2015	5021026	
MOR 3F SINGLE LUMEN CT PICC BASIC SHORT	H787121028175	12102817	593694	20	8/28/2013	1069286	
MOR 3F SINGLE LUMEN CT PICC BASIC SHORT PG	H787121028175	12102817	607846	1	5/15/2014	5013985	
MOR 3F SINGLE LUMEN CT PICC BASIC SHORT PG	H787121028175	12102817	610074	1	7/22/2014	5015730	
MOR 4F SINGLE LUMEN CT PICC BASIC SHORT	H787121028185	12102818	567871	5	4/16/2012	850090	
MOR 4F SINGLE LUMEN CT PICC BASIC SHORT	H787121028185	12102818	600707	10	12/17/2013	1108158	
MOR 4F SINGLE LUMEN CT PICC BASIC SHORT	H787121028185	12102818	606943	10	12/17/2013	1108158	
MOR 4F SINGLE LUMEN CT PICC BASIC SHORT PG	H787121028185	12102818	4783021	1	8/29/2014	5016847	
MOR 5F SINGLE LUMEN CT PICC BASIC SHORT	H787121028195	12102819	596486	20	8/28/2013	1069286	
MOR 5F SINGLE LUMEN CT PICC BASIC SHORT	H787121028195	12102819	603505	10	11/4/2013	1097752	
MOR 5F SINGLE LUMEN CT PICC BASIC SHORT	H787121028195	12102819	603505	15	11/27/2013	1108158	
MOR 7F DUAL LUMEN CT PICC BASIC SHORT WI	H787121028235	12102823	568325	15	3/21/2012	837530	

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MOR 7F DUAL LUMEN CT PICC BASIC LONG WIR	H787121028315	12102831	568692	50	3/28/2012	850090	
MOR 7F DUAL LUMEN CT PICC BASIC LONG WIR	H787121028315	12102831	571096	170	5/25/2012	850090	

- We do **NOT** have any affected product
- We have found affected product and are returning the quantity (eaches) indicated above

Return Authorization Number: 87MOR762 Product Return Date: _____

- Affected product was redistributed to another facility to which **we have forwarded a copy** of this Recall Notification.

Name of facility / Contact: _____

Address: _____

Telephone Number: _____ **Fax Number:** _____

To ensure regulatory compliance, please be certain to complete this form in its entirety.

Print Contact Name: _____ Title: _____

Facility Name: _____ Department: _____

Telephone #: ____ - ____ - _____ Fax #: ____ - ____ - _____ E-Mail: _____

Contact Signature: _____ Date: _____