



**URGENT: MEDICAL DEVICE NOTIFICATION
ACTION REQUIRED**

Field Corrective Action # 198

Product: Swan Ganz

Model Number(s): Refer to Attachment 1

Lot Number(s): Refer to Attachment 2

UDI Number(s): Refer to Attachment 1

<MM DD, YYYY>

<Customer #>

<Contact name or Dept.>

<Firm Name>

<Attention: RISK MANAGEMENT>

<Address>

<City/state/zip>

Dear Valued Customers and Distributors:

The purpose of this letter is to advise you that Becton Dickinson (BD) Advanced Patient Monitoring (APM) is voluntarily notifying customers of an increase in reported complaints regarding leaks/breakage from the (blue) proximal injectate lumen hub of the Swan Ganz catheter.

Details on affected devices:

-Intended Use and Purpose (for each model):

Swan-Ganz Catheter

Models: 131F7/131F7P, 141F7, 151F7, 834F75, 096F6/096F6P, C144F7, 782F75M, 132F5, C146F7, 831F75/831F75P, TS105F5, 774F75, 777F8, AIQSGF8

Swan-Ganz catheters are pulmonary artery catheters intended for short-term use in the central circulatory system for patients who require intracardiac hemodynamic monitoring, blood sampling and infusing solutions. When used with a compatible monitoring platform and accessories, Swan-Ganz catheters offer a comprehensive hemodynamic profile to help clinicians assess cardiovascular function and guide treatment decisions.

Swan-Ganz Jr Catheter

Models: SGPT54, SGPT64P, SGPT755P

Swan-Ganz Jr catheters are pulmonary artery catheters intended for short-term use in the central circulatory system for patients who require intracardiac hemodynamic monitoring, blood sampling and infusing solutions. When used with a compatible monitoring platform and accessories, Swan-Ganz Jr catheters offer a comprehensive hemodynamic profile to help clinicians assess cardiovascular function and guide treatment decisions.



Swan-Ganz Pacing Catheter

Models: D200F7

Swan-Ganz pacing-TD catheters are pulmonary artery catheters intended to serve as diagnostic and therapeutic tools for short-term use in the central circulatory system for patients who require intracardiac hemodynamic monitoring, temporary cardiac pacing, blood sampling and infusing solutions. Swan-Ganz pacing-TD catheters also provide electrocardiographic detection during catheter placement. When used with a compatible monitoring platform and accessories Swan-Ganz pacing-TD catheters offer a comprehensive hemodynamic profile to help clinicians assess cardiovascular function and guide treatment decisions.

-Indications for Use (for each model):

Swan-Ganz Catheter

Models: 131F7/131F7P, 141F7, 151F7, 834F75, 096F6/096F6P, C144F7, 782F75M, 132F5, C146F7, 831F75/831F75P, TS105F5, 774F75, 777F8, AIQSGF8

Swan-Ganz catheters are diagnostic, and monitoring tools used for hemodynamic monitoring of adult critically ill patients including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.

Swan-Ganz Jr Catheter

Models: SGPT54, SGPT64P, SGPT755P

Swan-Ganz Jr catheters are diagnostic, and monitoring tools used for hemodynamic monitoring of critically ill pediatric patients ≥ 12 years of age including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.

Swan-Ganz Pacing TD Catheter

Model: D200F7

The Swan-Ganz pacing-TD catheters are indicated for use for temporary, atrial, ventricular, or A-V sequential cardiac pacing of adult surgical and/or critically ill patients. This includes, but is not limited to, patients with arrhythmias, acute myocardial infarction, cardiac surgery, and coronary angiography. In addition, these catheters are indicated for use in hemodynamic monitoring of patients experiencing medical conditions such as, but not limited to, post-major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, stroke, and cardiac disease including heart failure.

Description of the problem and indication to the user and distributor:

There have been a growing number of complaints of leaks/breakage involving failures of the (blue) proximal injectate lumen hub on Swan-Ganz catheters. The issue is linked to manufacturing process and material changes and is associated with situations where the (blue) proximal injectate hub and lumen experience frequent manipulation or flexing. Most complaints are associated with performance of bolus thermodilution cardiac output procedures.

This has led to instances of leakage, lumen damage and breakage and may lead to infection, medication loss, and/or blood loss.



Advice for users and instructions to mitigate hub breakage issues:

When using affected Swan-Ganz catheters, consider the following instructions to reduce the potential for hub breakage issues.

- Minimize manipulation of the Swan Ganz (blue) proximal injectate hub and lumen.
- Pay frequent attention to the (blue) proximal injectate lumen for leakage or breakage, and exchange with another catheter if the issue is encountered.
- Modify existing clinical workflows to minimize flexing and stress of (blue) proximal injectate lumen. For example:
 - Securing the catheter lumens to an IV arm board to mitigate bending/flexing of the lumen(s).
 - Consider using the stopcock on white hub to allow for intermittent transducer pressure tubing changes without twisting white hub on Swan Ganz (blue) proximal injectate lumen.
 - Prevent CO-Set syringe and (blue) proximal injectate lumen from dangling/hanging without support of the CO-Set and (blue) proximal injectate lumen from the IV pole or OR/ICU bed.
 - Change to automated cardiac output models to mitigate stress placed on (blue) proximal injectate lumen during Intermittent Cardiac Output (iCO) with CO-Set.
- Providers and institutions with appropriate capabilities may choose to utilize transthoracic or transesophageal echocardiography in combination with techniques to monitor central venous pressure via a central venous catheter in patients in need of right ventricle monitoring and management.
- Converting to Acumen IQ / FloTrac sensor can provide continuous minimally invasive hemodynamic monitoring from the arterial line. Note: Utilizing arterial pressure waveform contour analysis has not been designed to evaluate right sided heart or pulmonary artery pressures. It does provide advanced hemodynamic parameters for monitoring preload, afterload, and contractility, and includes continuous cardiac output. Consider using ClearSight cuff for continuous non-invasive hemodynamic monitoring.
- Consider use of transpulmonic thermodilution cardiac output (VolumeView kit)
- A central venous oximetry catheter (EOCVC) or ForeSight sensor may be utilized to monitor regional tissue oxygenation.



Actions for Customers:

- You are not required to return any Swan Ganz units.
- Follow the instructions included in the enclosed Customer Acknowledgement Form to complete the acknowledgement process.
- E-mail the completed form at ([regional email contact information](#)), within 15 days from receipt of this notification.
- Contact BD Advanced Patient Monitoring Customer Service at XXX-XXX-XXX if you have further questions.

Action Requested for Distributors:

In addition to the actions above, please forward this customer communication to any of your customers who have purchased the impacted product.

Please provide this notice to all individuals within your organization who need to be aware of this correction. If the impacted product has been transferred or distributed to other facilities, please transfer this notice to other organizations.

Post this notice as a constant reminder to all staff. Your assistance is appreciated and necessary to ensure that this notice is reviewed and understood.

This Field Corrective Action has been communicated by Becton Dickinson (BD) Advanced Patient Monitoring (APM) to the applicable Regulatory authorities.

Sincerely,

Ivan A Lugo

Ivan Lugo
Sr. Vice President of Quality, Advanced Patient Monitoring



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ACKNOWLEDGEMENT FORM

<Customer #>

<Firm Name>.

<Attention: RISK MANAGEMENT>

<Address>

<City/state/zip>

- You are not required to return any Swan Ganz units.
- Review your inventory on hand.
- E-mail the completed form at ([regional email contact information](#)), within 15 days from receipt of this notification.
- Distribute this notice within your organization or to any organization where the potentially impacted product has been transferred.
- Contact BD Advanced Patient Monitoring Customer Service at XXX-XXX-XXX if you have further questions.

I acknowledge receipt of this communication and understand the advice for users and instructions to mitigate hub breakage issues.

Name (Print):	
Title/Dept:	
Telephone Number:	
E-mail:	
Signature / Date:	



Attachment 1 - Model and UDI Numbers

Catalog or Model	UDI
131F7P/131F7	00690103000405 00690103000412
141F7	00690103000504
151F7	00690103000566
834F75	00690103151756
SGPT755P	00690103219388
096F6P/096F6	00690103000245 00690103218602
C144F7	00690103005134
SGPT54	00690103219289
782F75M	00690103197303
SGPT64P	00690103219371
D200F7	00690103147315
132F5	00690103000467
C146F7	00690103153132
831F75P/831F75	00690103003031 00690103218282
TS105F5	00690103018295
774F75	00690103146998
777F8	00690103146554
AIQSGF8	00690103217094



Attachment 2 - Model and Lot Numbers

Model	Lot Number
096F6P	66687312
	66687922
	66687924
	66760161
	66779562
	66780053
	66780054
	66822159
	67027065
	67044161
131F7P	65988571
	65997478
	65997479
	65997481
	65997482
	66010506
	66010507
	66010508
	66023074
	66140447
	66140448
	66140449
	66140450
	66214346
	66214347
	66214348
	66214349
	66438197
	66438198
	66438199
	66438200
	66488597
	66529345
66739812	



	66739813
	66739814
	66739910
	66739911
	66739912
	66739913
	66739916
	66739917
	66740114
	66758828
	66769651
	66782067
	66946249
132F5	66467271
	66687936
	66708830
141F7	65891637
	66023075
	66023076
	66414681
	66739789
	66812062
	66826050
151F7	66616064
	66670993
	66758827
	66889370
774F75	66438185
	66465254
	66521746
	66544244
	66552322
	66552323
	66590395
	66844440
	66844441
	66844442
	66844443



	66844444
	66844445
	66844446
	66844447
	66844448
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	66844450
	66844451
	66844452
	66844453
	66913472
	66919298
	66919299
	66919300
	66920022
	66982698
	67012527
	67271888
	67271889
	67444189
777F8	66694839
	66782069
	66800668
	66928758
	66934659
782F75M	66725372
	66725374
	66725375
	66828120
	66895564
831F75P	66529347
	66704758
	66739799
	66758829
	66782068
	66873891
	67251719
	67313527



834F75	66739754
	66832094
	67197192
AIQSGF8	66414809
	66414812
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	66437583
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	66487803
	66487805
	66487806
	66493138
	66493140
	66493141
66493142	
C144F7	66822158
	66848048
	66848049
D200F7	66671608
	66725358
	66725359
SGPT54	66916234
	66916236
	66916239
	66916240
SGPT64P	66158803
	66916319
SGPT755P	67122784