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| Boston Scientific Corporation  Global Complaints System Complaint Notification Form (CNF)   * **Submit this form within 3 working days to the CCC, LCS or LCC** * **Complete clinical and product specific questions for which any information is available** * **Peripheral Intervention and Interventional Cardiology clinical and product specific questions are located in the Cardiovascular section; pages 4-13**   + **For ICardio complaints, complete the applicable sections: Withdrawal Resistance, Stent Thrombosis, Stent Dislodgement, Vessel Dissection/Perforation, Patient Allergic Reaction, or Balloon No-Deflate**   + **METAL STENTS -If product is a metal stent, answer all questions in this section** * **Endoscopy and Urology/Women’s Health clinical questions are located in the Endosurgery section; pages 14-18** * **Neurovascular clinical or product questions are located in the Neurovascular section; pages 19** * **Intra Vascular Ultra Sound clinical or product questions are located in the IVUS section; pages 20-22** * **Electrophysiology clinical or product questions are located in the Electrophysiology section; pages 23-24 (OR** [**92145140**](https://plm.bsci.bossci.com/Windchill/netmarkets/jsp/bsci/plm/viewable/LatestEffectiveReleased.jsp?number=92145140)**)** * **Left Atrial Appendage Closure (LAAC) / Watchman pages 25-26** * **Structural heart clinical or product questions are located in the Structural Heart section: pages 27 to 28 (OR** [**92149998**](https://plm.bsci.bossci.com/Windchill/netmarkets/jsp/bsci/plm/viewable/LatestEffectiveReleased.jsp?number=92149998)**)** * **AMS:** [**92005853**](https://plm.bsci.bossci.com/Windchill/netmarkets/jsp/bsci/plm/viewable/LatestEffectiveReleased.jsp?number=92005853) * **BSN:** [**9197363**](https://plm.bsci.bossci.com/Windchill/netmarkets/jsp/bsci/plm/viewable/LatestEffectiveReleased.jsp?number=9197363) **- BSN - Cosman specific:** [**92034717**](https://plm.bsci.bossci.com/Windchill/netmarkets/jsp/bsci/plm/viewable/LatestEffectiveReleased.jsp?number=92034717) * **CRM:** [**000073**](https://plm.bsci.bossci.com/Windchill/netmarkets/jsp/bsci/plm/viewable/LatestEffectiveReleased.jsp?number=000073) |

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| |  | | --- | | **Completed By:**       **Completed On:** (dd/mmm/yyyy) |   *Please remind the person reporting the complaint about an important personal data protection responsibility for the hospital/doctor involved in the complaint under applicable law in certain locations. Some laws require the patient to be informed by the hospital/doctor that data from the complaint will be used by Boston Scientific in a database of product performance reports.* | | | |
| *NOTE:* Only 1 device may be reported per form. | | | |
| Complaint Information | | | |
| General Information | | | |
| **Is Clinical?** (if the complaint is related to a BSC Post Market Clinical or Pre-Market Clinical study, answer YES)  Yes  No  **If yes, name of Clinical Trial and Study ID #:** | | | |
| Contact Information | | | |
| **Initial Reporter Name:** (enter prefix – Mr., Mrs., Ms., Dr., Br., Sr. – and first name, last name)  **Initial Reporter Occupation:**  **Physician Name:** (in some cases the reporter could be the physician himself) | | | **Initial Reporter Phone:**  **Initial Reporter Email Address :**  **Physician Phone:** |
| **First BSC Contact Name:** | | | **BSC Aware Date:** (date when the BSC first contact person heard about the complaint) (dd/mmm/yyyy) |
| **Complaint Notification Date:** (date when the complaint was received at the CCC; for CCC use only) | | | |
| Contact Method:  CNF  Electronic CNF  Email  Fax  FSR  Mail  Telephone  Voicemail Other – specify | | | |
| Complaint Source(s): (check all that apply) | Company Representative  Consumer  Distributor  Foreign  Health Professional | Literature  Study  User Facility  Other – specify (ex: Market Evaluation Form, Physician Preference Evaluation, Regulatory Authority, etc.) | |
| Sold To | | | |
| **BSC Sold To Name or Account Number:** | | | Distributor’s Sold To Customer: |
| **BSC Sold To City:** | | | **Distributor’s Sold To Customer City:** |

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| Product/Batch Information | | | | | | | | | |
| Product Detail | | | | | | | | | |
| **UPN description:** (required if UPN is unknown) | | | | | | **UPN#:** (if not known, enter UNKNOWN) | | | |
| **Business Unit of Product UPN:** | | Endoscopy  Urology/WH | | | | Interventional Cardiology  Peripheral Intervention | | | Neurovascular  Electrophysiology |
| **Batch/Lot/Serial #:** (if not known, enter UNKNOWN) | | | | | | | | | |
| **Is this a single use device?**  Yes  No | | | **Re-sterilized?** (Reprocessed)  Yes  No  Unknown  N/A | | | | | | |
| **If reprocessed and used on patient, enter reprocessor’s name and address:** | | | | **Used past expiry date?** Yes  No  N/A | | | | | |
| Product Movement | | | | | | | | | |
| **Product Expected?** Yes  No  No Information Available | | | | | **Quantity Expected:** | | | | |
| **Reason for No Return:**  Contaminated  Disposed  Implanted  Retained  Implanted  N/A  Other – specify | | | | | | | | | |
| **Patient Information** | | | | | | | | | |
| **Patient Identifier:** (if ‘Is Clinical?’ is checked YES, provide Patient ID; if NO, use initials or other identifier. DO NOT use patient’s name or SSN) | | | | | | | | | |
| **Patient Age at Time of Event:** (number)  **Age Unit:**  Days  Months  Years | | | **Is patient/user under 18?**  Yes  No  N/A | | | | | | |
| **Patient Date of Birth:** (dd/mmm/yyyy) | | | **Patient Weight:** (number)  **Weight Unit:**  Pounds  Grams  Kilograms | | | | | | |
| **Patient Sex:**  M  F  Unknown | | | **Anatomy or lesion location:** | | | | | | |
| **Relevant Lab Tests, Dates, and Results:** (EKG, angiography, blood work, cardiac enzymes, etc.) | | | | | | | | | |
| **Significant past medical history/ patient comorbidities:** (if any)  Multivessel disease  Trauma to chest | Diabetes - Insulin dependant?  Y  N  Renal Disease  Congestive Heart Failure | | | | | | | Coagulation Disorder – specify  Cancer  Other – specify | |
| **Does patient have known allergy to stainless steel?**  Yes  No  Not Applicable or  Unknown | | | | | | | | | |
| **Any other known allergies?**  Yes  No If YES, list: | | | | | | | | | |
| **Does patient have known sensitivity to any drugs?** Yes No | | | | Was patient immunocompromised?  Yes  No | | | | | |
| **Does patient have a contraindication to anti-platelet or anticoagulation therapy?**  Yes  No | | | | | | | | | |
| **Medications used Pre-procedure?** | | **During procedure?** | | | | | **Post-procedure and how long?** | | |
| **Concurrent medications known to interact with stent drug or antiplatelet (medication):** | | | | | | | | | |

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| **Procedure Information** | | | |
| **Initial Procedure Date:** (dd/mmm/yyyy) | | **Procedure Name:** | **Indication of procedure :** |
| **Implanted Date, if any:** (dd/mmm/yyyy)  **Explanted Date, if any:** (removal of a previously implanted device) (dd/mmm/yyyy) | | | |
| **Procedure Outcome:**  Completed with this device  Completed with another of same device  Completed with a different device  Not completed due to this event  Not completed due to same device unavailable  Not completed due to another reason  No information available | | | |
| **Was IVUS used?** Yes No | **Was a generator involved?** Yes  No  If YES, indicate Type:      and Settings: | | |
| **What was the patient condition following procedure?**  Stable  Surgery  Death  Other – specify | | | |

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| **Event Information** | | | | | | | |
| **Event Date:** | | | **Event Country:** China | | | | |
| **When was the problem noticed:**  Unpacking  Preparation  Introduction  During Procedure  Withdrawal  Procedure Closure  Post Procedure  No Information Available | | | | | | | |
| **Where did the problem occur?**  Inside the patient  Outside the patient  Not Applicable  No Information Available | | | | | | | |
| **Event Description:** (include the factors and sequence of events that led to the complaint, and include other devices used along with the subject device in the procedure) | | | | | | | |
| **Was the problem associated with labeled use?**  Yes  No If NO, explain: | | | | | | | |
| **Action taken by the physician to try to resolve the event:** (check all that apply)  Observation  Medications (Describe)  Blood/Blood products (Describe) | Surgery (Describe)  Device removed  Other Intervention (Describe) | | | Hospitalization or prolongation of hospitalization (length of stay and reason)  None | | | |
| **Patient outcome from the event:**  Death Date (dd/mmm/yyyy)  If Death, autopsy report/death certificate available | | Permanent impairment of a body function(describe)  Serious injury (describe) | | | No serious injury(describe)  No information available  None | |
| **Event resolved?**  Yes  No  Unknown | | | | | |
| **Physician assessment of the relationship of the event to the device**  Unrelated  Unlikely to be related  Related  Unknown | | | | | | | |
| **Other possible contributing factors to the event**  Procedure  Co-morbidity  Other – specify | | | | | |
| **Please check all those that can be forwarded to BSC:**  CT Scan  X-ray  Angio  Cine  Procedure Notes  Discharge notes  Other – specify | | | | | | |

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| Cardiovascular Questions | | | | |
| GENERAL PROCEDURE INFORMATION (TO BE FILLED IN BY ICardio/PI ONLY) | | | | |
| 1. Did patient have myocardial infarction <72 hours prior to procedure?  Yes  No | | | | |
| 1. Date of last myocardial infarction? | | | | |
| 1. **a.** Indicate the lesion location (select all that apply): | | | | |
| LAD  ICA  ACOM  PCOM  PICA  MCA  ACA  Vertebral artery  Basilar artery  Cerebral artery  Opthalmic artery  OM  RCA | Diag  LCX  PDA  PL  Ramus  LM - Protected  LM – Unprotected  LIMA  SVG  Carotid  Femoral  Iliac  Vena Cava | | | Renal  Other  Proximal  Distal  Mid  Bifurcation  Ostial  Internal  External  Common  Left  Right  Unknown |
| **b.** If other lesion location, please specify: | | | | |
|  | | | | |
| 1. What was the vascular access site? (select all that apply)  Radial  Brachial  Femoral  Right  Left  Unknown | | | | |
| 1. What was the length of the lesion (mm)? | | | 1. What was the vessel diameter (mm)? | |
| 1. Was the lesion anatomy tortuous? Select No or indicate severity (select all that apply):  No  Mild  Moderate  Severe  Unknown | | | | |
| 1. Did the user encounter significant resistance? Select No or specify (select all that apply):  No Insertion  Advancing  Operation  Repositioning  Withdrawal | | | | |
| 1. **a.** Was there a significant bend involved in the lesion?  Yes No   **b.** If YES, indicate degree:  <=45  >45 and <90  >=90 | | | | |
| 1. Was the lesion calcified? Select No or specify calcification:  No  Mild  Moderate  Severe | | | | |
| 1. **a.** What was the % of stenosis? | | **b.** Was there a total occlusion?  Yes  No | | |
| 1. What was the ejection fraction? | | | | |
| 1. What was the shape of the lesion?  Eccentric  Concentric | | | | |
| 1. Was the lesion (check all that apply):  de novo (progressive)  In-stent restenosis  Restenosis (POBA, brachy)   Graft anastomosis | | | | |
| 1. **a.** Was the lesion/stent predilated?  Yes No **b.** If Yes, specify type and size of balloon: | | | | |
| 1. What was the percent stenosis of the lesion immediately after pre-dilation? | | | | |
| 1. **a.** Was the lesion post-dilated?  Yes No **b.** If Yes, specify the type and size of balloon: | | | | |
| 1. What type and size of guide catheter was used? | | | | |
| 1. What type and size of guidewire was used? | | | | |
| 1. Implant date: | | | | |
| 1. Explant date (if applicable): | | | | |
| 1. **a.** How many stents were implanted?   **b.** If more than one stent was implanted indicate sequence and any overlapping stents: | | | | |
| 1. What type(s) and size(s) of stent were implanted? | | | | |
| 1. In what vessel(s) were the stent(s) implanted? | | | | |
| 1. Does the patient have Diabetes?  Yes  No | | | | |

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| Cardiovascular Questions (Continued) | | | | |
| **WITHDRAWAL RESISTANCE** | | | | |
| 1. Was there a stent involved during the withdrawal resistance?  Yes No If No selected, go to question 4. | | | | |
| 1. Was the lesion predilated?  Yes No | | | | |
| 1. Was the stent fully deployed and well apposed?  Yes No | | | | |
| 1. Was there difficulty removing the balloon from the stent?  Yes No | | |
| 1. Specify the type of contrast media and the contrast ratio in the inflation device (e.g., 100%, 75%, 50% or 25%):      % | | |
| 1. Did the physician have any difficulty inflating the balloon on the SDS? Select No or specify difficulty (select all that apply):   No No inflate  Slow inflate  Partial inflate  Eventually inflated | | |
| 1. To what pressure (atmospheres) was the balloon finally inflated? | | |
| 1. How long was the balloon inflated? | | |
| 1. Was the stent balloon fully inflated without waist?  Yes No | | |
| 1. How long was the inflation device under negative/neutral pressure before SDS withdrawal? | | |
| 1. Did the physician have any difficulty deflating the balloon? Select No or specify difficulty.  No  No deflate  Slow deflate  Partial deflate  Eventually deflated | | |
| 1. Was the balloon fully deflated before trying to pull back?  Yes  No | | |
| 1. **a.** What actions were undertaken to remove the balloon? (select all that apply)   Dialed up and dialed down  Pulled negative  Went neutral  Guide catheter deep seated | Pulled hard  Removed system as a unit  Surgery  Push guidewire  Other | **b.** If other actions were undertaken, specify: |
| 1. Was the device removed intact?  Yes No | | |
| 1. Was the balloon still inflated when removed?  Yes No | | |
| 1. Was there a previously implanted stent involved?  Yes No | | |
| 1. Was the shaft damaged?  No  Kinked/bent  Hole/perforated  Stretched  Detached/Separated  Other | | |
| 1. Did the stent remain implanted?  Yes No | | |
| 1. Describe any symptoms and/or complications related to the BWR and action taken (e.g., chest pain, bradycardia, tachycardia, dyspnea, etc.): | | |
| 1. Describe any patient complications related to withdrawal resistance: | | |
| **STENT THROMBOSIS** | | | | |
| 1. Was initial procedure emergent due to myocardial infarction?  Yes  No | | | | |
| 1. **a.** Was initial stent placement well positioned and well apposed?  Yes  No **b.** If NO, explain: | | | | |
| 1. During the initial procedure, was there a gap between multiple stents implanted?  Yes  No | | | | |
| 1. During the initial procedure did the stent or a part of the stent protrude into the lumen or necrotic core of plaque?  Yes  No | | | | |
| 1. **a.** What type of special technique, if any, was used?  Crushing  Kissing Balloons  Other   **b.** If other, specify techniques: | | | | |
| 1. Was dissection or perforation a complication during the initial procedure?  Yes  No   If Yes also complete **Vessel dissection/Perforation** section. | | | | |
| 1. **a.** Was antiplatelet medication given before the initial procedure?  Yes  No   **b.** If YES, specify medication: | | | | |
| 1. **a.** Was antiplatelet medication given during the initial procedure?  Yes  No **b.** If Yes, specify medication during initial procedure: | | | | |
| 1. **a.** Was antiplatelet medication given at discharge?  Yes  No **b.** If Yes, specify medication provided at discharge: | | | | |
| 1. **a.** In the opinion of the physician was the patient compliant with the medications?  Yes  No **b.** If No, specify physician opinion: | | | | |
| 1. Was the patient resistant to antiplatelet medication?  Yes  No | | | | |
| 1. **a.** Was antiplatelet medication stopped?  Yes  No **b.** Reason antiplatelet medications were stopped and when: | | | | |
| 1. What was the specific antiplatelet therapy at the time of the stent thrombosis event? | | | | |

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| Cardiovascular Questions (Continued) | | |
| **STENT THROMBOSIS – Continued** | | |
| 1. **a.** Date thrombosis was detected?       **b.** Was thrombosis recognized:  Acute (0-24 hours)  Subacute (1-30 days)  Late (31-365 days)  Very Late (>365 days)  Unknown **c.** If Acute is selected, specify hours after procedure: | | |
| 1. What led to the discovery of the thrombosis (e.g., chest pain, MI, etc.)? | | |
| 1. Was there unresolved vessel thrombus at the lesion?  Yes  No | | |
| 1. Describe any vessel closures (e.g., vessel spasm, thrombosis): | | |
| 1. In what vessel was the thrombosis detected? | | |
| **19**. **a.** Where in the vessel was the thrombosis located?  Edge of Stent  In-stent  Near the Stent  Unknown  Unstented Vessel **b.** If unstented vessel, specify: | | |
| **20.** Was there an aneurysm formation at the stent location?  Yes  No | | |
| **21.** Was there a hypersensitivity reaction?  Yes  No | | |
| **22.** What actions were taken to treat the thrombosis? | | |
| **STENT DISLODGEMENT** | | |
| 1. Did the stent come off the Stent Delivery System (SDS) inside the patient (dislodge) prior to full deployment?  Yes No If NO selected, skip this section. | | | | |
| 1. Did the stent move on balloon during preparation?  Yes No | | | | |
| 1. How many times did the SDS enter the body? | | | | |
| 1. **a.** Was there any procedural difficulty? If yes selected, check all that apply.  Yes No   Difficulty crossing lesion  Difficulty crossing another stent  Resistance felt | | Caught on sheath  Caught on guidewire  Caught on guide catheter | Difficulty withdrawing  Other  **b.** If Other is checked, specify: | |
| 1. Was excessive force used during the advancement of SDS?  Yes  No | | | | |
| 1. Was there any attempt to pull the stent back into the guide catheter?  Yes  No | | | | |
| 1. Specify the location where the stent came off of the SDS (dislodge)? | | | | |
| 1. Did the stent move in the body (embolized)?  Yes  No | | | | |
| 1. If stent embolized, where was the final location? | | | | |
| 1. Was there an attempt to retrieve the stent?  Yes  No If No selected skip to question 12. | | | | |
| 1. **a.** Was the attempt successful to retrieve the stent? If yes selected, indicate method of retrieval: (check all that apply)  Yes   No  Snare  Surgery  Other  **b.** If Surgery, specify type:  **c.** If Other retrieval method, specify: | | | | |
| 1. Describe any other actions taken regarding this stent? (e.g., crushing, deployed): | | | | |
| 1. Describe actions taken to complete the procedure: | | | | |
| 1. Describe any patient complications reported due to un-retrieved dislodged/embolized stent? | | | | |

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| Cardiovascular Questions (Continued) | | | | | |
| **VESSEL DISSECTION / PERFORATION** | | | | | |
| 1. Was this a dissection? If Yes, specify type (A - F)  No dissection  Type A  Type B  Type C  Type D   Type E  Type F  Unknown | | | | | |
| 1. Was this a perforation?  Yes  No | | | | | |
| 1. What BSC devices were used prior to dissection/perforation? | | | | | |
| 1. Was the lesion Chronic Total Occlusion(CTO)  Yes  No   If yes, were CTO products (CrossBoss catheter, Stingray guidewire/balloon catheter) used?  Yes  No | | | | | |
| 1. Which device(s) does the physician feel caused/contributed to the dissection/perforation? | | | | | |
| 1. **a.** Select which steps preceded the dissection/perforation during the procedure:   BWR  Guide catheter deep seated  Balloon Burst  Slow or no deflate  Stent damage  Shaft Fracture  Guidewire puncturing  Guidewire Fracture  Atherectomy device used  Guide catheter resistance  Other | | | | **b.** If balloon burst, specify atm:  **c.** If stent damage, specify (e.g., lifted, bent, or flared)  **d.** If atherectomy device used, specify (e.g., cutting balloon, rotablator, etc.):  **e.** If guide catheter resistance, specify (e.g. stiff or sticky):  **f.** If other, specify steps preceding dissection/perforation:  **g.** Describe any steps not described in **5a.-f.** above: | | | |
| 1. **a**. What was the vessel location of dissection/perforation? | | | | | | | | |
| LAD  ICA  ACOM  PCOM  PICA  MCA  ACA  Vertebral artery  Proximal  Mid  Distal | | | | Basilar artery  Cerebral artery  Opthalmic artery  OM  RCA  Diag  LCX  PDA  PL  Ramus | | | LM Protected  LM Unprotected  LIMA  SVG  Carotid  Femoral  Iliac  Vena Cava  Renal  Other  **b.** If other, specify lesion location details: | |
| 1. Describe any patient symptoms during this event and actions taken: | | | | | | | | |
| **PATIENT ALLERGIC REACTION (HYPERSENSITIVITY)** | | | | | | | | |
| 1. What were the presenting symptoms? | | | | | | | | |
| 1. What was the length of time from the procedure to the onset of symptoms? | | | | | | | | |
| 1. What actions had already been taken to treat the allergic reaction:  topical medication  antihistamine  steroids | | | | | | | | |
| 1. What was the duration of symptoms? | | | | | | | | |
| 1. If hypersensitivity reaction was related to a drug please describe? | | | | | | | | |
| 1. **a.** If hypersensitivity, what were manifestations? | | | Anaphylactic shock  Angioedema  Bronchospasm  Diarrhea (new) | | | Hives  Joint Pain or Swelling (new)  Rash & Itching (new)  Other  **b.** If other, specify hypersensitivity: | | |
| 1. What medications did the patient receive during the implant procedure (by any route of administration (e.g., IV contrast agent, PO or IM))? | | | | | | | | |
| 1. If there were any concurrent medical illness that may have contributed to the allergic reaction, specify illness and duration? | | | | | | | | |
| 1. If the patient has any known allergies please specify? | | | | | | | | |
| 1. Does the patient have a history of prior stenting?  Yes  No   If yes, describe total number and types of stents  If yes, provide implant dates | | | | | | | | |
| 1. Were there concomitant medications (e.g., Plavix, Aspirin, Statins, etc.) that may have contributed to the allergic reaction (specify dosage and duration of treatment)? | | | | | | | | |
| 1. Describe any de-challenge (agent withdrawal) or re-challenge (agent re-exposure) done with any of the concomitant medications. | | | | | | | | |

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| Cardiovascular Questions (Continued) | |
| **PATIENT ALLERGIC REACTION (HYPERSENSITIVITY) – Continued** | |
| **13. a.** Did the allergic symptoms resolve after the de-challenge and recur after the re-challenge?  Yes  No  **b.** If Yes, give allergic details: | |
| **14.** What treatment or intervention was needed to treat the symptoms (e.g., IV steroids)? | |
| **15. a.** Treatment outcome and patient condition (check all that apply):  Resolved  Not resolved  Emergency Intervention  Hospitalization | Permanent disability  Death  Other  **b.** If other, specify treatment and/or patient condition:  **c.** Specify date and duration of treatment(s) if applicable: |
| **16.** If there was patient death, what was physician's opinion of the cause (if related to the device, also answer next question)? | |
| **17.** Was there histological evidence of an eosinophilic reaction confined to the area of the stent at autopsy? | |
| **BALLOON NO-DEFLATE** | |
| 1. What type of inflation device was used? (if BSC device, please return for analysis) | |
| 1. Describe if there was any difficulty with the use of the inflation device, either inflating or deflating the balloon: | |
| 1. Were there any problems or unusually high forces when removing the device from its packaging hoop?  Yes  No | |
| 1. Were there any problems or unusually high forces when removing the stent protector and/or product mandrel?  Yes  No | |
| 1. **a.** Were any problems encountered during (select all that apply):   Flushing the wire lumen  Loading the guidewire  Prepping the balloon  Wire movement  Other | **b.** Give details on any problems:  **c**. If other, specify: |
| 1. Describe any difficulties the physician experienced during insertion/advancement to the target lesion? | |
| 1. Was the lesion predilated?  Yes  No | |
| 1. Was any extra force applied to the device during attempts to reach or cross the target lesion?  Yes  No | |
| 1. **a.** Select all which apply to difficulty inflating the balloon:  Not inflate at all  Inflate partially  Eventually inflate  Other **b.** If partial, eventual, or other provide details. | |
| 1. Was the balloon inflated on the first attempt?  Yes  No | |
| 1. What pressure was used to inflate the balloon? | 1. How many seconds was it inflated? |
| 1. Did the balloon inflate completely?  Yes  No | |
| 1. Specify the type of contrast media and the contrast ratio in the inflation device (e.g., 100%, 75%, 50% or 25%):      % | |
| 1. **a.** If an SDS, was the SDS balloon used for post-dilatation?  Yes  No. **b.** If Yes, specify # of times inflated: | |
| 1. If SDS balloon used, specify pressure (atm) and duration of each inflation (i.e. 15atm/30sec)? | |
| 1. **a.** If the physician had difficulty deflating the balloon, select what issue (select all that apply): Not deflate at all   Deflate partially  Eventually deflate.  **b.** If difficulty deflating balloon, provide details: | |
| 1. Describe the series of events immediately preceding the “No Deflate” event: | |
| 1. **a.** Describe efforts made to deflate the balloon (select all that apply):  Deep-seating  Over-inflation  Puncture with another guidewire  Negative pressure with large syringe  Exchange of inflation device  Re-inflate/deflate  Other **b.** If other, describe efforts: | |
| 1. **a.** What state was the balloon removed in?  Fully inflated  Partially inflated  Fully deflated **b.** Approximately how long was the balloon inflated prior to successful deflation? | |
|  | |
| 1. Was the device removed from the patient intact?  Yes  No | |
| 1. Describe any symptoms experienced by the patient during efforts to deflate or remove the balloon. | |
| 1. **a.** What were the patient complications—if any—at the end of the procedure? If so, please describe what actions taken:   **b.** Are there any patient complications related to the balloon inflation/deflation?  Yes  No | |

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| Cardiovascular Questions (Continued) |
| **METAL STENTS -If product is a metal stent, answer all questions in this section** |
| 1. **a.** Were all the stents Drug Eluting Stents (DES)?  Yes  No **b.** If No, how many were DES? |
| 1. Were two different manufacturers’ Drug Eluting Stents placed?  Yes  No |
| 1. If DES and non-DES were used were they placed concurrently?  Yes  No |
| 1. Were multiple lesions stented?  Yes  No |
| 1. Was stent delivery difficult due to lesion crossing?  Yes  No |
| 1. Did stent migrate immediately after placement?  Yes  No |
| 1. Did stent fully expand after deployment?  Yes  No |
| 1. Was stent final result well positioned and well apposed?  Yes  No |
| 1. Was there evidence of stent deformation / stent damage post deployment secondary to interaction with another device?   Yes  No  If yes, what was the nature of the deformation:  proximal stent edge compression  distal stent edge compression  stent elongation  What treatment or additional intervention was performed to address the stent deformation?  Was there an associated major cardiac event (MACE, ie death, ST, MI, CABG)?  Yes  No  Is CINE available for BSC review?  Yes  No |
| 1. Describe if the patient has other stent(s) (bare or DES) not related to event (Type / Location)? |
| **GUIDEWIRES** |
| 1. What was the location on the device of the problem?  Distal  Mid  Proximal |
| 1. Was the guidewire removed as a unit?  Yes  No |
| 1. Was the guidewire used with an entry needle, metal introducer, or cannula?  Entry Needle  Metal Introducer  Cannula |
| 1. Was there fracture of the guidewire?  Yes  No   If yes, were all pieces of the guidewire removed from the patient’s body?  Yes  No  If yes, what measures were taken to remove the pieces (snare, balloon, surgery), specify: |
| 1. **a.** Was an introducer sheath used?  Yes  No   **b.** If Yes, what size and type? |
| **POLARCATH PERIPHERAL DILATION SYSTEM** |
| 1. **a.** When did the error occur? Standby  Ready  Testing  Treating  Other   **b.** If other, when did error occur: |
| 1. **a.** Which indicator light displayed (select all that apply)?   All  Check Catheter (fast)  Unknown  Low Battery  Check Catheter (slow)  Other  Check Vacuum  Check Cylinder **b.** If other, specify light: |
| 1. **a.** Did the system complete its cycle?  Yes  No   **b.** If No please specify:  Did not go into “Treat” cycle  Balloon did not inflate  Did not enter “Ready” state  Balloon inflated, but short cycle (<10 sec) |
| 1. Were there difficulties (select all that apply):  Tracking over guidewire  Removing guidewire  Advancing guidewires |
| 1. If Yes to 4, please identify type of guidewire: |
| 1. Were you able to draw negative pressure on catheter?  Yes  No |
| 1. **a.** Select what part of the balloon was torn or ruptured (select all that apply):  Inner balloon torn  Outer balloon torn   Inner balloon ruptured  Outer balloon ruptured  **b.** Was there a placed stent involved in the procedure?  Yes  No |
| 1. **a.** Did the balloon appear inflated?  Yes  No   **b.** Did the balloon not deflate?  Yes No  **c.** If Yes to 8.a. and/or 8.b., did you rotate the catheter to wrap?  Yes  No |
| 1. How many times was the balloon inflated? |
| **INFLATION DEVICES** |
| 1. Where did this problem occur?  Gauge  Connector  Tube |
| 1. Was corrosion noticed and if yes, where? |
| 1. Was there a pressurization issue and if yes, explain*:* |
| 1. Was there a decompression issue and if yes, explain*:* |
| **GREENFIELD FILTERS AND CARRIERS** |
| 1. How many legs of the filter opened on deployment? |
| 1. How many hooks attached to the vessel wall? |
| 1. Did the carrier handle retract smoothly?  Yes  No |
| 1. Was the safety sleeve in place?  Yes  No |
| 1. Was the trigger in the locked position?  Yes  No |
| **DIREXION MICROCATHETER** |
| 1. Did or has the sales rep review the training information with this account/physician?  Yes  No |
| 1. Did the device kink or fracture?  Yes  No; If it did fracture, did it completely separate?  Yes  No   Please clarify if it was only the outer shaft (nitinol) or both the outer shaft (nitinol) and the inner lumen. |
| **3**. Was the event located outside of the patient?  Yes  No |
| **4**. Location of event/picture? |
| **5**. Presence of a guidewire when event occurred?  Yes  No |
| **6**. Was touhy (y-adapter/RHV) locked onto the device shaft when the device kinked?  Yes  No |

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| Cardiovascular Questions (Continued) | |
| **GRAFTS AND FABRICS** | |
| 1. Did any blood leak through the device?  Yes  No | |
| 1. How much blood leaked through the device? | |
| 1. From what part of the device did the leaking occur? | |
| 1. What was the duration of the leaking? | |
| 1. How was the leaking stopped? | |
| 1. Was the graft or fabric left in the patient?  Yes  No | |
| CUTTING BALLOONS | |
| 1. Was the lesion located within a stent?  Yes  No | |
| 1. Was the balloon catheter advanced through a previously placed stent?  Yes  No | |
| 1. Was the Cutting Balloon rotated between inflations?  Yes  No | |
| 1. Was the Cutting Balloon pulled back into the guide catheter between each inflation?  Yes  No | |
| **FILTER WIRES** | |
| 1. Was a buddy wire used?  Yes  No | |
| 1. **a.** Did the physician pre-dilate?  Yes  No   **b.** If Yes, what size balloon was used?       **c.** What pressure was used?      ATM | |
| 1. What was the size of the guide catheter used? | |
| 1. **a.** Was the retrieval sheath used, withdrawn then re-used?  Yes  No **b.** If Yes, was the sheath flushed?  Yes  No | |
| 1. Was the wire wiped down?  Yes  No | |
| 1. Was the wire undamaged before re-using?  Yes  No | |
| 1. Was the guidewire wrapped around the sheath?  Yes  No | |
| **COILS** | |
| 1. Had other coils been detached?  Yes, prior to this subject coil  Yes, after this subject coil  No | |
| 1. **a.** What catheter was used with the coil?       **b.** Manufacturer:       **c.** Type:       **d.** Size: | |
| 1. **a.** Did the coil detach prematurely?  Yes  No **b.** If Yes, was the coil removed?  Yes  No  **c.** If Yes, describe how: | |
| 1. **a.** After detachment, did any portion of the coil protrude out of the aneurysm or into the parent vessel?  Yes  No **b.** If Yes, describe what actions were taken (e.g. coil removed, stent placed to hold coil in place): | |
| 1. **a.** Was the coil inspected before use?  Yes  No **b.** If Yes, were any issues noticed?  Yes  No   **c.** If issue noticed, explain: | |
| **6.** Were new batteries and cables used in this procedure? (select all that apply)  None  Batteries  Cables | |
| **ROTALINK AND ROTALINK GUIDEWIRES** | |
| 1. What was the speed (RPM) at the time of the event? | |
| 1. What was the maximum rotational speed (RPM) of the burr during the ablation? | |
| 1. Was restriction felt at any time?  Yes  No | |
| 1. How many ablations were carried out prior to the event? | |
| 1. How long was the Rotalink in use prior to the event? | |
| 1. If there was a fracture or bend in the wire, where is it located? | |
| **7.**  If this was the Rotawire, was it used with another device or another Rotalink device, please specify device? | |
| **BALLOON CATHETERS** | |
| 1. Was the lesion located within a stent?  Yes  No | |
| 1. Was the catheter advanced through a previously placed stent?  Yes  No | |
| 1. Was the catheter rotated between inflations?  Yes  No | |
| 1. Specify pressure (atm) and duration of each inflation (i.e. 15atm/30sec)? | |
| 1. Was the catheter pulled back into the guide catheter between each inflation?  Yes  No | |
| 1. On which inflation did the event occur? | |
| 1. What was the maximum pressure (ATMs)? | |
| 1. **a.** Did the balloon burst?  Yes  No **b.** If Yes, at what pressure did the balloon burst (ATMs)? | |
| 1. **a.** Did the balloon leak?  Yes  No **b.** If Yes, at what pressure did the balloon leak (ATMs)? | |
| 1. Were there deflation difficulties?  Yes  No *If Yes, please complete Balloon No-Deflate Section* | |

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| Cardiovascular Questions (Continued) | | | |
| **BALLOON CATHETERS – Continued** | | | |
| 1. **a.** Did the balloon or a segment of the balloon detach inside the patient during the procedure?  Yes  No   **b.** If Yes,describe actions taken. | | | |
| 1. **a.** Were there any shaft kinks noted? (select all that apply)  No  Prior to use  During Insertion  During Procedure  Post Procedure  Distal shaft  Mid shaft  Proximal shaft  Guidewire exit port   Tip  Other  **b.** Specify if other: | | | |
| 1. **a.** Was an introducer sheath used?  Yes  No **b.** If Yes, what size, type, and manufacturer (intro.)? | | | |
| 1. **a.** Was an inflation device used?  Yes  No **b.** If Yes, what size, type, and manufacturer (device)? | | | |
| 1. What was the intended use for the balloon? Pre-dilatation  Post dilatation  Unknown | | | |
| 1. Was the balloon used for CTO therapy (Stingray balloon catheter)  Yes  No   If yes, was there any problem with re-entry due to balloon port restriction?  Yes  No | | | |
| **BIOPSY FORCEPS** | | | |
| 1. **a.** What was the indication for biopsy?  Tumor  Polyps  Vascular Lesion  Other   **b.** If other indication, specify: | | | |
| 1. What was the biopsy location? Specify organ: | | | |
| 1. Specify location within organ (e.g., ascending colon, etc): | | | |
| 1. **a.** Define amount of bleeding:  Expected as indicated for procedure  Greater than expected for procedure   Other **b.** If other bleeding amount, specify: | | | |
| 1. **a.** Treatment for bleeding?  None  Clip  Cautery  Surgery  Transfusion  Other **b.** If other treatment for bleeding, specify: | | | |
| 1. Provide description of pain (e.g., onset, location, frequency): | | | |
| 1. What is the patient pain rating:  Mild  Moderate  Severe | | | |
| 1. **a.** Identify associated symptoms:  None  Temperature/fever  Nausea  Vomiting  Chills  Other   **b.** If other symptoms, specify: | | | |
| 1. **a.** Will processing documentation be available?  Yes  No **b**. If yes, please indicate all that apply:  Recovery room record  Biopsy report  Procedure report  Other **c.** If other documentation, specify: | | | |
| 1. **a.** What radiological studies were conducted due to pain complaint or perforation?  None  Abdominal films  CT Scan  Contrast Studies  Other **b.** If other studies, specify: | | | |
| 1. **a.** Post procedure treatment for pain or perforation? Check all that apply.  None  Observation only  Re-endoscope   Surgery  Antibiotics  Other **b.** If other treatment, specify: | | | |
| 1. **a.** Patient condition on follow-up? Check all that apply. | | | |
| Resolved  Required continued hospitalization  Anatomical resection | Permanent disability  Death  Other | **b.** If patient condition is other, specify: | |
| 1. **a.** Surgical Intervention Indicated  Yes  No   **b.** If Yes, specify surgery type:       **c.** If Yes, specify surgery location: | | | |

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| **BILIARY STENT DEVICE (E.G. WALLSTENT)** |
| 1. What was the indication for treatment (e.g. relieve biliary strictures, etc.)? |
| 1. Did the distal tip of the stent perforate the outer sheath?  Yes  No |
| **BIOPSY DEVICE (E.G. TRUPATH, EASYCORE, ETC.)** |
| 1. What was the indication for treatment (e.g., prostate biopsy)? |
| 1. Did the device fire prematurely (i.e. fire prior to pressing the device button)?  Yes  No |
| 1. Was the yellow indicator on the handle present when the device fired prematurely?  Yes  No |
| 1. How many samples were taken prior to the issue? Specify quantity: |
| 1. What stage did the device fire prematurely?  During arming  While passing device  Before sample was taken  While retrieving sample  After sample was taken  Other **b.** If other stage, specify: |
| 1. **a.** What was the location of the device when it fired prematurely?  In clinician’s hand  On the table  Other   **b.** If other location, specify |
| 1. Was there difficulty pressing the lever down in order to get the device to cock (Cocked denoted by yellow indicator appearing in the window)?  Yes  No |
| 1. Were two hands required to press the lever down in order to get the device to cock?  Yes  No |

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| **Endosurgery Endoscopy Questions** | | | | |
| **ENDOSURGERY-ALL PRODUCTS-DAMAGED PRODUCT** | | | | |
| 1. **a.** Was product damaged upon removal from packaging?  Yes  No **b.** If Yes, specify product damage: | | | | |
| 1. Was packaging damaged?  Yes  No | | | | |
| 1. **a.** If packaging damaged, specify:  Outer Box  Inner Box/pouch  Kit  Other **b.** If other, specify damage: | | | | |
| 1. Did sterile barrier appear compromised?  Yes  No | | | | |
| **ENDOSCOPY-BIOPSY FORCEPS** | | | | |
| 1. **a.** What was the indication for biopsy?  Tumor  Polyps  Vascular Lesion  Other   **b.** If other indication, specify: | | | | |
| 1. What was the biopsy location? Specify organ: | | | | |
| 1. Specify location within organ (e.g., ascending colon, etc): | | | | |
| 1. **a.** Define amount of bleeding?  Expected as indicated for procedure  Greater than expected for procedure   Other **b.** If other bleeding amount, specify: | | | | |
| 1. **a.** Treatment for bleeding?  None  Clip  Cautery  Surgery  Transfusion  Other **b.** If other treatment for bleeding, specify: | | | | |
| 1. Provide description of pain (e.g., onset, location, frequency): | | | | |
| 1. What is the patient pain rating:  Mild  Moderate  Severe | | | | |
| 1. **a.** Identify associated symptoms:  None  Temperature/fever  Nausea  Vomiting  Chills  Other   **b.** If other, specify: | | | | |
| 1. **a.** Will processing documentation be available?  Yes  No **b**. If Yes, please indicate all that apply:  Recovery room record  Biopsy report  Procedure report  Other **c.** If other documentation, specify: | | | | |
| 1. **a.** What radiological studies were conducted due to pain complaint or perforation?  None  Abdominal films  CT Scan   Contrast Studies  Other **b.** If other studies, specify: | | | | |
| 1. **a.** Post procedure treatment for pain or perforation? Check all that apply.  None  Observation only  Re-endoscope   Surgery  Antibiotics  Other **b.** If other treatment, specify: | | | | |
| 1. **a.** Patient condition on follow-up? Check all that apply. | | | | |
| Resolved  Required continued hospitalization  Anatomical resection | Permanent disability  Death  Other | | **b.** If patient condition is other, specify: | |
| 1. **a.** Surgical Intervention Indicated?  Yes  No   **b.** If Yes, specify surgery type:       **c.** If Yes, specify surgery location: | | | | |
| **ENDOSCOPY-DILATION DEVICES-BALLOONS** | | | | |
| 1. Was a vacuum applied to the catheter before removing the protective sleeve?  Yes  No | | | | |
| 1. Was silicone spray applied to the balloon prior to the procedure?  Yes  No | | | | |
| 1. Was vacuum maintained to the catheter during insertion through the scope?  Yes  No | | | | |
| 1. What size scope was used? | | | | |
| **ENDOSCOPY – GUIDEWIRES(E.G. JAGWIRE)** | | | | |
| 1. What type of procedure was the device used in? | | | 1. Was the guidewire re-sterilized?  Yes  No | |
| 1. What was the location of the problem?  Distal  Mid  Proximal | | 1. Was the guidewire removed as a unit?  Yes  No | | |
| 1. Was there a detachment or separation of the distal tip?  Yes  No | | | | |
| 1. How long into the procedure until the problem was noticed? | | | | |
| 1. Did the clinician notice any resistance with the guidewire while trying to extract or move the guidewire within the scope/catheter?  Yes  No | | | | |
| 1. Was it necessary to apply more force than normal to move the guidewire within the scope/catheter?  Yes  No | | | | |
| 1. What other devices were used with the guidewire: | | | | |
| **a.** Scope?  Yes  No | **b.** If yes, scope Brand/Model: | | | |
| **c.** Catheter?  Yes No | **d.** If yes, catheter Brand/Model: | | | |
| **e.** Other device?  Yes  No | **f.** If yes, identify device/Brand/Model: | | | |

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| **Endosurgery Endoscopy Questions (Continued)** | | | | |
| **ENDOSCOPY – HEMOSTASIS DEVICE (E.G. RESOLUTION CLIP)** | | | | |
| 1. Was the scope in a retroflex position?  Yes  No | | | | |
| 1. **a.** Did the hemostasis device grasp tissue?  Yes  No **b.** If yes, did it release from the catheter and tissue?  Yes  No | | | | |
| 1. **a.** Did the hemostasis device fall off inside the patient?  Yes  No **b.** If yes, was device removed?  Yes  No | | | | |
| 1. Specify device used to remove hemostasis device? | | | | |
| 1. Was there a delay in the procedure?  No delay  1-5 minutes  6-15 minutes  15+ minutes | | | | |
| **ENDOSCOPY – RFA RADIOFREQUENCY ABLATION DEVICE (E.G. LEVEEN NEEDLE, RF3000)** | | | | |
| 1. What was the indication for treatment? | | | | |
| 1. What type of procedure was being performed? | | | | |
| 1. How was the procedure performed?  Percutaneously  Incision | | | | |
| 1. What part of the body was involved? | 1. If body part was liver, what was the texture?  Cerotic   Fibrotic | | | |
| 1. **a.** Were any solutions used in the procedure?  Ethanol Alcohol  Injections  Chemo agents  Other   **b.** If other solutions used, specify: | | | | |
| 1. Was a metal guide used in this procedure?  Yes  No | | | | |
| **Generator information** | | | | |
| 1. Was the algorithm followed? Yes No | 1. Were the recommended settings used?  Yes  No | | | |
| 1. What was the ablation time? | 1. What was the highest power achieved? | | | |
| 1. Was Roll Off (signal of desired clinical endpoint ) achieved?  Yes  No | | | | |
| 1. What was the total time energy was applied? | | | | |
| **Needle/Probe** | | | | |
| 1. Who is the manufacturer of the needle used? | | 1. What was the size of the needle used? | | |
| 1. Was the insulation intact when the needle was removed from the patient?  Yes  No If Yes, proceed to Question 20. | | | | |
| 1. Was there any insulation left inside the patient when the needle was removed?  Yes  No If No, proceed to Question 20. | | | | |
| 1. If there was insulation left inside the patient, how was it removed? Specify: | | | | |
| 1. Was all insulation successfully removed from the patient?  Yes  No | | | | |
| **Grounding Pads** | | | | |
| 1. How many pads were used during the procedure? | | | | |
| 1. How were the pads placed? | | | | |
| 1. Was the procedure successful in completing the intended ablation?  Yes  No | | | | |
| 1. What steps were taken to prep the patient for the procedure? | | | | |
| 1. Did the patient experience burn(s) as a result of the procedure?  Yes  No If No, proceed to Question 30. | | | | |
| 1. If Yes, specify where on the body the burn occurred? | | | | |
| 1. How large was the burn? Specify size: | | | | |
| 1. How did the clinician classify the burn?  Superficial  1st degree  2nd Degree  3rd Degree | | | | |
| 1. **a.** What other associated symptoms did the patient experience?  Redness  Blistering  Other   **b.** If other, specify associated symptom: | | | | |
| 1. **a**. How did the clinician treat the burn?  No treatment  Topical cream  Antibiotics  Other   **b**. If other treatments used, specify: | | | | |
| 1. What is the patient condition? | | | | |
| **ENDOSCOPY – BILIARY STENT DEVICE (E.G. WALLSTENT)** | | | | |
| 1. What was the indication for treatment (e.g. relieve biliary strictures, etc.)? | | | | |
| 1. Did the distal tip of the stent perforate the outer sheath?  Yes  No | | | | |

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| **Endosurgery Urology/WH Questions** | | |
| **UROLOGY – BIOPSY DEVICE (E.G. TRUPATH, EASYCORE, ETC.)** | | |
| 1. What was the indication for treatment (e.g., prostate biopsy)? | | |
| 1. Did the device fire prematurely (i.e., fire prior to pressing the device button)?  Yes  No | | |
| 1. Was the yellow indicator on the handle present when the device fired prematurely?  Yes  No | | |
| 1. How many samples were taken prior to the issue? Specify quantity: | | |
| 1. **a.** What stage did the device fire prematurely?  During arming  While passing device  Before sample was taken  While retrieving sample  After sample was taken  Other **b.** If other stage, specify: | | |
| 1. **a.** What was the location of the device when it fired prematurely?  In clinician’s hand  On the table  Other   **b.** If other location, specify: | | |
| 1. Was there difficulty pressing the lever down in order to get the device to cock (e.g., Cocked denoted by yellow indicator appearing in the window)?  Yes  No | | |
| 1. Were two hands required to press the lever down in order to get the device to cock?  Yes  No | | |
| **UROLOGY/WH – HYDRO THERMABLATOR** | | |
| 1. Was a tenaculum stabilizer used?  Yes  No | | 1. Was a speculum used?  Yes  No |
| 1. Did the clinician notice any fluid leaks during the hysteroscopy?  Yes  No | | |
| 1. How long into the procedure until the first fluid loss alarm went off? | | |
| 1. What was the rate of the lost fluid at the time of the alarm? | | |
| 1. How many fluid alarms occurred during the procedure? | | 1. Did the clinician complete the procedure?  Yes  No |
| 1. Did the patient experience burn(s) as a result of the procedure?  Yes  No If No, proceed to Question 14. | | |
| 1. Where did the clinician indicate that the burn occurred?  Inside the vagina  Outside the vagina  Both | | |
| 1. What was the specific location of the burn? | | 1. How large was the burn?   Specify burn size: |
| 1. How did the clinician classify the burn?  Superficial  1st degree  2nd Degree  3rd Degree | | |
| 1. **a.** How did the clinician treat the burn?  No treatment  Topical cream  Antibiotics  Other **b.** If other treatment used, specify: | | |
| 1. Did the purple tubing collapse?  Yes  No | 1. Was the purple tubing installed correctly?  Yes  No | |
| 1. If the purple tubing collapse, when during the procedure did this occur? | | |
| 1. Was excessive tissue noticed in the tubing?  Yes  No | | 1. Were any alarms generated?  Yes  No |
| 1. What is the patient condition? | | |
| **UROLOGY/WH – LITHOTRYPSY (E.G. LUMENIS)** | | |
| 1. What was the brand/model of the laser used within this procedure? | | |
| 1. Did the fiber break or blow off?  Fiber break  Fiber blew off | | |
| 1. What was the location of the fiber break or fiber blow off?  Inside the patient  Outside the patient | | |
| 1. If inside, specify the location inside the body where this occurred? | | |
| 1. How long into the procedure until the fiber break or blew off? | | |
| 1. Was the fiber removed from inside the body?  Yes   No | 1. How was the fiber removed (identify device(s) used)? | |
| **Questions 8-14 pertain to clinician injury due to fiber break** | | |
| 1. Was a burn sustained due to the fiber break?  Yes  No | 1. How large was the burn? Specify the burn size: | |
| 1. What was the classification of the burn?  None  Superficial  1st degree  2nd Degree  3rd Degree | | |
| 1. **a.** How was the burn treated? No treatment  Topical cream  Antibiotics  Other   **b.** Specify type if cream used:       **c.** If other, specify how burn was treated: | | |
| 1. What caused the fiber to break?  Fiber burnt out  Fiber degraded  Other | | |
| 1. What was the KJS at the time of the fiber break? | | |
| 1. What is the clinician’s condition? | | |

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| **Endosurgery Urology/WH Questions (Continued)** |
| **UROLOGY/WH - MICROWAVE SYSTEMS (E.G. PROLIEVE)** |
| 1. **a.** What part(s) of the device contributed to the complaint? Select all that apply:  Catheter  Anchoring Balloon   Rectal Temperature Monitor (RTM)  Heater Exchange Cartridge (HXC)  Other  **b.** Specify other suspect device(s): |
| **Catheter** |
| 1. Did the catheter leak?  Yes  No If yes – complete questions 3-4. |
| 1. **a.** How was the catheter leak detected?  Pressure warning(s)  Flow warning(s)  Fluid Leaking  Visual check   Other **b.** Specify how the leak was detected: |
| 1. **a.** Where did the leak occur?  Compression balloon  Anchoring balloon  At a seal  Along catheter body   Other **b.** Specify where the leak occurred: |
| 1. **a.** Did the catheter do any of the following?  Buckle  Kink  Other **b.** Specify other action of catheter:   If catheter buckled, kinked or other – complete questions 6-7. |
| 1. When was the failure observed?  Before procedure  During procedure  After procedure |
| 1. **a.** How was the problem detected?  Difficult to maneuver  Blood  Other **b.** If other, specify how detected: |
| **Anchoring Balloon (aka Foley Balloon)** |
| 1. Did the anchoring balloon leak?  Yes  No If yes – complete questions 9-14. |
| 1. **a.** What type of fluid was used to inflate the anchoring balloon?  Sterile water  Saline  Other   **b.** If other fluid used, specify: |
| 1. What was the volume of fluid used to inflate the anchoring balloon? |
| 1. Did the anchoring balloon fail to inflate?  Yes  No |
| 1. When was the failure to inflate detected?  Before procedure  During procedure  After procedure |
| 1. Did the anchoring balloon fail to deflate?  Yes  No |
| 1. When was the failure to deflate detected?  Before procedure  During procedure  After procedure |
| **Rectal Temperature Monitor (aka RTM)** |
| 1. Were there problems with the rectal temperature monitor?  Yes  No If Yes – complete questions 16-23. |
| 1. What is the estimated number of times that the RTM was used prior to this procedure? |
| 1. What is the RTM cleaning method used by the hospital? |
| 1. **a.** What types of problems were observed?  Temperature issues  Broken Unit  Other   **b.** If other problems observed, specify: |
| 1. When was the temperature issue observed?  Before procedure  During procedure  After procedure |
| 1. What temperature readings were displayed: **a.** Before procedure?       **b.** During procedure?   **c.** After procedure? |
| 1. Is the RTM physically broken?  Yes  No |
| 1. **a.** What part of the RTM is broken?  Handle  Cable  Bulb  Probe  Other   **b.** If other part broken, specify: |
| 1. **a.** When was the RTM break noticed?  During cleaning  During placement  After procedure  Other   **b.** If other break noticed, specify: |
| **Heater Exchange Cartridge (HXC)** |
| 1. Was there a cartridge leak?  Yes  No If yes – complete questions 25-29. |
| 1. Is fluid leaking out of the white, upper portion of the HXC?  Yes  No |
| 1. Was the HXC overfilled with fluid?  Yes  No |
| 1. Is fluid leaking out of the edge of one of the aluminum plates?  Yes  No |
| 1. If you squeeze the aluminum plates together, do they move or drip fluid out from the edges?  Yes  No |
| 1. Is one or both of the aluminum plates loose or can one or both of the plates be moved in any way?  Yes  No |
| 1. Was there a tubing leak?  Yes  No If yes – complete questions 31-32. |
| 1. Is fluid leaking out of the tubing?  Yes  No |
| 1. Is there a pinch in the tubing in the pump mechanism?  Yes  No |
| 1. Were there connection leaks?  Yes  No If yes, complete question 34. |

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| **Endosurgery Urology/WH Questions (Continued)** | | | |
| **UROLOGY/WH - MICROWAVE SYSTEMS (E.G. PROLIEVE) – Continued** | | | |
| 1. Is there a crack in the white connector at the end of the tubing set?  Yes  No   Note: Crack would be visible on the inside next to the small chrome pin. | | | |
| 1. Was the canister broken or cracked?  Yes  No If yes – complete questions 36-40. | | | |
| 1. What is the UPN and lot number of the catheter kit (include the first 4 “0000’s”)? | | | |
| 1. **a.** How was the heater exchanger filled?  manually by hand  automatically by system  Other **b.** If other, specify how filled: | | | |
| 1. What was the temperature reading when the break or crack was noticed? | | | |
| 1. Was the cartridge completely inserted?  Yes  No | | | |
| 1. Did the user inspect the sensor board (located inside the console) for possible fluid?  Yes  No | | | |
| 1. Was a low water level detected?  Yes  No If yes – complete questions 42-48. | | | |
| 1. Is the catheter tip separating in any way from the catheter body?  Yes  No   Note: The catheter tip may be attached to the anchoring balloon so close inspection may be required. Rotating or squeezing the tip may help detect separation. | | | |
| 1. Is the anchor balloon separating in any way from the catheter body?  Yes  No | | | |
| 1. Is there a pin hole in the compression balloon?  Yes  No | 1. Is there a tear in the anchor balloon?  Yes  No | | |
| 1. **a.** Can you identify the exact location where the fluid is leaking from?  Yes  No   **b.** If yes, specify location of leak: | | | |
| 1. Does the anchor balloon still hold 5cc of fluid?  Yes   No | 1. Does the anchor balloon slowly deflate?  Yes  No | | |
| **UROLOGY/WH – RESECTION DEVICE (E.G. PROSURG)** | | | |
| 1. What is the make/model of device? | 1. Was the device damaged?  Yes  No | | |
| 1. Was the scope damaged?  Yes  No | 1. Were both device and scope damaged?  Yes  No | | |
| 1. When was the device and/or scope damage detected?  Before procedure  During procedure  After procedure | | | |
| 1. Were there difficulties with components fitting with one another?  Yes  No If no, proceed to question 8. | | | |
| 1. **a.** Select all that apply:   Difficulty inserting devices into scope  Difficulty withdrawing device from scope  Device stuck in scope  Components are not compatible  Other  **b.** If other, specify difficulty: | | | |
| 1. Did the device produce sparks and / or arc (electrical current from device to scope)?  Yes  No | | | |
| 1. What is the make/model of the generator? | | 1. What was the power setting of the generator? | |
| **UROLOGY/WH – SUTURE DEVICE (E.G. CAPIO)** | | | |
| 1. **a.** Did the bullet tip fall off the device and into the patient?  Yes  No   **b.** If yes, was it removed?  Yes  No | | | |
| 1. If bullet tip was removed, specify how was the bullet tip removed from inside the patient? | | | |
| 1. Specify where the bullet tip fell off if someplace other than into the patient, where was it left? | | | |
| **UROLOGY/WH – INJECTABLE IMPLANTS DEVICE (E.G. COAPTITE)** | | | |
| 1. How was the procedure performed?  Transurethral  Periurethral | | | |
| 1. Was the injectable material injected directly from the pre-loaded syringe provided?  Yes  No | | | |
| 1. Was significant resistance encountered when pushing the device’s plunger shaft?  Yes  No | | | |
| 1. Was the green dot on the syringe aligned with the opening on the needle hub?  Yes  No | | | |
| 1. **a.** What type of needle was used in the procedure?  Chiba Tip Rigid Needle  Sidekick Rigid Needle   Other **b.** If other, specify needle type: | | | |
| 1. Was the procedure completed with the same needle?  Yes  No | | | 1. If different needle was it the same type?  Yes  No |
| 1. If not, specify needle type used to complete the procedure? | | | |
| 1. Were the instructions for use followed regarding the “unclogging” techniques to overcome resistance?  Yes  No | | | |
| 1. What was the level of moisture within the foil pouch? | | | |

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| **Neurovascular Questions** | | | | |
| **COILS** | | | | |
| 1. Had other coils been detached?  Yes, prior to this subject coil  Yes, after this subject coil  No | | | | |
| 1. **a.** What catheter was used with the coil?       **b.** Manufacturer:       **c.** Type:       **d.** Size: | | | | |
| 1. **a.** Did the coil detach prematurely?  Yes  No **b.** If Yes, was the coil removed?  Yes  No  **c.** If Yes, describe how: | | | | |
| 1. **a.** After detachment, did any portion of the coil protrude out of the aneurysm or into the parent vessel?  Yes  No **b.** If Yes, describe what actions were taken (e.g. coil removed, stent placed to hold coil in place): | | | | |
| 1. **a.** Was the coil inspected before use?  Yes  No **b.** If Yes, were any issues noticed?  Yes  No   **c.** If issue noticed, explain: | | | | |
| **6.** Were new batteries and cables used in this procedure? (select all that apply)  None  Batteries  Cables | | | | |
| **VESSEL DISSECTION / PERFORATION** | | | | |
| 1. Was this a dissection? If Yes, specify type (A – F)  No dissection  Type A  Type B  Type C  Type D   Type E  Type F  Unknown | | | | |
| 1. Was this a perforation?  Yes  No | | | | |
| 1. What BSC devices were used prior to dissection/perforation? | | | | |
| 1. Which device(s) does the physician feel caused/contributed to the dissection/perforation? | | | | |
| 1. **a.** Select which steps preceded the dissection/perforation during the procedure:   BWR  Guide catheter deep seated  Balloon Burst  Slow or no deflate  Stent damage  Shaft Fracture  Guidewire puncturing  Guidewire Fracture  Atherectomy device used  Guide catheter resistance  Other | | **b.** If balloon burst, specify atm:  **c.** If stent damage, specify (e.g., lifted, bent, or flared)  **d.** If atherectomy device used, specify (e.g., cutting balloon, rotablator, etc.):  **e.** If guide catheter resistance, specify (e.g. stiff or sticky):  **f.** If other, specify steps preceding dissection/perforation:  **g.** Describe any steps not described in **5a.-f.** above: | | |
| 1. **a**. What was the vessel location of dissection/perforation? | | | | |
| LAD  ICA  ACOM  PCOM  PICA  MCA  ACA  Vertebral artery  Proximal  Mid  Distal | | Basilar artery  Cerebral artery  Opthalmic artery  OM  RCA  Diag  LCX  PDA  PL  Ramus | | LM Protected  LM Unprotected  LIMA  SVG  Carotid  Femoral  Iliac  Vena Cava  Renal  Other  **b.** If other, specify lesion location details: |
| 1. Describe any patient symptoms during this event and actions taken: | | | | |

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| **IVUS Questions** |

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| GENERAL PROCEDURE INFORMATION (TO BE FILLED IN BY ICardio/PI ONLY) | | | | |
| 1. Did patient have myocardial infarction <72 hours prior to procedure?  Yes  No | | | | |
| 1. Date of last myocardial infarction? | | | | |
| 1. **a.** Indicate the lesion location (select all that apply): | | | | |
| LAD  ICA  ACOM  PCOM  PICA  MCA  ACA  Vertebral artery  Basilar artery  Cerebral artery  Opthalmic artery  OM  RCA | Diag  LCX  PDA  PL  Ramus  LM - Protected  LM – Unprotected  LIMA  SVG  Carotid  Femoral  Iliac  Vena Cava | | | Renal  Other  Proximal  Distal  Mid  Bifurcation  Ostial  Internal  External  Common  Left  Right  Unknown |
| **b.** If other lesion location, please specify: | | | | |
| 1. What was the vascular access site? (select all that apply)  Radial  Brachial  Femoral  Right  Left  Unknown | | | | |
| 1. What was the length of the lesion (mm)? | | | 1. What was the vessel diameter (mm)? | |
| 1. Was the lesion anatomy tortuous? Select No or indicate severity (select all that apply):  No  Mild  Moderate  Severe  Unknown | | | | |
| 1. Did the user encounter significant resistance? Select No or specify (select all that apply):  No Insertion  Advancing  Operation  Repositioning  Withdrawal | | | | |
| 1. **a.** Was there a significant bend involved in the lesion?  Yes No   **b.** If YES, indicate degree:  <=45  >45 and <90  >=90 | | | | |
| 1. Was the lesion calcified? Select No or specify calcification:  No  Mild  Moderate  Severe | | | | |
| 1. **a.** What was the % of stenosis? | | **b.** Was there a total occlusion?  Yes  No | | |
| 1. What was the ejection fraction? | | | | |
| 1. What was the shape of the lesion?  Eccentric  Concentric | | | | |
| 1. Was the lesion (check all that apply):  de novo (progressive)  In-stent restenosis  Restenosis (POBA, brachy)   Graft anastomosis | | | | |
| 1. **a.** Was the lesion/stent predilated?  Yes No **b.** If Yes, specify type and size of balloon: | | | | |
| 1. What was the percent stenosis of the lesion immediately after pre-dilation? | | | | |
| 1. **a.** Was the lesion post-dilated?  Yes No **b.** If Yes, specify the type and size of balloon: | | | | |
| 1. What type and size of guide catheter was used? | | | | |
| 1. What type and size of guidewire was used? | | | | |
| 1. Implant date: | | | | |
| 1. Explant date (if applicable): | | | | |
| 1. **a.** How many stents were implanted?   **b.** If more than one stent was implanted indicate sequence and any overlapping stents: | | | | |
| 1. What type(s) and size(s) of stent were implanted? | | | | |
| 1. In what vessel(s) were the stent(s) implanted? | | | | |
| 1. Were the stents fully-expanded and well-apposed by IVUS? | | | | |
| 1. Was there evidence of stent deformation following advancement of IVUS catheter?  Yes  No   If yes, what was the nature of the deformation:  proximal stent edge compression  distal stent edge compression;  stent elongation  What treatment or additional intervention was performed to address the stent deformation?  Was there an associated major cardiac event (MACE, ie death, ST, MI, CABG)?  Yes  No  Is CINE available for BSC review  Yes  No | | | | |
| 1. Does the patient have Diabetes?  Yes  No | | | | |

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| **IVUS Questions (Continued)** | | |
| **WITHDRAWAL RESISTANCE** | | |
| 1. Was there a stent involved during the withdrawal resistance?  Yes No If No selected, go to question 4. | | |
| 1. Was the stent fully deployed and well apposed?  Yes No | | |
| 1. Was there evidence of stent deformation following difficult removal of IVUS catheter? 0 Yes 0 No   If yes, what was the nature of the deformation:  0 proximal stent edge compression 0 distal stent edge compression 0 stent elongation  What treatment or additional intervention was performed to address the stent deformation?  Was there an associated major cardiac event (MACE, ie death, ST, MI, CABG)? 0 Yes0 No  Is CINE available for BSC review  Yes  No | | |
| 1. Was there difficulty removing the balloon from the stent?  Yes No | | |
| 1. Specify the type of contrast media and the contrast ratio in the inflation device (e.g., 100%, 75%, 50% or 25%):      % | | |
| 1. Did the physician have any difficulty inflating the balloon on the SDS? Select No or specify difficulty (select all that apply):   No No inflate  Slow inflate  Partial inflate  Eventually inflated | | |
| 1. To what pressure (atmospheres) was the balloon finally inflated? | | |
| 1. How long was the balloon inflated? | | |
| 1. Was the stent balloon fully inflated without waist?  Yes No | | |
| 1. How long was the inflation device under negative/neutral pressure before SDS withdrawal? | | |
| 1. Did the physician have any difficulty deflating the balloon? Select No or specify difficulty.  No  No deflate  Slow deflate  Partial deflate  Eventually deflated | | |
| 1. Was the balloon fully deflated before trying to pull back?  Yes  No | | |
| 1. **a.** What actions were undertaken to remove the balloon? (select all that apply)   Dialed up and dialed down  Pulled negative  Went neutral  Guide catheter deep seated | Pulled hard  Removed system as a unit  Surgery  Push guidewire  Other | **b.** If other actions were undertaken, specify: |
| 1. Was the device removed intact?  Yes No | | |
| 1. Was the balloon still inflated when removed?  Yes No | | |
| 1. Was there a previously implanted stent involved?  Yes No | | |
| 1. Was the shaft damaged?  No  Kinked/bent  Hole/perforated  Stretched  Detached/Separated  Other | | |
| 1. Did the stent remain implanted?  Yes No | | |
| 1. Describe any symptoms and/or complications related to the BWR and action taken (e.g., chest pain, bradycardia, tachycardia, dyspnea, etc.): | | |
| 1. Describe any patient complications related to withdrawal resistance: | | |

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| **IVUS Questions (Continued)** | | | | | |
| **VESSEL DISSECTION / PERFORATION** | | | | | |
| 1. Was this a dissection? If Yes, specify type (A - F)  No dissection  Type A  Type B  Type C  Type D  Type E  Type F  Unknown | | | | | |
| 1. Was this a perforation?  Yes  No | | | | | |
| 1. What BSC devices were used prior to dissection/perforation? | | | | | |
| 1. Which device(s) does the physician feel caused/contributed to the dissection/perforation? | | | | | |
| 1. **a.** Select which steps preceded the dissection/perforation during the procedure:   BWR  Guide catheter deep seated  Balloon Burst  Slow or no deflate  Stent damage  Shaft Fracture  Guidewire puncturing  Guidewire Fracture  Atherectomy device used  Guide catheter resistance  Other | | **b.** If balloon burst, specify atm:  **c.** If stent damage, specify (e.g., lifted, bent, or flared)  **d.** If atherectomy device used, specify (e.g., cutting balloon, rotablator, etc.):  **e.** If guide catheter resistance, specify (e.g. stiff or sticky):  **f.** If other, specify steps preceding dissection/perforation:  **g.** Describe any steps not described in **5a.-f.** above: | |
| 1. **a**. What was the vessel location of dissection/perforation? | | | |
| LAD  ICA  ACOM  PCOM  PICA  MCA  ACA  Vertebral artery  Proximal  Mid  Distal | Basilar artery  Cerebral artery  Opthalmic artery  OM  RCA  Diag  LCX  PDA  PL  Ramus | | LM Protected  LM Unprotected  LIMA  SVG  Carotid  Femoral  Iliac  Vena Cava  Renal  Other  **b.** If other, specify lesion location details: |
| 1. Describe any patient symptoms during this event and actions taken: | | | |
| **BALLOON CATHETERS** | | | |
| 1. Was the lesion located within a stent?  Yes  No | | | |
| 1. Was the catheter advanced through a previously placed stent?  Yes  No | | | |
| 1. Was the catheter rotated between inflations?  Yes  No | | | |
| 1. Specify pressure (atm) and duration of each inflation (i.e. 15atm/30sec)? | | | |
| 1. Was the catheter pulled back into the guide catheter between each inflation?  Yes  No | | | |
| 1. On which inflation did the event occur? | | | |
| 1. What was the maximum pressure (ATMs)? | | | |
| 1. **a.** Did the balloon burst?  Yes  No **b.** If Yes, at what pressure did the balloon burst (ATMs)? | | | |
| 1. **a.** Did the balloon leak?  Yes  No **b.** If yes, at what pressure did the balloon leak (ATMs)? | | | |
| 1. Were there deflation difficulties? If Yes, please complete Balloon No-Deflate Section.  Yes  No | | | |
| 1. **a.** Did the balloon or a segment of the balloon detach inside the patient during the procedure?  Yes  No   **b.** If Yes,describe actions taken. | | | |
| 1. **a.** Were there any shaft kinks noted? (select all that apply)  No  Prior to use  During Insertion  During Procedure  Post Procedure  Distal shaft  Mid shaft  Proximal shaft  Guidewire exit port   Tip  Other  **b.** Specify if other: | | | |
| 1. **a.** Was an introducer sheath used?  Yes  No **b.** If Yes, what size, type, and manufacturer (intro.)? | | | |
| 1. **a.** Was an inflation device used?  Yes  No **b.** If yes, what size, type, and manufacturer (device)? | | | |
| 1. What was the intended use for the balloon? Pre-dilatation  Post dilatation  Unknown | | | |

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| **Electrophysiology Questions** |
| **ELECTROPHYSIOLOGY CATHETERS** |
| 1. **a.** What type of catheter was being used?  Diagnostic  Ablation   **b.** Specify location in heart where the catheter was being used? |
| 1. What type of sheath was used? |
| 1. What were the insertion sites (including transseptal, puncture)? |
| 1. **a.** Was anticoagulation therapy used?  Yes  No   **b.** If anticoagulation was used, was it:  pre-procedure  post procedure  Intra-procedural  If transseptal puncture: Was anticoagulation initiated before or after transseptal puncture? Yes  No |
| 1. Which RF generator was being used?  EPT-1000  Maestro Other please list |
| 1. **a. I**f applicable, what were the ablation parameters?   **b.** Average power:       **c.** Temperature:       **d. Total** duration of the RF application: |
| 1. What was the total number of RF applications delivered? |
| 1. Was any char or coagulum noted on any of the devices?  Yes  No |
| 1. What other equipment was connected to the patient (e.g. model of recording system, model of defibrillator, model of stimulator)? |
| 1. Is a copy of the EP Log available for review?  Yes  No |
| **TEMPERATURE/IMPEDANCE ISSUES** |
| 1. Were they running in Temperature or Power mode?  Temperature Mode  Power Mode |
| 1. **a.** Was an error encountered?  Yes  No   **b.** If yes, was it on the first ablation attempt, or did it occur after several ablations? |
| 1. Was this a high temperature or low temperature situation?  High Temp  Low Temp 2. Was there a loss of temperature monitoring from the catheter?  Yes  No |
| 1. **a.** Were there high impedance errors or was the impedance higher than expected?  Yes  No    1. If yes, what was the range?   Was there sticking of the RF switches?  Yes  No |
| 1. **a.** Was the catheter replaced?  Yes  No   **b.** If yes, indicate same or list other catheter used (i.e., Blazer, Chilli, etc.): |
| 1. **a.** Was any equipment replaced when the catheter was replaced?  Yes  No   **b.** If yes, indicate what was replaced (i.e. cable, APM, POD, TTT): |
| **OTHER CATHETER ISSUES** |
| 1. Was there a curve issue noticed?  Yes  No   If yes, when was it noted?  Unpacking  During insertion  Post procedure |
| 1. Was the catheter pre-bent prior to insertion?  Yes  No |
| 1. **a.** Was the product kinked or over torqued?  Yes  No   **b.** If kinked or torqued, please explain: |
| 1. Were there any other observations? Please mark all that apply:   Deformation of shape of catheter  Embolism of the tip  Entrapment of cardiac tissue  Inability to pass catheter through guide  Clot on catheter or guide  Sticking of the RF switches  Failure of connecting cables in an unknown manner  Leaking connectors  Electrical noise |

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| **Electrophysiology Questions (Continued)** | | | |
| **EVENTS** | | | |
| 1. Was there a clinical event?  Yes  No If Yes see below | | | |
| 1. Was this a perforation?  Yes  No | | | |
| 1. Was a BSC device(s) used prior to dissection/perforation? | | | |
| 1. Which device(s) does the physician feel caused/contributed to the event? | | | |
| 1. **Please indicate which event(s) occurred AND description, if not included previously**   Pericardial effusion  w/tamponade  w/o tamponade  Embolism-system and/or cerebral  Hemorrhage  Pulmonary embolism  Esophageal perforation  Perforation: Location  Phrenic nerve paralysis  Coronary spasm  w/ MI  w/o MI  Venous thrombosis  Other: Please Explain: | | | |
| 1. Describe any patient symptoms during this event and actions taken if not already completed: | | | |
| 1. Did patient experience any hemodynamic instability?  Yes  No   If yes please explain: | | | |
| **VESSEL DISSECTION / PERFORATION** | | | |
| 1. Was this a perforation?  Yes  No | | | |
| 1. What BSC devices were used prior to dissection/perforation? | | | |
| 1. Which device(s) does the physician feel caused/contributed to the dissection/perforation? | | | |
| 1. **a.** Select which steps preceded the dissection/perforation during the procedure   Shaft Fracture  Guidewire puncturing  Guidewire Fracture  Guide catheter resistance  Other | | **b.** If guide catheter resistance, specify (e.g. stiff or sticky):  **c.** If other, specify steps preceding dissection/perforation:  **d.** Other: | |
| 1. What was the vessel location of dissection/perforation? | | | |
|  | Aorta | |  |
| 1. Describe any patient symptoms during this event and actions taken: | | | |
| **GROUNDING PADS** | | | | | |
| 1. How many pads were used during the procedure? | | | | | |
| 1. Where were the pads placed? | | | | | |
| 1. Was the procedure successful in completing the intended ablation?  Yes  No | | | | | |
| 1. What steps were taken to prep the patient for the procedure? | | | | | |
| 1. Did the patient experience burn(s) as a result of the procedure?  Yes  No | | | | | |
| 1. If yes, specify where on the body the burn occurred? | | | | | |
| 1. How large was the burn? Specify size: | | | | | |
| 1. How did the clinician classify the burn?  Superficial  1st degree  2nd Degree  3rd Degree | | | | | |
| 1. **a.** What other associated symptoms did the patient experience?  Redness  Blistering  Other   **b.** If other, specify associated symptom: | | | | | |
| 1. **a**. How did the clinician treat the burn?  No treatment  Topical cream  Antibiotics  Other   **b.** If other treatments used, specify: | | | | | |
| 1. What is the patient condition? | | | | | |

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| **LEFT ATRIAL APPENDAGE CLOSURE (LAAC) DEVICE (E.G. Watchman)** |
| 1. Is the patient currently prescribed warfarin?  Yes  No   If no, is the patient prescribed another oral anticoagulant?  Yes  No  If yes, specify: |
| 1. If the patient is taking warfarin, record last INR       Date of last INR |
| 1. Is patient currently prescribed antiplatelet medication  Yes  No   If yes specify: Aspirin  Clopidogrel  Ticlodipine  Other  Specify |
| 1. Have there been any interventions or surgical procedures between the initial LAAC procedure and this event?  Yes  No   If yes, explain |
| 1. Were other procedures performed during the LAAC procedure? (e.g catheter ablation)  Yes  No   If yes, explain  If ablation was performed, was irrigation used?  Yes  No  If yes, indicate volume used \_\_\_\_\_\_ mL’s |
| 1. Indicate below which best describes the event:   Air Embolism  Device embolization: please indicate final location:  Myocardial Ischemia  Perforation: Location  Pericardial Effusion with tamponade  Pericardial Effusion without tamponade  Stroke  Thrombus Location  Transient Ischemic Attack (TIA)  Valvular Damage  Vessel Damage – Describe appearance of vessel:  Perforation Laceration  Erosion  Other: Specify |
| 1. When did the event occur?:   Preprocedure  Intra-operatively  Post-procedure |
| 1. Which device is associated with this event? Access System Delivery System Watchman Device   other: please explain |
| 1. If Watchman implant, indicate which size is associated with the complaint:   21mm  24mm 27mm  30mm 33mm N/A |

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| **LAAC: PRODUCT INFORMATION** |
| 1. Was there a curve issue?  Yes  No Explain:   If yes, did the curve lead to the use of another product?  Yes  No  If yes which product**:** :  Access System  Delivery System  Other specify |
| 1. Which curve access system was used?  Single  Double Curve |
| 1. Was the catheter pre-bent by physician prior to insertion?  Yes  No   If yes, list which catheter: |
| 1. Was there a product kink associated with the Watchman Access System (WAS)?  Yes  No   Please indicate:  Access System  Delivery System  other : Explain:  If kinked, when was the kink noted?  Unpacking  During insertion  Accessing the LAA  During Recapture |
| 1. Was the WAS over-torqued?  Yes  No Explain: |
| 1. Was there a product kink associated with the Watchman Delivery System (WDS)?  Yes  No   Please indicate:  Access System  Delivery System  other : Explain:   1. If kinked, when was the kink noted?  Unpacking  During insertion  Accessing the LAA  During Recapture |
| 1. Was a pigtail catheter used to deliver the access sheath into the left atrial appendage?  Yes  No 2. Was the WDS able to be inserted into the WAS?  Yes  No  With Resistance |
| 1. Was WAS changed for a new WAS?  Yes  No 2. Was WAS removed and reinserted?  Yes  No |

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| **LAAC: RECAPTURE & TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE)** |
| 1. Was a partial recapture performed?  Yes  No   If yes, how many partial recapture attempts were performed?  Was recapture successful?  Yes  No  Was there significant resistance felt?  Yes  No |
| 1. Was a full recapture performed?  Yes  No   If yes, how many full recapture attempts were performed?  Was recapture successful?  Yes  No  Was there significant resistance felt?  Yes  No  If full recapture was completed, was a new device needed?  Yes  No Attempted  Other: specify |
| 1. What was the reason for recapture? |
| 1. Was Tug Test performed following device deployment?  Yes  No |
| 1. Pre-implantation transesophageal echocardiography measurement   Max Diameter \_\_\_\_\_\_(mm) Angle \_\_\_\_\_deg Not Obtained  Post-implantation transesophageal echocardiography measurement  Max Diameter \_\_\_\_\_\_(mm) Angle \_\_\_\_\_deg Not Obtained |
| 1. Was appropriate compression of device confirmed by fluoroscopy?  Yes  No |

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| Structural Heart Questions | | | |
| GENERAL PROCEDURE INFORMATION (TO BE FILLED IN BY Structural Heart ONLY) | | | |
| * 1. Did patient have myocardial infarction <72 hours prior to procedure?  Yes  No | | | |
| * 1. Date of last myocardial infarction? | | | |
| * 1. Was the aortic annulus calcified?  Yes  No | | | |
| * 1. Aortic valve area [AVA] (cm2) | * 1. AVA index | | |
| **6**. Aortic Valve Analysis: | | | |
| |  |  |  |  | | --- | --- | --- | --- | | Diameters (mm) | CT | US | XA | | Ascending Aorta Diameter |  |  |  | | Sinotubular Junction Diameter |  |  |  | | Sinus of Valsalva Diameter |  |  |  | | Min. Annulus Base Diameter |  |  |  | | Max. Annulus Base Diameter |  |  |  | | Min. LVOT Diameter |  |  |  | | Max. LVOT Diameter |  |  |  |  |  |  |  | | --- | --- | --- | | Lengths (mm) | CT | US | | Annulus to RBCA Length |  |  | | Annulus to Left Coronary Ostium length |  |  | | Annulus to Right Coronary Ostium length |  |  | | Annulus to Sinotubular Junction length |  |  | | Annulus to Sinus of Valsalva Length |  |  | | Aortomitral Continuity length |  |  | | LC Sinus of Valsalva Width |  |  | | RC Sinus of Valsalva Width |  |  | | NC Sinus of Valsalva Width |  |  | | |  |  |
| |  |  |  |  | | --- | --- | --- | --- | | Angles | CT | US | XA | | Retrograde Annulus Entrance Angle |  |  |  | | Aortic Arch Angulation |  |  |  |  |  |  | | --- | --- | | Ultrasound | Value | | Annulus to RBCA Length |  | | Annulus to Left Coronary Ostium length |  |   **Calcification details:** | | | |
| 1. Apex Analysis:  |  |  | | --- | --- | | Diameters | Value | | Myocardium Thickness |  | | Septal Wall thickness |  | | Anterograde Annulus Entrance Angle |  |   **Thrombus details:** | | | |
| 1. Was there prior brachytherapy of the target area?  Yes  No | | | |
| 1. What was the vascular access site? (select all that apply)  Radial  Brachial  Femoral  Right  Left  Unknown | | | |
| 1. Was the iliofemoral severely tortuous? Select No or indicate severity (select all that apply):  No  Mild  Moderate  Severe  Unknown | | | |
| 1. Was the iliofemoral severely calcified? Select No or indicate severity (select all that apply):  No  Mild  Moderate  Severe  Unknown | | | |
| 1. Did the user encounter significant resistance? Select No or specify (select all that apply):  No   Inserting  Advancing  Operation  Turning the control knob  Turning the release collar Insertion  Repositioning  Withdrawal | | | |
| 1. **a.** Was there a significant bend involved in the lesion?  Yes No   **b.** If YES, indicate degree:  <=45  >45 and <90  >=90 | | | |
| 1. What was the percent stenosis? | | | |
| 1. What was the ejection fraction? | | | |
| 1. What was the shape of the lesion?  Eccentric  Concentric | | | |
| 1. Was the lesion (check all that apply):  de novo (progressive)  In-stent restenosis  Restenosis (POBA, brachy)   Graft anastomosis | | | |
| 1. **a.** Was valvuloplasty performed?  Yes No **b.** If Yes, specify type and size of balloon: | | | |
| 1. What was the percent stenosis of the lesion immediately after valvuloplasty? | | | |
| 1. What type and size of introducer sheath used? | | | |
| 1. What type and size of guide catheter was used? | | | |
| 1. What type and size of guidewire was used? | | | |
| 1. Implant date: | | | |
| 1. Explant date (if applicable): | | | |
| 1. **a.** How many valves were required to complete the procedure?   **b.** If more than one valve was implanted indicate sequence: | | | |
| 1. Does the patient have Diabetes?  Yes  No | | | |

#### Complaint Call Centers (CCC) & Local Customer Service (LCS) & Local Call Centers (LCC)

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| **Marlborough** | Phone:866-868-4004  Fax:888-272-8438  e-mail: *endosurgerycomplaints@bsci.com* | Boston Scientific  Endosurgery Complaints  100 Boston Scientific Way  Marlborough, MA 01752 |
| **Japan Complaint Call Center** | | |
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