

Lubricious Coating Separation from Intravascular Medical Devices: FDA Safety Communication

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Audience:

- Health care providers who treat patients during or after intravascular procedures
- Health care providers who interpret imaging studies or study tissue samples following intravascular procedures

Device:

Medical devices such as intravascular catheters, guidewires, balloon angioplasty catheters, delivery sheaths, and implant delivery systems are commonly used during minimally invasive procedures in the cerebrovascular, cardiovascular and peripheral vascular systems. These devices often have hydrophilic and/or hydrophobic lubricious coatings (e.g., polyvinylpyrrolidone (PVP), polytetrafluoroethylene (PTFE), silicone, etc.) to reduce friction between the device(s) and blood vessels. These coatings offer physicians greater maneuverability, and may result in less trauma to blood vessels and reduced thrombogenicity for patients.

Purpose:

The FDA wants to make health care providers aware of the possibility that hydrophilic and/or hydrophobic coatings may separate (e.g., peel, flake, shed, delaminate, slough off) from medical devices and potentially cause serious injuries to patients. Coating separation can be caused by a number of factors, ranging from the difficulty of the procedure and the patient's anatomy to practitioner technique or using the wrong device for the procedure, to improper preconditioning of the device and improper storage conditions as well as issues with device design or manufacturing processes.

This communication contains important information physicians should consider to reduce the potential of adverse events. Based on current information, the FDA believes the overall benefits of these devices continue to outweigh the risks. However, health care providers should be aware of potential problems and consider certain actions prior to use.

Summary of Problem and Scope:

Hydrophilic and/or hydrophobic coated devices have been used for more than 20 years on millions of patients in minimally invasive diagnostic and therapeutic cerebrovascular, cardiovascular and peripheral vascular procedures. Both types of these coatings decrease friction between the device and blood vessels. These devices allow physicians to provide minimally invasive treatment options to patients. Without devices

with these coatings, some patients may not have alternative treatment options, or the other treatments might include more invasive procedures, which tend to have longer recovery times and increased risk of infections.

Although these devices offer patient benefits, evidence indicates that the coating may separate from intravascular devices in some circumstances. The FDA has received and analyzed information concerning serious adverse events associated with hydrophilic and/or hydrophobic coatings separating (e.g., peeling, flaking, shedding, delaminating, sloughing off) from intravascular medical devices. Since Jan. 1, 2010, there have been 11 recalls from various manufacturers associated with these coatings peeling or flaking off of medical devices. The majority of the recalls were associated with guidewires, but there have also been recalls for other types of devices including sheaths, retrieval devices and embolization device delivery wires used in the vasculature.

In addition, since Jan. 1, 2014, the FDA has received approximately 500 Medical Device Reports (MDRs) describing separation of hydrophilic and/or hydrophobic coatings on medical devices such as guidewires, catheters, and introducers that had been used for cerebrovascular, cardiovascular and peripheral vascular procedures. The majority of the reports were submitted for vascular guidewires and over 75% of the reports describe device malfunctions. MDRs are not, by themselves, definitive evidence of a faulty or defective medical device, and cannot be used to establish or compare rates of event occurrence. Therefore, the FDA has obtained and evaluated other relevant information besides MDRs, including medical literature and physician surveys.

Serious adverse events reported in these MDRs and in the scientific literature include pulmonary embolism, pulmonary infarction, myocardial embolism, myocardial infarction, embolic stroke, tissue necrosis, and death. Serious injuries associated with the peeling of coatings reported in MDRs included the persistence of coating fragments in patients, requiring surgical intervention to mitigate the consequences, adverse tissue reactions, and thrombosis. Eleven MDRs described patient deaths, two of which were not attributed to the device coating. The remaining nine death reports were also described in the published literature. In these cases, occlusion of blood vessels reportedly occurred due to embolization of coating particles from devices during heart and brain catheterization procedures contributing to clinical adverse events such as heart attack and bleeding inside the brain. It may be difficult for clinicians to associate these adverse events with malfunction of the coating; instead, they may mistakenly attribute the adverse events to other procedural complications or patient co-morbidities.

The FDA has not concluded that any specific manufacturer or brand of these devices is associated with higher risks than others. The cause of coating separation is multifactorial, and can be associated with factors including device design, device manufacturing, and use. Current FDA analysis suggests that use-related issues may be mitigated through proper device selection, preparation, and other considerations noted below.

Recommendations for Health Care Providers:

Based on current understanding of the benefits and risks of devices with these coatings, the FDA believes that the overall benefits of these devices continue to outweigh the risks. However, health care providers should consider the following information and actions to reduce the potential of serious adverse events:

- Be aware that many devices are designed, labeled and indicated for specific uses. For example, the coating and performance of a device meant to be used in the peripheral vasculature may be different than a device meant to be used in the cerebral vasculature.
- Follow manufacturer's instructions for proper device storage (e.g., shelf life, temperature, exposure to light, etc.) as improper storage can impact the integrity of the coating.

- When using two devices together (e.g., catheter and introducer sheath), ensure there is sufficient room for one to pass safely within the other, taking into consideration the features of the device (e.g., curved tip), and that some coatings may swell during use. For example, consider using a slightly larger French size for the introducer sheath than the catheter so there is sufficient room between the devices. Review the device labeling or consult the device manufacturer for further information.
- Follow the manufacturer's recommended preconditioning steps (if applicable) for the device. Preconditioning activates the lubricious properties of some device coatings for optimal use.
 - During preconditioning of the coating, use only the recommended solution (e.g., normal saline, heparinized saline, sterile water, etc.). Solutions may not be interchangeable and may affect the hydrophilic and/or hydrophobic coatings differently.
 - Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating which could affect the device safety and performance.
 - Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.
 - Avoid wiping the device with dry gauze as this may damage the device coating.
- Use caution when manipulating, advancing and/or withdrawing these devices through needles, metal cannulas, stents, or other devices with sharp edges, or through tortuous or calcified blood vessels. Manipulation, advancement and/or withdrawal past sharp or beveled edges may result in destruction and/or separation of the outer coating which may lead to clinical adverse events.
- Be aware that attempting to alter the shape of devices by bending, twisting, or similar methods may compromise the coating integrity and that damage to the coating may not always be noticeable to the naked eye.
- Consider replacing a device if it does not move freely, is visibly kinked or otherwise damaged, or does not perform as expected.

For further information on how to use a device safely, consult the labeling or contact the device manufacturer.

FDA Activities:

The FDA has collected and analyzed data from MDRs, recalls, labeling, medical literature, and information from clinicians, engineers and manufacturers. The FDA has not concluded that any specific manufacturer or brand of these devices is associated with higher risks than others. The causes of these issues are multifactorial, and can be associated with factors including device design, device manufacturing, and use.

The FDA will continue to work with stakeholders in an effort to develop non-clinical test methodologies to better characterize coating performance, establish performance criteria for evaluating coating integrity, and identify gaps in current national and international device standards. The Agency will also continue to work with device manufacturers to ensure accurate labeling that includes clear user instructions on how to minimize the occurrence of these issues.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect hydrophilic and/or hydrophobic coating separating (i.e., delaminating, sloughing off, peeling, flaking, degrading, disintegrating, etc.) from a device, we encourage you to file a voluntary report through **[MedWatch, the FDA Safety Information and Adverse Event Reporting program \(http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm\)](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**.

Device manufacturers must comply with the applicable [Medical Device Reporting \(MDR\) regulations. \(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm\)](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)

Healthcare personnel employed by facilities that are subject to the [FDA's user facility reporting requirements \(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm\)](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm) should follow the reporting procedures established by their facilities.

Other Resources:

MedSun survey: [Hydrophilic Coating and Hydrophobic Coating on Medical Devices \(/downloads/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/Newsletters/UCM464550.pdf\)Used in the Vasculature \(http://www.fda.gov/downloads/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/Newsletters/UCM464550.pdf\)](http://www.fda.gov/downloads/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/Newsletters/UCM464550.pdf)

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Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at [DICE@FDA.HHS.GOV \(mailto:DICE@FDA.HHS.GOV\)](mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.

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