Post-Market Medical Device Surveillance Report

MANUFACTURER: <mfr>

SCOPE:

There are several device components combined to create the custom-made device used in this case. Although one report was provided to the FDA via IDE, the FDA typically requires a separate report for each device used that may have caused or contributed to an adverse event. Additionally, the adverse event was submitted on paper rather than electronically, as is regulatorily required as of December 31, 2012. The electronic reporting format includes additional data fields that are not available on the <mfr> intake form.

Although the custom fenestrated stent-graft was used and is an investigational device, the <mfr> spiral wire, *****, and ***** sheath are approved/cleared under different FDA programs and MDR reporting is critical to ensure that issues with these devices are promptly reported to the FDA so that the reports are available to care providers seeking to make decisions about device safety and compatibility.

BACKGROUND FOR <mfr>:

<mfr> adverse event reports date back to 1995 when the FDA created MAUDE, its adverse event reporting database. MAUDE data is publicly available, but the search options only allow for searches of the last 10 years. Because the data in Public MAUDE is publicly reported, there are instances where a search on <mfr> returns results for other companies or for device components used with a <mfr> device. Additionally, there are reports of <mfr> devices submitted in reports from other manufacturers including ******, ****** and *********.

DEVICE IDENTIFIER:

FDA PRODUCT CODE [?]

Product Code	Product Code Name
MIH	SYSTEM, ENDOVASCULAR GRAFT, AORTIC ANEURYSM TREATMENT

Below is an example of the entry by the manufacturer for fenestrated grafts:

GMDN Preferred Term Name	GMDN Definition
Synthetic vascular graft	A sterile artificial substitute for a blood vessel intended to replace or bypass the diseased or injured vessel. It is typically made of woven or knitted polyethylene terephthalate (Dacron) or polytetrafluoroethylene (PTFE) fabrics and is best suited for large (more than 10 mm) diameter, high-flow vessel replacement (e.g., aortic or aorto-iliac artery reconstruction) and also for haemodialysis access and extra-anatomic bypass grafting. The device is used in many vascular bypass procedures (e.g., aorto-iliac, femoral-popliteal, axillo-axillary artery) except those involving the coronary arteries.

<mfr>-SPECIFIC ADVERSE EVENT REPORTS FOR FENESTRATED ENDOVASCULAR DEVICES:

MAUDE contains 14,628 adverse event reports to the FDA that reference a <mfr> fenestrated endovascular device. Of those, 9,923 were classified by the reporter as an injury and 465 were classified as Death.

Report Type

Check All | Uncheck All

- ☑ Injury (9,923)
- ☑ Malfunction (3,893)
- ☑ Death (465)
- ☑ Other (193)
- ☑ *blank* (154)

Note: It's important to note that when reports are submitted to the FDA, the submitter typically chooses the box that best represents what is known at that time for the device. The reporter has to choose whether a malfunction may have caused the injury or death. Only one box may be checked, and some companies have been cited by the FDA for under-reporting and misreporting deaths as malfunctions and injuries.

Of the 14,628 adverse event reports to the FDA for a <mfr> fenestrated vascular device, 13,607 were submitted by the manufacturer. Voluntary reports can be submitted by anyone (doctor, patient, family member), but manufacturers and hospitals must submit using the manufacturer form unless the hospital is part of the FDA's MedSun reporting program. User Facility reports are submitted by hospitals and surgery centers, and Manufacturer reports can come from any source that complains to the manufacturer, including attorneys. Physicians most often report to the manufacturer rather than to the

FDA because they are seeking a replacement device, but the FDA encourages direct reporting through a new iOS and Android application called MedWatcher.

Reporter Occupation

Check All | Uncheck All

- ☑ PHYSICIAN (5,485)
- ☑ ATTORNEY (3,885)
- ☑ OTHER (2,480)
- ☑ UNKNOWN (669)
- ☑ RISK MANAGER (569)
- ☑ OTHER HEALTH CARE PROF... (445)
- ☑ *blank* (383)
- ☑ NURSE (355)
- ☑ HEALTH PROFESSIONAL (164)
- ☑ PATIENT (45)
- ☑ RADIOLOGIC TECHNOLOGIST (36)
- ☑ RESPIRATORY THERAPIST (25)
- ☑ BIOMEDICAL ENGINEER (19)
- ☑ PHARMACIST (18)
- ☑ NOT APPLICABLE (11)
- ☑ PHYSICIAN ASSISTANT (11)
- ☑ AUDIOLOGIST (7)
- ☑ PATIENT FAMILY MEMBER ... (5)
- ☑ NO INFORMATION (4)
- ☑ MEDICAL TECHNOLOGIST (3)

less...

Physician reports account for 38% of the <mfr> adverse events, and reports from other types of healthcare providers account for another 16% of the reports. 92% of the physician reports were submitted to the manufacturer rather than directly to the FDA.

KEYWORD SEARCHES OF MAUDE DATA FOR ***** AND WIRE:

MAUDE contains 746 reports using the keywords "*****" and "wire." 565 of these adverse event reports were submitted by physicians. 36 reports reference spiral wires, 33 reference ABC wires, and 290 reports reference XYZ wires. The Device Problem coded most frequently in these reports is Difficult to Deploy which was used in 123 reports. The other problems are listed below in descending order of occurrence.

Device Problem

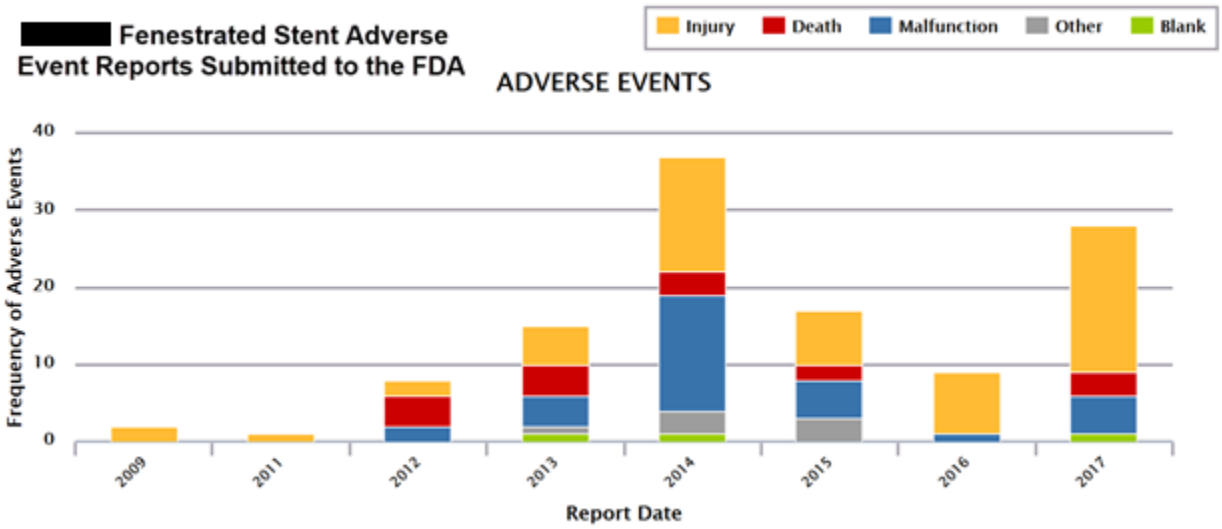
Check All | Uncheck All

- ☑ Difficult to deploy (123)
- ☑ Leak (85)
- ☑ Other (for use when an... (83)
- ☑ Difficult to remove (47)
- ☑ Occlusion within device (31)
- ☑ Explanted (18)
- ☑ Material separation (9)
- ☑ Material rupture (8)
- ☑ Migration of device or... (8)
- ☑ Deployment issue (6)
- ☑ Dissection (6)
- ☑ Kinked (5)
- ☑ Break (4)
- ☑ Coagulation in device ... (4)
- ☑ Disconnection (4)
- ☑ Device Issue (3)
- ☑ Difficult to position (3)
- ☑ Failure to advance (3)
- ☑ Failure to deploy (3)
- ☑ Material perforation (3)

less...

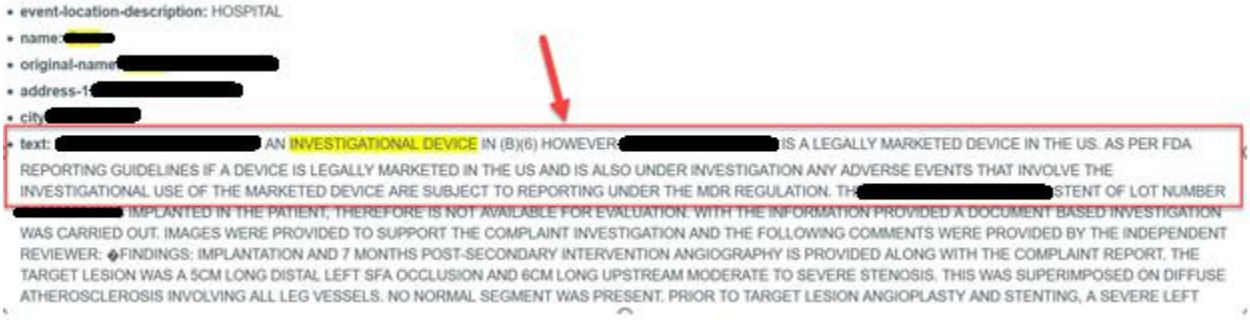
KEYWORD SEARCHES OF MAUDE DATA FOR ****** FENESTRATED GRAFT:

MAUDE contains 123 reports for ***** Fenestrated Grafts. There are 60 injury reports, 37 malfunctions, and 16 deaths. They are shown below in a trend chart:



<mfr> REPORT FOR ANOTHER INVESTIGATIONAL DEVICE:

This adverse event from FDA's MAUDE database provides background of <mfr>s' policy of reporting investigational device adverse events to the FDA as an MDR.



- **event-location-description:** HOSPITAL
- name: [redacted]
- original-name [redacted]
- address-1 [redacted]
- city [redacted]
- **text:** [redacted] AN INVESTIGATIONAL DEVICE IN (B)(6) HOWEVER [redacted] IS A LEGALLY MARKETED DEVICE IN THE US. AS PER FDA REPORTING GUIDELINES IF A DEVICE IS LEGALLY MARKETED IN THE US AND IS ALSO UNDER INVESTIGATION ANY ADVERSE EVENTS THAT INVOLVE THE INVESTIGATIONAL USE OF THE MARKETED DEVICE ARE SUBJECT TO REPORTING UNDER THE MDR REGULATION. TH [redacted] STENT OF LOT NUMBER [redacted] IMPLANTED IN THE PATIENT, THEREFORE IS NOT AVAILABLE FOR EVALUATION. WITH THE INFORMATION PROVIDED A DOCUMENT BASED INVESTIGATION WAS CARRIED OUT. IMAGES WERE PROVIDED TO SUPPORT THE COMPLAINT INVESTIGATION AND THE FOLLOWING COMMENTS WERE PROVIDED BY THE INDEPENDENT REVIEWER: FINDINGS: IMPLANTATION AND 7 MONTHS POST-SECONDARY INTERVENTION ANGIOGRAPHY IS PROVIDED ALONG WITH THE COMPLAINT REPORT. THE TARGET LESION WAS A 5CM LONG DISTAL LEFT SFA OCCLUSION AND 6CM LONG UPSTREAM MODERATE TO SEVERE STENOSIS. THIS WAS SUPERIMPOSED ON DIFFUSE ATHEROSCLEROSIS INVOLVING ALL LEG VESSELS. NO NORMAL SEGMENT WAS PRESENT. PRIOR TO TARGET LESION ANGIOPLASTY AND STENTING, A SEVERE LEFT

~~~ END OF REPORT ~~~