Use of the Stryker Wingspan Stent System Outside of Approved Indications Leads to an Increased Risk of Stroke or Death: FDA Safety Communication

Date Issued

April 25, 2019

Audience

- Health Care Providers: Neurologists, neurosurgeons, and neuroradiologists who perform neurointerventional procedures.
- Patients with intracranial arterial stenosis.
- Institutional Review Boards (IRBs) who approve the use of the Wingspan device.

Medical Specialties

Neurointervention, Neurology, Neurosurgery, Neuroradiology

Product

Stryker's Wingspan Stent System (Wingspan) is used to open narrowed arteries in the brain of patients diagnosed with intracranial stenosis who are experiencing repeated strokes. Intracranial arterial stenosis, or narrowing of arteries, is a serious condition caused by a buildup of plaque within the intracranial arteries. This may be referred to as intracranial atherosclerotic disease (ICAD). Patients with intracranial stenosis are at serious risk of life-threatening strokes due to reduced blood flow to the brain from narrowed or blocked arteries, and there are few treatment options available for managing this condition.

Wingspan is FDA-approved only for patients who are between 22 and 80 years old AND meet ALL the following criteria:

- who have had two or more strokes despite aggressive medical management;
- whose most recent stroke occurred more than seven days prior to planned treatment with Wingspan;
- who have 70-99 percent stenosis due to atherosclerosis of the intracranial artery related to the recurrent strokes; and
- who have made good recovery from the previous stroke and have a modified Rankin Scale score of three or less prior to Wingspan treatment. The Rankin scale is used to measure the degree of disability at the time of evaluation. Lower scores indicate less or no disability.

Wingspan is approved through the Humanitarian Device Exemption (HDE) (/medical-devices/premarket-submissions/humanitarian-device-exemption) regulatory pathway. Humanitarian Use Devices (/industry/developing-products-rare-diseases-conditions/designating-humanitarian-use-device-hud) (HUD) eligible for the HDE regulatory pathway are intended to treat or diagnose a disease or condition that affects not more than 8,000 people in the United States per year. Generally, a patient may be treated with Wingspan only if the treating physician has received Institutional Review Board (IRB) (/medical-devices/humanitarian-device-exemption/humanitarian-device-exemption-hde-postmarket-activities) approval to use the Wingspan at the clinical site.

Purpose

The FDA is providing results from the mandated postmarket surveillance study (Section 522 study) entitled "Wingspan StEnt System PostmArket SurVEillance (WEAVE) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=297&c_id=762)" to inform health care providers and patients that a significantly higher incidence of stroke or death occurred within 72 hours of the procedure when the Wingspan was used in patients outside of the FDA-approved indications for use.

Summary of Problem and Scope

In 2012, the FDA worked with Stryker to update their labeling for the Wingspan device, which included revised indications for use (noted above), based on safety information reviewed and feedback received during a public FDA Neurological Devices Panel of the Medical Devices Advisory Committee (https://www.federalregister.gov/documents/2012/02/13/2012-3243/neurological-devices-panel-of-the-medical-devices-advisory-committee-notice-of-meeting) meeting held on March 23, 2012. In addition, the FDA ordered Stryker to conduct a postmarket surveillance study (Section 522 study) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=297&c_id=762), and Stryker initiated the WEAVE study to fulfill the Section 522 study requirement. The FDA also publicly informed (http://wayback.archive-it.org/7993/20170722215747/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm314600.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) health care providers and patients about the revised labeling based on the review of available safety information.

The WEAVE study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=297&c_id=762) was recently completed and showed a higher incidence of stroke or death when the Wingspan was used outside of the FDA-approved indications for use. The WEAVE study was designed as a prospective, single arm, multi-center study. The study obtained Institutional Review Board approval and was conducted at 24 clinical sites in the United States to further assess the rates of stroke or death within 72 hours of the Wingspan Stent placement procedure. A total of 198 patients were treated using Wingspan in the study. Of the 198 patients treated, 152 patients met the FDA-approved indications for use criteria, and 46 patients did not meet the approved indications for use criteria. There was a higher incidence of stroke or death within 72 hours of the procedure when the Wingspan was used in patients outside of the FDA-approved indications for use. The following table lists the rates of stroke or death between these two groups.

Outcome (within 72 hours)	Patients who met the FDA-approved indications for use	Patients who did not meet the FDA-approved indications for use
Death	2 (1.3%)	2 (4.3%)
Stroke without death	2 (1.3%)	*9 (19.6%)
Total with stroke or death	4 (2.6%)	**11 (23.9%)
Total without stroke or death	148 (97.4%)	35 (76.1%)
Total number of patients treated	152	46

* All nine strokes occurred in the territory of the stented artery. Seven strokes were ischemic (https://medlineplus.gov/ischemicstroke.html) and two strokes were hemorrhagic (https://medlineplus.gov/hemorrhagicstroke.html). Out of nine patients who had a stroke, eight had modified Rankin Scale scores available at Day 90 follow up. Of these eight patients, 50 percent (4/8) recovered by day 90.
** Treatment outside of the FDA-approved indications included: less than seven days since the last stroke (n=4), less than two qualifying strokes (n=3), modified Rankin Scale score of 4 or 5 (n=3), not refractory to medications (n=1), treatment was unrelated to intracranial atherosclerosis disease (ICAD) (n=1). Patients may have had more than one condition outside of the FDA-approved indications.

Based on the WEAVE study results (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=297&c_id=762) and other available safety information, a very specific group of patients, consistent with the current FDA-approved indications and patient selection criteria listed above, may benefit from the use of Wingspan. The FDA's assessment of benefits and risks for this device considered that these patients are at serious risk of life-threatening stroke and have limited alternative treatment options.

Recommendations for Health Care Providers

- Use Wingspan only in patients who are between 22 and 80 years old AND who meet ALL the following criteria:
    - who have had two or more strokes despite aggressive medical management;
    - whose most recent stroke occurred more than seven days prior to planned treatment with Wingspan;
    - who have 70-99 percent stenosis due to atherosclerosis of the intracranial artery related to the recurrent strokes; and
    - who have made good recovery from previous stroke and have a modified Rankin Scale score of three or less prior to Wingspan treatment.
- Be aware that the use of Wingspan in patients who do not meet the FDA-approved indications for use criteria significantly increases the risk of stroke or death.
- Consider patient selection carefully after reviewing the approved labeling, including the indications for use, contraindications, warnings, and precautions.
- When using Wingspan, treat only the vessel that caused the stroke.
- Be aware that Wingspan is only approved by the FDA as an HDE device for a very specific group of patients.
    - Generally, a patient may be treated with Wingspan only if the treating physician has received Institutional Review Board (IRB) (/medical-devices/humanitarian-device-exemption/humanitarian-device-exemption-hde-postmarket-activities) approval to use the Wingspan at the clinical site.
- Only use Wingspan if you have been trained to perform neurointerventional procedures as well as properly trained and proctored by the manufacturer to use the device.
- If you plan to use the Wingspan device at your facility, share this communication with appropriate hospital staff, applicable Institutional Review Boards, and credentialing committees to ensure the clinical community is aware of the risk of stroke or death when Wingspan is used outside the FDA-approved indications for use.
- If a patient experiences a complication following treatment with Wingspan, please file a report through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

Recommendations for Patients and Caregivers

If your health care provider recommends interventional treatment for intracranial stenosis with Wingspan, be sure to:

- Discuss and consider all treatment options with your health care provider, including the risks and benefits associated with the use of Wingspan, as well as the option of medical management with oral blood thinners (anticoagulation drugs).
- Discuss with your health care provider if Wingspan is right for you:
    - Ask if you meet all of the FDA-approved indications for use criteria to see if you are a good candidate for treatment with Wingspan.

    - If you do not meet the FDA-approved indications for use criteria, ask your health care provider to explain why they are recommending Wingspan and make sure you understand your health care provider's recommendation.
- Be aware that there is an increased risk of stroke or death associated with use of Wingspan in patients who do not meet the FDA-approved indications for use criteria.

FDA Actions

In 2012, the FDA worked with Styker to update their labeling for Wingspan with revised indications for use, new contraindications and warnings. The FDA also ordered Stryker to conduct the postmarket surveillance study (WEAVE) to further assess the rates of stroke or death within 72 hours of the Wingspan Stent placement procedure. Postmarket surveillance studies (/medical-devices/postmarket-requirements-devices/522-postmarket-surveillance-studies) are important tools for collecting useful data about a device that can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect public health.

The FDA is now sharing the results of the WEAVE study (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=297&c_id=762) to promote patient safety.

The FDA will continue to work with Stryker to revise the Wingspan labeling to ensure health care providers are aware of the increased risks of stroke or death when used outside the FDA-approved indications for use.

The FDA will continue to communicate publicly if significant new information becomes available.

Reporting Problems to the FDA

If you experience an injury or adverse event with Wingspan, the FDA encourages you to file a voluntary report by phone at 1-800-FDA-1088 or online at MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda). Please include the details of the adverse event and medical and surgical interventions (if applicable) in your reports.

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices.

Additional Resources

- Wingspan StEnt System PostmArket SurVEillance (WEAVE) Study Results (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=297&c_id=762)
- Narrowed Indications for Use for the Stryker Wingspan Stent System: 2012 FDA Safety Communication (http://wayback.archive-it.org/7993/20170722215747/https:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm314600.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Contact Information

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) at DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.