

URGENT FIELD SAFETY NOTICE
ECLIPS BIFURCATION REMODELLING SYSTEM
FEBRUARY 25, 2020
ADVICE TO ALL USERS OF THE DEVICE

ATTENTION: All users of the eCLIPs Bifurcation Remodelling System

This Field Safety Notice, hereafter called FSN, has been issued by Evasc Medical Systems Corp., hereafter called “Evasc”, in relation to the eCLIPs Bifurcation Remodelling System, Model Number SYSS-0026, and relates to *all* such devices. This FSN contains advice provided by Evasc in terms of use of the device.

Details of Affected Devices:

eCLIPs Bifurcation Remodelling System, Model SYSS-0026, all devices.

Description of the Problem:

The reasons for this FSN is that an incident occurred when using the device that was mis-aligned before detachment such that the eCLIPs Bifurcation Remodelling System did not properly cover the neck of the aneurysm, so two additional stents, not eCLIPs Bifurcation Remodelling Systems, were placed *in situ* on top of the eCLIPs Bifurcation Remodelling System in “Y” formation. The patient was discharged from hospital, but presented three days later with a thalamic infarct and paresis.

There is a potential for increased risk of thrombus formation with the use of multiple devices. The use of the eCLIPs Bifurcation Remodelling System with other eCLIPs Bifurcation Remodelling Systems and/or other coil assisting devices has not been tested – this is clearly stated in the IFU.

There is no risk to other patients with previous use of the device.

Advise to all Users:

Please be advised that the use of the eCLIPs Bifurcation Remodelling System with other eCLIPs Bifurcation Remodelling System and/or other and/or other coil assisting devices has not been tested. There is a risk of stroke if the eCLIPs Bifurcation Remodelling System is used with other coil assisting devices.

There is no requirement to return product to Evasc.

Notification:

This FSN has been emailed to all end users of the eCLIPs Bifurcation Remodelling System.

Please pass this FSN to all personnel who need to be informed of this incident. Please be aware that this FSN is effective for all future use of the eCLIPs Bifurcation Remodelling System.

The following Competent Authorities have been informed of this FSN: BASG, BfArM, AEMPS, Lægemiddelstyrelsen.



