

Briennon, July 31st, 2020

Subject: SCAF – SAFETY AND CORRECTIVE ACTION FORM FOR A MEDICAL DEVICE–  
PRODUCT RECALL Femoral Stem STEMSYS MI

Ref. : CAPA 645

SCAF sent by email.

To the attention of the vigilance system correspondent

Identification of medical devices:

The medical devices concerned are femoral stems **STEMSYS MI**.

References: **H57 009, H57 L009 and H57 L010**.

The batches concerned are all batches put on the market related to the three a.m. references.  
You'll find the exhaustive list of the batches on page 5 for information.

Reason for issuing that safety form :

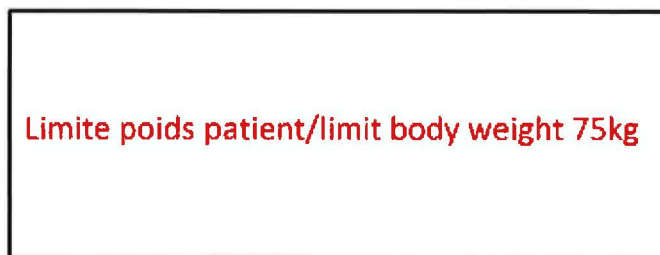
The last results of the resistance test don't comply with the ISO 7206-4 standard.  
The medical devices must therefore be used on patients whose weight doesn't exceed a certain limit.

The medical devices are recalled in order to add a label mentioning a weight limit of the patient up to 75 kg:

Existing labels:



Added label:



Risk for the patient:

A risk of breakage of the femoral stem could occur for an active patient whose weight exceeds that limit weight of 75 kg, and in case the implanted stem shows a bad bone fixation in the proximal zone.

Measures to take:

- acknowledge receipt of the current safety sheet by returning the page 3 to us
- check if the a.m. references are available in your stock
- for the distributors, send the current safety sheet to your customers
- return the medical devices to us for an exchange using page 4
- patients with a weight over 75 kg, who were operated and received one the three a.m. implants, must be followed-up by a surgeon to check that the osseous healing in the proximal zone is correct.

Person to contact:

For any question, please contact Gérard Péliçon by email at [qualite@evolutis42.com](mailto:qualite@evolutis42.com) or at following phone number +33 (0)4 77 60 79 99, or contact directly your distributor.

This information has been reported to the ANSM – Agence Nationale de Sécurité du Médicament et des Produits de santé - (the French competent authority for drugs and healthcare products), and relayed to distributors and users.

We stay at your disposal for any further information you may require.  
We thank you in advance for your collaboration and support to implement that recall.

Best regards

  
President  
