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Briennon, 2021/11/16

Objet : FSN – FIELD SAFETY NOTICE FOR A MEDICAL DEVICE– MOONSTONE and SPHERIC RL bipolar cup

Ref : AQ1531

Letter sent by mail

For the attention of the Materiovigilance manager

Identification of the medical devices:

The medical devices concerned are the MOONSTONE (references **H35 R2843 to H35 R2859**) and SPHERIC RL (references **1-0191543 to 1-0191559**) bipolar cups.
All the manufacturing batches are concerned.

Reason for this safety notice:

We wish to inform users of the bipolar cup in retentive version (without ring) of a sudden increase in reports of intra-prosthetic dislocation over the last 6 months (5 materiovigilance reports), bringing the total number of reports over the last 22 years of use with this version of the cup to 9.
To date, the occurrence rate of this complication is 0.066% (9/13,500 devices sold since 1999).

No cause related to a manufacturing or misuse of the device (intra- or post-operative) could be identified. The patient characteristics (age, BMI, level of activity), when correctly documented, are consistent with those of the target population for the device.

Out of the 9 incidents that occurred between the 1st and 42nd postoperative day, 5 were consecutive to a closed reduction immediately following an intra-articular dislocation (dislocation between the cup and the acetabulum).
The circumstances of 2 incidents were not documented.
The remaining 2 intra-prosthetic dislocations are clearly not related to a forced manipulation of the joint or a fall.
The rate of intra-prosthetic dislocation under normal conditions of use can therefore be calculated at 0.015% (2/13,500). According to our risk analysis table, this rate is classified as an "unlikely" level of risk (≤ 0.05%).

There is no reference in the literature for the evaluation of occurrence of intra-prosthetic dislocation of bipolar cups. A dislocation rate of 3% for bipolar hemi prostheses (leading to or not leading to revision) has been reported in very large series, without distinction of the type of dislocation (intra-articular or intra-prosthetic) or the type of ball head locking system in the bipolar cup (with or without ring).

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Actions to follow:

a) When placing the MOONSTONE/SPHERIC RL retentive cup:

It is not anticipated that the MOONSTONE/SPHERIC RL bipolar cup will have improved resistance to dislocation compared to the implants evaluated in the literature. Therefore, there will always be a risk of postoperative dislocation associated either with uncontrolled movement of the patient in the immediate postoperative period (fall, foot wedge when changing weight bearing, etc.), or with a technical error during implant placement (anteversion of the femoral stem, length of the femoral neck, size of the bipolar cup, etc.).
Bipolar cups are naturally difficult to reduce intraoperatively due to the large diameter of the prosthetic head which is equivalent to that of the anatomical femoral head. In order to ensure the correct length of the prosthetic assembly and the resulting intra-articular stability, it is important to perform limb length trials and joint reductions in a perfectly relaxed muscular environment under the supervision of the anaesthetist, and to confirm this length with respect to the contralateral at the end of the operation.

b) During the reduction of a post-operative intra-articular dislocation:

To reduce the risk of intra-prosthetic dislocation during a closed reduction of a cup/bone dislocation, it is recommended to:
- Perform the closed reduction under general anesthesia with optimal muscle relaxation (curarization).
- Perform the reduction manoeuvre with as little forced movement as possible (especially with a large lever arm), which may lead to dislocation of the small joint if the bipolar cup is blocked (e.g., by an osteophyte or in the soft tissues). In cases of excessive resistance, it is recommended to perform an open reduction, allowing, if necessary, to correct the cause of the dislocation (retroversion of the femoral implant, length of the femoral head...).

People to contact:

For any questions contact Gérard Pélisson +33 (0) 4-77-60-79-99 qualite@evolutis42.com or your distributor.

This information has been declared to the ANSM and sent to customers and distributors.

Yours faithfully

[redacted]

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Objet: FSN – SECURITY NOTE FOR A MEDICAL DEVICE – MOONSTONE and SPHERIC RL bipolar cup

Ref: NC018715

PROOF OF RECEPTION

I the undersigned ..... authorised representative of the company / institution ..... declare having read and understood this security notice. I confirm that it has been sent to users concerned.

Date:

Signature:

This proof of reception should be returned to Evolutis by mail or fax or post:

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