11/06/2019

To : NEWSPINE

Customer information note

Dear Customer,

Titanium radiopaque markers were placed in cages instead of Tantalum markers. The objective of these markers is to verify the position of the cage during and after surgery. Since titanium is less radiopaque than tantalum, once the cage is implanted the environment and the power of the imaging devices explain why cages with titanium markers are less visible.
Post-operative controls performed by MRI or CT-Scan are not impacted, their better sensitivity compared to radio makes it possible to clearly verify the position of the cage.

The cages in question are ranges of:
- PEEK cervical cages (IMPIX MANTA, IMPIX MANTA+, IMPIX C and C-Curve)
- PEEK lumbar cages (IMPIX-L)

The relevant lots and references are available as attachment (annexe 2)

Potential risks:

- Low visibility of the markers if X-ray control is used: it is during the operation that the risk of the cage not being visible would be highest because at this stage the brightness amplifiers are of limited power to protect the patient and the surgeon. However, for cervical cages, the risk of the cage not being visible with titanium markers is negligible because titanium remains an opaque radio material and the thickness of the surrounding tissues is low in the cervical area. Even if in the lumbar area the risk of low visibility is higher, it is still possible to evaluate the correct positioning of the cages because they are linked to opaque radio instruments (gripper). The less visible markers and the instrument allow the implant positioning to be checked.
- Sensitivity reaction to Titanium: this risk is very low because the titanium used for the markers is a biocompatible material identical to that used for other orthopaedic implants such as screws, cases of allergies are extremely rare. The cages concerned are often used in addition to a system that already includes Titanium material (screws, rod). This risk is all the lower because of the surface in direct contact (0.78mm2) and the nature of the contact (hard tissue: vertebral body, no contact with fluid circulating in the body)

MEDICREA INTERNATIONAL Actions :

For lumbar cages (IMPIX L): MEDICREA proposes to replace cages in the customer's warehouse if visualization difficulties have been reported. This exchange should be planned according to available stocks and can be carried out within 3 to 6 months depending on the references.

Immediate measures for the user:

We invite you to read this notice carefully and take the actions described below:

1. **Distribute this notice to all concerned/assigned persons in your facility.**
2. **Place a copy of this document in the files of patients implanted with an implant affected by this safety notice**

a) Please provide us with the contact details so that MEDICREA can contact users directly

b) If you are a distributor, we remind you that it is your responsibility to inform your customers concerned

3. **Please report any adverse reactions and/or difficulties in viewing the cage. Comply with local regulations regarding the reporting of adverse events to the appropriate authorities**
4. **If the markers on the intraoperative images are difficult to see, the post-operative check-up should be carried out in a radiology centre, by MRI or CT-Scan for a good visibility of the markers.**
5. **Complete the attached customer response form. Please complete this form even if you no longer have this device in stock. Your answer will allow us to update our files and avoid any unnecessary follow-up on this subject.**

We ask you to respond to this notice within 7 days of its receipt

This FSN has been notified appropriately to the National Competent Authority for your country.

For any further information, you can contact the Vigilance Correspondent of MEDICREA……

We apologize for the inconvenience.

We remain at your disposal and kindly ask you to accept, Madam, Sir, our best regards.

…….

Annexe 1

Acknowledgement form : MAT2019-11

Please complete even if you no longer have any of the subject devices in your physical inventory.

SENDER :
Etablissement

RECIPIENT
MEDICREA INTERNATIONAL
Karine TROGNEUX
Correspondant Matériovigilance
5389 route de Strasbourg
69140 RILLIEUX LA PAPE

Tel – N° **04.69.85.95.39**
Fax - N° **04 72 01 87 88**
Mail : ktrogneux@medicrea.com

I, undersigned.....

From the Hospital or the organisation.....

Certified to have verified the products delivered for which we are concerned :
☐ **We have not located any of these device in our inventory**

☐ **We found the following device** *(please delete if not applicable) :*

Product reference	**Lot Number**	**Quantity in our inventory**

We have further distributed subject devices to the following organization:
Facility name:
Facility address:

Contact name and title_____**to organize the recall**
Phone number:_____**/ Email address :** _____
Date :
Signature :

Cachet de l'Etablissement :

Annexe 2- List of reference and batch of subject devices

ref Article	Désignation	lot
B20181773	IMPIX-MANTA ON HOLDER SMALL 7mm - 3°	17D0590
B20171963	PRE-FILLED IMPIX-MANTA ON HOLDER MEDIUM 6mm - 3°	17G0679
B20181963	IMPIX-MANTA ON HOLDER MEDIUM 6mm - 3°	17G0746
B20181963	IMPIX-MANTA ON HOLDER MEDIUM 6mm - 3°	17G0746R
B20181953	IMPIX-MANTA SUR PREHENSEUR MEDIUM 5mm A 3°	17L0036R
B20181953	IMPIX-MANTA SUR PREHENSEUR MEDIUM 5mm A 3°	17L0036R1