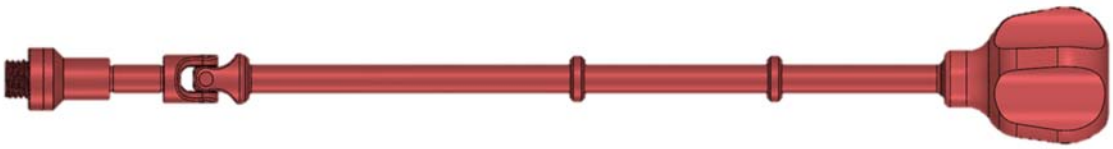
URGENT FIELD SAFETY NOTICE

Please read thoroughly

Incipio Devices – OFFSET CUP IMPACTOR

Product Deficiency

Offset Cup Impactor (as sold)



Positioning Handle Assembly

Offset Cup Impactors		
Reference	**Lot**	**Quantity**
183-151/00	19J8932, 19J8931, 20J9151, 20J9174, 20J9188, 20J9236	30
50341603	20J9956	4
01.15.10.0538	20J9057	5
50340409	19J7479	1

16, Av. des Pâquiers
2072 St. Blaise
Switzerland

Chris Taylor
Incipio Devices
16, Av. des Pâquiers
2072 St. Blaise
SWITZERLAND

Quality Rep
Customer Name
Address
Post code, City
COUNTRY

24 June 2020

RE: **URGENT SAFETY INFORMATION**

Dear Customer:

The purpose of this letter is to advise you that Incipio Devices has initiated a Field Safety Corrective Action (FSCA) for specific lots of Offset Cup Impactors following determination that the lots concerned do not meet specifications. Offset cup impactors are reusable surgical instruments, sold non-sterile, used primarily for the placement of acetabular cup implants during hip arthroplasty.

Reason for Field Safety Corrective Action:

Incipio Devices has become aware of an issue with specific lots of **OFFSET CUP IMPACTORS** following an incident in which a pin from the device's positioning handle assembly fell out during surgery and remained lodged in the patient's acetabulum behind the implanted cup. Subsequent investigation revealed that the weld joints of the cardan did not meet the weld depth specification required.

Risk Assessment:

The weld depth of the pins of the cardan joint do not meet specification on certain lots of product. The deficiency of the weld depth may cause premature failure of the positioning handle assembly. Failure of the welds may result in the retaining pins falling into the surgical site, causing an extension of surgery time. If the loss of the pin is not detected prior to wound closure, possible consequences are patient tissue irritation and the possible need for surgical intervention to remove it.

Overall, the probability of failure for these devices is HIGH. This risk of patient harm is considered to be MEDIUM, given the high probability that the devices will fail.

There have been no reports of serious injury or death related to this malfunction. However, in the interest of ensuring a high level of safety for patients and users, Incipio Devices is initiating a field safety corrective action to recall the affected positioning handle assemblies.

This Field Safety Corrective Action is being performed with the knowledge of the appropriate authorities.

Frequency of Failure:

The failure rate for pin weld failures is 0.7% to date. One (1) instrument within the scope of this FSCA has been returned.

Adverse Events:

There have been no reports of serious injury or death for this failure mode. One reportable incident occurred in which a pin was lost during use and was retained in the patient.

Instructions to Customers:

THIS NOTICE NEEDS TO BE PASSED ON ALL THOSE WHO NEED TO BE AWARE WITHIN YOUR ORGANIZATION OR TO ANY ORGANIZATION WHERE THE POTENTIALLY AFFECTED DEVICES HAVE BEEN TRANSFERRED.

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Switzerland

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS FIELD SAFETY CORRECTIVE ACTION

1. Review the enclosed FSN Response Form. This form contains important information about your specific account. It must be returned to us even if you do not have any Offset Cup Impactors in your possession. For your convenience, we have pre-populated the form with information we have in our records concerning the relevant Offset Cup Impactors shipped to you.

2. Examine your inventory and identify all the relevant Offset Cup Impactors that are in your possession and quarantine those devices immediately.

3. Complete the FSN Response Form, indicating if you have the device or not and email it to Incipio Devices at surveillance@incipiodevices.com.

4. When returning the product, please ensure that the product is appropriately decontaminated and sterilized. Once we receive your FSCA response form, we will send you a pre-paid FedEx return label. If additional labels are needed, please contact Incipio Devices at +41 32 754 34 34 or at surveillance@incipiodevices.com .

Please note: Only the Positioning Handle Assembly component must be returned. The impactor body may be retained and used with replacement components.

5. You have concluded the actions to be taken in response to this Field Safety Corrective Action. We sincerely thank you for your assistance.

We deeply regret this inconvenience, and we greatly appreciate your understanding as we take actions to ensure patient and user safety. If you have any questions or need help completing these actions, please contact us at +41 32 754 3434, or email us at surveillance@incipiodevices.com and we will be happy to assist you.

Sincerely,

Chris Taylor
Sr. Regulatory Affairs Specialist
Incipio Devices

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