AMPLITUDE

**Healthcare facility**
Address

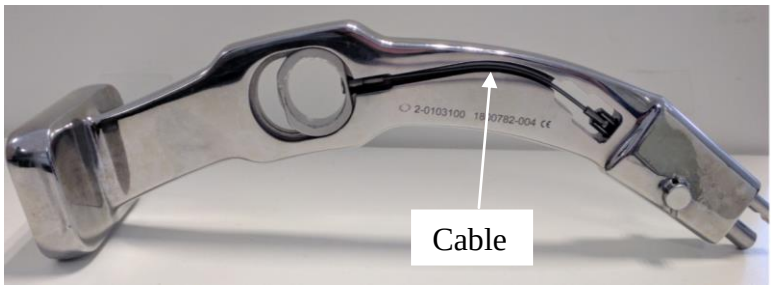
To the attention of the vigilance Safety Officer
and orthopedic surgery departments

Valence, June 27th 2019,

Ref. AMPLITUDE: COMP-1061 (EN)

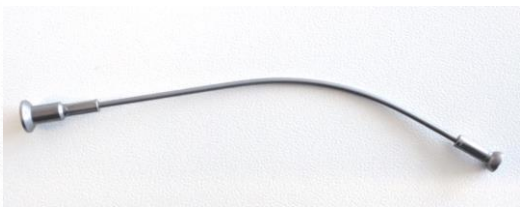
Object: **BATCH RECALL**
Instrument – Broach handle - AMPLITUDE

*Reason for recall*
Following feedbacks from healthcare facilities, a risk of breakage of Nitinol cables assembled on curved broach handles used for surgeries of Amplitude hip prostheses has been identified. The broach handles on the market exist in 2 versions: with Nitinol cables or braided cables (see below pictures). This recall concerns only the broach handles with Nitinol cables.




Picture of concerned broach handle

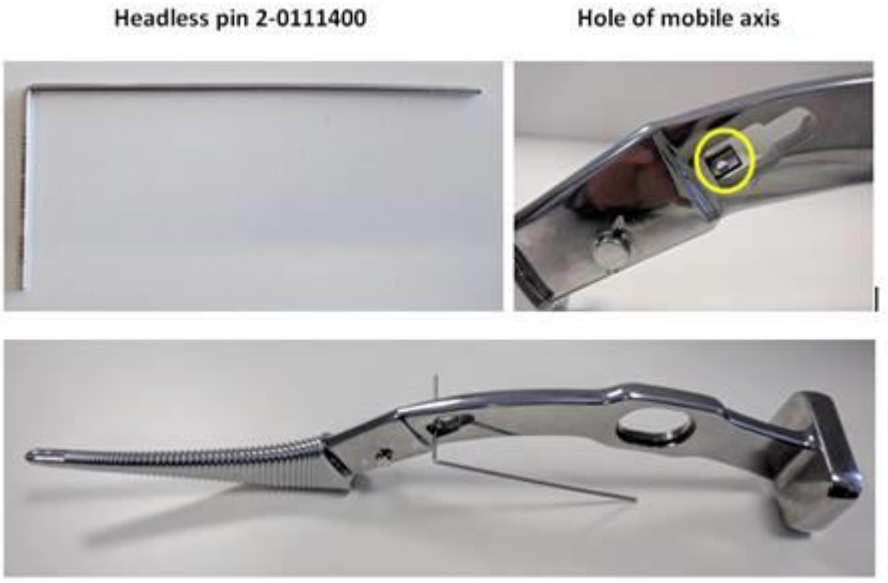
Picture of braided cable
Not concerned by this recall



Picture of Nitinol cable (smooth cable)
Concerned by this recall

*Circumstances and risks for the user and/or the patient*

No patient risk associated to this breakage was identified. In case of breakage of the cable, the broach will remain attached to the handle. The consequence could be an increase in surgical time to disassembly the broach from handle. This disassembly can be done by moving the mobile axis. The use of headless pin available in the instrument set (reference 2-0114000) is recommended to pull the mobile axis and therefore release the broach.




*Concerned devices*

The traceability data indicate that you have received devices of one or several of the involved batch numbers:

| Reference | Designation | Batch numbers |
|---|---|---|
| 2-0103100 | Broach handle | 1600624 |
| | | 1800012 |
| | | 1800013 |
| | | 1800014 |
| | | 1800015 |
| | | 1800780 |
| | | 1800781 |
| | | 1800782 |
| | | 1800783 |

The batches are partially involved (only broaches with Nitinol cables are concerned by this recall)

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*What you must do*

Please circulate this notice to the appropriate individuals.
Your local representative will contact you to organize the replacement of the devices.

We remind you that any adverse event experienced using these devices must be declared to the competent authority and your local representative.

*Other information*

Swissmedic and the French competent authority have been advised about this recall.

We apologize for inconvenience and thank you for your comprehension.

Mireille LEMERY
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