AMPLITUDE

Healthcare Facility
Address

L.R.A.R. N°xx xxx xxx xxxx x

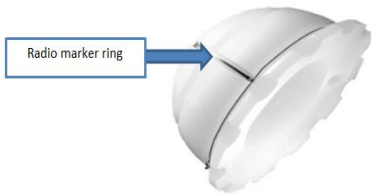
To the attention of the vigilance Safety Officer
and orthopedic surgery departments

Valence, October 30th 2020

Ref. AMPLITUDE Issue-0661

Object : FSN - **BATCH RECALL**
INITIALE® polyethylene cup - Monobloc – cemented – AMPLITUDE

Reason for recall
During an internal analysis, we identified that the raw material certificate for a component of some batches of the INITIALE® cup (radio marker ring) do not mention the ISO 5832-1 standard as described in the documentation of the device.
The batches of INITIALE® cup manufactured with these radio marker rings have been identified thanks to the review of all raw material certificates. These devices have been put on the market since 2000. However all the batches of INITIALE® cup are not involved.
The analysis shows that the specifications are very similar to the ones described in the ISO 5832-1 standard (Mass fraction % of Carbon superior of 0.03, Mass fraction % of Chrome, Nickel and Molybdenum inferior to specifications of ISO 5832-1).
This component was designed to be a X-ray marker. These differences have no effect on the performance and safety of the device.
Amplitude initiates a recall of the involved batches on the market.



Picture of the INITIALE® cup

Circumstances and risks for the user and/or the patient
No patient consequences related to this deviation were reported.

For patient already implanted with the involved devices, no specific follow-up is recommended.

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Concerned device

The traceability data indicates that you were provided the concerned device(s):

Reference REF	Designation	Batch : LOT
1-0104752	INITIALE® polyethylene cup - Monobloc – cemented Ø 28 Size 46/52	253499
1-0104754	INITIALE® polyethylene cup - Monobloc – cemented Ø 28 Size 47.5/54	249047, 249044, 231185, 231410
1-0104756	INITIALE® polyethylene cup - Monobloc – cemented Ø 28 Size 49/56	231411, 231186
1-0104758	INITIALE® polyethylene cup - Monobloc – cemented Ø 28 Size 51/58	237897
1-0104760	INITIALE® polyethylene cup - Monobloc – cemented Ø 28 Size 53/60	267821, 237923, 276726, 276691, 274862, 268826, 233447
1-0105440	INITIALE® polyethylene cup - Monobloc – cemented Ø 22.2 Size 37/40	231187, 273416
1-0105442	INITIALE® polyethylene cup - Monobloc – cemented Ø 22.2 Size 38.5/42	266266, 276702, 290948, 245320
1-0105444	INITIALE® polyethylene cup - Monobloc – cemented Ø 22.2 Size 40/44	253505, 249052, 249051, 241193, 231188
1-0105446	INITIALE® polyethylene cup - Monobloc – cemented Ø 22.2 Size 41.5/46	246426
1-0105460	INITIALE® polyethylene cup - Monobloc – cemented Ø 22.2 Size 53/60	300257, 300298

What you must do

- Please circulate this notice to the related individuals in order to prevent the use of those devices in the Healthcare facility.
- Hold the devices concerned by this recall in quarantine.
- Return these devices to your local representative.

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

The national competent authority is advised about this recall procedure.

We apologize for the inconvenience and thank you for your comprehension.

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