

7 Allée du Moulin Berger
69130 Ecully - France

To the attention of the Materiovigilance
Correspondent, Director of the establishment.

ECULLY, 01-juin-26

Ref : FSN-20260313_NC25-063

ID : 1174 - SYNERGIC EVOLUTION SDN BHD

Manufacturer Single Registration Number (SRN): **FR-MF-000025400**

URGENT – FIELD SAFETY ACTION Extension

Devices concerned: **Polyaxial & reduction screwdriver assembly
(VEOS/KAPHORN range)**

REF.: INA-LU-PSD

Description : Reusable surgical instrument, used to tighten or untighten polyaxial and reduction screws. It is made made of Stainless steel and Heat-Stabilized Polypropylene (HSPP).

Lot: 250400901
220400804
221000320
230701801
230701802
230701803
230701804
230701805
240601603-H
240601605

UDI-DI: 03760315526844

Action: **Lot Recall**

Dear Customer,

We inform you that DISTIMP SAS, legal manufacturer of medical devices, voluntarily initiates the field safety corrective action FSN-20260309_NC25-063 on the medical devices listed above to prevent any incident or risk of serious injury relating with the potential risk we have identified.

Details on the devices concerned

The Polyaxial & reduction screwdriver assembly REF. INA-LU-PSD from DISTIMP SAS is a non-sterile reusable surgical instrument. It is used to tighten or untighten polyaxial and reduction screws.

Description of the issue:

DISTIMP SAS has decided to extend the Field Safety Corrective Action undertaken for the lot 250400901 to Lots 220400804 / 221000320 / 230701801 / 230701802 / 230701803 / 230701804 / 230701805 / 240601603-H / 240601605 of Polyaxial & reduction screwdriver assembly REF. INA-LU-PSD.

Indeed, those parts might have a functional defect on the threaded part which is connected during tightening of the VEOS VLSP/VLCP screw. The Polyaxial & reduction screwdriver might be dimensionally non-compliant.

This recall extension is being carried out purely as a precautionary measure. It should be noted that, since the recall of lot 250400901, we have not received any field alerts or complaints regarding these additional batches. The affected lots of screwdrivers will be replaced.

This dimensional non-compliance may result in improper engagement of the screwdriver in the screw head during assembly leading to:

- Loosening or failure of the connection between the instrument and the implant
- Damage (even breakage) of the screwdriver tip
- Difficulty to tight the screw to the screwdriver and implant the screw

Patient risk

The risk analysis carried out by DISTIMP SAS made it possible to identify several risk scenarios related to the defect observed:

Scenario 1:

The surgeon has difficulty to connect the screwdriver on the screw head: the device connection is unreliable. It is needed to replace the screwdriver by the second unit included in the instrumentation kit. The defect is detectable during the surgery; however, it may lead to in prolonged surgery (estimation 15 min to 45 min).

Scenario 2:

The surgeon cannot connect the screwdriver on the screw head: the device connection is unreliable. It is needed to replace the screwdriver by the second unit included in the instrumentation kit but this one is also unusable. It is impossible to continue with the surgery, resulting in the need for an additional surgery.

Actions to follow

Our traceability system indicates that we have made available Polyaxial & reduction screwdriver assembly, affected by this action.

We count on your diligence to:

1. Identify all the medical devices in your inventory that are affected by this action.
2. Quarantine the medical devices concerned.
3. Transmit this notice as soon as possible to all the persons concerned within your establishment.
4. Transmit this notice as soon as possible to any organization, department or person to whom the devices concerned have been delivered so that the corrective measures indicated are applied effectively for the time they are in your/their possession.
5. Complete the attached customer response form and return it to us by email quality@spineway.com within **7 calendar days** of receipt of this notification.

To ensure the effectiveness of the corrective action, please apply the necessary reminders to ensure that the end users have received the information.

DISTIMP will contact you as soon as possible to arrange for the physical return of non-compliant products and their replacement.

In accordance with the recommendations of the Meddev Vigilance Guidance document ref. 2.12-1, we confirm that this Field Safety Corrective Action has been transmitted to the local competent authorities of the countries concerned.

We apologize for the inconvenience and thank you for your understanding and cooperation.

We naturally remain at your disposal for any additional information you would like to have on this subject.

Please believe, Dear Customer, in our sincere greetings.

Your vigilance correspondent:
Sabina AHADDAD
Director of Quality, Regulatory, Clinical

PO

Amélia REYMOND

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CUSTOMER RESPONSE FORM
Safety Action – Batch Recall

DISTIMP SAS – Instrument, Polyaxial & reduction screwdriver assembly

Ref : FSN-20260313_NC25-063

ID: 1174 - SYNERGIC EVOLUTION SDN BHD

I hereby certify that I:

- Have received the safety notification from DISTIMP SAS relating to the recall of lot of Polyaxial & reduction screwdriver assembly and have distributed it to the persons concerned.
- Have read and understood the reminder letter and intend to follow the instructions provided.
- Have verified the inventory for the presence of the devices concerned.
- For distributors only: have identified the establishments in possession of the products concerned and have distributed this communication to them so that they comply with it.

The stock and all storage and use areas have been checked and the results are as follows (please check the appropriate box):

☐ We have no/no more products concerned

☒ We have affected products. (Please indicate the quantity for each lot concerned):

Reference	Designation	Lot	Quantity delivered by the manufacturer	Quantity in your stock to be completed
INA-LU-PSD	Polyaxial & reduction screwdriver assembly	220400804	#N/A	#N/A
		221000320	1	1
		230701801	#N/A	#N/A
		230701802	#N/A	#N/A
		230701803	#N/A	#N/A
		230701804	4	-
		230701805	#N/A	#N/A
		240601603-H	6	6
		240601605	#N/A	#N/A

Contact Name:	NURASIKIN KAMARUDDIN	Stamp of the property:	
Function:	SALES AND INVENTORY COORDINATOR		
Date and Signature:	 05th June 2026		
Telephone:		Email:	asikin@synergicevo.com