



Pega Medical

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Urgent Field Safety Notice – Recall

Simple Locking Intramedullary (SLIM) System (SLM-HND100)
FSCA-Recall identifier: 3000327445-05/24/19-001-R
Type of action: Replacement
Recall HC Priority#: II

Date:XXXXXX

Attention: XXXXXXXXX
XXX
XXXXXXXXXX
XXXXXXXXXX
XXXXXX
XXXXXX

Dear Customer,

It has been brought to our attention that there is a potential problem with the Handle of the Driver of the Simple Locking Intramedullary (SLIM) System. Therefore, Pega Medical is proceeding with a systematic recall of the instrument.

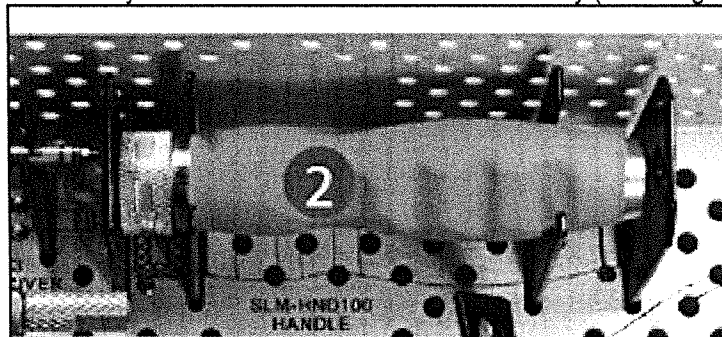
Our records indicate that we provided you with one of these devices on April 23, 2019. If the device is still in your possession, we are requesting you to return this device to Pega Medical as soon as possible.

Details on affected devices:

Part Number: SLM-HND100

Lot#: 160427-01

Description: Handle of the SLIM System included inside the instrument tray (see image below)



PMREC-9014-5 rev00 (2011-01-13)

Pediatric Orthopedic Devices at their Best

Description of the problem:

The Connector Ring inside the knob could potentially disengage (see image below) and cause jamming of the Handle and the Driver once assembled. This situation could make the disassembly of the Driver from the implant very difficult once the implant has been placed.



Advise on actions to be taken by the user:

- Identify the device with the same catalogue number and lot number
- Return the device to Pega Medical Inc. as soon as possible to the address shown below using the following FedEx Account: 260747673

Contact reference person:

Enrique Garcia
1111 Chomedey Highway
Laval, QC, H7W 5J8
Canada
Phone: 450-688-5144 ext. 242
Email: egarcia@pegamedical.com

Transmission of this Field Safety Notice:

This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

The undersigned confirms that this notice will be notified to the appropriate Regulatory Agency.

If you need any further information, please do not hesitate to contact me.

Yours Truly,

Enrique Garcia
VP Operations