



OrthoPediatrics Corp.

Date January 15, 2026

# **URGENT: Field Safety Notice**

## **Drive Mechanism**

### **(1) Attention to Customer:**

Dear Customer/Distributor,

### **(2) Purpose of this letter**

The purpose of this letter is to advise you that OrthoPediatrics is recalling the Drive Mechanism used in the OrthoPediatrics Drive Rail System (Part Number 20-2012). Intended use: The drive rail system is intended to be used on adult or pediatric patients in treatment of conditions of the long bones of the arms and legs including limb lengthening, acute or gradual multiplanar correction of long bone deformities, fractures and diseases which generally may result in joint contractures or loss of range of motion, fractures requiring distraction, open or closed fractures, non-unions, and infected fractures or non-unions.

No injuries have been reported related to this issue.

### **(3) Reason for the Recall:**

Post Market Engineering identified that subcomponents in Lot 266718-D do not meet the minimum hardness specification of 40 HRC. Three complaint devices from this lot measured approximately 27 HRC. Supplier identified two additional lots that may fall within the affected scope: 270235-D and 275097-D.

Comparative testing showed that mechanisms at ~27 HRC exhibited significant wear and visible deformation after cycling and torque application, indicating a potential for degraded performance.

Frequency of failures and complaints: No injuries reported; complaints investigated led to this action.

### **(4) Risk to Health:**

**4a)** Under-hardened drive mechanism components may exhibit accelerated wear and deformation during use, potentially resulting in increased torque required, reduced mechanism efficiency, or intraoperative delay. While no injuries have been reported, continued use could lead to procedural delays or the need to replace the mechanism.



**4b)** Users may notice unusual resistance during rotation, reduced translation of the plunger for a given rotation, visible wear or a deformation divot on the plunger after use. If any of these signs are observed, discontinue use immediately and quarantine the device.

**(5) Actions to be taken by the Customer/User:**

- Discontinue use of the affected product immediately.
- Identify and quarantine all affected units in your possession.
- Return all affected units to OrthoPediatrics for replacement or credit.
- Complete and return the attached Acknowledgement and Receipt Form via email to [RECALLS@ORTHOPEDIATRICS.COM](mailto:RECALLS@ORTHOPEDIATRICS.COM).
- Sub-distributors must notify their customers immediately and coordinate return of affected product.

**(6) Product and Distribution Information:**

Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number
Drive Mechanism - 00817867020122	20-2012	266718-D
Drive Mechanism - 00817867020122	20-2012	270235-D
Drive Mechanism - 00817867020122	20-2012	275097-D

**(7) Type of Action by the Company:**

OrthoPediatrics is initiating a removal of the affected lots and will provide replacement products or credits for returned units. The company is working with the supplier to determine next steps to resolve the issue and implement corrective actions. Additional containment and re-inspection activities are underway for all related inventory.

Failure Investigation findings: Under-hardening of a subcomponent was confirmed in Lot 266718-D (~27 HRC). Lots 270235-D and 275097-D are included based on supplier/device history review indicating potential exposure to the same condition.

All appropriate Competent Authorities have been notified.

**(8) OTHER INFORMATION:**

For questions, please contact:  
Recall Team – OrthoPediatrics, Inc.  
2850 Frontier Drive, Warsaw, IN 46582  
(574) 268-6379 | [RECALLS@ORTHOPEDIATRICS.COM](mailto:RECALLS@ORTHOPEDIATRICS.COM)



Authorized by:  
Name: (Print)

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Signature:

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Title:

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# MEDICAL DEVICE RECALL RETURN RESPONSE

## Acknowledgement and Receipt Form

Response is Required

**Customer Information:**

Customer Name  
Street Address  
Town, State, Zip Code

# PRODUCT NAME

I have read and understand the recall instructions provided in the <date of> letter. Yes \_ No \_

**Affected Product Information: Include information that is applicable for affected product.**

Product/Brand Names, UDI ( if applicable)	Product Number/Catalog Number	Lot/Serial Number	Quantity in inventory	Quantity being returned

**Return Response Box:**

**Please provide any additional information, if applicable.**

Distributors:

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**)



**Questions: (when applicable)**

Signature of Receipt \_\_\_\_\_

Name/Title	
Telephone	
Email address	

PLEASE SEND COMPLETED RESPONSE FORM TO: [RECALLS@ORTHOPEDIATRICS.COM](mailto:RECALLS@ORTHOPEDIATRICS.COM)  
OR MAIL TO:  
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2850 Frontier Drive  
Warsaw, IN 46582  
(574) 268-6379