

Urgent Field Safety Notice

Product Name: POLYCENTRIC 4 BAR MANUAL LOCKING KNEE

Product Code: 2-01-S400L

UDI/GTIN no.: 4895200305330

Action Type: Please pass this letter to the prosthetists who have installed these devices in specific Lot No. 2437, and the patients who have this Lot No. 2437 knee joint in the prostheses. The prosthetists and the patients need to be alerted on below incident.

Date of this report: 27 June, 2025

Device Type: Polycentric 4 Bar Knee Joint

Regal FSN Reference: REGAL-FSN-FSN002

Regal FSCA Reference: REGAL-FSCA-FSN002

Reason for this Field Safety Notice:

This FSN is to inform you that a UK clinic reported a 2-01-S400L knee joint failure on May 29, 2025. The Serial No. is 11706, Lot No. 2437. We received the Yellow Card notification on June 11, 2025.

As the practitioner described, the patient was walking in garden, suddenly the bolt cover fell off allowing central bolt to come out of knee joint and knee collapsed in half as a result. See the below photo:



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While our technical department is still investigating and inspecting the broken knee joint, we have initial assessment as below:

1. We have sold this 2-01-S400L knee joint to the world market for more than 10 years, with over 8,000 units. The design of this mentioned part has no change. This is the first time a clinic reported such failure.
2. Our latest periodical re-test on the 2-01-S400L was made on March 22, 2022, under Novita Tech, Australia (NATA Accredited Laboratory No. 2953), according to ISO 10328:2016(E), test report no. 493530. The result is passed under 125kg loading. This test report will be available upon request.
3. We manufactured total 200 pieces for the Lot NO. 2437. All units were sold to 8 different distributors (including the German distributor) between Nov 2024 to Jan 2025. Now only a UK clinic reported this incident. No other customer or patient report any issue.
4. We have sold Lot 2437 to the German market total 6 pieces in following information:
 - a. Neuhof PO BEL2402840, serial no. 11709
 - b. Neuhof PO BEL2402852, serial no. 11710
 - c. Neuhof PO BEL2403018, serial no. 11713, 11714, 11715
 - d. Neuhof PO BEL2500077, serial no. 11722
5. Therefore, our initial assessment of this incident may be an isolated case.

Root Cause:

1. The practitioner described bolt cover falling off allowing central bolt to come out of knee joint is NOT the real cause. The bolt cover is for cosmetic purpose. The bolt cover has no function to keep the central bolt intact.
2. The critical component to keep the central bolt in position is the two set screws (see below photo)


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3. When these two set screws get loose or removed, then the central bolt will come out.
4. But these two set screws are not mentioned in the IFU. They are NOT adjustable components. No practitioner should adjust these two set screws at any reason.
5. Therefore, we still need to physical inspect the broken knee joint to find out if the set screws are still intact or gone missing.

Action Required:

1. Although the cause of failure is still unknown at this moment, for a precautionary measure, we would suggest the practitioners to have safety check on these 6 patients who have the Lot no. 2437 knee joints installed into their prostheses.
2. When the practitioner performs the checking, please make sure the two set screws are still intact. No need to make any adjustment.

If you find any issue in the knee joint due to the above incident, please contact the local authority and Regal Prosthesis Limited:

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For and on behalf of

Regal Prosthesis Limited



Wong Tai Wai

Director

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