stryker

The Coroner's Office for the County of Dorset
Civic Centre, Bourne Avenue
Bournemouth, BH2 6DY

Per email: coroner.service@bcpcouncil.gov.uk

26 March 2025

Dear Mr. Middleton,

Re: Regulation 28 Report, REF: 35392141

I write in response to the Regulation 28 Report to Prevent Future Deaths dated 21 January 2025, REF: 35392141, issued by the Coroner for the County of Dorset ("the Report"). Stryker UK Ltd ("Stryker") has taken the opportunity to carefully review the Report, investigated the reported adverse event and considered the Matters for Concern which were raised therein. The following outlines Stryker's position and response to the concerns identified.

I. Use of the Gamma Nail Distal Targeting System

Concern Raised:

Each jig is used many times in surgery having been sterilized after each procedure. It is hammered into the thigh bone and on this occasion may have become deformed over time.

Stryker's Response:

The Distal Targeting System ("Targeting System") is an instrument designed to assist healthcare professionals in the precise application and implantation of compatible Stryker implants, such as the Long Gamma Nail. The instrument should only ever be used by licensed healthcare professionals who are qualified by appropriate training methods and are fully familiar with the instruments intended use and all the applicable surgical techniques.

The Targeting System is specifically designed and intended for repeated use. Its major components are comprised of carbon fiber composite material, ensuring high strength, durability, resistance to deformation and long-term structural integrity. When the instrument is cleaned, sterilized and maintained according to the Instructions for Cleaning, Sterilization, Inspection and Maintenance ("Maintenance Instructions"), it remains undamaged and retains its shape, and its serviceable lifespan is not affected.

Importantly and contrary to the concern raised, the Targeting System is not hammered into place. The Operative Technique ("OT") explicitly states that the instrument itself is not designed to be struck and notes that the insertion of the Long Gamma Nail into the femoral canal should progress smoothly, without excessive force. The only instance where a force may be applied is if dense bone is encountered and sufficient reaming has already been confirmed. In such instances, a specific strike plate is attached to the Nail Holding Screw component of the instrument and a designated slotted hammer may be used, with caution. Striking the Targeting System directly is against protocol, and the OT, Instructions for Use ("IFU") and Maintenance Instructions all warn that hammering the instrument may result in damage or breakage, rendering it unsuitable for further use.

The OT, IFU and Maintenance Instructions require the healthcare professional to ensure and verify that all components function correctly with each other and are free from damage. The Maintenance Instructions provide

clear directions for performing a functional check, stating that if any failure or damage is detected, the instrument must be replaced and must not be used as it may have reached the end of its serviceable life.

Additionally, the OT and IFU emphasize that throughout the procedure, the instrumentation must be repeatedly checked to ensure correct angles, optimal alignment and secure connections between the implant and the instrument, to allow for proper and precise positioning and fixation of the implant.

The Targeting System is designed for durability and proper function when used as intended. The provided guidelines clearly outline correct handling, maintenance, and functional checks to prevent the device from being used in the unlikely event it has been damaged. This ensures the Targeting System remains fit for purpose when used according to the provided guidance.

II. Location of the Distal Targeting System

The following concern was raised:

The jig was sent away to the manufacturer for analysis but was lost and so no information was available to the court in relation to its integrity.

Stryker's response:

Stryker confirms that the Targeting System has not been returned to the manufacturer for analysis. Immediately upon notification of the adverse event, Stryker initiated a Product Investigation (ref: PI 3492425) and coordinated with the hospital for collection of the instrument. Stryker was informed that the Kit containing the Targeting System was placed in the trauma loan instrument storeroom for retrieval, as per the standard process for the collection of devices. Despite Stryker making arrangements for the Kit's collection, it could not be located in the relevant storeroom. Stryker worked with the hospital in searching for the Kit and following several attempts at locating the Kit and investigating its potential whereabouts, it remained unaccounted for.

III. Quality control of the Distal Targeting System

The following concern was raised:

There is no quality control in place in relation to the examination of jigs being used (other than when it is assembled in theatre by a nurse) prior to surgery. There is no auditing/spot checks in relation to the integrity of the jigs.

Stryker's response:

Stryker confirms all devices and instrumentation undergo vigorous quality control measures during manufacturing to ensure they are free from design, material or manufacturing defects. These stringent quality controls ensure that only compliant products are placed on the market.

All instrumentation, including the relevant Targeting Device, is placed with the hospital under a Consignment Agreement. This Agreement explicitly assigns responsibility for appropriate maintenance, handling, inspection, sterilization and storage of the instrumentation to the hospital. This includes pre-use inspections by the operating surgical team.

Stryker remains committed to supporting hospital and healthcare professionals by ensuring access to instrumentation in good working condition. However, as outlined in Section I above, the OT, IFU and Maintenance Instructions of the instrument outline the necessity of a functional check before each procedure and indicate that the responsibility for inspecting and verifying the integrity of the instrumentation prior to its use lies with the hospital and healthcare professionals using the device. These documents provide clear guidance on necessary

pre-use checks and quality controls, emphasizing that any instrument showing signs of wear or damage must not be used and should be replaced.

In this case, according to the feedback received by Stryker when carrying out the investigation, all necessary checks were carried out and no deformation or damage was observed on the relevant Targeting System. Additionally, prior to the revision surgery, a Stryker representative removed the Kit containing the Targeting System and carried out an inspection of the instrumentation, finding no quality or functional issues.

Conclusion

Stryker is committed to patient safety and product integrity. The Targeting System is designed and manufactured to withstand repeated use when handled and maintained according to the provided guidelines. The OT, IFU and Maintenance Instructions outline the necessary precautions, handling and inspection procedures to ensure the safe and successful use of the instrument.

Stryker acknowledges the concerns raised but does not propose any additional actions at this time. The safeguards in place, as outlined above, provide sufficient risk mitigation. Furthermore, the reported incident rate remains an extremely rare occurrence, with only 12 similar adverse events reported globally since 2013, despite over 2.6 million lag screws being distributed and implanted successfully in that same timeframe.

Stryker appreciates the opportunity to review this matter and provide our feedback. We remain open to continued engagement and are committed to upholding the highest standards of medical device safety.

Should you have any questions in relation to this letter, do not hesitate to contact me.

Sincerely,

A Auluck

Electronically signed by: A Auluck
Reason: I approve this document
Date: Mar 31, 2025 14:29 GMT+1

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REF35392141 - Stryker Response - PI 3492425 and PI 3492428

Final Audit Report 2025-03-31

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