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URGENT - Field Safety Notice

To the user of of the Ø 3.5 mm Cortical Screws 1.25 mm Pitch, Full Thread, Length 50 mm.

Date : 8 July 2026

Re: Ø 3.5 mm Cortical Screws 1.25 mm Pitch, Full Thread, Length 50 mm with risk of fractured during surgery. Quantity 1 piece of screw.

Dear customer,

This letter is to inform you of a potential malfunction and hence hazard to patients when using the **Ø 3.5 mm Cortical Screws 1.25 mm Pitch, Full Thread, Length 50 mm with risk of fractured during surgery, Manufacturing Lot Number: 041925-09-V, Product Code: 2040050.**

When does this malfunction occur and what are the potential risks?

The reported malfunction may occur during insertion of the **Ø 3.5 mm Cortical Screw** into the bone, particularly while the screw is engaging the second cortex and before the screw head is fully seated against the bone plate.

The screw may fracture during insertion, leaving a broken screw fragment within the patient's bone. If this occurs, the surgeon may need to perform additional surgical procedures to remove the fractured fragment or use an alternative fixation method.

The potential risks associated with this malfunction include:

- Prolonged surgical time;
- Additional surgical intervention to retrieve the fractured screw fragment;
- Injury or damage to the surrounding bone, tissue, nerves, or blood vessels;
- Inadequate or delayed fracture fixation;
- Post-operative pain, infection, or delayed recovery;
- Retention of the fractured screw fragment if removal is not clinically appropriate; and
- The need for revision surgery or additional medical treatment.

To date, the reported incident involved screw fracture during insertion and required an additional procedure to remove the broken fragment. No further patient injury has been reported based on the information currently available.

What steps can the user take to avoid the potential risk of this issue?

End User/ Surgeons should observe the following precautions when using the affected Ø 3.5 mm Cortical Screw:

- Verify the implant packaging and confirm the manufacturing lot number before implantation.
- Prepare the pilot hole using the recommended drill bit and drill guide.

- Perform tapping where indicated by the surgical technique, particularly in dense cortical bone.
- Ensure the screw is aligned with the prepared pilot hole before insertion and avoid cross-threading or off-axis insertion.
- Insert the screw gradually using controlled, steady torque. Do not apply excessive insertion force.
- Pay particular attention while the screw engages the second cortex. If unusually high resistance is encountered, stop insertion immediately and assess the cause before proceeding.
- Do not continue tightening the screw if deformation, excessive resistance, or any abnormal mechanical behaviour is observed. Remove and replace the screw with a new implant if necessary.
- Use only compatible instruments supplied or recommended by the manufacturer and ensure the instruments are in good condition.
- If screw fracture occurs during insertion, manage the situation according to the surgeon's clinical judgement, including retrieval of the fractured fragment where clinically appropriate and selection of an alternative fixation method if required.
- Apply only the minimum torque required to securely seat the screw in the intended position.

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly. Please ensure that this safety notice is placed in the System's instructions for use. Your personnel should maintain awareness over an appropriate defined period.

If you have sold this medical device and it is no longer in your possession, we kindly ask that you forward this safety notice to the new owner of this medical device.

The Medical Device Authority will be informed of this notice.

Sincerely Yours,



Dr. Hyzan bin Mohd. Yusof
Managing Director