



HOSPITAL ADDRESS  
GERMANY

Eragny, 2022 February XX

Registered letter given in person

**Subject: FIELD SAFETY NOTICE – FSN#2022-02**

**Affected Device:** Original and Essential Kit Pedicle Screw systems

**Référence dossier :** FSN2022-02 – Germany

Dear Surgeon,

Safe Orthopaedics intends to clarify information about an incident that occurred in the German market in October 2021 when using our Pedicle Screw systems.

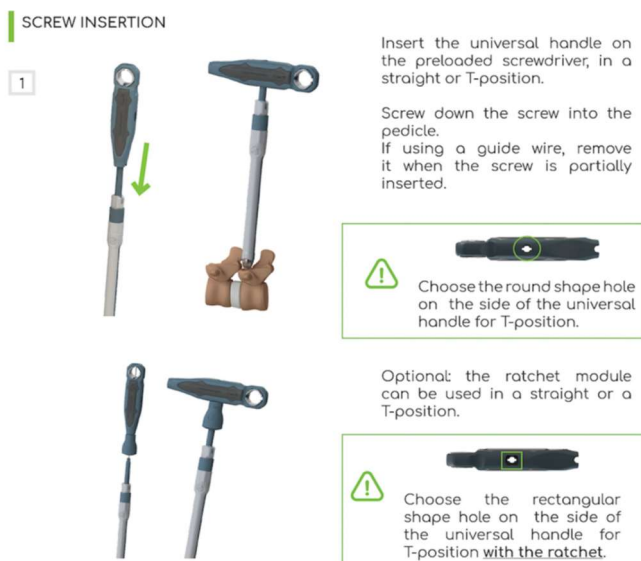
Safe Orthopaedics has highlighted that a clear indication was missing on our surgical guides distributed together with our Pedicle Screw instrumentation kits: Original and Essential.

During the screw insertion step, while using our Essential instrument kit, our client had one of the screwdrivers break. The breakage was due to the wrong insertion of the screwdrivers on the universal handle. Mechanical validation tests done on the correct insertion of the screwdriver on the universal handle shows that the screwdriver can resist a stress of 10.55Nm.

After investigation, Safe Orthopaedics identified that the positioning of the universal handle on the screwdriver was not clearly defined in the surgical guide.

The Universal Handle can be used in two positions (straight and t-handle) with the option of a ratchet module in both. There are specific holes on either side of the Universal Handle for the two t-handle options (with ratchet or without ratchet).

**To improve usability and safety of our product, Safe Orthopedics have decided to update the surgical guide:**





Safe Orthopaedics has decided to notify it's German customers currently using the Pedicle Screw system of this change in the Surgical Guide.

Furthermore, as a corrective action, your sales representative will personally explain to you this improvement and deliver the new version of the Surgical Guide released in February 2022.

Kindly:

1. Disseminate this notice to all relevant departments in your organization.
2. Remain internally vigilant against this notice until all required actions are taken within your organization.

We confirm Bfarm have been notified of the actions described herein.

Be assured that the safety and well-being of patients and healthcare professionals remain the priority of Safe Orthopaedics and we thank you in advance for your comprehension, your confidence and your collaboration.

For further questions, please contact your Safe Orthopaedics representative.

Please accept the expression of our distinguished greetings.

Sincerely,

[Redacted signature]

[Redacted signature]