cc. Chairman Medical Board and relevant Head-of-Department

Urgent Field Safety Notice

SPIGGLE & THEIS Medizintechnik

Article-No.: 10-806-12, 10-807-12, 10-808-12, 10-809-12, 10-810-12, 10-811-12, 10-812-12, 10-815-12, 10-817-12, 10-818-12, 10-819-12, 10-830-17, 10-867-12, 15-808-12, 20-001-15, 20-002-15, 20-003-15, 30-1834, 30-1836, 30-1838, 30-1840, 30-1842, 30-1844, 30-1846, 30-1852, 30-1856, 30-1858, 30-1860, 30-1870, 30-1835

Product Description: Reusable surgical panetti and acoustic neurinoma instruments for surgical-invasive procedures in the ENT area or for head and neck surgery excluding the areas of the central circulatory system (CCS) and the central nervous system (CNS).

Enclosed you will find details of a Field Safety Notice initiated by SPIGGLE & THEIS Medizintechnik GmbH for the above listed products. This notice is addressed to users and is intended to provide them with specific instructions for the proper use of the below listed products. Our records indicate that you have received at least one of the products in question and are therefore affected by this measure.

Please read the attached Field Safety Notice and then return the signed confirmation form stating that you have received a copy of the Field Safety Notice and that you understand the instructions for the proper use of the products in question.

You can continue to use the products safely in accordance with the information and precautions in the instructions for use.

Please complete the confirmation form even if you no longer have the products in question in use.

We also use this form to update our records and to avoid further unnecessary communications.

As part of this corrective action, we would like to ask you to complete the enclosed confirmation form and return it to us as follows:

Mrs. Martina Zell (Safty Officer) or Mr. Thomas Nüsse (QMB)

Phone: +49 (0) 2206 9081 - 41 Phone: +49 (0) 2206 9081 - 26

[redacted] [redacted]

[redacted] [redacted]

We hereby confirm that this safety notice has been brought to the attention of the responsible German supervisory authority, the BfArM (Federal Institute for Drugs and Medical Devices) and our Notified Body DQS (0297).

We would like to take this opportunity to thank you for your cooperation in this matter!

NAME OF ESTABLISHMENT:

DEPARTMENT:

NAME:

POSITION:

DATE:

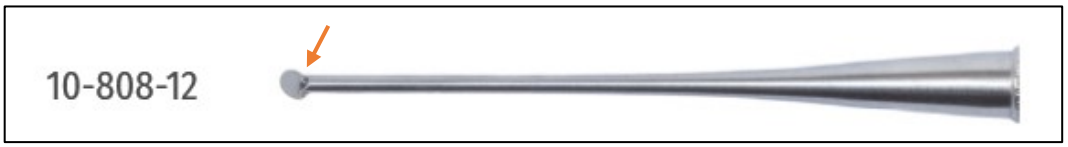
SIGNATURE:

Urgent Field Safety Notice

This letter provides important information regarding the potential for the panetti and acoustic neurinoma instruments to fracture when they are overstrained by excessive force application.

A corresponding warning will be added to the Instruction for Use (IFU).

Specifically twisting and levering may result in a fracture of the fine microsurgical blades of the panetti and acoustic neurinoma instruments.



There have been no deaths or serious adverse events. To ensure patient safety, please comply with the instructions and warnings included in the IFU.

- **The instruments are intended exclusively for microsurgical procedures on soft tissue types such as fine tissue incisions and for the suction process, but not for rinsing. The instruments are not suitable for bone surgery.**
- **Attention: The instruments are sensitive to impacts, throwing, dropping, the use of wire brushes/steel wool and abrasives as well as excessive use of force. It is therefore imperative to take appropriate care when handling them. The instruments are not allowed to be overstressed by twisting or levering. This may result in damage to or breakage of the product or injury to the patient.**
- **Caution: If an instrument breakage occurs due to excessive force on the microsurgical instrument and metal pieces enter the operating field, they should be removed from the operating field as safely, and in a manner that is as minimally invasive, as possible e.g. by flushing or other appropriate intervention. Metal pieces may be localized by X-ray examination in order to remove them completely. In some cases the physician may decide against removal.**

Thank you for reviewing this information. Additional details are included in the following pages. Please follow information indicated in the newly revised IFU for the benefit of your patients. If you have any questions regarding this letter, or would like additional information, please feel free to contact us.

All instruments must be inspected for damage and deterioration prior to clinical use. Particular attention must be paid to fractures, cracks and bends. Damaged instruments must be sorted out. As far as possible, all instruments must be subjected to a functional test.

Immediately inform SPIGGLE & THEIS Medizintechnik GmbH of any adverse events concerning the use of the subject devices. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

As an immediate part of this corrective action an additional warning on the instructions for use, wording "Instrument for microsurgical intervention on soft tissues. Not suitable for bone surgery!" will be added.