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Instruction for use (IFU) Tuning Fork

Scope of validity:

038100FX, 038101FX, 038102FX, 038103FX, 038104FX, 038105FX, 038200FX, 038201FX, 038202FX, 038203FX, 038204FX, 038205FX, 038300FX, 038301FX, 038302FX, 038310FX, 038311FX, 038312FX, 038400FX, 038401FX, 038600FX, 038700FX

1. USED SYMBOLS

	Manufacturer		Consult Instructions
	Caution		Article number
	Production batch, batch		Non steril
	CE- labeling		

2. PURPOSE OF THIS INSTRUCTION

This document describes the correct handling and function of the product as well as the recommended treatment.

It must not be used for the performance or training of surgical operations. Therefore we assume that the relevant regulations, norms and recommendations (such as the RKI http://www.rki.de and the AKI http://www.a-k-i.de) are known and we therefore restrict ourselves by providing the user with such instructions and information that are interest for our products.

It is absolutely necessary that the requirements and specific information in these instructions shall be complied and taken into account. Otherwise the products for the clinical application cannot be used.

3. INTENDED USE

The intended use of tuning forks is to resonate a sound of a specific wavelength for diagnostic and non-invasive examinations in order to assess the patient's hearing ability, bone fracture or to check the vibration sense as part of the peripheral nervous system.

4. INDICATIONS

Only used for ear/ nose/ throat (ent) examinations.

5. CONTRAINDICATIONS

The instruments may be used exclusively for designated use in the ear/ nose/ throat (ent) area by accordingly qualified and certified staff.

6. SAFETY INSTRUCTION

The products must be used only by qualified medical experts and in medical facilities.

- Check the products for completeness and damage after their delivery
- Read the instructions and comply with the same
- Store the product only for proper use, see chapter 3 PROPER USE

The state of the art and national legislation request the compliance of validated processes.

- The user is generally responsible for the validation of his process. Ensure that the treatment, material and staff are capable of achieving the required results.

Infection hazard for patients and medical professionals. The products shall be delivered in non-sterile condition and are reusable.

- **clean/ disinfect the product before the first and each following use**
- **We are not responsible for the use of the product, when it is used by patients with Cruetzfeldt Jacob disease (CJD) or its variants**

Risk of injury due to defect product!

- **Check all functions before its use**
- **Use only a proper product**
- **Respect the valid local regulations during all manual cleaning and drying procedures**
- **During storage, transport and preparation, ensure that the product is not subjected to mechanical loads**

Respect the following measures to avoid material damage:

- ➔ Do not expose the product to impacts
- ➔ Deposit the product carefully

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7. PREPARATION FOR USE

a. Function control:

Hazard of injury due to defect instrument!

- Perform a function control before the first and each following use (i.a. operability of the product)
- Use only a proper product
- Clean/disinfect the product before the first and each following use
- Ensure that no parts are missing or loose
- Ensure that the instrument does not have residues of cleaning or disinfection means
- Examine product on contaminations and damages of any type, such as dents, scratches, and sharp edges

b. Provision:

- Clean/ disinfect product before the first and each following use

8. INSTRUCTIONS FOR REPROCESSING ACCORDING TO DIN 17664

Safety instructions:

Take special care when cleaning narrow lumina or bore! Our products are generally delivered in non-sterile form and must be prepared and sterilized before their first use, according to the following described procedures.

Restriction of reprocessing: Frequent reprocessing has a low impact on our instruments. The end of the product's lifetime is normally determined by wear and damage through use.

For return and repair, the defect products must go through the whole reprocessing process.

Safe storage and transportation to the reprocessing area to avoid any damage.

a. Cleaning:

After using, the instrument may not be cleaned in the sterilizer. After the normal cleaning with soft soap or washing-up liquids the tuning fork should be rubbed off with a cotton or disposable cloth. Afterwards the tuning fork should be disinfect and lubricated with medical instrument oil.

b. Functional Testing, Maintenance:

- Visual inspection for cleanliness.
- If necessary perform reprocessing process again until the instruments are visibly clean.

c. Storage:

No special requirements for storing the instruments.

9. ADDITIONAL INSTRUCTIONS

It is the duty of the user to ensure that the reprocessing process including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly.

10. SERVICE AND REPAIR

Only by the use of original parts, the original technical specifications and operational safety of the product are ensured. If a reparation is performed by a repair center that is not authorized by the FENTEX medical GmbH. all guarantee claims and rights with regards to the product shall be null and void. Reparations are only performed by the FENTEX medical GmbH, when this is economical in relation to the new price of the product.

- In case of return (such as for reparation or complaint), clean, disinfect and sterilize the product.

- The product may only be repaired by the FENTEX medical GmbH (return thereto the defect product)

- The product should ideally be returned in the original package (if this is not possible, pack the product safely for transport). The FENTEX medical GmbH is not liable for any damages caused by improper shipment.

11. DISPOSAL

- Comply with the country-specific rules and laws for the disposal of medical products
- Alternative: Return the product to the manufacturer