

NuVasive Specialized Orthopedics

PRECICE System Instructions for Use - Sterile Instrument

Product Description:

The **PRECICE System** utilizes instruments that are single-use sterile-packed devices. For detailed information concerning product identification (associated implant or model numbers), please refer to the device marking and/or package labeling.

It is recommended that the user is familiar with the uses, compatibility and correct handling of the devices. Additional information is available upon request such as surgical techniques, marketing collaterals, and Instructions for Use that will provide details on the use within the systems. These devices shall only be utilized with NuVasive Specialized Orthopedics Systems.

Intended Use:

Intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device.

Warnings:

- Single-use devices cannot be reused, because they are not designed for reuse. Repeated use can change the mechanical, physical or chemical characteristics of the devices. Repetitive use and re-sterilization may compromise the materials, and/or integrity of the device leading to diminished safety and performance.
- Do not use NuVasive Specialized Orthopedics devices in conjunction with other manufacturers' system unless otherwise specified in the operative technique.
- Guide wires and drill bits are single-use products and therefore must be discarded at the end of each procedure and not reused.

Precautions:

- Ensure that drilling and cutting tools are sharp.
- Devices used should only be for their intended purposes. Improper use could lead to loss in function or durability.
- Before every operation, ensure the devices will assemble and function together properly.
- The device/instrument design shall not be altered in any way.

Other Information:

- These sterile devices are provided sterile through Gamma Irradiation Sterilization.
- Please refer to the package label for the expiration date of these devices/instruments.
- Do not use if the sterile barrier is broken or the package is damaged..

Table 1: Symbols Definition:

Symbol	Definition
	Unsafe in Magnetic Resonance Imaging (MRI) Environments
	For Single Use Only, Do not re-use
	Do not use if package is damaged
	Do not Resterilize
	Non-Sterile
Rx Only/ 	Federal (US) law restricts the sale of this device for use by or on the order of a physician.
	Manufacturer
	Date of Manufacture
REF	Model Number
LOT	Lot Number
 www.globusmedical.com/eifu/	See Instructions for Use www.globusmedical.com/eifu/
	Expiration Date
STERILE R	Sterilized by Gamma Irradiation



NuVasive Specialized Orthopedics

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