

Instruction for Use

PEEK Needle

Device Description

A sterile, semi rigid needle intended for during brachytherapy procedures. The configurations available include:

Family	Size (Fr.)	Length (cm)	Type	colour
PEEK Needle	5	200	Bold Tip Sharp Tip	Black
		260		
		300		
		310		
	6	230		
		260		

Intended Purpose

Peek Needle are intended for brachytherapy procedures.

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical Conditions to be Treated

- Aspiration or drainage of fluid collections (e.g., cysts, abscesses)
- Administration of therapeutic agents into targeted tissues or cavities
- Biopsy sampling of soft tissue or fluid for diagnostic evaluation
- Minimally invasive access for interventional procedures in urology or related specialties

Performance Characteristics of the Device

PEEK Needle is a thermoplastic polymer with has desirable properties such as high tensile strength, buckling resistance, good push ability and radiopacity. Flexible for better access into the body.

Indications

- Brachytherapy
- Laryngeal and Hypopharyngeal Cancer

Contraindications

- Severe un-correctable coagulopathy
- Hemodynamic Instability

Precautions & Warnings

Carefully read all instructions for use and product labelling. Do not use this product without reading and understanding the complete instructions enclosed herein. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- The intended user of the device must be an otolaryngologist or oncologist specializing in the treatment of ENT disorders or cancer and related procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Device is not recommended for use in patients with the above-mentioned contraindicated conditions.
- Store the PEEK Needle at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- PEEK Needles are for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient such as bio-contamination due to release of infectious agents from device into the body which further may result in Infection.
- Do not use the device if there is any indication that the sterility of the device has been compromised. If the sterile package is damaged or possibly opened, do not use. Contact "Manufacturer or Distributor" and replace the product.
- Do not reprocess or re-sterilize, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to failure which, in turn, may result in patient injury.

Intended Patient Population

- The PEEK Needle can be used in patients of all age groups based on doctors' decision.
- The device can be used in both male and female patients.

Shelf-life

The shelf life of the PEEK Needle is 3 years (Indicated on product label with the following use-by symbol).

Sterility – This product is Sterile unless the package has been opened or damaged

- The Peek Needle have been sterilized by exposure to Ethylene Oxide.
- Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct colour.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage.
- The Peek Needle is packed single. Product in each pack must be utilized immediately when opened.

Directions for Use

- Open the package from the Chevron side ('V' Notch) of the pouch. Suggested instructions for using Peek Needle:

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PEEK Needle

- PEEK Needle is used to puncture in brachytherapy procedures.
- Place the needle in the desired position to be punctured in order to pass the catheter and apply force while puncturing.















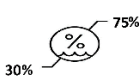




Removal Instructions

- Remove the PEEK Needle by gently pulling on the end.
- If resistance is encountered during removal, stop and determine the cause of resistance before proceeding.

Disposal Instructions

Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical Practice and applicable local, state and federal laws and regulations.

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		Unique Device Identifier		Do not re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Humidity Limit
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		



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Bibliography

- Single Use medical device:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.