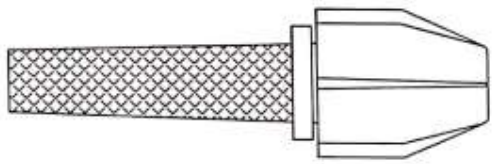
Prymax Angi

Torque Device

DEVICE DESCRIPTION:

Torque Device is used as an Accessory of Angio kit used to manipulate guidewire movement & placement; used for easy maneuverability of guidewire during interventional procedures.

Drawing of product:



MATERIAL USED:
Poly carbonate, Poly propylene, Brass

INTENDED PURPOSE:
INTENDED USE: Torque Device is intended to manipulate guidewire movement & placement; used for easy maneuverability of guidewire during interventional procedures.

INTENDED USER: The device is intended to be used only by a qualified medical professional.

INTENDED PATIENT POPULATION: All patient population irrespective of age and gender.

INDICATIONS:
Angioplasty and Angiography

CONTRAINDICATIONS:
- This device is not designed, sold, or intended for use except as indicated.
- The Patient is known or is suspected to be allergic to materials contained in the device

CLINICAL BENEFITS & PERFORMANCE CHARACTERISTICS

Clinical Benefits:
- Torque devices helps in improving gripping of guidewires, which can help prevent damage to the wire.

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- Torque devices can be operated with one hand, which can be more comfortable.

PERFORMANCE CHARACTERISTICS:
Hemostasis

INSTRUCTIONS FOR USE:
- Open the product in sterile environment.
- Visually inspect the product & packing for any visual defects. Improper transportation & handling can cause structural/functional damage to the device or packaging.
- Rotate open the aperture of Torque device.
- Insert the distal end of the guidewire in to the torque device.
- Rotate the torque device for proper tight grip.
- Use the guidewire along with the attached torque device for further operation.

WARNING & PRECAUTIONS:
- The use of this product is restricted to a qualified doctor or a surgeon trained in the technique.
- Read all the information mentioned in instruction for use. Failure to do so may result in severe patient injury or death. The product should be used according to the instructions for use.
- The product is guaranteed, sterile till the package has not been opened or damaged within the expiry date.
- Do not use if the sterile pack is opened or damaged.
- Sterile, Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death.

ADVERSE EFFECTS:
Infection, Bleeding & Thrombosis

RE-USE HAZARDS:
Transmission of infection from one patient to another.

PACKAGING:
The device is packed in Header Pouch, which is further packed in inner carton & master carton.

STERILIZATION:
Device is EO sterilized, and sterilization is done in-house.

STORAGE CONDITION:
Temperature Limit: 15^{o}C to 40^{o}C.

DEVICE SHELF LIFE: 3 Year

COUNTRY CODE: 356

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DISPOSAL

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 law and regulation.

REPORTING OF ADVERSE EVENTS:

In case of any serious adverse event please report the same to info@prymaxhealthcare.com & gloizou@compliancems.com.au.

Note: For product used in EU also report to the competent authority of the Member State in which the user and/or patient is established.

GOODS RETURN POLICY

Refer to the company's return good policy.

Please contact the branch office or customer service at info@prymaxhealthcare.com or call +91 129 4011818.

SYMBOLS USED ON PRODUCT LABEL

Lot number


Do not re-use

Sterilized by Ethylene Oxide


Manufacturing date


Use-by date


Caution


Non-pyrogenic

Do not resterilize

Catalogue number


Manufacturer

Storage Temperature Range

Conformité Européenne


Do not use if package is damaged


Consult instructions for use


Single Sterile Barrier System

UDI Carrier

Medical Device

Country of Manufacturer

Prepared by:	Approved By:

Manufactured By:

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