P36-940-0001-S Single-Use Torque Limiting Instrument

INTRODUCTION

This Instruction For Use manual is the most comprehensive source of information for the safe and effective use of P36-940-0001-S Torque Limiting Instrument (TLI). This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians.

Federal law in the USA restricts this device to sale by or on the order of a physician.

DESCRIPTION / INTENDED USE

P36-940-0001-S Torque Limiting Instrument is a sterile single-use (single-procedure) manual surgical instrument designed to facilitate the insertion and/or locking of medical fasteners. The TLI limits the maximum output torque in the clockwise (CW) direction at the value indicated on the label. The TLI resists torque in the counterclockwise (CCW) direction.

INDICATION FOR USE

Refer to implant system documentation for associated indications.

CONTRAINDICATIONS

Refer to implant system documentation for associated contraindications.

USER / PATIENT SAFETY

WARNINGS:

- Before using this instrument, read and understand the instructions. Pay particular attention to WARNING information.
- For use by qualified personnel trained in the use of surgical instruments and relevant surgical procedures.
- **DO NOT** use if packaging is opened, damaged, or show signs of tampering. The packaging of this product should be inspected for compromised sterile barrier.
- **DO NOT** use the product if the shelf-life expiration date has passed. For shelf-life expiration date, refer to date printed on the product label.
- Upon removal from packaging, inspect the instrument to ensure there is no damage. If damage is observed, discard the damaged instrument, and open a new single-use instrument.
- Before every operation, ensure that all devices to be used during the operation function correctly with each other.
- **DO NOT** attempt to disassemble or lubricate. This product is factory sealed and has no adjustable mechanism.
- **DO NOT REUSE or REPROCESS.** This product is single-use only and intended for use on one patient during a single procedure. Single-use equipment must be disposed of following the facility's waste disposal policy. All used single-use instruments are defined as biohazard waste and therefore must be disposed of in accordance with facility's procedures.
- Modification or mishandling of the instruments will invalidate the functionality of the instruments and may result in improper performance of the instruments.
- Single-use devices cannot be reused, as they are not designed to perform as intended after the first usage. Changes in mechanical, physical, or chemical characteristics introduced under conditions of repeated use, cleaning and re-sterilization may compromise the integrity of the design and/or materials leading to diminished safety, performance and/or compliance with relevant specifications.
- ECA Medical has not evaluated the safety and compatibility of the instruments in Magnetic Resonance (MR) environment and has not tested for heating or migration in the MR environment.

STERILITY

P36-940-0001-S TLI is provided sterile and has been exposed to a minimum of 25 kGy of gamma radiation from a cobalt 60 source. The packaging of all sterile products should be inspected for flaws in the sterile barrier or expiration of shelf life before opening. In the presence of such a flaw or expiration of shelf life, the product must be assumed non-sterile. Care must be taken to prevent contamination of the component.

STORAGE AND HANDLING

Devices should be handled with care at all times. Storage zones for surgical instruments should be away from areas of humidity and must be out of contact with UV rays and sources of electro-magnetic radiation.

INSTRUCTIONS FOR USE

Upon removal from packaging, inspect the instrument for any defect. Refer to the appropriate surgical technique documentation for specific requirements related to the implant system.

Before use, ensure the 2 mm external hexagonal feature mates with intended 2 mm recess in corresponding medical fasteners.

Drive the fastener as you normally would. When locking the fastener, apply sufficient torque via the handle until audible / tactile feedback is obtained from the device. P36-940-0001-S instruments' performance has been verified for 30 actuations.

NOTE: One actuation is sufficient to achieve torque set-point.

After use, dispose of the TLI in accordance with facility's waste disposal policy.

CAUTION:

- **DO NOT** apply heavy side and/or axial load on the TLI as it could damage the device or increase output torque.
- This TLI can be used to remove fasteners inserted and/or locked by the device itself during the same procedure. **DO NOT** attempt to remove fasteners from a previous procedure (revision surgery) with this instrument, as they might require higher torque and could cause damage to the implant and/or instrument.
- **DO NOT** exceed the maximum number of fasteners as it can void the torque setting.

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

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SYMBOL	SYMBOL TITLE	SYMBOL DESCRIPTION
	General Warning Sign	Signifies a general warning.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Rx Only	Prescription Only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
	Do Not Re-Use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
STERILE R	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation.
	Manufacturer	Indicates the medical manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	Use-By Date	Indicates the date after which the medical device is not to be used.
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.
	Distributor	To indicate the entity distributing the medical device into the locale.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Single sterile barrier system	Indicates a single sterile barrier system.
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.
MD	Medical Device	Indicates the item is a medical device.
UDI	Unique Device Indicator	Indicates a carrier that contains unique device identifier information.
P/N	Part Number	Indicates the manufacture's part number of the device.

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Instruction For Use

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Newbury Park, CA (USA)
91320
Phone: 805-376-2509

Distributed by:
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