

Instructions for Use

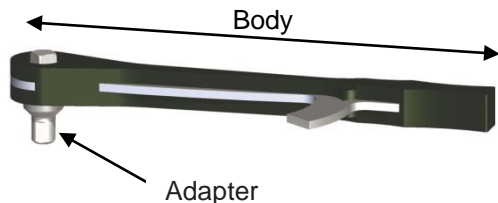
General Information

Park Dental Research Corporation Continuous Feedback Torque Wrench is made of polyetheretherketone (PEEK) and stainless steel with a torque range from 10 - 80 N-cm. The torque wrench design is favorable for surgical and prosthetic use. It is delivered with a torque wrench adapter. This instruction for use applies to the following components:

- Graduated torque wrench, 10 - 80 N-cm
- Adapter for Continuous Feedback Torque Wrench

Figure 1

The torque wrench incorporates the following parts:
1) Body 2) Adapter



Indications

- A dental torque wrench for placing dental implants during surgical procedures.
- A dental torque wrench for placing, adjusting or removing dental prosthetic components.

Warning

Potential adverse incidents may include but are not limited to the following list. Proper use of this instrument may help to reduce these risks.

- Warped or fractured implant necessitating additional surgical procedures.
- Warped or fractured prosthetic components necessitating additional surgical procedures.
- Ingestion or aspiration of adapter or attachments due to inadequate connection to torque wrench.

Cautions

- This device must be autoclaved prior to use.
- Do not use device if it has been overloaded, dropped or misused. Function cannot be guaranteed if this device is not used according to instructions.
- Torque should not exceed 80 N-cm on arm scale.
- Do not use the torque wrench or adapter for any procedure or function not listed in the "indications" section. Do not use this device with other components or equipment that may interfere with function or integrity of the torque wrench and adapter.
- Do not use metal brushes or other abrasive instruments to clean this device as it will compromise the finish.

- Only use recommended detergents and disinfectants. See "Cleaning & Disinfection" section.
- User is responsible for inspecting torque wrench and adapter prior to use. See "Storage & Use" section.

Instructions for Use

Preparation for Use

1. The head of the torque wrench indicates the direction of function. "**IN**" indicates advancement function and "**OUT**" indicates reverse function.
2. Push Adapter into head of torque wrench. Rotate the Adapter in the direction of the arrow on the head of the torque until there is an audible click.

Directions for Use

Procedure for implant and component placement

1. Ensure adapter is properly inserted into the torque wrench. The head of torque wrench should indicate "**IN**" for advancement.
2. Attach the Multi-Purpose Driver to the Adapter. Make sure it is proper seated to avoid disconnection during use.
3. Place adapter assembly over the head of the Low MDI implant.
4. Position the operator's fingers supportively under the patient's jaw, the thumb over the top of the torque wrench applying downward force upon the axis of the implant.
5. Turn the wrench in the direction of the arrow until desired torque is achieved.



WARNING:

Excessive torque and/or lateral forces can cause the implant or component to warp or fracture which may cause injury to the patient and necessitate additional surgical procedures.

Maintenance

1. After every use and when contaminated, disassemble Adapter and Multi-Purpose Driver from torque wrench for cleaning, disinfecting and sterilizing. Refer to "Wrench Disassembly" section.
2. Avoid all contact between disassembled parts during the cleaning and disinfecting process. Refer to "Cleaning & Disinfecting" section.
3. After cleaning and disinfection torque wrench, Adapter and other components, sterilize according to local regulations. Refer to "Sterilization Procedure" section.
4. Store device according to "Storage and Use" section.

Wrench Disassembly

1. For cleaning, remove Multi-Purpose Driver or other attachments from Adapter.
2. Firmly press Adapter to remove it from head of torque wrench.
3. Once adapters and attachments are removed from torque wrench, the parts are prepared for cleaning, disinfecting and sterilization.

Cleaning & Disinfecting

The United States CDC (Center for Disease Control) guidelines recommend cleaning and disinfection with a detergent or enzymatic cleaner.

1. Detergent selection considerations
 - 1.1. Applicable detergent for cleaning devices.
 - 1.2. Compatibility of detergent with thermal disinfectant unit. Use according to manufacturer's guidelines.
 - 1.3. Compatibility of detergent with disinfectant.
 - 1.4. Instructions according to the manufacturer's guidelines for use of the detergent concerning concentration and soak time.
2. Disinfectant selection considerations
 - 2.1. Applicable disinfectant for disinfection of devices.
 - 2.2. Compatibility of disinfectant with detergent.
 - 2.3. Approved efficiency of disinfectant, i.e., DGHM/VAH, RKI approval or CE marking or at least intermediate level disinfectant.
 - 2.4. Instructions according to the manufacturer's guidelines for use of the detergent concerning concentration and soak time.
3. Mandatory preparation for cleaning and disinfecting procedures
 - 3.1. Remove any debris from devices and attachments immediately after use.
 - 3.2. Use a soft brush to remove debris. Do not use metal brushes or abrasive instruments to remove debris.
 - 3.3. Thoroughly rinse torque wrench and attachments to remove detergent and disinfectant.
 - 3.4. Follow manufacturer's guidelines for detergents and disinfectants.

Sterilization Directions

4. Parts are provided non-sterile and any sterilization is under user's responsibility.

Storage & Use

- Handle contaminated devices with protective gloves and local regulations.
- Contaminated devices should be contained and transported according local regulations.
- Reprocess devices immediately after use for best care of device.
- Remove excess debris with cloth/paper wipes.
- Avoid allowing debris to dry and fixate on device.
- Store sterilized devices in a dry and dust-free environment.
- Sterilization can only be preserved if devices remain packaged, impermeable to microorganisms, following a validated process.
- Status of the sterilization must be marked on the package or container.

- Keep sterile and non-sterile products separate.
- Do not sterilize in Park Dental's original packaging.
- This device should be observed for deterioration. In the event of a defect, return to Park Dental. Do not use.
- If Adapter is lost, reorder from Park Dental.

Customer Information

No person is authorized to provide information which deviates from the information within this document.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

Park Dental Research Corporation warrants this product to be free of defects for a period of one (1) year from the purchase date. At its option, PDR will replace or refund the purchase price of this device, to the original purchaser, for returned items due to defects in material and workmanship. If a defect is found in a product, the product should not be used. This warranty covers only the cost of the product and not clinical and professional fee associated with the use of the product.

Limitation of Liability

Park Dental Research Corporation is not liable for any damages due to changes made to product by the user. It is the manufacturer's intention that the product be utilized in a manner that has been submitted to the appropriate governing regulatory bodies. The user is responsible for determining the suitability of the product for its intended application.



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