reed dental®

Instruction for Use
FlexDrive®

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PRODUCT DESCRIPTION

FlexDrive® is intended for dental implant placement as well as for the insertion and tightening of prosthetic screws.

FlexDrive consists of a driver holder with an integrated flexible joint, designed to be connected to a contra-angle handpiece or a wrench adapter, and a set of dedicated drivers. The driver holder is engineered to bend without breaking or undergoing permanent deformation, while maintaining excellent torsional rigidity for reliable and precise torque transmission.

FlexDrive is available as a single instrument or as a kit.

Single instruments (driver holders)

- **FlexDrive S**: Surgical driver holder with a firmer spring for reliable torque delivery and greater control during implant insertion.
- **FlexDrive P**: Prosthetic driver holder with a more flexible spring for improved access and controlled tightening of prosthetic screws.

Both driver holders offer the same high torsional rigidity for consistent torque transmission, while their different flexural rigidity is optimized for each clinical application.

Kits

- **FlexDrive Surgical Kit**: Contains dedicated implant drivers for the most commonly used implant systems, together with FlexDrive S.
- **FlexDrive Prosthetic Kit**: Contains dedicated prosthetic screwdrivers for the most commonly used implant systems, together with FlexDrive P.

Each kit is supplied as a complete set with the related driver holder and dedicated drivers arranged in an aluminum cylindrical tray that functions as a display, cleaning, and sterilization tray.

All components of FlexDrive® kits, including the aluminum cylindrical tray, are manufactured from medical-grade materials.

INDICATIONS FOR USE

FlexDrive® is intended for use by qualified dental professionals for the following applications:

- **FlexDrive S and FlexDrive Surgical Kit**: dental implant placement
- **FlexDrive P and FlexDrive Prosthetic Kit**: insertion and tightening of prosthetic screws

CONTRAINDICATIONS

None known at the time of publication.

SIDE EFFECTS

None known at the time of publication.

PRECAUTIONS

- Do not apply excessive pressure or force on the FlexDrive driver holders. The holders are designed to bend up to a maximum of 30°. Once this limit is reached, the instrument will start to wobble, providing a clear tactile and visual indication to the user that the maximum bending angle has been exceeded.
- Immediately remove from service any instrument that shows signs of corrosion, damage, deformation, or loss of function.
- FlexDrive single instruments and kits are supplied non-sterile and are designed for multiple uses. All instruments must be cleaned, disinfected, and sterilized before each use on a patient, including the first use after receipt.

INSTRUCTIONS FOR USE

FlexDrive is particularly useful for dental implant placement and prosthetic screw insertion and tightening in situations with limited interocclusal space or restricted mouth opening.

Implant Placement

1. Select the appropriate implant driver that matches the implant system and implant to be placed.
2. Connect the selected implant driver to FlexDrive S.
3. Connect the assembled driver holder and implant driver to one of the following:
   a. A contra-angle handpiece (for mechanical-driven implant placement), or
   b. A wrench adapter and manual wrench (for manual insertion).
4. Proceed with implant insertion following the implant manufacturer's instructions for engagement, depth, and torque application.

Prosthetic Screw Insertion and Tightening

1. Select the appropriate prosthetic screwdriver that matches the prosthetic screw to be inserted.
2. Connect the selected prosthetic screwdriver to FlexDrive P.
3. Connect the assembled screwdriver holder and prosthetic screwdriver to one of the following:
   a. A contra-angle handpiece (for mechanical-driven screw insertion and tightening), or
   b. A wrench adapter and manual wrench (for manual insertion and tightening).
4. Proceed with prosthetic screw insertion and tightening following the implant manufacturer's instructions for engagement and recommended torque values.

REPROCESSING INSTRUCTIONS

Important Disclaimer: The reprocessing instructions provided below have been validated by Reed Dental Technologies Sàrl in accordance with EN ISO 17664.
FlexDrive driver holders have been validated for 50 processing cycles without adverse effect on the functionality or safety of the products. Users are solely responsible for any deviation from these instructions and/or for the use of alternative methods. Reed Dental Technologies Sàrl accepts no liability for any damage, injury, or legal responsibility resulting directly or indirectly from such deviations. Users must observe all applicable national and international laws, regulations, and safe practices.
Read these reprocessing instructions carefully and keep them for future reference. Failure to follow them may result in injury to the patient or damage to the product.

SAFETY INSTRUCTIONS

For hygiene and infection control reasons, all FlexDrive components must be cleaned, disinfected, and sterilized before and after each use on a patient, including the first use after receipt (as they are supplied non-sterile).
Comply with the hygiene regulations and legal requirements applicable in your country or region. Only use validated cleaning, disinfection, and sterilization procedures and equipment.

CLEANING, DISINFECTION AND STERILISATION

All reprocessing must be performed by trained personnel in a dedicated area with clearly separated clean and unclean zones.

- Cleaning agents must not contain aldehydes or alcohols.
- Follow the manufacturer's instructions regarding concentration and contact times for all solutions used.
- Successful sterilization requires thorough prior cleaning and disinfection.
- Dirty instruments must always be kept separate from clean ones.

MANUAL PRE-CLEANING

(This does not replace automated cleaning and serves primarily to protect personnel)

1. Immediately after use, rinse all instruments thoroughly under running water (ambient temperature) for at least 1 minute and soak them in an aldehyde-free pre-cleaning solution (e.g., Neodisher Mediclean Forte). Avoid highly aggressive agents such as hydrochloric acid which may corrode the instruments.

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2. Brush the instruments with a soft brush (nylon, polypropylene, or acrylic) until no visible debris remains. Do not use metal brushes. Rinse thoroughly under running tap water for at least 1 minute. Cavities, lumens, and joints must be cleaned twice. Move the flexible joint in all directions at least twice during cleaning.
3. Rinse thoroughly again under running tap water for at least 1 minute.
4. Visually inspect all instruments for cleanliness. Use magnifying glasses if necessary.

Repeat steps 1 to 4 if any residue is still visible.

AUTOMATED CLEANING AND DISINFECTION

1. Place the instruments in an appropriate holder (e.g., bur block) inside a washer-disinfector compliant with EN ISO 15883. Ensure all surfaces can be directly reached by the spray arms.
2. Run the **Vario TD program** (Miele®) or an equivalent validated program with an **A_0 value ≥ 3,000** (or, for older machines, 90 °C for ≥ 5 minutes). Use an enzymatic detergent validated for machine cleaning (e.g., Neodisher Mediclean Forte at 0.4 %).

Pre-Cleaning	Cleaning	Disinfection		A_0 Value
		Duration	*Temperature*	
< 45 °C	≥ 55 °C	≥ 300 s	≥ 90 °C	≥ 3,000

3. Perform a visual inspection of cleanliness and integrity. Use magnifying glasses if needed.

Repeat steps 1 to 3 if residues are still visible.

MAINTENANCE, INSPECTION AND TESTING

After cleaning and disinfection, inspect each instrument for:

- Corrosion
- Damage or wear
- Loss of function (especially the flexible joint)

Any instrument showing defects, corrosion, or functional impairment must be removed from service immediately and not used on patients.

PACKAGING AND STERILIZATION

FlexDrive individual instruments and kits are supplied non-sterile and must not be sterilized in their original packaging.

Before the first use, all components, including the tray, must be cleaned and disinfected according to the instructions above.

After cleaning and disinfection of a kit, place all instruments (driver holder and drivers) back into the tray and pack the kit in a sterile pouch compliant with EN ISO 11607-1. Seal the packaged individual instruments and kits with a suitable sealing machine. Ensure that the instruments are not under tension inside the pouch, as this may compromise the sterile barrier.

1. Sterilize in a Class B steam sterilizer with fractionated pre-vacuum (EN 13060). Only the following parameters are covered by validation:
   a. 132 °C for 4 minutes
   b. 134 °C for 3 minutes
   c. 134 °C for 18 minutes

   We recommend 134 °C for 18 minutes when prion risk is a concern.
2. Label the packaged individual instruments and kits with the following information:
   a. Device name and variant
   b. Sterilization date
   c. Expiry date (if applicable)
   d. Sterilization cycle reference
   e. Name or initials of the person responsible for release

Store the sterilized individual instruments and kits in a clean, dry, dust-free environment.

DISPOSAL

Dispose of FlexDrive components in accordance with local regulations and environmental laws, considering the degree of contamination. Decontamination prior to disposal may be required.

Any serious incident related to FlexDrive must be reported to the manufacturer and/or the competent authority in the country where the user is established.

MANUFACTURER

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SYMBOLS USED ON LABELS



Reference



Non-sterile



Lot number



Autoclave 134°


Consult instructions for use or consult electronic instructions for use


Manufacturer



Prescription use only


Distributor

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