Caution: *U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.*

Description of the Product

Elegant Direct® Duranext abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to an endosseous implant for retention of a cemented or screw-retained dental prosthesis. They may be indicated for single- and multiple-tooth restorations. Titanium abutments are attached to the implant fixture with a titanium screw compatible with the specified implant system. Elegant Direct® Duranext abutments and abutment screws are manufactured from titanium alloy (Ti6AL4V).

Dental Implant Compatibility

Elegant Direct® Duranext abutments manufactured by IDS Elegant Direct® Duranext are generally compatible with the implant systems and platform sizes listed in the table below. The availability of a particular type of abutment varies by implant system, and may be limited by
geographical territory. The platform-specific compatibility of each component is indicated on the individual product label.

Implant System	Manufacturer's Recommended Torque
Nobel Biocare NobelActive®	35 Ncm
Nobel Biocare NobelReplace®	35 Ncm
Zimmer Dental Screw-Vent®	30 Ncm

NobelActive® is a registered trademark of the Nobel Biocare group. NobelReplace® is a registered trademark of the Nobel Biocare group. SCREW-VENT® is a registered trademark of Zimmer Dental Inc.

INDICATIONS FOR USE

Elegant Direct® Duranext Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

All digitally designed abutments for use with Elegant Direct® Abutments for CAD/CAM are intended to be sent to an Elegant Direct® validated milling center for manufacture.

Contraindications

- Wall thickness less than 0.5 mm
- Gingival margin diameter less than 0.5 mm wider than implant
- Angle corrections of more than 30 degrees
- Less than 0.5 mm margin height
- Gingival Height greater than 6 mm
- Less than 4 mm post height
- Titanium Abutment 4.5 and Titanium Abutment 6.0 are for straight abutments only.

Side Effects

No side effects, according to current knowledge.

Adverse Effects

The following adverse effects have been observed when using prosthetic components and accessories:

- Components used in the patient's mouth have been aspirated or swallowed.
- The abutment screw has fractured due to application of excessive torque.

The abutment is not adequately secured due to inadequate application of torque

Warnings

An Elegant Direct® abutment is intended to be used on an individual patient only. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection. Small-diameter implants and angled abutments are not recommended for the molar region of the mouth.

Precautions

Elegant Direct® abutments may only be used for their intended purpose in accordance with general rules for dental/prosthetic treatment, occupational safety, and accident prevention. Elegant Direct® abutments must only be used for dental procedures with the implant systems they were designed for. If the indications and intended use are not clearly

specified, treatment should be suspended until these considerations have been clarified. All components that are used intraorally must be secured to prevent aspiration or swallowing.

Prior to placement, ensure that the required components, instruments, and ancillary materials are complete, functional, and available in the correct quantities

Training

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry and are not intended to substitute for formal clinical or laboratory training. Elegant Direct® abutments should only be used by individuals with training and experience specific to their clinically accepted applications

Disclaimer of Liability

Integrated Dental Systems, Inc. is not liable for damages resulting from treatment ou side of our control. The responsibility rests with the provider.

MRI

Elegant Direct® Duranext abutments have not been evaluated for safety and compatibility in the MR environment, and have not been tested for heating, migration, or image artifact in the MR environment. The safety of Elegant Direct® Duranext abutments in the MR environment is therefore unknown. Magnetic resonance imaging (MRI) scan who bears this device may result in patient injury.

Sterility

Elegant Direct® Duranext abutments may be shipped sterile or non-sterile. For product-specific sterility information, please refer to the individual product labels.

Abutments labeled STERILE should not be resterilized. They are for single use only, prior to the expiration date.

Non-sterile abutments and screws must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method.

- ***Cleaning***: Wash using a broad-spectrum cleaning solution, followed by thorough rinsing and drying.

The recommended disinfection process is based on ANSI/AAMI ST79 guidelines, as follows:

- ***Disinfection***: Immerse abutments in disinfectant[1], rinse with distilled water and dry.

The recommended sterilization process is based on the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 guidelines, as follows:

- ***Sterilization***: Gravity-fed sterilizers: Autoclave in sterilization pouch for 30 minutes at 121°C (250°F)[2]. Devices are to be used immediately after sterilization, as a specific dry-time has not been validated.

NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

[1]Oral disinfectant containing *Chlorhexidine* is recommended; refer to the disinfectant manufacturer's instructions. [2]ANSI/AAMI ST79

Instructions for Use

1) Select the appropriate abutment for the implant to be restored.
2) Remove any replica soft tissue from the patient model.

CAD/CAM preparation

1. Scan the laboratory model.

CAD software producing the appropriate digital file.

2. Send the digital file to a designated milling center for machining of abutment/coping/restoration or,
3. Convert the CAD design file into an appropriate file format using an appropriate CAM software and send to a designated milling center for machining of abutment/coping/restoration.
4. Bond coping to abutment prior to placement intraorally. Remove excess bonding material and polish. Titanium Abutments with zirconia copings are for straight abutments only.
5. Fasten the final abutment to the implant with the abutment screw and tighten the abutment screw to the torque recommended by the implant manufacturer.

6. Attach the final restoration to the abutment.

a. Cement-retained:
   i. Seat the restoration on the abutment and check both occlusion and interproximal contacts
   ii. Fill the screw access channel with a block-out material to preserve abutment screw access
   iii. Cement the restoration using permanent cement according to the manufacturer's instructions

b. Screw-retained:

Single-tooth
   i. Seat the restoration on the abutment and check both occlusion and interproximal contacts
   ii. Fill the screw access channel with a block-out material to preserve abutment screw access

NOTE: It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment