

## **Instructions for use**

Titanium Base abutments plus screw and associated restorative and dental laboratory components.

**Description:** Titanium Base with screw for Individual abutments and Multi-Unit abutments for CE-Series, CL-Series, CN-Series, CH-Series, CF-Series, CR-Series, CS-Series, CC-Series, CK-Series, CV-Series.

### **Indications:**

Abutment Direct Inc. manufactures dental abutments and restorative components designed for the restoration of dental implant treatment including single tooth and multi-tooth restorations. The individual abutments can be combined with copings, crowns or suprastructures made of dental ceramics.

The Titanium Bases with screw for the CE-Series are indicated for Nobel Replace Straight Groovy<sup>®</sup>, Replace Select Tapered<sup>®</sup>, Replace Select Straight<sup>®</sup>, Nobel Replace Tapered Groovy<sup>®</sup>, NobelSpeedy Replace<sup>®</sup>, NobelReplace platform shift<sup>®</sup>, manufactured by Nobel Biocare<sup>®</sup>.

The Titanium Bases with screw for the CC-Series are indicated for Camlog™ implants, manufactured by Camlog<sup>®</sup>.

The Titanium Bases with screw for the CF-Series are indicated for NobelActive™ implants, manufactured by Nobel Biocare<sup>®</sup>.

The Titanium Bases with screw for the CH-Series are indicated for Biomet 3i Certain<sup>®</sup> implants, manufactured by Biomet 3i<sup>®</sup>.

The Titanium Bases with screw for the CK-Series are indicated for Branemark™ implants, manufactured by Nobel Biocare<sup>®</sup>.

The Titanium Bases with screw for the CL-Series are indicated for Bone Level implants, manufactured by Straumann<sup>®</sup>.

The Titanium Bases with screw for the CN-Series are indicated for synOcta<sup>®</sup> implants, manufactured by Straumann<sup>®</sup>.

The Titanium Bases with screw for the CR-Series are indicated for Tapered Screw-vent<sup>®</sup> implants, manufactured by Zimmer<sup>®</sup>.

The Titanium Bases with screw for the CS-Series are indicated for OsseoSpeed<sup>®</sup> implants, manufactured by Astra Tech<sup>®</sup>.

The Titanium Bases with screw for the CV-Series are indicated for Astra-Tech EV™ implants, manufactured by Dentsply<sup>®</sup>.

Each Titanium Base is delivered with an abutment screw for fixation on the implant or Multi-Unit abutment.

The article number is the order number.

**Composition:** Titanium Base and abutment screw made from titanium Ti6Al4V medical grade 5, ASTM 136.

**Instruction for clinician:** Close cooperation between surgeon, restorative dentist, and dental laboratory technician is required for successful implant treatment. Abutment Direct Inc. titanium bases include an internal screw to attach the dental abutment to the dental implant or Multi-Unit abutment. Please follow the recommended torch levels specific to the implant-abutment combination in your Abutment Direct catalogue. If you do not have a catalogue, please contact 1-855-604-0465 to order our catalogue. We recommend that clinicians, new and experienced users, go through training on any new product concepts they encounter. Abutment Direct Inc. provides hands-on guidance to all customers. Contact your local Abutment Direct Inc. representative for more information.

**Contraindications:**

The Titanium Base with screw of each Series can only be combined with the matching implant, e.g. the CE-Series shall be combined exclusively with Nobel Replace® implants. They cannot be combined with implants of a different implant type or manufacturer. The diameter of the Titanium Base must correspond in size to the used implant in order to prevent peri-implant tissue irritation.

The Titanium Bases are indicated for single use only. If they are used multiple times, they might damage the implants.

- The 3.0mm platform Titanium Bases with screw for the CV-Series are only indicated for Mandibular incisors and Maxillary lateral incisors. Other uses are strictly prohibited and void all warranties.

For fixation of the Titanium Base on the implant, the correct torque force, recommended by the implant manufacturer, has to be considered carefully to avoid the damage of the implant-bone connection.

Ncm	Abutment				
20	CS-Series	CC-Series			
25	CV-Series	CH-Series			
30	CR-Series				
35	CN-Series	CE-Series	CL-Series	CF-Series	CK-Series

**Warnings:**

Dental implant surgery and the restoration of implants involve complex dental procedures that are not without risk. It is the obligation of the clinician to inform the patient about the nature and risk(s) of the procedure(s).

Achievement of a satisfactory outcome requires appropriate training prior to implant system use. Improper technique and/or inadequate training can lead to implant/abutment failure and/or loss of supportive bone. Dental implants and prosthetics systems may only be used by dentists or physicians who have had appropriate education and training. Proper clinical and radiographic evaluation of the patient should be performed prior to any implant placement.

Implants or abutments can break in function for any number of reasons. It is important that the clinician use an adequate number of implants in order to provide support to, and distribute the load between, the abutments. Implants should not be placed if there is not sufficient alveolar bone width and height to surround and sustain the implant. Abutments are provided in a non-sterile state and are intended for single use only. Under no circumstances should re-use be attempted.

For Laboratory Technician:

- Do not inhale dust and vapours when machining
- Ensure suitable air extraction/ventilation at the workplace and corresponding Machinery.

-Mechanical treatment of the connection part of the Titanium Bases will damage the correct fitting of the Titanium Base to the matching implant.

**Handling Method:**Ceramic Abutments:

Milling with CAD/CAM-machines of zirconium oxide or aluminum oxide ceramics according to the anatomic form of a crown or coping.

The Ceramic copings or crowns shall be milled or polished with a diamond instrument and with minimal pressure and water-cooling. The minimal thickness shall be 0.5mm sharp edges must be avoided.

Veneering:

Copings shall be veneered with appropriate ceramics before cementing onto the Titanium Base. The instructions for use of the ceramic manufacturers have to be considered.

Treatment of the Titanium Base and the ceramic abutment before cementing:

Sandblasting of the contact surfaces with Al<sub>2</sub>O<sub>3</sub>, 50um for intensive cleaning of dust and grease.

It is recommended to protect the connection part of the Titanium Base with an implant analog during handling.

### Cementing:

It is recommended to cement the ceramic abutment onto the Titanium Base with Panavia® F2.0(Kuraray) with RelayXUnicem® (3M Espe) or other equivalent cements. The instructions for use of the cements shall be followed carefully.

The Titanium Base shall be fixed onto an implant analog with the abutments screw. The head of the screw has to be covered with wax or resin. The mixed cement is applied onto the contact part of the Titanium Base. The abutment is pressed onto the Titanium Base. The final position is evaluated by slight rotation. The gap between abutment and the Titanium Base must be as small as possible. Remaining cement shall be removed immediately.

### Polishing:

After hardening the remaining cement shall be removed with rotating silicon instruments. The cement inside the screw channel has to be removed carefully.

**Scan Body:** For the CAD/CAM scanning of the model, the scan body is used to indicate the position of the implant. The size of the scan body shall be corresponding to the original implant system, implant diameter and Titanium Base Series. The chamfer of the scan body prevents the rotation of the ceramic abutment. The scan body is fixed on the implant analog with the abutment screw. After correct positioning, there is no gap visible between implant and scan body. Rotation of the scan body is impossible.

**Article Number:** The article number of scan body and scan base is a combination of the code for the Series: CE, CF, CC, CK, CV, CH, CL, CN, CR, and CS with the code 1400 for scan body.

**Warnings:** Metal dust is harmful to your health. When Milling and sandblasting use a suction extraction system and a breathing mask.

Allergies to alloy or contents of the alloy or electrochemically base reactions may very rarely occur.

**Warranty:** 10 years on the mechanical stability of the Titanium Base, if it was processed according to the Instructions for use. Whether given verbally, in writing or by practical instructions, our recommendation for use is based upon own experience and trials and can only be considered as standard values. Our products are subject to a constant further development. Therefore alterations in construction and composition are reserved.

**Cleaning, Disinfection and Sterilization:** All prosthetic components are supplied in non-sterile condition.

### Cleaning:

Automatic cleaning procedure based on Vario TD program:

- Cold water rinse 1 min
- Cleaning at 55°C/131°F (± 2°C/3.6°F) for 5 min with cleaning agent neodisher® MediClean (0.5% v/v)

- Neutralization with cold water for 2 min
- Cold water rinse 1 min

Sterilization:

- Seal in a suitable autoclave foil.
- Steam sterilization with 3x fractionated pre-vacuum:
- 132°C (270°F) for 4 minutes, drying time: 20 minutes

**Abutment Direct Inc.**  
**102-7351 Victoria Park Avenue**  
**Markham, Ontario**  
**L3R 3A5**  
**Tel: 1-905-604-0465**  
**Fax:1-905-605-0900**

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