## TruAbutment Solution for CEREC ${ }^{\circledR}$

## TruAbutment Solution for CEREC Workflow



Removal of Healing Abutment


## Select TruScan Post based on patient tissue height

Chart below shows the recommended TruScan Post height depending on the patient's overall tissue height. TruAbutment always recommends selecting a lower GH than the patient's overall tissue height to have enough room to design your emergence profile.

| Patient <br> Tissue <br> Height | Recommended <br> Scan Post <br> Height |
| :---: | :---: |
| 2 mm | GH 1 |
| 3 mm | $\mathrm{GH} 1-\mathrm{GH} 2$ |
| 4 mm | $\mathrm{GH} 2-\mathrm{GH} 3$ |
| 5 mm | $\mathrm{GH} 3-\mathrm{GH} 4$ |
| 6 mm | GH 4 |

A. Crown sprue will be rotated $90^{\circ}$ clockwise from the notch of the TruScan Post for screw retained crown.
(Note: This does not apply to abutment with crown restoration)
B. Face the notch of the TruScan Post toward the indicated direction as shown below to keep the sprue on the lingual side.

■ Tooth \#1~\#8 / \#17~\#24: Face the notch of the scan post mesially.
■ Tooth \#9~\#16 / \#25~\#32: Face the notch of the scan post distally.


Notch Direction of TruScan Post

A. Align the flat sides of both TruScan Cap and TruScan Post.
B. Engage the TruScan Cap onto the TruScan Post using the flat side as a reference point indicating the direction of engagement.
C. Once you hear the click sound, it is fully engaged.
D. If you do not hear the click sound, replace the TruScan Cap with a new one.


## Administration

A. Select the type of restoration.
B. Select the implant system according to the compatibility chart.
C. Select "ScanPost" under "Scanbody Type" when using the TruScan Post.
*Clinician must choose the corresponding implant library from the chart provided here.



## STEP

Hybrid Abutment Parameter Set
Minimal Radial Thickness : $500 \mu \mathrm{~m}$

■ Minimal Occlusal Thickness : $500 \mu \mathrm{~m}$

- Telescope Angle: $4^{\circ}$

■ Potential Issues with Thickness
Design
*Follow the minimum thickness requirement for abutment parameter set.

## STEP <br> 



Milling
*Post-procedures such as shading, sintering, and polishing to follow.

## STEP



TruBase Selection on Chairside
Each TruScan Post and TruBase must be used as a pair with the correlating gingival heights. E.g. If TruScan Post GH2 is used for scanning, TruBase GH2 must be used for restoration.


GH1


GH3


## STEP <br> 

Final Restoration


## TruAbutment Solution for CEREC <br> 

custom Restorationootions Healing Abutment
 Measurement

ruscan Post Selection


## Dentist

## Digital Impression

Prep/Antagonist/Buccal
TruScan Post
Send your scan file to TruAbutment via Sirona Connect


Download $\rightarrow \square \mathrm{ox}$ 든

TruAbutment
 Crown Design


04
Send
Send the Products Send Core (DXD/STL) File
06
Final Restoration

05
Deliver
(1) After acquisition (scanning), select Connect Case Center to initiate your case submission.
Make sure to uncheck the Anonymous box to keep the case reference name.Select TruAbutment Inc. USA as the recipient.


How to Submit CEREC* ACQUISITON Details to TruAbutment
Sirona Connect
4) Select the case(s) to submit to TruAbutment.
(5) Click Submit Cart to complete the order process.

6. Once you Commission the selected case(s) on this pop-up, login to shop.truabutment.com to fill out the prescription ( Rx ) detail.
1) Select Order tab to begin your order.
(2) Select New Order.
(3) Select TruAbutment DS for Custom Abutment/ Healing Abutment/AOT/T-L/ASC Solutions.Select Digital Impression.Select Sirona Connection Portal.Fill in Reference Name.Select Need Design Confirmation if desired.Select .dxd file for CAD service option if desired.
No need to attach scans here if your scan has been sent via Sirona ConnectSelect Add Abutment to fill in the prescription ( Rx ) detail.

(10) Fill in the Order Details.
(11) ScanBody Type
a. Select ScanPost if you used TruScan Post for CEREC ${ }^{\circledR}$
b. Select ScanBody if you used TruScan Body
(12) Save to proceed and exit the pop-up.
(13) Save to proceed to the order summary page.

(14) Select Add Crown and fill out the pop-up to request a crown design file(.stl file).
(15) Submit to complete the order.


## TruAbutment Solution for CEREC Products




|  |  |  |  |  |  | Packing Unit: Tr (ex. AE30-BS08 | $\begin{aligned} & \text { Base }+2 \text { Screws } \\ & 5+\text { AE30-BS×2) } \end{aligned}$ |  | Packing U (ex. | Unit: TruScan Po AE30-SSP08 + | t + TruScan Cap MM-SSC4 + AE3 | $\begin{aligned} & 0+1 \text { Screw } \\ & 30-B S) \end{aligned}$ |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Compatible with |  |  | Abutment Type |  | TruBase |  |  |  | TruScan Post |  |  |  | TruScan Cap | Screw | $\underset{\text { Kit }}{\text { TruScan Post }}$ |
| Manufacturer | Brand | Platform | DS/BASE/AOT/T-L | ASC | GH1 | GH2 | GH3 | GH4 | GH1 | GH2 | GH3 | GH4 |  |  |  |
| Dentsply Sirona | Astra Tech OsseoSpeed EV | 3.0 | Torque |  |  | AE30-BS18S | AE30-BS28S | AE30-BS38S | AE30-SSP08 | AE30-SSP18 | AE30-SSP28 | AE30-SSP38 | CMM-SSC4 | AE30-BS | AE30-SBCASE |
|  |  |  | $25 \mathrm{~N} \cdot \mathrm{Cm}$ |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Driver |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | 0.050 " Hex 1.25 mm |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | 3.6 | Torque |  | AE36-BS08S | AE36-BS18S | AE36-BS28S | AE36-BS38S | AE36-SSP08 |  | AE36-SSP28 | AE36-SSP38 | CMM-SSC4 | AE36-BS |  |
|  |  |  | $25 \mathrm{~N} \cdot \mathrm{Cm}$ |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Driver |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | 0.050 " Hex 1.25 mm |  |  |  |  |  |  |  |  |  |  |  | AE36-SBCASE |
|  |  | 4.2 | Torque |  | AE42-BS08S | AE42-BS18S | AE42-BS28S | AE42-BS38S | AE42-SSP08 |  |  |  | CMM-SSC4 |  |  |
|  |  |  | $25 \mathrm{~N} \cdot \mathrm{Cm}$ |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Driver |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | 0.050 " Hex 1.25 mm |  |  |  |  |  |  |  |  |  |  | AE42-BS | AE42-SBCASE |

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|  |  |  |  |  |  | acking Unit: T (ex. NRW-BS | $\begin{aligned} & \text { ABase }+2 \text { Screv } \\ & 3 S+\text { NRR-BS } 2 \text { ) } \end{aligned}$ |  | Packing U (ex. | it: TruScan Po NRW-SSP08 + | $\begin{aligned} & t+\operatorname{TruScan} \mathrm{Ca} \\ & \mathrm{MM}-\mathrm{SSC} 4+\mathrm{NF} \end{aligned}$ | $\begin{aligned} & +1 \text { Screw } \\ & \text { R-BS) } \end{aligned}$ |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Compatible with |  |  | Abutment Type |  | TruBase |  |  |  | TruScan Post |  |  |  | TruScan Cap | Screw | TruScan Post Kit |
| Manufacturer | Brand | Platform | DS/BASE/AOT/T-L | ASC | GH1 | GH2 | GH3 | GH4 | GH1 | GH2 | GH3 | GH4 |  |  |  |
| Nobel Biocare | Nobel Replace | WP | Torque |  | NRW-BS08S | NRW-BS18S | NRW-BS28S | NRW-BS38S | NRW-SSP08 | NRW-SSP18 | NRW-SSP28 | NRW-SSP38 | CMM-SSC4 | NRR-BS |  |
|  |  |  | $35 \mathrm{~N} \cdot \mathrm{Cm}$ |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | Driver |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | NobelBiocare Unigrip |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | 6.0 | Torque |  | NR6-BS08S |  |  |  |  |  |  |  |  |  |  |
|  |  |  | $35 \mathrm{~N} \cdot \mathrm{Cm}$ |  |  |  |  |  |  |  |  |  |  | [T] |  |
|  |  |  | Driver |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  | NobelBiocare Un |  |  |  |  | NR6-BS38S | NR6-SSP08 | NR6-SSP18 | NR6-SSP28 | NR6-SSP38 | CMM-SSC4 | NRR-BS | NR6-SBCASE |

Packing Unit: TruBase +2 Screws
(ex. SBN-BSO8S + SBN-BW×2)


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[^3]
## TruScan Post Alpha Kit

Kit includes 1 of each TruScan Post size with a TruScan Cap and a screw for each gingival height in an autoclavable case. Ideal for single unit restorations.



TruScan Post

| BioHorizons | Internal | 3.0 | BHN-ALPHA |
| :---: | :---: | :---: | :---: |
|  |  | 3.5 | BH35-ALPHA |
|  |  | 4.5 | BH45-ALPHA |
|  |  | 5.7 | BH57-ALPHA |
| Dentium | SuperLine | - | DSU-ALPHA |
| Dentsply Sirona | Astra Tech OsseoSpeed EV | 3.0 | AE30-ALPHA |
|  |  | 3.6 | AE36-ALPHA |
|  |  | 4.2 | AE42-ALPHA |
|  |  | 4.8 | AE48-ALPHA |
|  |  | 5.4 | AE54-ALPHA |
|  | Astra Tech OsseoSpeed TX | 3.5-4.0 | AS4-ALPHA |
|  |  | 4.5-5.0 | AS5-ALPHA |
| Hiossen | ET | Mini | OTM-ALPHA |
|  |  | Regular | OTR-ALPHA |
| MegaGen | AnyRidge | - | MRD-ALPHA |
| Neodent | GM | - | NDG-ALPHA |
| Nobel Biocare | Nobel Active | NP | NAN-ALPHA |
|  |  | RP | NAR-ALPHA |
|  | Nobel Replace | NP | NRN-ALPHA |
|  |  | RP | NRR-ALPHA |
|  |  | WP | NRW-ALPHA |
|  |  | 6.0 | NR6-ALPHA |
| Straumann | BLX | RB | SXR-ALPHA |
|  |  | WB | SXW-ALPHA |
|  | Bone Level | NC | SBN-ALPHA |
|  |  | RC | SBR-ALPHA |
| URIS | OMNI | Narrow | UON-ALPHA |
|  |  | Regular | UOR-ALPHA |
| Zimmer Biomet | 3i Certain | 3.4 | BC34-ALPHA |
|  |  | 4.1 | BC41-ALPHA |
|  |  | 5.0 | BC50-ALPHA |
|  | TSV | 3.5 | ZV3-ALPHA |
|  |  | 4.5 | ZV4-ALPHA |
|  |  | 5.7 | ZV5-ALPHA |

## TruScan Post Beta <br> 

Kit includes 3 of each TruScan Post size with a TruScan Cap and a screw for each
gingival height in an autoclavable case. Ideal for single and multi-unit restorations.


| BioHorizons | Internal | 3.0 | BHN-BETA |
| :---: | :---: | :---: | :---: |
|  |  | 3.5 | BH35-BETA |
|  |  | 4.5 | BH45-BETA |
|  |  | 5.7 | BH57-BETA |
| Dentium | SuperLine | - | DSU-BETA |
| Dentsply Sirona | Astra Tech OsseoSpeed EV | 3.0 | AE30-BETA |
|  |  | 3.6 | AE36-BETA |
|  |  | 4.2 | AE42-BETA |
|  |  | 4.8 | AE48-BETA |
|  |  | 5.4 | AE54-BETA |
|  | Astra Tech OsseoSpeed TX | 3.5-4.0 | AS4-BETA |
|  |  | 4.5-5.0 | AS5-BETA |
| Hiossen | ET | Mini | OTM-BETA |
|  |  | Regular | OTR-BETA |
| MegaGen | AnyRidge | - | MRD-BETA |
| Neodent | GM | - | NDG-BETA |
| Nobel Biocare | Nobel <br> Active | NP | NAN-BETA |
|  |  | RP | NAR-BETA |
|  | Nobel Replace | NP | NRN-BETA |
|  |  | RP | NRR-BETA |
|  |  | WP | NRW-BETA |
|  |  | 6.0 | NR6-BETA |
| Straumann | BLX | RB | SXR-BETA |
|  |  | WB | SXW-BETA |
|  | Bone Level | NC | SBN-BETA |
|  |  | RC | SBR-BETA |
| URIS | OMNI | Narrow | UON-BETA |
|  |  | Regular | UOR-BETA |
| Zimmer Biomet | 3 C Certain | 3.4 | BC34-BETA |
|  |  | 4.1 | BC41-BETA |
|  |  | 5.0 | BC50-BETA |
|  | TSV | 3.5 | ZV3-BETA |
|  |  | 4.5 | ZV4-BETA |
|  |  | 5.7 | ZV5-BETA |

## Tif Ojuris Instructions for use

## LABELING SYMBOLS

Symbols may be used on some international package labeling
for easy identification

| (8) | Do not reuse |
| :---: | :---: |
| 近 | Use by date |
| LOT | Batch code |
| M] | Date of manufacture |
| 今 | Non-Sterile |
| REF | Catalogue number |
| 4 | Caution, consult accompanying documents |
| - | Manufacturer |
| [i] | Consult instructions for use |
| (4) | Do not use if package is damaged |
| Rx Only | Prescription only |

## Device Description

TruBase consists of a two-piece abutment, where the titanium base is a pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that composes the final abutment.

TruBase abutments are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications and are provided in a various prosthetic platform diameters.
They also feature

- Cylindrical shape
- Hexagonal indexing at the apical end of the connection

TruBase is provided non-sterile therefore must be sterilized after the cementation of the customized superstructure on the TruBase.

Design Limitation for Zirconia superstructure

| Design Parameter | Design Limit |
| :--- | :---: |
| Minimum and Maximum Abutment Angle | $0 \sim 15^{\circ}$ |
| Minimum and Maximum Cuff Height | $0.5 \sim 5 \mathrm{~mm}$ |
| Minimum and Maximum diameter at <br> Abutment/Implant Interface | $\varnothing 5.0 \mathrm{~mm} \sim \varnothing 8.0 \mathrm{~mm}$ |
| Minimum Thickness | 0.4 mm |
| Minimum and Maximum Length of <br> Abutment Post (Length Above the Abutment <br> Collar/Gingival Height) | $4 \sim 6 \mathrm{~mm}$ |

## Indication for Use

## TruBase

TruBase is a titanium component that is directly connected to endosseous dental implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

## Cautions before use

1) Abutment is a prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation
2) Before using the product clinically, dentists must fully familiarize themselves with the product and obtain full informed consent from the patient by reviewing both advantages and limitations of implants. For their part, patients must clearly understand the function and aesthetical limitations of implants.
3) We are under no obligation to replace our products or give a refund in case any defect or problems arise from the use of non-TruAbutment components (i.e. using our abutments with different screws).
4) Since the design of abutments is an important factor affecting the service life of the dental prosthesis, it is imperative that the design of the abutment has been reviewed prior to submission for milling.
5) Before selecting an abutment for a patient, their oral condition must be checked. A restorative plan is to be established based on thorough analysis.
6) Once the product has been used on a patient, all efforts should be made to prevent the patient from aspirating or ingesting the product

## Handling Procedure

## Clinical Procedure

1) Take a conventional open or closed tray impression, following the implant manufacturers' and the impression material manufacturers' guidelines
2) Send the physical impression with the completed order form to TruAbutment.

## Laboratory Procedure

1) Conventional model fabrication from an impression: Assemble the impression coping and implant replica and carefully re-position it into the impression. Fabricate a working model with removable gingival material. 2) Send the working model with the completed order form to TruAbutment.
2) Alternatively, the laboratory can choose to scan the models, design the abutment, and submit the STL to TruAbutment for manufacturing.

## Cautions when using the product

1) When affixing an abutment onto a fixture, the recommended torque value is equivalent to the original manufacturers' value for the respective implant system. The torque value should be determined based on the clinical assessment of the bone quality, fixture dimensions, and prosthesis type, etc.
2) The product must be used by an appropriately trained professional. Damaged tools should not be used

Arbitrarily changing or modifying the product is not recommended and will void the warranty of the abutments.
3) Prior to fabrication and delivery of prosthesis, confirm osseointegration of the implants by utilizing $X$-ray imaging and percussion testing.
4) Temporary prosthesis should be carefully adjusted for the condition of the patient's oral cavity, especially until the implants prove to be osseo-integrated.
5) No cement should be applied to the Morse taper area between fixtures and abutments

## Risks and Side Effects

Below is a list of conditions that bear higher risks of implant surgeries but specialists should examine the patient case by case and plan accordingly.

1) Metabolic disorders such as diabetes and etc.
2) Endocrine disorders such as hypothyroidism, hyperthyroidism, adrenal gland disorders, and etc.
3) Endocrine disorders such as hypothyroidism, hyperthyroidism, adrenal gland disorders, and etc.
4) Circulatory disorders such as angina pectoris, myocardial infarction, congestive heart failure, chronic valvular heart disease, high and low blood pressure, and etc.
5) Respiratory disorders such as asthma and etc.
6) Kidney and blood-related disorders.
7) Bone disorders such as osteoporosis, osteomalacia, Behcet's disease, and etc.
8) Collagen disease.

## Contraindications

) Severe intraoral infections.
2) Impacted tooth, cysts, tumors, etc.

Unclear medical history.
5) Poor health of alveolar bone (i.e. osteoporosis, osteomalacia, and Behcet's disease)
6) Not enough space of alveolus membrane
7) Unhealthy adjacent tooth.
8) Do not use these components if the patient has a known hypersensitivity to titanium, titanium alloy.

## Proper storage and care

After sterilization, place the devices in a dry dark place such as a closed cupboard or drawer.
Follow the instructions of the manufacturer of the FDA-cleared pouches regarding storage conditions and expiration date of sterilized goods.

## End-user Sterilization Information

TruBase is for one-time use only and provided non-sterile therefore must be sterilized prior to use.
All TruBase components are cleaned using multiple sessions of ultrasonic baths to remove contaminants from the milling process.

1. First session

Immerse finished products into trichloroethylene at $30^{\circ} \mathrm{C}\left(86^{\circ} \mathrm{F}\right)$, running the process for 15 minutes.
2. Second session

Immerse products into ethanol at $30^{\circ} \mathrm{C}\left(86^{\circ} \mathrm{F}\right)$, running the process for 15 minutes
3. Third session

Immerse products into distilled water at $30^{\circ} \mathrm{C}\left(86^{\circ} \mathrm{F}\right)$, running the process for 15 minutes.
4. Place cleaned products into a dryer then run at $120^{\circ} \mathrm{C}\left(248^{\circ} \mathrm{F}\right)$ for 10 minutes using hot air.

## Rinsing:

Whether mechanical or manual cleaning has been performed, the device should be thoroughly rinsed to ensure that loosened debris and detergents are adequately removed. Tap water can be used for rinsing to ensure that copious volumes are used but since the quality of tap water varies considerably by region, the final rinse should be performed with treated water that is of a quality that does not contribute to staining or contamination.
Recommended validated sterilization parameters for wrapped devices:

| Method | Moist heat sterilization |
| :---: | :---: |
| Cycle | Pre-vacuum |
| Temperature | $270^{\circ} \mathrm{F}\left(132^{\circ} \mathrm{C}\right)$ |
| Exposure time | 4 minutes |
| Drying time | 20 minutes in chamber |

(Source: ANSI/AAMI ST79 Table 5)
Wraps made by Kimberly-Clark Corp is used during sterilization.
All autoclaves/sterilizers should comply with the requirements of, and be validated, maintained and checked in accordance with EN 285/EN 13060, EN ISO 17665, ANSI AAMI ST79.

According to EN ISO 17665, the final responsibility for validation of cleaning, disinfection and sterilization techniques and equipment lies directly with the end user. To ensure optimal processing, all cycles and methods should be validated

Storage:
Follow the instructions of the manufacturer of the FDA-cleared pouches regarding storage conditions and expiration date of sterilized goods.

## Warnings

The TruBase has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of TruBase in the MR environment is unknown. Scanning a patient who has this device may result in patient injury,
Federal law restricts the sale of this device to or on the order of licensed dentists.
The TruBase is a device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, generally referred to as prescription ( Rx ) devices.
truabutment.com


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