Esthetic Healing Abutments with ScanPeg

This Instructions For Use (IFU) is for Neoss Esthetic Healing Abutments with ScanPeg. For additional information on Neoss implants and detailed information on the other specific Neoss Implant System products you are using, please consult general Instructions For Use (10538) and Neoss Implant System Guidelines (10501).

Introduction
The Esthetic Healing Abutment functions as a regular healing abutment with the purpose to create a soft tissue profile during healing. The Esthetic Healing Abutments are part of the Esthetiline solution. Together with the ScanPeg inserted in the Esthetic Healing Abutment, a digital impression can be recorded with an intra-oral scanner.

Indications for use Esthetic Healing Abutment
The Esthetic Healing Abutments are intended to protect the implant inner bore and the abutment seating area during healing and to form the soft tissue prior to fastening the final prosthesis. In addition these Esthetic Healing abutments are also equipped with features making it possible to attach a ScanPeg for digital impression taking.

Indications for use ScanPeg
The ScanPeg is a scan body momentarily fitted in the screw access hole of the Esthetic Healing Abutment to enable digital acquisition of the implant position in relation to the adjacent teeth and soft tissue and is intended for single unit restorations only.

Product description Esthetic Healing Abutment and ScanPeg
The Esthetic Healing Abutments have a specific non-exchangeable screw and are designed to enable the ScanPeg to be fitted in the healing abutment with a press-fit.
The ScanPeg is designed to fit the screw access hole of the Esthetic Healing Abutments. The combination of these two components is used to take a digital impression without removing the healing abutment from the implant.

Procedure
Healing abutment placement and screw access hole protection

Indexing
The abutment profile of the gingival margin is fixed in relation to the non-rotational feature on all Esthetiline abutments and thus related to the position of the implant – indexing. The Esthetiline solution is best applied by ensuring one groove in the implant to be oriented in the buccal direction during implant installation. This will require the least adjustment. Indexing throughout the treatment is possible utilizing the indexing features as shown.
The groove inside the Esthetic Healing Abutment is oriented buccally when placed in the implant. The Esthetic Healing Abutment is tightened to a maximum of 10 Ncm.
Note: The height of the Esthetic Healing Abutments shall not be adjusted since the scanning accuracy can be impaired. However, minor adjustments of the gingival profile may be carried out by grinding with a bur as the material is PEEK.

In order to protect the screw channel and thereby the scanning accuracy, fill the cavity with a PTFE tape alternatively silicon impression paste at placement.

Cleaning the screw access hole prior to ScanPeg seating
Clean the screw access hole thoroughly without using sharp instruments that can damage the inside and the ScanPeg seating.

ScanPeg seating and scanning
Correct seating
When correctly placed, the ScanPeg will rest on the shelf inside the screw channel and the upper edge of the horizontal groove will be flush with the healing abutment.
The ScanPeg is incorrectly seated if the horizontal groove is clearly visible.
Note: The groove cannot be used as an indicator if the abutment height has been reduced.

Step-by-step
1. Center the ScanPeg in the screw access hole of the Esthetic Healing Abutment.
2. Align the lug on the ScanPeg with the groove inside the Esthetic Healing Abutment.
3. Push in until properly seated.
4. Scan according to the manufacturer’s instruction.
5. Pull out ScanPeg and dispose of it.
Note: Avoid repetitive placements as it can affect the retention.

Compatible scanners
The following intra-oral scanners are compatible and currently validated for use with the ScanPeg. For latest version of this instruction please see the Product Information section under Resources on the Neoss website.

<table>
<thead>
<tr>
<th>Scanner (manufacturer)</th>
<th>Compatibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trios (3Shape)</td>
<td>✔️</td>
</tr>
<tr>
<td>CEREC Omnicam (Sirona Dentsply)</td>
<td>✔️</td>
</tr>
<tr>
<td>CS 3500/3600 (Carestream)</td>
<td>✔️</td>
</tr>
<tr>
<td>Dental Wings</td>
<td>✔️</td>
</tr>
<tr>
<td>iTero (Align Technology)</td>
<td>In progress</td>
</tr>
<tr>
<td>True Definition Scanner (3M)</td>
<td>In progress</td>
</tr>
</tbody>
</table>
Design of final restoration
The Esthetic Healing Abutment in combination with the ScanPeg is included in Neoss 3D libraries for design of matching CAD/CAM abutments in design software from 3shape, Exocad and Dental Wings. The CAD/CAM abutments can be provided with straight or angulated screw channels in Ti, CoCr and ZrO.*
The following versions and higher of the Neoss Brand Library are compatible with the Esthetic Healing Abutments with ScanPeg:
- 3shape: Neoss Brand Library 0.8
- Exocad: Neoss Brand Library 0.5
- DWOS: Neoss Brand Library 0.4

The libraries are available for download, together with the installation and ordering guidelines and order forms, on www.neoss-cadcam.de after securing a login and password.

* Contact your local representative for availability on your market. Certain design software have limitations in combining intra-oral scan with ScanPeg and angulated screw channels.

In addition, the ScanPeg is compatible with the Cerec Omnicam scanner from Sirona Dentsply and the inLab designs SW 4.x software. The compatibility is based on referring to the Sirona Dentsply ScanPost and Scan Body during the model making and design for the Neoss TiBase. It is also possible to export and use the design file created in inLab for production of a Neoss Individual Abutment.*

The Esthetic Healing Abutments are part of the Esthetiline range and like the Tissue Formers match the profiles of stock abutments – Prepable Abutments, Zirconia Abutments and NeoLinks (with plastic coping set).

Contraindications
Treatment is contraindicated where the patient has a preexisting allergy to the used parts. Use of Esthetic Healing Abutments with other than Neoss products and use of a ScanPeg with other than Esthetic Healing Abutments is contraindicated. The ScanPeg is solely to be used with validated intra-oral scanners and compatible abutment design software.

General Precautions
Surgical and restorative products used to achieve and maintain osseointegration should be utilized by persons trained in this method. Such training is offered at a number of centers. Please contact the manufacturer for information.

Pre-operative patient evaluation and close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for success.

Adverse Effects
Implant techniques have normal contraindications and risks. These are extensively documented in the dental literature. Incorrect clinical placement or loading resulting in loss of implant anchorage or loss of the prosthesis are possible events after surgery. Lack of bone quantity or quality, infections, poor patient hygiene or cooperation, and general diseases are some potential causes for loss of anchorage and function.
Sterility
Esthetic Healing Abutments with screw are co-packed with a ScanPeg and supplied sterile.

ScanPeg as spare part
ScanPeg provided separately as spare parts are non-sterile and shall be disinfected with a commonly used water-based disinfectant, e.g. “Dentavon® Liquid” from Schülke & Mayr, before using it on the patient. Please note the ScanPeg cannot be autoclaved.

Disposal
Handling of hazardous material according to established procedures at the hospital/clinic.

Cautions

• Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist.

• Esthetic Healing Abutments and ScanPegs must be used solely on one patient. Single use devices should not be reused due to risks of product contamination, patient/user infection and/or failure of the device to perform as intended.

• Care must be taken that Esthetic Healing Abutments and ScanPegs are not swallowed or aspirated by the patient.

General packaging symbols

<table>
<thead>
<tr>
<th>USE BY/EXPIRY DATE</th>
<th>STERILIZED USING ETHYLENE OXIDE</th>
<th>NON-Sterile</th>
<th>DO NOT RE-USE (Single use only)</th>
<th>TEMPERATURE LIMIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>KEEP AWAY FROM SUNLIGHT</td>
<td>MANUFACTURER</td>
<td>DATE OF MANUFACTURE</td>
<td>CATALOGUE NUMBER</td>
<td>LOT/BATCH NUMBER</td>
</tr>
<tr>
<td>STERILE BY IRRADIATION</td>
<td>(Contents of inner package sterile)</td>
<td>DO NOT USE IF PACKAGE IS DAMAGED</td>
<td>CONSULT INSTRUCTIONS FOR USE (Also available on <a href="http://www.neoss.com/IFU">www.neoss.com/IFU</a>)</td>
<td>CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician or dentist</td>
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Rx only