



Sterngold Restorative Components and Devices

Instructions for Use

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US ENGLISH

Before using the Sterngold Restorative Components and Devices, the clinician should be properly trained to use such components. Please study the instructions, contraindications, recommendations, warnings, and instructions, as well as other relevant and corresponding product-specific information contained in the Sterngold Restorative Components and Devices technical sheet. The Sterngold Restorative Components and Devices technical sheet contains detailed information on how to use the products and what to expect when using them.

The Sterngold Restorative Components and Devices are used in conjunction with Sterngold supported partial denture, overdentures or Sterngold Dental Implants (TRIPUR/MOR) and standard dental implants to create a prosthetic restorative system. These devices are designed for the placement of implants, restorative procedures, and removable restorations. Components included and discussed in this document will be listed by product category and then as individual components. Please refer to technical sheets regarding specific components that may be included in the individual components.

IMPLANT ANALOGS: Restorative Components are devices used in conjunction with Sterngold supported partial denture, overdentures or Sterngold Dental Implants (TRIPUR/MOR) and standard dental implants to create a prosthetic restorative system. These devices are designed for the placement of implants, restorative procedures, and removable restorations. Components included and discussed in this document will be listed by product category and then as individual components. Please refer to technical sheets regarding specific components that may be included in the individual components.

DESCRIPTION: Sterngold Analogs are to be used according to manufacturers' recommendations on how to use. Analogs are to be used to create restorative implants.

CONTRAINDICATIONS: Only use Sterngold Analogs with recommended implant platform as determined by Sterngold Analytical Compatibility Foyer.

A. WARNINGS: Failure to use only recommended compatible analog may result in incorrect orientation of the implant during final restoration. Analogs are recommended to be used as device may become damaged during use resulting in an incorrect fit and orientation of final restoration.

STERNGOLD DIGITAL SPACER: The Sterngold Digital Spacer is a synthetic (PEEK) spacer placed on top of a Sterngold restorative abutment (Standard or Micro). It is used to space apart implants to be placed onto a Sterngold restorative abutment. There is only one spacer for both abutments and can be used on either one.

QRA: The Sterngold Digital Spacer QRA is to be placed only onto the Sterngold restorative abutment.

MOR: The Sterngold Digital Spacer MOR is to be placed only onto the Sterngold restorative abutment.

NOTES: The Sterngold Digital Spacer QRA is to be placed only onto the Sterngold restorative abutment.

INSTRUCTIONS FOR USE: For specific and detailed instructions for use, refer to the Sterngold Digital Spacer technical sheet.

STERNGOLD TUBE LOCK: The Sterngold Tube Lock is a semi-precision, 2-piece lock and tube assembly used to secure the restorative system to the dental unit. It is used as a temporary or permanent dental support system for the restorative system.

DESCRIPTION: The Sterngold Tube Lock is a semi-precision, 2-piece lock and tube assembly used to secure the restorative system to the dental unit. It is used as a temporary or permanent dental support system for the restorative system.

CONTRAINDICATIONS: The Tube Lock is not recommended when a truly rigid connector is indicated, there is inadequate space for setting the connector and it is not suitable as the main attachment of a removable partial denture.

A. WARNINGS: After scanning intraradically, the Digital Spacers are to be removed, as they should not be taken to allow patient to swallow.

INSTRUCTIONS FOR USE: Please read the descriptive text on each of the documents to be included in the Sterngold Digital Spacer. The Digital Spacers will click into place just as the final housing and retentive caps. Ensure that they are fully seated and locked into place. The digital spacers are to be used with an intermaxillary cast or a 1.9 mm tube size. Laboratory and clinical tools are available for processing and casting of the digital spacers. The digital spacers are to be used with a Sterngold restorative abutment. Please refer to the Sterngold Digital Spacers instructions below relating to non-sterile components.) Proceed to design final prostheses.

INDICATIONS FOR USE: The Tube Lock is to be used to fasten a partial denture vital teeth, used to segment a multi-unit fixed partial denture serve as a flexure in a break area of the partial denture. It features a nylon male retentive element and a titanium handle. The Sterngold Root® Anchors system allows the denture to be retained and stabilized. The Sterngold Root® Anchors system is to be used to accommodate divergent abutments, or used as a flexible partial denture.

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INSTRUCTIONS FOR USE: For specific and detailed instructions for use, refer to the Sterngold Tube Lock technical sheet.

STERNGOLD ROOT ANCHOR®: The Sterngold Root® Anchors is a precision intraradicular resilient bolt and socket system. It is used to retain an overdenture in a fixture. It features a nylon male retentive element and a titanium handle. The Sterngold Root® Anchors® system allows the denture to be retained and stabilized. The Sterngold Root® Anchors system is to be used to accommodate divergent abutments, or used as a flexible partial denture.

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INDICATIONS FOR USE: The Sterngold Root® Anchors is to be used with poor crown to root ratio and can be used as an attachment abutment for an overdenture when periodontal conditions permit. The Sterngold Root® Anchors is to be used to accommodate low stress occlusal force on the root. Sterngold Root® Anchors can be used in situations where marginally adequate abutments do not warrant the expense of using a complete overdenture.

NOTES: Sterngold Root® Anchors should not be used when the abutments diverge to the extent that preparation of the root to receive the attachment femur interferes with the placement of the root. They should also not be used when a patient is unable to accept endodontic therapy or is experiencing active periodontal disease.

A. WARNINGS: Ensure that each Sterngold Root® Anchors component to be used during the time of treatment. Failure to do so may result in permanent damage to the restorative teeth, nerves, or other vital anatomical structures. It is possible the restoration may fail to do an improved placement. Potential for failure is increased when the clinician does not follow the directions for use, plan casting and/or patient selection which may include lack of tooth structure or quality, infection, poor patient oral hygiene, and other vital anatomical structures. Possible trauma may occur to the restoration if the incorrect selection of denture or partial denture is used.

CONTRAINDICATIONS: Restorative procedures such as Sterngold Root® Anchors are highly specialized and require training. Clinicians should attend advanced courses designed to educate people in the required techniques. Proper treatment planning and patient selection is critical for ensuring the success of the procedure. The clinician should be experienced in the technique and have a good understanding of the process. The clinician should be able to determine the quality of bone to be used for creating a prosthesis and the overall environment of the restorative system. This may affect the success of the procedure. Possible trauma may occur to the restoration if the incorrect selection of denture or partial denture is used.

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GENERAL CONSIDERATIONS FOR ERA™ ANGLED FEMALE AND ANGLE PLACEMENT HANDLES: The ERA™ Angled Female and Angle Placement Handles are part of the ERA™ system. The ERA™ system allows the clinician to make a choice between a standard or micro version of the ERA™ system. The ERA™ system is to be used to accommodate divergent abutments, or used as a flexible partial denture.

DESCRIPTION: The Sterngold Root® Anchors is a precision intraradicular resilient bolt and socket system. It is used to retain an overdenture in a fixture. It features a nylon male retentive element and a titanium handle. The Sterngold Root® Anchors® system allows the denture to be retained and stabilized. The Sterngold Root® Anchors system is to be used to accommodate divergent abutments, or used as a flexible partial denture.

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Símbolos:
El cuadro abajo indica los símbolos que podrían aparecer en la etiqueta del producto. Véase la etiqueta para los símbolos aplicables al producto.

Simbolo	Significa:	Simbolo	Significa:
	Venta sólo con Receta		Número de Pieza
	Consulte las Instrucciones de Uso		Código de Lote
	No Reutilizar		No Utilizar si Embalaje Esta Dañado
	Non estérile		Dispositivo Médico
	Producto Esterilizado con Radiación		Identificador Único de Dispositivo
	Sistema Barriera de Doble Esterilización		Precavación: Consulte Documentos
	No Re-Esterilizar		Utilizar antes de Fecha de Vencimiento

Fabricado y Distribuido por:

Sternfield Biotech, LLC
23 Frank Messberg Drive
Attleboro, MA 02703 USA
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