DESCRIPTION

Renishaw LaserBridges™ (Implant Bridge) are custom-made devices intended for aiding prosthetic functional and aesthetic rehabilitation. The Implant Bridges are manufactured centrally by Renishaw to designs created by a dental laboratory using a Renishaw DS10™ scanner and Dental CAD software*. Designs for Implant Bridges can be created using a range of third-party scanners and CAD software packages*. In such circumstances, the manufacture by Renishaw of customer-supplied designs is in accordance with the applicable essential requirements of the Medical Devices Directive (93/42/EEC) and under a quality management system that complies with BS EN ISO 13485:2003.

* See the Renishaw website for the full and up-to-date list and instructions for each.

Notes:
The CE mark only applies to the screws in the LaserBridges kit and not to the custom-made bridge itself.
These instructions for use are valid for the fitting of the Implant Bridge to a range of implant systems, an up to date list of which can be found on the Renishaw website.

IMPORTANT: Refer to the original equipment manufacturer's (OEM) implant documentation throughout the clinical and laboratory processes.

⚠ WARNINGS AND PRECAUTIONS

The OEM instructions for the implant and any tooling must be closely followed, alongside the information provided in these instructions for use.

In very extreme cases, electrochemical reactions or allergies to the Implant Bridge material may occur.

② Renishaw LaserBridges are customised specifically to one patient and are suitable for single use only.

The OEM instructions for the screws provided by Renishaw with the Implant Bridge must be closely followed, alongside the information provided in these instructions for use (http://www.dess-abutments.com/pdf/documento-informativo-en.pdf).

These instructions for use assume that both dental clinicians and laboratory technicians have been appropriately trained in their respective professions to carry out the design and placement of the Implant Bridge.

Clinicians and technicians should exercise their professional judgment to determine whether the Implant Bridge is suitable for a particular patient. Any reshaping of the Implant Bridge is therefore a clinical determination.

Ensure close cooperation is maintained between the clinician and technician throughout the implant and Implant Bridge fitting process.

Ensure threads and internal surfaces are clean and free of any foreign matter before sterilisation.

The Implant Bridge is packed and delivered in a non-sterile state. The packaging is unsuitable for sterilisation purposes. They should be sterilised using a vacuum steriliser (EN 13060 type B).

The Implant Bridge should be used immediately after sterilisation and following this, aseptic handling is imperative.

The usual clinical measures should be taken to avoid any swallowing or aspiration of the prosthetic components by the patient.

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Renishaw LaserBridges™

Instructions for use

EN

NON STERILE

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Customer information

Renishaw has made considerable efforts to ensure that the content of these instructions for use is correct at the date of publication. Renishaw may update this document or any associated documentation from time to time, so users are advised to ensure they have the latest version by visiting the dental section of our website at www.renishaw.com. To the maximum extent permissible at law, Renishaw excludes liability, howsoever arising, for any inaccuracies in these instructions for use.

Trade marks

INDICATIONS

- Screw retained Implant Bridge framework for partially or fully edentulous jaws.
- Suitable for anterior and posterior restorations.
- Intended for a range of dental implant systems.

CONTRAINDICATIONS

- Allergies to any of the materials used including the following:

  Co, Cr, Mo, W, Si, Fe, Mn.
- Angle between implants exceeding 60° (subject to implant interface limitations).
- Patients suffering from bruxism or significant malocclusion.
- Implant systems other than those stipulated by Renishaw (see www.renishaw.com/dental)

UNIVERSAL INFORMATION

The Implant Bridge is supplied with screws that are specific to the Implant Bridge design submitted. These screws are **not** interchangeable with the equivalent OEM's implant screws but can be secured using the implant OEM driver.

The screws are single use only. Follow the manufacturer's instructions and do not over-tighten or under-tighten them.

INFORMATION FOR THE TECHNICIAN

General

Avoid excessive porcelain masses.

Avoid the 'blocking out' technique prior to scanning.

Any grit blasting should be done with 50 µm alumina grit at 5 bar (73 psi) using a pencil nozzle.

The Implant Bridge is supplied with two sets of screws: one is reserved for the final fitting by the clinician, the other is for use by the technician. If additional screws are required for laboratory use, they must be purchased exclusively from Renishaw.

Finishing

Emergence profile should be polished before returning to the clinician.

Supra-gingival surface requires grit blasting before porcelain lay-up.

Oxide firing should be done for 5 minutes at 950-980 °C with vacuum.

Porcelain application

Maximum thickness of 1.5 mm.

Use ISO 9693 compliant porcelains with firing temperatures of up to 980 °C.

The CoCr has a CTE (25 – 500 °C) of (14.0 – 14.5) × 10^{-6} K^{-1}, use porcelains with a similar CTE.

Use according to OEM instructions and recommendations.

Use polishing aid to protect the screw holes.

Apply opaque material in 2 firings – apply a thin layer followed by a second opaque layer.

Wash part under running water before applying the next ceramic coating.

Remove the porcelain mechanically only. Acid removal will cause corrosion of the metal.

TECHNICIAN PROCEDURE

1. Apply veneer to the Implant Bridge.
2. Seal in original packaging and send to clinic.

INFORMATION FOR THE CLINICIAN

Ensure that the patient's implant is fully integrated and healed before placement.

Do not fit a pre-used screw for final placement of the Implant Bridge.

Preventative measures should be taken to avoid aspiration during intraoral placement.

Do not attempt to remove the veneer from the Implant Bridge.

For screw torque recommendations, refer to the OEM implant instructions for use.

CLINICIAN PROCEDURE

1. Rinse the Implant Bridge in tap water and remove any foreign matter with a soft-bristled brush.
2. Clean using an ultrasonic bath.
3. Rinse thoroughly with deionised water and dry using a lint-free cloth.
4. Using a sterilisation pouch, sterilise individually with a vacuum steriliser (EN 13060 type B) at 134 °C for 18 minutes.
5. Hand tighten the screws ensuring the Implant Bridge fully engages with the implant.
6. Using the OEM's torque wrench and driver connection, tighten the screws. Refer to their documentation for instructions and torque values.
7. Fill the screw access channels with a composite resin.

For guidance on cleaning procedures and composites, see document – *Clinical and laboratory recommendations* (Part no. H-5489-8405).

ADDITIONAL INFORMATION

The implant bridge material has a CTE (25 – 500 °C) of (14.0 – 14.5) × 10^{-6} K^{-1}.

For detailed instructions relating to the use of Renishaw's Dental CAD software, the designing of LaserBridges and use of the DS10 scanner, please refer to document – *Renishaw CAD training manual* (Part no. H-5489-8405).

For detailed recommendations and best working practices with all Renishaw materials and dental products, please refer to document – *Clinical and laboratory recommendations* (Part no. H-5489-8500).

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Symbol Key

Non-sterile

Warning / Caution

Use once only

Manufacturer

Refer to IFU

Batch number

Catalogue number

English language

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