Warnings:

Application, activation, deactivation, repairs and regular servicing of the components from the "Holder-Bar" system should only be carried out by trained personnel using original instruments and components.

Mechanically cleaning of the components from the "Holder-Bar" system with a toothbrush and toothpaste can cause premature wear and tear of the functional components

The manufacturer disclaims any liability for damage caused by failure to follow these instructions.

Caution: Federal law (US) restricts this device to the sale, distribution, and use by or on the order of a licensed professional.

Disclaimer of liability

This Holder Bar System is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendations of BHI Implant Ltd.

Use of products made by third parties in conjunction with BHI's Holder Bar components will void any warranty or other obligation, expressed or implied, of BHI Implant Ltd.

The user of BHI Implant Holder bar system is obligated to determine whether the products and/or accessories are suitable for the particular patient and circumstances.

BHI Implant Ltd. disclaims any liability, expressed or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of BHI's Implant products. The dentist is also obligated to study the latest developments in regard to BHI Implant products and their applications regularly.

In cases of doubt, the dentist must contact BHI Implant Ltd. Since the processing and restoration application of this product is under the control of the clinician, it is under his/her responsibility.

BHI Implant Ltd assumes no liability whatsoever for damage arising thereof.

Please read all information carefully. Failure to properly follow the instructions may lead to unanticipated surgical and or restoration consequences.

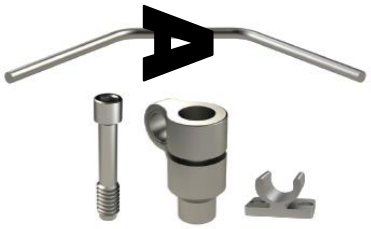
Important: This package insert is designed to provide Instructions for Use for the BHI Implants Ltd. Holder Bar System. It is not a reference to surgical and or restoration techniques.

1. **Description**

The BHI Implant Ltd. "Holder-Bar" system include a variety of components (refer to the full product list) for the treatment of totally edentulous and soon to be edentulous mandibles and/or maxilla's. With the aid of different standardized guides and templates, two to six implants are placed in a predetermined position, corresponding with the "Holder-Bar" system prefabricated prosthetic bar. The bar includes a fixation mechanism towards the implants to allow for some deviation in the implant placement.

Materials:

1. The Bar (A) itself is made of Pure titanium (grade 2) Ti > 98.9375 %
2. The abutments (B), screws(C), clips(D) and small ball bearing joints, which are assembled with the abutment, are all made of Ti-Al6-V4 ELI (grade 23) Ti > 89.478 %, Al 6.0 %, V 4.0%



2. **Intended Use**

The **"Holder-Bar" system** components, manufactured by BHI Implants Ltd, serve as connectors for implant-supported removable dental prostheses. The prosthetic component intended use is to act as a screw retained bar seated on implants, together with a removable prosthesis.

The components are provided as non-sterile, therefore need to be sterilized before use, **read the following cleaning and sterilization instructions carefully**.

These components are labeled as single-use devices and should NOT be reused

3. **Indications for Use**

The BHI Holder bar system is indicated for use rehabilitation of complete edentulous mandibles and/or maxilla's, for the purpose of restoring chewing function and esthetics.

SAFETY IN USE –
Read precautions carefully

4. **Precautions:**

The device is to be used as per the following instructions by physician or licensed practitioner. RxOnly

- Always wear gloves when handling contaminated instruments.
- Do not apply excessive pressure on the …
- Do not reuse.
- Read carefully the labels on the packaging.
-

Important:

- Assumption: Case planning completed, the "Holder-Bar" system is indicated, implants can be loaded.
- Do not unscrew fixation screw from the abutment.
- Due to the small size of the components, care must be taken that they are not swallowed or aspirated by the patient.
- Secure parts to prevent aspiration
- Prophylaxis: Seal the cavities and fissures with antibacterial, high-viscosity silicone material.
- The cohesion of the parts can be increased by coating the pins with silicone.
- Do not cut inside of the patient mouth to avoid injury

Training

The Restoration Techniques require specialization and skills, therefore formal training is recommended. Inadequate training may result in failure of the restoration and further complications.

Knowledge of dentistry and dental technology as well as instruction on the handling of the "Holder-Bar" system by an experienced person are required.

Training courses are regularly provided by BHI Implants Ltd, among others.

The activation, deactivation, repair and periodic maintenance of the "Holder-Bar" system should be carried out solely by specialists. Only original auxiliary tools and parts should be used for this procedure.

Allergies

With patients having an existing allergy to one or several elements of the materials contained in any one of the components from the "Holder-Bar" system, this particular product must not be used. With patients suspected of having an allergy to one or several of these elements contained in any one of the components from the "Holder-Bar" system, this product can only be used after preliminary allergological testing and proof of a non-existing allergy.

MR environment

- The device has not been evaluated for safety and compatibility in the MR environment
- The device has not been tested for heating or migration in the MR environment

5. **Adverse Reactions**:
   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 can occur after surgery.
   Other complications that can occur include infection, bone loss, patient discomfort, implant mobility, local soft tissue degeneration, excessive fastening forces and unfavorable implant placement or alignment.

6. **Contraindications:**
   Pre-operative patient evaluation is necessary to determine any factors that may put the patient at risk or factors that may affect healing capabilities.
   Treatment is contraindicated where the patient has a known preexisting allergy to the used parts. The use of drills and/or other instruments with non-BHI's products is contraindicated.

7. **Warnings:**
   Due to the small size of the components, care must be taken that they are not swallowed or aspirated by the patient.
8. **Non-Sterile products** Components & Instruments
   The devices delivered non-sterile have a "non-sterile" marking on the label. 

9. Warnings and recommendations for disinfection, cleaning and sterilization
   a. **General Warnings:**
      i. The Holder Bar Products must be disinfected, cleaned and sterilized by trained and qualified staff.
      ii. Check for the presence, the cleanliness, the operational state and the qualification (calibration, maintenance, etc.) of all the necessary material before starting the cleaning and sterilization cycle.
      iii. The handling and processing of contaminated devices must be done by the use of personal protective equipment (gloves, glasses, mask, etc.).
      iv. The drying, packaging and sterilization process must be performed in a clean and orderly – designated environment.
      v. Use cleaning/disinfection products that are suitable for the prosthetic products and the materials they are made of. Do not use products containing chlorine, iodine, phenols, strong acids or alkaline (do not use sodium hypochlorite, bleach), oxalic acid, sodium hydroxide or hydrogen peroxide, or normal saline. Beware of the too highly chlorinated tap water. Avoid any product containing aldehyde because of their ability to bind proteins.
      vi. For all products and materials (for cleaning/disinfection, washer-disinfector, ultrasound vat, sterilization pouch, autoclave etc.), carefully follow all manufacturer's instructions (dosage, soaking time, temperature etc.) and expiration dates.
      vii. For the washer-disinfector: Only use agents recommended by the manufacturer and prefer the use of slightly alkaline products (pH between 7 and 10.5).
      viii. Avoid as far as possible shocks and contacts with other instruments.

ix. Please clean products made from the same material in the same container.
x. Do not leave contaminated instruments to dry before the cleaning / sterilization cycle.

b. **Cleaning**

Manual cleaning using ultrasonic cleaner

i. As soon as possible after their use (if more than 30 minutes, wrap the instruments in a damp cloth to prevent debris/contaminants from drying), place the instruments in a suitable container, avoiding shocks and transfer them to the area dedicated for the cleaning process.
Dismantled instruments if necessary (in the case of the torque ratchet) and completely soak the instruments in a freshly prepared cleaning agent (according to solution's manufacturer instructions). Avoid contact with phenol alcohol, chlorine, acid or quaternary ammonia.

ii. Carefully remove all the post-operative residues (blood, bone, etc.) from the instruments (use a soft nylon brush if necessary) and from within (for products with an internal irrigation or hollow products) by flushing a mild alkaline detergent or a natural one.

iii. Rinse thoroughly with cool-to-lukewarm purified water for at least 2.5 minutes.

iv. Place the components in an ultrasonic cleaner with an enzymatic detergent diluted with purified/sterile water per the manufacture's guidelines.

v. Sonicate for 10 minutes and rinse with purified/sterile water for three minutes.

vi. Immediately after washing, dry all the instruments surfaces with a lint-free clean single-use absorbing wipes by scrubbing carefully.

vii. Inspect the devices visually for any remaining bone fragments or debris and scrub as necessary

Automated cleaning using automated washer

Applicable for all reusable instruments prior to first use and after each use,
Proceed with the following cleaning procedure-

i. Place the components in a qualified in an automatic washer with neutral or mild pH enzymatic detergent diluted per the manufacturer's instructions
ii. Perform the washing cycle, with following cycle
Parameters (Typical for Vario TD cycle):
  - 2 minutes cold prewash tap water at Cold, <45°C
  - 5 minutes cleaning wash at Heated, 55°C
  - 2 minute first rinse at Cold, <45°C
  - 2 minute second rinse at Cold, <45°C
  - 5 minutes thermal rinse at Heated, 93°C with Reverse Osmosis Water
  - 22 minutes dry Heated, 50°C

- Inspect the devices visually for any remaining bone fragments or debris and scrub as necessary

Functional Testing & Maintenance

Visual inspection for cleanliness should be performed with magnifying glasses.
If necessary perform reprocessing process again until the instruments are visibly clean.

c. **Sterilization**

i. The components shall be sterilized by moist heat (134°C for 6 minutes followed by 30min drying cycle) using steam autoclaves suitable for medical devices sterilization.
ii. Verify the good progress of the cycle, the integrity of the pouches as well as the physico-chemical indicator of sterilization (if necessary, repeat the process from point 5.a.v). Indicate the sterilization date, batch code etc., on every pouch (and any information necessary for control and traceability), which will then be stored in conditions, preserving the products safety and sterility (a clean, dry, safe and stress-free place, at room temperature and out of direct sunlight).
iii. Periodic testing, cleaning, and calibration of the autoclave/equipment are recommended to ensure the unit remains in proper working order.

10. Packaging:

The BHI Holder-Bar System components are provided clean but non-sterile and must be sterilized prior to being used intraorally and with accordance with the above instructions. Care must be taken when handling contaminated instruments.

11. Storage

Prior to first use the products should be kept in their original package, in a dry area at room temperature.
Following cleaning and sterilization the products should be kept in the sterilization packets, in a dry area at room temperature.

12. Complications and Adverse Effects

The risks and complications with the Holder Bar products , prosthetics, and implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) implant and/or abutment breakage; (3) abutment screw and/or retaining screw loosening; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts;
Short-term risks associated with the use of these products include anesthetic and surgical risks psychological and psychiatric risks, pain, gingivitis, speech problems.
Long-term risks include nerve damage, bone loss, local or systemic bacterial infections, infectious endocarditis**.**
The following table lists the organ systems that may be affected together with the associated risks;

Organ System	Effect
Cardiovascular	Arrhythmias, coronary heart disease, cardiovascular failure
Respiratory	Chronic obstructive pulmonary disease
Gastrointestinal	Hepatitis, malabsorption, inflammatory bowel disease
Genitourinary	Chronic renal failure
Musculoskeletal	Arthritis, osteoporosis
Hematological	Anemia, leukemia, blood clotting disorders
Endocrine	Diabetes, thyroid diseases, pituitary and adrenal disorders

13. Change in performance

It is the user responsibility to inform the patient about the precautions, side effects, and contradictions, should the performance of the device be in question.
It is the responsibility of the patient to seek medical care if any of the side effects occur.

14. Traceability

In order to guarantee the safety of patients, the user must keep the reference and batch number for all the products that has been set or used. These specifications are stipulated on the adhesive detachable labels on the BHI's products. Please to not use any of BHI's products when the packs are damaged or when the labels are illegible.

Each package includes Lot number LOT on its label
This number must be quoted in any correspondence regarding to the product.

15. Validation of Cleaning and Steam Sterilization

The above detailed processes have been validated to prepare BHI non-sterile products for use. It remains the responsibility of the user to ensure that the sterilization and reprocessing as actually performed, using the equipment, materials and personnel in the reprocessing facility achieve the required results.
Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

16. E-Labeling

The Instructions for Use can be accessed online by visiting BHI's website. Additional translations are also available in electronic format for download. To request a paper copy of the Instructions for Use, send an email to the address provided on the label and additional instructions will be provided.
A paper copy may also be requested, by phone, using the telephone number listed below.
This document can be provided in a paper form at no additional cost within 7 days of request.

17. Labeling

Symbols used as part of the Holder Bar Products labeling:

Batch Code

Non-Sterile

Catalogue Number

Consult Instructions For Use

Date of Manufacture

Keep Away from Rain

General Warning Sign, consult accompanying documents

Keep Away from Sunlight

Do Not Use if Package is Damaged

RxOnly

Prescription Only. U.S. Federal Law Restricts this Device to Sale by or on the Order of a Physician or Properly Licensed Practitioner

Manufacturer:

BHI Implants Ltd.
2 Ha'amal St. Afula
1857107, Israel
Tel: +972-4-6094458
Fax: +972-4-6597812
www.bh-implants.com