Warnings:

BHI implants products are intended for use by adequately certified dentists with specific implant training.

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 Multi Unit 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 Multi Unit components will void any warranty or other obligation, expressed or implied, of BHI Implant Ltd.
The user of BHI Implant Multi Unit 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 regarding 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. Multi Unit System. It is not a reference to surgical and or restoration techniques.

1. Description

The BHI Implant Ltd. “Multi Unit” system include a variety of components (refer to the full product list) for screw retained restoration on BHI Implants. The Multi Unit abutments are available in straight, angular 17° and 30° degrees.

The angular abutments are assembled with an Angular Multi Unit Holder.

The Multi Unit system includes the following: Straight abutments (with hex connection), Angular abutments, healing cap, Open tray transfer, analog, Titanium and Plastic sleeves and Ti Base.

Materials:

1. The Multi Unit abutments, healing caps, screws and Titanium sleeve are all made of Ti-Al6-V4 ELI.
2. The Multi Unit transfer and angular abutment holder are all made AISI SS 303.
3. The Multi Unit plastic sleeve is made of white Delrin.

2. Intended Use

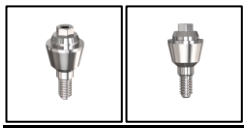
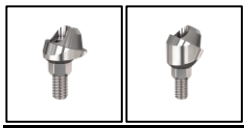
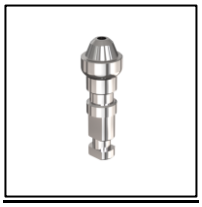
The **"Multi Unit" system** components, manufactured by BHI Implants Ltd, are intended to be used in both mandibles and/or maxilla's for supporting tooth replacements for restoring chewing function and esthetics.
The Multi Unit components are indicated for multiple unit restoration when screw retained prosthetics is preferred
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 Multi Unit components are prefabricated prosthetics products, which are connected directly to the implant. Its' indicated for use in rehabilitation of both mandibles and/or maxilla's, for the purpose of restoring chewing function and esthetics.

4. Clinical Procedure

Stage #	Stage Description	Bhi Implants Multi unit components involve in the procedure
1	**Select the abutment** - Measure the tissue depth from the top of the implant to the top of the tissue at its highest point. Select a Multi Unit abutment with a collar height which is 1-2mm taller than what is measured and also matches the platform size and angulation needed for proper coping position.	

<table>
<tr><td>2</td><td>Place the abutment –
Straight abutment – Place each abutment using the multi unit driver.
Angular abutment – Place each abutment, using its holder. Tighten its screw using a standard prosthetic driver. Unscrew the holder.</td><td><u>Straight MU abutments</u>
  </td><td><u>Angular MU abutments</u>
 
<u>MU Holder</u>
  </td></tr>
<tr><td rowspan="2">3</td><td rowspan="2">Impression –
1. Take the impression of the Multi Unit abutments using the Multi unit Open impression technique, using open Tray transfer and Analog.
2. If digital scan is applicable - Connect Titanium Ti Base to all the multi unit abutments, and scan.</td><td><u>MU Transfer</u>
  </td><td><u>MU Analog</u>
  </td></tr>
<tr><td><u>Ti Base for MU</u>
  </td><td><u>Screw connecting to the abutment</u>
  </td></tr>
<tr><td>4</td><td>Connect the multi unit healing cap to protect the multi unit upper connection, or place a provision restoration</td><td colspan="2"><u>MU Healing cap</u>
  </td></tr>
<tr><td>5</td><td>Send to the laboratory.</td><td colspan="2"></td></tr>
<tr><td>6</td><td>Remove the temporary restoration / healing caps, if applicable.</td><td colspan="2"></td></tr>
<tr><td>7</td><td>Connect the Multi Unit abutments to the prosthetics</td><td colspan="2"></td></tr>
<tr><td>8</td><td>Close the screw access channel.</td><td colspan="2"></td></tr>
</table>

SAFETY IN USE –
Read precautions carefully

5. **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 reuse.
- Read carefully the labels on the packaging.

Important:

- It is essential to achieve a passive adaptation of the prosthetics to the implant abutments in order to achieve proper stress distribution.
- Excessive bone loss or breakage of the restoration components may occur in a non-passive fit.
- All instruments and tooling used must be maintained in good condition and care must
- be taken not to damage implants or other components.
- Always use new patient screws for prostheses final insertion on top of the Multi Unit 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

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 "Multi Unit" 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 "Multi Unit" 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 "Multi Unit" 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 "Multi Unit" 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

6. <u>Adverse Reactions</u>:

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.

7. <u>Contraindications:</u>

Pre-operative patient evaluation is necessary to determine any factors that may put the patient at risk or factors that may affect healing capabilities.
The Multi-Unit abutments are contraindicated for single unit restorations.
The Multi-Unit abutments are not intended for use with a cemented prosthesis.
The Multi-Unit abutments are contra indicated for patients in whom numbers, adequate size and desirable positions of implants are not reachable for achieving safe support of functional loads.
Multi-Unit abutments are contraindicated for patients allergic or hypersensitive to commercially pure titanium or titanium alloy Ti-6Al-4V ELI.
Patient who are medically unfit for an oral surgical procedure.
Treatment is contraindicated where the patient has a known preexisting allergy to the used parts.

8. <u>Warnings:</u>

Due to the small size of the components, care must be taken that they are not swallowed or aspirated by the patient.

9. <u>Non-Sterile products</u> <u>Components & Instruments</u>

All Mutli Unit products are delivered non-sterile and have a “non-sterile” marking on the label. 

10. <u>Sterilization</u>

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.

11. Packaging:

The BHI Multi Unit 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.

12. 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.

13. Complications and Adverse Effects

The risks and complications with the Multi Unit System 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

14. 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.

15. 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.

16. 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.

17. 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.

18. Labeling

Symbols used as part of the Holder Bar Products labeling:

	Batch Code		Non-Sterile
	Catalogue Number		Consult Instructions For Use
	Manufacturer		Keep Away from Rain
	General Warning Sign, consult accompanying documents		Keep Away from Sunlight
	Do Not Use if Package is Damaged		Do Not Re-use

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

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