Warnings:

Surgical and restorative techniques required to place dental implants are highly specialized and complex procedures. BHI's Surgical Tools and Accessories are intended for use by adequately certified dentists with specific implant training. Improper technique can cause bone loss, patient injury, pain and implant failure.

Surgical instruments are susceptible to damage and wear and should be inspected and cleaned before each use. Over time, repeat sterilization may affect cutting efficiency and color appearance

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

1. Disclaimer of liability:

This surgical Tools and Accessories are 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 Implant surgical components will void any warranty or other obligation, expressed or implied, of BHI Implant Ltd.

The user of BHI Implant Surgical components 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 regards to BHI Implant products and their applications regularly.

In cases of doubt, the dentist has to contact BHI Implant Ltd. Since the processing And surgical 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 consequences.

Important: This package insert is designed to provide Instructions for Use for the BHI Implants Ltd. Surgical Tools and Accessories. It is not a reference to surgical techniques.

2. Description:

The BHI Implant Ltd. Surgical Tools and Accessories include a variety of prosthetic/surgical components (refer to full product list) that are manufactured from Surgical Stainless Steel and from Titanium alloy Ti-6Al-4V ELI.

Successful prosthetic restorations requires proper stress distribution, passive adaptation and fitting of the bridge to the implant abutments, adjusting occlusion to the opposing jaw and avoiding excessive transverse loading forces (particularly in immediate loading cases)

3. Indications for Use:

The BHI Implant system is indicated for use in surgical and restorative applications for implant placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient chewing function.
Surgical dental implant accessories are manually or powered devices intended to aid in the placement of or removal of dental implants and abutments; prepare the site for placement of dental implants; aid in the fitting of dental implants and aid in the fabrication of dental prosthetics.

Insertion Drivers

Hexagonal head drivers and motor mount drivers are made of surgical stainless steel and intended for insertion and removal of BHI's implants and prosthetic products such as cover screws, healing abutment screws, abutment screws and other products.

Drill Extender

Drill Extender is made of surgical stainless steel and intended for extending the length of motor mount products such as drills and motor mount drivers.

Parallel Guide

The parallel guide is made of surgical stainless steel tool and intended to aid the dental surgeon to drill parallel hole for the adjacent implant. Following pilot drilling (Diameter 2mm) of the osteotomy for the first implant the parallel guide pin is inserted to the osteotomy. Thus providing the surgeon ability to drill with a pilot drill - trough dedicated hole in the parallel guide - an exact parallel hole in 7 mm distance (from center to center) for the adjacent implant.

Parallel Pins

The parallel pins are made of Titanium alloy and intended to aid in measuring the drilled osteotomy depth and suitability to the selected implant. The diameter of the Parallel Pins is best suited for osteotomy drilled by the pilot drill (Diameter 2mm).

Ratchet Wrench and Torque Ratchet

The ratchets are and their components are made of surgical stainless steel and intended for connection to the Hexagonal Head drivers and allows the user to apply torque for fastening or loosening of the implants and prosthetics with the drivers. The Torque Ratchet is intended to preset the recommended preload torque.

4. Precautions:

All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care, and the limits for acceptable tissue handling are much narrower than in general oral surgery. All drilling procedures should be performed at low speed (approximately 800 rpm for tapered drills and up to 2000 rpm for straight drills). Pre-tapping (threading of the bone) and implant placement should be accomplished at very low speed (~ 25–30 rpm) or manually. All drilling

and pre-tapping procedures require the use of dedicated, sharp instruments under constant and profuse irrigation for cooling. All instruments used in surgery must be maintained in good condition and care must be taken that instrumentation do not damage implants or other components. The Restoration Techniques require specialization and skills therefore formal training is recommended.

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 surgical tools and accessories 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 surgical instruments 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. It is not recommended to use the surgical tools and accessories after more than 15 sterilization cycles. In any case, all components must be checked before use.
iii. 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).
iv. Periodic testing, cleaning, and calibration of the autoclave/equipment are recommended to ensure the unit remains in proper working order.

10. Limitations on reprocessing:

Maximum recommended number of sterilization cycles by autoclave: 15.
All products should be visually inspected for signs of wear and tear prior to reuse and discarded if necessary.

11. How Supplied:

The BHI Surgical Tools and Accessories are provided non-sterile and must be clean and sterilized prior to use and between subsequent uses in 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 surgical kit box or sterilization packets, in a dry area at room temperature.

Dispose of worn/unusable products in sharps disposal containers in accordance to local regulations.

Take appropriate precautions to avoid decontamination prior to next use.

13. Complications and Adverse Effects

The risks and complications with surgical tools and accessories, 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 implant be in question.
It is the responsibility of the patient to seek medical care if any of the side effects occur.

15. 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.

16. Traceability

In order to guarantee the security 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.

17. Labeling

Symbols used as part of the surgical tools and accessories 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

Class I CE Mark Devices

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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