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. **Indications For Use**
   BHI's Surgical Tools and Accessories are indicated for use with BHI's implants and associated components for surgical and restorative applications for 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 patients' chewing function .In addition, they are also indicated for use with BHI's implants and associated components for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

2. **Note**
   Care and maintenance of reusable instruments are crucial for a successful treatment and are essential for the outcome of the total treatment.

3. **Non-Sterile Surgical Tools and Accessories**
   The Surgical Tools and Accessories, which are delivered non-sterile, are marked as "non- sterile".

4. **Contraindications**
   a. Pregnancy
   b. Renal failure
   c. Steroid use
   d. Hypertension above 170/110 mm Hg
   e. Osteoradionecrosis
   f. Unexplained hypersensivity
   g. Patients receiving corticosteroids anticonvulsives or immunosuppressive therapy

h. Organ transplantation
i. Fibrous dysplasia
j. Ehler-Danios syndrome Prophylactic antibiotics
k. Bone metabolism disorders
l. Hypersensivity to implant components
m. Abnormal values for BUN, serum calcium or creatinine
n. Anticoagulation therapy
o. Granulocyto penia
p. Hemophilia
q. Regional enteritis
r. Thyroid or parathyroid disease

5. Packaging

Surgical Tools and Accessories have been cleaned and packaged for convenience and immediate use. They are provided in a sealed polybag. The label on the outer packaging contains a lot number that should be recorded in the patient's file to ensure complete traceability of the product.

6. 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 of contaminated devices must be done by using personal protective equipment (gloves, glasses, mask, etc. ...).
iv. The drying, packaging and sterilization process must be performed in a clean and orderly 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**

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. Arrange in a clean and adapted packaging, dismantled if necessary (in the case of the torque wrench) and completely soak the instruments in a freshly prepared disinfecting solution (according to solution's manufacturer instructions), without any bubbles (the use of an ultrasonic cleaner is also appropriate). Let the instruments soak until all visible residues have been removed. Rinse thoroughly under cool-to-lukewarm drinkable, tap water until the absence of chemical and / or other residues on the device.

ii. Carefully remove all the post-operative residues (blood, bone, etc...) from the instruments (use a nylon brush if necessary) and from within (for products with an internal irrigation or hollow products) by using a mild alkaline detergent (not a strong one) or a neutral one. Rinse thoroughly (preferably use deionized water for the final rinse).

iii. **In case of a manual cleaning**: Immediately after cleaning, dry all the instruments surfaces with a lint-free clean absorbing paper by scrubbing carefully or with compressed air for medical use.

iv. **In case of a washer-disinfector**: Immediately after cleaning, put the instruments in the washer-disinfector avoiding contacts between the devices and start the cycle following the manufacturer's instructions and using the appropriate disinfecting / rinsing aids.

v. Visually inspect the cleanliness and the absence of humidity or stains on the components and make sure that no deterioration may affect their safety, integrity or functionality. If necessary, repeat the cleaning cycle from point 6.b. Reassemble the instruments when needed. Put one or several products in a sterilization pouch, big enough so that no tension is applied upon closure.

vi. Prior to surgical use, the components shall be rinsed with cool-to-lukewarm drinkable, tap water for 2.5 (two-and-one-half) minutes.

vii. Place the components in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes and rinse with drinkable, tap water for three minutes.

viii. Place the components in sterilization packets.

c. **Sterilization**

i. The components shall be sterilized by moist heat (134°C for 6 minutes followed by 30min drying cycle) using standard hospital/clinic steam autoclaves suitable for medical devices

sterilization. It is not recommended to use the surgical tools and accessories after more then 8 sterilization cycles. In any case, all components must be checked before use.

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 on every pouch (and any information necessary for the 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.

7. Storage

Store the sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C/41°F- 104°F. The products that have to be eliminated are thrown away in sharp disposal containers.

8. 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

9. Change in performance

It is the clinician's 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.

10. Properties of Products

The Surgical Tools and Accessories are constructed of **the following materials:**

a. Titanium Alloy: TI-6AL4V ELI ASTM F-136
b. Stainless Steel: SS 316, SS 303, SS 17-4PH
c. Delarin
d. Silicon

11. eLabeling

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 appropriate telephone number listed below.

12. Traceability

In order to guarantee the security of patients, the practitioner 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 BHI's products when the packaging is damaged or when the label is unreadable.

This document can be provided in printed paper form at no additional cost within 7 days of request.

13. European representative

MedNet GmbH
Borkstraße 10
48163 Münster
Germany

14. Manufacturer

BHI Implants Ltd.
2 Hamal St.
P.O.B 1063 Industrial park
Afula 1857107, Israel
TEL +972-4-6094458
FAX +972-4-6597812

Symbol	Description
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