

## **Surgical / Prosthetic Tool Kit**

### **INSTRUCTIONS FOR USE**

#### **Disclaimer of liability:**

These prosthetic/surgical components 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 Adin Dental Implant Systems Ltd. Use of products made by third parties in conjunction with Adin Dental Implant Systems prosthetic / surgical components will void any warranty or other obligation, expressed or implied, of Adin Dental Implant Systems.

The user of Adin Dental Implant Systems prosthetic components has the duty to determine whether or not any products are suitable for the particular patient and circumstances. Adin Dental Implant Systems 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 Adin Dental Implant Systems products.

The clinician is also obligated to study the latest developments in regards to Adin Dental Implant Systems products and their applications regularly. In cases of doubt, the clinician has to contact Adin Dental Implant Systems. Since the processing and surgical application of this product is under the control of the clinician, it is under his / her responsibility.

Adin Dental Implant Systems assumes no liability whatsoever for damage arising thereof.

#### **Description:**

The Adin Dental Implant System Tool Kits include a variety of prosthetic / surgical components (refer to full product list) that are manufactured from Surgical Stainless Steel except for abutment retrieval screws which are part of a Prosthetic Kit and manufactured from Titanium-6Aluminum-4Vanadium ELI- ASTM F136.

Successful prosthetic restorations require: 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).

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

#### **Indications for Use:**

Adin implants are intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit restorations including cement retained, screw retained, over-denture restorations and terminal or intermediate abutment support for fixed bridgework. Adin drills and surgical instruments and are used for the sole placement of Adin dental implant systems.

ADD: Adin surgical drills are intended for the purpose to drill bone tissue and provisionally soft tissues during and before surgical procedures requiring dental implants.

Surgical dental implant accessories are manually 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.

#### **Instructions for Use:**

The restoration procedures are recommended to be done under acceptable practice conditions with specifically designed prosthetic instruments. When constructing the prosthesis, chewing forces and differences between the movability of the prostheses placed on the implants and original teeth have to be considered.

It is important to achieve perfect articulation as far as incisors, canines and molars are considered. Prior to starting restoration process, the inner part of the implant needs to be well cleaned and rinsed.

#### **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 does not damage implants or other components. The Restoration Techniques require specialization and skills therefore formal training is recommended.

### 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, and unfavorable implant placement or alignment. Additional information and steps to be taken can be found in Adin's Product Catalog.

### 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 preexisting allergy to the used parts. Drills and instruments that are used with none Adin products is contraindicated.

### Cleaning:

- After use, place tools in a beaker of plain water with mild soap or a specialized cleaning solution.
- Rinse with tap water for a minimum of two minutes while brushing with a soft bristled brush to remove visible debris. Clean the interior lumen with a thin wire to remove any remaining debris.
- Inspect visually for any remaining bone fragments or debris and scrub as necessary.
- Place component's in the prosthetic kit and pour ethyl alcohol over the burs and tray to remove soap residue and minerals from the water. This step is important to help prevent corrosion and spotting.
- Wrap the surgical tray in paper or autoclave-approved bags twice in order to prevent a tear in the outer packaging and also to protect from contact with contaminated instruments.

### Limitations on reprocessing:

Repeated reprocessing in line with these instructions has only minimal effect on Adin dental tools and drills. End of useful life is normally determined by wear and attrition during use rather than by the effects of reprocessing. Drills should be visually inspected for signs of wear and tear prior to reuse.

### Sterilization:

- This Kit is delivered non-sterile.  
For sterilization use steam sterilization for 30 minutes at 134°C/274°F.
- If any modification has been made to the components & instruments clean prior to sterilization. Dry instruments for thirty (30)

minutes to mitigate the risk of stainless corrosion.

- Do not use fixation agents or hot water (>40°C/104°F) as this could influence your subsequent cleaning results.

### How Supplied:

Adin tools and drills are provided as non-sterile and must be sterilized prior to first use and between subsequent uses in accordance with the above instructions. Care must be taken when handling contaminated drills and instruments.






### Storage:

Devices are stored at room temperature. Take appropriate precautions to avoid recontamination prior to next use. Disposable at end of useful life.

### Caution:

Improper technique can contribute to reconstructive failure and/or patient discomfort. Adin's Prosthetic tools are intended for use only in the indicated applications. Federal (USA) law restricts this device to be sold by or on the order of a licensed dentist or physician. Within the USA only, the (DLC) Diamond Like Carbon Drills are indicated for single use only.

### Explanation of Pictograms:

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|  Batch number        |  Manufacturer |
|  Catalogue number    |  Attention    |
|  Non-sterile product |  |

 0473 is the Notified Body number for Intertek

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