

Paltop

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Instructions for Use

Dental Implants System

Implant Family	Connection Type
Advanced	Internal Hex
Advanced +	
Dynamic	
PAI	
PAI ^{TC}	
Dynamic Conical	Conical
Dynamic Conical ^{MC}	
PCA	

1. Description

- 1.1** The Paltop Dental Implant System includes implants, abutments, and associated surgical tools/instruments, restorative, and dental laboratory components. Paltop dental implants are surgically inserted into the upper and/or lower jawbone and serve as a replacement tooth root, which provides a stable foundation for a restoration. NOTE: See Paltop Catalog or Prosthetic Manual for listing of implant and prosthetic compatibility information.
- 1.2** Paltop implants are made of biocompatible Ti-6AL-4V ELI and have a large grit sandblasted, acid-etched surface in various lengths and diameters. The Paltop dental implants have either an internal hexagonal or conical connection and indexing hex feature, which are intended for single use. Each implant is accompanied by a standard cover screw. There are no medicinal substances or human blood derivatives found in Paltop Implant Systems implants, abutments, and associated surgical, restorative, and dental laboratory components.
- 1.3** Paltop Dental Implant System implants are available in the following sizes:

System Name	Connection	Platform	Ø (mm)	Length (mm)					
				6	8	10	11.5	13	16
Paltop Dental Implant System	Internal Hex	NP (Narrow)	3.0			X	X	X	X
			3.25			X	X	X	X
		SP (Standard)	3.75		X	X	X	X	X
			4.2	X	X	X	X	X	X
			5.0	X	X	X	X	X	X
	WP (Wide)	6.0	X	X	X	X	X	X	
	Conical	Conical	3.25			X	X	X	X
			3.75		X	X	X	X	X
			4.2	X	X	X	X	X	X
			5.0	X	X	X	X	X	X

- 1.4** Paltop Surgical Tools include surgically invasive instruments and non-invasive tools which assist with implant surgery and are made of stainless-steel grades and of Ti-6AL-4V ELI.
- 1.5** Paltop Surgical Tools are used for dental implant procedures such as rehabilitation site, implant placement, and implant restorations within the specific indications of each implant system. These tools are manufactured from stainless steel or titanium materials and are intended for use in dental surgical rehabilitation surgery to drill into the upper or lower jaw and may be used to prepare the osteotomy.
- 1.6** Paltop dental prosthetics are made of biocompatible Ti-6AL-4V ELI, Gold parts (Au60%Pt19%Pd20%), or PEEK (Polyetheretherketone).
- 1.7** Paltop Dental Prosthetic components are part of the Paltop Dental Implant System and are pre-manufactured components compatible with Paltop dental implants. They are intended to be used as an aid in prosthetic rehabilitation. Paltop dental prosthetic components comprise abutments and associated prosthetic parts. Paltop Prosthetic Abutments are designed to engage directly with compatible Paltop Dental implants, providing a secure and stable connection that supports

appropriate clinical outcomes, temporary or long-term, in line with the components' intended use. The components also interface with corresponding prosthetic screws, forming part of the complete restorative system assembly. Paltop Dental Prosthetic components are single use. Reuse of the device is not allowed as it may cause microbial contamination and loss of performance.

2. Indications for Use

System Name	Connection(s)	Platform	Ø (mm)	Lengths (mm)	Indications for Use
Paltop Dental Implant System	Internal Hex	Standard and Wide	3.75-6.0	8.0-16.0	The Paltop dental implant system Internal Hex Standard and Wide Platforms implants (implant diameters 3.75 and above and lengths 8mm and above) as well as Conical Connection implants (implant diameters 3.75 and above and lengths 8mm and above), are indicated for use in 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 patient's chewing function. The Paltop dental implant system is indicated also for immediate loading in extraction sockets, when good primary stability is achieved and with appropriate occlusal loading.
	Conical	Conical	3.75-5.0	8.0-16.0	
	Internal Hex	Narrow	3.0-3.25	10.0-16.0	The Paltop Narrow Implant (Internal Hex and Conical Connections, for implant diameters 3.25 and below and lengths 10mm and above) is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the interdental spaces are limited by the adjacent teeth and roots, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Paltop Narrow Implant is indicated also for immediate loading in extraction sockets, when good primary stability is achieved and with appropriate occlusal loading.
	Conical	Conical	3.25	10.0-16.0	
	Internal Hex	Standard and Wide	4.2-6.0	6.0	Paltop Short Implants (Internal Hex and Conical Connections) are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw as an artificial root structure for single tooth replacement or for fixed bridgework to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Paltop Short Implants are indicated to be used only with straight abutments and are for delayed loading only.
	Conical	Conical	4.2-5.0	6.0	

Instructions for Use

- 2.1** Paltop Dental Prosthetics are pre-manufactured components intended for prosthetic rehabilitation in conjunction with endosseous dental implants. These components are designed for either direct connection to the dental implant (e.g., abutments) or indirect connection (e.g., associated prosthetic parts).

3. Patient Population

- 3.1** Implant placement is recommended only for patients who have completed jawbone growth, ranging from adolescents to the elderly population.

4. Directions for Use

- 4.1** The implantation drilling sequence procedure and the prosthetics restoration procedure should be performed under aseptic conditions using only sterile Paltop Dental Implant System surgical tools/instruments. Refer to the Cleaning and Sterilization procedures listed below. A drilling protocol with copious irrigation is recommended for implant placement in the surgical site. The use of the Paltop Dental Implant System Surgical and restorative Manuals are recommended to aid in implant placement.
- 4.2** Following site preparation, attach the surgical ratchet and/or handpiece adapter to the implant driver. To maintain the sterility of the implant, remove the implant and cover screw from the vial as follows. The implant is packaged in an outer vial with shrink wrap. This outer vial holds an inner sleeve/cap with the implant and cover screw. The surgical assistant opens the outer vial and removes the vial cap, without touching the inner sleeve/cap and tips the contents into the sterile field. The clinician holds the sterile inner sleeve/cap to remove the implant and cover screw with the appropriate sterile drivers.
- 4.3** Thread the implant into the prepared site in a clockwise direction, seating the implant at bone level, as indicated in the Surgical Manual. Place the cover screw/healing cap onto the implant and hand tighten. Close and suture the tissue. Refer to the Paltop Dental Implant System Surgical Manual for additional information on implantation. *All implants are provided with a cover screw found in the cap of the implant vial.
- 4.4** For prosthetic restoration stage, clean the implant site thoroughly, and seat the final abutment or prosthetic component. Tighten the abutment screw to the recommended torque as specified in IFU document no. 11-50026 or engaging prosthetic components. Continue with the chosen protocol as outlined in the Paltop Prosthetic Manual 100057-EN01-ROW.

NOTE: Refer to the Paltop Dental Implant System Prosthetic Manual for detailed explanation of restorative procedures. Available upon request from Paltop Dental.

5. Contraindications

- 5.1** The Paltop Dental Implant System is contraindicated for patients:
- 5.1.1** Who are medically unfit for dental implant procedures.
 - 5.1.2** Who are allergic or hypersensitive to any of the raw materials listed above.
 - 5.1.3** In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads, unless an augmentation procedure can be considered.
 - 5.1.4** The Paltop Dental Implant System is relatively contraindicated for patients:
 - 5.1.5** With unfinished cranial growth with incomplete tooth eruption.
 - 5.1.6** Less than 1 year post head and neck radiation therapy.
 - 5.1.7** With uncontrolled Diabetes
 - 5.1.8** Taking systemic bisphosphonate medication (±2 yr)
 - 5.1.9** With renal osteodystrophia
 - 5.1.10** With Osteoporosis
 - 5.1.11** Having different conditions and medications interfere with an uncomplicated wound healing and place the patient at higher risk for implant failure, e.g., alcoholism, smoking ±20 cig/d tobacco users and drug abuse
 - 5.1.12** With poor oral hygiene,
 - 5.1.13** With poor oral habits e.g., bruxism clenching

6. Warnings General

- 6.1** The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry and are not intended to substitute for formal clinical or laboratory training. These devices should only be used by dental clinicians with training and experience specific to their clinically accepted application.
- 6.2** Dental implant surgery and restoration are not without risks. It is the obligation of the clinician to inform the patient about risks associated with these procedures.
- 6.3** Pre-operative evaluation of the patient is necessary to determine factors that may either cause risk to the patient or affect the healing process of the bone and/or soft tissue.
- 6.4** Care should be taken that the patient does not swallow or aspirate components. It is recommended to use a throat pack to prevent swallowing or aspiration of small parts during the surgical and restorative phases.
- 6.5** Product may not be effective in patients with any of the following conditions: chronic bleeding problems, psychological impairment, metabolic bone or connective tissue diseases, treatment with corticosteroids, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor oral hygiene, bruxism, or alcoholism.
- 6.6** It is important that the clinician uses an appropriate number and diameter of implants to provide adequate support and properly distribute load between abutments, to minimize the potential for implant failure or fracture.
- 6.7** It is strongly recommended that Paltop implants be used with dedicated Paltop surgical instruments and prosthetic components. Utilizing components not precisely engineered for optimal compatibility may result in mechanical failure of instruments, tissue damage, or unsatisfactory aesthetic outcomes. To ensure optimal functionality and long-term success, practitioners are advised to consult the official Paltop Catalog for detailed information regarding compatible component combinations and the prescribed workflows specific to each implant platform.
- 6.8** Implant mobility, bone loss, or chronic infection may result in implant failure.
- 6.9** Implants should not be used if their surface is damaged.
- 6.10** Single-use devices shall not be reused. Reuse of device may lead to infection of tissue, infectious diseases, and/or failure of the device to perform as intended.
- 6.11** Restorative components are intended for single use only.
- 6.12** Do not alter implants.
- 6.13** Use caution when handling drills as the tips of these devices are sharp.
- 6.14** It is recommended that the PEEK Concave Temporary Abutment and temporary restorations be kept out of occlusion and excursive movements.
- 6.15** The use of electro-surgical instruments or lasers around metallic implants and their abutments may cause electric and/or heat conductivity.
- 6.16** Do not use if package is damaged.
- 6.17** Temporary abutments are not intended for angular correction and are not intended to be cast.
- 6.18** Warnings specific to Paltop Ø 3.0mm and Ø 3.25mm Internal Hex and 3.25mm Conical Connection Narrow Implants:
- 6.18.1** The Ø 3.0 and Ø 3.25mm Narrow implants are not recommended for posterior placement and/ or in areas of poor bone quality.
- 6.18.2** Narrow diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.
- 6.19** Warnings 6.0mm length Short Implants (internal hex and conical connections):
- 6.19.1** Short 6.0 mm length implants are not to be immediately loaded.
- 6.19.2** Because of the reduced surface area for anchorage in the bone, Paltop Short 6mm implants should be used with caution because they present greater risks to failures compared to standard implants and are recommended for the following situations:
- 6.19.2.1** As an additional implant together with longer implants to support implant-borne restorations
- 6.19.2.2** As an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.
- 6.19.3** When a short implant is the treatment of choice perform a two-stage surgical approach, splinting of implants, and placement of the widest possible implant. For Paltop Short 6mm implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone

loss, changes in the implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. Allow longer periods for osseointegration in both the maxillae & mandible jaw compared to longer dental implants.

- 6.19.4** Paltop Short 6mm implants should not be placed in patients who demonstrate untreated occlusal parafunction, such as bruxism or clenching.

7. Precautions

- 7.1** Determine local anatomy and suitability of the available bone prior to implant placement. Adequate radiographs, direct palpation, and visual inspection of the implant site are necessary prior to treatment.
- 7.2** Product should only be used by surgical or restorative clinicians who have had appropriate education and training. Improper techniques can contribute to implant failure and/or bone loss.
- 7.3** Collaboration between the surgeon, restorative dentist, and dental laboratory technician is essential for a successful implant treatment plan.
- 7.4** Products which are provided sterile and are modified by the end-user, must be cleaned and re-sterilized after any modification are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.
- 7.5** Pre-operative hard tissue or soft tissue deficits not identified may yield a compromised result or unfavorable implant angulation.
- 7.6** Clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to implant's response to percussion, or radiographic changes in bone to implant contact along the implant's length.
- 7.7** Special attention should be given to patients who have localized or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, uncontrolled diabetes, oral-facial radiotherapy, steroid therapy, infections in the neighboring bone).
- 7.8** If the implant shows mobility it should be removed.
- 7.9** If the implant shows bone loss it should be evaluated.
- 7.10** Do not use damaged or worn instruments.
- 7.11** Products are intended for use only in the applications defined in the Paltop Dental Implant System Surgical and/or Prosthetic Manual.

8. Procedural Precautions

- 8.1** All implant drilling and placement procedures should be done at speeds recommended in the Paltop Dental Implant System Surgical Manual.
- 8.2** All drills must be sharp and sterile prior to use.
- 8.3** Paltop Dental recommends a maximum of 20 uses and sterilization cycles for Surgical tools/ instruments, or prior to that if cutting efficiency declines.
- 8.4** All drilling should be done using intermittent drilling action with minimal pressure and continuous irrigation using ample chilled sterile saline.
- 8.5** Do not open sterile packaging until the correct implant size has been determined and the operative site has been prepared.
- 8.6** It is recommended to have a replacement implant on hand.
- 8.7** Mandatory precautions for surgery should be properly evaluated such as asepsis.
- 8.8** Failure to recognize actual lengths of step/twist drills relative to radiographic measurements or drilling beyond the depth intended can result in permanent injury to vital structures, potentially resulting in permanent numbness to the lower lip and chin or leading to hemorrhage in the floor of the mouth.
- 8.9** Excessive insertion torque may cause damage to the implant, implant connection and surrounding bone.
- 8.10** Clean and dry the inside of the internal connection of the implant before hand- tightening the Healing Cap or Cover Screw.
- 8.11** Application of excessive force to the implant area should be avoided, especially during the healing period.
- 8.12** After implant surgery, the clinician should evaluate patient bone quality and implant stability to

determine when implants may be loaded.

- 8.13** Proper occlusion should be evaluated, and restorations should have a passive fit to the abutments.

9. Adverse Effects

Immediately after insertion of dental implants, activities that demand considerable physical exertion should be avoided. Risks and complications with product are similar to those of other dental implant systems and include, but are not limited to:

- Infection
- Persistent pain, numbness, or paresthesia
- Lack of osseointegration, mobility of implant
- Loss of implant
- Implant fracture
- Perforation of the maxillary sinus
- Perforation of the labial and/or lingual plates
- Loosening of the abutment screw
- Bone loss
- Local soft tissue degeneration

It is recommended that the dental personnel brief the patients to abstain from smoking, drink fluids through a straw, and maintain dental hygiene. Residual risks associated with the Paltop dental implant system may result in harms that include procedural delays, infection, damage to adjacent anatomical structures, or circumstances that require an additional surgical procedure due to failure of the implant or undesired surgical outcomes.

10. Adverse Events

- 10.1** To help ensure a successful treatment we recommend informing the patient of the precautions to be taken for a regular follow up after implant treatment and how to maintain good oral hygiene protocol.
- 10.2** In the case of a serious incident, for a patient/user/third party, please contact Keystone/Paltop Dental.
- 10.3** In the European Union and in countries with a similar regulatory regime (Regulation 2017/745/EU on Medical Devices), if a serious incident has occurred during the use of this device or as a result of its use, please report it to Paltop Inc. and the competent authority of the Member State in which the user and/or patient is established.
- 10.4** Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.
- 10.5** Risks and complications with product are similar to those of other dental implant systems and include, but are not limited to: • Infection • Persistent pain, numbness, or paresthesia • Lack of osseointegration, mobility of implant • Loss of implant • Implant fracture • Perforation of the maxillary sinus • Perforation of the labial and/or lingual plates • Loosening of the abutment screw.

11. Sterility

- 11.1** Paltop Dental Implant System implants and some abutments are sterilized using gamma sterilization and are delivered sterile. These products are intended for single use before the “use by” date printed on the product label. The sterile packaging must not be opened until immediately prior to insertion.
- 11.2** The intact sterile packaging protects the gamma-sterilized implant from outside influences, if stored correctly ensures sterility up to the expiration date.
- 11.3** When removing the implant from the sterile packaging, the rules of asepsis must be observed.
- 11.4** The sterile packaging must not be opened until immediately prior to insertion of the implant.
- 11.5** Implants or sterile abutments with damaged sterile packaging must not be used due to the risk of contamination.
- 11.6** Sterile implants must not be resterilized. Resterilization can cause risk or harm to the patient. Paltop Dental does not accept any responsibility for reesterilization of products supplied sterile.
- 11.7** Some Paltop branded system components are supplied non-sterile. Refer to individual product labels for sterilization information. Products provided non-sterile for use in a clinical environment need to be cleaned and sterilized prior to use.

12. Cleaning Instructions for Paltop Metal/PEEK Prosthetic Devices, Tools, and Surgical Instruments

- 12.1 Prosthetic Devices provided non-sterile should be cleaned and sterilized prior to use.
- 12.2 Prosthetic Devices which are provided sterile and are modified by the end-user, must be cleaned after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.
- 12.3 Use of personal protective equipment as recommended by cleaning agent supplier (minimum water impermeable protection gown, gloves, face and eye shield), is recommended.
- 12.4 Tools/Instruments must be cleaned and sterilized prior to first use.
- 12.5 All tools/instruments must be cleaned and sterilized after each use based on established procedures. Proper instrument care is an important part of successful implant dentistry.
- 12.6 All instruments were developed for sterilization by autoclave. Automated washers should not be used as it may reduce the life of the instruments.
- 12.7 Cleaning of the devices is performed in the dental clinic according to the following parameters:
 - 12.7.1 Tools/Instruments inside a kit should be removed from the tray using dental tweezers.
 - 12.7.2 Surgical kit trays should be picked up and all tools/instruments should be removed from the bottom of the kit.
 - 12.7.3 Used tools/instruments should be soaked immediately in instrument cleaning solution to avoid the drying of blood, saliva and tissue residue.
 - 12.7.4 Multiple-part tools/instruments must be disassembled prior to cleaning and sterilization.
 - 12.7.5 Internal debris/residue on devices must be removed with a soft brush.
 - 12.7.6 Devices should be inspected, cleaned separately, and discarded if damaged.
 - 12.7.7 Devices should be placed in an ultrasonic bath with an enzymatic solution, approved and appropriate for dental use (for example, PowerZyme, Deconex 50FF). Refer to the Instructions for Use (IFUs) of the cleaning agents to ensure the appropriate and effective utilization of each material.
 - 12.7.8 Wash the devices in an ultrasonic device according to the device's instructions, for 15 minutes.
 - 12.7.9 Clean the plastic parts, the kit, the tray, including the grommets, with soap (for example, 18%, st-moritz) and water and wash well with running water and dry.
 - 12.7.10 Remove the devices from the ultrasonic bath at the end of the cycle and wash with running water.
 - 12.7.11 Use a soft brush to remove any residue from the devices and wash again with running water and dry.

13. Sterilization for Paltop Metal/PEEK Prosthetic Devices, Tools, and Surgical Instruments

- 13.1 Devices may be delivered sterile or non-sterile. Please see indication on device package prior to use. Devices placed in the patient's mouth must be sterile prior to use. Use of non-sterile device may lead to infection of tissues or infectious diseases.
- 13.2 Sterilization of non-sterile packaged devices or prosthetic devices which are provided sterile and are modified by the end-user or laboratory, must be re-sterilized after any modifications are made, or any procedures used which may compromise the sterility of the device, prior to use in the patient.
- 13.3 As validated according to the ISO standard 17665-1:2006, sterilization of these non-sterile devices should be performed in the dental clinic setting by steam autoclave sterilization according to the following parameters.

Sterilization Method	Steam, Gravity Displacement	Steam, Pre-vacuum method (Dynamic Air Removal)
Temperature	273°F (134°C)	273°F (134°C)
Cycle Time	10 minutes	3 minutes
Dry Time	30 minutes	16 minutes
Packaging	510(k)-cleared sterilization pouch	510(k)-cleared sterilization pouch
Sterility Assurance Level	$\leq 10^{-6}$	$\leq 10^{-6}$
Chamber Pressure	up to 2.3 bars (34 psi)	~296 KPa
Load Configuration	Coldest spot in the chamber, near the door. The autoclave may be loaded up to the maximal load, as determined by the autoclave manufacturer.	Coldest spot in the chamber, near the door. The autoclave may be loaded up to the maximal load, as determined by the autoclave manufacturer.

- 13.4 Follow the autoclave manufacturer’s instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the tools/instruments being sterilized including the internal surface and tubes channels. Allow tool/instrument to air cool to room temperature before use.
- 13.5 Products labeled as sterile should be considered sterile until the indicated “use by” date on the label unless the package has been opened or damaged. Never use products if the “use by” date has expired.
- 13.6 After sterilization, place the device in a dry and dark place such as a closed cupboard or drawer. Follow the instructions of manufacturer of the sterilization pouches regarding storage conditions and expiration date of sterilized goods.

14. Clinical Benefits

- 14.1 Enable replacement of missing teeth, thus restoring function, aesthetics, comfort, and phonetics.
- 14.2 Offer restorative solutions without requiring traditional fixed or removable treatment work to replace missing teeth.
- 14.3 Offer a long-term solution for tooth replacement*.
- 14.4 Stimulate the bone and maintain its dimension in edentulous sites in a manner similar to healthy natural teeth.
- 14.5 A decreased risk of caries and endodontic problems of adjacent teeth.

*For short 6mm length implants, as an auxiliary implant for implant-borne bar constructions supporting full dentures in a seriously atrophied mandible.

15. MRI Safety Information MR Conditional 

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

- 15.1 A patient with a Paltop Dental Implant System device made of Ti6Al4V ELI, Gold, or PEEK can be

scanned safely in an MR system under the following conditions:

Device Name	Paltop Dental Implant System
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone.
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode).
Maximum Head SAR	Not evaluated for head landmark.
Scan Duration	No specific constraints due to implant heating.

15.2 Implant/ MRI Safety Card

Paltop Advanced Dental Solutions Inc. is interested in equipping patients who have received a permanent implantable device, with the information they need about the transplant procedure they have undergone. An Implant/ MRI Safety Card is placed inside the implant package or is provided with each shipment containing Prosthetic components. This is to be filled out by the dentist performing the implantation with personal details and given to the patient. This card is easy to keep in the patient's wallet for future access of implant or MRI information.

15.3 Implant/ MRI Safety Card Instructions

Implant carton box contents:

- a) Dental implant and cover screw, packaged in plastic vial
- b) Implant/ MRI Safety Card
- c) Doctor label (2)- provided separately inside the outer carton box, specific for the attached implant batch, and is intended to be affixed to the Implant/ MRI Safety Card and for the dentist's clinical records.

Prosthetic components package:

- a) Prosthetic device, packaged in blister or foil pouch.
- b) Doctor label (2)- provided separately inside the outer carton box or inside the foil pouch, specific for the attached implantable Prosthetic component's batch, and is intended to be affixed to the Implant/ MRI Safety Card and for the dentist's clinical records.

* Implant/ MRI Safety Card will be provided separately (in each shipment)

Implant/ MRI Safety Card- generic card:

Front

Implant Card

MRI Safety Card

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KeystoneDentalGroup

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(hr) Zubni implantat
(es) Zubni implantat
(fr) Implant dentaire
(de) Zahnimplantat

(el) Οδοντικό εμφύτευμα
(hu) Fogászati implantátum
(it) Impianto dentale
(lt) Danties implantas
(pl) Implant zębowy

(pt) Implante Dentário
(ro) Implant dentar
(ru) Зубной имплантат
(es) Implante dental

MD

Paltop Advanced Dental Solutions Inc.
13645 Altos Pkwy Ste A
Irvine, CA 92618, USA

Place for doctor label

Doctor label- example:

Paltop Advanced
 \emptyset XX LXX

mm mm

REF ItemID YYYY-MM-DD

LOT BatchID YYYY-MM-DD

UDI-EN (01)XXXXXXXXXXXXXXXX(1)YYMMDD(17)YYMMDD
(10)WO-XXXXXX(21)XX-XXXXXX

15.3.1 Fill out the details on the Implant/ MRI Safety Card

- Name of the patient or patient ID. To be filled by the healthcare institution/dentist.
- Date of implantation. To be filled by the healthcare institution/dentist.
- Name and address of the healthcare institution. To be filled by the healthcare institution/dentist.
- The Doctor label with device's details should be attached to the card (provided in the package).

Explanations of Symbols	
	Patient Name or Patient ID
	Implant Site
	Date of Implantation
	Name and Address of the Implanting Healthcare Institution /Provider
	Name and Address of the Manufacturer
	Information Website for Patients
MD	Device Name
LOT	Lot Number /Batch Code
	MR Conditional

16. Storage and Handling

- 16.1** Product must be stored in its original, sterile (if applicable) packaging under dry, room temperature conditions, out of direct sunlight. The tools/instruments should be stored individually in a protective tray. There are no additional storage and handling conditions for Paltop Dental Implant System implants, abutments, and associated surgical, restorative, and dental laboratory components.

17. Torque Ratchet with Bending Beam

- 17.1** The Torque Ratchet with Bending Beam is a manual reusable ratchet used to confirm that the correct torque is applied during manual tightening of prosthetic abutments and screws. The Torque Ratchet with Bending Beam can be connected to a prosthetic screwdriver utilizing a torque ratchet adapter that is inserted into the torque ratchet. The torque level is reached when the tear drop lever arm is pulled to a specific value on the shaft of the torque wrench.
- 17.2** For prosthetic components that require a torque value which ends in a unit of 5 (example 25 Ncm displayed) the tear drop lever arm should be located between the 20 Ncm and 30 Ncm marks on the shaft.
- 17.3** Do not exceed the recommended maximum prosthetic torque for the abutment screw or prosthetic screw (see table below). Overtightening of abutment screw may lead to fracture.

NOTE: See Torque Ratchet with Bending Beam IFU for further information about care and use of the torque ratchet.

18. Disposal

After use, devices may be disinfected and thrown in a designated bin for biohazard waste (follow local regulations and environmental requirements).

- 19. CAUTION: US Federal law restricts the sale of this device to, or on the order, a licensed dentist or physician.**

- 20. Disclaimer: Some products are not available for sale in all markets.**

21. Disclaimer of Liability

Paltop disclaims any liability for the performance, outcomes, or complications of Paltop Dental Implant Systems products when used in conjunction with non-original Paltop components. For detailed information on compatible component combinations and the prescribed workflows for each implant platform, please consult the Paltop Catalog. Use of products and tools made by third parties detracts from the efficient functioning of the Paltop Dental Implant System and will void any warranty or other obligation, expressed or implied by Paltop Inc.. Use of this product is not within the control of Paltop Inc., it is the responsibility of the user. All liability for loss or damage attributable to the use of this product is excluded. Within the framework of the Conditions at Sale and Delivery of Paltop Inc., we warrant the quality of the Paltop Dental Implant System. Paltop Dental Implant System and components are not represented to be "pyrogen-free", and makes no claims regarding the absence of pyrogens in the products.

22. Copyright and Trademarks

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- 23. The most up to date revision of this IFU can be found at the Keystone Dental website www.KeystoneDental.com, in the dedicated section.**

Drill Speed Chart		
Speed RPM	Type/Size Drill (mm)	
1200-1500	Spade Drill	
900-1100	1.5/2.0	Step Drill
700-900	2.0/2.4	
500-700	2.4/3.2	
400-600	3.2/3.8	
400-850	3.0	Final Drill
	3.25	
	3.75	
	4.2	
	5.0	
	6.0	

Torque Value Reference Table (Ncm)	
Prosthetic	Torque
Healing Cap* Multi-Unit/Single-Unit Abutment Healing Caps* PEEK Temporary Abutments** Temporary Abutment, Immediate** Cover Screw* Impression Coping Screw	15
Multi-Unit Prosthetic Screw*	20
Titanium Temporary Abutments** NP Angulation Corrective System Screw	25
Titanium Temporary Abutments** SP/WP/Conical Straight Multi- Unit Abutments Single-Unit Abutments Paltop Equator Abutments Ball Abutments Abutment Screw, NP/SP/WP/Conical (for Titanium/Gold/Ti- Base/Ti-Blank) Multi-Unit Abutment Screw for Angulated	30

* Recommended not to exceed 20 Ncm

** Clinician should use best clinical judgment when lowering the recommended torque value for any temporary abutment/cylinder placed at time of implant placement.

NOTE: It is recommended that the PEEK Concave Temporary Abutment and temporary restorations be kept out of occlusion and excursive movements.

Symbol Definitions	
	Catalogue number
	Batch code
	Medical device
	Caution, consult accompanying documents
	Do not re-use
	Non-sterile
	Single sterile barrier system
	Do not use if package is damaged and consult instructions for use
	Sterilized using irradiation
	By Prescription Only
	Use-by-date
	Do not re-sterilize
	Manufacturer
	Date of manufacture
	Authorized representative in the European Union
	Keep away from sunlight
	Consult instructions for use or consult Electronic instructions for use
	MR Conditional
	Unique device identifier

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The SSCP can be accessed in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI of Paltop products, which can be found: <https://ec.europa.eu/tools/eudamed>. If EUDAMED is not active, the SSCP will be made available upon request, contact Paltop at: customersupport@keystonedental.com

For MR patient safety card please visit [KeystoneDental.com/pages/mr](https://www.KeystoneDental.com/pages/mr)



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