

# BonePen Kit

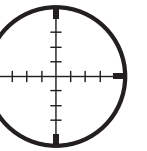
## Implant surgical guides

Distributed Exclusively by:



Guide Drills Ø 2.0  
and Pins

USER GUIDE



Instructions for Use

For more information,  
please visit [www.hubermed.com](http://www.hubermed.com)  
or call 1-888-789-9928

Distributed Exclusively by:



1-888-789-9928  
[www.hubermed.com](http://www.hubermed.com)

Manufactured by:

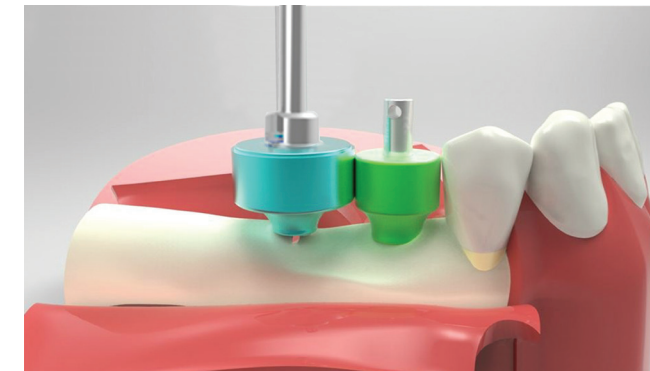
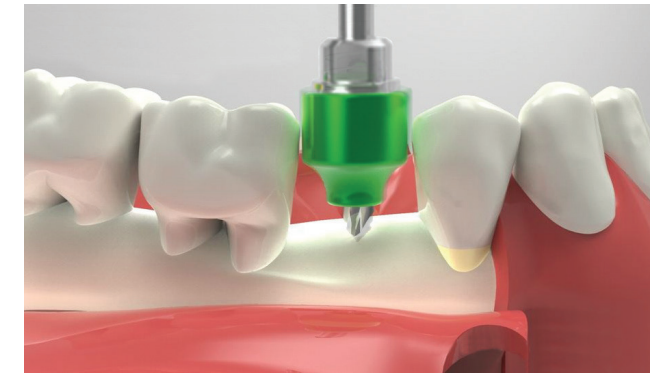


Acrodent CO. LTD.  
5, Jeonha-ro 85 beon-gil, Gimhae-si,  
Gyeongsangnam-do, Korea  
T: +82-55-314-4607-8  
[www.acrodent.com](http://www.acrodent.com)

Symbols	Used for
	Catalog number
	Batch code
	Date of manufacture
	Consult Instructions for Use
	Non-Sterile
	Manufacturer
	Caution: Law prohibits dispensing without prescription



ISO13485, CE



**NOTE: The BonePen Guide Drills are available in five (5) diameters and are shipped non-sterile. Drills may be used for up to thirty (30) preparations, depending on bone density. Guide Pins are recommended for multiple uses.**

The BonePen Guide Kit and related instruments must only be used by dentists and surgeons with training and experience as dental professionals. HuberMed or Acrodent or its partners, collectively as the manufacturer, the importer, and the distributor are not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

The instruments that make up the BonePen Guide Kit are susceptible to damage and wear and should be inspected before use. If inspection reveals signs of wear, damage, or unrecognizable color or label identification, replace the instrument(s) accordingly.

- Close the surgical kit and wrap it with autoclave paper twice, or place it within two (2) autoclave-approved bags.
- GRAVITY DISPLACEMENT STERILIZER (FULL CYCLE) The exposure time is a minimum of fifteen (15) minutes at a temperature of 270 – 275°F (132-135°C). – Or – PRE-VACUUMED STERILIZER (HI-VAC) The exposure time is a minimum of four (4) minutes, four (4) pulses at a temperature of 270 – 275°F (132-135°C).
- Post-sterilization drying time is a minimum of thirty (30) minutes.

**Note: To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.**

### Storage

- Instruments should be dried completely and stored in a moisture-free environment. Failure to do so may result in stainless steel corrosion or staining.
- Prior to use, the exterior of each sterilized package should be inspected for integrity. If a package is suspect, it should not be used and should be reprocessed as per the above sterilization procedure.
- Shelf life and sterility of wrapped instrument cases are dependent on storage in a manner to avoid extreme temperature, moisture and/or other contamination. Care must be exercised in the handling of wrapped cases to prevent damage to the sterile barrier. The probability of an occurrence of contamination increases over time, with handling, and based on the packaging method.

\* The recommended sterilization procedures have NOT been validated with the BonePen Kit and responsibility resides with the individual responsible to administer and follow accepted Sterility assurance guidelines for all surgical instruments and their use therein.

**NOTE: All components that are used intra-orally must be secured to prevent aspiration or swallowing**

- Using a clean beaker, prepare a solution for ultrasonic cleaning using distilled water with a specialized enzymatic detergent per the detergent manufacturer's recommendations.
- Place all instruments in a single layer into the beaker of solution. Place the beaker containing the instruments into the ultrasonic bath and turn on for five (5) minutes.
- Remove each instrument and repeat the scrubbing procedure; ream lumens of instruments having interior canals.
- Rinse by flushing instruments for one (1) minute with a steady stream of running tap water. Note: This step is important to prevent spotting.
- Inspect each instrument visually and check for cleanliness, any remaining bone fragments, visible soil or residual debris, and for visible damage and/or wear. Repeat the scrubbing procedure as necessary. Set aside the instruments specific to the BonePen Kit for packaging.

### Cleaning of BonePen Kit

- Expose the tray block, cover and grommets. Scrub all surfaces of the tray block, cover and grommets with mild soap using a soft bristled brush.
- Rinse tray block, cover and grommets with running tap water for a minimum of two (2) minutes and inspect surfaces for cleanliness.
- Re-assemble the grommets by placing them in tray block and insert the cleansed colour coated instruments into matching colour coated grommets.

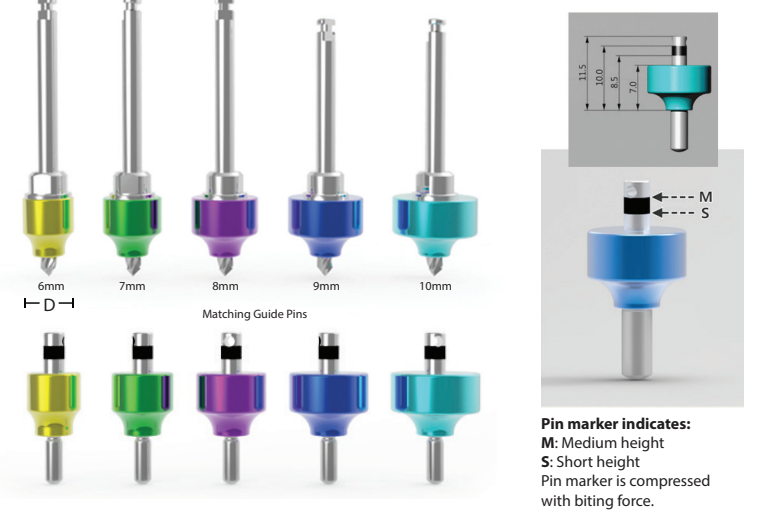
### Packaging Kit for Sterilizer

- Pour ethyl alcohol over the BonePen Guide Tray, cover and onto the instruments to rinse and remove residual soap and water minerals. Allow the instruments to dry before wrapping.

### Indications

**BonePen Mini Drill Guide Ø 2.0** diameter is an instrument that assists the clinician to mark the initial drilling starting position for implant(s) placement in consideration of the prosthetic anatomy and space available for the final restoration(s) in conjunction with the use of the matching **Guide Pin**.

**Note: BonePen Mini Drill Guide Ø 2.0 diameter is NOT indicated to replace conventional 2mm twist drills**



Drill Guide Part Number	Colour	Length (L) mm	Diameter (D) mm	Length of Total Compressed Drill* mm	Matching Guide Pin Part Number
T7031	Yellow	33.0	6	8.3	T7058
T7032	Green	33.0	7	8.3	T7059
T7033	Mauve	33.0	8	8.3	T7060
T7034	Blue	30.5	9	8.3	T7061
T7035	Aqua	30.5	10	8.3	T7062

\* T7065 - Kit contains all 5 drills and 5 Guide Pins + Tray Block / cover  
 \* Depth markings are not indicated with total depth being 8.3mm once the guide is completely depressed  
 Clinicians are advised to take individual measurements.

### Precautions

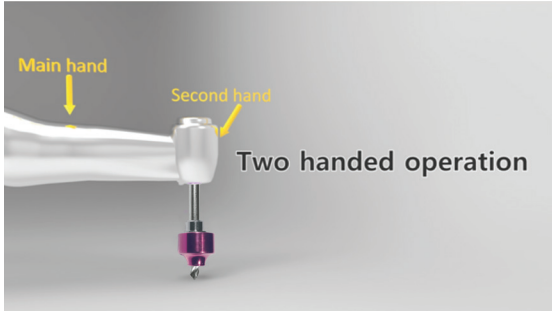
- Instrument is susceptible to damage and wear and should be inspected before use.
- Verify the latch lock shank for wear to ensure that the connection is not damaged due to re-use.
- Instrument must be cleaned and sterilized prior to use.

### Procedure

- Take the restorative measurement(s) of the future prosthetic restoration(s) within the available boney space.
- Select from the range of available diameters of the BonePen Mini Drill guides Ø 2.0 from the matrix above. Refer to Diagram of Product Matrix – Specifications and Type that best matches the calculation of measurements recorded in Step1.

**Note: BonePen Mini Drill Guide Ø 2.0 do NOT have depth markings and when fully compressed extend to a depth of 8.3mm**

- Using the pre-determined selected Drill Guide width, attach the latch type shank to the handpiece of the implant motor. **Note: Prior to use, ensure that the chamber is secured by rotating in a clockwise direction as well visually inspect the chamber for wear.**



**To achieve better positional stability, use both hands. Hold the handpiece grip with main hand softly and let the other hand touch handpiece head.**

- Recommended drill speed is 300~1,500 rpm with torque of 45-55Ncm with irrigation.
- After the Site has been marked switch to the conventional 2.0 twist drill found in the Implant Surgical tray routinely used.
- Repeat Steps 1-5 should multiple restorations be considered.
- How to use Pin: Final restoration height can be inferred by biting the Pin that matches the Drill Guide.

### CAUTION

- Irrigation must be used.
- Recommended Drill speed is 300~1,500 rpm with maximum torque not greater than 55Ncm.
- Recommended USE is thirty (30) times. Discard the instrument after thirty (30) use and re-order.
- Refer to Cleaning and Sterilization instructions  
**Note: BonePen Mini Drill Guides Ø 2.0 require to be Disassembled prior to Cleaning and Sterilization DO NOT USE IF ALL (4) four components, (guide drill, hub, spring and Chamber) are NOT included in the Final Assembly. (Additional spare springs ten (10) are provided in the original kit and can be ordered separately).**
- Guide Pins are recommended for multiple uses.

### Cleaning and Sterilization of the BonePen Guide Instruments

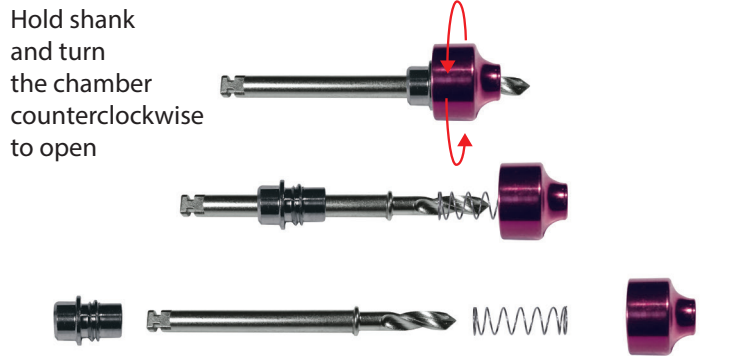
Cleaning and Sterilization of the BonePen Guide and Surgical – Prosthetic instruments and instrument cases are susceptible to damage for a variety of reasons, including prolonged use, misuse, and rough or improper handling.

Care must be taken to avoid compromising their performance. To maintain the quality of surgical instruments, a standardized cleaning and sterilization protocol should be adopted. The recommended cleaning and sterilization procedures in this document apply to the BonePen Kit Basic and the instruments housed within.

### Warnings and Precautions

- DO NOT place used instruments back into the tray prior to proper cleaning per the following procedure (Steps 1-7).
- Unless otherwise indicated, instrument kits are NOT sterile and must be thoroughly cleaned and sterilized prior to use.
- Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided.

- Unwrapped instrument cases DO NOT maintain sterility.
- The following procedures DO NOT apply to powered instrumentation.



For cleaning and sterilization note that the chamber needs to be unscrewed, exposing the drill, hub and spring. For a total four (4) individual parts. Guide Pins are monoblocks and cannot be disassembled.

- For the BonePen Guide drills, disassembly is required.
- For the Guide Pins disassembly is NOT required.
- Follow recommended procedures for cleaning and sterilization of the BonePen Kit, drills and guides.

### Materials Required For Procedures

- Solutions
- Neutral-pH detergent, or specialized cleaning solution
  - Proteolytic enzyme detergent
  - Ethyl alcohol (Ethanol); do not use rubbing alcohol (isopropyl alcohol)
  - Tap water
  - Distilled water

### Tools

- PPE: Personal Protective Equipment (gloves, goggles, apron, etc.)
- Glass beakers
- Soft bristled brushes of various sizes
- Thin wire brush
- Autoclave-approved paper or bags

### Equipment

- Ultrasonic cleaning unit
- Steam autoclave

### Step-By-Step Instructions

#### Cleaning of Instruments

**Note: Individuals who clean surgical instruments need to wear appropriate personal protective equipment.**

- Following completion of a clinical surgical procedure, gather all instruments, prepare a solution for soaking using tap water (tepid or lukewarm) and a neutral-pH detergent at a dilution recommended by the detergent manufacturer. Place instruments in a single layer at the bottom of a glass beaker containing the dilute solution. Soak the instruments for at least ten (10) minutes.  
**Note: It is important to clean instruments as soon as possible; if immediate cleaning is not possible, continue to soak the instruments to prevent blood from drying on the surfaces.**
- Rinse with running tap water for a minimum of two (2) minutes while brushing exteriors of items individually with a soft bristled brush to remove visible debris; clean interior lumens of specified instruments with small brushes.