Instructions for Use

Crown Down Surgical Drilling Kit

CLASSIFICATION	FDA 510(k) cleared Class II dental device (21 CFR 872.4130)	**STATUS**	Non-sterile / Reusable surgical instrument
MANUFACTURER	Stomatotech Inc.	**REGULATORY**	FDA 510(k) cleared, Class II
DOCUMENT	IFU-CDK-001 Rev. 01	**EFFECTIVE**	May 8, 2026

> **Read this entire document before use.** The Crown Down Surgical Drilling Kit is supplied non-sterile and must be cleaned, disinfected, and sterilized before first clinical use and before each reuse. For use only by trained dental professionals qualified to perform dental implant surgery.

1. Important Notice Before Use

Read this entire Instructions for Use document before using the Crown Down Surgical Drilling Kit. Failure to follow these instructions may result in incorrect osteotomy preparation, overheating of bone, excessive drilling depth, tissue injury, infection, implant placement error, or device damage.

The Crown Down Surgical Drilling Kit is supplied non-sterile. The kit must be cleaned, disinfected, inspected, packaged, and sterilized before first clinical use and before each reuse.

This IFU does not replace professional Crown Down Drilling training, implant surgery training, surgical judgment, radiographic planning, anatomical assessment, or the instructions supplied by the dental implant manufacturer.

2. Device Description

The Crown Down Surgical Drilling Kit is a reusable dental implant surgical drilling kit intended for osteotomy preparation in the maxilla and mandible during dental implant surgery.

The kit contains reusable dental surgical drills and accessories intended to support a Crown Down drilling sequence. The drills are connected to a compatible dental surgical handpiece and are used by trained dental professionals to mechanically prepare bone before dental implant placement.

The surgical drills are manufactured from solid tungsten carbide and are TiN coated. The kit is supplied non-sterile and must be reprocessed before use.

3. Kit Contents

The standard Crown Down Surgical Drilling Kit includes:

Component	Description
Surgical drills	Eight reusable dental surgical drills
Drill sizes	#20, #30, #35, #40, #45, #50, #55, #60
Approximate drill diameters	2.75 mm, 3.0 mm, 3.5 mm, 4.0 mm, 4.5 mm, 5.0 mm, 5.5 mm, 6.0 mm
Drill stoppers	Two reusable drill depth stoppers (additional 3D stoppers in 8, 10, and 12 mm working depths are optional accessories sold separately)
Sterilization box	Reusable box for organization, storage, handling, and sterilization
Drilling chart	Clinical reference chart for drill selection and sequence
IFU / user manual	Instructions for safe use, reprocessing, warnings, and precautions

Check the kit before use to confirm that all required components are present and undamaged.

4. Intended Purpose

The Crown Down Surgical Drilling Kit is intended for preparation of osteotomies in the maxilla and mandible during dental implant surgery.

5. Indications for Use

The Crown Down Surgical Drilling Kit is indicated for use in preparing osteotomies for dental implant placement in the maxilla and mandible.

The device is used as part of dental implant surgery in accordance with accepted clinical practice, patient-specific treatment planning, implant manufacturer instructions, and the Crown Down drilling chart.

6. Intended Users

The Crown Down Surgical Drilling Kit is intended for professional use only by trained dental professionals, including dentists, oral surgeons, periodontists, prosthodontists, and other clinicians qualified to perform dental implant surgery.

The device is not intended for use by patients, lay users, untrained personnel, or unauthorized users.

7. Intended Patient Population

The intended patient population includes partially or fully edentulous patients requiring dental implant placement in the maxilla or mandible, where implant treatment is considered clinically appropriate by the treating clinician.

Patient selection, medical evaluation, treatment planning, implant site evaluation, radiographic assessment, and surgical judgment remain the responsibility of the treating dental professional.

8. Contraindications

Do not use the Crown Down Surgical Drilling Kit where dental implant surgery is contraindicated.

Contraindications may include, but are not limited to:

- Patients medically unsuitable for oral surgery.
- Insufficient bone volume or bone quality where implant placement is not clinically appropriate.
- Untreated active infection at or near the surgical site.
- Clinical conditions where implant surgery is contraindicated according to the clinician's judgment.
- Use by untrained or unauthorized users.
- Cases where the clinician cannot confirm compatibility with the selected implant system, surgical guide, handpiece, or planned protocol.

9. Warnings

- For professional use only by trained dental professionals.
- The device is supplied non-sterile and must be cleaned, disinfected, and sterilized before first use and before each reuse.
- Inspect each drill, stopper, and accessory before use. Do not use damaged, deformed, contaminated, corroded, dull, fractured, or otherwise compromised instruments.
- Incorrect drill selection, excessive drilling depth, improper angulation, inappropriate speed, or excessive force may cause tissue injury, bone damage, overheating, implant instability, or implant site preparation error.
- Use appropriate radiographic and clinical evaluation before surgery.
- The clinician is responsible for identifying and avoiding anatomical structures, including nerves, sinuses, blood vessels, adjacent teeth, and cortical plates.
- Follow the applicable Crown Down drilling chart together with the selected implant manufacturer's instructions.
- Verify compatibility with the surgical handpiece, surgical motor, surgical guide where used, drill stoppers, and selected implant system before use.
- Do not apply excessive lateral force during drilling.
- Do not use the drill as a lever.
- Do not use the device if the drill is not securely engaged in the handpiece.
- Do not use if the drill stopper is loose, incorrectly seated, damaged, or incompatible with the selected drill or guide system.
- Inadequate cleaning, disinfection, sterilization, drying, inspection, or storage may result in infection risk.
- Bone overheating may impair healing. Maintain appropriate drilling speed, pressure, drill condition, and clinical technique.
- The Crown Down Surgical Drilling Kit does not include dental implants, surgical motors, handpieces, surgical guides, CBCT systems, or implant planning software.

10. Precautions

- Use only with compatible dental surgical handpieces that properly accept the drill shank connection.
- Verify that the drill is fully seated and securely locked in the handpiece before rotation.
- Verify the correct drill size and sequence using the Crown Down drilling chart before each osteotomy.
- Maintain control of drilling depth, angulation, speed, and pressure throughout the procedure.
- Use drill stoppers only when properly seated and compatible with the selected drill and surgical guide.
- Confirm planned osteotomy depth using radiographic planning and clinical judgment.
- Avoid excessive axial pressure and excessive lateral pressure during drilling.
- Remove accumulated bone debris from the drill as needed during the procedure.
- Clean instruments promptly after use to prevent drying of blood, bone, and biological material.
- Use appropriate personal protective equipment during handling and reprocessing.
- Store instruments in a clean, dry environment after reprocessing.
- If resistance, vibration, unusual noise, loss of cutting efficiency, or abnormal heat generation is observed, stop use and inspect the drill.
- Do not modify, bend, sharpen, grind, or repair the drills or stoppers.
- Do not mix components from other systems unless compatibility has been verified by the clinician.

11. Potential Adverse Events and Residual Risks

Potential risks associated with dental implant osteotomy drilling may include:

- Thermal injury to bone.
- Bone trauma or excessive compression.
- Inaccurate osteotomy diameter or depth.
- Injury to nerves, sinus, blood vessels, adjacent teeth, or cortical bone.
- Implant malposition.
- Implant instability due to incorrect osteotomy preparation.
- Infection due to inadequate reprocessing.
- Surgical delay due to instrument damage or fracture.
- Retained instrument fragment in the surgical site.
- Poor cutting performance due to dullness, damage, or contamination.
- Tissue injury due to incorrect handling or excessive force.

Residual risks are controlled by professional-use limitation, planning, clinical judgment, inspection, drilling chart use, compatibility verification, validated or justified reprocessing procedures, and adherence to this IFU.

12. Products Used in Combination

The Crown Down Surgical Drilling Kit may be used with the following products, when clinically appropriate and compatible:

- Dental surgical motor.
- Dental surgical handpiece.

- Dental implants.
- Surgical guide, where applicable.
- Drill stoppers supplied with the Crown Down kit.
- Dental imaging and planning systems.
- Standard dental implant surgery instruments.

The Crown Down Surgical Drilling Kit does not include dental implants, motors, handpieces, CBCT equipment, surgical planning software, or surgical guides.

The clinician is responsible for confirming that all devices used together are compatible and suitable for the planned procedure.

13. Compatibility Requirements

Before use, confirm the following:

- The handpiece accepts and securely retains the Crown Down drill shank.
- The surgical motor and handpiece provide appropriate rotational control.
- The selected implant system is compatible with the Crown Down drilling chart used for the case.
- The selected drill stopper is compatible with the drill and, where applicable, the surgical guide sleeve.
- The planned osteotomy diameter, depth, and angulation are suitable for the selected implant.
- The selected clinical protocol is appropriate for the patient's anatomy and bone quality.

Do not use the kit if compatibility cannot be confirmed.

14. Preparation Before Clinical Use

14.1 Before First Use

The device is supplied non-sterile. Before first use:

- Remove the kit from packaging.
- Confirm kit completeness.
- Inspect all drills, stoppers, and the sterilization box.
- Clean the instruments according to the cleaning instructions in this IFU.
- Disinfect where applicable according to the reprocessing instructions.
- Dry thoroughly.
- Inspect again after cleaning.
- Package or place instruments in the sterilization box according to clinic sterilization procedures.
- Sterilize before clinical use.
- Store in a clean, dry environment until use.

14.2 Before Each Reuse

Before each reuse:

- Confirm that the kit was properly cleaned, disinfected, inspected, packaged, and sterilized after the previous use.
- Inspect the sterile barrier or sterilization packaging before opening.

- Confirm that instruments are dry and free from visible residues.
- Inspect for damage, dullness, corrosion, deformation, contamination, or wear.
- Confirm drill identification and drill size.
- Confirm stopper fit and function.
- Confirm handpiece compatibility before clinical use.
- Do not use any instrument that does not pass inspection.

15. Pre-Use Inspection Criteria

Inspect each drill and stopper visually and functionally before each use.

Reject and remove from service any instrument showing:

- Visible contamination or biological residue.
- Cracks, chips, fracture, bending, or deformation.
- Corrosion, discoloration, pitting, or surface degradation.
- Dull or damaged cutting surfaces.
- Worn, damaged, or unclear markings.
- Damaged shank or poor handpiece engagement.
- Excessive vibration during trial rotation.
- Loose or damaged stopper fit.
- Any condition that may affect safe use or cutting performance.

When in doubt, do not use the instrument.

16. Clinical Use Instructions

16.1 General Clinical Principles

The Crown Down Surgical Drilling Kit must be used only after appropriate patient evaluation, treatment planning, and radiographic assessment.

The clinician remains responsible for:

- Patient selection.
- Implant position selection.
- Implant diameter and length selection.
- Bone quality assessment.
- Selection of the correct Crown Down drill sequence.
- Avoidance of anatomical structures.
- Confirmation of osteotomy depth and angulation.
- Final clinical decision-making.

16.2 Drill Selection

- Review the patient's treatment plan, CBCT/radiographic information, implant system, implant diameter, implant length, and bone anatomy.
- Select the appropriate Crown Down drilling chart for the implant system or clinical case.

- Identify the planned drill sequence using the Crown Down chart.
- Confirm the selected drill size before use.
- Confirm compatibility with the selected implant system and surgical approach.

16.3 Crown Down Drilling Concept

The Crown Down drilling protocol uses a reduced drilling sequence in which coronal/cortical preparation is performed first, followed by final depth preparation.

The first selected drill is used to prepare the coronal portion of the osteotomy, including the cortical bone region, according to the drilling chart and clinical judgment.

The second selected drill is used to prepare the osteotomy to the planned depth according to implant length, bone quality, implant system compatibility, and clinical judgment.

16.4 Surgical Workflow

A typical clinical workflow may include:

- Perform patient evaluation and treatment planning.
- Select implant position, diameter, and length.
- Review CBCT/radiographs and anatomical risk areas.
- Select the Crown Down drilling sequence according to the drilling chart.
- Confirm kit cleaning, sterilization, and inspection status.
- Prepare the surgical site according to the clinician's preferred technique.
- Confirm the selected drill is securely engaged in the handpiece.
- Use the first selected drill for coronal/cortical preparation.
- Remove and manage bone debris/chips according to the clinician's protocol.
- Use the second selected drill for final depth preparation.
- Verify osteotomy depth, diameter, angulation, and clinical suitability.
- Place the dental implant according to the implant manufacturer's instructions.
- Complete post-operative management according to accepted clinical practice.

16.5 Drilling Speed and Pressure

Use the drilling speed specified in the applicable Crown Down drilling chart and validated clinical protocol.

Where the Crown Down protocol specifies reduced-speed drilling, use controlled reduced-speed drilling, commonly around 200 rpm, unless the case-specific chart, implant system, or clinician's judgment requires adjustment.

During drilling:

- Use controlled pressure.
- Avoid excessive axial force.
- Avoid lateral force.
- Avoid prolonged stationary rotation in bone.
- Stop drilling if abnormal resistance, vibration, heat, or loss of cutting efficiency is observed.
- Remove bone debris from the drill as needed.

16.6 Depth Control

Depth control remains the responsibility of the clinician.

Use depth markings, drill stoppers, surgical guides, radiographic planning, and clinical judgment as applicable.

Before drilling:

- Confirm planned osteotomy depth.
- Confirm stopper selection, if used.
- Confirm stopper seating.
- Confirm guide sleeve compatibility, if used.
- Confirm drill length and working depth.

Maintain visual and tactile control throughout drilling.

Do not rely exclusively on the stopper. Always verify depth clinically and radiographically as appropriate.

16.7 Use With Surgical Guides

When used with a surgical guide:

- Confirm guide fit before drilling.
- Confirm guide stability.
- Confirm compatibility between drill, stopper, guide sleeve, and planned drilling sequence.
- Confirm the stopper is correctly seated before initiating rotation.
- Avoid lateral pressure against the guide sleeve.
- Verify depth and angulation throughout the procedure.

Do not use the device with a surgical guide if compatibility cannot be confirmed.

17. Post-Use Handling at Point of Use

Immediately after use:

- Keep instruments moist until cleaning if immediate cleaning is not possible.
- Remove visible bone, blood, and tissue residues as soon as possible.
- Do not allow biological material to dry on the instruments.
- Handle sharp drills carefully to avoid injury.
- Transport contaminated instruments in a closed, puncture-resistant container according to clinic infection control procedures.

18. Cleaning Instructions

The device must be cleaned before sterilization. Sterilization is not a substitute for cleaning.

18.1 Manual Pre-Cleaning

- Wear appropriate personal protective equipment.
- Rinse instruments under running water to remove gross soil.
- Use a soft brush suitable for surgical instruments to clean the drill flutes, shank, stoppers, and box surfaces.
- Do not use metal brushes or abrasive tools that may damage surfaces.

- Pay special attention to cutting surfaces, grooves, markings, stopper interfaces, and areas where debris may accumulate.
- Use a neutral or mildly alkaline enzymatic detergent suitable for dental surgical instruments, following the detergent manufacturer's instructions.
- Rinse thoroughly with clean water to remove detergent residues.
- Inspect for visible soil. Repeat cleaning if any residue remains.

18.2 Ultrasonic Cleaning, Where Available

If ultrasonic cleaning is used:

- Place instruments in an ultrasonic cleaner suitable for dental surgical instruments.
- Use a compatible cleaning solution according to the solution manufacturer's instructions.
- Ensure instruments do not contact each other in a way that may damage cutting edges.
- Process according to the ultrasonic cleaner manufacturer's instructions.
- Rinse thoroughly after ultrasonic cleaning.
- Dry completely.
- Inspect for visible residue or damage.

18.3 Automated Washer-Disinfector, Where Available

If an automated washer-disinfector is used:

- Use only equipment suitable for surgical instruments.
- Load instruments to allow contact with cleaning and rinsing solutions.
- Follow the washer-disinfector manufacturer's instructions.
- Use compatible cleaning agents.
- Confirm that instruments are visibly clean and dry after processing.
- Repeat cleaning if visible residue remains.

19. Disinfection

Disinfection may be performed as part of an automated washer-disinfector cycle or according to clinic infection control procedures using products compatible with dental surgical instruments.

Disinfection does not replace sterilization. The device must be sterilized before clinical use.

Do not use chemicals that may corrode, degrade, discolor, or damage tungsten carbide drills, TiN coating, stoppers, or the sterilization box.

20. Drying

After cleaning and rinsing:

- Dry instruments thoroughly using clean, lint-free material or filtered compressed air where appropriate.
- Ensure drill flutes, shanks, stopper interfaces, and the sterilization box are completely dry.
- Do not package wet instruments for sterilization.
- Inspect again after drying.

21. Inspection After Cleaning

After cleaning and before sterilization, inspect all components under adequate lighting.

Confirm:

- No visible blood, bone, tissue, or residue remains.
- Cutting edges are intact.
- Drill body and shank are not bent, cracked, chipped, or damaged.
- Markings are legible.
- Stoppers are intact and fit correctly.
- Sterilization box is clean and functional.
- No corrosion, discoloration, or surface damage is present.

Repeat cleaning if residue remains. Remove damaged instruments from service.

22. Packaging for Sterilization

Before sterilization:

- Place instruments in the sterilization box or suitable sterilization packaging.
- Arrange drills to prevent contact damage to cutting edges.
- Ensure packaging or container allows steam penetration and drying.
- Use sterilization wraps, pouches, or containers compatible with steam sterilization and clinic procedures.
- Follow local infection control requirements and sterilizer manufacturer instructions.

23. Sterilization Instructions

The Crown Down Surgical Drilling Kit must be sterilized before first use and before each reuse.

Use steam sterilization in a validated autoclave cycle suitable for reusable dental surgical instruments.

Recommended sterilization cycle, subject to validation and local requirements:

Sterilization method	Temperature	Exposure time	Drying time
Pre-vacuum steam sterilization	134°C	Minimum 3 minutes	Follow sterilizer/packaging instructions
Gravity steam sterilization, where applicable	121°C	Minimum 15 minutes	Follow sterilizer/packaging instructions

Important:

- Use only validated sterilization equipment.
- Follow the sterilizer manufacturer's instructions.
- Follow local infection control regulations.
- Do not overload the sterilizer.
- Ensure instruments are dry after sterilization.

- Do not use instruments if the sterilization cycle fails or if packaging is wet, torn, opened, or compromised.
- Maintain sterilization records according to clinic procedures.

24. Storage After Sterilization

After sterilization:

- Allow instruments to cool and dry before handling.
- Store sterilized instruments in intact packaging or in the sterilization box according to clinic procedures.
- Store in a clean, dry environment protected from dust, moisture, contamination, chemicals, and physical damage.
- Do not store heavy items on top of the kit.
- Do not use if sterile packaging is damaged or sterility cannot be confirmed.

25. Reuse, Maintenance, and Service Life

The Crown Down Surgical Drilling Kit is reusable when properly cleaned, disinfected, inspected, sterilized, stored, and used according to this IFU.

No instrument should be reused if it shows any sign of unacceptable wear, dullness, deformation, corrosion, contamination, damage, compromised cutting efficiency, or poor handpiece engagement.

The user must inspect the device before each use. Continued use depends on instrument condition, not only the number of uses.

Remove instruments from service when they no longer meet the inspection criteria in this IFU.

Do not attempt to sharpen, repair, modify, recoat, or reshape the drills.

26. Disposal

Dispose of damaged, worn, contaminated, or unusable instruments according to local regulations for contaminated surgical instruments and sharps.

Before disposal, contaminated instruments must be handled according to infection control procedures.

Do not dispose of contaminated instruments in general waste unless permitted by local regulations and facility procedures.

27. Complaints and Incident Reporting

Report complaints, suspected device defects, performance problems, packaging problems, labeling problems, or adverse events to Stomatotech Inc.

Serious incidents involving the device should be reported to Stomatotech Inc. and, where applicable, to the competent regulatory authority in the country where the user and/or patient is established.

Include the following information when reporting:

- Device name.
- Lot or batch number.

- Catalogue/reference number, if available.
- Description of the event or complaint.
- Clinical procedure context.
- Photographs of the device, where possible.
- Whether the device is available for return or investigation.
- Contact information of the reporting user or facility.

28. Labeling and Symbols

The labeling may include the following symbols or statements, where applicable:

Symbol / statement meaning	Explanation
Manufacturer	Identifies Stomatotech Inc.
Catalogue number	Identifies product reference
Batch code / lot number	Supports traceability
Non-sterile	Indicates the device is supplied non-sterile
Consult instructions for use	Read IFU before use
Caution	Indicates warnings and precautions apply
Medical device	Identifies the product as a medical device
Unique device identifier	Identifies UDI carrier, where applicable

29. Required Label Statements

The device label and/or packaging label should include, where applicable:

- Crown Down Surgical Drilling Kit.
- Stomatotech Inc.
- 4919 Boulevard Saint-Charles, Pierrefonds, Quebec, Canada.
- Non-sterile.
- Reusable.
- Lot/batch number.
- Catalogue/reference number.
- UDI/Basic UDI-DI, where applicable.
- Read instructions before use.
- Sterilize before use.
- Store clean and dry, protected from damage and contamination.

30. Non-Sterile Statement

> **NOTE** NON-STERILE. Clean, disinfect, and sterilize before first use and before each reuse according to this Instructions for Use document.

31. Reusable Device Statement

> **NOTE** Reusable device. Inspect before each use. Do not use if the device is damaged, deformed, contaminated, corroded, dull, worn, fractured, or otherwise compromised.

32. Limitations

The Crown Down Surgical Drilling Kit does not replace:

- Dental implant surgery training.
- Implant manufacturer instructions.
- Patient-specific treatment planning.
- CBCT or radiographic assessment.
- Anatomical risk assessment.
- Clinical judgment.
- Local infection control requirements.

The clinician is responsible for determining whether the device is appropriate for each case.

33. Document Control

Control element	Information
Document title	Instructions for Use - Crown Down Surgical Drilling Kit
Document number	IFU-CDK-001
Revision	Rev. 01
Date	May 8, 2026
Prepared by	Stomatotech Inc.
Approved by	Stomatotech Inc.

34. Revision History

Revision	Date	Description of change	Prepared by	Approved by
01	May 8, 2026	Initial IFU for Crown Down Surgical Drilling Kit	Stomatotech Inc.	Stomatotech Inc.

35. Manufacturer Contact

Stomatotech Inc.
4919 Boulevard Saint-Charles
Pierrefonds, Quebec, Canada H9H 3E4

For complaints, technical questions, or incident reporting, contact Stomatotech Inc. using the official contact details supplied on the device label, packaging, website, or controlled quality system records.

MANUFACTURER

Stomatotech Inc.
4919 Boulevard Saint-Charles
Pierrefonds, Quebec, Canada H9H 3E4

REGULATORY CLEARANCE

FDA 510(k) cleared
Class II dental device under 21 CFR 872.4130

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