Complications:

Complications and Adverse Events
Generic component-level risks associated with the use of this device include:

• Mechanical failure of the device during use, including chuck loosening, handle failure, or component fracture

• Drill bit detachment or fracture during use if drill bit is not correctly secured, if excessive force is applied, or if an incompatible drill bit is used

• Unintended tissue contact or injury arising from operator technique, inadequate visualisation, or loss of device control during use

• Risk of infection if the device is used clinically without appropriate prior terminal sterilisation, if sterile presentation is compromised, or if aseptic technique is not maintained

• Risk associated with reuse, including cross-contamination and mechanical degradation, if the single-use restriction is not observed

Inspect the device before use, follow these instructions for use, and apply appropriate clinical technique to minimise these risks.

Procedure-specific complications and adverse events are determined by the clinical user based on the surgical procedure for which this device is selected.

Reporting Serious Incidents

In the event of a serious incident involving this device, report to the manufacturer (contact details on this page) and to the competent authority of the country in which the user and/or patient is established.

Exclusive Worldwide Distributor:

Delta Surgical Ltd
Unit 10, Evolution, Lymedale Business Park,
Newcastle under Lyme,
Staffordshire ST5 9QF
United Kingdom

+44 (0)1782 637009
sales@deltasurgical.co.uk

Additional Information

Contraindications: This device has no inherent clinical contraindications when used as described in these instructions for use. Do not use if any of the following apply:

• Product, individual packaging, or shipping packaging is damaged, compromised, or shows signs of tampering

• Beyond expiry date marked on the packaging

• Visible signs of damage, contamination, or defect on pre-use inspection

Procedure-specific clinical contraindications are determined by the clinical user based on patient assessment and the intended surgical procedure.

Shelf Life: See product labelling.

Storage & Transportation: Ensure the product is stored in a clean, dry environment and out of direct sunlight.

MR Safety Information: MR Unsafe. This device contains ferromagnetic components and must not be brought into the MR scanner environment.

Symbol Guide

- Manufacturer
- Date of manufacture
- Use by
- Do not reuse
- Do not use if package is damaged
- Keep away from sunlight
- Keep dry
- LOT — Batch code
- REF — Reorder number
- EC REP — Authorised Representative in the European Community
- UK REP — UK Responsible Person
- CE mark
- MD — Indicates the item is a medical device
- UDI — Indicates a carrier that contains unique device identifier
- Caution
- NON STERILE — Indicates a medical device that has not been subjected to a sterilization process
- Consult instructions for use

(MANUFACTURER)
Name: Shenzhen Ruixie Industrial Co., Ltd.
Address:East Side, 1/F., No.1 Building, Hengguan Industry Zone, Xinqiao, Shajing, Baoan, Shenzhen , China

(UK RESPONSIBLE PERSON)
UK REP
Name: Calibre Models Ltd
Address: Unit 7, Irfon Industrial Estate, Garth Rd, Builth Wells LD2 3NL, UK

(EUROPEAN REPRESENTATIVE)
EC REP
Name: MedPath GmbH
Address: Mies-van-der-Rohe Straße 8, Munich, 80807 DE

Important Information

Please Read These Instructions Before Use

Manual Surgical Drill, Single-Use

REF D5001CM

Description: The device comprises an ergonomic outer case, folding drive handle, internal geared mechanism, drive shaft, and three-jaw drill chuck. The geared mechanism provides controlled rotation suitable for fine surgical drilling, operated manually by the user. Compatible with surgical drill bits of diameter 0.5mm to 6.5mm. Drill bits are not supplied with this device.

GMDN: 65754 - Manual surgical rotary handpiece, single-use.
Current IFU Version: V3 May 2026

Sterility: Non-sterile. Intended for terminal sterilisation by the kit producer or sterilisation provider. If this device is supplied as part of a sterile surgical procedure pack, refer to the outer pack labelling for sterility information.
Single use only. Do not reuse. Do not re-sterilise.

Indications for use:
The Manual Surgical Drill, Single-Use is a non-sterile, single-use manual surgical rotary handpiece intended for use by qualified medical professionals.

The device is designed to hold and rotate a compatible surgical drill bit during surgical drilling procedures. The drill bit is a separate medical device and is not supplied with this handpiece.

Specific clinical applications, anatomical sites, and drill bit specifications appropriate to the procedure are determined by the clinical user.

Please read both sides of these instructions

CE

Caution

Please Read All Instructions Before Use

Single use only. Do not reuse. Do not re-sterilise.

- Do not use if inner packaging or product is damaged
- Do not use this product beyond expiration date
- Ensure drill bits (not supplied) are of a compatible diameter and a shank that is appropriate to the three-jaw chuck
- The product is a medical device. Users must ensure they have the relevant expertise and clinical training before use
- Read & understand the instructions before using this manual surgical drill
- Before each use, operate the device by rotating the handle and drill chuck clockwise and anticlockwise respectively and inspect each component for damage. DO NOT use any component if damage is detected
- Do not apply excessive pressure, allow drill bit to rotate freely
- The appropriate rotating speed is important for the surgical operation. Please rotate the handle carefully and slowly
- After installing the drill bit, inspect and ensure that it is secured before operating the hand drill
- Dispose of the used hand drill according to the laws and regulations of the medical waste disposal method. Failure to comply may result in environmental pollution and human injury
- Drill bit may become loose in the drill chuck. Please ensure chuck is fully tightened before use

Failure to follow these warnings may result in patient or healthcare staff injury

Instructions For Use

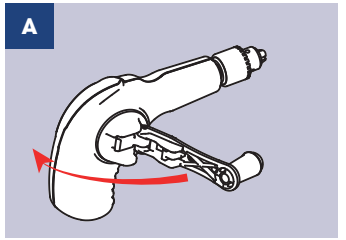
1. Perform all procedures in accordance with established clinical techniques and protocols.
2. Handle Securing - Unfold the handle arm and lock it into the open position. Verify that the handle is securely fastened (refer to Figure A).
3. Drill Bit Selection and Installation - Select the appropriate drill bit for the procedure and insert it into the chuck as depicted in Figure B.

   NOTE: To adjust the chuck wider for the drill bit diameter, rotate the chuck counter clockwise.
4. Securing the Drill Bit - Tighten the drill bit using the provided chuck key to ensure it is securely in place. Apply even pressure by rotating the chuck key clockwise at all three designated points, ensuring accurate alignment (refer to Figure C).
5. Verification of Drill Alignment - Rotate the handle both clockwise and counter clockwise to confirm that the drill bit is aligned properly and rotates without deviation. If any misalignment is detected, loosen the chuck and re-secure the drill bit by following the previous steps.

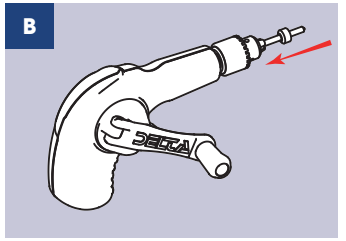
   Note: To remove the drill bit, repeat the above procedure, rotating the chuck counter clockwise.
6. Procedure setup Complete Use the device in accordance with the clinical procedure and the warnings and precautions in this IFU.

Please read both sides of these instructions

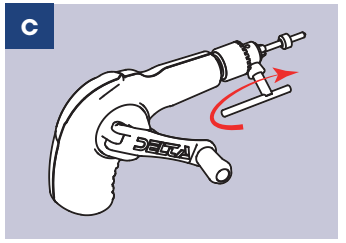
A



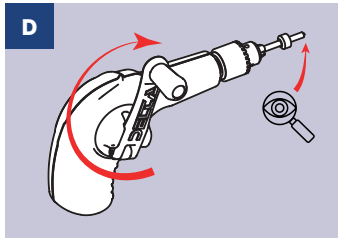
B



C



D



Precautions:
To prevent slippage of drill bit, slowly rotate until drill bit is fully engaged.

Manual Surgical Drill, Single-Use

REF D5001CM