Instructions for Use

Drills, Tools, Kits and Sets

Document No.	Title	Version	Date
MK-006-EN	Drills, Tools, Kits and Sets	H	02.06.2026

1. Scope of These Instructions

These instructions for use apply to all dental drills, handpiece / motor mount tools, and surgical kits/sets manufactured by ARDS Industries Ltd. covered by Technical Documentation TFMDR-AI-002. The complete product list is provided in document 1.1.7.3 (ARDS Product List Class IIa, Rev. 19).

These Instructions for Use are enclosed with each product, in the official language(s) required by the Member State where the product is placed on the market, in accordance with Regulation (EU) 2017/745, Annex I, Chapter III, Section 23.1(d). An electronic version (eIFU) is available at https://www.ardsimplants.com/ifu and https://www.ai-ifu.com, in the same required languages.

Where ARDS relies on the eIFU as a means of provision, it does so only in compliance with Commission Implementing Regulation (EU) 2021/2226 (devices intended exclusively for professional users): an eIFU risk assessment is maintained, the website provides the required language versions, and a paper copy is provided free of charge, on request, within 7 calendar days. The paper IFU enclosed with the product is the primary means of provision; the eIFU is supplementary.

2. Intended Use and Indications

ARDS dental drills, trephine burs, tissue punches, bone profiler drills, bone condenser drills, surgical guide drills, final drills, and related tools are bone-cutting or bone-preparation instruments intended exclusively for use in dental implant surgery by drilling or cutting into the maxillary or mandibular bone to prepare the osteotomy site for endosseous dental implant placement. May also be used for preparation of augmentation procedures.

- Marking/lance drills: identify and mark the osteotomy entry point
- Twist drills (classic, short, long, extra-long, step, conical, final): sequential osteotomy preparation to implant diameter and depth
- Final drills (FD series): final osteotomy preparation to the exact implant diameter and depth
- Countersink drills: enlarge the coronal area of the implant site in dense cortical bone for passive fit of the implant neck
- Trephine drills: remove bone around an implant; indicated for retrieval of non-osseointegrated or damaged implants
- Tissue punches: flapless gingival punch for crestal access
- Bone profiler drills: level and profile the crestal bone surface
- Bone condenser drills: condense and compact bone in low-density (D3/D4) sites
- Zygomatic and pterygoid drills: prepare osteotomies for zygomatic and pterygoid implant placement respectively
- Surgical guide drills (SG4D, SG5D, SGOD series): guided osteotomy preparation through 4.0mm or 5.5mm surgical guide sleeves
- Diamond burr drills: shaped bone preparation using diamond coating
- Drill extensions (MT0012): extend drill reach for deep/posterior applications
- Handpiece / motor mount tools: connect implants or abutment screws to powered surgical handpieces for torque-controlled insertion
- Drills with stoppers (DRPS series) and separate stoppers (DS series): provide controlled drilling depth

These devices have no stand-alone intended use — they are used exclusively in conjunction with ARDS dental implants.

3. Intended User and Patient Population

For professional use only. Devices must be used exclusively by licensed dental professionals (oral surgeons, implantologists, periodontists, general dentists with appropriate implant training).

Intended for adult patients (≥18 years, skeletally mature) requiring dental implant placement.

4. Contraindications

- Active local infection or inflammation at the surgical site
- Insufficient bone volume or quality for stable implant placement
- Active radiotherapy to the head and neck region
- Uncontrolled systemic conditions impairing wound healing (uncontrolled diabetes, severe immunosuppression)
- Current or prior high-dose IV bisphosphonate therapy (MRONJ risk); specialist consultation required for oral bisphosphonate patients
- Known allergy to stainless steel (400-series / AISI 420; or stainless steel 316 used in co-packed Class I accessories), titanium alloy Ti-6Al-4V ELI (co-packed accessories), or the AlTiN surface coating
- Pediatric or skeletally immature patients (under 18 years)

5. Warnings

- For professional use only — not for use by untrained or unlicensed personnel.
- All devices are supplied NON-STERILE. Must be cleaned, disinfected, and steam-sterilized before each use per Section 8.
- Maximum reuse: 50 reprocessing cycles (cleaning + sterilization), as validated by wear resistance study. Discard immediately if worn, bent, corroded, or damaged regardless of cycle count.
- All drilling procedures must be performed at a maximum speed of 800–1,300 RPM with copious sterile isotonic saline irrigation. Lower RPM (800–1,000) is recommended for harder bone types (D1/D2).
- Pre-tapping and implant insertion: maximum 25–30 RPM, maximum torque 45 Ncm.
- Do not use a blunt, bent, or damaged drill — replace immediately.
- Do not use if packaging is damaged.
- Use only with ARDS dental implant systems and compatible ISO 1797-1 handpieces.
- Surgical Guide drills must only be used with the correct sleeve size (4.0mm or 5.5mm) as specified by the catalog number.
- Kit contents (BOX series): kits are intended for multiple cases. Replace individual components that reach 50 cycles before kit maximum is exceeded. Kit box (Radel R / polyphenylsulfone) withstands autoclave sterilization — inspect for cracks before each use.

6. Materials

Product Group	Material
Dental drills – all bone-cutting families	Stainless steel 400-series (AISI 420)
Drill surface coating	AlTiN (Black) hard black PVD coating; Diamond burrs: industrial diamond coating
Handpiece / motor-mount drivers	Stainless steel 420 (S.S 420)
Drill extension, SG handpiece/guide tools	Stainless steel 400-series (AISI 420)
Drills + stoppers / stoppers	Stainless steel 400-series (AISI 420)
Kit box (BOX series)	Radel R / polyphenylsulfone (PPSU) – autoclave-compatible
Silicone holder inserts	Medical-grade silicone – autoclave-compatible
Co-packed Class I accessories – ratchet wrench, height indicator, screwdriver; SG anchor tools	Titanium alloy Ti-6Al-4V ELI or Stainless steel 316

Do not use in patients with known allergy or hypersensitivity to any of the above materials.

7. Drill Selection

These sharp instruments are used to prepare the surgical sites for dental implants. They have different shapes: precision drill, crown drill, countersink, conical, cylindrical, short, long and XL long for distal use, bone profilers.

Depending on the implant system they belong to, they may have internal irrigation or depth lines to determine the working depth and may be designed for connection with a depth stop. Consult the catalogues of the implant system in question for detailed technical features.

Surgical drills come in successive diameters. They have a cylindrical and conical shape. Surgical drills have two working lengths (short 11.5mm, 16mm, 20mm and 25mm long, and extra-long such as 30, 60, 80 mm for Omega). Nominal length marked by circular marks is measured from the beginning of the sharp edge. The length of the drill includes a cutting edge of triangular shape. Surgical drills with a flat cutting edge are also available, as are surgical drills with internal or external irrigation.

8. Surgical Protocol

8.1 Drilling Sequence

Always follow the ARDS implant system surgical protocol for the specific implant being placed. General sequence:

- Step 1: Mark entry point with lance/marking drill (DR0010, DR0012, DR0015, MDR0015)
- Step 2: Pilot drill to initial depth
- Step 3: Sequential enlargement using progressively larger drills (2.0mm → final diameter in 0.4–0.5mm steps)
- Step 4: Conical drills (DRC) or SG drills (SG4D / SG5D) or Final drill (FD series) preparation to exact implant diameter and depth
- Step 5: Apply countersink (CD) in D1/D2 bone if required for implant neck seating
- Step 6: Use bone condenser (BCD) in D3/D4 bone to condense trabeculae before insertion if needed

Adapt drill sequence for bone density: D1/D2 = full sequence; D3/D4 = may skip one or more sizes.

8.2 Operating Parameters

- Drill speed: 800–1,300 RPM maximum with continuous copious irrigation
- Recommended speed by bone type: D1/D2: 800–1,000 RPM; D3/D4: 1,000–1,300 RPM
- Implant insertion: 25–30 RPM, maximum torque 45 Ncm
- Irrigation: sterile isotonic saline (0.9% NaCl) — use internal and/or external irrigation as available
- Use in-and-out drilling motion; do not force; allow bone to cool between steps

8.3 Guided Surgery (SG series)

Surgical guide drills must be used with the correct sleeve system: SG4D drills with 4.0mm guide sleeves; SG5D drills with 5.5mm guide sleeves. Use the matching SG HP Tool for handpiece engagement. Follow the guided surgery protocol for the specific surgical guide system used.

9. Reprocessing Instructions

All products are reusable and must be reprocessed before each clinical use. Maximum 50 reprocessing cycles per instrument.

9.1 Pre-treatment (at point of use)

- Immediately after use: rinse under running water to remove gross contamination while brushing outer and inner surfaces with a soft nylon brush
- Transport to reprocessing area in a closed container

9.2 Manual Cleaning and Disinfection

1. Choose appropriate cleaning detergent (e.g. neodisher® Mediclean or equivalent)
2. Ultrasonic cleaning at 35 kHz in deionized water with cleaning solution per manufacturer's instructions
3. Rinse all surfaces and cavities 3× under deionized water at room temperature (20 ± 5 °C) for ≥ 10 seconds each
4. Wipe with 70% IPA alcohol using a soft, disposable lint-free wiper
5. Disinfect using an approved disinfection solution (e.g. CIDEX® OPA) per manufacturer's instructions
6. Place the disassembled and cleaned instruments in the disinfection bath. Ensure the instruments are covered by the disinfection solution, filling all lumens and eliminating air pockets
7. Follow the disinfection solution manufacturer's instructions (15–20 min)
8. Rinse out all cavities of the instruments three times with disinfection solution at the beginning and at the end of the action time using a disposable syringe (minimum syringe volume 20 ml)
9. Remove the instruments from the disinfection bath

9.3 Rinsing

1. Immerse instruments completely in a large volume of water for a minimum of 1 minute
2. Rinse instruments thoroughly with water at least three times. Rinse out all cavities and lumens of the instruments with water three times using a disposable syringe (minimum syringe volume 20 ml)
3. Remove the instruments and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose
4. Repeat step 3 for a total of three rinses, with large volumes of fresh water to remove the disinfection solution residues. Residues may cause serious side effects

9.4 Drying

1. Dry the instruments inside/out with filtered compressed air or for 30 min at room temperature
2. Pack the instruments as quickly as possible after removal
3. Make sure instruments are dry before packing them for sterilization. If additional drying is necessary, dry in a clean location

9.5 Automated Cleaning and Disinfection

Ensure that the washer-disinfector is validated and suitable for dental surgical instruments. Choose an appropriate cleaning and disinfection detergent (e.g. neodisher® Mediclean or equivalent) and follow the manufacturer's instructions.

1. Place the instruments in the disinfector so that joints are opened, and water can flow out of cannulas and blind holes
2. Make sure that the instruments do not touch each other
3. Start the appropriate program suitable for instruments
4. Perform thermal disinfection at 90 °C for 5 minutes
5. Inspect and pack the instruments as quickly as possible after removal
6. Ensure the instruments are dry before packaging them for sterilization. If additional drying is necessary, dry them in a clean location

Use a washer-disinfector approved per EN ISO 15883. Validated with the BOX000 master kit as worst-case product. See Technical File section 6.16 for validation data.

9.6 Drying, Inspection and Packaging

1. Dry thoroughly — ensure no moisture remains. Moisture causes corrosion and compromises sterilization
2. Inspect each instrument: discard if showing wear, deformation, corrosion, dullness, or damage
3. Package in sterile pouches or the kit box (BOX series)
4. Inspect packaging integrity before use — repackage and re-sterilize if damp or compromised

9.7 Steam Sterilization (Autoclave)

Cycle Type	Temperature	Min. Time	Min. Dry Time
Gravity Displacement	135 °C / 275 °F	10 min	30 min
Pre-vacuum	132 °C / 270 °F	4 min	3 min

Note: apply the sterilization parameters in accordance with the validated reprocessing study.

10. Storage

- Store instruments in sterile pouches or kit box in a dry, clean environment away from direct sunlight, UV radiation, heat, and moisture
- Avoid mechanical stress, compression, or contact with corrosive substances
- Do not use if the sterile barrier is breached
- Use distilled or deionized water for cleaning to prevent mineral deposits

11. Combination with Other Devices (Annex I 23.4(z))

ARDS drills and tools are designed for use with the ARDS dental implant system. Compatible implant systems are described in the following ARDS Instructions for Use:

- MK-002 — ARDS Dental Implants All Types
- MK-003 — ARDS Zygomatic Implants
- MK-005 — ARDS Abutments and Superstructures

Handpiece tools are compatible with standard contra-angle and straight surgical handpieces conforming to ISO 1797-1. Use only with a calibrated surgical motor unit (physiodispenser) with torque control. ARDS does not warrant performance when instruments are used with non-compatible equipment.

Surgical guide drills must be used with matched guide sleeves (4.0mm or 5.5mm) from validated ARDS guided surgery systems. Use of non-ARDS surgical guide systems with these drills is not validated.

12. Labelling Symbols

Symbol / Meaning	Symbol / Meaning
Catalogue / reference number	Batch code / lot number
Unique Device Identifier (UDI)	Manufactured by
Date of manufacture and country of manufacture	Non-sterile – supplied non-sterile; clean and sterilize before use
Regulatory compliance (CE)	Consult instructions for use / electronic IFU (www.ai-ifu.com)
Authorised representative in the European Community	Importer
Distributor	Quantity
Caution — consult accompanying documents	Do not use if package is damaged

13. Manufacturer and Authorized Representative

Manufacturer	EU Authorized Representative
ARDS Industries Ltd. Gonen 18 Str., Petah Tikvah, 4925920, Israel	AR Experts B.V. Boeingavenue 209, 1119 PD Schiphol-Rijk

Manufacturer	EU Authorized Representative
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Appendix A — IFU Language Availability

Member State	IFU Language	Available Format
Germany	German	Paper + Electronic
Austria	German	Paper + Electronic
France	French	Paper + Electronic
Italy	Italian	Paper + Electronic
Spain	Spanish	Paper + Electronic
Netherlands	Dutch (English permitted, professional use)	Paper + Electronic
Belgium	Dutch / French / German	Paper + Electronic
Portugal	Portuguese	Paper + Electronic
Poland	Polish	Paper + Electronic
Sweden	Swedish (English permitted, professional use)	Paper + Electronic
Denmark	Danish (English permitted, professional use)	Paper + Electronic
Finland	Finnish / Swedish	Paper + Electronic
Ireland / Malta	English	Paper + Electronic
Greece	Greek	Paper + Electronic
Czech Republic	Czech	Paper + Electronic
Romania	Romanian	Paper + Electronic
Hungary	Hungarian	Paper + Electronic
All other EU/EEA Member States	Official language(s) of that Member State	Paper + Electronic