ORTHODONTIC TEMPORARY ANCHORAGE MINI SCREW & MANUAL DRIVER

Technical / Specification / Safety Data Package

DOCUMENT CLASSIFICATION

Product Specifications • Technical Data Sheet (TDS) • Instructions for Use (IFU) • Safety Data Sheet (SDS / MSDS)

DOCUMENT CONTROL	
Product	Orthodontic Temporary Anchorage Mini Screw (TAD / Orthodontic Micro Implant) & Manual Insertion Driver Set
Reference standard	ISO 19023:2018 Dentistry - Orthodontic anchor screws
Revision	A
Document date	2026
Intended audience	Dental / orthodontic professionals, distributors, compliance and quality teams

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Document Contents

01 **Product Specifications**

Product description, material, construction, intended use and dimensions.

02 **Technical Data Sheet (TDS)**

Mechanical properties, driver parameters, packaging, storage and tolerances.

03 **Instructions for Use (IFU)**

Indications, contraindications, warnings, insertion/removal and sterilization.

04 **Safety Data Sheet (SDS / MSDS)**

Sixteen-section safety profile prepared for the finished solid medical device.

PROFESSIONAL USE

This document is organized for technical review. Product handling and clinical use should be performed by appropriately trained dental professionals.

01 Product Specifications

PRODUCT IDENTIFICATION	
Product name	Orthodontic Temporary Anchorage Mini Screw (TAD / Orthodontic Micro Implant) & Manual Insertion Driver Set
Model options	Mini screw: multiple diameter & length options. Hand driver: manual handle + interchangeable driver tip compatible with square collar mini screw.
Mini screw material	Medical Grade Titanium Alloy Ti-6Al-4V (ASTM F136 / ISO 5832-3) OR Medical Stainless Steel ASTM F138 / ISO 5832-1.
Driver material	Medical Stainless Steel AISI 316L.
Intended use	Temporary skeletal anchorage for orthodontic treatment to provide a stable anchor point for tooth movement. Device shall be removed after orthodontic therapy completion.

Structure Description

1. Mini Screw: Mushroom head with lateral hole, square collar, self-tapping / self-drilling tapered thread and sharp tip.
2. Manual Driver: Ergonomic black plastic grip, knurled metal chuck and stainless steel drive tip.

Product Characteristics

- Self-drilling / self-tapping thread design.
- Mini screw: single-use only.
- Hand driver: reusable and autoclavable for repeated clinical use.

Dimension List

Screw Diameter	Available Length
1.6 mm	6, 7, 8, 9, 10, 12 mm
2.0 mm	6, 7, 8, 9, 10, 12, 14, 17, 21 mm

02 Technical Data Sheet (TDS)

TECHNICAL DOCUMENT IDENTIFICATION	
Product	Orthodontic Mini Temporary Anchorage Screw & Manual Driver
Assembly standard reference	ISO 19023:2018 Dentistry - Orthodontic anchor screws
Revision / Date	Revision A / 2026

Mechanical Properties - Ti-6Al-4V Titanium Alloy Screw

Tensile Strength	≥ 860 MPa
Yield Strength	≥ 795 MPa
Elongation	≥ 10%
Hardness	300-380 HV
Max recommended insertion torque	≤ 15 Ncm
Max removal torque	≤ 10 Ncm

Mechanical Properties - Stainless Steel Screw

Tensile Strength	480-1210 MPa
Yield Strength	170-1210 MPa
Elastic Modulus	193 GPa

Driver Technical Parameters

Material	AISI 316L stainless steel

Autoclave resistance	134°C / 18 min repeated sterilization
Compatibility	Square collar head mini screw
Max operating torque	20 Ncm

Surface, Packaging & Tolerances

- Surface finish: Machined bright surface.
- Screw packaging option: Non-sterile / Gamma irradiated sterile (25 kGy).
- Storage condition: Dry, room temperature, away from direct sunlight.
- Corrosion resistance: Resistant to normal oral fluid corrosion.
- Thread outer diameter tolerance: ±0.05 mm; overall length tolerance ±0.2 mm.

03 Instructions for Use (IFU)

PRESCRIPTION ONLY

Orthodontic Temporary Anchorage Mini Screw & Manual Hand Driver - for professional orthodontic use.

Indications

Temporary intraoral skeletal anchorage for orthodontic tooth movement. For use in patients ≥12 years old.

Contraindications

- Severe osteoporosis, uncontrolled metabolic bone disease.
- Active local infection, gingivitis / periodontitis at insertion site.
- Known allergy to titanium or stainless steel.
- Poor patient oral hygiene.
- Bone defects or pathology at planned insertion site.

Warnings

1. Mini screw is SINGLE USE ONLY. Do not re-use. Reuse risks fracture, infection and cross-contamination.
2. Hand driver is reusable and must be fully cleaned, disinfected and autoclaved before every use.
3. Do not exceed maximum recommended insertion torque (15 Ncm). Over-tightening may cause screw fracture.
4. Pre-operative periapical X-ray is mandatory to evaluate root spacing and bone anatomy.
5. If screw breaks during insertion, stop operation immediately, evaluate and manage residual fragment.
6. For professional dentist / orthodontist use only. Not for sale directly to patients.

03A Clinical Procedure

Insertion Steps

1. Prepare insertion site: administer local anesthesia and mark entry point.
2. Assemble mini screw onto the driver tip and securely lock connection.
3. Hold manual handle, rotate clockwise slowly and steadily, and apply minimal axial pressure.
4. Stop when collar reaches mucosal surface. Take post-insertion X-ray to verify screw position.
5. Attach orthodontic elastic / wire to the lateral hole on screw head.

Removal Steps

1. After orthodontic treatment completion, attach driver tip to screw head.
2. Rotate counter-clockwise gently to back the screw out from bone. Local anesthesia usually not required.

Cleaning & Sterilization for Hand Driver

1. Immediately after use: rinse with purified water to remove debris and perform ultrasonic cleaning.
2. Dry completely. Pack inside sterilization pouch.
3. Autoclave options: 121°C / 30 min or 134°C / 18 min.
4. Inspect for scratches, bending or wear before next use. Discard if deformed.

Potential Adverse Reactions

Local pain, gingival irritation, inflammation, screw loosening, root contact injury, screw fracture and metal hypersensitivity.

Storage

Store in cool, dry place, temperature 5-30°C, humidity <60%. Avoid heavy squeeze or impact.

04 Safety Data Sheet (SDS / MSDS)

MATERIAL SCOPE

Orthodontic Mini Screw (Ti-6Al-4V / 316L Stainless Steel). Prepared according to the supplied GHS / OSHA / REACH classification information.

1. Identification

Product name	Orthodontic Temporary Anchorage Mini Screw & Manual Driver
Product use	Orthodontic dental medical device
Manufacturer	Dental OEM
Manufacturer Emergency Phone	Medical device emergency contact

2. Hazards Identification

Not classified as hazardous substance under GHS.

- Physical hazard: No fire / explosion risk under normal use.
- Health hazard: Solid metal part, no normal skin absorption. Rare hypersensitivity for titanium / nickel (stainless steel contains trace nickel).
- Mechanical hazard: Broken sharp fragments may cause cut / puncture wound.
- Environmental hazard: No known environmental hazard.

3. Composition / Information on Ingredients

1. Titanium Alloy Ti-6Al-4V: Ti ~90%, Al ~6%, V ~4%.
2. Stainless Steel AISI 316L: Fe, Cr, Ni, Mo, Mn, Si. No carcinogenic or toxic additives.

4. First Aid Measures

- Skin contact: Wash skin with water if touched. If cut by sharp fragment: clean wound, apply antiseptic.
- Eye contact: Rinse eyes with running water if metal fragment enters eye; seek medical help.
- Ingestion: Not expected. If swallowed, seek emergency medical service.
- Allergy reaction: Remove device; administer anti-allergy treatment by physician.

5. Fire Fighting Measures

Not flammable. Metal dust may be fire hazard only when finely powdered. Use water spray, CO2 or dry powder for fire.

6. Accidental Release Measures

Solid metal parts. Collect broken fragments with tweezers, avoid puncture injury. Dispose as medical waste.

7. Handling and Storage

Handling: Wear gloves when handling sharp components. Avoid dropping / bending the screw. Storage: Dry ambient storage, separate from strong acid / corrosive chemicals.

8. Exposure Controls / Personal Protection

No routine exposure risk. PPE: Nitrile gloves during handling; protective eyewear when cutting / trimming.

04 Safety Data Sheet (SDS / MSDS) - Continued

9. Physical and Chemical Properties

Appearance: Silver metallic solid screw / driver. Odor: Odorless. Melting point: >1600°C. Solubility in water: Insoluble. Stability: Stable under normal temperature.

10. Stability and Reactivity

Stable under normal storage and clinical use. Reacts with concentrated strong acid. No dangerous polymerization.

11. Toxicological Information

- Acute toxicity: Not toxic as solid metal.
- Sensitization: Rare nickel allergy (SS version); titanium allergy is extremely uncommon.
- Carcinogenicity: Not listed as carcinogen.

12. Ecological Information

Not biodegradable. Low ecotoxicity. Dispose as regulated medical waste.

13. Disposal Considerations

Discard contaminated used mini screw as regulated biohazard medical waste. Scrap metal driver parts: medical metal waste recycling. Follow local medical waste regulation.

14. Transport Information

Not dangerous goods for air / sea / land transport. No UN number required.

15. Regulatory Information

Compliant with ISO 10993 biocompatibility, ISO 19023 for orthodontic anchor screw, FDA 21 CFR / EU MDR medical device rules.

16. Other Information

This SDS is prepared for finished solid medical device. Not for raw metal ingot. Valid for export custom and customer audit.

DOCUMENT STATUS

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