AEGIS STAR
DENTAL TECHNOLOGIES

SAFETY DATA SHEET (SDS)

Manufacturer:
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SDS Version: 1.0
Date Issued: May 18, 2025
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SECTION 1: Identification
Product Name: Keles™ Keyless Expander
Products: KKE 8 mm, KKE 10 mm, KKE 12 mm (available with or without legs)
Recommended Use: Orthodontic expansion device for dental professionals

SECTION 2: Hazard Identification
GHS Classification (OSHA HCS 2012): Not classified as hazardous.
Label Elements: No labeling required for finished medical devices under OSHA guidelines.

SECTION 3: Composition / Information on Ingredients

Hazardous Components (%Wt):

- Carbon: < 0.048% (Typical range: 0.02–0.05%) — ASTM F138
- Silicon: < 0.91% (Typical range: 0.5–1.0%) — ASTM A240
- Manganese: < 1.74% (Typical range: 1.0–2.0%) — ASTM A240
- Phosphorus: < 0.039% (Safe limit: < 0.04%) — ASTM A240
- Sulfur: < 0.03% (Typical limit: < 0.03%) — ASTM A240
- Chromium: < 21.21% (Typical range: 16–22%) — ASTM F899 / ISO 5832-1
- Molybdenum: < 0.82% (Typical range: 0.5–3.0%) — ASTM F899
- Niobium: < 0.17% (Trace element: < 0.3%) — ASTM A240
- Nickel: < 9.891% (Typical range: 8–12%) — ISO 5832-1 / ASTM F138
  Note: The total nickel content reflects contributions from both the stainless steel body and the integrated NiTi spring component embedded within the built-in activation mechanism. The NiTi alloy is included within this value and conforms to ASTM F2063, the standard specification for wrought Nickel-Titanium alloys used in surgical and orthodontic applications. Nickel in both the stainless steel and NiTi components is bound within stable alloy matrices with low ion release under normal use conditions. However, individuals with known nickel hypersensitivity may still experience allergic reactions even at low exposure levels. Evaluate patient history before use.
- Titanium: < 0.19% — Present in NiTi spring
  Note: This value reflects the total Titanium content in the device, which comes entirely from the embedded NiTi spring mechanism. The spring is composed of approximately 55% Nickel and 45% Titanium and conforms to ASTM F2063 — the standard specification for wrought Nickel-Titanium alloys used in surgical and orthodontic applications. Titanium is not present in the stainless steel portion of the device. As such, this amount is consistent with trace element levels when considered in relation to the total device mass.

- The remainder of the composition consists primarily of Iron, which forms the base of the alloy — consistent with stainless steel formulations under ASTM and ISO specifications. All elements are present in amounts compliant with standards for biocompatible stainless steels approved by FDA-recognized ASTM and ISO material standards for medical devices (e.g., ASTM F138, ASTM F899, ISO 5832-1).

SECTION 4: First-Aid Measures
Inhalation: Not typically applicable for a solid medical device. However, inhalation may occur during processing activities such as grinding or cutting. If inhaled, move the person to fresh air and monitor for respiratory symptoms. Seek medical attention if irritation persists.

Skin Contact: Adverse effects are not expected under normal clinical use. In rare cases, individuals with metal sensitivity (e.g., to nickel) may experience irritation. If skin contact occurs with dust generated from processing activities, wash the affected area with mild soap and water for at least 5 minutes. Monitor for rash or redness. Seek medical attention if symptoms persist.

Eye Contact: Not applicable in the product's solid form. However, if dust generated during processing activities enters the eyes, flush with sterile eye wash or clean water for at least 15 minutes. If irritation persists or vision is affected, seek medical attention.

Ingestion: Accidental ingestion of the entire device is highly unlikely when handled by dental professionals due to its size and safety design. The device features a locking mechanism to prevent disassembly. If ingestion occurs, seek medical advice immediately. Monitor for signs of obstruction or irritation.

While the materials used (medical-grade stainless steel and NiTi) are not known to be toxic, mechanical obstruction or local irritation may occur.

SECTION 5: Fire-Fighting Measures
Appropriate Extinguishing Methods: No specific extinguishing media required.
Special Firefighting Instructions: No special procedures necessary.
Fire or Explosion Hazards: No known fire or explosion risks.

SECTION 6: Accidental Release Measures
Not applicable for solid, non-spillable medical devices.

SECTION 7: Handling and Storage
Handling: For professional dental use only. Handle with gloves.
Storage: Store in a clean, dry environment at room temperature.
Storage Duration: Shelf life is 5 years.
Handling Guidelines: At room temperature, the product is not expected to pose any health risks. However, when heated during processing, it may release fumes and vapors that can irritate the eyes and respiratory system. After the activation phase is complete, the clinician may choose to cut the stainless steel activation arm to prevent overactivation. This should be done using suction and coolant to reduce heat and metal debris. The cut surface must be smoothed before contacting oral tissue.

SECTION 8: Exposure Controls
This section applies to both clinical and occupational settings where the device may be altered through cutting, grinding, welding, or finishing processes.

Cutting the Activation Arm (Optional Clinical Use):
After the activation phase of treatment, if the stainless steel activation arm is cut intraorally by a dental professional using a rotary instrument (e.g., carbide bur), high-volume evacuation (HVE) suction and continuous coolant must be used to reduce heat generation and minimize metallic aerosol or debris within the oral cavity. The cut surface should be smoothed and finished to avoid irritation to oral tissues. These measures are essential to protect both patients and clinicians.
Laboratory and Manufacturing Processes:
In laboratory or production settings, device components may be subject to additional processing activities including, but not limited to: cutting or grinding, laser welding, electropolishing, thermal modification, or surface finishing. These procedures can generate metallic dust, fumes, or vaporized metal oxides. As such, appropriate engineering controls and PPE are essential.
Engineering Controls: Use local exhaust ventilation when cutting, grinding, laser welding, or heating to prevent accumulation of airborne dust and fumes. Use particulate and fume extraction systems near the source of generation. Implement controls to mitigate dust generation. Use controls to mitigate metallic fumes and oxides released during welding or high-temperature processing. Maintain proper grounding and shielding during laser welding operations. Personal Protective Equipment (PPE): Eye protection (e.g., safety goggles, welding shield), dust-resistant or fume-rated respirator (e.g., N95 or P100) in accordance with OSHA 29 CFR 1910.134, chemical-resistant gloves when handling electrolytes or components post-polishing, protective clothing to avoid skin contact with dust or surface residues, and heat-resistant gloves when working with recently welded or heated parts.
Regulatory Guidance: Refer to NIOSH and OSHA guidelines for applicable workplace exposure limits for chromium, nickel, and related metal constituents. All laboratory processing activities must comply with OSHA's Hazard Communication Standard (29 CFR 1910.1200), and appropriate safety training and SOPs should be implemented.

SECTION 9: Physical and Chemical Properties
Appearance: Metal Palatal Expander
Odor: Odorless
Solubility: Insoluble in water
Melting Point: >1300°C (stainless steel); ~1310°C (NiTi)
Stability: Stable under normal conditions

SECTION 10: Stability and Reactivity
Hazardous Reactions: None known. The product does not undergo hazardous polymerization.
Stability: Stable under normal conditions.
Incompatible Materials: None currently identified.
Conditions to Avoid: No specific conditions are known to cause instability under normal clinical or storage conditions. However, if the stainless steel activation arm is cut without adequate suction and coolant, localized heat and airborne metallic debris may be generated. Proper clinical technique—including cooling and smoothing of the cut surface—is recommended to minimize irritation or material degradation.

Hazardous Decomposition Products: The device poses no known fire or explosion risks. However, in occupational settings involving high-temperature processing, such as welding, grinding, or machining, exposure to heat may release metallic fumes, including metal oxides (e.g., iron, chromium, nickel compounds). These emissions are not expected during routine clinical use; however, minor metallic debris may be generated if the clinician cuts the stainless steel activation arm after the activation phase. In such cases, suction and coolant should be used to minimize exposure and ensure patient safety. Use appropriate local exhaust ventilation and personal protective equipment (PPE) in manufacturing environments where such processes occur. Refer to OSHA (29 CFR 1910 Subpart Z) and NIOSH guidelines, including the NIOSH Pocket Guide to Chemical Hazards, for applicable workplace exposure limits and engineering controls.

SECTION 11: Toxicological Information
Acute Toxicity: Not considered acutely toxic in its solid, finished medical device form.
Skin Irritation: Not expected under normal use. However, nickel content may cause allergic skin reactions in sensitized individuals.
Sensitization: Nickel is a known skin sensitizer. Even at low ion release levels, nickel-sensitive individuals may experience local or systemic allergic responses. Careful evaluation of patient history is recommended prior to use.
Carcinogenicity: This product contains no components classified as carcinogenic by OSHA. Nickel compounds, in some soluble forms, are classified as IARC Group 2B (possibly carcinogenic to humans), but such forms are not present in the alloy composition of this device.
Chronic Exposure: Repeated inhalation of metal dust or fumes generated during cutting, grinding, or thermal processing may cause respiratory irritation or sensitization.
Biocompatibility and Ion Release: An artificial saliva study, designed to simulate up to two years of intraoral use, was conducted at physiological pH (6.6–7.1) and 37°C. The test demonstrated extremely low metal ion release (< 0.01 µg/cm² for all tested metals). While this accelerated in vitro method is not a substitute for long-term clinical data, the results are consistent with the expected performance of biocompatible stainless steel and NiTi alloys in orthodontic applications. These findings support the safety profile of FDA-recognized materials, as defined by ASTM F138 (stainless steel) and ASTM F2063 (Nickel-Titanium alloy).

SECTION 12: Ecological Information
No ecological hazards are associated with this finished medical device. The product is not biodegradable and poses minimal risk to the environment in its solid, inert form.

SECTION 13: Disposal Considerations
Dispose of the product in accordance with local, state, and federal regulations. This device is not classified as hazardous waste but should not be incinerated or disposed of in municipal waste streams if metal recycling options are available.

SECTION 14: Transport Information
This product is not classified as dangerous goods under transport regulations.
DOT (U.S.): Not regulated as a hazardous material.
IATA: Not regulated.
IMDG: Not regulated.

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SECTION 15: Regulatory Information

U.S. FDA Medical Device Classification:
This product is classified as a Class I, 510(k)-exempt medical device under the Federal Food, Drug, and Cosmetic Act and 21 CFR 872.5410, corresponding to FDA Product Code DYJ (Retainer, Screw Expansion, Orthodontic). It is intended for use as an orthodontic appliance. The device has been registered and listed with the U.S. Food and Drug Administration by Aegis Star Dental Technologies, Inc.

OSHA Hazard Communication Standard (29 CFR 1910.1200):
As a finished medical device intended for end-use, this product is not considered hazardous under OSHA's Hazard Communication Standard and is exempt from SDS and labeling requirements during normal conditions of use.

SECTION 16: Other Information

Revision Date: May 24, 2025
Prepared by: Regulatory Affairs, Aegis Star Dental Technologies, Inc.
Disclaimer: This SDS is provided in good faith based on current knowledge.