TransformS™ CT-HT

Product Safety Information Sheet | United States

Document: ETUS-PSIS-CTHT-001 | **Revision:** 1 | **Issue date:** October 20, 2026
Supply condition: Sterile | **Document owner:** EndoTech USA

Safety and handling information for a finished dental instrument, arranged under the familiar 16 safety-information headings. Read with the product label and instructions for use (IFU). This voluntary information sheet is not a statutory hazardous-substance SDS or a regulatory approval.

1. Product and company identification

Item	Information
Product	TransformS™ CT-HT - Root-canal preparation instruments. Sizes, tapers, lengths and catalogue references: as labelled on the supplied pack.
Use / restrictions	Professional mechanical root-canal preparation within the product IFU. Use only by appropriately trained dental professionals. This sheet covers the finished instrument; separate chemicals, powders and cleaning agents are outside its scope.
Supply	Supplied sterile, as confirmed by EndoTech on October 19, 2026. Refer to the label for expiration, lot and single-use / reuse instructions.
US product contact	EndoTech USA 1629 Jills Court #4 Bellingham, WA 98226, United States.
Product information	steve@endotechus.com www.EndoTechUS.com
Emergency	Medical emergency: **911**. [7] Suspected poisoning: **Poison Help 1-800-222-1222** (US public advice, 24 hours). [8] These are public services, not an EndoTech customer line or contracted product emergency service.
Manufacturer evidence	The submitted SGS reports name Shandong Hengfeng Kerui Medical Equipment Co., Ltd, Qingdao, Shandong, China. The reports identify laboratory sample models rather than this EndoTech commercial product name; see Section 16.

2. Hazard identification

Physical / clinical hazards: sharp surfaces and small parts can cause cuts, puncture or foreign-body injury. Damaged instruments may fracture. Used instruments may be contaminated with blood or other biological material. Assess metal-allergy history using the product IFU.

Chemical classification: no OSHA Hazard Communication chemical classification or chemical label elements are assigned by this voluntary sheet. The supplied screens do not establish a complete classification of the finished product. The conditions for article treatment are discussed in Section 15.

3. Composition / information on ingredients

Metal-alloy working part. The exact alloy, treatment and component specifications are not established by the supplied chemical screens.

Shank, handle, stop, surface treatment, joining materials and additives vary by construction; full identities and concentration ranges are not available in the assessed evidence. The reports are chemical screens, not complete bills of materials. Nickel and cobalt screening findings must be read with Section 11. [1-3]

4. First-aid measures

Cut / puncture: stop work, wash the affected area with soap and water and follow the practice exposure procedure. Obtain prompt medical assessment after a contaminated sharps injury. **Eye / mucosal contamination:** rinse with clean water or saline; seek care for injury or persistent symptoms. **Swallowed / inhaled instrument:** obtain urgent medical assessment. Call 911 for choking, breathing difficulty or another medical emergency. [6-7, 10]

Suspected allergic reaction: stop exposure and seek medical advice; call 911 for severe symptoms. Give the treating clinician the pack label, lot number and this sheet. Instrument retrieval and other clinical complications require professional management.

5. Fire-fighting measures

Select extinguishing media and firefighter protection for the surrounding fire. Packaging and polymer parts may burn or decompose under high heat; avoid smoke and decomposition fumes. No product-specific fire or decomposition test is supplied by the assessed reports. This sheet does not cover fine metal dust produced by grinding or other alteration of the instrument.

6. Accidental release measures

Restrict access to dropped instruments and recover them with suitable tools while preventing cuts or puncture. Do not handle loose sharps with unprotected hands. Segregate contaminated instruments under the practice infection-control procedure. Prevent entry to drains. Isolate packs or instruments affected by damage or contamination and follow the product IFU for their disposition.

7. Handling and storage

Maintain the sterile barrier until use. Do not use a sterile pack that is opened, punctured, wet, damaged or expired. Store in the original protective packaging, in a clean, dry place protected from contamination, moisture and physical damage. Observe any temperature or other storage conditions on the label.

Inspect instruments before and during use. Stop using a visibly damaged, distorted or corroded instrument. Follow the product IFU for motor mode/settings, compatible equipment and technique. Do not reprocess or reuse a product labelled single use. This information sheet does not specify a sterilization cycle, reuse limit or shelf life.

8. Exposure controls / personal protection

Use procedure-appropriate gloves, eye/face protection and other PPE under the practice infection-control programme. Gloves do not eliminate sharps risk. [6] Follow the product IFU for patient protection and metal-allergy precautions.

No product-specific airborne exposure study was supplied. Grinding, welding or thermal modification is outside intended use. If a process generates dust or fumes, assess the actual metal species, applicable OSHA permissible exposure limits (PEL), ACGIH threshold limit values (TLV), other relevant limits, ventilation and respiratory protection. No numerical limit is assigned to an unidentified screening compound.

9. Physical and chemical properties

Property	Available information
Physical form / appearance	Finished solid root-canal instrument with a metallic working part and fitted components as supplied. Exact color, dimensions and configuration: see product label.
Odour / odour threshold	Not determined in the available evidence.
pH	Not applicable to the dry formed instrument; no aqueous formulation is covered.
Melting / freezing point; boiling point / range	Product-specific values not supplied.
Flash point / flammability; explosive limits	Product-specific determinations not supplied.
Vapour pressure / density; relative density	Product-specific values not supplied.
Solubility; n-octanol/water partition coefficient	No assembled-product data supplied; partition coefficient is not a property of the instrument as an assembled article.
Auto-ignition / decomposition temperature	Product-specific values not supplied.
Kinematic viscosity	Not applicable to a solid formed instrument.
Particle characteristics	Not supplied as loose particles. Wear-debris / particle-release measurements are not provided by the assessed screens.

10. Stability and reactivity

Preserve the intended geometry, surface and packaging. Avoid unauthorized heating, chemical processing and physical damage. Use only processing agents and conditions permitted by the product IFU. No finished-product reactivity, incompatible-material or hazardous-decomposition study was provided in the assessed evidence. The screening reports do not validate compatibility with irrigants, disinfectants or repeated sterilization.

11. Toxicological information

The assessed evidence does not include a finished-product biological evaluation, dose-response or clinical release study. It does not establish product-specific conclusions for acute toxicity; skin/eye irritation or corrosion; respiratory/skin sensitisation; mutagenicity; carcinogenicity; reproductive toxicity; specific target-organ toxicity (single/repeated exposure); or chemical aspiration hazard. Mechanical aspiration is a separate foreign-body risk.

Screening context: the CMR report lists cobalt (CAS 7440-48-4) at **0.1928%** in sample group 004 / A8. Nickel-/cobalt-compound rows marked ** are worst-case calculations from selected elements, not confirmed molecular ingredients. These sample results are not established as the composition or exposure level for every named EndoTech product. [3]

12. Ecological information

No product-specific ecotoxicity, persistence/degradability, bioaccumulation, soil mobility or other environmental-effects data were supplied. Prevent instruments and debris entering drains, soil or water. A restricted-substance screening pass does not establish the environmental safety of the assembled product.

13. Disposal considerations

Place used single-use files into a labelled, rigid, puncture- and leak-resistant sharps container at the point of use. Use an authorized regulated medical-waste service under applicable state/local arrangements. Do not place contaminated instruments in recycling or loose general waste. Follow the waste contractor procedure for unused/damaged sharps and separate uncontaminated packaging where permitted. [6]

14. Transport information

Pack unused instruments to prevent puncture, contamination and damage to the sterile barrier. The assessed evidence does not provide a product-specific dangerous-goods transport determination: UN number, proper shipping name, class/subsidiary risk, packing group, environmental hazard and marine-pollutant status are not assigned here. Obtain the manufacturer transport information when a formal shipping declaration is required. Used or contaminated instruments require assessment under the applicable US medical-waste, DOT and transport-mode requirements.

15. Regulatory information

This is a **voluntary product safety information sheet for a finished medical device**. OSHA's Hazard Communication Standard excludes articles meeting its definition, including the conditions concerning release of hazardous chemicals during normal use and employee health risk. The submitted screens alone do not establish a product-specific article exemption or complete chemical classification. [4]

FDA medical-device labeling under 21 CFR Part 801 is separate from OSHA SDS duties. This sheet does not replace the device label/IFU or establish FDA clearance, approval, registration or listing. If a hazardous-chemical SDS is required, OSHA Appendix D calls for a US responsible-party address and telephone number plus an emergency phone number. Website/email and public emergency numbers do not replace the responsible-party US telephone number. [5, 9]

16. Other information and sources

Issue: October 20, 2026, Revision 1. **Revision history:** first US product-specific issue under this document number. Update when product, composition, instructions, safety evidence or regulatory status changes. Sterile supply confirmed by EndoTech on October 19, 2026. US business contact details match the approved Steve Shepherd business card.

Laboratory scope: sample models SSK 3102 080, YBZ 3105 050, GBZ 3105 050, BBZ 3105 050 and GF5 2505 050; batch 25071401. Reports do not independently map all EndoTech trade names/catalogue references. RoHS and SVHC reports record passes within their stated scopes; the CMR report directs the reader to its results/obligations. SVHC yellow solid A14: melamine **0.095%**, below the stated 0.1% criterion. ND means below the reporting limit. [1-3]

[1] SGS RoHS report SHAEC26010353501, April 29, 2026, 16 pages; results for selected submitted components.

[2] SGS SVHC report SHAEC26010353502, April 29, 2026, 18 pages; 253-substance screen against the list dated on/before February 4, 2026.

[3] SGS CMR report SHAEC26010347601, June 3, 2026, 7 pages; results p4 and calculation notes p5.

[4] OSHA: 29 CFR 1910.1200 - Hazard Communication: scope and article definition.

[5] OSHA: Appendix D - information required in a hazardous-chemical SDS.

[6] CDC: Standard Precautions and occupational blood-exposure first aid for dental personnel.

[7] National 911 Program: emergency calling guidance.

[8] HRSA Poison Help: public US poison advice, 1-800-222-1222, available 24 hours daily.

[9] FDA: General Medical Device Labeling Requirements - 21 CFR Part 801.

[10] CDC: Best Practices for Occupational Exposure to Blood.

Abbreviations: IFU instructions for use; SDS safety data sheet; OSHA Occupational Safety and Health Administration; FDA Food and Drug Administration; CMR carcinogenic, mutagenic or toxic to reproduction; SVHC substance of very high concern. The laboratory reports have not been independently authenticated with SGS.