

INSTRUCTIONS FOR USE

TransformX ET

Sterile, single-use nickel-titanium rotary endodontic instruments

For use by trained dental professionals only. Read this IFU before use.

ROTARY SHAPING SYSTEM

DOCUMENT: ETNZ-IFU-TXET-001

REVISION: A - design aligned draft

MARKET: New Zealand

SUPPLY: Sterile / single use

Clinical quick view

Engineered for progressive canal shaping after access, negotiation, working length determination and reproducible glide path preparation.

1. Device description

Device family

TransformX ET instruments are sterile, single-use nickel-titanium endodontic instruments intended for use during root canal treatment. The instruments are supplied in sterile blister packaging and are intended to be used with appropriate endodontic handpieces and torque-controlled endodontic motors, according to the approved product sequence and the clinician's assessment of canal anatomy.

2. Intended purpose

TransformX ET instruments are intended for mechanical cleaning and shaping of root canals during non-surgical endodontic treatment, after appropriate canal access, negotiation, working length determination and glide path preparation.

3. Indications for use

- Mechanical preparation of root canals during non-surgical root canal treatment.
- Progressive shaping of canals after canal access, negotiation and glide path preparation.
- Use as part of a complete endodontic workflow including irrigation, disinfection, obturation and restoration.

4. Contraindications

- Do not use in patients with a known or suspected hypersensitivity to nickel, titanium or nickel-titanium alloys where clinical risk is considered unacceptable.
- Do not use where safe straight-line access, canal negotiation or working length control cannot be established.
- Do not use outside the intended dental/endodontic application or by untrained users.

5. Clinical workflow context

Assess	Access	Glide	Shape	Clean 3D	Seal	Restore
--------	--------	-------	-------	----------	------	---------

Clinical step	Guidance
Entry condition	Use only after canal scouting, working length determination and a reproducible glide path.
Primary role	Rotary shaping and finishing according to canal anatomy and selected file size/taper.

Clinical control	Use light pressure, frequent irrigation and flute cleaning; avoid apical forcing.
Exit condition	Final apical preparation and taper are selected by the clinician according to anatomy, irrigation objectives and restoration plan.

6. Warnings

Important single-use warning

These instruments are supplied sterile and are single use only. Do not reprocess or reuse.

- Single use only. Do not clean, disinfect, reprocess, re-sterilise or reuse. Reuse may increase the risk of instrument separation, cross-contamination, infection, loss of cutting efficiency or unpredictable clinical performance.
- Use only after appropriate diagnosis, treatment planning and working length determination.
- Always use rubber dam isolation and appropriate aspiration/swallowing precautions.
- Use a torque-controlled endodontic motor and compatible handpiece. Do not force the instrument apically.
- Inspect the instrument before and during use. Discard immediately if unwinding, distortion, bending, visible wear, corrosion, deformation or any other defect is observed.
- In highly curved, narrow, calcified or complex canals, use additional caution, frequent irrigation, recapitulation and regular inspection of the instrument.
- Do not use beyond the established working length. Instrumentation beyond the apical foramen may cause iatrogenic injury.
- The clinician is responsible for selecting the appropriate file size, sequence, speed, torque and clinical technique based on canal anatomy, access, irrigation protocol and treatment plan.

7. Precautions

- Confirm canal patency and working length using clinical assessment, radiographs and/or electronic apex location as appropriate.
- Create a reproducible glide path before using shaping instruments. If resistance is encountered, withdraw, irrigate, recapitulate and reassess the canal path.
- Use each instrument with light apical pressure and short, controlled strokes. Remove frequently to clean flutes and inspect the instrument.
- Irrigate frequently and avoid forcing debris apically. Use an irrigation protocol appropriate to the clinical case.
- Do not use in canals that are not adequately lubricated or irrigated.
- Do not use heat, chemical agents or chairside processing methods that could alter the sterile state, alloy properties or instrument geometry.
- Dispose of used instruments as contaminated sharps in accordance with local requirements.

8. Before use

- Confirm the product name, part number, size, taper, length and expiry date on the package.
- Check that the sterile barrier is intact. Do not use if the blister is damaged, punctured, wet, opened or expired.
- Open the sterile package immediately before use using aseptic technique.
- Confirm that the selected file sequence and motor settings are appropriate for the clinical case and any current EndoTech product information.

9. Recommended clinical technique

Use TransformX ET instruments with a light, controlled brushing or pecking motion as clinically appropriate. Do not force the instrument apically. If resistance is encountered, withdraw, clean the flutes, irrigate, recapitulate and reassess the glide path before continuing.

- Use gentle apical pressure only and avoid forcing the instrument.
- Clean the flutes frequently and inspect the instrument throughout treatment.
- Maintain irrigation, lubrication and recapitulation according to the clinical case.
- If canal anatomy is complex, curved, calcified or uncertain, use additional caution and consider smaller instruments, hand negotiation, magnification and/or staged preparation.

10. Product range and order information

Part number	File / size	Tip size	Taper	Length	Pack	UDI/GTIN
TXET-230921RF	23/.09	23	.09	21 mm	6	TBC
TXET-230925RF	23/.09	23	.09	25 mm	6	TBC
TXET-230931RF	23/.09	23	.09	31 mm	6	TBC
TXET-150421RF	15/.04	15	.04	21 mm	6	TBC
TXET-150425RF	15/.04	15	.04	25 mm	6	TBC
TXET-150431RF	15/.04	15	.04	31 mm	6	TBC
TXET-200421RF	20/.04	20	.04	21 mm	6	TBC
TXET-200425RF	20/.04	20	.04	25 mm	6	TBC
TXET-200431RF	20/.04	20	.04	31 mm	6	TBC
TXET-250421RF	25/.04	25	.04	21 mm	6	TBC
TXET-250425RF	25/.04	25	.04	25 mm	6	TBC
TXET-250431RF	25/.04	25	.04	31 mm	6	TBC
TXET-300421RF	30/.04	30	.04	21 mm	6	TBC
TXET-300425RF	30/.04	30	.04	25 mm	6	TBC
TXET-300431RF	30/.04	30	.04	31 mm	6	TBC
TXET-350421RF	35/.04	35	.04	21 mm	6	TBC
TXET-350425RF	35/.04	35	.04	25 mm	6	TBC
TXET-350431RF	35/.04	35	.04	31 mm	6	TBC
TXET-400421RF	40/.04	40	.04	21 mm	6	TBC
TXET-400425RF	40/.04	40	.04	25 mm	6	TBC
TXET-400431RF	40/.04	40	.04	31 mm	6	TBC
TXET-150621RF	15/.06	15	.06	21 mm	6	TBC
TXET-150625RF	15/.06	15	.06	25 mm	6	TBC
TXET-150631RF	15/.06	15	.06	31 mm	6	TBC
TXET-200621RF	20/.06	20	.06	21 mm	6	TBC
TXET-200625RF	20/.06	20	.06	25 mm	6	TBC
TXET-200631RF	20/.06	20	.06	31 mm	6	TBC
TXET-250621RF	25/.06	25	.06	21 mm	6	TBC
TXET-250625RF	25/.06	25	.06	25 mm	6	TBC
TXET-250631RF	25/.06	25	.06	31 mm	6	TBC
TXET-300621RF	30/.06	30	.06	21 mm	6	TBC
TXET-300625RF	30/.06	30	.06	25 mm	6	TBC
TXET-300631RF	30/.06	30	.06	31 mm	6	TBC
TXET-350621RF	35/.06	35	.06	21 mm	6	TBC
TXET-350625RF	35/.06	35	.06	25 mm	6	TBC
TXET-350631RF	35/.06	35	.06	31 mm	6	TBC
TXET-400621RF	40/.06	40	.06	21 mm	6	TBC
TXET-400625RF	40/.06	40	.06	25 mm	6	TBC
TXET-400631RF	40/.06	40	.06	31 mm	6	TBC

UDI/GTIN values are to be confirmed on final released labelling and product master data before commercial distribution.

11. Sterility, storage and handling

- Supplied sterile. Do not use if the sterile barrier is damaged, opened, wet or otherwise compromised.
- Store in a clean, dry environment away from direct sunlight, excessive heat, moisture and chemical exposure.
- Do not use after the expiry date stated on the packaging.
- Do not subject unopened sterile packs to chairside sterilisation or processing.

12. Disposal and traceability

- After use, dispose of instruments as contaminated sharps in accordance with local clinical waste requirements.
- Record product identification, lot number and expiry information where required by practice policy, distributor requirements or regulatory procedures.
- Report product complaints, suspected defects or adverse events to EndoTech NZ and retain the product and packaging where practicable.

13. Symbols and labelling terms

Symbol / label text	Meaning
STERILE	Supplied sterile. Check the sterile barrier before use.
Single use only	Do not clean, disinfect, reprocess, re-sterilise or reuse.
LOT	Batch or lot number. Record as required for traceability.
EXP	Use-by or expiry date. Do not use after expiry.
REF	Catalogue or part number.
NiTi	Nickel-titanium alloy. Do not use in patients where NiTi allergy risk is clinically unacceptable.

14. Sponsor, manufacturer and supply details

Role	Details
New Zealand Sponsor / Distributor	ENDOTECHNZ LIMITED, 3C/14 Beaumont Street, Freemans Bay, Auckland 1010, New Zealand
Supply format	Sterile, single-use instruments supplied in sterile blister packaging, 6 instruments per pack unless stated otherwise.

15. Document control

Document number	ETNZ-IFU-TXET-001
Revision	A - design aligned draft
Effective date	[insert]
Prepared for	EndoTech NZ product file
Document owner	ENDOTECHNZ LIMITED