

<p><b>INSTRUCTIONS FOR USE</b></p> <h1>TransformX PT</h1> <p>Sterile, single-use nickel-titanium rotary endodontic instruments</p> <p><b>For use by trained dental professionals only. Read this IFU before use.</b></p>	<p><b>SEQUENCE-BASED SHAPING SYSTEM</b></p> <p>DOCUMENT: ETNZ-IFU-TXPT-001</p> <p>REVISION: A - design aligned draft</p> <p>MARKET: New Zealand</p> <p>SUPPLY: Sterile / single use</p>
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**Clinical quick view**

A sequence-based rotary file family for progressive shaping using SX, S1, S2 and finishing files selected according to canal anatomy.

## 1. Device description

**Device family**

TransformX PT 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 PT instruments are intended for progressive mechanical cleaning and shaping of root canals during non-surgical endodontic treatment, using a sequence-based rotary shaping approach selected according to canal anatomy and treatment objectives.

## 3. Indications for use

- Mechanical preparation of root canals during non-surgical root canal treatment.
- Progressive shaping using SX, S1, S2 and finishing instruments as clinically indicated.
- 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	Finish	Clean 3D	Seal
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Clinical step	Guidance
Entry condition	Use after canal negotiation, working length determination and glide path preparation.

Primary role	Progressive sequence-based shaping using SX/S1/S2 and selected finishing files.
Clinical control	Do not skip required canal negotiation or force finishing files to length.
Exit condition	Finishing file is selected by the clinician according to apical size, canal taper and irrigation objectives.

## 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 PT instruments in the recommended clinical sequence and in accordance with the clinician's judgement. Establish access, patency, working length and glide path before shaping. Remove each file frequently to clean flutes and inspect the instrument.

- 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
TXPT-SX-19	SX	19	Variable / progressive	19 mm	6	TBC
TXPT-S1-21	S1	18	Variable / progressive	21 mm	6	TBC
TXPT-S1-25	S1	18	Variable / progressive	25 mm	6	TBC
TXPT-S1-31	S1	18	Variable / progressive	31 mm	6	TBC
TXPT-S2-21	S2	20	Variable / progressive	21 mm	6	TBC
TXPT-S2-25	S2	20	Variable / progressive	25 mm	6	TBC
TXPT-S2-31	S2	20	Variable / progressive	31 mm	6	TBC
TXPT-F1-21	F1	20	.07	21 mm	6	TBC
TXPT-F1-25	F1	20	.07	25 mm	6	TBC
TXPT-F1-31	F1	20	.07	31 mm	6	TBC
TXPT-F2-21	F2	25	.08	21 mm	6	TBC
TXPT-F2-25	F2	25	.08	25 mm	6	TBC
TXPT-F2-31	F2	25	.08	31 mm	6	TBC
TXPT-F3-21	F3	30	.09	21 mm	6	TBC
TXPT-F3-25	F3	30	.09	25 mm	6	TBC
TXPT-F3-31	F3	30	.09	31 mm	6	TBC
TXPT-F4-21	F4	40	.06	21 mm	6	TBC
TXPT-F4-25	F4	40	.06	25 mm	6	TBC
TXPT-F4-31	F4	40	.06	31 mm	6	TBC
TXPT-F5-21	F5	50	.05	21 mm	6	TBC
TXPT-F5-25	F5	50	.05	25 mm	6	TBC
TXPT-F5-31	F5	50	.05	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

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