

DIRECTIONS FOR USE

DENTSPLY
TULSA DENTAL
SPECIALTIES

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Rx Only For Dental Use Only



Single Use Only



Sterilized Using Irradiation



CONSULT
INSTRUCTIONS
FOR USE



Do Not Use
if Seal is Broken



NONRETURNABLE
IF SEAL IS BROKEN

TRUShape® 3D conforming files for endodontic treatment are provided in the following configurations: four tip sizes (20/.06v, 25/.06v, 30/.06v, 40/.06v) with three lengths each (21 mm, 25 mm, 31 mm). The **v** indicates the files have variable, reduced taper.

COMPOSITION

The cutting part of these files is made of a nickel-titanium alloy with proprietary processing.

1. INDICATIONS FOR USE

The **TRUShape® 3D conforming files** are used in endodontic treatment for shaping and cleaning the root canal system.

2. CONTRAINDICATIONS

In common with all mechanically driven root canal files, the **TRUShape® 3D conforming files** should be used with caution in cases of very severe and sudden apical curvatures.

3. WARNINGS

- Per the 2010 American Association of Endodontists position statement, use a dental dam during the endodontic procedure.
- **TRUShape® 3D conforming files** are provided sterile and reuse can increase the risk of cross contamination or breakage.
- These files are to be used only in a clinical environment by qualified users.

4. PRECAUTIONS

- **TRUShape® 3D conforming files** are single use devices. They can become less efficient after multiple uses causing undue stress to the file. This can lead to file separation.
- Exercise caution in the apical area and around significant curvatures.
- **TRUShape® 3D conforming files** may lengthen 0.1 mm in normal use when compressed in narrow canals. The most elongation the file may undergo is 0.2 mm. This should be considered when setting the working file length.
- For your own safety, wear personal protective equipment (gloves, glasses, mask).

5. ADVERSE REACTIONS

This product contains nickel and should not be used when treating individuals with known allergic sensitivity to this metal.

6. STEP BY STEP INSTRUCTIONS FOR THE TRUShape® 3D conforming files

1. Estimate the working length using well-angulated preoperative radiographs.
2. Prepare a conservative access cavity sufficient enough to reveal all root canal orifices.
3. Scout canals with a #10 K-file in the presence of ProLube.
 - a. If the file advances easily to estimated working length (WL), confirm patency and determine WL using an electronic apex locator.
 - b. If the file meets resistance and the file does not progress gently to WL, use a dedicated NiTi file to modify the orifice to create a coronal receptacle for the subsequent TRUShape® 3D conforming file. Negotiate, confirm patency and determine WL.
4. Create a reproducible glide path to WL with PathFile® Root Canal Drills O13 and PathFile® Root Canal Drills O16.
5. Irrigate with sodium hypochlorite through-out the shaping procedure.
6. Choose the appropriate preprogrammed torque-controlled electric motor setting (300 RPM and 300 g-cm) for the selected TRUShape® 3D conforming file.
7. Advance the selected TRUShape® 3D conforming file (based on canal anatomy) passively in the presence of sodium hypochlorite with a gentle 2-5 mm in-and-out motion to shape the middle third. Use smooth 2-3 mm amplitude in-and-out motions towards the apex. Avoid abrupt pecking motions. When shaping canals that have a larger buccal-lingual dimension consider shaping as two canals.
8. Clean cutting flutes routinely upon removal of the TRUShape® 3D conforming files and remove debris with an alcohol moistened gauze.
9. If the selected TRUShape® 3D conforming file does not progress easily, remove, irrigate, and recapitulate with a #10 K-file to confirm canal patency and move to the next smaller TRUShape® 3D conforming file.
10. Inspect cutting flutes routinely upon removal for presence of unwinding and straightening. If deformation is noted, discard and use a new TRUShape® 3D conforming file. Reconfirm file working length setting.
11. Advance the TRUShape® 3D conforming file towards WL in a gentle/passive in-and-out motion.
12. Use copious irrigation; re-verify canal patency and working length throughout and upon completion of shaping. Gauge the size of the foramen with an appropriate hand file. If the gauging hand file is snug at length, the preparation is finished. If the gauging file is loose at length, use a larger TRUShape® 3D conforming file to finish the preparation.
13. Irrigate using sodium hypochlorite with activation in canal. Rinse with sterilized saline or de-ionized water and then activate QMix® 2in1 Irrigating Solution for 60-90 seconds per the QMix® 2in1 Irrigating Solution protocol.
14. Dry the canal thoroughly and obturate with a technique that promotes a three-dimensional fill.
15. Restore the endodontically treated tooth in a timely manner.