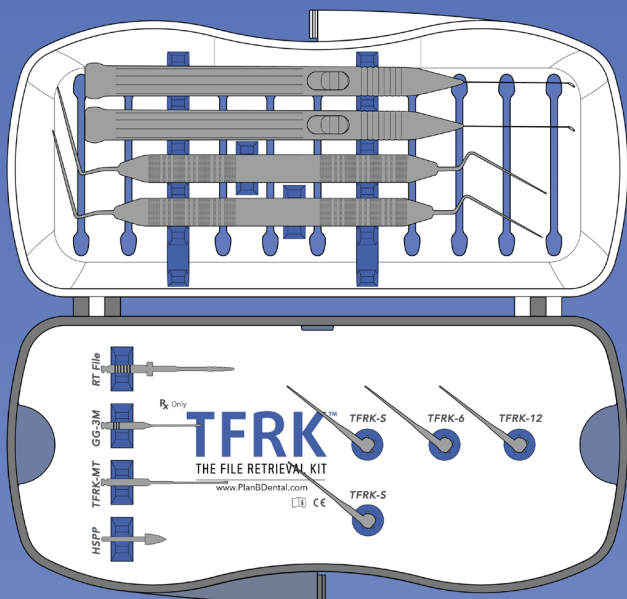


# THE FILE RETRIEVAL KIT (TFRK™)



## INSTRUCTIONS FOR USE

Applicable to Models TFRK-SET+, TFRK-EMS+,  
and replacement instruments



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**These Instructions for Use are applicable to the following KITS:**

- TFRK-EMS+ with EMS Style Ultrasonic Tips
- TFRK-SET+ with Satelec Style Ultrasonic Tips

**These Instructions for Use are applicable to the following replacement instruments:**

- TFRK-ME: Micro-Explorer Hand Instrument
- TFRK-GPR: Gutta-Percha Removal Hand Instrument
- GG-3M: Modified #3 Gates Glidden Bur
- TFRK-MT: Micro-Trephine bur
- TFRK-SM: Ultrasonic Tip Straight
- TFRK-S: Ultrasonic Tip Straight
- TFRK-6M: Ultrasonic Tip 6 o'clock
- TFRK-6: Ultrasonic Tip 6 o'clock
- TFRK-12M: Ultrasonic Tip 12 o'clock
- TFRK-12: Ultrasonic Tip 12 o'clock
- TFRK-L+: Loop+

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# INTRODUCTION

## TFRK Intended Purpose:

The File Retrieval Kit (TFRK) is a set of tools used to remove broken endodontic file segments from the root canal of a tooth.

This Instruction for Use is applicable to:

- **TFRK-EMS+:** The File Retrieval Kit with EMS style ultrasonic tips
- **TFRK-SET+:** The File Retrieval Kit with Satelec style ultrasonic tips

Note: The TFRK comes with two styles of ultrasonic tips (EMS style and Satelec style), where the thread pitch is finer on the EMS (4 flat planes) and coarser on the Satelec (2 flat planes) – see photo.



A suffix is used to distinguish between the style of ultrasonic tip provided with the TFRK, e.g., TFRK-EMS+ or TFRK-SET+.

For Professional Use Only

## Indications for Use:



- \* Sterilize Before Use.  
Esterilizar antes de usar.  
Stériliser avant utilisation.  
vor Gebrauch sterilisieren.

See Pages 24-29 of Instructions for Use.



- Read Instructions Before Use.**  
Manufacturer recommends that user familiarize themselves with the device components and read all instructions before using the device.

\* While this symbol is used to indicate that "a device that is normally provided sterile in the same or similar packaging has not been sterilized," this symbol is also used to indicate that "a device that the manufacturer intends to be sterilized has not yet been through the sterilization process."

**Contraindications:** *None Known*



### **WARNING**

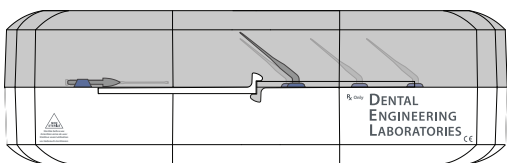
- **For Professional Use Only**
- **Not Intended for Use by Dental Assistant or Hygienist**
- **To Be Used in a Dental Office Setting**

**Adverse Reactions:** *None Known*

### **Risks:**

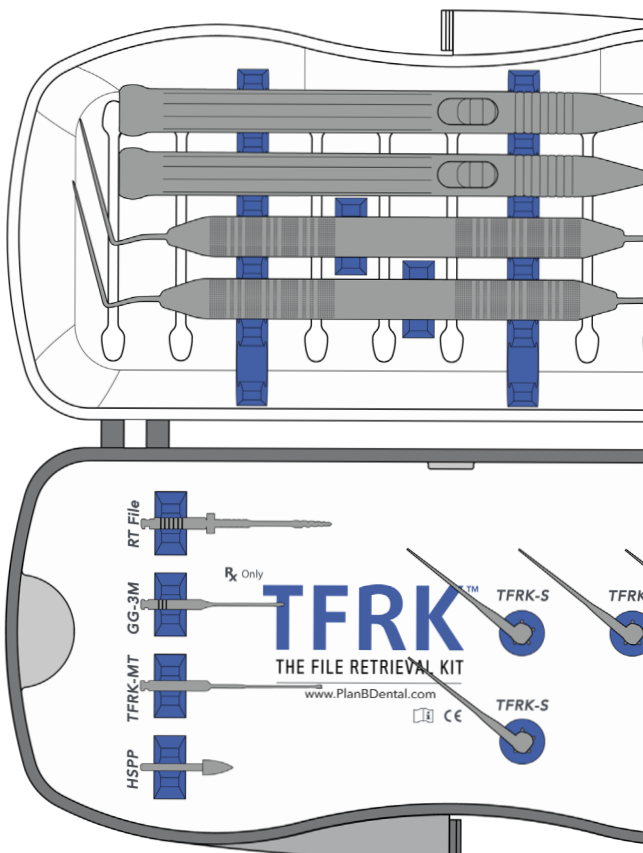
- Harmful effects: *None Known*
- Incidence of Harmful Effects: *None Known*
- Environment Factors That Influence Device Use: *None Known*

# WHAT'S INCLUDED

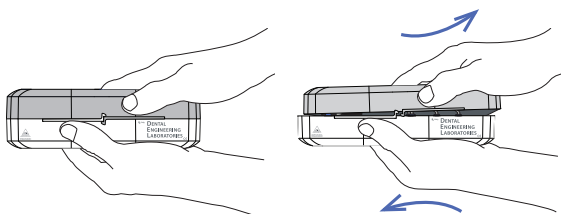


## Autoclavable Cassette

The File Retrieval Kit (TFRK) comes in an autoclavable cassette that opens and stacks so all the pieces are accessible.







## Opening the Cassette

Flex the top and the bottom parts of the TFRK cassette sideways apart from each other to open the cassette. After opening the cassette, lift the top plate, rotate and install it in the cassette lid so all the tools are visible and accessible.

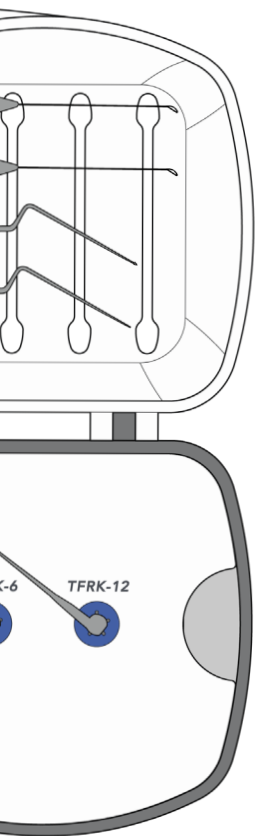
### Inside the Cassette

#### Bottom Shelf

- (2) Loop+:TFRK-L+
- (1) Micro-Explorer Hand Instrument: *TFRK-ME*
- (1) Gutta-Percha Removal Hand Instrument: *TFRK-GPR*
- (2) TrueTooth® Training Replicas (not pictured)

#### Top Plate

- Retreatment Rotary File
- (1) Modified #3 Gates Glidden Bur: *GG-3M*
- (1) Micro-Trephine Bur: *TFRK-MT*
- (1) High Speed polishing point: *HSPP*
- (2) Ultrasonic Tip Straight: *TFRK-S/ TFRK-SM*
- (1) Ultrasonic Tip 6 o'clock: *TFRK-6/ TFRK-6M*
- (1) Ultrasonic Tip 12 o'clock: *TFRK-12/ TFRK-12M*



## Rotary Devices



### Retreatment Rotary File

This instrument is used to enlarge the canal to the separated instrument when the coronal diameter of the separated file is larger than 0.45 mm (this can be determined by gauging with a #45 K-file or Buchanan pluggers place on the separated file), or the canal curvature is greater than 15 degrees. It is used at 500 rpm in a clockwise direction.



### GG-3M

The GG-3M is a modified #3 Gates Glidden bur: the pilot tip is removed but the football shape is retained so it cuts a staging preparation down to the file segments following the canal path already shaped by the separated file before the fracture. The maximum diameter of this bur is 0.9 mm and the tip diameter is 0.45 mm. It is used at 1,000 rpm in a clockwise direction.



### TFRK-MT

The TFRK-MT is a Micro-Trephine bur. It has a tiny cylinder with cutting blades on its tip to create a trough 1 mm deep around the coronal portion of the separated file. The outer diameter of the TFRK-MT is 0.6 mm so that it will sequentially follow a canal enlarged with the Retreatment File and/or the GG-3M. The inner diameter of the trephine is 0.45 mm so that it can cut around separated files with diameters smaller than 0.45 mm at the broken edge. The TFRK-MT is used at 600 rpm in a counter-clockwise direction to encourage separated files to unthread from the canal as the trough is cut.

## Ultrasonic Tips

There are two spoon tips (TFRK-6/ TFRK-6M and TFRK-12/ TFRK-12M) and two straight tips (TFRK-S/ TFRK-SM) in the TFRK. These ultrasonic tips are carefully bent to meet the fractured file surface on the inside of the canal curvature.

The latch-grip polishing point is used to sharpen the TFRK-S/ TFRK-SM every time it is used.

### TFRK-6/ TFRK-6M & TFRK-12/ TFRK-12M

The TFRK-6/ TFRK-6M and TFRK-12/ TFRK-12M Ultrasonic Tips are micro-spoons with cupped surfaces facing toward or away from the hand-piece, respectively. The TFRK-6 and TFRK-12 are Satelec style tips, whereas the TFRK-6M and TFRK-12M are EMS style tips. The output power of the TFRK-6 / TFRK-6M is 0.046Watts. The output power of the TFRK-12/ TFRK-12M is 0.056Watts. These instruments are used (dry) to wedge into the space on the inside of the canal curve between the separated file and the canal wall, creating a small space adjacent to the fractured file edge. After the initial use to cut a semicircular slot next to the file segment, use the TFRK-S/ TFRK-SM to complete the semicircular space. The ultrasonic preparation continues until the movement of the broken instrument is confirmed under the magnification.



TFRK-6 view from handpiece.



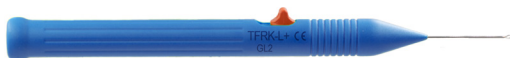
TFRK-12 view from handpiece.

### TFRK-S/ TFRK-SM

When rotation of the handpiece is limited by oral structures, the straight tip can be used to widen the inside-of-the-curve slot if needed. The straight tip is provided both as a Satelec style tip (TFRK-S) and EMS style tip (TFRK-SM). The output power of the TFRK-S/TFRK-SM is 0.022Watts. The main function of the TFRK-S/ TFRK-SM ultrasonic tip is to give ultrasonic agitation to the separated file after space has been cut with one or both micro-spoons. The tip moves file tips out of the canal most effectively in the presence of 17% aqueous EDTA solution.



TFRK-S view from handpiece.



TFRK-L+

### TFRK-L+

The TFRK-L+ is a micro-lasso comprised of a tiny wire loop at the end of a stainless steel cannula and a blue handle with a red sliding retraction button that tightens the loop when pulled back away from the tip. The loop can

be used to capture and retrieve a separated file segment that is loosened but remains in place after using the TFRK ultrasonic tips. This is a common situation when the file segment is longer than 4.5 mm.



**WARNING: The TFRK-L+ is a fragile device. With proper care, it is very effective. Please keep the following in mind when using the loop:**

1. The separated file must be loosened in the canal with the TFRK ultrasonic tips before using the TFRK-L+. The loop will not be able to pull out a file fragment that is still stuck in the canal; attempting this will break the loop before the file will exit the canal.
2. When engaging the red button to tighten the lasso, move the button very gently. Abrupt movement can kink the lasso and break or weaken the micro-lasso.
3. Tighten the micro-lasso only after securing the separated file; unnecessary tightening and loosening of the wire will shorten its lifespan.
4. Use gloved fingers to bend the tube portion as needed. Using pliers will pinch the structure and break it.
5. Use a DG16 endodontic explorer to form and adjust the loop size. Place the loop over the tip portion of the explorer to make the loop size smaller, the middle portion of the explorer to make it medium size loop, and the shank end of the explorer to make it larger.
6. Bend the formed loop to 45 degrees by rotating the DG16 explorer it is formed around. This angle imparted to the formed micro-lasso will facilitate its placement over the separated file.



## Retreatment Hand Instruments

The retreatment hand instruments have two ends that are extra long and angled obtusely and acutely to accommodate different canal angles.



### TFRK-ME

The Micro-Explorer (TFRK-ME) hand instrument has extremely fine spear-shaped tips with a smooth surface for bypassing ledged canals and exploring the canal for broken files or other impediments. This instrument can be bent to meet the canal curvature so that the TFRK tips can be precurved the same way as it is before use. When there is a ledge formed coronal to the separated file in the canal, the TFRK-ME can be used to locate the original canal and the ledge can be reduced by using it with several push-pull strokes. When the tip portion gets short or blunt, it can also be sharpened with the polishing point in the kit.



### TFRK-GPR

The gutta-percha removal instrument (TFRK-GPR) has arrow-shaped barbed cones on both ends to engage filling material remnants during removal procedures.

## STEP-BY-STEP INSTRUCTIONS

**For separated files with coronal diameters greater than 0.45 mm, or canal curvature greater than 15 degrees:**

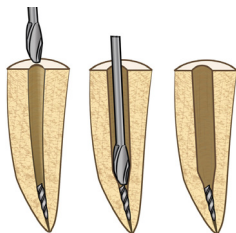
### Using the NiTi Rotary File

If the coronal diameter of the separated file appears to be larger than 0.45 mm (this can be determined by gauging with a #45 K-file or Buchanan Pluggers placed on the separated file), or the canal curvature is greater than 15 degrees, use the Retreatment Rotary File included in the TFRK (instead of the GG-3M) to cut a staging preparation to the separated file edge. The Retreatment Rotary File should be used at 500 rpm in a clockwise direction.

**For separated files with coronal diameters less than 0.45 mm, or canal curvature less than 15 degrees:**

### Using the Modified #3 Gates Glidden Bur, GG-3M

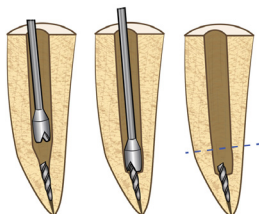
If the coronal diameter of the separated file appears to be smaller than 0.45 mm (this can be ascertained by gauging the canal space just behind the broken edge of the separated instrument), use the GG-3M in a clockwise motion at 1,000 rpm to create working space for the Micro-Trephine bur (TFRK-MT), which will cut the canal wall to expose the coronal portion of the file segment. Using the GG-3M at this point will reduce the risk of ledge formation with the TFRK-MT.



### Using the Micro-Trephine Bur, TFRK-MT

Use the TFRK-MT in a counter-clockwise (CCW) motion

at 600 rpm. This CCW rotation imparts an unscrewing effect on the separated file which may then be spun out of the canal. If the rotational speed of the bur exceeds 800 rpm, you run the risk of creating a ledge, especially in a curved canal. Especially when the separated file is less than 3mm, theoretically it may possibly be removed with the TFRK-MT burs as the coronal 1 mm of the separated files can be freed by this bur.



## Using TFRK Ultrasonic Tips (after coronal enlargement):

### Creating a small space on the inside curve canal wall

After the canal preparation for instrument retrieval with the GG-3M and TFRK-MT, the next step is to use TFRK Ultrasonic Tips to complete the root canal preparation. Use of the burs in the previous steps should have exposed the coronal portion of the separated file; however, the space created on the inner curve still needs to be extended in the apical direction with the TFRK Ultrasonic Tips. The TFRK Ultrasonic tips must be firmly tightened onto the handpiece mounting threads with either a hemostat or a 3 mm tip wrench.



**WARNING: The maximum peak to peak amplitude of the ultrasonic tips may exceed 200µm under no load.**



Caution! Aggressive ultrasonic troughing around the separated file prior to TFRK-MT use may result in secondary fracture of the file segment.



TFRK Ultrasonic Tips are best turned to ideal power settings by beginning their use at the lowest power setting and gradually increasing the power until resonance is achieved. These are perhaps the smallest ultrasonic tips in dentistry, and as such will not withstand a high setting (medium power is considered a high power setting for these tips), nor is it necessary to make them cut effectively. A setting of 2-5 out of the full power

range of 20 (or 1-3 on a Dentsply ProUltra Piezo unit) is typically an ideal setting. Depending on the ultrasonic unit you use, the settings may be different, but should be closer to a 1/8-1/4 power setting of a medium setting.

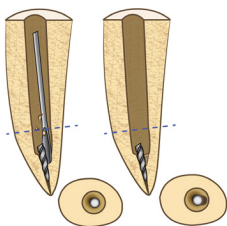
In most cases, the coronal one-third of the separated file is the source of removal complications. This portion is usually surrounded by the canal wall, susceptible to secondary breakage, and resistant to mechanical force for disengagement. It must be freed from its engagement in dentin before attempting removal. Creating a thin space on one side (always the inner side of a curved canal) is sufficient to loosen the separated file instead of troughing around it. Freeing the coronal one third of the separated file must be done in dry conditions using air coolant to both maintain clear vision and cool the tip in the operative field.



TFRK Ultrasonic Tips have very elongated geometry, and as such, should not be operated unengaged (held free in the air while switched on) as the sine wave of vibration that ripples down the long, narrow stalk in an unengaged situation will cause premature failure due to cyclic fatigue. The tips require the dampening effect of being in light contact with a hard surface (e.g. tooth structure, any metal instrument, etc.) as the power setting is tuned and during use. Pulsing activation is recommended while in contact with dentin to avoid premature breakage.

### Exposing the coronal portion of separated files

If rotary instruments other than the GG-3M and TFRK-MT were used to enlarge the canal to the separated file in the previous stage, then you must use Ultrasonic Tips to manually expose the coronal portion of the separated file. Use the micro-spoon tips (TFRK-6/ TFRK-6M and TFRK-12/ TFRK-12M) around the coronal aspect of the separated file on the inside of the curvature of the canal.







The greatest power achieved between the TFRK Ultrasonic Tip end and dentin around the separated file segment is upon delivery of the first pulse of power. It's like cracking a whip: If you can imagine the stalk of the instrument sending a wave down its length, when it arrives at the tip there is a remarkably violent, yet microscopic, movement against the dentin canal wall. You will get the greatest amount of troughing around the broken file end and the longest life of the tip when it is used with intermittent power switching, in other words, by "popping" the foot control repeatedly to activate the tip.

This method of use delivers optimal movement of the cutting end while reducing the generation of heat and cyclic fatigue accumulation in the instrument (cyclic fatigue accumulates every second the tip is being powered). Heat produced by continuous ultrasonic activation is another cause of premature failure, so the intermittent powering suggested will reduce the heat generated and help extend the ultrasonic tip life. Usually it is ideal to send 1-2 second amount of ultrasonic power pulses through the tip with constant air coolant given from the three-way syringe by your assistant to prevent temperature rise, then remove it. When the separated file is covered with debris, take the tip out and rinse the canal. Wipe the tip with alcohol gauze, which will provide the time to bring the heated tip back to room temperature. Inspect the tip and sharpen, if needed, using the HSPP provided in the kit then put it back into the canal to do more work.



The troughing spoons (TFRK-6/ TFRK-6M and TFRK-12/ TFRK-12M) and the straight tip (TFRK-S/ TFRK-SM) are used dry (bent to work only on the inside of the canal curve) until the file has been loosened, then Aqueous EDTA solution is added to take advantage of cavitation effect (turbulence) created by the ultrasonic energy resulting in propelling the segment out of the canal with the straight tip once again engaged on the inside of the canal curvature only. The activated straight tip should be moved in short push-pull motions within the thin space created previously in the presence of EDTA solution to induce the micro-cavitation (micro-turbulence) needed in the canal to encourage the separated file segment to exit the canal. The straight tip has to always be sharp and thin to make room for the separated file to exit

the canal and it is used in this final wet conditions with the continuous activation mode as the EDTA solution in the canal buffers both the heat rise and the ultrasonic activation. The straight tip should be sharpened with the included metal polishing point (HSPP, provided with the TFRK), every time it is used. During the dry use of these tips, the above suggestions are especially important. The sharpened straight tip is used in the final wet step with the same intermittent moving and activation mode.

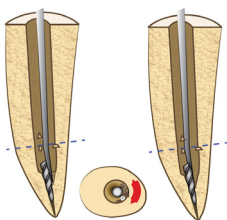


Caution! Files may fracture into even smaller pieces:

A fatigued separated file is extremely susceptible to secondary fracture by ultrasonic activation, even when tips are at the lowest power setting. To reduce the risk of fracture, cut a semicircular trough on one side (the side of the file segment on the inside of the canal curvature), as this leaves the outside of the curved canal wall to support the file segment, thus reducing the likelihood of secondary file separation. Especially in a curved canal, you should always apply ultrasonic activation to the narrow space between the separated fragment and the inside curvature. In other words, the dentin wall supporting the separated file fragment (on the outside of canal curvature) must always be present opposite the ultrasonic activation site on the inside of the canal curvature to prevent secondary fracture of the file segment.

### Using the TFRK-S/ TFRK-SM Ultrasonic Tip to loosen file segments

Repeated polishing of the straight tip with the included polishing point (HSPP) is critical. The straight tip should be as thin as possible to maximize visibility in the operative field, prevent over-enlargement of the canal wall, and to provide an escape space for the separated file. The thinner the straight tip is, the more effectively it creates the microcavitation needed.



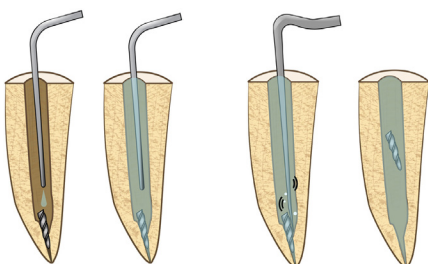
Use the troughing spoons to create a semicircular space; these tips have a concave shape that look and

function like extraction elevators to wedge between the canal wall and separated file and dislodge the file. The straight tip is used to extend the space apically and laterally to complete the semicircular space and eventually loosen the separated file that's engaged in the canal wall. If the troughing spoon loosens the separated file while preparing the canal, the preparation is considered done. In such a case, the use of the straight tip is no longer necessary in the preparation stage.

When the straight tip is wedged in the small space and activated on the inside curvature, it may cause the separated file to be shifted to a more coronal level or completely freed. If the tip is activated on the outside curvature of the canal, the ultrasonic energy will drive the separated file further into the canal. Check for a smooth canal wall. Once a narrow space is established, it is important to make sure that the canal wall is smooth from the separated file to the coronal extent; bumps, impediments, or overhangs on the outside canal wall may block the removal path for the separated file. Use a bent straight tip to carefully smooth the canal wall on the outside of the curvature after troughing the inside-of-the-curvature canal wall and loosening the file segment to remove any impediments that can block the escape path for the separated file.

### How to agitate with TFRK Ultrasonic Tips

Fill the canal with EDTA solution to enhance the ultrasonic cavitation effect and acoustic streaming for separated file removal.



**WARNING: Don't wedge the file fragment further into the canal:**

Ultrasonic activation should be applied to the space created between the separated file and the inside curve of the canal in push-pull motions until the file fragment is removed. Again, please remember, when ultrasonic energy

is applied to the outside of the canal curvature, the file segment will be driven further apically. To avoid breaking the ultrasonic tips, use short pecking motions within the thin space. Wedging the tip tightly between the separated file and the canal wall when activated will increase the possibility of breaking the thin tip.

### **When to remove more dentin**

If the separated file is shorter than 4.5 mm and it shows resistance to disengagement (no movement with ultrasonics) for more than 60 seconds after the one-third space of the separated file length is created, more dentin wall needs to be cut with the straight tip apically along the inside-of-the-curvature wall adjacent to the separated file. In this process, you are deepening (dry) the pocket in dentin wall and loosening the file fragment from the canal wall. Then, again, fill the canal with EDTA solution and use a bent straight tip on the inside-of-the-curvature canal wall to free the file fragment. Even if the separated file is shorter than 4.5mm, it will tend to show more resistance to disengagement as it gets closer to 4.5mm. If this is the case, do not hesitate to use the TFRK-L+ instead of continuously activating ultrasonics to retrieve it. It is faster to use the loop to remove a broken file shorter than 4.5mm when it doesn't exit the canal with ultrasonics in 10 seconds.

### **How to Use the TFRK-L+**

If the separated file is longer than 4.5 mm and it can be seen shaking from ultrasonic activation, or if a separated file shorter than 4.5 mm hasn't come out of the canal in 10 seconds of ultrasonic activation, the TFRK-L+ should be used to capture the coronal portion of the separated file and pull it out of the canal.

### **Creating space for the TFRK-L+**

The canal must be at least 0.4 mm wide (the width needed for the Loop wire) in addition to the coronal diameter of the separated file, to secure the operative field for the TFRK-L+ device. In other words, if the broken edge of the file segment gauges at .35 mm, the operative space for the TFRK-L+ would require 0.75 mm. Dentin sacrifice to create extra space for the TFRK-L+ is typically not significant as the coronal end of a separated file that is longer than 4.5 mm will usually be in the middle third of the root surrounded by a thick dentin wall (the maximum diameter of most conventional rotary files is between 1-1.2mm so this amount

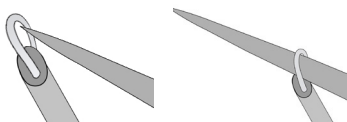
of enlargement is within the size of most root canal shaping objectives). Place a yellow Buchanan plugger to see if there is enough space available for the loop as the diameter of the #2 Buchanan plugger is a little larger than 0.4mm. If the tip of this plugger can be placed between the separated file and the space created in the preparation stage, the TFRK-L+ can also be safely placed in it.

If needed, additional space can be most easily created by using the Retreatment Rotary followed by re-use of the appropriate troughing spoon on the inside-of-the-curve canal wall.

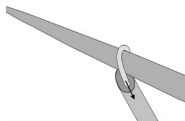
### Preparing the TFRK-L+

Once the coronal portion of the separated file is peripherally exposed by at least 0.7 mm on average (e.g., when a 3 mm segment of a 20-.04 rotary file has separated in the canal, the coronal diameter will be around 0.32 mm and the needed operative space is an additional 0.4 mm), the loop size must be adjusted to the coronal end of the separated file with an endodontic explorer. This is done as follows:

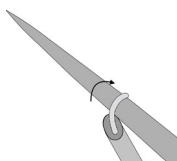
1. First insert the tip of the explorer into the loop and slide the explorer into the loop until the diameter of the loop adjusts to the coronal end of the separated file.



2. Tighten the loop around the explorer by gently pulling back on the red button on the blue handle.



3. Then rotate the explorer to bend the loop at a 45 degree angle to the loop cannula.



- This allows the end of the loop to enter the trough prepared space next to the broken file segment, after which the remainder of the loop is pushed back to 90 degrees as it further surrounds the separated file when the loop cannula lands on the file in its final position in the canal.



### Retrieving a file fragment with a TFRK-L+

Bring the loop into the canal with the loop cannula on the inside-of-the-curvature side of the file segment and the loop extended toward the outside-of-the-curve side of the file segment and place it over the exposed portion of the separated file. Secure the separated file segment by sliding your finger down the red button- activating it and carefully pull back on it until the loop starts to tighten around the freed end of the file segment. You will feel tension on the button from tightening the loop around the separated file. Gently lift the loop out of the canal while maintaining this tension. Typically, only a single gentle pull will be required to dislodge the file fragment as it is already loosened. If you feel greater resistance when lifting the TFRK-L+, try pulling it anti-clockwise direction, one of which will eventually result in instrument retrieval depending on the free space available in the canal to let it pass through.

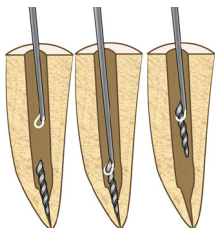
If the loop slips off the file fragment, simply remove the TFRK-L+, again create a round shape in the micro-lasso by tightening it around the appropriate diameter of an explorer, rotate the explorer parallel to the loop cannula to bend it to a 45 degree angle, re-insert it and re-engage the file segment.



Close-up of a bent TFRK-L+ cannula without kinking for insertion into a canal.

More than one attempt may be required to secure the loop around the file segment. Be certain before you use the TFRK-L+ that the file segment has been loosened by the Ultrasonic Tips before attempting to remove it with the TFRK-L+. The separated file also has to be tightened firmly with the loop while the tension on the loop is maintained

securely enough not to slip off the file fragment as it being pulled out. Do not mistake a file segment's flexing for it being loose. A long separated file segment is apt to flex with ultrasonics, seemingly loosened when in fact it is still engaged in the canal wall and not yet ready to be removed with the TFRK-L+.



Never tighten the loop against the cannula end when it is not engaged around an explorer or file segment as this will kink and weaken the micro-lasso wire, accelerating its failure.

When used correctly, the TFRK-L+ will usually remove 2-3 file fragments before breaking.

# CARE INSTRUCTIONS

## Dental Engineering Laboratories LLC

### Processing instructions: The File Retrieval Kit (TFRK)

Dental Engineering Laboratories has conducted sterility testing of The File Retrieval Kit (TFRK) after following the processing procedures identified below, and confirms the TFRK is sterile at the conclusion of the defined steam-gravity cycle.

However, national authorities can require the final effectiveness of the process provided below to be verified by the user.

Moreover, national authorities may allow or require the use of an alternative process than provided. In such cases, national authorities may require validation of those processes by the user.

### WARNINGS



#### WARNING

**If the TFRK has been used on a patient with Creutzfeldt-Jakob Disease (CJD) (confirmed or suspected CJD), the kit cannot be used again. Since even with processing and sterilization the risk of cross contamination cannot be eliminated, the kit has to be destroyed.**



#### WARNING

**Check each of the instruments for wear and tear before use. Re-use is not advised in case of damage to any component.**



#### WARNING

**The maximum peak to peak amplitude of the ultrasonic tips may exceed 200µm under no load.**






### Limitations on processing



#### Caution

The reprocessing and further use of The TFRK should only take place where permitted by national law and while complying with the requirements laid down in Directive 93/42/EEC.



	<p><b>Caution</b></p>	<p>The autoclavable cassette, complete with silicon supports, has been tested in 200 sterilization cycles.</p>
	<p><b>Caution</b></p>	<p>When used correctly, each TFRK-L+ will remove 2-3 file fragments before breaking. Do not re-use the TFRK-L+ more than five times.</p>
<h2>Instructions</h2>		
<h3>Initial treatment at the point of use</h3>		
	<p><b>Caution</b></p>	<p>The sterilization equipment must be maintained and checked regularly, according to equipment manufacturer's instructions.</p>
	<p><b>Caution</b></p>	<p>New autoclavable cassettes and silicon supports must be washed before first use.</p> <p>When sterilizing, use the tray with silicon supports to hold surgical tools.</p> <p>Sterilize all instruments in cassette provided.</p> <p>Sterilize unwrapped.</p>
	<p><b>Caution</b></p>	<p>It is a good idea to wash the autoclavable cassettes with soap and water before each use in order to keep bacterial levels low. If the autoclavable cassette has not been used in a long time, or if contamination with biological material is suspected, the cassette should undergo a deep cleaning in which the silicon supports are removed and disinfected using the typical procedure for the preparation of instruments and surgical tools for steam sterilization.</p> <p>If the silicon supports have been removed, dry the cassette before reassembly.</p> <p>A visual inspection can verify the integral state of the cassette.</p>



Sterilizable in a steam sterilizer (autoclave)  
Maximum temperature of 135°C  
Cycle duration of 3 minutes.



### Caution

Autoclavable cassettes are not able to retain sterility; to keep them sterile, they must be placed, together with their contents, inside bags which are able to preserve sterility.

## Preparation before cleaning

### Instructions:

1. Place the tools to be sterilized in their proper supports which will hold them still during the sterilization cycle.
2. Laboratory tools should be inserted into the silicon support by their stems, leaving the area to be sterilized uncovered. Surgical tools should be inserted handle first and not by their working end.
3. The tray with utensils should be placed inside the cassette which can then be closed.

## Cleaning– Automated

### Instructions:

1. Remove TFRK-L+ (Loops) from autoclavable cassette and set aside. \*See Instructions for cleaning TFRK-L+ (Loops) manually.
2. Submerge entire TFRK autoclavable cassette in ultrasonic cleaner using solution recommended by unit manufacturer.
3. Use pH-balanced cleaners.
4. Activate ultrasonic unit for 5-7 minutes depending upon unit manufacturer specifications.
5. Remove TFRK autoclavable cassette and rinse with demineralized water after each ultrasonic cleaning.

## Cleaning– Manual

### Instructions:

1. Clean instruments externally with alcohol.
2. Rinse with sterile saline or water.

### \*Instructions for cleaning TFRK-L+ (Loops) manually:

1. TFRK-L+ (Loops) push red button in forward position with loop extended.
2. Hand-clean using mild soap or wipe externally with alcohol.
3. Rinse with demineralized water and set aside.

4. Loops are fragile – be gentle.
5. Retract TFRK-L+ loops into handle before returning to autoclavable cassette.
6. TFRK is ready for steam autoclave sterilization process.

**Disinfection– N/A**

**Drying– N/A**

### Maintenance, Inspection and Testing

The autoclavable cassettes must be washed before first use.

Depending on use, it is a good idea to wash with water and detergent before each subsequent use.

The box should be cleansed with mild and non-abrasive detergents.

No other maintenance is necessary.

**Packaging– N/A**

### Sterilization



#### Caution

Autoclavable cassettes are not able to retain sterility. For this reason it is necessary to put the autoclavable cassettes with the utensils to be sterilized in special bags (with reference to EN 868).

### Instructions:

1. Place the tools to be sterilized in their proper supports which will hold them still during the sterilization cycle.
2. Laboratory tools should be inserted into the silicon support by their stems, leaving the area to be sterilized uncovered. Surgical tools should be inserted handle first and not by their working end.
3. The tray with utensils should be placed inside the cassette which can then be closed.
4. Insert autoclavable cassette in sterilization unit or machine.
5. Following unit manufacturer instructions, set 3-minute cycle with 0-1 -minute dry time.
6. Temperature: 135 degrees Celsius (275 degrees Fahrenheit)
7. Allow for complete drying cycle before use or storage.
8. TFRK is ready for use.
9. The user is responsible for the sterility of the instruments.

**Steam - Gravity:**

Temperature:

Cycle Time:

Drying Time:

**Unwrapped Instruments:**

135°C (275°F)

3 minutes

0-1 minutes

## Storage



### Caution

Autoclavable cassettes are not able to retain sterility; to keep them sterile, they must be placed, together with their contents, inside bags which are able to preserve sterility.



### Caution

After using the tools, the autoclavable cassette must be placed in a protected place to avoid unnecessary contamination until re-use.

## Additional information

Exposure to sunlight can cause the cassette to change color but will not compromise its resistance to sterilization or its ability to be sterilized.

The box and tray are made from Radel®. For disposal, the product should be incinerated at a suitable incineration facility with authorization by the proper authorities. Where local regulations allow, it can be disposed of in a landfill.

## Manufacturer contact

Dental Engineering Laboratories, LLC  
ATA PlanB Dental

315 Bollay Drive #150  
Goleta, CA 93117

[www.planbdental.com](http://www.planbdental.com)  
[info@planbdental.com](mailto:info@planbdental.com)

USA & Canada 1.800.528.1590  
International +805.899.4529

The instructions provided above have been validated as being capable of preparing the TFRK for use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

Date issued: January 2023

## General Precautions



**Sterilize Before Use.**  
**Esterilizar antes de usar.**  
**Stériliser avant utilisation.**  
**vor Gebrauch sterilisieren.**

- For professional use only.
- Follow instructions and recommendation provided by sterilization unit manufacturer.
- Allow for complete drying cycle before storing or use.

### Rotary Devices

- Do not cut the Retreatment Rotary File or the TFRK Burs to the broken file edge when the curvature of the canal is over 30 degrees or the end of the separated file is in the apical one third of the canal to avoid perforation.
- The Retreatment Rotary File should be used at 500 rpm in a clockwise direction. The GG-3M should be used at 1000 rpm in a clockwise direction. The TFRK-MT should be used at 600 rpm in a counter clockwise direction.
- Ensure proper attachment to compatible low-speed handpiece.

### Ultrasonic Tips

- Ensure proper attachment to compatible ultrasonic handpiece.
- Use the ultrasonic handpiece between 1/8 and 1/4 of its power band when using ultrasonic tips.
- Use tips in intermittent power modes, never continuously.
- Use an air stream from an air/water syringe and intermittently wipe tips with a chilled alcohol gauze to keep cool when used dry.

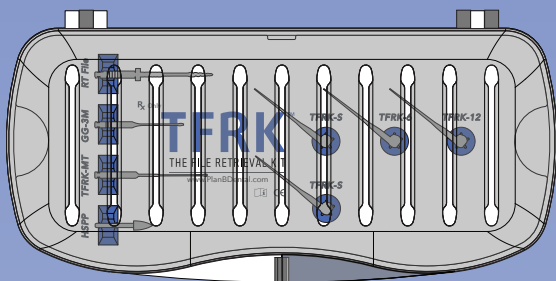
### TFRK-L+

- Never tighten the micro-lasso without an explorer or file segment engaged.
- Never use the TFRK-L+ until the broken file segment has been loosened with the TFRK Ultrasonic Tips.

## Hand Instruments

- Remove plastic packaging tube from tips of TFRK-GPR and TFRK-ME.





For more information:  
Call **PlanB Dental** at  
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