

EndoVac®

Apical Negative Pressure
Irrigation System



Instructions for Use

DISCUS™

Discus Dental, LLC.
8550 Higuera Street
Culver City, CA 90232 (USA)
North America: (800) 817-3636
International: +1 310 845 8260
discusdental.com

EC REP

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

CE 0470

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Table of Contents

Description of the Device	1
How Supplied	1
Indications for Use	2
Contraindications	2
General Warnings & Precautions.....	2
Preclinical Considerations	3
Multi-Port Adapter and MDT Set-Up in the Operatory	4
MDT Use During Instrumentation.....	6
MacroCannula – Clinical Set-up.....	8
MacroCannula – Clinical Use	9
MicroCannula – Clinical Set-up.....	10
Micro Evacuation.....	11
MicroCycle Technique	12
Troubleshooting.....	15
Sterilization and Maintenance	17
Warranty	17

Description of the Device

The EndoVac® apical negative pressure irrigation system (the “EndoVac system”) presents a unique and safe new way to irrigate during root canal treatments. Unlike positive pressure systems which use a cannula or side-port needles to deliver irrigants in the canal, the EndoVac system is a true apical negative pressure system that draws fluid apically by way of vacuum suction. Because the system utilizes negative pressure irrigation, solutions are suctioned from the pulp chamber, apically, to the apical termination and then away into the office Hi-Vac system. Negative pressure irrigation means that irrigants are never forced through the apical foramen, virtually eliminating any risk of an irrigation accident.

This patented system is comprised of three parts: The Master Delivery Tip (MDT), which allows for abundant and simultaneous irrigation and evacuation without leaks and spills into the patient’s mouth; The MacroCannula, which removes coarse debris left in the canal from instrumentation; and the MicroCannula, which removes microscopic debris at the apical 1 mm via 12 microscopic, laser-drilled holes, each 100 µ in diameter.

How Supplied

The EndoVac Starter Kit includes all major components*:

- | | |
|---------------------------------------|---|
| A. Handpiece | H. 3 cc Syringes for EDTA (15-17%) |
| B. Fingerpiece | I. MDT Evacuation Tubing (Blue Connectors) |
| C. Multi-Port Adapter | J. Handpiece/Fingerpiece Evacuation Tubing (White Connectors) |
| D. MacroCannulas | K. Instructions for Use (not shown) |
| E. MicroCannulas** | L. Quick Setup Guide (not shown) |
| F. 20 cc Syringes for NaOCl (5.25-6%) | |
| G. Master Delivery Tips (MDT)† | |



*All components above can also be re-ordered separately.
 **MicroCannulas can be reordered in 21, 25, 31 mm and 50 mm lengths.
 †When re-ordering MDTs, be sure to indicate that you are ordering the MDTs with the BLUE luer fitting. The previous version of EndoVac MDTs had a red connection.

Indications for Use

The EndoVac® system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures. It should only be used after carefully reviewing and understanding these instructions for use and only by a licensed and trained dental professional.

Contraindications

The EndoVac® system should not be used for any purpose other than to deliver and evacuate endodontic irrigation solutions during root canal procedures.

General Warnings & Precautions

⚠ Prior to EndoVac irrigation, the clinician must take every precaution necessary to ensure that the **integrity of the rubber dam seal** and any potential communication from the pulp chamber to the oral cavity are absolutely secure. An example would be deep caries below the level of the rubber dam that could result in irrigants leaking into the oral cavity via the pulp chamber. In this example, the caries would be removed and replaced with a temporary sealing material.

⚠ **Always protect the patient's eyes** with safety glasses and their clothing from sodium hypochlorite splatter or spill.

⚠ **Never place the MDT's delivery tip closer than five (5) millimeters from the coronal opening** of any pulp canal.

⚠ **Never aim the MDT directly into the orifice** of the canal as this will create a positive force of irrigant into the canal.

⚠ In order for the MicroCannula to be placed to full WL, it requires a minimum canal preparation size of **at least a size #35 / .04** taper, to full working length (WL) or at least a size #45 when a non-tapered instrument, such as LightSpeed@LSX™, is used.

⚠ Always use the EndoVac system in the sequence described herein. Skipping or deviating from the following steps can cause the EndoVac cannulas to clog and the clinician to become unnecessarily frustrated.

⚠ Pre-fill various syringes: 20 cc syringes with 5-6% sodium hypochlorite, 3 cc syringes with 15-17% EDTA, and optional syringes with irrigants of the clinician's choice. Make sure no air bubbles are trapped in the pre-filled syringes, as this will cause uncontrolled irrigant extrusion after releasing the plunger pressure.

Preclinical Considerations

- Recent studies by Clegg (J Endod, May 2007) and others have demonstrated that total pulp canal cleanliness cannot be achieved unless 6% sodium hypochlorite is used as an organic solvent. Furthermore, O'Connell (J Endod, Dec. 2000) and others showed that 15% EDTA can completely remove the smear layer. Accordingly, the EndoVac endodontic irrigation technique employs both these irrigants. Desai (IADR, July 2008) concluded: "The EndoVac is safe for deep intracanal delivery and suctioning the irrigant from the chamber to full working length."
- The EndoVac's fluid mechanics depend on an intact clinical crown with an access opening measuring at least 6-8 millimeters from cavosurface angle to the pulp floor. If the clinical crown is compromised, create a temporary crown using a composite material.
- **Final apical shape must be at least a #35 with a 4% taper.** In order to bring the apical preparation to an acceptable minimum size for EndoVac irrigation, it is recommended that LightSpeedLSX be used as a finishing file to enlarge to at least a size #45. This will provide adequate space for the MicroCannula to reach full WL and help ensure a cleaner canal.
- Alternatively, hand files can be used to adjust the final apical size to at least a size #35. Example: If the final apical instrument is a ProTaper® #3, then a hand #35 at 2% is used to refine the last 0.5 mm up to a #35, or if the final apical instrument were a ProTaper #2 then a hand #30 and #35 at 2% tapered instrument would refine the last 0.75 mm. These hand instruments should be considered "adjusting" instruments as they only affect the last millimeter in most cases.

Multi-Port Adapter and MDT Set-up in the Operatory

The EndoVac® system is intended for the delivery and evacuation of endodontic irrigation solutions during root canal procedures. It should only be used after carefully reviewing and understanding these instructions for use and only by a licensed and trained dental professional.



Figure 1. The Multi-Port Adapter (red arrow) is placed in a Hi-Vac connection as it sits in the evacuation rack. Ensure suction control valve (yellow arrow) is fully open. (Figure 1)



Figure 2. Install Fingerpiece/Handpiece tubing set (white connectors) into both holes (red arrows) at the top of the Multi-Port Adapter. Loop the clear tubing behind the evacuation rack (yellow arrows).



Figure 3. Install the Master Delivery Tip (MDT with blue connector) onto the 20 cc syringe that holds NaOCl.

Keep several 20 cc syringes full of NaOCl available for rapid change when required.



Figure 4. Firmly insert one end of the MDT tubing set (blue connectors) to the blue connector of the MDT (red arrow).



Figure 5. Firmly insert the opposite end of the MDT tubing set (blue connectors) to the lower port of the Multi-Port Adapter (red arrow).



Figure 6. Hang the MDT on the screw (red arrow) attached to the front of the Multi-Port Adapter.



Figure 7. The assistant or dentist now has convenient access to the MDT at all times.

MDT Use During Instrumentation

Overview

The MDT provides both a constant source of fresh sodium hypochlorite from its metal delivery tip (red arrow) into the pulp chamber and the immediate removal of any excess irrigant via the plastic evacuation hood (blue arrow) surrounding the delivery tip (Figure 9). This dual action provides a method of maintaining a pulp chamber brim full with fresh sodium hypochlorite. The delivery tip is placed just inside the access opening while the evacuation hood remains on the outside. A stream of irrigant is directed from the delivery tip at an axial wall and never should be aimed directly into a pulp canal orifice. The rate of irrigant delivery through the MDT varies according to each phase of irrigation.

⚠ Reminder: It is possible to create positive pressure into the pulp canal, thus creating the risk of a sodium hypochlorite accident — if the clinician fails to follow these points: (a) always discharge the irrigant from the MDT into a natural or temporary intact access opening measuring at least six to eight (6-8) millimeters from cavosurface angle to pulp floor; (b) always direct the irrigant stream at an axial wall approximately 45 degrees from the pulp canal's axial plane in molars, 60 degrees in premolars, and 90 degrees in anteriors; and (c) never place the MDT's delivery tip closer than five (5) millimeters from the coronal opening of any pulp canal. (Figure 9)



Figure 8.

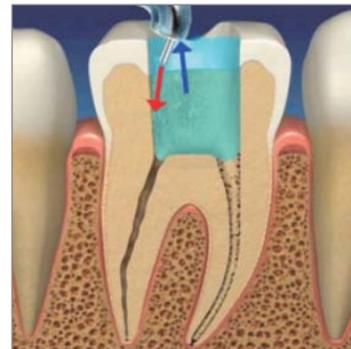


Figure 9.

Use

Instrumentation generates significant debris that must be evacuated from the pulp chamber via evacuation and fresh irrigant replacement. Use the MDT to deliver approximately one (1) cc of sodium hypochlorite at each instrument change in order to evacuate the debris and refresh the irrigant in the pulp chamber.

Gripping the Syringe/MDT

Gripping the syringe plunger with the palm of the hand (green arrow) rather than with the thumb will reduce hand fatigue. (Figure 10). The needle component of the MDT was intentionally designed with a small internal diameter to prevent spills via a controlled flow. Some doctors or assistants do not have enough hand strength to comfortably express the NaOCl through a 20 cc syringe. In this case it is recommended to use 10 cc syringes and change the syringe more often.

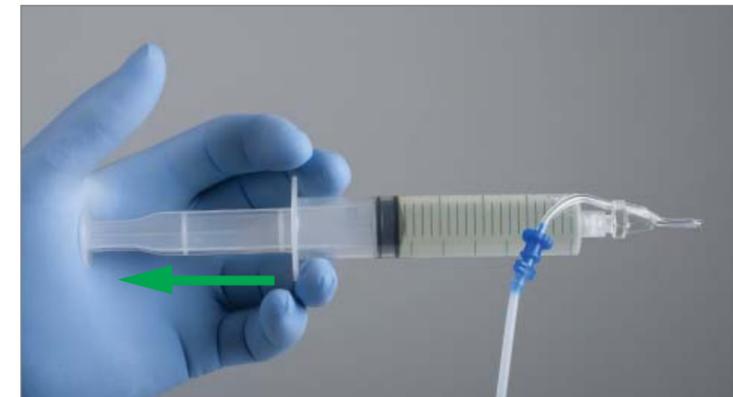


Figure 10.

MacroCannula Clinical Set-up



Figure 11. Firmly insert the MacroCannula into the Handpiece.



Figure 12. Remove the white connector closest to the front of the Multi-Port Adapter (red arrow).



Figure 13. Firmly insert it into the back of the Handpiece (red arrow).



Figure 14. The assistant (or doctor) uses the MDT to deliver irrigant into the pulp chamber.

Note: Check that the MacroCannula is suctioning properly. If not, check the Hi-Vac system and that the connections were made properly.

MacroCannula Clinical Use

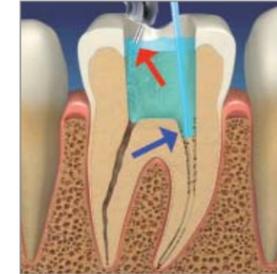


Figure 15. After instrumentation, significant debris may remain on the pulp canal walls and in fin areas. This debris could clog the holes of the MicroCannula later in the procedure. Accordingly, the MDT supplies a copious volume of irrigant (red arrow) as the MacroCannula is worked up and down rapidly starting at the orifice (blue arrow) past the mid-root area and into the apical third (yellow arrow 2nd picture).

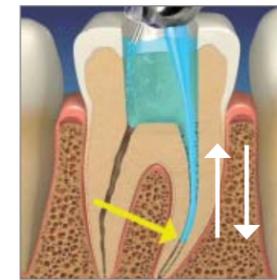


Figure 16. This vigorous up and down action lasts 30 seconds per canal (white arrows). Failure to properly perform this procedure may result in unnecessary clogging of the MicroCannula.



Figure 17. Clinical Note: The picture shows the tip of a broken instrument aspirated by the MacroCannula during Macro evacuation. The presence of the broken instrument stopped the irrigant flow through the Macro and debris can be seen along the inside of the MacroCannula. This case demonstrates that all mid-root and coronal debris must be removed from the Macro first, then the Macro reused for the proper amount of time.

MicroCannula Clinical Set-up



Figure 18. Select the appropriate length MicroCannula (21, 25, 31 or 50 mm). Leave the cap on the MicroCannula to prevent damaging it during insertion into the Fingerpiece.



Figure 19. During insertion, the base of the MicroCannula is held as shown. Use **extremely** firm pressure when the two are mated. This mating pressure insures that the MicroCannula will not separate during use, especially in a curved canal.



Figure 20. Remove the cap of the MicroCannula. Clinical Note: Use the provided rubber stopper or a Sharpie® marker to indicate Working Length. In this picture, a red Sharpie marker is used to indicate 18 mm and the black mark represents 20 mm. It is suggested to mark the longest and shortest working lengths and interpolate the middle distance.



Figure 21. After the MicroCannula has been inserted into the Fingerpiece and length marked, the Fingerpiece replaces the Handpiece on the clear tubing (white connector).

Micro Evacuation

The final phase of EndoVac irrigation is completed using the MicroCannula to flush and evacuate two separate irrigants, 5.25-6% NaOCl and 17% EDTA. The total sequence and time of each protocol is broken down into three cycles (“MicroCycles”).

- First MicroCycle: Dissolves and removes organic debris from the pulp canal walls using 5.25 – 6% sodium hypochlorite.
- Second MicroCycle: Disassociates and removes the smear layer thereby exposing the dentinal tubules by using 15 – 17% EDTA.
- Third MicroCycle: Dissolves and removes the contents of the now exposed dentinal tubules, by again using 5.25 – 6% sodium hypochlorite.

Purging Hydrolysis Bubbles

During the instrumentation phase, the use of NaOCl produces gas bubbles — the hydrolysis of organic material. These microscopic gas bubbles adhere to the canal walls and must be evacuated. This evacuation is realized by delivering irrigant in 10 second intervals, then stopping briefly to purge the entire canal system of NaOCl and the consequential bubbles. See flow chart on next page for details.



Figure 22. The length of the Fingerpiece is designed to match that of a file handle, (Figure 22) making insertion into the pulp canal easy. The Fingerpiece is used to guide the MicroCannula into canal curvatures and leave the access opening readily available for irrigant delivery from the MDT.



Figure 23. Once the Micro is placed at full Working Length, the clinician may remove her/his fingers and proceeds with irrigant delivery via the MDT. (Figure 23)

MicroCycle Technique — Single-Canal

See flow chart on pages 13 and 14 for detailed instructions

MicroCycle 1: NaOCl, MDT, 20 cc Syringe, MicroCannula, 30 seconds active, passive 60 seconds.

1. Place MicroCannula to full WL and deliver NaOCl from MDT for 10 seconds. Stop delivery and watch for MicroCannula to suction (PURGE) all NaOCl from the canal.
2. Repeat previous step again.
3. Again deliver NaOCl for 10 seconds — BUT — instead of purging, quickly remove the MicroCannula while the MDT continues to deliver NaOCl. This is referred to as “charging” the canal.
4. Let the NaOCl work for at least 60 seconds (passive wait) before proceeding to the next step. See flow chart on pages 13 and 14.

MicroCycle 2: EDTA, MDT, 3 cc Syringe, MicroCannula, 30 seconds, passive 60 seconds.

1. Place MicroCannula to full WL and deliver EDTA from MDT for 10 seconds, leaving the canal filled (charged) with EDTA for 60 seconds.

MicroCycle 3: NaOCl, MDT, 20 cc Syringe, MicroCannula, 30 seconds active, passive 60 seconds.

1. Place MicroCannula to full WL and deliver NaOCl from MDT for 10 seconds. Stop delivery and watch for MicroCannula to suction (purge) all NaOCl from the canal.
2. Repeat previous step for another 10 seconds.
3. Repeat again, but after delivery for 10 seconds remove the MicroCannula immediately before removing the MDT, leaving the canal filled (charged) with NaOCl.
4. Let the NaOCl work for at least 60 seconds before proceeding to the next step. While waiting, fitting of a gutta-percha point is optional.

Dry Canal: MicroCannula, Paper points.

1. Place MicroCannula to full WL for at least 3 seconds.
2. Confirm canal is dry or continue drying with paper points.

See MicroCycle Flow charts for technique when 2 or more canals are irrigated.

Micro Cycle Flow Charts

Micro Cycles #1 and #3

Irrigant: 5.25 to 6.00% NaOCl.

WL: Set MicroCannula at full depth AND remove fingers from Fingerpiece.
10 seconds addition NaOCl from MDT and **PURGE** the pulp canal, then
10 seconds addition NaOCl from MDT and **PURGE** the pulp canal, then
10 seconds addition NaOCl from MDT and **CHARGE*** the pulp canal

*Charging: As the assistant is adding NaOCl, quickly remove the MicroCannula.



Passive Wait:

After the canal has been charged, the number in this symbol represents the amount of time that must transpire until proceeding to the next procedure indicated by the flow chart.



Micro Cycle #2

Irrigant: 17% EDTA

WL: Set MicroCannula at full depth AND remove fingers from Fingerpiece.
Irrigation Flow: Add EDTA from MDT for ten (10) seconds — then charge.
Charging: See above.



Final Passive Wait and Gutta-Percha Fit:

During the last Passive Wait, fit the Gutta-Percha point(s) while the canals are wet and totally clean. If Passive Wait = 0, proceed immediately to Gutta-Percha fit.



Drying

Irrigant: None.

WL: Set MicroCannula at full depth for about three (3) seconds. Then confirm dryness with absorbent point(s).

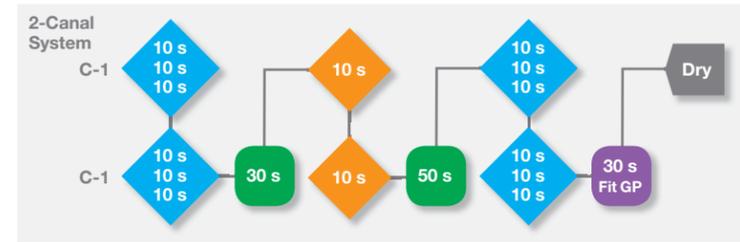


Example for 1 Canal

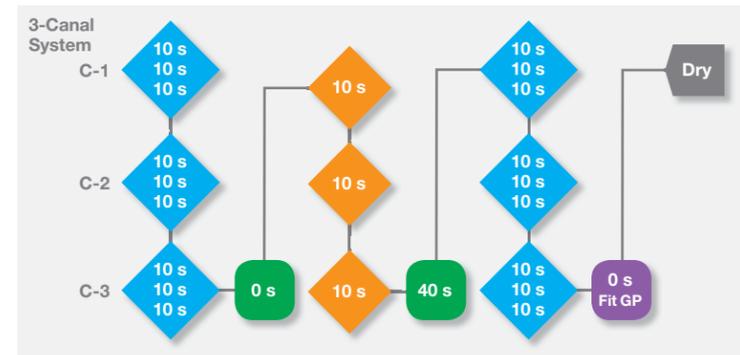


Examples for 2, 3 and 4 canals on next page.

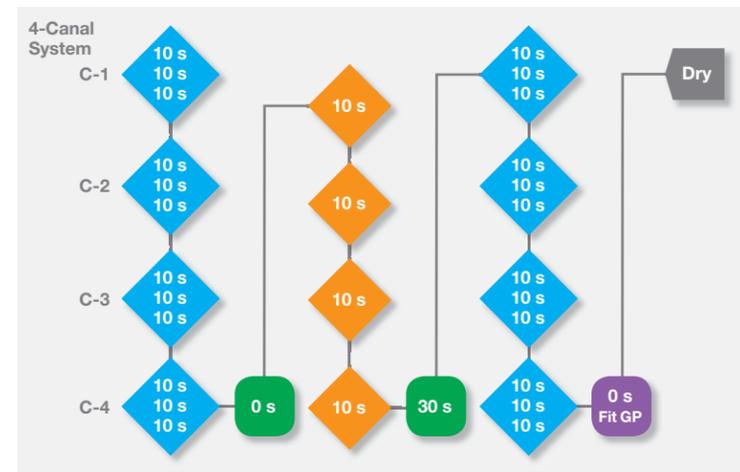
Example for 2 Canals



Example for 3 Canals



Example for 4 Canals



Troubleshooting

Unclogging the Cannulas

Cannula clogging is an indication that the EndoVac is working to remove all debris, which is a positive sign. However, this can be almost completely avoided. Correct use of MacroCannula to remove the gross debris will minimize MicroCannula clogging. Once the clinician gains proficiency in clinical use, clogging becomes a non-issue and happens infrequently. When either cannula should become clogged, try unclogging it by attaching the back end of either the Fingerpiece or Handpiece onto a syringe filled with water. Push the plunger and in most cases the hole(s) are immediately cleared, as noted in the photos below. (Figures 24 and 25)



Figure 24.



Figure 25.

Retreatment

In the case of retreatment, all pulp canals must be fully prepared, cleared and dried of gutta-percha solvent as much as possible before proceeding to both Macro and Micro evacuation. Still, clogging may occur as this is the very nature of retreatment. When this occurs, unclog as noted above.

In anticipation of excessive clogging during retreatment, adequate clearing of the canal before evacuation reduces the chances of this happening.

Failure to Initially Draw Irrigant

Failure to achieve Micro flow can occur if the MicroCannula is taken through the foramen. If any of the Micro's twelve (12) holes extend beyond the apical foramen, they will not draw irrigant. If the clinician experiences this, withdraw the MicroCannula 0.5 mm at a time until flow starts. The MicroCannula is often described as a pneumatic apex locator.

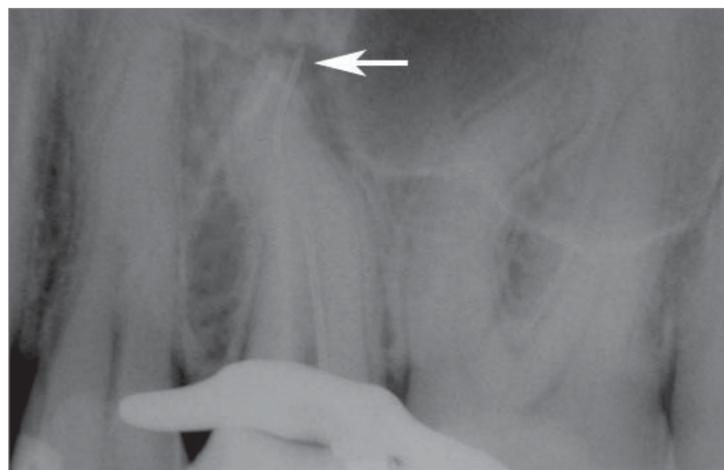


Figure 26. In the case above, the Micro did not initially draw irrigants and a check X-ray demonstrated the Micro's tip extended into the periapical tissue 0.75 mm. Once the tip was withdrawn 0.75 mm it functioned properly. Note: The "S" shaped curve to the Micro. The Fingerpiece was required to provide the necessary proprioceptive sensitivity necessary to guide the Micro to full working length.

Sterilization & Maintenance

1. After treatment, discard the Macro and MicroCannulas as well as the MDT.
2. Ultrasonically clean (with mild detergent) and autoclave the Handpiece, Fingerpiece and Multi-Port Adapter.
3. Disinfect the evacuation lines according to state regulations.

Warranty

Discus Dental, LLC warrants certain components of the EndoVac® system against defects in material and workmanship for 12 months from the date of purchase, subject to proper usage. During that twelve-month period, Discus Dental will replace:

- Master Delivery Tips, if received clogged.
- MacroCannulas, if received in unusable condition.
- MicroCannulas, if received in unusable condition.

Defects caused by misuse, neglect, accident or abuse are not covered by this warranty. Discus Dental, LLC assumes no liability resulting from improper use, damage or breakage due to misuse of these components by the purchaser. Discus Dental, LLC assumes no liability for damage to the EndoVac system components, injuries to patients or users or other problems resulting from improper use of accessories or other materials not supplied by Discus Dental, LLC.

Return defective components to:

Contact Discus Dental 800-817-3636 for Return Authorization and Return Address.

For Technical Support:

Phone: 800-817-3636
Fax: 310-845-5167
discusdental.com

For Sales Orders and Product Information Contact:

Manufactured by: Discus Dental, LLC (USA)
8550 Higuera Street
Culver City, CA 90232
Tel: 800-817-3636
email: info@discusdental.com
discusdental.com

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