



# PICCOLO

## Participant evaluation handbook

Welcome to the Piccolo User Evaluation Trial,

Thank you for agreeing to take part in our evaluation of Piccolo, a new powered interdental cleaning device with Smart Motion. Your honest feedback will help us understand how effective Piccolo is in everyday use and whether people would choose to buy it as part of their oral care routine.

This study is being conducted by COATES PTY LIMITED ACN 121 227 914 of Unit 2, 10 Gillies Street, Wollstonecraft in New South Wales and administered by TT3 Dental ABN: 36 325 604 230

You are required to sign a participant consent form and complete a survey prior to receiving your free Piccolo. On receipt of your consent form and the survey we will dispatch to you a Piccolo with an invitation to make an appointment to have the Piccolo detailed to you and to answer any questions about the user evaluation trial.

At the end of the user evaluation trial, you may keep the Piccolo or return the Piccolo to us.

### 1. Purpose of the Evaluation

The purpose of this six-week user evaluation trial is to determine:

- Whether Piccolo is effective as an interdental cleaner
- How participants use the Piccolo in their daily oral care routine
- How participants feel about its design, ease of use, and performance
- Whether participants would be willing to purchase Piccolo having used the device.

Your participation will directly help us refine the product and prepare for launch.

### 2. Your Commitment

By joining the Piccolo User Evaluation Trial, you agree to:

1. Sign a participant consent form
2. Read the instructions for use, and ask questions to clarify your understanding of how to use the Piccolo
3. Use Piccolo once a day (or as close to daily as practical) for the six-week period.
4. Follow Piccolo on Instagram to receive updates, tips, and news.
5. Complete a short online survey each week during the six-week period.
6. Be completely honest in your feedback — we value criticism as much as praise.
7. Agree to receive EDMs (emails) from us, which may include guidance, reminders, and follow-up questions.
8. Agree to receive SMS messages from us, which may include guidance, reminders, and follow-up questions.
9. Provide feedback not only on Piccolo but also on our communications and content.

We estimate that your total time commitment will be less than 30 minutes per week, assuming you use the Piccolo daily.



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### 3. Support and Contact

If you have any questions, need assistance, or require replacement tips during the trial, please contact us:

✉ Email: [tmartin@tt3.com.au](mailto:tmartin@tt3.com.au)

☎ Phone: +61 407512378

In the unlikely event that you require more tips we will post replacement tips to you promptly at no cost.

You can also access the following materials at any time via our [HubSpot resource page](#):

- Instructions for Use (IFU)
- Frequently Asked Questions (FAQs)
- User Evaluation Trial Protocol
- Educational materials about interdental cleaning and Piccolo

### 4. Anonymity and Use of Data

- All the information collected from you for the study will be treated confidentially, and only the researchers named above will have access to it.
- All feedback collected will remain anonymous and de-identified.
- While we may use aggregate comments or data for marketing, white papers, or publication, no participant will ever be personally identified.
- All data collected will be entered electronically and stored on the Microsoft 365 data base.
- Your insights will help shape how we communicate the benefits of Piccolo and improve the products design and performance.

### 5. Safety and Reporting

#### Risks

- All medical procedures - whether for diagnosis or treatment, routine or experimental involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. Despite all precautions, you might develop medical complications from participating in this study. The risks of participating in this study are very low. The risk of cleaning between the teeth (interdentally) causing harm to healthy individuals is extremely small. There may be a slight risk of interdental gum bleeding/sensitivity when participants commence regular interdental cleaning. The instructions for use will provide information to counter this event.
- While Piccolo has been designed to be gentle and safe, if you experience tooth or gum sensitivity pain, discomfort, or trauma while using the product:
  - Stop using it immediately, and
  - Report the incident to us via email or phone.
- We take all feedback seriously and will record and investigate any reported adverse events.



# P I C C O L O

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### **Trial Conditions**

- This user evaluation trial is voluntary and unpaid.
- Participation is at your own discretion and risk.
- You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. If you do decide to withdraw from the user evaluation trial, please advise the support and contact team immediately
- The trial has not been reviewed or approved by an ethics committee.

By participating, you acknowledge that TT3 -Dental and Coates Pty Ltd and its affiliates accept no liability for any loss, injury, or damage arising from the use of Piccolo during the evaluation.

### **7. Primary Outcome**

While we intend that this user evaluation furthers our knowledge of the commercial risks with respect to the launch of the Piccolo, it may not be of direct benefit to you. However, you will have received a Piccolo free of charge.

At the conclusion of the six-week evaluation, we will ask one key question:

#### **Will you continue using Piccolo after the trial?**

Your answer — and your reasons — will help us understand Piccolo's true value in everyday use.

### **8. Thank You**

This handbook is for you to keep

We appreciate your time, honesty, and commitment to helping us make Piccolo the most effective and user-friendly interdental cleaning device possible.

Your participation matters — every comment and experience helps us improve.