



PICCOLO

User Evaluation Protocol

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1. Background and Protocol

Interdental cleaning plays a vital role in oral hygiene, yet many current methods are uncomfortable and inefficient, leading to poor user compliance

The Piccolo's design allows a cleaning filament with a unique design incorporating a helix, the tip, to move both rotationally and axially in confined space, improving cleaning effectiveness and user ergonomics. We call this **Smart Motion**.

The claims that are being made about the Piccolo are that it is

- **Perfect for everyone:** Including those with tight contacts, orthodontic appliances, implants, crowns and periodontal conditions—one size fits all.
- **Gentle & Safe:** Piccolos' tip with smart motion means no more, black triangles from over brushing or using too much force, or micro abrasion of tooth surfaces compared to wood picks, oral irrigators, floss or interdental brushes. And the patient has full control over the depth of insertion.
- **Thorough:** Removes plaque & food debris effortlessly and supports gum health
- **Convenient;** One-handed use, no mess, no stress, fast and easy.
- **Affordable and ecofriendly:** Lower cost than leading oral irrigators and over a year less expensive than interdental brushes. Less waste.

2. Rational for Completing the User Evaluation Trial

Patient compliance with interdental cleaning has always presented Oral Health clinicians with challenges. Consumers have shown more interest in “cleaning devices” which could make the process more effortless.

The Piccolo has been developed almost 18 years ago for the purpose of cleaning between the teeth with a powered mechanical device as opposed to a manual cleaning device and/or the use of an oral irrigator. Since the first design the Piccolo has been continually improved and is now considered by the inventor to be at minimally valuable product (MVP) and ready for market launch.

If we can prove that the Piccolo, when used properly is the preferred device for cleaning interdentally this may have a meaningful impact on inspiring consumers to clean interdentally daily and decrease the risk of tooth decay, gum disease and other diseases such as diabetes and systemic disease.

3. Hypothesis

Null hypothesis: there will be no preference for Piccolo as the preferred device for cleaning interdentally.



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4. User Evaluation Trial Objectives

4.1 Primary Objectives

To undertake a user evaluation trial to determine whether there is a preference for Piccolo as the preferred device for cleaning interdentally.

4.2 Secondary Objectives

4.2 (i) To see if the Participants intention to purchase Piccolo changes as they become more familiar with the product.

4.2 (ii) To see if the Participants oral health habits change over the period of the trial.

4.2 (iii) To determine if the pricing strategy for the Piccolo and replacement tips is correct.

4.2 (iv) To review the oral health habits of the user evaluation trial participants with a view to informing future product development.

5. User Evaluation Trial Design

5.1 **Expected Participant numbers;** 100 subjects would be enrolled into the user evaluation trial. The group being comprised of consumers and oral care professionals’.

5.2 **Centers:** The evaluation will be conducted at the participants preferred location as per part of their routine at home care.

5.3 **Duration of the user evaluation trial:** The user evaluation trial will take approximately 15 weeks beginning on December 8, 2025, and finishing on the 16 March 2026. The last Participant will be recruited to the evaluation no later than the 2 February 2026. Data collection completes by the 30 March 2026. Write up complete by the 6 April 2026.

5.4 **Ethics:** No ethics application will be made.

5.6 User Evaluation Trial Participants Inclusion Criteria

- Gender: no restriction.
- Age range: >18 years.
- At least 24 natural teeth.
- Willingness to provide informed consent and willingness to participate and comply with the user evaluation trial requirements.

6. User Evaluation Trial Procedure

6.1. Participants are recruited to the user evaluation by personal invitation

6.2. Participants log onto a HubSpot landing page to

- Read and download, if desired, the User evaluation user handbook
- Complete and submit the consent form

6.3. On receipt of the consent form

- A Piccolo is dispatched with an invitation to make a time to go through the Piccolo
- An invitation to complete the Evaluation Questionnaire to understand their oral health habits and their experience with interdental cleaning products.
- .An invitation to follow Piccolo on Instagram and LinkedIn



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6.4. The participant is sent

- A weekly follow up, for six weeks, to understand their experience of using the Piccolo and if their experience of using the Piccolo changes through the period of the user evaluation.
- Marketing material via EDM and SMS

6.5. At the end of the evaluation

- The Participant will be sent a final Piccolo buying intentions survey
- Data from the surveys will be considered and conclusions made
- Participants can keep or return the Piccolo.

7. User Evaluation Trial Procedure Risks

There is a very small possibility that misuse of the Piccolo could cause gingival trauma. To mitigate that risk all participants will receive an information for use (IFU) leaflet with the Piccolo, access to FAQ's and IFU on the HubSpot landing page and an invitation to participate in a demonstration and tutorial about the proper use of the Piccolo by a trained member of the team.

8. Participant Recruitment and Screening

- Participants are recruited to the user evaluation by personal invitation.
- Participants are identified through word of mouth at, workplaces, business networks and reaching out to the profession through EDM in the Newcastle area, direct visits to dental practices and through professional associations such as the Oral Health Association of Australia (OHAA). Oral health.
- professionals may invite their patients to participate.
- Participants will be screened by the researcher that they meet the inclusion criteria and then be directed to the HubSpot landing page to review the Participants handbook, and complete the Consent form.

9. Participants Enrolment

Potential participants will be enrolled into the user evaluation trial after the informed consent process has been completed, and the participant has been assessed to meet all the inclusion criteria. User evaluation trial participants will receive a user evaluation trial enrolment number which will relate to the number of the Piccolo they receive, and this will be documented in the participant's HubSpot records.

10. Information and Consent

Potential participants would be provided with a link to a HubSpot landing page to discover a User Evaluation Participants Handbook, Consent form, and other useful documents such as IFU, User evaluation protocol and FAQ's related to the use of the device. The dispatch of the Piccolo will occur after receipt of the consent form accompanied by an invitation to attend a training meeting on the device.

11. Randomisation Procedure

None required.



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12. Withdrawal Procedure

A participant can leave the research user evaluation trial at any time. When withdrawing from the user evaluation trial, the participant should let the research team know that they wish to withdraw, either in person, by phone or by email. A participant may provide the research team with the reason(s) for leaving the user evaluation trial but is not required to provide their reason.

13. End of User Evaluation Trial

At the end of the end of the six-week user evaluation the participant will be invited to remain in the trial until the completion of the data collection on the 8 February 2026. The participant may keep the Piccolo or return the Piccolo to us

14. Outcomes

The data collected from the survey responses will be analysed for changes over the period of the user evaluation trial and for the participants preference for the Piccolo.

15. Data Collection

Data will be collected by Microsoft forms a web-based application that allows researchers to create and share on-line surveys. Microsoft Forms customer data is stored at rest in Australia.

Data is collected anonymously with only the researcher having access to the forms data. All data is de-identified.

Participant contact information will be stored in HubSpot. HubSpot is a cloud-based platform that provides software, tools, and solutions to help businesses attract and delight customers. It was founded in 2006 with a simple yet powerful mission: to make marketing and sales more human. HubSpot's product infrastructure is hosted on Amazon Web Services (AWS) in Australia.

Participants will be able to save their survey responses but will not be able to access the responses of other participants.

16. Quality Control and Assurance

The surveys will be sent and data collected as per the trial protocol

Any amendments to the survey questions will be reviewed by the audit committee prior to implementation.

17. Ethics

No ethics approval has been sought. The responsible investigator will ensure that the user evaluation trial is completed as close to as is possible to the guidelines set out in the National Statement on Ethical Conduct in Human Research (2007) (the National Statement) and the CPMP/ICH Note for Guidance on Good Clinical Practice and any other relevant legislation/guidelines. All participant data will be de-identified.



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18. Safety

18.1 An **Adverse event (Device)** is very unlikely. There is a very low risk that there may be a malfunction or deterioration of the Piccolo or the Piccolo tip, in which case a replacement will be offered, and spare tips and tip guides are being included. There is also a low risk that the participants may cause trauma to the gingiva if the Piccolo is used incorrectly; however, they will have been provided with oral hygiene instructions on how to use the Piccolo correctly. If the participant does experience gingival trauma, they should contact the researcher at their earliest convenience for advice.

The Researcher commits to adhering to the NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods guidelines.

18.2 **Serious adverse event reporting.** All serious adverse events will be reported immediately to Coates Pty Ltd. The reports will be followed by a detailed written report. Follow-up reports will identify the participant/s by the unique code assigned to participants (rather than by name). The Piccolo is used in routine at-home care, so serious adverse events are highly unlikely. The trial is very low risk. Potentially high-risk patients will be screened out during enrolment into the trial.

18.3 **Early termination.** Is unlikely due to the researcher not being able to continue. In the event the researcher is unable to continue Coates Pty will nominate additional researchers

Confidentiality and Storage and Archiving of Trial

The researcher will store all documents related to the User Evaluation Trial within office 365 with access restricted to the researcher. Hard copy files will be destroyed. Electronic files will be permanently deleted after ten years

19. Trial Sponsorship and Financing

The product will be provided FOC by Coates Pty Ltd. and participants will have the opportunity to retain their device at the end of the User Evaluation Trial. All other resources are supplied by TT3.

20. Indemnity

20.1 **Compensation.** Reasonable precautions against harms are being taken. The Piccolo has been available for many years and used by the office holders of Coates Pty and TT3 with no adverse incidents. The risk of harm occurring is extremely low. In the event of harm occurring, the participants will receive immediate support and advice. No monetary compensation will be provided to participants.