"Odne Endodontic Root Preservation Therapy RPT: A non-interventional, multicenter, post-market registry."

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Sponsor:

Odne AG

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1 Purpose and Scope

The purpose of this registry is to collect usability and performance data from the participating dentist for the Odne Obturation system- RPT workflow in a dental clinical environment.

This plan is applicable to Odne obturation system- Root Preservation Therapy(RPT) workflow only.

2 Terms and Abbreviations

See List of Terms and Abbreviations.

AE	Adverse Event
CBCT	Cone Beam Computed Tomography
RPT	Root preservation Therapy
GCP	Good Clinical Practice
HIPPA	Health Insurance Portability and Accountability Act
ICF	Informed Consent form
PAI	PeriApical Index
FDA	Food and Drug Administration
RCT	Root Canal Treatment
VAS	Visual Analogue Scale
ISO	International Organization for Standardization

3 Overview of the Registry

3.1 Introduction

Root canal treatment is the treatment of choice for irreversible root canal infection or inflammation. It helps preserve and maintain the function of the teeth in the oral cavity. It is a multi-step process that includes root canal cleaning and shaping, debridement and disinfection followed by obturation of the root canal.

Odne has developed Odne obturation system that allows the dentist to obturate a minimally shaped canals (ISO 20.04), hence supporting root dentine preservation (“Root preservation therapy, RPT”). The system is simple, easy to use, and requires less time. Currently, the procedural methodologies available in the market pose many challenges entailing long tedious procedures, excessive canal shaping, and incomplete obturation of complex root canals.

Odne (previously Lumendo) has developed devices to simplify the process of root canal obturation-

1. **OdneFill** is a hydrophilic, radiopaque, light-curable endodontic sealer. It consists of a liquid, highly flowable material that is applied into the prepared and cleaned root canal and converted into a solid polymer by photocuring. OdneFill is a one-material obturation solution that does not require gutta-percha points to obturate minimally prepared canals. OdneFill is classified as a class II medical device, product code KIF, and FDA-cleared under K231387.

2. **OdneCure** is a handheld dental curing light used to precisely photocure dental materials in small areas. OdneCure is classified as a class II medical device, product code QNF, and FDA-cleared under K232076.

Odne devices aim to overcome the disadvantages of current devices by making root canal treatment workflow safe, simple, and efficient for dentists and patients and preserving root dentine structure during the process.

3.2 Objectives

- Capture demographic information of the new Odne customer base consisting of general dentists and endodontists.
- Create awareness and excitement for using the new root preservation therapy (RPT) by the Odne obturation system via participation in the registry.
- Gather participating dentist feedback on their experience with and the usability of the Odne obturation System.
- Collecting market feedback and market intelligence data from users of the Odne obturation system.
- Documentation of Participating Dentist' clinical cases using the Odne obturation system with the potential for long-term reporting.
- Confirmation of Odne obturation systems' performance and claims.
- To improve Odne obturation system based on the knowledge gained from the feedback of the Participating Dentist.

3.3 Project Design

This market survey project is a registry to collect Participating Dentist demographic information, usability market feedback, performance, and longevity data of the Odne obturation system in clinical practice. The project is intended as a survey questionnaire to retrospectively collect user experience and market feedback data from Participating Dentist regarding their clinical use in treating patients in need of root canal treatment with the Odne obturation system. The data repository will have the potential to educate, train, and create further awareness about root preservation therapy, and provide real-world vigilance and long-term follow-up data on the Odne obturation system. This will also provide future opportunities for publications on documented cases and to design studies based on market needs by assessing the data trends in uploaded surveys / cases and improving the products based on user feedback. OndeFill and OdneCure are FDA-cleared medical devices and can be legally marketed for their intended use with the U.S.A.

3.4 Setting/ Participating Dentist

The setting includes dental practices in the United States of America using the Odne obturation system. There will be a maximum of 300 dental professionals/ offices participating in the clinical registry. The approximate number of cases per participant is 10 cases, and there is no maximum number of cases per dental practice.

3.5 Data Collection Process and Frequency

Goal: To increase the number of dentists using the Odne obturation system for root canal treatment.

Performance measure: 300 dentists will actively participate in the data collection associated with Odne Obturation system Market Survey Project.

Benchmark: By June 2025 there will be 100 dentists within the Odne Market Survey Project.

Data Collection Plan: The registry will be introduced to potential Participating Dentist from April 2024 by our sales team. Each month starting in May, the enrollment records will be reviewed to ensure an increase in participation. If the participation goals are not met changes in the marketing strategy will be made to reflect increased participation. All data will be collected via electronic surveys for Participating Dentist based on questions developed by the Sponsor. The Participating Dentist will be trained in the collection of data and the use of the registry electronic database. The recommended frequency of data collection is every 6 months during the first year and yearly after the first year of treatment.

1. The Participating Dentist will upload their well-documented patient cases treated using the Odne obturation system.
2. Patient data will be anonymized before uploading it into the registry (No Personally Identifiable Information (PII) data will be entered into the registry).
3. Patient's pain score, and PeriApical Index (PAI) score determined using oral examination and intraoral x-ray/ CBCT scans respectively (as part of the standard of care for follow up assessments) will be uploaded as part of the registry after the completion of treatment.
4. Post-treatment follow-up data will be collected by the Participating Dentist and uploaded into the database repository after the completion of the routine visit.
5. A series of questions pertaining to the use of Odne obturation system, user experience, usability and performance feedback will be provided by the Participating Dentist.

4 Schedule for Data Collection

Project Phase	Participant Enrollment	Baseline and treatment visit	Observation visits after treatment +/- 3 months						
Visit number			**1-month**	**6-month**	**1-year**	**2-year**	**3-year**	**4-year**	**5-year**
Schedule									
Participating Dentist Agreement	X								
Participating Dentist Enrollment	X								
Patient Informed Consent		X							
Patient Demographics, Medical and Dental History		X							
Pain score using VAS scale		X	X	X	X	X	X	X	X
Other clinical symptoms (Swelling, abscess)		X	X	X	X	X	X	X	X
Intraoral Radiograph		X		X	X	X	X	X	X
CBCT scans		X		X	X	X	X	X	X
Periapical index (PAI) score		X		X	X	X	X	X	X
Treatment plan details		X							
Final Shaping file used		X							
Irrigant and activation device used		X							
Obturation quality using CBCT assessment		X							
Post-obturation filling procedure details		X							

5 Background information and Rationale

Root canal treatment is the treatment of choice to preserve the esthetics and function of the tooth in the oral cavity. As this involves multiple steps there is a market demand to simplify and reduce the time taken to complete the treatment. Awareness about minimal shaping and conservative root canal procedures is increasing and technology to support minimal shaping in the dental clinical is of the utmost urgency. Odne RPT workflow provides a unique opportunity for the dentist to completely obturate minimally shaped complex root canal structures successfully.

5.1 General Information

- The purpose of developing the Market Survey Project is to collect usability and performance feedback about the Odne obturation system and RPT workflow.
- To confirm the RPT workflow concept using the Odne obturation system for root canal treatments.
- To capture Market trends among general dentists and endodontists in root canal treatment procedures.
- The Participating Dentist will be a variety of general dentists and endodontists.
- The funding source will be provided by **Odne.**

5.2 Compliance Statement

The data collected will be conducted in full accordance with the HIPAA privacy rule. Any episode of non-compliance will be documented.

The Participating Dentist will collect the data in accordance with this document and will obtain patient consent for sharing their anonymised data with the sponsor. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of patients during and after the data collection process.

5.3 Relevant Literature and Data

Periapical periodontitis or apical periodontitis (AP) is **an acute or chronic inflammatory lesion around the apex of a tooth root, mostly caused by bacterial invasion of the pulp of the tooth.** This disease is amongst the most prevalent pathologies in endodontics. Half of the adult population worldwide have at least one tooth affected with apical periodontitis[1].

Root canal treatment is the treatment of choice for apical periodontitis in order to retain teeth in the oral cavity. The ultimate goal of this treatment is to rid the tooth of any infected pulp and associated bacteria followed by establishing a seal in the apical and coronal end of the root canal to ensure no future reinfection or leakage.

The current root canal obturation method uses a gutta percha and sealer combination to seal the root canal. This 2 component obturation poses many drawbacks like postoperative pain, sealer extrusion, incomplete healing, incomplete seal, voids, and complex application procedure. According to the literature search undertaken by Odne the current methods have an incidence of mild to moderate postoperative pain in 31% of cases, sealer extrusion in 53% of cases, and incomplete healing in 4-5% of cases. This leads to higher failure rates for the current methods.

A single component easy to apply root canal obturation technique has been a requirement to circumvent the disadvantages of conventional RCTs (root canal treatment) and achieve a void free effective seal to promote healing of the periapical tissue. OdneFill is a flowable, hydrophilic, radiopaque, light-curable endodontic root canal sealer. OdneFill forms a hydrogel upon curing which gives them mechanical properties similar to those of natural tissues. Furthermore, hydrogels are known for their excellent biocompatibility, causing minimal inflammatory response and tissue damage. [2] (Nguyen KT et al. 2002). The water-like flowable property of OdnFill allows it to flow into the side canals and isthmuses without the need for undue mechanical compaction rendering complete sealing of the root canal.

OdneFill is an easy-to-use one-material root canal obturation solution that circumvents the disadvantages of existing products, thus improving ease of handling and treatment time while maintaining or improving the clinical outcome of root canal treatments compared to the level of state-of-the-art treatment methods.

6 Project Objectives

6.1 Primary Objective

The primary objective of this Market Survey Project is to provide a portal to store Participating Dentist information using the Odne obturation system and their completed cases that have received the OdneFill obturation.

7 Registry Plan

7.1 General schema of the Market Survey Design

The participating sites will be dental practices across the United States. The data collected pertains to participating dentists and users of the Odne obturation system. General data will be collected related to the participating dentist, their demographics, placement of OdneFill, performance and longevity of the obturation and their feedback on the usability of Odne obturation system.

7.1.1 Description of collecting Sites

A listing of dental practice sites providing the data for the Market Survey Project will be established. The resources required for the project will be the same as in the dental clinic. The participating dentist and their assistants will be trained by Odne on the collection of data requested in the questionnaire and how to upload the data into the database system.

7.1.2 Overview of the Data Collection

All data will be collected via Questionnaires (developed by the sponsor) within the registry database.

7.2 Registry Duration

The completed cases will be included if the treatment with the Odne obturation system was received between March 2024 to December 2029.

7.3 Total Number of participating Dentists and Number of Cases Projection

The data will be collected from approximately 300 dental practitioners from the United States of America. Each participant will document approximately 10 cases using the Odne Obturation system. It is expected that approximately 3000 cases could be documented as part of the entire project.

7.4 Registry Population

For a case to be eligible to be documented in the registry, the participating dentist must have used OdneFill. Participating Dentist will have determined the suitability of the patient for root canal treatment in their practice based on their own clinical judgement derived from their historical training and experience.

7.4.1 Relative Indication for Root Canal Treatment

As this is a Market Survey Project the inclusion criteria is not beyond the patient having OdneFill obturation agreeing to allow their case data uploaded, some general considerations are as follow:

- Male and female patients aged ≥ 18 y.o.
- Patients having at least one tooth obturated using Odne obturation system.
- Availability for 5-year duration of the registry.

7.4.2 Relative Contraindications for the Root canal Treatment

Similarly, a case for the registry does not have exclusion criteria beyond a patient not having OdneFill obturation, some general considerations that would preclude a patient from having endodontic therapy based on the OdneFill's contraindications are as follows:

- Uncontrolled bleeding in the root canal due to furcation involvement or lateral perforation.
- Teeth with deep root caries or large root resorption.
- Teeth with apical resorption or a radiographically undefined apex.
- Fractured instrument or file in the root canal.
- Non-removable root canal filling or post.
- Fractured teeth with poor prognosis for endodontic treatment.
- Children or adolescents with immature apex.
- Hypersensitivity against components of OdneFill, including methacrylates.

8 Registry Evaluations and Measurements

8.1 Data Collection Procedures and Case Documentation

The data will come from the patient's clinic record. All the information required for the clinical registry is routine information collected during a dental visit for root canal treatment or follow-up as part of the standard of care.

The data collection will be performed by the Dentist and/ or assigned staff. Baseline and treatment data will be abstracted from clinic records. All patient data will be anonymized prior to inclusion in the registry database.

Dental record Review

- Age at the time of treatment
- Gender
- Smoking status
- Medications
- Oral hygiene status

8.1.1 Survey Plan

There are 3 surveys that will be used during the data collection process.

Dentists Demographics:

Initial survey that will be sent to the Participating Dentist to compile demographics about the clinicians and their practice.

Case Baseline Survey:

This survey will be completed by the dentist once root canal treatment is completed using the Odne obturation system. These surveys pertain to the patient's age, sex, general conditions and medical and dental history, the root canal treatment information, the usability data and the feedback from the dentist on the system.

Case follow up Survey:

This questionnaire will be completed by the participant after each follow-up visit i.e. 6-month, 1-year, 2-year, 3-year, 4-year, and 5-year. The data collected will be regarding quality and longevity of the Odne obturation system.

8.2 Data Collection

8.2.1 Visit 1 (Baseline visit)

- Patient informed consent
- Patient demographics/medical history
- Dental history
- Clinical assessment
- Intraoral X rays
- CBCT scans
- Final canal size
- Obturation quality
- Post obturation filling.
- Adverse event assessment

8.2.2 Visit 2 (1 month)

- Clinical assessment- Participant

8.2.3 Visit 3 (6 month)

- Clinical assessment- Participant
- Intraoral x rays

- CBCT scans

8.2.4 Visit 4 (1 year)

- Clinical Assessment- Participant
- Intraoral x rays
- CBCT scans

8.2.5 Visit 5 (2 year)

- Clinical Assessment- Participant
- Intraoral x rays
- CBCT scans

8.2.6 Visit 6 (3 year)

- Clinical Assessment- Participant
- Intraoral x rays
- CBCT scans

8.2.7 Visit 7 (4 year)

- Clinical Assessment- Participant
- Intraoral x rays
- CBCT scans

8.2.8 Visit 8 (5 year)

- Clinical Assessment- Participant
- Intraoral x rays
- CBCT scans

8.3 Patient Completion/ Withdrawal

Patients may withdraw their consent to allow data to be collected for the Market Survey Project at any time without prejudice to their care. They may also be discontinued at the discretion of the clinicians for lack of adherence to the registry plan or visit schedules. The Participating Dentist or the Sponsor may also withdraw patients to protect the patient for reasons of safety or for administrative reasons. It will be documented whether or not each patient completes the registry plan.

9 Market Survey Project/ Repository Administration

9.1 Registry Organization

Dentists will be introduced to the long-term Market survey Project by the marketing team at Odne. Once the dentist agrees to participate, a Dentist Demographic Survey will be completed, and the dentist will be enrolled into the registry as a participant.

Once the OdneFill obturation is completed the participant will compile the anonymized data pertaining to the root canal treatment, quality and usability into the Baseline Survey.

Once the obturation is completed the dentist will complete surveys at 6 months using data pertaining to post treatment clinical assessment and longevity into the Follow-up Survey.

The Follow-up survey is repeated at 1, 2-, 3-, 4- and 5-year post treatment.

The participant will have access to the data results at the conclusion of the project.

9.2 Data Collection and Management

9.2.1 Computer Systems

An electronic database will be developed that encompasses a protected user level interface for each participant. A unique user ID and password will be generated for each participant. Survey fields will correspond with the data queries from various surveys.

9.2.2 Confidentiality of Cases

- The participant can log in to the database only by using their unique ID and password.
- The Survey questionnaire will be answered by the participating dentist.
- All cases will have an identifier generated by the database.
- The participant can log-in, enter, and confirm the collected data for each particular patient case survey for that specific timepoint.
- Participating Dentist will not have access to other participating dentist data or patient cases except his own patients.

10 Regulatory and Ethical Considerations

10.1 Risks & Benefits

The Market Survey Project is designed as a retrospective data collection tool for collecting and storing information regarding participating dentists, their demographics and their user experience about the quality and performance of Odne obturation workflow. The patients' case data will be recorded post treatment and at follow-up visits. The patient is exposed to no additional risk with the Market Survey Project.

The participating dentist will benefit as the procedure is easy and will reduce the chair side time per patient. The documentation of the case will help in future reference and training. The patient will indirectly benefit from lesser time in the dental chair and root dentine preservation.

At no point during the registry will the sponsor have access to the patient's personal information. Any data collected in the registry will be anonymized before sharing with the sponsor. The patient's privacy and confidentiality are maintained throughout all timepoints of the registry plan. The dental clinic will provide only the patients case data requested in the survey form.

10.2 Participant Recruitment and Case Selection Strategy.

Odne will target endodontists and dentists willing to participate in the data collection process to support new technology in their confirmation of claims. Odne will also approach new endodontists, educate, train them, and offer an incentive to participate in the data collection process.

The Participating Dentist will select well-documented patient cases to be part of the Market survey project. They will select the patients based on their knowledge and experience, consenting to share anonymized data.

10.3 Informed Consent Process

It is the responsibility of the Participating Dentist to ensure that each patient reads, understands, signs, and dates the Informed Consent Form.

A patient who is voluntarily willing to allow their data to be part of the Market Survey Project registry will provide a written informed consent to share anonymized clinical data. After signing the ICF, the Participating Dentist will share the patients anonymized clinical data which has been abstracted from their clinic chart with the sponsor via the Market Survey Project.

10.4 Confidentiality

The participating dental offices will log all data into the secure registry database. The database will include automatic header information of the registry plan number, the site number, patient case number and visit number. All data and records generated during this Market Survey Project will be kept anonymized in accordance with the HIPAA privacy rule and that the Participating Dentist and other site personnel will not use such data and records for any purpose other than conducting the registry. Safeguards are described under Data Collection and Management.

11 Safety Management

The repository is a minimal risk Market Survey Project.

11.1 Adverse Events

Unanticipated problems involving risks to patients and others will be monitored throughout the Market Survey Project.

11.2 Adverse Event Reporting

Since the Market Survey Project procedures are not greater than minimal risk and are limited to existing data, SAEs are not expected.

12 Publication

The data collected and analysed during the Market Survey Project may be published in the future. Publications may be made throughout the data collection process and at the culmination of the Marketing Survey Registry plan.

13 References

1. Tibúrcio-Machado, C.S., Michelon, C., Zanatta, F.B., Gomes, M.S., Marin, J.A. and Bier, C.A. The global prevalence of apical periodontitis: a systematic review and meta-analysis. International Endodontic Journal 54(5), 712–735 (2021). doi:10.1111/iej.13467
2. Photopolymerizable hydrogels for tissue engineering applications Author links open overlay panelKytai Truong Nguyen, Jennifer L. West Department of Bioengineering, Rice University, 6100 Main Street, MS142, Houston, TX 77251-1892, USA

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