# Implant Concierge 2025 Product Experience Policy

Implant Concierge stands behind our services and products. If at any time, you believe that an Implant Concierge service or product did not meet reasonable expectations, please let us know. As an FDA Registered facility, Implant Concierge follows a strict Quality Management System which includes detailed documentation of complaints and product experiences. Below is an overview of the Implant Concierge Product Experience Policy.

- A Product Experience Concern must be submitted within 30 days from case shipment
  - Reports may be made in the following ways:
    - An email to <u>support@implantconcierge.com</u>
    - A note placed on your case
    - A phone call to Customer Service at (866) 977-2228
- Implant Concierge will open and complete an investigation within 30 days of the reported concern
  - Information and documents to aid in the investigation will be requested and must be received within
     14 days or the investigation will be closed
- Information which <u>may</u> be requested to assist in the investigation
  - o Completed Product Experience Form
  - o Clear image(s) of your Surgical Guide or Provisional
  - o Returned Surgical Guide or Provisional
  - Returned Stone Models
  - Post Operative CBCT

#### **Pilot Surgical Guide Investigation Limitations**

A pilot surgical guide's primary purpose is to precisely guide the initial drill during the implant drilling sequence. The remainder of the drilling sequence is free-handed by the clinician, leaving depth, timing, and trajectory uncontrolled. Therefore, concerns with Final Angulation and/or Final Implant Placement do not qualify for investigation.

 Trajectory Concerns with Pilot Guides will only be investigated if no other drills are required prior to implant placement

#### **Provisional Appliance Investigation Limitations**

Due to human anatomy and expected surgical variables which are beyond the control of Implant Concierge surgical guides, chairside modifications to Implant Concierge pre-surgery provisionals are to be anticipated. Below are limitations and guidelines for investigations on Surgery-Ready Provisionals.

- Essix prostheses are expected to be manually modified after surgery to accommodate for swelling and other post-surgical healing. Essix are not designed to wrap around the posterior of the distal teeth.
- Surgery-Ready Provisionals are designed on a profiled ridge as well as out of occlusion and should be evaluated for interferences once placed by the clinician. Bite or occlusion concerns are not investigated.

<sup>\*</sup>Please note this policy is subject to annual review. The current and valid policy is that which is posted to Implant Concierge website. The above is valid for 2025 calendar year.

### **The Investigation Process**

- 1. The concern is reported to the Product Experience Team
- 2. The Product Experience Team Evaluates the case, including:
  - a. Your Chief Concern
  - b. A thorough review of the case notes
  - c. The CBCT and Model Registration
  - d. Treatment Planning documentation
  - e. Recorded Meetings and Calls
  - f. Guide or Provisional Design
  - g. Your completed Product Experience Form
  - h. Any additional requested documentation (listed above)
- 3. Once the investigation is completed, you will be contacted by email with the resolution or to schedule a meeting to discuss the findings.
- 4. Implant Concierge will investigate items in which we have control over. Therefore, we do not:
  - o Evaluate the final implant trajectory when a Pilot Surgical Guide is used
  - Evaluate the final implant trajectory when the implant is placed free-hand or without a Fully Guided
     System
  - Evaluate concerns regarding implant failure or lifespan
  - Evaluate the performance of a guide when the planned/placed implant is not supported by the selected guided surgical kit
  - Evaluate the performance of a guide when the Print Only workflow is selected
  - o Evaluate the implant positioning when the Design Only workflow is selected
  - Evaluate cases in which a doctor chose to proceed with a Model which had concerns or was rejected
  - Rework a case at no charge if the doctor chooses to change the treatment plan after authorizing and/or receiving their case.
- **5.** We take the stance of "We assume we made a mistake, and our investigation is to prove we did not". We do not automatically assume the fault is that of the customers.
- **6.** We conduct a robust investigation following FDA Guidelines with the intent to identify where the problem occurred as well as to learn and educate one another so we can prevent repeat issues in the future.

# Implant Concierge Provisional Appliance - Product Warranty Policy

## **Provisional Warranties**

- If there is a performance issue related to the provisional, Implant Concierge will evaluate the appliance for a remake under our Provisional Warranty
- Proper documentation such as photos and return of the appliance are required to properly investigate the
  case
- Warranty does not include redesign of the provisional.
- Warranty begins once the case ships from Implant Concierge
- 3 Month Warranty on Essix Retainers
  - o Applies only to appliances which replace three (3) or less sequential teeth
    - If the appliance replaces four (4) or more sequential teeth, the appliance can be remade at normal pricings
- 3 Month Warranty includes reprint and parts on the following Provisional Products
  - Custom Tissue Formers, Full Contour Screw Retained Crowns, Bridges, Immediate Surgical Dentures, and Full Arch PMMA

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