

Protocol 1601 “*ROSE QUARTZ*”- Study Synopsis- July 16, 2016

Study Title:	A Prospective, Multicenter Study of the Integration Success of the Eztetic™ Dental Implant System in Immediate Loading Cases
Sponsor:	Zimmer Biomet, Palm Beach Gardens, Florida
Study Objective:	To determine the safety and efficacy of the <i>Eztetic</i> dental implant when placed and loaded immediately (within 24 hrs) in the anterior region of the maxilla (“esthetic zone”) and the mandible.
Study Hypothesis:	Implant survival and marginal bone changes after implant placement will be no different for the Eztetic implants than for a standard diameter implant.
Study Design:	This will be a prospective, observational multicenter study. All implants will be placed in the anterior maxilla or mandible and immediately loaded with a provisional prosthesis out of occlusion. Final restorations insertion will take place no later than 6 months following implant placement surgery. All implants will be restored with a single crown or splinted to a pre-existing implant if in the pre-molar region (no 2 adjacent edentulous sites).
Treatment Group:	<i>Eztetic</i> implant- 3.1mm diameter, lengths 8, 11.5, 13, 16mm (Model CT (MTX Microtextured surface cervical MTX treatment and Microgrooves)
Prosthesis Design:	Cement-retained single tooth restoration using Hex-Lock Contour abutments
Study Sites:	Multicenter- up to total 5 sites (2 US, 2 EMEA, 1 S. America)
Sample Size:	200 patients (each contributing at least 1 implant/case= total 200 implants) to be enrolled across all participating sites within 6 months. Each site will endeavor to enroll 40 patients.
Study Visits:	1. Screening / baseline period/ tooth extraction (days -7 to -1) 2. Implant placement surgery (day 0)/ immediate temporary abutment/

- prosthesis (this visit may include tooth extraction)
- 3. Permanent prosthesis delivery- (2-6 months)
- 4. Follow-up visits: 1 year, 2 years

Inclusion Criteria:

- 1. Patients of either sex and greater than 18 years of age
- 2. Patients for whom a decision has already been made to use a dental implant for the restoration of existing partial edentulism in the anterior (central and lateral incisors) or pre-molar regions in the mandible or maxilla.
- 3. Immediate extraction or a prior extracted site
- 4. Patients must be physically able to tolerate conventional surgical and restorative procedures.
- 5. Patients with at least 1mm residual bone adjacent to the implant surface and a horizontal (inter-tooth width) of 5.1 to 6mm
- 6. Patients having a thick gingival biotype (based on the transparency of the periodontal probe through the gingival margin while probing the buccal sulcus)
- 7. Presence of opposing dentition; study implants will be initially restored with a non-occluding provisional prosthesis
- 8. Patients who provide a signed informed consent.
- 9. Patients who agree to be evaluated for each study visit.
- 10. Minimum primary stability, insertion torque > 35Ncm

Exclusion Criteria

- 1. Patients with known systemic diseases such as uncontrolled diabetes, endocrine disease, heart disease, immuno-compromised, or mental disorders.
- 2. Patients with current use of non-steroidal anti-inflammatory drugs, bisphosphonates or corticosteroid treatments.
- 3. Patients with active infection or severe inflammation in the areas intended for implant placement.
- 4. Patients in need of bone grafting at the intended study site.
- 5. Patients with a > 10 cigarette per day smoking habit.
- 6. Patients with a history of therapeutic radiation to the head or jaw.
- 7. Patients in need of bone grafting at the site of the intended implantation site(s).

8. Patients who are known to be pregnant at the screening visit or planning to become pregnant within 6 months of study enrollment.
9. Patients with evidence of severe parafunctional habits such as bruxing or clenching.
10. Patients with HIV or Hepatitis infection
11. Patients who have previously failed implants at the site intended for study implant placement
12. Patients in need of other treatments or surgeries at a site adjacent to the intended implantation site

Evaluation Criteria: Clinical Evaluations:

1. Peri-implant probing depths (PPD), bleeding on probing (BOP)
2. Soft tissue maintenance- measurement of most apical aspect of buccal gingiva to the incisal edge of implant/ prothesis
3. Resonance Frequency Analysis (ISQs) (availability of Smartpegs TBD)
4. Bone quality, gingival inflammation (site-specific), implant mobility, peri-implant radiolucency, and suppuration, global scoring for gingival/ plaque indices
5. Crestal bone levels (radiographic)
6. Adverse events (dental or medical)

Primary Outcome(s): Implant stability, implant survival

Secondary Outcome(s): Crestal bone regression