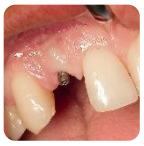
GalvoSurge Dental Implant Cleaning System GS 1000 Clinical Considerations

This document summarizes the clinical considerations identified by Drs C. Hämmerle, M. Danesh-Meyer, I. Urban, L. de Stavola, O. Gonzalez, F. Lambert, N. Nänni, I. Rocchietta, and G. Tabanella based on their first-user experience with the product and does not constitute a quick guide nor replace the Instructions for Use (IFU).
Please review the Instructions for Use at www.galvosurge.com/ifu before using the product.

Workflow and clinical considerations



1. Diagnosis with peri-implantitis

- Assess the severity and defect morphology, and evaluate patient expectations to help determine the best treatment plan
- Depending on defect morphology, guided bone regeneration (GBR) may be required to regain function and esthetics
- Smaller lesions may be more predictably managed with resective surgery providing they are not in a high esthetic area

2. Suitability assessment for treatment with GalvoSurge

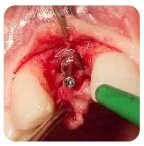
- Carefully evaluate oral parameters (presence of plaque, bleeding on probing, present or prior periodontitis), etiology of peri-implantitis (inappropriate implant diameter or position, occlusal overload, poor prosthetic design), morphology of the bone defect (maximum vertical defect size 8 mm from implant shoulder), and soft tissue characteristics for optimized treatment plan (see classification of bone defects on reverse for more details)
- General contraindications include inability to undergo oral surgery, allergy to any materials used during GalvoSurge cleaning, etc.; consult IFU for the full list of contraindications

3. Optional: Presurgical periodontal and anti-infective therapy

- Reduce inflammation to limit risk of complications, particularly if complex regenerative procedures are planned
- Recommended therapy includes scaling, air powder cleaning, local and/or systemic antibiotics (in case of recurrent episodes or aggressive infection), or local disinfectants

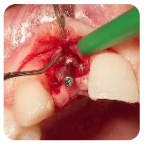
4. Local anesthesia

- Ensure a large enough area around the site to be treated is anesthetized
- Apply block anesthesia in the proximity of major vascular-nerve trunks (e.g., Inferior Dental Nerve Block in mandible, incisive canal in maxilla)
- If block anesthesia is contraindicated, apply palatal and labial infiltration anesthesia and extend it to neighboring teeth



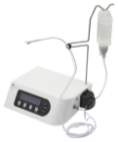
5. Flap elevation

- Full thickness muco-periosteal flap at infra-bony defects with bone dehiscence; flap design should follow the GBR needs
- Resective therapy when GBR is not indicated
- Soft tissue grafting may be performed independent of flap design
- Limited full thickness flap can be performed in case of infra-bony defects without bone dehiscence



6. Manual removal of granulation tissue and hard deposits

- Remove hard deposits with hard instruments (e.g. curettes) and/or other suitable devices (e.g. Ti brushes)
- When GBR is contemplated, take care not to unnecessarily damage the implant surface



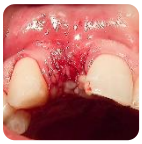
7. Implant cleaning with GalvoSurge

- Prior to GalvoSurge treatment, inform patients about a strong salty taste of the solution during treatment and that there is reasonable volume of liquid that will flow into the mouth (which will be suctioned out)
- Warning: use nonmetallic suction only. Do not place suction tips too close to the treated area to ensure that the implant is being continuously covered by the cleaning solution
- Appearance of bubbles within the solution indicates the correct use of GalvoSurge system
- On completing the GalvoSurge, it is recommended to thoroughly flush the area around the implant and under the flap with sterile saline to clear away any residual coagulum or solution

8. Optional: GBR, connective tissue graft

- Evaluate suitability for a successful GBR procedure and possible risks as for regular GBR treatment
- Wound dehiscence and graft exposure may result in re-infection of the site
- As with any complex surgical procedure apply state-of-the-art tissue management to support quick and successful wound healing

Clinical images: courtesy of Dr L. de Stavola.



9. Flap closure

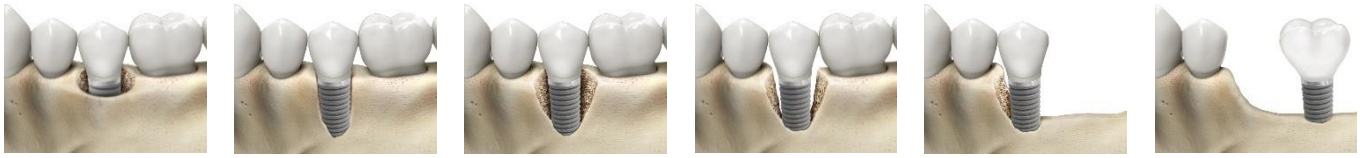
- Closed healing environment with the placement of a sterile cover screw or a short healing abutment strongly advised in case complete regeneration is planned
- Consider adjusting treatment to bone defect type (see below for classification)
  - Class I-II defects: resorbable membrane, 4-6 months healing time
  - Class III-V defects: non-resorbable membrane, 6-9 months healing time
- Transmucosal healing is applied only when closed healing is not possible or when complete regeneration is not planned
- Use tension-free flap closure (e.g., periosteal releasing incision and horizontal mattress sutures)

10. Patient follow-up

- Treatment success defined in part by patient expectations (functional vs. functional and esthetic)
- Successful decontamination if peri-implant soft tissue parameters (bleeding on probing (BoP), pocket depth (PD), no pus) indicate absence of inflammation/infection and radiographic bone levels remain stable (at 6-8 months post-surgery)
- Successful functional and esthetic treatment outcome is assessed based on regular X-ray examinations (stable bone levels over time, bone gain after GBR), and clinical examinations (absence of BoP, no increase in PD, improved/stable clinical attachment levels)
- Regular local professional cleaning, regular assessment of plaque removal and regular hygiene instructions as needed
- Be aware that GalvoSurge ensures an effective cleaning of the implant surface but will not eliminate the possible cause/contributing factors

Classification of bone defect types

Modification of the defect types originally described by Renvert and Giovannoli in Chapter 6: Treatments. In: Renvert S, Giovannoli JL, editors. Peri-Implantitis. France: Quintessence International; 2012.



Class I
Infra-bony defect with all 4 walls present

Class IIa
Narrow infra-bony defect with 3 walls and a dehiscence, most frequently on the buccal side

Class IIb
Infra-bony defect with 3 walls present

Class III
Infra-bony defect with 2 intact walls and large dehiscence, usually on the buccal side and extended to the proximal area

Class IV
Infra-bony defect with 1 intact wall

Class V
Supra-bony defect, with supra-crestal threads exposed and no wall support

Frequently asked questions

FAQ: How do I position the sponge in narrow spaces, for example in the pre-molar area?
A: The sponge becomes very elastic once it is wet and it is then easy to adapt to narrow spaces to enable good connection with the implant.

FAQ: How do I know if the treatment was successful?
A: Close monitoring showing limited or no plaque accumulation and limited or no bleeding on probing, stable bone levels based on radiographs, and no suppuration indicate a successful decontamination of the implant surface and absence of reinfection.

FAQ: What complications could occur after the surgical intervention?
A: Particular attention should be given to those cases where GBR procedures were performed since there is a risk of wound dehiscence and graft exposure, thus creating a possibility of re-infection and failure of the bone graft.

FAQ: When should I perform a bone augmentation procedure?
A: Certain clinical situations favor GBR, while others suggest implant removal should be considered. Follow the summary shown below for key clinical considerations to facilitate your decision making.

Favorable for GBR

- Viable soft tissue (thick soft tissue with good vascularization, sufficient width of keratinized mucosa, good suture properties to allows tension-free flap closure)
- Appropriate implant position – correct axis, offers anchorage to the prosthesis, implant diameter consistent with ridge dimensions
- No or minimal interproximal bone resorption
- Bone defects class I-II

Unfavorable for GBR

- Consider implant removal
- Poor soft tissue properties (thin soft tissue with poor vascularization, insufficient width of keratinized mucosa, spongy morphology that cannot sustain a firm suture, loss of vestibular fixed mucosa)
- Inappropriate implant position – implant placed too far buccally or its axis does not offer sufficient prosthetic support
- Advanced interproximal bone resorption
- Bone defects class III - V

The information contained in this Clinical Considerations has been verified by the Legal Manufacturer to be in line with the IFU, however this Clinical Considerations is not meant to replace or supplement the IFU, and the experience as related by the Clinicians, identified in GalvoSurge Dental Implant Cleaning System GS 1000 Clinical Considerations, are opinions of the Clinicians only, and do not represent an instruction on proper use of the device. Neither the Legal Manufacturer nor Nobel Biocare assume any liability for such opinions. Please refer to the IFU for complete information on the use of the device.