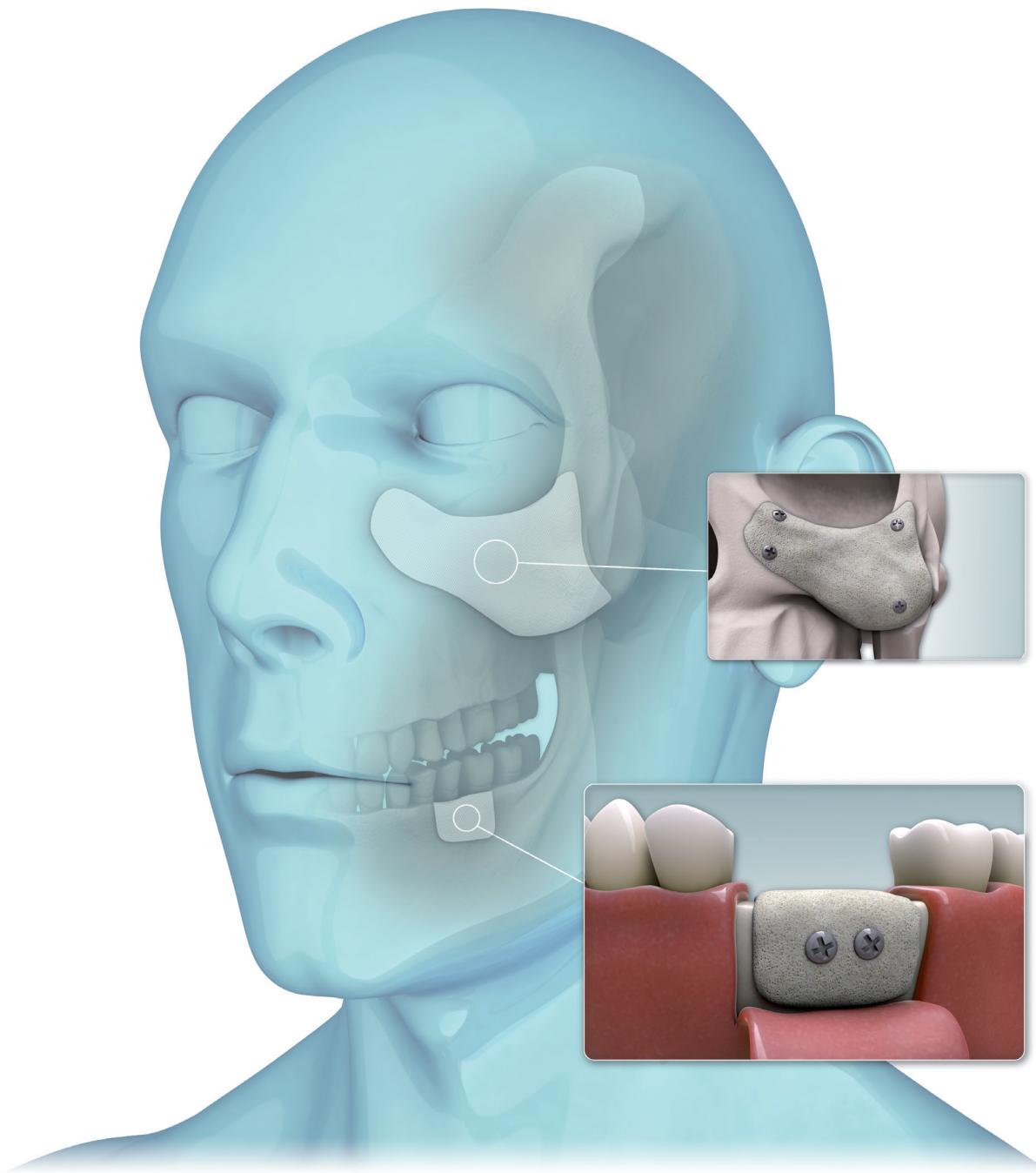


SmartBone® Surgical Procedures

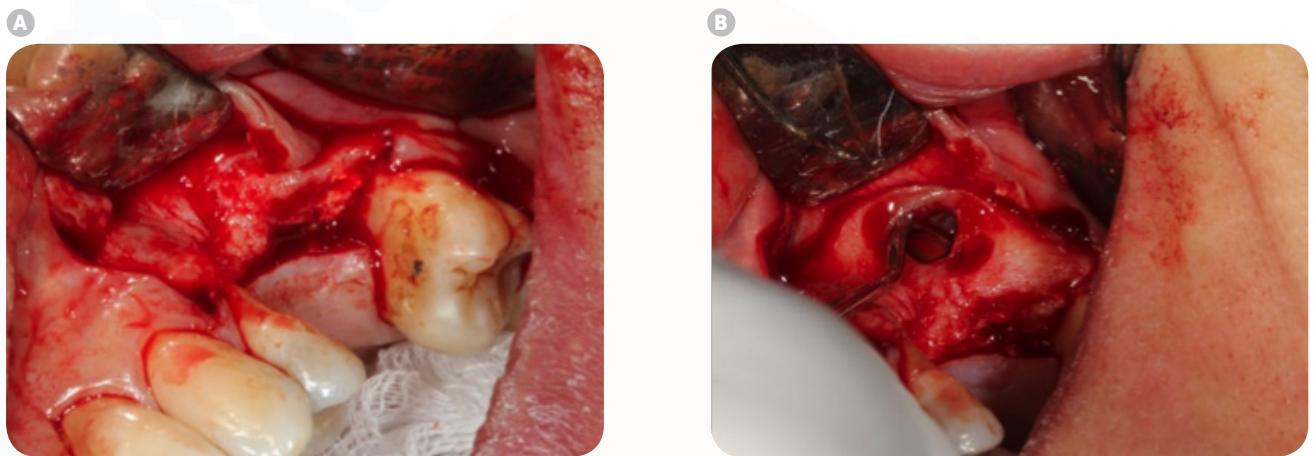


smartbone®

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Sinus lift procedure with SmartBone® Microchips

- Evaluate the oral epithelium of the gum, which must be well keratinized.
- It is suggested making an incision a few millimeters above the muco-gingival junction from the canine eminence anteriorly to the zygomatic buttress posteriorly. Elevate the mucoperiosteal flap from the incision buccally/superiorly and create a oval window in the canine fossa with the help of 4 mm, 6 mm chisels and mallet. Remove muscle fibers, using a dissector, and incise a muco-periodontal flap. (Figure A).
- Proceed with a blunt dissection of the muco-periodontal flap and elevate it in distal direction to access the bone. (Figure B).



- Use a drill to incise a bone window; be careful not to perforate the Schneider membrane (if necessary, fix the perforation with a resorbable membrane). If this should happen, cover with a collagen membrane if the perforation is small. Instead if the damage on the Schneider membrane is large you have to stop the surgery, close the flap and wait 9 months for a new surgery.
- Proceed with a blunt dissection of the membrane in both distal and apical directions.
- Using SmartBone® Microchips/Granules, fill the newly-formed bone cavity between the floor of the maxillary sinus and the Schneider membrane. (Figure C).
- It's always a good practice to hydrate the SmartBone® microchips/granules exclusively with patient's blood.



E



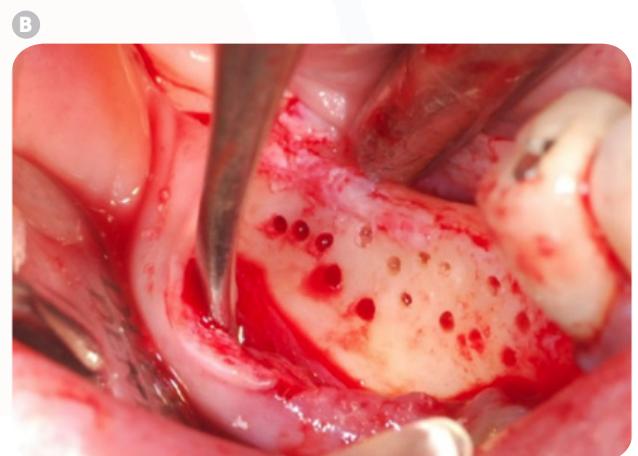
- Cover the surgical area with a resorbable membrane to stabilize the platelet, bovine pericardium membrane is suggested. (Figure D).
- Suture the flaps. (Figure E).
- Once SmartBone is placed, close the tissue with stitches. Implants can be placed 5-6 months later in order to ensure a good regenerated bone. Before placing the implant, it is always a good practice to proceed with specific clinical evaluation using radiography/CT scan.

Remember:

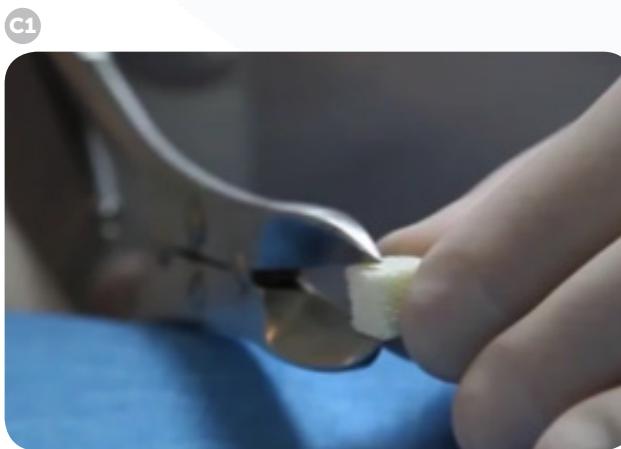
- The amount of bone used will vary, but usually several millimeters of bone is added above the jaw.
- The main risk of a sinus lift is that the sinus membrane could be punctured or torn. Please pay attention not to perforate the Schneider membrane.
- Consider to elevate correctly the Schneider membrane.
- For placing the implant during the bone augmentation it is necessary to have a sufficient thickness of residual cortical bone in the maxillary sinus floor in order to have a good primary stability.

Bone graft for thickness transverse recovery with SmartBone® Block

- Evaluate the oral epithelium of the gum, which must be well keratinized.
- Perform a surgical incision on the crest of the bottom right arch.
- Remove muscle fibers, using a dissector, and incise a muco-periodontal flap, only in the area where the bone block is inserted, because apically a partial thickness has to be performed in order not to have tension on the flaps during the closure. (Figure A).
- Proceed with a blunt dissection of muco-periodontal flap and elevate it in distal direction to access the bone.
- Perform an intramedullary canalization to let the blood flow towards the surgical area;
- SmartBone® is highly hydrophilic and absorbs blood quickly. The platelet promotes cellular colonization of the biomaterial, in particular by the mesenchymal stem cells that promote the osteogenic process. (Figure B).



- Cut and shape SmartBone®. Mechanical tools are suggested. If modelling is performed by drill or Piezo, it is preferable to maintain a cold environment by using a sterile water spray in order not to overheat the biomaterial, because this could modify its biomechanical properties (Do not use saline solution). If SmartBone® is shaped intensely, its polymeric coating could be widely compromised and a partial resorption could be observed during the first inflammation period. (Figure C).



- Place the block in its anatomic seat. Do not overfill the surgical area in order to avoid creating any tension on the flaps. Thanks to its polymeric coating, SmartBone® is not reabsorbed during the first healing/osteointegration period. If it is preferred to add extra material, 5-10 % extra-volume should not be exceeded. (Figure D).
- It's always a good practice to hydrate the SmartBone® blocks exclusively with patient's blood.
- Fix the block with osteo-synthesis screws in order to obtain perfect stability. (Figure E).

D

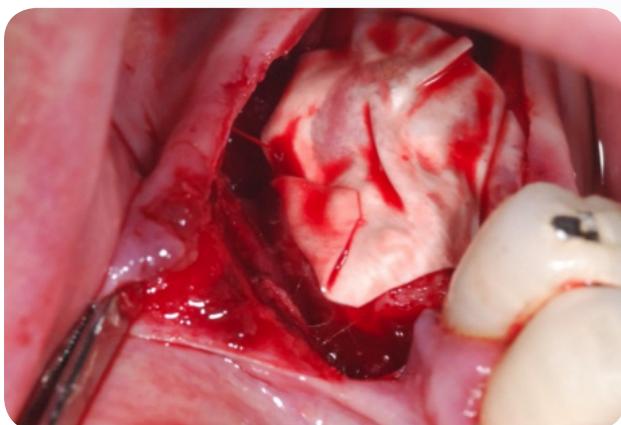


E



- Cover the surgical area with a resorbable membrane to stabilize the platelet, bovine pericardium is suggested. (Figure F).
- Suture the flaps:
Evaluate the passive mobilization of the flap, already performed previously with the partial apical thickness, and if needed ease/loose the apical part better, to guarantee a passive coverage of the graft and the membrane without any tension. It is preferred to use at least 2 horizontal mattress sutures, to enable the contact between the connective wall of the opening flaps, avoiding eventual epithelial migration, and use single sutures after complete closure of the flaps. The closure must be perfect without leaving any opening space. (Figure G).
- After 6-8 months, it is possible to proceed with the implant placement; however, each individual case needs clinical evaluation.

F



G



Remember:

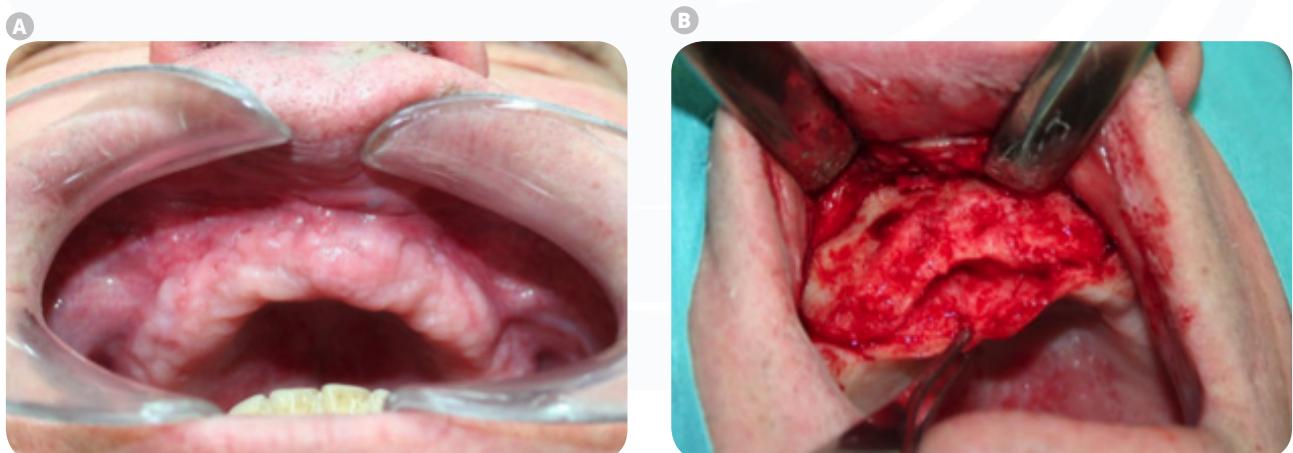
- Drill: it is preferable to maintain a cold environment by using a sterile water spray in order not to overheat the biomaterial, as this could modify its biomechanical properties. If SmartBone® is shaped/drilled intensely, its polymeric coating is widely compromised and a partial resorption could be observed during the first inflammation period.
- Avoid extensive modelling of the bone graft. For shaping the graft, the use of the bone cutter is preferred instead of drills.
- To perform an intramedullary canalization the Ø 1,1 mm drill or the round burr drill can be used. Be careful not to drill near the screws area.
- Do not dip the graft in saline solution before placing it; it has been observed that the sodium chloride (saline solution) starts the degradation process of the mineral bovine matrix.
- Do not mix different kind of bone substitutes. Do not put the particles under the bone graft. Particles can be used to fill eventual gaps around, or on top of the graft.
- The use of osteosynthesis screws, SmartScrews, are suggested.
- Besides these recommendations, it is widely suggested preparing the gums in order to have sufficient soft tissue to close the wound and to suture tightly.
- Always put a membrane on top of graft, before suturing.
- To avoid the dehiscence of the soft tissue, it is imperative to suture without tension. It is recommended the use an atraumatic needle.

Bone graft for vertical-orizontal augmentation procedure with SmartBone® On Demand™

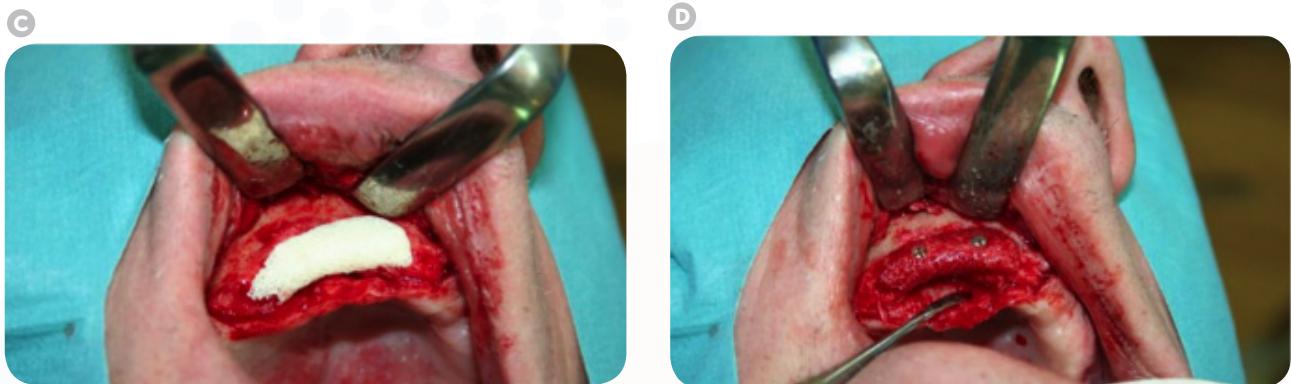


It is suggested proceeding with these steps:

- Evaluate the oral epithelium of the gum, which must be well keratinized. (Figure A).
- Perform a surgical incision on the crest.
- Remove muscle fibers, using a dissector, and incise a muco-periodontal flap, only in the area where the bone block is inserted, because apically a partial thickness has to be performed in order to avoid tension on the flaps during the closure.
- Proceed with a blunt dissection of the muco-periodontal flap and elevate it in distal direction to access the bone. (Figure B)
- Perform an intramedullary canalization to let the blood flow towards the surgical area; SmartBone® is highly hydrophilic and absorbs blood quickly.
- The platelet promotes cellular colonization of the biomaterial, in particular by the mesenchymal stem cells that promote the osteogenic process.
- Before placing the custom bone graft, it is always a good practice to hydrate the graft during the fixing process exclusively with patient's blood.



- Place the block of SmartBone On Demand™ in the patient's bone defect. Thanks to the polymeric coating, SmartBone® is not reabsorbed during the first healing/osteointegration period. SmartBone® allows to manage the flaps easily without using a bigger volume compared to the real needed volume: flaps tension, after suturing, will be reduced. If it is preferred to add extra material, 5-10% extra-volume should not be exceeded. (Figure C)
- Fix the block with osteo-synthesis screws in order to ensure perfect primary stability to prevent any future micro movements. SmartBone® has a good screw tenacity, so it can be fixed with screws without the risk of breaking the biomaterial; furthermore, this procedure enhances its stability. (Figure D)



- Cover the surgical area with a resorbable membrane to stabilize the platelet, bovine pericardium membrane is suggested. (Figure E)
- Suture the flaps. Ensure an adequate release of the flap to obtain a closure without tension and reconnect the flap of the soft tissue; release the periosteum to facilitate the closure. It is preferable to suture using an atraumatic needle, and ensure a continuous closure by primary intention without tension. (Figure F).
Evaluate the passive mobilization of the flap, already performed previously with the partial apical thickness, and if needed ease/loose the apical part better, to guarantee a passive coverage of the graft and the membrane without any tension. It is preferred to use at least 2 horizontal mattress sutures, to enable the contact between the connective wall of the opening flaps, avoiding eventual epithelial migration, and use single sutures after complete closure of the flaps. The closure must be perfect without leaving any opening space.
- After 6-8 months, it is normally possible to proceed with the implant placement; however, each case needs a specific clinical evaluation by radiography/CT scan.



SmartBone® is a new composite bone substitute based on a novel concept of biomaterials assembly: it is obtained combining natural mineral structures with bioactive agents. SmartBone has extremely high mechanical performances, it can easily withstand heavy surgical manoeuvres and fixation devices, it can be precisely shaped and adapted to match the target defect, and it offers a very high tenacity to screws.

Remember:

- Drill: it is preferable to maintain a cold environment by using a water spray in order not to overheat the biomaterial, because this could modify its biomechanical properties. If SmartBone® is shaped/drilled intensely, its polymeric coating is widely compromised and a partial resorption could be observed during the first inflammation period.
- Avoid extensive modelling of the bone graft. The custom-made bone graft is designed to fit perfectly with the patient. If necessary, the drill or the round burr to adjust the external sides can be used.
- To perform an intramedullary canalization the Ø 1,1 mm drill or the round burr drill can be used. Be careful not to drill near the screws area.
- Do not dip the graft in saline solution before placing it; it has been observed that the sodium chloride (saline solution) starts the degradation process of the mineral bovine matrix.
- It is important not to mix different kind of bone substitutes.
- Do not put the particles under the customized bone graft. Particles can be used to fill eventual gaps around, or on top of the graft. The on demand bone grafts are designed to fit with the patient's defect.
- It is very important that the surgeon holds and keeps the graft strongly pressed against the receiving bone while drilling and screwing. The screw must keep the graft tightly adjacent to the native bone to ensure perfect primary stability. Even as little as 1mm of free space left between graft and native bone may result in grafting failure! The contact between graft and native bone must be complete.
- It is suggested using our osteosynthesis screws, SmartScrews.
- Besides these recommendations, it is widely suggested preparing the gums in order to have sufficient soft tissue to close the wound and to suture tightly.
- Always put a membrane on top of the graft before suturing.
- To avoid the dehiscence of the soft tissue, it is imperative to suture without tension. The use of an atraumatic needle is recommended. If the graft is too large for the surrounding soft tissue, a small part of the bone graft can be removed using for example a drilling apparatus, in order to reduce the stress of the soft tissue.



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