



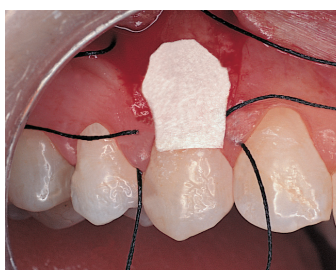
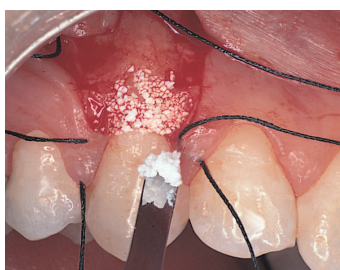
CENTRO DI ODONTOIATRIA OPERATIVA s.r.l.
MEDICAL DEVICE

GUIDED TISSUE REGENERATION MATERIAL SYSTEM COLLAGENE AT® - IDROSSILAPATITE AT®

MANUFACTURER: CENTRO DI ODONTOIATRIA OPERATIVA S.r.l. BIOMATERIALS AND RESEARCH DIVISION

Date of issue - 16 november 2018

INDICATIONS, WARNINGS AND INSTRUCTIONS FOR USE

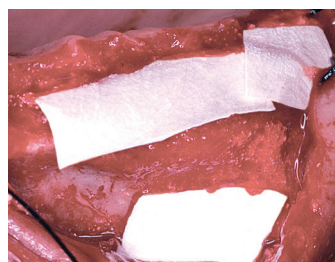
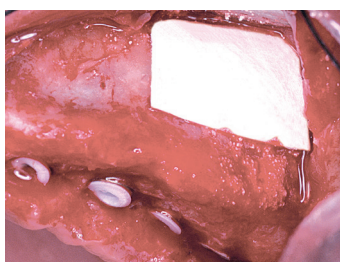


The Idrossilapatite AT® and resorbable Collagene AT® membranes application prevents epithelial and connective tissue cells from interfering with bone growth and periodontal tissue growth.

The maintenance of a space beneath the membrane by Idrossilapatite AT® allows production of new bone tissue and new periodontal tissue.

Surface nanometric micro-irregularity of Idrossilapatite AT® allows the absorption of plasmatic proteins with function of growth factors and with osteoinductive action.

Fast hardening Idrossilapatite micrometrica AT® increases the stability of implants, it applies in a few seconds and can be used with any kind of implant.



SYSTEM COMPONENTS



COLLAGENE AT® (code 4101 - 4102 - 4103) General Features:

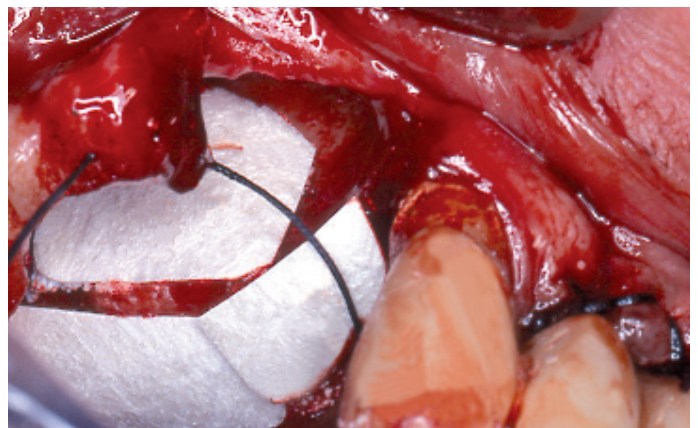
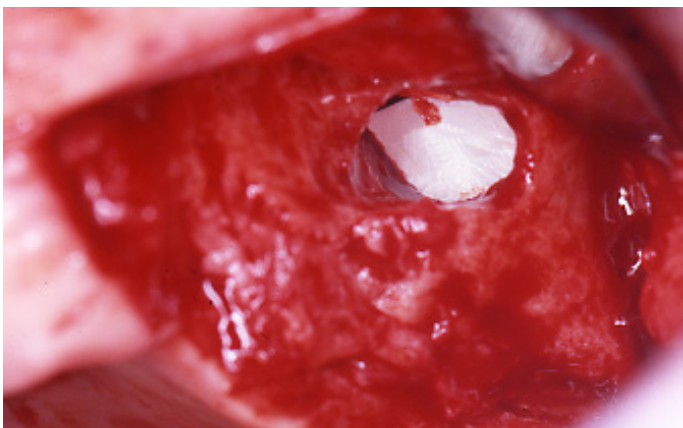
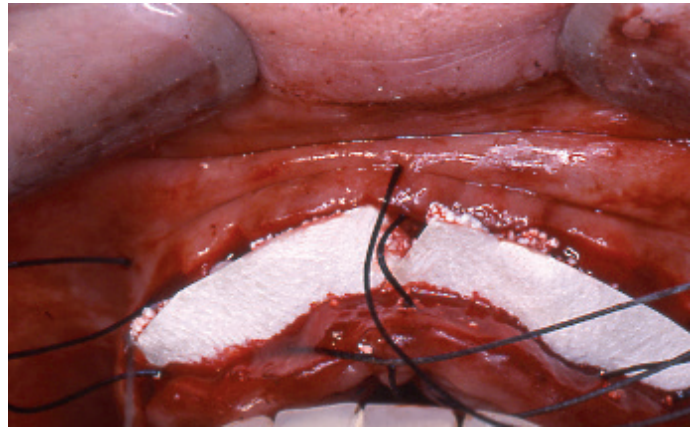
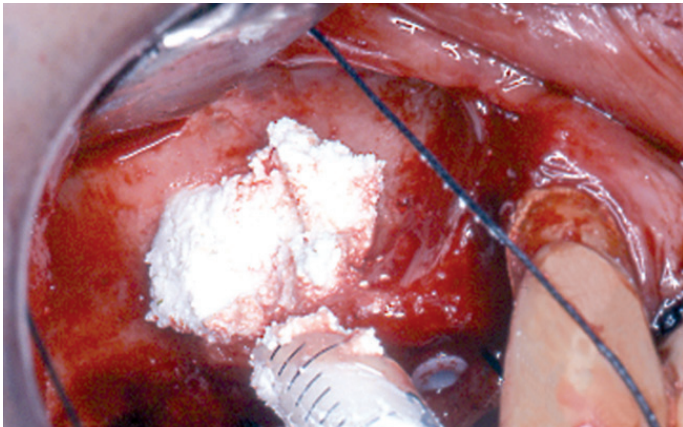
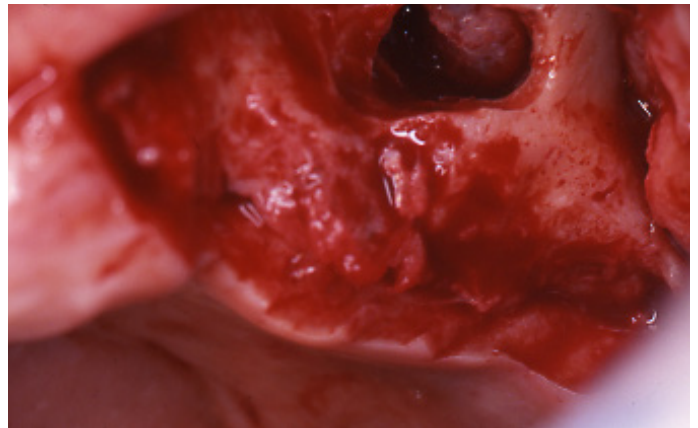
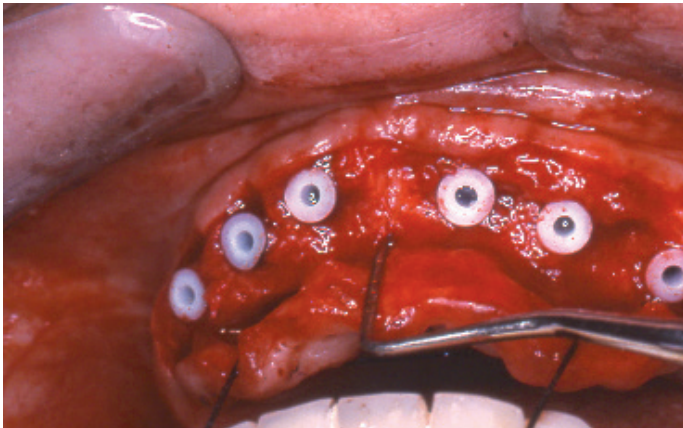
- Material** Lyophilized collagen of equine extraction.
- Structure** Membrane with nanometric micro-irregularities surface and about 20 micron wide porosity, allowing spontaneous adhesion on tissue without sutures and barrier effect against cellular migration.
- Reabsorption** Within 180 days.
The average speed of cell migration for the colonization of the sites below the collagen membranes correspond to some tenth of a millimeter and a few millimeters per day per week.
For the use of collagen membranes within the intraosseous periodontal pockets and the interior of the post-extraction sockets and inside cavity periapical that have horizontal dimension of at most a few millimeters cellular migration then ends in a maximum of 1-2 weeks.
In the case of wider cyst-cavities or broader atrophic alveolar ridges in order to obtain a good stability of the hydroxylapatite below collagen membranes are applied in multiple layers one above the other, in this way the reabsorption times stretch proportionately.
The time of reabsorption of the collagen membranes is of a few weeks and depends on their thickness and by the local metabolism of the tissues. In the case of fabrics with signs of inflammation reabsorption is obviously faster for the presence enzymatic factors capable of cleaving more rapidly collagen molecules into polypeptides.
The reabsorption time of 180 days mentioned in the warnings and instructions for use of the product " Material System for Guided Regeneration Collagene AT® Idrossilapatite AT® " corresponds to a standard time limit that must not be exceeded in order to obtain the official definition of resorbable product, and corresponds to the requirement that the product has been required to obtain CE certification of resorbable product
- Sterilization** Gamma rays.
- Package contents** 6 quadrangular membranes of 22x22mm (code 4101) in individually sterilized envelopes.
6 circular membranes of 17mm (code 4102) with individually sterilized envelopes.
This form naturally adapts to the convexity of teeth in intraosseous periodontal pockets.
3 quadrangular membranes of 22x22mm and 3 circular membranes of 17mm (code 4103) in individually sterilized envelopes.
- Warnings** Manipulate the membrane with perfectly dry instruments and press with dry gauzes.
The membrane should be applied on Idrossilapatite AT® used as an osteo-conductor support material or on bone graft to create a perfect tent barrier effect.

SYSTEM COMPONENTS

Collagene AT® is single use only.
Supplied in heat-sealed envelopes.
Open only before use.
Store at room temperature.
Avoid exposure to temperatures over 40° C.
Use only intact envelopes.

Packaging

Cardboard boxes sealed with heat-laced film.



SYSTEM COMPONENTS



IDROSSILAPATITE AT[®] (code 2600 - 2601 -2609) General Features:

Material	Calcium hydroxylapatite with molecular weight 502,32.
Structure	Granulometry 200÷500 micron. Predetermined granulometry obtained by a drying, shattering and sifting process; nanometric microgranulometry at surface.
Reabsorption	Reabsorbable progressively in centripetal direction, towards the inside of the granule in a time span of 6÷60 months, during the formation of new bone.
Sterilization	Gamma rays.
Package contents	1 glass bottle of 17 g (code 2600) with bakelite cap. 10 glass bottle of 1 g (code 2601) with cap. 2 glass bottle of 1 g in blister(code 2609) double welding.
Warnings	Use the product only if the bottle is intact.
Packaging	Cardboard boxes sealed with heat-laced film.



IDROSSILAPATITE AT[®] MICROMETRICA (code 2607) General Features:

Material	Calcium hydroxylapatite with calcium sulphate and calcium phosphate.
Use	Fast hardening hydroxylapatite to increase the primary stability of the implants.

SYSTEM COMPONENTS

Structure	Granules with a diameter of less than 200 microns and greater than 105 microns predetermined and obtained with treatment of drying, crushing and sieving; nanometric microgranulometry at surface.
Reabsorption	Reabsorbable progressively in centripetal direction, towards the inside of the granule in a time span of 4-10 weeks during the formation of new bone.
Sterilization	Gamma rays.
Package contents	2 glass bottle of 0,50 g single use (code 2607) with bakelite cap in blister with double welding.
Warnings	Use the product only if the bottle is intact.
Packaging	Cardboard boxes sealed with heat-laced film.

MAIN UTILIZATIONS OF SYSTEM COMPONENTS

ORAL SURGERY: FILLING OF POST-EXTRACTIVE SOCKETS

ORAL SURGERY: FILLING OF SINUS-ORAL POST-EXTRACTIVE COMMUNICATION

ENDODONTIC SURGERY: FILLING OF PERIAPICAL CAVITIES

PERIDONTAL SURGERY: GUIDED REGENERATION IN INTRABONY POCKETS

IMPLANT SURGERY: APPLICATION OF REGENERATION MATERIALS TO PREVENT POST-OPERATIVE RIDGE ATROPHY

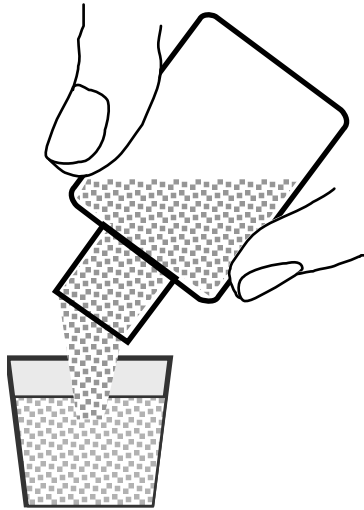
IMPLANT SURGERY: ATROPHIC RIDGES AUGMENTATION BEFORE IMPLANT SURGERY

IMPLANT SURGERY: GUIDED BONE REGENERATION IN MAXILLARY SINUS LIFT

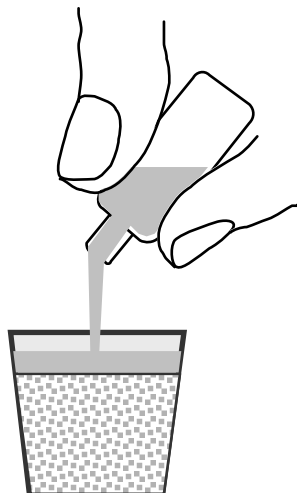
IMPLANT SURGERY: TO INCREASE THE IMMEDIATE STABILITY OF THE IMPLANTS IN THE BONE TISSUE TYPE 3 AND 4

GENERAL INSTRUCTIONS FOR USE OF IDROSSILAPATITE AT[®], AND COLLAGENE AT[®]

1) pour Idrossilapatite AT[®] in a sterile glass:

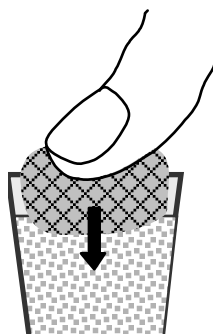


2) add physiologic solution to Idrossilapatite AT[®]:



3) continue adding till reaching a liquid level on Idrossilapatite AT[®]:

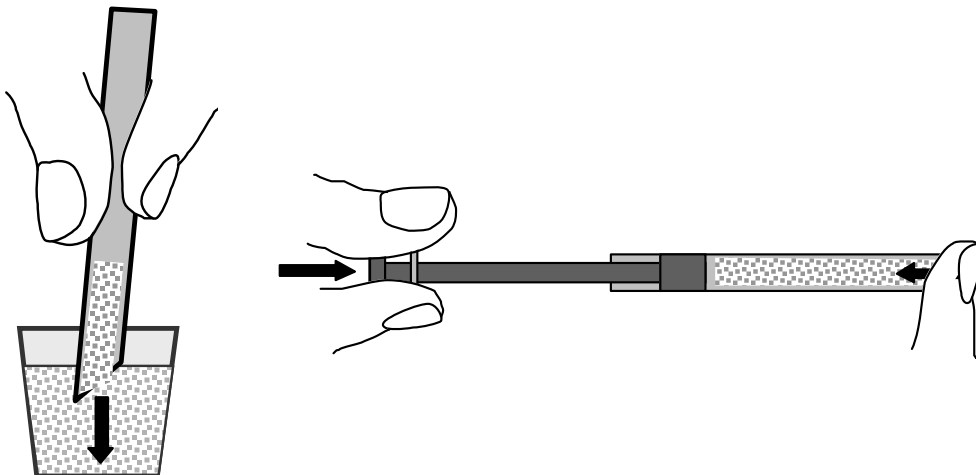
4) remove the surplus physiologic solution pressing with sterilized dry gauzes till the surplus physiologic solution is completely removed:



5) the precise mixing is reached when Idrossilapatite AT[®] granules adhere one to another due to capillarity;



6) Idrossilapatite AT[®] can be put inside a sterilized syringe;



7) apply Idrossilapatite AT[®] directly on the surgical site;

8) compact Idrossilapatite AT[®] with dry gauzes;

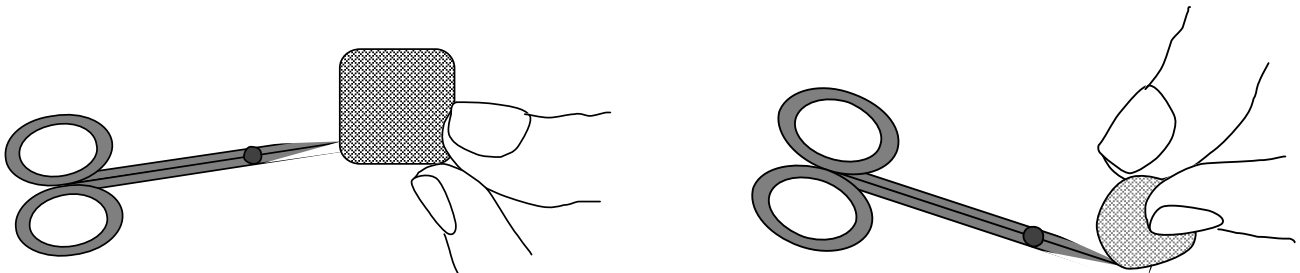
Warning: avoid using the surgical aspirator on the surgical site; press with dry gauzes to control bleeding, to avoid displacing regeneration materials.

9) take a resorbable Collagene AT[®] membrane for GTR;

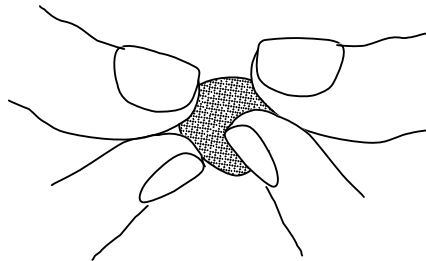


Warning: open the blister envelope only before use.

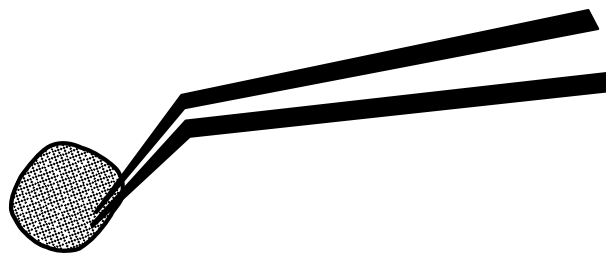
10) cut the membrane with surgical scissors. The membrane must cover around for about two millimeters the bony or dental tissue.
If the membrane is too little, place another membrane on the first, covering its borders for two millimeters;



11) shape the membrane with fingers covered by surgical gloves;



12) place the Collagene AT[®] membrane on the Idrossilapatite AT[®] using dry dental tweezers. (They must be dry to avoid adhesion to the membrane);



13) if necessary, move the Collagene AT[®] membrane using dry and blunt instruments (for instance a periodontal probe).

14) if necessary, press the Collagene AT[®] membrane with dry gauzes;

Warning: the gauzes must be perfectly dry (otherwise the membrane adheres to the gauzes instead to the underlying Idrossilapatite AT[®]).

15) tie the sutures without displacing the regeneration materials.

INSTRUCTIONS FOR USE OF IDROSSILAPATITE MICROMETRICA AT®

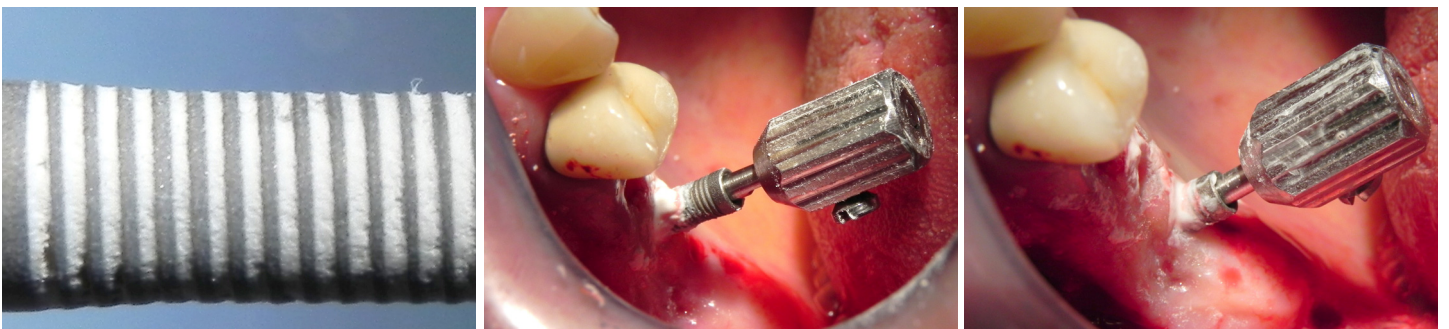
1) pour Idrossilapatite micrometrica AT® in a sterile glass and add physiologic solution, removing any excess with a sterile gauze



2) apply Idrossilapatite micrometrica AT® on the lateral surface of the implant and in small amounts inside the hole

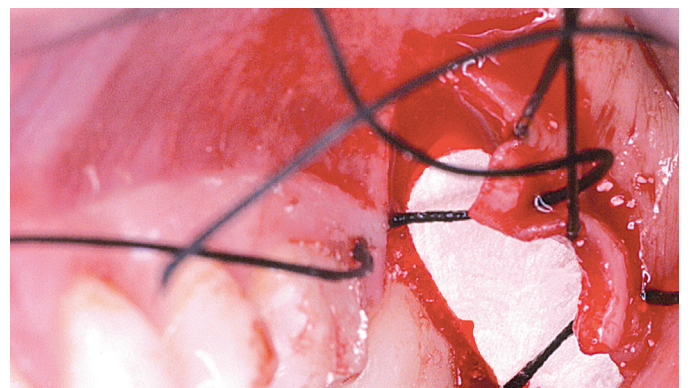
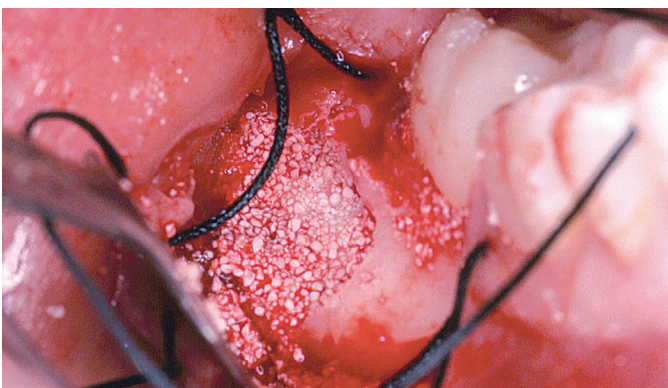
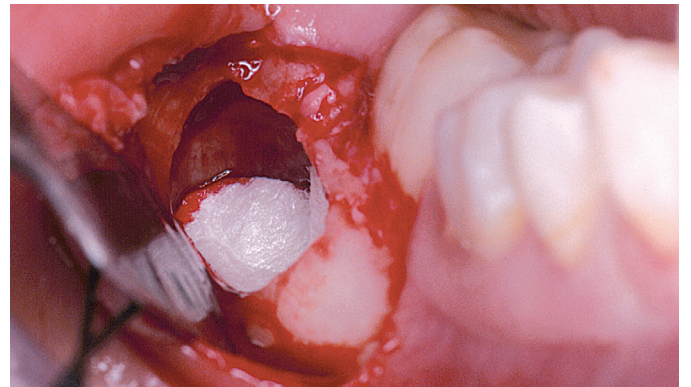
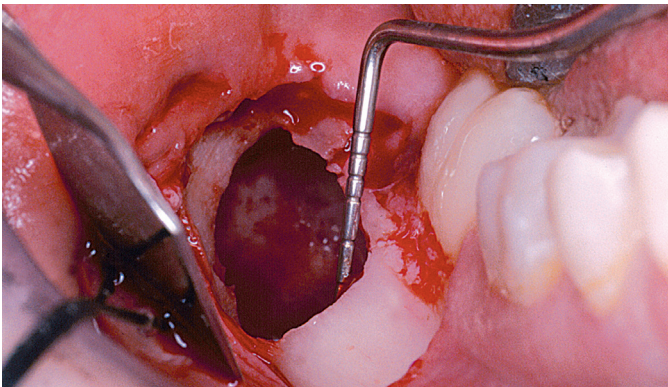
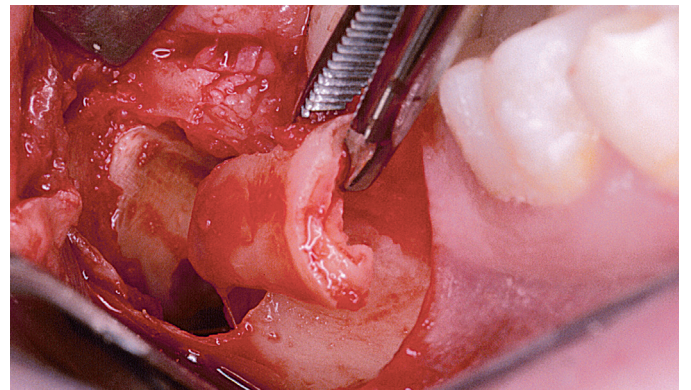
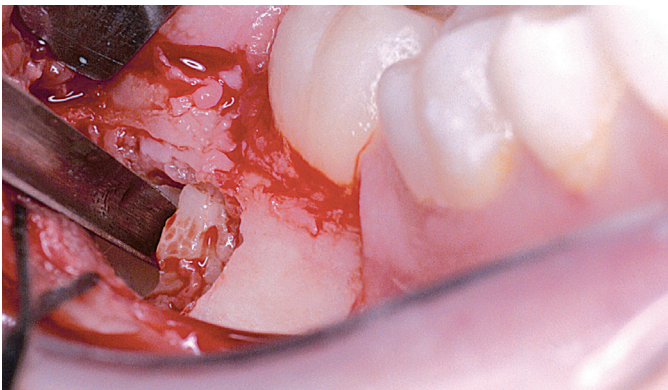
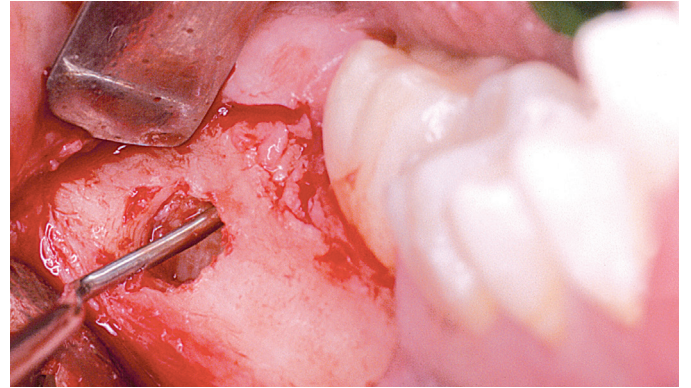
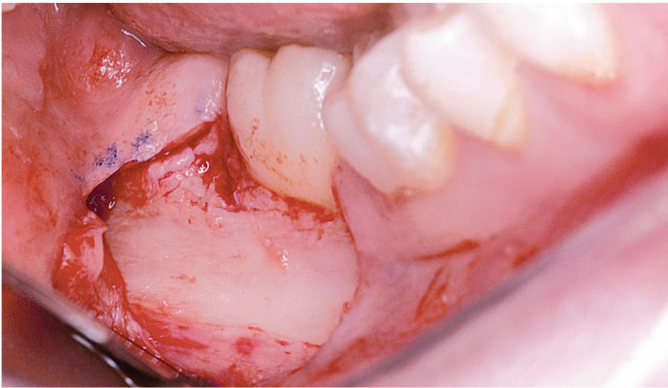


3) screw the implant and remove the hydroxylapatite in excess:



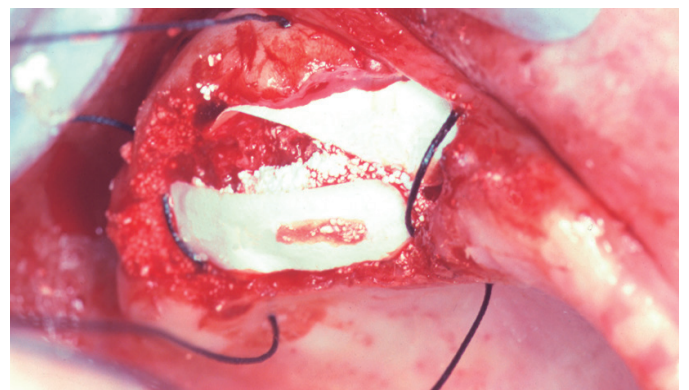
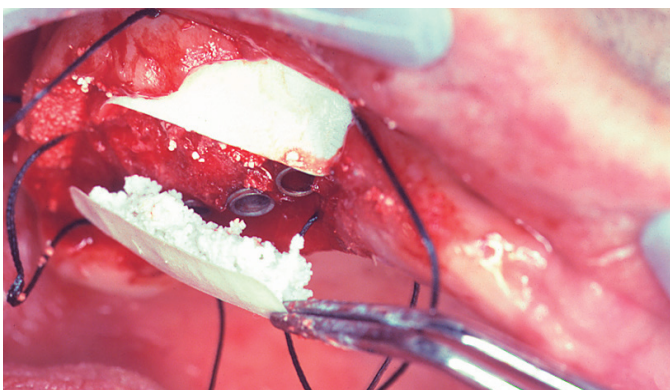
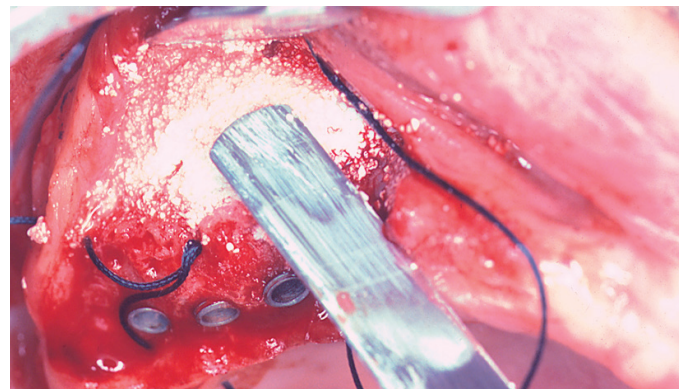
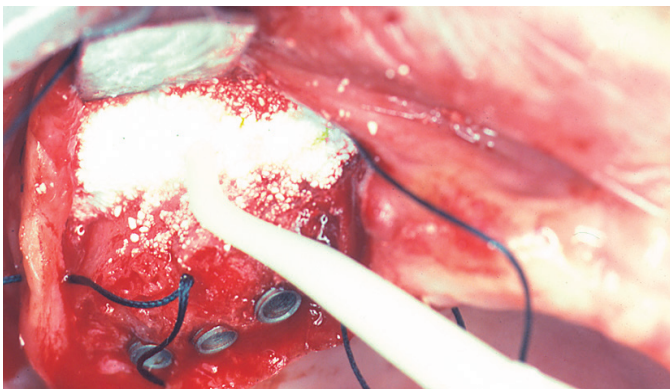
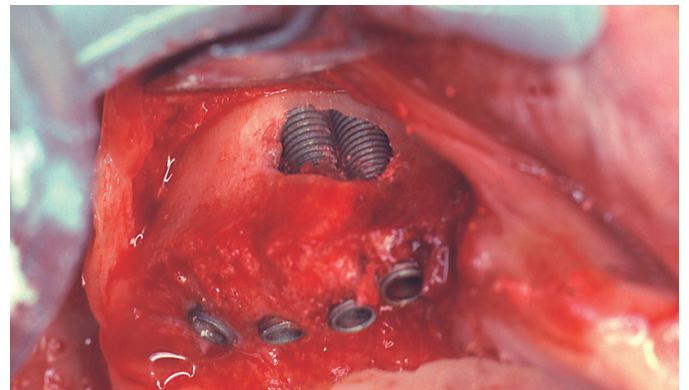
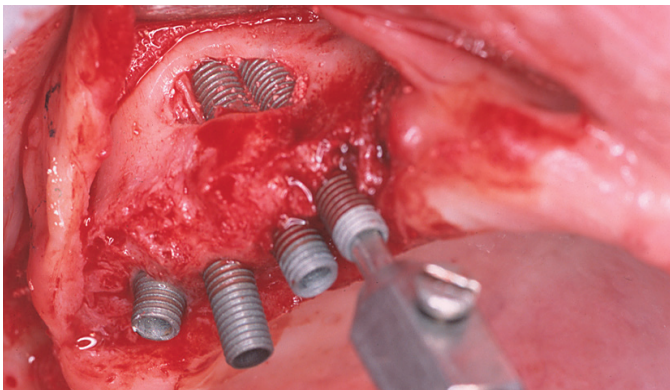
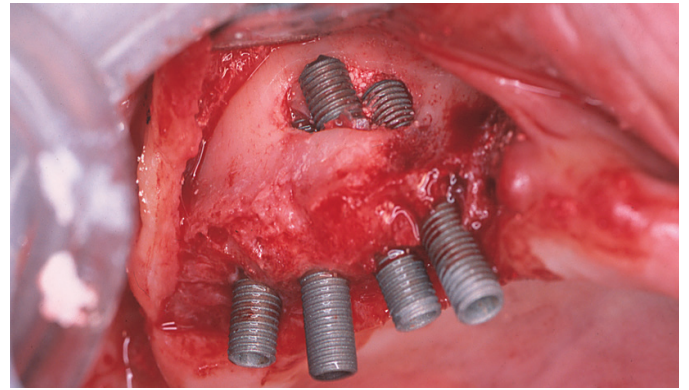
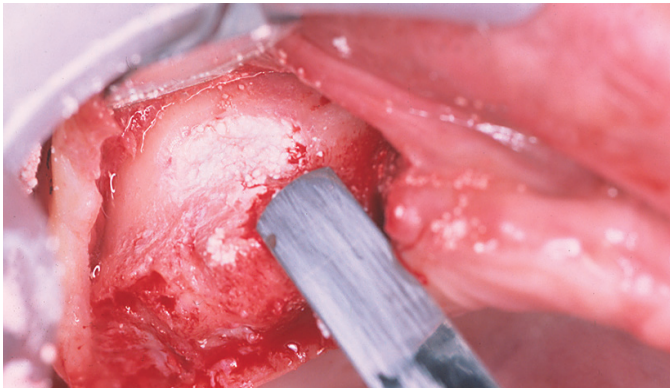
- The Idrossilapatite micrometrica AT® remains in the internal thread and stabilizes the system in a few minutes increasing the primary retention.
- The external thread in direct contact with the bone allows the first osseointegration.
- The Idrossilapatite micrometrica AT® is reabsorbed in the following months with the extension of osseointegration.
- The Idrossilapatite micrometrica AT® increases the torque of the implants up to 100%.
- The Idrossilapatite micrometrica AT® is the solution for primary stability of implants in the bone tissue type 3 and 4.

BONY REGENERATION IN THE SOCKET OF THE WISDOM TOOTH



**EXAMPLE OF SPECIFIC USE OF THE MATERIALS FOR GUIDED
REGENERATION COLLAGENE AT® IDROSSILAPATITE AT®**

FILLING WITH HYDROXYLAPATITE AND MEMBRANES IN SINUS LIFT

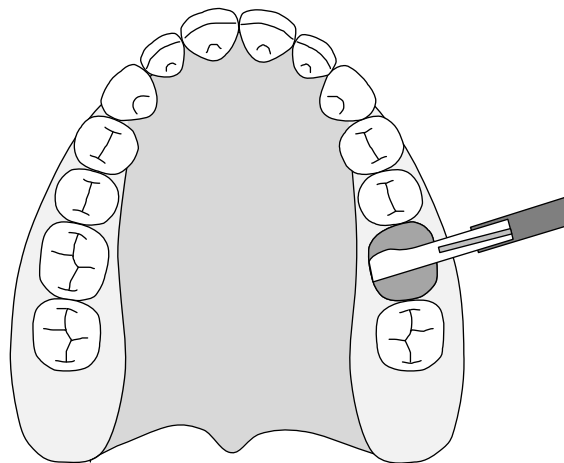


**SPECIFIC INDICATIONS AND INSTRUCTIONS FOR
GUIDED REGENERATION MATERIALS SYSTEM
COLLAGENE AT® IDROSSILAPATITE AT®
ORAL SURGERY: FILLING OF POST-EXTRACTIVE SOCKETS**

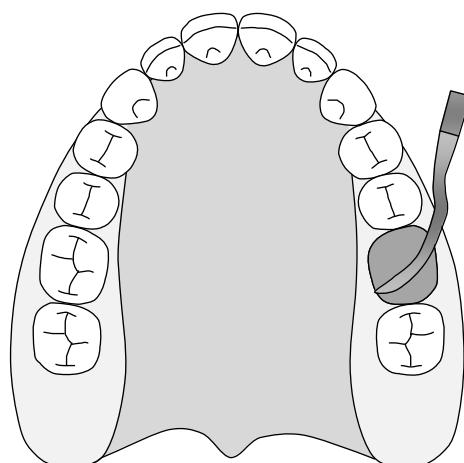
The filling of post-extractive sockets with Idrossilapatite AT® and Collagene AT® membranes prevents bone atrophy and promotes bone growth avoiding epithelial and soft connective tissue cells migration inside the socket.

The filling can be performed without slipping of flaps to close the socket; in this case the membrane is exposed and must be covered with a surgical dressing till the healing tissue growth.

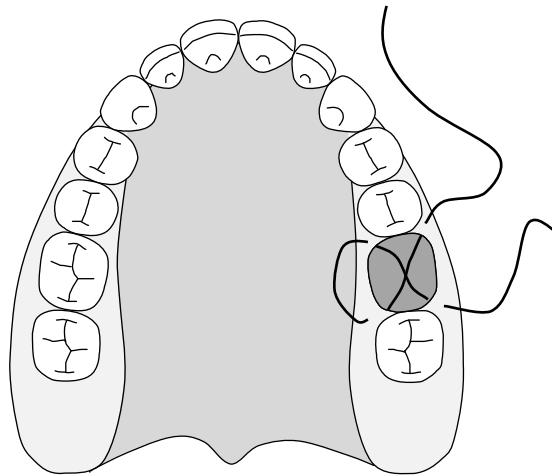
1) after tooth extraction, make a surgical incision with scalpel all around the alveolar ridge;



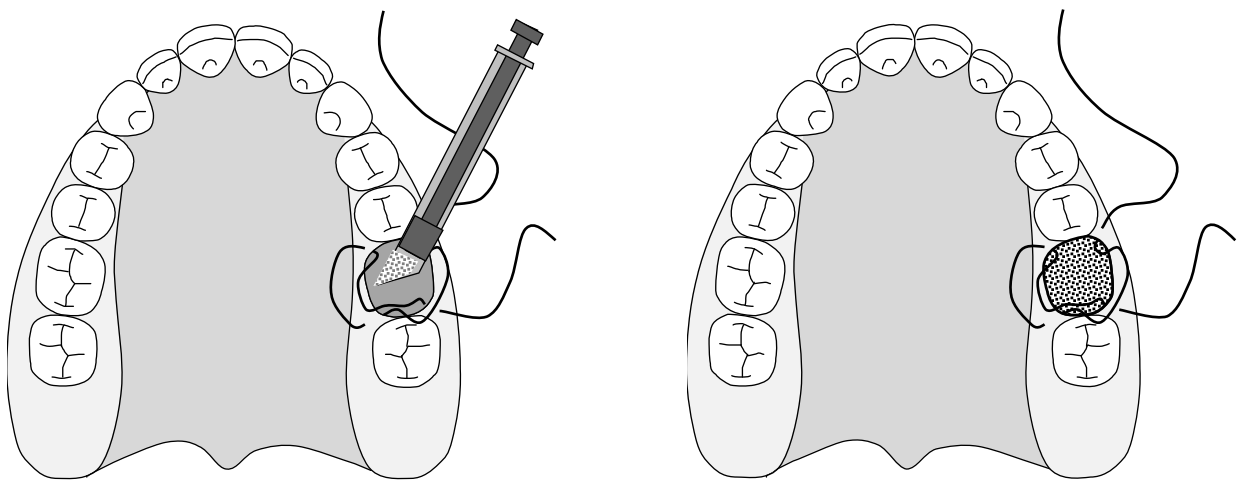
2) expose bone all around the socket for few millimeters;



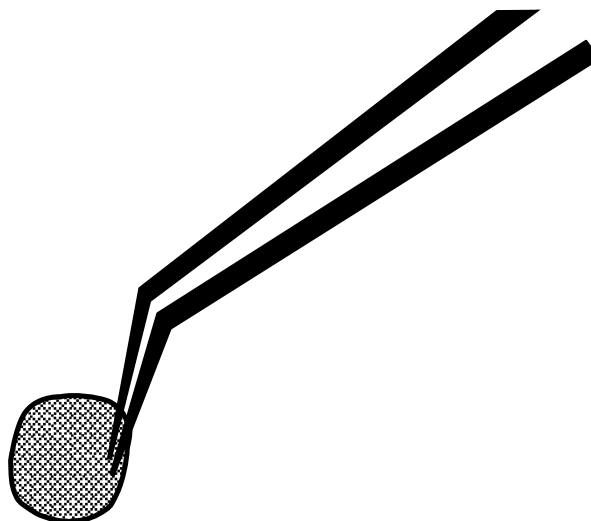
3) pass the sutures without tying. Use simple sutures or crossed sutures. Sutures must pass over the socket;



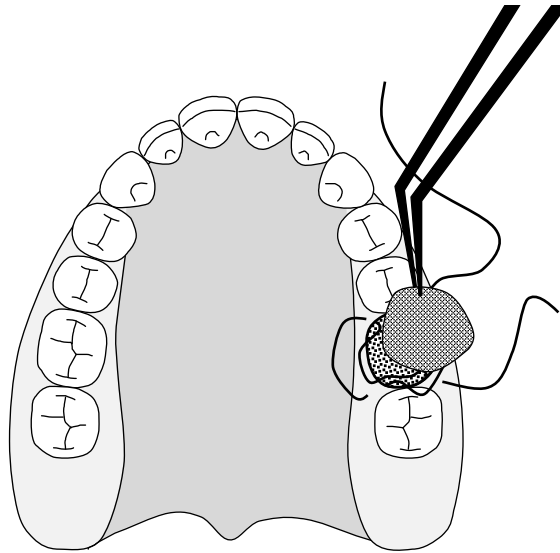
4) fill the socket completely with Idrossilapatite AT® and press with a dry gauzes;



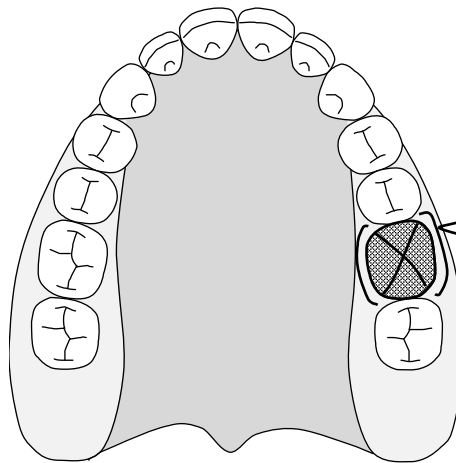
5) cut a quadrangular Collagene AT® membrane wide enough to cover the bony socket margin for about two millimeters;



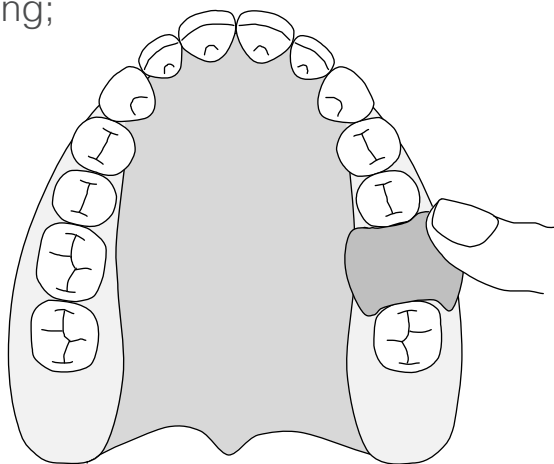
6) apply the Collagen AT® membrane with dental tweezers and adapt it with blunt instruments;



7) press with dry gauzes;
8) tie and complete the sutures;



9) apply a surgical dressing;



10) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

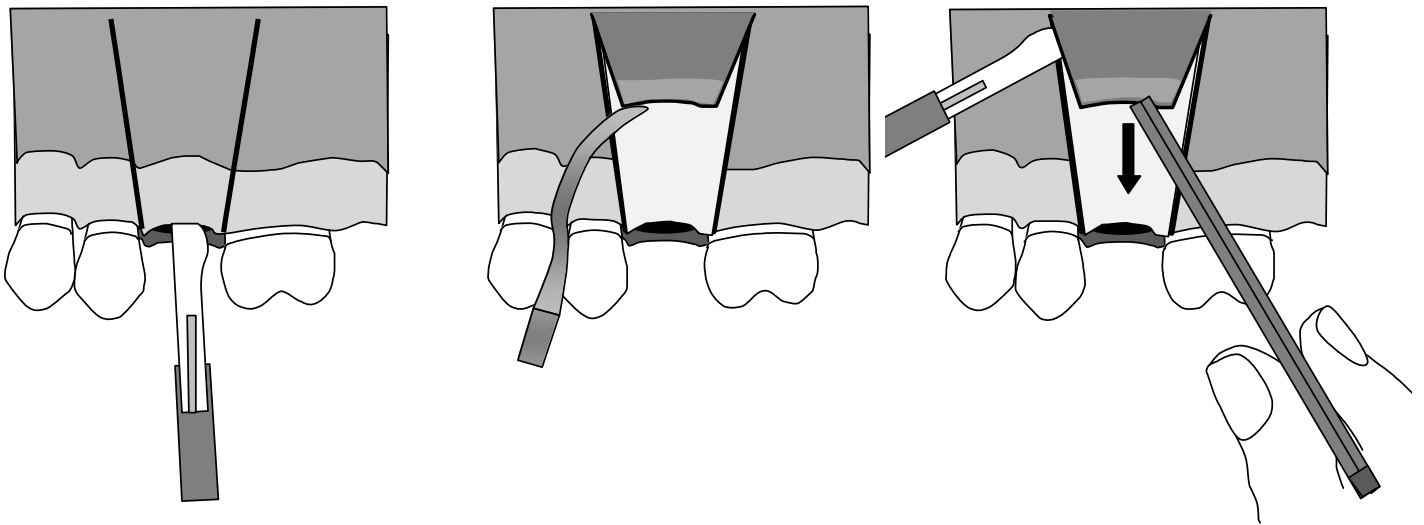
After one week remove surgical dressing and sutures.

Warning: apply a surgical dressing again, if needed, till the healing tissue covers all the socket.

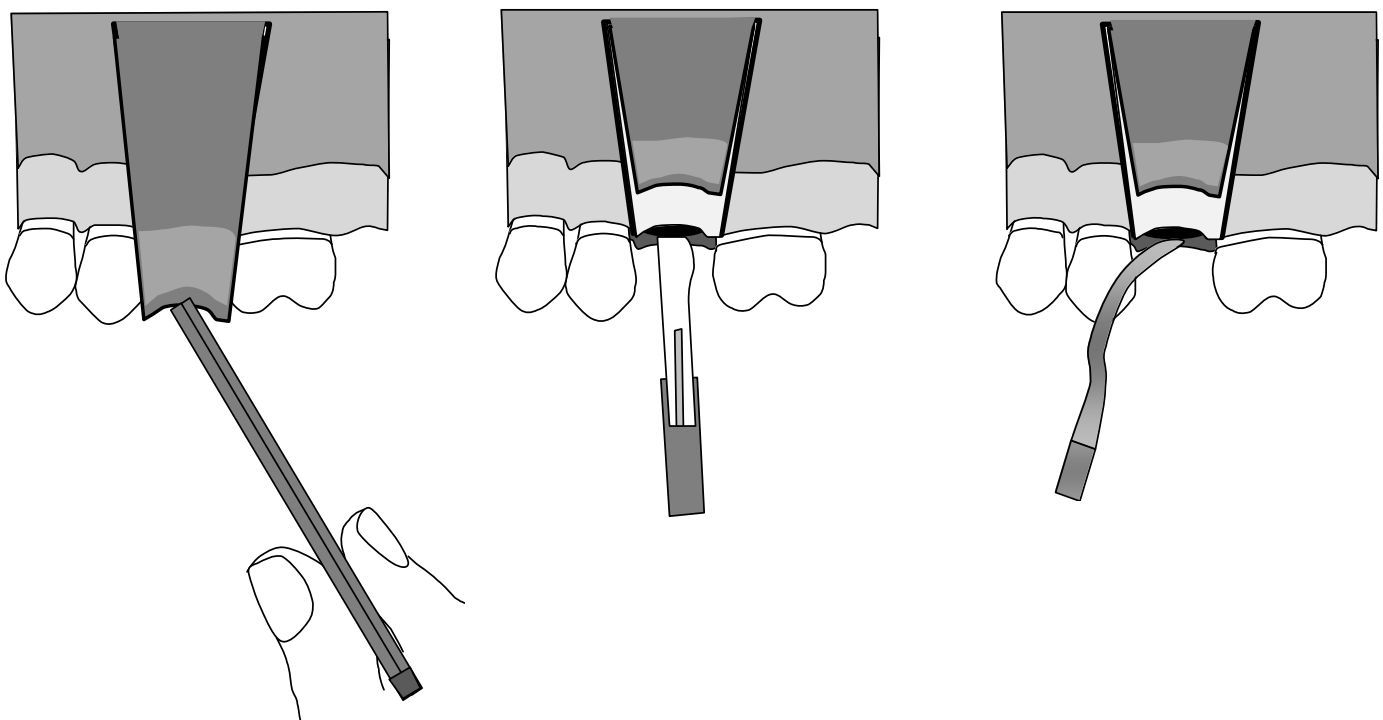
ORAL SURGERY: FILLING OF SINUS-ORAL POST-EXTRACTIVE COMMUNICATION

The application of two Collagene AT® membranes, one on the sinus side, the other in occlusal side of the socket, and the filling of the socket with Idrossilapatite AT® allows to close the sinus-oral communication.

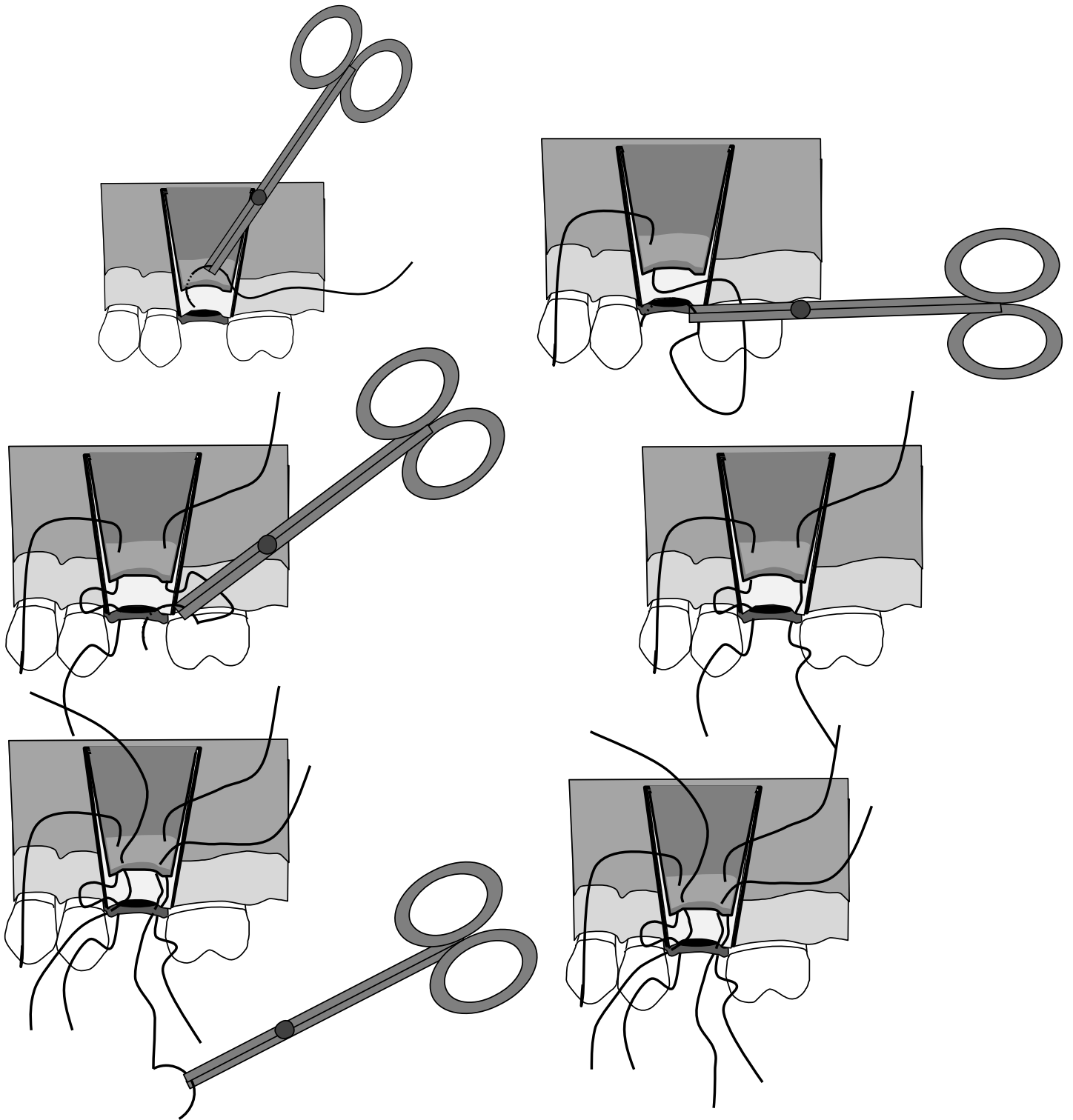
1) after tooth extraction and diagnosis of sinus-oral communication, make a surgical incision with scalpel all around the socket;



2) reflect buccally a full thickness mucoperiosteal flap exposing bone margin with two vertical incisions, with 20-30 degrees angle, to get a valid mobilisation;

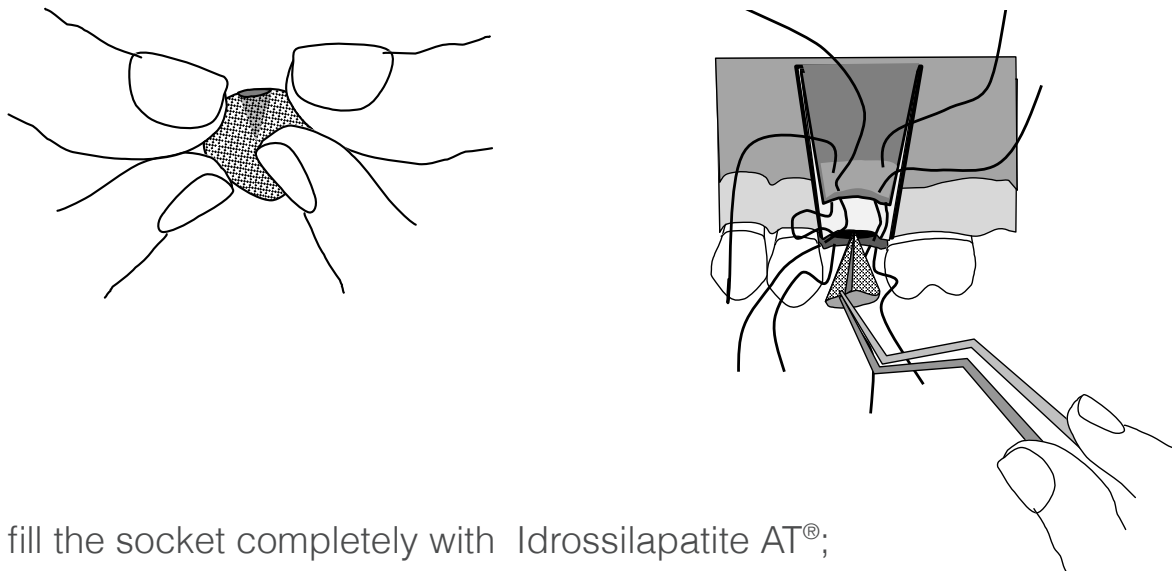


3) pass the sutures without tying;

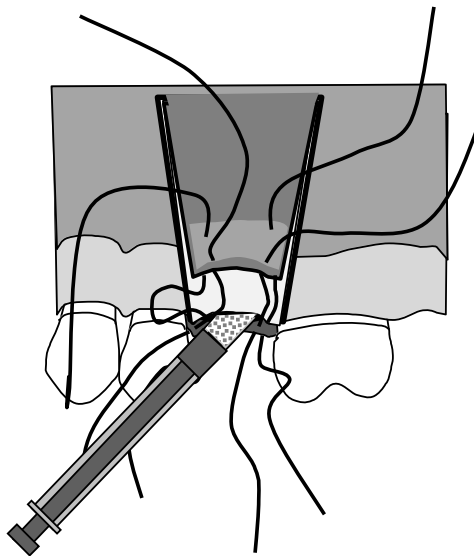


4) cut a quadrangular Collagene AT® membrane and apply it in the socket depth corresponding to the communication; the membrane must be very wide to cover the deep bone margin for many millimeters;



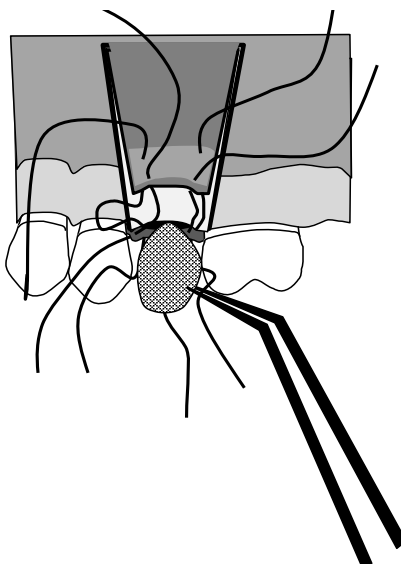


5) fill the socket completely with Idrossilapatite AT®;

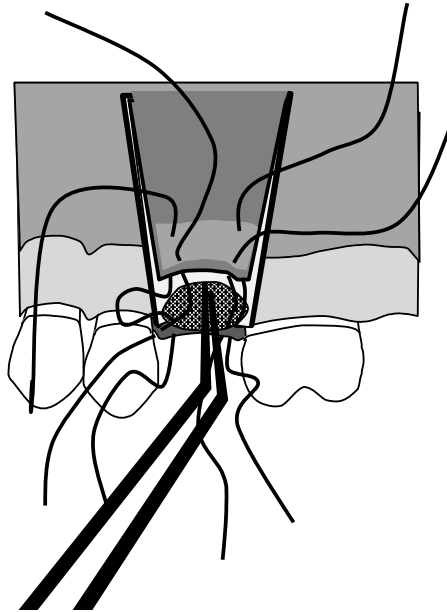


Warning: press with a gauze with moderate pressure, to avoid the hydroxylapatite displacing into the maxillary sinus.

6) cut another quadrangular Collagene AT® membrane wide enough to cover occlusal socket bone margins for about two millimeters;

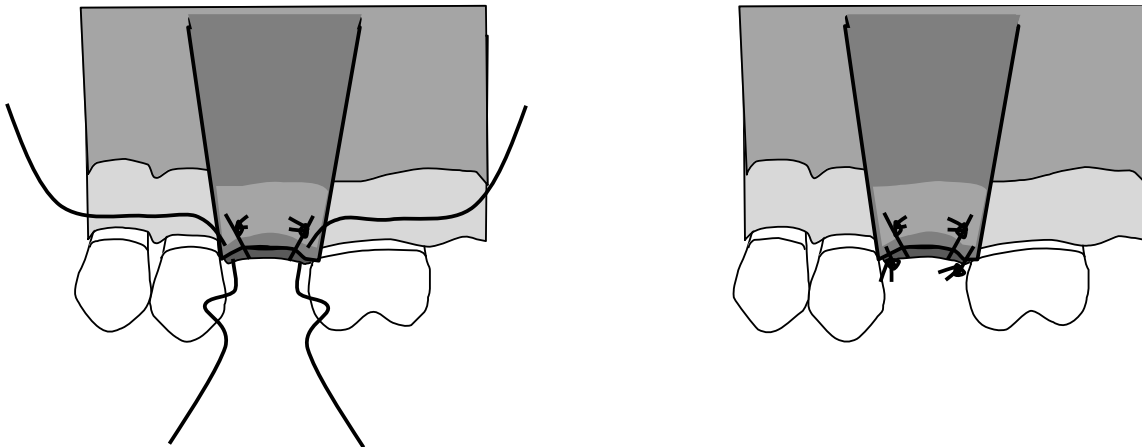


7) apply the Collagene AT[®] membrane with dental tweezers and adapt with blunt instruments on the occlusal socket margins;



8) press with dry gauzes;

9) tie and complete the sutures;



10) apply a surgical dressing;

11) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

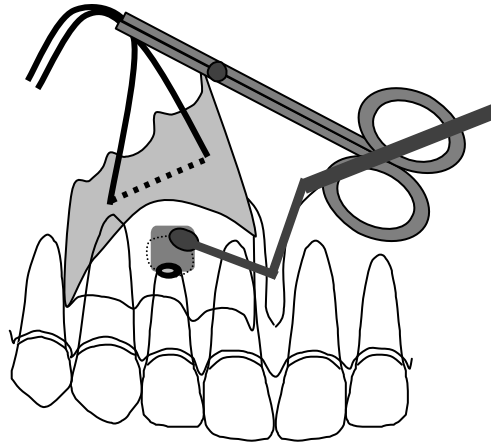
After one week remove surgical dressing and sutures.

Warning: if wound dehiscence occurs, apply a surgical dressing again, till the healing tissue covers all the socket.

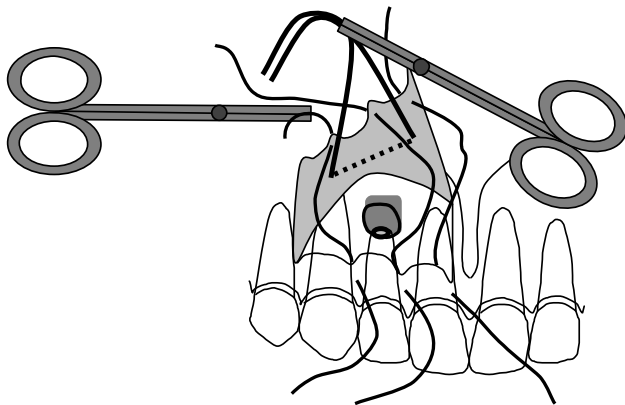
ENDODONTIC SURGERY: FILLING OF PERIAPICAL CAVITIES

The use of guided regeneration materials Idrossilapatite AT[®] and Collagene AT[®] allows new bone growth in the periapical zone without residual cavity.

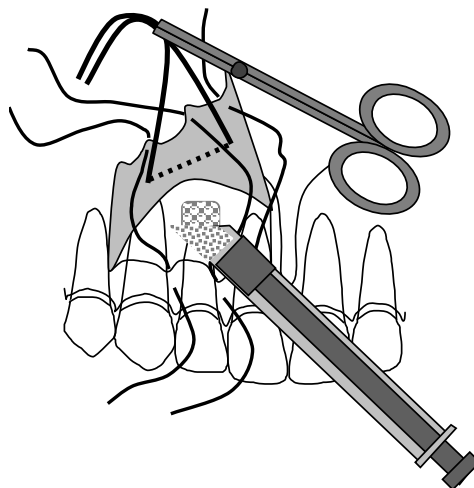
1) after apicectomy is performed, remove all soft tissues inside the periapical lesion;



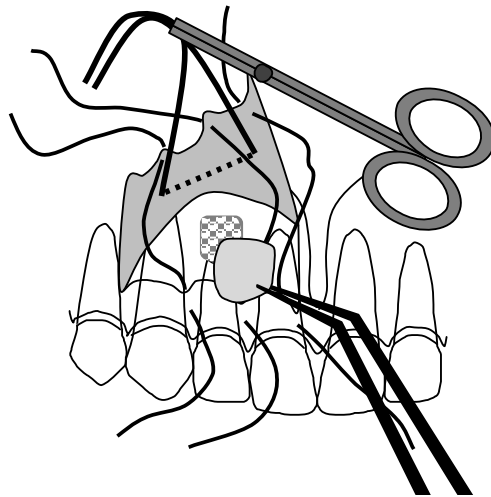
2) pass the sutures without tying and prepare the guided regeneration AT[®] materials.



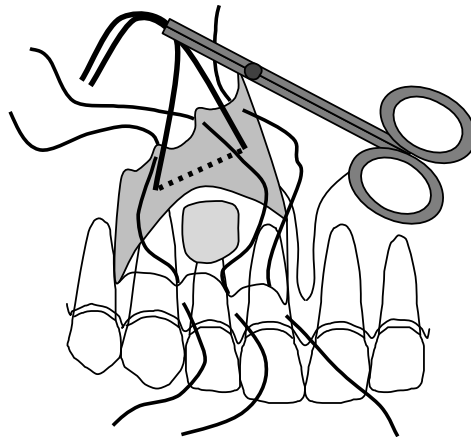
3) put Idrossilapatite AT[®] into the cavity and press with flat obturators and dry gauzes till the complete filling of the periapical cavity;



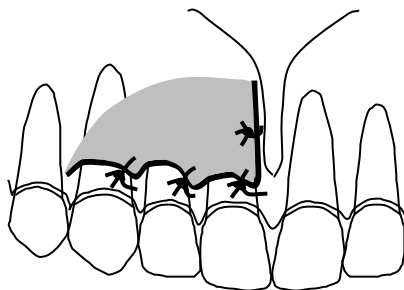
4) apply a Collagene AT® membrane of suitable sizes, covering the bone margins for about two millimeters;



5) adapt the membrane with blunt dry instruments and dry gauzes;



6) tie and complete the sutures so that the flap covers the membrane and the bone completely;



7) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

After one week remove sutures.

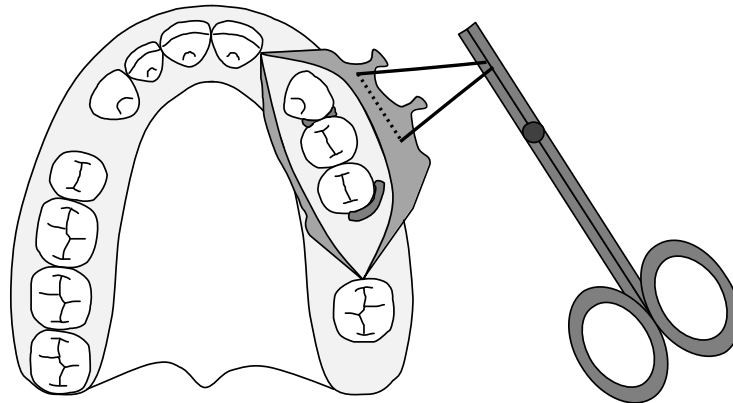
Warning: if wound dehiscence occurs, let the wound heal applying a surgical dressing for protection.

PERIODONTAL SURGERY: GUIDED REGENERATION IN INTRABONY POCKETS

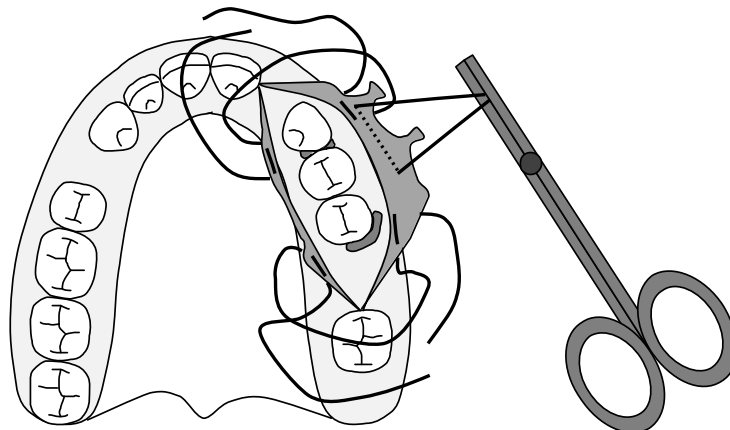
The filling of intrabony pockets with Idrossilapatite AT® and the placing of Colla-gene AT® membranes permits the growth of new periodontal and bone tissues, due to the barrier effect which avoids the soft epithelial and connective tissue cells migration.

Guided bone regeneration and guided periodontal tissue regeneration are as greater as deeper and narrower are the intrabony pockets.

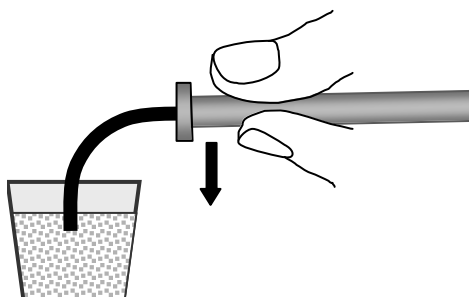
- 1) reflect the flaps and completely expose the intrabony pockets;



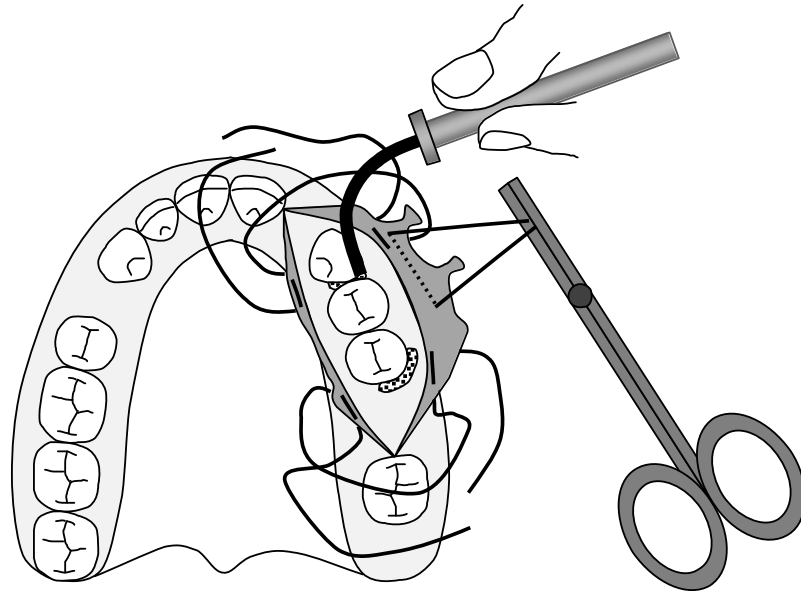
- 2) remove all the soft tissue inside the pockets;
- 3) completely clean and polish the dental walls of the pockets;
- 4) pass the sutures without tying;



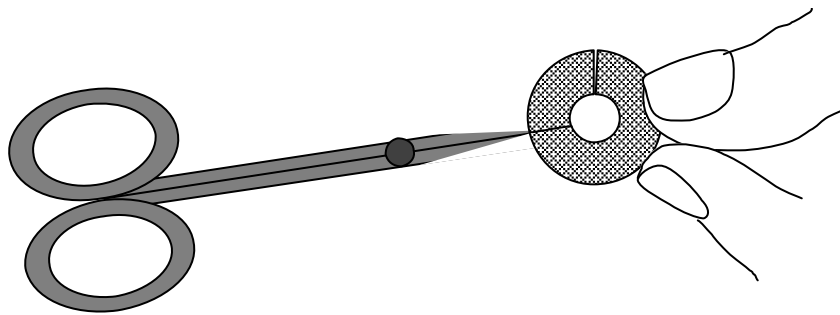
- 5) prepare Idrossilapatite AT®;



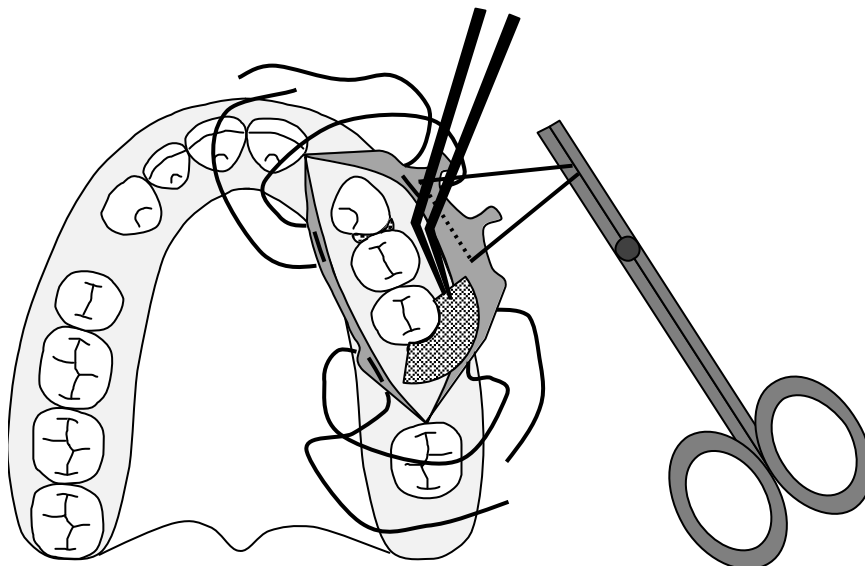
6) introduce the Idrossilapatite AT® pressing with a flat condenser and dry gauzes till the complete filling of the pockets;



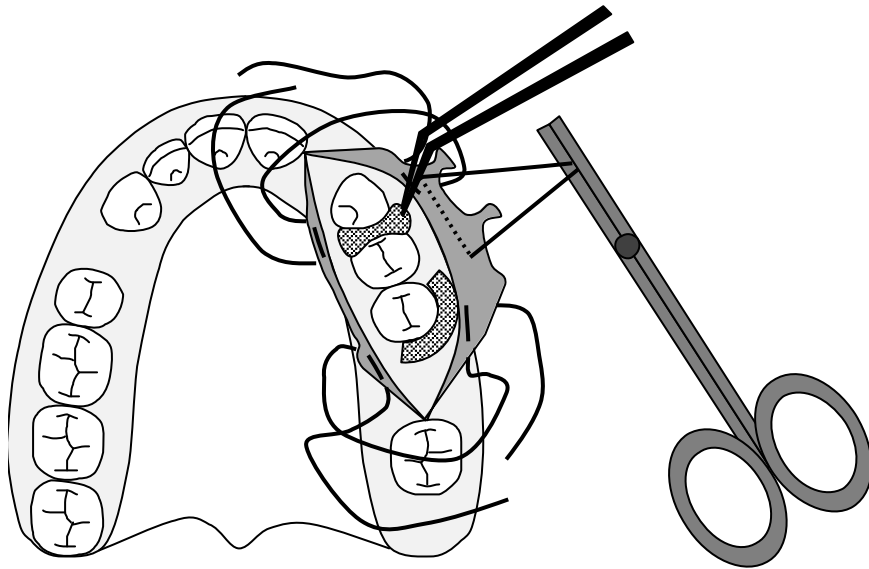
7) cut a circular Collagene AT® membrane wide enough to cover the bony and dental walls of the pockets for about two millimeters;



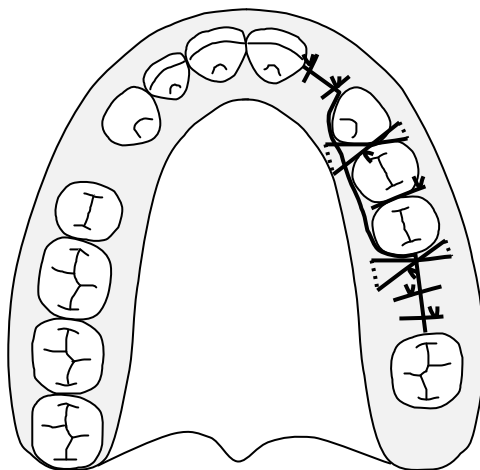
8) apply and adapt the membranes with dry blunt instruments and dry gauzes;



9) tie and complete the sutures. The flap must completely cover the membranes;



10) protect the surgical zone with a surgical dressing;



11) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

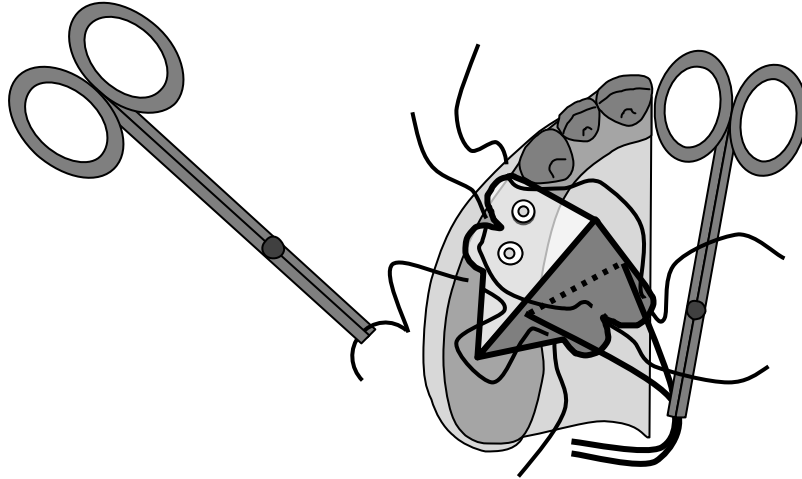
After one week remove surgical dressing and sutures.

Warning: if wound dehiscence occurs, let wound heal applying more surgical dressings.

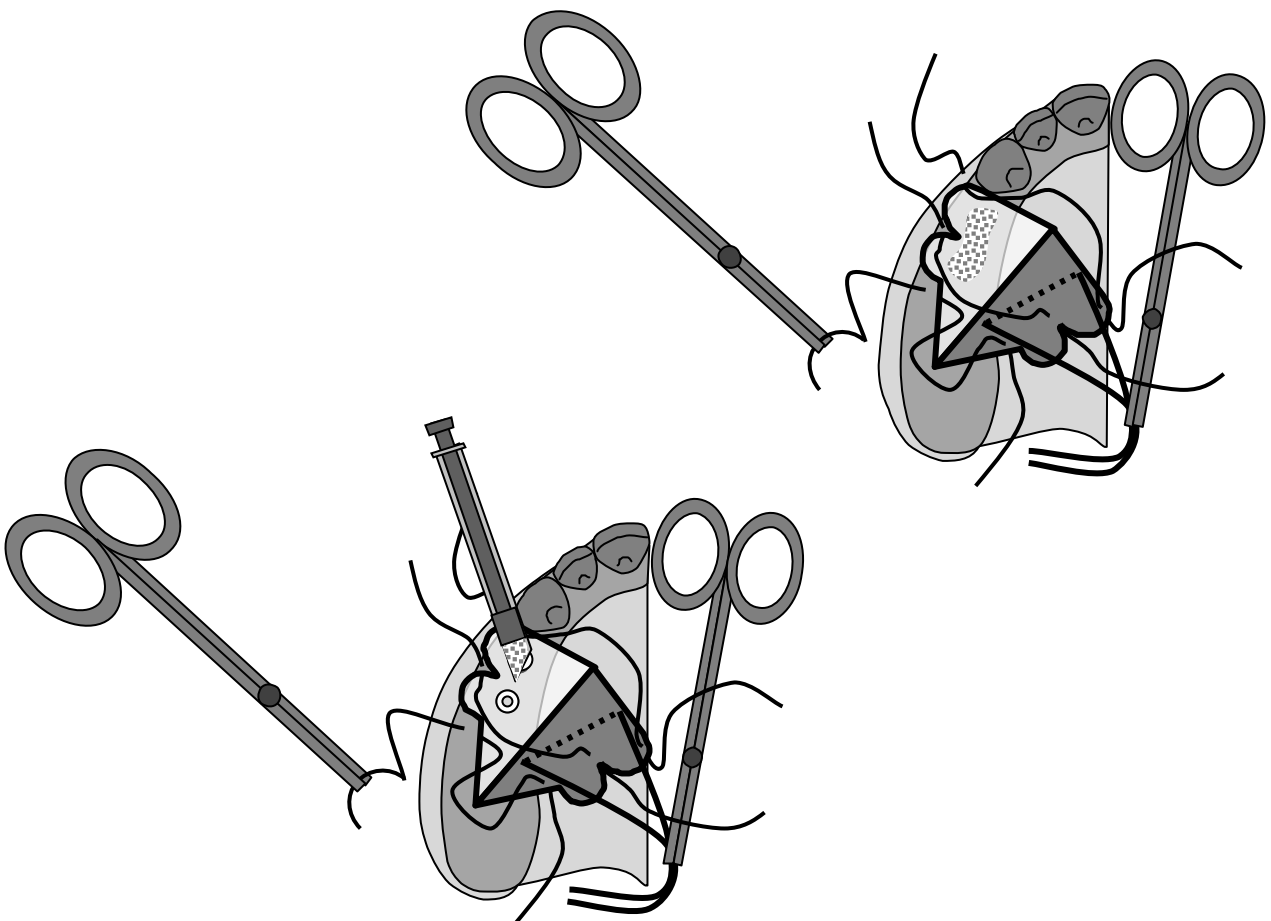
IMPLANT SURGERY: APPLICATION OF REGENERATION MATERIALS TO PREVENT POST-OPERATIVE RIDGE ATROPHY

The application of guided regeneration materials into the micro-space around and on the implants promotes osteoblasts migration in the underlying space reducing the risk of ridge atrophy after implant surgery.

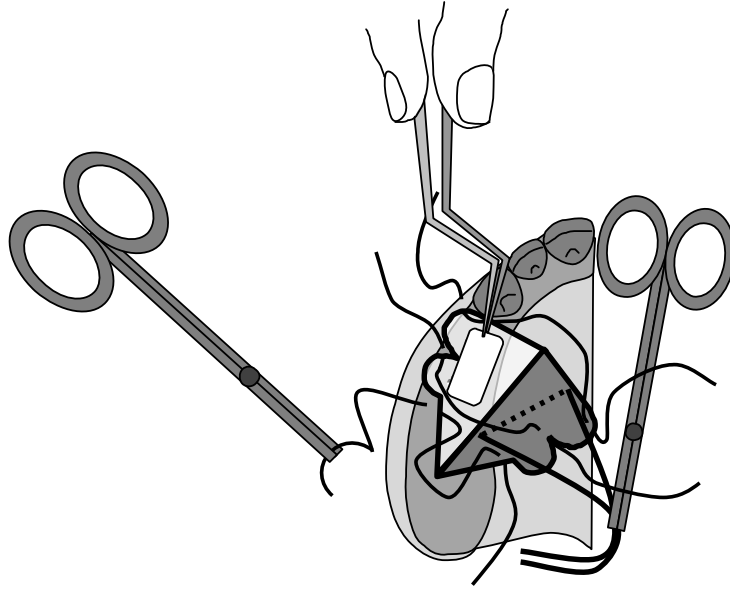
- 1) after the implants insertion, pass the sutures without tying and prepare the guided regeneration AT[®] materials;



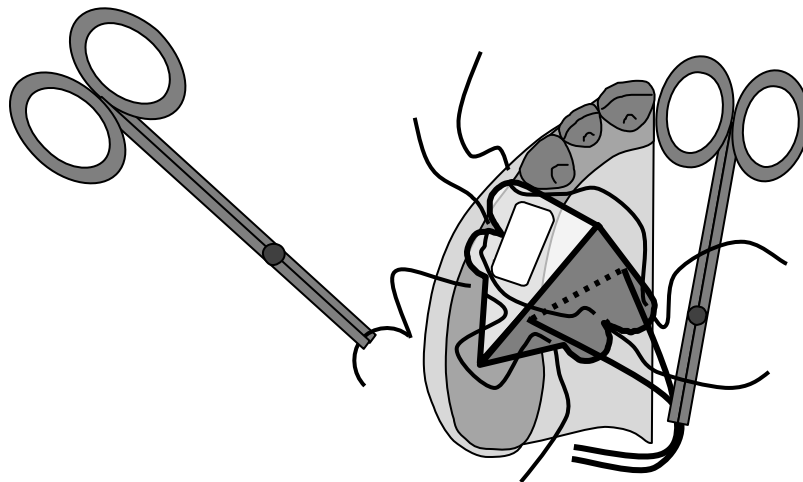
- 2) put the Idrossilapatite AT[®] pressing with dry gauzes to cover the implants;



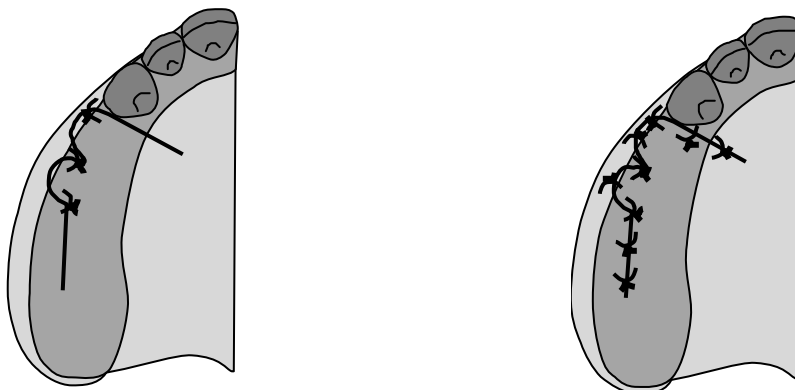
3) apply a Collagene AT® membrane of suitable size to cover the bone margins for about two millimeters;



4) adapt the membrane with dry blunt instruments and dry gauzes;



5) tie and complete the sutures so that the flap completely covers the membrane;



6) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

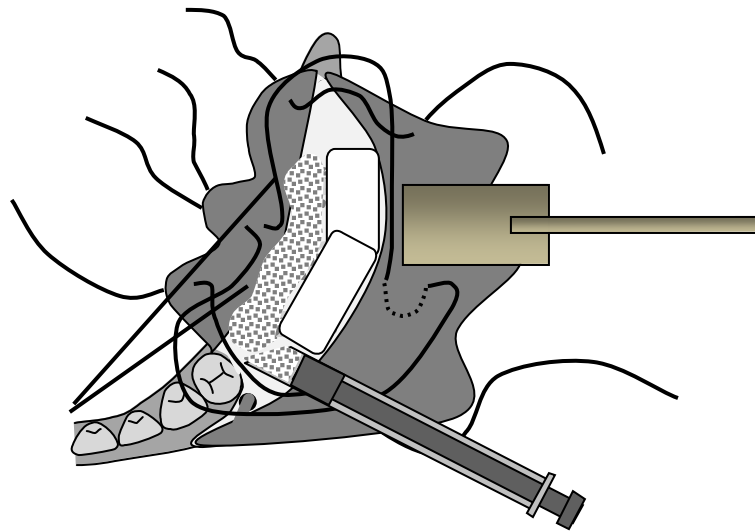
After one week remove sutures.

Warning: if exposure of the guided regeneration materials AT® occurs, allow delayed wound healing applying a surgical dressing.

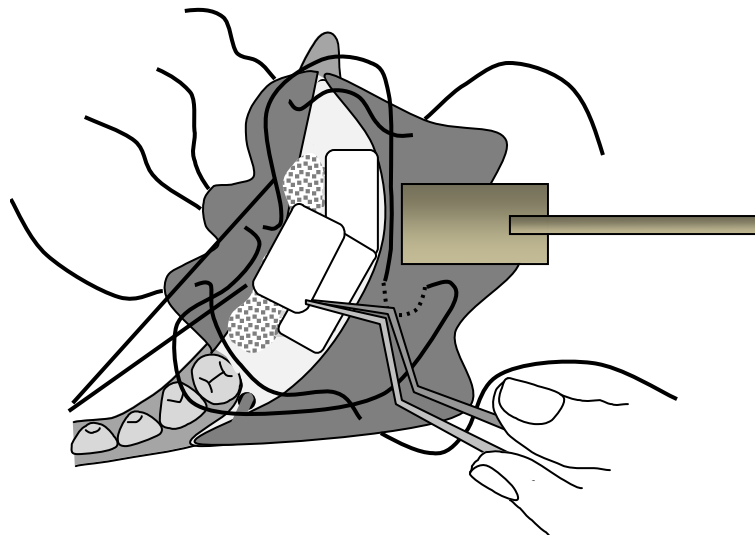
IMPLANT SURGERY: ATROPHIC RIDGES AUGMENTATION BEFORE IMPLANT SURGERY

The application of guided regeneration AT[®] materials laterally and on the atrophic ridges, permits osteoblasts migration and bone growth due to the barrier effect.

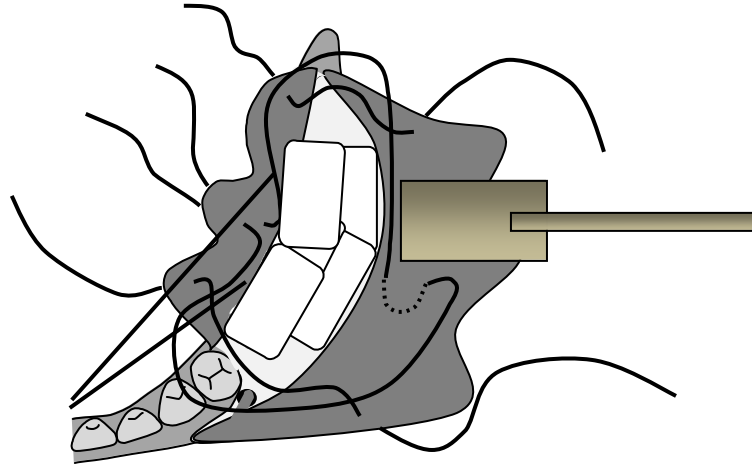
- 1) pass the sutures without tying and prepare the guided regeneration AT[®] materials;
- 2) put Idrossilapatite AT[®] pressing with a flat condenser and dry gauzes;



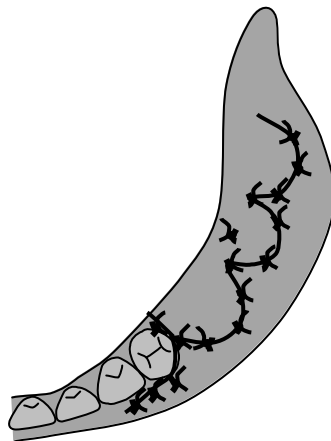
- 3) apply Collagene AT[®] membranes with suitable size covering bone margins for about two millimeters;



4) fit the Collagene AT® membrane with dry blunt instruments and dry gauzes; if the stabilization is insufficient, apply more membranes;



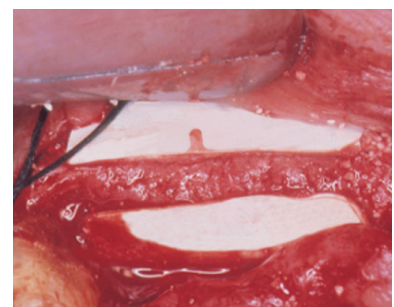
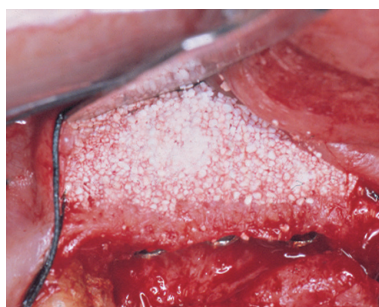
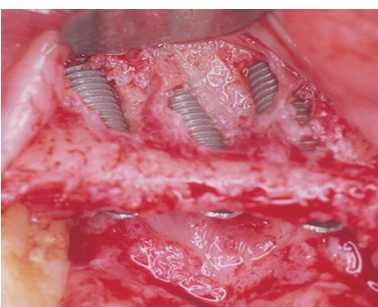
5) tie and complete the sutures so that the flaps completely cover the membrane;



6) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

After one week remove sutures.

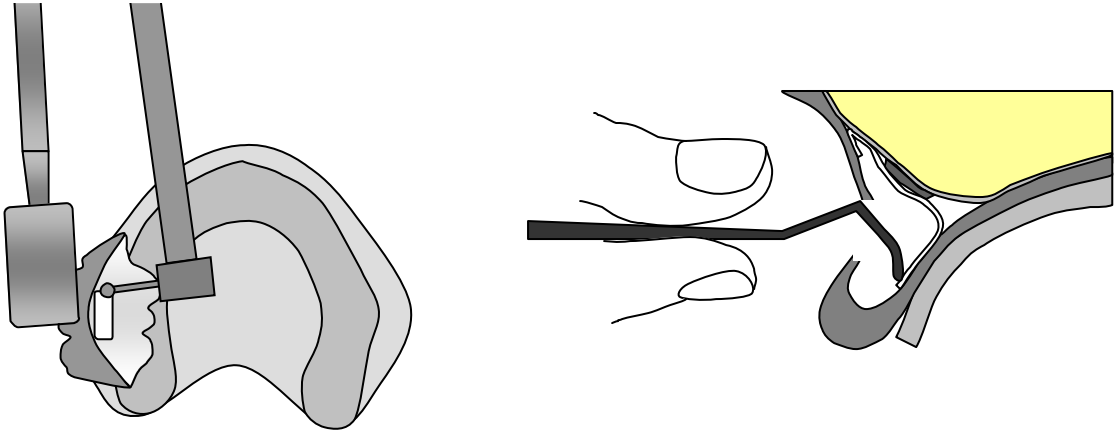
Warning: if exposure of the guided regeneration AT® materials occurs, allow delayed wound healing applying a surgical dressing.



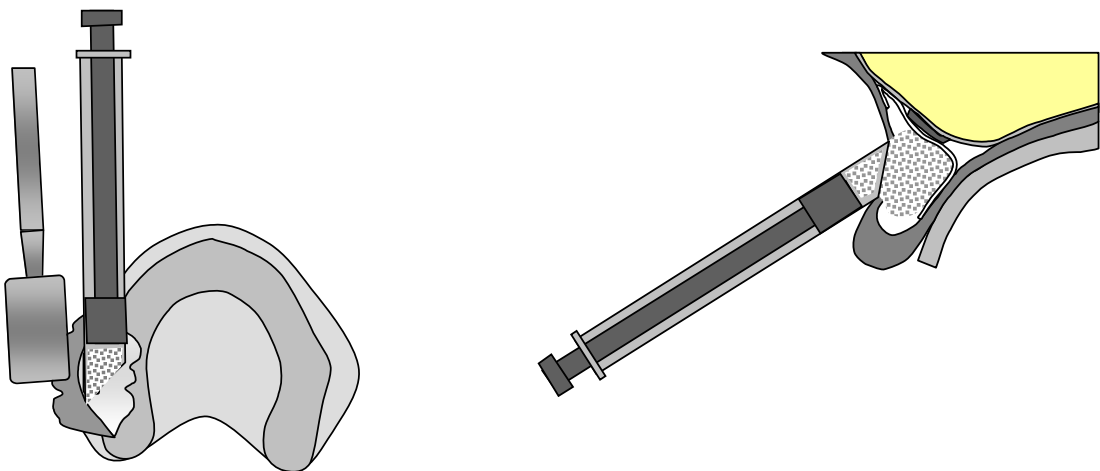
IMPLANT SURGERY: GUIDED BONE REGENERATION IN MAXILLARY SINUS LIFT

The application of guided regeneration AT® materials permits new bone growth in the space obtained after maxillary sinus lift.

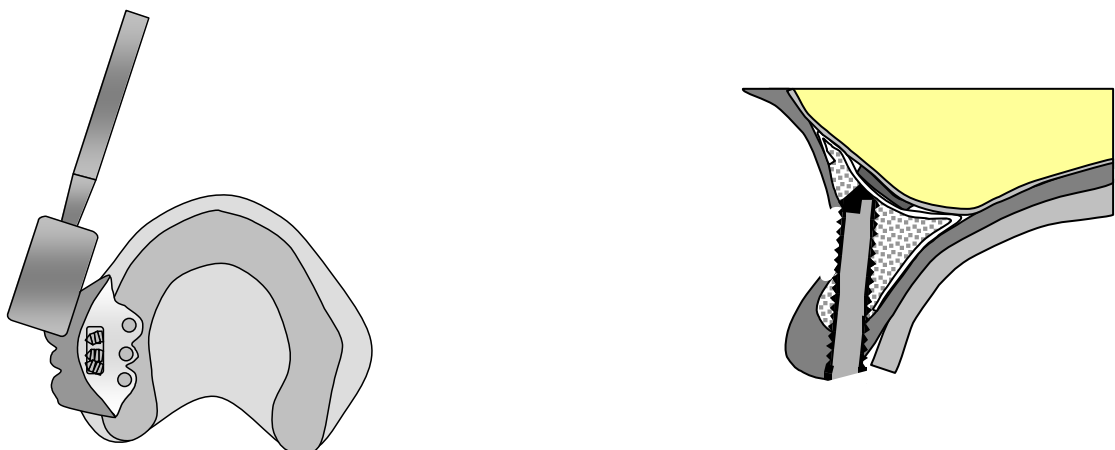
1) perform the bony window to reach the maxillary sinus and lift the sinus mucous membrane;



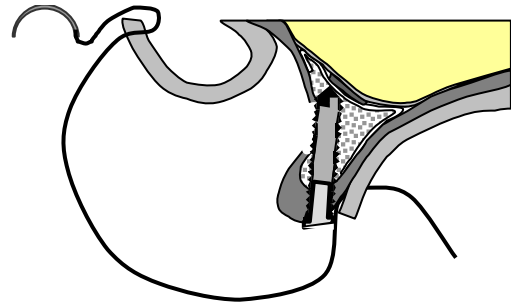
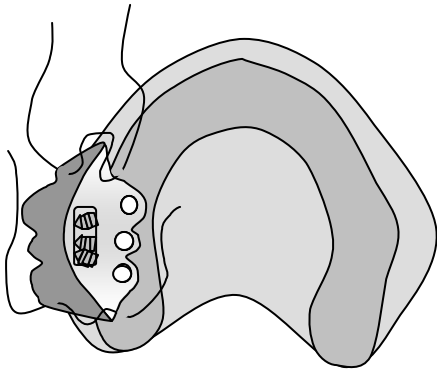
2) apply a first quantity of Idrossilapatite AT® in the most apical and palatal areas, gently pressing with dry gauzes;



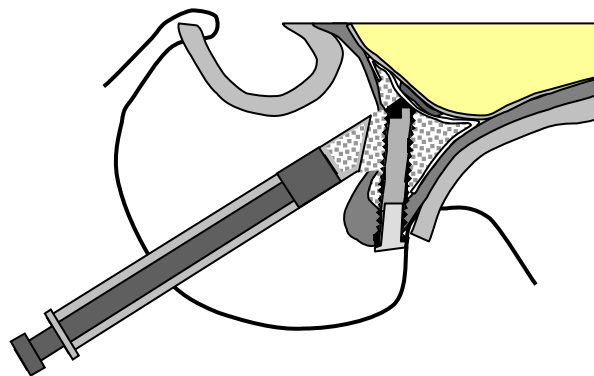
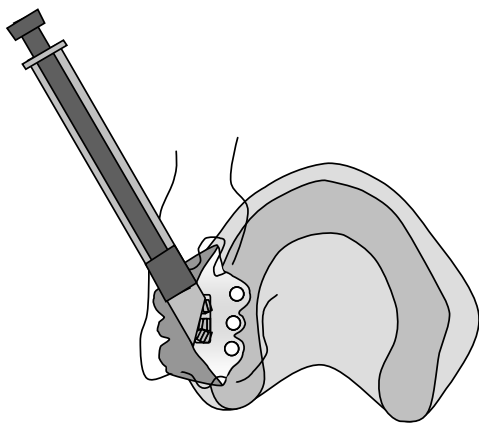
3) insert the implants after making the holes in the residual alveolar ridge;



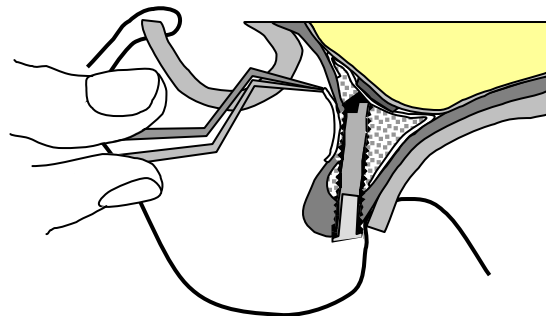
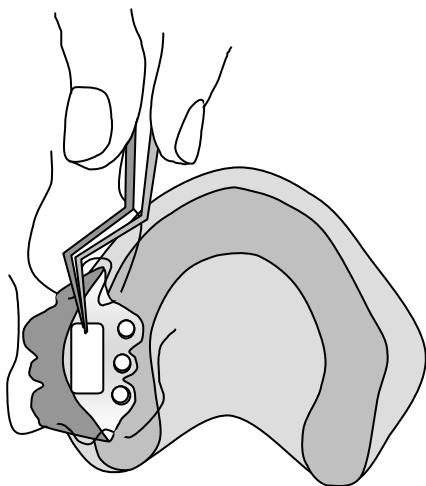
4) pass the sutures without tying;



5) apply more Idrossilapatite AT® and compact it with dry gauzes;



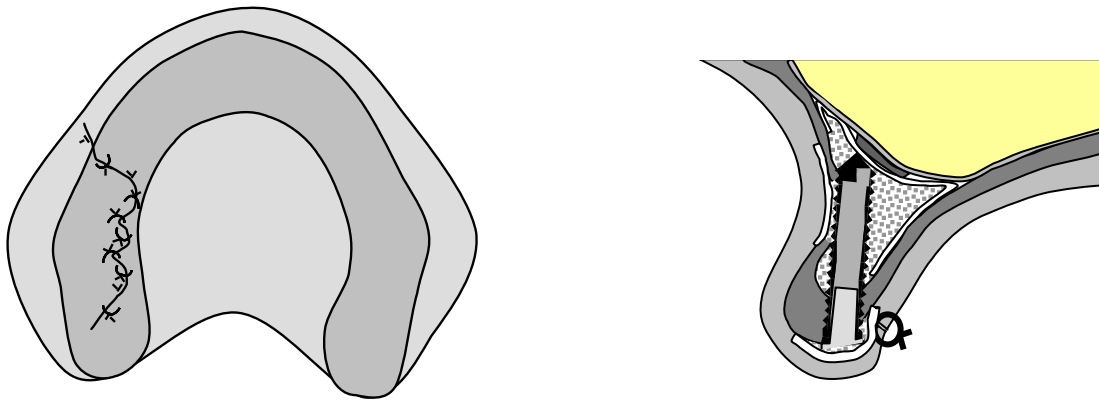
6) cut a quadrangular Collagene AT® membrane and apply on the bony window. The membrane must be wide enough to cover the bony window margins for at least two millimeters;



7) apply the membrane with dental tweezers and fit it with dry blunt instruments on the bony window margins;

8) gently press the membrane with dry gauzes;

9) tie and complete the sutures;

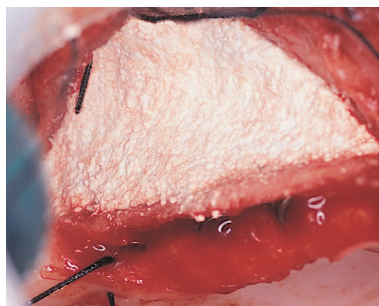
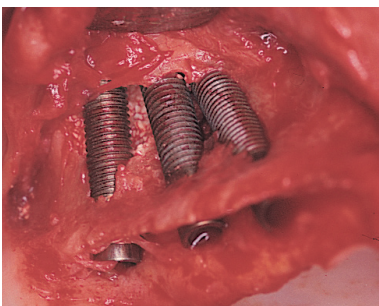


10) prescribe a pharmacological treatment and advise to avoid chewing in the operated zone till sutures removal.

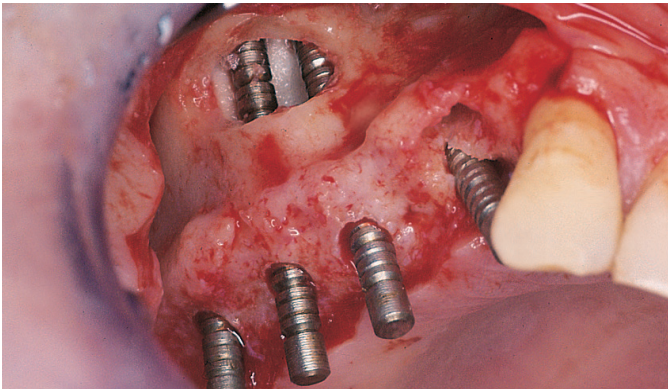
Warning: if sinus-oral communication occurs during the sinus membrane lifting, apply another Collagene AT® membrane covering the margins of communication for many millimeters to close the communication; insert gently and carefully Idrossilapatite AT® material to avoid dispersion inside of the maxillary sinus.

After one week remove sutures.

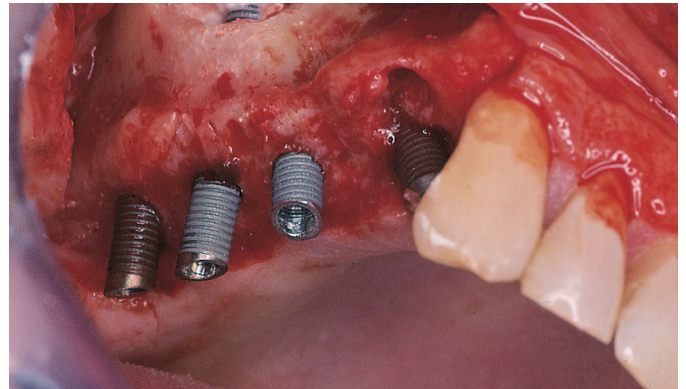
Warning: if exposure of guided regeneration AT® materials occurs, allow delayed wound healing applying a surgical dressing.



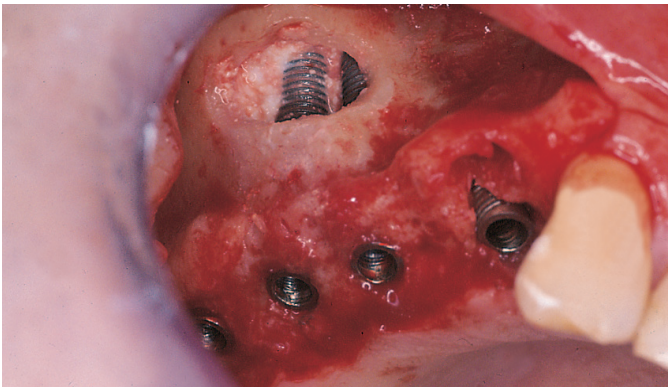
UTILIZATION OF GUIDED TISSUE REGENERATION MATERIALS COLLAGENE AT® IDROSSILAPATITE AT® IN SINUS LIFT



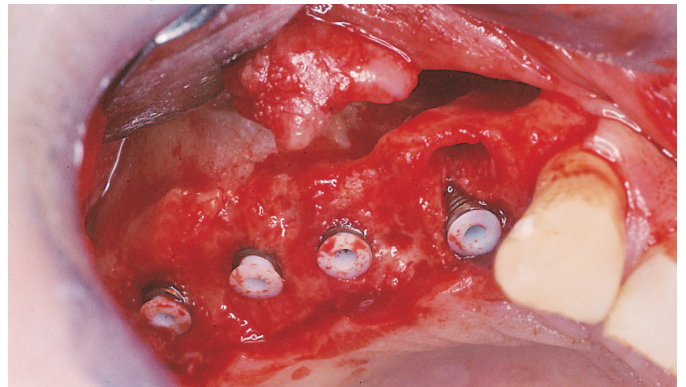
You screw implants with margin angled at 20 degrees and with progressive thread to get the maximum primary stability.



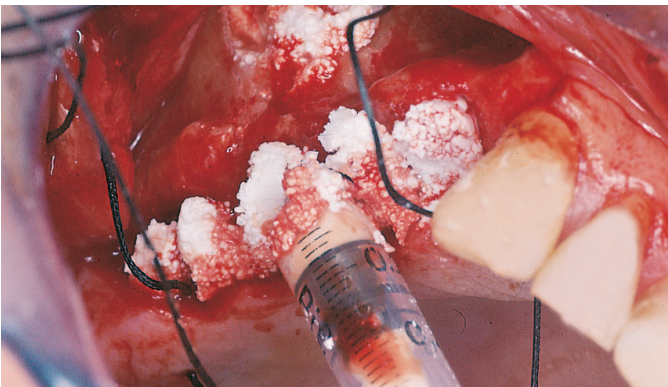
At the end of the insertion by rotating the implants are made to correspond the inclined planes of the margins to the configuration of the ridge.



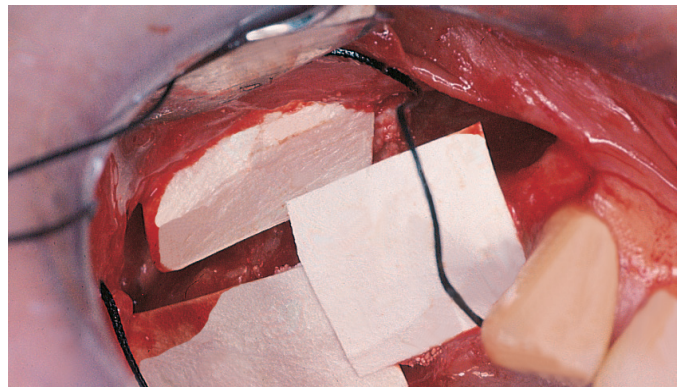
The implants meet in the side wall of the maxillary sinus bone from the inside and their bicorticalism increases the primary stability.



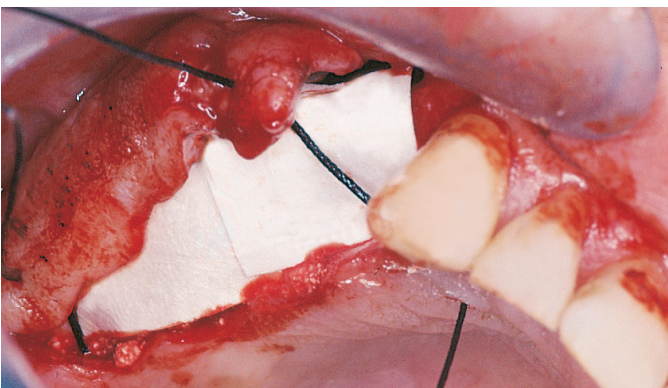
Apply into the inner holes of the implants the closing elastic seals to keep the membranes for GBR lifted up.



Apply the osteoconductive material in the side window and above the margins of the implants.



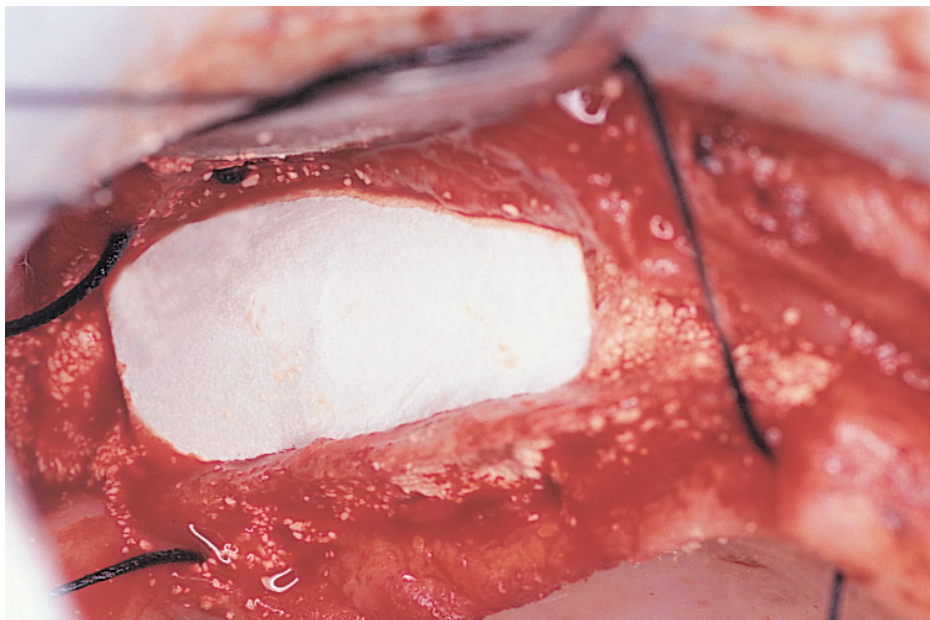
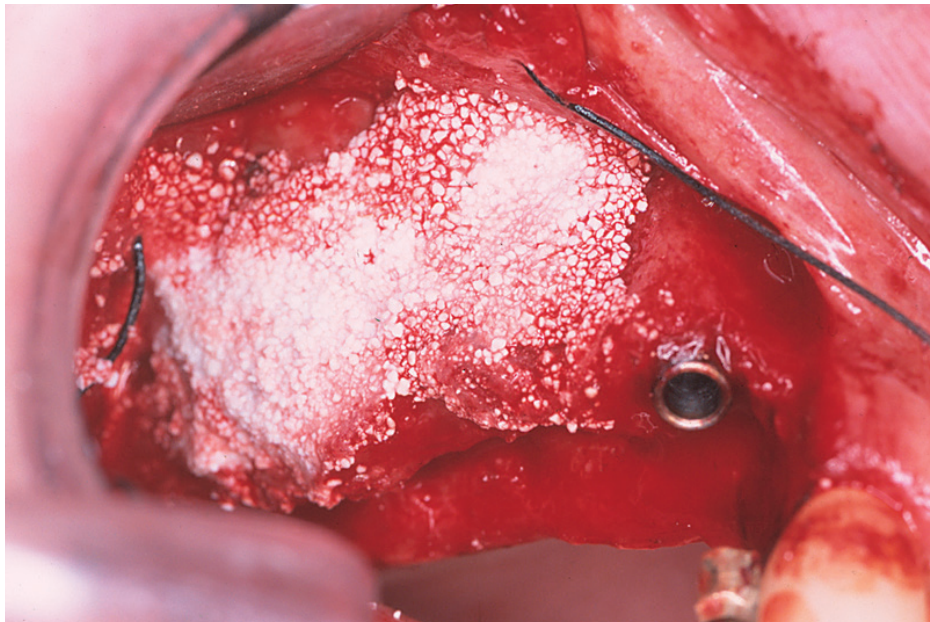
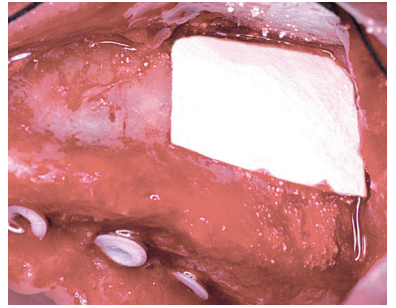
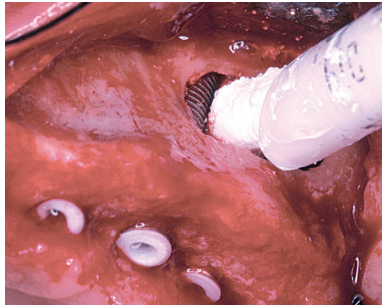
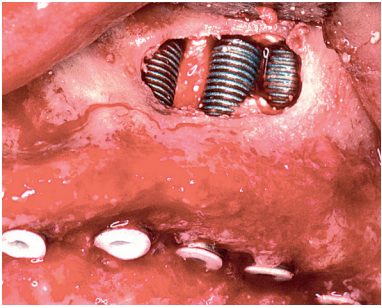
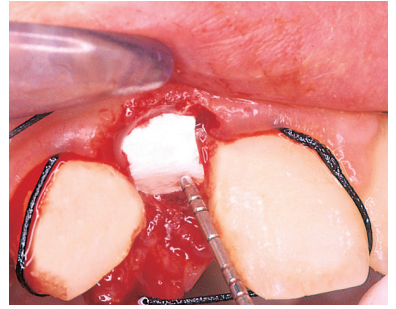
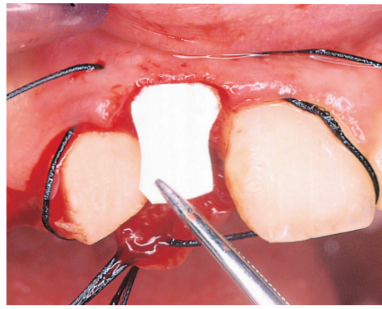
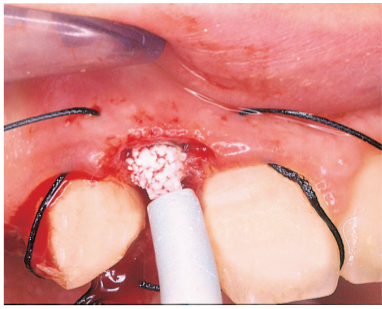
Apply collagen membranes to promote bone growth around the implants and above the hermetic inserts.

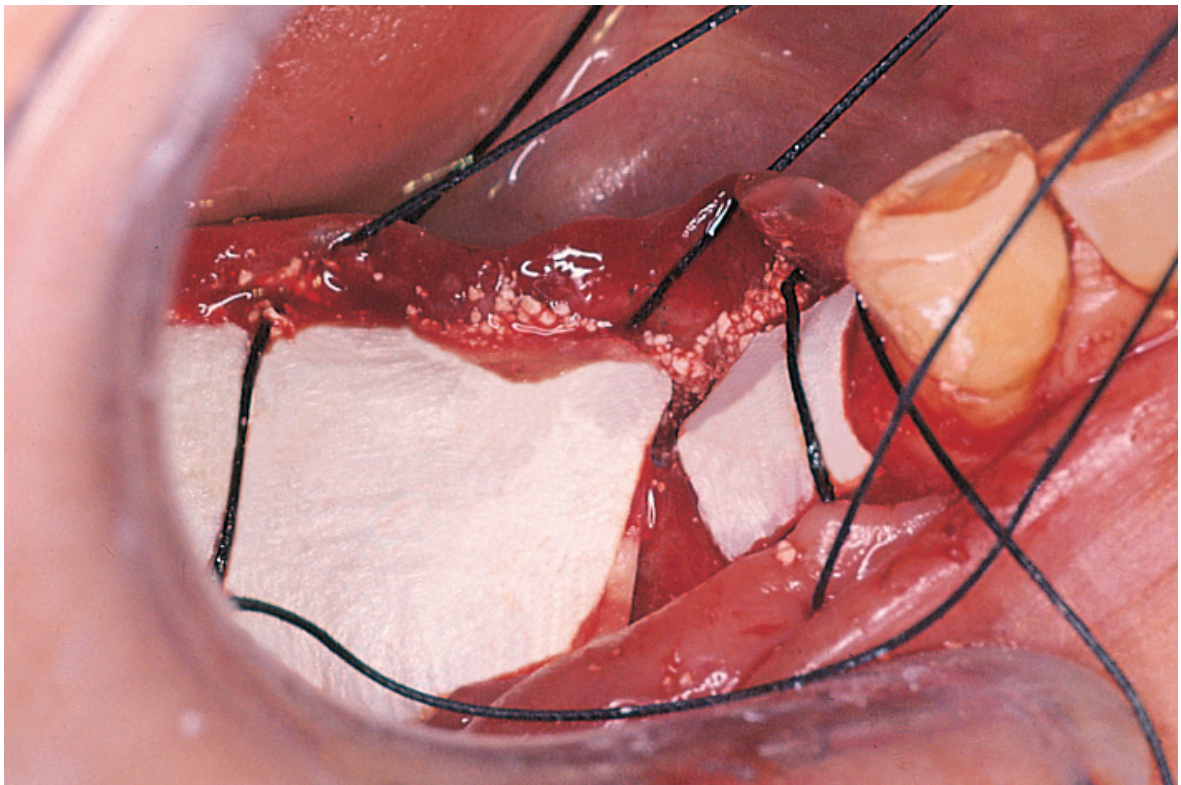
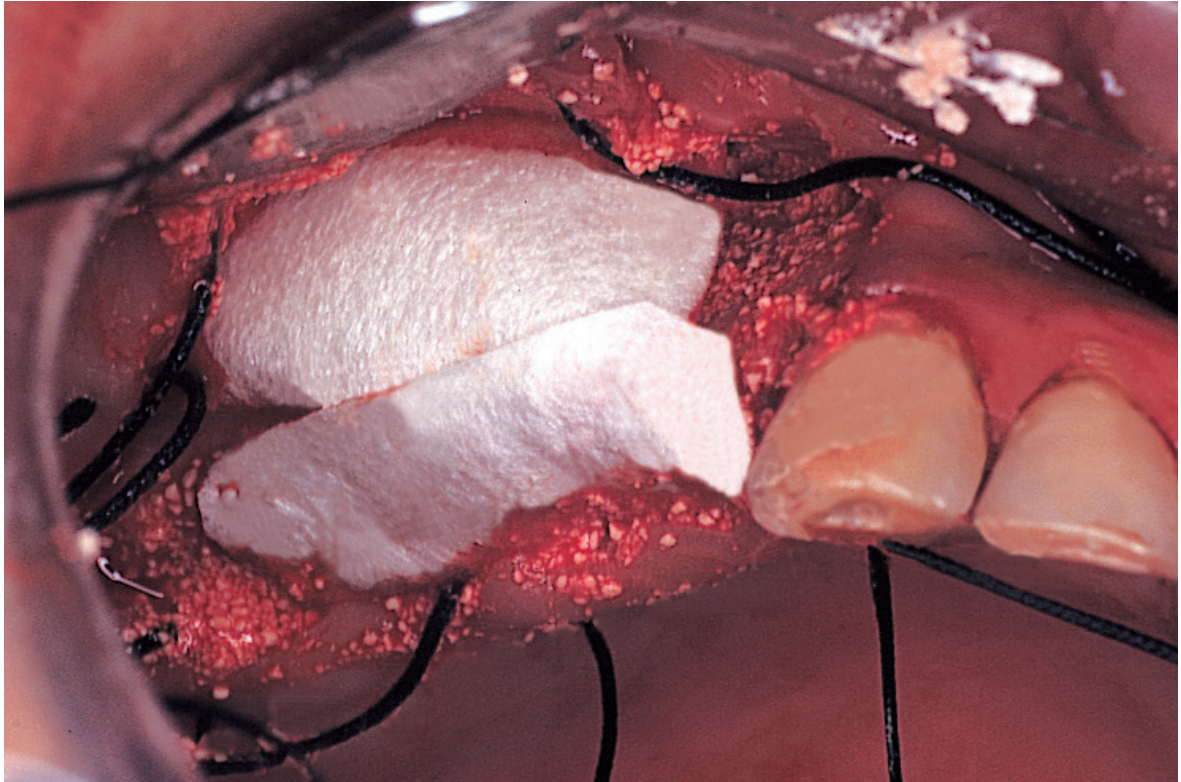


Knot the suture threads corresponding to the main sutures that stabilize the flap above the materials for regeneration.



With other suture it is obtained obtain the full collapse of margins of the incisions and the stabilization of the full thickness flap.





Date of issue - 16 november 2018

Legend of the symbol used for the packaging labels



Notify Body
Medical Device



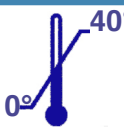
Sterilization by irradiation



Disposable



See the use instructions



Storage temperature



Lot



Expiry

CENTRO DI ODONTOIATRIA OPERATIVA s.r.l.
35125 Padova via Guizza, 309 - Tel. 049 681123 - Fax 049 8806560
www.odopguizza.it
e-mail info@odopguizza.it