

MODfix
Modular Fixation System

UNIfix
Universal Fixation System

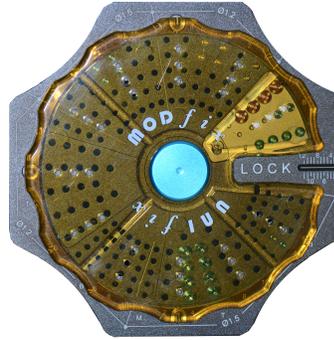
Surgical Manual



Cassettes and organizers



Organizer cassette for storage and sterilization of all MODfix™ and UNifix™ drivers and components.



Organizer wheel for storage and sterilization of MODfix™ screws, MODfix™ abutments and UNifix™ screws.



UNifix™ cassette for storage and sterilization of all drivers and components.

Sterilization

The drivers are sold non-sterile and need to be sterilized before use. The drivers may be used several times, but need to be cleaned and sterilized before each use. The following steps are recommended:

1. Completely disassemble instruments
2. Remove any visible debris from the instruments, using a soft bristle brush and an appropriate detergent. Rinse thoroughly.
3. Once cleaned and inspected, the drivers should be placed into a standard FDA cleared medical grade steam sterilization pouch, such as, the Cardinal Health, Self-Seal Sterilization pouch. The pouch should be large enough to contain the drivers without stressing the packaging.
4. Caution: do not exceed single sterilization pouch to ensure adequate sterilization by following validated parameters. The drivers should be sterilized with moist heat using the following validated steam sterilization guidelines.

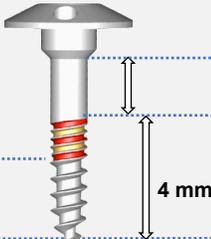
Method	Cycle	Temperature	Exposure Time
Steam	Pre- Vacuum	132°C	4 Minutes Steam Time
		270°F	20 Minutes Dry Time

Note About Stainless Steel Instruments

Stainless steel should not be exposed to the following chemicals: Sodium Hypochlorite (household bleach), Tartaric Acid (stain and tartar remover), Aluminum Chloride, Barium Chloride, Bichloride of Mercury, Calcium Chloride, Carbolic Acid, Chlorinated Lime, Citric Acid, Dakin's Solution, Ferrous Chloride, Lysol, Mercuric Chloride, Mercury Salts, Phenol, Potassium Permanganate, Potassium Thiocyanate or Stannous Chloride, Aqua Regia, Ferric Chloride, Sulfuric Acid, Hydrochloric Acid or iodine.

UNI*fix*TM Universal Fixation system

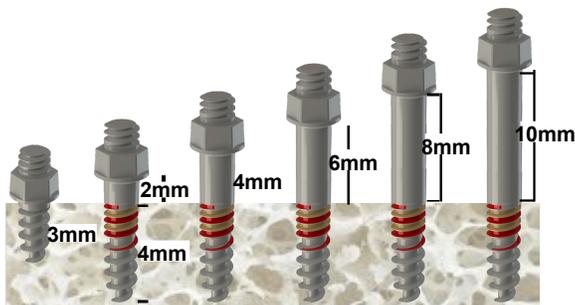
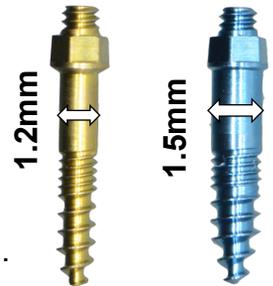
The UNI*fix*TM universal fixation systems is comprised of titanium alloy Ti6Al4V fixation screws designed for oral and maxillofacial bone regeneration. All screw are available in 1.2mm (gold shaded) and 1.5mm (blue shaded) diameters. Screws are composed of macro- and micro-threads for optimal primary stability. The screws are installed and removed using a hex driver, providing a very stable user interface. There are three types of UNI*fix*TM screws:

Membrane fixation (M)	Tenting (T)	Block fixation (B)
<p>The UNI<i>fix</i>TM Membrane fixation screw is intended for stabilization of barrier membrane against host bone.</p> 	<p>This screw is used to create a tent-pole effect under barrier membrane in guided bone regeneration (GBR). The 4-mm wide head is optimal for creation of a stable space. The eyelets can be used for passage of suture to stabilize a flap or membrane to the screw.</p> 	<p>This screw is used to fixate a block bone graft to host bone. The narrow flared head can stabilize block bone and press donor block against host bone.</p> 

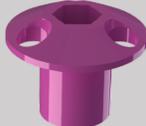
MOD*fix*TM Modular Fixation System

The MOD*fix*TM modular fixation systems is comprised of titanium alloy Ti6Al4V modular fixation screws and complementary titanium alloy Ti6Al4V abutments, designed for oral and maxillofacial bone regeneration.

MOD*fix*TM screws are available in two diameters with color-coding. The 1.2mm diameter screws are gold-shaded and 1.5mm diameter screws are blue-shaded.

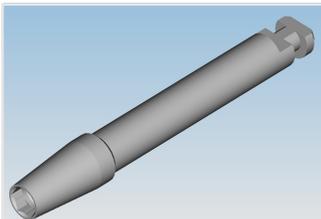


MOD*fix*TM screw lengths range from 3 to 14mm. The self-tapping threaded length is 3mm for the 3mm long screws and 4mm for all other screws. The threaded portion of the screws are intended for anchorage in bone, while the non-threaded portions of screws are intended to extend outside of the bone and provide tenting effect for bone augmentation.

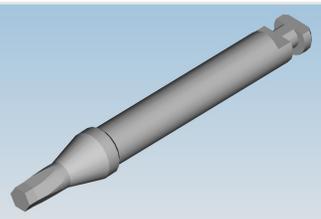
 MOD <i>fix</i> TM Membrane fixation (M)	 MOD <i>fix</i> TM Tenting (T)	 Block fixation (B)
<p>The M abutment is used in conjunction with MOD<i>fix</i>TM screw for stabilization of barrier membrane against host bone. The low profile fixates membrane against bone. This can also be used for tenting.</p>	<p>The T abutment screw is used in conjunction with MOD<i>fix</i>TM screw to create a tent-pole effect under barrier membrane. The 4-mm wide head is optimal for creation of a stable space. The eyelets can be used for passage of suture to stabilize a flap or membrane to the screw.</p>	<p>The B abutment is used in conjunction with MOD<i>fix</i>TM screw to fixate a block bone graft to host bone. The narrow flared head can stabilize block bone intimately against host bone by pressing the block graft as the abutment is progressively connected to the screw.</p>

UNIfix™ screw and MODfix™ screw and abutment installation, instrumentation and protocol.

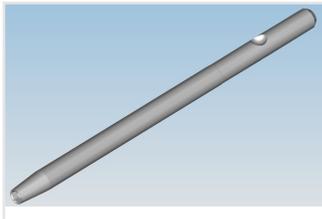
The MODfix™ screws may be inserted, using specially designed internal hex drivers. The MODfix™ abutments may be inserted, using external hex drivers. UNIfix™ screws may be inserted, using external hex drivers. Both internal and external hex drivers are made of surgical grade stainless steel and are available with two types of connections. Swivel drivers are to be connected to a swivel handle to manually insert screws or abutments. There is also a latch-type driver, which may be used in a contra-angle handpiece, connected to a micromotor. The latch-type external hex driver may also be placed in an adaptor for manual connection of MODfix™ abutments.



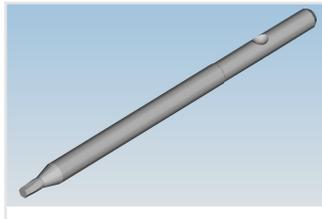
Latch-type in internal hex driver for insertion of MODfix™ screws.



Latch-type external hex driver for insertion of MODfix™ abutments and UNIfix™ screws.



Swivel internal hex driver for insertion of MODfix™ screws.



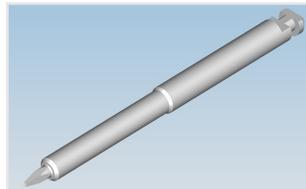
Swivel external hex driver for insertion of MODfix™ abutments and UNIfix™ screws.

Latch adaptor for attachment of latch-type drivers

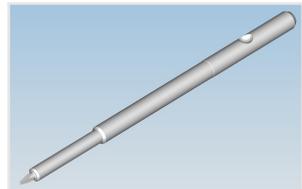


Swivel handle for attachment of swivel drivers

In high-density bone, it is required to use a pilot drill to pre-drill the osteotomy followed by insertion of the screw.

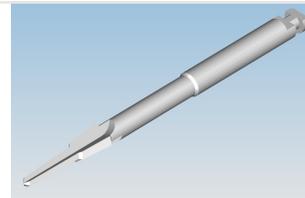


Latch-type pilot drill



Swivel pilot drill

In order to fixate a block bone graft, the donor block has to be first prepared with the countersink drill. This drill can create both the channel through the block for passage of screw, as well as counter-sink to accommodate the block fixation abutment.



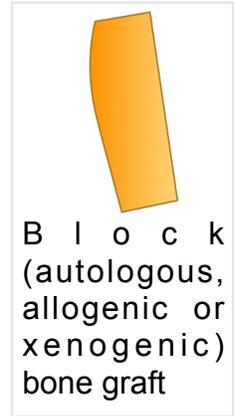
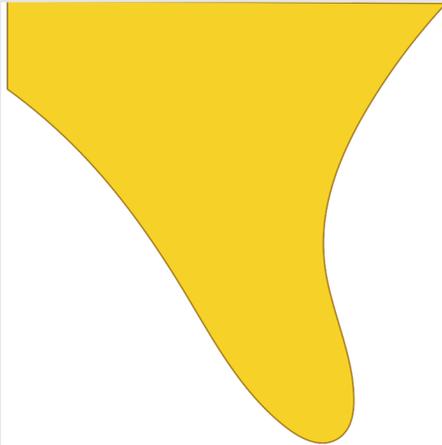
Countersink drill for preparation of block bone graft to accommodate MODfix™ screws plus B (Block fixation) abutments or UNIfix™ B (Block fixation) screws.

In order to fixate a barrier membrane using MODfix™ screw and MODfix™ M (Membrane fixation) abutment, the membrane has to be perforated using the membrane punch. With the membrane draped over MODfix™ screw, the head of the screw is located by the punch, which is pressed against the screw for perforation.

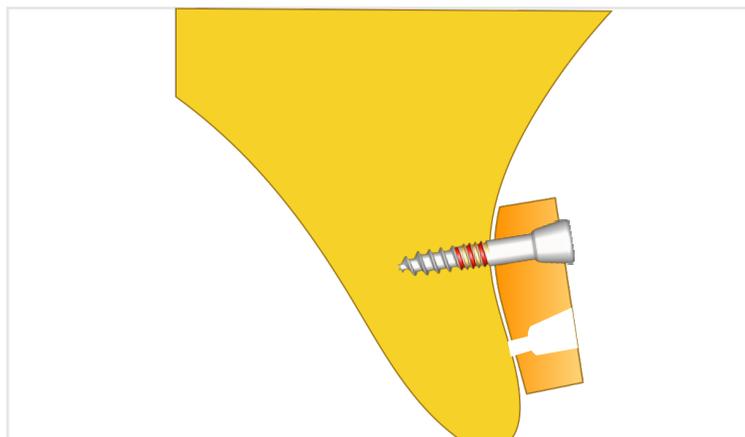
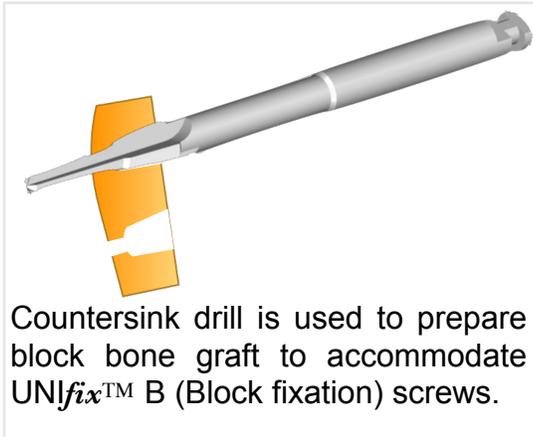


Membrane punch for punching through barrier membrane to allow for connection between MODfix™ screws and M (Membrane fixation) or T (Tenting) abutments.

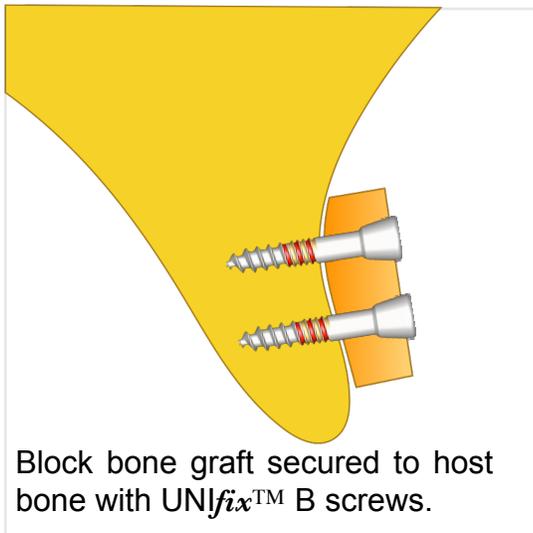
UNIfix™ Block Fixation (B) screw installation protocol



Atrophic jaw may be prepared to create an appropriate recipient bed for the block bone graft. This may entail making an osteotomy in a shape complementary to the intaglio of the block bone graft. If the host bone is dense, pilot osteotomies may be made in positions corresponding to the intended positions of the UNIfix™ B (Block fixation) screws. The recipient bed may also be decorticated by making perforations into the cortical bone to facilitate circulation between bone marrow and block bone graft.

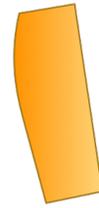
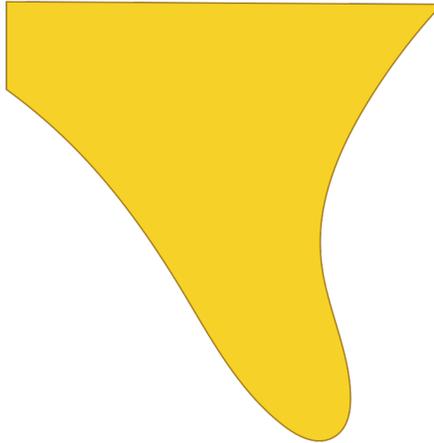


Appropriate diameter and length of UNIfix™ B screws are selected. The thickness of the block bone graft is measured and a UNIfix™ B screw with a non-threaded neck length, which approximates the graft thickness, may be selected. Prepared block bone graft is positioned over the prepared recipient site. UNIfix™ B screws are inserted through the perforated block bone graft and anchored into the recipient host bone.

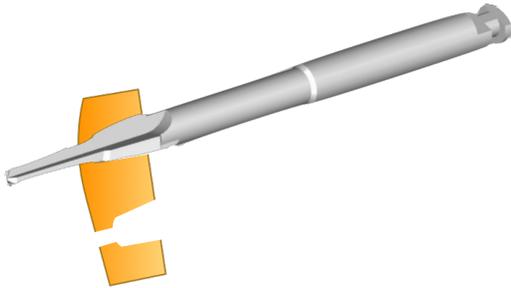


MODfix™ screw and Block Fixation (B) abutment installation protocol

Atrophic jaw may be prepared to create an appropriate recipient bed for the block bone graft. This may entail making an osteotomy in a shape complementary to the intaglio of the block bone graft. If the host bone is dense, pilot osteotomies may be made in positions corresponding to the intended positions of the MODfix™ screws. The recipient bed may also be decorticated by making perforations into the cortical bone to facilitate circulation between bone marrow and block bone graft.

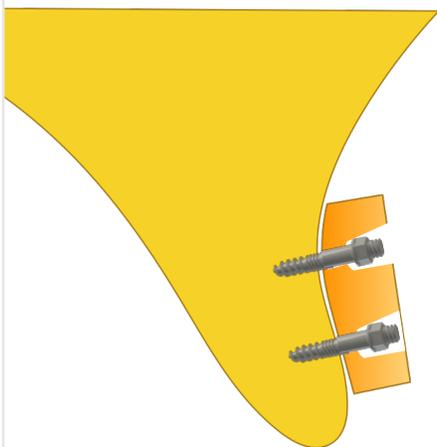
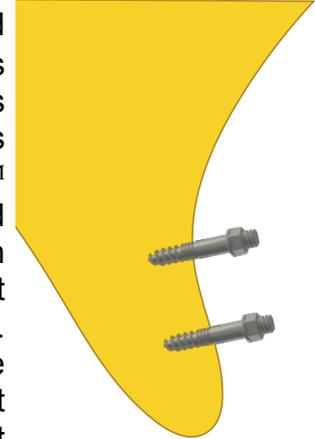


Block (autologous, allogenic or xenogenic) bone graft

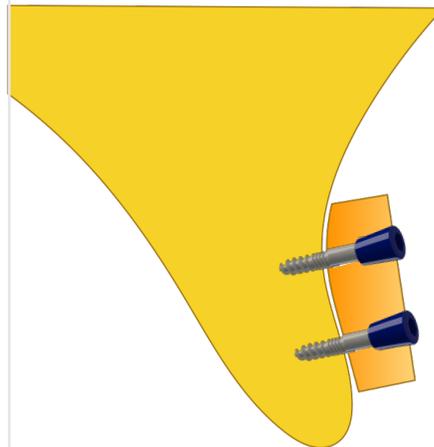


Countersink drill is used to prepare block bone graft to accommodate MODfix™ screws plus B (Block fixation) abutments.

Appropriate diameter and length of MODfix™ screws are selected. The thickness of the block bone graft is measured and a MODfix™ screw with a non-threaded neck length, which approximates the graft thickness may be selected. MODfix™ screws are installed in the locations at which the block bone graft has been perforated.



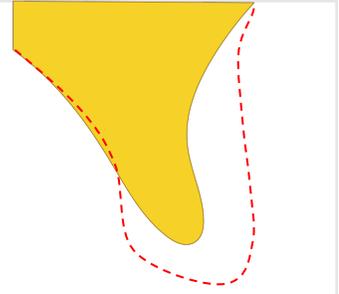
The perforated block bone graft is inserted over the installed MODfix™ screws.



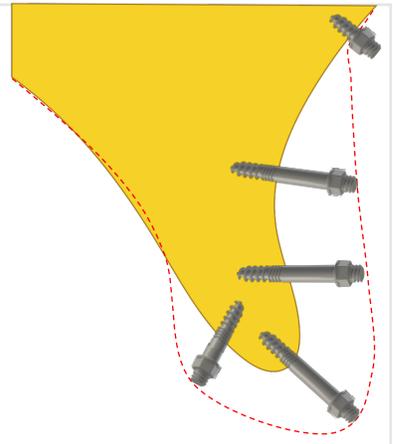
MODfix™ Block fixation (B) abutments are connected to the MODfix™ screws.

MODfix™ screw and Membrane Fixation (M) or Tenting (T) abutment installation protocol

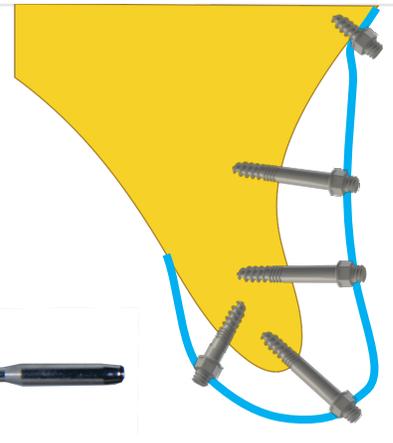
Atrophic jaw may be prepared for guided bone regeneration. If the host bone is dense, pilot osteotomies may be made in positions corresponding to the intended positions of the MODfix™ screws. The recipient bed may also be decorticated by making perforations into the cortical bone to facilitate circulation between bone marrow and block bone graft. The desired augmentation contour is envisioned (dotted red outline).



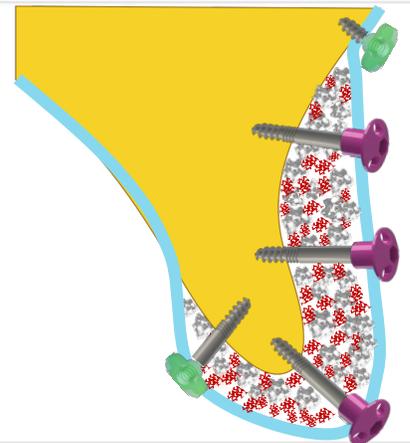
Appropriate diameter and length of MODfix™ screws are selected. The MODfix™ screws with non-threaded neck length, which approximates the intended augmentation width are selected. MODfix™ screws are installed approximately 7 to 10mm apart in an effort to support the membrane and prevent its compression. The screws are inserted in an orientation is perpendicular to the eventual barrier membrane.



A barrier membrane (depicted with blue outline) is draped over the MODfix™ screws. The membrane is perforated with the aid of membrane punch. With the membrane draped over MODfix™ screw, the head of the screw is located by the punch, which is pressed against the screw for perforation. Particulate graft material may be placed over the alveolar bone either before or after placement of membrane.

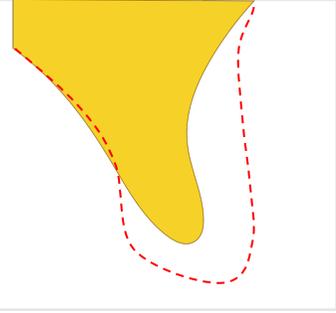


MODfix™ Membrane fixation (M) or Tenting (T) abutments are connected to the MODfix™ screws. The choice of T (pink-shaded) versus M (green-shaded) abutment depends on the available space. T abutment is wider and has higher profile. The membrane is perforated with the aid of membrane punch. Particulate graft material may be placed over the alveolar bone either before or after placement of membrane. Particulate autogenous bone, such as bone prepared using Rotary Bone Harvester (RBH) may be combined with other bone substitutes for more effective results.

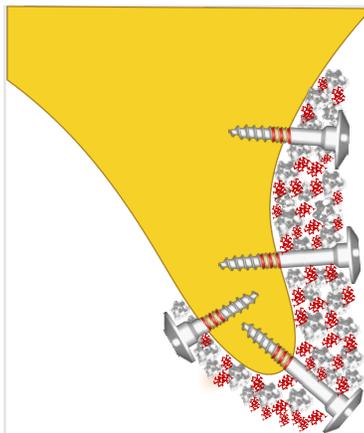
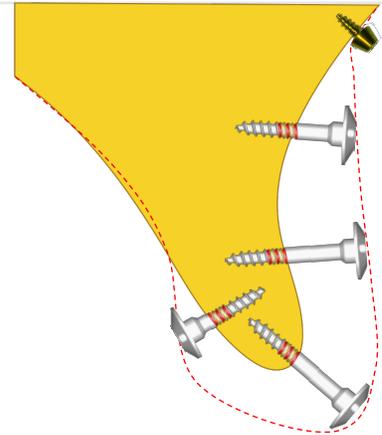


UNIfix™ Tenting (T) and Membrane Fixation (M) screw installation protocol

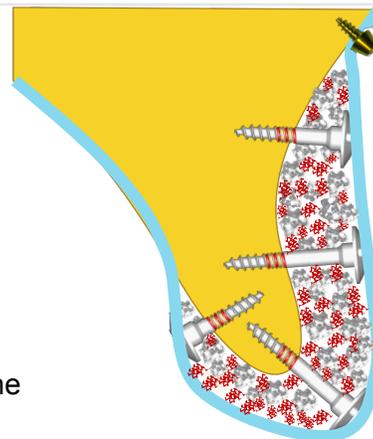
Atrophic jaw may be prepared for guided bone regeneration. If the host bone is dense, pilot osteotomies may be made in positions corresponding to the intended positions of the UNIfix™ screws. The recipient bed may also be decorticated by making perforations into the cortical bone to facilitate circulation between bone marrow and block bone graft. The desired augmentation contour is envisioned (dotted red outline).



Appropriate diameter and length of UNIfix™ screws are selected. The UNIfix™ T screws with non-threaded neck length, which approximates the intended augmentation width are selected. UNIfix™ T screws are installed approximately 7 to 10mm apart in an effort to support the membrane and prevent its compression. The screws are inserted in an orientation perpendicular to the eventual barrier membrane.



 Bone substitute
 Particulate autogenous bone



Particulate graft material is placed over the alveolar bone. Particulate autogenous bone, such as bone prepared using Rotary Bone Harvester (RBH) may be combined with other bone substitutes.

A barrier membrane (depicted with blue outline) is draped over the UNIfix™ T screws. UNIfix™ Membrane fixation (M) screws are used to stabilize the membrane.

 **REGENimmune, Inc.**

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