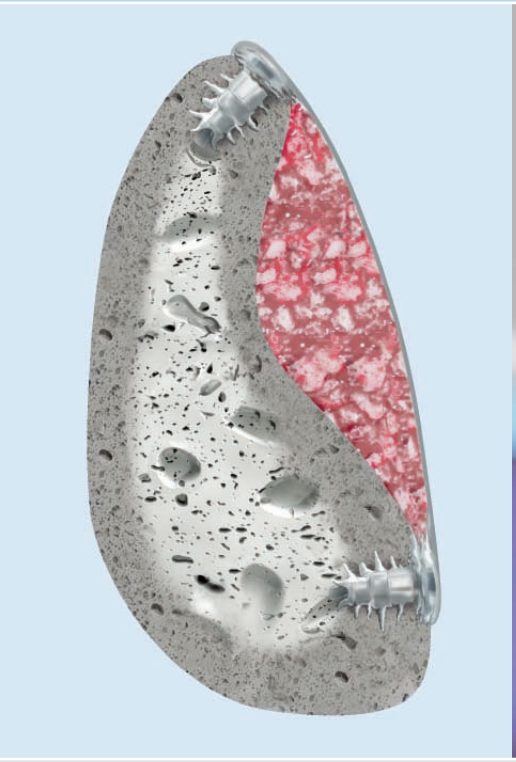
Osteosynthesis



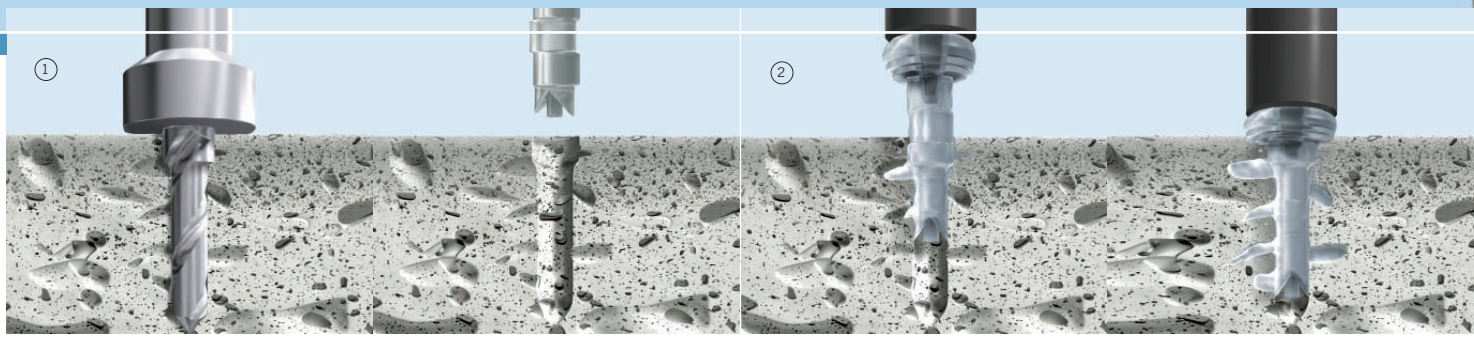
SonicWeld Rx®

GUIDED BONE REGENERATION
AND PREPROSTHETIC AUGMENTATION

KLS martin GROUP

Preprosthetic augmentation with

SonicWeld Rx®

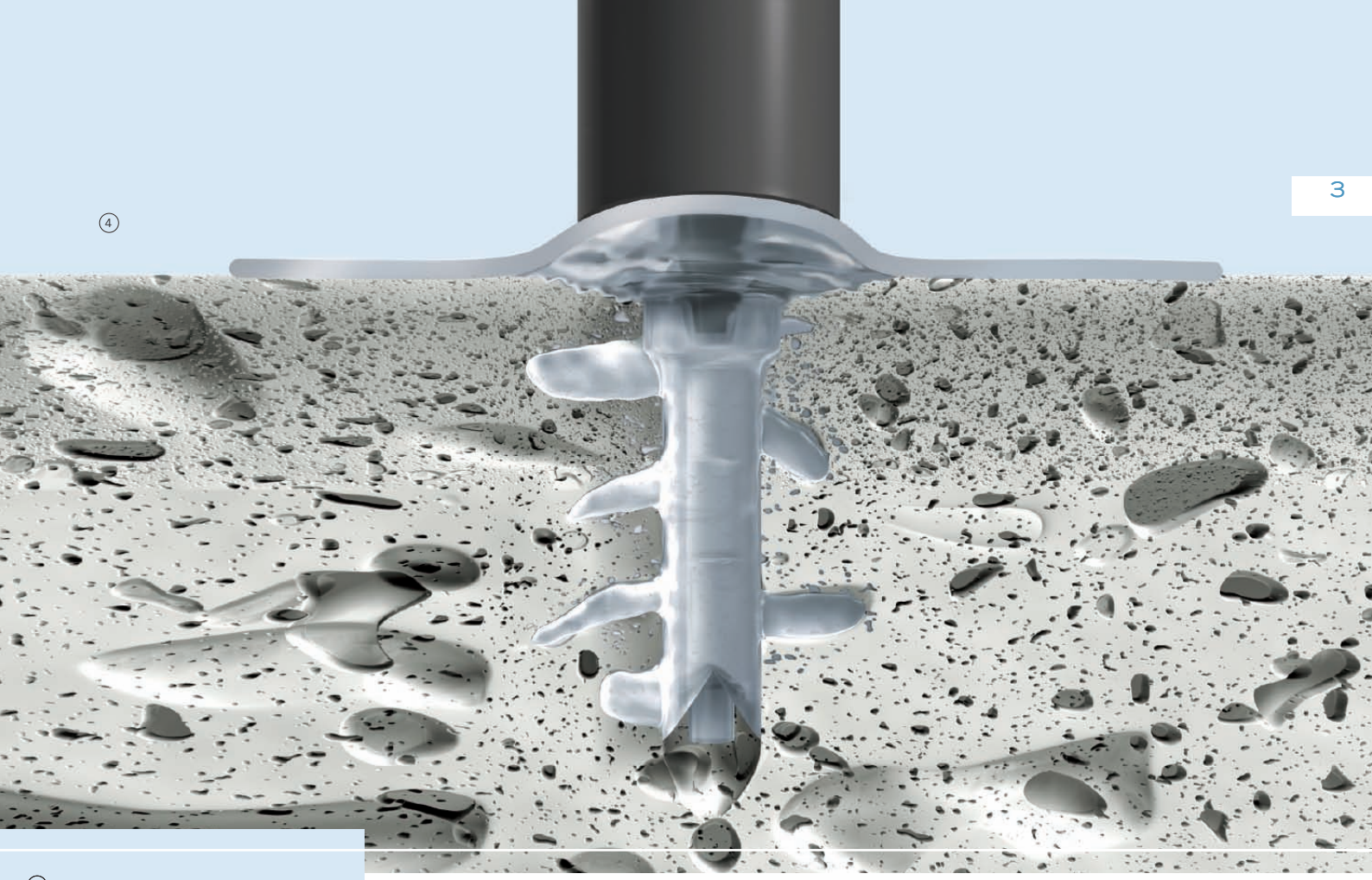


Membrane fixation with SonicWeld Rx® is so simple: Predrill the hole (1) and place the SonicPin Rx (2). The sonotrode's ultrasonic vibrations cause the SonicPin Rx to melt on the surface and to glide into the bone cavities (3). Subsequently, the membrane is attached to the pins already placed, and ultrasound is then used to weld it in place (4).

SonicWeld Rx® is a completely new technique for implanting osteosynthetic materials and fixing membranes. An ultrasound generator is used to generate ultrasonic waves of a precisely defined frequency which are then focused with a sonotrode to apply them to a resorbable pin that is placed on a predrilled hole. The resulting vibration liquefies the pin surfaces along the borders, thus enabling the pin to glide into the predrilled hole and, on account of its changed state of aggregation, to penetrate even into bony cavities that could never be reached by a conventional bone screw. This explains the hitherto unknown initial strength. Moreover, the pin-head bonds with the membrane placed on it and creates a pressure stable, three-dimensional locking mechanism.

However, the system would not be complete without its counterpart: 100% amorphous poly-D-L-lactic acid, simply called PDLLA, a chemical substance made up of lactic acid molecular chains, which are in fact natural constituents of the human body. Therefore, this material is characterized by an unbeatably high body compatibility, combined with reliable degradation characteristics. As the lactic acid molecular chains react and form a bond with the body fluids around them, they absorb the water contained in those fluids. The water then works as a catalyst, supporting a process of targeted decomposition in which the molecular chains are continuously broken down into ever simpler structures until they are just converted into carbon dioxide and water. You can describe the process as a kind of inner degradation that leaves nothing but natural residues.

④



③

For the user, the SonicWeld Rx® method has a number of very significant advantages:

- No second intervention, which would be a considerable physical and psychological trauma for the patient.
- No risks or damage caused by a second intervention: No scarring, no risk of an infection, no damage to tissue and nerves, no anesthetic risk.
- Extraordinarily high initial strength which is due to two important factors:

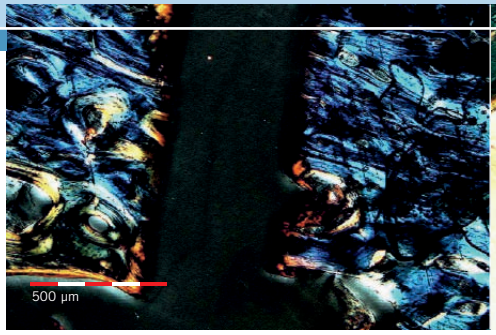
  a) Three-dimensional infiltration of the pin into the osseous structure. This may be referred to as a proper material-tissue interdigitation.

  b) Locking mechanism between the membrane and the SonicPin Rx. The head of the pin bonds to the membrane forming a load-bearing unit.

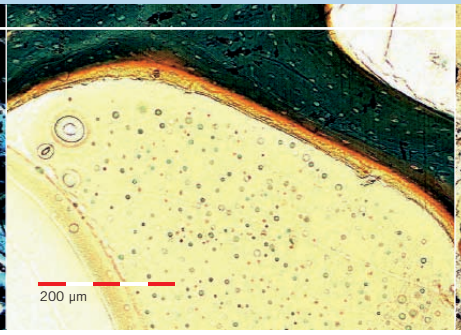
- Distinctly reduced intervention times. Compared to resorbable screw systems, the time required for the implantation of the membrane is demonstrably halved.
- A distinctly lower complication rate during pin insertion.

Clinical findings

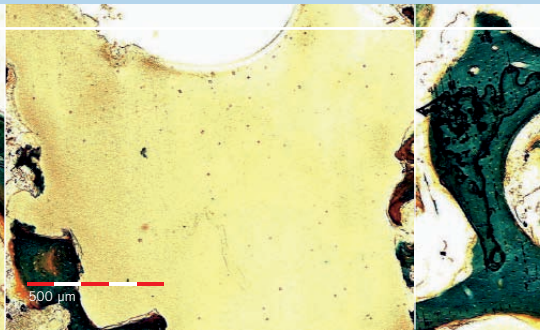
Biological basic research, comprehensive mechanical and histological test series and clinical validation give you the confidence and peace of mind you need as a user: SonicWeld Rx® has an excellent initial strength, is perfectly body-compatible and characterized by a calculable and safe biological degradation process.



Longitudinal section through SonicPin Rx and supporting tissue twelve days after the intervention.



Two weeks after the intervention.



Thirty-two days after insertion of SonicPin Rx.

- The best body compatibility and a safe degradation process which is due to the biochemical properties of the initial PDLLA material. Extensive animal experiments and clinical studies substantiated the following statements for SonicWeld Rx® predominantly:

  - Completely intact carrier bone at any time during the degradation process.
  - No inflammatory reaction in the drill hole.
  - No signs of thermal damage or necroses.
  - Uneventful cell reactions around the implants.
  - No signs of plate dislocations or dehiscences.
  - Complete bio degradation without residues and knitting of the implant site.

Clinical testing and histological examination:

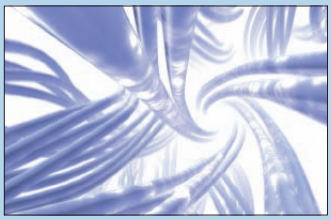
Technical University of Dresden, Faculty of Medicine,
Hospital and Policlinic for Oral and Maxillofacial Surgery

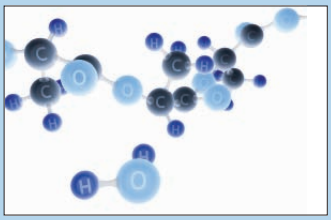
Professor Dr. Dr. Uwe Eckelt (M.D.)
Dr. Eckart Pilling (M.D.)
Dr. Ronald Mai (M.D.)

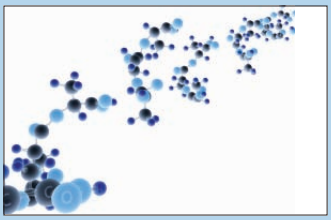
Mechanical basic research:

Technical University of Dresden, Faculty of Medicine,
Policlinic for Prosthetic Dentistry

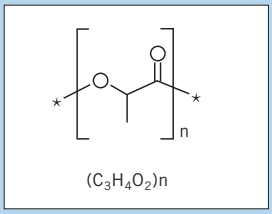
Professor Dr. Bernd Reitemeier (M.D.)
Dr. Gert Richter (engineer)
Heike Meißner (certified engineer)

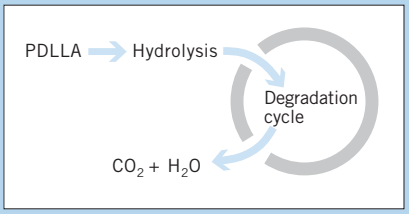




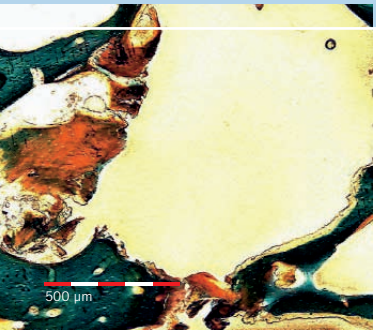


The decomposition process – what you cannot see:
The complex polymer chains (1) of the PDLLA absorb the H_2O content of the surrounding body fluid (2) (hydrolysis). The embedded water splits the polymer chains in ever-shorter molecule chains (3) and (4). Human metabolism then transforms the D and L lactides into carbon dioxide and water, which are finally discharged through the metabolic channels. The decomposition takes place in a controlled manner free from residues.





Molecular structure of the basic material: poly(D,L-lactide)



Three months after the intervention.

Histological findings

- No thermal tissue damage or even necroses have ever been observed.
- No clinical or histological indication for an initial inflammatory response caused in the surrounding tissue by ultrasound application.
- There are no bone-damaging consecutive reactions.
- The soft-tissue response is classified clinically as well as histologically as non-irritating.

Mechanical findings

- SonicPins Rx have a distinctly higher mechanical strength then conventional resorbable fixing systems.
- The fact that is particularly striking is the increased primary stability of the SonicPins Rx due to a direct anchorage of the polymer in the trabecular meshwork of the bone.

The program with a system

SonicWeld Rx® is a modular and flexible system, fully compatible with KLS Martin's Resorb x® membranes, meshes and plates. All SonicWeld Rx® membranes, meshes and plates can be freely combined as required. The entire system has been validated. It carries the CE-mark and has obtained FDA approval.

Membranes and meshes

- 100% intrinsically amorphous PDLLA membrane.
- Perfect contouring properties.
- Completely transparent – perfect overview at any point in time, even after the intervention.
- When welded in place, the result is a three-dimensional structure that is dimensionally stable and resistant to pressure, thus making a collapse of the membrane impossible. The augmentate is always stationary in the desired volume.

SonicPins Rx

- The SonicPins Rx are available in diameters of 1.6 mm and 2.1 mm.
- The SonicPins Rx are self-retaining as they can be picked up with the sonotrode tip.
- The optimized shape of the SonicPins Rx guarantees easy insertion on the one hand and a strong hold in the bone on the other hand.

Clip magazines

- Pins confectioned in clips of 2 and 5.
- Sterile, ready-to-use delivery.
- Safe removal from the clip magazine.
- SonicPins Rx anchor in cortical as well as cancellous osseous structures.
- Even small fragments can be fixed rotationally stable without screw-in resistance.
- SonicPins Rx are flexible and can be placed even in narrow locations and under difficult anatomic conditions, such as in angular positions.

SonicWelder Rx and sonotrode are the heart of the SonicWeld Rx® system.

Sonotrode

- Self-retaining SonicPins Rx and a handle that illuminates the surgical site offer a maximum of safety and convenience.
- Completely sterilizable (134°C / 273°F, 2 bar).
- Easy replacement of all components.

Angled sonotrode

- Permits safe work on regions difficult to access, such as the lateral tooth region.

SonicWelder Rx

- The micro-vibrations generated by a defined ultrasonic frequency cause the external surface of the pin to melt. The SonicPin Rx then simply glides into the pre-drilled hole.
- Various pre-programmed application stages as well as manual adjustment options permit the surgeon to master any clinical task. The system is easy to operate thanks to the clearly arranged menu interface.
- Activation by foot switch.

Guided bone regeneration

The development of the membrane technique for the regeneration of bone in dentistry bases on the assumption that various cellular components have a different migration rate into the wound region during the healing process. A mechanical barrier is used to prevent the fibroblasts and other soft-tissue cells to penetrate the bone defect so that the slower migrating cells can occupy the defect with osteogenetic potency (Dahlin et al., 1988). At the beginning of the 1980s already, Nyman et al. (1982a, 1982b) recognized the significance of this technique in dentistry.

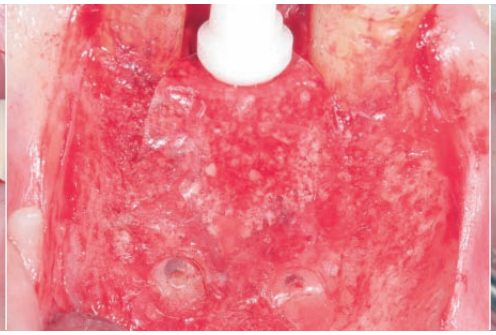
Case example*

The patient before the intervention.

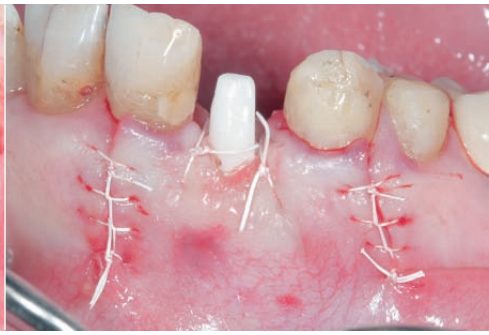
Incision line and flap.

Pre-drilling of the implant site and placing of the lateral SonicPins Rx.

- The 0.1 mm membrane always ensures perfect transparency.
- Initially, it can be contoured very well.
- Once welded in place, it will cover the augmentate rigidly due to its dimensional stability.
- Undesired dislocation is a thing of the past.



- Using the scalpel, the membrane can be cut to shape in situ.
- If and when necessary, another membrane can be welded on top.



After wound closure.

** Case photos by courtesy of Dr. Ulrich Volz, D-Konstanz*

The implant placed is laterally supported by autologous bone, own blood plus bone replacement materials if required.

Order recommendation – Guided bone regeneration

SonicPins Rx

Dimensions in mm	Order No. *Pack of 2*	Order No. *Pack of 5*
1.6 x 4	52-516-24	52-516-54
1.6 x 5	52-516-25	52-516-55

Rx membrane/mesh t = 0.1 mm

Dimensions in mm	Order No.
25 x 25	52-301-28

Pilot drill for angle unit with dental attachment

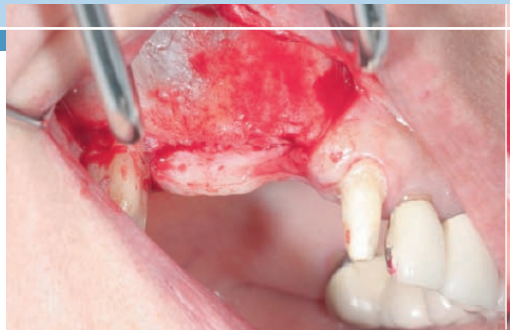
for 1.6 mm SonicPins Rx

Dimensions in mm	Order No.
1.0 x 20 x 5	52-509-05
1.0 x 20 x 6	52-509-06

Membrane fixation with SonicPins Rx

If the bone to be augmented is ground and enriched with own blood, bone replacement material or growth factors, it is sensible to use a membrane to protect the augmentation against the masticatory forces. The membrane prevents the migration of epithelial cells and is used as a placeholder for periodontal ligament and for bone regeneration. Usually, this membrane is laterally fixed by metal pins. However, these titanium pins have to be removed in a second intervention that can be very time-consuming (as they are grown in). Membrane fixation with SonicWeld Rx® eliminates this time-consuming second intervention and permits the surgeon to work with a clear view of the site throughout.

Case example*



Sinus lift procedure with SonicWeld Rx®
First of all, the windows technique is used for sufficient preparation of the sinus.

Then SonicPins Rx are welded in around the sinus.

Only now is the augmentate inserted into the sinus. Subsequently, the site is safely closed with a 0.1 mm membrane. In the process, the membrane is welded onto the pins.

The moment the pins are placed, the operating site is usually invisible for the surgeon because the commercially available membranes are opaque. Thus, there is always some uncertainty as to where the pin is anchored exactly.

When using resorbable membranes, it is usually impossible to drill through the membrane into the carrier bone. The resorbable membrane always winds around the drill and is thus destroyed.

In case of SonicWeld Rx®, there is a simple but very efficient trick:

First of all the pins are pre-positioned in the carrier bone, and afterwards the membrane is welded onto the already existing pins. As the membrane as well as the SonicPins Rx melt on the surface, a rigid inseparable bond is produced. The process is very easy and fast, best of all compared to the welding of soft PVC sheets.

As all SonicWeld Rx® implants are transparent, the operating site can be viewed completely all the time.

** Case photos by courtesy of Dr. Ulrich Volz, D-Konstanz*

Advantages of this special method:

- Distinctly faster than conventional pins, saving about 2 minutes per pin.
- No risk of pin breakage.
- Membrane can be contoured very well in warm state.
- Thinner membranes can also be contoured to a certain extent in cold state.
- Free view of the augmentation region at any time, even after the intervention.
- No risk of membrane getting tangled.
- No rotational forces on the membrane.

Order recommendation – Membrane fixation

SonicPins Rx

Dimensions in mm	Order No. *Pack of 2*	Order No. *Pack of 5*
1.6 x 4	52-516-24	52-516-54
1.6 x 5	52-516-25	52-516-55
2.1 x 4	52-521-24	52-521-54
2.1 x 5	52-521-25	52-521-55

Rx membrane/mesh t = 0,1 mm

Dimensions in mm	Order No.
25 x 25	52-301-28

Pilot drill for angle unit with dental attachment

for 1.6 mm SonicPins Rx

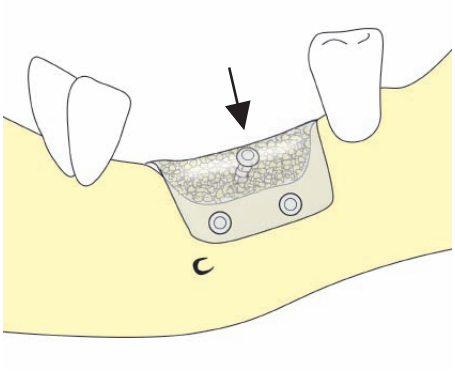
Dimensions in mm	Order No.
1.0 x 20 x 5	52-509-05
1.0 x 20 x 6	52-509-06

for 2.1 mm SonicPins Rx

Dimensions in mm	Order No.
1.6 x 20 x 5	52-515-05
1.6 x 20 x 6	52-515-06

Membrane support, also called “space making” or “tenting”

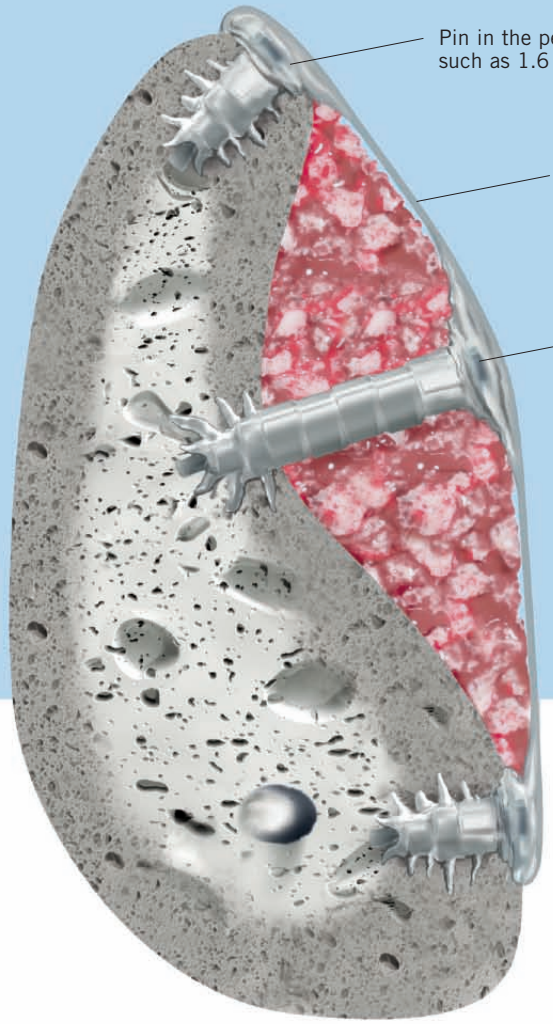
In case of augmentation regions which are subjected to human masticatory forces in particular, it is important that the augmentate is protected against the muscular tensile forces. Like using a central tent pole, the surgeon can use long SonicPins Rx which protect the fresh implant region against dislocation and deformation. Again the covering membrane can be welded firmly to the central pin. Additional short pins can be placed in the periphery for lateral delimitation and fixation of the augmentation region.



Membrane-assisted augmentation in model.
The central pin has been marked with an arrow.

Indications for this special method:

- Insertion of ground autologous bone augmentates or bone replacement materials.
- Limitation of relapse during the ossification phase.
- Vertical bone atrophy.
- Prevention against muscular or muco-gingival tensile forces.
- Prevention of migration of epithelial cells.



Advantages of this method:

- Stable central protection against all masticatory forces up to an advanced stage of osseous consolidation.
- Solid welding of the SonicWeld Rx® membrane to the central pin.
- The pin changes its state of aggregation only where it meets with osseous resistance. Otherwise the pin remains dimensionally stable.
- Perfect view of the implant region as the pins are placed first and the membrane is welded on only later. Again, all system components are permanently transparent.

Order recommendation – Membrane support

SonicPins Rx (peripheral pins)

Dimensions in mm	Order No. *Pack of 2*	Order No. *Pack of 5*
1.6 x 4	52-516-24	52-516-54
1.6 x 5	52-516-25	52-516-55
2.1 x 4	52-521-24	52-521-54
2.1 x 5	52-521-25	52-521-55

SonicPins Rx (central pins)

Dimensions in mm	Order No. *Pack of 2*
2.1 x 11	52-521-31
2.1 x 13	52-521-33
2.1 x 15	52-521-35
2.1 x 17	52-521-37

Rx membrane/mesh t = 0,1 mm

Dimensions in mm	Order No.
25 x 25	52-301-28

Pilot drill for angle unit with dental attachment

for 1.6 mm SonicPins Rx

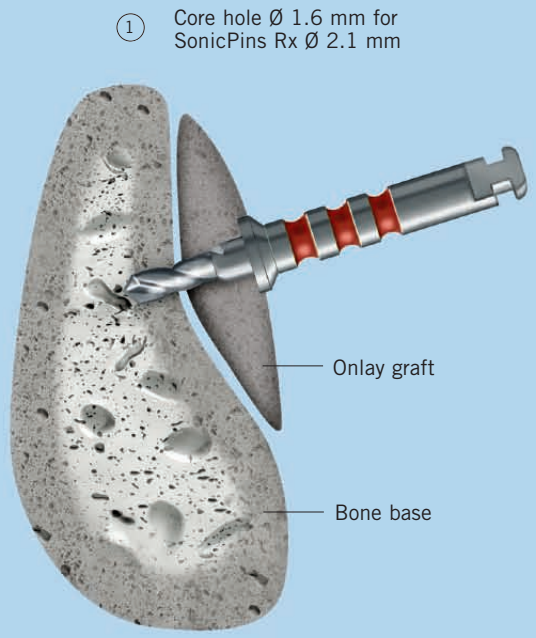
Dimensions in mm	Order No.
1.0 x 20 x 5	52-509-05
1.0 x 20 x 6	52-509-06

for 2.1 mm SonicPins Rx

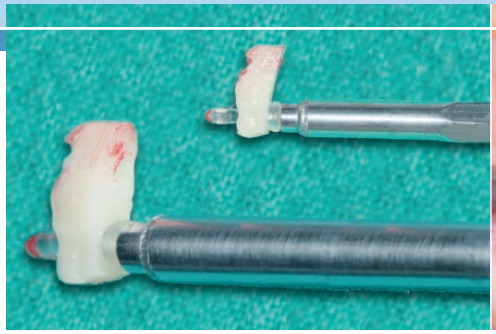
Dimensions in mm	Order No.
1.6 x 20 x 5	52-515-05
1.6 x 20 x 6	52-515-06
1.6 x 20 x 10	52-515-10

Onlay grafts

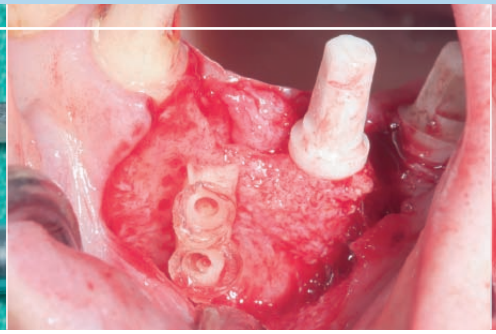
The augmentate may be attached horizontally as well as vertically. By means of special long SonicPins Rx it is possible to weld bone blocks in place. For this purpose, gliding holes are drilled through the augmentate (bone block) so that the SonicPins Rx can be anchored in the carrier bone only. In other words, the SonicPins Rx take hold in the distal carrier bone only. Through a lag screw effect, the augmentate is gently pulled into its anchoring position.



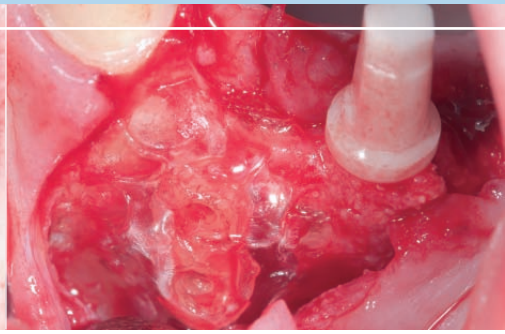
Case example*



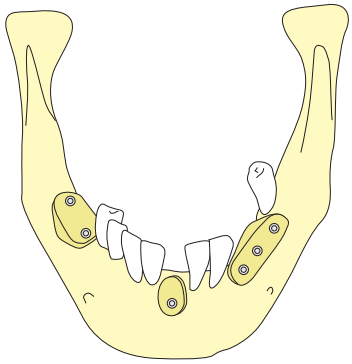
The implant already placed is supported laterally by a bone chip.



Beforehand already, the bone chip has been provided with a gliding hole so the SonicPin Rx can now be inserted.



Hardly to be seen: the 0.1 mm membrane is welded onto the SonicPins Rx three-dimensionally. The bone block is fixed by two SonicPins Rx.



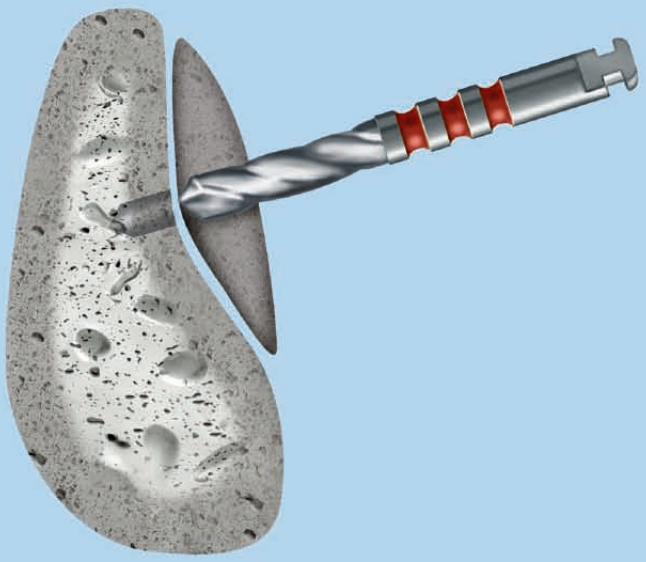
The model shows several augmentation regions that have all been treated completely with SonicWeld Rx®.

Special advantages of this method for the patient

- No second intervention is required as the augmentation pin is completely resorbed and no metal parts have to be removed.
- Perfect initial stability, even in case of difficult apposition or superposition.
- Even very shallow anchoring depths are sufficient for a stable pin fixation.
- Only one-time traumatization of the mucosa as no second intervention is required.
- Good blood flow in the onlay graft prevents degradation response.

** Case photos by courtesy of Dr. Ulrich Volz, D-Konstanz*

② Gliding hole Ø 2.1 mm



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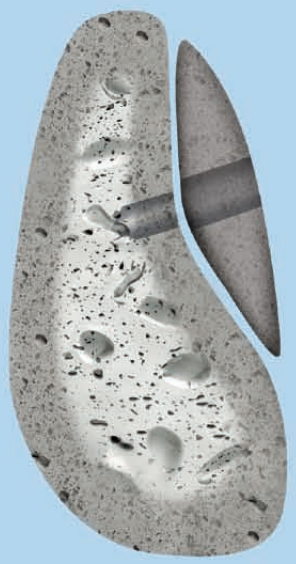
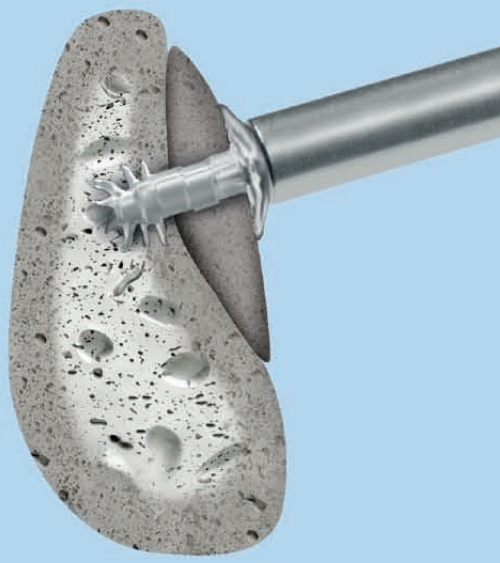
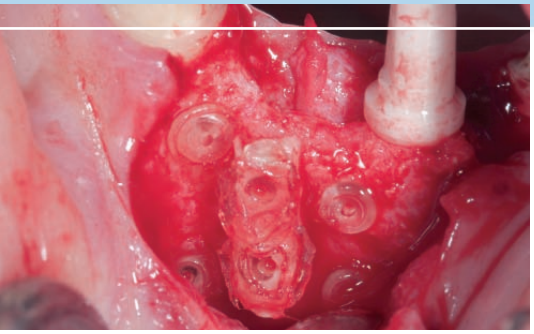


④ Pin can sink into core hole only. Bone graft is pulled in place.





Prior to wound closure. The membrane is firmly anchored, retaining its three-dimensional shape. Any remaining cavities are filled with own blood and ossify as well.

The principle of core hole and gliding hole

① Use the drill Ø 1.6 x 20 x 10 mm (52-515-10) to drill through the augmentate into the receiving bone. Attention: Extend the hole in the receiving bone, still using the drill Ø 1.6 x 20 x 10 mm (52-515-10), maintaining the previous angulation.

② Use the drill Ø 2.1 x 24 x 12 mm (52-522-10) to enlarge the gliding hole in the augmentate.

③ Proceed the fixation with the SonicPin Rx of your choice.

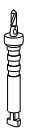
④ The SonicPin Rx is fixed only in the distal end of the receiving bone while the pin head blocks the augmentate against the receiving bone.

Order recommendation – Onlay grafts

SonicPins Rx

Dimensions in mm	**Order No.** (*Pack of 2*)
2.1 x 11	52-521-31
2.1 x 13	52-521-33
2.1 x 15	52-521-35
2.1 x 17	52-521-37

Pilot drill for angle unit with dental attachment



Core hole drill for 2.1 mm SonicPins Rx

Dimensions in mm	**Order No.**
1.6 x 20 x 5	52-515-05
1.6 x 20 x 6	52-515-06
1.6 x 20 x 10	52-515-10

Gliding hole drill for 2.1 mm SonicPins Rx

Dimensions in mm	**Order No.**
2.1 x 24 x 12	52-522-10

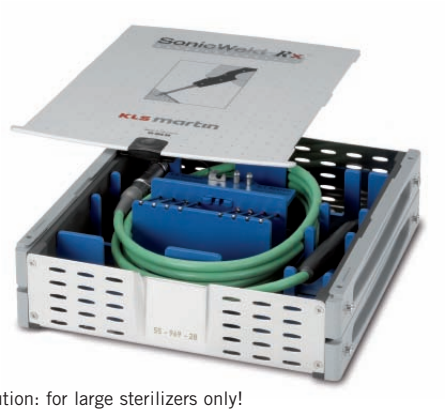
Order and set recommendations

52-501-01

52-501-02

SonicWeld Rx®

Unit	Order No.
SonicWelder basic set	52-500-00
consisting of:	
SonicWelder	–
Foot switch	52-500-02
Handpiece	52-500-03
Sonotrode, straight	52-501-01
Open-ended wrench for sonotrode	52-502-01
separately available:	
Sonotrode, angled	52-501-02
Extension cable for handpiece – 3 m	52-500-33



Caution: for large sterilizers only!

Storage and sterilization tray

Category	Scope	Order No.
Storage tray	complete	55-969-38
External dimensions: 240 x 240 x 65 mm (L x W x H)		
Internal dimensions: 197 x 230 x 54 (L x W x H)		
consisting of:		
Storage tray without lid	alone	55-969-28
Lid for storage tray	alone	55-963-38

Alternative storage: Storage and sterilization container for dental sterilizer

Category	Order No.
MicroStop® - Mini-Set container	55-861-40
External dimensions: 310 x 189 x 65 mm (L x W x H)	
Internal dimensions: 283 x 177 x 40 mm (L x W x H)	
Silicone mat for container	55-009-00

Xcelsior water bath

Category	Scope	Order No.
Water bath	complete	52-400-10
consisting of:		
Thermal unit	alone	–
Water container	alone	52-400-12
Cover hood	alone	52-400-13

Pilot drill for SonicPins Rx Ø 1.6 mm

52-509-05
52-509-06

Pilot drill for SonicPins Rx Ø 2.1 mm

52-515-05
52-515-06
52-515-10

Gliding hole drill Ø 2.1 mm

52-522-10

Pilot drill for the angle unit with dental attachment

Category	Order No.
for 1.6 mm SonicPins Rx ●	
1.0 x 20 mm, stop 5 mm	52-509-05
1.0 x 20 mm, stop 6 mm	52-509-06
for 2.1 mm SonicPins Rx ●	
1.6 x 20 mm, stop 5 mm	52-515-05
1.6 x 20 mm, stop 6 mm	52-515-06
1.6 x 20 mm, stop 10 mm	52-515-10
Gliding hole drill	
2.1 x 24 x 12 mm	52-522-10

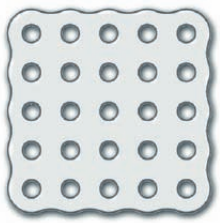
Pilot drill for Stryker attachment

Category	Order No.
for 1.6 mm SonicPins Rx ●	
1.0 x 50 mm, stop 4 mm	52-510-04
1.0 x 50 mm, stop 5 mm	52-510-05
1.0 x 50 mm, stop 6 mm	52-510-06
1.0 x 50 mm, stop 7 mm	52-510-07
1.0 x 50 mm, stop 8 mm	52-510-08
für 2,1 mm SonicPins Rx ●	
1.6 x 50 mm, stop 4 mm	52-516-04
1.6 x 50 mm, stop 5 mm	52-516-05
1.6 x 50 mm, stop 6 mm	52-516-06
1.6 x 50 mm, stop 8 mm	52-516-08
1.6 x 50 mm, stop 10 mm	52-516-10
Gliding hole drill for long 2.1 mm pins	
2.2 x 70 mm	50-022-01

Order and set recommendations

1/1

52-301-28



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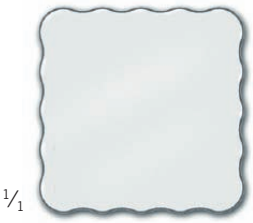
52-303-25



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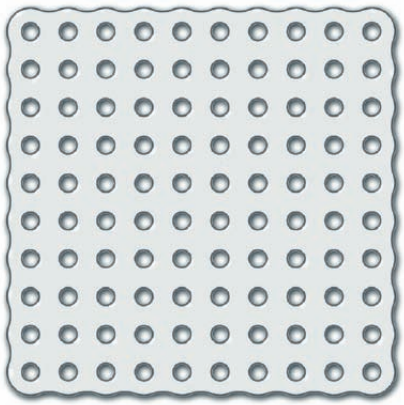
52-303-28



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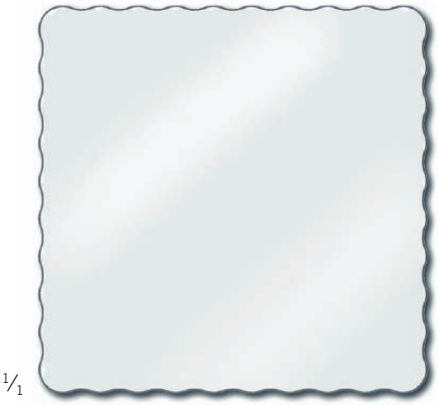
52-303-50



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52-303-52

Membrane / Mesh

Category	Order No.
Resorb-x® membrane 25 x 25 mm, t = 0.1 mm	52-301-28
Resorb-x® mesh 25 x 25 mm, t = 0.3 mm perforated	52-303-25
Resorb-x® membrane 25 x 25 mm, t = 0.3 mm non-perforated	52-303-28
Resorb-x® mesh 50 x 50 mm, t = 0.3 mm perforated	52-303-50
Resorb-x® mesh 50 x 50 mm, t = 0.3 mm non-perforated	52-303-52

SonicPins Rx

Category	Order No. *Pack of 2*	Order No. *Pack of 5*
1.6 x 4 mm	52-516-24	52-516-54
1.6 x 5 mm	52-516-25	52-516-55
1.6 x 6 mm	52-516-26	52-516-56
1.6 x 7 mm	52-516-27	52-516-57
2.1 x 4 mm	52-521-24	52-521-54
2.1 x 5 mm	52-521-25	52-521-55
2.1 x 7 mm	52-521-27	52-521-57
2.1 x 9 mm	52-521-29	52-521-59
2.1 x 11 mm	52-521-31	
2.1 x 13 mm	52-521-33	
2.1 x 15 mm	52-521-35	
2.1 x 17 mm	52-521-37	

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