



SonicWeld Rx[™]

The Perfect Choice

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It's the head that counts – and the face. There is nothing with which we identify ourselves more than with the face. We are how we see ourselves. And more still: four of our five senses – sight, hearing, smell, and taste – are located in the head and the face.

Congenital facial deformities put individuals at a disadvantage not only in terms of outward appearance, but functionally too because severe loss of function is a frequent side-effect of such conditions. Of course, acquired defects can have similar consequences as well. Given the anatomical complexities of the cranial and facial structures, reconstruction and correction require a sort of specialization that fits into the broader context. But that's not all - because successful treatment wouldn't be possible without the availability of high-precision and reliable products.

KLS Martin is one of the globally leading suppliers in the field of craniomaxillofacial surgery. Our product portfolio offers you everything you need for advanced osteosynthesis and distraction. This implies that you get more than just standard products. We are always ready to develop patient-specific solutions wherever the need arises.

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SonicWeld Rx™

In 2001, KLS Martin launched the osteosynthesis system Resorb x[®], thus offering the first completely resorbable implants made of pure PLLA. But this was just the beginning.

In 2005, KLS Martin revolutionized the field of resorbable osteosynthesis by introducing SonicWeld Rx[™], a unique ultrasound technology for insertion of SonicPins Rx.

In 2013, KLS Martin opened a new resorbable chapter when it introduced Resorb xG (RxG), a PLLA-PGA polymer with improved mechanical features.

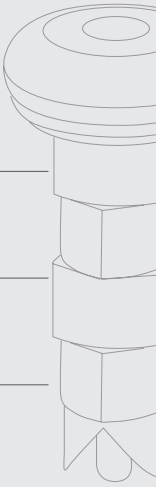
Now, KLS Martin is setting up another milestone: The second generation of SonicWeld Rx[™]. This novel device is an optical highlight in every OR, offering improved and additional features for a user-friendly application. Just see for yourself.

2014: SonicWeld Rx[™]
second generation

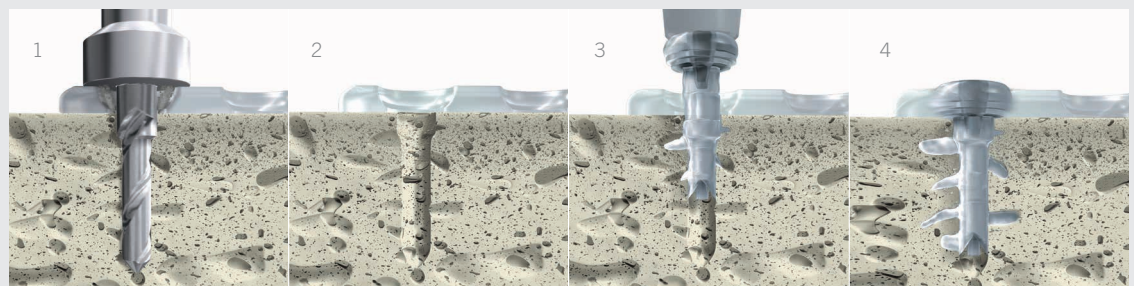
2013: Resorb xG

2005: SonicWeld Rx[™]

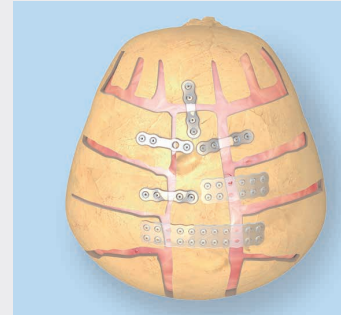
2001: Resorb x[®]



SonicWeld Rx[™]. The perfect choice.



Indications



Osteosynthesis in non-load-bearing areas of the craniomaxillofacial skeleton

Resorb x®

Indications

For United States

Intended for use in fracture repair and reconstructive procedures of the craniofacial skeleton in pediatric and adult populations. In addition, resorbable meshes, plates, screws and pins may be used in non-loadbearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in reconstruction of the craniofacial or mandibular areas.

For Canada

Intended for fractures of the craniofacial skeleton including, but not limited to, comminuted fractures of the naso ethmoidal and infraorbital area, comminuted fractures of the frontal sinus wall, and midface fractures; and reconstructive procedures of the midface or craniofacial skeleton.

Contraindications

For United States

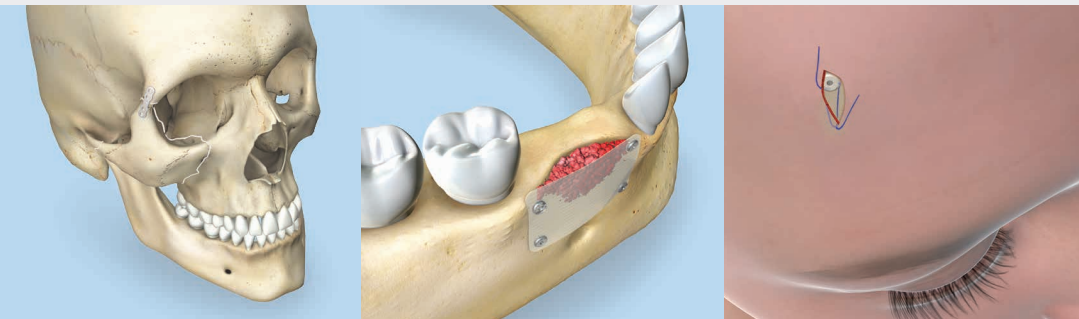
Not intended for the following:

1. Load-bearing applications unless used in conjunction with traditional rigid fixation.
2. Areas with active or latent infection.
3. Patient conditions including limited blood supply or insufficient quantity or quality of bone.
4. Use in the spine.

For Canada

Not intended for the following:

1. Use in the mandible or full load-bearing situations.
2. Areas of active infection.
3. Patients with conditions including blood supply limitations, insufficient quantity or quality of bone, or latent infections.



Midface trauma

Preprosthetic augmentation

Endobrow fixation

Resorb xG*

Indications for cranial use

Resorb xG is intended for use in non-load-bearing fracture repair and reconstructive procedures in pediatric and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load-bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in cranial reconstruction.

Contraindications for cranial use

1. High-load regions in the absence of traditional rigid fixation.
2. Active or latent infections.
3. Patients in a bad general state of health or suffering from metabolic disorders.

Indications for oral-maxillofacial use

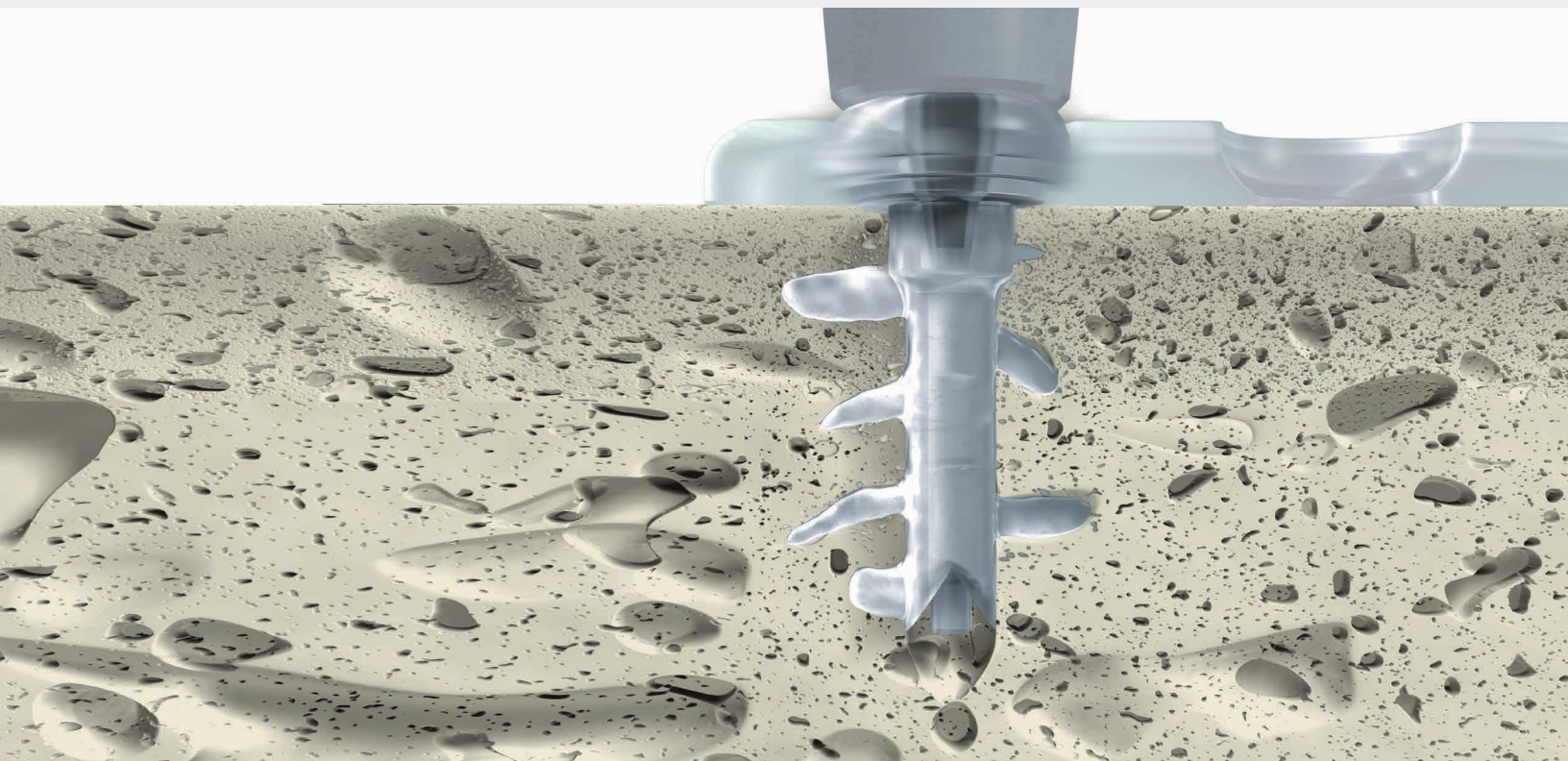
Resorb xG is intended for use in non-load-bearing fracture repair and reconstructive procedures in adolescent and adult populations. In addition, resorbable meshes, plates and pins may be used in non-load-bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in oral and maxillofacial reconstruction.

Contraindications for oral-maxillofacial use

1. High-load regions in the absence of traditional rigid fixation.
2. Active or latent infections.
3. Patients in a bad general state of health or suffering from metabolic disorders.

*RxG pins are not currently available in Canada

Feature, Function and Benefit

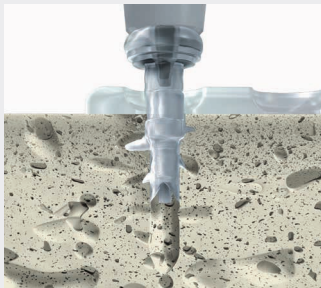


SonicWeld Rx™ is a revolutionary technique for use in non-load bearing craniomaxillofacial osteosynthesis. It combines highly advanced ultrasound technology with resorbable implants to provide extremely stable fixation and completely eliminate the need for a second operation.

The procedure is simple: resorbable meshes are heated up, shaped to fit the application site and then secured with SonicPins Rx. Using a sonotrode, SonicPins Rx are placed into pre-drilled holes. Ultrasonic vibration combined with friction partially liquefy the SonicPins Rx, causing them to penetrate into bone cavities and subsequently bond with plates and meshes. The result is a securely anchored construct.

The method is clinically certified, validated and patient-friendly. The implants degrade through hydrolysis in a natural and controlled process. SonicWeld Rx™ is primarily stable and safe, but also convenient and easy to use. SonicWeld Rx™ is designed for cranial fixation, ideal for pediatric trauma, and also indicated for cancellous bone structures.

SonicWeld Rx™

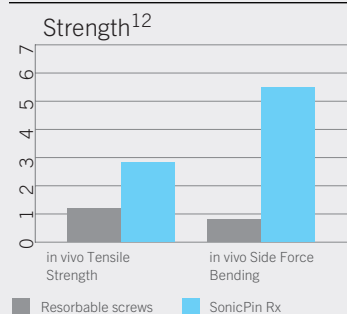


Feature and Function

- The ultrasonic energy sets the SonicPin Rx into mechanical vibration
- The liquid SonicPin Rx penetrates into the bone cavities
- The principle works both in cortical and cancellous spongy bone
- Low power effort during SonicPin Rx insertion
- Implantation of the SonicPin Rx in angle position is possible
- Relies on ultrasonic vibration and friction to provide optimal heat for SonicPin Rx fixation
- Immediately following deactivation of ultrasound, polymer cooling ensues
- No risk of pin/screw breakage

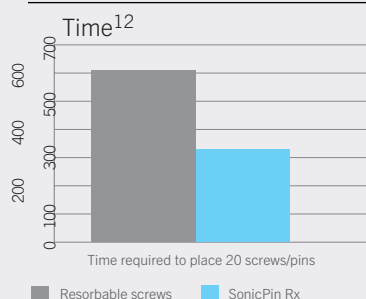
Benefit

- The material liquifies at the interface between the pre-drilled bone and the SonicPin Rx via friction
- The material reaches bone cavities beyond the reach of common screws
- Excellent three-dimensional stability both in cortical and spongy bone
- Does not rely on thick cortical bone alone^{3,5}
- Repositioning of small bone fragments
- Especially suitable in cramped corners without dislocation
- No bone necrosis^{2,4-15}
- Fast cooling down of the material and surrounding bone
- Secure anchorage of the SonicPin Rx in the bone only three seconds after activation
- No emergency system is necessary



- Locking effect between the SonicPin Rx and the pre-drilled hole
- Locking effect between the SonicPin Rx head and the plate/mesh
- Locking mechanism can be reversed by drilling through the inserted SonicPin Rx

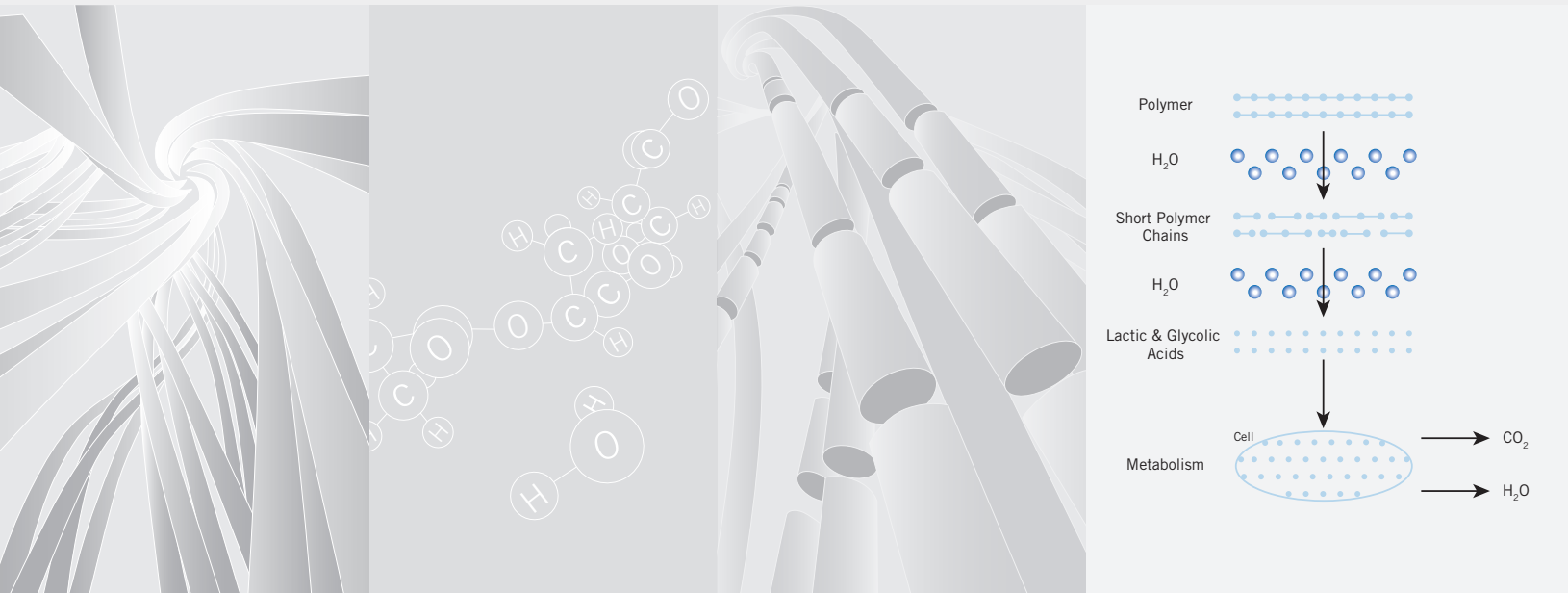
- Extremely stable fixation of the SonicPin Rx in the pre-drilled hole
- Sonicpins Rx offer up to twice the strength of resorbable screws^{1,12}
- Simple implant removal
- Simple correction of the implant position



- No need for pre-tapping

- Exceptionally fast implantation of the SonicPin Rx¹²
- Reduction in surgical time

Feature, Function and Benefit



Two resorbable polymers for osteosynthesis, PDLLA and PLLA-PGA, have been well-established in craniomaxillofacial surgery.

Resorb x® polymer is a 100% Poly-D, L-Lactic Acid (PDLLA).

Resorb xG polymer consists of 85% Poly-L-Lactic Acid (PLLA) and 15% Poly Glycolic Acid (PGA).

Both resorbable materials maintain the majority of their strength for 8-10 weeks, allowing complete fracture healing and bone regeneration.^{4,7,8}

The core of the degradation process:

The complex polymer chains absorb the water contents (H₂O molecules) of surrounding body fluids through a process called hydrolysis. The stored water initiates the degradation process by continuously breaking down the long polymer chains into ever shorter structures or simpler molecules. Metabolic pathways subsequently transform the molecules into carbon dioxide and water; both of these compounds are discharged naturally.

Resorb x®

Feature and Function

Benefit



- Polymer consists of 100% Poly-D,L-Lactic Acid (PDLLA)

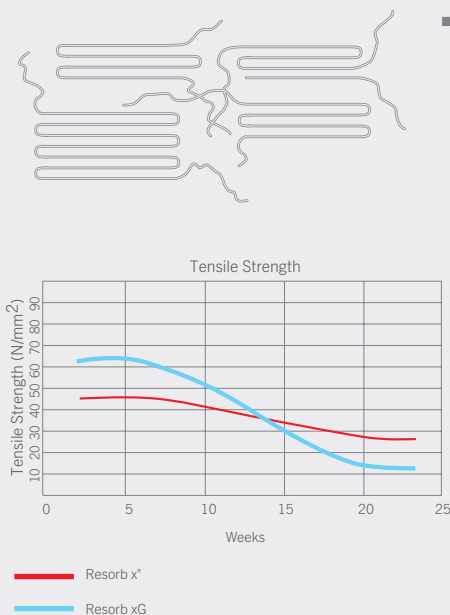
- Totally amorphous polymer
- Residue free degradation
- Numerous animal and clinical studies prove excellent biocompatibility and a safe degradation process^{2,4-15}
- Resorption time observed in ultrasound follow-up: 12 - 30 months^{4,7,8}



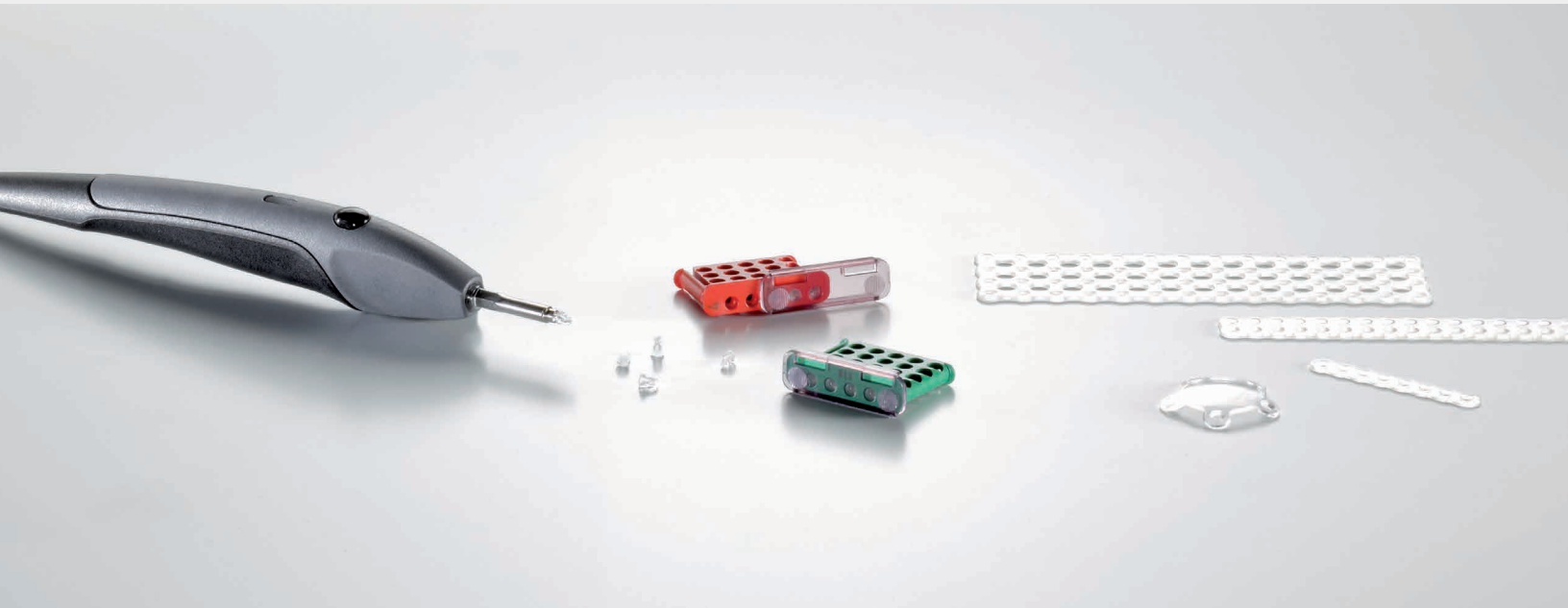
Resorb xG

- Polymer consists of 85% Poly-L-Lactic Acid (PLLA) and 15% Poly Glycolic Acid (PGA)

- Higher initial strength⁸
- Faster degradation of both strength and mass⁸
- Resorption time: approximately 12 - 14 months⁸



Feature, Function and Benefit

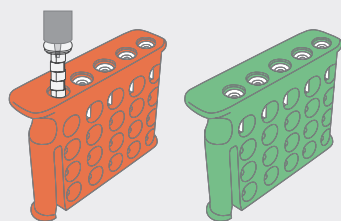


SonicPins Rx are characterized by their unique geometry. The geometry guarantees maximum polymer outflow in the surrounding bone cavities during SonicPin Rx insertion, thus reducing the power effort for SonicPin Rx insertion to a minimum. SonicPins Rx are available in two diameters:

- **green clip:** Ø 1.6 mm
- **red clip:** Ø 2.1 mm

Resorbable implants are available in various designs and thicknesses to give the surgeon options to match every indication. The holes of the plates and meshes are perfectly adapted to the geometry of the SonicPins Rx. Thus the head of the SonicPin Rx is optimally countersunk in the implant.

SonicPin Rx



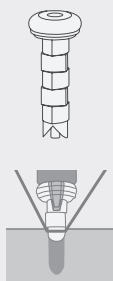
Feature and Function

- Color-coded clip magazines
 - green: SonicPins Rx Ø 1.6 mm
 - red: SonicPins Rx Ø 2.1 mm
- Self-retaining pin head
- Optimized pin geometry
- Both SonicPin Rx sizes fit all implants of Resorb x[®] and Resorb xG product range
- Sterile delivery

Benefit

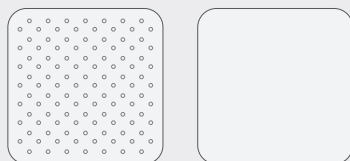
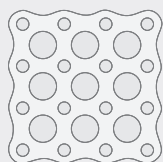
- Easy identification of the appropriate SonicPin Rx diameter
- Convenient pin removal from clip magazine
- Maximum polymer outflow in the surrounding bone structure
- Easy pin insertion
- Complete cross compatibility
- Always ready to use

SonicPin Rx types



- Standard SonicPin Rx
- Endobrow SonicPins Rx with specially designed pin tip for sutures

- Perfect solution for a wide range of applications
- Ideal for endobrow lifting



- Huge variety of different geometries, sizes and thicknesses
- Round edge geometry
- Can easily be contoured in the Xcelsior water bath and cut with scissors intraoperatively
- Flexible meshes
- Membranes and foils with minimal thickness (0.1, 0.2 or 0.3 mm)
- All Resorb x[®] and Resorb xG implants fit both SonicPin Rx diameters (1.6 and 2.1 mm)
- Sterile delivery

- Right implant for every indication
- Minimal palpability and susceptibility
- Easy adaption to patient-specific anatomy
- Very easy to adapt to patient specific anatomy
- Ideal for preprosthetic augmentation
- Complete cross compatibility
- Always ready to use

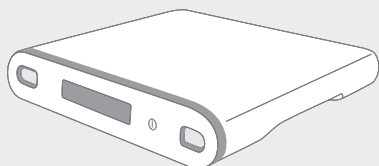
Feature, Function and Benefit



The ultrasonic unit of the SonicWeld Rx™ system converts electric energy into mechanical vibrations (ultrasound).

When using a standard sonotrode, the ultrasonic energy causes a phase change of the resorbable material at the interfaces between the bone and the SonicPins Rx via friction. Thus the SonicPin Rx glides into the predrilled hole. A supplemental tool, the smoothing sonotrode may be used to smooth out resorbable implants and mitigate rough edges (e. g. a membrane).

Ultrasonic unit



Feature and Function

- Simple and elegant design
- Round edge geometry
- Two handles to carry the device
- Two connecting sockets for handpieces
- One pre-defined power level
- Opportunity to choose the individual system language

Benefit

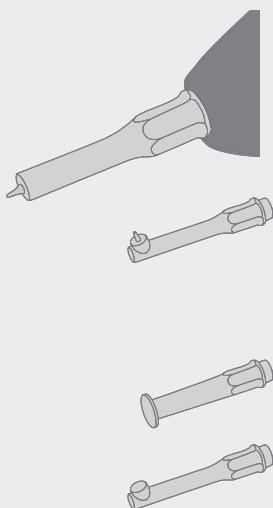
- Improved user interface
- Easy to clean
- Secure fit of the device during transportation
- To work alternatingly with two sonotrodes (e.g. a standard and a smoothing sonotrode or two standard sonotrodes)
- Optimal system setting
- User-friendly application
- No comprehensive problems



- Ergonomically designed handpiece
- Finger activation
- Light and acoustic support during activation
- Autoclavable

- Well balanced and comfortable fit
- Exclusive concentration on the hand during SonicPin Rx insertion or smoothing
- 1:1 feedback during activation period
- Guaranteed warranty for 250 sterilization cycles

Sonotrodes



- Standard sonotrodes
 - straight
 - angled
- Smoothing sonotrodes
 - straight
 - angled

- Ideal for SonicPin Rx insertion in straight position
- Combined sonotrode
Ideal for SonicPin Rx insertion in angled position (e. g. orbital or side tooth area)
- Smoothing of implants in straight position
- Smoothing of implants in straight or angled position (e. g. orbital or side tooth area)

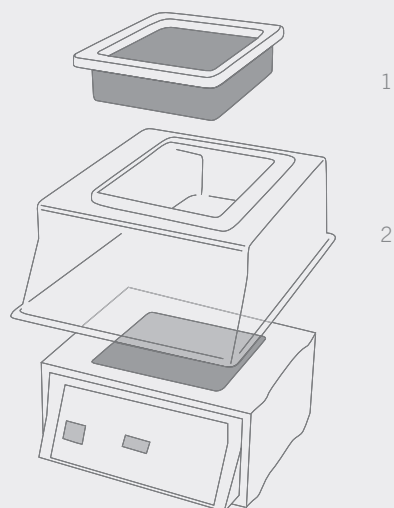
Feature, Function and Benefit



The Xcelsior water bath is intended for heating up resorbable implants in order to adapt them to patient specific anatomy (e. g. bone surface). Various templates are available that help adapt the implants to the shape of the bone.

The Battery Operated Drill (BOD) is a fully-fledged and universally applicable drill system. The battery tools do not require a charger or base unit and are always ready – wherever and whenever you need them.

Xcelsior water bath



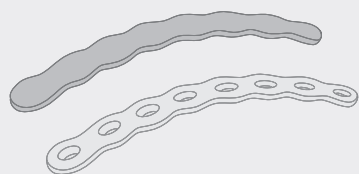
Feature and Function

- Tool for heating up Resorb x[®] and Resorb xG implants in the hot water (70 - 90 °C / 158 - 194 °F) to adapt it to the patient-specific bone contour

- Sterilizable material ^{1 2}

Benefit

- Perfect temperature range to adapt Resorb x[®] and Resorb xG implants
- To be used in the sterile area of the OR



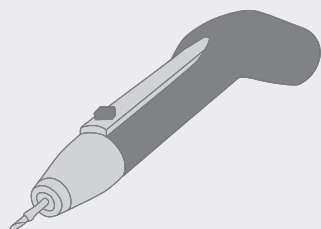
- Various templates available

- Adaption of the implant to the patient's anatomical condition in the Xcelsior water bath

- Template reflects the implant 1-to-1

- Perfect fit of implant

Battery Operated Drill



- 600 rev/min, high-speed forward
- Ergonomic design
- Lightweight handle weighing only 200g
- Can be operated with a finger
- Sterile battery pack simply needs to be clicked into place

- Ideal for predrilling
- Safe fit in the user's hand
- Key when dealing with a large number of implants
- Comfortable to use
- Always charged and ready for use

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REV 07 · 2018.01 · SonicWeld Perfect Choice · The information presented is intended to demonstrate a KLS Martin LP product. Please refer to the IFU for the full list of indications, contraindications, warnings, precautions, and sterilization information. Always refer to the IFU before using any KLS Martin LP product. Surgeons must always rely on their own clinical judgment when deciding which products and techniques to use with their patients.



The KLS Martin SonicWeld Rx™ solution is based on the BoneWelding™ technology¹⁾ protected by the industrial property rights of WoodWelding AG, Switzerland, and has been licensed by this company.

¹⁾ "BoneWelding™" is a registered Swiss trademark.