

SonicWeld Rx™



THE NEW ERA IN RESORBABLE
CRANIOFACIAL OSTEOSYNTHESIS

Endobrow Fixation

SonicWeld Rx™ Suture Anchor System

KLS martin® L.P.

SonicWeld Rx™ — the osteosynthesis revolution

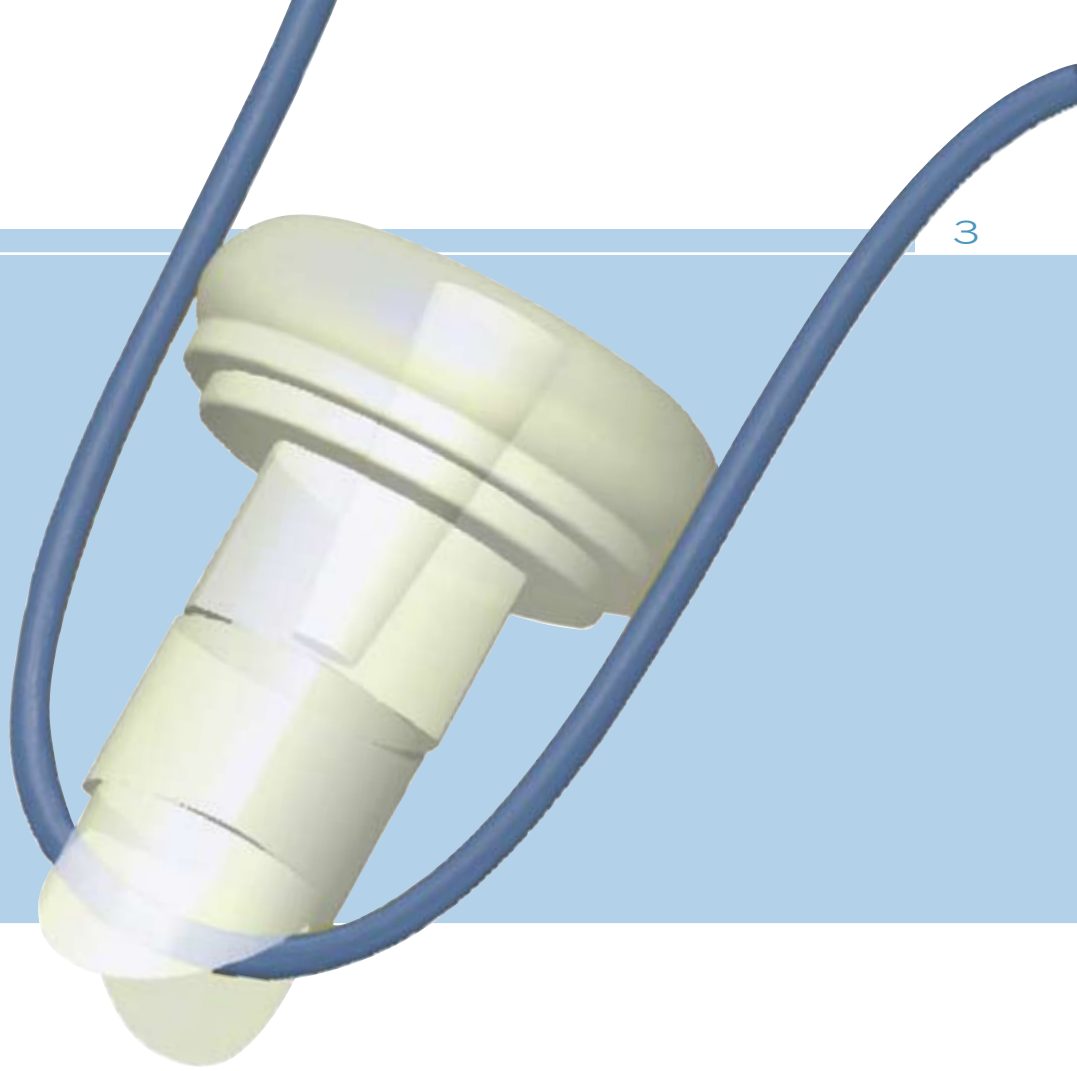
“Endoscopic-assisted brow lift technique has become a mainstream technique for brow lift for over ten years now. Fixation of the suspended brow has evolved from improvised external titanium screws, to internalized screws, to resorbable materials. While other resorbable fixation techniques are available, they have disadvantages of being bulky or cumbersome to apply. The KLS Martin® SonicWeld Endobrow Pin has advantages of secure fixation, along with ease and speed of application.”

-Dr. Stephen Beals, Paradise Valley, Arizona, Associate Professor of Plastic Surgery at Mayo Clinic College of Medicine

The Start of a New Era

SonicWeld Rx™ opens up totally new horizons. The ultrasonic technique, coupled with resorbable materials, makes the surgeon's operative technique distinctly easier. Thanks to the completely novel, ultrasound-controlled welding process, the resorbable material penetrates deep into the bone structures, leading to a three-dimensional anchorage that gives the surgeon fast and unrivaled stability with little effort. Since the entire implant is resorbable, no second operation is required.

The SonicWeld Rx™ system is truly an innovative product that has already changed the methods of bone fixation surgery. The SonicWeld Rx™ system including Resorb-X® mesh and plates has been widely adopted as the premier system for craniofacial osteosynthesis, and has been successfully used in thousands of cases worldwide.



Contents:

Fast & Safe The SonicWeld Rx™ principle	Page 4
Amorphous & Pure The material	Page 6
Questions & Answers Clinical results	Page 8
Complete & Flexible The components	Page 10
Info & More Products brochure and CD-ROM	Page 12

SonicWeld Rx™ principle

With SonicWeld Rx™, suture anchoring becomes much easier. A completely resorbable SonicPin Rx is inserted into a predrilled hole by ultrasound. It penetrates into bone cavities and carries the suture into the pilot hole. The pin solidifies, creating a solid three-dimensional anchor.

A new paradigm in bone fixation

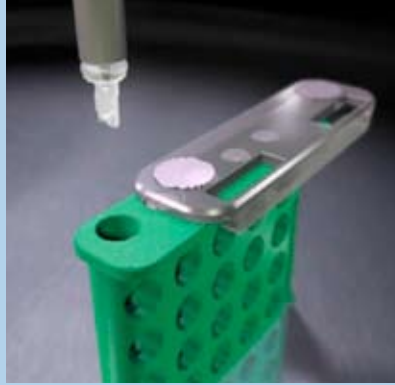
SonicPins Rx not only increase stability in dense bone, but allow you to use the system in thin, poor quality, or cancellous bone. This novel technology also potentially eliminates the need for follow-up operations because the implants are completely resorbable.

The advantages

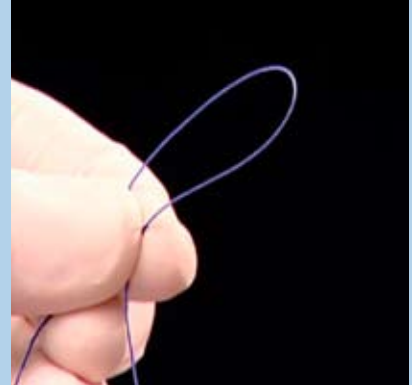
- **Stable:** The SonicPin Rx fills the cavities of the bone structure, ensuring the highest three-dimensional stability ever seen in a resorbable implant.
- **Versatile:** The SonicPin Rx takes excellent hold in any bone structure, whether cortical or cancellous.
- **Flexible:** The SonicPin Rx can easily be applied in difficult anatomical conditions where screws are difficult to insert. Pins can even be applied at an angle.
- **Fast:** Easy handling shortens operating time.
- **Convenient:** A single intervention, no removal!
- **Patient Friendly:** Very little palpability with safe, proven resorption.



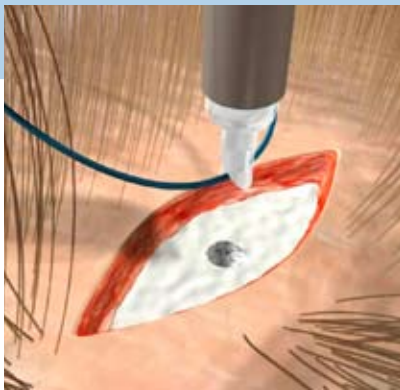
Drill pilot hole using Battery Operated Drill (BOD), hand drill, or OR drill system.



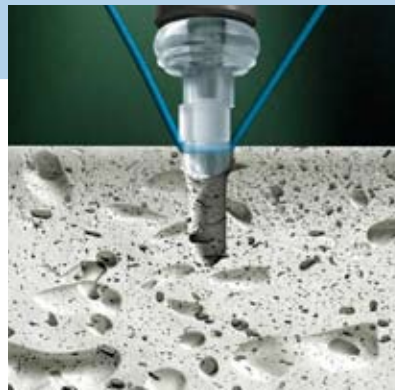
Load a pin on the sonotrode.



Make a loop in the suture.



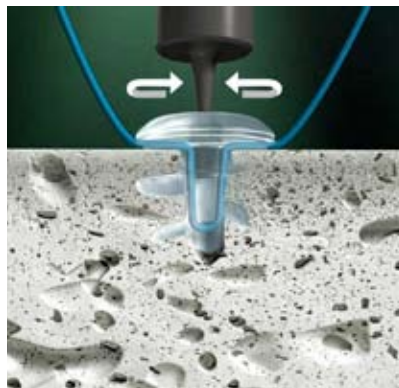
Align suture with groove in pin.



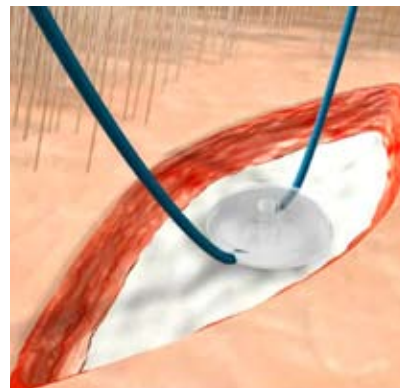
Use pin groove to insert suture into the pilot hole with the tip. The tip must be resting inside the hole 1 mm. Suture should not be loaded with force.



Press foot pedal and insert pin into bone. Remove foot from foot switch and allow pin to cool for a moment.



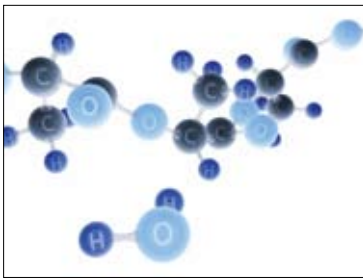
Twist sonotrode to rotate and disengage sonotrode tip from head of pin.



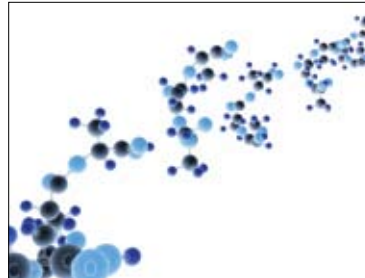
Allow pin to completely cool for a few seconds, then test anchor to ensure proper insertion was accomplished. Complete tissue fixation using both ends of the suture.

The material

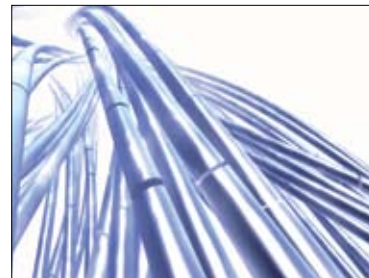
SonicWeld Rx™ is based on our certified PDLLA implants. PDLLA consists of lactides and is 100% amorphous. The biological degradation process by hydrolysis is predictable. All constituents are completely discharged through the metabolic channels – no crystalline residues remain.



2



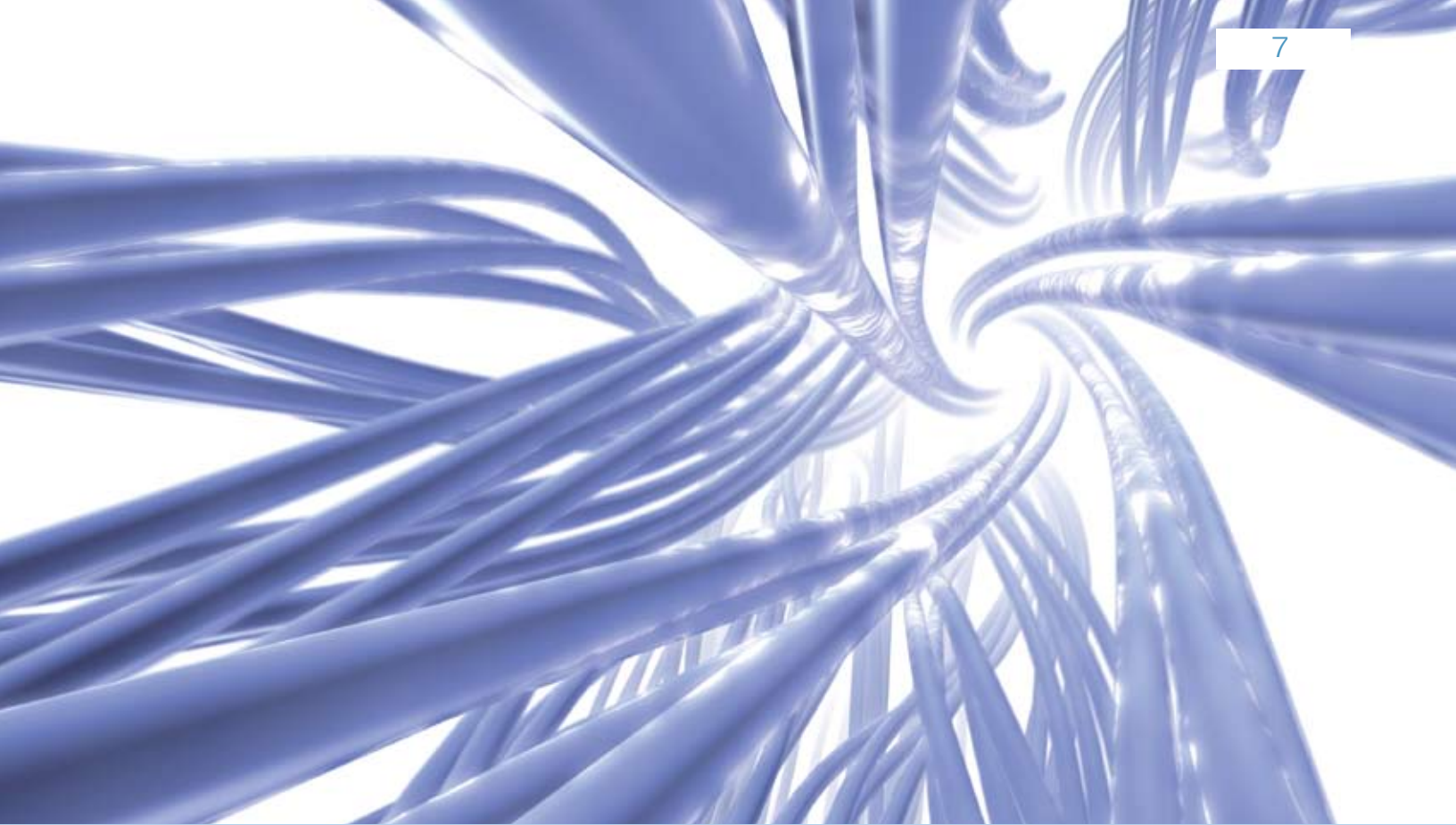
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The advantages

- **Controlled:** PDLLA is an intrinsically amorphous material consisting of D-lactide and L-lactide (each 50%). As both components are present in the same proportion, the biological degradation process is both predictable and safe.
- **Compatible:** The implants are tissue-friendly to the highest possible degree.
- **Natural:** Implant degradation takes place through hydrolysis. All constituents of the material are completely discharged by metabolic processes.
- **Validated:** In conjunction with PDLLA, SonicWeld Rx™ offers you a clinically certified, validated and patented total system that has been thoroughly tested.



The core of the innovation: a step into the future

The PDLLA material's complex polymer chains absorb the water contents (H_2O molecules) of surrounding body fluids – a process called “hydrolysis”. The stored water then initiates the degradation process, continuously breaking down the long polymer chains into ever shorter structures or simpler molecules. The human metabolism subsequently transforms the D-lactides and L-lactides into carbon dioxide and water. Both of these compounds are finally discharged naturally. This degradation process is predictable and complete.

The degradation process

- **Supporting:** The material's defined mechanical strength at implantation time is retained for eight to ten weeks.
- **Complete:** Complete degradation of the SonicPins Rx and full drill-hole ossification in one to two years.

Clinical results

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.

Before



After



Clinical patient results: Dr. Stephen Beals, Paradise Valley, Arizona,
Associate Professor of Plastic Surgery at Mayo Clinic College of Medicine

Mechanical findings

- The mechanical strength of a SonicPin Rx is significantly higher than that of conventional screw osteosyntheses.
- Particularly impressive is the increased primary strength of the SonicPins Rx, due to direct polymer anchorage in the trabecular meshwork of the bone.

Important questions & answers

Does SonicPin Rx liquefaction heat up the tissue around the pin?

With proper technique, temperature increase is minimal and disappears within seconds causing no pain or necrosis.

Does the treatment cause traumatization?

No. With proper technique, clinical experience supports the following statements:

- No bone destruction or degradation as a result of thermal damage
- Intact bone structures at the pin implantation site
- No difference concerning the dynamics and quality of bone regeneration, compared with traditional screw fixation
- No signs of inflammation
- No scars or tissue adhesions

Does this surgical technique cause pain?

The Sonic technique causes no more pain than any other fixation technique.

What suture should be used?

We recommend 2.0 Vicryl™© (polyglactin).
We do not recommend PDS (polydioxanone) suture.

Dexon™ (polyglycolic), Ethilon™© 3.0, and Ethicon™© silk 3.0 have all been successfully tested.

How long will the SonicPin Rx maintain strength?

The SonicPin Rx will retain its mechanical strength for 10 weeks.

Indications

- Suture fixation in craniomaxillofacial bone

Contraindications

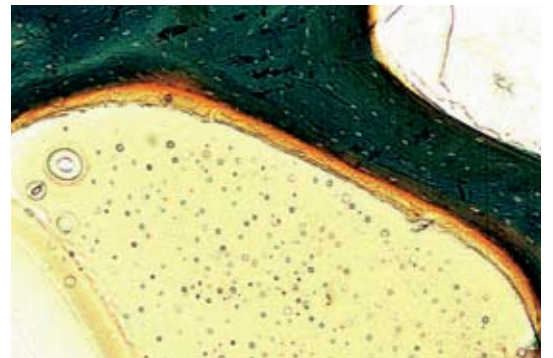
- High-load regions
- Acute or latent infections
- Patients in poor health or suffering from metabolic disorders (e.g. diabetes)



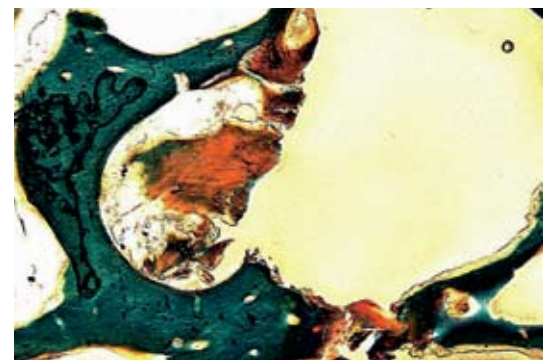
Longitudinal section through SonicPin Rx and supporting tissue immediately after the operation



32 days after pin insertion



3 months after the operation



Another image taken 3 months after the operation

Histological images: University Carl Gustav Carus of the Technical University of Dresden, Hospital for Oral and Maxillofacial Surgery, Dr. Dr. Ronald Mai and Prof. Dr. Dr. Uwe Eckelt (director)

Clinical results: University Carl Gustav Carus of the Technical University of Dresden, Hospital for Prosthetic Dentistry, headed by Prof. Dr. Bernd Reitemeier

The system components

Different requirements, different dimensions. Always right: SonicWeld Rx™ and its comprehensive range of accessories. Optimally adapted for use in the OR – and optimally integrated into a total system.

SonicPins Rx

- The SonicPins Rx are available in 2.1mm diameter.
- The SonicPins Rx are self-retaining so they can be safely and conveniently picked up with the tip of the sonotrode.
- The optimized shape of the SonicPins Rx guarantees easy insertion and a strong hold in the bone.

Sonotrode Hand Piece with Cable

- Maximum safety and operator convenience due to the self-retaining SonicPins Rx and a handle that illuminates the surgical site.
- Completely sterilizable (134°C/273°F).
- Easy replacement.

SonicWeld Rx™

Designation/ Unit	Quantity	Item Number
SonicWelder Rx basic set	1 unit	52-500-00
consisting of:		
SonicWeld Rx™	1 unit	52-500-01
Footswitch	1 unit	52-500-02
Handpiece	1 unit	52-500-03
Sonotrode, straight	1 unit	52-501-01
Open-ended wrench*	1 unit	52-502-01
* for sonotrode		
Case	1 unit	52-502-02
Power Cord	1 unit	52-400-99
Additional Fuse, 2/pkg		52-503-04

SonicWelder Rx

- The SonicWeld Rx™ technology utilizes the principle of ultrasonic frequency. The micro-vibrations generated by a defined ultrasonic frequency cause the pin's edges to melt as it comes in contact with a hard surface like bone. As a result, the SonicPin Rx simply flows into the predrilled hole. The system is simple to setup and is preset for pin insertion.

Battery Operated Drill (BOD)

- Our BOD is an ideal compliment to the SonicWeld Rx™ system. This battery-operated drill provides excellent cordless drilling capability. It can be disinfected and steam-sterilized (at 134°C/273°F).
- Thanks to the perfect combination of ergonomics and design, high-quality materials, and advanced manufacturing technologies, this product has received the International Design Forum Award 2005.





SonicWelder



Sonotrode

Hand piece with cable



SonicPins Rx

Suture Anchor SonicPins



Dimensions (mm)	Item Number
2.1 x 4	52-641-14

1 per cartridge



Twist Drills (for predrilling)

Twist Drills

	Dimensions (mm)	Item Number
for BOD	1.6 x 40 x 5	52-616-05
for 2.1-mm Pins	1.6 x 40 x 4	52-616-04
Notched attachment		
for 2.1-mm Pins	1.6 x 50 x 5	52-516-05
	1.6 x 50 x 4	52-516-04
for Hand Drill		
for 2.1-mm Pins	1.6 x 50 x 5	52-416-05
	1.6 x 50 x 4	52-416-04



product design award 2005



Battery Operated Drill



Hand Drill Driver

Drills

	Item Number
BOD	
Battery Operated Drill Handle	50-800-03
Battery Pack, 10/Pkg, sterile	50-800-02
Battery Pack, 1/Pkg, sterile	50-800-02-1
Hand Drill Driver	25-402-99

If you have any questions...

...we will be glad to answer them anytime with additional information in the form of product brochures and a CD-ROM that vividly describe and illustrate the SonicWeld Rx™ principle. Of course, you can also reach us personally, either by e-mail or through our customer hotline.

Additional product brochures and information materials

- SonicWeld Rx™ Brochure (Bone fixation)
- Resorb-X® Brochure
- SonicWeld Rx™ CD-ROM
- Level One Catalog (Bone fixation)
- Battery Operated Screwdriver & Drill (BOS & BOD)

Customer hotline: 800.625.1557
E-mail: sonicweld-rx@klsmartin.com

www.sonicweldrx.com



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

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