RFS™ Resorbable Material - PLGA - What is it?

The RFS™ Pins and Solid/Cannulated Screws are made of PLGA, a bioabsorbable poly lactic/glycolic acid copolymer (PLGA). These polymers have a long history of safe medical use and they degrade in vivo by hydrolysis into alpha-hydroxy acids that are metabolized by the body. The manufacturing process generates the high initial mechanical strength and stiffness of the screws.

A special characteristic of the RFS™ screw is auto-compression. It is a lengthwise contraction of the screw by 1-2% (Figure 1), and related expansion in the diameter of the screw once the screw is implanted and hydrolysis begins. This memory effect, based on mechanical activity, both creates compression on the fracture line and prevents the screw from loosening as metal screws commonly do. The fixation achieved with the RFS™ Screw improves by itself over the first postoperative weeks. Wright’s RFS™ Screw is the only bioabsorbable screw offering controlled long-term compression on the healing fracture. The RFS™ Pin’s functionality begins during surgery with instant locking due to the grooved surface design (Figure 2), and they actively contribute to improving fixation after implantation due to a self-locking property based on a hydrolytical shape memory. The product’s properties create optimal conditions for bone repair, leading to better ossification. Using the RFS™ Pin allows surgeons to attend to more patients, as the removal procedure is no longer needed.

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>Tornier RFS™ Screw</th>
<th>Arthrex TRAM™-11 Screw</th>
<th>ConMed/Linvatec SmartScrew™ II</th>
<th>BioMet/Arthrotek Reunite™ Screw</th>
<th>Inion Optima Screw (non-RFS Screw)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to Strength Loss (&lt;80%)</td>
<td>8 - 16 weeks</td>
<td>&gt;24 weeks</td>
<td>20 - 50 weeks</td>
<td>8 - 12 weeks</td>
<td>18 - 36 weeks</td>
</tr>
<tr>
<td>Resorption Time</td>
<td>approx. 2 years</td>
<td>N/A</td>
<td>2 - 4 years</td>
<td>9 - 15 months</td>
<td>2 - 4 years</td>
</tr>
</tbody>
</table>

References:
* http://www.arthrex.com/
** http://www.conmed.com/products_fracturefix_smartscrew.php
**** http://www.inion.com/Products/CMF_surgery/en_GB/Inion_CPS_System
**Feature Advantage**

85/15 PLGA  
The copolymer degrades in vivo by hydrolysis into alpha hydroxy acids that are metabolized by the body.

Maintains Strength Through the Healing Process  
The RFS™ Cannulated Screw is designed to maintain its functional structure for at least 8 weeks and to completely resorb within approximately 2 years.

Fully Cannulated System  
Allows the screw to be precisely placed for maximum purchase.

Bioabsorbability  
No retained hardware = no hardware prominence or hardware removal.

Auto Compression  
The implant is designed to change its dimensional characteristics in hydrolytic conditions. Diameter increases and length decreases 1% - 2% compared to initial dimensions. This innovative feature provides sustained compression during bone healing and reduces the risk of unstable fixation.

Multiple Applications  
Indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures of upper extremity, ankle and foot in the presence of appropriate immobilization.

Accepts Additional Strength  
4.0 mm and 4.5 mm RFS™ Cannulated Screw can be used, applying a combination technique with a 1.5 mm RFS™ by inserting the pin inside an RFS™ Cannulated Screw.

Fully Threaded and Lag Options  
Allows for multiple techniques.

**The RFS™ Cannulated Screws** are constructed of oriented bioresorbable L-lactic/co-glycolic acid copolymer (PLGA 85L/15G) and feature a small, low-profile resorbable screw head, industry standard compatible screw thread design and a detachable industry standard compatible head adaptor offering ease of insertion and greater confidence. The cannulated screw and associated instruments provide for precise placement and procedural simplicity.

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The RFS™ Advantage

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1. Select the appropriate RFS™ Cannulated Screw for the indication.

Optional Technique: Insert additional guide wire for extra stabilization and guidance.

2. Drill the screw hole through the drill sleeve to a sufficient depth under image intensification (not including the last 5 mm of the guide wire) using an appropriate cannulated drill bit. Use irrigation.

3. Tap the screw hole manually through the drill sleeve to a sufficient depth using an appropriate cannulated bone tap.

4. Countersink (optional). In areas where soft tissue coverage is minimal, and when the head of the fully threaded screw is needed as additional support, the appropriate countersink can be used in order to make space for the screw head and to avoid soft tissue irritation by the protruding screw head. Use appropriate cannulated countersink without drill sleeve.

5. Countersink (optional). In areas where soft tissue coverage is minimal, and when the head of the fully threaded screw is needed as additional support, the appropriate countersink can be used in order to make space for the screw head and to avoid soft tissue irritation by the protruding screw head. Use appropriate cannulated countersink without drill sleeve.

6. Insert guide wire through the drill sleeve to appropriate depth under image intensification.

Optional Technique: Insert additional guide wire for extra stabilization and guidance.

7. Fully insert the screw along the guide wire into the drill hole.

NOTE: When the reduction is good and drilling and tapping are done properly, the insertion should be easy with the two finger technique. In case the friction increases too much during insertion, the screw must be removed and the hole must be rinsed and/or retapped.

8. Remove and discard the guide wire.

After the screw is fully inserted, the Insertion Adapter must be detached from the screw (e.g. with screwdriver or with pliers). Once detached, dispose the Insertion Adapter.

After insertion in cases where the screw head is not needed (e.g. in the case of the syndesmosis screw), the screw is cut along the bone or plate surface after insertion to avoid soft tissue irritation by the protruding screw head. Scissors, reciprocating saw or a hot wire can be used to cut the RFS™ Cannulated Screw. DO NOT cut the head of a LAG-screw.
Measure the screw length by sliding the tapered end of the cannulated depth gauge along the guide wire to the bone surface. If countersink has been used, the measuring device must be placed at the bottom of the countersink. Read the scale at the end of the guide wire to determine appropriate screw length. This reading will place the screw 5 mm short of the guide wire tip to maintain the stabilization effect of the guide wire throughout the procedure.

The prepared hole should be irrigated prior to screw insertion to flush out bone debris.

Open the RFS™ Cannulated Screw Holder cap.

Pick the screw out of the RFS™ Cannulated Screw Holder by the appropriate cannulated screwdriver.

In areas where soft tissue coverage is more than 20 mm, protection sleeve can be inserted through a small incision and all the steps can be done through the sleeve to prevent soft tissue damage. In step 6, the surgeon must remove the insertion adapter from screw before insertion and insert the screw with the customized direct driver through the protection sleeve. Remove the guide wire after insertion.

Optional Technique to Increase Strength

In cases where more shear strength of the implant is needed, it is possible to increase strength of the 4.0 mm and 4.5 mm RFS™ Cannulated Screws by inserting the 1.5 mm RFS™ Pin implant inside the cannulated screw (e.g. with the RFS™ Pin Applicator). This technique also allows the RFS™ Pin to fill the distal end of the guide wire hole to increase the overall strength of the screw. The 3.5 mm RFS™ Cannulated Screw can NOT be used with the RFS™ Pin.

Optional Technique for Steps 1-8

Select appropriate length of the 1.5 mm RFS™ Pin implant and insert pin inside the RFS™ Cannulated Screw with customized RFS™ instrumentation according to the normal insertion technique of the RFS™ Pin.

Additional Information

• On the basis of the surgeon’s decision, radiographs are taken before wound closure.
• After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.
• Meticulous hemostasis and complete primary skin closure over the implant are essential.
RFS™ Solid Screw

The RFS™ Screws are constructed of oriented bioresorbable L-lactic/co-glycolic acid copolymer (PLGA 85L/15G) and feature a small, low-profile resorbable screw head, industry standard compatible screw thread design and a detachable industry standard compatible head adaptor offering ease of insertion and greater confidence.

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<td>AO Compatibility</td>
<td>Industry standard compatible design with detachable screw head.</td>
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<td>Indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures of upper extremity, ankle and foot in the presence of appropriate immobilization.</td>
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Select the appropriate RFS™ Solid Screw for the indication. Drill a screw channel through the fracture plane using appropriate drill bit. Use irrigation.

Tap the screw hole manually to a sufficient depth using the appropriate AO-compatible bone tap (corresponding to the screw diameter) before screw insertion. Make sure to tap the drill canal all the way in.

When the head of the fully threaded screw is needed as additional support, appropriate countersink can be used in order to make space for the screw head and to avoid soft tissue irritation by the protruding screw head.

The prepared hole should be irrigated prior to screw insertion to flush out bone debris. Open the RFS™ Solid Screw Holder cap. Pick the screw out of the RFS™ Screw Holder by the appropriate AO-compatible screwdriver.

The prepared hole should be irrigated prior to screw insertion to flush out bone debris. Open the RFS™ Solid Screw Holder cap. Pick the screw out of the RFS™ Screw Holder by the appropriate AO-compatible screwdriver.

Hold the screwdriver and the screw parallel to the long axis of the drill hole and insert the screw fully into the drill hole. **NOTE:** When the reduction is good and drilling and tapping are done properly, the insertion should be easy with the two finger technique. In case the friction increases too much during insertion, the screw must be removed and the hole must be rinsed and/or retapped.

Additional Information

- After insertion in cases where the screw head is not needed (e.g. in the case of the syndesmosis screw), the screw is cut along the bone or plate surface after insertion to avoid soft tissue irritation by the protruding screw head. Scissors, reciprocating saw or a hot wire can be used to cut the RFS™ Solid Screw. **DO NOT** cut the head of a LAG-screw.
- On the basis of the surgeon's decision, radiographs are taken before wound closure.
- After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.
- Meticulous hemostasis and complete primary skin closure over the implant are essential.
RFS™ Pin

The RFS™ Pins are constructed of bioabsorbable lactic/glycolic acid copolymer (85/15 PLGA). These polymers have a long history of safe medical use and they degrade in vivo by hydrolysis into alpha hydroxy acids that are metabolized by the body. The implants’ functionality begins during surgery with instant locking due to the grooved surface design, and they actively contribute to improving fixation after implantation due to a self-locking property based on a hydrolytical shape memory.

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<td>Auto Compression</td>
<td>Allows for the RFS™ Pin to expand 1-2% in hydrolytic conditions.</td>
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<tr>
<td>Grooved Design</td>
<td>Ridges on the outer surface of the pin resist rotation.</td>
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</table>

RFS™™ Pins are 50 mm long and are available in 1.5 mm, 2.0 mm and 2.7 mm diameters individually packaged in a Pin Holder.

Note: The Guide Wire for the 2.0 mm Pin has a stepped shaft to accommodate standard pin drivers.
Surgical Technique

Select the appropriate RFS™ Pin for the indication.

1. Drill a hole which corresponds to the pin diameter through the fracture/osteotomy plane. To prevent overdrilling, multiple reaming with the drill bit should be avoided.

2. Open the RFS™ Pin Holder cap.

3. Pick the pin by pushing the RFS™ Pin Applicator Piston/Arthroscopic Piston distal head into the RFS™ Pin Holder until it is attached to the pin.

4. Slide attached pin and piston inside to the RFS™ Pin Applicator Sleeve through the twist lock by twisting the Piston clockwise.

5. Introduce the pin into the hole by sliding the Piston.

6. During insertion of the pin, hold the applicator and the pin parallel to the long axis of the drill hole so that it slides easily to the drill hole. Insert the pin by lightly tapping the Piston with a mallet.

Tap the Piston until entire pin is forced fully into the drill hole. The RFS™ Pin Applicator is designed so that it sinks the pin 1-2 mm when the Piston is tapped to the end of the sleeve. This prevents the head of the pin from protruding which could cause soft tissue irritation.

Additional Information

- After insertion, if the pin is too long, scissors, reciprocating saw, or a hot wire can be used to cut the RFS™ Pin. In such a case, the proximal end of the pin must be pushed 1-2 mm below the cortical surface or smoothened at least to the cortical level, to avoid soft tissue irritation.

- Two or more pin fixations can be applied if necessary (depending on the nature and size of the fracture). In such a case, it is recommended that pins be inserted at divergent angles to one another, rather than parallel, for best results.

- On the basis of the surgeon’s decision, radiographs are taken before wound closure.

- After fixation, the wound is closed in layers applying standard principles of orthopaedics and traumatology.

- Meticulous hemostasis and complete primary skin closure over the implant are essential.
Indication and Procedure Matrix

Scarf Osteotomy

Phalangeal Fusion

Closing Wedge

Closing Wedge Osteotomy

Maleolar
Chevron/Austin Bunionectomy
Calcaneal Slide Osteotomy
Syndesmotic
Reverdin Green
Prior to using any Wright device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

RFS™ Cannulated Screw Product Information

The RFS™ Cannulated Screw system includes a procedure-specific instrument set and screws in the following sizes:

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5 mm Cannulated</td>
<td>24 mm - 40 mm</td>
</tr>
<tr>
<td>3.5 mm Cannulated LAG</td>
<td>24 mm - 45 mm</td>
</tr>
<tr>
<td>4.0 mm Cannulated</td>
<td>35 mm - 90 mm</td>
</tr>
<tr>
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<td>35 mm - 90 mm</td>
</tr>
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<td>4.5 mm Cannulated</td>
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</tr>
<tr>
<td>4.5 mm Cannulated LAG</td>
<td>40 mm - 90 mm</td>
</tr>
</tbody>
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RFS™ Cannulated Screw Indications:
The RFS™ Cannulated Screw is indicated for fixation of bone fractures, osteotomies, arthrodeses, bone grafts and osteochondral fractures of the upper extremity, ankle and foot in the presence of appropriate immobilization.

RFS™ Cannulated Screw Contraindications:
• Fractures and osteotomies of diaphyseal bone (except in the hand & foot)
• Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient’s cooperation cannot be guaranteed

RFS™ Solid Screw Product Information

The RFS™ Solid Screw system includes a procedure-specific instrument set and screws in the following sizes:

<table>
<thead>
<tr>
<th>Diameter</th>
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<tr>
<td>2.7 mm Fully Threaded</td>
<td>14 mm - 24 mm</td>
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<td>4.5 mm Fully Threaded</td>
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RFS™ Solid Screw Contraindications:
• Fractures and osteotomies of diaphyseal bone (except in the hand & foot)
• Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient’s cooperation cannot be guaranteed

RFS™ Pin Information

Each RFS™ DPA contains a scored Guide Wire for pre-drilling and measurement, an Applicator Piston for aseptic Pin access, and an Applicator Sleeve to facilitate accurate insertion.

<table>
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<tr>
<th>Pin Size</th>
<th>Pin CAT#</th>
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<tbody>
<tr>
<td>1.5 mm</td>
<td>RFS™-P015</td>
<td>RFS™-PA15</td>
</tr>
<tr>
<td>2.0 mm</td>
<td>RFS™-P020</td>
<td>RFS™-PA20</td>
</tr>
<tr>
<td>2.7 mm</td>
<td>RFS™-P027</td>
<td>RFS™-PA27</td>
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</tbody>
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RFS™ Pin Surgical Indications:
Fixation of bone fractures, osteotomies, arthrodeses and osteochondral fractures in the presence of appropriate immobilization.

RFS™ Pin Contraindications:
• Fractures and osteotomies of diaphyseal bone (except in the hand & foot)
• Fractures and osteotomies in weight bearing cancellous bone
• Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient’s cooperation cannot be guaranteed