**WARNINGS:**
This system must not be applied to a vertebral body in which pedicle screws will be placed.

The Trephine System should not be used on patients who suffer from osteoporosis or any condition which may result in loss of bone density or degradation of bony tissue.
The ideal autograft harvest

Traditionally, posterior and anterior lumbar spinal fusions require autologous bone graft to promote arthrodesis.1 Autograft is considered the optimal graft material to obtain a fusion. Although iliac crest harvest can supply the essential autograft material, the second surgical site often results in pain and morbidity.2 The vertebral body provides an alternate location for procuring material for fusion without inducing additional trauma and morbidity to the patient. Vertebral bone may be locally harvested in the proximity of the fusion site. However, the vertebral body loses some strength from the harvest of bone; therefore, it is critical to fill the resulting void with a structural filler. Simulated mechanical testing supports the ability of a structural filler to restore the vertebral body strength.3, 4 A second surgery for bone harvesting is no longer necessary, and the ideal grafting material is readily available for subsequent use in interbody fusion.

The ultimate goal of interbody fusion

With fusion and structural integrity as the ultimate goal, Synthes has developed systems to promote the AO principles of interbody fusion. The SynFrame retractor system supports a less invasive surgical technique without compromised visualization. Allograft implants such as the FRA Spacer and associated instruments are designed to promote restoration of anatomic alignment and maintain stability while using atraumatic technique. The Trephine System is designed for harvesting autogenous bone for the ideal biologic fusion. These systems are essential for lumbar interbody fusion and adhere to fundamental AO principles.

Instruments for the Trephine System

The Trephine instruments are designed to harvest autograft bone from the vertebral body and insert an allograft implant to fill the resulting void during Anterior Lumbar Interbody Fusion (ALIF) procedures using a direct anterior or anterolateral approach. The implant should be inserted into the void to support the structural integrity of the vertebral body.5, 4

WARNING: This system must not be applied to a vertebral body in which pedicle screws will be placed.
In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation. They are:

– Anatomic reduction
– Stable internal fixation
– Preservation of blood supply
– Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.

**AO Principles as Applied to the Spine**

**Anatomic alignment**
Restoration of normal spinal alignment to improve the biomechanics of the spine.

**Stable internal fixation**
Stabilization of the spinal segment to promote bony fusion.

**Preservation of Blood Supply**
Creation of an optimal environment for fusion.

**Early, active mobilization**
Minimization of damage to the spinal vasculature, dura, and neural elements, which may contribute to pain reduction and improved function for the patient.

Two of these principles, preservation of blood supply (creation of optimal fusion bed) and early, active mobilization, apply directly to the harvest technique for autogenous bone. Autogenous bone harvested from the iliac crest provides graft material for biologic fusion, but at the expense of pain at the harvest site. A system to alternatively harvest autograft bone from the local vertebral body, rather than the iliac crest, was developed to provide autogenous bone for biologic fusion using an atraumatic technique.
1

Approach

Instruments

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>297.011</td>
<td>Trephine Guide Wire</td>
</tr>
<tr>
<td>387.633</td>
<td>Trephine Centering Pin</td>
</tr>
<tr>
<td>387.635</td>
<td>Trephine Radiographic Template</td>
</tr>
<tr>
<td>395.38.99</td>
<td>Simple T-Handle</td>
</tr>
</tbody>
</table>

The anterior lumbar spine is accessed from either an anterior or anterolateral aspect at the level of pathology. Identify the surrounding anatomy and precise location of the selected vertebral body. Prepare the vertebral body chosen as the harvest site.

Connect the simple T-handle to the trephine guide wire and tighten the setscrew.

Insert the guide wire into the center of the vertebral body using the T-handle and a hammer. Place the guide wire in the center of the vertebral body, ensuring that the endplates are not violated. Advance the guide wire as far as the stop (22 mm). Disconnect the T-handle from the guide wire.
Place the trephine radiographic template over the guide wire. Determine the appropriate drill diameter using the radiographic template and a lateral radiograph to project the implant diameters onto the vertebral body. Select the appropriate diameter: 15 mm or 17 mm. Remove the radiographic template.

**Note:** Ensure that the implant diameter will fit properly in the vertebral body and that the endplates will remain intact.

Place the trephine centering pin over the guide wire, ensuring that the larger end is seated against the vertebral body.
1

**Approach** continued

**Instruments**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>387.631</td>
<td>Trephine Drill</td>
</tr>
<tr>
<td>or 387.641</td>
<td></td>
</tr>
<tr>
<td>387.634</td>
<td>Trephine Pusher</td>
</tr>
</tbody>
</table>

Place a trephine drill over the centering pin and guide wire assembly. Rotate the drill until it stops at the maximum depth as shown by the window in the drill handle. Remove the drill. The centering pin and guide wire should remain within the vertebral body.

**Note:** If the entire assembly remains in the drill after removal, extraction is not necessary. If this is the case, proceed directly to Step 3, “Insert implant.”

The trephine pusher may be used to remove the centering pin and guide wire from the drill (as shown on page 8).
2

Extract

Instruments

387.632 Trephine Extractor
or 387.642

Place a trephine extractor over the centering pin and guide wire assembly. Manually, or with a hammer, gently insert the extractor without rotating the instrument until the maximum depth is reached. (Refer to the window in the drill handle)

Once the maximum depth has been reached, rotate the extractor 90°. Remove the extractor assembly to extract the autogenous bone. The centering pin and guide wire will remain inside the extractor during removal.

IMPORTANT: Do not rotate the extractor before the maximum depth is reached, otherwise the autograft cylinder will break prematurely, preventing its complete removal.
3 Insert implant

Instruments

| 387.637 | Trephine Implant Holder  
or 387.643 |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>387.638</td>
<td>Trephine Inserter</td>
</tr>
</tbody>
</table>

Insert the VerteFill allograft implant into a trephine implant holder. Ensure that the anterior portion of the implant is placed inside the implant holder; the bevel on the posterior edge of the implant should be visible when the implant lies in the holder. Refer to the implant brochure for specific information regarding implant preparation.

2 Extract continued

Instruments

| 387.634 | Trephine Pusher |

Remove the centering pin and guide wire from the extractor using the trephine pusher. Remove the vertebral autograft cylinder and reserve for filling the ALIF allograft implant.

Vertebral autograft attached to the guide wire

The cancellous posterior end of VerteFill should be visible in the implant holder prior to insertion.

Position the VerteFill implant with cortical end in the implant holder.
Position the implant holder at the vertebral body graft site. Place the trephine inserter in the implant holder. Gently impact the end of the inserter until the anterior surface of the implant reaches the surface of the vertebral body.

Fill an ALIF allograft implant, such as the FRA spacer, with the harvested vertebral bone and proceed with insertion.

**Note:** This system is recommended only for use with the structural implants designed to fill the void. Do not attempt to fill such voids with other materials or implants.
### Instruments

<table>
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<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>297.011</td>
<td><strong>Trephine Guide Wire</strong></td>
</tr>
<tr>
<td></td>
<td>- Used to center subsequent instruments for harvesting</td>
</tr>
<tr>
<td></td>
<td>- Penetrates bone to a maximum depth of 22 mm</td>
</tr>
<tr>
<td>395.38.99</td>
<td><strong>Simple T-Handle</strong></td>
</tr>
<tr>
<td></td>
<td>Attaches to the Guide Wire to facilitate wire insertion</td>
</tr>
<tr>
<td>387.633</td>
<td><strong>Trephine Centering Pin</strong></td>
</tr>
<tr>
<td></td>
<td>Fits over the Guide Wire to center the Trephine Drill and Trephine Extractor</td>
</tr>
<tr>
<td>387.635</td>
<td><strong>Trephine Radiographic Template</strong></td>
</tr>
<tr>
<td></td>
<td>Used intraoperatively with a lateral radiograph to determine the appropriate drill diameter</td>
</tr>
<tr>
<td>387.631</td>
<td><strong>15 mm Trephine Drill</strong></td>
</tr>
<tr>
<td>387.641</td>
<td><strong>17 mm Trephine Drill</strong></td>
</tr>
<tr>
<td></td>
<td>- Drills into vertebral body</td>
</tr>
<tr>
<td></td>
<td>- Window at the top of the handle permits visualization of drilling depth</td>
</tr>
</tbody>
</table>
387.632 15 mm Trephine Extractor
387.642 17 mm Trephine Extractor
– Extracts the vertebral autograft cylinder from the vertebral body
– Window at the top of the handle enables visualization of insertion depth

387.634 Trephine Pusher
Facilitates removal of the Guide Wire and Centering Pin assembly from the Extractor

387.637 15 mm Trephine Implant Holder
387.643 17 mm Trephine Implant Holder
Securely holds the implant for controlled insertion

387.638 Trephine Inserter
Impacts the implant into the vertebral body through the Implant Holder
**Graphic Case**
690.037  Trephine Graphic Case

**Instruments**
- 387.631  15 mm Trephine Drill
- 387.632  15 mm Trephine Extractor
- 387.633  Trephine Centering Pin
- 387.634  Trephine Pusher
- 387.635  Trephine Radiographic Template
- 387.637  15 mm Trephine Implant Holder
- 387.638  Trephine Inserter
- 387.641  17 mm Trephine Drill
- 387.642  17 mm Trephine Extractor
- 387.643  17 mm Trephine Implant Holder
- 395.38.99  Simple T-Handle

Note: For additional information, please refer to package insert.

For detailed cleaning and sterilization instructions, please refer to [http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm](http://us.synthes.com/Medical+Community/Cleaning+and+Sterilization.htm) or to the below listed inserts, which will be included in the shipping container:
- Processing Synthes Reusable Medical Devices—Instruments, Instrument Trays and Graphic Cases—DJ1305
- Processing Non-sterile Synthes Implants—DJ1304


4. Data on File. Please refer to the *VerteFill Implant Brochure* for detailed mechanical testing results.
