Surgical Technique Cont’d.

5 Place Implant between two vertebrae in the prepared area.

6 Graft Material into the joint and onto the lateral masses using the Bone Graft Delivery Tool.

Instructions for Use

INTENDED PURPOSE

The DTRAX SS instruments are designed for spinal inter-body or intra-facet insertion of a bone allograft.

Intended conditions of use: The system is indicated for facilitating surgical treatment of the spine for patients requiring allograft placement.

CONTRAINDICATIONS

DTRAX SS should not be used in any of the following instances:

• Absence of posterior spinal elements including the pedicle, pars interarticularis, facet joints, spinous process and the majority of the lamina.
• Active infection process or significant risk of infection (immunocompromise).
• Signs of local inflammation.
• Fever or leukocytosis.
• Morbid obesity.
• Pregnancy.
• Marital illness.
• Grossly distorted anatomy caused by congenital abnormalities.
• Any medical or surgical condition which would preclude the potential benefit of a spinal allograft surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation in the WBC differential count.
• Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
• Any case where a bone graft and fusion is unnecessary or where fracture healing is not required.

CONTRAINDICATIONS

Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.

Any patient in which allograft use would interfere with anatomical structures or physiological performance.

Any patient unwilling to follow post-operative instructions.

Any case not described in the indications.

SINGLE USE

Instruments should not be re-used. Cleaning may not remove all contaminants; resterilization can affect the plastic parts and bonding. Instruments might deform not allowing proper use.

WARNINGS and PRECAUTIONS

The following Warnings and Precautions should be considered before use of DTRAX SS:

• Patient should have failed conservative treatment(s).
• There are no particular risks expected during other investigations and/or treatment.
• Physicians using DTRAX SS should have significant experience in spinal surgery, including spinal fusion.
• The surgical techniques shown are for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

To order a DTRAX product, contact Providence Medical Technology.
Disposable Instruments for Spinal Fusion

**DTRAX Spinal System** is a set of single-use disposable orthopedic surgical instruments that provides tissue-sparing access to the spine. The system includes instruments for access, distraction, and decortication to facilitate spinal fusion. Specific devices in the system include:

1. **Access Chisel**: An instrument with a flat leading edge for accessing and scoring the joint.
2. **Decortication Trephine**: Used to strip muscle from bone and decorticate in a circular fashion.
3. **Fork Mallet**: Replaces a mallet when used to advance instruments.
4. **Guide Tube**: Used for maintenance of joint distraction and serves as a working channel.
5. **Decortication Rasp**: Used to abrade the inferior and superior surfaces of the target joint to remove the cartilaginous endplate.
6. **Allograft Delivery Instrument**: Used to deliver allograft into the targeted joint.
7. **Bone Graft Tamp**: Used to apply injectable bone graft material into the decorticated joint and lateral masses.

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**Surgical Technique**

1. Advance Access Chisel to gain access to the posterior bony elements.
2. Use Decortication Device to strip the muscle from the posterior lamina out to the facet and decorticate the lateral masses.
3. Advance the Guide Tube over the Access Chisel.
4. Use the Chisel Rasp to decorticate the joint.

To learn more about DTRAX, please visit www.providencemt.com
Disposable Instruments for Spinal Fusion

**DTRAX Spinal System** is a set of single-use disposable orthopedic surgical instruments that provides minimally invasive access to the spine. The system includes instruments for access, distraction, and decortication to facilitate spinal fusion. Specific devices in the system include:

1. **Access Chisel**: An instrument with a flat leading edge for accessing and scoring the joint.
2. **Decortication Device**: Used to strip muscle from bone and decorticate in a circular fashion.
3. **Decortication Fork**: Replaces a mallet when used to advance instruments.
4. **Guide Tube**: Used for maintenance of joint distraction and serves as a working channel.
5. **Chisel Rasp**: Used to abrade the inferior and superior surfaces of the target joint to remove the cartilaginous endplate.
6. **Allograft Delivery Tool**: Used to deliver allograft into the targeted joint.
7. **Bone Graft Delivery Tool**: Used to apply injectable bone graft material into the decorticated joint and lateral masses.

**Surgical Technique**

1. **Advance Access Chisel** to gain access to the posterior bony elements.

2. **Use Decortication Trephine** to strip the muscle from the posterior lamina out to the facet and decorticate the lateral mass.

3. **Advance the Guide Tube** over the Access Chisel.

4. **Use the Decortication Rasp** to decorticate the joint.

To learn more about DTRAX, please visit [www.providencemt.com](http://www.providencemt.com)
Indirect Decompression and Fusion

Surgical Technique Continued

5 Place Implant between two vertebrae in the prepared area.

6 Apply graft material on to the joint and the lateral mass using the Bone Graft Tamp.

Instructions for Use

INTENDED PURPOSE

The DTRAX SS instruments are designed for spinal inter-body or intra-facet insertion of a bone allograft.

Intended conditions of use: The system is indicated for facilitating surgical treatment of the spine for patients requiring allograft placement.

CONTRAINdications

DTRAX SS should not be used in any of the following instances:

- Absence of posterior spinal elements including the pedicle, pars interarticularis, facet joints, spinous process and the majority of the lamina.
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- Signs of local inflammation.
- Fever or leukocytes.
- Morbid obesity.
- Pregnancy.
- Marital illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any medical or surgical condition which would preclude the potential benefit of a spinal allograft surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
- Any case where a bone graft and fusion is unnecessary or where fracture healing is not required.

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Any patient in which allograft use would interfere with anatomical structures or physiological performance.

Any patient unwilling to follow post-operative instructions.

Any case not described in the indications.

SINGLE USE

Instruments should not be re-used. Cleaning may not remove all contaminants; resterilization can affect the plastic parts and bonding. Instruments might deform not allowing proper use.

WARNINGS and PRECAUTIONS

The following Warnings and Precautions should be considered before use of DTRAX SS:

- Patient should have failed conservative treatment(s).
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- Physicians using DTRAX SS should have significant experience in spinal surgery, including spinal fusion.
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