

# Boning Up on Spinal Implants

Will Curtis

**The ideal treatment for replacing a part of the body with an implant would be to restore the area to a natural state. Unfortunately, this is not possible with traditional materials used for spinal implants, which can cause issues for the patient in years following surgery. This article looks at a natural alternative to those materials and the equipment being used to make these products.**

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Rapid custom manufacturing is lifting the orthopedics industry to new heights. Surgeons are beginning to use the technology to quickly produce implants from nearly any material, which yields a wide range of important benefits for patients.

AlloSource, one of the nation's largest non-profit bone and tissue providers, is a perfect example. Using an assembly line of Roland desktop milling machines, the company is quickly manufacturing custom spinal implants used in spine fusion surgeries.

"Desktop mills are ideal for producing medical implants," said Thomas Cycyota, AlloSource president and CEO. "The machines give us a seamless workflow and flawless results. They're even resistant to our extensive sanitization, which is a vital part of our process."

Rapid custom manufacturing technology offers a major improvement over current clinical processes, such as mass-producing one-size-fits-all parts or tediously hand sculpting unique parts. Best of all, implants made from human bone will not be rejected by the body.

The chances of disease and/or infection transmission from allograft transplantation

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are minute, estimated to be less than one in 1.6 million. There has never been a confirmed incident of disease transmission from AlloSource tissue.

In fact, the implant becomes a part of the patient's body. The body actually assimilates it as part of its own and begins to grow new tissue from it naturally. This is in sharp contrast to the traditional implant made from metal, which the body always treats as a foreign object. It just remains a piece of metal, and as the body changes over the years, it remains the same.

### Design



AlloSource's bone grafts closely resemble similar implants made from PEEK or titanium in size and shape. The full product offering satisfies the needs of any medical device company. The bone implants have optimal cross-sectional areas depending on the vertebral space available, yet they are small enough to make their way through some pretty delicate structures.

The designer builds a 3D model using any one of a number of software platforms and then compares it to what can realistically be placed within the human body. The result is a mix of design inputs, anatomy, marketing research, and technician input.

### Production

Using the Roland desktop milling mills, AlloSource produces spinal implants in great quantity—anywhere from a couple hundred to close to a thousand per week. Lumbar grafts tend to have five or six sizes (heights) in 2.0-mm increments for a given footprint. Cervical grafts can have eight or nine in smaller increments, usually 1.0 mm apart.

The Roland machines enable AlloSource to produce more parts in a smaller work area than traditional, room-sized CNC machine. Additionally, they can easily add machines as production needs increase.

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In general, rapid custom manufacturing gives medical manufacturers an easy solution that reduces labor costs. It also lets them use a wide range of FDA-approved materials available on the open market. One machine does it all, from early prototyping to final production.

### Bonafide Bones



AlloSource requires a comprehensive donor physical assessment, as well as a complete medical and social history to identify and eliminate tissue donors who are at high risk of being carriers of certain viruses and diseases. The organ procurement organization then proceeds with recovery of the organs and/or tissue. All recoveries are performed using sterile surgical techniques, and the bone, skin, and soft tissue are stored pending donor eligibility determination, serological, and microbiological test results.

All donors are tested for:

- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core IgG/IgM Antibody (HBc)
- List Antibody to Human Immunodeficiency Virus 1/2 (HIV 1/2)
- Antibody to Human T-Cell Lymphotropic Virus Type I & II (HTLV I/II)
- Antibody to Hepatitis C (HCV)
- Rapid Plasma Reagin or Serologic Test for Syphilis (RPR or STS)
- HIV-1 HCV NAT using Transcription-Mediated Amplification (HIV-1/HCV NAT via TMA) or HIV DNA using Polymerase Chain Reaction (HIV DNA by PCR)

### Industry Outlook

From prototype to final production, Roland rapid custom manufacturing technology makes it possible to quickly produce parts that are a custom fit for each patient. It enables medical manufacturers to customize their designs on a case by case basis. The technology offers a major improvement over current clinical processes and offers the flexibility to choose from a wide range of FDA-approved materials.

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Roland MDX series milling machines produce highly detailed parts with smooth surface finishes and tight tolerances. They are ideal for producing prototypes, medical implants, and other RCM parts. The desktop machines handle a wide variety of materials including aluminum and plastics. Roland RCM solutions come complete with CAM software, creating a seamless workflow with all major 3D CAD applications.

### Online

For additional information on the technologies and products discussed in this article, see *MDT* online at [www.mdtmag.com](http://www.mdtmag.com) [1] and the following websites:

- [www.allosource.org](http://www.allosource.org) [2]
- [www.rolanddga.com](http://www.rolanddga.com) [3]

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