PROCURE™ BONE MARROW ASPIRATION KIT

Sterile-packed kit for aspirating bone marrow
Indications for use
Intended for the purpose of aspirating bone marrow.

General Precautions
Intended for use only by a licensed physician. The physician should be familiar with the contraindications of performing a bone marrow aspiration. Physician’s judgment is required to consider patient’s risk factors such as anticoagulant therapy or clotting disorders, prior to performing an aspiration.

Caution
For Single Patient Use Only. Do NOT attempt to clean or resterilize this product. After use, this product is considered biohazardous. Handle and dispose of in accordance with applicable laws and regulations pertaining to sharps disposal.

Important
These instructions are NOT intended to define or suggest surgical protocol. The physician determines appropriate protocol and techniques required for bone marrow aspiration.

Please see directions for use for complete information on indications, contraindications, warnings, and precautions.
PROCURE™ Bone Marrow Aspiration Kit is for use in obtaining autologous bone marrow from the iliac crest. The compact, self-contained PROCURE Bone Marrow Aspiration Kit incorporates a “J” style marrow aspiration needle, 20 mL Luer lock syringe, stylet with a 3-sided serrated tip and an optional single-port or multi-port needle for enhanced ease in aspirating bone marrow.

### FEATURES AND BENEFITS

<table>
<thead>
<tr>
<th>Features</th>
<th>Benefits</th>
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<tbody>
<tr>
<td>Compact, Self-Contained System</td>
<td>11 gauge “J” style marrow aspiration needle and 20 mL Luer lock syringe</td>
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<tr>
<td>Multi-Port Aspiration Needle</td>
<td>Side ports on needle shaft facilitate bone marrow aspiration over a larger surface area</td>
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<tr>
<td>3-Sided, Serrated Stylet Tip</td>
<td>Reduces the force required to penetrate dense cortical bone</td>
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<tr>
<td>1 cm Etch Lines</td>
<td>Increases safety by identifying depth of penetration. Thick line at 5 cm and double line at 10 cm</td>
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</table>

11 gauge multi-port needle  
710.111.995  11 cm  
710.151.995  15 cm

11 gauge single-port (distal hole) needle  
710.150.995  15 cm
1

Locate site
Locate site for aspiration of bone marrow, depending on the approach to be used:

- For a **posterior approach**, palpate the patient to locate the superior aspect of the posterior iliac crest.

- For an **anterior approach**, palpate the patient to locate the anterior aspect of the superior iliac crest.

- For a **lateral approach**, place the patient in a right or left lateral decubitus position, depending on which is more convenient to the surgical site, and palpate to locate the superior aspect of the posterior iliac crest.

2

Prepare surgical site
Using a sterile technique, prepare the surgical site and anesthetize the area.

3

Make incision
With a scalpel, make a small stab incision in the skin above the area from which the bone marrow is to be aspirated.

4

Prepare needle
After removing the plastic guard from the aspiration needle, remove and reinsert the stylet one time to ensure that it can be easily separated from the cannula of the needle. To remove the stylet, rotate it 90° counterclockwise and pull it straight out. Replace the stylet in the cannula and lock it back in place by rotating it 90° clockwise so that it aligns with the lower portion of the needle handle.
5 Grasp needle
Hold needle with proximal end in palm and index finger against the shaft near the tip. This position stabilizes the needle and enhances needle control.

6 Introduce needle
Introduce the needle through the prepared incision site with the trajectory determined by the approach used:

- For a **posterior approach** (Figure 1), introduce the needle through the prepared incision site with the initial trajectory of the needle approximately 40° lateral from the sagittal plane and 35°–40° inferior from the transverse plane. A general rule is to aim at the tip of the greater trochanter.

- For an **anterior approach** (Figure 2), introduce the needle through the prepared incision site with the initial trajectory of the needle medially in line with the pelvic wing, as gauged by palpation of the inner and outer tables. The trajectory should be aimed slightly posteriorly at the iliac tubercle, to enter the medullary canal just beneath it.

- For a **lateral approach** (Figure 3), hold the needle horizontally and introduce it through the prepared incision site into the center of the posterior iliac prominence, with the initial trajectory 15° caudal.

- For a **vertebral body approach** (Figure 4), introduce the needle through the holes that have been prepared for the insertion of pedicle screws.
7 **Advance needle**
Using the 1 cm, 5 cm, and 10 cm markings as a guide, advance the needle using gentle but firm pressure. Rotate the needle in alternating clockwise-counterclockwise motion or gently tap the needle handle with a mallet. Decreased resistance may be encountered upon penetration of the cortex and entrance into the marrow cavity.

8 **Remove stylet**
Remove the stylet by rotating the upper section of the handle counterclockwise and slowly pulling straight out.

9 **Screw syringe into hub**
Using sterile technique, screw the distal end of the included syringe into the proximal hub of the bone marrow aspiration needle. Ensure a firm fit, but do not over-tighten.
Aspirate bone marrow
Withdraw the syringe plunger to draw 2–4 mL of bone marrow into the syringe chamber. Only 2–4 mL of marrow should be aspirated per site, to minimize diluting the marrow with peripheral blood.

If marrow does not aspirate easily, reposition the needle slightly. If marrow still does not aspirate, remove the syringe from the needle, remove the needle from the incision, reinsert the stylet, and repeat Steps 5 to 10 with a slight change in needle trajectory.

For additional bone marrow
If more than 2–4 mL of marrow is required, remove the syringe from the needle, reinsert the stylet, and either penetrate deeper within the same site or use the fan technique to pull marrow from a new site using the same incision.

• If pulling additional marrow from deeper within the same site (Figure 1), advance the needle 1 cm along the same trajectory (the markings on the needle are 1 cm apart and may be used as a guide). The needle may also be rotated 90° to expose side holes to bone from which marrow has not yet been drawn.

• If using the fan technique (Figure 2), slightly withdraw the needle and reinsert it as described in Step 7 at a new trajectory along the same plane as the original insertion.

Repeat Steps 8–10 to aspirate bone marrow.
Removal of bone marrow aspiration kit
Disengage the syringe containing the aspirated bone marrow. Remove the aspiration needle and dispose of the needle and stylet in accordance with applicable laws and regulations including those pertaining to sharps disposal.
**PRODUCT INFORMATION**

**PROCURE Bone Marrow Aspiration Kit, sterile**
(needle and syringe included)

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>710.111.99S</td>
<td>11 gauge, 11 cm needle, multi-port (side holes)</td>
</tr>
<tr>
<td>710.151.99S</td>
<td>11 gauge, 15 cm needle, multi-port (side holes)</td>
</tr>
<tr>
<td>710.150.99S</td>
<td>11 gauge, 15 cm needle, single-port (distal hole)</td>
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11 gauge multi-port needle
710.111.99S 11 cm
710.151.99S 15 cm

11 gauge single-port (distal hole) needle
710.150.99S 15 cm
Limited Warranty and Disclaimer: DePuy Synthes Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.