



Kit for the preparation of a resorbable hydrogel coating with a protective barrier effect for orthopedic implants

<p>1</p> <p>The powder contained in the syringe may be too compact, so it is recommended to pull the plunger slightly back maintaining the protective cap screwed and gently tap the syringe to unpack the powder.</p>	<p>2</p> <p>Connect the syringe to the backstop in order to prevent the disassembly of the piston and make the mixing procedure easier.</p>	<p>3</p> <p>Proceed with the preparation of the antibiotic solution (Vancomycin or Gentamicin) at 2%. Example 1- for reconstituting 300mg of DAC® powder with vancomycin 5%, hydrate the antibiotic as follow: add 10 ml of sterile water for injections into the vial containing 500 mg of vancomycin; add 20 ml sterile water for injections into the vial containing 1g. Use the empty syringe contained into the kit and withdraw 5 ml of antibiotic solution.</p>
<p>4</p> <p>Example 2: For reconstitution 300mg of DAC® powder with Gentamicin 3.2%, withdraw 4 ml of antibiotic solution (corresponding of 2 vials containing 80 mg / 2ml antibiotic each) and add 1 ml of sterile water for injections, obtaining 5 ml of antibiotic solution.</p>	<p>5</p> <p>Remove the protective cap from the syringe containing the DAC® powder and screw the Luer-Lock connector.</p>	<p>6</p> <p>Connect the syringe containing 5 ml of antibiotic solution previously obtained to the one containing 300 mg of DAC® powder. Position the assembly vertically with the DAC® syringe down.</p>
<p>7</p> <p>In order to facilitate the mixing of the powder, transfer the solution of water for injections and antibiotic and vigorously pulling the plunger of the DAC® syringe for the first 3 mL., then complete the transfer of the remaining 2 mL.</p>	<p>8</p> <p>Bring the assembled syringes in the horizontal position and continue with the mixing procedure, transferring the contents from one syringe to another until the gel is became homogeneous (verify the absence of lumps of the DAC® powder in the syringe). It is recommended for the first steps to not push the plunger of the DAC® syringe all the way down, to avoid compacting the powder in the extrusion area.</p>	<p>9</p> <p>Once the mixing procedure is finished, transfer the entire contents into the DAC® syringe and disconnect it. It is recommended to let the gel rest for 10 minutes before use.</p>
<p>10</p> <p>Connect the spreader to the DAC® syringe. The product obtained must be used within 4 hours.</p>	<p>11</p> <p>Spread the hydrogel directly on the implant</p>	<p>12</p> <p>Use the spreader to evenly distribute the product on the device to be implanted. Be careful not to leave uncovered any area of the implant surface.</p>

