

BCG VACCINE (for Percutaneous Use)

Instructions for Use

Please read this leaflet carefully before administering BCG VACCINE. The vaccine is to be administered after fully explaining the risks and benefits to the vaccinee, parent, or guardian. BCG vaccination should not be given to individuals previously infected with *M. tuberculosis*. The sterile, single-use multiple puncture device is for use with the BCG VACCINE only.

1. The vaccine should only be administered percutaneously utilizing the supplied sterile, single-use multiple puncture device. Do not inject intravenously, subcutaneously, intramuscularly, or intradermally. The multiple puncture device consists of a plastic holder for a thin, wafer-like stainless steel plate from which 36 points protrude (Figure 1).

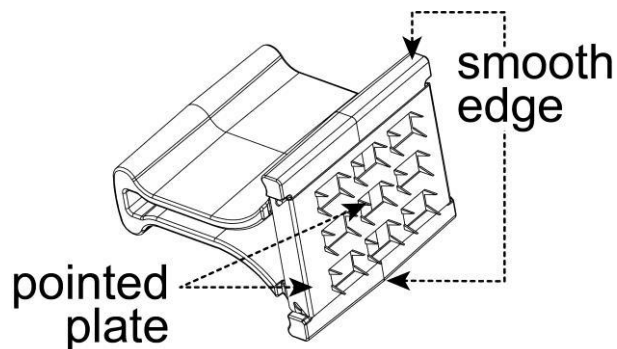


Figure 1

2. After the vaccine is prepared, clean the skin site with an alcohol or acetone sponge and allow to dry thoroughly.
3. Administer the vaccine in the deltoid region (Figure 2). Position the arm to maintain a horizontal surface where the vaccine is to be placed.

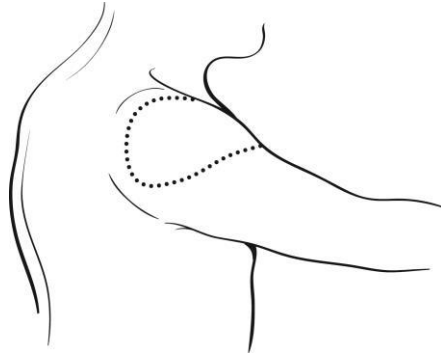


Figure 2

4. Drop the immunizing dose of 0.2–0.3 mL of BCG VACCINE from the syringe and needle onto the cleansed surface of the skin (Figure 3) and spread over a 1" by 2" area using the smooth edge of the multiple puncture device (Figure 4).

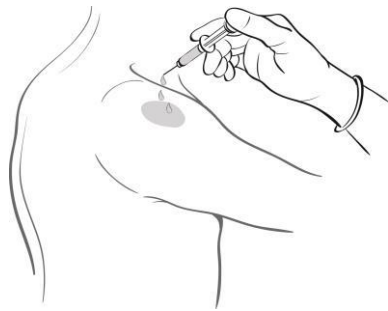


Figure 3

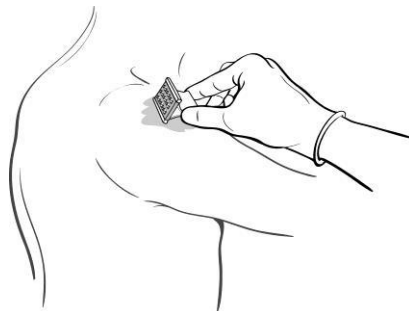


Figure 4

5. Grasp the arm firmly from underneath, tensing the skin. Center the multiple puncture device over the vaccine and apply firm downward pressure such that the device points are well buried in the skin (Figure 5).

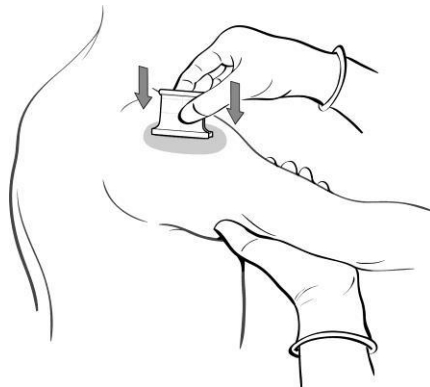


Figure 5

6. Maintain pressure for 5 seconds. Do not “rock” the device. Release the pressure underneath the arm and remove the device. In a successful procedure the points puncture the skin. If the points do not puncture the skin, the puncture procedure must be repeated.
7. After successful puncture, spread vaccine as evenly as possible over the puncture area with the smooth edge of the device (Figure 4). An additional 1–2 drops of BCG VACCINE may be added to ensure a very wet vaccination site.
8. Use the multiple puncture device once and discard in a standard biohazardous sharps container.
9. Loosely cover the site and keep dry for 24 hours.
10. Advise the patient that the vaccine contains live organisms. Although the vaccine will not survive in a dry state for long, infection of others is possible.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Multiple puncture devices may be obtained separately from the Order Management Center, Merck Sharp & Dohme LLC, 351 North Sumneytown Pike, North Wales, PA 19454-2505, Telephone number: 800-637-2579.

Manufactured for:
Merck Teknika LLC, Durham, NC 27712, USA

For patent information: www.msd.com/research/patent

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