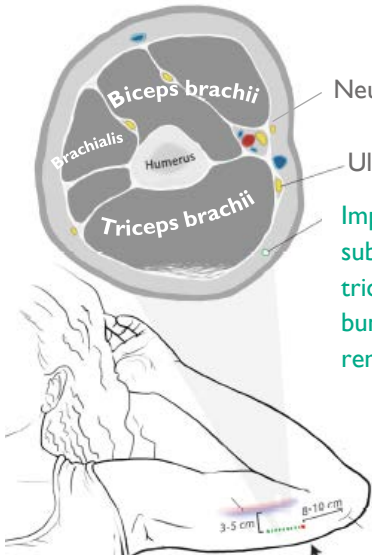


Frequently asked questions regarding the insertion site updates to Implanon NXT

#	Question	Answer
1	<p>What is the new insertion recommendation for the single-rod etonogestrel subdermal implant (Implanon NXT) from Merck/Merck Sharp & Dohme Corp. (MSD)?</p>	<p>The single-rod etonogestrel subdermal implant, or Implanon NXT, was previously inserted at the inner side of the non-dominant upper arm about 8-10 cm (3-4 inches) above the bony protrusion on the inside of the elbow (i.e. proximal to the medial epicondyle of the humerus) and avoiding the groove between the biceps and triceps muscles (i.e. the medial bicipital sulcus, where the neurovascular bundle is located).</p> <p>The new guidance recommends the insertion to be over the triceps muscle about 8-10 cm (3-4 inches) above the bony protrusion on the inside of the elbow (i.e. proximal to the medial epicondyle of the humerus) and 3-5 cm (1.25-2 inches) toward the back of the arm from the groove between the biceps and triceps muscles (i.e. posterior to the medial bicipital sulcus).</p>  <p>Implanon NXT should be inserted subdermally (just under the skin) over the triceps muscle, avoiding the neurovascular bundle, for proper placement and easy removal.</p>
2	<p>What is the advantage of inserting Implanon NXT over the triceps?</p>	<p>Results from a 2018 anatomic assessment of the inner upper arm to identify potential sites for insertion of Implanon NXT indicated that major arteries, veins, and nerves (such as the neurovascular bundle) are not commonly located in the area over the triceps muscle, 8-10 cm (3-4 in) above the bony protrusion on the inside of the elbow (i.e. proximal to the medial epicondyle) and 3-5 cm (1.25-2 in) toward the back of the arm from the groove between the biceps and triceps muscles (i.e. posterior to the medial bicipital sulcus). Furthermore, bending the elbow (i.e. elbow flexion) moves away the ulnar nerve, minimizing risk of injury in the rare instances of accidental deep insertion.</p> <p>The study concluded that Implanon NXT insertion at this location minimizes risk of injury to nerves, blood vessels, muscles, and other body tissues associated with improper deep insertion.</p> <p>Iwanaga J, Fox MC, Rekers H, Schwartz L, Tubbs RS. Neurovascular anatomy of the adult female medial arm in relationship to potential sites for insertion of the etonogestrel contraceptive implant. <i>Contraception</i>. 2019 Jul;100(1):26-30. doi: 10.1016/j.contraception.2019.02.007. Epub 2019 Mar 8</p>

#	Question	Answer
3	<p>Would the recommendations affect where the 2 rod subdermal implants such as Jadelle or Sino-Implant (II)/Levoplant are inserted?</p>	<p>The recommendations for the new insertion site apply only to Implanon NXT.</p> <p>The insertion approach and how the 2-rod implants are positioned under the skin (i.e. subdermally) are considered by the experts' group to be safe, effective and appropriate. The angular, "V"-shaped position of the implants and existing guidance to avoid the arteries, veins, and nerves in the groove between the biceps and triceps muscles (i.e. the neurovascular bundle in the medial bicipital sulcus) protects against accidental injuries commonly associated with improper deep insertion. Thus, the manufactures of Jadelle and Sino-Implant (II)/Levoplant have not updated their insertion guidance in a similar manner.</p> <p>Bayer. (2016). Jadelle (levonorgestrel implant): Highlights of prescribing information. Shanghai Dahua Pharmaceutical Co. Ltd. (2017). Sino-Implant (II) (levonorgestrel implant): Summary of product characteristics.</p>
4	<p>For those who will need to replace their Implanon NXT implant and wants to continue using it, what is the recommendation?</p>	<p>The new guidance recommends that the new Implanon NXT implant should be inserted in the same arm and using the same incision from which the previous implant was removed, <i>as long as the site is in the new location</i>, toward the back of the arm, over the triceps muscle.</p> <p>In cases where the previous insertion was in the old insertion site over the groove between the biceps and triceps muscles (i.e. the medial bicipital sulcus), the provider will need to shift to the new insertion site.</p> <p>It is critical to inform the client know of the new insertion site.</p>
5	<p>What do regulatory bodies say about the new guidance for inserting the Implanon NXT?</p>	<p>Merck/MSD has secured the approval of the European Union regulatory bodies, the US Food and Drug Administration, and national regulatory agencies regarding the label update to the insertion site for Implanon NXT.</p>
6	<p>Do we need to educate trainers on the new insertion site?</p>	<p>Trained, experienced Implanon NXT trainers and mentors will need to receive information and appropriate instructions detailing the change in practice. A package of materials including job aids will be useful for supporting providers. Local stakeholders may find value in convening a workshop to plan for dissemination and mentoring.</p>
7	<p>What kind of educational updates will be needed for current providers to adopt the new insertion site and technique?</p>	<p>The insertion technique for Implanon NXT remains unchanged except for the additional steps of:</p> <ol style="list-style-type: none"> 1. Positioning the arm in which the implant will be inserted (preferably the non-dominant hand) so that the hand is under client's the head, causing the elbow to bend (i.e. flex) enough to move the ulnar nerve away from the insertion site; and 2. Inserting at 8-10 cm (3-4 in) above the bony protrusion on the inside of the elbow (i.e. proximal to the medial epicondyle) and 3-5 cm (1.25-2 in) toward the back of the arm from the groove between the biceps and triceps muscles (i.e. posterior to the medial bicipital sulcus), above the triceps. <p>No other updates have been made to the insertion technique for Implanon NXT.</p> <p>Trained and competent Implanon NXT providers will need to receive instructions detailing the change in practice. An updated job aid on insertion can supplement the instructions. The need for a short educational update on the new insertion site and technique should be assessed by local stakeholders and addressed accordingly.</p>

#	Question	Answer
8	Should providers stop inserting Implanon NXT until they have received information and/or orientation?	The safety of the clients is paramount. It is also important not to disrupt the provision of contraceptive services, particularly for clients opting to use Implanon NXT. Competent providers who are confident of their proficiency with inserting Implanon NXT may continue to their practice. However, it is imperative that the new information and appropriate instructions are disseminated widely and in a timely fashion to start implementing the new recommendations.
9	How does this new guidance impact future trainings for new Implanon NXT providers?	Going forward, all healthcare providers being trained in Implanon NXT services should be trained in the new insertion site and technique. However, they should also be made aware of the prior guidance so that they can appropriately serve clients who received their implant prior to this update and come in for follow-up care.
10	What do we tell providers when following up with women who are using Implanon NXT in terms of where to look for the implants?	<p>There will be a period of transition where women with implants inserted into either the old or the new site follow up with providers. During this time, it is critical that providers ask women where their Implanon NXT implant was inserted and where they can currently feel it. Providers should verify the position and, if they are unable to feel the implant, check the other insertion site and, if necessary, the other arm before managing the case as a missing or deeply-inserted implant.</p> <p>This information must be disseminated to anyone involved in follow-up care to minimize the possibility of incorrectly referring clients for missing implants.</p>
11	What materials do we need to ensure that the information on new site for Implanon NXT insertion is widely disseminated and practiced?	<p>Merck/MSD disseminated information about the updated insertion technique and site to all signatories of the Cooperation Agreement for the Receipt and Use of Implanon. These governments, procurers, and organizations are responsible for ensuring that health care providers who have been previously trained or will be trained in the future are informed of the updated insertion site and technique.</p> <p>This FAQ and the other materials referenced in this package can be used by the signatories, Ministries of Health, Family Planning Technical Working Groups, professional associations, training institutions, and other stakeholders to update trainings and communicate further details about these updates to providers already providing Implanon NXT services.</p>

#	Question	Answer
12	What materials are available to support the change in practice?	<p>Merck/MSD’s Implant Training and Education Resources are available in multiple languages here: https://toolkits.knowledgesuccess.org/toolkits/implants/msd-implant-training-and-education-resources. These resources include:</p> <ul style="list-style-type: none"> • A slide deck explaining the new insertion site and updated insertion technique for educating previously-trained health care providers • A video demonstrating the new insertion site and technique from Merck for educating previously-trained health care providers • Clinical training slide sets, insertion videos, and removal videos for training previously-untrained health care providers <p>Partner-developed resources are available in multiple languages at this site: https://toolkits.knowledgesuccess.org/toolkits/implants/training</p> <ul style="list-style-type: none"> • This frequently asked questions document • A checklist for updating relevant family planning documents and resources • An illustrated job aid updated to reflect the new insertion site and technique • Illustrated job aids updated to reflect standard and difficult removal of implants inserted into the new site
13	What if you have additional questions not listed in this FAQ document?	<p>If you have additional questions regarding the updated insertion guidance, please contact your local FP2020 Focal Points. If you have any questions about operationalizing this update in your country, please reach out to Implants.Quality@jhpiego.org. Additional tools, training materials, and other resources, as well as translations of the enclosed documents, will also be made available going forward.</p>

This document was prepared by the Implants Access Program (IAP) Operations Group. The IAP Operations Group is comprised of representatives from the Bill & Melinda Gates Foundation, the United Nations Population Fund, the United States Agency for International Development, the World Health Organization, and Jhpiego. For any questions on the guidance or resources shared, please write to implants.quality@jhpiego.org.