

Field Safety Notice

Product name: PrePex Catalogue Numbers DW0201, DW0202, DW0203, DW0204 and DW0205, manufactured by Circ MedTech (CMT)

FSN-identifier: 001_2016

Type of action: Updated indication for use and labeling.

Date: March 10th, 2016

Attention: Users of the adult male circumcision device PrePex, manufactured by CMT.

Details on affected product:

Following clinical studies that have demonstrated the PrePex safety and efficacy in male adolescents ages 13-17, CMT is updating the indication for use of the PrePex to include men of aged 13 and above. Accordingly the PrePex Information for Users (IFU) is being revised to revision 16. This FSN details the updates to the IFU from Rev 15 to Rev 16.

Updates to the IFU include:

1. The PrePex is intended to be used in men aged 13 and above
2. Added: "Intended Users: Physicians and nurses that have been trained and authorized to perform the PrePex procedure."
3. Added: Use of the PrePex device on men who have penis size smaller than size A is contraindicated until further notice
4. Added: "adhesions" to the contraindications list
5. Added: Warnings: Providers must be trained to recognize the following:
 - a. when a patient is not eligible for the PrePex due to inability to retract the foreskin;
 - b. discomfort while attempting to retract the foreskin;
 - c. when there are adhesions or phimosis.
 - d. Failure to recognize non-eligibility is likely to lead to adverse events such as increased infection risk due to failure of adequately prepare the skin prior to device placement or incomplete skin removal due to failure to apply the device in the correct anatomical position. "
6. Added: "Because after measurement using the PSP some patients will be excluded due to small penis size, there may be an excess of unused devices. Hence it is recommended that extra PSP are purchased to ensure non-wastage of devices. "
7. Added: "For adolescent consent follow local law and regulations."

8. Added: "Note: Special care should be taken while counseling adolescents under local laws and regulation"
9. Added: reference to a study of PrePex in adolescent population
10. Corrected a mistake in IFU Rev 15 regarding the number of dressings to supply the patient to take home, the correct number of dressings is 1 to be placed on the penis at the clinic and 4 to take home

Advice on actions to be taken by the user:

- All PrePex providers must read the updated IFU (Rev 16) and implement the changes to the PrePex procedure.
- Implementing partners that are utilizing PrePex in their VMMC program, must distribute the updated IFU (Rev 16) to all their known PrePex providers, together with this FSN.
- If any of the instructions in the updated IFU (rev 16) are not clear, PrePex providers should contact CMT directly for clarifications (e-mail: alon@PrePex.com).
- Trainers of PrePex must implement the updates in the IFU (rev 16) in to the PrePex training.
- Post-market surveillance and safety monitoring should include reporting of all adverse events (AEs) to the national program and to CMT.

Additional Actions to be taken by the manufacturer:

- CMT will contact customers that have purchased PrePex devices to coordinate further actions regarding the updated IFU.
- CMT will issue a refresher training session which will be delivered to PrePex training centers to perform refreshment training to PrePex providers.
- CMT will work with training centers to assure proper implementation of the updated IFU (rev 16) in the PrePex training courses and materials.

Transmission of this Information Notice for Users:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where PrePex is being used.

Contact person for further information:

Alon Kushnir, e-mail: alon@PrePex.com



