Field Safety Notice

Product name: PrePex, manufactured by Circ MedTech

FSN-identifier: 001_2014

Type of action: advice given by manufacturer regarding use of the device and follow-up with patients.

Date: 30/11/2014

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

Details on affected product:

Three cases of tetanus occurring after PrePex circumcision have been reported in two countries. It is the first time that cases of tetanus have been reported as an adverse event during or after a PrePex procedure. Over 60,000 PrePex procedures were conducted to date in Sub-Sahara Africa.

Description of the problem:

In November 2014, Circ MedTech received notification of three serious adverse events that occurred after circumcision with the PrePex adult and adolescent male circumcision device. According to the said notifications, the adverse events were clinically diagnosed as *Clostridium tetani* infection leading to tetanus. Two of the three reported cases occurred in one country in South East Africa, where usage of PrePex has been expanded recently, resulting in the two deaths. These events may indicate an increase in risk of a serious health deterioration or death due to tetanus of an individual occurring after a PrePex procedure. Vaccination status of the patients for the 3 cases could not be confirmed.

Circ MedTech is undertaking a technical and clinical investigation to ascertain the root cause of these 3 cases. Circ MedTech will be analyzing the potential risks related to the product and will determine the appropriate corrective actions and preventive actions, if required. At this stage, it is not possible to ascertain with certainty whether the use of PrePex may, or may not, increase the risk of tetanus infection.

The following **interim preventive action** is recommended on an interim basis to mitigate the risk until further notice.

The risk of infection with *Clostridium tetani* can be mitigated by protective immunity via immunization with tetanus vaccine. Programmes are urged to consider tetanus vaccination (and demonstration of protective immunity) for any adult or adolescent males presenting for male circumcision. If vaccination history cannot be confirmed, there might be a risk of contracting tetanus.

Advise on actions to be taken by the user:

- Individuals who recently had the PrePex placed should be contacted for follow-up, including systematic collection of data on any signs and symptoms of tetanus infection.
- Protective immunity against tetanus toxoid should be confirmed in any individual presenting for placement of PrePex device until completion of the ongoing investigation and further notice;

The above recommended action(s) are to be taken by all recipients of this notice until the investigation is completed and further advice notification will be issued.

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 the PrePex is being used.

Contact person for further information:

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