

Alert for Prehma 27 Gauge Long Single-Use Dental Needle (4/11)

Several isolated mishaps have occurred using the 27 gauge long needles from PREHMA, Deepak Products, Inc. The most common complaint has been that the effective needle sheath comes off before the butt-end sheath when the needle container is twisted or pulled while preparing to place the needle onto the syringe. There have also been at least two reports of the needle separating from the hub.

These needles can be identified by their grey effective needle sheath cover. Affected lot numbers are #091104, #101102, and #100726. Preliminary inspection by the Dental Evaluation and Consultation Service (DECS) demonstrated that some PREHMA needles separated

where the white polymer attached to the yellow hub polymer materials. Laboratory tests demonstrated that the PREHMA needles passed the minimum ISO 7885 standard for the union between the hub and needle. There currently is no standard for assessing the union of the effective needle sheath and the butt end sheath. Premature separation of the effective needle end sheath (instead of the butt end sheath) was observed in the DECS laboratory. DECS will provide an update when all testing has been completed.



Deepak Products, Inc., the manufacturer, is not aware of problems from any other customers. Several other federal dental service clinics using PREHMA needles have not experienced the problem described above. Deepak will conduct internal testing before any decision is made to formally recall the product. Clinics that have the PREHMA needles are entitled to a refund from the dental supply distributor, not Deepak. At the clinic in question, the PREHMA needles were substituted by default when the prime vendor put the regularly ordered needles on backorder; PREHMA is considered to be an acceptable substitute pending further testing.

For additional technical information please contact DECS at (210) 539-2982, DSN 389-2982, or BHT_DECScommander@amedd.army.mil. Please contact AFMOA at (210) 395-9895 or DSN 969-9895 for all other inquiries.