



# Developmental complications can occur in neonatal patients exposed to high levels of DEHP.

- What is it?** DEHP is a plasticizer used to soften naturally stiff PVC.
- Where is it?** DEHP typically accounts for 20–40% of the material in a PVC medical device, but can be as high as 80% for PVC devices used in applications where flexibility is required.
- Why is it a problem?** DEHP is not chemically bound to the PVC polymer and can leach out of the device, potentially causing adverse effects on the developing male reproductive system.

## FDA Public Health Notification:

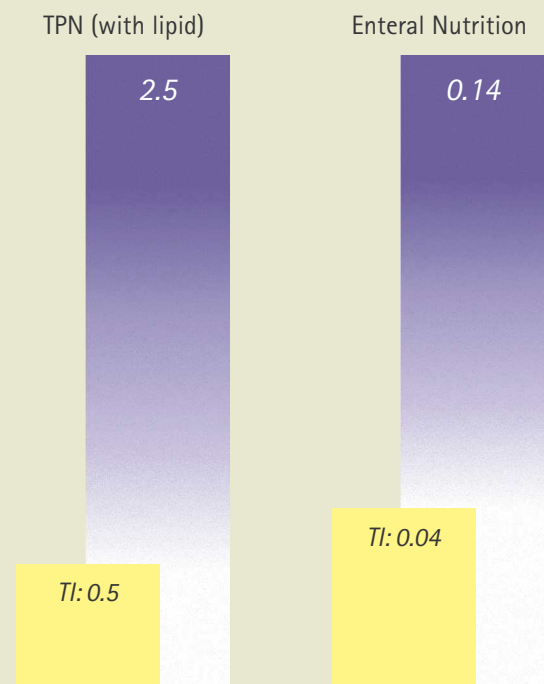
"...precautions should be taken to **limit the exposure** of the developing male to DEHP."

"...you should not avoid the procedures... **devices that do not contain DEHP** can be substituted."

"We recommend considering such alternatives when these **high-risk procedures** are to be performed on male neonates."

Source: *FDA Public Health Notification: PVC Devices Containing the Plasticizer DEHP*, Dept of Health and Human Services, Rockville MD, July 12, 2002. Notification is available at [www.fda.gov/cdrh/safety/dehp.pdf](http://www.fda.gov/cdrh/safety/dehp.pdf)

## DEHP Exposure versus Tolerable Intake (TI) in the NICU



Figures in mg/kg/day

# Using DEHP-free, non-PVC alternatives such as Silicone and Tecoflex® polyurethane offers many advantages.



Nutri-Cath®

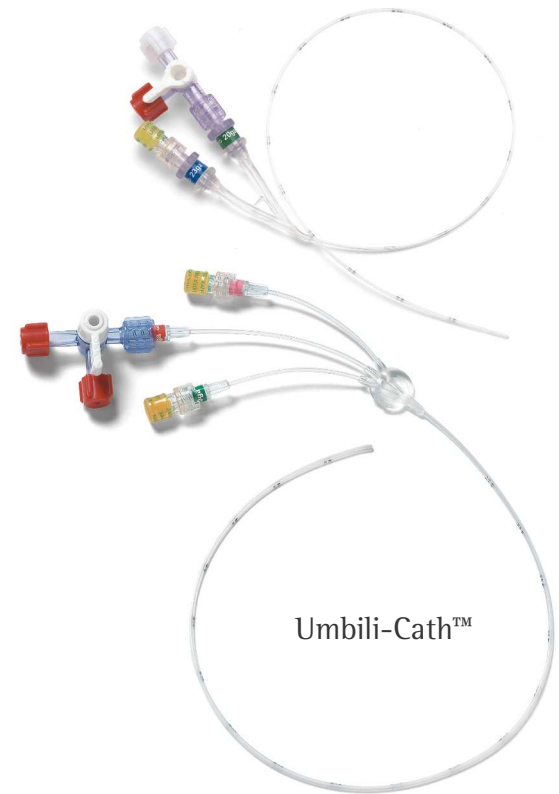
Silicone and Tecoflex polyurethane are naturally soft and flexible without plasticizers, eliminating the hardening that is characteristic of PVC catheters.

## Enteral Usage

- Silicone allows for longer indwell times than PVC, limiting multiple insertions, irritation, possible infection and the development of hyperactive gag reflex.
- Softness of silicone is better tolerated by neonatal patients, potentially contributing to improved sleep cycles.

## Parenteral Usage

- Silicone is highly biocompatible and non-irritating to vascular tissue, while Tecoflex polyurethane is much more tissue-friendly than PVC and other polyurethanes.
- Silicone and Tecoflex polyurethane catheters are non-supportive to bacterial growth and resist encrustation, potentially reducing the incidence of sepsis and maintaining line patency.



Umbili-Cath™