

Look.Check.Connect.

SAFE MEDICAL DEVICE CONNECTIONS SAVE LIVES

www.fda.gov/cdrh/luer



Medical Device Safety Calendar 2009



INTRODUCTION

Hospitals and other healthcare facilities depend on a variety of catheters, tubing and syringes to deliver medications and other substances to patients through vascular, enteral, respiratory, epidural and intrathecal delivery systems. These delivery systems frequently employ fittings called Luer connectors to link various system components. The male and female components of Luer connectors join together to create secure yet detachable leak-proof connections. Multiple connections between medical devices and tubing are common in patient care.

Unfortunately, because Luer connectors are ubiquitous, easy-to-use and compatible between different delivery systems, clinicians can inadvertently connect wrong systems together, causing medication or other fluids to be delivered through the wrong route. Such errors have occurred in diverse clinical settings, causing serious patient injuries and deaths. The Food and Drug Administration (FDA), The Joint Commission (TJC), the Institute for Safe Medication Practices (ISMP), the United States Pharmacopeia (USP), the ECRI Institute and others have all received reports of misconnection errors. The problem is well-known and well-documented. Yet despite efforts on the part of FDA and other organizations to reduce misconnections through education, protocol and monitoring, the use of Luer connectors in incompatible medical delivery systems continues to create situations where dangerous misconnections can, and do, occur.

To further reduce the occurrence of these misconnections, FDA is actively participating in an international effort to develop and implement standards for non-interchangeable connectors for small bore medical connectors. A joint working group established by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) leads this effort to develop a series of standards for incompatible connectors used in intravascular (IV), breathing systems, enteral, urethral/urinary, cuff inflation and neuraxial applications. Once implemented, these connectors will facilitate correct connections and eliminate incompatible tubing misconnections.

Until standards are completed and manufacturers design and produce products that can't be misconnected, all interested parties must continue their efforts to keep these dangerous misconnections from happening. "Actions must be taken at the patient bedside, within all levels of health care organizations and throughout the channels of regulation, manufacturing and distribution of these devices in order to eradicate the serious problem of tubing misconnections," said Peter B. Angood, M.D., Vice President and Chief Patient Safety Officer for The Joint Commission (TJC).

This Medical Device Safety Calendar is one of those efforts. The calendar provides a graphic depiction of misconnection cases that have occurred, coupled with recommendations from TJC on ways to prevent these types of errors.

We hope you'll post the Medical Device Safety Calendar as a year-long reminder to staff that these errors can occur in any clinical setting. We also urge you to use the case synopses and recommendations as ongoing training materials. To that end, we have made the photos, case studies and additional resources available, free of charge, at www.fda.gov/cdrh/luer. We encourage you to visit this web site to download and make further use of these materials.

Let's continue to work together to prevent these tragic errors.

Daniel G. Schultz, M.D.
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration

RESOURCES

Gallauresi, Beverly, R.N., B.S., M.P.H., Eakle, Melissa, R.N., M.B.A., M.S.N., Morrison, Audrey, R.N. Misconnections Between Medical Devices With Luer Connectors: Under-recognized but Potentially Fatal Events in Clinical Practice, *Safe Practices in Patient Care*. July 2007, Vol. 3, No. 2. <http://www.safe-practices.org/SafePractice8.pdf>

The Joint Commission Sentinel Event Alert. Tubing Misconnections—A Persistent and Potentially Deadly Occurrence. April 3, 2006, Issue 36. http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_36.htm

ISMP Medication Safety Alert! Problems Persist With Life-Threatening Tubing Misconnections. June 17, 2004. <http://www.ismp.org/newsletters/acutecare/articles/20040617.asp>

WHO Collaborating Centre for Patient Safety Solutions. Patient Safety Solutions. Avoiding Catheter and Tubing Misconnections. May 2007, Vol. 1, Solution 7. <http://www.ccforspatientsafety.org/fpdf/presskit/PS-Solution7.pdf>

FDA Patient Safety News. More Patient Deaths from Luer Misconnections. October 2007. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=68#5>

Association for the Advancement of Medical Instrumentation (AAMI). ISO/IEC small bore connector new work proposal package including contact information. August 2006. http://www.aami.org/Applications/CommitteeCentral-app/Documents/SBC_PA.pdf

International Organization for Standardization (ISO). ISO/CD 80369-1. Updated 2008. http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=45976

Medical Device Safety Calendar 2009
<http://www.fda.gov/cdrh/luer>

ACKNOWLEDGEMENTS

The 2009 FDA Safe Medical Device Safety Calendar Working Group:
Beverly Gallauresi, R.N., M.P.H.
Anita Rayner, M.P.H.
Alex Koustenis
Barbara Richards
Aron Yustein, M.D.
Jay Crowley, M.S.
Jill Marion
Edie Seligson
Nancy Pressly
Susan Gardner, Ph.D.

Calendar Design:
Bonnie Hamalainen
National Institutes of Health (NIH), Division of Medical Arts

Photography:
Ernie Branson
National Institutes of Health (NIH), Division of Medical Arts

Special Thanks to:
Dorothy Brownlie, RN, CCRN
Montgomery General Hospital, Olney, MD
for providing technical support

KEY

Each month cites a MISCONNECTION error based on an actual reported event:

EVENT

Example of the misconnection error; POTENTIAL FOR HARM is also cited

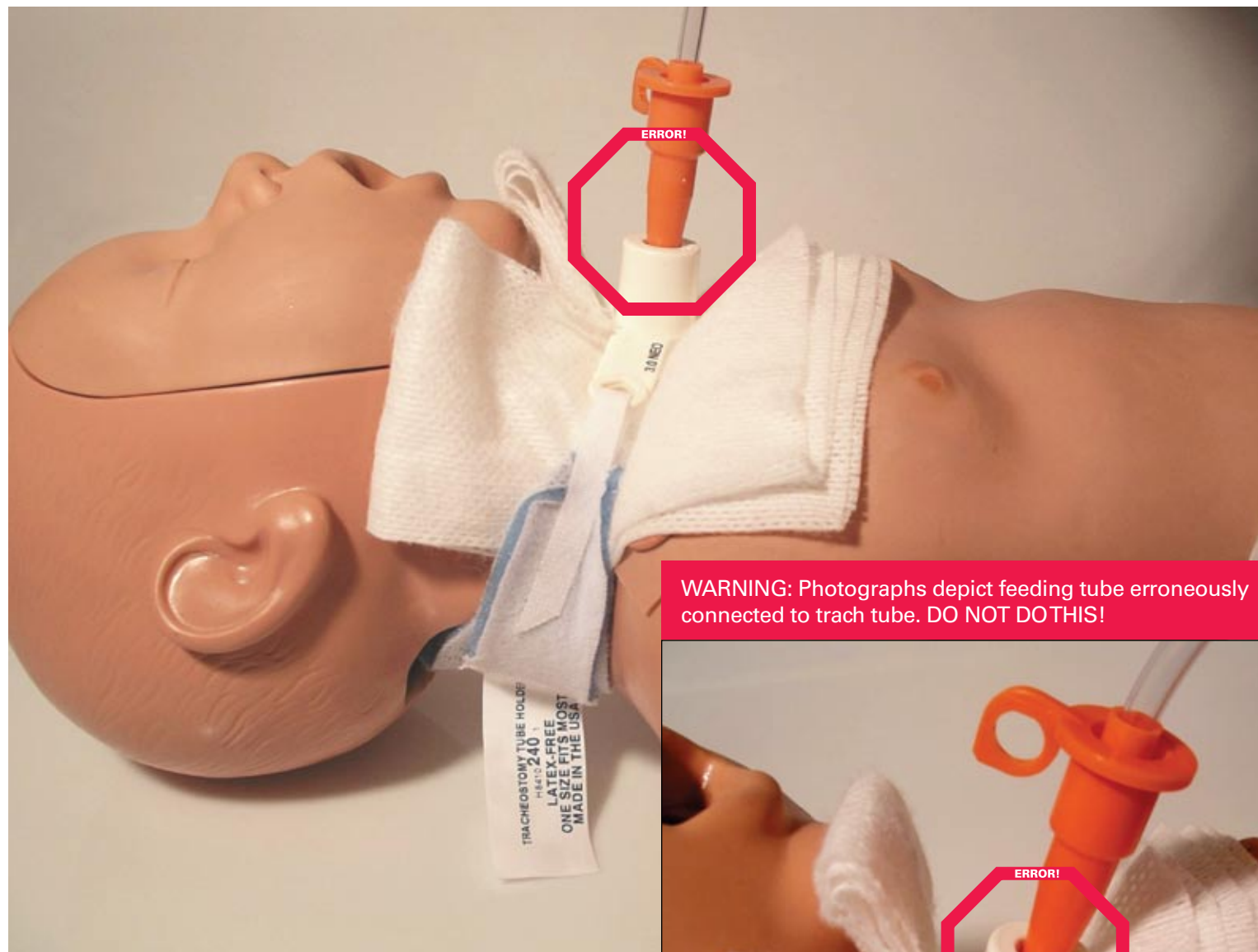
CASE STUDY

Bulleted description of the specifics pertinent to each event

THE JOINT COMMISSION SAFETY TIP

Safety tip from The Joint Commission (TJC) to help prevent event recurrence

Photographs show staged "erroneous misconnections" to illustrate the reported error. Photographs have warning labels – where appropriate – to reiterate the fact that they are erroneous connections.



WARNING: Photographs depict feeding tube erroneously connected to trach tube. DO NOT DO THIS!



EVENT

Feeding tube erroneously connected to trach tube

POTENTIAL FOR HARM

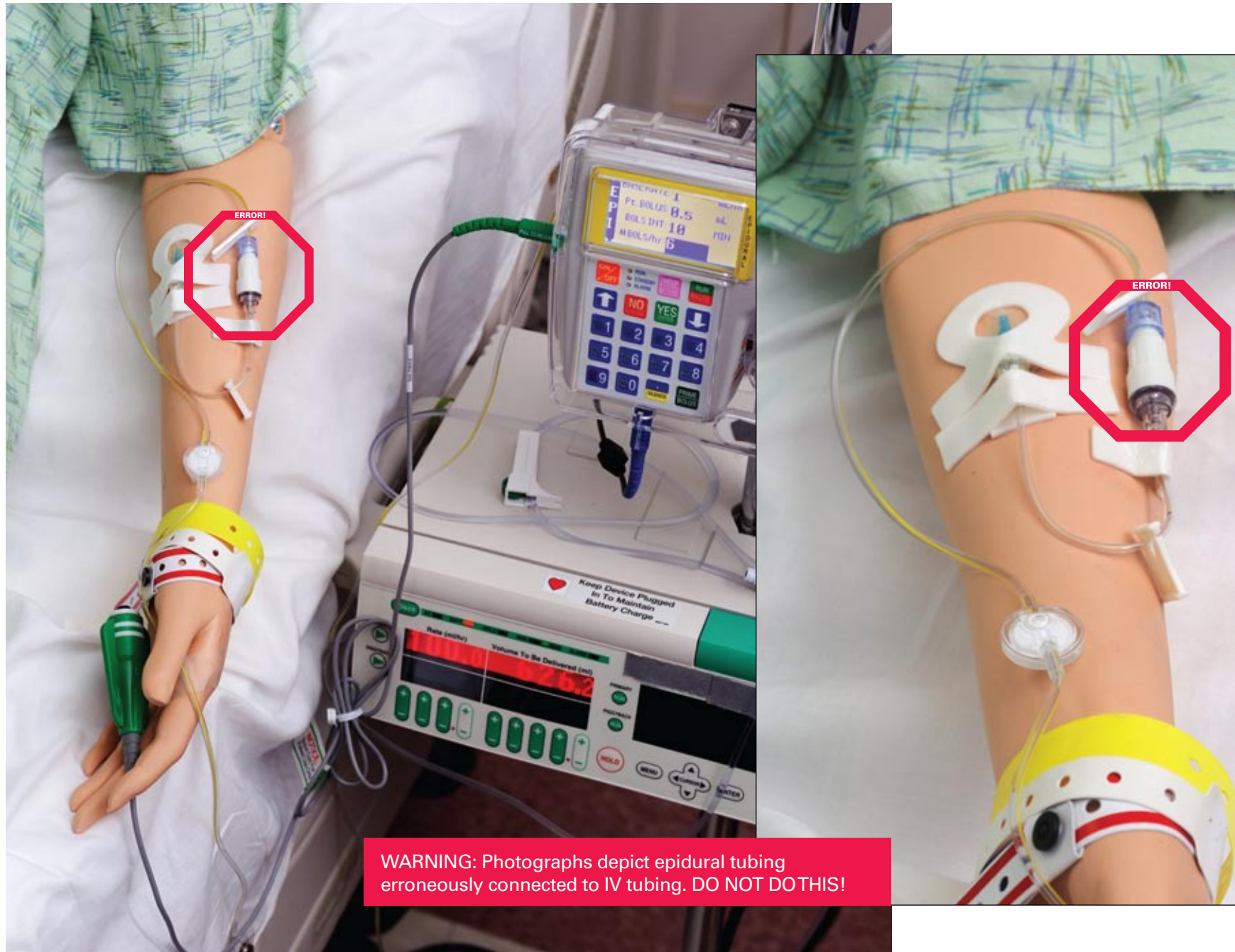
High

CASE STUDY

- An infant in the pediatric intensive care unit had both a feeding tube and a trach tube
- The feeding tube was inadvertently placed in the trach tube and milk was delivered into the infant's lungs
- The infant died

THE JOINT COMMISSION SAFETY TIP

Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion



EVENT

Epidural tubing erroneously connected to IV tubing

POTENTIAL FOR HARM

High

CASE STUDY

- An anesthetist and a midwife mistakenly connected an epidural set to the patient's IV tubing
- The epidural medication was delivered to the IV
- The patient died

THE JOINT COMMISSION SAFETY TIP

For certain high-risk catheters (e.g., epidural, intrathecal, arterial), label the catheter and do not use catheters that have injection ports



WARNING: Photographs depict IV tubing erroneously connected to trach cuff. DO NOT DO THIS!

EVENT

IV tubing erroneously connected to trach cuff

POTENTIAL FOR HARM

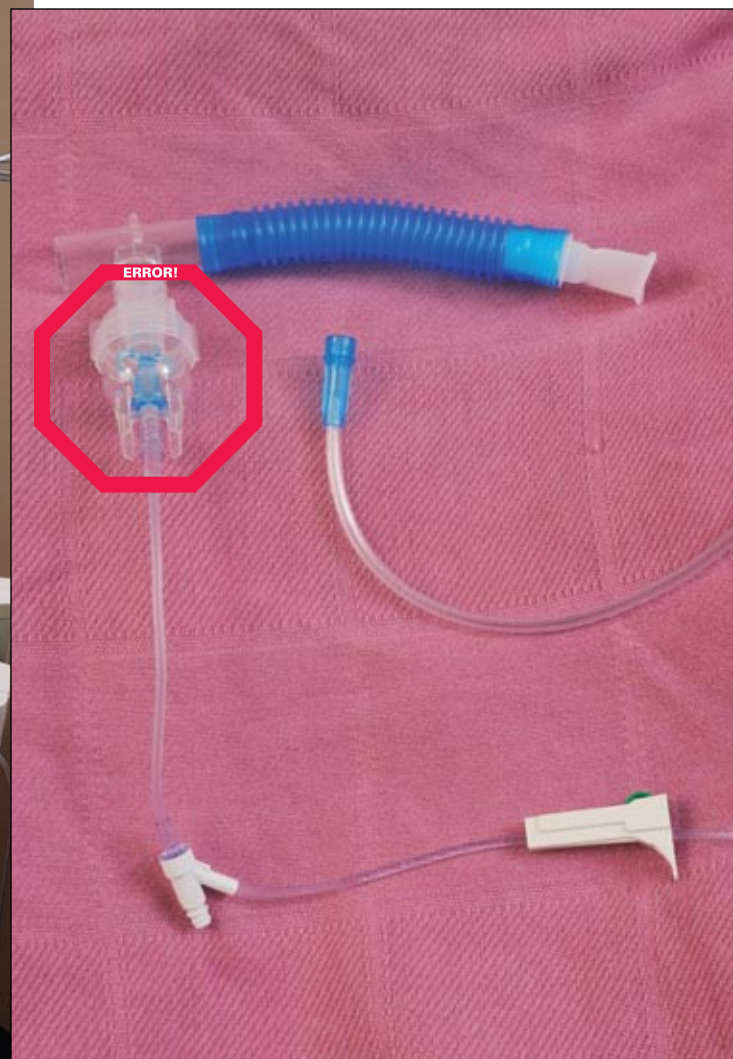
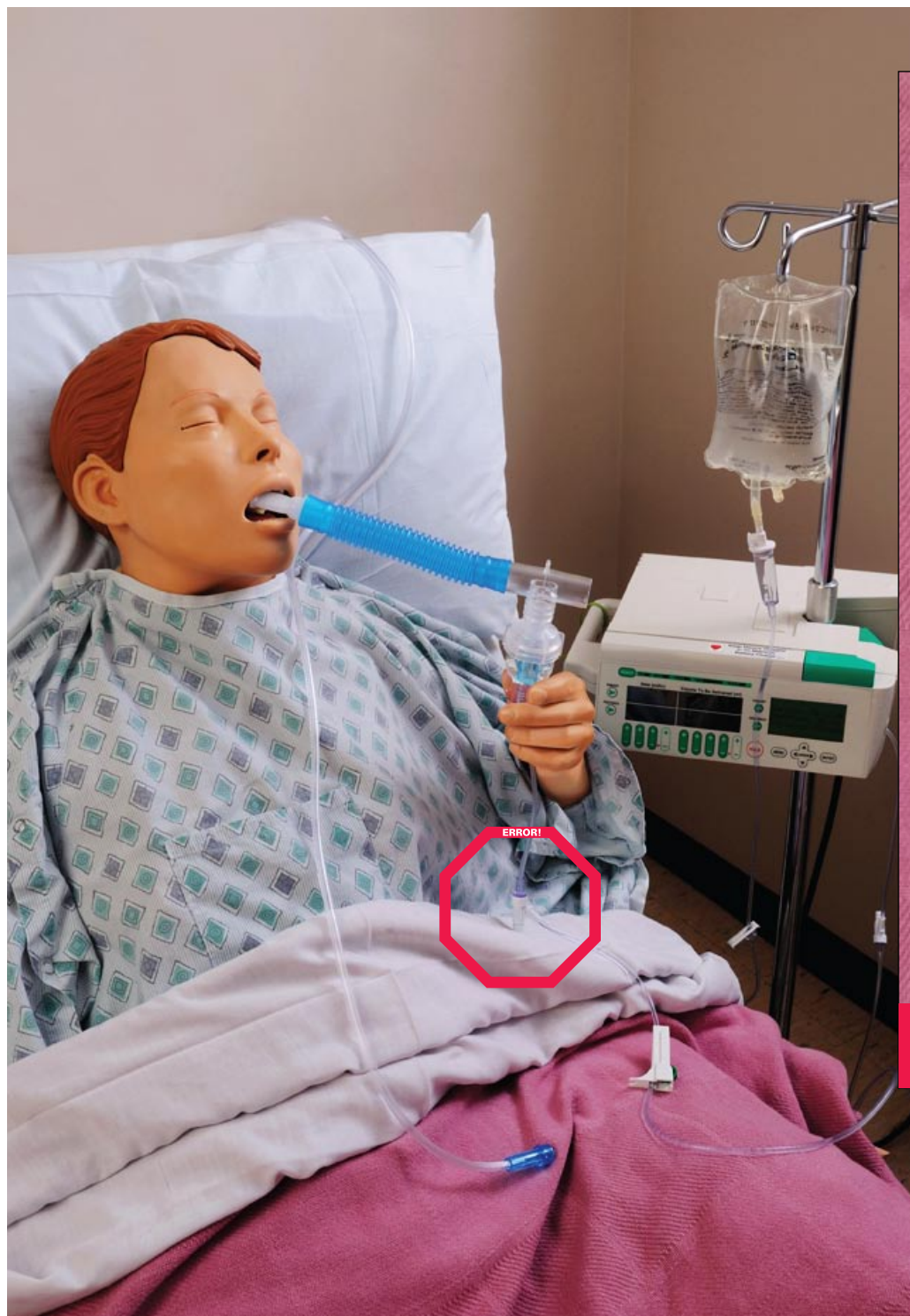
High

CASE STUDY

- A child in a pediatric intensive care unit had both an IV line and a trach tube
- The IV tubing was inadvertently connected to the trach cuff port
- The IV fluid over-expanded the trach cuff to the point of breaking and continuous IV fluids entered the child's lungs
- The child died

THE JOINT COMMISSION SAFETY TIP

Emphasize the risk of tubing misconnections in orientation and training curricula



WARNING: Photographs depict IV tubing erroneously connected to nebulizer. DO NOT DO THIS!

EVENT

IV tubing erroneously connected to nebulizer

POTENTIAL FOR HARM

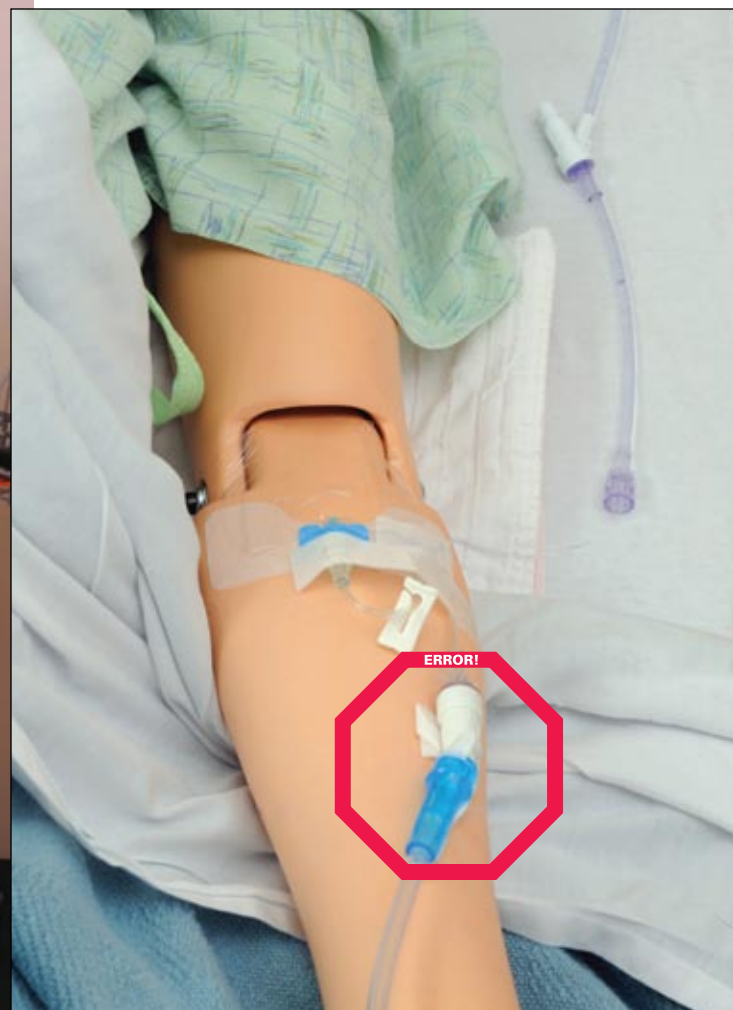
High

CASE STUDY

- During a nebulizer treatment, the patient's oxygen tubing fell off the nebulizer and the patient's IV tubing was inadvertently attached to the nebulizer
- When the patient inhaled, a moderate amount of IV fluids was aspirated into the patient's lungs
- The misconnection was identified by the respiratory therapist and the patient survived

THE JOINT COMMISSION SAFETY TIP

Do not purchase non-intravenous equipment that is equipped with connectors that can physically mate with a female luer IV line connector



WARNING: Photographs depict oxygen tubing erroneously connected to a needleless IV port. DO NOT DO THIS!

EVENT

Oxygen tubing erroneously connected to a needleless IV port

POTENTIAL FOR HARM

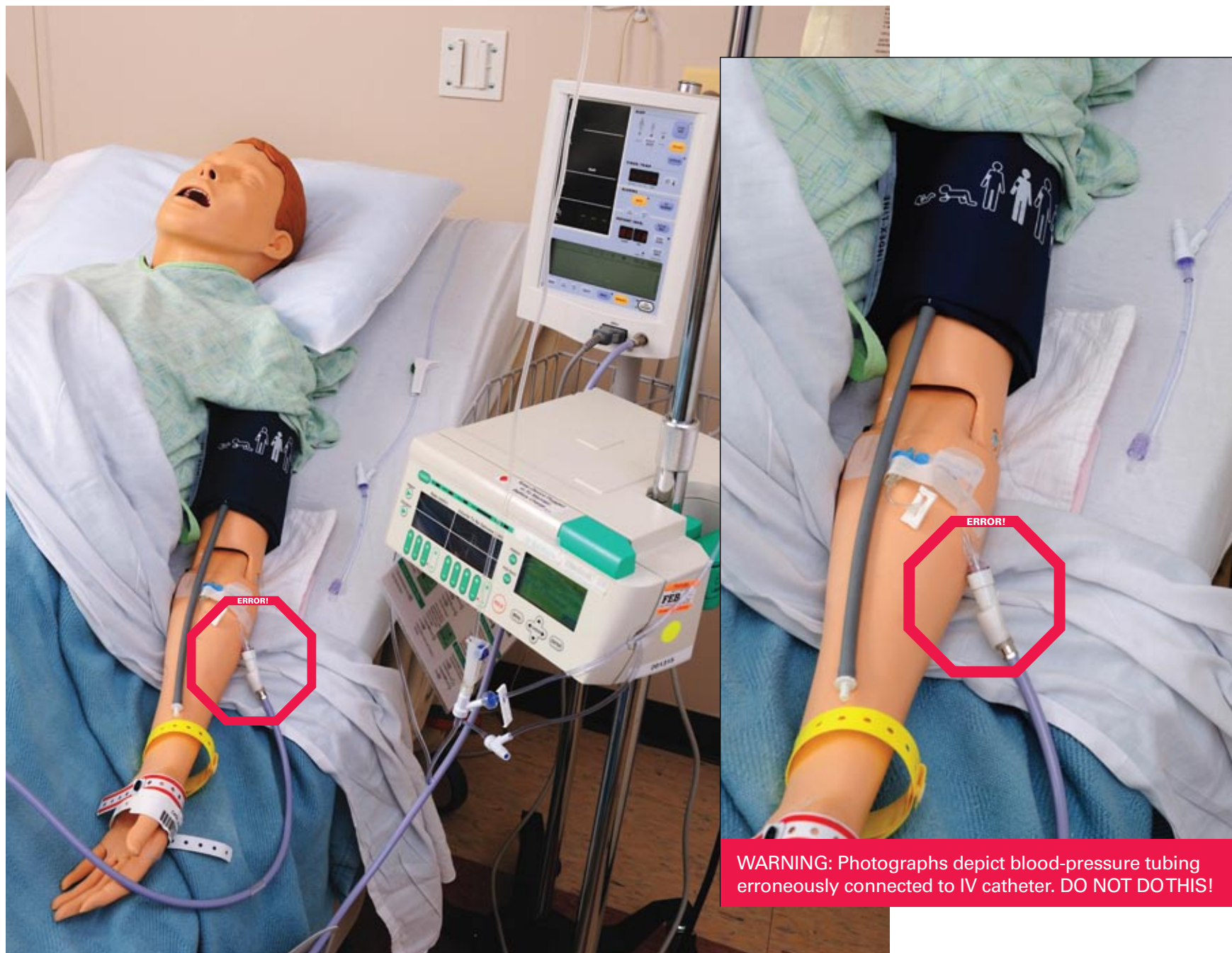
High

CASE STUDY

- A patient's oxygen tubing became disconnected from his nebulizer and was accidentally reattached to his IV tubing Y-site by a staff member who was completing a double shift
- The patient died from an air embolism, even though the connection was broken within seconds

THE JOINT COMMISSION SAFETY TIP

Identify and manage conditions and practices that may contribute to healthcare worker fatigue, and take appropriate action



EVENT

Blood pressure tubing erroneously connected to IV catheter

POTENTIAL FOR HARM

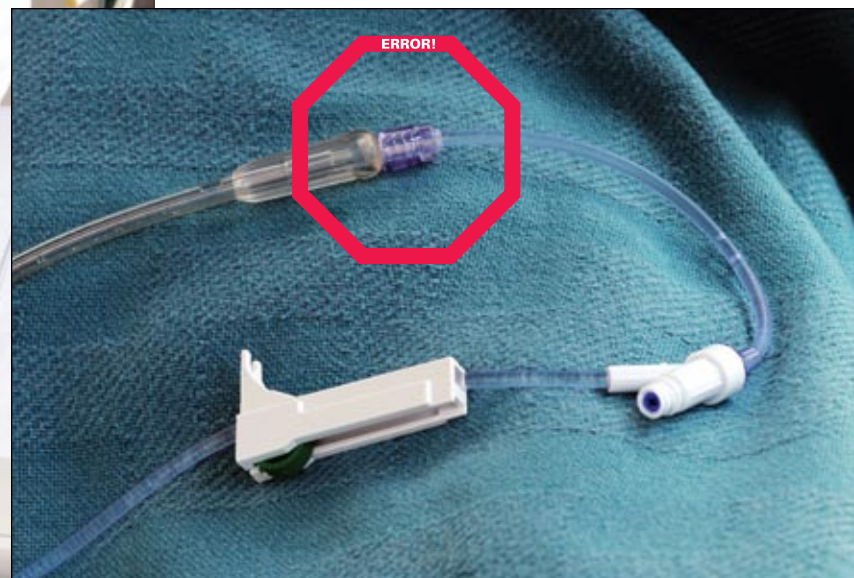
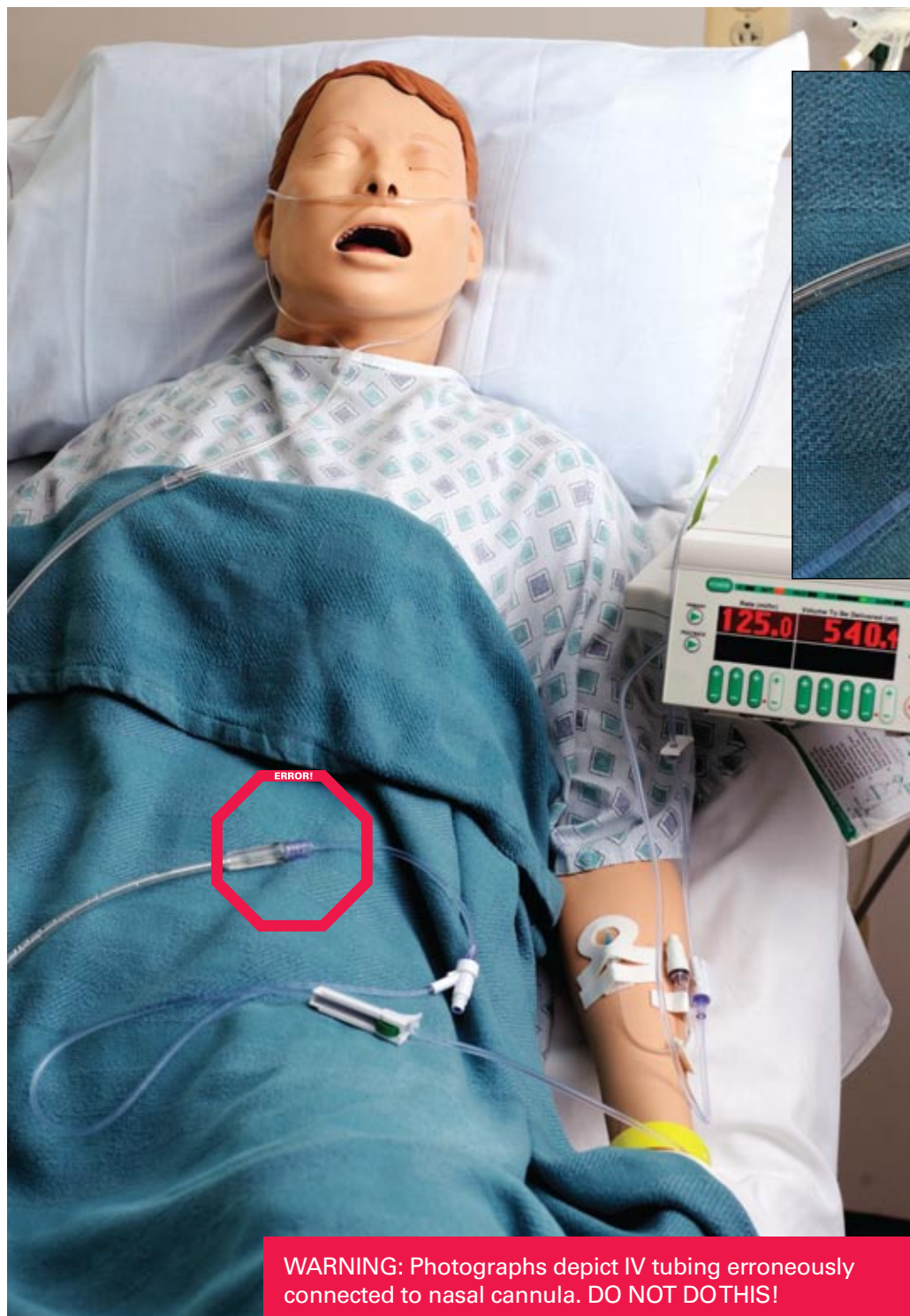
High

CASE STUDY

- An ER patient had an IV heparin lock but no IV fluids had been started. The patient also had a noninvasive automatic BP cuff placed for continuous monitoring
- The BP cuff tubing was disconnected when the patient went to the bathroom
- When she returned, her spouse mistakenly connected the BP cuff tubing to the IV catheter and approximately 15 mL of air was delivered to the IV catheter
- The patient died from a fatal air embolus, despite resuscitation efforts

THE JOINT COMMISSION SAFETY TIP

Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions



EVENT

IV tubing erroneously connected to nasal cannula

POTENTIAL FOR HARM

High

CASE STUDY

- A nurse's aide inadvertently connected a patient's IV tubing to the nasal oxygen cannula upon transfer to the step down unit
- The misconnection was not noted until 4 hours later, when the patient complained of chest tightness and difficulty breathing
- The patient was treated for congestive heart failure and survived

THE JOINT COMMISSION SAFETY TIP

Recheck connections and trace all patient tubes and catheters to their sources upon the patient's arrival in a new setting or service as part of the hand-off process. Standardize this "line reconciliation" process.



WARNING: Photographs depict IV tube erroneously connected to enteral feeding tube. DO NOT DO THIS!



EVENT

IV tubing erroneously connected to enteral feeding tube

POTENTIAL FOR HARM

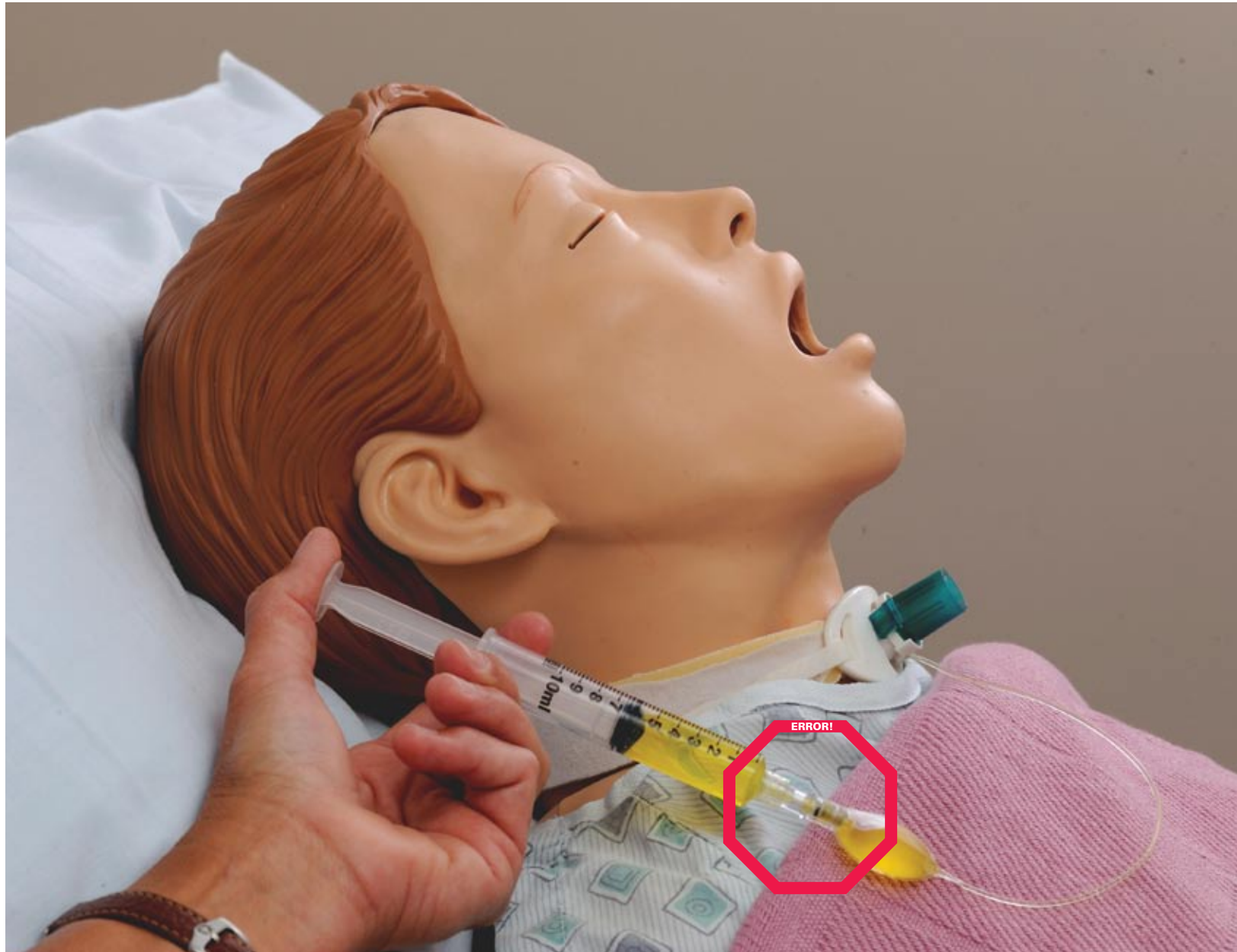
Moderate

CASE STUDY

- A child had both a gastric feeding tube for nutrition and an IV for medication and hydration
- When the child's gown was changed, a family member inadvertently attached the IV tubing to the gastric feeding tube
- The medication was delivered through the feeding tube into the stomach
- There was no patient harm since the event was noted in a timely manner

THE JOINT COMMISSION SAFETY TIP

Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions



WARNING: Photographs depict syringe erroneously connected to trach cuff. DO NOT DO THIS!

EVENT

Syringe erroneously connected to trach cuff

POTENTIAL FOR HARM

High

CASE STUDY

- The patient had both a central line with 3 ports and a trach tube
- Medication intended for the central line was inadvertently injected into the trach cuff
- The trach cuff was damaged and the medication entered the patient's lungs
- A new trach tube was inserted and the patient survived

THE JOINT COMMISSION SAFETY TIP

Always trace a tube or catheter from the patient to the point of origin before connecting any new device or infusion



EVENT

Foley catheter erroneously connected to NG tube

POTENTIAL FOR HARM

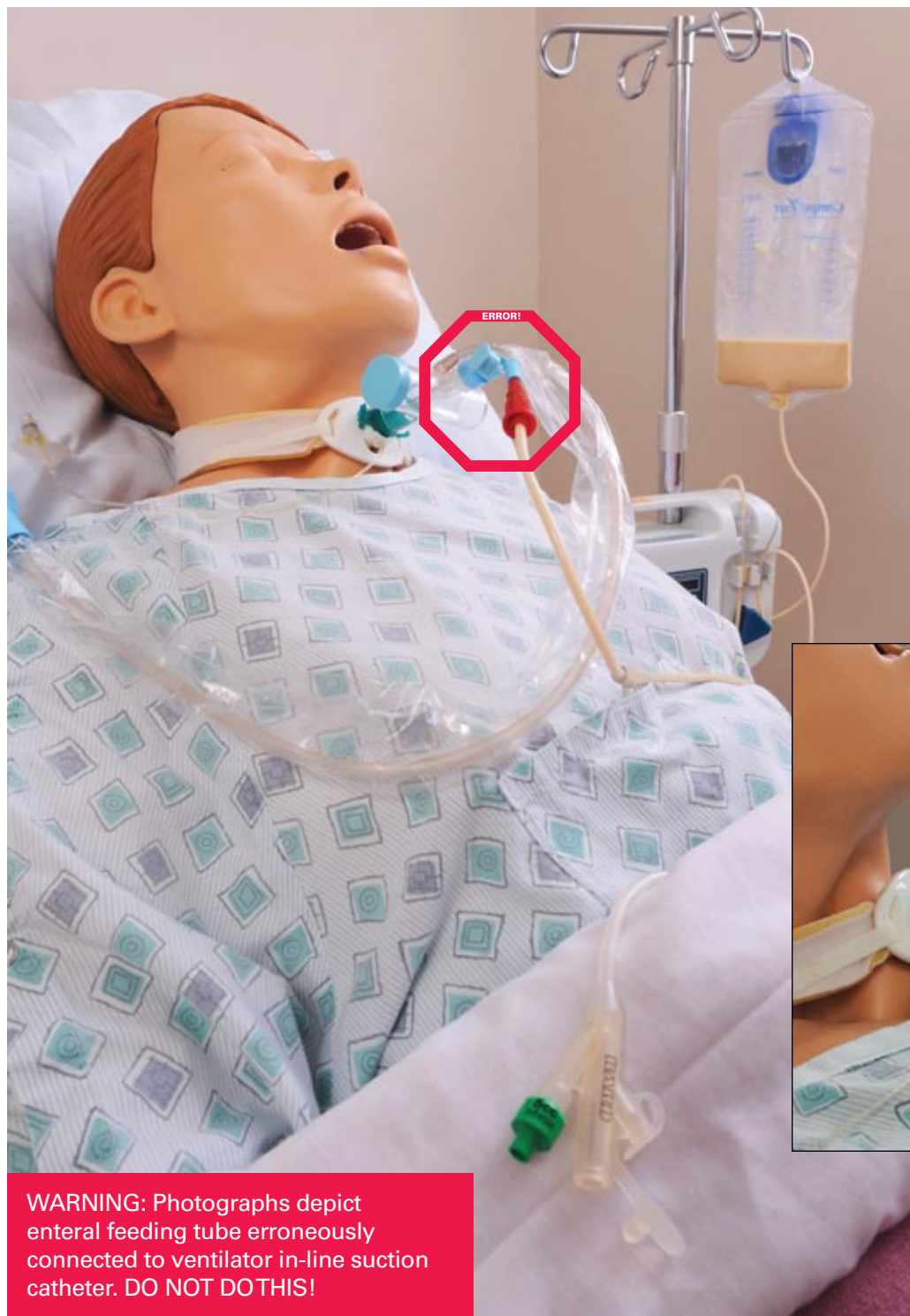
Low

CASE STUDY

- A patient was found with her Foley catheter disconnected from its drainage bag. One end of the catheter was still in her bladder and the other end was connected to her nasogastric (NG) tube
- Urine was noted to be flowing into her NG tube
- The NG tube was connected to suction and more than 300 mL of urine drained
- The patient's vital signs were stable and her laboratory results were within normal limits

THE JOINT COMMISSION SAFETY TIP

Inform non-clinical staff, patients and their families that they must get help from clinical staff whenever there is a real or perceived need to connect or disconnect devices or infusions



WARNING: Photographs depict enteral feeding tube erroneously connected to ventilator in-line suction catheter. DO NOT DO THIS!

EVENT

Enteral feeding tube erroneously connected to ventilator in-line suction catheter

POTENTIAL FOR HARM

High

CASE STUDY

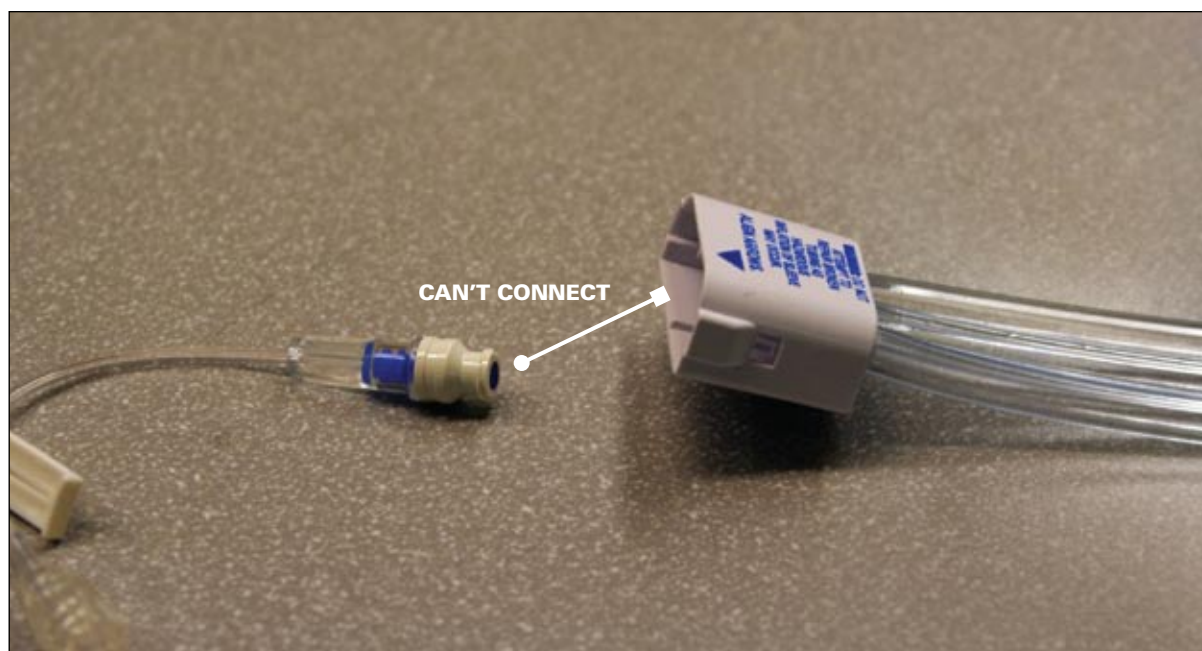
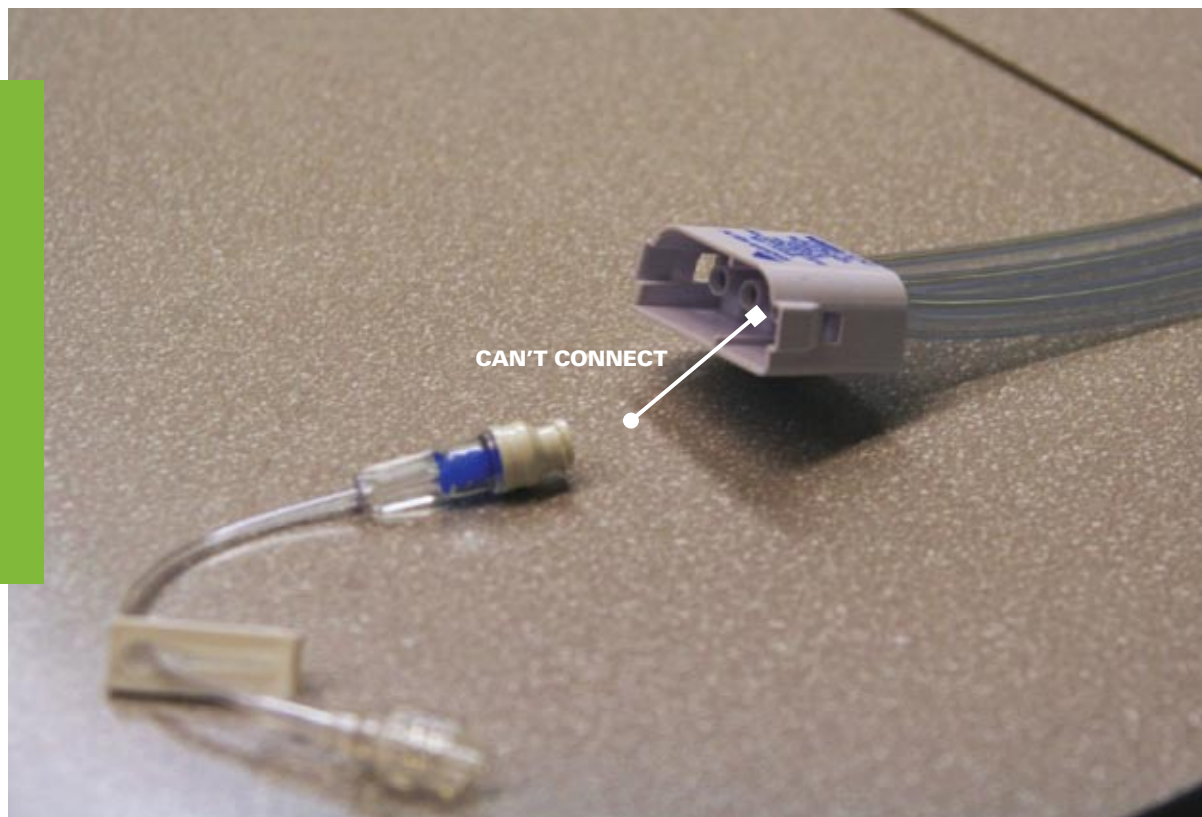
- A patient's feeding tube was inadvertently connected to the instillation port on the ventilator in-line suction catheter
- Tube feeding was delivered into the patient's lungs
- The patient died

THE JOINT COMMISSION SAFETY TIP

Emphasize the risk of tubing misconnections in orientation and training curricula

SUCCESS STORY!

These photos show that PAS pump tubing is now NOT CAPABLE of connecting to IV vascular access devices.



EVENT

Pulsatile anti-embolism stocking erroneously connected to IV heparin lock

POTENTIAL FOR HARM

High

CASE STUDY

- A patient admitted for stroke had a pulsatile anti-embolism stocking (PAS) on the left lower extremity and an IV heparin lock in the right ankle
- The patient was alert and oriented on admission but shortly after was found unresponsive and cyanotic
- The PAS pump tubing was found connected to the IV heparin lock in the patient's right ankle
- The patient died of a massive air embolus

THE JOINT COMMISSION SAFETY TIP

Manufacturers should implement "designed incompatibility" as appropriate, to prevent dangerous misconnections of tubes and catheters

