

**OUR MOTO:** REDUCING THE RISK ASSOCIATED WITH SMALL BORE CONNECTOR MEDICAL DEVICE TUBING MISCONNECTIONS.

#### WHAT ARE SMALL BORE CONNECTORS?

MANY DIFFERENT TYPES OF MEDICAL DEVICES INCORPORATE SMALL-BORE CONNECTORS. SMALL-BORE CONNECTORS ARE PARTS USED TO CONNECT MEDICAL DEVICES SUCH AS TUBING, SYRINGES, AND OTHER ACCESSORIES THAT DELIVER FLUIDS AND GASES FOR PATIENT CARE. SMALL-BORE REFERS TO THE SMALL SIZE OF THE DIAMETER OPENING (LESS THAN 8.5 MILLIMETERS) OF THE CONNECTOR.

#### WHAT IS MEDICAL DEVICE MISCONNECTION?

MEDICAL DEVICE MISCONNECTIONS MAY OCCUR WHEN ONE TYPE OF MEDICAL DEVICE IS MISTAKENLY ATTACHED TO ANOTHER TYPE OF MEDICAL DEVICE THAT PERFORMS A DIFFERENT FUNCTION. BECAUSE THESE CONNECTORS ARE EASY TO USE AND MAY BE COMPATIBLE WITH DIFFERENT MEDICAL DEVICES, USERS CAN MISTAKENLY CONNECT UNRELATED SYSTEMS TO ONE ANOTHER. THIS MAY CAUSE MEDICATION OR OTHER SUBSTANCES TO BE DELIVERED THROUGH THE WRONG TUBING INTO THE INCORRECT AREA OF THE BODY. THESE ERRORS ARE SOMETIMES CALLED TUBING MISCONNECTIONS, WRONG ROUTE ERRORS, CATHETER MISCONNECTIONS, OR LUER MISCONNECTIONS AND CAN RESULT IN PATIENT INJURY OR DEATH.

DEVICE MISCONNECTIONS CAN OCCUR FOR MANY REASONS, INCLUDING:

- THE CURRENT SIMILAR DESIGN OF MANY CONNECTORS AND WIDESPREAD USE OF CONNECTORS WITH SIMILAR SIZES AND SHAPES.
- HUMAN ERROR, ARISING FROM CONDITIONS SUCH AS MULTIPLE CONNECTIONS ON ONE PATIENT, POOR LIGHTING, LACK OF TRAINING, TIME PRESSURE, FATIGUE OR HIGH-STRESS ENVIRONMENTS.

MANUFACTURERS AND HEALTH CARE FACILITIES HAVE TRIED MANY METHODS TO PREVENT DEVICE MISCONNECTIONS, INCLUDING COLOR-CODING, LABELS, TAGS, AND TRAINING. HOWEVER, THESE METHODS ALONE HAVE NOT EFFECTIVELY SOLVED THE MISCONNECTION PROBLEM BECAUSE THEY ARE NOT CONSISTENTLY APPLIED, NOR DO THESE METHODS PHYSICALLY PREVENT THE MISCONNECTIONS.

#### HOW REDUCING THE RISK OF MISCONNECTION?

THE WAY DEVICES CONNECT TO EACH OTHER ARE CHANGING, GREATLY REDUCING THE RISK FOR MISCONNECTIONS. NEW DESIGN STANDARDS ARE BEING DEVELOPED FOR TUBING CONNECTORS FOR HIGH-RISK MEDICAL APPLICATIONS (E.G., ENTERAL, RESPIRATORY, NEURAXIAL), SO THAT UNRELATED DEVICES CANNOT CONNECT WITH EACH OTHER.

**HENCE,** MEDZUS MEDICAL IS COMMITTED TO THE PREVENTION OF MISCONNECTIONS AND ACTIVELY SUPPORTS THE ONGOING WORLDWIDE PATIENT SAFETY INITIATIVES DEDICATED TO REDUCING TUBING MISCONNECTIONS BY SUPPLYING ISO 80369 COMPLIANCE DEVICES.

SMALL BORE CONNECTORS ARE BEING DEFINED WITH APPROPRIATE ANATOMICAL LOCATION & ARE CATEGORIZED TO USE FOR SPECIFIC APPLICATION WITH UNIQUE GEOMETRICAL DESIGN. THESE NEW CONNECTORS ARE BEING DESIGNED TO AVOID MISCONNECTION.

MEDZUS MEDICAL ROUTINELY FOLLOWS BELOW ISO STANDARDS FOR BELOW SPECIFIC APPLICATIONS-

- **ISO 80369-2: RESPIRATORY/BREATHING SYSTEM CONNECTORS: BREATHING OR RESPIRATORY SYSTEMS** SUCH AS ANESTHESIA MACHINES AND VENTILATORS USED TO FACILITATE A PATIENT'S BREATHING. WORK ON THE INTERNATIONAL STANDARD FOR BREATHING AND RESPIRATORY SYSTEMS IS STILL UNDERWAY. THE MEDZUS MEDICAL ANTICIPATES RECOGNIZING THIS STANDARD ONCE IT IS FINALIZED.
- **ISO 80369-3: ENTERAL FEEDING CONNECTORS: ENTERAL DEVICES** DELIVER LIQUID NUTRIENTS OR MEDICINE TO THE STOMACH OR INTESTINES IN PATIENTS WHO ARE UNABLE TO EAT OR DRINK BY MOUTH OR NEED SUPPLEMENTAL NUTRITION. FEEDING TUBES ARE OFTEN INSERTED INTO THE PATIENT'S ABDOMEN. PATIENTS USE PRE-PACKAGED FOOD PURCHASED FROM NUTRITION MANUFACTURERS OR BLEND THEIR OWN DIETS AT HOME. ISO 80369-3:2016 WAS PUBLISHED IN JULY 2016 AND THE MEDZUS MEDICAL RECOGNIZES THIS STANDARD. THIS STANDARD PROVIDES SPECIFICATIONS FOR CONNECTORS INTENDED FOR ENTERAL APPLICATIONS.
- **ISO 80369-4: URINARY/URETHRAL CONNECTORS:** URINARY / URETHRAL DEVICES DRAIN THE URINE FROM BLADDER THROUGH URETHRA. THIS STANDARD IS YET TO PUBLISHED & PROVIDES SPECIFICATIONS FOR CONNECTORS INTENDED FOR URINARY/URETHRAL APPLICATIONS.
- **ISO 80369-5: BLOOD PRESSURE (LIMB CUFF INFLATION) CONNECTORS: BLOOD PRESSURE CUFFS DEVICES** AND OTHER NON-INVASIVE BLOOD PRESSURE DEVICES ARE USED TO INFLATE THE BLOOD PRESSURE CUFF TO TEST A PATIENT'S BLOOD PRESSURE. IEC 80369-5:2016 WAS PUBLISHED IN MARCH 2016 TO PROVIDE SPECIFICATIONS FOR THE SMALL-BORE CONNECTORS USED WITH BLOOD PRESSURE CUFFS.
- **ISO 80369-6: NEURAXIAL (SPINAL, EPIDURAL & REGIONAL ANAESTHESIA) CONNECTORS: NEURAXIAL DEVICES,** SUCH AS EPIDURAL CATHETERS, ARE USED TO DELIVER MEDICINES OR ANESTHESIA TO NEURAXIAL SITES, SUCH AS THE EPIDURAL SPACE, OR ARE USED TO MONITOR OR REMOVE CEREBRAL-SPINAL FLUID FOR THERAPEUTIC OR DIAGNOSTIC PURPOSES. ISO 80369-6:2016, WAS PUBLISHED IN MARCH 2016, TO PROVIDE SPECIFICATIONS FOR DESIGNING THE CONNECTORS FOR USE WITH NEURAXIAL DEVICES. MEDZUS MEDICAL RECOGNIZES THIS STANDARD.
- **ISO 80369-7: INTRAVASCULAR/HYPODERMIC CONNECTORS (KNOW AS LUER FITTINGS): INTRAVASCULAR OR HYPODERMIC DEVICES,** SUCH AS ARTERIAL OR INTRAVENOUS (IV) LINES, WHICH ARE GENERALLY USED TO DELIVER MEDICATIONS OR FLUIDS THROUGH A PATIENT'S NECK, CHEST OR VEINS IN THE ARM. ISO/FDIS 80369-7, IS BEING FINALIZED AND WILL PROVIDE MANUFACTURERS WITH SPECIFICATIONS FOR INTRAVENOUS AND HYPODERMIC APPLICATIONS.



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