NRFit™

DO YOU KNOW?

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NRFit™

New Generation Connectors
Are Preparing To Be Placed In Clinical Practices

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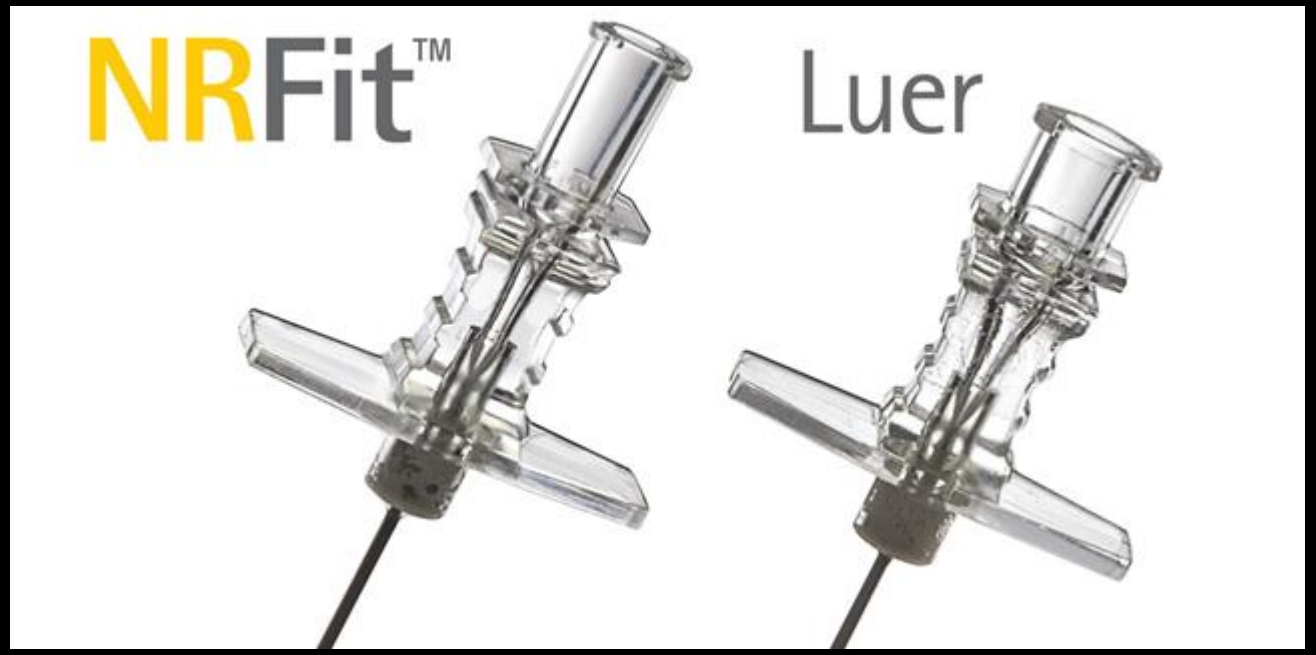

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NEW GENERATION CONNECTORS COME IN NEURACIAL APPLICATIONS!

In order to increase patient safety, the connectors used in healthcare applications (so-called Luer connectors) have been revised to meet the internationally recognized design standards and exchange needs.

This change was made by the creation of a new generation of connectors, identified as NRFit ™.

The purpose of this presentation is to inform sector professionals and employees about the international design changes to the Luer connectors and the new design NRFit ™.

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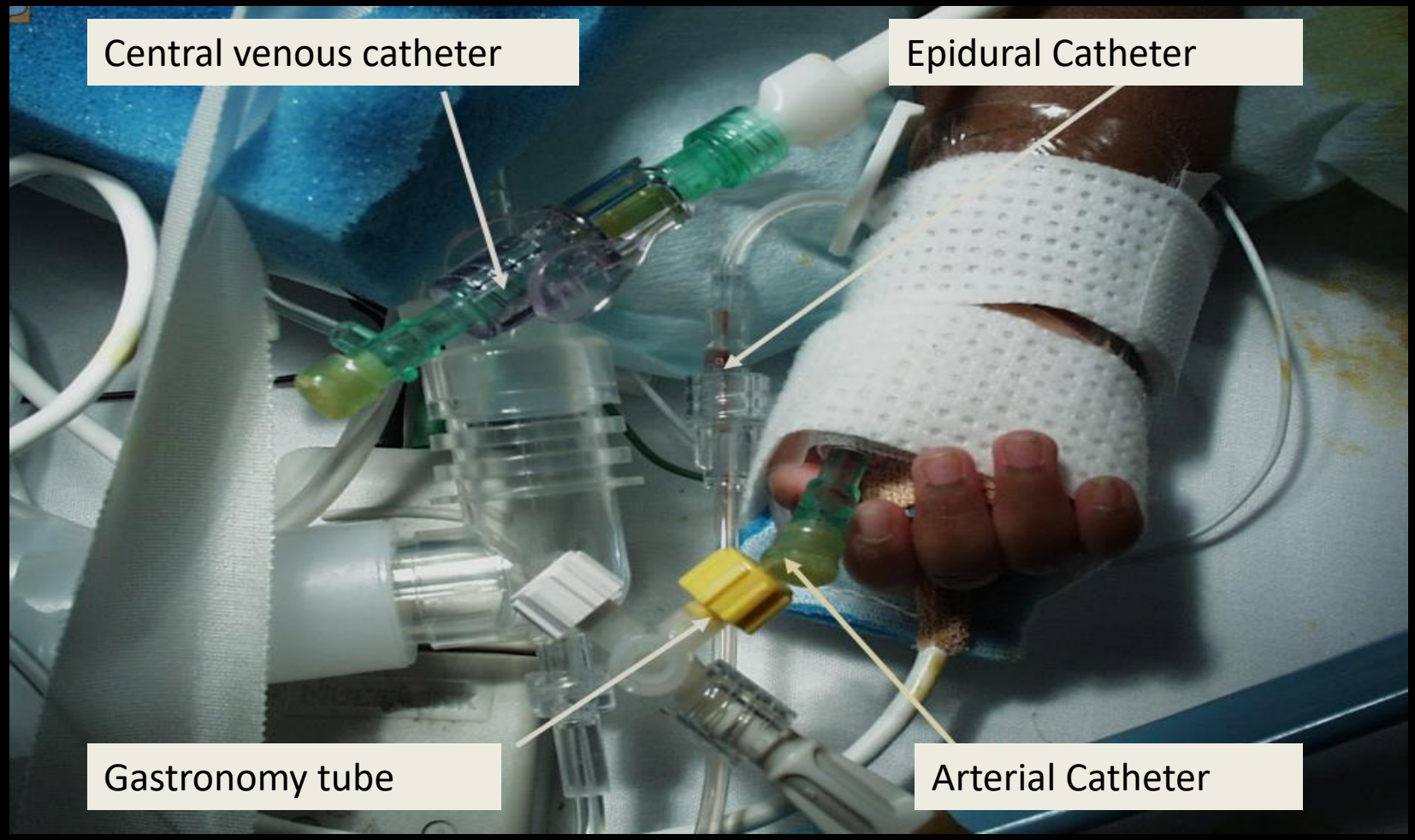

Picture.1 Incorrect implementation of different non-related connections

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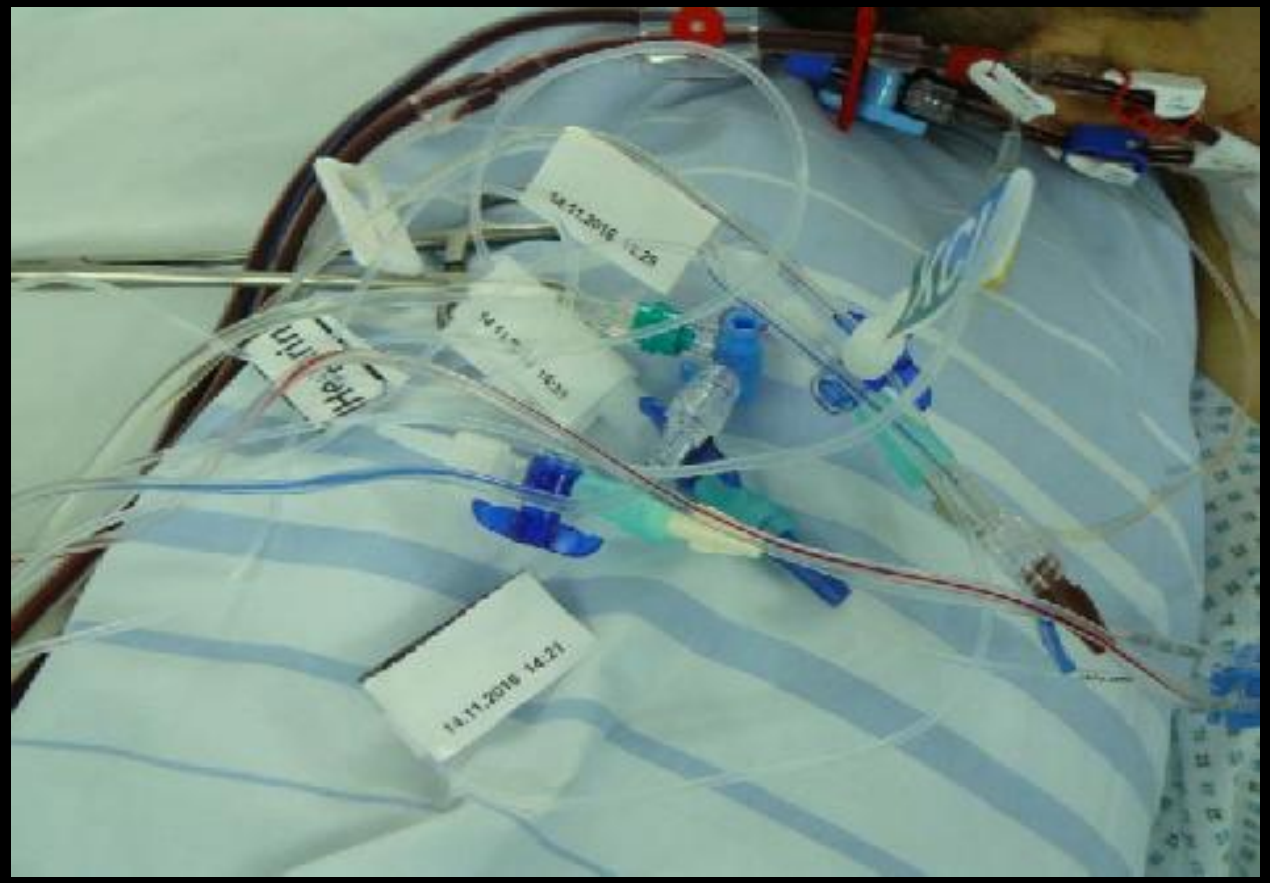


Picture 2 Incorrect implementation of different non-related links

Incorrect Connections in Medical Practices

Due to the fact that functionally unrelated medical devices and connectors can be connected to each other, there are various variations of drug mistakes in practice.

For example;

- Connections can be made to allow transmission lines that can lead to lethal consequences, such as the transmission of toxic chemotherapy drugs to the spinal canal.
- Incorrect orientation of neuraxial drugs such as bupivacaine from intravenous routes.
- Connecting the enteral feeding tube to IV.

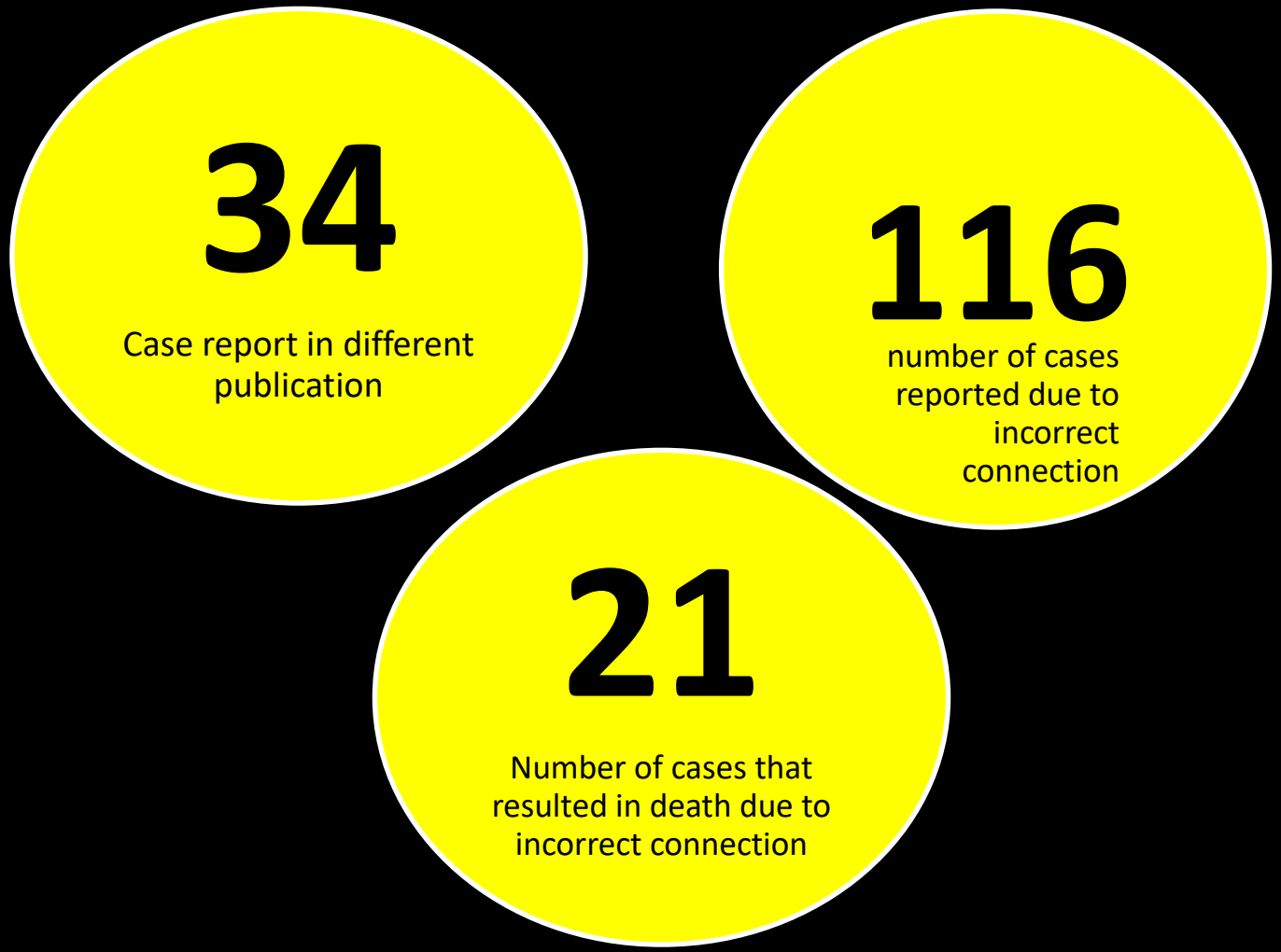
Incorrect Connections in Medical Practices

Despite case reports that result in death, false links (if not harming the patient) are not reported, it is only reported in another category such as drug failure. In all of these reports, there are two groups that are victims:

1. Patient and his/her family
2. Clinicians

Although clinicians or users do not deliberately make these mistakes, undesirable consequences arise because the currently used Luer links and connectors have a design that allows them to connect with unrelated devices.

Incorrect Connections in Medical Practices



Source: Simmons D, et al: Tubing misconnections: normalization of deviance, *Nutrition in Clinical Practice* 2011;26:286

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Incorrect Connections in Medical Practices

Process / Application	*Line that needs to be connect.*	*The place of connection*	*Reference source*
Epidural solution	Epidural line	Peripheral or central IV catheter	Hicks RW, Becker S. An overview of intravenous-related medication administration errors as reported to MEDMARX, a national medication error-reporting program, Journal of Infusion Nursing, 2006;29:20-27
IV infusion	IV line	Nasogastric tube	Hicks RW, Becker S. An overview of intravenous-related medication administration errors as reported to MEDMARX, a national medication error-reporting program, Journal of Infusion Nursing, 2006;29:20-27 11. The Joint Commission: Tubing misconnections – a persistent and potentially deadly occurrence, Sentinel Event Alert #36, April 3, 2006 (accessed June 4, 2014)
Enteral feed	Gastric or Nasal	Tracheostomy tube	Institute for Safe Medication Practices and Baxter Healthcare Corporation. Tubing misconnections self assessment for healthcare facilities, November 2011.
Bladder irrigation using primer IV tubing	Secondary infusion line	Peripheral or central IV catheter	Hicks RW, Becker S. An overview of intravenous-related medication administration errors as reported to MEDMARX, a national medication error-reporting program, Journal of Infusion Nursing, 2006;29:20-27 The Joint Commission: Tubing misconnections – a persistent and potentially deadly occurrence, Sentinel Event Alert #36, April 3, 2006 (accessed June 4, 2014)

DRUG MISTAKES IN REGIONAL ANESTHETIC APPLICATIONS.

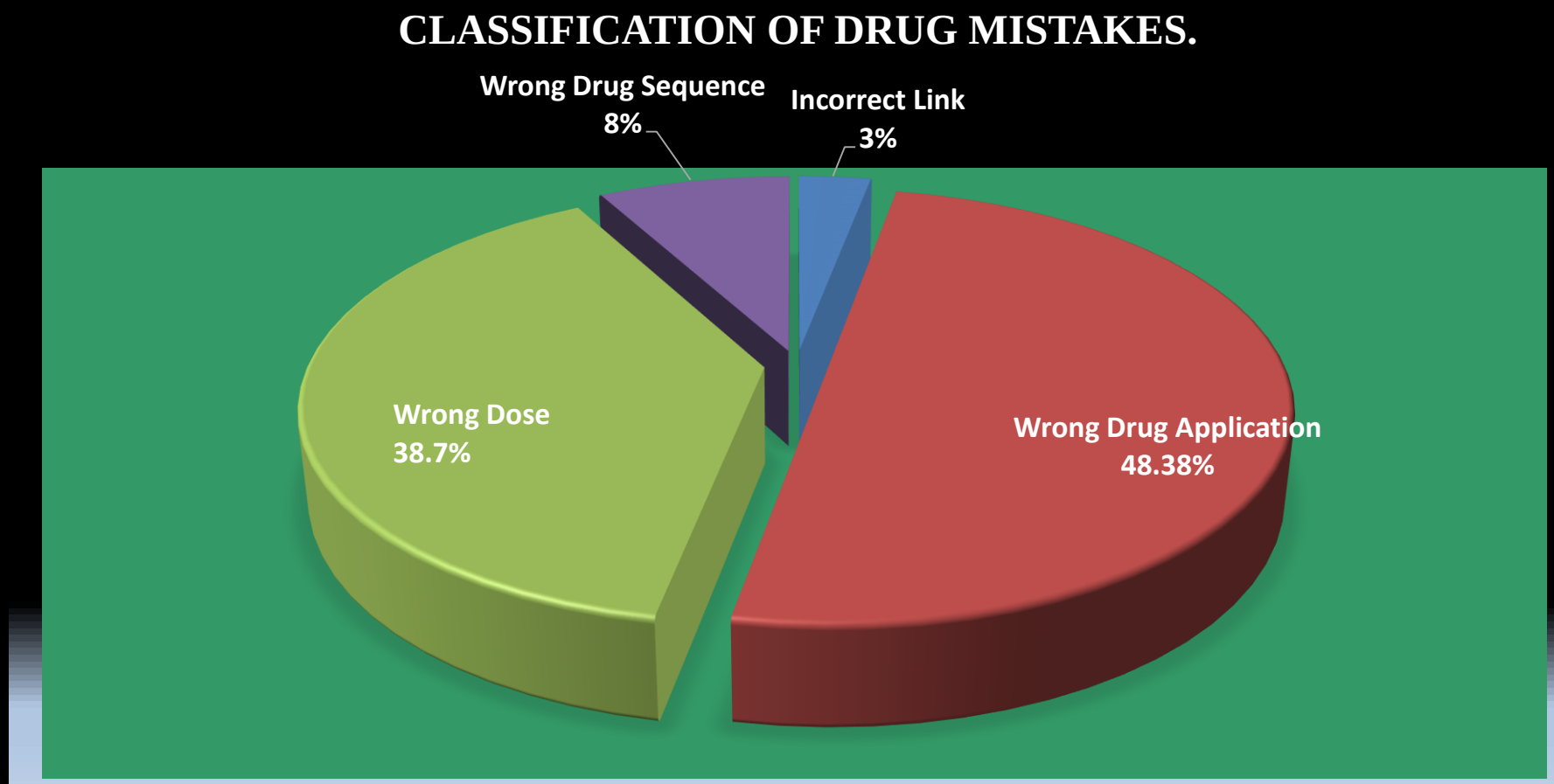
It is difficult to define the "literature on drug mistakes" because there is no consensus on the definition of drug mistakes. As a result of a group study, 62 cases of drug applications reported under the subheading "anesthesia";

- **From the wrong drug application of 30,**
- **From the incorrect dose application of 24,**
- **From the drugs given in the wrong order of 5,**
- **And 2, the application through the wrong connection,**

have been defined as the source.

(Source:Litigation related to drug errors in anaesthesia: an analysis of claims against the NHS in England 1995–2007 , J. Cranshaw,1 K. J. Gupta2 and T. M. Cook2 1 Consultant Anaesthetist, Royal Bournemouth Hospital, Bournemouth, UK 2 Consultant Anaesthetist, Royal United Hospital, Bath, UK)

CATEGORIZATION OF ERRONEOUS DRUG TRANSFER DURING REGIONAL ANESTHESIA.



- Distribution was made according to the reported 62 cases total.
  http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2009.06107.x/pdf

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EXAMPLES OF STUDIES ON DRUG MISTAKES.

Author	Working Subject	Results
Patel and his Friends 2015	Systematic review of obstetric neuraxial drug administration errors.	The review found 29 drug application error cases. 14 ampoule failure, 8 injector failure, 3 mixing lines of application and 4 infusion faults.
Beckers and his friends 2012	Systematic review of undesirable epidural injection of drugs for intravenous use.	With the injector swap and ampoule failure, they found that the epidural catheter-IV line confusion is the common cause of the error.
Hew and his friends 2003	Systematic review of undesirable epidural injection of drugs for intravenous use.	"Injector mount", "ampoule fault", and in 36 (97%) of 37 cases, the main source of the accident was the mixing of the epidural / intravenous line.

Case Report-1

According to a report prepared by the US-based Institute of Medicine in 2000, adverse event rates in hospital admissions ranged from 2.9% to 3.7%, of which 6.6% to 13.6% were fatal. Based on these figures, the report estimated that 44,000 to 98,000 deaths a year were attributable to medical malpractices in US hospitals, which accounted for 50% of the adverse events could have been prevented. [Wacker and his friends 2014]

Case Report-2

According to the report of 687 anesthesiologists who participated in the survey by the Anesthesiologists Association in Canada, 4 death cases were detected. [Orser and his friends 2001]

Case Report-3

In a systematic literature review, a total of 29 faulty cases were recorded during obstetric neuraxial drug application, and 4 of them were fatal.[Patel and his friends 2015]

Case Report-4

Accidental intracerebral administration of vincristine, gradually increasing Asendan Radicullo Myelo Encephalopathy has been repeatedly reported. *[Pongudom and his friends 2011, Qweider and his friends 2007, Dettmeyer and others 2001]*

Case Report- 5

Systemic evaluation of intrathecal chemotherapy: Case reports on intrathecal drug mistakes, clinical trials and surveillance articles were included in the evaluation. Intrathecally, there have been so many antineoplastic agents for parenteral administration. Vincristine was included in the evaluation 31 times, of which 25 resulted in death. Like vincristine, Vindesine, Asparaginase, Bortezomib, Daunorubicin and Dactinomycin have also caused serious toxicity and usually death. (ref. Gilbar 2014)

Case Report- 6

Repeated injuries and deaths due to epidural intravenous misconnections have been reported in the United States (United States) and the United Kingdom (England). Bir makalede, 2 ay içinde, epidural olarak yanlışlıkla uygulanan 2 intravenöz magnezyum sülfat infüzyonu vakası bildirilmiştir. *(Kaynak:Oakeshott I. 200 Epidural blunders admitted after 3 women die. The Times of London. June 18, 2006. Available at: http://www.thetimes.co.uk/tto/news/. Accessed October 18, 2011.9)*

Case Report- 7

The Institute for Safe Drug Applications (ISMP) reports numerous misconnection errors between peripheral and central venous infusion routes, neuroaxial lines (epidural and spinal), enteral feeding and bladder irrigation watering systems.*(Source:Epidural-IV route mix-ups: reducing the risk of deadly errors. Institute for Safe Medication Practices. July 3, 2008. Available at: http://www.ismp.org/newsletters/acutecare/articles/20080703.asp. Accessed October 18, 2011.)*

Case Report- 8

It is the result of accidental delivery of an infusion of epidural solution to the intravenous line of a non-epidural patient, resulting in the death of the pregnant mother. (metzer J, Baker C, Byrne FD, Cohen MR. Shaping systems for better behavioral choices: lessons learned from a fatal medication error. *Jt Comm J Qual Patient Saf* 2010;36:152-63.)

Case Report-9

In the 2006 36th issue of The Joint Commission 's Sentinel Event Alert, nine cases involving 7 adults and 2 babies were reported due to incorrect connection in drug administration. In these 9 cases: 8 resulted in death and 1 resulted in permanent dysfunction. (Source:Landro L. Tackling tube misconnections—hospitals scramble to prevent errors, redesign devices. The Wall Street Journal Online. June 27, 2007. Available at: http://online.wsj.com/article/SB118289594893449089-search.html. Accessed October 18, 2011.)

Case Report-10

Since 1985, 13 cases have been reported which resulted in 10 deaths and 3 permanent strokes due to the false intrathecal administration of intravenous Vincristine in the UK. (Source:Noble DJ, Donaldson LJ. The quest to eliminate intrathecal vincristine errors: a 40-year journey. *Qual Saf Health Care* 2010;19:323-6)

NRFit ™

NEW GENERATION CONNECTOR DESIGN

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WHY NRFit ™ ?

The standard connector that has been used for many years in the medical device field has become the traditional LUER. Since LUER has been considered to have an effective and reliable design, it has been used with many different device applications such as Vascular, Enteral, Respiratory, Epidural and Intrathecal.

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WHY NRFit ™ ?

The use of identical connector types for different target applications, and the risks associated with the misuse of drugs and associated cases, have identified the Luer linkage system as the root cause. It has been determined that the use of a different connector type other than Luer has the potential to "prevent the whole of the errors detected in published case reports".

WHY NRFit ™ ?

In this context, the International Standards Organization (ISO) initiated the study and published the ISO 80369 standard series to determine and finalize the design of connectors used in clinical practice.

This package aims to reduce the risk of cross-connections between applications by defining the criteria for design and performance characteristics of connectors that can be used in different medical device applications. With its publication in 2016, it has become an international norm.

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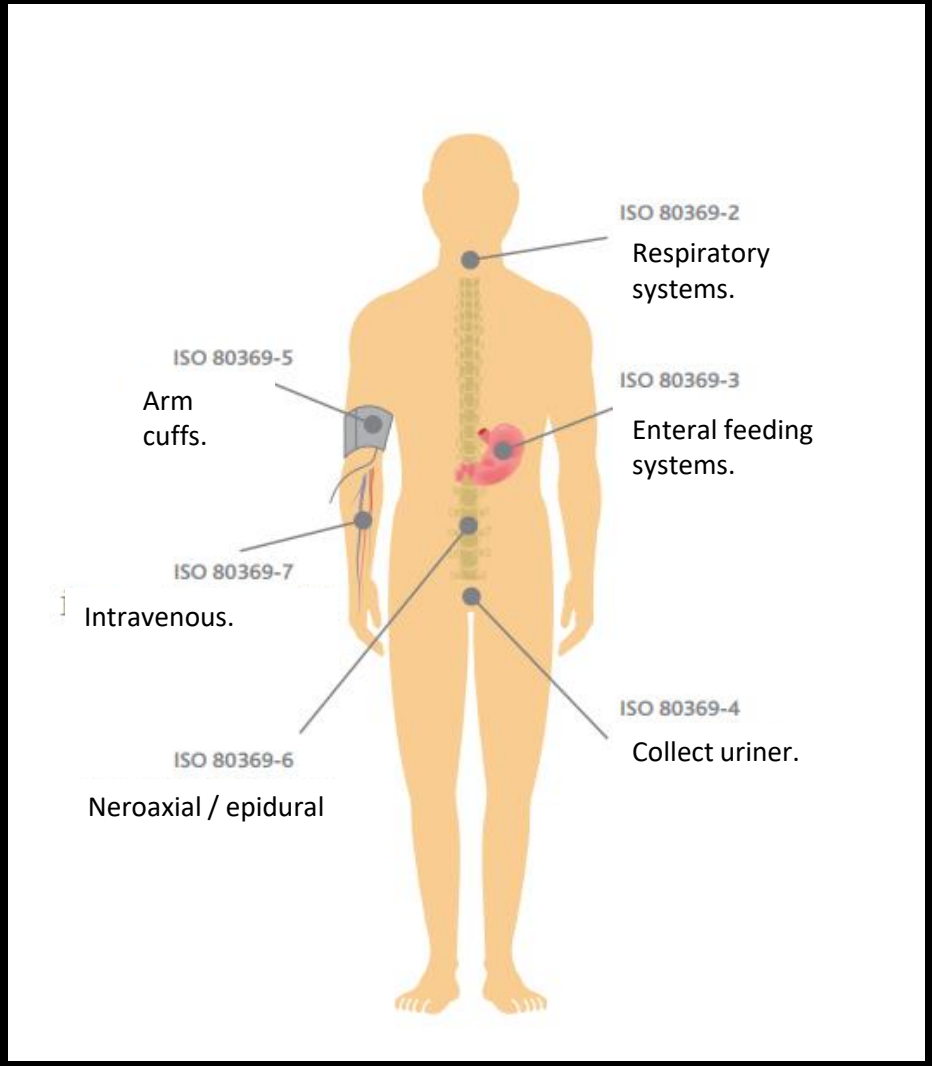
Figure.1: ISO 80369 Series Application Areas



ISO 80369

Small diameter connectors for liquids and gases in health care applications.

- ISO 80369-1: General Requirements
- ISO 80369-2: Respiratory systems
- ISO 80369-3: Enteral Applications
- ISO 80369-4: Urethral Applications
- ISO 80369-5 : Blood pressure cuffs
- ISO 80369-6: Neuroaxial applications and major regional anesthesia (NRFit ™)
- ISO 80369-7 : Intravascular and hypodermic applications
- ISO 80369-20:Ortak Common Test Methods

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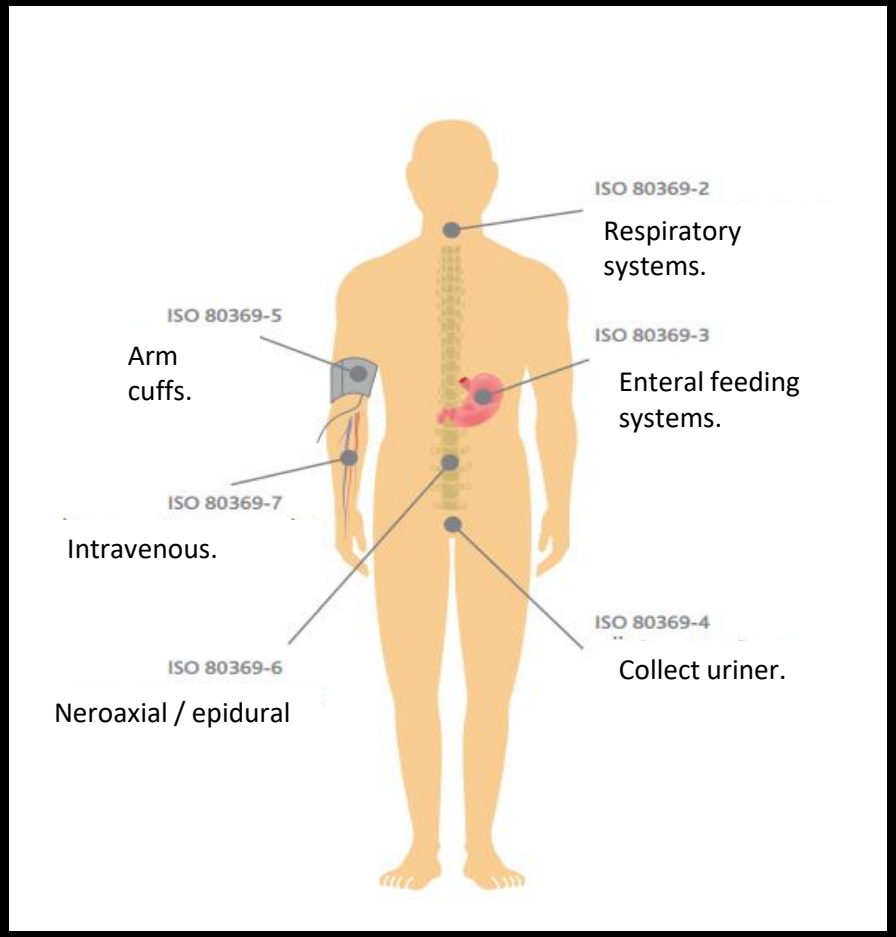
This standard series has been approved for 80369-6, which focuses on connectors used in neuroaxial applications, and published on March 15, 2016.Nöroaksiyel ve Rejyonel

The new connector design to be used in anesthesia is called NRFit ™.



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IMPORTANT DEFINITIONS ABOUT NRFit ™

GEDSA: Abbreviation for Global Enteral Device Suppliers Association..

It is an non-profit association established to help the international standards of connectors used to address the problems encountered by enteral appliance manufacturers, suppliers and distributors. GEDSA also owns the registered NRFit ™ brand. egemen® has obtained written permission and documentation from GEDSA for the use of this trademark.

ww.gedsa.org

STAY CONNECTED: GEDSA is a platform for providing information on the use of safer connectors in medical applications. This platform brings together the professional, supplier, and sector professionals on the transition and features to the new connectors with the global communication program they have developed. NRFit ™ is a trademark of GEDSA.

www.stayconnected.org

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NRFit™ vs. LUER

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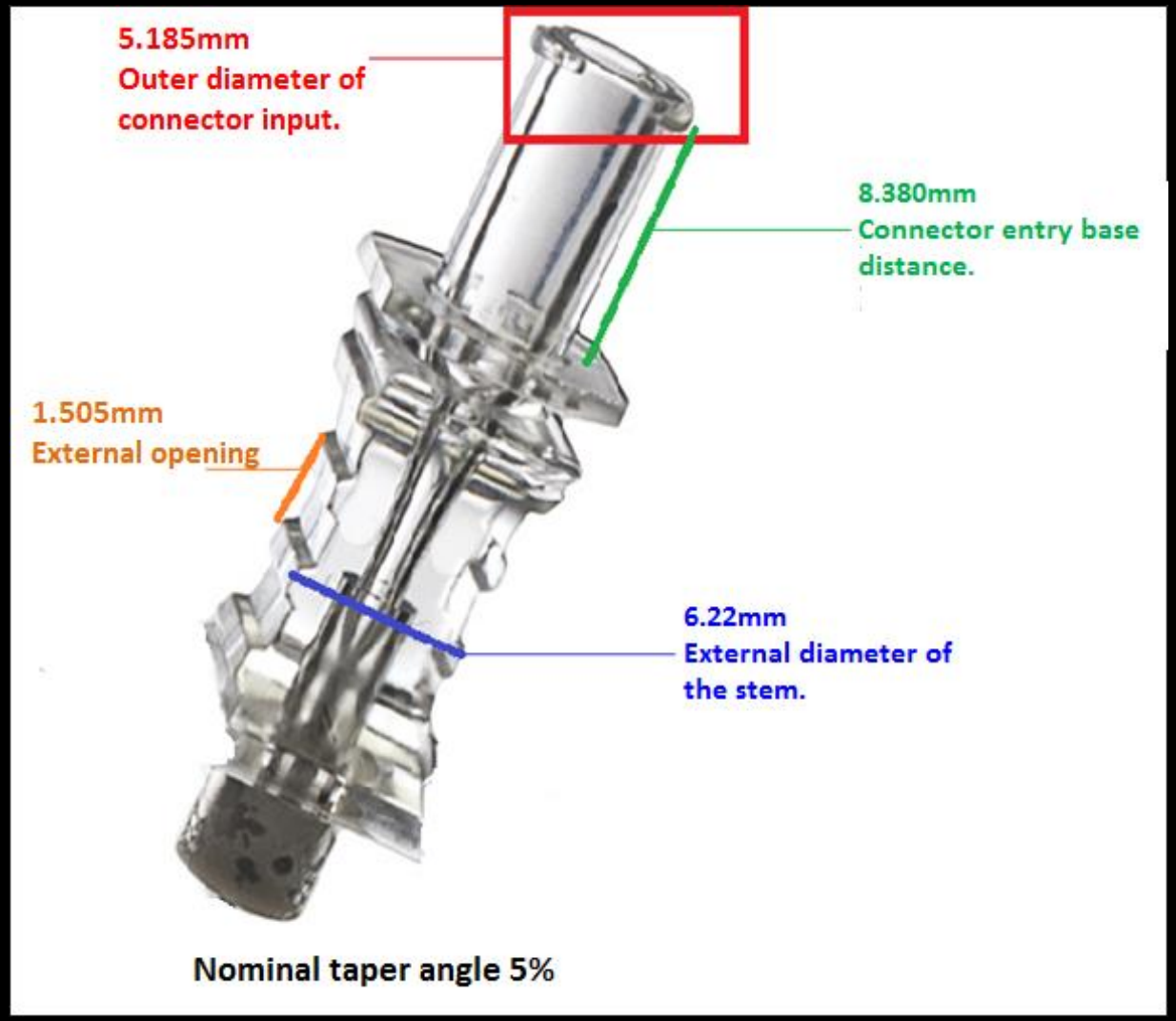
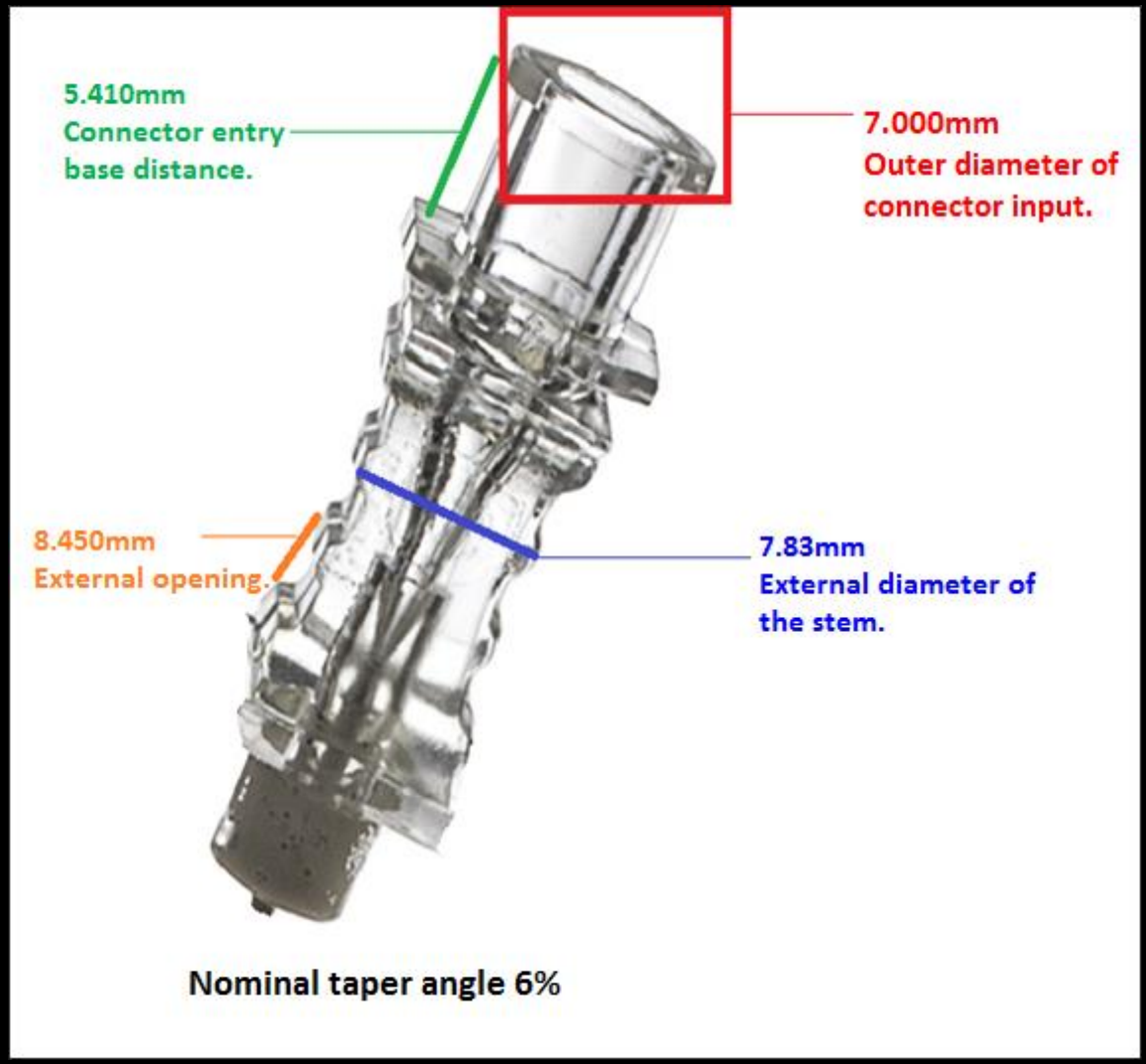
NRFit™ vs. LUER





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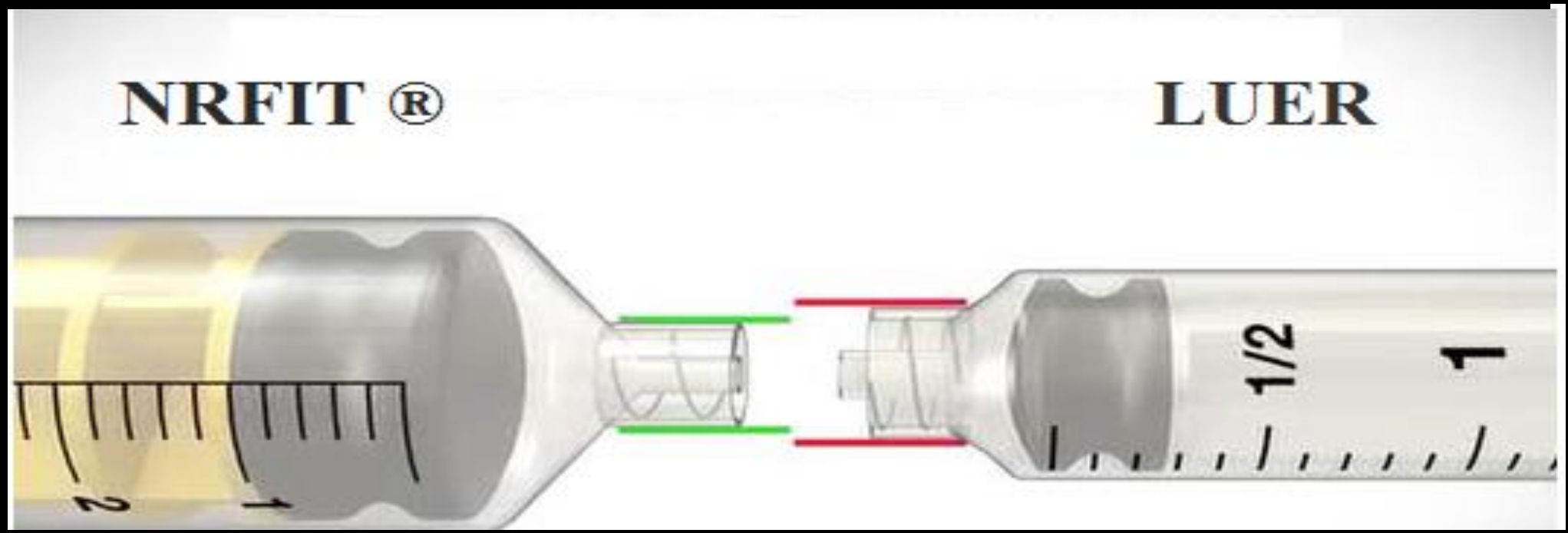
NRFit™ vs. LUER

✓Although the new connector design NRFit is similar to traditional LUER connectors, it has approximately 20% smaller dimensions.

✓ Although the color is not specified in the standard, many manufacturers prefer yellow color to make NRFit ™ distinguishable from other products.

NRFit™ vs. LUER

The injector is easily distinguished in the set of procedures commonly used in the clinical setting. The new NRFit ™ injector design features a smaller collar mouth and tip, but maintains the same internal diameter at the tip. (ID = 3.43mm)



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NEW CONNECTOR DESIGN NRFit ™

TRANSITION AND COMPATIBILITY

PROCESS

OF

OUR PRODUCTS

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GE

Transition Plan

ÇİŞ PLANI

With the publication of the standard 80369-6 on March 15 2016, a binding harmonization process for producers has begun. In regional anesthetic products group harmonization process, egemen®, which is one of the leading brands on the world and number one in Turkey has prepared a 3-stage transition plan to meet the requirements of the standard.

TRANSITION PLAN- STEP 1

In the first quarter of year 2018, completion of the design changes that the new standard bring (Engineering drawing, mold design and production, prototype production)

TRANSITION PLAN- STEP 2

In the second quarter of year 2018, organizing presentative and informative meetings about NRFit™ to hospitals, clinicians, healthcare workers and proffessionals and medical sector proffesionals, giving information about timing

TRANSITION PLAN- STEP 3

Furnishing all products that are related with the Regional Anesthesia **application processes** field with new NRFit™ connectors, and providing NRFit™ labeled products and sets until the end of second quarter of year 2019 to the market.

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Our devices to be harmonized by design change with the publication of ISO 80369-6.

- Catheter connector (Tuohy Burst)

- Epidural Filter (EPIFIT®)

- Loss of resistance syringe (EPILOR)

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Our devices to be harmonized by design change with the publication of ISO 80369-6.

- Automatic LOR Syringe (EPIJET®)

- Hub design of our Spinal and

  Epidural Needles

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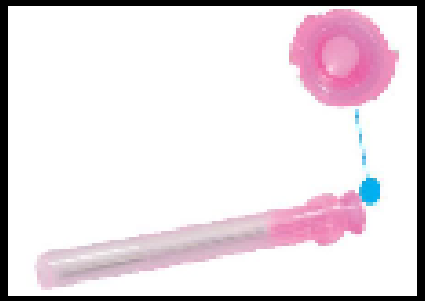
Our devices to be harmonized by design change with the publication of ISO 80369-6.

- Drug aspiration cannula (for spinal anesthesia procedure)



- Syringes in the premium kit (2ml and 5ml syringes)

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OUR GOAL

Our goal is to help our customers be informed about the new ISO standard and the new NRFit ™ connector design that comes along, to be prepared and to facilitate the steps to adopt the change.

To ensure the availability of new connectors at the national level, egemen® INTERNATIONAL will work with global regulatory authorities and industry partners to integrate the transition process into the most accurate and fastest way possible.

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Referance List

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6. Metzer J, Baker C, Byrne FD, Cohen MR. Shaping systems for better behavioral choices: lessons learned from a fatal medication error. Jt Comm J Qual Patient Saf 2010;36:152-63.)
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