Sécurisation des dispositifs péri medullaires

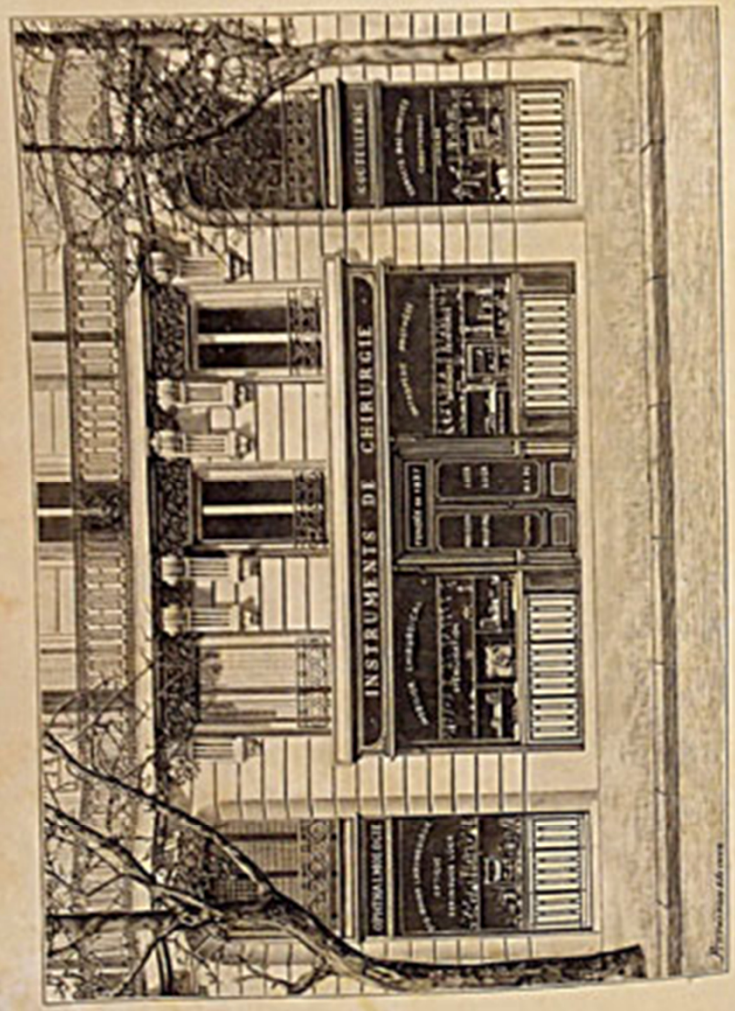
La norme ISO 80369-6 (NRFit)

Ne plus se tromper de voie…

dominique.chassard@chu-lyon.fr

Tear duct syringe acc to. Dominique Anel

Source: Gedeon, A.: Science and Technology in Medicine, page 70



FABRIQUE D'INSTRUMENTS DE CHIRURGIE
ET D'APPAREILS DE MÉDECINE

CHIRURGIE, MÉDECINE, HYGIÈNE & SCIENCES

Maison LUER

Fondée en 1837

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Fournisseurs titulaires de la Faculté de Médecine et des Hôpitaux de Paris, de l'Institut Pasteur, des Ministères, des Chemins de fer, des Hôpitaux et des Universités françaises et étrangères.

MÉDAILLES AUX EXPOSITIONS FRANÇAISES

1844 *Médaille de Bronze* ° 1849 *Médaille d'Or* ° 1855 *Première Médaille* ° 1889 *Médaille d'Or* ° 1900 ***Grand Prix***

FACULTÉ DE MÉDECINE DE PARIS : PRIX BARRIER 1898

MÉDAILLES AUX EXPOSITIONS ÉTRANGÈRES

1862, DÉCORATION DE LA LÉGION D'HONNEUR
à la suite de l'Exposition de LONDRES

1851, Première Médaille à LONDRES
Mention unique de supériorité pour invention et exécution remarquables de divers instruments pour les opérations de l'œil

1853, 1re Médaille à NEW-YORK
1862, 1re Médaille à LONDRES
1888, 1re Médaille d'Or à BARCELONE
1893, Hors Concours à CHICAGO (Etats-Unis)
1904, Grand Prix à SAINT-LOUIS (Etats-Unis)
1905, Deux Grands Prix à LIÉGE
1906, Grand Prix et Diplôme à MILAN
1908, Grand Prix à LONDRES
1910, Grand Prix à BRUXELLES
1910, Grand Prix à BUENOS-AIRES
1911, Grand Prix à TURIN

COMMISSION ▪ EXPORTATION

PARIS
104, BOULEVARD SAINT-GERMAIN, 104
(Près de l'École de Médecine)
Anciennement : 6, RUE ANTOINE-DUBOIS

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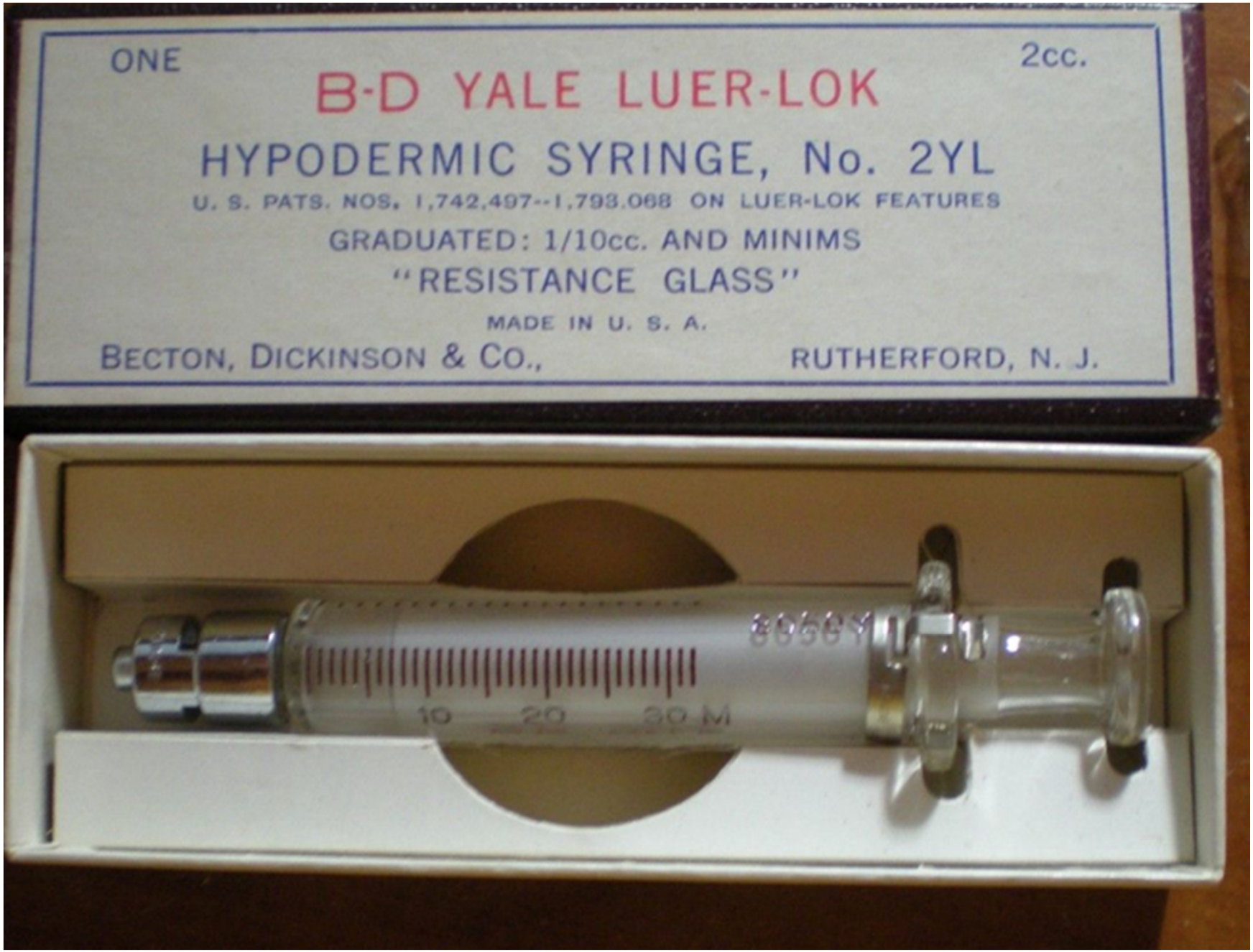
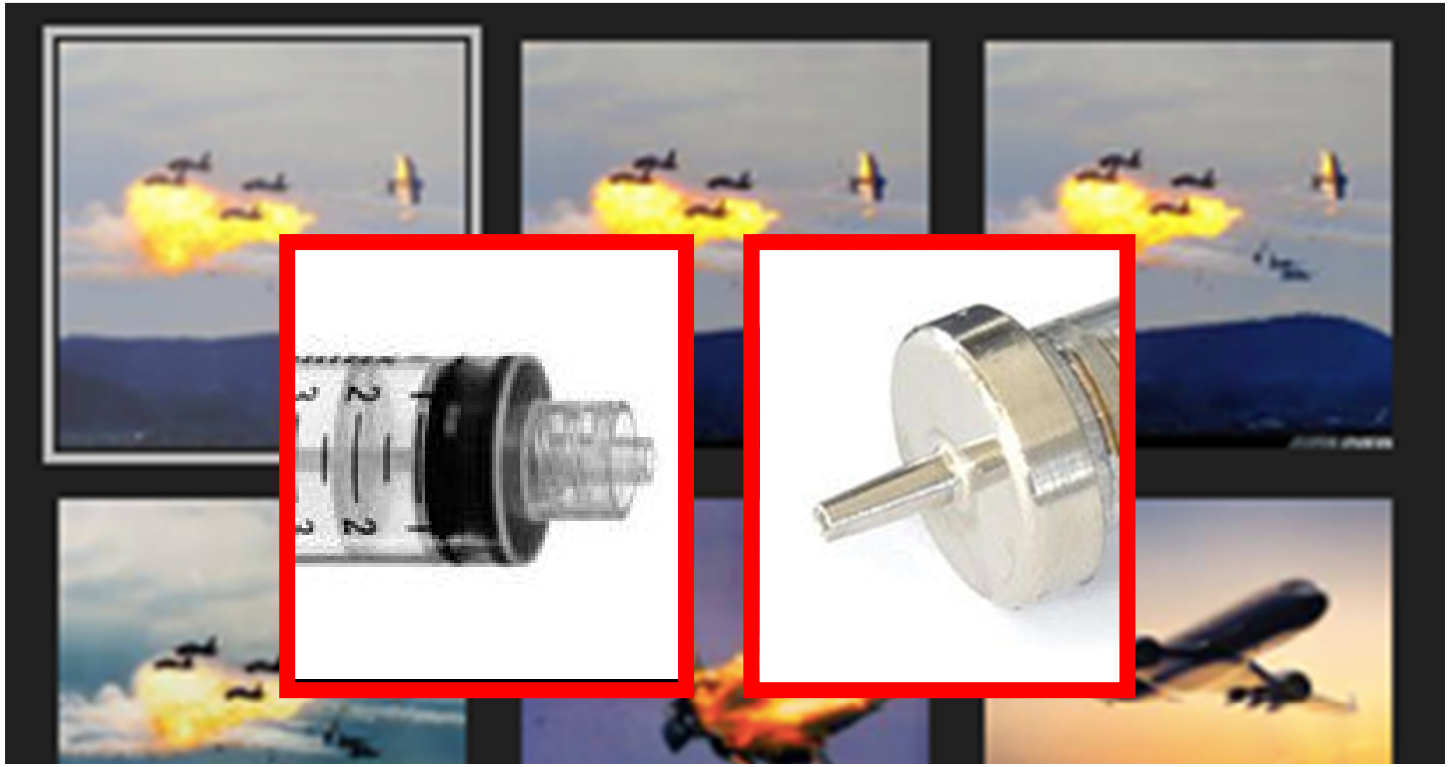
Téléphone 813-09


ONE
2cc.
B-D YALE LUER-LOK
HYPODERMIC SYRINGE, No. 2YL
U. S. PATS. NOS. 1,742,497--1,793,068 ON LUER-LOK FEATURES
GRADUATED: 1/10cc. AND MINIMS
"RESISTANCE GLASS"
MADE IN U. S. A.
BECTON, DICKINSON & CO.,
RUTHERFORD, N. J.
10
20
30 M


„Original Record“
Pfallring-Marke



Ramstein 1988: 70 morts 346 blessés graves

1.1. Erreurs médicamenteuses fréquentes :

En anesthésie, évaluées à 1/900 à 1/130 *(sous estimation car chiffres issus déclarations volontaires)*

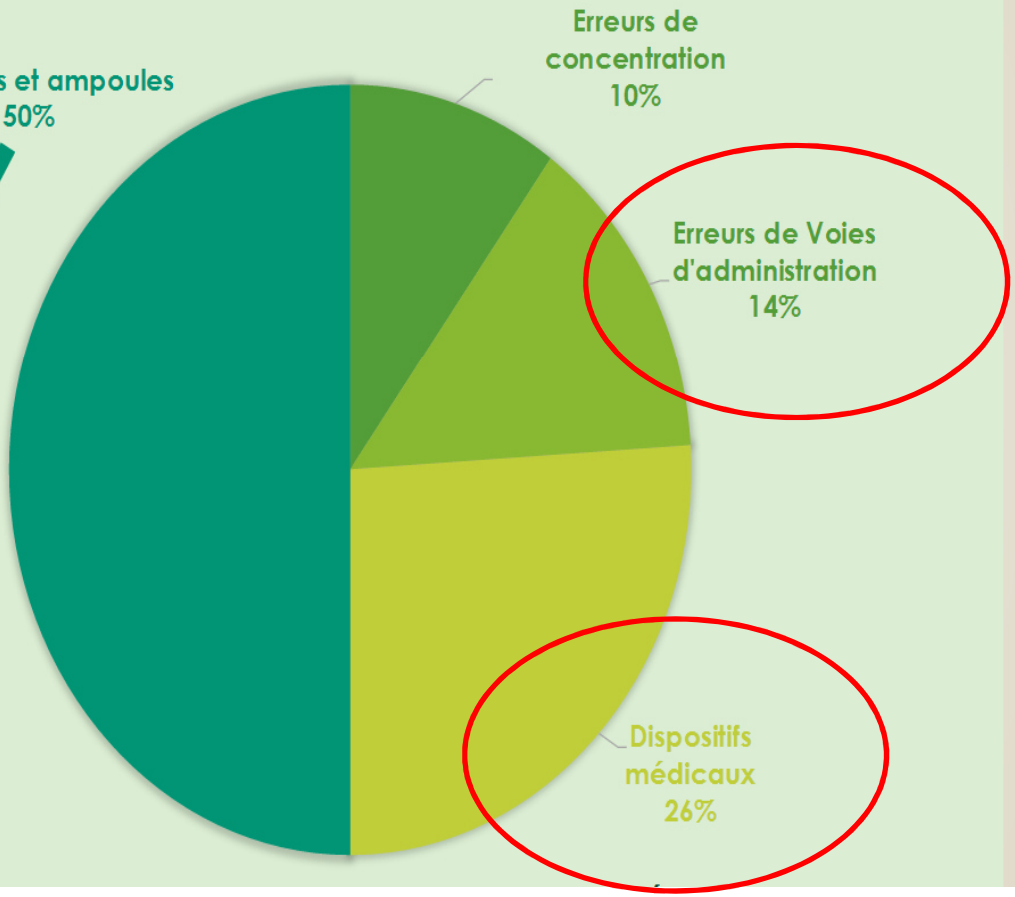
4

- Erreur de seringue lors de l'administration : 55%

+

- Erreur d'étiquetage, de spécialité lors de la reconstitution : 45%

Confusion de spécialité 62%

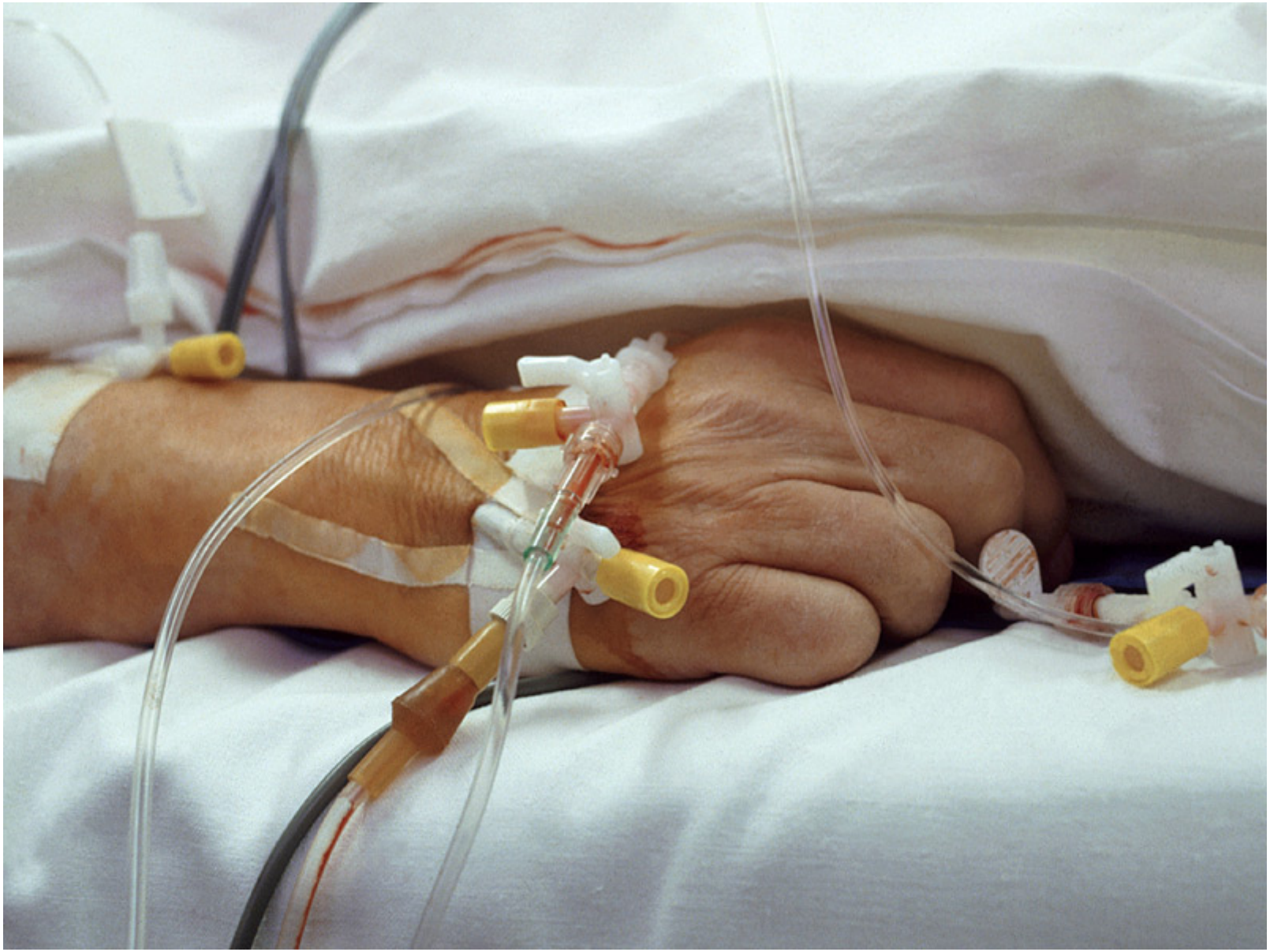


Drug errors: consequences, mechanisms, and avoidance

Table 1
A comparison of results from two prospective studies on medication error in anaesthesia c
South Africa[14]

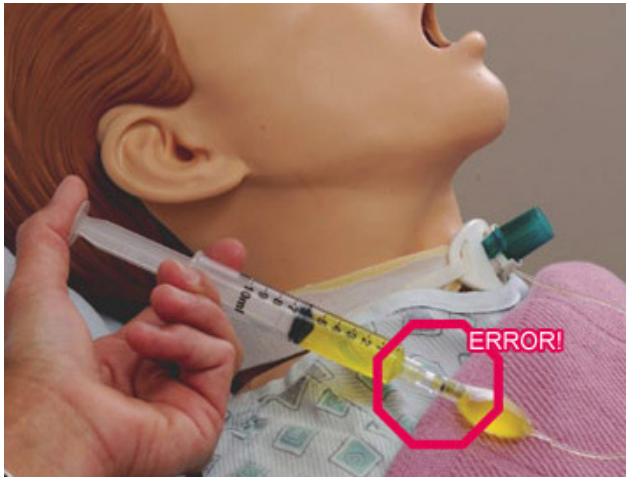
	New Zealand	South Africa
Number of anaesthetics	10 806	30 412
Response rate (%)	72	53
Incidence of error or near miss (%)	0.75	0.36
Adverse outcomes (actual numbers)	3	5
Incorrect dose (%)	32	23
Substitution (%)	27	60
Omission (%)	19	4
Repetition (%)	11	6
Wrong route (actual numbers)	2	7

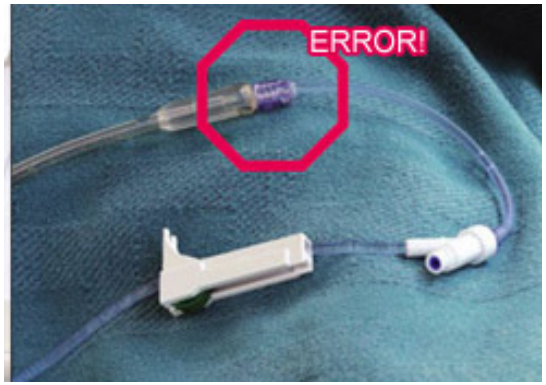
2001 et 2009

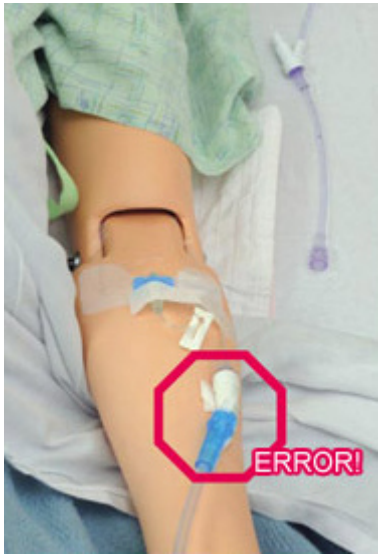


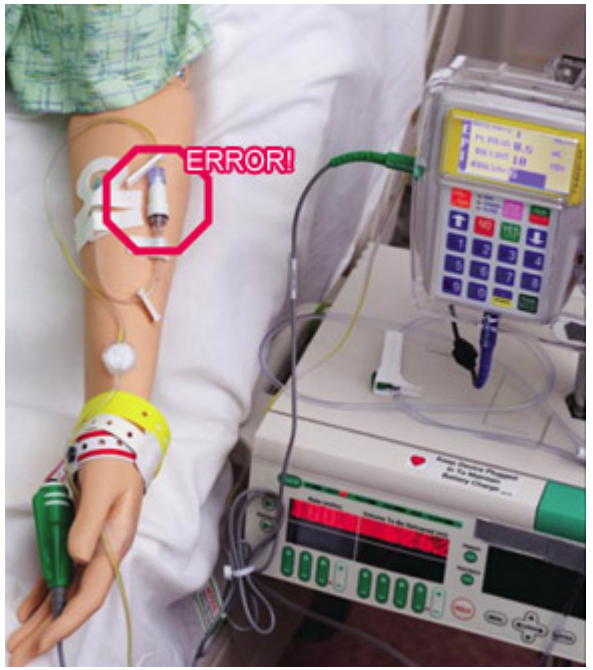
Le système Luer a été introduit dans tous les dispositifs médicaux

C'est donc une source potentielle d'erreur









Anaesth Intensive Care 2003; **31:** 44-49

Avoiding Inadvertent Epidural Injection of Drugs Intended for Non-epidural Use

C. M. HEW*, A. M. CYNA†, S. W. SIMMONS‡
Department of Women's Anaesthesia, Women's and Children's Hospital, Adelaide, South Australia

TABLE 2

Factors contributing to the inadvertent administration of non-epidural drugs into the epidural space and possible preventive strategies

Category (References)	Number of reported incidents*	Possible solutions
Syringe swap	27	Prefilled syringe;
Same size (4-7, 9, 13, 15, 32)	10	Non Luer syringe coupling;
Unlabelled (4)	1	Bar coding
Person administering drug not person who drew it up (6, 8, 12)	4	
Similar location of syringes containing intravenous and regional medications (4-9, 12, 13, 32)	12	
Ampoule error	10	Prefilled syringe;
Similar ampoule (1, 16-23, 28)	10	Non Luer syringe with connector to ampoule that only accesses regional medications
Epidural/Intravenous line confusion	11	Non Luer coupling
Unlabelled catheter (10, 16, 24, 29)	4	
Unlabelled injection port (14, 24, 27, 30, 31)	5	
Inadequate knowledge (10, 29)	2	
Incorrect preparation of infusion solution at pharmacy level (12)	1	Avoid in-hospital manufacture of solutions; Bar coding of prescription to medication

10 à 20% des erreurs en neuraxial ?

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… advertent epidural injection of ondansetron. J Clin … ;18:216–7
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… M. Responsiveness to the chlorhexidine epidural … ental block? J Law Med 2012;19:436–43

Succinylcholine
Curares
Thiopental
Benzodiazépines
Ephédrine
Ondansétron
Chlorhexidine
Eau
Potassium
Nutrition
Ether
Syntocinon

Epidural drug drip 'killed' new mother

By Matthew Hill
BBC West Health Correspondent

"My wife just didn't die, she was killed. For me, intentionally or not, that's the bottom line."

Myra Cabrera worked as a nurse at the Great Western Hospital

Just hours after Arnel Cabrera's son Zak was born, his wife Mayra died. Instead of being placed on a saline drip, she was given a drug used in epidurals.

It was a fatal mistake compounded by the fact the two infusion bags looked almost identical and were both kept in the same unlocked drawers.

An inquest ruled her death at Swindon's Great Western Hospital in May 2004 was unlawful.

Warnings issued after similar incidents appeared to have gone unheeded.

In 2000 a patient at the Royal Liverpool University Hospital died after an identical mistake.

Bupivacaine pour l'analgésie péridurale injectée en intraveineux

Misconnections in the Critically Ill: Injection of High-Dose Gadolinium into an External Ventricular Drain

Sumit Singh, MD,* Sepehr Rejai, MD,* Zarah Antongiorgi, MD,* Nestor Gonzalez, MD, FAANS, FAHA,† and Matthias Stelzner, MD, FACS‡

We report an unfortunate case of accidental administration of intrathecal gadolinium through an external ventricular drain in a postcraniotomy patient during magnetic resonance imaging of the brain. The incident occurred after the venous contrast line was connected mistakenly to the ventricular drainage catheter. The patient subsequently developed confusion, aphasia, and right facial droop with new computed tomography evidence of diffuse cerebral edema and stroke. Review of the magnetic resonance image revealed the inappropriate presence of subarachnoid gadolinium. Despite all interventions, the patient developed irreversible neurologic disability. We address the clinical sequelae, management strategies, and factors contributing to the catheter misconnection that led to this event. (A&A Case Reports. 2016;6:121–3.)

It has now been 3 years since an editorial published in *Anesthesia & Analgesia* urged the anesthesia community to act.[1] Yet, substantial action has not occurred. As reports of epidural and spinal catheter misconnections continue, so does our responsibility if we are to remain at the forefront of patient safety. Implementing an alternative non-Luer

J'Accuse! Failure to Prevent Epidural and Spinal Catheter Misconnections

David J. Birnbach, MD, MPH,* Sorin J. Brull, MD, FCARCSI (Hon),†
and Richard C. Prielipp, MD, MBA, FCCM‡

GEDSA and members of the ISO joint working group have proposed the use of the name “NRFit” (pronounced ‘ner-fit’) for the new connectors used for neuraxial and major regional applications. NRFit is a name that will be used to identify devices that comply with the ISO 80369-6 standard.

EDUCATIONAL PROGRAMS

ISMP considers education to be a core co mponent of its mission. If everyone in the healthcare continuum, including patients, learns more about the nature and causes of medication errors, there is a greater possibility of preventing errors and ensuring safe medication use.

With this goal in mind, ISMP continually devotes time, energy, and resources to educational initiatives. Funded by unrestricted educational grants and donations, all of ISMP's unparalleled educational programs provide independent and unbiased information. Programs and sessions cover a wide variety of venues, including freestanding events, teleconferences

Resources
Educational Programs Main
Presentations/Lectures
Webinars
Medication Safety Intensive
Practitioner in Residence Program
Educational Symposia

The new ISO Standard for neuraxial applications: ISO 80369-6

ISO International Organization for Standardization

- 27,2 % Ingénierie
- 22,5 % Technologies des matériaux
- 17,6 % Électronique, technologies de l'information et des télécommunications
- 10,7 % Transport et distribution des marchandises
- 9,1 % Généralités, infrastructures, sciences et services
- 5,7 % Agriculture et technologie alimentaire
- 4 % Santé, sécurité et environnement
- 2,5 % Construction
- 0,8 % Technologies spéciales

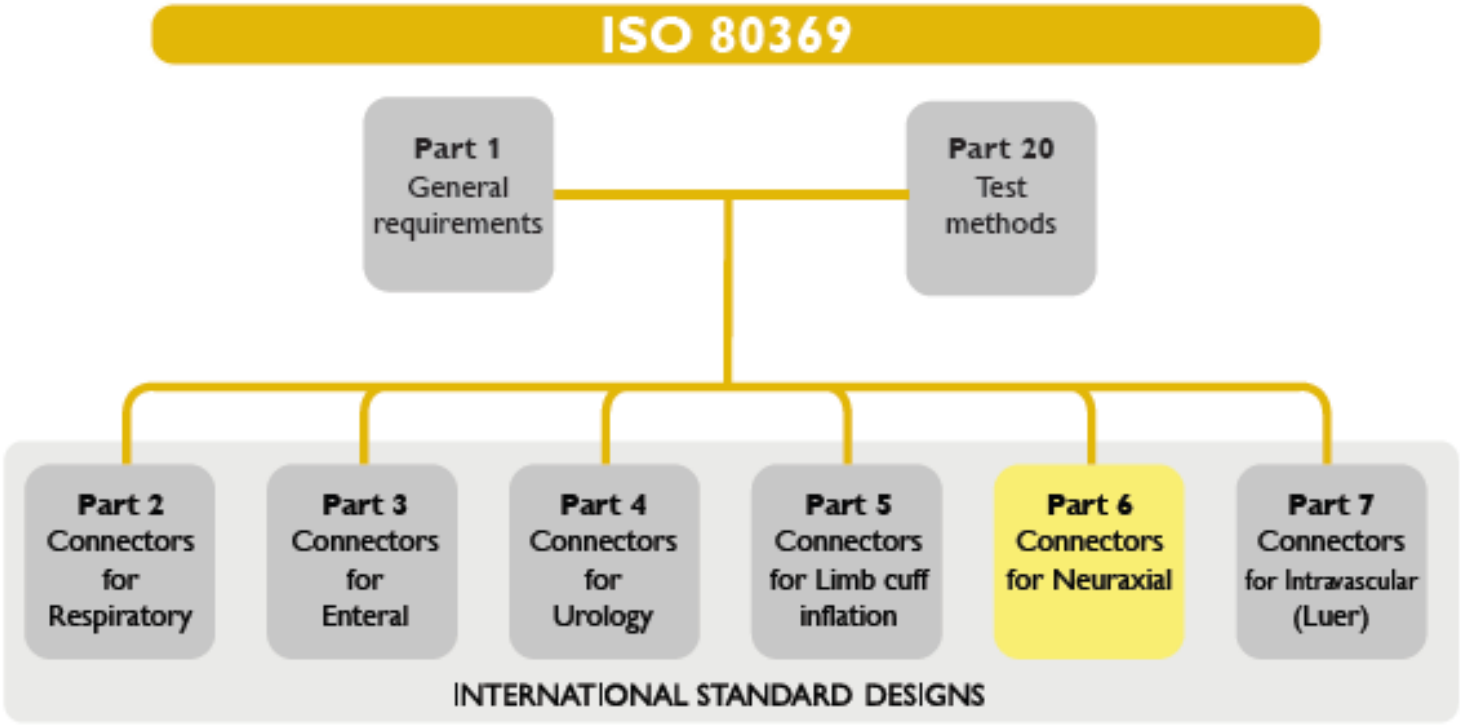
21.000 normes ISO

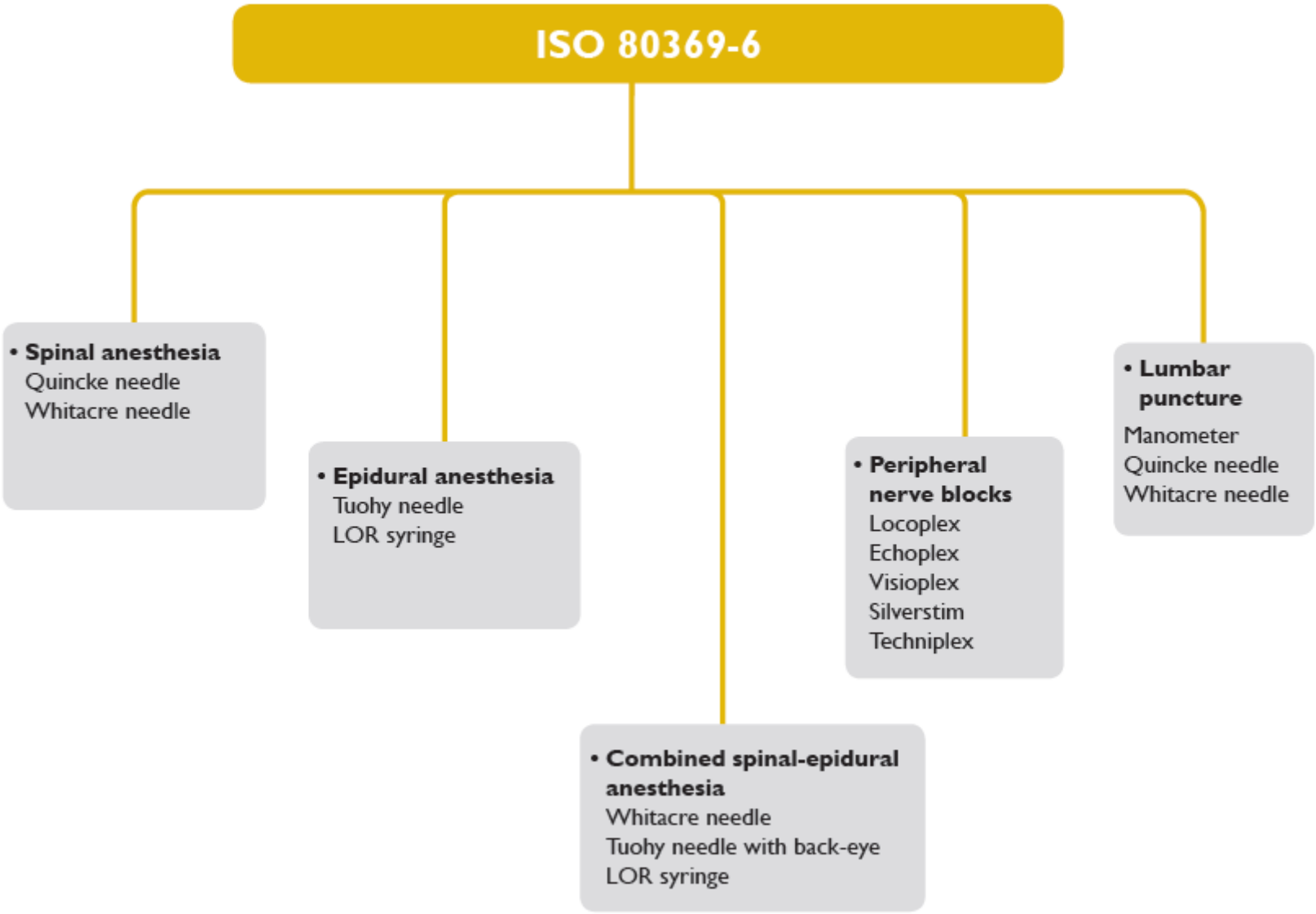
ISO 9706 PAPIER PERMANENT

ISO 14001

CERTIFIED ISO 9001 CERTIFIED

ISO Accréditation MDC QUALITE 17020

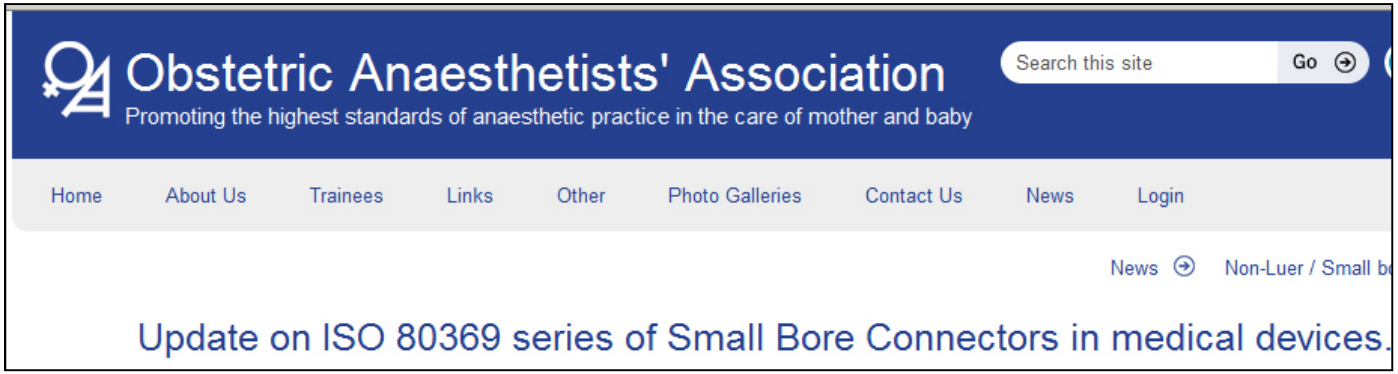

ISO 80369
Part 1
General requirements
Part 20
Test methods
Part 2
Connectors for Respiratory
Part 3
Connectors for Enteral
Part 4
Connectors for Urology
Part 5
Connectors for Limb cuff inflation
Part 6
Connectors for Neuraxial
Part 7
Connectors for Intravascular (Luer)
INTERNATIONAL STANDARD DESIGNS



With following accessories:

Nouvelle norme obligatoire en janv 2017 en Californie

En UK en 2017



Headline messages

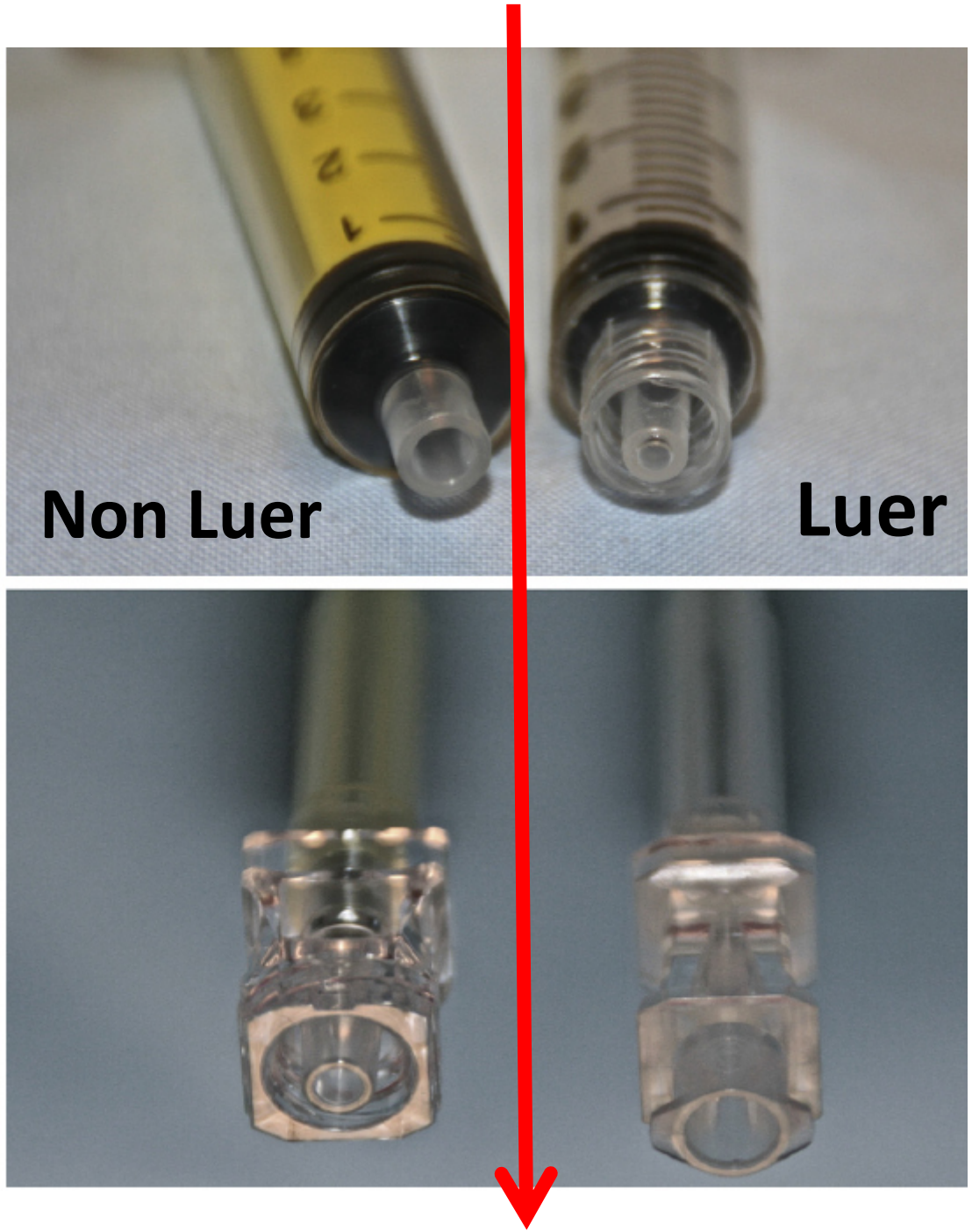
1) The change to an Internationally agreed (ISO) connector for neuraxial / neural devices is soon to be deployed.

2) The change is currently anticipated to commence at the end of the first quarter of 2017.

3) Most Luer and proprietary non-Luer connectors currently in use will cease to be produced.

4) The change affects a wide distribution of users within your organisations, many more than you may be aware of.

5) It is anticipated that the preparation to change in your organisation may take over 6 months to co-ordinate.


Non Luer
Luer

British Journal of Anaesthesia **108** (1): 134–9 (2012)
Advance Access publication 23 November 2011 · doi:10.1093/bja/aer359

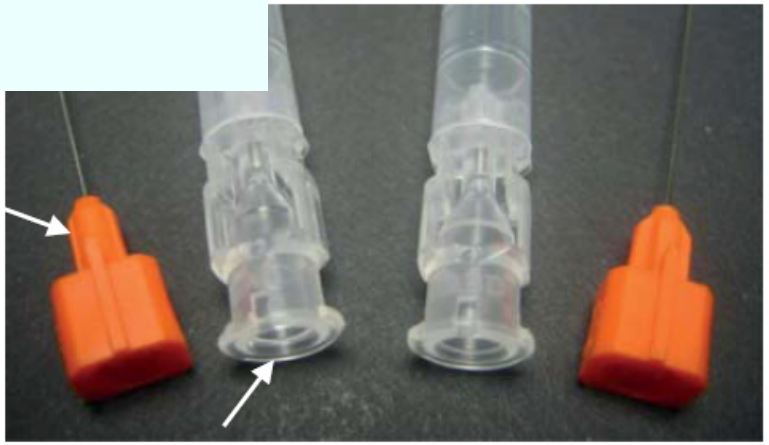
BJA

REGIONAL ANAESTHESIA

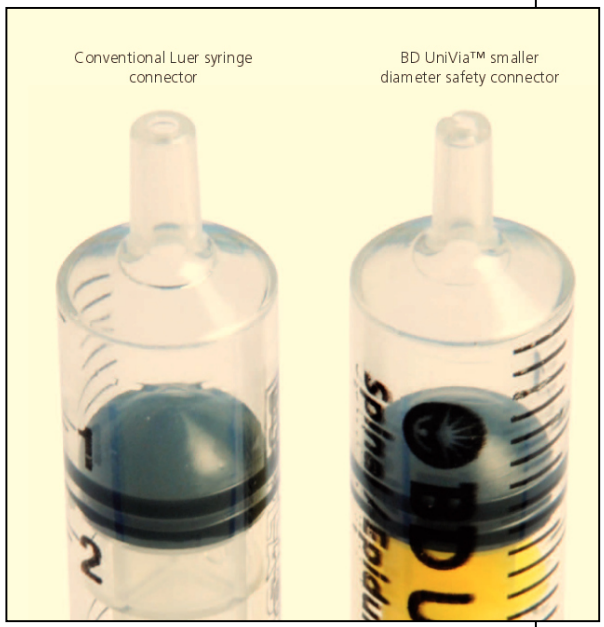
Simulated evaluation of a non-Luer safety connector system for use in neuraxial procedures

R. Onia*, Y. Wu, V. Parvu, I. Eshun-Wilson and K. Kassler-Taub

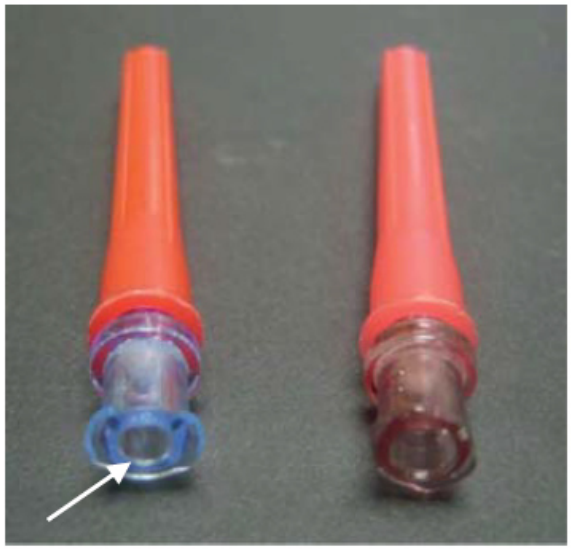
BD UniVia-6 Safety Connector system



BD non-Luer spinal needle hub (left, translucent) has a smaller inner diameter and the stylet handl (left, orange) has a smaller nose



BD non-Luer slip syringe (left) has a smaller tip



BD non-Luer blunt fill filter needle hub (left) has a smaller inner diameter and a light blue colour

The procedures were performed on an artificial back model (Lumbar Puncture & Epidural Simulator II, Kyoto Kagagu, Co., Ltd, Kyoto, Japan).
49 médecins dont 39 anesthésistes, 5 neuro et 5 oncologues

Table 2 Equivalence of the safety non-Luer system when compared with the conventional Luer reference system.
*Somewhat agree, agree, and strongly agree

Statement	Agreement with statement*	
	n (%)	95% lower bound
The safety system takes no more time to use than a conventional system	49 (100)	94.1
The safety system performs the same as a conventional system	48 (98.0)	90.7
The safety system feels identical to the conventional system	46 (93.9)	84.9
The safety system is as easy to use as a conventional system	49 (100)	94.1
The safety connection technique is identical to that of the conventional system	48 (98.0)	90.7

Globalement les nouveaux standards sont aussi faciles à utiliser que les systèmes Luer

Table 3 Statements evaluating procedural flow. *Somewhat agree, agree, and strongly agree. **$n=48$, one clinician did not complete this question

Statement	Agreement with statement*	
	n (%)	95% lower bound
The safety syringe is easy to connect and disconnect from the blunt fill filter needle	48 (98.0)	90.7
Attaching the safety blunt fill filter needle to the safety syringe feels identical to when attaching a conventional blunt fill filter needle to a conventional syringe	47 (96.0)	87.7
Drawing up medication through the safety blunt fill filter needle is easy	48 (98.0)	90.7
The performance of a safety syringe is identical to the performance of a conventional syringe	48 (98.0)	90.7
The tactile feel of the safety spinal needle is identical to the tactile feel of a conventional spinal needle	47 (96.0)	87.7
The safety stylet is easy to remove from the safety spinal needle hub	46 (93.9)	84.9
The visualization of CSF flashback for the safety spinal needle is identical to the CSF flashback of a conventional spinal needle**	48 (100)	94.0

Anaesthesia 2012, 67, 1217–1224 doi:10.1111/j.1365-2044.2012.07297.x

Original Article

A clinical evaluation of four non-Luer spinal needle and syringe systems

S. M. Kinsella,[1] A. Goswami,[2] C. Laxton,[3] L. Kirkham,[2] N. Wharton[1] and M. Bowen[4]

	Luer	Polymedic	Pajunk	Sarstedt	Smiths
Good feel of dural puncture	90/100 (90%)	79/94 (84%)	65/95 (68%)	72/96 (75%)	89/98 (91%)
Trocar easy to remove	99/100 (99%)	88/98 (90%)	64/99 (65%)	87/99 (88%)	98/99 (99%)
Free aspiration	99/100 (99%)	78/88 (89%)	86/91 (95%)	81/86 (94%)	87/92 (94%)
Easy to see CSF in hub	100/100 (100%)	70/96 (73%)	89/96 (93%)	91/96 (95%)	94/97 (97%)
Leak of injectate	1/100 (1%)	1/93 (1%)	8/95 (8%)	5/96 (5%)	1/96 (1%)
Connection problem	0/100 (0%)	12/94 (13%)	31/95 (33%)	10/96 (10%)	7/96 (7%)
Disconnection problem	0/100 (0%)	1/94 (1%)	2/94 (2%)	0/96 (0%)	0/96 (0%)

Anaesthesia 2012, 67, 1217–1224 doi:10.1111/j.1365-2044.2012.07297.x

Original Article

A clinical evaluation of four non-Luer spinal needle and syringe systems

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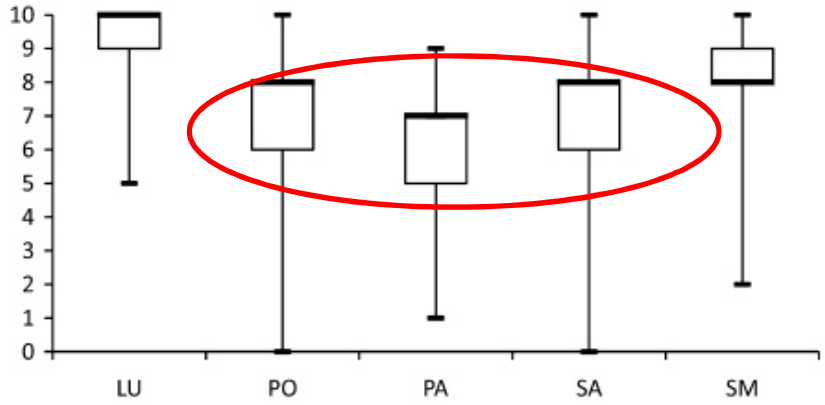


Figure 2 Numeric satisfaction scores for all spinal equipment. LU, Luer; PO, Polymedic; PA, Pajunk; SA, Sarstedt; SM, Smiths. Values are median (line), IQR (box) and range (whiskers).

depending on the needle type. Between 22% and 76% of non-Luer evaluations were rated with satisfaction worse than the usual Luer equipment compared with 0–14% rated better. Specific concerns included poor feel of tissue planes and observation of cerebrospinal fluid (Polymedic), difficulty with connection of the syringe to the spinal needle and trocar removal (Pajunk), poor feel of tissue planes and needle flexibility (Sarstedt) and difficulty with connection of the syringe to the spinal needle (Smiths). We could not demonstrate a short-term learning curve for

Anaesthesia 2013, 68, 562–570 doi:10.1111/anae.12228

Original Article

An evaluation of non-Luer safety connectors for neuraxial procedures*

P. Sharpe[1], S. Scott[2] and J. M. Gross[1]

	Sarstedt	BD	Pajunk	Neurax	Smiths	Vygon	BBraun	p value
Satisfaction with needle	n = 24 19 (79%)	n = 32 23 (72%)	n = 26 22 (85%)	n = 33 23 (70%)	n = 31 26 (84%)	n = 23 21 (91%)	n = 27 26 (96%)	NS
Satisfaction with all equipment	n = 22 18 (82%)	n = 30 22 (73%)	n = 25 21 (84%)	n = 33 21 (64%)	n = 31 25 (81%)	n = 21 19 (90%)	n = 26 26 (100%)	p = 0.02
Would use again	n = 23 23 (100%)	n = 30 26 (87%)	n = 24 22 (92%)	n = 29 21 (72%)	n = 31 28 (90%)	n = 23 23 (100%)	n = 26 25 (96%)	p = 0.009

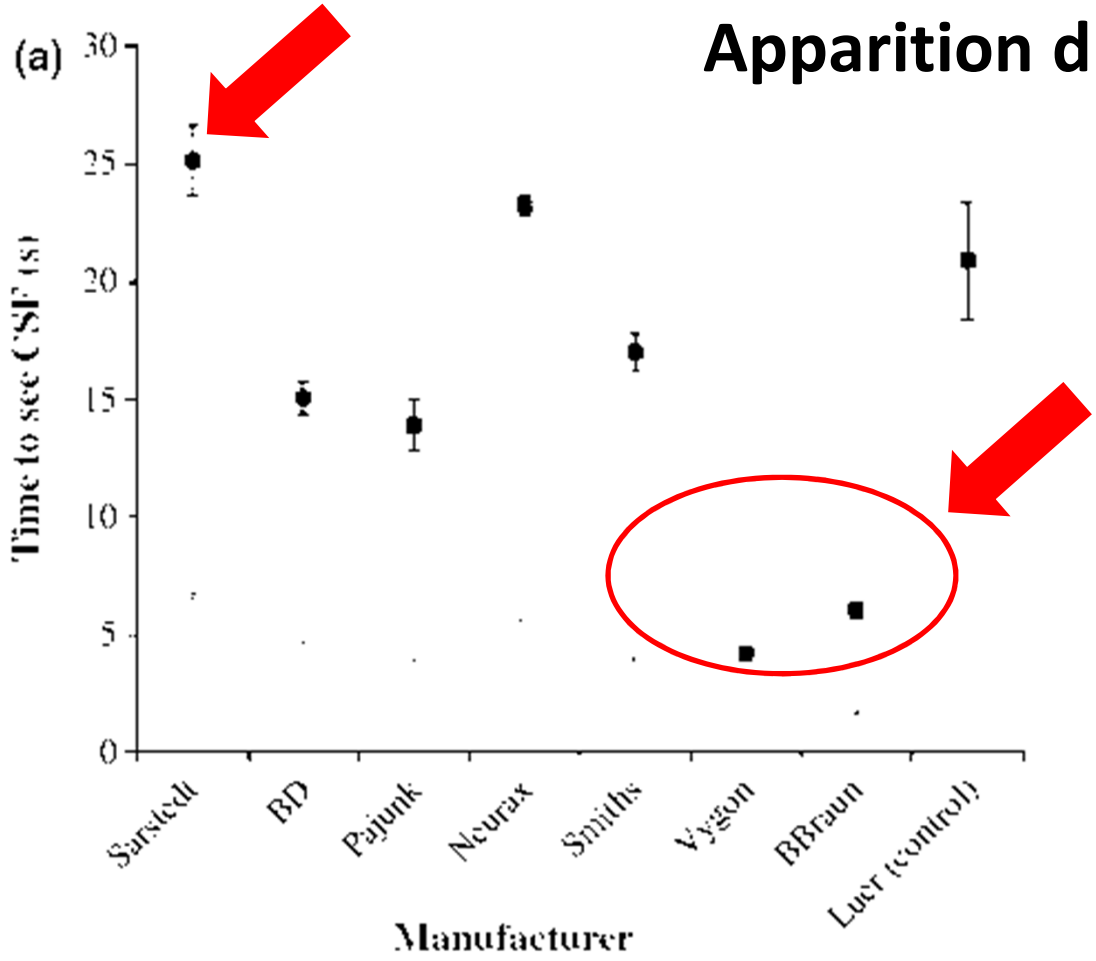
Anaesthesia 2013, 68, 562–570 doi:10.1111/anae.12228

Original Article

An evaluation of non-Luer safety connectors for neuraxial procedures*

P. Sharpe[1], S. Scott[2] and J. M. Gross[1]

Apparition du LCR



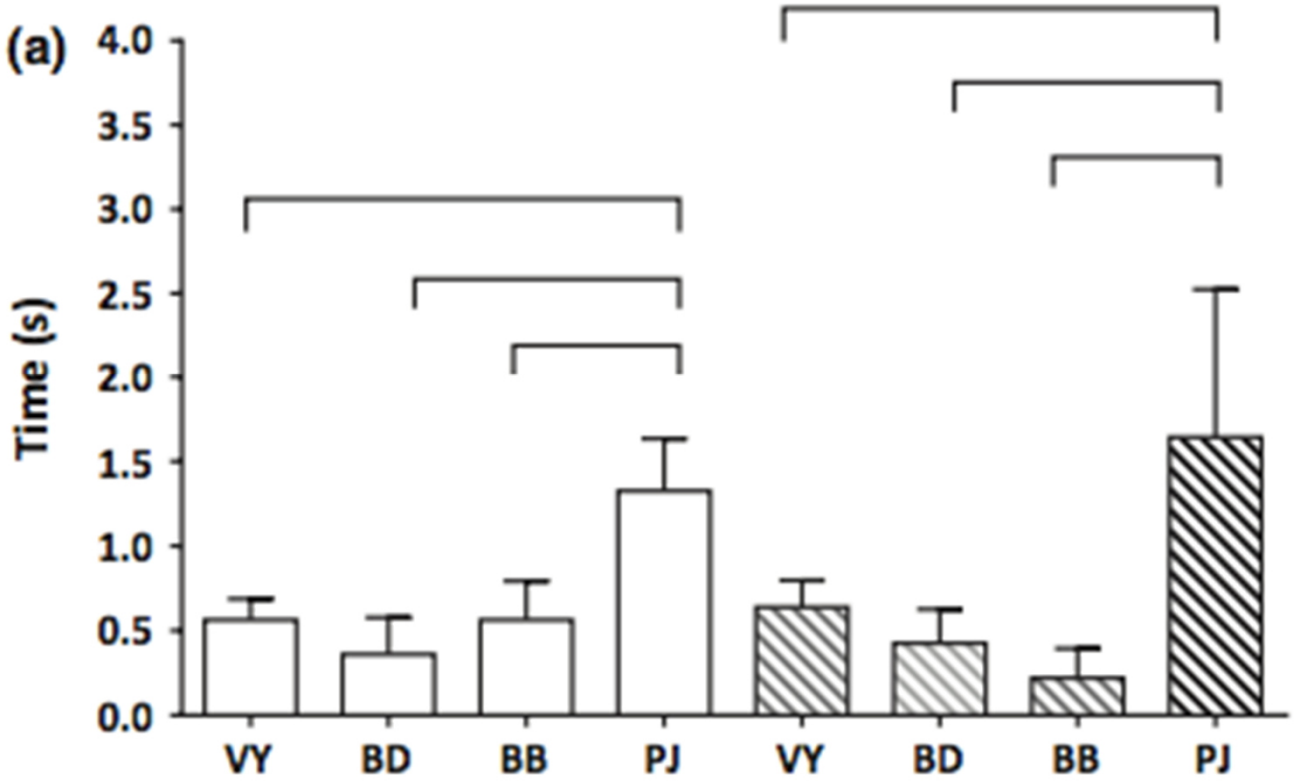
Anaesthesia 2017, 72, 749–754 doi:10.11

Original Article

Flow characteristics of Luer and non-Luer spinal needles*

R. S. Monteiro,[1] A. Pillai,[2] S. W. Choi,[3] D. Bogod[4] and S. M. Yentis[5]

Apparition LCR



Anaesthesia 2017, 72, 749–754 doi:10.11

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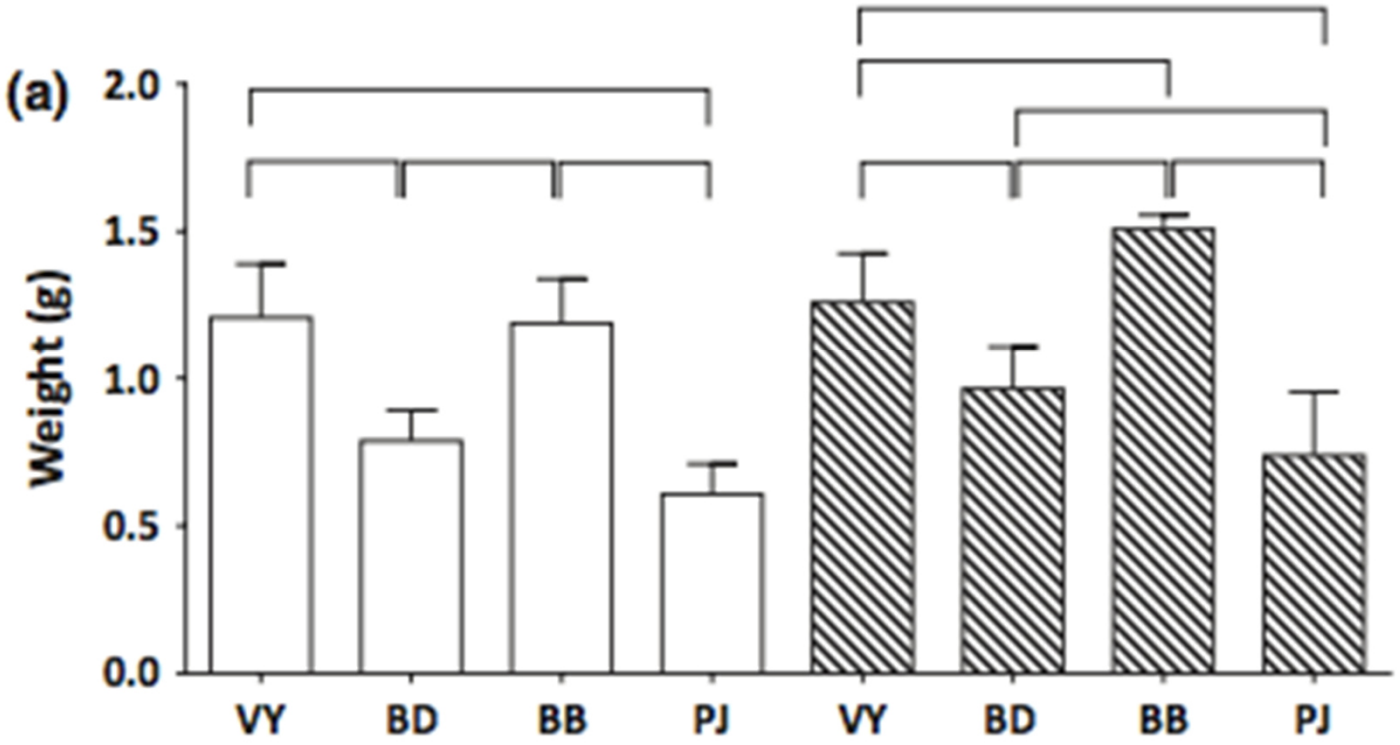
Volume drainé
Sur 120 sec



Smiths Medical non Luer spinal

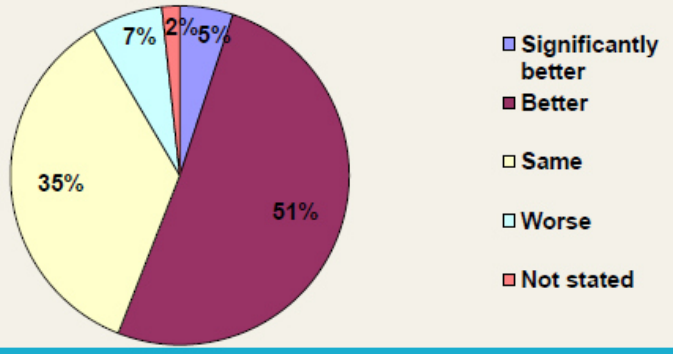
Obstetric Anaesthesia 2014
22-23 May 2014, The Convention Centre
DUBLIN

K Bosworth, P Prasad - Department of Anaesthetics, George Eliot NHS Trust

Results

Question	Yes (%)	No (%)	N/A (%)
Was dural puncture easily felt?	66	34	-
Was it easy to remove the trocar?	100	0	-
Was CSF seen in the needle hub?	100	0	-
Was CSF easy to aspirate?	98	2	-
Was the trocar easy to reinsert?	76	0	24
Were there any connection problems?	5	95	-
Was there any unwanted needle movement?	0	100	-
Any CSF leakage?	0	100	-
Were there any disconnection problems?	2	93	5
Did the needle bend?	2	98	-
Was there an adequate block?	95	5	-
Did the spinal fail due to the needle?	0	100	-

Overall Satisfaction



Comments

Positive	Negative
Easier to connect syringe	Difficulty feeling dural puncture
Less leaking	Needle feels flimsy

Surety® connectors in the NHS

NHS Improvement

From December 2017 the brand owner of Surety® will no longer manufacture or supply these devices to the NHS or their partners. NHS trusts need to review all transition plans and compliance to previous alerts.

Current situation	Current Range of Devices	Considerations	2018 (Q1)
Group 1	a) Surety® for selected procedures b) Luer for others	a) Surety® withdrawal b) Availability of NRFit™ c) Prioritising	NRFit™
Group 2	Luer for all procedures	a) Availability of NRFit™ b) Prioritising	NRFit™
Group 3	Surety® for all procedures	a) Surety® withdrawal b) Availability of NRFit™ c) Prioritising d) Balancing risk (Luer)	NRFit™

Anaesth Crit Care Pain Med 36 (2017) 253–258

SFAR
Société Française d'Anesthésie et de Réanimation

Preventing administration route errors chiefly involves active checking of the injection site and of the entire line before the injection. Passive measures consist of labeling the administration routes (using colors specific of each route), absence of hubs and connectors on regional anesthesia catheters and lines, and physical systems designed to minimize errors (error-reduction devices that use different connectors depending on the route of administration). Unfortunately, these systems were not yet commercially available in France at the time of this writing. An international standard (ISO TC210 JWG4 "Small Bore Connectors") is being developed under the aegis of the Food and Drug Administration (FDA) and Association for the Advancement of Medical Instrumentation (AAMI), in connection with the French Standards

SFAR
Société Française d'Anesthésie et de Réanimation

EUROPHARMAT

SFPC
Société française de pharmacie clinique

Date : Septembre 2017

Nouvelle connectique NRFit™ : sécurité patient améliorée en anesthésie locorégionale

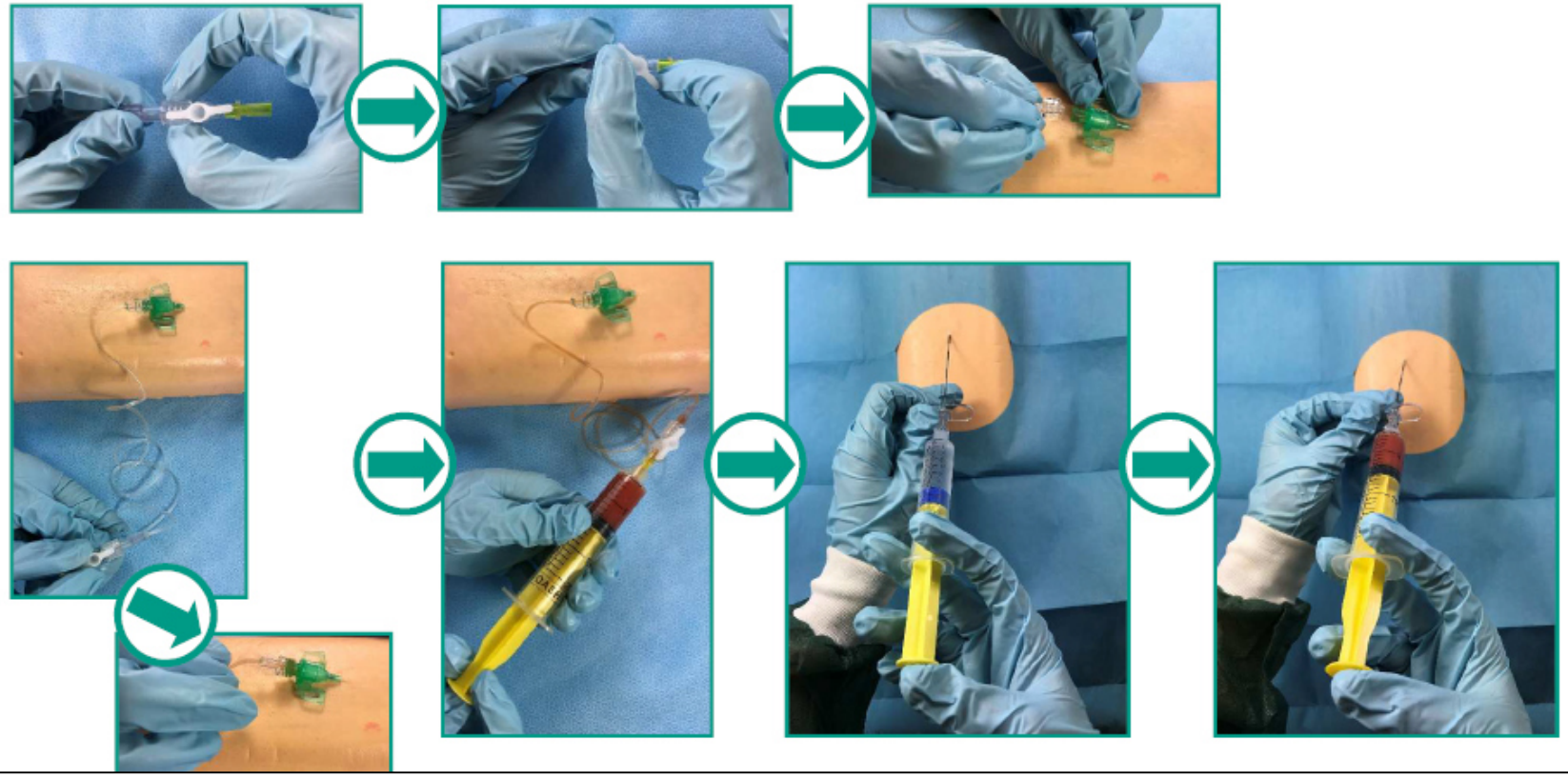
Dans l'attente de préconisations par les autorités, la SFAR, la SFPC et Europharmat recommandent conjointement l'utilisation de ces dispositifs qui améliorent la sécurité des patients. Nous vous sollicitons donc pour intégrer dès à présent leur déploiement dans votre démarche d'amélioration continue de la qualité et de la sécurité des soins. Ce changement de pratiques nécessite d'établir et de mettre en œuvre, avec tous les services concernés, un plan d'actions global de l'achat à l'emploi du dispositif médical. La multiplicité des professionnels

E	**ECHANGE AVEC LE FOURNISSEUR**	- Identifier les fabricants du domaine - Questionner les fabricants sur le changement de ces DM en listant les DM concernés - Utilisez les nouveaux raccords NR-FIT avec tous les produits concernés - Tenez compte des délais nécessaires à la transition en fonction de votre stock
T	**TRANSMISSION de COMPETENCES**	- Former l'équipe de la pharmacie au changement de DM en communiquant sur l'importance du changement pour améliorer la sécurité du patient - Expliquer ce que changeront les nouveaux dispositifs et montrer comment ils seront raccordés (simulation) - Compléter, le cas échéant, par une formation assurée par le(s) fabricant(s)
A	**APPRENTISSAGE**	- Assurer une formation spécifique destinée aux personnels de la pharmacotechnie - Assurer la formation du personnel assurant la continuité pharmaceutique
P	**PROCESSUS**	- Développer des mécanismes de communication entre les médecins, les infirmiers et la pharmacie afin d'identifier les patients concernés par les actes - Participer activement à l'équipe de transition pluridisciplinaire mise en place par la CoMéDiMS afin d'inclure les nouveaux raccords dans les procédures et protocoles actuels - Évaluer et mettre à jour les procédés et les protocoles de livraison et de préparation des médicaments afin d'y incorporer les nouveaux dispositifs NR FIT - Identifier l'impact du changement en matière de stockage et séparer les gammes en s'assurant d'un étiquetage différencié - Évaluer l'espace de stockage et le flux de travail pour la gamme - Sécuriser les libellés des dispositifs concernés dans le livret thérapeutique - Etablir un support d'information à destination des utilisateurs et/ou des patients
E	**EVALUATION**	- Evaluation des différentes mesures mises en œuvre : la formation, la compréhension du support, la communication …

Tout n’est pas résolu: Jonction entre les 2 normes (exemple blood patch), filtre, manomètre, transfert dans une autre structure

Epidural Filter

Procedure NRFit blood patch kit



Conclusions

Nouvelle norme mais pas d'obligation à ce jour

Matériel disponible en UK, USA

Evite les erreurs de connexion mais pas les autres

évaluer les dispositifs (performance variable +++)

Renforce la sécurité des codes couleurs