NEONATOLOGY

Infection control

aim at ZERO

Vygon's initiative to
fight infections in NICUs

VYGON

Value Life

Neonatal infections, a worldwide challenge

1 million neonatal deaths are attributed to infection[1]

The additional cost for an infection in the NICU is 11750 €[2]

The infant will stay an additional 24 days in hospital[3]

Infection outcomes include refusal to feed, increased[4, 5, 6, 7] respiratory support, apnea and can lead to death

Infection has a significant influence on neurodevelopment[8]

"For every 1°C (1.7°F) decrease in admission temperature the odds of late onset sepsis is increased by 11% and the risk of death increased by 28%."[9]

The "number of unsuccessful insertion attempts is the biggest predictor of complications" in a PICC line[10]

aim at ZERO, a Vygon initiative

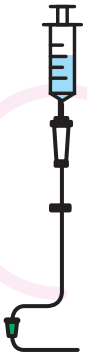
aim at ZERO is a new campaign designed by Vygon to help hospitals win the fight against Hospital-Acquired Infections in Neonatal Intensive Care Units.
This initiative provides infection reduction solutions at key stages of IV therapy: during the preparation phase, during the insertion of the line and during the infusion.
Each product solution has been specially designed for the neonates, based on international recommendations and is supported by both clinical studies and data.

Preparation

- **VYSET**
  Umbilical & PICC placement packs
- **neohelp**
  Heat loss prevention suit

Insertion

- **expert UVC**
  Single and double lumen antimicrobial umbilical catheters
- **microsite**
  Micro Seldinger Technique insertion kit



Infusion

- **premistar**
  1 Fr antimicrobial catheter
- **bionector**
  Neutral Displacement Needleless Connector

Preparation

VYSET placement pack - Umbilical & PICC placement

The VYSET placement packs ensure maximum barrier precautions during the patient's preparation.

All required components are contained in one single, sterile unit in order to:

- improve aseptic control,
- reduce preparation time & simplify traceability,
- improve stock management & reduce waste,
- support a standardised procedure for insertion.

The VYSET umbilical & PICC placement packs contain components specifically designed for newborns:

- Fenestrated transparent peelable drape, which allows constant visibility of the baby and avoids the dislocation of the catheter after placement
- Soft swabs and umbilical tape to preserve the fragile skin of the newborns
- Neonatal tourniquet designed to reduce skin trauma

International recommendation[11]

"Use of a standardised supply kit that contains all necessary components for CVCs is an element of performance"

National Association of Neonatal Nurses Guidelines – 2015

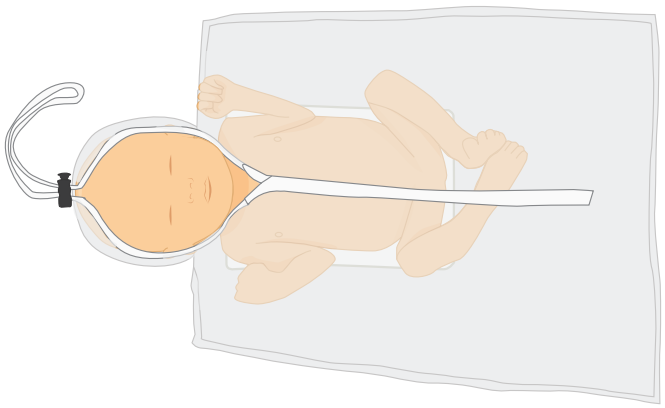
Preparation

neo**help**™ - Heat Loss prevention suit

neo**help**™ is a polyethylene occlusive suit to prevent hypothermia of newborns. Heat loss due to environmental factors (evaporation, convection, conduction and radiation) is considerably reduced.

neo**help**™ consists of:

- a double layer of polyethylene which creates a greenhouse effect and protects from drafts. The heat loss through radiation, convection and evaporation is reduced,
- a fully adjustable hood which limits the dispersion of heat from the head and doesn't let air in,
- a preformed foam cushion, which helps to keep the baby's airway open and provides a barrier against heat loss by conduction, while maintaining his position and offering comfort to the baby.



According to UNICEF, such interventions can help reduce neonatal mortality or morbidity **by 18-42%**[6]

Clinical performances[12,13]

"Meta-analysis of […] studies found that plastic wraps (polyurethane or polyethylene bag) were statistically significantly more effective than routine care in reducing heat losses in infants aged < 28 weeks' of gestation. Stockinette caps were not effective in reducing heat loss in infants".

"The transparency of bags makes it easier for caregivers to observe and manage the infant with minimal disruption of the wrap."

International recommendations[14,15]

"A more effective method of keeping the preterm babies (especially < 28 weeks) warm is to cover the head and body of the baby (apart from the face) with plastic wrapping, without drying the baby before hand, and then to place the baby so covered under radiant heat."

World Health Organization; 2012 & European Resus citation Council Guideline - 2010

"The transport incubator used to limit heat loss can be cumbersome and difficult to obtain. It may be «replaced» by a stockinette cap and a transparent polyethylene bag wrapping whilst the baby is still wet. This greatly reduces the risk of hypothermia."

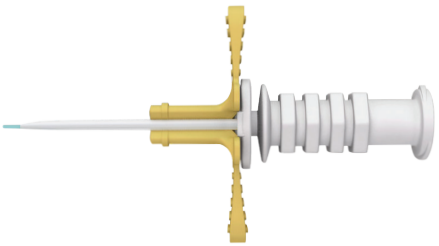
French Society of Anesthesia and Intensive Care - 2009

Insertion

micro**site** - Micro Seldinger Technique (MST) insertion kit

micro**site** is a MST introducer kit specially designed for premature babies and infants with poor venous access :
- it enhances successful placement & safety
- it makes it easier to puncture veins difficult to access,
- it reduces the risk of injuring or tearing the vein

micro**site** is used for the placement of 1Fr & 2Fr Central Venous Catheters. It contains:
- a 24G puncture needle
- a symmetrical Nitinol guidewire
- a sheath dilator enabling a smooth transition



Clinical performances[17]

"The modified Seldinger technique allows insertion of the PICC via smaller peripheral veins while decreasing venous trauma and enhancing the rate of successful placement"

"Modified Seldinger technique allows much more movement of the patients without danger of dislocating the MI [Micro Introducer]"

International recommendations[18, 19]

"Advantages of MST include increased success rates of PICC insertion, less venous trauma and decreased insertion complications such as nerve injury and inadvertent arterial puncture".

The Journal of the Association for Vascular Access - 2009

"Using an MST (also referred to as micropuncture) allows a smaller introducer to be used".

PICCs guidelines - NANN - 2007

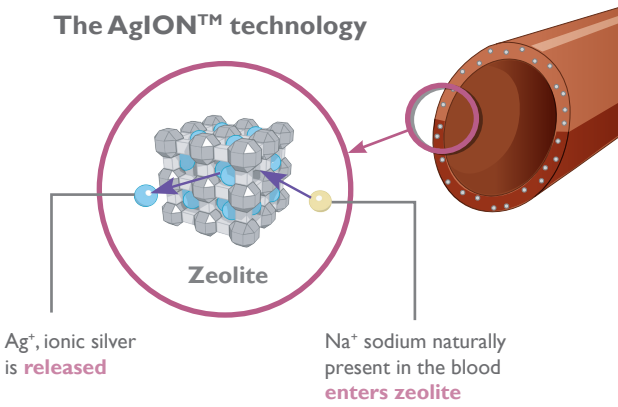
Insertion

expert umbilical catheter - Single & double-lumen antimicrobial umbilical catheters

The **expert** umbilical catheter is the only umbilical catheter with an integrated antimicrobial technology, called AgION™, to fight against CRBSI in NICUs.

The AgION™ technology is made of ionic silver bound into zeolite, a bio-inert ceramic integrated in the catheter material[20].
When the catheter comes in contact with blood the zeolite naturally releases the Ag^+ ions and replaces them by Na^+ ions present in the blood. It is a pure ionic exchange.

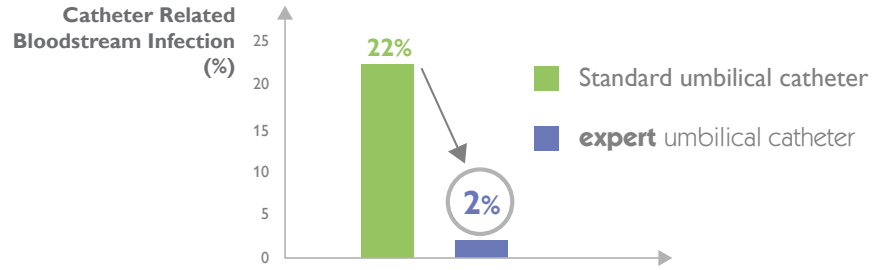
Ionic silver is a highly efficient antimicrobial technology with[20, 21]:
- a broad spectrum of action on $Gram^+$, $Gram^-$ and fungi
- a low toxicity
- a tri-modal action



Clinical performances [22]

"Reduction of catheter-related bloodstream infections in preterm infants by the use of catheters with the AgION antimicrobial system"
Carregi University Hospital of Florence - 2013

- **Results - 86 preterm infants**



"Preterm with expert UVC had shorter hospital stay and lower case fatality rate".

"There was no case of intolerance to the AgION catheters and none of these catheters had to be removed due to a local skin infection. Moreover, none of the patients in the AgION catheter group showed signs of silver toxicity."

International recommendation[23]

"II. Special approaches for preventing CLABSI […]
4.Use silver zeolite–impregnated umbilical catheters in preterm infants (in countries where it is approved for use in children)".

Society for Healthcare Epidemiology of America - 2014

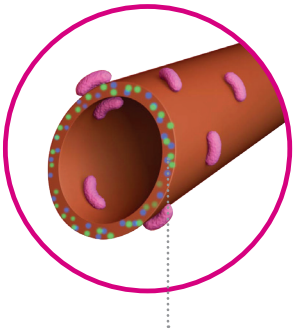
Insertion

premi**star** - 1Fr antimicrobial catheter

premi**star** is the only impregnated 1Fr PICC, especially developed to fight against CBRSI in NICUs.

The Star Technology is the innovative combination of two active substances, Rifampicin and Miconazole, chosen for their synergic properties:

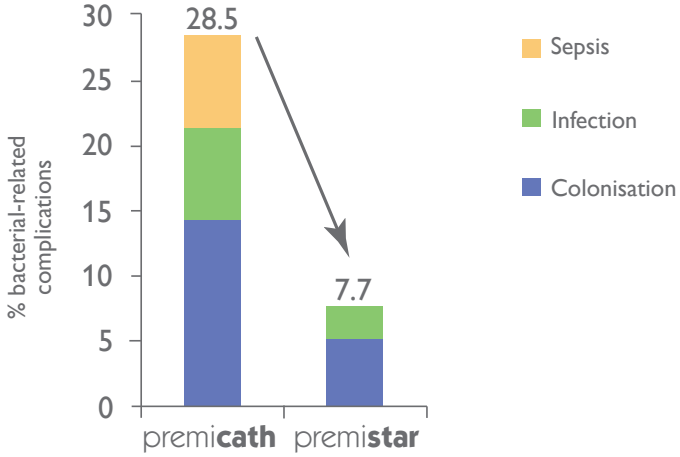
- overlapping spectrum of efficacy on Gram$^+$, Gram$^-$ & fungi[24, 25],
- multiple level of action on the bacteria,
- low risk of bacterial resistance development[25].



Clinical performances[26]

"Preventing catheter-related infections in neonates- PECTIN-trial "
Ludwig Maximilians University in Munich & Central Teaching Hospital of Bozen - 2013

- **Results - 83 preterm infants**



"The complications; colonisation, infection & sepsis, were divided by 4 thanks to the use of premi**star** *and no sepsis occurred among the preterms".*

"Maximal concentrations of Rifampicin or Miconazole resulting from the insertion of a polyurethane catheter loaded with these antibiotics are [..] far below the concentrations resulting from a systemic therapy with the same antimicrobial agents. Even in the worst case, the danger of selecting resistant strains seems remote because the systemic drug levels [released from the catheter] are magnitudes of order below subinhibitory concentrations"[25]

International recommendations[27,28]

"The most promising options for reducing catheter-related bloodstream infections are […] antibiotic-impregnated central venous catheters"

Current Opinion in Infectious diseases, 2008

"Certain catheters and cuffs that are coated or impregnated with antimicrobial or antiseptic agents can decrease the risk for CRBSI and potentially decrease hospital costs associated with treating CRBSIs"

CDC guideline for the Prevention of Intravascular Catheter-Related Infections - 2011

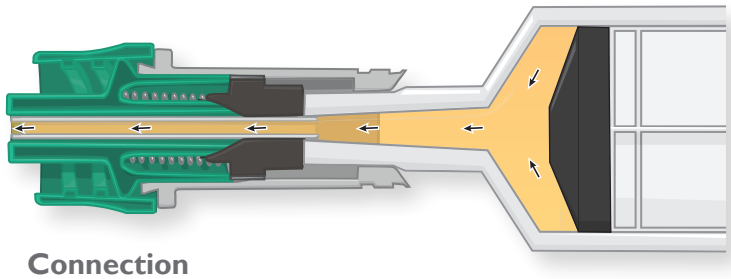
Infusion

bionector - Neutral Displacement Needleless Connector

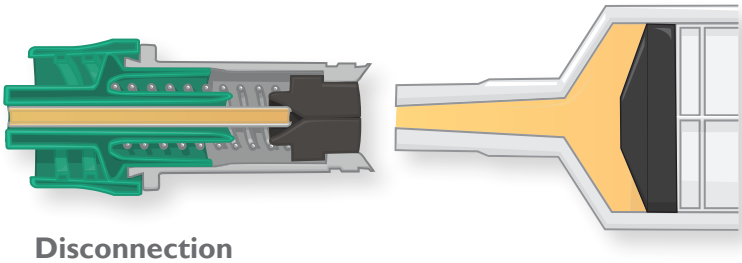
bionector is a neutral displacement needleless connector for use with all IV equipement. When connected you can infuse, inject, sample and change your IV tubing without opening the IV circuit to the atmosphere.
bionector is a one-piece device with:
- a protective split septum enabling a direct fluid pathway
- an easily cleanable membrane
- a neutral fluid displacement

bionector is compatible with MRI & High Pressure.

One of the smallest dead volumes on the market **0.03 ml**



Connection



Disconnection

Clinical performances[29, 30]

• **Effective disinfection of the membrane**
Tests show that microorganisms don't penetrate into the sterile line when a deliberately contaminated **bionector** is swabbed with a sterile disinfectant.

• **A truly closed system**
When sterile **bionector** are immersed in a high concentration suspension (>108cfu/ml) of Brevundimonas diminuta, tests show that there is no evidence of bacteria entering the sterile line. No growth occurred after 48 hours incubation at 30°C ± 2°C in 500ml of sterile saline travelling through sterile **bionector**. Under those rigorous test conditions we can conclude that **bionector** really is a closed system.

International recommendations[28]

"When needleless systems are used, a split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves [197–200]. Category II"
"Use of needleless connectors […] appear to be effective in reducing connector colonization"

CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections - 2011

Technical features

Preparation	VYSET **placement pack UC**	80199.695		
	VYSET **placement pack PICC**	80199.519		
	neo**help** **SMALL**	37.09.14	< 1KG L. 38 x W. 30 cm	
	neo**help** **MEDIUM**	37.09.15	1KG - 2.5KG L. 44 x W. 38 cm	
	neo**help** **LARGE**	37.09.16	> 2.5KG L. 50 x W. 38 cm	
Insertion	micro**site**	1147.02	Insertion of 1Fr & 2 Fr catheters	Puncture needle 24G Sheath dilator 20G
	2.5 Fr Single-lumen **expert** UC 30 cm	8270.230	Flow rate 2.2 ml/min Priming vol 0.1ml	Ext Ø 0.8 mm Int Ø 0.5 mm
	3.5 Fr Single-lumen **expert** UC 40 cm	8270.340	Flow rate 12 ml/min Priming vol 0.3ml	Ext Ø 1.2 mm Int Ø 0.8 mm
	4 Fr Single-lumen **expert** UC 40 cm	8270.440	Flow rate 12 ml/min Priming vol 0.3ml	Ext Ø 1.5 mm Int Ø 0.8 mm
	5 Fr Single-lumen **expert** UC 40cm	8270.540	Flow rate 27 ml/min Priming vol 0.4ml	Ext Ø 1.7 mm Int Ø 1 mm
	8 Fr Single-lumen **expert** UC 40cm	8270.840	Flow rate 109 ml/min Priming vol 0.8ml	Ext Ø 2.5 mm Int Ø 1.5 mm
	4 Fr Double-lumen **expert** UC 20cm	8272.420	Flow rate 13.8 ml/min Priming vol 0.3ml	Ext Ø 1.5 mm Int Ø 0.5 mm
	4 Fr Double-lumen **expert** UC 40cm	8272.440	Flow rate 8.1 ml/min Priming vol 0.4ml	Ext Ø 1.5 mm Int Ø 0.5 mm
	5 Fr Double-lumen **expert** UC 40cm	8272.540	Flow rate 6.4ml/min Priming vol 0.3ml	Ext Ø 1.7 mm Int Ø 0.7 mm
	1 Fr premi**star** with breakaway needle 20cm without stylet	6261.20	Flow rate 0.7 ml/min Priming volume 0.09ml	Ext Ø 0.35 mm
	1 Fr premi**star** with breakaway needle 20cm with stylet	6261.203		
	1 Fr premi**star** without introducer 20cm with stylet	6261.206		
	1 Fr premi**star** without introducer 30cm with stylet	6261.306	Flow rate 0.6 ml/min Priming volume 0.11ml	
Infusion	**bionector**	896.01 Supplied in rigid non-touched applicator		Flow rate 105 ml/min Priming volume 0.03ml
		896.03 Supplied in soft blister pack		

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