



NEONATOLOGY
Infection control



aim at ZERO

Vygon's initiative to
fight infections in NICUs



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

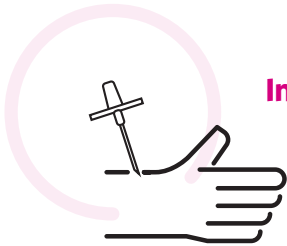


VYSET

Umbilical & PICC placement packs

neohelp

Heat loss prevention suit



Insertion



expert UVC

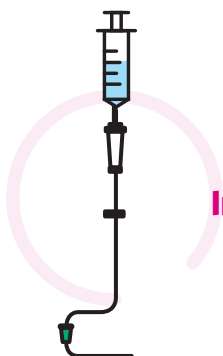
Single and double lumen antimicrobial umbilical catheters

microsite

Micro Seldinger Technique insertion kit

premiSTAR

1 Fr antimicrobial catheter



Infusion



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

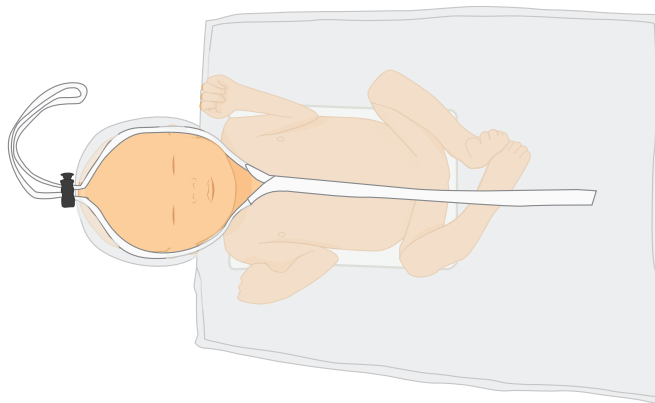
Preparation

neohelp™ - Heat Loss prevention suit

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

neohelp™ consists of:

- a transparent double-layer of polyethylene which limits heat loss by radiation, convection and evaporation and enables the visualisation of the skin color and the baby's breathing movement
- an adjustable hood which limits the dispersion of heat from the head and doesn't let air in,
- a pre-shaped foam cushion, which helps maintain an open airway (by raising the shoulders level) and provides a barrier against heat loss by conduction.



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 Resuscitation 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

microsite - Micro Seldinger Technique (MST) insertion kit

microsite 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

microsite 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

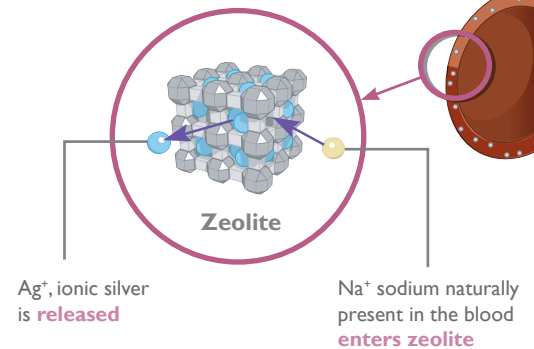
The **expert** umbilical catheter is the only umbilical catheter with an integrated antimicrobial technology, called AgION™, to fight against CRBSI in NICUs.

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

The AgION™ technology

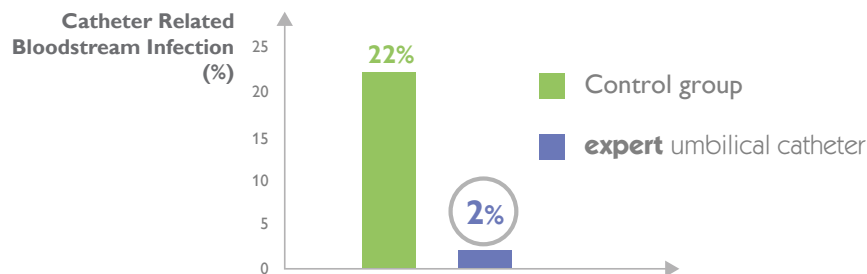


Clinical performances ⁽²²⁾

“Reduction of catheter-related bloodstream infections in preterm infants by the use of catheters with the AgION antimicrobial system”

Bertini G et al, Early Hum Dev (2012)

• 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

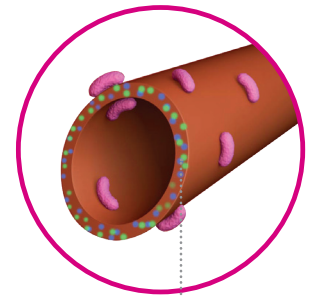
Insertion

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⁾.



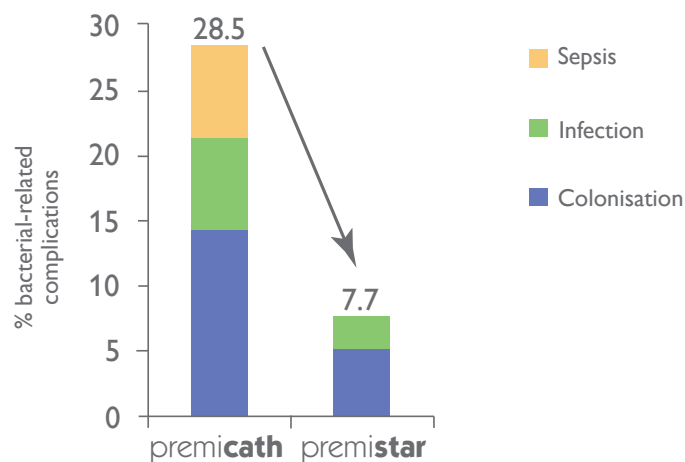
Miconazole
+
Rifampicin

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

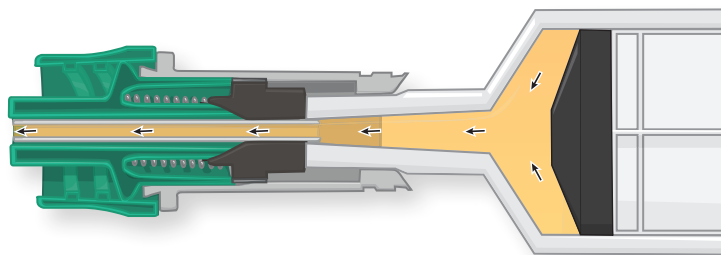
bionector is a neutral displacement needleless connector for use with all IV equipment. When connected you can infuse, inject, sample and change your IV tubing without opening the IV circuit to the atmosphere.

bionector is a one-piece device with:

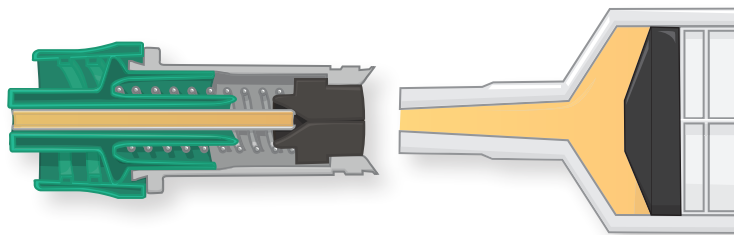
- a protective split septum enabling a direct fluid pathway
- an easily cleanable membrane
- a neutral fluid displacement

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 | page 4 | VYSET placement pack UC | 80199.695 | | |
| | | VYSET placement pack PICC | 80199.519 | | |
| | page 5 | neohelp SMALL | 37.09.14 | < 1KG L. 38 x W. 30 cm | |
| | | neohelp MEDIUM | 37.09.15 | 1KG - 2.5KG L. 44 x W. 38 cm | |
| | | neohelp LARGE | 37.09.16 | > 2.5KG L. 50 x W. 38 cm | |
| Insertion | page 6 | microsite | 1147.02 | Insertion of 1Fr & 2 Fr catheters | Puncture needle 24G Sheath dilator 20G |
| | page 7 | 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 |
| | page 8 | 1 Fr premistar 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 premistar with breakaway needle 20cm with stylet | 6261.203 | | |
| | | 1 Fr premistar without introducer 20cm with stylet | 6261.206 | | |
| | | 1 Fr premistar without introducer 30cm with stylet | 6261.306 | Flow rate 0.6 ml/min Priming volume 0.11ml | |
| Infusion | page 9 | 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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 OBSTETRICS NEONATOLOGY ENTERAL

For further information, please contact: questions@vygon.com

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