

stkrk

Neurovascular

AXS Infinity LS™ Long Sheath

⚡ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING: Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found call a Sterykr Neurosurveur.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, disposal of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The AXS Infinity LS Long Sheath is a single lumen, flexible, variable stiffness long sheath. It has a radiopaque marker band on the distal end and a Luer lock at proximal end. The AXS Infinity LS Long Sheath is compatible with ⚡ or smaller introducer catheters.

Contenu

- Une (1) AXS Infinity LS Long Sheath (GÉN-10476-70, GÉN-10476-80, ou GÉN-10476-90)
- Une (1) hémostatique avec extension tubulaire et un long dilateur. Dimensions de la gaine longue AXS Infinity LS sont indiquées sur l'étiquette du dispositif.

UTILISATION/INDICATIONS

The gaine longue AXS Infinity LS est indiquée pour l'introduction de dispositifs interventionnels dans le système vasculaire périphérique, coronaire et intracranénel.

CONTRA-INDICATIONS

Aucune contre-indication connue.

MISES EN GARDE

Une fois à l'intérieur du système vasculaire, la gaine longue AXS Infinity LS doit être manipulée sous radioscopie de haute qualité. Ne pas avancer ni rétracter la gaine longue AXS Infinity LS si une résistance se fait sentir dans le patient; déterminer la cause de la résistance avant de pousser.

PRÉCAUTIONS

- Ne pas utiliser des dispositifs pliés, endommagés ou courvés.
- Utiliser la gaine longue AXS Infinity LS avant la date limite d'utilisation spécifiée sur l'emballage.
- Une exposition à des températures supérieures à 54°C (130°F) peut affecter la performance du dispositif. Ne pas laisser le produit à l'autoclave à température supérieures à 54°C (130°F).
- La torsion ou le déplacement de l'une des parties peut endommager ce dernier ou causer une lésion vasculaire.
- Maintenir une perfusion continue de solution de rinçage appropriée.
- En cas de diminution du débit dans le dispositif, ne pas tenter de déloger la lumière par aspiration. Retirer le dispositif et le remplacer par un nouveau.

CONTENU

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INTENDED USE/INDICATIONS FOR USE

The AXS Infinity LS Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronar, and intracranial vasculature.

CONTRAINDICATIONS

There are no known contraindications.

WARNINGS

When the AXS Infinity LS Long Sheath is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the AXS Infinity LS Long Sheath if resistance is met during manipulation; determine the cause of the resistance before proceeding.

PRECAUTIONS

- Do not use bent, kinked, damaged, or open devices.
- Use the AXS Infinity LS Long Sheath prior to the "Use By" date specified on the package.
- Exposure to temperatures above 54°C (130°F) may damage device. Do not autoclave.
- Torsion or moving the device or any part of it may result in damage to the vessel or device.
- Maintain a constant infusion of appropriate flush solution.
- If through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

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- One (1) AXS Infinity LS Long Sheath (GÉN-10476-70, GÉN-10476-80, or GÉN-10476-90)
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FRANCAIS

AXS Infinity LS™

Gaine longue

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Attention: La legge federale americana, ce dispositif ne peut être vendu que sur prescription d'un médecin.

MISE EN GARDE

Contenu STÉRILISÉ à l'oxyde d'éthylène (EO). Ne pas utiliser si l'emballage stérile est endommagé. Si le produit est endommagé, contacter le représentant de Sterykr Neurovascular.

A usage unique. Ne pas réutiliser, retraiter ou restériliser. La réutilisation, le retraitement ou la reesterilisation de dispositifs interventionnels peut compromettre l'intégrité structurelle et/ou le fonctionnement. Le réusage, la réesterilisation, le traitement ou la reesterilisation peut également créer un risque de contamination du dispositif et/ou causer une infection ou une contamination croisée, mais n'est pas limitée à la transmission de maladies infectieuses d'un patient à un autre. La contamination du dispositif peut causer des blessures, des maladies ou le décès du patient.

Après utilisation, éliminer le produit et l'emballage conformément aux règlements de l'établissement, de l'administration ou du gouvernement local.

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DESCRIPTION DU DISPOSITIF

La gaine longue AXS Infinity LS est une gaine longue à lumière unique, flexible et à rigidité variable. Elle comporte un ruban radiopaque sur l'extrémité distale et une embase Luer à l'extrémité proximale. Le corps de la gaine longue AXS Infinity LS est doté d'un revêtement lubrifiant pour réduire la friction pendant l'utilisation. La lumière interne de la gaine longue AXS Infinity LS est compatible avec des cathéters interventionnels de ⚡ à 9 mm.

Contenu

- Une (1) gaine longue AXS Infinity LS (GÉN-10476-70, GÉN-10476-80 ou GÉN-10476-90)
- Une (1) hémostatique avec tubulure d'extension et un dilateur long. Les dimensions de la gaine longue AXS Infinity LS sont spécifiées sur l'étiquette du dispositif.

UTILISATION/INDICATIONS

La gaine longue AXS Infinity LS est indiquée pour l'introduction de dispositifs interventionnels dans le système vasculaire périphérique, coronaire et intracranénel.

CONTRA-INDICATIONS

Aucune contre-indication connue.

MISES EN GARDE

Une fois à l'intérieur du système vasculaire, la gaine longue AXS Infinity LS doit être manipulée sous radioscopie de haute qualité. Ne pas avancer ni rétracter la gaine longue AXS Infinity LS si une résistance se fait sentir dans le patient; déterminer la cause de la résistance avant de pousser.

PRÉCAUTIONS

- Ne pas utiliser des dispositifs pliés, endommagés ou courvés.
- Utiliser la gaine longue AXS Infinity LS avant la date limite d'utilisation spécifiée sur l'emballage.
- Une exposition à des températures supérieures à 54°C (130°F) peut affecter la performance du dispositif. Ne pas laisser le produit à l'autoclave à température supérieures à 54°C (130°F).
- La torsion ou le déplacement de l'une des parties peut endommager ce dernier ou causer une lésion vasculaire.
- Maintenir une perfusion continue de solution de rinçage appropriée.
- En cas de diminution du débit dans le dispositif, ne pas tenter de déloger la lumière par aspiration. Retirer le dispositif et le remplacer par un nouveau.

CONTENU

- Une (1) gaine longue AXS Infinity LS (GÉN-10476-70, GÉN-10476-80 ou GÉN-10476-90)
- Une (1) hémostatique avec tubulure de prolongement et un dilateur long. Les dimensions de la gaine longue AXS Infinity LS sont indiquées sur l'étiquette du produit.

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