

Neo Bag Grip®

FR	Manuel d'instructions
EN	Instruction Manual

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Prolinx GmbH
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[Utilisation Prévue]

Ce sac d'extraction à usage unique est conçu pour la récupération de tissus infectieux ou suspect ainsi que des calculs durant des procédures endoscopiques.



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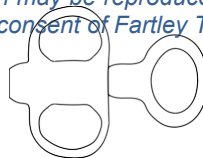
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Product Code No.	Poignée	Volume (mL)
40350006	Yes	200
40350007	Yes	500
40350008	Yes	800
40350009	Yes	1200
40350010	Yes	1500
40350011	No	200
40350012	No	400
40350013	No	800
40350014	No	800



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【AVERTISSEMENTS ET PRECAUTIONS】

Les procédures endoscopique doivent être uniquement pratiquées par des personnes ayant reçus les formations et connaissant les techniques adéquates. Consulter la littérature médicale relative aux techniques, complications et danger de certaines procédures chirurgicales.

- L'utilisation du sac d'extraction nécessite un trocart de 10mm minimum.
- Le Sac d'extraction est emballé dans une gaine et ne doit pas être déployé avant l'insertion. Un déploiement prématuré du sac de sa gaine pourrait endommager le sac et le rendre inopérant. Le sac ne peut pas être remballé.
- Le sac d'extraction doit être inséré dans le trocart encore emballé.
- Fartley n'a pas conçu ce dispositif pour être re-stérilisé ou réutilisé et ne peut donc pas confirmer que le retraitement peut nettoyer et-ou stériliser et/ou maintenir l'intégrité structurelle du dispositif afin d'assurer la sécurité de l'utilisateur et/ou du patient.
- Ce dispositif medical à usage unique n'est pas destiné à être réutilisé. N'importe quelle institution, praticien, ou le tiers qui retraite, remettent à neuf, fabriquent à nouveau, restérilisent, et-ou réutilisent ce dispositif médical à usage unique doit porter l'entière responsabilité de sa sécurité et de son efficacité.

【Mode d'emploi】

- 1) En suivant les techniques recommandées, préparer le patient pour la procédure endoscopique chirurgicale.
- 2) En utilisant des techniques stériles, retirer le sac d'extraction de son emballage.
- 3) Pour insérer le sac d'extraction (ne pas activer la poignée) : Attraper la tige et insérer le sac d'extraction à travers un trocart de 10mm minimum.
- 4) Déployer et ouvrir le sac
- 5) Attraper les tissus devant être extraits et les placer dans le sac.
- 6) Fermer le sac en tirant le fil de la poignée vers l'arrière. Pour garder le sac



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fermé lors du retrait une tension doit être maintenue sur le fil de la poignée durant la procédure de retrait.

- 1) Retirer le sac avec les tissus.

【Mise en garde】

- ✓ La stérilité est garantie à moins que le sac ou la pochette stérile ne soit endommagés.
- ✓ Dispositif jetable à usage unique..
- ✓ Stérilisé par EtO.
- ✓ Ne pas réutiliser ni re-stériliser.
- ✓ Vérifiez la date de production et la date d'expiration imprimée sur la poche stérile.
- ✓ Ne pas stocker à la lumière directe du soleil, à des températures extrêmes ou dans une humidité élevée.
- ✓ La réutilisation peut causer une infection croisée.



【MISE AU REBUT DU PRODUIT】

Après utilisation, ce produit peut être potentiellement contaminé. Jeter le dispositif en accord avec les protocoles d'hygiène de l'établissement et les réglementations en vigueur.



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【Explication des symboles】

Symbol	Explication	Symbol	Explication
	Fabricant		Tenir à l'abri de la lumière du soleil
	Représentation autorisée dans la communauté Européene		Tenir à l'abri de l'humidité
	Date de Fabrication		Limite de température
	Date de péremption		Ne pas ré-utiliser
	N° de lot		Consulter la notice d'utilisation
	Stérilisé à l'Oxyde d'Ethylène		Attention
	Ne pas utiliser si l'emballage est endommagé		Référence
 0197	L'organisme notifié et le produit répondent aux exigences de base de MDD93 / 42 / EEC		

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【Intended Use】

Disposable Endoscopic Retrieval Bag is designed to assist in the retrieval of infectious or suspicious tissue and gall stones during endoscopic procedures.



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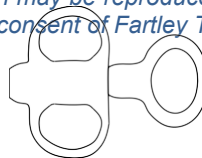
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【Warnings and Precautions】

Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to the performance of any surgical procedure.

- Use of the Endoscopic Retrieval Bag requires use of a 10mm or larger trocar sleeve.
- The Retrieval Bag is packed in a sheath and should not be deployed prior to insertion. Premature deployment of the pouch from the sheath may damage the pouch and render the device inoperative. The pouch cannot be repackaged.
- The Endoscopic Retrieval Bag must be inserted through the trocar sleeve as packaged.
- Fartley did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.
- This disposable medical device is not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses this disposable medical device must bear full responsibility for its safety and effectiveness.

【Directions for Use】

- 1) Following recommended technique, prepare the patient for the endoscopic surgical procedure.
- 2) Using sterile technique, remove the Retrieval Bag from its package.
- 3) To insert the Retrieval Bag (DO NOT ACTIVATE HANDLE): Grasp the shaft and insert the Retrieval Pouch sheath through a 10mm or larger trocar sleeve.
- 4) Deploy and open the pouch.
- 5) Grasp tissue to be removed and place into the pouch.



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- 1) Close the pouch by pulling back the handle spool. For the pouch to remain closed, tension must be maintained on the handle spool during the removal process.
- 2) Remove the pouch with tissue.

【Caution】

- ✓ Sterility is guaranteed unless the sterile pouch is damaged or seal is broken.
- ✓ Disposable device for single use.
- ✓ Sterilized by EO Sterilization.
- ✓ Do NOT re-use or re-sterile.
- ✓ Check the production and expiry date printed on the sterile pouch.
- ✓ Do not store in direct sunlight, at extreme temperature, or in high humidity.
- ✓ Re-use may cause cross-infection.



【Product Disposal】

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.



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[Symbol Explanation]

Symbol	Explanation	Symbol	Explanation
	Manufacturer		Keep away from sunlight
	Authorized representative in the European Community		Keep dry
	Date of manufacture		Temperature limit
	Use-by date		Do not re-use
	Batch code		Consult instructions for use
	Sterilized using ethylene oxide		Caution
	Do not use if package is damaged		Reference
	Notified Body, and product meet the basic requirements of MDD93/42/EEC		

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