Crow's Nest™ Biopsy Catchment System

Single Use Device for Collecting Dislodged
Tumor Cells After a Core Needle Biopsy

For In Vitro Diagnostic Use

INSTRUCTIONS FOR USE

Corramedical

One Biopsy, Many Answers

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INTRODUCTION

The Crow's Nest™ Biopsy Catchment System is a simple device for **collecting dislodged tumor cells** created after a core needle biopsy procedure.

It allows the user to create a **second specimen from each biopsy** – a liquid specimen stable at room temperature for five years – that's even better[1] for molecular testing than fixed tissue core from a paraffin block, because it hasn't been damaged by formalin or other tissue fixative.

The result of using the Crow's Nest is that dislodged cells that would normally be lost to medical waste are instead retained, and thereby available to be used in molecular testing (e.g. genomic sequencing) to the benefit of the patient. As a result, *any* patient who undergoes a core needle biopsy may have the chance to **receive the benefits of genomic sequencing** and other molecular testing, instead of just the 35% of patients who do so today.

It may alleviate the frustration of biopsy *tissue exhaustion* by **potentially eliminating instances of "QNS"** (quantity not sufficient) when molecular testing is requested.

Each Crow's Nest™ Biopsy Catchment System is provided pre-loaded with two liquid solutions in its inner chambers: (1) sterile medical grade 0.9% saline solution in its upper chamber – in the funnel interior of the proprietary closed-funnel top piece, and (2) a cell lysing and nucleic acid stabilization and preservation solution in the lower chamber – the 25 mL collection tube.

[1] Based on the widely accepted principal that DNA that hasn't been cross-linked and fragmented by formalin is a superior input material (substrate) for all molecular testing, especially genomic sequencing or Next Generation Sequencing (NGS).

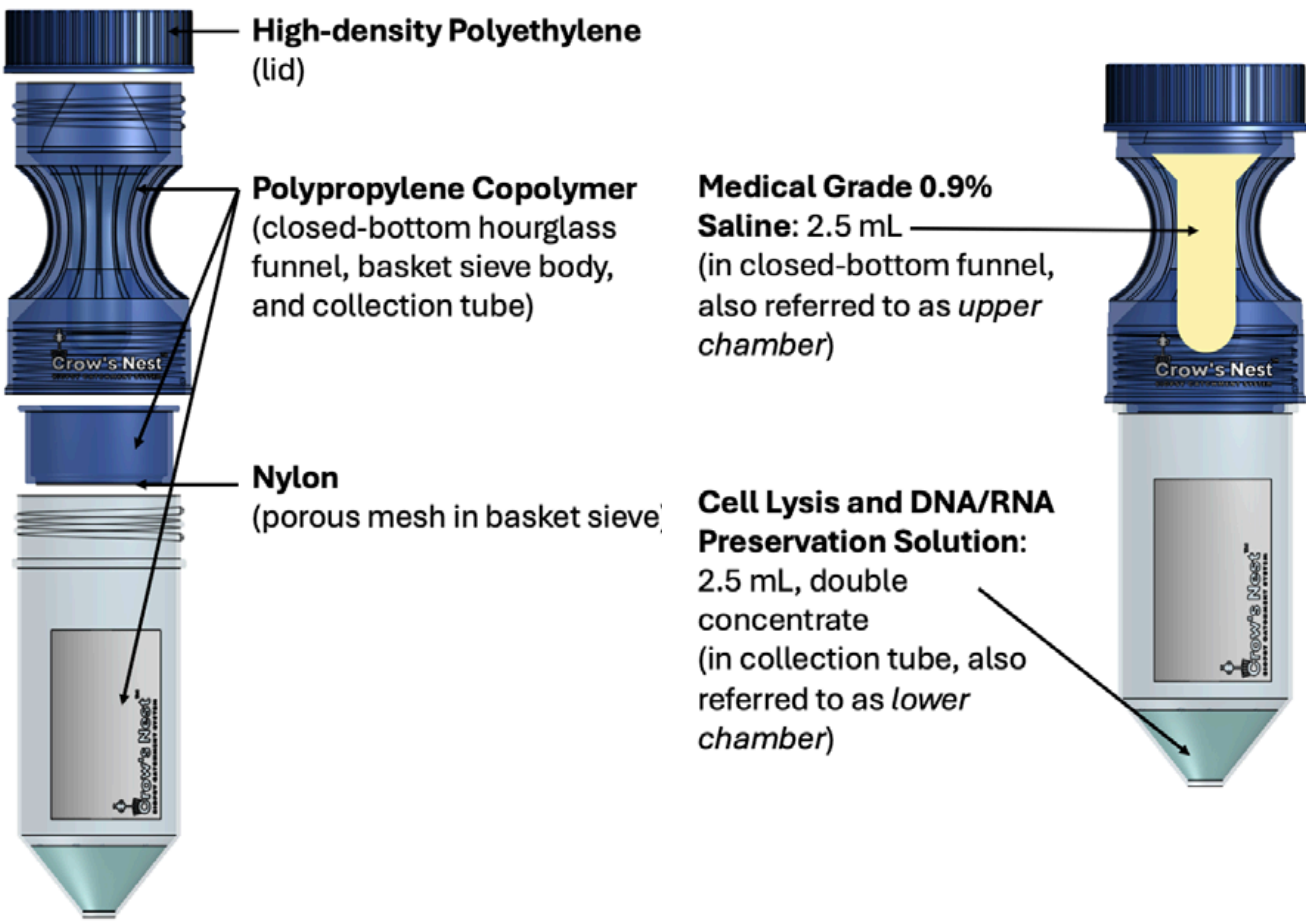
INDICATIONS

The Crow's Nest™ Biopsy Catchment System is used by a clinician to deposit tissue and preserve loose cells retrieved from a patient via a core needle tumor biopsy immediately following the biopsy procedure.

For Laboratory Use: Per 16 CFR Part 1500, Customer should not use the Crow's Nest Biopsy Catchment System for any diagnostic or therapeutic purpose, or otherwise in any manner that conflicts with its labeling statement.

MATERIALS

The Crow's Nest™ Biopsy Catchment System is comprised of the following materials:



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CONTRAINDICATIONS

The Crow's Nest™ is not intended to be used after biopsies with tissue volumes larger than a core needle biopsy, such as surgically excised biopsies. The Crow's Nest™ is not intended for use with liquid biopsies.

WARNINGS

Do not resterilize. Dispose of used core needle biopsy needles in a sharps container similar to any other medically-used sharp device. Inspect the tamper-evident heat-sealed Tyvek/Polypropylene pouch around each Crow's Nest unit and use only if the edge seals are intact. Return any damaged unused Crow's Nest™ Biopsy Catchment Systems to Corramedical, Inc. Visually inspect the sides of each Crow's Nest unit for any signs of liquid leakage and confirm that the contents are intact. Reagent stability after opening cannot be guaranteed. Opened reagents should not be stored for later use.

STORAGE

Store unopened Crow's Nest™ Biopsy Catchment Systems in their box at room temperatures (defined as 15°C to 25°C or 59°F to 77°F) for up to five years with the box oriented up, as indicated by the arrows on the packaging label "this side up." The box and product are not sensitive to light. The product has no known sensitivity to humidity. In the event that the product is subject to freezing, the shelf life of the reagents may be extended from their five years at room temperature to indefinite shelf life.

INTERNAL REAGENTS

2.5 mL of medical grade 0.9% saline solution is pre-loaded in the Crow's Nest upper chamber (the closed-bottom funnel). Saline is not classified as hazardous. Its manufacturers provide no hazard nor precautionary statements.

Facts about the purity and quality, and conformity with generally recognized and available standards:

Product / Trade Name: **0.9% Sodium Chloride Injection, USP**

Common / Generic Name: Sodium chloride

ANDA number: 207956

- **Classification**
- OSHA Regulatory The product is not regulated under U.S OSHA 29 CFR 1910.1200 Status: Hazard Communication Standard EU Regulatory Status: The product is not regulated under the European Directive 67/648/EEC

Chemical Name	CAS number	UN; EINECS	% (weight)	GHS Classification
Sodium chloride	7647-14-5	231-598-3	< 1	Not listed
Water for injection	732-18-5	231-791-2	> 99	Not listed

Physical state	Liquid
Appearance	Aqueous solution
Color	Clear, colorless
Odor	None
Odor threshold	No information available

pH	4.5 -7
Melting point / range	No information available
Boiling point / range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	Non inflammable
Flammability or explosive limits	Non inflammable or explosive
Vapor pressure	No information available
Vapor density	No information available
Relative density	1.006 g/L
Solubility	No information available
Partition coefficient (n-octanol / water)	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available

Source: *Laboratorios Grifols, S.A. Parque Empresarial Can Sant Joan, Avinguda de la Generalitat, 152-158, 08174 Sant Cugat del Vallès, Barcelona, SPAIN*

Toxicologic Information on likely routes of exposure

Eye contact: not expected to cause eye irritation.

Skin contact: not expected to cause skin irritation.

Ingestion: not expected to be hazardous by ingestion.

Inhalation: inhalation not likely under normal conditions.

The medical grade saline in this product is sourced from one of the following Approved Suppliers:

- ICU Medical, 951 Calle Amanecer, San Clemente, CA 92673
- Aquabiliti, Haywood Oaks Park, 5209 Linbar Drive, Suite 640, Nashville, TN 37211

Lot numbers traceable to the manufacturing history of the medical grade saline are available from Corramedical, Inc., by inquiring and providing the Crow's Nest unit's lot number. Upon receiving a query, Corramedical will reference the lot number with the company's batch history records, and provide the corresponding saline lot number and purity data or certificate of analysis.

2.5 mL of Cell Lysis and DNA/RNA Preservation solution is pre-loaded in the Crow's Nest lower chamber (the collection tube). This is Zymo DNA/RNA Shield™ manufactured for Corramedical, Inc. by Zymo Research Inc. DNA/RNA Shield preserves nucleic acids in biological samples for at least 60 months at room temperature (defined as 15°C to 25°C (59°F to 77°F)) and is a validated, reliable solution for unbiased RNA and DNA downstream analyses, such as Next-Generation Sequencing (NGS), qPCR, microarray, and proteomics. Denatured proteins can be analyzed by most downstream applications upon dilution. The appearance of the reagent is normally clear to yellow/ brownish in tint. The tint does not affect the performance of the reagent.

Cell Lysis and DNA/RNA Preservation Solution Hazards for Users:

2 Hazard(s) identification

Classification of the substance or mixture


GHS07

Acute Toxicity - Oral 4	H302 Harmful if swallowed.
Skin Irritation 2	H315 Causes skin irritation.
Eye Irritation 2B	H320 Causes eye irritation.

- ***Label elements***
- ***GHS label elements*** The product is classified and labeled according to the Globally Harmonized System (GHS).
- ***Hazard pictograms*** GHS07
- ***Signal word*** Warning
- ***Hazard statements***
  Harmful if swallowed.
  Causes skin and eye irritation.
- ***Precautionary statements***
  Wash thoroughly after handling. Do not touch eyes.
  Do not eat, drink or smoke when using this product.
  If swallowed: Call a poison center/doctor if you feel unwell.

Rinse mouth.
If on skin: Wash with plenty of water.
Specific treatment (see on this label).
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/ international regulations.

Classification system:

NFPA ratings (scale 0 - 4)

Health = 2
Fire = 0
Reactivity = 0

HMIS-ratings (scale 0 - 4)

Health = 2
Fire = 0
Reactivity = 0

Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

For a quantification of the *purity* and *quality* of the Zymo DNA/RNA Shield 2x concentrate solution in the collection tube, as well as a quantitative declaration of any impurities present, please send an email to info@corramedical.com and include the lot number on the package of this Crow's Nest unit. A Corramedical representative will consult the Zymo Certificate of Authenticity for the Zymo DNA/RNA Shield 2x concentrate solution that was used in the assembly of this Crow's Nest unit, which is maintained in the company's batch history records, and provide you with the results.

PERSONAL PROTECTIVE EQUIPMENT

Latex gloves are recommended when using the Crow's Nest Biopsy Catchment System. In the event of a breach of the users' gloves, rinse hands thoroughly with water. Of the two fluid solutions contained in the Crow's Nest Biopsy Catchment System:

- Medical Grade 0.9% Saline (in the upper chamber) is salt water and has no harmful effect on human skin.

- Zymo DNA/RNA Shield™ (in the lower chamber) is classified as a mild skin irritant. It could cause a mild erythematous of pruritic (itching) skin reaction if contacted and not rinsed off with water.

DESCRIPTION OF CORE NEEDLE BIOPSY PROCEDURE

A core needle biopsy uses a long, hollow tube to obtain a sample of tissue for diagnostic purposes. A side of the needle toward the tip is cut away with a sliding metal inner cylinder, creating a sampling chamber that excises a 1 mm wide column of tissue powered by a spring in the handle. Advanced imaging techniques are often used to guide the operator of the needle, typically an interventional radiologist. Once the needle is withdrawn from the patient, the thin tissue specimen is typically deposited in a plastic cup containing formalin, then sealed, labeled and sent to a pathology laboratory for paraffin embedding and sectioning. The use of the Crow's Nest™ Biopsy Catchment System inserts a new process that is conducted after the core needle biopsy is taken and before the tissue is deposited in a formalin cup.

STEP-BY-STEP USAGE INSTRUCTIONS

1. Open the corrugated cardboard shipper box.
2. Retrieve either a 4-pack or a 1-pack from the shipper box.

3. Press in on the box where indicated and separate along perforation. Remove the top half of the box. The bottom half of the box now serves as a tabletop rack holding Crow's Nest units.

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4. Select one of the Crow's Nest units from the box, and peel open the sealed Tyvek/poly pouch.

5. Place the unsealed Crow's Nest unit back in the box. You may use the box like a tabletop rack.

Alternatively, if you have a standard desktop tube rack and prefer to use that, it works equally well to hold the unit in place

6. Unscrew the lid of the Crow's Nest. Now the unit is ready to be used after a core needle biopsy procedure.

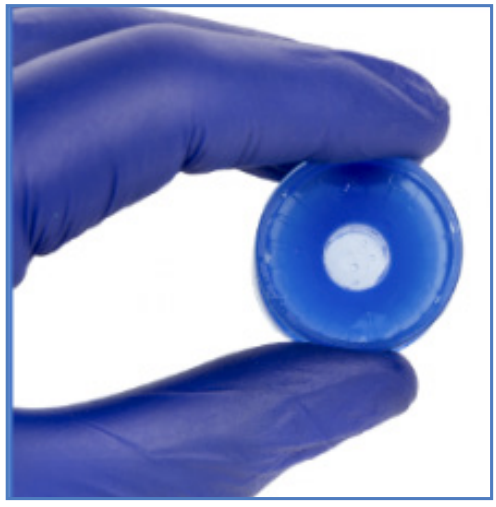
7. Perform a core needle biopsy on a target area of interest – a suspected solid tumor location.

8. Insert the tip of the biopsy needle, submerging the needle and the tissue all the way into the receptacle containing the provided sterile medical grade 0.9% saline solution and swirl it vigorously, dislodging the tissue in the liquid, just as you would with the tissue retrieved from the last pass of a biopsy in a formalin cup. The box-stand serves to stabilize the Crow's Nest unit during needle swirling, while also storing and maintaining the sterility of the unused units.

9. Unscrew and remove the top of the Crow's Nest at the midpoint.

10. Invert the top of the Crow's Nest, and pour the contents (the solid tissue and the saline containing loose dislodged cells) into the blue basket sieve.

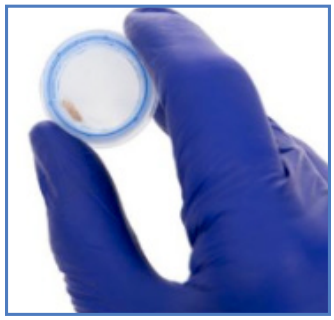
11. Examine the top of the Crow's Nest and look into the funnel, to ensure that no solid tissue remains in the interior of the closed funnel.

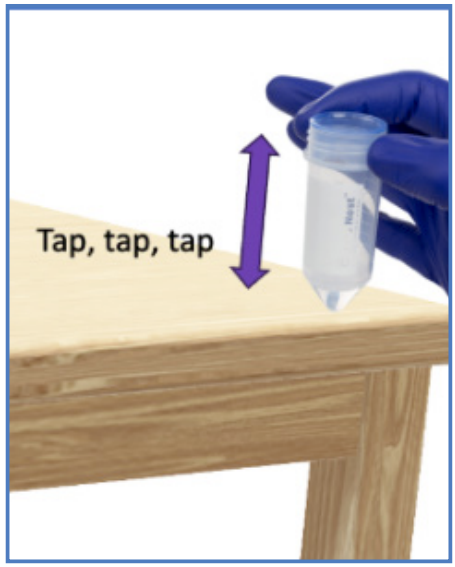


13. In the more likely scenario that the solid tissue is in the basket sieve, examine it to ensure that all the visible saline has passed through the sieve.

12. In the event that any solid tissue remains in the closed funnel interior, invert it and tap on the top of an open formalin cup or other tissue collection container until the solid tissue falls into the container.

14. If any visible saline fluid remains in the basket sieve, tap the collection tube lightly on a solid surface (a countertop, lab bench, or table) to prompt the remaining fluid to fall through the sieve.





15. Remove the basket sieve with the tissue from the 25 mL collection tube, and drop it in a standard formalin cup or other tissue collection container labeled with the patient's record number and/or other identifying information.

16. Place the Crow's Nest lid on the 25 mL collection tube, and screw it in place. The tube features a marker-friendly area for labeling.

17. Place the lid on the formalin cup containing the solid tissue from the biopsy and screw it in place.

Label and route the two specimens to their proper destinations: (right) The formalin cup with the solid tissue to the pathology lab for formalin-fixation paraffin-embedding (FFPE) treatment, and (left) the 25 mL collection tube from the Crow's Nest for either (a) a molecular testing lab, or (b) storage in a pathology lab at ambient (room) temperature. For a list of 3rd party clinical labs that accept liquid specimens in 25 mL collection tubes, go to www.corramedical.com and choose Labs That Accept Liquid Specimens (LTALS).

With any questions, please contact Corramedical, Inc. customer service, at:

1-833-4-BIOPSY (1-833-424-6779)

or contact us by email at: info@corramedical.com

STERILITY

The Crow's Nest™ Biopsy Catchment System, comprised of four interlocking parts and two pre-filled internal fluid-containing chambers, is provided as a sterile device. Do not resterilize. Do not use if package is opened or damaged. Do not use after expiration date.

HOW SUPPLIED

The Crow's Nest™ Biopsy Catchment System is provided in a custom 1-pack or 4-pack package, with this package insert.

GLOSSARY OF SYMBOLS USED FOR LABELING, PER ISO 15223-1 Medical Device – Symbols to Be Used with Medical Device Labels, Labeling, and Information to Be Supplied -- Part 1: General Requirements

Catalog Number


Read Instructions for Use


Do Not Reuse


Use By Date

Sterilized Using e-beam Radiation


Packaged in a Single Sterile Barrier System with Protective Packaging Outside

Do Not Resterilize


Please Store This Way Up

Medical Device

For In Vitro Diagnostic Use

Store at Room Temperature

Batch Code


Manufactured by Corramedical, Inc.


Do Not Use if Package is Damaged

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