

Visible performance.
Undeniable value.



Clearify™
Visualization System



COVIDIEN

Value Analysis and Product Information

Table of Contents

Visualization in Laparoscopic Surgery	3
Introducing Clarify™	4
Features & Benefits	6
Safety	10
Competitive Cost Analysis	12
The Power of Covidien	21
Regulatory Clearance	22
Instructions for Use	25



Visualization in Laparoscopic Surgery

Clearify™
Visualization System

An insightful look at visualization challenges.

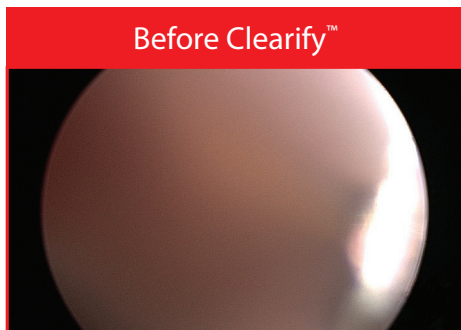
A crisp, clear, high-resolution view is essential for laparoscopic and robotic surgery.

And it's easy to see why.

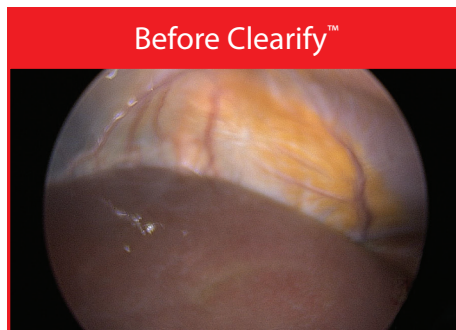
- Continually removing the scope for defogging and cleaning can impede performance¹
- Fogged, soiled, or damaged lenses compromise accurate visualization¹

Most surgeons, nurses, and scrub techs currently rely on a combination of visualization solutions. But these can cause issues of their own.

- Procedural delays
- Scope and lens damage
- Fire, burn, and hot water hazards



Fogged lens



Smearred lens



Introduction

Introducing Clearify™ Visualization System.

With the Clearify™ system, surgical performance and patient safety are brought to the forefront. This highly effective, all-in-one system enables optimal visualization throughout your procedure for a smoother case flow.

- Defogs your scope
- Cleans your scope and trocar
- Protects your scope

The Clearify™ system is multifunctional, intuitively designed, and is used right at the surgical site. And it's available at a remarkably affordable price.

Considering all it does, and how effectively it does it all, it's hard to find a better value in visualization systems than Clearify™.



Introduction

Clearify™
Visualization System



- 1 Warming hub
- 2 Micro pad
- 3 Activation button
- 4 Accommodates scopes up to 12.5mm
- 5 Converter for 3-5mm scopes
- 6 Trocar wipe†
- 7 Two microfiber cloths

†Fits trocars 5mm and up

Features & Benefits

Clearify™
Visualization System

Continuous clarity, from start to close.

Few things are more challenging than visualization issues during laparoscopic and robotic surgery. But Clearify™ is an effective, multifunctional system that addresses them all, with its one-handed Dip/Wipe/Swipe technique.

WARMS in	5	minutes
CLEANS in		seconds
LASTS for		hours

Eliminates fogging

- Clearify™ hub warms the anti-fogging and cleaning solution in 5 minutes, cleans the scope in 5 seconds, and stays warm for 5 hours
- Combination of heat and powerful anti-fogging solution works faster than hot water or anti-fogging agents alone^{2,3}

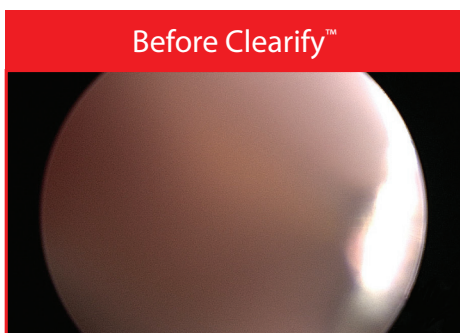


Figure 1 Fogged view after initial insertion of cold laparoscope.

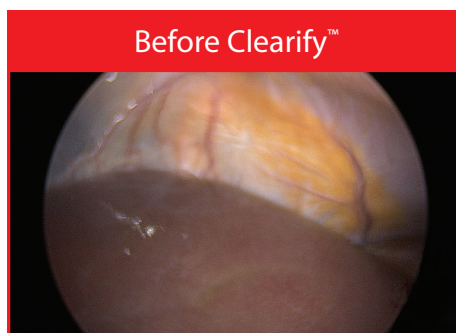


Figure 2 View remains smeared after lens wiped/warmed on liver surface.



Figure 3 View after conditioning lens in Clearify™ for five seconds, and using the micro pad and trocar wipe in the Dip/Wipe/Swipe technique.

Features & Benefits

Clearify™
Visualization System

Restores visualization quickly

- Cleans scope in 5 seconds
- Dip/Wipe/Swipe to remove smudges, oils, and caked-on debris
- Microfiber cloth can be used to polish away persistent smudges

Removes trocar debris

- Insert trocar wipe into the cannula to clean quickly and thoroughly
- A clean trocar won't compromise your lens

Protects lens from damage

- Micro pad on hub and microfiber cloths are softer than cotton
- Won't scratch or smudge delicate lens the way gauze can⁴

Ensures true white balance⁵

- White-balance any time scope is inserted
- Surgical gauze is not true white

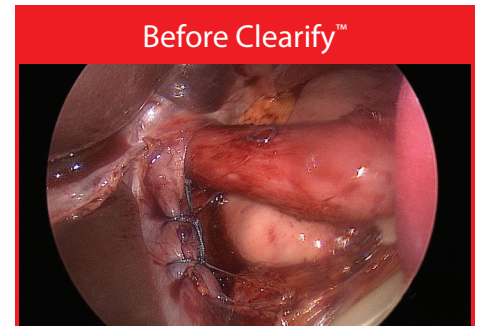


Figure 4 View after right side of lens is smudged through contact with viscera.



Figure 5 Same view as Figure 4, restored after using the Dip/Wipe/Swipe technique.

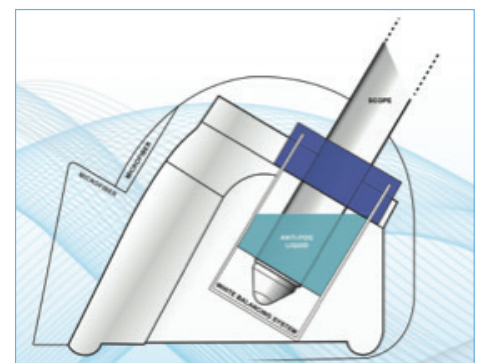


Figure 6 Clearify™ checks white balance while scope warms.

Features & Benefits

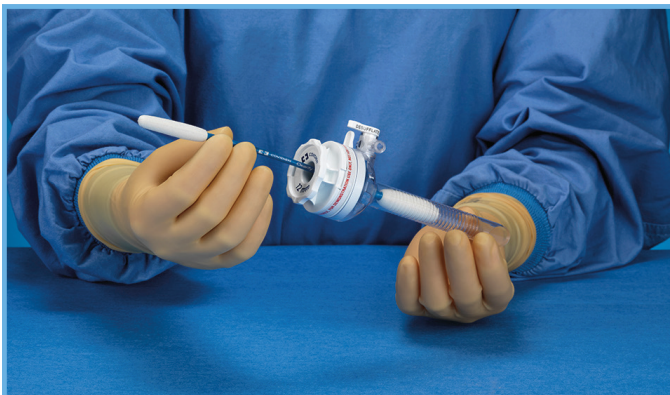
Clearify™
Visualization System

Dip/Wipe/Swipe

Clearify™ has a soft foam hub that safely warms the defogging and cleaning surfactant solution within its spill-proof reservoir. To defog or clean your scope, just dip, wipe, and swipe.



Dip the scope in the hub's reservoir and let it rest for five seconds.



Wipe debris out of the trocar with the trocar wipe.



Swipe the scope on the hub's white micro pad or with one of the microfiber cloths.

Features & Benefits

Clearify™
Visualization System



With all it does, it's no wonder that Clearify™ is rated 4 out of 5 on a range of satisfaction indicators:⁶

- Lens cleaning and visualization
- Less fog
- Saves time

Stay focused.

- Comprehensive, all-in-one system that's easy to use
- Makes defogging and cleaning an intuitive, efficient part of your case flow
- Fewer and shorter procedural delays



I have been doing laparoscopy since 1990 and this is the first effective innovation that reliably eliminates fogging in a simple, cost-effective manner.

Michael Nussbaum, M.D., Shands Jacksonville

Protect

your scope

your patient

yourself

Every second counts, for you and your patient.

- Restore visualization in 5 seconds
- Surfactant solution is more effective than hot water alone²
- 5-second cleaning allows you to react instantly to bleeders and other issues
- Save time during procedures^{4,6}
- Potentially reduce patient time under anesthesia

Ensure true white balance.⁵

- Get realistic color for accurate diagnostics
- True white, versus surgical gauze's approximation

Reduce risk of foreign bodies and incorrect counts.

- Microfiber cloths and trocar wipe don't shed lint or dust
- No scopes accidentally discarded in warming sleeves
- No gauze left behind

Lower scope repair costs.

- Conditions, protects, and maintains delicate scopes
- The hub's adhesive backing affixes to the patient's drapes so your scope stays safely at the surgical site, from start to close
- No risk of scope toppling in water baths and less risk of it being dropped

Lessen the risk of fire.

- Fluid reservoir dissipates the heat from fiber-optic light-source to avoid overheating
- No need to put the scope on standby

Reduce burn and scalding hazards.

- No hot water at the surgical site
- Less risk of burns or fires from the high-intensity light source when scope is kept in the hub

I like the safety that the Advanced Laparoscopic Care Kit* represents.
I no longer worry about patient or staff burn injuries, or scope damage from a
thermos filled with hot water spilling over into the field.

Robert D. Fanelli, M.D., Berkshire Medical Center

*Clearify™ was formerly marketed as the D-H.E.L.P. Advanced Laparoscopic Care Kit.

Competitive Cost Analysis

Clearify™
Visualization System

Replace all this:

- Foam pad with anti-fog
- Anti-fogging gel or solution
- Thermal bath
- Scope warmer
- Special drapes
- Sleeve
- Shield
- Basin
- Proctology cotton swab
- Gauze
- Scope warmer bottle
- Hot water
- Humidified CO²
- Alcohol wipes

With one system:



Incredibly effective — and incredibly cost-effective.

In an independent survey of 118 general surgeons attending ACS, 95% of respondents reported using defogging supplies.⁷ Most hospitals also provide surgeons a method for heating the scope. Clearify™ replaces them both, with no capital costs.

- Warms, defogs, and cleans your scope
- All-in-one, multifunctional unit
- Saves kitting and stocking costs
- Saves time in the O.R.
- May reduce repair costs⁶
- Improves safety

What makes Clearify™ such an incredible value?

- No need to purchase numerous separate components
- Unique combination of warming with powerful surfactant solution
- Added value and functionality of trocar wipe and microfiber cloths

How much can you save with Clearify™?

- Between 6.3 and 21.7 minutes, depending on the duration and type of procedure⁶
- Estimated savings per procedure can be between \$31 and \$129, depending on current products used.

The following charts summarize the cost of current visualization systems, and highlight the savings when Clearify™ is used instead.

Clearify™ vs. Warmer Bottle

Clearify™
Visualization System

- Need for purchasing disposable seals and sterile water
- Hidden costs such as sterilizing the scope warmer bottle, gauze, and electrical usage
- Placing scope in metal container may scratch lens
- Scope may render unit top-heavy and unstable, increasing risk of knocking over thermos
- Longer cases require warm water to be replenished

Scope warmer bottle costs per typical 2-hour procedure

TABLE 1

DISPOSABLE SUPPLIES	QTY	EST. COST PER UNIT	TOTAL COST
WARMER BOTTLE SEAL (DISPOSABLE)	1	\$4	\$4
STERILE WATER (LITER)	2	\$4	\$8
ANTI-FOG SOLUTION	1	\$4	\$4
STERILE COTTON SWABS (5-PACK)	1	\$1	\$1
RAYTEC SPONGES/GAUZE	1	\$3	\$3
SPD COSTS:			
STERILIZATION: LABOR & CAPITAL	1	\$2	\$2
WRAPPING: LABOR & MATERIALS	1	\$5	\$5

Est. total cost per procedure \$27*

* Does not include cost of canister (\$100) and base (\$60)

Clearify™ vs. Warming sleeves

Clearify™
Visualization System

The image shows the Clearify Visualization System components, including a clear plastic sleeve, a blue tube, and a white container with a blue cap. The sleeve has "INSERT HERE" printed on it.

- Keep scopes warm for only one hour
- Procedure delays and long or complex procedures may require two or more sleeves per case
- Risk of accidentally discarding sleeves with scope still inside

Disposable scope warmer sleeve costs per typical 2-hour procedure

TABLE 2

DISPOSABLE SUPPLIES	QTY	EST. COST PER UNIT	TOTAL COST
DISPOSABLE SCOPE WARMER SLEEVE	2	\$10	\$20
ANTI-FOG SOLUTION	1	\$4	\$4
STERILE COTTON SWABS (5-PACK)	1	\$1	\$1
RAYTEC SPONGES/GAUZE	1	\$3	\$3

Est. total cost per procedure \$28

Clearify™ vs. Electrical fluid warming machines

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Visualization System

- Machines are bulky
- Significant capital costs
- Require additional components, such as sterile plastic sheets and disposable scope cradles
- Time consuming set-up
- Water may take several minutes to reach optimum temperature
- Unnecessary clutter
- Risk of spills and scalding
- Hidden costs of high-wattage heaters

Fluid warming system costs per typical 2-hour procedure

TABLE 3

DISPOSABLE SUPPLIES	QTY	EST. COST PER UNIT	TOTAL COST
WARMING BATH DRAPE	1	\$50	\$50
STERILE WATER	2	\$4	\$8
ANTI-FOG SOLUTION	1	\$4	\$4
STERILE COTTON SWABS (5-PACK)	1	\$1	\$1
RAYTEC SPONGES/GAUZE	1	\$3	\$3

Est. total cost per procedure \$66

Clearify™ vs. FloShield™ Device

Clearify™
Visualization System

A photograph of the Clearify Visualization System components, including a camera, a light source, and a control unit, all connected by cables. The components are arranged on a white surface.

- Requires different SKU for each scope size and angle
- Can be difficult to assemble

FloShield™ device costs per typical 2-hour procedure

TABLE 4

DISPOSABLE SUPPLIES	QTY	EST. COST PER UNIT	TOTAL COST
FLOSHIELD™	1	\$125	\$125

Est. total cost per procedure \$125

Competitive Cost Analysis

Clearify™
Visualization System

Cleaning and defogging

<p>Other cleaning and defogging methods</p> <ul style="list-style-type: none"> • Consume an average of 5.8 minutes per procedure⁸ • Usually used at back table • Hot water alone may not be effective at completely removing fats, tissue, and other debris 	<p>Clearify™ Visualization System</p> <ul style="list-style-type: none"> • Reduces defogging/cleaning time by 50% (2.9 minutes)⁸ • Surgeons save between 6 and 22 minutes per procedure, depending on duration/complexity⁶ • Used at surgical site • Powerful defogging/cleaning surfactant works better than water alone²
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In a recent study that calculated average costs per minute for anesthesia, staff, and other hospital expenses, O.R. time was shown to cost the hospital \$16 per minute.⁹

Clearify™ operative time savings per typical 2-hour procedure

TABLE 5

ACTIVITY	MINUTES SAVED	COST PER MINUTE	COST SAVINGS
SCOPE CLEANING AND DEFOGGING	2.9	\$16.00	\$46.40

Competitive Cost Analysis

Clearify™
Visualization System

Clearify™ operative time savings by type/duration of procedure

TABLE 6

ACTIVITY	AVG MINUTES SAVED ⁶	COST PER MINUTE	AVG COST SAVINGS
Laparoscopic (45 min. or less)	6.4	\$16.00	\$102.40
Laparoscopic (45 min. or more)	15.5	\$16.00	\$248.00
Robotic	13.7	\$16.00	\$219.20

Clearify™ vs current methods* Estimated savings per procedure

TABLE 7

	Clearify™	Thermos Heating	Warming Sleeve	Electrical Warming	FloShield™
SUPPLY COSTS	\$42.00	\$27.00*	\$28.00	\$66.00	\$125.00
OPERATIVE TIME COSTS (@ \$16 per min.)	\$46.40	\$92.80	\$92.80	\$92.80	\$92.80
TOTAL AVERAGE COST	\$88.40	\$119.80	\$120.80	\$158.80	\$217.80
NET SAVINGS with CLEARIFY™		-\$31.40	-\$32.40	-\$70.40	-\$129.40

* Does not include cost of canister (\$100) and base (\$60)

When you realize the true, complete costs associated with your current visualization system, you'll see that Clearify™ has the potential to offer you significant savings - especially when annualized. It's hard to find a better value than that.

Competitive Cost Analysis

Clearify™
Visualization System

Scope repair costs

- Annual hospital budget for laparoscope repairs: \$10,000 to \$75,000¹⁰
- Median annual laparoscope repair budget: \$27,143¹⁰
- Repair costs for just one robotic scope can exceed \$30,000

Litigation costs

- Injuries from surgical fires can lead to expensive litigation.
- Evidence typically demonstrates that the fire was preventable and/or the result of human error.¹¹

If it prevents even one fire, adopting technology like Clearify™ can save your hospital a significant amount of money.

You know a good value when you see one.

- Clearer visualization.
- Smoother case flow.
- Fewer repairs.
- Fewer delays.
- Reduced kitting and stocking costs.

All this, for the price of a trocar. Anyone can see what a great value that is. But most important, Clearify™ can enable better performance, and better patient outcomes. And those are absolutely priceless.



The Power of Covidien



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Clearify™ is an exceptional stand-alone value. But when using the full array of complementary products within Covidien's extensive portfolio, you enhance the cost-to-value advantages for your facility. For starters, you can save money and improve operational efficiencies by reducing part numbers and the number of vendors you work with.

How to Order Clearify™

To order the Clearify™ Visualization System now, contact Customer Service at 1.800.772.8772, and refer to Reorder Code #21-345. There is no minimum order fee.

10 disposable Clearify™ units per case. Individual units include the Clearify™ warming hub, two microfiber cloths, and one trocar wipe.



Regulatory Clearance - 510(k)

D-H.E.L.P.™ is now Clarify™



COVIDIEN



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

New Wave Surgical Corporation
% Ms. Erin Sparnon
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462

OCT - 5 2006

Re: K062779

Trade/Device Name: Defogging Heated Endoscopic Lens Protector (D.H.E.L.P) and
Defogging Endoscopic Lens Protector (D.E.L.P)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: GCJ, KOG

Dated: September 15, 2006

Received: September 18, 2006

Dear Ms. Sparnon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Regulatory Clearance - 510(k)

D-H.E.L.P.™ is now Clearify™



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Page 2 – Ms. Erin Sparnon

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

^{to}
Mark N. Melkerson
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Regulatory Clearance - 510(k)

D-H.E.L.P.™ is now Clarify™



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Indications for Use

510(k) Number (if known): Not Assigned as of now

Device Name: Defogging Heated Endoscopic Lens Protector (D.H.E.L.P)

Indications for Use:

DHELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Barbara Buchanan for MDM

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K062779



HOW TO USE THE ADVANCED LAPAROSCOPIC CARE KIT



PREPARING D-HELP™

1. Activate device
 - Press black button to activate D-HELP™ at least 5 minutes before use.
 - Make sure blue light is on (Light indicates heating started. Light may be difficult to see before room is darkened.)
2. Insert Scope into D-HELP™
 - Push scope in firmly and rest scope on back table.
 - It is ok if some fluid spills from D-HELP™
 - There is no risk of overheating from the light-source while scope is inside D-HELP™. For robotic scopes turn off camera light if left in D-HELP™ longer than 5 minutes.
 - Use the attached rubber reducer for 3-5mm scopes.
 - For flexible-tip scopes, first open the valve with a rigid instrument to ease insertion.
3. White balance scope
 - Activate white balance anytime while scope is inside D-HELP™.
 - If light intensity is too high, (e.g. some robotic scopes) white balance may fail. Pull scope away from target or reduce light intensity. If necessary, white balance with the MicroPad. DO NOT use gauze.
4. Attach device to drapes
 - Secure to surgical field by peeling the adhesive bottom or secure with a clamp.
 - Do not hold scope upright. Once secured, the scope can rest flat.



USING D-HELP™


Follow these simple steps anytime the scope is removed from body:

1. Insert into D-HELP™ for at least 5 seconds. This step is important. Quickly inserting and withdrawing the scope is insufficient to warm the scope or break up debris from the lens. Keeping a secondary scope in the D-HELP throughout the procedure is ok, but may reduce battery life of device.
2. Clean the lens using a MicroPad or on the D-HELP™ microfiber surface; do not use gauze to clean lens. Under high-fog conditions do not wipe away all of the anti-fog liquid from the lens. Tap or shake the scope to remove any excess fluid without wiping away all of the anti-fog coating.
3. Return scope quickly from D-HELP™ into the body to prevent the scope from cooling.



USING THE TROCARWIPE™

1. Use the small foam head for 5mm trocars, and the large foam head for trocars >7mm.
2. On certain trocar models that have a spring-loaded valve, open the valve during insertion or retraction of the TrocarWipe. Be sure the trocar does not have any sharp edges that can snag the TrocarWipe. Do not extend the foam head beyond the distal end of the trocar. Not compatible with Snowden-Pencer trocars or other metal trocars.
3. Grasp the blue handle and push the foam head straight into the trocar. Do not release or bend the TrocarWipe.
4. TrocarWipe and MicroPad are radiopaque.

Warnings:  Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner)

Information on the risks of re-using this device is available by contacting New Wave Surgical.

ALCK is intended for single use. After use, ALCK should be disposed in accordance with local guidelines for medical waste that includes batteries.

Device is sterile if the package is dry, unopened and undamaged. Do not use if the pouch is damaged or package seal is broken. Moisture may be present inside the zip-loc bag.

Discard device if mishandling has caused possible damage or contamination, or if the device is past its expiration date.

Indications:
D-HELP is intended to be used prior to and during endoscopic and laparoscopic procedures to prevent fogging of the scope lens.

Storage:
D-HELP should be stored in a clean, dry location at room temperature.



CE 0459

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NW-0155-REV. 7



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- ⁵ US Patent EP 2659829 A2.
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- ⁷ Market Access Partners Report. Survey at ACS, October 2013.
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