



501-0100.27/002

CAUTION:

1. U.S. Federal Law restricts this device to sale by or on the order of a physician.
2. Prior to use, read this entire package insert.

INDICATIONS FOR USE:

The Eagle Eye Platinum catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

The Eagle Eye Platinum ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

DESCRIPTION:

The Eagle Eye Platinum catheter incorporates a cylindrical ultrasound transducer array. The array radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The Eagle Eye Platinum catheter utilizes an internal lumen that allows the catheter to track over the 0.014\" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cutdown into the vascular system.

Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.

This catheter is for exclusive use with Volcano sS Series, CORE Series and IntraSight Series of Systems. This catheter will not operate if connected to any other imaging system. Consult your System Operator's Manual.

INCLUDED ACCESSORIES:

Flushing Tool One (1)

CONTRAINDICATIONS:

The Eagle Eye Platinum catheters are generally contraindicated in situations presenting a reasonable probability of tissue or organ damage. This device is not currently indicated for use in cerebral vessels.

ADVERSE EFFECTS:

Possible adverse effects include, but are not limited to, the following: myocardial infarction; occlusion; coronary vessel dissection; perforation, rupture or injury; restenosis; hemorrhage or hematoma; unstable angina; arrhythmias; drug reactions; allergic reaction to contrast medium; hypo/hypertension; infection; vessel spasm; arteriovenous fistula; embolism; entry puncture site bleeding; vascular wall injury; vessel thrombosis; pseudoaneurysm (at site of catheter insertion); renal failure; coronary aneurysm; vessel trauma requiring surgical repair or intervention, death.

WARNINGS:

- Use of the Eagle Eye Platinum catheters should be restricted to specialists who are familiar with, and have been trained to perform, the procedures for which this device is intended.
- The product is supplied sterile; if the pouch is opened or damaged compromising the sterile barrier, please discard the product. This product cannot be re-sterilized or re-used.
- The Eagle Eye Platinum catheter is designed for single use only. Volcano Corporation ("VOLCANO"), makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of the catheter.
- In addition, VOLCANO assumes no responsibility or liability for incidental or consequential damages which may result from such re-use. Re-use including resterilization of unused product may result in, but is not limited, to the following:
 - Potential critical harm to patient due to Device Separation, Material Deformation or Infection/Sepsis
 - Failure to Image or other device malfunctions
- The catheter transducer is a delicate electronic assembly, deliberate misuse by bending, twisting or any other severe physical manipulation will void the warranty.
- Do not use the device for purposes other than those indicated.
- The device may not be safe in those patients who cannot be properly anticoagulated or who cannot receive anti-platelet or anti-coagulation therapies.

PRECAUTIONS:

The Eagle Eye Platinum device is a delicate scientific instrument and should be treated as such. Always observe the following precautions:

- Prior to use, carefully inspect the scanner and catheter body for bends, kinks or other damage. Do not use a damaged or suspected damaged catheter.
- Protect the catheter tip from impact and excessive force.
- Do not cut, crease, knot, or otherwise damage the catheter.
- Protect the electrical connections from exposure to fluid.
- Do not handle the transducer.
- The outside diameter along the entire length of the guide wire should not exceed the maximum specified.
- During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.
- Clean guide wire and flush catheter thoroughly with heparinized saline before and after each insertion.
- When inserting the guide wire both catheter and wire must be straight with no bends or kinks, or damage to inner lumen may occur.
- Do not advance the guide wire against significant resistance. If binding occurs between the catheter and the guide wire while inside the patient, CAREFULLY REMOVE BOTH the wire and catheter and do not use. If binding occurs outside of the patient, remove the catheter and do not use.
- The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis.
- During the procedure, provide appropriate anticoagulation to the patient as needed.
- When advancing or re-advancing the catheter over a guide wire and through a stented vessel, in the event that the stent is not fully apposed against the vessel wall, the guide wire / and/or catheter may become entangled in the stent between the junction of the catheter and guide wire or within one or more stent struts. This may result in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation. Never use force to advance the catheter.
- Use caution when re-advancing a catheter over a guide wire and into a stented vessel. Forceful advancement of the IVUS catheter could cause entanglement between the catheter and the stent(s) resulting in entrapment of catheter/guide wire, catheter tip separation, and/or stent dislocation.
- Use caution when removing the catheter over the guide wire from a stented vessel to minimize patient risk.
- **If resistance is encountered during pullback, remove the entire system (guide wire, IVUS catheter, sheath/guide catheter) at the same time.**

INSTRUCTIONS FOR USE:

The Eagle Eye Platinum catheter may be introduced into the vascular system percutaneously or surgically and advanced to the desired location. The frequency and duration of administration is subject to the discretion of the physician and depends upon the procedure and information required.

- Review the Volcano Imaging System Operator's Manual thoroughly prior to use of this device. Check system operation prior to the use.
- If using VH IVUS, review the Volcano Imaging System Operator's Manual prior to use.
- Remove the Eagle Eye Platinum catheter from its sterile packaging when in a sterile field.
- Remove the stylet.
- Attach the flushing device to a 10 cc or larger syringe filled with heparinized normal saline. Insert the distal tip of the catheter into the device. Inject the saline into the lumen. Fluid should be observed flowing out of the Guide Wire Exit Port.
- Remove the clear/white cap from the PIM connector (if applicable).
- Connect the PIM connector of the Eagle Eye Platinum catheter to the Patient Interface Module as described in the Volcano Imaging System Operator's Manual. Verify that the device is imaging.
- Place the Eagle Eye Platinum catheter onto the intravascular guide wire which has been previously positioned into the artery. A guide wire of 0.014\" (0.36 mm) or smaller can be used.

- Advance the catheter over the guide wire to the site of the vasculature to be imaged.
- Check the Monitor for an image. Once the image has been obtained, the catheter can be advanced over the guide wire to image additional segments of vasculature.
- If an image is not obtained or is not satisfactory, consult the Volcano sS Series or CORE Series of Systems Operator's Manual.
- When the procedure is completed, remove and discard the catheter in accordance with local regulations.

STORAGE AND HANDLING:

Products should be stored in a dry, dark, cool place in their original packaging.

PRODUCT SPECIFICATIONS:

Model	Eagle Eye Platinum
Catalog Number	85900P
Crossing profile at transducer	3.5F (0.046\", 1.17 mm)
Maximum guide wire	0.014\" (0.36 mm)
Minimum guide catheter O.D.	5F (0.066\" 1.67 mm)
Minimum guide catheter I.D.	0.056\", 1.42 mm
Usable length	150 cm

Acoustic Output Parameter	B-Mode	Chromaflo
ISPTA.3 (mW/cm ²)*	2.93x10 ⁻³	7.98x10 ⁻²
ISPPA.3 (W/cm ²)*	7.5x10 ⁻³	175.0x10 ⁻³
Pr.3 (MPa)	20.0x10 ⁻³	81.5x10 ⁻³
PD (µs)	161.0x10 ⁻³	125.0x10 ⁻³
PRF (Hz)	53760	75368
Center Freq (MHz)	18.6	17.9
MI**	4.5x10 ⁻²	1.92x10 ⁻²
TI**	2.06x10 ⁻⁵	1.56x10 ⁻⁴

* Maximum overall uncertainty + 33.9% / - 30.5%

** As estimated in tissue

TI: Thermal Index defined as $TI = \frac{W_{0.1x1c}}{210}$

W0.1x1: Bounded-square Output (mW)

f_c: Center Frequency (MHz)

MI: Mechanical Index defined as $MI = Pr.3 / (f_c^{1/2})$

ISPPA.3: Derated Intensity, Spatial Peak Pulse Average (W/cm²)

ISPTA.3: Derated Intensity, Spatial Peak Temporal Average (mW/cm²)

Pr.3: Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)

W₀: Total Power (mW)

PD: Pulse Duration (µs)

PRF: Pulse Repetition Frequency (Hz)

LIMITED WARRANTY:

Subject to the conditions and limitations on liability stated herein, VOLCANO Corporation ("VOLCANO") warrants that the Eagle Eye Platinum catheter (the "Catheter"), as so delivered, shall materially conform to VOLCANO'S then current specification for the Catheter upon receipt for a period of one year from the date of delivery. ANY LIABILITY OF VOLCANO WITH RESPECT TO THE CATHETER OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO CATHETER REPLACEMENT OR, IF REPLACEMENT IS INADEQUATE AS A REMEDY OR, IN VOLCANO'S OPINION, IMPRACTICAL, TO REFUND OF THE FEE PAID FOR THE CATHETER. EXCEPT FOR THE FOREGOING, THE CATHETER IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF FITNESS, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE OF NONINFRINGEMENT. FURTHER, VOLCANO DOES NOT WARRANT, GUARANTEE, OR MAKE ANY REPRESENTATIONS REGARDING THE USE, OR THE RESULTS OF THE USE, OF THE CATHETER OR WRITTEN MATERIALS IN TERMS OF CORRECTNESS, ACCURACY, RELIABILITY, OR OTHERWISE. Licensee understands that VOLCANO is not responsible for and will have no liability for any items or any services provided by any persons other than VOLCANO. VOLCANO shall have no liability for delays or failures beyond its reasonable control.

Additionally, this warranty does not apply if:

1. The Catheter is used in a manner other than described by VOLCANO in the Instructions For Use supplied with the Catheter.
2. The Catheter is used in a manner that is not in conformance with purchase specifications or specifications contained in the Instructions For Use.
3. The Catheter is re-used or re-sterilized.
4. The Catheter is repaired, altered, or modified by other than VOLCANO authorized personnel or without VOLCANO authorization.

If claims under this warranty become necessary, contact VOLCANO for instructions and issuance of a Return Material Authorization number if the Catheter is to be returned. Equipment will not be accepted for warranty purposes unless the return has been authorized by VOLCANO.

This product is licensed to the customer for single use only.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO VOLCANO CORPORATION IN THE USA.

Legal Manufacturer:

Volcano Corporation
3721 Valley Centre Drive, Suite 500
San Diego, CA 92130 USA
(800) 228-4728
IGTD.CustomerInquiry@philips.com

USA & Canada:
(800) 228-4728
IGTD.CustomerInquiry@philips.com

International:
vecomplaints@philips.com or
IGTD.CustomerInquiry@philips.com

Authorized European Representative:

EC REP
Volcano Europe SA/NV
Excelsiorlaan 41
B-1930 Zaventem, België
Téléfono: +32.2.679.1076
Fax: +32.2.679.1079



ISO 15223-1 Batch code - Código de lote; Batchkod; Eräkoodi; Chargenbezeichnung; Codice del lotto; партиден код; Κωδικός παρτίδας; Numéro de lot; Batchcode; Batchkode; Sarzs kód; lotnummer; код партии; Sifra serije; Código do lote; Parti kodu; Kód série; Codul lotului; kod partii; Broj serije



ISO 15223-1 Catalog number - Número de catálogo; Katalognummer; Luettelonumero; Katalognummer; Numero di catalogo; каталожен номер; Αριθμός καταλόγου ; Numéro de référence; Catalogusnummer; Katalognummer; Katalógusszám; katalognummer; номер по каталогу; Kataloški broj; Número de catálogo; Katalog numaras; Katalogové číslo; Numărul de catalog; numer katalogowy; Kataloški broj



ISO 15223-1 Manufacturer - Fabricante; Tillverkare; Valmistaja; Hersteller; Fabricante; производитель; Κατασκευαστής; Fabricant; Fabrikant; Producent; Gyártó; produsent; производитель; Proizvođač; Fabricante; Urećic; Vyrobce; Producător; producent; Proizvođač



ISO 15223-1 Do not use if package damaged - No utilizar si el envase está dañado; Använd inte om förpackningen är trasig; Ei saa käyttää, jos pakkaus on vahingoittunut; Bei beschädigter Verpackung nicht verwenden; Non utilizzare se la confezione è danneggiata; не использовать при повреде́на опако́вка; No μην χρησιμοποιείται εάν η συσκευασία έχει υποστεί ζημιό; Ne pas utiliser si l'emballage est endommagé; Niet gebruiken als de verpakking beschadigd is; Må ikke anvendes, hvis emballagen er ødelagt; Ne használja fel, ha a csomagolás sérült; må ikke brukes hvis pakningen er skadet; не использовать, если упаковка повреждена; Ne koristite ako je pakiranje oštećeno; Não utilizar se a embalagem estiver danificada; Paket hasarlıysa kullanmayın; Nepoužívejte, je-li obal poškozen; A nu se utiliza dacă ambalajul este avariat; nie używać, jeśli opakowanie jest uszkodzone; Nemojte koristiti ako je pakovanje polomljeno



ISO 15223-1 - Sterilized using ethylene oxide - Esterilizado con óxido de etileno; Steriliserad med etylenoxid; Steriloitu etyleenioksidilla; Mit Ethylenoxid sterilisiert; Sterilizzato ad ossido di etilene; стерилизовано с этиленов оксид; Αποστειρωμένο με χρήση αιθυλενοξείδιου; Stérilisé à l'oxyde d'éthylène; Gesteriliseerd met ethyleenoxide; Steriliseret med ethylenoxid; Etilénoxiddal sterilizálva; sterilisert med etylenoksid; стерилизовано этиленоксидом; Sterilizirano etilen-oksidom; Esterilizado com óxido de etileno; Etilen oksit kullanılarak sterilize edilmiştir; Sterilizováno etylenoxidem; Sterilizat cu oxid de etilenă; wysterylizowano tlenkiem etylenu; Sterilisano korišćenjem etilen-oksida



ISO 15223-1 - Store in a dry, dark, cool place - Guardar en un sitio fresco, oscuro y seco; Förvaras svalt, mörkt och torrt; Säilytä kuivassa, pimeässä ja viileässä; An einem trockenen, dunklen, kühlen Ort lagern; Conservare in luogo fresco, asciutto e al riparo dalla luce; Сохранявайте на сухο, тьмном и хладном място; Να φυλάσσεται σε ξηρό, σκοτεινό και δροσερό χώρο; Conserver dans un endroit sec et frais à l'abri de la lumière; Op een droge, donkere en koele plaats bewaren; Opbevares tørt, mørkt og køligt; Száraz, fénytől védett és hűvös helyen tárolandó; Opbevares på et tørt, mørkt og kjølig sted; Хранить в сухом, темном и прохладном месте; Čuvati na suhom, tamnom i hladnom mjestu; Armazenar em local fresco, seco e escuro; Serin ve kuru bir yerde saklayın; Skladujte v suchu, temnu a chladu; Depozitați într-un loc uscat, întunecat și răcoros; Przechowywać w suchym, ciemnym i chłodnym miejscu; Čuvati na suvom, mračnom, hladnom mestu



ISO 15223-1 - Do not re-use - No reutilizar; Återanvänd inte; Ei saa käyttää uudelleen; Nicht wiederverwenden; Non riutilizzare; не использовать повторно; No μην επαναχρησιμοποιείται; Ne pas réutiliser; Niet hergebruiken; Må ikke genbruges; Ne használja újra; må ikke brukes på nytt; не использовать повторно; Nemojte ponovo upotrebljavati; Não reutilizar; Yeniden kullanmayın; Nepoužívejte znovu; A nu se reutiliza; nie używać ponownie; Nemojte ponovo da koristite



ISO 15223-1 - Do not re-sterilize - No volver a esterilizar; Omsterilisera inte; Ei saa steriloida uudelleen; Nicht resterilisieren; Non ristertilizzare; не стерилизовать повторно; No μην επαναποστειρώνεται; Ne pas restériliser; Niet opnieuw steriliseren; Må ikke reesteriliseres; Ne sterilizálja újra; må ikke steriliseres på nytt; не стерилизовать повторно; Nemojte ponovo sterilizirati; Não reesterilizar; Yeniden sterilize etmeyin; Nesterilizuje znovu; A nu se reesteriliza; nie serylizować ponownie; Nemojte sterilizovati



ISO 15223-1 - Non-pyrogenic - Apirógeno; Ikke-pyrogen; Pyrogeeniton; Nicht-pyrogen; Apirogeno; непиrogenно; Μη πυρογενές; Apyrogène; Pyrogeenvrij; Uden pyrogener; Nem pirogén; ikke-pyrogen; апиrogeno; Nepirogeno; Não pirogénico; Pirojenik deġildir; Neryrogenní; Apirogen; wyrób niepirogenny; Nepirogeni



ISO 15223-1 - Authorized representative in the European community - Representante autorizado en la Comunidad Europea; Auktoriserad representant i Europeiska gemenskapen; Valtuutettu edustaja Euroopan yhteisössä; Autorisierte EU-Vertretung; Rappresentante autorizzato nella Comunità europea; уполномощен представител в Европейската общност; Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή κοινότητα; Représentant autorisé pour la Communauté européenne; Erkende vertegenwoordiger in de Europese gemeenschap; Autoriseret repræsentant i EU; Hivatalos képviselő az Európai Közösségben; autorisert EU-representant; уполномоченный представитель в Европейском сообществе; Ovlašteni zastupnik za Europsku zajednicu; Representante autorizado na Comunidade Europeia; Avrupa topluluğu yetkil temsilcisi; Autorizovaný zástupce v Evropském společenství; Reprezentant autorizat în Comunitatea Europeană; autoryzowany przedstawiciel na terenie Unii Europejskiej; Ovlašćeni predstavnik za Evropsku zajednicu



IEC 60878 2794 - Use by date - Fecha de caducidad; Sista förbrukningsdag; Viimeinen käyttöpäivä; Verfallsdatum; Utilizzare entro; срок на годность; Τελική ημερομηνία ανάλωσης; Date limite d'utilisation; Uiterste gebruiksdatum; Sidste anvendelsesdato; Lejáratí dátum; utløpsdato; использовать до; Upotrijebiti do; Data de validade; Son kulanma tarihi; Datum použitelnosti; A se utiliza până la data de; termin ważności; Rok trajanja



IEC 60878 2794 - Packaging unit - Unidad de embalaje; Förpackningsenhet; Pakkausyksikkö; Verpackungseinheit; Unità di imballaggio; опаковъчна единица; Μονάδα συσκευασίας; Unité de conditionnement; Verpackung; Emballageenhet; Csomagolási egység; emballasjeenhet; упаковочная единица; Pakiranje; Unidade de embalagem; Paket ünitesi; Balici jednotka; Unitate ambalare; jednostka opakowania; Jedinica pakovanja

Contents: Catheter: One (1) Flushing tool: One (1)	Съдържание: Катетър: Един (1) брой Инструмент за промиване: Един (1) брой	Sadržaj pakiranja: Kateter: jedan (1) Alat za ispiranje: jedan (1)	Obsah: Katét: Jeden (1) Proplachovací nástroj: Jeden (1)	Indhold: Kateter: Ét (1) Skylleværktøj: Ét (1)
Inhoud: Katheter: Een (1) Spoelgereedschap: Een (1)	Sisu Kateeter: üks (1) Loputustööriist: üks (1)	Sisältö: Katetri: Yksi (1) Huuhtelutyökalu: Yksi (1)	Contenu : Cathéter ; un (1) Outil de purge ; un (1)	Inhalt: Katheter : ein Stück (1) Spülwerkzeug: ein Stück (1)
Περιεχόμενα: Καθετήρας: Ένα (1) Εργαλείο έκπλυσης: Ένα (1)	Tartalom: Katéter: Egy (1) Tisztító eszköz: Egy (1)	Contenuto: Catetere: uno (1) Strumento di irrigazione: uno (1)	Innhold: Kateter: En (1) Skylleddskap: En (1)	Zawartość: Cewnik: jedna (1) sztuka Przyrząd do przepłukiwania: jedna (1) sztuka
Conteúdo: Cateter: um (1) Ferramenta de lavagem: uma (1)	Conținut: Cateter: Unul (1) Instrument de clătire: Unul (1)	Contenido: Catéter: Uno (1) Útil de lavado: Uno (1)	Innehåll: Kateter: En (1) Spolningsverktyg: Ett (1)	İçindekiler: Kateter: Bir (1) Yıkama aparatı: Bir (1)
Содержимое: Катетер; одна (1) шт. Инструмент для промывки; одна (1) шт.				



FDA final rule - Prescription only - Norma final de la FDA: Solo con prescripción médica; Slutlig FDA-regel – endast på ordination; FDA:n lopullinen sääntö – Vain lääkärin määräyksestä; Endgültige FDA-Entscheidung – Rezeptpflichtig; Norma definitiva FDA - Solo su prescrizione; Последно правило на FDA – само по предписание; Τελικός κανόνας FDA - Μόνο κατόπιν ιατρικής συνταγής; Règlement final de la FDA – Sur prescription uniquement; Oordeel FDA - Alleen op recept; FDA endelig beslutning - Kun på recept; FDA végső szabály – Csak rendelvényre; Endelig avgjørelse fra Food and Drug Administration (FDA) – selges kun på resept; окончательное правило FDA — только по предписанию; Konačna odluka agencije FDA – samo na recept; Regra final da FDA – Apenas com receita médica; Nihai FDA kuralı - Yalnızca reçete ile satılır; Konečné pravidlo FDA – Pouze na předpis; Regulament final FDA - Doar pe bază de prescripție; Przepis końcowy FDA – tylko na zlecenie lekarza; Konačno pravilo agencije FDA – Samo po nalogu zdravstvenog radnika



Not made with natural rubber latex - No está fabricado con látex de caucho natural; Inte framställd med naturgummlatex; Valmistuksessa ei ole käytetty luonnonkumia/lateksia; Nicht mit Naturlatex hergestellt; Non realizzato in lattice di gomma naturale; He e произведено с естествен каучуков латекс; Δεν κατασκευάζεται με λάτεξ από φυσικό καουτσούκ; Fabriqué sans latex de caoutchouc naturel; Niet gemaakt met natuurlijke rubberlatex; Ikke fremstillet med naturgummlatex; Természetes gumilátexet nem tartalmaz; Inneholder ikke naturgummlateks; изготовлено без применения натурального каучукового латекса; Nije izrađeno od prirodnoga gumenog lateksa; fabricado sem látex de borracha natural; Doğal kauçuk lateksten üretilmemiştir; Neni vyrobeno za použití přírodního latexu; Nu este fabricat cu latex din cauciuc natural; Wyprodukowano bez dodatku naturalnej gumy lateksowej; Ne sadrži prirodni gumeni lateks



Part number - Número de referencia; Artikelnummer; Osanumero; Teilenummer; Numero di parte; Каталожен номер; Αριθμός προϊόντος; Référence; Onderdeelnummer; Reserveredsnummer; Cikkszám; Delenc; номер по каталогу; Broj dijela; Referência; Parça numarası; Císlo; Numărul de catalog; Numer wyrobu; Broj dela