

**Federal Insurance Company v. Caldera Medical, Inc.,  
U.S.D.C., Central District of California Case No. 2:15-  
cv-00393**

**NOTICE OF PROPOSED CLASS ACTION SETTLEMENT**

A Court authorized this Notice. This is not a solicitation.

**TO: ALL CLAIMANTS IN CALDERA TRANSVAGINAL MESH  
MEDICAL PRODUCT CASES**

**You may be entitled to a payment from a class action Settlement.**

You are receiving this Notice to inform you that a Settlement has been reached in connection with lawsuits and unfiled claims against Caldera Medical, Inc. ("Caldera"). The claims being settled relate to injuries allegedly caused by transvaginal mesh ("TVM") devices manufactured, marketed, sold and distributed by Caldera and its affiliates and suppliers under the following trade names: T-Sling®, Desara®, Ascend®, Hydrix®, POPmesh®, and Vertessa®. These claims are collectively referred to as "Transvaginal Mesh Medical Product Claims" or "Caldera TVM Claims."

If approved by the Court, the Settlement will create a cash Settlement Fund of \$11.75 million for the benefit of claimants asserting Caldera TVM Claims.

**This Settlement includes all Caldera Transvaginal Mesh Medical Product Claims.**

The claimants assert that Caldera manufactured, marketed, sold, and distributed TVM devices that it knew or should have known were hazardous and dangerous to patients who were implanted with them. Caldera denied and continues to deny that it did anything wrong. The principal reasons for the Settlement are to maximize the share of Caldera's limited resources that are paid to claimants, and to eliminate the expense, uncertainty and risk of further litigation.

If the Settlement is approved by the Court, those included in the Settlement Class will receive a cash payment from the Settlement Fund. You must file a Claim Form to get payment. Your legal rights are affected whether you act or don't act. Please read this notice carefully.

<b>YOUR LEGAL RIGHTS AND OPTIONS IN THIS SETTLEMENT</b>	
<b>SUBMIT A CLAIM FORM BY MAY 2, 2016</b>	The only way to receive a payment.
<b>OBJECT BY APRIL 25, 2016</b>	Write to the Court if you don't like the Settlement. You will still be a Member of the Class
<b>GO TO A HEARING ON JUNE 13, 2016</b>	Ask to speak in Court about the fairness of the Settlement.
<b>DO NOTHING</b>	Get no payment from the Settlement and still give up your legal rights.

- These rights and options – **and the deadlines to exercise them** – are explained in this Notice.
- The Court still has to decide whether to approve the Settlement and whether to certify the Settlement Class. Payments will only be made if the Court approves the Settlement. Please be patient.

**Para asistencia en Español por favor llame a Spanish Language Notice 1-800-683-4872**

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## **Basic Information**

### **1. Why is there a notice?**

You or someone in your family was implanted with a TVM device manufactured, marketed, sold, or distributed by Caldera. The Court directed that this Class Settlement Notice be sent to Settlement Class Members because you have a right to know about the proposed Settlement of a class action lawsuit, and about your options, before the Court decides whether to finally approve the Settlement.

### **2. What is the lawsuit about?**

For several years and throughout the country, more than 2,000 Transvaginal Mesh Medical Product Claims have been filed in court or otherwise asserted against Caldera. As part of a nation-wide settlement of all of the Caldera TVM Claims, a Settlement Class must be certified in order to process and pay claims.

The Caldera TVM Claims allege in part the following things. Caldera manufactured, marketed, sold, and distributed TVM devices that it knew or should have known were hazardous and dangerous to patients who were implanted with them. As a result of the implantations of Caldera's TVM devices, claimants suffered serious bodily injuries, including, but not limited to, extreme pain, erosion of internal bodily tissue, dyspareunia, painful scarring, and other injuries. These injuries would not have occurred but for the defective nature of the TVM devices implanted and/or Caldera's wrongful conduct, acts, omissions, and fraudulent misrepresentations. As a result of Caldera's claims and representations regarding the effectiveness and safety of the products, claimants Plaintiffs and their healthcare providers used the products in accordance with its directions. Had Caldera properly disclosed risks associated with the products, claimants and their healthcare providers would not have used the products and claimants would not have suffered serious and permanent injuries.

The Caldera TVM Claims further contend the following additional things. At the time claimants used the TVM devices, Caldera knew or should have known that the TVM devices created an increased risk to consumers of serious personal injury, including but not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence and, prolapse of organs. Despite the fact that Caldera knew or should have known of the serious health risks associated with the use of the TVM devices, Caldera failed to warn the claimants or their health care providers of these serious risks.

Caldera denies any wrongdoing (including the allegations in the paragraphs above) and the Court has not made a final decision either way. The parties have agreed to resolve this case by settlement to avoid the time, expense and uncertainty associated with continued litigation, and to provide benefits to the Settlement Class at the soonest practical time.

On January 25, 2015, the Court entered a Preliminary Approval Order, which preliminarily approved the Settlement, directed that this Class Settlement Notice be sent to attorneys for potential Settlement Class Members, and scheduled the Final Approval Hearing for June 13, 2016, to consider whether to grant final approval of the Settlement.

### **3. What is a class action?**

In a class action, one or more people, called "Class Representatives," sue on behalf of people who have similar claims. All persons and entities with similar claims to the Class Representatives are a "Class" or "Class Members."

### **4. Why is there a Settlement?**

The Class Counsel and other attorneys representing claimants asserting Caldera TVM Claims believe that these claims have merit. They recognize, however, the expense and length of continued proceedings necessary to pursue claims against Caldera through trial and appeals, as well as the associated risks that individual claimants may not prevail (as Caldera has denied all of the allegations asserted against it). There is also a risk that, if there is no class action settlement, Caldera will run out of money and will not be able to pay judgments or individual settlements on any of the claims. It has been determined that the best, fairest, and swiftest way to for payments to

be made to all claimants asserting Caldera TVM Claims is through a class action settlement.

The Court has not decided in favor of the claimants or Caldera; and Caldera does not believe it did anything wrong. But both sides want to avoid the cost of further litigation and to provide benefits to the claimants as soon as is practical. The Settlement provides substantial benefits now as compared to the risks that a similar or smaller recovery would be achieved after trial and appeal, possibly years in the future, or that no recovery would be achieved at all.

Attorneys for claimants have investigated the facts and applicable law regarding the Transvaginal Mesh Medical Product Claims against Caldera and Caldera's defenses. The attorneys also have pursued extensive litigation, including litigation relating to the actions entitled *In Re Transvaginal Mesh Litigation*, Los Angeles Superior Court Case No.: JCCP 4733 (the "JCCP Action") and *Federal Insurance Company v. Caldera Medical, Inc.*, U.S.D.C., Central District of California Case No. 2:15-cv-00393 (the "Interpleader Action"). In connection with the Interpleader Action, representatives for the Settlement Class, Caldera, and Caldera's insurance company, Federal Insurance Company, engaged in lengthy negotiations and mediation.

The \$11.75 Million being paid into the Settlement Fund represents virtually all of Caldera's funds. Caldera has represented to the Court that the only assets it has to pay Transvaginal Mesh Medical Product Claims are the proceeds of insurance policies issued by Federal Insurance Company. Under the terms of these policies, Federal Insurance Company has to pay the lawyers defending against Caldera TVM claims and these payments reduce the remaining funds that can be paid to claimants asserting Caldera TVM claims. Federal Insurance Company and Caldera disagree regarding the amount of the funds remaining in the policies. If there is no settlement, there is a danger that Federal Insurance Company could prevail on arguments that would reduce or eliminate the insurance proceeds available to be paid to claimants asserting Caldera TVM Claims. Also, if there is no settlement, the insurance proceeds available to be paid to claimants asserting Caldera TVM Claims will be reduced or eliminated by payments to the lawyers defending against the TVM claims.

Although Federal Insurance Company has argued that the total amount of the funds now remaining in the insurance policies is less than \$12.25 million, as a result of the mediation and in order to achieve the Settlement, Federal Insurance Company has agreed to make a total payment \$12.25 million. If the Settlement is approved by the Court, \$11.75 million will be paid immediately into the Settlement Fund. The remaining \$500,000 will be reserved to be used in connection with any later-filed claims against Caldera that are not covered by this Settlement and, if not used within five years, will be distributed to the Settlement Class.

The Settlement resolves, releases, or bars all Transvaginal Mesh Medical Product Claims that were or could have been brought against Caldera. This is a NON-OPT OUT settlement, which means that in order to receive any award from Caldera you must participate in this Settlement Class and complete all of the necessary forms.

### **Who is in the Settlement?**

To see if you are entitled to benefits from the Settlement, you first have to determine if you are a member of the Settlement Class.

### **5. How do I know if I am part of the Settlement?**

Anyone who has filed a lawsuit asserting any claim against Caldera relating to injuries allegedly caused by a Caldera TVM device, or who has entered into a tolling agreement with Caldera relating to the filing of such claims, is automatically a member of the Settlement Class and is entitled to submit a Claim Form as described in Paragraph 8, below. If such an individual is deceased, that individual's estate, heirs or beneficiaries may be entitled to payment.

If you have not filed a lawsuit or entered into a tolling agreement, you still may be entitled to participate in the Settlement if you or someone in your family was implanted with a TVM device manufactured, marketed, sold, or distributed by Caldera, and you believe that the Caldera TVM device has caused any injuries. If the Court approves the Settlement, it will bar any person who has an actual or alleged Caldera TVM Claim as of the date of settlement approval from subsequently filing that claim in court. To obtain any payments relating to such an actual or alleged Caldera TVM Claim, you will need to join the Settlement Class and submit a Claim Form as described in Paragraph 8, below.

### **6. What if I am still not sure if I am included in the Settlement Class?**

If you are not sure whether you are included in the Settlement Class, you can call 1-800-683-4872 for free help or visit [www.calderaclaims.com](http://www.calderaclaims.com) for more information. Or, you can fill out and return the Claim Form described in Paragraph 8 to see if you qualify.

## **The Settlement Benefits**

### **7. What benefits does the Settlement provide?**

The Settlement provides that a \$11.75 Million Settlement Fund will be established for the benefit of Class Members, and to pay attorneys' fees, expenses of litigation, and costs of administering the Settlement. All Class Members who submit Claim Forms will be entitled to receive a cash payment. The amount of the payment to any claimant will be determined based on a series of factors, including but not limited to, the total number of individuals submitting Claim Forms and the severity of the claimant's injuries.

### **8. How do I submit a claim to receive Settlement benefits?**

To receive cash available under the Settlement, you must fill out and submit a Claim Form. You may obtain, complete and submit a Claim Form online at the Settlement website, [www.calderaclaims.com](http://www.calderaclaims.com). You may also call the Claims Administrator at 1-800-683-4872 and request that a Claim Form be mailed to you at no charge. Read the instructions on the Claim Form carefully. To the best of your ability, fill out the Claim Form and include all the information requested. Then sign the form and mail it to: The Settlement Alliance, Attn: Caldera Claims Administrator, P.O. Box 92040, Southlake, TX 76092.

Claim Forms may also be submitted by fax to the Claims Administrator at 281-738-4310. Members of the Settlement Class have until May 2, 2016 to submit a Claim Form. The Claim Form must be postmarked or received by this date.

In addition to submitting a claim form, in order to receive a payment from the Settlement Fund, you will need to sign a release giving up claims that relate to injuries allegedly caused by TVM devices manufactured, marketed, sold or distributed by Caldera. The "released claims" – the claims you are giving up - are described more fully in the Settlement Agreement, which describes exactly the legal claims that you give up if you participate in the Settlement. The Settlement Agreement and a copy of the release are available at [www.calderaclaims.com](http://www.calderaclaims.com).

No payments will be provided to Class Members until after the Court approves the Settlement and any appeals are resolved (see Paragraph 17). It is uncertain how long resolution of any appeal will take. Please be patient.

### **9. What happens if I choose not to participate in the Settlement?**

If you choose not to participate in the Settlement, you cannot submit a Claim Form, receive any cash available under the Settlement, sue Caldera, continue to sue, or be part of any other lawsuit against Caldera asserting TVM Claims.

Whether or not you submit a Claim Form or sign a release, if the Court approves the settlement, you will not be able to be part of any lawsuit about the legal issues in this case. These issues in part include (a) all claims that could be asserted relating to allegations concerning Caldera's negligence, failure to warn of the defects of its TVM devices, the defective design of its TVM devices, breach of express warranties, deceit by concealment, negligent misrepresentation, fraud, and loss of consortium; and (b) any claim for any actual or alleged injury caused by a Caldera TVM device existing as of May 2, 2016 asserted against Caldera, Biomedical Structures, Encision, Coloplast (on its own behalf and as successor in interest to Mpathy), Parker Hannifin, or J-PAC LLC .

## **You Cannot Opt-Out of this Settlement**

This is a NON-OPT OUT settlement class. If you choose not to participate in the settlement you will not be able to sue Caldera, continue to sue, or be part of any other lawsuit about the legal issues in this case.

## **The Lawyers Representing You**

### **10. Do I have a lawyer in this case?**

The Court has appointed attorney David Bricker as counsel for all Class Members. This is commonly referred to as "Class Counsel." You will not be separately charged for Attorney Bricker's representation. The Court will

determine the amount of Class Counsel's fees and expenses which will be paid from the Settlement Fund.

If you already are being represented by another attorney, both that lawyer and Attorney Bricker will continue to represent you. If you are not already are being represented by another attorney, and want to be represented by your own lawyer, you may hire one at your own expense.

**11. How will the lawyers be paid?**

Class Counsel has not received any payment for his services in pursuing the claims against Caldera on behalf of the Settlement Class, nor has he been paid for his litigation expenses. The Court will decide how much Class Counsel will be paid. Class counsel has not submitted requests for attorneys' fees or reimbursement of litigation expenses at this time. Attorneys' fees, expenses will only be awarded after the Court has determined they are fair and reasonable.

The application for attorneys' fees and expenses will be filed with the Court by March 25, 2016 and will be available at [www.calderaclaims.com](http://www.calderaclaims.com) after it is filed. Neither the application nor any order by the Court regarding it will have any effect on any fee arrangement you may have with any attorney separately retained by you.

**Objecting to the Settlement**

You can tell the Court that you don't agree with the Settlement or some part of it.

**12. How do I tell the Court I don't like the Settlement?**

If you are a member of the Settlement Class, you can object to any part of the Settlement, the Settlement as a whole, and/or Class Counsel's request for fees and expenses. You do not need to retain your own attorney in order to object to the Settlement. To object, you must do three things.

You must submit a letter that includes the following:

- Your name, address, and telephone number;
- A statement identifying your letter as an "Objection to the Settlement of the Caldera TVM Claims" ;
- The reasons you object to the Settlement, along with any supporting materials or arguments; and
- Your signature.

You must deliver your objection to the Settlement Administrator by emailing it to [admin@calderaclaims.com](mailto:admin@calderaclaims.com) or mailing it to The Settlement Alliance, Attn: Caldera Claims Administrator, P.O. Box 92040, Southlake, TX 76092.

You must ensure that any objection is received or postmarked no later than April 25, 2016.

If you submit your objection on time, the Settlement Administrator and Class Counsel will provide a copy to the Court. **Please do not write directly to the Court about any objection to the Settlement.**

**Even if you file an objection, you must still submit a Claim Form as directed by Paragraph 8 in order to receive any money under the Settlement.**

**The Court's Settlement Approval Hearing**

The Court will hold a hearing, called the "Final Approval Hearing," to decide whether to approve the Settlement and Class Counsel's requests for fees and expenses. You may attend, but do not have to do so.

**13. When and where will the Court decide whether to approve the Settlement?**

The Court will hold the Final Approval Hearing on June 13, 2016, at 1:30 p.m. Pacific Time. The hearing will be held before the Honorable Stephen V. Wilson in the United States District Court for the Central District of California Case, located at 312 N. Spring Street, Los Angeles, California 90012. The Court may change the date and time of the hearing without another notice being sent. The latest information will be posted on the website [www.calderaclaims.com](http://www.calderaclaims.com). If you want to come to the hearing, you should check with Settlement Administrator before coming to be sure that the date and/or time has not changed. At this hearing, the Court will consider whether the Settlement is fair, reasonable and adequate. The Court will also consider any request by Class Counsel for attorneys' fees and expenses. If there are objections, the Court will consider them. After the hearing,

the Court will decide whether to approve the Settlement.

**14. Do I have to come to the hearing?**

No. Class Counsel will answer questions the Court may have. But you may come at your own expense. If you send an objection, you do not have to come to the Final Approval Hearing to talk about it. As long as you submit your written objection on time, to the proper address, the Court will consider it. You may also pay your own lawyer to attend, but you do not need to do so.

**15. May I speak at the hearing?**

You may ask the Court for permission to speak at the Final Approval Hearing.

If you have not retained your own attorney, in order to request permission to speak at the Final Approval Hearing, you must do three things.

You must submit a letter that includes the following:

- Your name, address, and telephone number;
- A statement identifying your letter as an “Request to Appear at the Final Approval Hearing on the Settlement of the Caldera TVM Claims”;
- The reasons you wish to be heard, along with any supporting materials or arguments; and
- Your signature.

You must deliver your Request to Appear to the Settlement Administrator by emailing it to [admin@calderaclaims.com](mailto:admin@calderaclaims.com) or mailing it to The Settlement Alliance, Attn: Caldera Claims Administrator, P.O. Box 92040, Southlake, TX 76092.

You must ensure that any Request to Appear sent is received or postmarked no later than April 27, 2016. If you submit your Request to Appear on time, the Settlement Administrator and Class Counsel will provide a copy to the Court.

If you have retained your own attorney and you wish for your attorney to appear at the Final Approval Hearing, then, by April 27, 2016, your attorney must file a “Request to Appear at the Final Approval Hearing on the Settlement of the Caldera TVM Claims” with the Court presiding over the Interpleader Action and serve a copy of the Request on all parties that have appeared in the Interpleader Action. Your attorney’s Request to Appear must set forth the reasons why he or she wishes to be heard, and must include any arguments, papers, exhibits or other evidence or information that you or your attorney wish to present to the Court.

**If You Do Nothing**

**16. What happens if I do nothing at all?**

If you do nothing you will not get money from this Settlement and you will not be able to start a lawsuit, continue with the lawsuit, or be part of any other lawsuit asserting Caldera TVM Claims against Caldera, Biomedical Structures, Encision, Coloplast (on its own behalf and as successor in interest to Mpathy), Parker Hannifin or J-PAC, LLC.

**Additional Information**

**17. How do I get more information?**

This notice summarizes the proposed Settlement. More details are in the Settlement Agreement available at the Settlement website, [www.calderaclaims.com](http://www.calderaclaims.com).

For assistance, you may call the Claims Administrator toll free at 1-800-683-4872; write to The Settlement Alliance, Attn: Caldera Claims Administrator, P.O. Box 92040, Southlake, TX 76092.; or visit the website of the Claims Administrator at [www.calderaclaims.com](http://www.calderaclaims.com) where you can find answers to frequently asked questions about the Settlement, download copies of the Settlement Agreement, Claim Form and other court documents, and locate other information.

Dated: