Zimmer Spine
7375 Bush Lake Road
Minneapolis, MN 55439
952-832-5600

5301 Riata Park Court,
Bldg F
Austin, TX 78727
512-918-2700

June 5, 2012

URGENT MEDICAL DEVICE CORRECTION AND REMOVAL

To: Distributors, Sales Representatives, and Distribution Operation Managers Distributing the *Zimmer*® PathFinder NXT Spinal Pedicle Screw System

Subject: PathFinder NXT Fixed Rod Holder Instruments

Affected Products: **PathFinder NXT Fixed Rod Holder Instruments Part numbers 3573-1 (angle handle) and 3573-2 (straight handle); All lots.**

Zimmer Spine, Inc. (Zimmer) is initiating a voluntary correction and removal of PathFinder NXT rod holders because Zimmer has received complaints that the tip of the rod holder may crack or break when the rod is manipulated during surgery.

This notification is to inform Zimmer Spine Distributors and Sales Agents of the actions to take to notify surgeon customers of the issue and that a redesigned instrument with an improved tip is currently under development and will be provided, when available, to replace part numbers 3573-1 and 3573-2.

These instruments are intended for rod insertion, positioning, and orientation through the extender sleeves into the pedicle screw heads during minimally invasive surgical procedures intended to fuse the spine using the PathFinder NXT Pedicle Screw System.

Your Responsibilities

1. **Hand-deliver the enclosed Surgeon Letter to each PathFinder NXT Surgeon Customer in your territory.**
   - **Record the Surgeon's name, address, date, and phone number on the enclosed Surgeon Contact Certification Form to certify that they have received and understood the contents of the Surgeon Letter.**
   - **Return the completed Surgeon Contact Certification Form within 10 working days from receipt of this notification to ronald.musselman@zimmer.com or FAX to 1-512-258-0995.**

Other Information

This voluntary correction and removal will be reported to the U.S. Food and Drug Administration ("FDA"). The FDA will also receive from Zimmer progress reports on the implementation of this correction and removal. Your urgent cooperation is requested.

MedWatch Reporting: Any adverse reactions experienced with the use of these instruments, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

David J. Kunz
Vice-President Quality Assurance & Regulatory Affairs

June 5, 2012

URGENT: MEDICAL DEVICE RECALL

ZIMMER SPINE, INC.
PATHFINDER NXT PEDICLE SCREW SYSTEM

PERCUTANEOUS ROD HOLDER INSTRUMENTS

FIXED ROD HOLDER
3573-1 (angle handle)
3573-2 (straight handle)

Surgeon Contact Certification Form

Return via FAX to: Zimmer Spine at **1-512-258-0995**

Use the table below to document the **Surgeon Customers** in your territory that have received the **Surgeon Letter.**

Surgeon Name	Address	Date Delivered	Phone Number

By signing below, I certify that I have delivered the **Surgeon Letter** to the **Surgeon Customers** documented above.

Signature: _____Printed Name: _____

Title: _____Telephone: (____)_____-_____ Date: ____/____/_____

Agency Name: _____

Agency Address: _____

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June 5, 2012

URGENT MEDICAL DEVICE CORRECTION AND REMOVAL

To: Surgeons using *Zimmer*® PathFinder NXT Spinal Pedicle Screw System

Subject: Recall of PathFinder NXT Fixed Rod Holder Instruments

Affected Products: **PathFinder NXT Fixed Rod Holder Instruments Part numbers 3573-1 (angle handle) and 3573-2 (straight handle); All lots.**

Dear Surgeon:

Zimmer Spine, Inc. (Zimmer) is initiating a voluntary correction and removal of PathFinder NXT rod holders because Zimmer has received complaints that the tip of the rod holder may crack or break when the rod is manipulated during surgery.

This notification is to inform surgeon users of recommended actions to take when using the PathFinder NXT Fixed Percutaneous Rod Holder instruments to reduce the potential for rod holder tip breakage until a newly designed instrument is available for use. Once the new design is available, Zimmer will replace the instruments currently in use with the new design.

You are receiving this letter because, according to our records, you are a current user of Zimmer PathFinder NXT Spinal Implants and associated instrumentation. The instruments cited in this notification are intended for rod insertion, positioning, and orientation through the extender sleeves into the pedicle screw heads during minimally invasive surgical procedures intended to fuse the spine using the PathFinder NXT Pedicle Screw System.

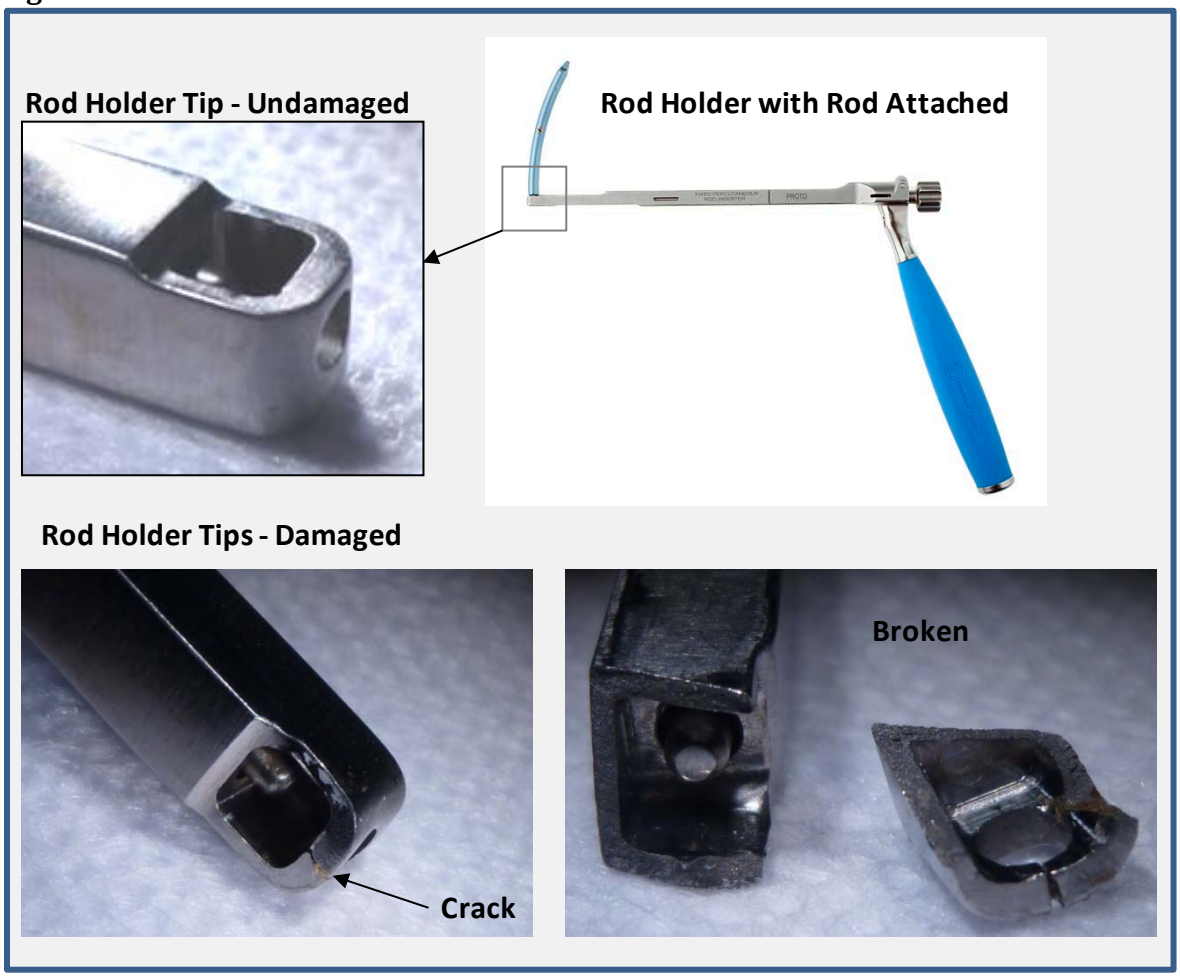
Revised Instructions for Use/Risk Mitigation

Zimmer is providing you with the following revised Instructions for Use (IFU) and Surgical Technique guidance in order to identify and mitigate potential rod holder tip damage when performing the Fixed Angled Percutaneous Technique procedure until a new instrument design becomes available. The revised IFU and Surgical Technique guidance included in this notice contain additional information to reduce rod holder tip damage.

REVISED IFU/SURGICAL TECHNIQUE GUIDANCE

Step	**Current IFU and Surgical Technique Guidance**	**Additional Guidance / Information to Reduce Rod Holder Tip Damage**	
PRIOR TO PROCEDURE	Inspect instrument for damage If damage or wear is noted that may compromise proper function, do not use	See Figure 1 for example of crack that may lead to breakage	If damage to the rod holder tip is found before or during use, Fixed Grip 5.5mm Rod Holder (part number 3562-1) may be utilized with a mini open technique
ROD PLACEMENT	Turn set screw knob until it seats fully on the percutaneous rod	The rod is fully seated when the knob is finger tight	
CLOSURE TOPS PLACEMENT	N/A	When inserting closure tops, ensure that the extender sleeves and rod holder are not touching/wedging together and creating a lever effect on the distal end of the rod holder	
ROD HOLDER REMOVAL	Disengage the rod from the rod holder by rotating the knob counterclockwise until stopped Translate the rod holder away from the construct and remove from the incision	The knob should be fully loosened prior to removal Translate the distal tip away from the rod/screw construct Do not rock the holder excessively to disengage from the rod	
POST USE	N/A	Inspect the rod holder tip for damage after each use. See Figure 1 If damaged, remove from service	

Figure 1


Rod Holder Tip - Undamaged
Rod Holder with Rod Attached
Rod Holder Tips - Damaged
Crack
Broken

Detection and Retrieval of Rod Holder Fragments from the Surgical Site

If a rod holder tip has fragmented and requires retrieval from the surgical site, operating room staff may be able to retrieve the pieces without incident using common tools available in the surgery. However, if the pieces are no longer visible or cannot be captured with available tools, other means may be necessary to locate the device, such as by x-ray, fluoroscopy, or through additional procedures.

Once detected, it will be up to the surgeon to use their best medical judgment in deciding whether it is appropriate to access, and to remove, the fragment(s). As always, final decisions on patient treatment remain the responsibility of the medical team.

Risks

The immediate health consequence could be a prolongation of surgery while trying to retrieve the fragment(s) from the surgical site, resulting in a patient's extended exposure to anesthesia. Potential extended surgery time could also expose patients to the standard risks associated with general anesthesia.

The long range health consequence of leaving a fragment in-vivo is unknown. This instrument is made from 455 Stainless Steel and is considered biocompatible for use in medical instruments, but is not intended to be implanted and fragments which are not retrieved carry the risk of migrating within the body and/or causing a foreign body reaction. The foreign body reaction could result in pain and medical intervention to retrieve the foreign body as could direct pressure of the displaced fragment(s) on a neurovascular structure.

The surgical incision may need to be extended if using a percutaneous approach to remove the fragment or to perform a mini-open procedure.

Rate of Occurrence

Rate of Occurrence for Rod Holder Damage

	Rod Holder Damage – All Types; Deformation, cracking, and breakage	Rod Holder Damage -Breakage Resulting in Patient Impact
# of Reported Events as Specified	80	2* [See details below]
Number of Estimated Device Usages	1036	
Rate of Occurrence	7.7%	0.2%

* Patient Impact Details:

1) Tip of rod inserter broke off during procedure. Surgeon made unsuccessful attempt to retrieve the tip fragment and left it in.

2) Tip of rod inserter broke off during procedure. Surgeon made successful attempt to retrieve tip fragment but had to increase incision size as a result.

Replacement Instrumentation

A redesigned instrument with an improved tip is currently under development and will be provided, when available, to replace part numbers 3573-1 and 3573-2.

Why is Zimmer telling me about this risk instead of mediating it?

Zimmer is warning you of the risks and potential for fragment retrieval from the operative site, and how to locate fragments if they do occur, while we are working to redesign the instrument. We will make the redesigned instrument available to you as soon as we are able to do so.

Your Responsibilities

1. **Review this notification and ensure you are aware of the content.**

2. **Inspect all PathFinder NXT Fixed Rod Holder Instruments and do not use any instruments showing signs of damage.**

3. **Implement the revised use instructions in this letter upon receipt.**

Other Information

Notifications of this correction and removal are being sent to all affected accounts of Zimmer Spine. For any related questions or assistance about this please contact Zimmer Spine Customer Service at 866-774-6368.

This voluntary correction and removal will be reported to the U.S. Food and Drug Administration ("FDA") & Competent Authorities. The FDA & Competent Authorities will also receive from Zimmer Spine progress reports on the implementation of this correction and removal. Your urgent cooperation is requested.

MedWatch Reporting: Problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Online: http://www.fda.gov/medwatch/report.htm. Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787 Fax: 1-800-FDA-0178.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities, please refer to: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm. Please keep Zimmer Spine informed of any adverse events associated with this device or any other Zimmer Spine product.

David J. Kunz
Vice-President Quality Assurance & Regulatory Affairs

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June 5, 2012

URGENT MEDICAL DEVICE CORRECTION AND REMOVAL

To: Facilities using the *Zimmer*® PathFinder NXT Spinal Pedicle Screw System

Subject: Recall of PathFinder NXT Fixed Rod Holder Instruments

Affected Products: **PathFinder NXT Fixed Rod Holder Instruments Part numbers 3573-1 (angle handle) and 3573-2 (straight handle); All lots.**

Dear Hospital Manager,

Zimmer Spine, Inc. (Zimmer) is initiating a voluntary correction and removal of PathFinder NXT rod holders because Zimmer has received complaints that the tip of the rod holder may crack or break when the rod is manipulated during surgery.

This notification is to inform user facilities of the correction and removal actions, and the recommended actions for surgeons to take when using the PathFinder NXT Fixed Percutaneous Rod Holder instruments to reduce the potential for rod holder tip breakage until a newly designed instrument is available for use. Once the new design is available, Zimmer will replace the instruments currently in use with the new design.

You are receiving this letter because, according to our records, your facility is a current user of Zimmer PathFinder NXT Spinal Implants and associated instrumentation. The instruments cited in this notification are intended for rod insertion, positioning, and orientation through the extender sleeves into the pedicle screw heads during minimally invasive surgical procedures intended to fuse the spine using the PathFinder NXT Pedicle Screw System.

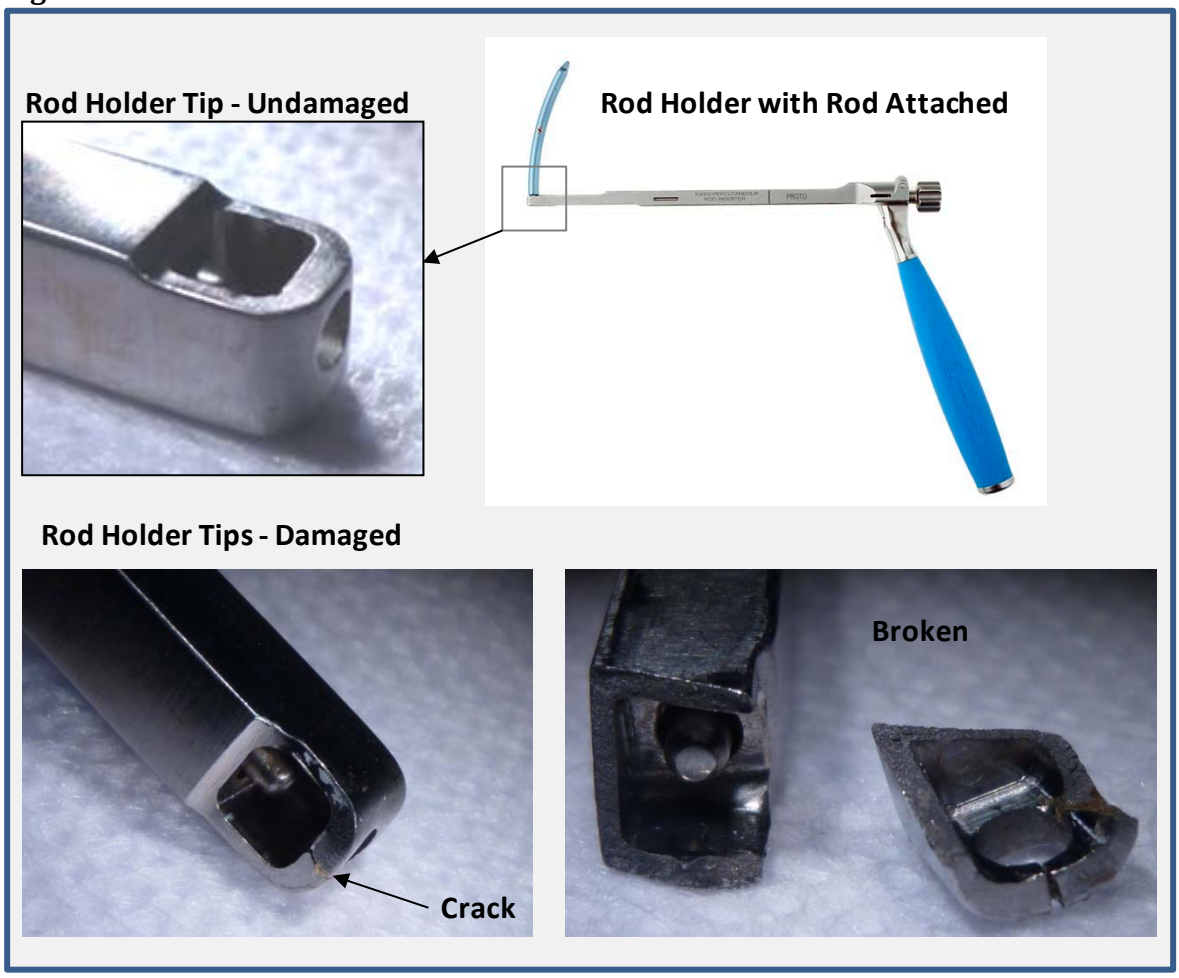
Revised Instructions for Use/Risk Mitigation

Zimmer is providing surgeon customers with the following revised Instructions for Use (IFU) and Surgical Technique guidance in order to mitigate potential rod holder tip damage when performing the Fixed Angled Percutaneous Technique procedure until a new instrument design becomes available. The revised IFU and Surgical Technique guidance contain additional information to reduce rod holder tip damage.

REVISED IFU/SURGICAL TECHNIQUE GUIDANCE

Step	**Current IFU and Surgical Technique Guidance**	**Additional Guidance / Information to Reduce Rod Holder Tip Damage**	
PRIOR TO PROCEDURE	Inspect instrument for damage If damage or wear is noted that may compromise proper function, do not use	See Figure 1 for example of crack that may lead to breakage	If damage to the rod holder tip is found before or during use, Fixed Grip 5.5mm Rod Holder (part number 3562-1) may be utilized with a mini open technique
ROD PLACEMENT	Turn set screw knob until it seats fully on the percutaneous rod	The rod is fully seated when the knob is finger tight	
CLOSURE TOPS PLACEMENT	N/A	When inserting closure tops, ensure that the extender sleeves and rod holder are not touching/wedging together and creating a lever effect on the distal end of the rod holder	
ROD HOLDER REMOVAL	Disengage the rod from the rod holder by rotating the knob counterclockwise until stopped Translate the rod holder away from the construct and remove from the incision	The knob should be fully loosened prior to removal Translate the distal tip away from the rod/screw construct Do not rock the holder excessively to disengage from the rod	
POST USE	N/A	Inspect the rod holder tip for damage after each use. See Figure 1 If damaged, remove from service	

Figure 1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Rod Holder with Rod Attached
Rod Holder Tips - Damaged
Crack
Broken

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Once detected, it will be up to the surgeon to use their best medical judgment in deciding whether it is appropriate to access, and to remove, the fragment(s). As always, final decisions on patient treatment remain the responsibility of the medical team.

Risks

The immediate health consequence could be a prolongation of surgery while trying to retrieve the fragment(s) from the surgical site, resulting in a patient's extended exposure to anesthesia. Potential extended surgery time could also expose patients to the standard risks associated with general anesthesia.

The long range health consequence of leaving a fragment in-vivo is unknown. This instrument is made from 455 Stainless Steel and is considered biocompatible for use in medical instruments, but is not intended to be implanted and fragments which are not retrieved carry the risk of migrating within the body and/or causing a foreign body reaction. The foreign body reaction could result in pain and medical intervention to retrieve the foreign body as could direct pressure of the displaced fragment(s) on a neurovascular structure.

The surgical incision may need to be extended if using a percutaneous approach to remove the fragment or to perform a mini-open procedure.

Rate of Occurrence

Rate of Occurrence for Rod Holder Damage

	Rod Holder Damage – All Types; Deformation, cracking, and breakage	Rod Holder Damage -Breakage Resulting in Patient Impact
# of Reported Events as Specified	80	2* [See details below]
Number of Estimated Device Usages	1036	
Rate of Occurrence	7.7%	0.2%

* Patient Impact Details:

1) Tip of rod inserter broke off during procedure. Surgeon made unsuccessful attempt to retrieve the tip fragment and left it in.

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Replacement Instrumentation

A redesigned instrument with an improved tip is currently under development and will be provided, when available, to replace part numbers 3573-1 and 3573-2.

Why is Zimmer telling me about this risk instead of mediating it?

Zimmer is warning you of the risks and potential for fragment retrieval from the operative site, and how to locate fragments if they do occur, while we are working to redesign the instrument. We will make the redesigned instrument available to surgeons as soon as we are able to do so.

Your Responsibilities

1. **Review this notification and ensure you and appropriate staff are aware of the content.**

2. **Complete the enclosed acknowledgement certification form and return it, via FAX to 1-512-258-0995.**

Other Information

Notifications of this correction and removal are being sent to all affected facilities using the *Zimmer*® PathFinder NXT Spinal Pedicle Screw System. For any related questions or assistance about this correction and removal please contact Zimmer Spine Customer Service at 866-774-6368.

This voluntary correction and removal will be reported to the U.S. Food and Drug Administration & Competent Authorities. The FDA & Competent Authorities will also receive from Zimmer progress reports on the implementation of this correction and removal. Your urgent cooperation is requested.

MedWatch Reporting: Problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Online: http://www.fda.gov/medwatch/report.htm. Regular Mail: use postage-paid FDA form 3500 available at: http://www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787 Fax: 1-800-FDA-0178.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities, please refer to: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm. Please keep Zimmer Spine informed of any adverse events associated with this device or any other Zimmer Spine product.

David J. Kunz
Vice-President Quality Assurance & Regulatory Affairs

June 5, 2012

URGENT: MEDICAL DEVICE RECALL

ZIMMER SPINE, INC. *PATHFINDER NXT* PEDICLE SCREW SYSTEM

FIXED ROD HOLDER
3573-1 (angle handle)
3573-2 (straight handle)

Hospital Risk Manager Acknowledgement Form

Return via FAX to: Zimmer Spine at **1-512-258-0995**
or
Call Zimmer Spine Customer Service at **866-774-6368**

By signing below and returning this form to Zimmer Spine (or by calling Zimmer Spine Customer Service to confirm), I acknowledge receipt and understand the contents of the enclosed Risk Manager Letter regarding the PathFinder NXT Percutaneous Rod Holder Instruments.

Signature: _____ Printed Name: _____

Title: _____ Telephone: (____) _____-_____ Date: ____/____/_____

Hospital Name: _____

Hospital Address: _____