Urgent: Field Safety Notice
October 27, 2016

DOMAIN SURGICAL
1370 South 2100 East
Salt Lake City, UT 84108
www.domainsurgical.com
(801) 924-4950
(801) 924-4951

Dear Valued Customer,

The purpose of this letter is to advise you that Domain Surgical, Inc., a subsidiary of OmniGuide Holdings, LLC, is performing a Field Safety Corrective Action (FSCA) for its *FMsealer Open Shears* device.

The FMsealer Open Shears, part of Domain Surgical's FMX Ferromagnetic Surgical System, is a sterile, single-patient use, hand-held surgical instrument intended for use in general and gynecologic surgery and other open surgical procedures where ligation of vessels or cutting and coagulation of soft tissue is desired.

Field Safety Corrective Action Rationale
While the FMsealer Open Shears was made commercially available in a limited distribution capacity 9 months ago, it has recently come to our attention that the product has experienced failures during clinical usage in three cases reported to date. According to customer feedback, the *FMsealer Open Shears* has exhibited failure at or near the jaw assembly during active use. There were no adverse events resulting in patient injury or death associated with the reported *FMsealer Open Shears* product failures.

Risk to Health
While the reported product failures did not result in any adverse clinical events, we want to ensure that further occurrences of the fracturing of the fixed portion of the *FMsealer Open Shears'* jaw do not affect patients, or members of the perioperative staff. During clinical usage, the fixed portion of the *FMsealer Open Shears* may fracture which can also contribute to the heat-spreading feature becoming partially dislodged from the moving jaw insulator. Such an occurrence, albeit rare, could result in an inability to seal vessels, and cut or coagulate soft tissue. Said occurrence would therefore result in delays in surgical procedures and related therapies as the effectiveness of the device is considered, the anatomy in question is investigated and ultimately a new form of medical device is sought.

Actions to be Taken by Customer
Please discontinue usage of the *FMsealer Open Shears* unit immediately. Please note that we do intend for this Field Safety Corrective Action (FSCA) to be transitory as we address the product failures while actively working on an enhanced version of the *FMsealer Open Shears* product. In the interim, please consider alternative advanced energy products for surgical cases requiring the sealing of vessels and the cutting or coagulation of soft tissue.

We request that you return all purchased units of the *FMsealer Open Shears* to Domain Surgical, Inc., at the address below:

Domain Surgical, Inc.
Attention: Customer Service
1370 South 2100 East
Salt Lake City, UT 84108
www.domainsurgical.com
801.924.4950 (Phone)
801.924.4951 (Fax)

Product & Distribution Information

Please view the product table below for information pertaining to your *FMsealer Open Shears* units.

Product Name	Model Number	Lot/Serial Number	Distribution Dates	Expiration Date	Quantity
FMsealer Open Shears	FM3001	161871 / 161442	9/29/2016	08/2019 / 08/2019	20 20
FMsealer Open Shears	FM3001	160321 / 160991	5/23/2016	03/2019 / 04/2019	20 10
FMsealer Open Shears	FM3001	161311	6/30/2016	05/2019	5
FMsealer Open Shears	FM3001	153411	6/22/2016	12/2018	2
FMsealer Open Shears	FM3001	160991	6/6/2016	04/2019	5
FMsealer Open Shears	FM3001	160531	4/28/2016	03/2019	2
FMsealer Open Shears	FM3001	162091	9/14/2016	08/2019	10
FMsealer Open Shears	FM3001	161442	9/15/2016	08/2019	15
FMsealer Open Shears	FM3001	160991	6/27/2016	04/2019	1
FMsealer Open Shears	FM3001	160991	6/2/2016	04/2019	15
FMsealer Open Shears	FM3001	160991	6/1/2016	04/2019	1
FMsealer Open Shears	FM3001	160531	3/12/2016	03/2019	2
FMsealer Open Shears	FM3001	153411	1 – 2/11/16 2 – 3/04/16	12/2018	3
FMsealer Open Shears	FM3001	153411	3/31/2016	12/2018	4

Action Taken by Company

As patient safety and product quality are of the utmost importance to Domain Surgical, we have taken the necessary steps to further investigate and refine the design of the *FMsealer Open Shears*. Such steps include a reinforced jaw and heat spreader attachment redesign to provide a more robust jaw assembly. Please be assured that producing a safe and *FMsealer Open Shears* is of paramount importance for Domain Surgical.

Contact Information

Please take a moment to complete the enclosed Field Safety Notice Return Response form.

For questions or comments regarding the Field Safety Corrective Action (FSCA) of the *FMsealer Open Shears* or completion of the Field Safety Notice Return Response form, please contact:

Domain Surgical, Inc.
Attention: Customer Service
1370 South 2100 East
Salt Lake City, UT 84108
www.domainsurgical.com
801.924.4950 (Phone)
801.924.4951 (Fax)

We sincerely appreciate your support and for giving us the opportunity to provide you with a portfolio of advanced energy solutions to benefit both your patients and surgeons.

Best Regards,

Holley Moss
Regulatory Affairs
Domain Surgical, now a part of OmniGuide Holdings, Inc.
801.924.4950 (Phone)
801.924.4951 (Fax)
hmoss@omni-guide.com

FIELD SAFETY NOTICE RETURN RESPONSE
Acknowledgement and Receipt Form

Response is Required

Customer Information:

Customer Name: _____

Street Address: _____

Town, State, Zip Code: _____

FMsealer Open Shears

Lot/Serial numbers:

I have read and understand the Field Safety Notice Return instructions provided in the 10/27/2016 letter. Yes _ No_

Any adverse events associated with Field Safety Notice product? Yes _ No _

If yes, please explain:

_____
_____
_____
_____

Affected Product Information: Include information that is applicable for affected product.

Affected Product Information Table					
Product/Brand Names, UDI (if applicable)	Manufacturer's Product Number/Catalog Number	Lot/Serial Number shipped to Customer	Quantity in inventory	Quantity relabeled	Quantity destroyed/ returned

Return Response Box:

Please provide any additional information, if applicable.

Distributors:
I have checked my stock and have quarantined inventory consisting of _____ <units, cases, etc.>.

I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification**); <or>
Attached is a list of customers who received/may have received this product. Please notify my customers.

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____

Name/Title	
Telephone	
Email address	

PLEASE MAIL, E-MAIL OR FAX COMPLETED RESPONSE FORM TO:

Holley Moss
Regulatory Affairs
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801.924.4950 (Phone)
801.924.4951 (Fax)
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