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Field Safety Notification: Field Safety Corrective Action for IFU in DEX Forceps and Scissors

Dear Customer,

Thank you very much for being a valued user of our DEX forceps and scissors. We highly appreciate your loyalty and trust in our products. With this Field Safety Notification, we would like to draw your attention to the Instruction for Use (IFU) for DEX products with part numbers listed in Table 1.

Kindly note: a comprehensive table of affected lot numbers is found in Annex 1 of this FSN. Each customer will receive an individual list in another attachment.

TABLE 1

PART NUMBER	DESCRIPTION
DVF4005-23	23ga DEX NanoTapered AWH Forceps
DVF4005-25	25ga DEX NanoTapered AWH Forceps
DVF4005-25-S	25ga DEX Stiff NanoTapered AWH Forceps
DVF4005-27	27ga DEX Stiff NanoTapered AWH Forceps
DVF4010-23	23ga DEX Morris Parafovea Forceps
DVF4010-25	25ga DEX Morris Parafovea Forceps
DVF4010-25-S	25ga DEX Stiff Honey Badger Forceps
DVF4010-27	27ga DEX Stiff Honey Badger Forceps
DVF4014-23	23ga DEX Asymmetrical Tano Forceps
DVF4014-25	25ga DEX Asymmetrical Tano Forceps
DVF4014-25-S	25ga DEX Stiff Asymmetrical Tano Forceps
DVF4016-23	23ga DEX Serrated Forceps
DVF4016-25	25ga DEX Serrated Forceps
DVF4016-25-S	25ga DEX Stiff Serrated Forceps
DVF4019-23	23ga DEX Maculorhexis Forceps
DVF4019-25	25ga DEX Maculorhexis Forceps
DVF4019-25-S	25ga DEX Stiff Maculorhexis Forceps
DVF4019-27	27ga DEX Stiff Maculorhexis Forceps
DVF4022-23	23ga DEX End Grasping Forceps
DVF4022-25	25ga DEX End Grasping Forceps
DVF4022-25-S	25ga DEX Stiff End Grasping Forceps
DVF4022-27	27ga DEX Stiff End Grasping Forceps
DVF4034-23	23ga DEX Super Grip Forceps
DVF4034-25	25ga DEX Super Grip Forceps
DVF4034-25-S	25ga DEX Stiff Super Grip Forceps
DVF4034-27	27ga DEX Stiff Super Grip Forceps
DVSS101-25-S	25ga DEX Stiff Vertical Scissors

The correct IFU for these DEX products, intended to be implemented in March 2025, includes:
 appropriate CE mark (marked in red)

another precaution (marked in yellow)

changes the verbiage in "ADVERSE REACTIONS" to "KNOWN/POSSIBLE COMPLICATIONS AND ADVERSE EVENTS" to clarify potential complications (marked in red)

The incorrect IFU does not include the CE mark and does not identify these potential complications. These are pictured in images 1 and 2.

Image 1: Correct IFU

Image 2: Incorrect IFU

Katalyst Surgical, LLC
 Dex™ (Forceps and Scissors)
 STERILE, SINGLE USE
 DESCRIPTION/INDICATION FOR USE (by physicians in the operating room)

This instrument is designed for intraocular use. FORCEPS are designed to grasp and manipulate tissues during a surgical intervention. SCISSORS are designed to cut segmental tissue during eye surgery.

CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

INSTRUCTIONS FOR USE AND EXPIRATION DATE:

- Release the instrument from pouches and ensure aseptic transfer to the sterile field.
- Remove protective tube.
- The instrument is ready for surgical use.
- Squeeze basket handle to push together the tips

REORDER CODES:

REF	Type	Y = Gauge
DV14XXX-2Y	Forceps	21ga, 23ga, 25ga, 27ga
DV15XXX-2Y	Scissors	
DV164XXX-2Y	Slim Forceps	
DV165XXX-2Y	Slim Scissors	

FEATURES:

- Various tip designs allow for different surgical applications.
- Sterilized by Ethylene Oxide, single use, latex free.

CAUTION:

This device is to be used only by qualified physicians. Follow medical operating procedures during surgery. This product is intended for single use, one patient only.

Reuse or re-sterilization may cause diminished product performance, contamination or infection.

PRECAUTION:

Do not use if package is open, damaged or wet.
 Do not use if expiration date shown on the label is exceeded.
 Do not use or disassemble, use if ribbs is open.

KNOWN/POSSIBLE COMPLICATIONS AND ADVERSE EVENTS:

Complication is associated with the procedure being performed (to be assessed by the physician) can include damage to the retina, poor wound healing, leakage, infection and endophthalmitis. Complications associated with the device can include damage to the retina.

WARNINGS:

Do not use this device as a tamponade, unless specifically indicated.
 Do not use this device for foreign body removal, unless specifically indicated.

RX only

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FEATURES:

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Reuse or re-sterilization may cause diminished product performance, contamination or infection.

PRECAUTION:

Do not use if package is open, damaged or wet.
 Do not use if expiration date shown on the label is exceeded.

ADVERSE REACTIONS:

There are no adverse reactions associated with the use of this product other than those related to the specific procedure being performed (to be assessed by the physician).

WARNINGS:

Do not use this device as a tamponade, unless specifically indicated.
 Do not use this device for foreign body removal, unless specifically indicated.

RX only

Risk for patient, users or thirds

The IFU that should have been included reflects potential adverse effects that the user should be aware of. These changes do not affect the safety of the product itself but could have the unlikely potential to affect the performance of the product based on user familiarity with the product. Unfortunately, the utilization of the incorrect IFU with the part numbers listed in Table 1 does not comply with some applicable standards and our internal procedures.

FIELD SAFETY ACTIONS REQUIRED

As a customer identified in the receipt of one or more of the affected lots, you are requested/required to take the following steps:

1. Please confirm receipt of this Field Safety Notification by email, either by replying to the sender or using the email addresses listed in the signature at the bottom of this notice.
2. Review the 'Individualized List of Affected Lot Numbers by Customer' provided in the email for lots that were distributed to your facility. Identify all of these lots that currently remain in your stock and place them on hold.
3. Provide information to Katalyst Surgical team identifying which lots are currently in stock and on hold at your facility. Katalyst Surgical will send a replacement correct IFU for each affected box.
4. Upon receipt of the correct IFU, remove the incorrect IFU, replace the correct IFU in the box, and destroy the incorrect IFU. Approval for Modification including instructions will accompany the replacement IFUs.
5. We recommend you reach out to your customers/users of these DEX products with this information. Katalyst Surgical will gladly provide correct replacement IFU documents to you for further distribution.

Katalyst Surgical deeply regrets the inconvenience this causes. We assure you of our continuous support and commitment to safety and quality. Please do not hesitate to contact our team if you have any further questions.

Yours sincerely,

ANNEX 1 :

Lot Number	Part Number	Country
M50529	DVF4005-23	Argentina
M50530	DVF4005-25	Argentina; USA
M47363	DVF4014-25-5	France
M47364	DVF4014-25-5	France
M47588	DVF4014-25-5	France
M47582	DVF4016-25-5	France
M48049	DVF4016-25-5	France
M51038	DVF4016-25-5	France
M49921	DVF4019-23	France
M51128	DVF4019-23	France
M49164	DVF4019-25	Peru; Korea
M49268	DVF4019-25	Korea
M49269	DVF4019-25	Japan
M49773	DVF4019-25	Peru
M49772	DVF4019-25	Japan; USA
M49922	DVF4019-25	France; USA; Japan
M49923	DVF4019-25	France
M50067	DVF4019-25	France
M50066	DVF4019-25	Peru
M50072	DVF4019-25	France
M50421	DVF4019-25	France
M50420	DVF4019-25	France
M50533	DVF4019-25	France
M50535	DVF4019-25	France
M47122	DVF4019-25-5	France

ANNEX 1:

Lot Number	Part Number	Country
M47123	DVF4019-25-5	France
M47336	DVF4019-25-5	France
M48308	DVF4019-25-5	France
M48660	DVF4019-25-5	USA
M49294	DVF4019-25-5	France, USA
M49784	DVF4019-25-5	France
M49839	DVF4019-25-5	France
M49910	DVF4019-25-5	France, USA
M49929	DVF4019-25-5	USA
M49930	DVF4019-25-5	France, USA
M50215	DVF4019-25-5	USA
M50427	DVF4019-25-5	France
M50428	DVF4019-25-5	USA
M50429	DVF4019-25-5	USA
M50073	DVF4019-27	France, Japan
M50287	DVF4019-27	Japan, France
M50677	DVF4019-27	Japan
M50991	DVF4019-27	Japan, France
M51071	DVF4019-27	Japan
M50093	DVF4022-25-5	France
M50293	DVF4022-25-5	USA, France
M50216	DVF4022-25-5	USA
M50543	DVF4022-25-5	USA
M50431	DVF4022-25-5	USA
M50634	DVF4022-25-5	USA

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Lot Number	Part Number	Country
M50903	DVF4022-25-5	USA
M47116	DVF4034-25	Japan, France
M48162	DVF4034-25	France, USA
M48276	DVF4034-25	Japan, USA
M48303	DVF4034-25	Japan
M49168	DVF4034-25	USA
M49270	DVF4034-25	USA, Japan
M49285	DVF4034-25	Japan
M49286	DVF4034-25	Japan
M49775	DVF4034-25	USA
M49829	DVF4034-25	Japan
M49905	DVF4034-25	Japan
M50289	DVF4034-25	Japan
M50208	DVF4034-25	Japan
M50290	DVF4034-25	Japan
M50916	DVF4034-25	Japan
M51033	DVF4034-25	France
M51074	DVF4034-25	Japan
M51234	DVF4034-25	Japan
M51521	DVF4034-25	Japan, France
M47337	DVF4034-25-5	USA
M50921	DVF4034-25-5	USA
M47331	DVF4034-27	Japan
M48044	DVF4034-27	Japan
M48163	DVF4034-27	Japan

ANNEX 1 :

Lot Number	Part Number	Country
M47512	DVF4034-27	Japan
M48071	DVF4034-27	Japan
M48164	DVF4034-27	Japan
M48470	DVF4034-27	Japan
M48471	DVF4034-27	Japan
M48043	DVF4034-27	Japan
M47511	DVF4034-27	Japan
M48472	DVF4034-27	Japan
M48658	DVF4034-27	Japan
M48657	DVF4034-27	Japan
M49169	DVF4034-27	Japan
M49170	DVF4034-27	Japan
M49287	DVF4034-27	Japan
M49777	DVF4034-27	japan
M49776	DVF4034-27	Japan
M49830	DVF4034-27	Japan
M49831	DVF4034-27	Japan
M49925	DVF4034-27	japan
M49926	DVF4034-27	japan
M50539	DVF4034-27	japan
M50932	DVF4034-27	Japan
M50993	DVF4034-27	Japan
M51292	DVF4034-27	Japan
M51293	DVF4034-27	Japan

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M50529	DVF4005-23	Argentina
M50530	DVF4005-25	Argentina; USA
M47363	DVF4014-25-5	France
M47364	DVF4014-25-5	France
M47588	DVF4014-25-5	France
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M49269	DVF4019-25	Japan
M49773	DVF4019-25	Peru
M49772	DVF4019-25	Japan; USA
M49922	DVF4019-25	France; USA; Japan
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M50067	DVF4019-25	France
M50066	DVF4019-25	Peru
M50072	DVF4019-25	France
M50421	DVF4019-25	France
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M49839	DVF4019-25-5	France
M49910	DVF4019-25-5	France, USA
M49929	DVF4019-25-5	USA
M49930	DVF4019-25-5	France, USA
M50215	DVF4019-25-5	USA
M50427	DVF4019-25-5	France
M50428	DVF4019-25-5	USA
M50429	DVF4019-25-5	USA
M50073	DVF4019-27	France, Japan
M50287	DVF4019-27	Japan, France
M50677	DVF4019-27	Japan
M50991	DVF4019-27	Japan, France
M51071	DVF4019-27	Japan
M50093	DVF4022-25-5	France
M50293	DVF4022-25-5	USA, France
M50216	DVF4022-25-5	USA
M50543	DVF4022-25-5	USA
M50431	DVF4022-25-5	USA
M50634	DVF4022-25-5	USA
M50903	DVF4022-25-5	USA
M47116	DVF4034-25	Japan, France

Lot Number	Part Number	Country
M481 62	DVF4034-25	France, USA
M482 76	DVF4034-25	Japan, USA
M483 03	DVF4034-25	Japan
M491 68	DVF4034-25	USA
M492 70	DVF4034-25	USA, Japan
M492 85	DVF4034-25	Japan
M492 86	DVF4034-25	Japan
M497 75	DVF4034-25	USA
M498 29	DVF4034-25	Japan
M499 05	DVF4034-25	Japan
M502 89	DVF4034-25	Japan
M502 08	DVF4034-25	Japan
M502 90	DVF4034-25	Japan
M509 16	DVF4034-25	Japan
M510 33	DVF4034-25	France
M510 74	DVF4034-25	Japan
M512 34	DVF4034-25	Japan
M515 21	DVF4034-25	Japan, France
M473 37	DVF4034-25-5	USA
M509 21	DVF4034-25-5	USA
M473 31	DVF4034-27	Japan
M480 44	DVF4034-27	Japan
M481 63	DVF4034-27	Japan
M476 12	DVF4034-27	Japan
M480 71	DVF4034-27	Japan
M481 64	DVF4034-27	Japan

Lot Number	Part Number	Country
M48470	DVF4034-27	Japan
M48471	DVF4034-27	Japan
M48043	DVF4034-27	Japan
M47611	DVF4034-27	Japan
M48472	DVF4034-27	Japan
M48658	DVF4034-27	Japan
M48657	DVF4034-27	Japan
M49169	DVF4034-27	Japan
M49170	DVF4034-27	Japan
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M49831	DVF4034-27	Japan
M49925	DVF4034-27	japan
M49926	DVF4034-27	japan
M50539	DVF4034-27	japan
M50932	DVF4034-27	Japan
M50993	DVF4034-27	Japan
M51292	DVF4034-27	Japan
M51293	DVF4034-27	Japan