
Medical Device Recall
Infiniti Bracket (Sold as part of CIVCO brand Biopsy Starter Kits and Biopsy Bracket)

February 26, 2018

Attention: Ultrasound Department

Dear Valued Customer,

This is to inform you of a product recall involving the products labeled as identified below:

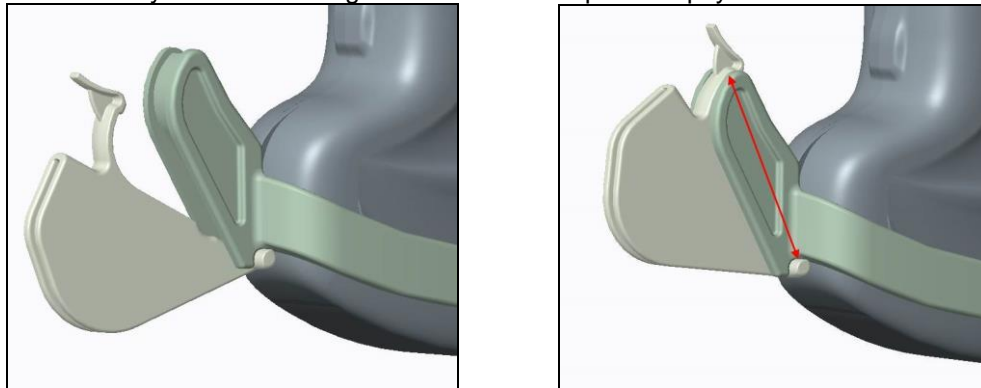
- 639-026 – Biopsy Starter Kit for use with Esaote LA332 and SL332 transducers
- 698-009 – Biopsy Starter Kit for use with Zonare C9-3 transducers
- 698-016 – Biopsy Bracket for use with Zonare C9-3 transducers
- 620-116 – Biopsy Starter Kit for use with BK Medical 18L5 and 8870 transducers

CIVCO has recently discovered a quality issue with Infiniti bracket. You are being notified, as your facility has been identified as having received product from the affected manufacturing lots. The affected brackets were included in the kits identified and manufactured between 11/2009 through 12/2017.

For detailed product information see Attachment 1 to this customer letter!

Description of the Problem:

If the length of the mount may be longer than specified, it can allow the needle guide insert to puncture the cover which is applied between the mount and needle guide during assembly. This does not prevent the assembly from functioning as intended to keep the biopsy needle in the ultrasound scanning plane.



Action to be Taken by the Customer:

CIVCO requests return of all Infiniti brackets from kits identified in the Attachment 1 to this letter.

To return the needle guide procedure contact your local Distributor within the country.

Distributor Name

Address

Contact Number

For international contact: Customer Consultant at 800-445-6741 or 319-248-6757 or via email at order@civco.com to schedule the return and arrange for replacement product to be sent.

Transmission of this Recall Notification:

This notice is being communicated to all customers who have purchased a kit in which a bracket is contained from affected lots. CIVCO requests you provide this notification to the appropriate personnel within your facility. If the affected product was distributed outside of your organization, please notify those locations down to the medical facility level.

Thank you for your cooperation and communication on this issue. Please feel free to contact me if you have any questions or concerns regarding the above information

Sincerely,

James Leong
Regulatory Manager
CIVCO Medical Solutions

Urgent Medical Device Recall
Infiniti Bracket (Sold as part of CIVCO brand Biopsy Starter Kits and Biopsy Bracket)

Return By: 5 March 2018

I have been informed of the recall notice by CIVCO Medical Solutions involving the Infiniti Bracket.
This notice has been read and understood by the responsible party involved.

1. _____ I have reviewed my inventory for the affected products and no longer have any in stock.
2. _____ I have reviewed my inventory for the affected products and they are in specifications. No further action is required.
3. _____ I have reviewed my inventory for the affected products and I need a Return Authorization Number to return the product.

List Lot Number	List # units	List Lot Number	List # units
_____	_____	_____	_____

4. _____ Other, please provide details.

Facility Name

Street Address

City, State

Phone

Print Name / Title

Signature

Date

Please return this certification by FAX to your local distributor or to us directly at 319-248-6660 or email to order@civco.com.

Please contact your local Distributor in your country or for International contact CIVCO Customer Service representative for additional assistance. You may reach your Customer Consultant by calling CIVCO Medical Solutions, Multi-Modality Imaging, at 800-445-6741 or 319-248-6757 between 7:00AM and 5:30PM CST. You may also contact us via email at order@civco.com.

Thank You.

Attachment 1 Detailed information for Products to be recalled by CIVCO

Lot numbers:

639-026

M206950	M605540	M851530	M358570	M734570
M664690	M706720	M983170	M427660	M912740
M897110	M570610	M358570	M440600	
M119380	M543670	M381520	M526300	

698-009

M427370	M103030	A010473	M103030	M771190
M427390	M293590	M427370	M105150	M089260
M515370	M293580	M888920	M427370	M220960
M558420	M560740	M909270	M096330	M388690
M558220	M695400	M085550	M917410	M419650
M879530	M964370	M093020	M723180	A010459


698-016

M567620	M052860			
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620-116

M080890	M559550	M425050	M056610	M092800
M041630	M186540	M122250	M335740	M043310
M499390	M483250	M109060	M275630	M912150
A023904	M457560	M051670	M091360	M895560
A015235	M202260	M869430	M056610	M027090
M308820	M831280	M547370	M253050	M083160
M865470				

Manufacture Date Products with manufacture date between 11/2009 to 12/2017








REF 639-026 **LOT XXXXXX** 


QTY 1 **SN XXXXXXXXXX**

Biopsy Starter Kit
 Reusable non-sterile bracket with Infiniti Plus™ (12, 14, 16, 18GA) needle guides (2), Infiniti Plus™ (18, 20, 21/22, 25GA) needle guides (3), (14 x 91.5cm) CIV-Flex™ covers (5) for use with Esaote LA332 and SL332 transducers


R_x ONLY

[DA] Biopsi-startpakke **[IT]** Kit di avvio per biopsia **[ZH-CN]** 活组织切片检查套件
[NL] Startset biopsie **[JA]** 生検スタートキット **[ES]** Equipo inicial para biopsia
[FI] Biopsia-aloituspakkaus **[KO]** 생검 스타터 키트 **[SV]** Biopsi Nybörjar Kit
[FR] Kit de base pour biopsies **[NO]** Startsett for biopsi **[TR]** Biyopsi Başlangıç Kiti
[DE] Biopsie-Startset **[PT-PT]** Kit de biopsia
[EL] Κιτ Εισαγωγής Βιοψίας **[RU]** Начальный набор для биопсии













85°F
(29°C)
Temperature
limitation




0120




Date of Manufacture:
XXXX.XX.XX




Keep away
from
sunlight




Consult
instructions
for use



102 First Street South
Kalona, IA 52247 USA
319.248.6757
WWW.CIVCO.COM



(01)00841438105552
(10)XXXXXXXX
(11)XXXXXXXX
(17)XXXXXXXX
(21)XXXXXXXXXXXX



M366330264M

639-026-B REV. H

Date of Manufacture in YYYY.MM.DD format

