
Medical Device Recall

Large Gauge Infiniti Plus Guide (Sold as part of CIVCO brand Needle Guide Starter Kits and Biopsy Starter Kits)

Nov 23, 2015

Attention: Ultrasound Department

Dear Valued Customer,

This is to inform you of a product recall involving the products labeled as identified below manufactured between 02/2013 to 01/2015:

1. **Infiniti Plus Needle Guide 12-18 GA**
2. **Needle Guide Starter Kit**
3. **Biopsy Starter Kit**
4. **Sales Demo Kit**

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

CIVCO has recently discovered a quality issue with our large gauge Infiniti plus needle guides. You are being notified, as your facility has been identified as having received product from the affected manufacturing lots. The affected Infiniti guides were included in the kits identified and manufactured between 02/2013 through 01/2015.

Description of the Problem:

The large gauge version of the disposable Infiniti plus guide contained 2 unintended points of contact on the sides of the needle guide. When assembled to the bracket mount area, these contact points can pinch the cover in the bracket channel during attachment and breach the cover.



Front View



Side View (unattached)



Side View (fully attached)

Action to be Taken by the Customer:

CIVCO requests return of all Infiniti guides packaged separately and those included in the biopsy and starter kits identified in the attachment 1 to this letter.

For the kits identified as **Infiniti Plus Needle Guide (12-18 GA)** as listed in category #1, please contact your local Distributor or international CIVCO to return the inventory you may still have for replacement.

For kits identified as **Needle Guide Starter Kit** or **Biopsy Starter Kit** as listed in categories #2 and #3, this will require you to remove the individually packaged needle guides supplied in the kits. The needle guides in the kits will be labeled with the title **Infiniti Plus Needle Guide (12-18 GA)**. The part number reference on

the package will reference one of the part numbers identified in category #1. Please remove the packaged needle guides from the kit for return. The remaining items and components in your starter kit are not affected and can be retained for use.

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 an Infiniti plus guide 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. CIVCO regrets any inconvenience your might have with this recall. CIVCO has determined the root cause of this problem and assures you that all appropriate steps been taken to avoid reoccurrence.

Sincerely,

James Leong
Regulatory Manager
CIVCO Medical Solutions

Attachment 1 Detailed information for Products to be recalled by CIVCO Nov2015

1. **Infiniti Plus Needle Guide 12-18 GA.** These are the kit configurations containing a large gauge infiniti plus needle guide manufactured between 02/2013 to 01/2015 and packaged and labeled with these part numbers in the table.

610-1215	610-1235	610-1235-5	610-1234	610-1236
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2. **Needle Guide Starter Kit:** These are kits with a specific transducer bracket and contain two of the large gauge infiniti plus needle guides procedures identified in #1 above manufactured between 02/2013 to 01/2015 and packaged and labeled with these part numbers in the table.

674-030	674-030-T	674-031	674-031-T	674-035
674-036	674-044	674-052	674-059	674-061

3. **Biopsy Starter Kit:** These are kits with a specific transducer bracket and contain two of the large gauge infiniti plus needle guides procedures identified in #1 above manufactured between 02/2013 to 01/2015 and packaged and labeled with these part numbers in the table.

10787043	11001906	613-247	620-116	639-014
639-016	639-021	639-024	639-025	639-026
639-027	639-033	639-035	639-047	639-051
658-001	667-106	667-127	667-132	672-001
698-007	698-009	698-013	698-015	742-397-T
742-416	H48392LT	667-132		

4. **Sales Demo Kit.** This kit configuration containing a large gauge infiniti plus needle guide along with a variety of other guides and covers. These were provided only to internal sales personnel and select OEM's and Distributors and contain guides manufactured between 02/2013 to 01/2015 and packaged and labeled with these part numbers in the table.

DEMOGPGUIDE				
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Lot numbers: Lots between M030030 to M665970 and M998920 shown on the boxes or manufactured between the dates identified.

For simplicity, you can reference the manufacturing date located on the label and return any manufactured between 2013.02 and 2015.01 for replacement. (see example below for manufacture date location)

REF 610-1215 QTY 24

Infiniti Plus™ Needle Guide







Sterile needle guide with (1.4 x 29.2cm) telescopically-folded CIV-Flex™ wireless transducer cover

Nålguide
Naaldvoerder
Neulaohjain
Guide-aiguille
Nadelführung
Οδηγός Βελόνος
Guida dell'ago

注射針ガイド
나침 가이드
Nålstyring
Guia de agulhas
Проводник иглы
针导引器

Guía de aguja
Nålguide
İğne Kilavuzu

12-18GA

Do not reuse

Do not use if package is damaged

Caution, consult accompanying documents

STERILE EO
Sterilization using ethylene oxide


52°F (11°C) - 85°F (29°C)
Temperature limitation

Rx ONLY


Use By XXXX.XX

Date of Manufacture XXXX.XX

LOT XXXXXXX



M36681012152A*



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610-1215-B-REV A

Date of Manufacture in YYYY.MM format