

August 9, 2012

Medical Device Correction

SUBJECT: “-12” Version Tip Cover for 8mm Monopolar Curved Scissors (Hot Shears™)

AFFECTED PRODUCTS:

PART NUMBERS

400180-12

DESCRIPTION

Tip Cover Accessory
(shown on right)



Dear Customer,

Intuitive Surgical has recently discovered a very rare issue that may affect the individual pouches used to package its Tip Cover Accessory product, part number 400180-12. During the manufacturing process, to package each Tip Cover, each part is placed into the top open end of a rectangular, pre-made pouch which is sealed along the sides and bottom edges. To seal the pouch containing the product, the edge on the open end is clamped and sealed by applying heat and pressure, creating a closed seal impressed with a thatched pattern.

Our analysis has shown that in less than 20 out of 10,000 pouches manufactured, the sealed edge was not formed uniformly, and pleats or creases were formed within the seal area of the pouch. Of those non-uniform seals, our tests indicate that in a small percentage of non-uniform seals, there may be a breach in the barrier integrity of that seal. Based on our tests, the overall rate of a pouch seal barrier breach is less than 5 out of 10,000. Thus, the vast majority of Tip Cover accessories are unaffected by this issue, and it is possible that none of the Tip Covers shipped to your facility are defective. Nonetheless, we are taking prompt action to assure that we locate any potentially defective product, and assure that it is removed from your remaining inventory.

Twenty manufacturing lots of the “-12” version Tip Cover product pouches, which started shipping in November, 2011 were affected by this sealing issue, and we have ensured that any lots manufactured after July 27, 2012 are not affected. No complaints of any infections associated with the pouches have been reported since November, 2011.

To ensure the highest level of safety and performance, we will have an Intuitive Surgical representative visit your site within the next 5 days to identify and segregate any of the affected lots of product from your inventory, and to inspect each individual pouch of that segregated lot. If an individual pouch is found to have a defect, only that pouch should be destroyed and discarded. Remaining Tip Cover pouches from the same box that are not defective are safe to use.

We expect that the process of identification, segregation and inspection of your Tip Cover inventory will take less than an hour. We apologize for any inconvenience this process may impose on your staff.

Sincerely,



Viorica Filimon
Vice President, Product Quality

Please take the following actions related to this product notification:

1. Forward this letter to other managers within your facility (e.g., Risk Management and OR Director) that should be informed of this important medical device correction.
2. Identify and segregate affected product using the lot numbers listed below.
3. Work with your Intuitive Surgical Representative to inspect individual Tip Cover pouches.
4. If defective product is identified, destroy and discard the individual pouch, and call Customer Service for an RMA number to receive credit.
5. Complete the attached acknowledgement form and fax to Intuitive Surgical.

Identify & Segregate Affected Product

Segregate the following lot numbers for inspection. The lot number is printed on the Tip Cover pouch or box labels as shown below. All other lot numbers may be used without an inspection.

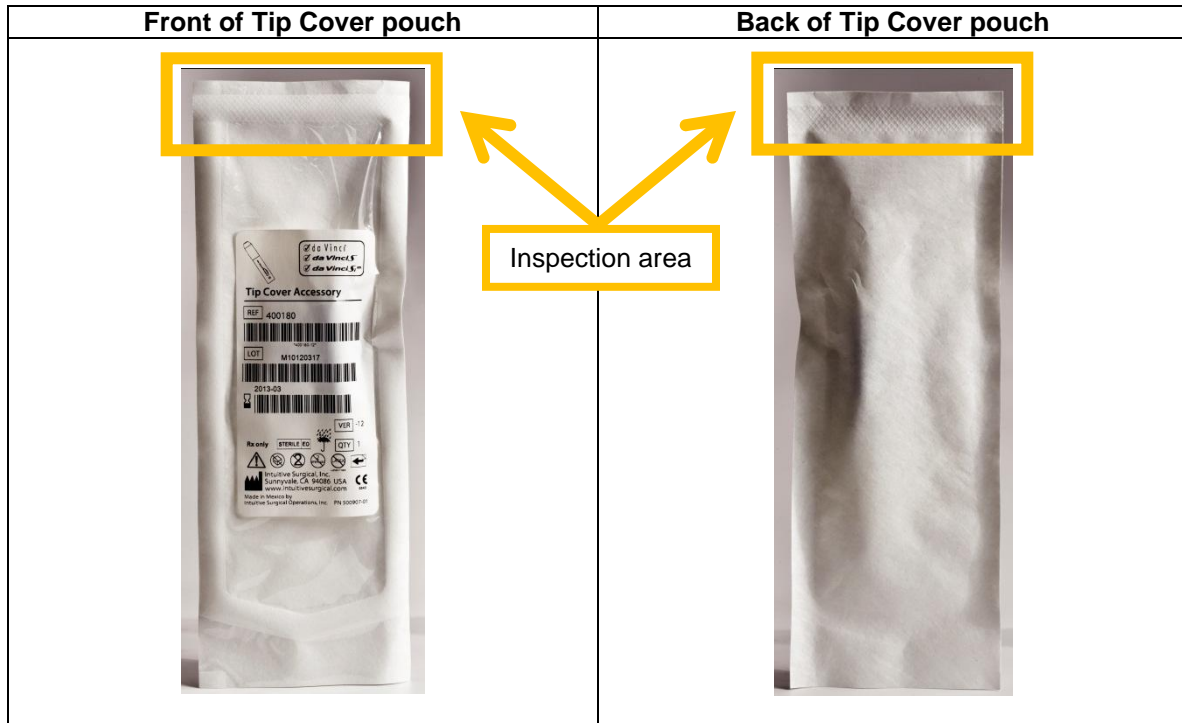
Newest Lots				Oldest Lots
M10120601	M10120430	M10120329	M10120312	M10111214
M10120516	M10120426	M10120321	M10120208	M10111208
M10120510	M10120419	M10120317	M10120207	M10111201
M10120507	M10120413	M10120315	M10120130	M10111028

Tip Cover pouch label	Tip Cover box label

Inspect Products for Defects

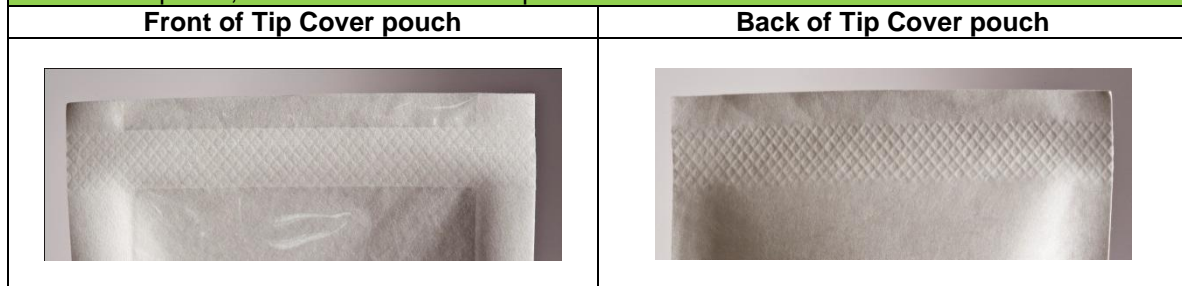
An Intuitive Surgical representative will inspect the affected Tip Cover inventory at your hospital and identify products with defects.

To perform the inspection, hold the bottom of the pouch and rotate it in bright light. Visually check the front and back of the straight seal on the top of the pouch as shown below. Defective products will have pleats, creases or folds that interrupt the thatch pattern of the seal.



Example of non-defective product that can be used*

- Pouch seal is uniform with uninterrupted thatch pattern
- No pleats, creases or folds on the pouch seal



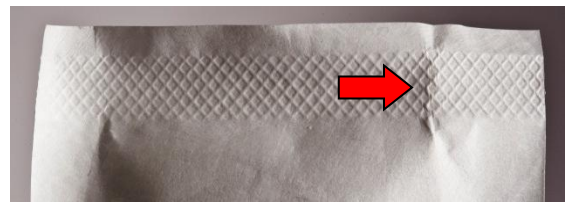
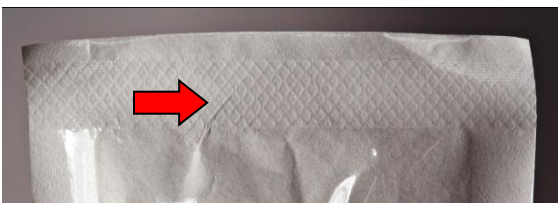
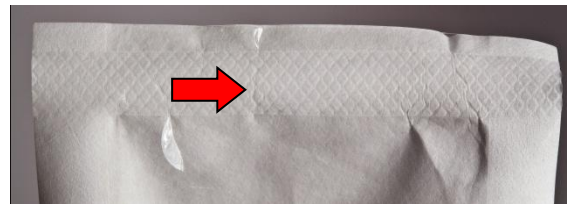
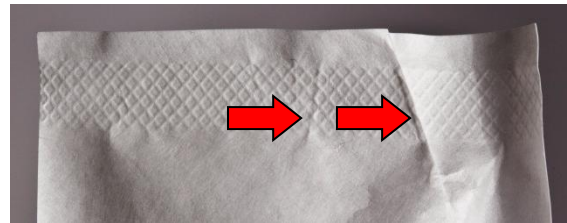
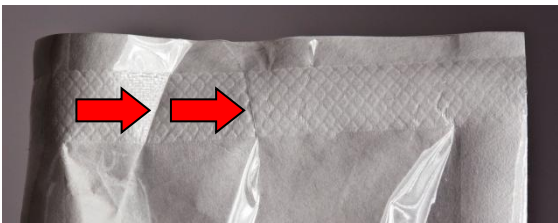
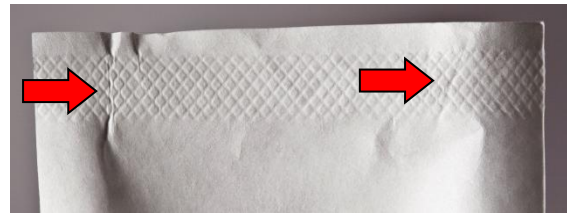
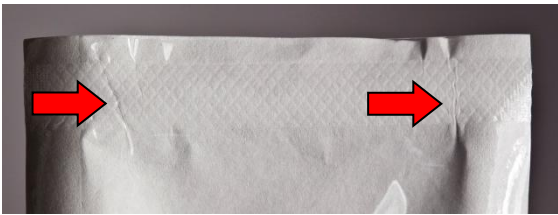
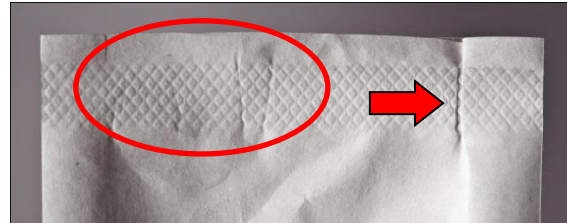
*Examples shown are ~85% actual size.

Examples of defective product that should be destroyed and discarded*

- Pouch seal is not uniform
- Pleats, creases, or folds on the pouch seal

Front of Tip Cover pouch

Back of Tip Cover pouch



Acknowledgement Form
TO BE COMPLETED BY INTUITIVE SURGICAL REPRESENTATIVE

SUBJECT: *Tip Cover Accessory (400180-12) packaging inspection*

Hospital Name _____

Address _____

City, State, Zip _____

Step 1.) Segregate the affected Tip Cover lot numbers listed below and inspect each pouch seal, as instructed in the attached Medical Device Correction letter.

If an individual pouch is found to have a defect, only that pouch should be destroyed by opening the pouch and discarding the tip cover. If there are doubts that a pouch seal has a defect, please destroy and discard. Record the quantities inspected and destroyed in the table below.

Affected Product Lot Numbers (newest to oldest)	Number of Pouches Inspected	Number of Pouches Destroyed
M10120601		
M10120516		
M10120510		
M10120507		
M10120430		
M10120426		
M10120419		
M10120413		
M10120329		
M10120321		
M10120317		
M10120315		
M10120312		
M10120208		
M10120207		
M10120130		
M10111214		
M10111208		
M10111201		
M10111028		

Step 2.) If no defective pouches are found, go to step 3. If any pouches are identified as defective, call Customer Service at **1-800-876-1310** for an RMA (Return Material Authorization) number so that credit can be granted to the site. **Do not return** any defective product back to Intuitive Surgical.

Record RMA (Return Material Authorization) number: _____

Note: A credit for 1 box of Tip Covers will be issued for 1 to 10 defective Tip Cover pouches.

Acknowledgement form is continued on next page.



Acknowledgement Form (continued from previous page)

Hospital Name _____

Address _____

City, State, Zip _____

Step 3.) Sign the acknowledgement below and fax both pages of this form to Intuitive Surgical.

I acknowledge that I have received Intuitive Surgical Inc.'s Medical Device Correction letter dated August 9, 2012 concerning the Tip Cover Accessory packaging inspection. By signing this form, it is acknowledged that all of the affected lots of Tip Cover Accessories have been inspected and pouches found to be defective have been destroyed and discarded.

Intuitive Surgical Rep: (print) _____
Signature: _____ Date: _____

Hospital Contact: (print) _____
Signature: _____ Date: _____
Phone Number: _____

**PLEASE FAX THIS FORM TO: Intuitive Surgical Inc., ATTN: REGULATORY AFFAIRS
US (408) 716-3040**