

Dear Valued Hologic Customer:

This is to inform you of a voluntary product field action involving:

Product(s):

- ILS 0914-12: 9G Introducer Localization Set for ATEC 0914-12MR Handpiece
- ILS 0914-20: 9G Introducer Localization Set for ATEC 0914-20MR Handpiece

Serial Lot Numbers:

- Product with lot numbers 20Jddnn or later (where 20 is year 2020, J is month of September, dd is date of manufacture, nn is sequential number)

This field action was initiated to address customer complaints on the ATEC ILS kits regarding detachment of the brown cap from the introducer sheath. We are notifying you because you have purchased the affected products with lot numbers identified within the scope of the correction. The product issue has the potential to result in a needle stick.

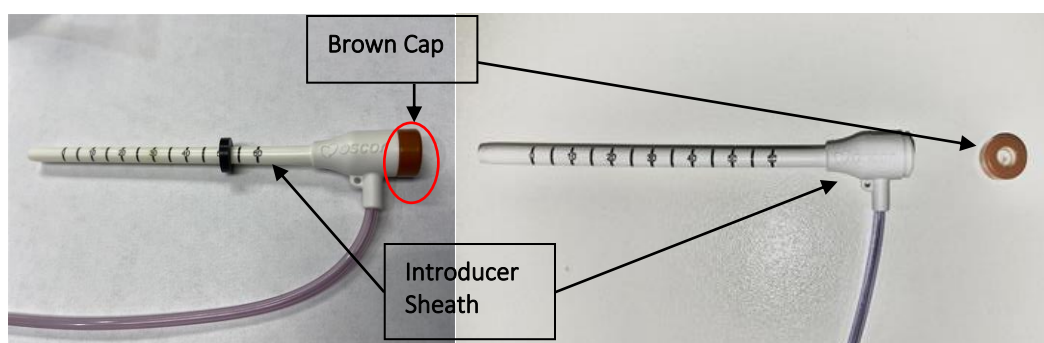


Figure 1.0 ILS Assembly Intact

Figure 2.0 Brown Cap Detached

Based on Hologic investigation, the following instructions for use are recommended for impacted lots of product.

Prior to use of the ILS:

1. Visually inspect to confirm the brown cap is adhered to the white introducer sheath.
2. Apply rotational force to the brown cap while holding the white introducer sheath steady.
3. If the cap is loose, exchange this device with another kit and notify Hologic of the issue by contacting breasthealth.support@hologic.com.

To prevent interruption to MRI biopsy procedures, Hologic will continue to supply ILS kits while the investigation and corrective action for this issue are underway.

At Hologic, we are committed to continually evaluating and improving the quality and reliability of our products. We value your business and thank you for your cooperation during this time. Our goal is to ensure the continued safe use of your system in a manner that creates as little disruption to your practice as possible. If you have any questions, please do not hesitate to reach out to Technical Support at breasthealth.support@hologic.com or 1-877-371-4372.

Sincerely,
Robert Kielinen
Sr. Director, Quality
Hologic, Inc.